PRODUCT DOCUMENT

SURGICAL INNOVATIONS

Product Index

ECMO

- Cardiohelp System
- HLS Sets
- HLS Cannulae
- Cardiohelp II
- Rotaflow II

Endoscopic Vessel Harvesting

- Vasoview Hemopro 2
- EVH Equipment

Advance Hemodynamic Monitoring

- PulsioFlex Monitoring Platform
- ProAqt Technology
- PiCCO Technology
- Pulsiocare

Intra-Aortic Balloon Pump

- Cardiosave
- Sensation Plus

Off-Pump Products

- Acrobat-i
- Beating Heart

Surgical Adhesive

- Ne'x Glue
- Ne'x Glue IFU

Ligating Clips & Clip Appliers

- LigaV
- Vclip
- Click'aV

Scissors, Dissectors, Graspers

- Reusable Endoscopic Instruments
- Disposable Endoscopic Instruments
- Limited Use Endoscopic Instruments
- Hemostatic Powder
- Retrieval Bags

For more info please visit **Acute Care Therapies - GetNet**

Contact Details

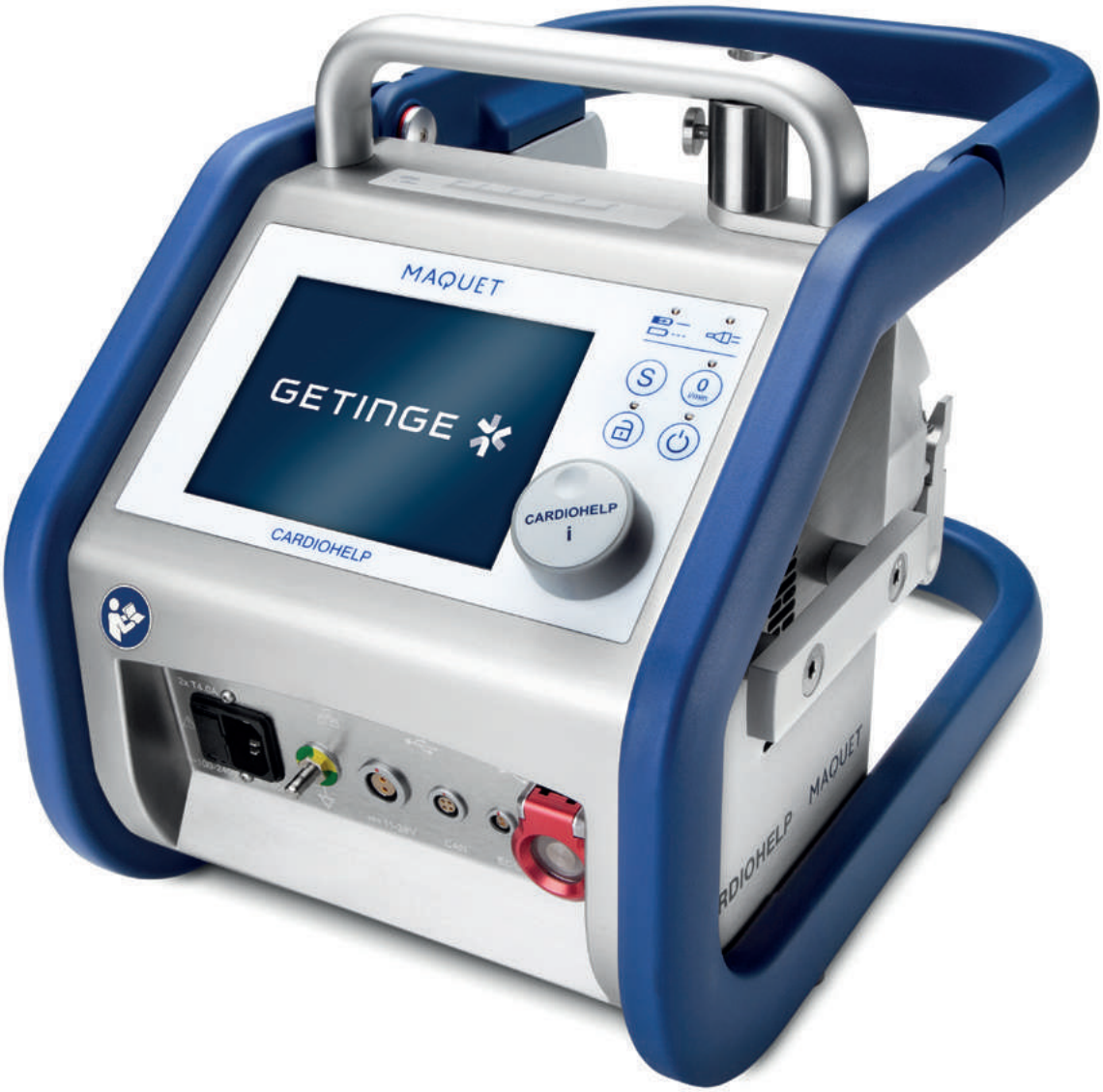
Nici Fouche
Regional Sales Manager (Coastal)
0799116938
nicolenef@surgicalinnovations.co.za

Mariette Kock
Regional Sales Manager (Inland)
0828708234
mariettek@surgicalinnovations.co.za

Henli Faber
Application Specialist (Inland)
0829084207
henlif@surgicalinnovations.co.za

Name:	Territory:	Number:	Email Address:
Bianca Lehy	• Gauteng North • Limpopo	0829247072	biancal@surgicalinnovations.co.za
Reginald Seakamela	• Gauteng East • Mpumalanga	0721151143	reginalds@surgicalinnovations.co.za
Tsholofelo Mokgwelwa	• Gauteng West • North West	0674151763	tsholofelom@surgicalinnovations.co.za
Isaac Sebeela	• Gauteng Central • Vaal Triangle	0664808789	isaacs@surgicalinnovations.co.za
Kobus Calldo	• Free State • Northern Cape	0662513700	mariettek@surgicalinnovations.co.za
Leonard Stannard	• Free State • Northern Cape	0828931651	mariettek@surgicalinnovations.co.za
Fransune Flynn	• Western Cape • Garden Route • Eastern Cape	0723994422	fransunef@surgicalinnovations.co.za
Shivash Lakhan	• KwaZulu Natal South	0649388693	shivashl@surgicalinnovations.co.za
Jezreel Govender	• KwaZula Natal North	0734545650	jezreelg@surgicalinnovations.co.za

ECMO



Cardiohelp System

Extracorporeal life support wherever you need it

This document is intended to provide information to an international audience outside of the US.

GETINGE


RPM
× 1000
MAQUET
GETINGE GROUP
04:55 PM
rpm
3600
l/min
4.50
mmHg
285
%
- 32
mmHg
75.0
19
CARDIOHELP
CARDIOHELP

The world's leading ECLS System

Your choice for heart-lung support

With critically ill or injured patients, there's no time for delay. That's why Getinge has long been committed to advancing ECLS technology.

As one of the world's leading manufacturers of heart-lung machines and related components, we understand the impact that a portable extracorporeal life support (ECLS) system can have on patient outcomes.

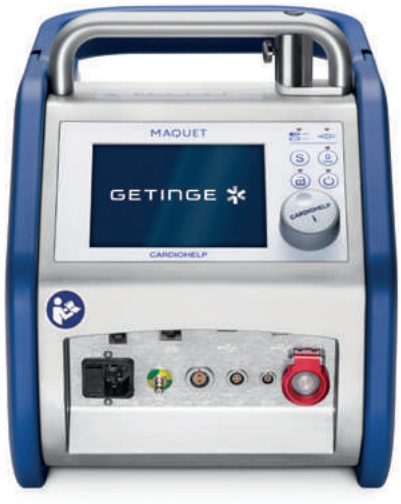
A broad range of indications

The Cardiohelp System is a small and lightweight heart-lung support system. Although extracorporeal life support provided by the Cardiohelp System is not a therapy itself, it acts as a bridge for recovery or transplantation. This gives caregivers more time to optimize the patient's therapy while easing the body's workload.

It can be used for a wide range of indications in intensive care, emergency medicine, cardiology, and cardiac surgery.

We put patients first

For more than a century, Getinge and its well-known brands – such as Maquet – have put patients first. It's why we remain committed to close clinical relationships that identify real-world healthcare challenges, and address them with cost-effective, clinically relevant solutions.



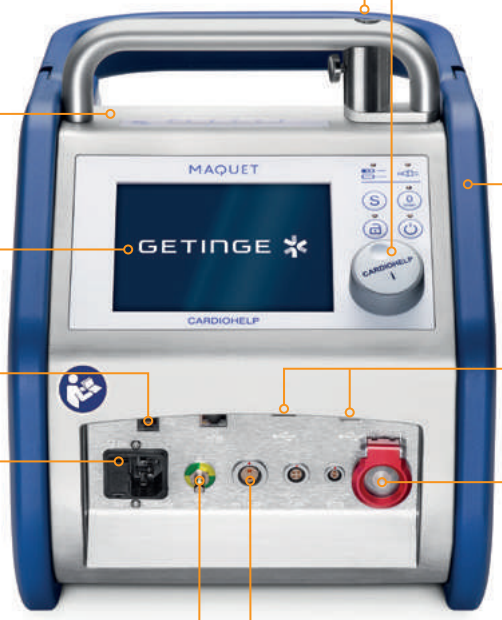
Gentle extracorporeal circulation

Giving the organs time to heal

A multi-functional system

The Cardiohelp System is a compact heart-lung support system suitable for all indications requiring extracorporeal circulation for cardiopulmonary support.

Highly portable, the Cardiohelp System can be rapidly deployed for transport of patients requiring respiratory and / or circulatory support.



Cardiohelp Emergency Drive Holder

Battery pack for at least 90 min

Control panel: user-friendly touchscreen

"Alarm outlet" connection, e.g., ward call

Main power supply: together with the DC device socket, the Cardiohelp device can be used with common voltages and currents worldwide.

Equipotential bonding connection

Adjustment of flow and speed

The protective frame protects the Cardiohelp Device against crushing

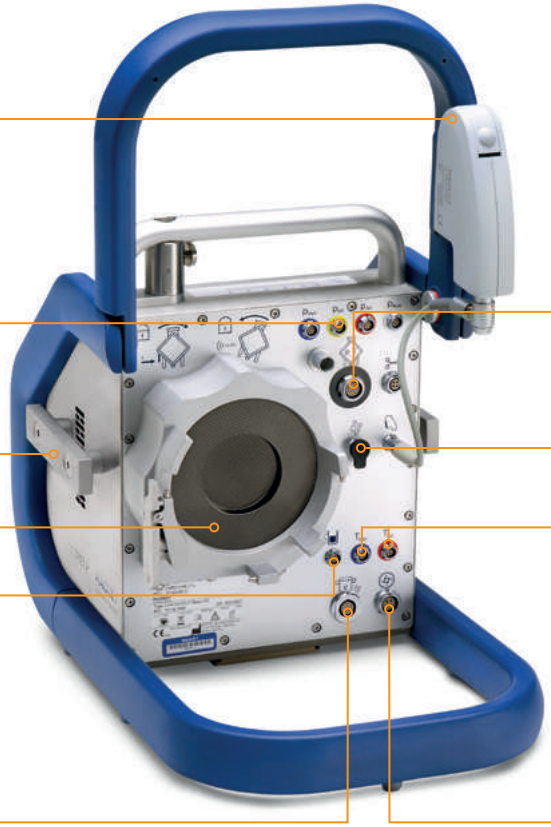
USB port type A and USB port type B

"Emergency mode" button

DC device socket

A cost-effective resource

As hospitals face increasing cost pressures, it's crucial to invest in cost-effective technologies that can be used by multiple departments.



One system

Multiple treatment options

The Cardiohelp System can support cardiac and / or pulmonary function using either veno-venous or veno-arterial ECLS.

Veno-arterial life support is used with patients whose hearts are not adequately supporting their circulation or patients who have arrested.

Veno-venous life support provides respiratory assistance for lung disorders. Support can be extended to complete substitution of the organ function.

When paired with optimized ventilation techniques, the Cardiohelp System provides adaptable treatment for a variety of conditions.

Application	Respiratory and cardiac assist	Respiratory assist	Intervention
Disposable	**HLS Set Advanced 5.0** **HLS Set Advanced 7.0**	**HLS Set Advanced 5.0** **HLS Set Advanced 7.0**	**Cardiac Intervention Set**
Place	ICU / CathLab / ER / OR	ICU / ER / OR	CathLab / Hybrid OR
Fields of application	• Respiratory failure with cardiac impairment • Circulatory failure with respiratory impairment • Cardiogenic shock • Myocardial infarction • Resuscitation • Bridge to transplant	• Acute respiratory distress syndrome (ARDS) • Pulmonary embolism • Septic shock • Bridge to lung transplant	• Elective high risk PCI • Other elective cardiac interventions
Flow	HLS 5.0: 0.5–5.0 l/min HLS 7.0: 0.5–7.0 l/min	HLS 5.0: 0.5–5.0 l/min HLS 7.0: 0.5–7.0 l/min	0.5–7 l/min
Transport	Air / ground	Air / ground	-
	 v-a ECLS	 v-v ECLS	 MECC

The Cardiohelp System

The fully equipped Sprinter Cart XL

HLS Set Advanced

Combining a low damage blood pump with a highly efficient gas module

When a patient's heart or lungs are failing, they need safe and effective cardiopulmonary support to avoid hypoxic injury.

The right technology can ease the body's workload, providing support both at the bedside and during transport.

Improved safety for critically ill patients

The HLS Set Advanced, with the HLS Module Advanced as its core component, is a state-of-the-art oxygenator providing circulatory and/or respiratory extracorporeal life support (ECLS). It expands therapy applications with a continuous use for veno-venous or veno-arterial extracorporeal support.

Integrated monitoring technology helps to improve patient safety and handling of the device in a high risk setup.

The core of the HLS Set Advanced, the HLS Module Advanced

The core is an integrated low-trauma centrifugal pump. With the HLS Set Advanced, patient safety is integrated into the system.

Multiple sensors measures important blood parameters, including:

- Venous oxygen saturation (S_vO_2)
- Hematocrit (Hct)
- Hemoglobin (Hb)
- Venous temperature (T_{Ven})

Integrated sensors provide continuous measurement:

- Venous pressure
- Arterial pressure
- Internal pressure (measured between centrifugal pump and gas module)
- Arterial temperature

Flow Bubble Sensor (FBS) for bubble detection and for reducing the risk of embolisms.

The HLS Set Advanced is available in different versions:

HLS Set Advanced 5.0 accommodates a blood flow of up to 5 l/min and HLS Set Advanced 7.0 accommodates a blood flow of up to 7 l/min. Both HLS Set Advanced have a biocompatible Bioline Coating.

For patients who are susceptible to heparin-induced thrombocytopenia a set with Softline Coating is available, the HIT Set Advanced 5.0 and HIT Set Advanced 7.0.

HLS Set Advanced

Benefits at a glance

Safety

- Integrated noninvasive sensor technology minimizes the hazards of air embolism, stagnant zones, clotting and cavitation from external pressure sensors. There are no pressure lines that need flushing.
- Rapidly detect cannulae misplacement and kinking by monitoring pressure changes with Cardiohelp.
- Various sensors reduce the risk of embolism caused by air entering the circuit and helps to early recognize formation of clots.
- Low priming volume minimizes hemodilution.

Usability

- Quick and easy set-up and priming for routine and rapid deployment in emergency situations.
- The sterile packaging contains all the necessary components and tubing.
- An integrated heat exchanger helps to precisely manages temperature.
- Color-coded tubing supports safe patient connection.
- Provided as a standard set it allows for consistent trainings of users, familiarity with the product in any situation and routine handling.
- With Cardiohelp and HLS Set Advanced, patients can be safely transported between hospitals.

Cardiac Intervention

Short term support – a life-saving decision

Supporting patients during high-risk percutaneous cardiac interventions

When treating patients with high-risk PCI, the physician should take into account a 7–10% risk of acute hemodynamic instability; this almost always leads to the need for urgent circulatory support.[1] Cardiac assist devices can be used to regain stability and to support the patient as quickly and effectively as possible.

Background:

- Rising numbers of cardiac interventions are occurring, especially in older and sicker patients.[2,3,4]
- Increasingly complex cardiac interventions occur after the introduction of new stent variations (e.g. drug eluting or dissolving stents) and evolving technologies (e.g. minimally invasive valve-replacement).[5]
- Increased need for, and acceptance of circulatory support during high-risk PCI[1,6,7] or valve replacement.

1 Briguori C et al. Elective versus provisional intra-aortic balloon pumping in ULMS. Am. Heart J. 2006; 152 (3): 565-572

2 Vainer J et al. Elective high-risk percutaneous coronary interventions supported by extracorporeal life support. Am. J. Cardiol. 2007; 99 (6): 771-3

3 Anastasiadis K et al. Successful high-risk percutaneous coronary intervention with the use of minimal extracorporeal cirulation system. Catheter Cardiovasc Interv. 2012; 80 (5): 845–9

4 Tsao et al. Extracorporeal membrane oxygenation-assisted primary percutaneous coronary intervention may improve survival of patients with acute myocardial infarction complicated by profound cardiogenic shock. J. Crit. Care. 2012; 27 (5): 530.e1-530.e11

5 Dardas P et al. ECMO as a bridge to high-risk rotablation of heavily calcified coronary arteries.Herz. 2012; 37 (2): 225-30

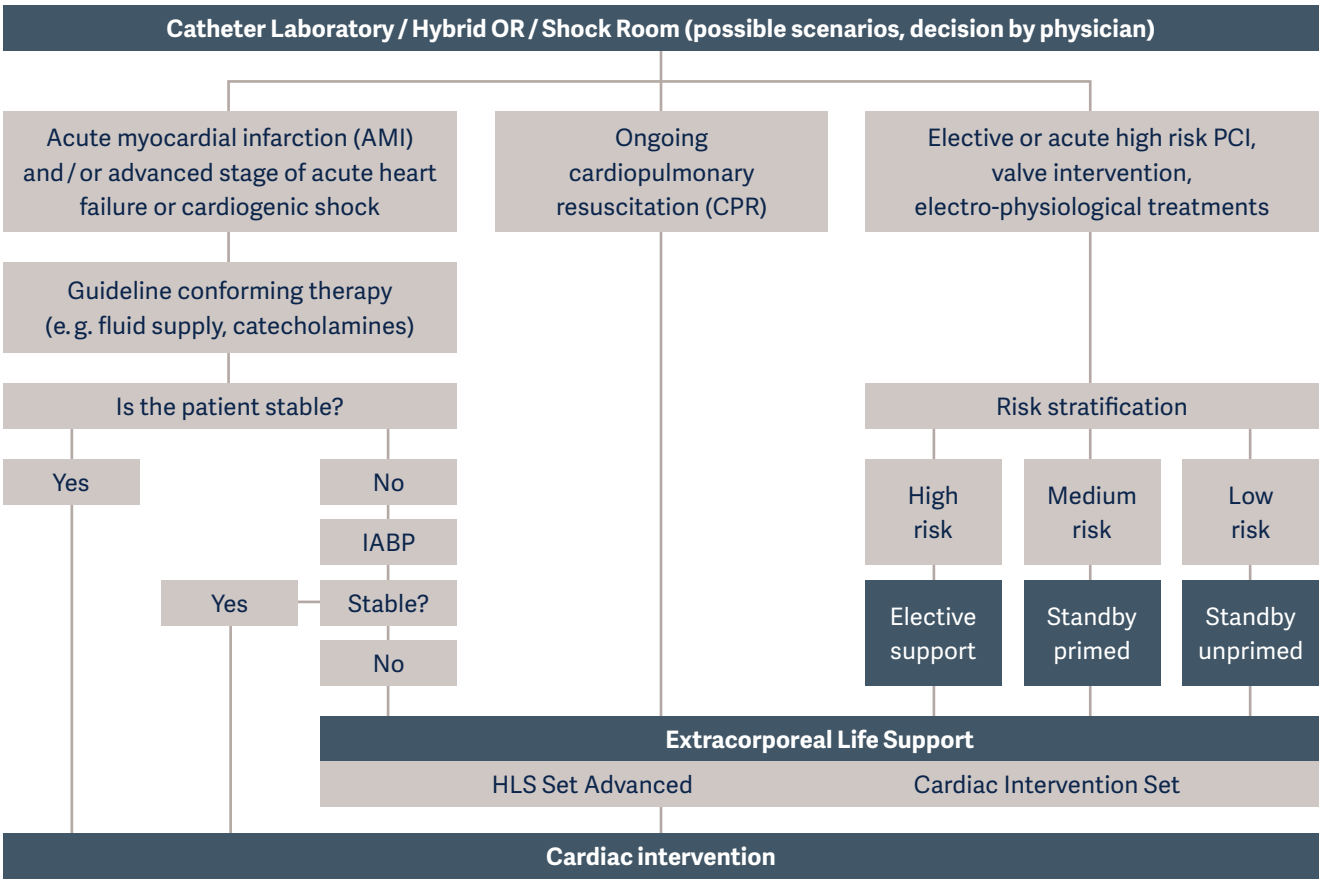
6 Bagai J et al. Efficacy and safety of percutaneous life support during high-risk percutaneous coronary intervention, refractory cardiogenic shock and in-laboratory cardiopulmonary arrest. J. Invasive Cardiol. 2011; 23 (4): 141-7

7 Webb DP et al. Novel multi-functional life support system. J. Extra Corpor. Technol. 2010; 42 (3): 232-4

Cardiac Intervention Set

Benefits at a glance

- First standardized tubing set for ECLS during high-risk PCI
- Designed to be used for up to 6 hours this set can serve as a back-up solution to cover the phase of highest risk of instability and take over full support if necessary
- Quick and easy set-up and priming for fast deployment in emergency situations
- Low priming volume minimizes hemodilution
- Connection of external pressure measurement and arterial temperature is possible
- Integrated centrifugal pump and heat exchanger for precise temperature management



According to ESC and ACC / AHA guidelines

Avalon Elite

Bi-Caval Dual Lumen Catheter

Reduce patient trauma with a single cannulation site for extracorporeal life support.

The Avalon Elite Bi-Caval Dual-Lumen Catheter permits for single site cannulation into the patient's internal jugular vein. This facilitates patient extubation and mobilization, increases patient comfort and improving patient outcomes.

The Avalon Elite Bi-Caval Dual-Lumen Catheter is the world's first single site, kink resistant, veno-venous device designed to enable optimal extracorporeal life support. It matches the body's natural flow ratios by simultaneously removing deoxygenated blood from both the superior vena cava (SVC) and inferior vena cava (IVC), and returning oxygenated blood to the right atrium (RA).

Advantages

- A broad range of sizes for all patient types: neonatal, pediatric or adult
- Radiopaque to assist in catheter insertion and placement
- Constructed with an unique material that combines the durability of polyurethane with the flexibility and biocompatibility of silicone

Characteristics:

- Wire-reinforced catheter with a one-piece, dual lumen construction.
- The catheter consists of two separate lumina, this allows for both venous drainage and reinfusion of blood during extracorporeal life support procedures.
- The product is offered in a range of sizes to address varying patient size requirements.

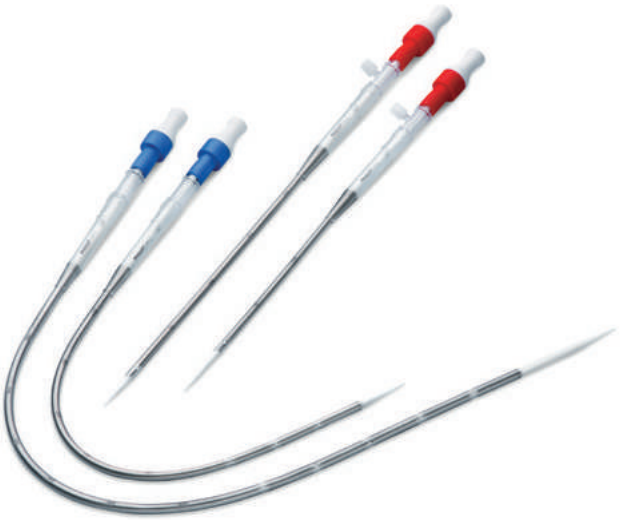
HLS Cannulae

VV and VA access

Reliable and minimally traumatic solution for vascular access.

HLS cannulae can be inserted percutaneously or through surgical cut-down, offering reliable veno-venous or veno-arterial connection of peripheral vessels to the extracorporeal circuit.

HLS cannulae is also available with Bioline Coating (heparin-albumin coating) for improvement of the physical surface properties of products for the extended respiratory and / or circulatory support.



Exceptional performance characteristics:

- Reinforced with a flat wire for the thinnest wall and highest flow rates.
- Reinforced side holes for reduced kinking risk
- Versions with Bioline Coating for extended respiratory and / or circulatory support.

Easy to use:

- Locking mechanism keeps introducer in place during insertion
- Optimized transition between introducer and cannula tip
- Depth marks to control insertion depth, a stop ring to define maximum insertion depth
- Selectively hardened proximal cannula body, reduces the risk of kinking after insertion

The portable life support system

– anytime, anywhere

The Cardiohelp System can be easily and rapidly deployed at the bedside or in the field, offering patients portable, seamless heart-lung support.

It is effective in all forms of patient transport, including intra-hospital transport between departments, or inter-hospital transport by helicopter or ambulance. The portable system enables adequate patient oxygen supply and CO_2 reduction for efficient organ perfusion.

Key features include:

- Secure installation in any ambulance or helicopter
- Integrated lithium-ion batteries provide at least 90 minutes of operating time when fully charged
- The Cardiohelp Transport Guard provides additional stability and crash protection

A broad variety of transport-specific accessories are available, including mobile holder and base plate for secure fixation of the device.

Cardiohelp with additional transport guard

Trolley transport system

Benefits at a glance: A proven life support system

- Ideal for use in multiple settings in the ICU, OR, CathLab, Hybrid OR, and the emergency room
- Compact and functional design provides flexibility and easy handling
- The touchscreen user interface allows intuitive control even in emergency situations
- Integrated sensor technology enables continuous monitoring of patients blood parameters, pressures and bubble detection
- Individual alarms, warning limits, and interventions assure safety during use
- The back-up system offers a 90 min battery supply when fully charged, and an emergency drive

GETINGE

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

This document is intended to provide information to an international audience outside of the US. The products in this brochure may be pending regulatory approvals to be marketed in your country. Contact your Getinge representative for more information.

Maquet Cardiopulmonary GmbH · Kehler Str. 31 · 76437 Rastatt · Germany · +49 7222 932-0

www.getinge.com

HLS Set Advanced

Extracorporeal respiratory and / or cardiocirculatory support

This document is intended to provide information to an international audience outside of the US.

GETINGE

Cardiohelp System and HLS Set Advanced – the leading ECMO system

Extracorporeal membrane oxygenation (ECMO) provides cardiopulmonary support and reduces strain on vital organs. The Cardiohelp System with its state-of-the-art extracorporeal circuit – the HLS Set Advanced – is the leading ECMO system and has proven its effectiveness in thousands of patients.

Integrated sensors measure the arterial temperature (T_{art}) and the post-oxygenator pressure (P_{art})

Integrated centrifugal pump

Integrated sensors measure the venous pressure (P_{ven}) and the internal pressure (P_{int})

Interface for measurement of S_vO_2, Hb, Hct, T_{ven}

The HLS Set Advanced includes a high performance oxygenator with integrated centrifugal pump, pressure and temperature sensors (HLS Module Advanced). Integrated non-invasive sensors help to increase the safety during the application and avoid the need for external measuring lines.

As a compact and lightweight system, the Cardiohelp System allows for versatile use, including transport of patients inside and outside the hospital.

Monitoring of critical blood parameters in combination with Cardiohelp

- Venous oxygen saturation (S_vO_2)
- Hematocrit (Hct)
- Hemoglobin (Hb)
- Venous temperature (T_{ven})
- Venous line pressure
- Arterial line pressure
- Internal pressure (measured between centrifugal pump and gas module)
- Arterial temperatur
- Flow-Bubble Sensor (FBS) for bubble detection
- A venous bubble sensor is optionally available

HLS Set Advanced – Technical data

	HLS Set Advanced 5.0	HLS Set Advanced 7.0 HIT Set Advanced 7.0
Blood flow rates	0.5 – 5 l/min	0.5 – 7 l/min
Tube size (inside diameter x wall thickness)	3/8" x 3/32" (9.53 mm x 2.38 mm)	3/8" x 3/32" (9.53 mm x 2.38 mm)
Centrifugal pump speed	0 – 5,000 rpm	0 – 5,000 rpm
Oxygenation membrane surface area	1.3 m²	1.8 m²
Heat exchanger surface area	0.3 m²	0.4 m²
Gas exchange fibres	Polymethylpentene (PMP)	Polymethylpentene (PMP)
Priming volume HLS Set Advanced with 2 x 2.3 m tubing length	570 ml	600 ml
Priming volume HLS Module Advanced	240 ml	273 ml

Available in different versions

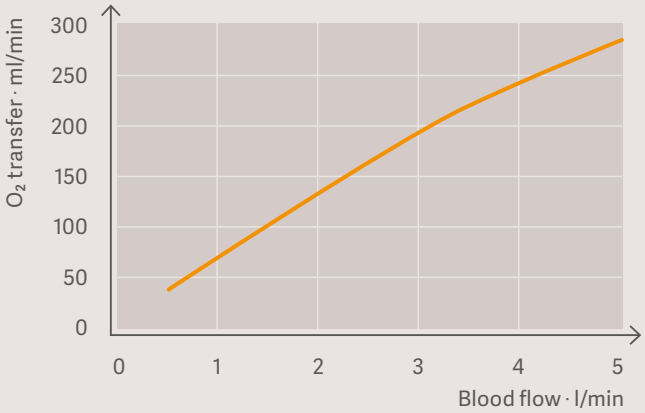
HLS Set Advanced 5.0 accommodates a blood flow of up to 5 l/min, HLS Set Advanced 7.0 accommodates a blood flow of up to 7 l/min. Both HLS Set Advanced sets have a biocompatible Bioline Coating, which ensures a homogenous surface and minimizes the blood damaging effects of foreign surfaces. For HIT patients, there is a dedicated HIT Set Advanced with Softline Coating available.

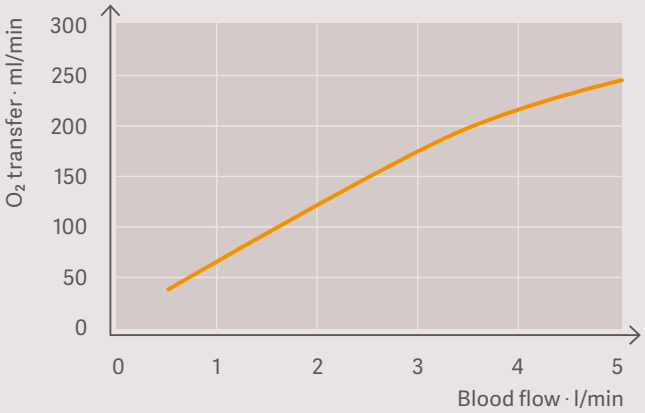
Version	REF	Coating	
HLS Set Advanced 5.0	BE-HLS 5050	Bioline Coating	0.5 – 5 l/min
HLS Set Advanced 7.0	BE-HLS 7050	Bioline Coating	0.5 – 7 l/min
HIT Set Advanced 7.0	BO-HLS 7050	Softline Coating	0.5 – 7 l/min

Performance data

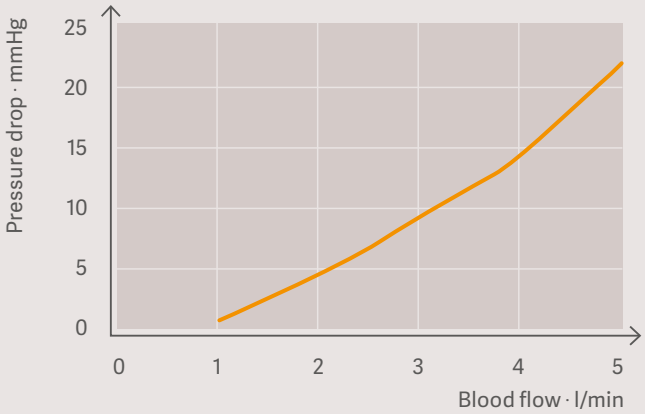
HLS Set Advanced 5.0

O_2 transfer
37 °C | Gas-blood flow ratio 1:1

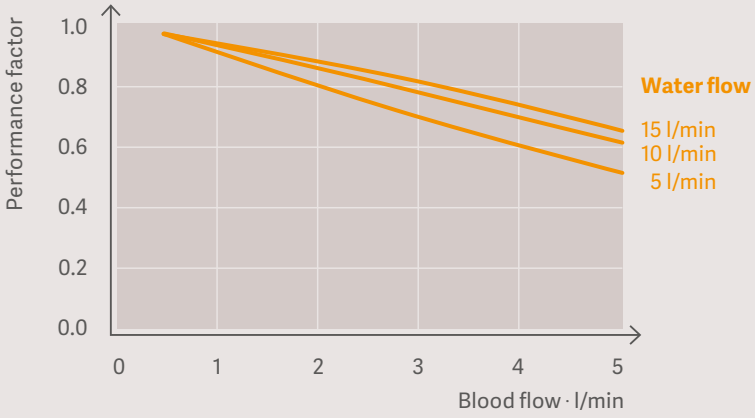




Pressure drop oxygenator

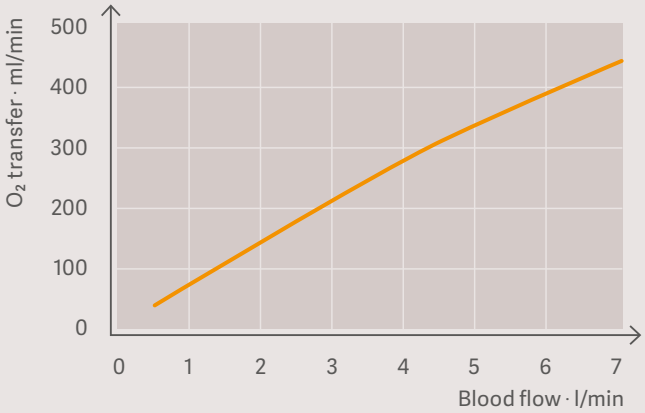


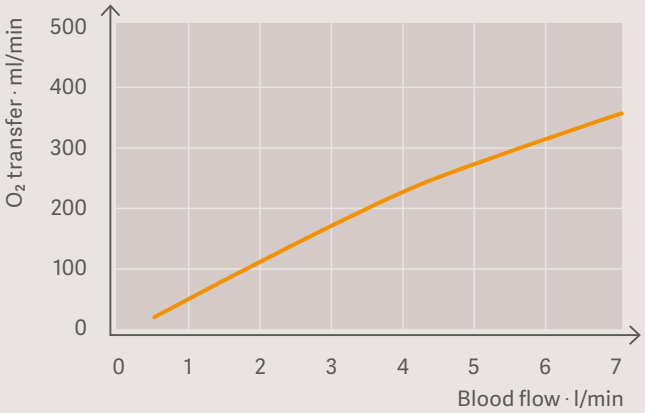
Heat exchanger performance
37 °C | ISO 7199 Standard



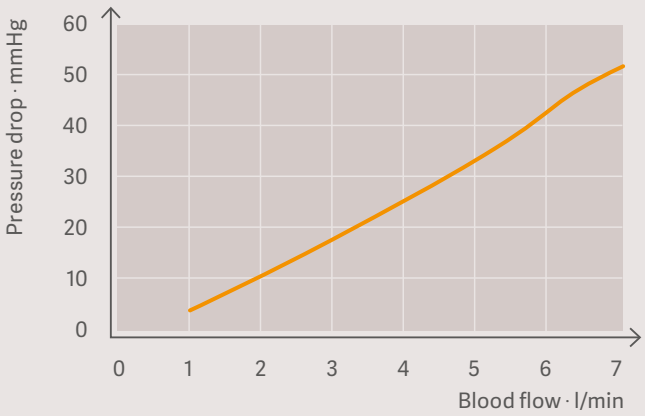
HLS Set Advanced 7.0 | HIT Set Advanced 7.0

O_2 transfer
37 °C | Gas-blood flow ratio 1:1

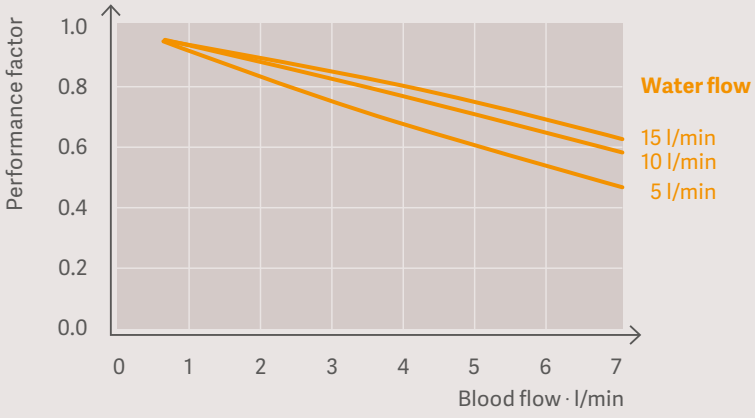




Pressure drop oxygenator



Heat exchanger performance
37 °C | ISO 7199 Standard



Benefits at a glance

- Integrated non-invasive sensor technology helps to avoid the need for external measuring lines.
- Integrated pressure monitoring for increased safety during application.
- Quick and easy set-up and priming for routine and rapid deployment in emergency situations.
- An integrated heat exchanger helps to precisely manage temperature.
- Provided as a standard set, supporting routine handling in any situation and consistent training of users
- The Cardiohelp System and HLS Set Advanced are approved for safe intra- and inter-hospital patient transport.
- Dedicated softline-coated set to treat patients who are sensitive to heparin-induced thrombocytopenia


CARDIOHELP
MAQUET

GETINGE

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

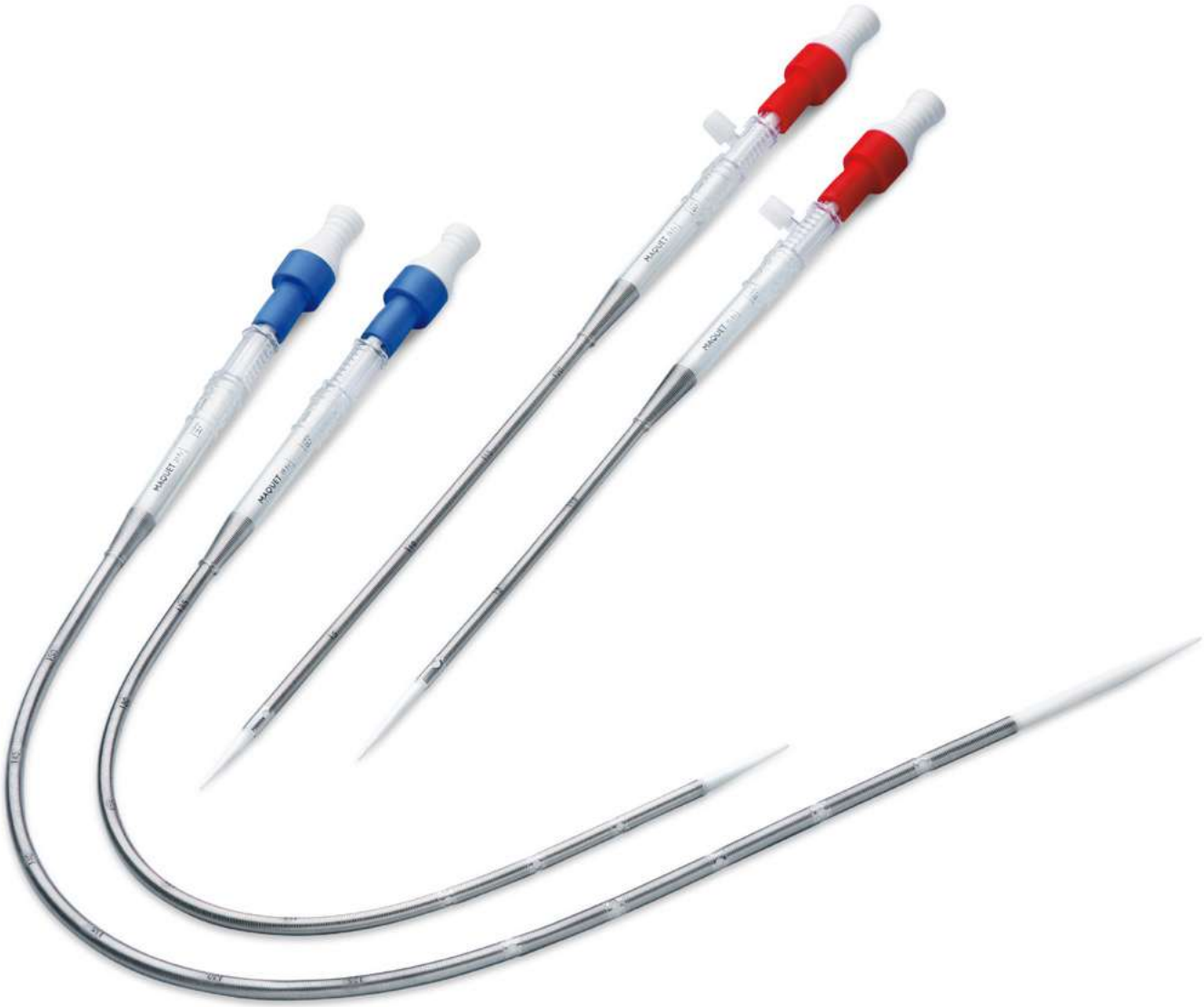
This document is intended to provide information to an international audience outside of the US.
Products may be pending regulatory approvals to be marketed in your country. Contact your Getinge representative for more information.
Contact your Getinge representative for more information. Refer to Instructions for Use for current indications, warnings, contraindications and precautions.

All information presented in this brochure is either referenced by the below publications or is on file at Getinge.

Maquet Cardiopulmonary GmbH · Kehler Str. 31 · 76437 Rastatt · Germany · +49 7222 932-0

www.getinge.com

DMS-0005282 · 09/2023 · Getinge is a registered Trademark · Copyright by Maquet Cardiopulmonary GmbH · Subject to modifications due to technical development.



HLS Cannulae

Solutions from tip-to-tip

This document is intended to provide information to an international audience outside of the US.

GETINGE

Smooth transition between introducer and cannula tip

Stop ring defines maximum insertion depth

HLS Cannulae

Trusted vessel access

The HLS Cannulae are indicated for cannulation of all suitable vessels (e.g. femoral vessels) and can be inserted percutaneously, using the Seldinger technique, or under visual control into the previously exposed vessel.

An excellent flow performance, a wide range of cannulae sizes and different coating options make it one of the most popular peripheral cannulae – the perfect choice for vessel access during extracorporeal circulation.

Performance characteristics:

- Thin cannula walls support an excellent pressure / flow performance
- Reinforced side holes help reduce the risk of kinking
- Versions with Bioline Coating for duration of use of up to 30 days*

Safety features:

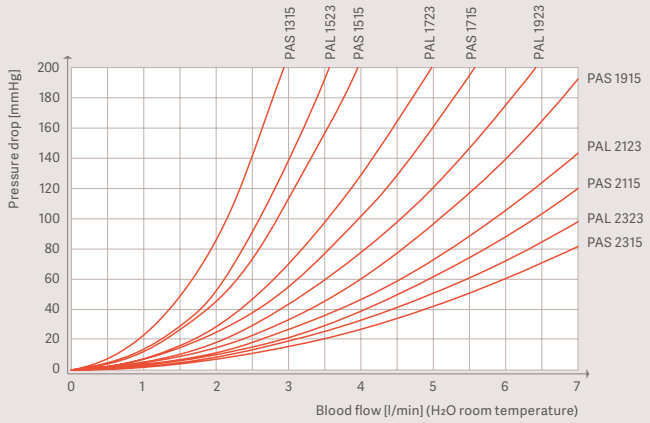
- Locking mechanism keeps introducer in position during insertion
- Smooth transition from introducer to cannula to support a safe cannula insertion
- Depth marks to control insertion depth, a stop ring to define maximum insertion depth
- Selectively hardened proximal cannula body, reduces the risk of kinking after insertion

A pair of side holes on every arterial tip

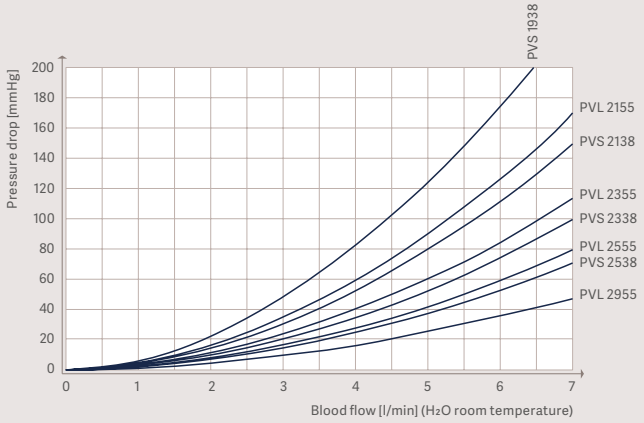
Multiple drainage openings on every venous cannula

* HLS cannulae with Bioline Coating in combination with PLS Set, PLS Set Plus or HLS Set Advanced (all with Bioline Coating) can be used for up to 30 days in CE region.

Pressure drop for all arterial HLS Cannulae ⅜"



Pressure drop for all venous HLS Cannulae ⅜"



Product order details arterial HLS cannulae

Type	Outer diameter	Insertion length	Side holes	Perforation length	Connector	Bioline Coating
PAS 1315	13 Fr (4.3 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1315
PAS 1515	15 Fr (5.0 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1515
PAS 1715	17 Fr (5.7 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1715
PAS 1915	19 Fr (6.3 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1915
PAS 2115	21 Fr (7.0 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 2115
PAS 2315	23 Fr (7.7 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 2315
PAL 1523	15 Fr (5.0 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1523
PAL 1723	17 Fr (5.7 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1723
PAL 1923	19 Fr (6.3 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1923
PAL 2123	21 Fr (7.0 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 2123
PAL 2323	23 Fr (7.7 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 2323

One cannula per carton

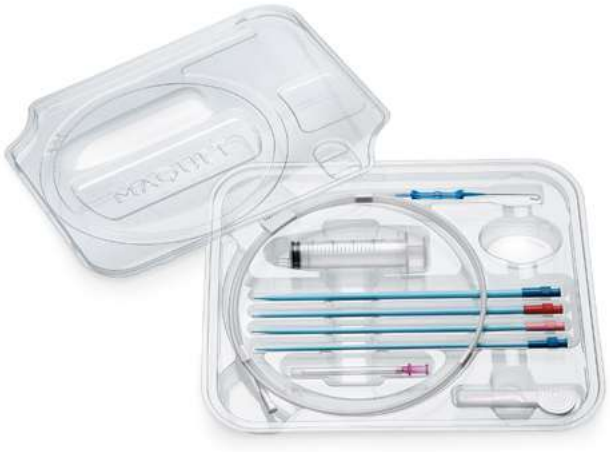
Product order details venous HLS cannulae

Type	Outer diameter	Insertion length	Side holes	Perforation length	Connector	Bioline Coating
PVS 1938	19 Fr (6.3 mm)	38 cm	12	10 cm	3/8"	BE-PVS 1938
PVS 2138	21 Fr (7.0 mm)	38 cm	12	10 cm	3/8"	BE-PVS 2138
PVS 2338	23 Fr (7.7 mm)	38 cm	16	10 cm	3/8"	BE-PVS 2338
PVS 2538	25 Fr (8.3 mm)	38 cm	20	10 cm	3/8"	BE-PVS 2538
PVL 2155	21 Fr (7.0 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2155
PVL 2355	23 Fr (7.7 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2355
PVL 2555	25 Fr (8.3 mm)	55 cm	24	20 cm	3/8"	BE-PVL 2555
PVL 2955	29 Fr (9.7 mm)	55 cm	32	20 cm	3/8"	BE-PVL 2955

One cannula per carton

Percutaneous Insertion Kit

Kit to prepare for arterial or venous peripheral cannulation of vessels for extracorporeal circulation.



The kit includes:

- 4 vessel dilators: 10/12 Fr., 12/14 Fr., 14/16 Fr., 16/18 Fr.
- PIK 100: guide wire for arterial cannulae 0.038" (0.097 cm) x 100 cm, J-tip
- PIK 150: guide wire for venous cannulae 0.038" (0.097 cm) x 150 cm, J-tip
- Guidewire advancer
- 18 Ga (1.27 mm) puncture needle
- Mini scalpel
- 10 ml (10 cc) syringe
- Additional dilator sizes and guidewires available

Order details percutaneous insertion kits and cannulae accessories

Article No.	Guide wire length	Description
PIK 100*	100 cm	Percutaneous insertion kit for arterial HLS cannulae
PIK 150*	150 cm	Percutaneous insertion kit for venous HLS cannulae
PIK dilator set L**		Cannulae accessories: 3 multi-step dilators, dilator sizes 18/20 Fr., 20/22 Fr., 22/24 Fr.
PIK dilator S**		Cannulae accessories: 1 multi-step dilator, dilator size 08/10 Fr.
PIK guidewire 100**	100 cm	Cannulae accessories: separate guidewires for arterial cannulae
PIK guidewire 150**	150 cm	Cannulae accessories: separate guidewires for venous cannulae

* One kit per carton, sterile packed

** 5 pcs. per carton, sterile packed

Note
All information presented in this brochure is either referenced by the below publications or is on file at Getinge.
HLS Cannulae Set· Instructions for Use · 70104.8192 · G-139 · Version 05 · NONUS · 2021-04
Percutaneous Insertion Kit· Instructions for Use · 70104.8194· G-137 · Version 06 · GLOBAL · 2020-06

Manufacturer · Maquet Cardiopulmonary GmbH · Kehler Str. 31 · 76437 Rastatt · Germany · +49 7222 932-0

www.getinge.com

GETINGE

Cardiohelp II

Excellence. Advanced.

GETINGE

Discover Cardiohelp II.
Advancing a Legacy of Excellence.

GETINGE

Compact and lightweight design 01

Over 25% weight reduction for easier transport and improved mobility in critical situations.

Compact and lightweight design 01

Over 25% weight reduction for easier transport and improved mobility in critical situations.

New intuitive user interface

02

Larger touchscreen with an intuitive layout for ease of operation.

Comprehensive user guidance

03

Integrated guidance tools support during setup, operation, and troubleshooting.

Innovative electronic gas blender

04

Seamlessly integrates into the console for precise gas management – even during transport.

Enhanced monitoring capabilities

05

New monitoring features and refined trusted technologies for advanced insights.

Discover Cardiohelp II.
Advancing a Legacy of Excellence.

01
Compact and lightweight design

Over 25% weight reduction for easier transport and improved mobility in critical situations.

02
New intuitive user interface

Larger touchscreen with an intuitive layout for ease of operation.

03
Comprehensive user guidance

Integrated guidance tools support during setup, operation, and troubleshooting

04
Innovative electronic gas blender

Seamlessly integrates into the console for precise gas management – even during transport.

05
Enhanced monitoring capabilities

New monitoring features and refined trusted technologies for advanced insights.

GETINGE

Disclaimer:

This information is intended for an international audience outside the US.

Therapies, solutions, software or products mentioned might not be available or allowed in your country. Please contact your local distributor for details.

This information is aimed exclusively at healthcare professionals or other professional audiences and are for informational purposes only, is not exhaustive and therefore should not be relied upon as a replacement of the Instructions for Use, service manual or medical advice. Getinge shall bear no responsibility or liability for any action or omission of any party based upon this material, and reliance is solely at the user's risk.

Manufacturer · Maquet Cardiopulmonary GmbH · Kehler Str. 31 · 76437 Rastatt · Germany · +49 7222 932-0 · info@getinge.com

www.getinge.com

GETINGE

Rotaflow II

Extracorporeal Life Support System

This document is intended to provide information to an international audience outside of the US.

GETINGE


GETINGE
ROTAFLOW II
10:16:02
LPM
4.02
l/min
Ven
RPM
2410
r/min
Art

Proven strength. Reinvented.

Rotaflow is by your side

Critically ill patients need trusted extracorporeal support and the highest quality care. Hospitals need safe, reliable and easy-to-use technology.

The Rotaflow II Centrifugal Pump System delivers everything you need, with a low total cost of ownership.

The Rotaflow II System is a reliable, high quality extracorporeal life support (ECLS) system that gives you the flexibility you need to provide quality patient care. As pioneers in the field of ECLS, Getinge is a leader in developing products and solutions in this area.

The Rotaflow II System can be used for both veno-arterial (VA) and veno-venous (VV) ECLS / ECMO. VA-ECMO supports both, the heart and lung in the case of cardiac and or respiratory failure, while VV-ECMO offers therapy to patients who have severe pulmonary insufficiency and cannot be supported using conventional ventilation strategies. Both ECMO approaches can serve as a bridge to recovery or further treatment.

Rotaflow II not only comes in a completely new housing and with an enhanced and simplified user interface, but also offers many valuable features and improvements. And is still compatible with the proven PLS Set.

Compact Holder can be attached to the left or the right side of the Rotaflow II device handle or to the Fixation Point.

Fixation Point attaching the Compact Holder to a standard rail (vertical or horizontal) or a vertical round pole, such as on a mast.

Compact Holder with Fixation Point, Rotaflow II Drive and the PLS module combines the components in one ergonomic holder concept.

Support without compromise

A helping hand in critical situations

1 New design of the Rotaflow II System

Together with the Compact Holder, the Rotaflow II Drive and the primed PLS Set, the newly designed base unit weights approx. 11 kg, which is significantly less than the previous models. This impacts ergonomics and makes transport within the hospital easier.

All elements that can or must be operated by the user are highlighted in yellow. Users can immediately see where they have to touch to be able to carry out a command.

2 Improved and simplified user interface

The user interface, with familiar elements, is easy-to-use and intuitive to operate. A simplified user interface is more user-friendly and can shorten the learning curve, for a safe use of the system.

Supporting features such as a step by step priming wizard guides **(A)** and assists during the setup of the device, the connection and priming of the PLS Set as well as a functional test, if required.

The advanced alarm management with supplementary information and guided assistance **(B)** supports you in better troubleshooting and patient management.

A

B

3 Redesigned Rotaflow II Drive

The hot-plug capability of the new Rotaflow Drive ensures immediate exchange during operation for gentle and continuous patient care. Color-coded parts and a new plug-in connection ease the operation and avoid confusion with old drive versions, the old Rotaflow Drive version is not compatible with Rotaflow II Base Unit.

4 Improved intra-hospital transport concept

The new concept attaches the Rotaflow II Drive and the PLS-i Oxygenator to a single compact holder. A predefined distance between the components creates a small footprint with an ergonomic and clearly arranged work area to improve staff and patient safety. All important components are under control with just one hand.

The Fixation Point allows flexible positioning of the Compact Holder close to the patient, resulting in shorter tubing and minimized contact with foreign surfaces. A clean and organized workplace reduces the risk of tripping or unintentional decannulation.

5 New battery management concept

Rotaflow II offers a more sustainable and consumption-based replacement of batteries by the customer. The concept enables the customer to calibrate the systems batteries, without Getinge intervention. The user interface provides a clear overview for monitoring the battery charge level and the health status of the battery. Both calibration and battery replacement can be handled in-house by trained hospital employees, cost-effectively and predictably for significantly reduced downtime.

6 Interfaces to external devices

Electrical interface for transmitting alarms to external systems, such as nurse call. Ethernet network connection and RS232 serial interface transmit application and device data to external systems.

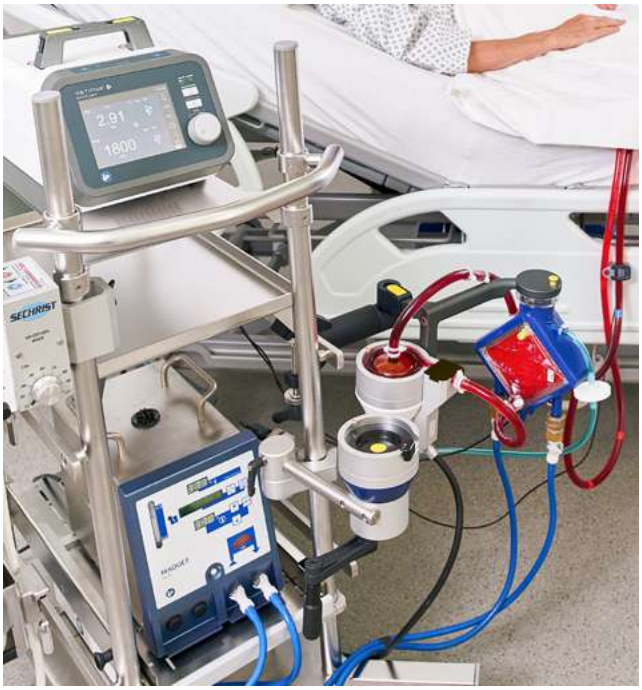
Compact set-up

Ease your daily work

Rotaflow II System

Low total cost of ownership

- Compact and intuitive holder concept for safe and resource-saving intra-hospital transport as well as optimal integration into the workplace.
- The battery management concept allows calibration and replacement of the battery by the end user, giving the user full control over battery maintenance.
- Minimal number of preventive maintenance parts (e.g. battery), this ensures a cost-effective product life cycle.
- The lean manufacturing and service-oriented design minimizes service times and optimizes assembly processes for rapid replacement and maintenance of components.
- Simplified user interfaces for reduced training effort and safe handling of the device.
- The associated PLS Set stands for attractive price-performance ratio.



Permanent Life Support (PLS)

A therapy option for intensive care patients: The PLS Set is developed to support patients requiring respiratory and / or circulatory support with blood flows from 0.5 l/min to 7.0 l/min.

Rotaflow II with the PLS Set can be used in the intensive care unit, cardiac catheterization laboratory as well as operating, trauma and emergency rooms.

Focus on sustainability

Improving battery life and reducing waste is a sustainability goal. The integrated smart battery management is one step to extended replacement intervals.

Carbon emission over the entire life cycle of the system is another goal. Independent calibration and changing of the battery by the hospital increases efficiency and reduces the need for travel.

Full remote certification service trainings make it simple and convenient to keep building vital skills for your future.

GETINGE

ENDOSCOPIC VESSEL HARVESTING

Vasoview Hemopro 2 Endoscopic Vessel Harvesting System

Precision and safety for unsurpassed conduit quality

GETINGE

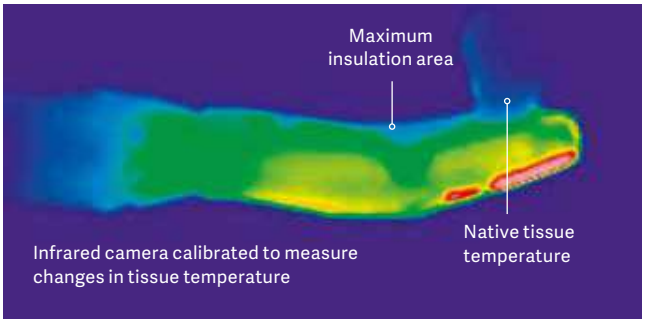
Over 20 years and more than 2 million EVH procedures

For patients undergoing coronary artery bypass, the harvested vessel seems like an afterthought. In reality, conduit quality and incision-related complications can have a dramatic impact on the success of their heart surgery. That's why for more than 20 years, Getinge has worked to refine EVH technology to deliver the efficient, effective results found in Getinge Vasoview Hemopro 2.

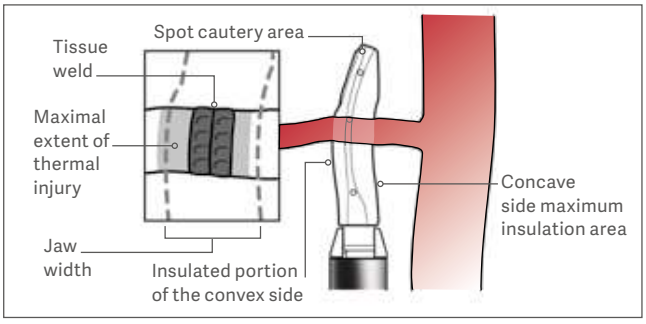
Getinge is built on a foundation of genuine compassion for people's wellbeing and safety through trusted brands, such as Maquet. Our continuing commitment to protecting patients with advanced medical technology helps you proactively avoid complications and prevent common causes of escalating health care costs.

Safely acquire high-quality conduits

Maquet Vasoview Hemopro 2 helps harvesters efficiently and safely acquire high-quality conduits to improve outcomes in cardiac surgery. Used in more than 2 million procedures, it represents the gold standard in vessel harvesting for both the saphenous vein and radial artery. Vasoview Hemopro 2 is inspired by the hands-on experience of clinicians who performed vessel harvest procedures every day. It is the embodiment of the Getinge commitment to highly refined technology and robust design that improves the quality of care.



Thermal imagery demonstrates minimal effect on surrounding tissue.



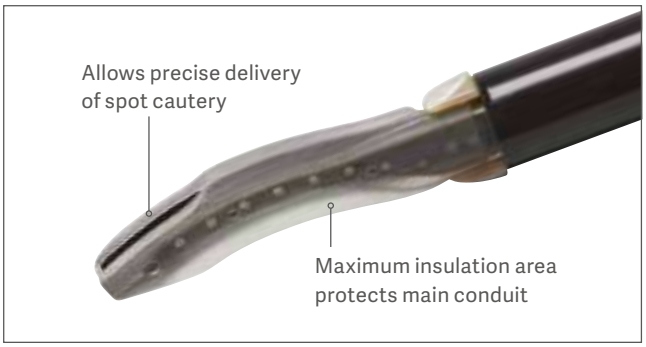
When used as instructed, Vasoview Hemopro 2 ensures hemostasis with virtually no thermal effect on surrounding tissues.[1]

Clinical benefits

- Easy-to-learn techniques enable harvesters to position the jaws while protecting the main conduit[2]
- Advanced system design helps to enhance the efficiency and safety of vessel harvest
- Insulated jaws provide maximum protection against thermal spread[3] to preserve conduit quality

Features

- Enhanced cutting capability for easier fasciotomy
- Spot cautery feature for quick response to ensure hemostasis
- Natural grip handle is comfortable to hold
- Easy-activation toggle
- One-fingertip control is simple, smooth, and highly responsive
- Design and ergonomic sophistication
- Delivering superb visualization and exceptional maneuverability



Society recommendations for EVH

2017 ISMICS consensus statement

Endoscopic Vessel Harvesting and Endoscopic Radial Artery Harvesting should be the standard of care for patients who require these conduits for coronary revascularization (Class I, Level B).[4] (Based on evidence from 76 studies including 281,459 patients.)

2018 ESC/EACTS guidelines

Endoscopic vein harvesting, if performed by experienced surgeons, should be considered to reduce the incidence of wound complications (Class IIa, Level A).[5]

Product ordering information

Description	Code
Vasoview Hemopro 2 Endoscopic Vessel Harvesting System	VH - 4000
Vasoview Hemopro 2 Harvesting Tool Vasoview Hemopro 2 Harvesting Cannula Vasoview Short Port Blunt Tip Trocar (BTT) with Endoscope and Cannula Seal 5 cc Syringe 30 cc Syringe Conical Dissection Tip	
Vasoview Hemopro 2 EVH System with Vasoshield Pressure Controlling Syringe	VH - 4001
Vasoview Hemopro 2 Extension Cable	VH - 4030
Vasoview Hemopro 2 Adapter Cable for use with Hemopro Power Supply	VH - 4020
Vasoview Hemopro Power Supply	VH - 3010
7 mm Extended-length Endoscope	VH - 1111

References

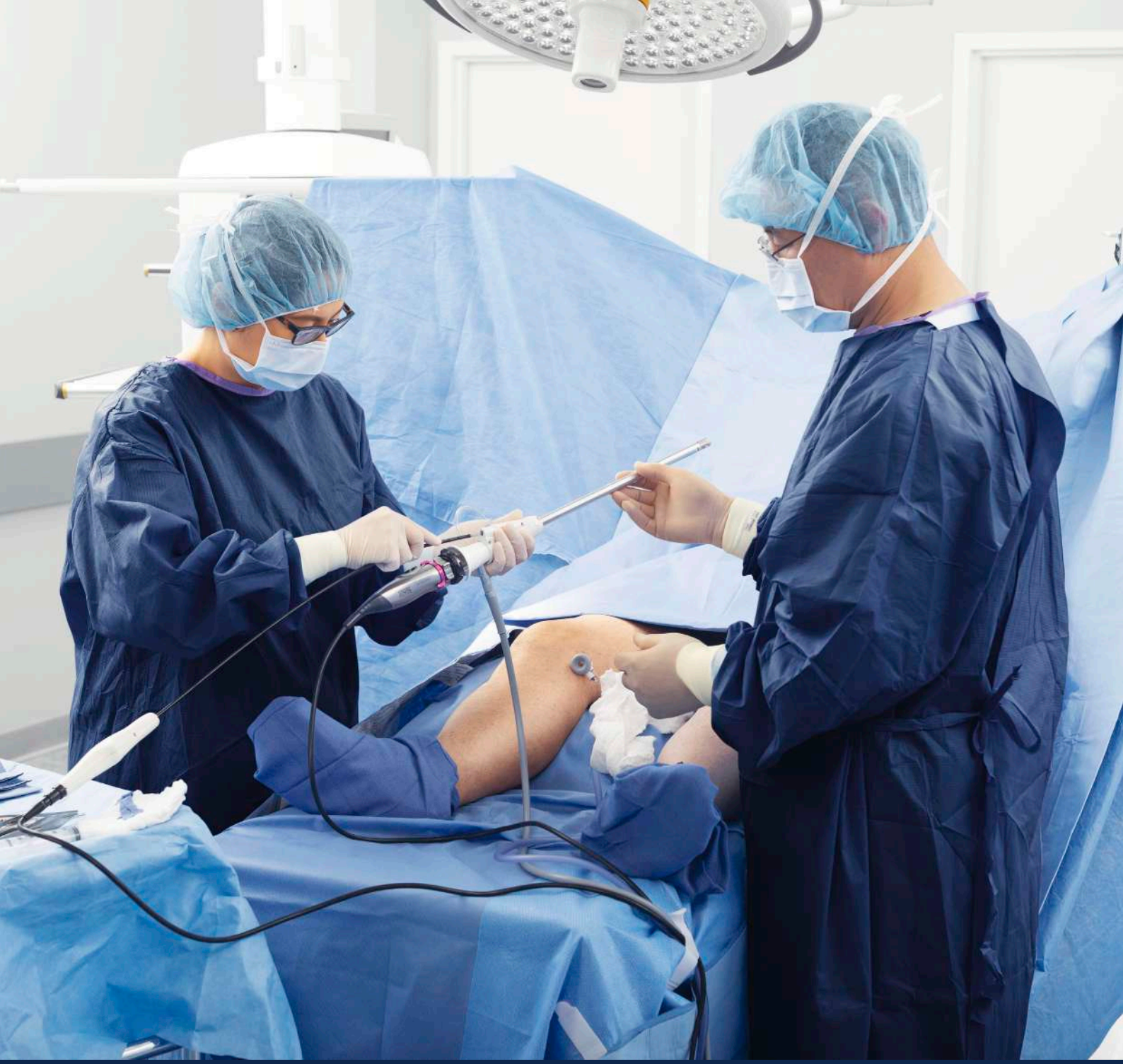
1. Data on file, Maquet Cardiovascular; 2008.
2. When used in accordance with Instructions for Use.
3. Thermal spread is defined as the extent (length) of thermal injury of the vessel extending laterally outward from the edge of the jaws at the location of the interaction between the jaws and the vessel.
4. Ferdinand FD, MacDonald JK, Balkhy HH, et al. Endoscopic Conduit Harvesting in Coronary Artery Bypass Grafting Surgery: An ISMICS Systematic Review and Consensus Conference Statements. *Innovations.* Sep/Oct 2017;12(5):301-319.
5. Neumann FJ, Sousa-Uva M, Agksson A, et al. 2018 ESC/EACTS Guidelines on Myocardial Revascularization. *Eur Heart J.* 2018; 00:1-96.

GETINGE

Getinge • 45 Barbour Pond Drive • Wayne, NJ 07470 • USA • 888 627 8383

www.getinge.com

MCV00071865 REVB



Vasoview Hemopro 2

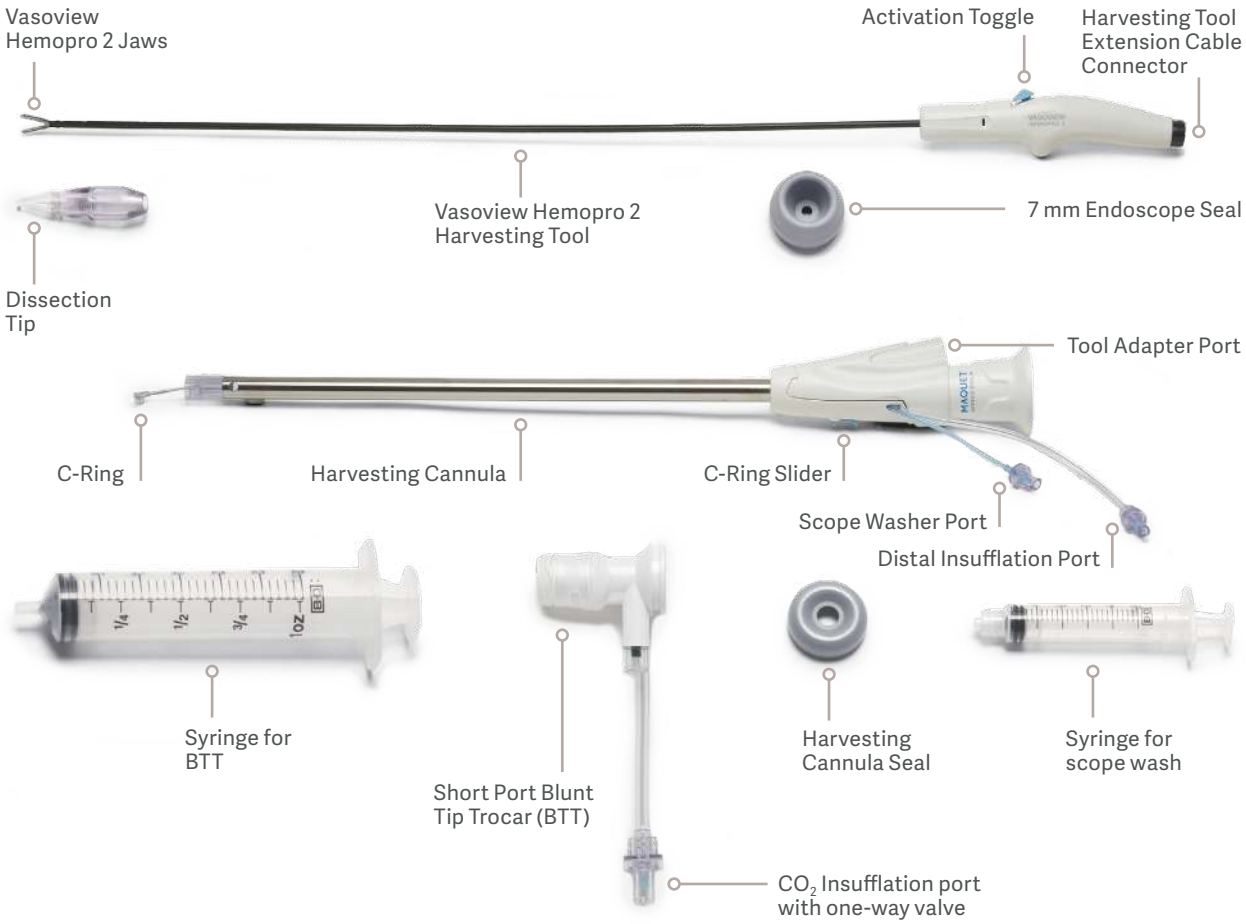
Equipment Overview

GETINGE

Vasoview Hemopro 2

Endoscopic Vessel Harvesting Harvesting System

Getinge disposables



Getinge hardware*

- 7mm Extended Length Endoscope
- Vasoview Hemopro Power Supply
- Vasoview Hemopro 2 Adapter Cable
- Vasoview Hemopro 2 Extension Cable

7mm Extended Length Endoscope

- 49cm in length (end to end)
- Threaded distal end

Vasoview Hemopro 2 Extension Cable

Vasoview Hemopro Power Supply

Power Cord

Vasoview Hemopro 2 Adapter Cable

Hospital hardware required

Tower equipment

- CO_2 Insufflator & CO_2 Tank/Source
- Camera Box
- Video Monitor
- Light Source
- Fiber Optic Cable
- Sterile CO_2 Insufflation Tubing
- Camera Head compatible to Endoscope (sterile or appropriate disposable sterile camera head)
- Video recorder (optional)

*Hardware is to be re-used based on IFU Sterilization

Hospital additional items (optional)

- Sterile water-soluble Lubricant
- Basic minor instrument set for incision, direct dissection and ligation of vessel
- Anti-fog solution
- #11 Blade
- Marking pen

Product ordering information

Material description	Catalog Number
7mm Extended Length Endoscope	VH-1111
Vasoview Hemopro 2 Adapter Cable	VH-4020
T.W. Power Supply	VH-3010
Vasoview Hemopro 2 Extension Cable	VH-4030
Vasoview Hemopro 2: • Endoscopic Vessel Harvesting System • Vasoview Hemopro 2 Harvesting Tool • Vasoview Hemopro 2 Harvesting Cannula • Vasoview Short Port Blunt Tip Trocar (BTT) and Cannula Seal • 5cc Syringe • 30cc Syringe • Conical Dissection Tip	VH-4000
Vasoview Hemopro 2 with Vasoshield	VH-4001
Vasoview Endoscopic Vessel Harvesting System Accessory Pack: • Vasoview Short Port Blunt Tip Trocar (BTT) and Cannula Seal • 30cc Syringe • Conical Dissection Tip	VH-2004

*GETINGE

Getinge · 45 Barbour Pond Drive · Wayne, NJ 07470 · USA · 1 888 627 8383

www.getinge.com

MCV00107775 REVA

ADVANCE HEMODYNAMIC MONITORING

PulsioFlex Monitoring Platform

Flexible and patient-focused advanced hemodynamic monitoring

This document is intended to provide information to an international audience outside of the US.

GETINGE

Making therapeutic decisions is not easy

Let us help

The PulsioFlex Platform for advanced hemodynamic patient monitoring is easily adaptable to every patient's individual needs and specific physician requirements, at all times.

- Adjustable to various clinical settings (OR, ER, ICU)
- Specific to the physicians need for information
- Easily scalable to patient's risk level

Intelligent visualization for advanced patient monitoring

- Brilliant 8" LED color touch screen with high resolution
- Glass touch screen and intuitive user interface
- Space saving thanks to minimal dimensions and low weight
- Flexible mounting and installation possibilities
- Modular expandability with automatic module detection
- Network compatible e.g. print function via clinic network

By your side

Patient-centered flexibility

The PulsioFlex Monitoring Platform is a flexible, patient-focused hemodynamic monitoring device. This convenient and compact bedside monitor is easy to set up and assists users through smart and intuitive handling – to help guide the next therapeutic steps.

Identify your patients' risk level continuously and intuitively

PulsioFlex offers the possibility to choose between different pre-configured displays which can be individually adjusted. The special color concept provides a comprehensive picture of the measured parameters. An example is the 'Spider-View' feature which shows an overview of the most important parameters at a glance. When the spider changes color, the patient's condition has changed.

Stay continuously updated about any change in your patient's condition – enable immediate and purposeful adjustment of treatment.

Additional benefits:

- Expandable modular design – ready for future technologies
- Usable as stand-alone monitor
- Simple set-up through individually coded cables
- Intuitive menu guidance

PulsioFlex

Platform setup

At a certain point you will need more information about your patient's hemodynamic condition.

The PulsioFlex Monitoring Platform combines the technologies of PiCCO, ProAQT, CeVOX and LiMON. This will give you the information you need to help assess the hemodynamic status of your critically ill patient, on-site.

Get the complete picture with:

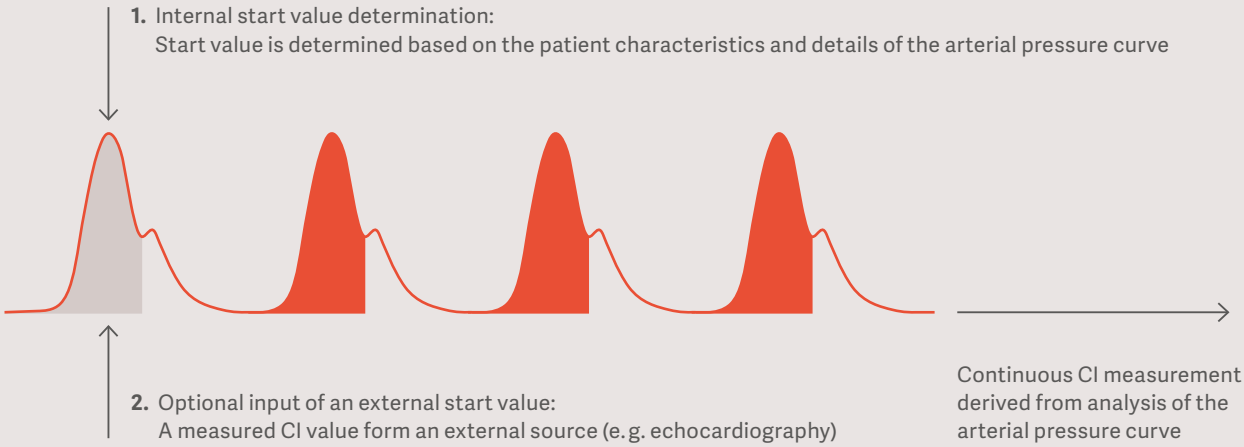
- Calibrated cardiac output monitoring with PiCCO
- Minimally invasive peri-operative cardiac output trend monitoring with ProAQT
- Continuous central venous oxygen saturation monitoring with CeVOX
- Non-invasive global liver function monitoring with LiMON

ProAQT Technology

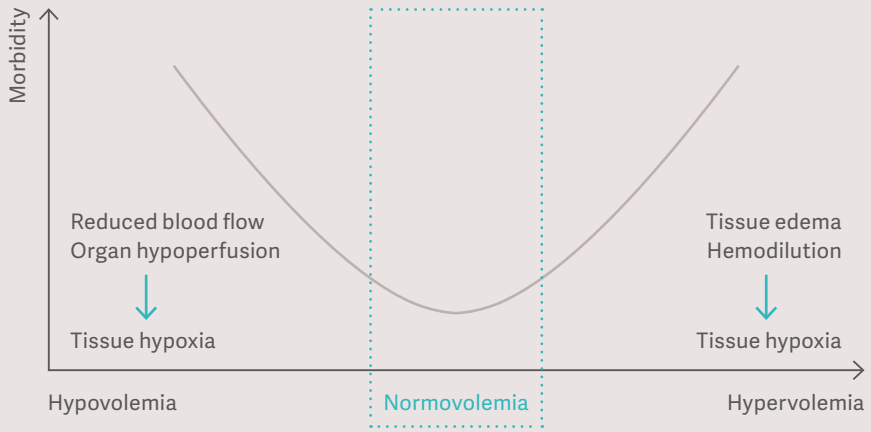
Peri-operative fluid optimization

Beat-to-beat cardiac output and volume responsiveness based on arterial pulse contour analysis with ProAQT.

ProAQT principle and calibration procedure



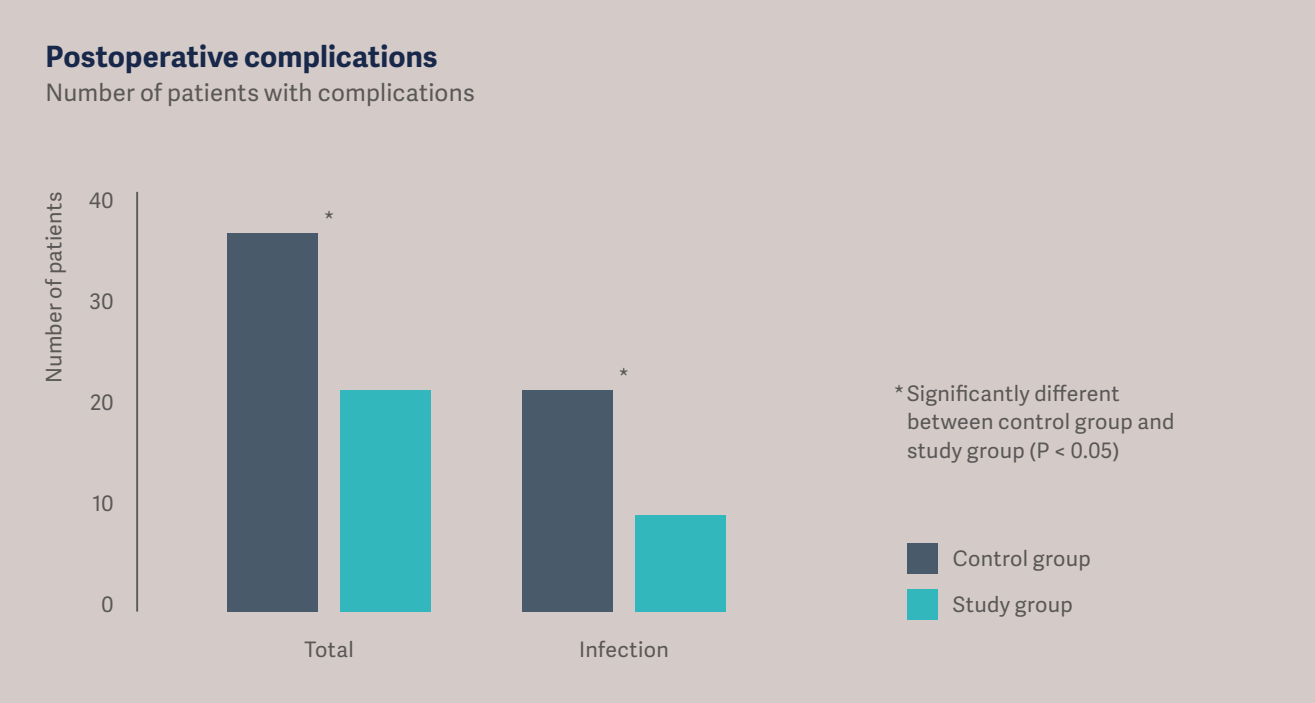
Individualized fluid therapy helps avoid hypervolemia or hypovolemia (and) related complications [1]



ProAQT is applicable for:

- Complex procedures with high-risk of intra- and post-operative complications
- Anticipated high blood loss (> 20%) and volume shifts during procedure which can result in hypo- or hypervolemia
- Protracted surgery time (> 120 min)

Improve outcome in major abdominal surgery



»... hemodynamic goal-directed therapy using pulse pressure variation, cardiac index trending and mean arterial pressure as the key parameters leads to a decrease in postoperative complications in patients undergoing major abdominal surgery« [2]

PiCCO Technology

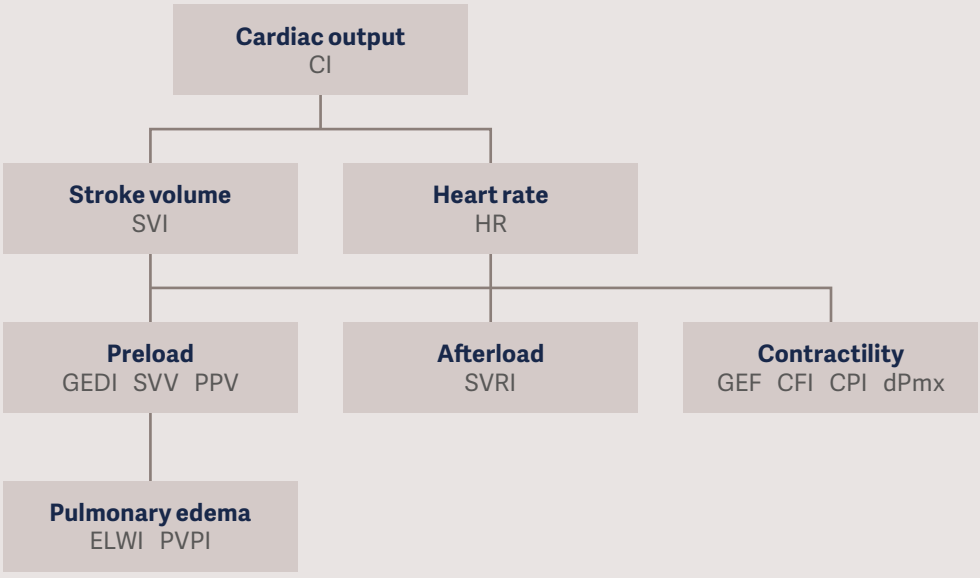
Get the complete picture of the hemodynamic situation in critically ill patients

PiCCO Technology is based on two physical principles: transpulmonary thermodilution and pulse contour analysis. Both principles allow the calculation of advanced hemodynamic parameters and have been clinically tested and established for more than 20 years.[3,4]

PiCCO helps you to answer these questions:

- What is the current cardiovascular situation?
- What is the cardiac preload and afterload?
- Is the patient fluid responsive?
- Is the patient developing lung edema?

Hemodynamic parameters



Simplify hemodynamics

- Clinically proven and widely accepted minimally-invasive alternative to the pulmonary artery catheter
- The precise PiCCO parameters allow physicians to perform patient-individualized therapy with optimal use of inotropes and vasopressors
- PiCCO enables the measurement of extra-vascular lung water for pulmonary edema assessment

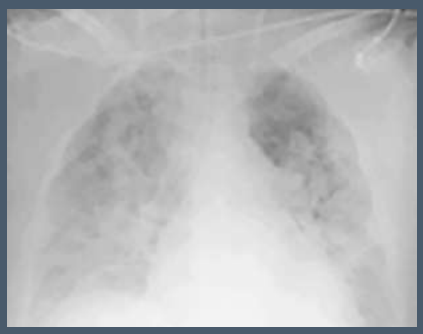
»PiCCO provides a comprehensive picture of the haemodynamic condition through relevant information on preload responsiveness indexes, cardiac output and extravascular lung water. In critically ill patients and particularly in those with both cardiovascular and respiratory disorders, PiCCO thus allows clinicians to take rapidly appropriate decisions on when to start, to continue and to stop fluid administration.«

Jean-Louis Teboul, MD, Professor Service de Réanimation médicale, Centre Hospitalier Universitaire de Bicètre, Paris, France

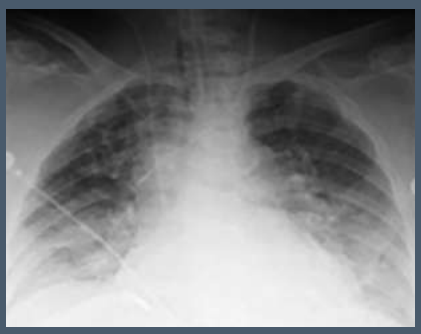
PiCCO Technology offers direct and accurate bedside quantification of pulmonary edema by measuring extravascular lung water index (ELWI). This enables sensitive and early detection of the development of pulmonary edema and allows early therapeutic intervention before the pulmonary edema can cause alveolar damage or complications. The ELWI measurement is significantly more accurate than pulmonary edema estimation from chest X-rays.[5–7]

Examples of chest X-rays that do not reflect the level of pulmonary edema

ELWI = 21 ml/kg
Severe pulmonary edema



ELWI = 14 ml/kg
Moderate pulmonary edema



ELWI = 8 ml/kg
No pulmonary edema

Pulmonary edema is not easily detected by chest X-rays as shown above. ELWI is more sensitive than chest X-ray.[8]

O_2 CeVOX Technology

Sensitive continuous measurement of oxygen balance for early detection of tissue hypoxia

CeVOX Technology is based on spectrophotometry.

Infrared light of specific wave lengths is emitted by LEDs and transmitted through a fiber optic into the vessel.

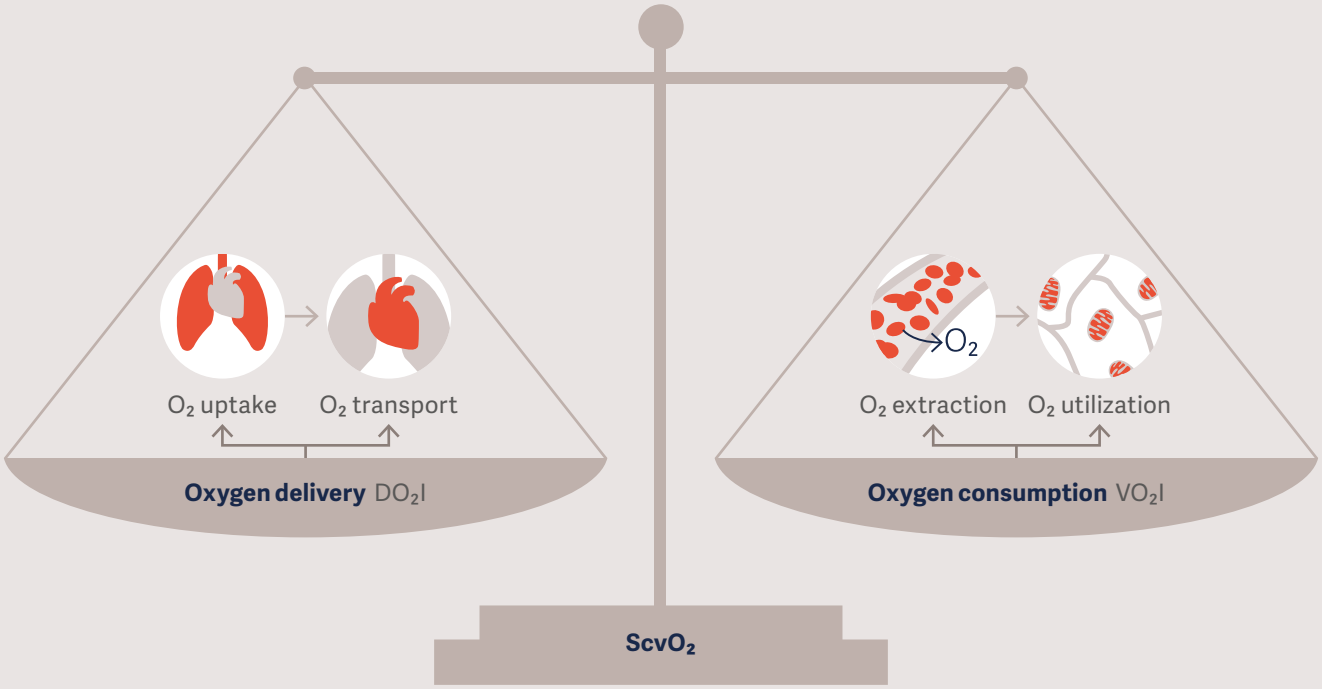
The light is then reflected by the red blood cells and transmitted back through a separate fiber optic to the optical module.

Enables early intervention

- Traditional vital signs may be late indicators of inadequate oxygen delivery to tissue
- Detects acute changes in systemic balance between oxygen delivery and consumption
- Tracks therapeutic effects immediately and continuously

Reduces complications and mortality

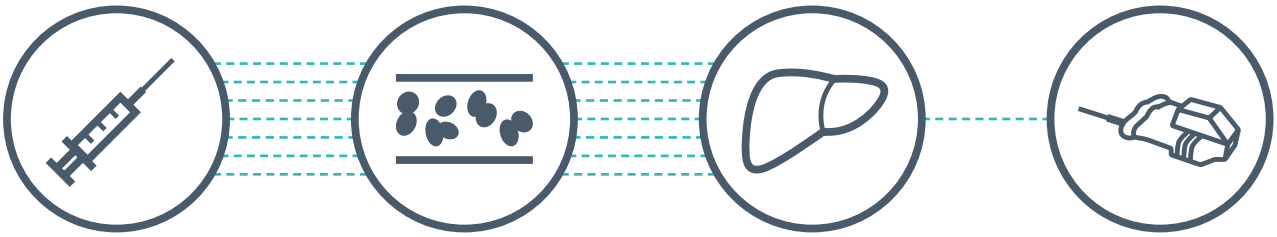
- Low $ScvO_2$ is related to an increased risk of post-operative complications in high-risk surgery[9]
- Decreases risk of infection by reducing frequency of BGA sampling
- Identifies early life-threatening drop in systemic oxygen delivery



LiMON Technology

Non-invasive global liver function assessment at the bedside

LiMON Technology detects the elimination of diagnostic dye indocyanine green (ICG) by modified pulse oximetry.



Intravenous injection of ICG

ICG binds immediately and completely to plasma proteins

ICG is exclusively eliminated by the liver into the bile

Non-invasive detection of the ICG signal by the LiMON Sensor

LiMON supports physicians in various applications

- Significantly better specificity and sensitivity than standard liver function tests [10]
- Quantification of remaining liver function before liver resection [11,12]
- Early identification of post-operative liver dysfunction in liver resection and transplantation [13–15]
- Identification of post-operative complications in liver surgery [16]

Overview

Technologies and parameters

Method		PiCCO	ProAQT	CeVOX	LiMON
Pulse contour analysis (continuous)	**Flow**	CI_{PC*}, SVI	$CI_{Trend/Cal**}$, SVI		
	Contractility	dPmx, CPI	dPmx, CPI		
	Afterload	SVRI	SVRI		
	Volume responsiveness	SVV, PPV	SVV, PPV		
Thermodilution (discontinuous)	**Flow**	CI_{TD***}			
	Preload	GEDI			
	Contractility	CFI, GEF			
	Pulmonary edema	ELWI, PVPI			
Oxymetry	**Oxygen saturation**			$ScvO_2$	
ICG elimination	**Liver function**				PDR, R15

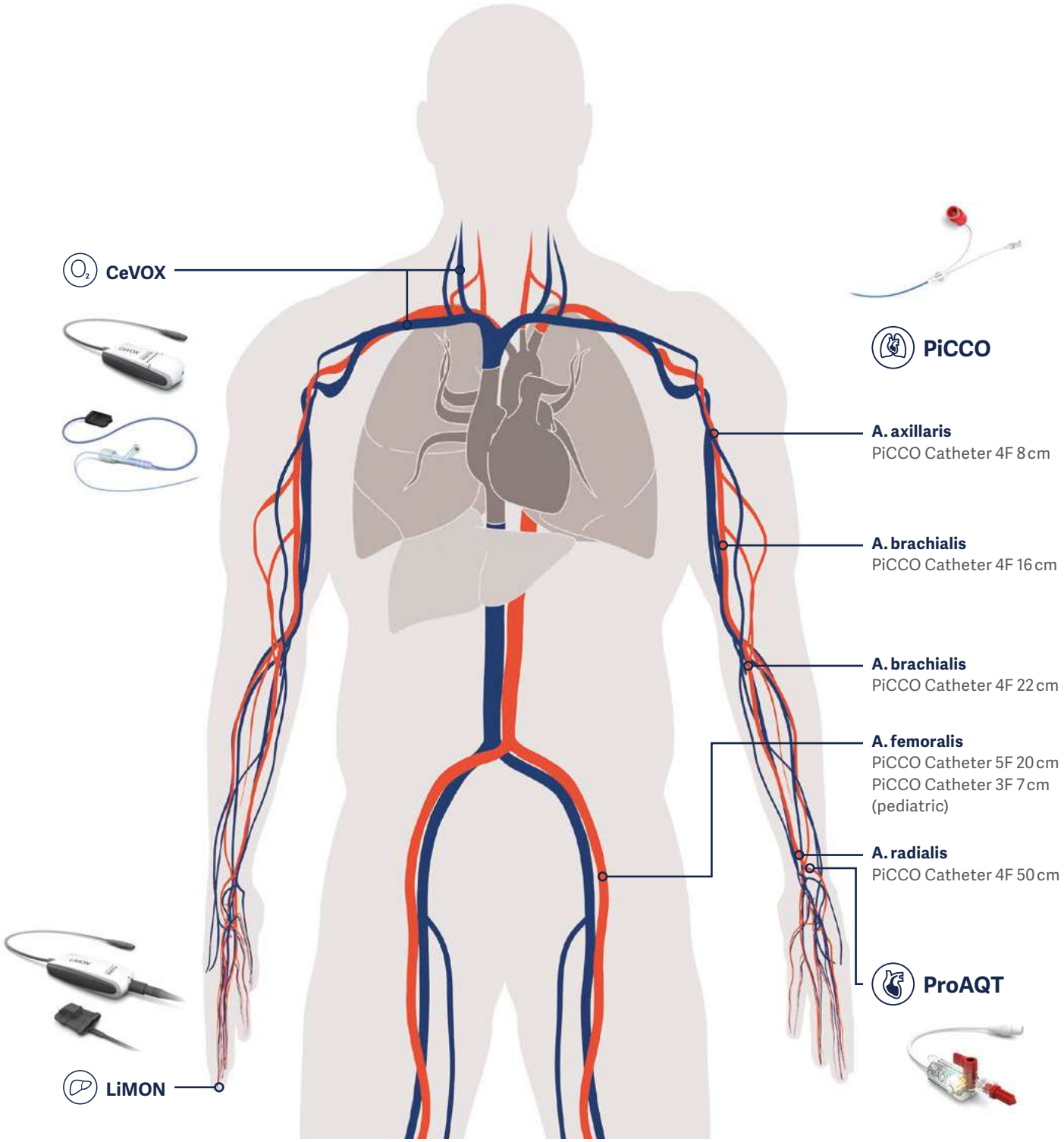
* Cardiac index derived from pulse contour ** Calibrated from internal or external reference value
*** Cardiac index derived from thermodilution

Literature

1. Boulain T & Cecconi M., Can one size fit all? The fine line between fluid overload and hypovolemia, Intensive Care Med 2015, DOI 10.1007/s00134-015-3683-7
2. Salzwedel C. et al., Perioperative goal-directed hemodynamic therapy based on radial arterial pulse pressure variation and continuous cardiac index trending reduces postoperative complications after major abdominal surgery: a multi-center, prospective, randomized study. Crit Care 2013, 17(5): R191.
3. Michard F. et al., Global end-diastolic volume as an indicator of cardiac preload in patients with septic shock. Chest 2003, 124(5): 1900-1908.
4. Adler C. et al., Fluid therapy and acute kidney injury in cardiogenic shock after cardiac arrest. Resuscitation 2013, 84(2): 194-199.
5. Brown LM, Calfee CS, Howard JP, Craig TR, Matthay MA, McAuley DF. Comparison of thermodilution measured extravascular lung water with chest radiographic assessment of pulmonary oedema in patients with acute lung injury. Ann Intensive Care 2013; 3(1): 25.
6. Saugel B, Ringmaier S, Holzapfel K, Schuster T, Phillip V, Schmid RM, Huber W. Physical examination, central venous pressure, and chest radiography for the prediction of transpulmonary thermodilution-derived hemodynamic parameters in critically ill patients: A prospective trial. J Crit Care 2011; 26(4): 402-10.
7. Lemson J, van Die LE, Hemelaar AE, van der Hoeven JG. Extravascular lung water index measurement in critically ill children does not correlate with a chest X-ray score of pulmonary edema. Crit Care 2010; 14(3): R105
8. Sakka S. G. et al., Assessment of cardiac preload and extravascular lung water by single transpulmonary thermodilution. Intensive Care Med 2000, 26(2): 180-187.
9. Pearse R. M. et al., Changes in central venous saturation after major surgery, and association with outcome. Crit Care 2005, 9(6): R694-699.
10. Levesque E. et al., Plasma disappearance rate of indocyanine green: a tool to evaluate early graft outcome after liver transplantation. Liver Transpl 2009, 15(10):1358-1364.
11. Scheingraber S et al., Indocyanine green disappearance rate is the most useful marker for liver resection. Hepatogastroenterology. 2008 Jul-Aug;55(85):1394-9
12. Poon RT et al., Assessment of hepatic reserve for indication of hepatic resection: how I do it. J Hepatobiliary Pancreat Surg. 2005;12(1):31-7
13. Scheingraber S. et al., Indocyanine green disappearance rate is the most useful marker for liver resection. Hepatogastroenterology 2008, 55(85): 1394-1399.
14. de Liguori Carino N, O'Reilly DA, Dajani K, Ghaneh P, Poston GJ, Wu AV, Perioperative use of the LiMON method of indocyanine green elimination measurement for the prediction and early detection of post-hepatectomy liver failure, Eur J Surg Oncol 2009; 35(9):957-62
15. Tralhao JG, Hoti E, Oliveiros B, Botelho MF, Sousa FC, Study of perioperative liver function by dynamic monitoring of ICG-clearance, Hepatogastroenterology 2012; 59(116): 1179-83
16. Imamura H, Sano K, Sugawara Y, Kokudo N, Makuuchi M, Assessment of hepatic reserve for indication of hepatic resection: decision tree incorporating indocyanine green test. J Hepatobiliary Pancreat Surg 2005; 12: 16-22

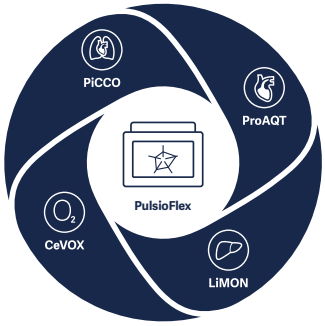
Recommended application sites

of PulsioFlex Technologies



Passion for life

Improving outcomes for critically ill patients



Advanced hemodynamic monitoring helps physicians understand complex conditions of patients in intensive care units and during high risk surgeries and helps to optimize their hemodynamic condition.

Pulsion's core competence is the development and production of medical devices for monitoring critically ill patients. Pulsion Medical Systems SE was founded in 1990 and is located in Feldkirchen, Greater Munich. Since 2014, Pulsion is wholly-owned by, and fully-integrated with, Getinge.

Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and life science companies and institutions.

Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving everyday life for people – today and tomorrow.

GETINGE

Pulsion Medical Systems SE · Hans-Riedl-Str. 17 · 85622 Feldkirchen · Germany · +49 89 459914-0 · zentrale.pulsion@getinge.com

www.getinge.com

MPI4102EN_R08 · 09/2018 · PulsioFlex, PiCCO, ProAQT, CeVOX and LiMON are registered Trademarks · Copyrights by Pulsion Medical Systems SE

PiCCO Technology

Hemodynamic monitoring at the highest level

This document is intended to provide information to an international audience outside of the US.

GETINGE

Simplify hemodynamics

Understand complex conditions with PiCCO

The life of your critically ill patient depends on the right decision for the next therapeutic step. Therapeutic conflicts often arise at the critical care bedside, where you need dependable information you can trust. A set of reliable hemodynamic parameters can help determine the best individual treatment for your patients.

The PiCCO Technology was introduced in 1997 by the Munich based company Pulsion Medical Systems. With more than 20 years of experience in the hemodynamic monitoring industry, Pulsion has developed PiCCO into the established standard for advanced hemodynamic monitoring, today.

As the evidence, PiCCO has achieved modular integration with world market leaders for patient-monitoring devices including Philips / Dixtal, Drager, GE, Mindray and Nihon Kohden.

Over the last 15 years, nearly 1,000 publications worldwide have confirmed the accuracy and clinical benefit of the PiCCO Technology.

Today, PiCCO is used more than 140,000 times per year, in over 60 countries globally.

since
1997

publications
1,000

annual PiCCO applications
140,000

Basics of hemodynamic monitoring

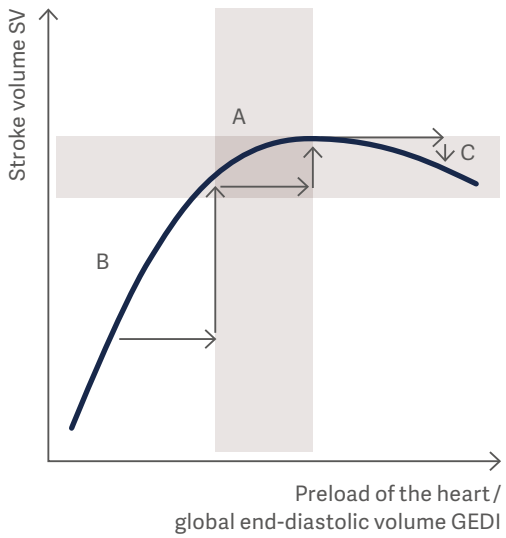
Monitoring cardiocirculatory function is of major importance in all intensive care patients.

Monitoring with standard parameters: ECG non-invasive blood pressure and pulse oximetry provides insufficient information for deciding on the adequacy of treatments. Only advanced hemodynamic monitoring with minimally-invasive measurement of cardiac output and its determinants (preload, afterload, contractility) as well as the quantification of pulmonary edema allows a targeted treatment.

Frank-Starling mechanism

The Frank-Starling law states that the greater the volume of blood entering the ventricle during diastole (end-diastolic volume), the greater the volume of blood ejected during systolic contraction (stroke volume) and vice-versa. This is an adaptive mechanism of the organism to compensate for slight changes in the ventricular filling.

The power of the heart muscle depends on its initial load before the start of contraction.

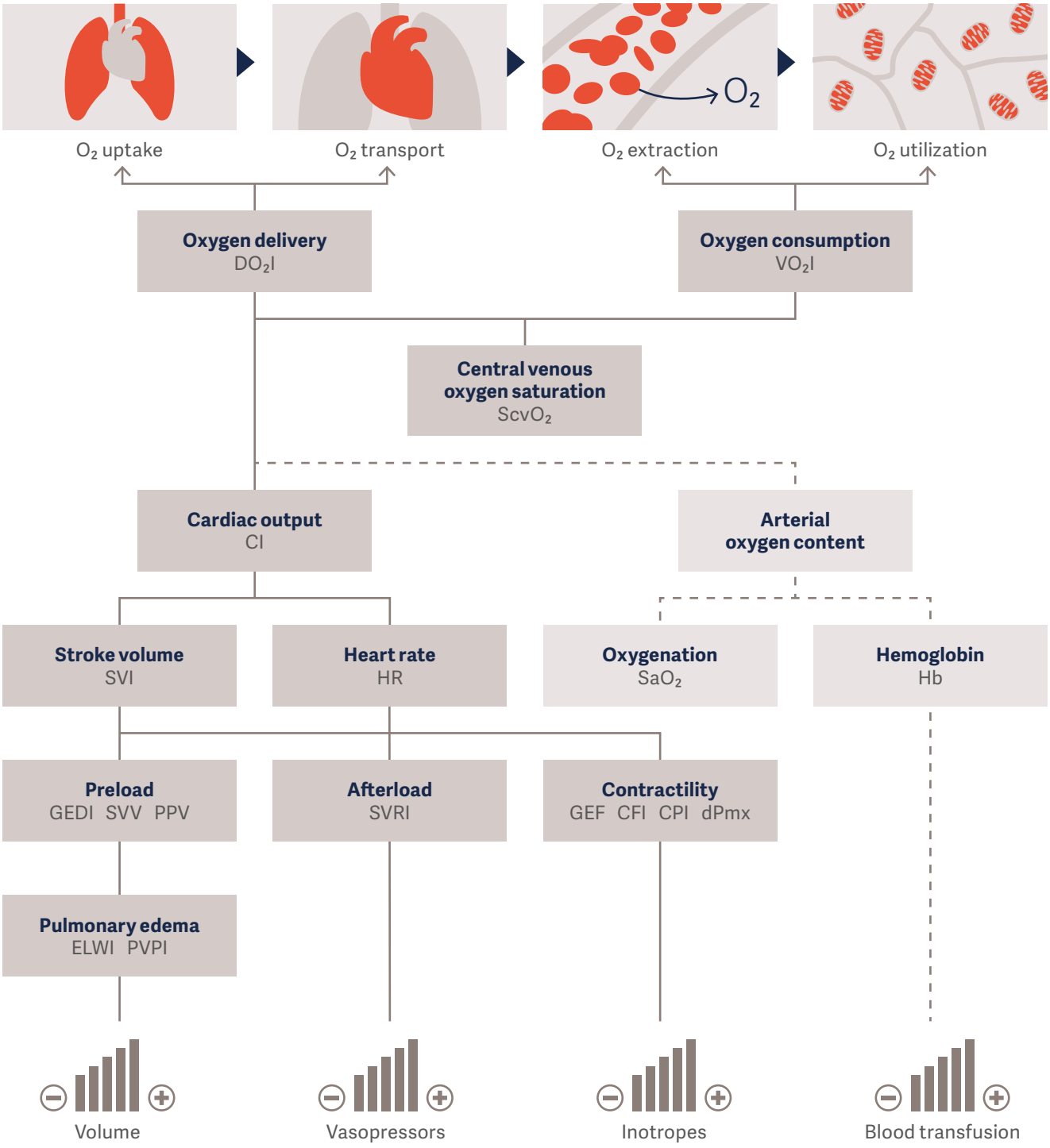


Schematic Frank-Starling curve for verification of the preload status
A = Optimal preload, B = Volume reponsive, C = Volume overload

However, it can also be used to increase stroke volume by volume administration for therapeutic reasons. The force that any single cardiac muscle fibre generates is proportional to the initial sarcomere length (known as preload), and the stretch on the individual fibres is related to the end-diastolic volume of the ventricles.

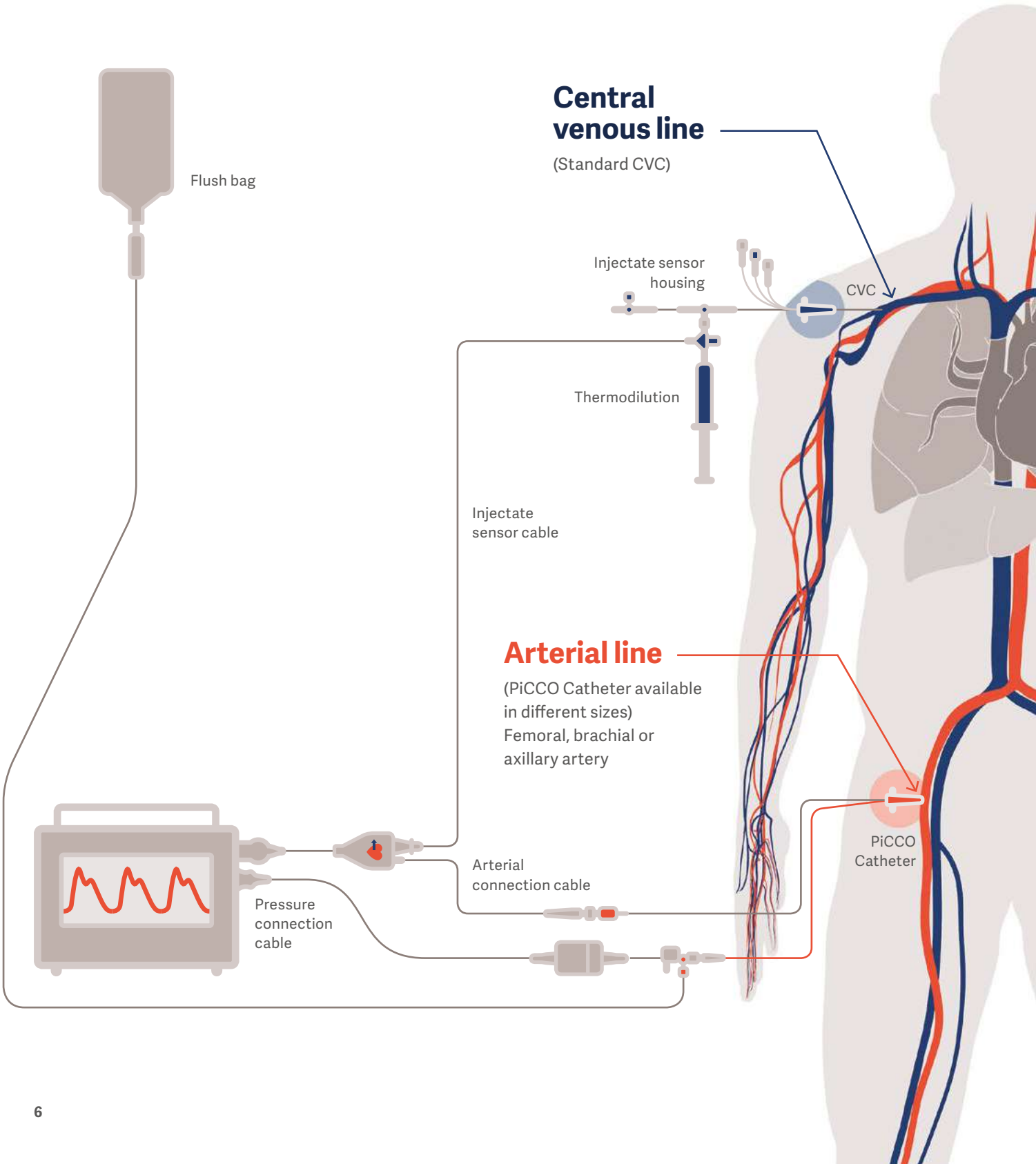
An increase in preload will, to a certain extent, lead to an increase in stroke volume (SV), based on optimal myocardial muscle fibre pre-stretching. Up to a certain limit, the more the sarcomeres of the muscle cells are stretched the greater the contraction. On the other hand, contractility may decrease in conditions of volume overload.

Hemodynamic parameters



Get the complete picture

How PiCCO Technology works



Two components of the PiCCO Technology

PiCCO Technology is based on two physical principles, namely, transpulmonary thermodilution and pulse contour analysis. Both principles allow the calculation of hemodynamic parameters and have been clinically tested and established for more than 20 years.[1, 2]

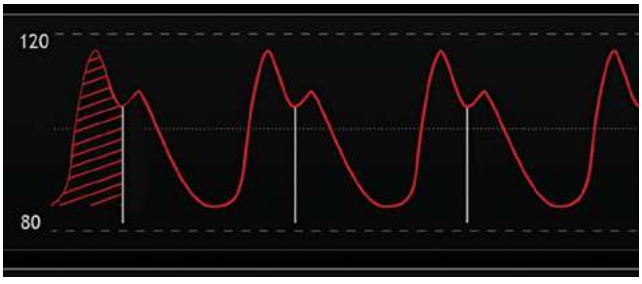
Arterial pulse contour analysis

The pulse contour analysis provides continuous information while transpulmonary thermodilution provides static measurements. Transpulmonary thermodilution is used to calibrate the continuous pulse contour parameters.

Transpulmonary thermodilution

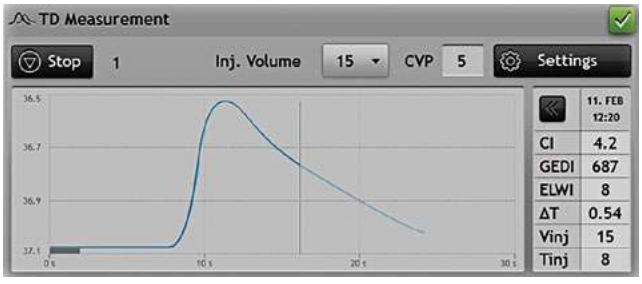
For the transpulmonary thermodilution measurement, a defined bolus (e. g. 15 ml cold normal saline) is injected via a central venous catheter.

The cold bolus passes through the right heart, the lungs and the left heart and is detected by the PiCCO Catheter, commonly placed in the femoral artery. This procedure should be repeated around three times in under 10 minutes to obtain an accurate average that is used to calibrate the device and to calculate the thermodilution parameters. These thermodilution parameters (i. e. they are updated only when the thermodilution procedure is performed) should be checked whenever there is a significant change in the patient's condition or therapy. It is recommended to calibrate the system at least 3 times a day.



Arterial pulse contour analysis

The shaded area below the systolic part of the pressure curve is proportional to the stroke volume.



Transpulmonary thermodilution

Pulse contour analysis

The theoretical basis of pulse contour analysis was established for the first time in 1899.[3]

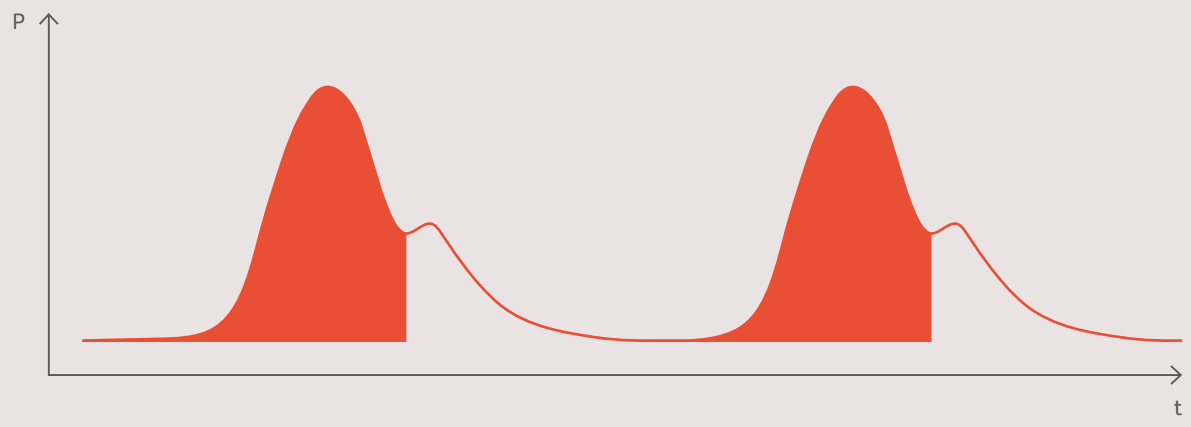
The basic idea was to use the analysis of the continuous arterial pressure signal to get more information than just the systolic, diastolic and mean value.

From a physiological perspective the arterial pressure curve provides information about the opening of the aortic valve (point of the increase of the systolic pressure) and when the aortic valve closes (incision in the pressure curve / the dicrotic notch). The time in between represents the duration of the systole and the area under the systolic part of the pressure curve directly reflects the stroke volume (SV), the amount of blood in milliliters which is ejected by the left ventricle with every heart beat.

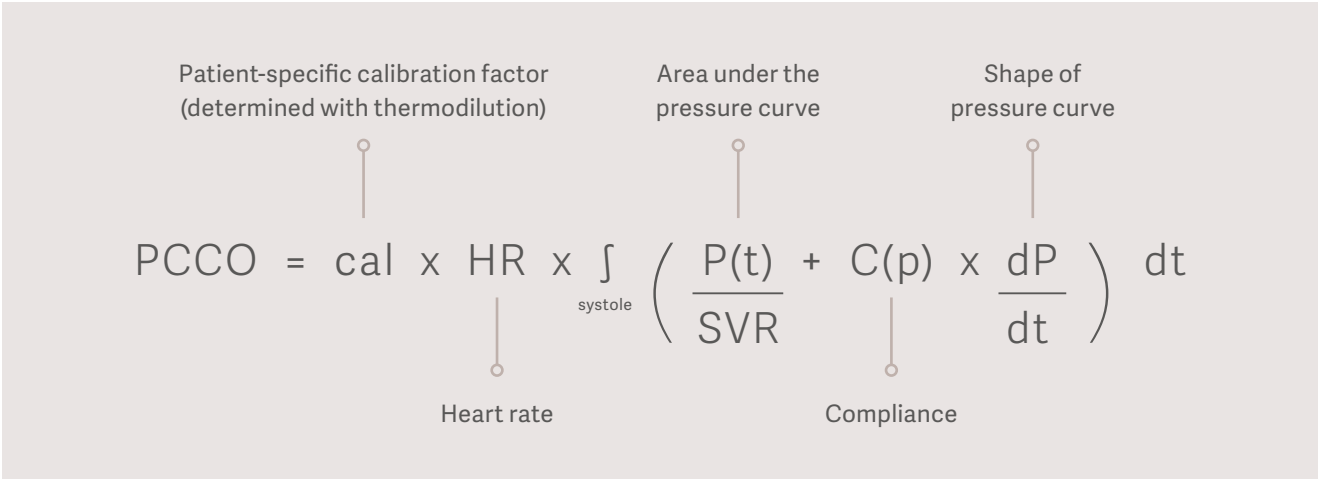
However, the shape of the arterial pressure curve and the area under the curve is influenced not only by the stroke volume, but also by the individual compliance of the vascular system.

This is especially true of intensive care patients where a potentially rapid change in the vascular compliance occurs due to the disease process or medications. The individual calibration factor is determined with the initial calibration and needs to be updated regularly.[1, 4] In PiCCO Technology, this calculation factor is derived from the transpulmonary thermodilution measurement.

Analysis of the arterial pressure curve for the area under the systole



With the sophisticated algorithm, the stroke volume is calculated continuously and, by multiplying the stroke volume with the heart rate, a continuous cardiac output is derived, the pulse contour cardiac output (PCCO).[5]



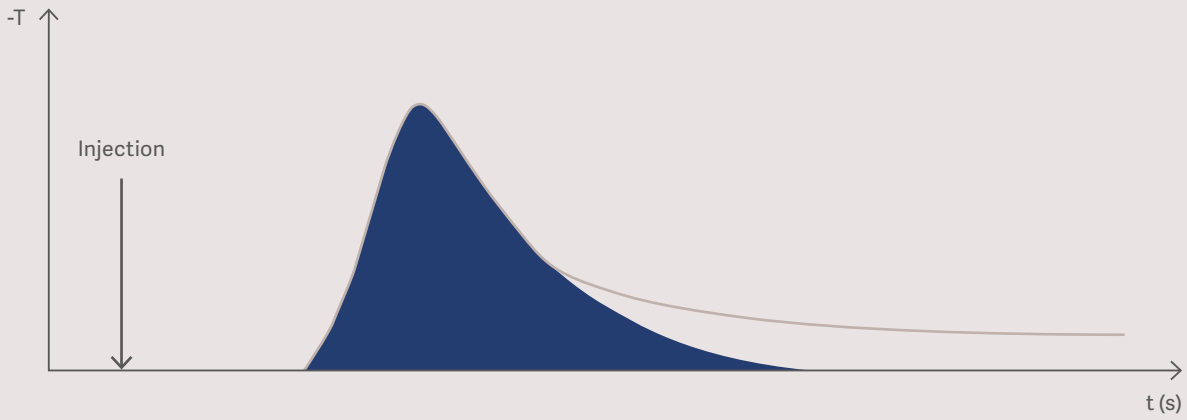
Basic formula to calculate pulse contour cardiac output (PCCO)

The PiCCO pulse contour algorithm has been extensively validated and has proved to be very reliable in daily critical care routine:

Overview of comparative studies on cardiac output measurement using PiCCO pulse contour and pulmonary arterial thermodilution [5–13]

Reference	Accuracy (l/min)	Standard deviation (l/min)	Regression coefficient
Felbinger TW et al., J Clin Anesth 2005	0.220	0.26	0.92
Della Rocca G et al., Can J Anesth 2003	0.080	0.72	–
Mielck F et al., JCVA 2003	-0.400	1.30	–
Felbinger TW et al., J Clin Anesth 2002	-0.140	0.33	0.93
Della Rocca G et al., BJA 2002	0.040	–	0.86
Rauch H et al., Acta Anaesth Scand 2002	0.140	1.16	–
Godje O et al., Med Sci Monit 2001	-0.020	1.20	0.88
Zollner C et al., JCVA 2000	0.310	1.25	0.88
Buhre W et al., JCVA 1999	0.003	0.63	0.93

Transpulmonary thermodilution



The CO is calculated from the area under the thermodilution curve[14–15]

$$CO = \frac{(T_b - T_i) \times V_i \times K}{\int \Delta T_b \times dt}$$

Blood temperature

Injectate temperature

Injecate volume

Correction constant*

Area under the thermodilution curve

* comprises specific weight and specific heat of blood and injectate fluid

The cardiac output (CO) is determined from the trans-pulmonary thermodilution.

The thermodilution curves are analysed and the CO is determined by using a modified Stewart-Hamilton algorithm.[14, 15] This method of calculating the cardiac output is used similarly by the right heart (pulmonary artery) catheter.

Overview of comparative studies on cardiac output measurement using transpulmonary and pulmonary arterial thermodilution

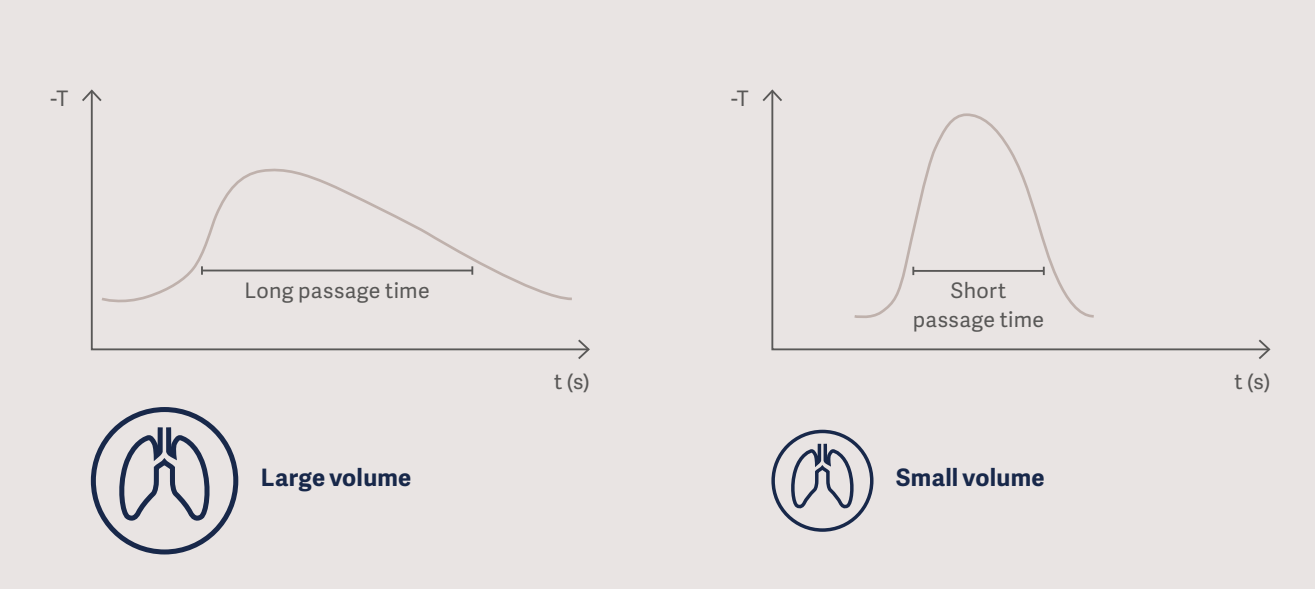
Clinical studies confirm the accuracy of the cardiac output values measured with transpulmonary thermodilution.[16]

Author	Patient group	Age	N	n	r	Bias (%)	Precision (%)
Della Rocca et al., 2002	Liver transplant	24–66	62	186	0.93	+1.90	11.0
Friesecke et al., 2009	Severe heart failure n. a.	29	325		ni	10.30	27.3 (PE*)
Goedje et al., 1999	Cardiac surgery	41–81	24	216	0.93	-4.90	11.0
Holm et al., 2001	Burns	19–78	23	109	0.97	-8.00	7.3
Kuntscher, 2002	Burns	21–61	14	113	0.81	ni	ni
Mc Luckie et al., 1996	Pediatrics	1–8	10	60	ni	+4.30	4.8
Segal et al., 2002	Intensive care	27–29	20	190	0.91	-4.10	10.0
von Spiegel et al., 1996	Cardiology	0.5–25	21	48	0.97	-4.70	12.0
Wiesenack et al., 2001	Cardiac surgery	43–73	18	36	0.96	+7.40	7.6
Zöllner et al., 1999	ARDS	19–25	18	160	0.91	-0.33	12.0

N = number of patients; n = number of measurements; r = regression coefficient; ni = not indicated
* PE= percentage error according to Critchley

An advantage of transpulmonary thermodilution is that it is independent from breathing or ventilatory cycles. Additionally, because the indicator passes through the heart and lungs, this allows the determination of intravascular and extravascular volumes inside the chest area, in particular, the preload volume and lung water.

Physiological principles



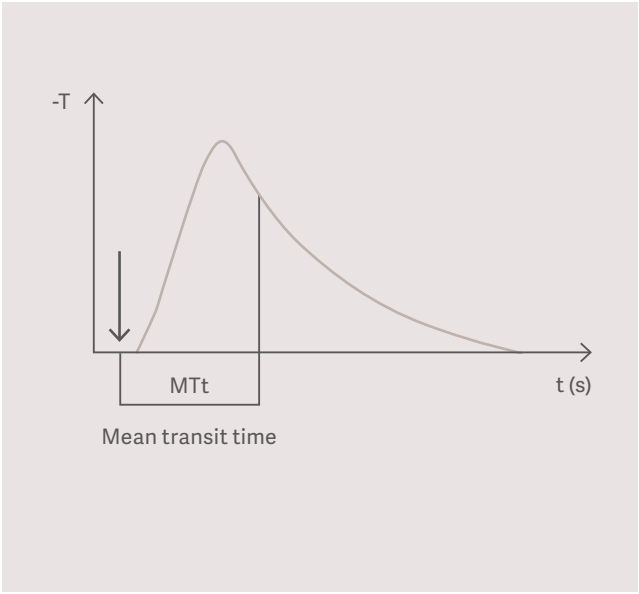
Large volume of intravascular and extravascular volumes

Small volume of intravascular and extravascular volumes

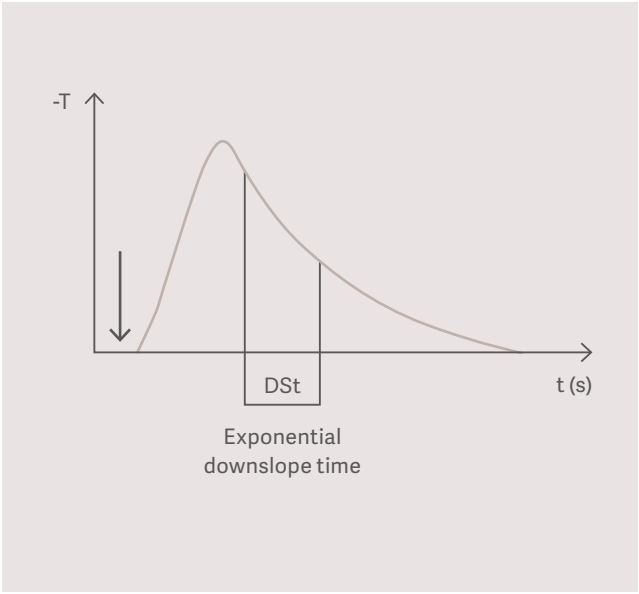
Assessment of volumes from transpulmonary thermodilution

The shape of the transpulmonary thermodilution curve is strongly influenced by the amount of intravascular and extravascular volume between the injection point (central venous) and detection point (central arterial). This means that the larger the volume amount in the chest, the longer the passage time of the indicator and vice versa. Determination of specific transit times of the thermal indicator thus enables quantification of specific volumes in the chest.

This analysis and calculation is based on a publication by Newman et al.[17] and has also been described by other authors.[18–24]



Determination of mean transit time



Determination of exponential downslope time

Mean transit time (MTt)

Mean transit time represents the time when half of the indicator passes the detection point (central artery). It is determined from the bisector of the area under the curve.

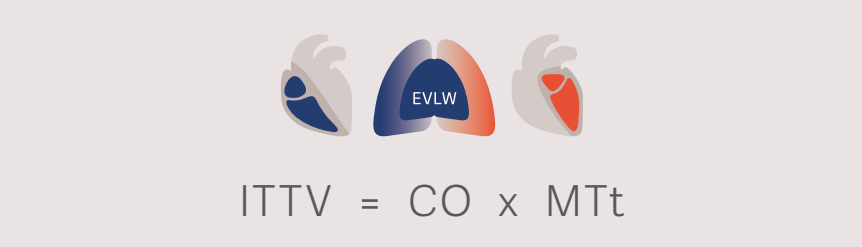
Exponential downslope time (DSt)

The exponential downslope time represents the wash-out function of the indicator. It is calculated from the downslope part of the thermodilution curve.

Both mean transit time and exponential downslope time serve as the basis for calculation of the following volumes.

Intrathoracic thermal volume

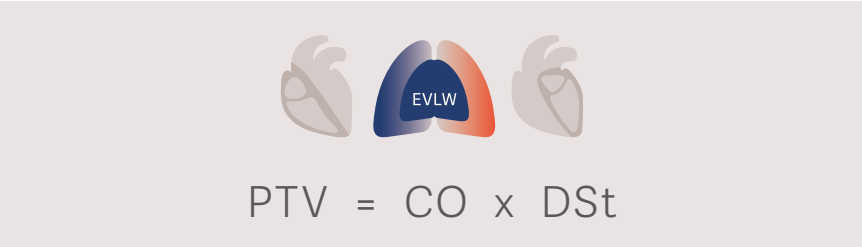
The multiplication of the mean transit time (MTt) with cardiac output (CO) represents the intrathoracic thermal volume (ITTV).



Scheme and calculation of the intrathoracic thermal volume (ITTV)

Pulmonary thermal volume

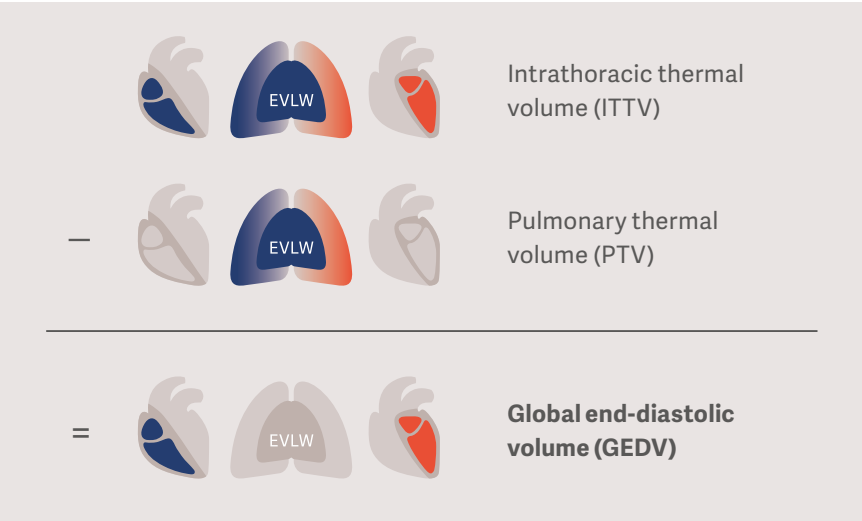
The exponential downslope time always characterises the volume of the largest mixing chamber in a row of mixing chambers. In the cardiopulmonary systems this is the lung. Thus the multiplication of the exponential downslope time (DSt) with the cardiac output (CO) represents the pulmonary thermal volume (PTV).



Scheme and calculation of the pulmonary thermal volume (PTV)

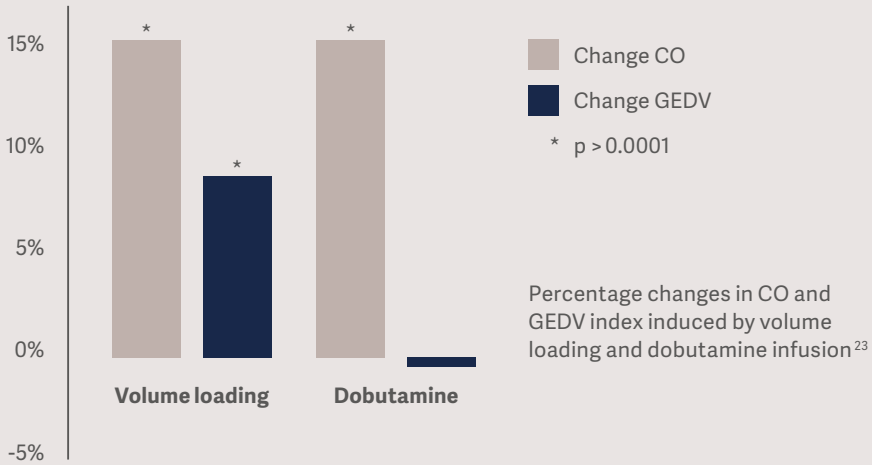
Quantification of the preload volume

By simply subtracting the pulmonary thermal volume from the intrathoracic thermal volume, the global end-diastolic volume (GEDV) is derived. GEDV indicates the level of preload volume.



Calculation of global end-diastolic volume (GEDV)

Cardiac output and transit times are derived from the same thermodilution signal. This raises the question of mathematical coupling, which has been investigated several times,[23] concluding that CO increases without a corresponding increase in GEDV.

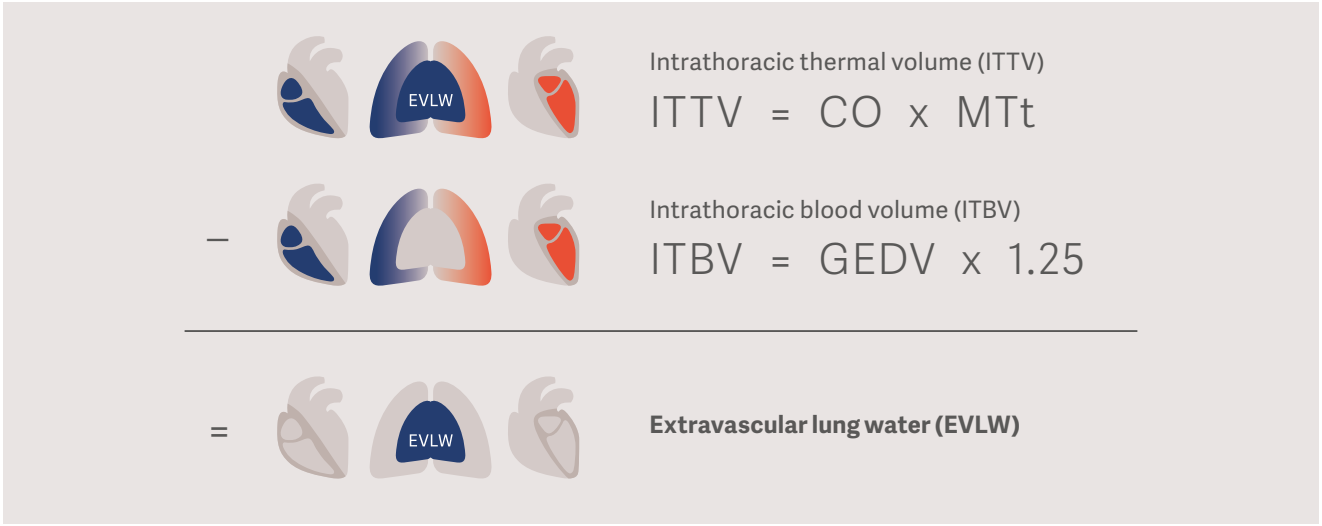


Percentage changes in CO and GEDV index induced by volume loading and dobutamine infusion[23]

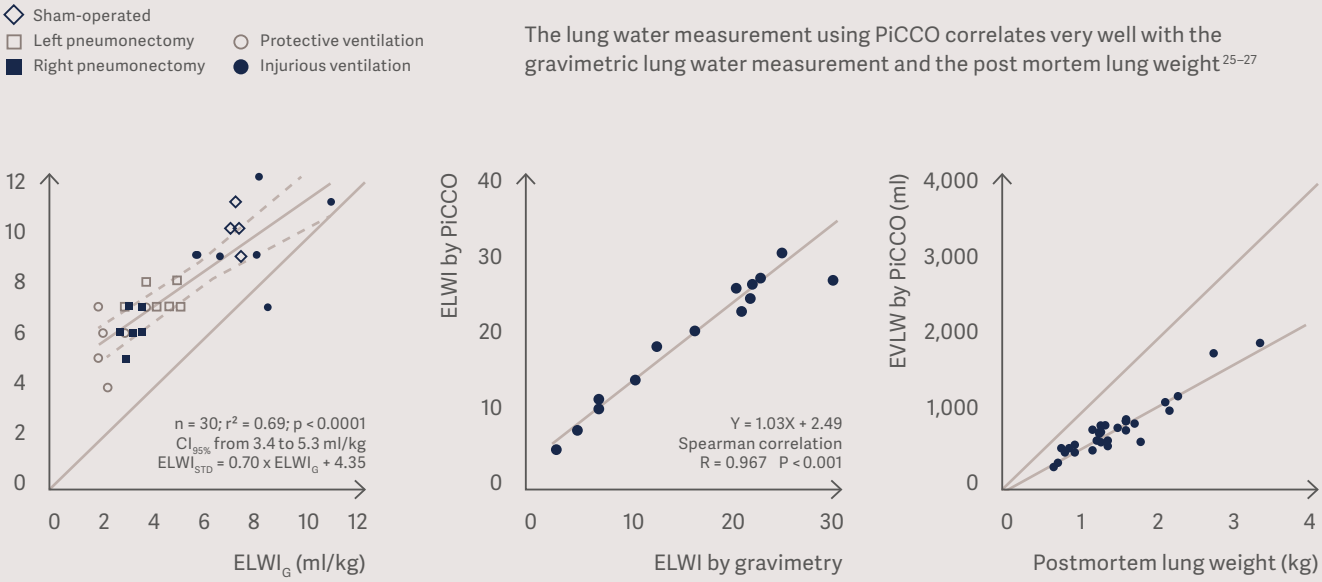
Quantification of a pulmonary edema

Using further calculations, the PiCCO Technology also provides quantification of the amount of pulmonary edema, expressed as extravascular lung water (EVLW). The only additional information required for this calculation is the amount of intravascular volume (ITBV). A clinical study using double-indicator dilution technology to measure ITBV and EVLW[24] found that intrathoracic blood volume is consistently 25% higher than the global end-diastolic volume. Thus, the intrathoracic blood volume can simply be calculated by multiplying the global end-diastolic volume with the factor 1.25. The calculated intrathoracic blood volume (ITBV) is then subtracted from the intrathoracic thermal volume (ITTV) to derive the extravascular lung water (EVLW).

Several validation studies comparing gravimetry and lung weight show that both this method and the introduction of the fixed factor for calculation of extravascular lung water show high accuracy.[25–27]



Calculation of extravascular lung water (EVLW)



PiCCO parameters

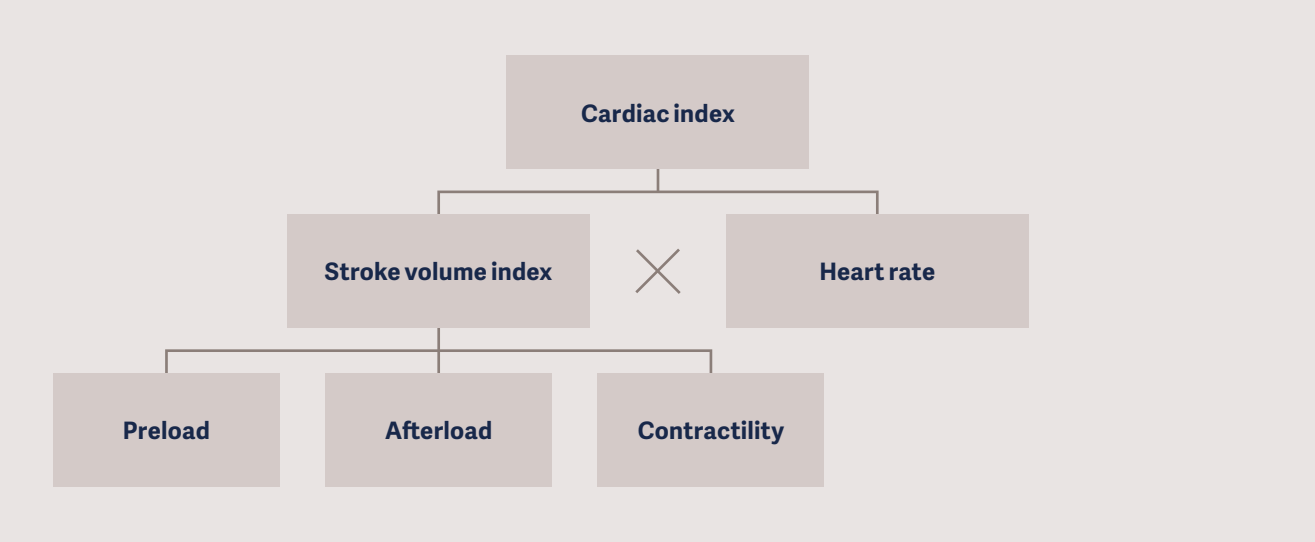
Cardiac index (CI), stroke volume index (SVI)

Cardiac index is the amount of blood pumped by the heart per minute indexed to 1 m² of the body surface area (BSA); the cardiac index represents the global blood flow. The PiCCO Technology provides discontinuous (transpulmonary thermodilution) and continuous (pulse contour analysis) parameters.

A decrease in cardiac index is a clear alarm signal and requires appropriate measures to manage the situation.

But knowledge about cardiac index alone is not enough to make a therapeutic decision, as the cardiac index is influenced by several factors. First of all it is the product of stroke volume and heart rate. Stroke volume is dependent on preload, afterload and contractility.

Thus, in addition to the cardiac index, further information on its determinants is required for appropriate treatment.



Cardiac index and its determinants

CI
3–5 l/min/m²

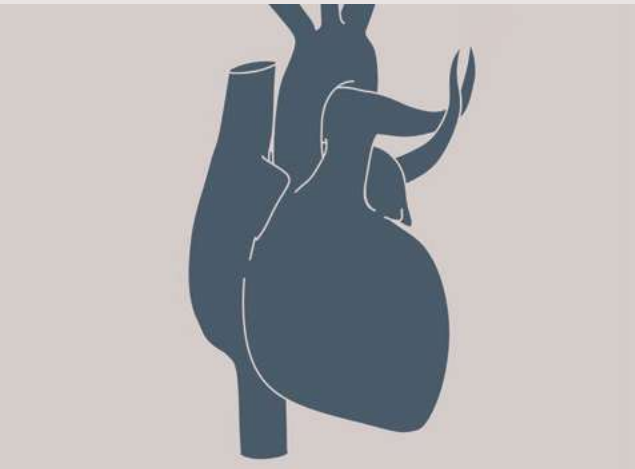
SVI
40–60 ml/m²

Preload

Global end-diastolic volume index (GEDI)
The preload is, along with afterload and contractility, one of the determinants of stroke volume and therefore cardiac output. Theoretically, it can be best described as the initial stretching of a single muscle cell of the heart prior to contraction, which means at the end of diastole. As this cannot be measured in vivo, other measurements have therefore to be substituted as estimates. In the clinical setting, preload is referred to as the end-diastolic pressure or (more precisely) end-diastolic volume.
A higher end-diastolic volume implies higher preload.

A higher central venous pressure (CVP) and / or a higher pulmonary capillary wedge pressure (PCWP) is still often regarded as an indicator of higher preload (CVP for the right heart, PCWP for the left heart). However, many studies have shown that CVP and PCWP are not reliable indicators for this purpose. This is mainly due to the limitation that pressure cannot be directly transferred into volume. So any volumetric parameter assessing the filling of the ventricle at the end of diastole reflects the actual preload more precisely.

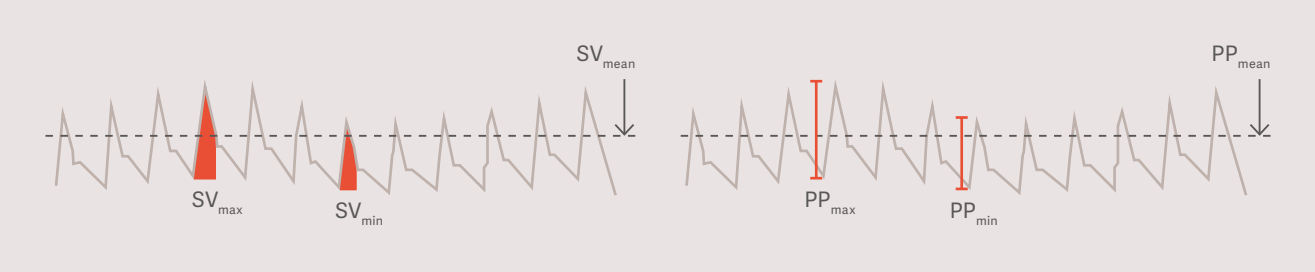
In the clinical setting, preload is referred to as the end-diastolic pressure or (more precisely) end-diastolic volume.



OK

GEDI
680–800 ml/m²

Volume responsiveness



Stroke volume variation (SVV)

Pulse pressure variation (PPV)

Stroke volume variation (SVV) and pulse pressure variation (PPV)

The stroke volume variation (SVV) or pulse pressure variation (PPV) give – provided there is a continuously ventilated patient with a stable heart rhythm – information as to whether an increase in preload will also lead to an increase in stroke volume.

Mechanical ventilation induces cyclic changes in vena cava blood flow, pulmonary artery blood flow and aortic blood flow. At the bedside, changes in the aortic blood flow are reflected by swings in the blood pressure curve (and thus variations in stroke volume and blood pressure). The magnitude of these variations is highly dependent on the volume responsiveness of the patient. With controlled ventilation, the rise in intrathoracic pressure during early inspiration leads to a squeezing of the pulmonary blood into the left ventricle. This process in turn increases the left ventricular preload. With a volume responsive patient, this results in an increased stroke volume or pulse pressure.

An increase in intrathoracic pressure also results in reduced right ventricular filling. With a volume responsive right heart, this will reduce the volume ejected. Thus, during late inspiration a couple of heartbeats later, the left ventricular preload will decrease as will the stroke volume or pulse pressure. The variations in stroke volume and pulse pressure can be analysed over a 30 second time frame by the following formula:

$$SVV = \frac{(SV_{max} - SV_{min})}{SV_{mean}}$$

$$PPV = \frac{(PP_{max} - PP_{min})}{PP_{mean}}$$

The higher the variation the more likely the patient is to be volume responsive. For proper use of the parameters, the following preconditions must be fulfilled:

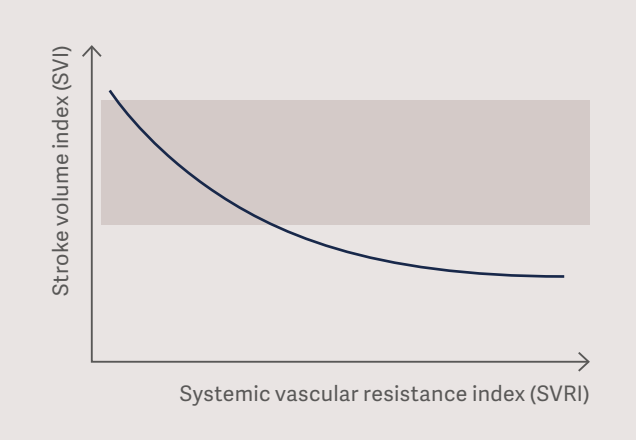
- Fully controlled mechanical ventilation with a tidal volume ≥ 8 ml/kg PBW (predicted body weight)
- Sinus rhythm
- Pressure curves free of artifacts

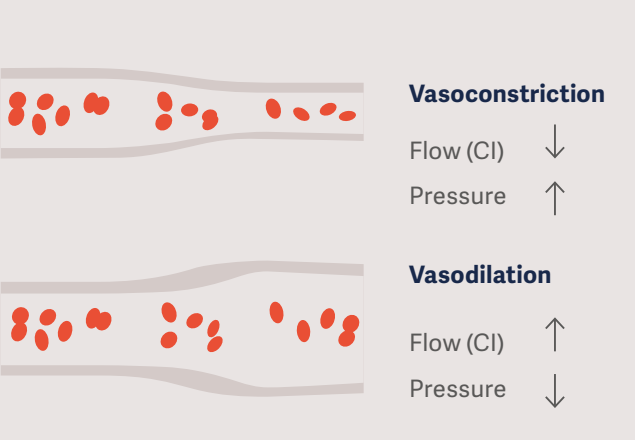
OK

SVV/PPV

< 10%

Afterload





Systemic vascular resistance index (SVRI)

The afterload is another determinant of stroke volume / cardiac output. The physiological meaning of SVRI is the tension or pressure that builds up in the wall of the left ventricle during ejection. Following Laplace's law, the tension upon the muscle fibers in the heart wall is the product of the pressure within the ventricle and the ventricle radius, divided by the ventricle wall thickness.

In the clinical context things are often simplified and so the afterload is seen as the resistance the heart has to pump against; the systemic vascular resistance index (SVRI) is the parameter that represents this.

- If the afterload (SVRI) is increased, the heart must pump with more power to eject the same amount of blood as before.
- The higher the afterload, the less the cardiac output.
- The lower the afterload, the higher the cardiac output.

If the afterload exceeds the performance of the myocardium, the heart may decompensate.

$$SVRI = \left[\frac{(MAP - CVP)}{CI} \right] \times 80$$

OK

SVRI

1,700–2,400 dyn*s*cm^{-5}*m^2

Contractility

Contractility influences cardiac output.

Contractility of the myocardium represents the ability of the heart to contract independent of the influence of preload or afterload. Substances that cause an increase in intracellular calcium ions lead to an increase in contractility. Different concentrations of calcium ions in the cell lead to different degrees binding between the actin (thin) and myosin (thick) filaments of the heart muscle. Direct determination of cardiac contractility is not possible in the clinical setting. Therefore, surrogate parameters are used to evaluate or estimate the contractility.

Global ejection fraction (GEF)

Ejection fraction represents the percentage of volume in a heart chamber which is ejected with a single contraction. The measurement of the global ejection fraction offers a complete picture of the overall cardiac contractility.

$$GEF = \frac{4 \times SV}{GEDV}$$

Cardiac function index (CFI)

The cardiac function index can be used to estimate cardiac contractility. It represents the relation of the flow (cardiac output) and the preload volume (GEDV). Thus, cardiac function index is a preload related cardiac performance parameter.

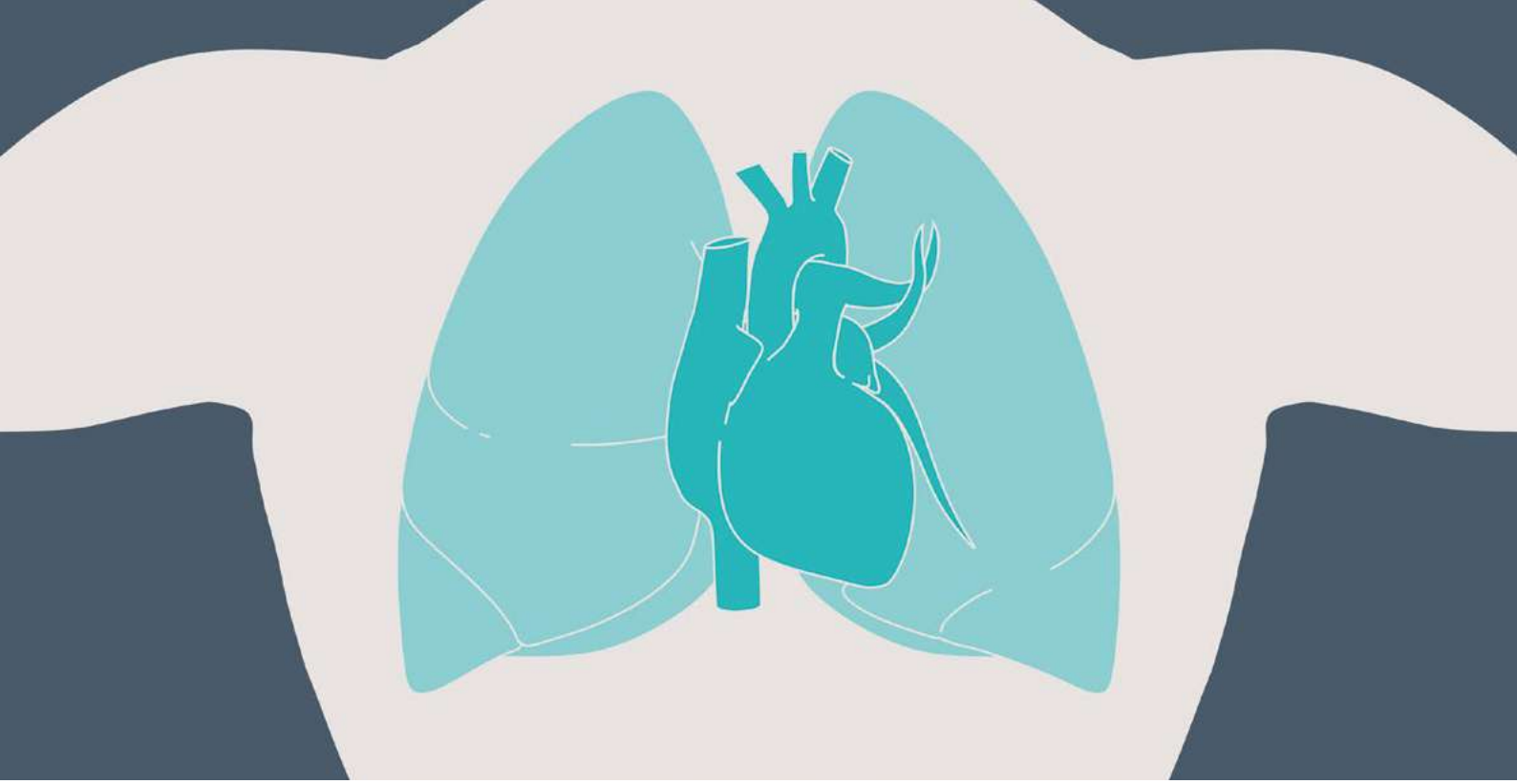
$$CFI = \frac{CI_{TD} \times 1{,}000}{GEDV}$$

Cardiac power index (CPI)

CPI represents the power of left ventricular cardiac output in watts. It is the product of pressure (MAP) and flow (CO). In clinical studies it has been found to be the strongest independent predictor of hospital mortality in cardiogenic shock patients.[28, 29]

$$CPI = CI_{PC} \times MAP \times 0.0022$$

GEF	CFI	CPI
25–35%	4.5–6.5 1/min	0.5–0.7 W/m²



Left ventricular contractility (dPmx)

From the arterial pressure curve, the pressure changes during the systolic phase can be analysed and a measure of the pressure increase over time (analysed in speed) is calculated. The steeper the upslope of the curve, the higher the contractility of the left ventricle.

As the upslope also depends on the individual compliance of the aorta, the parameter should primarily be viewed and evaluated as part of the overall trend.

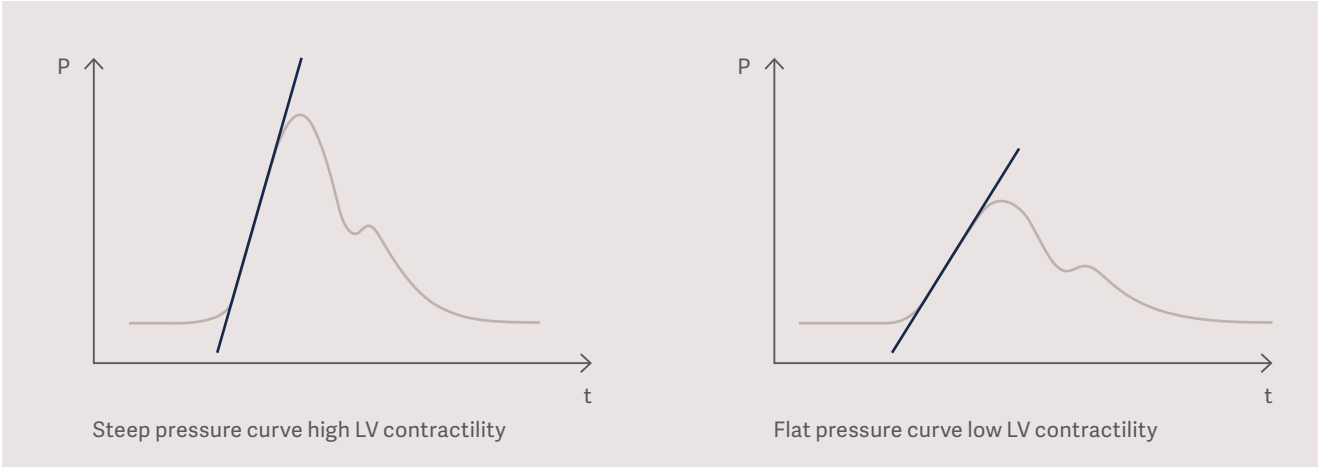


Diagram of steep / flat pressure increase with high / low contractility

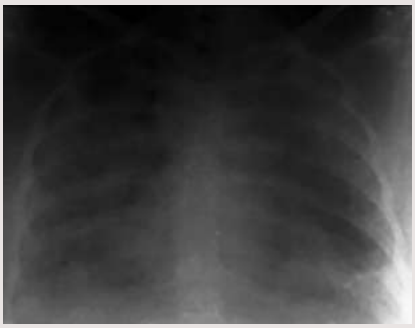
OK

dPmx

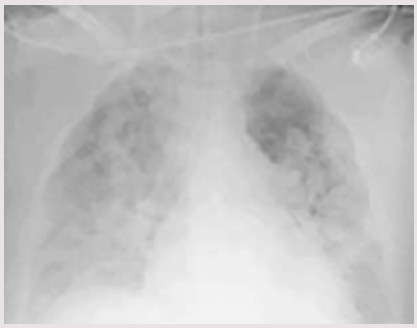
mmHg/s trend information

Assessment of pulmonary edema using PiCCO Technology

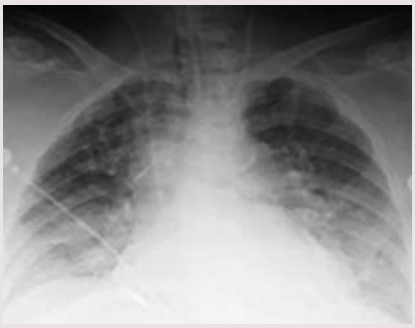
Examples of chest X-rays that do not reflect the level of pulmonary edema



ELWI = 21 ml/kg
Severe pulmonary edema



ELWI = 14 ml/kg
Moderate pulmonary edema



ELWI = 8 ml/kg
No pulmonary edema

Extravascular lung water index (ELWI)

A pulmonary edema is characterized by an accumulation of fluid in the interstitium of the lung tissue and / or the alveoli. This leads to impaired gas exchange and may even cause pulmonary failure. The amount of the pulmonary edema can easily be quantified at the bedside by measuring the extravascular lung water index (ELWI). The usual clinical signs of pulmonary edema (white-out on the chest X-ray, low oxygenation index, decreased lung compliance) are non-specific and only indicative when the edema is at an advanced stage. In the critical care routine, the chest X-ray is often used to estimate pulmonary edema in patients at risk. This approach is imperfect as the chest X-ray provides only a black and white density image of all components in the chest, including gas volume, blood volume, pleural effusion, bones, muscles, lung tissue, fat, skin edema and also pulmonary edema.

A more advanced approach using extravascular lung water provides a systematic route to therapeutic options. Extravascular lung water is indexed to the body weight in kg, written as the extravascular lung water index (ELWI). By indexing to the patient's predicted body weight (PBW), underestimation of lung water, particularly in obese patients, is avoided.

OK

ELWI
3–7 ml/kg

Pulmonary vascular permeability index (PVPI)

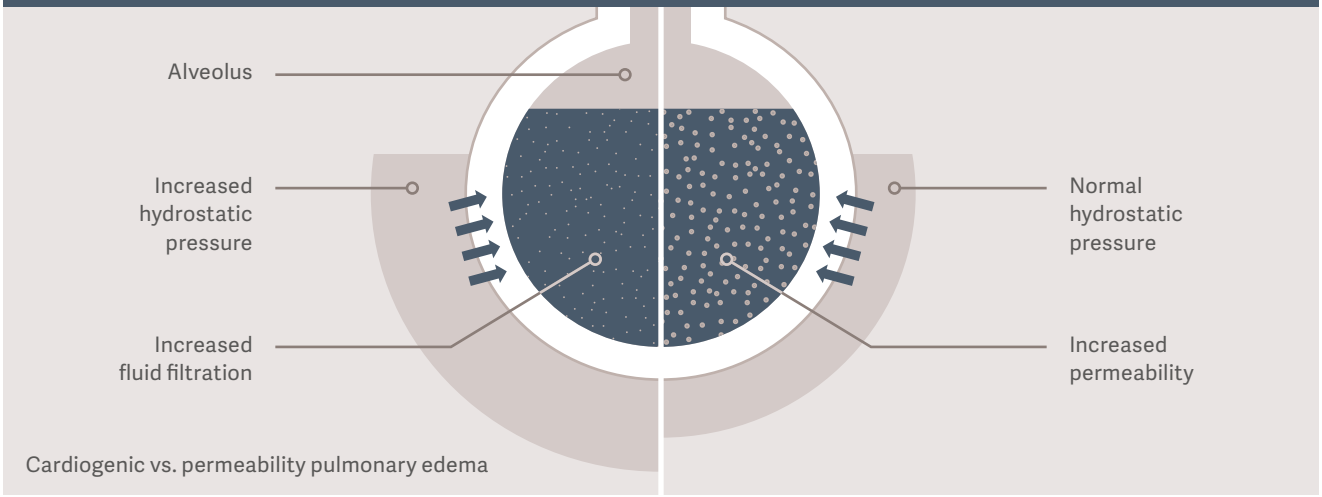
When pulmonary edema is present (measured using extravascular lung water), the next important question is: What is the reason for the pulmonary edema? In general there are two main sources of pulmonary edema:

Cardiogenic pulmonary edema

Caused by intravascular fluid overload, hydrostatic pressure increases. This causes fluids to leak into the extravascular space.

Permeability pulmonary edema

Vascular permeability is increased by an inflammatory reaction caused, for example, by sepsis. This leads to the increased transfer of fluids, electrolytes and proteins from the intravascular to the extravascular space, even with a normal to low intravascular fluid status and hydrostatic pressure.



Cardiogenic vs. permeability pulmonary edema

A differential diagnosis of the pulmonary edema is important because the therapeutic approach is quite different. In cardiogenic pulmonary edema, a negative fluid balance is sought, while in cases of permeability pulmonary edema treating the cause of inflammation has priority. The pulmonary vascular permeability index (PVPI) enables this differential diagnosis. This parameter is calculated from the relation between extravascular lung water (EVLW) and pulmonary blood volume (PBV). A PVPI value in the range of 1 to 3 points to a cardiogenic pulmonary edema, while a PVPI value greater than 3 suggests a permeability pulmonary edema.

OK

PVPI

< 3 cardiogenic edema / ≥ 3 permeability edema

Indications and clinical benefits

PiCCO indications

PiCCO Technology is indicated in patients who present with unstable hemodynamics and unclear volume status and in situations of therapeutic conflict. These situations are usually present in:

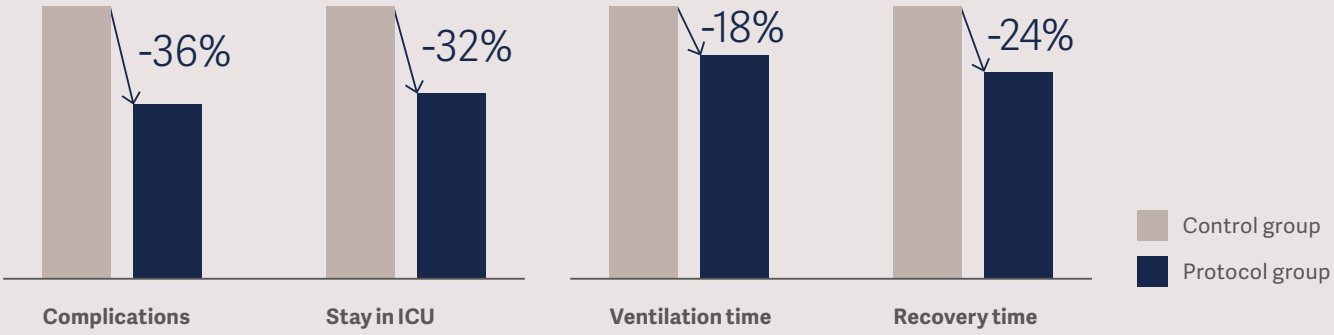
- Septic shock
- Cardiogenic shock
- Traumatic shock
- ARDS
- Severe burn injuries
- Pancreatitis
- High risk surgical procedures

Medical benefits

Monitoring does not lower patient mortality or morbidity. Per se, however, it provides valuable information which should be used to set up a treatment plan and apply goal-directed therapy to the patient as early as possible. The success of early goal-directed therapy (EGDT) is documented and clearly shows the following advantages:

- Reduction in ventilation time
- Reduction of ICU stay
- Reduction in complications
- Reduction of recovery time

Goal-directed therapy based on validated information improves outcomes.



Preload – GEDV (Göpfert et al. 2013 [30])

Preload – GEDV (Göpfert et al. 2007 [31])

Overview of technologies and further parameters

Along with PiCCO Technology, Pulsion has other innovative technologies that may be used with the PulsioFlex Monitoring Platform.

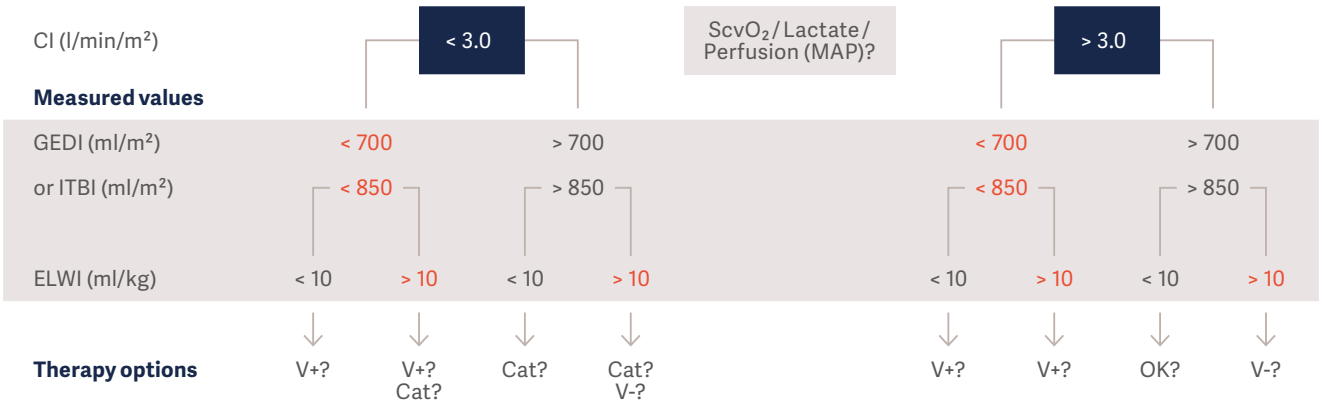
The PulsioFlex Monitor is equipped with the ProAQT Technology. You can easily extend the hemodynamic spectrum with modules featuring PiCCO, CeVOX, and LiMON technologies. In the future, additional innovations will be integrated in the technology portfolio of the PulsioFlex Platform. The following table lists the parameters available with the current modules:

Method		PiCCO	ProAQT	CeVOX	LiMON
Pulse contour analysis (continuous)	**Flow**	CI_{PC*}, SVI	$CI_{Trend/Cal**}$, SVI		
	Contractility	dPmx, CPI	dPmx, CPI		
	Afterload	SVRI	SVRI		
	Volume responsiveness	SVV, PPV	SVV, PPV		
Thermodilution (discontinuous)	**Flow**	CI_{TD***}			
	Preload	GEDI			
	Contractility	CFI, GEF			
	Pulmonary edema	ELWI, PVPI			
Oxymetry	**Oxygen saturation**			$ScvO_2$	
ICG elimination	**Liver function**				PDR, R15

* Cardiac index derived from pulse contour ** Calibrated from internal or external reference value
*** Cardiac index derived from thermodilution

Hemodynamic decision model

This decision model is not obligatory. It cannot replace the individual therapeutic decisions of the treating physician.



Targeted values

GEDI (ml/m²) (if ELWI > 10 → 700–800)	> 700
GEF (%)	> 25
CFI (1/min)	> 5
ELWI (ml/kg) (slow response)	≤ 10

Volume responsiveness?
(Passive leg raising / endexpiratory occlusion test / volume challenge / SVV / PPV?)

Contractility problem?
(GEF / CFI / echo?)

V+ = volume loading, V- = volume withdrawal , Cat = catecholamine / cardiovascular agents
Please reevaluate your clinical decisions and the set target parameters.

OEM partner modules

Patient centered flexibility

The versatile PiCCO Technology has been developed to match and adapt to different clinical settings.

To allow easy integration into your existing product portfolio, Getinge is partnering with various monitoring companies like GE, Philips, Dräger, Mindray and Nihon Kohden.

Getinge modules can be implemented seamlessly with negligible footprint and maintaining the already familiar user interface. All while relying on the clinically well proven and documented advantages of the PiCCO Technology.

All OEM partner modules are fully compatible with the original PiCCO disposable products.

Literature

1. Wesseling KH et al. A simple device for the continuous measurement of cardiac output. Adv Cardiovasc Phys 1983; 5: 16-52
2. Baudendistel LJ et al. Evaluation of extravascular lung water by single thermal indicator. Crit Care Med 1986; 14(1):52-56
3. Frank O. Die Grundform des Arteriellen Pulses. Erste Abhandlung. Mathematische Analyse. Z Biol 1899: 483-526
4. Thomas B. Monitoring of cardiac output by pulse contour method. Acta Anaesthesiol Belg 1978; 29(3): 259-270
5. Goedje O et al. Accuracy of beat-to-beat cardiac output monitoring by pulse contour analysis in haemodynamical unstable patients. Med Sci Monit 2001;7(6): 1344-1350
6. Felbinger TW et al. Cardiac index measurements during rapid preload changes: a comparison of pulmonary artery thermodilution with arterial pulse contour analysis. J Clin Anesth 2005; 17(4): 241-248
7. Della Rocca G et al. Cardiac output monitoring: aortic transpulmonary thermodilution and pulse contour analysis agree with standard thermodilution methods in patients undergoing lung transplantation. Can J Anaesth 2003; 50(7): 707-711
8. Mielck F et al. Comparison of continuous cardiac output measurements in patients after cardiac surgery. J Cardiothorac Vasc Anesth 2003;17(2): 211-216
9. Felbinger TW et al. Comparison of pulmonary arterial thermodilution and arterial pulse contour analysis: evaluation of a new algorithm. J Clin Anesth 2002;14(4): 296-301
10. Della Rocca G et al. Continuous and intermittent cardiac output measurement: pulmonary artery catheter versus aortic transpulmonary technique. Br J Anaesth 2002;88(3): 350-356
11. Rauch H et al. Pulse contour analysis versus thermodilution in cardiac surgery patients. Acta Anaesthesiol Scand 2002;46(4): 424-429
12. Zollner C et al. Beat-to-beat measurement of cardiac output by intravascular pulse contour analysis: a prospective criterion standard study in patients after cardiac surgery. J Cardiothorac Vasc Anesth 2000;14(2): 125-129
13. Buhre W et al. Comparison of cardiac output assessed by pulse-contour analysis and thermodilution in patients undergoing minimally invasive direct coronary artery bypass grafting. J Cardiothorac Vasc Anesth 1999;13(4): 437-44
14. Stewart GN. Researches on the circulation time and on the influences which affect it. J Physiol 1897; 22 (3): 159-83
15. Hamilton WF et al. Further analysis of the injection method, and of changes in haemodynamics under physiological and pathological conditions. Studies on the Circulation 1931: 534-551
16. Reuter DA et al. Cardiac output monitoring using indicator-dilution techniques: basics, limits, and perspectives. Anesth Analg 2010; 110(3):799-811
17. Newman EV et al. The dye dilution method for describing the central circulation. An analysis of factors shaping the time-concentration curves. Circulation 1951; Vol. IV (5): 735-746
18. Sakka SG, Meier-Hellmann A. Evaluation of cardiac output and cardiac preload. Yearbook of Intensive Care and Emergency: 671-679
19. Michard F, Perel A. Management of circulatory and respiratory failure using less invasive haemodynamic monitoring. Yearbook of Intensive Care and Emergency Medicine 2003: 508-52
20. Genahr A, McLuckie A. Transpulmonary thermodilution in the critically ill. Brit J Int Care 2004: 6-10
21. Oren-Grinberg A. The PiCCO Monitor. Int Anesthesiol Clin 2010; 48(1): 57-85
22. Sakka SG et al. The transpulmonary thermodilution technique. J Clin Monit Comput 2012; 26: 347-353
23. Michard F et al. Global end-diastolic volume as an indicator of cardiac preload in patients with septic shock. Chest 2003; 124(5): 1900-1908
24. Sakka SG et al. Assessment of cardiac preload and extravascular lung water by single transpulmonary thermodilution.Intensive Care Med 2000; 26(2): 180-187
25. Kuzkov VV et al. Extravascular lung water after pneumonectomy and one-lung ventilation in sheep. Crit Care Med 2007; 35(6): 1550-1559
26. Tagami T et al. Validation of extravascular lung water measurement by single transpulmonary thermodilution: human autopsy study. Crit Care 2010; 14(5): R162
27. Katzenelson R et al. Accuracy of transpulmonary thermodilution versus gravimetric measurement of extravascular lung water. Crit Care Med 2004; 32(7): 1550-1554
28. Mendoza DD, Cooper HA and Panza JA, Cardiac power output predicts mortality across a broad spectrum of patients with acut cardiac disease. Am Heart J 2007; 153(3): 366-70.
29. Fincke R et al., Cardiac power is the strongest haemodynamic correlate of mortality in cardiogenic shock: a report from the SHOCK trial registry. J Am Coll Cardiol 2004; 44(2): 340-8.
30. Goepfert MS et al. Individually Optimised Haemodynamic Therapy Reduces Complications and Length of Stay in the Intensive Care Unit – A Prospective, Randomised Controlled Trial. Anesthesiology 2013; 119(4):824-836
31. Goepfert MS et al. Goal-directed fluid management reduces vasopressor and catecholamine use in cardiac surgery patients. Intensive Care Med 2007; 33:96-103

Hand in hand for better patient care

Getinge is built on a genuine compassion for people's health, safety, and wellbeing. Founded in 1904 with roots dating back to 1838, Getinge has grown organically and fostered partnerships to become a global market leader.

Getinge's portfolio offers solutions and support throughout the clinical pathway, and features recognizable and reliable brands, such as Maquet and Pulsion.

Ours is a legacy of trust, and an ongoing commitment to advancing medical technology. We maintain close global partnerships with clinical leaders to address real-world clinical needs. We help you protect patients, proactively avoid complications, and prevent common causes of escalating health-care costs.

As a global leader in medical technology, Getinge has the firsthand experience to improve everyday life for people – today and tomorrow.

GETINGE

This document is intended to provide a general overview of the products and related information to an international audience outside the US. Indications, contradictions, warnings and instructions for use are listed in the separate instructions for use. This document may be subject to modifications. Any reference values mentioned herein or any other product related information shall solely serve as a general information and are subject to modifications and updates according to the current state of science and do not replace the individual therapeutic decision of the treating physician. Products may be pending regulatory approvals to be marketed in your country. All graphics shown herein are produced by Pulsion Medical Systems SE, unless otherwise noted.

Pulsion Medical Systems SE · Hans-Riedl-Str. 17 · 85622 Feldkirchen · Germany · +49 89 459914-0 · zentrale.pulsion@getinge.com

www.getinge.com

MPI8102EN_R07 · 09/2018 · PiCCO is a registered Trademark · Copyright by Pulsion Medical Systems SE

ProAQT Technology

Your navigator in perioperative hemodynamic monitoring

This document is intended to provide information to an international audience outside of the US.

GETINGE


MAQUET

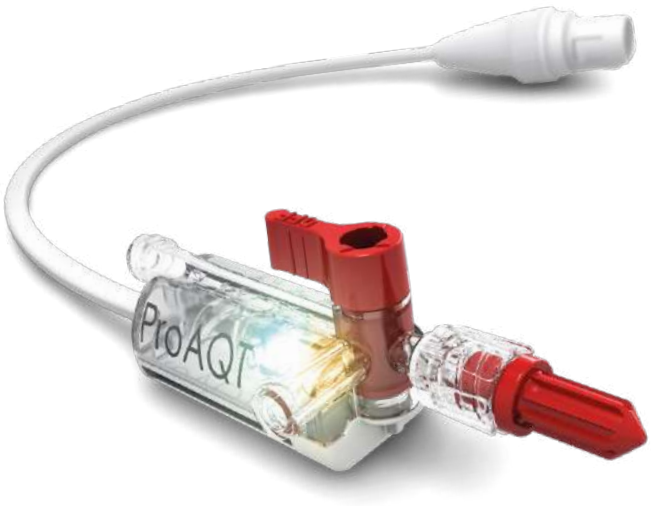
Proactive decision-making

Individualized therapy with ProAQT

Patients undergoing high- and medium-risk surgeries always benefit from close vigilance[1]. Optimal perioperative fluid administration is the key to successful recovery[2,3]. With a dynamic range of hemodynamic parameters, you can successfully optimize the best individual treatment for your patients[4].

Based on over 20 years of research with the PiCCO pulse contour algorithm, ProAQT allows a reliable interpretation of your patient 's hemodynamic status by measuring a variety of parameters, less invasively. The ProAQT sensor can be easily integrated into the existing blood pressure measurement system and provides valuable parameters such as blood flow, volume responsiveness, afterload and contractility.

ProAQT's outstanding technological profile allows the implementation of goal-directed fluid therapy, continuous hemodynamic monitoring in the perioperative period and a review of interventional success.



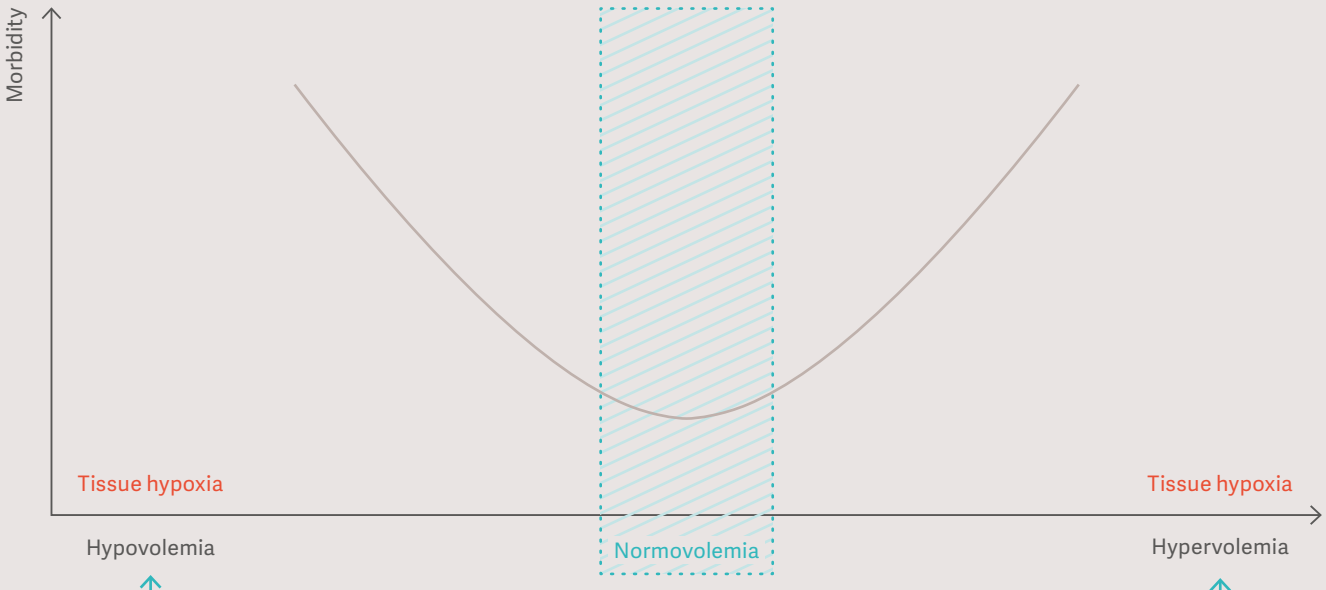
- Easy, fast and safe setup
- Based on PiCCO pulse contour algorithm
- Utilizes existing arterial-lines
- Less invasive
- Automatic start value determination of advanced hemodynamic parameters with optional calibration via CI value from an external source (e.g. echo)

Why hemodynamic monitoring?

Visualizing hemodynamics gives us information on the performance of the heart and perfusion of the tissue. Our ability to monitor hemodynamics allows dynamic interventions in high- and medium-risk care. It has been demonstrated that advanced dynamic and flow-based parameters are more reliable than conventional static measurements predicting fluid responsiveness in patients.[5,6]

In critical and anesthesiological care, the goal of hemodynamic monitoring is to guide fluid therapy via dynamic parameters in order to optimize the balance between oxygen delivery and oxygen consumption. Keeping the patient's fluid status in balance between hypo- and hypervolemia is the most effective way to combat global tissue hypoxia, shock and multi organ failure.[3]

Individualized fluid therapy helps avoid hypervolemia or hypovolemia (and) related complications [5]



Fluid under-resuscitation

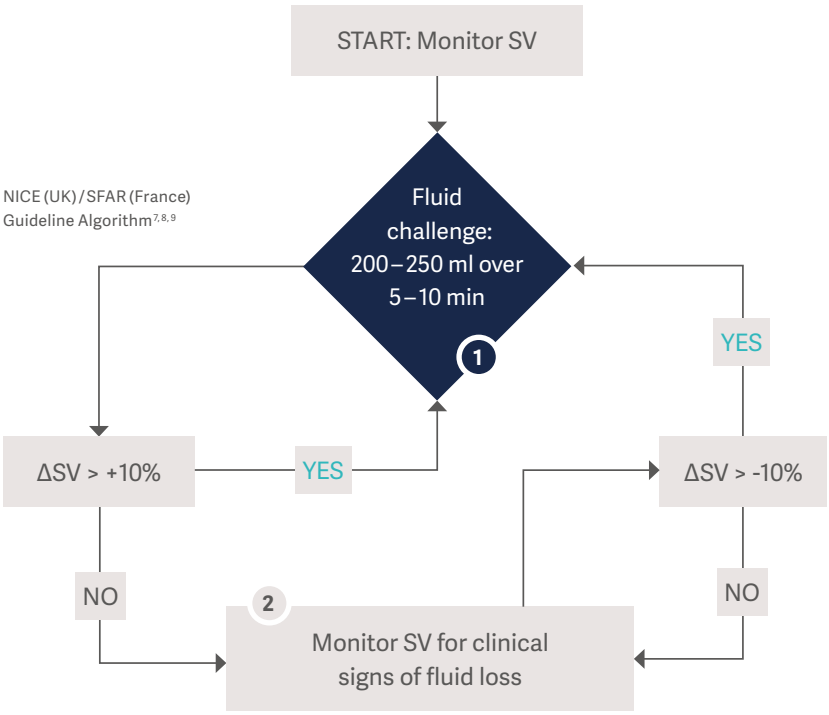
Low cardiac output
Infection
Organ failure
Poor wound healing
Reduced blood flow
Organ hypoperfusion

Fluid over-resuscitation

Tissue/lung edema
Hypoperfusion
Hemodilution
Congestive heart failure
Organ dysfunction
Tissue edema

How to perform perioperative fluid management?

NICE (UK) / SFAR (France) Guideline Algorithm[7,8,9]



Improve patient outcome

ProAQT provides multiple advanced hemodynamic parameters that can be used in GDFT to control variability in volume administration to help you maintain your patient in the optimal volume range. ProAQT quickly provides a dynamic assessment of fluid responsiveness which helps to guide fluid therapy in pre-, intra- and postoperative settings.

1 SV MAX (Fluid First)
Give fluid, observe response, continue to give fluid and other therapies until target is achieved

2 Hemodynamic Stability (Observe First)
Measure deterioration of clinical condition and titrate therapy using a variety of parameters

Significant difference of infectious complications

The Swalzwedet et. al. study shows the evidence of the beneficial effects of perioperative GDFT with ProAQT (in abdominal surgery).[2]

~ 71,1 %
less complications

Control Group:
Number of Patients: 81
Patients with infectious complications: 21

Study Group:
Number of Patients: 79
Patients with infectious complications: 9

Why combine hemodynamic monitoring and lung recruitment?

Lung recruitment fact

5–10 %

of all surgical patients develop postoperative pulmonary complications (PPCs). In thoracic or abdominal surgeries up to 30–40 % develop PPCs[10].

Fluid management fact

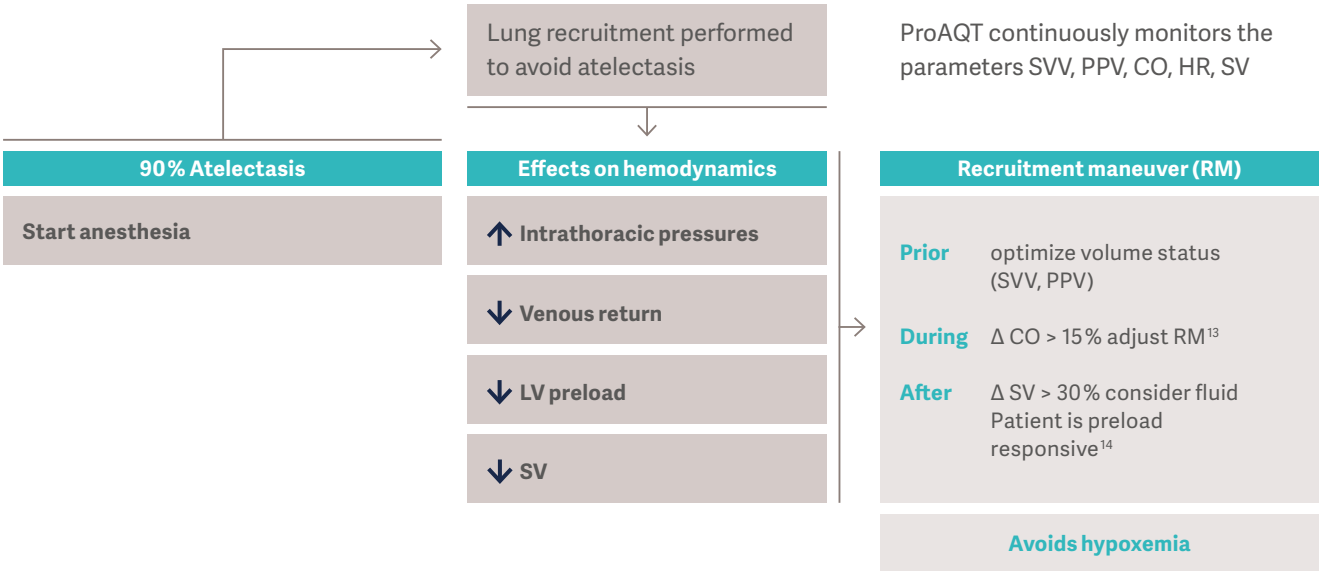
37 %–55 %

of postoperative complications can be prevented through perioperative goal-directed fluid therapy [11,12].

Use of advanced patient monitoring shows your patient's response to lung recruitment

The change of CO and SV is detected in realtime. Preload (SVV, PPV), afterload (SVRI) and contractility (dPmx, CPI) parameters provide clinicians with better insights. Occult hypovolemia can be detected prior to the recruitment maneuver, followed by appropriate perioperative fluid management that will decrease postsurgical complications.

Heart-lung interactions during the recruitment maneuver can be monitored by the ProAQT Technology



Reduce complications, increase efficiency

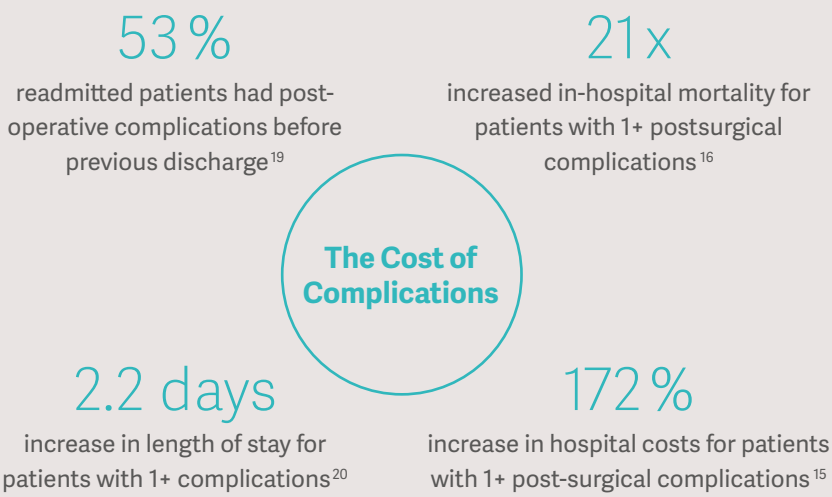
Financial advantages

Postoperative complications are associated with an increase in mortality, length of hospital stay, and hospital costs.[15,16,17]

Complications are costly

Healthcare expenditure is currently rising exponentially, and postoperative complications contribute significantly to these increased costs[18,21].

Patients who develop complications consume a disproportionately larger share of the available resources[17]. Postoperative morbidity has effects that last beyond discharge e.g. prolonged sick leave or permanent incapacity for patients[17].



Cost saving potential

Many studies have shown decreased morbidity in major surgery when GDFT is used[18,21]. The premise is simple: GDFT helps reduce postoperative complications which, in turn, reduces costs. Indeed, a favourable financial impact of GDFT resulting from reduction of complication rates has been reported in many studies[19,22].

32–55 million USD
the total potential savings per year for GDFT implemented for colectomies in the USA[24]

2.5–4 USD savings
from each dollar invested by hospitals to implement GDFT[24]

1.16–1.95 days
reduction in length of stay when GDFT was implemented[18,23]

GDFT is recommended by:

- National Health Service in UK[4]
- French Society of Anesthesiology[15]
- Enhanced Recovery After Surgery (ERAS) Society in Europe[16]

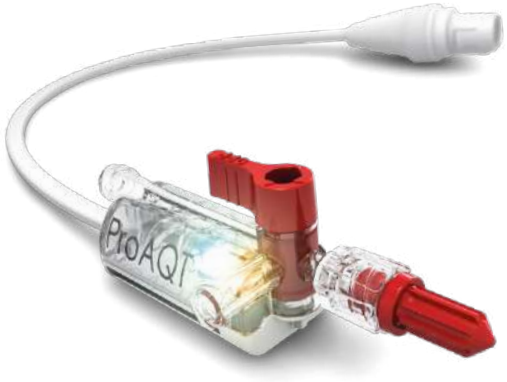
Application areas and benefits

Key features of ProAQT

ProAQT allows optimized fluid management by providing key flow parameters to help determine your patient's fluid status[2].

ProAQT has the following applications:

- Perioperative fluid management in goal-directed fluid therapy[2]
- Complex procedures with high-risk of intra- and postoperative complications[2]
- Anticipated high blood loss and volume shifts during the procedure which can result in hypo- or hypervolemia[2]
- Extended surgery time (> 120 min)[2]



Exceptional flexibility of the PulsioFlex monitor

- Small footprint conserves precious space in care units
- Seamless integration into existing PDMS system
- Integration of PiCCO, CeVOX and LiMON technology allows easy escalation of monitoring options
- Flexible mounting options permit outstanding mobility

ProAQT provides support during the perioperative period.

Outstanding clinical performance of ProAQT

- Continuously derived hemodynamic parameters support physicians in critical therapeutic decisions[5]
- Provides a minimally invasive approach by utilizing existing arterial access of choice (e.g. radial artery)
- Possibility to use automatic start-value determination or external manual calibration (e. g. echocardiography)
- Tracking of fluid challenges like passive leg raising (PLR) or fluid bolus[25]
- Tailor your fluid therapy to your patient's specific parameters[2]
- Recognize unstable patients quicker[2]
- Track the success of your therapy

Parameters provided by ProAQT

Blood Flow		Preload		Contractility		Afterload
CI_{Trend}	**SVI**	**SVV**	**PPV**	**dPmx**	**CPI**	**SVRI**
Cardiac Index	Stroke Volume Index	Stroke Volume Variation	Pulse Pressure Variation	Left Ventricular Contractility	Cardiac Power Index	Systemic Vascular Resistance

Monitoring continuous hemodynamic parameters in moderate – and high-risk surgical patients not only improves outcome, but also provides an actual and relative cost savings[4, 24]. This has important implications for the management of these patients and the the cost-burden of anesthesia[2].

The rationale behind hemodynamic optimization is simple and clear: goal-directed fluid therapy improves clinical outcome and reduces costs at the same time.[18]

ProAQT Parameters

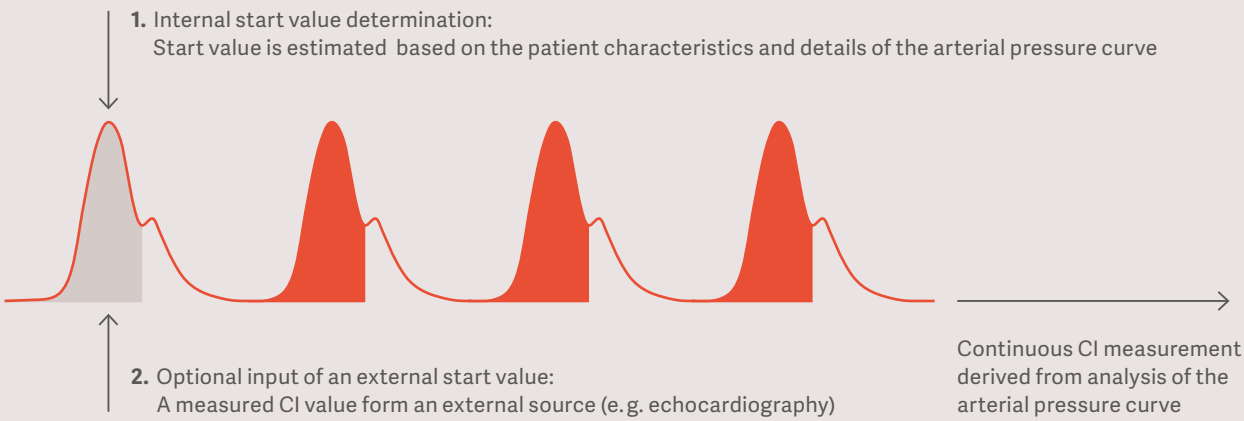
Basics of the pulse contour analysis and calibration procedure

The theoretical basis of pulse contour analysis was published for the first time in 1899 [26].

Principle of pulse contour analysis

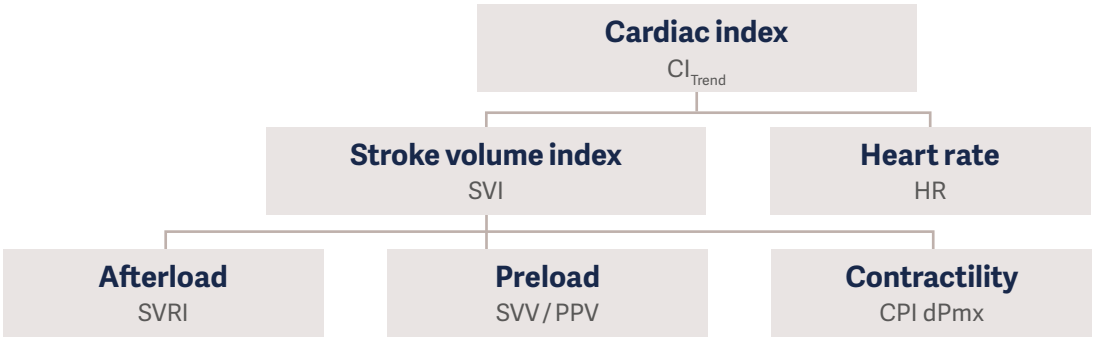
- The analysis of the continuous arterial pressure provides more information than just the systolic, diastolic and mean value.
- The algorithm detects the opening of the aortic valve (moment of the increase of the systolic pressure) and its closure (incision in the pressure curve: the dicrotic notch).
- The time in between represents the duration of the systole and the area under the systolic part of the pressure curve directly reflects the stroke volume (SV): the volume of blood (in millilitres) which is ejected by the left ventricle with every single heartbeat.
- SV multiplied by heart rate (HR) gives cardiac output, the pump flow of the heart in litres per minute.
- The shape of the arterial pressure curve and thus the area under the curve is influenced not only by the stroke volume, but also by the individual compliance of the vascular system. The ProAQT system estimates dynamic parameters through arterial pressure waveform analysis.

ProAQT principle and calibration procedure



The patient characteristics used within the ProAQT calibration algorithm operate on some assumptions about patient demographics and change in vascular tone of the patient. This may lead to some discrepancies in the calculated values.

Blood flow and afterload



Cardiac index and its determinants

Cardiac index (CI)

Cardiac index is the amount of blood pumped by the heart per minute indexed to 1m² of the body surface area (BSA); the cardiac index represents the global blood flow. A decrease in cardiac index is a clear alarm signal and requires appropriate measures to manage the situation.

Stroke volume index (SVI)

Stroke volume, the volume of blood pumped by the left ventricle per beat, is affected by preload, afterload and contractility. Thus, information on the determinants of cardiac index allow a more comprehensive picture of the hemodynamic status for choosing an appropriate treatment.

Systemic vascular resistance index (SVRI)

The physiological meaning of SVRI is the tension or resistance that builds up in the wall of the left ventricle during ejection. In the clinical context things are often simplified and so the afterload is seen as the resistance the heart has to pump against.

- If the afterload (SVRI) is increased, the heart must pump with more power to eject the same amount of blood as before
- A higher afterload may decrease the cardiac output
- A lowered afterload may increase the cardiac output

$$SVRI = \left[\frac{(MAP - CVP)}{CI} \right] \times 80$$

If the afterload exceeds the performance of the myocardium, the heart may decompensate.

Vasoconstriction

Flow (CI) ↓ Pressure ↑

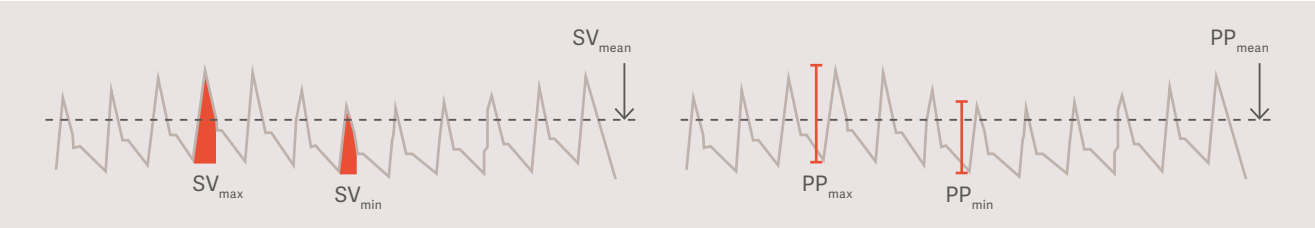
Vasodilation

Flow (CI) ↑ Pressure ↓

OK

CI	SVI	SVRI
3 – 5 l/min/m²	40 – 60 ml/m²	1700 – 2400 dyn*s*cm^{-5}*m²

Volume responsiveness



Stroke volume variation (SVV)

Pulse pressure variation (PPV)

Stroke volume variation (SVV) and pulse pressure variation (PPV)

- Prediction of the response of blood flow to volume loading
- Quantification of fluctuations in the arterial pressure curve due to mechanical ventilation

Explanation:
The inspiration and expiration phases in mechanical ventilation changes the intrathoracic pressure. High ventilation induced intrathoracic pressure reduces the venous return and the filling capacity of the heart and vessels. This variation of the vascular filing status is visible by a ventilation cycle induced fluctuation of the arterial pressure curve.

$$SVV = \frac{(SV_{max} - SV_{min})}{SV_{mean}}$$

$$PPV = \frac{(PP_{max} - PP_{min})}{PP_{mean}}$$

The higher the variation the more likely the patient is to be volume responsive. For proper use of the parameters, the following preconditions must be fulfilled:

- Fully controlled mechanical ventilation with a tidal volume ≥ 8 ml/kg PBW (predicted body weight)
- Sinus rhythm
- Pressure curves free of artifacts

If these criteria cannot be met, the following tests can be performed:

- End-expiratory occlusion (EEO) Test
- Tidal Volume Challenge
- Lung Recruitment Maneuver (RM)

OK

SVV/PPV
< 10 %

Contractility

Contractility of the myocardium represents the ability of the heart to contract independent of the influence of preload or afterload. Substances that cause an increase in intracellular calcium ions lead to an increase in contractility. Different concentrations of calcium ions in the cell lead to a different degree of binding between the actin (thin) and myosin (thick) filaments of the heart muscle. Direct determination of cardiac contractility is not possible in the clinical setting. Therefore, surrogate parameters are used to evaluate or estimate the contractility.

Cardiac power index (CPI)

CPI represents the power of left ventricular cardiac output in watts. It is the product of pressure (MAP) and flow (CO). In clinical studies it has been found to be the strongest independent predictor of hospital mortality in cardiogenic shock patients.[27,28]

$$CPI = CI \times MAP \times 0.0022$$

Left ventricular contractility (dPmx)

From the arterial pressure curve, the pressure changes during the systolic phase can be analyzed and a measure of the pressure increase over time (analyzed in speed) is calculated. The steeper the upslope of the curve, the higher the contractility of the left ventricle. As the upslope also depends on the individual compliance of the aorta, the parameter should primarily be viewed and evaluated as part of the overall trend.

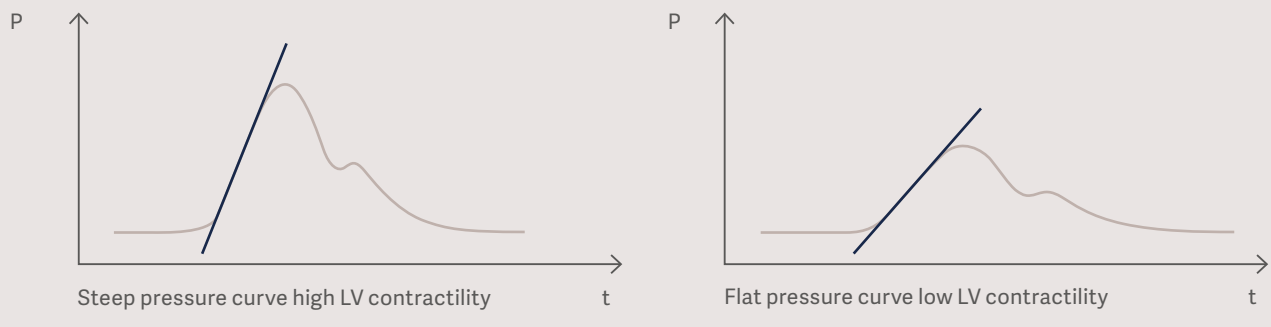


Diagram of steep / flat pressure increase with high / low contractility

OK

dPmx
mmHg/s trend information

CPI
0.5 – 0.7 W/m²

Advanced patient monitoring platform

The PulsioFlex monitor platform is equipped with the ProAQT technology.

You can easily extend the hemodynamic scope with modules featuring NICCI, PiCCO, CeVOX, and LiMON. This will give you the information you need to help assess the hemodynamic status for a broad range of patients, on-site.

The following table lists the parameters available with the current technologies:



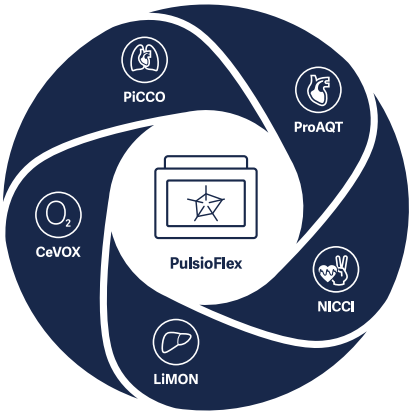


	NICCI	ProAQT	PiCCO	CeVOX	LiMON
Invasiveness	Noninvasive	Minimally invasive arterial line	Less invasive arterial catheter	Less invasive	noninvasive
Pulse contour analysis (continuous)					
Chronotropy	PR	HR	HR		
Blood Pressure	AP_{sys}, AP_{dia}, MAP	AP_{sys}, AP_{dia}, MAP	AP_{sys}, AP_{dia}, MAP		
Flow	$CI_{Trend/Cal}$ **, SVI	$CI_{Trend/Cal}$ **, SVI	CI_{PC} *, SVI		
Contractility	dPmx, CPI	dPmx, CPI	dPmx, CPI		
Afterload	SVRI	SVRI	SVRI		
Volume responsiveness	SVV, PPV	SVV, PPV	SVV, PPV		
Thermodilution (discontinuous)					
Flow			CI_{TD} ***		
Preload			GEDI, ITBI		
Contractility			CFI, GEF		
Pulmonary edema			ELWI, PVPI		
Oxymetry					
Oxygen saturation				$ScvO_2$	
ICG elimination					
Liver function					PDR, R15
Besides the PulsioFlex, the Advanced Patient Monitoring Technologies are integrated into the following OEM platforms:					
		Nihon Kohden	Philips, Mindray, Drager Medical, General Electric, Nihon Kohden	Philips, Mindray, Nihon Kohden	

* Cardiac index derived from pulse contour ** Calibrated from internal or external reference value *** Cardiac index derived from thermodilution

Passion for life

Improving outcomes for critically ill patients



Advanced hemodynamic monitoring helps physicians understand complex conditions of patients in intensive care units and during high-risk surgeries and helps to optimize their hemodynamic condition.[2]

Pulsion's core competence is the development and production of medical devices for monitoring critically ill patients. Pulsion Medical Systems SE was founded in 1990 and is located in Feldkirchen, Greater Munich. Since 2014, Pulsion is wholly-owned by, and fully-integrated with, Getinge.

Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and life science companies and institutions.

Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving everyday life for people – today and tomorrow.

References

1) Groh J., Van Aken H., Peter K. "The Anesthetist In Perioperative Care." Anaesthesist 46.Supplement 2 (1997): SVIII-SX. Print.

2) Salzwedel C., et al. Perioperative goal-directed hemodynamic therapy based on radial arterial pulse pressure variation and continuous cardiac index trending reduces postoperative complications after major abdominal surgery: a multi-center, prospective, randomized study. Crit Care 2013;17(5):R191.

3) Bellamy M. Wet, dry or something else?. Br J Anaesth. 2006;97(6):755-757.

4) Benes J., Giglio M., Brienza N., Michard F. The effects of goal-directed fluid therapy based on dynamic parameters on post-surgical outcome: a meta-analysis of randomized controlled trials. Critical Care. 2014;18(5).

5) Boulain T., Cecconi M. Can one size fit all? The fine line between fluid overload and hypovolemia, Intensive Care Med 2015, DOI 10.1007/s00134-015-3683-7.

6) Hamilton, et al., A Systematic Review and Meta-Analysis on the Use of Preemptive Hemodynamic Intervention to Improve Postoperative Outcomes in Moderate and High-Risk Surgical Patients. Anesthesia & Analgesia. 2010;112(6):1392-1402.

7) National Institute for health and Clinical Excellence, CardioQ-ODM oesophageal doppler monitor. NHS 2011

8) Kuper M., et al., Intraoperative fluid management guided by oesophageal Doppler monitoring. Bmj 2011; 342: d3016.

9) Vallet B., et al., Strategie du remplissage vasculaire perioperatoire/ Guidelines for perioperative haemodynamic optimization. Societe Francais d'Anesthesie et de Reanimation. Afar 2013; 32(6): 454-462.

10) Khuri SF., Henderson WG., DePalma RG., Mosca C., Healey NA., Kumbhani DJ. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. Ann Surg 2005, 242: 326-341.

11) Cecconi M., Fasano N., Langiano N., et al. Goal-directed haemodynamic therapy during elective total hip arthroplasty under regional anaesthesia. Critical Care 2011, 15:R132.

12) Goepfert M. S., et al., Individually Optimized Hemodynamic Therapy Reduces Complications and Length of Stay in the Intensive Care Unit: A Prospective, Randomized Controlled Trial. Anesthesiology 2013;119(4):824-836.

13) Tusman G., Belda JF. Treatment of anesthesia-induced lung collapse with lung recruitment maneuvers. Current Anesthesia & Critical Care 21 2010, 244-249.

14) Biais M., Lanchon R., Sesay M., et al. Changes in Stroke Volume Induced by Lung Recruitment Maneuver Predict Fluid Responsiveness in Mechanically Ventilated Patients in the Operating Room. Anesthesiology 2016, V 126: 1-8.

15) Manecke G., Asemota A., Michard F. Tackling the economic burden of postsurgical complications: would perioperative goal-directed fluid therapy help? Critical Care 2014;18(5).

16) Eappen S., Lane BH., Rosenberg B. Relationship between occurrence of surgical complications and hospital finances. JAMA. 2013;309:1599-1606.

17) Lang M., Niskanen M., Miettinen P., Alhava E., Takala J. Outcome and resource utilization in gastroenterological surgery. Br J Surg. 2001;88:1006–1014.

18) Corcoran T., Rhodes J., Clarke S., Myles P., Ho K. Perioperative Fluid Management Strategies in Major Surgery. Survey of Anesthesiology. 2013;57(5):265-266.

19) Lawson E., Hall B., Louie R., et al. Association Between Occurrence of a Postoperative Complication and Readmission. Ann Surg. 2013;258(1):10-18.

20) Boltz M-, Hollenbeak C., Ortenzi G., Dillon P. Synergistic Implications of Multiple Postoperative Outcomes. American Journal of Medical Quality. 2012;27(5):383-390

21) Pearse, et al. Effect of a Perioperative, Cardiac Output–Guided Hemodynamic Therapy Algorithm on Outcomes Following Major Gastrointestinal Surgery. JAMA 2014;311(21):2181.

22) Nicholson A., Lowe M., Parker J., Lewis S., Alderson P., Smith A. Systematic review and meta-analysis of enhanced recovery programmes in surgical patients. British Journal of Surgery. 2014;101(3):172-188.

23) Grocott M., Dushianthan A., Hamilton M., Mythen M., Harrison D., Rowan K. Perioperative increase in global blood flow to Explicit defined goals and outcomes after surgery: a Cochrane Systematic Review. Br J Anaesth 2013;111(4):535-548.

24) Michard, et al., Potential return on investment for implementation of perioperative goal-directed fluid therapy in major surgery: a nationwide database study. Perioper Med 2015, 4(11): 1-8.

25) Monnet X., et al., Passive leg raising predicts fluid responsiveness in the critically ill*. Crit Care Med 2006; 34(5): 1402-1407.

26) Frank O. Die Grundform des Arteriellen Pulses. Erste Abhandlung. Mathematische Analyse. Z Biol 1899:483-526

27) Mendoza DD., Cooper HA., Panza JA. Cardiac power Output predicts mortality across a broad spectrum of patients with acute cardiac disease. Am Heart J 2007;153(3):366-370.

28) Fincke R. et al., Cardiac power is the strongest haemodynamic correlate of mortality in cardiogenic shock: a report from the SHOCK trial registry. J Am Coll Cardiol 2004;44(2):340-348.

GETINGE

Pulsion Medical Systems SE · Hans-Riedl-Str. 17 · 85622 Feldkirchen · Germany · +49 89 45 99 14-0 · zentrale.pulsion@getinge.com

www.getinge.com

MKT-000003-01 ProAQT Technology Brochure-EN · 04/2020 · ProAQT is a registered Trademark · Copyright by PULSION Medical Systems SE

Pulsiocare

GETINGE

Critical information – always in sight

From the OR to the ICU, Pulsiocare gives you the full picture of your patient's hemodynamic status to support immediate, data-driven decision making when you need it most.

Pulsiocare

GETINGE

Integrated **PiCCO** and **ProAQT** technology

Flexible and portable set-up

Simple and user-friendly interface

Complete hemodynamic status at a glance

INTRA-AORTIC BALLOON PUMP

MAQUET
GETINGE GROUP

CARDIOVASCULAR

INTRODUCING CARDIOSAVE™
MORE THAN A PUMP. A REVOLUTION.

INTRODUCING CARDIOSAVE™
MORE THAN A PUMP. A REVOLUTION.

INTRODUCING A WHOLE NEW PARADIGM IN HEMODYNAMIC SUPPORT

CARDIOSAVE represents a giant leap forward in functionality and versatility while continuing to deliver the performance and intuitiveness of the Datascope pumps you know and trust. With its large touchscreen display, dramatically smaller and lighter design, and seamless transition from in-hospital use to transport mode, this revolutionary pump redefines counterpulsation therapy.

CARDIOSAVE.
Setting a new standard in hemodynamic support.

CARDIOSAVE™ hybrid

CARDIOSAVE Hybrid retains the familiar look of Datascope pumps, while offering an improved user interface and improved algorithms & pneumatics to allow for enhanced therapy. CARDIOSAVE Hybrid easily and quickly converts from hospital configuration to transport configuration.

Enhanced algorithms for easier management of the most complex patients

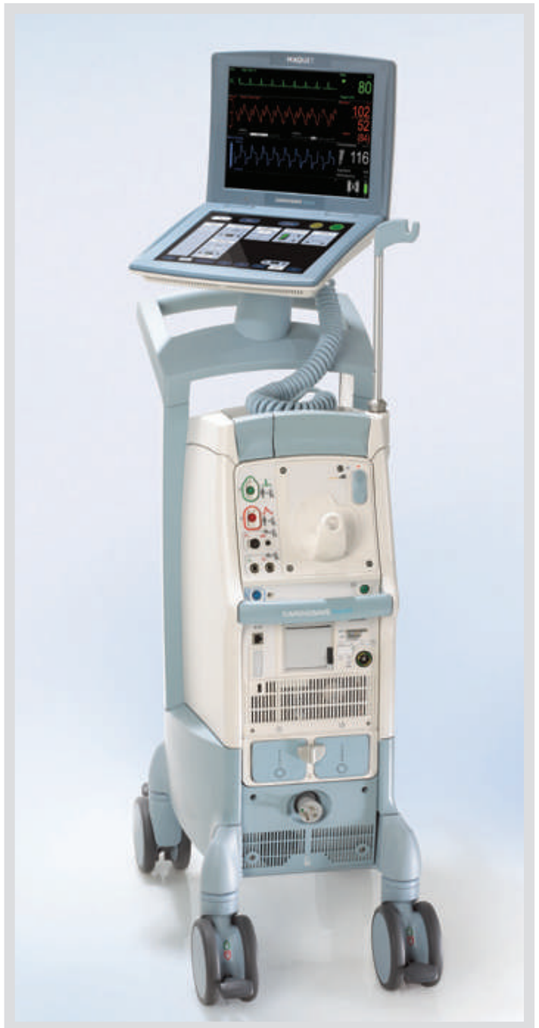
- Enhanced pacer detection
- More sophisticated management of lead faults
- Advanced triggering performance

Enhanced pneumatics to help optimize diastolic augmentation

- Faster pneumatic speed
  - HR 80 – 10.0% faster than CS300 (normotensive patient)*
  - HR 150 – 16.4% faster than CS300 (normotensive patient)*
  - Faster pneumatic speed allows balloon to stay inflated longer during diastole

Quieter for patient convenience

- Significantly quieter when compared to earlier generation MAQUET/Datascope IABPs



Improved user interface for ease-of-use

- Backlit monitor display
- Backlit touchscreen control
- Improved help screen navigation

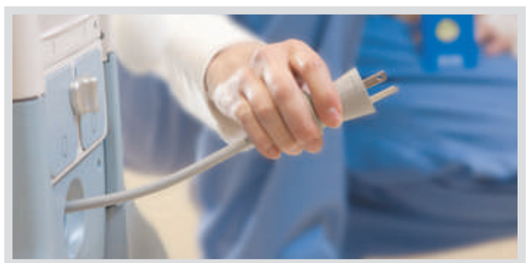
Improved patient interconnects for ease-of-use

- Better organized patient interface connections
- Easier access to connection panel
- Color coded and keyed connections

Improved user convenience attributes

- Self retracting power cord
- Out-of-sight helium tank compartment

Designed for use with all MAQUET/Datascope IABs



SPECIFICATIONS

WEIGHT

Including console, cart, control monitor, helium tank and 2 batteries
51.8 kg 114 lbs
All weights ± 5%

DIMENSIONS

Display Closed
111.8 cm high x 68.6 cm deep x 59.9 cm wide
44 in high x 27 in deep x 22 in wide

Display Open 90°
134.6 cm high x 68.6 cm deep x 59.9 cm wide
53 in high x 27 in deep x 22 in wide

* All dimensions ± 5%. Dimensions include the Pneumatic Module

*Data on file

CARDIOSAVE™ rescue

CARDIOSAVE Rescue is the smallest and lightest intra-aortic balloon pump ever produced by MAQUET/ Datascope. CARDIOSAVE Rescue is designed to meet the rigorous requirements of transporting patients by ambulance or helicopter. The size and weight reduction make for significantly easier lifting and placement into the vehicle, while the hot-swappable, lithium ion batteries offer potentially unlimited run-time with spare batteries.

Improved physical characteristics for better inter-facility transports

- Lighter weight - approximately 40% of the weight of CS300 UTS
- Smaller size - approximately 55% of the size of CS300 UTS
- Hot-swappable lithium ion batteries – virtually unlimited run-time with spare batteries*

Standard accessories for transport applications

- 2 bay battery charging station
- Helium refilling station
- Vehicle transport mount
- AC transport power supply

Improved user interface for ease-of-use

- Backlit monitor display
- Backlit touchscreen control
- Improved help screen navigation

*Additionally, the ability to "hot swap" batteries allows virtually unlimited battery run time capability and allows patients who are being supported by the pump in one facility to be easily transported to another without any interruption in support regardless of the length of transport.

*Data on file

Enhanced algorithms for easier management of the most complex patients

- Enhanced pacer detection
- More sophisticated management of lead faults
- Advanced trigger processing

Enhanced pneumatics to help optimize diastolic augmentation

- Faster pneumatic speed
  - HR 80 – 10.0% faster than CS300 (normotensive patient)*
  - HR 150 – 16.4% faster than CS300 (normotensive patient)*
  - Faster pneumatic speed allows balloon to stay inflated longer during diastole

Improved patient interconnects for ease-of-use

- Better organized patient interface connections
- Easier access to connection panel
- Color coded and keyed connections

Designed for use with all current MAQUET/Datascope IABs

SPECIFICATIONS

WEIGHT
Including Rescue console, control monitor and 2 batteries
24.1 kg 53 lbs
All weights ± 5%

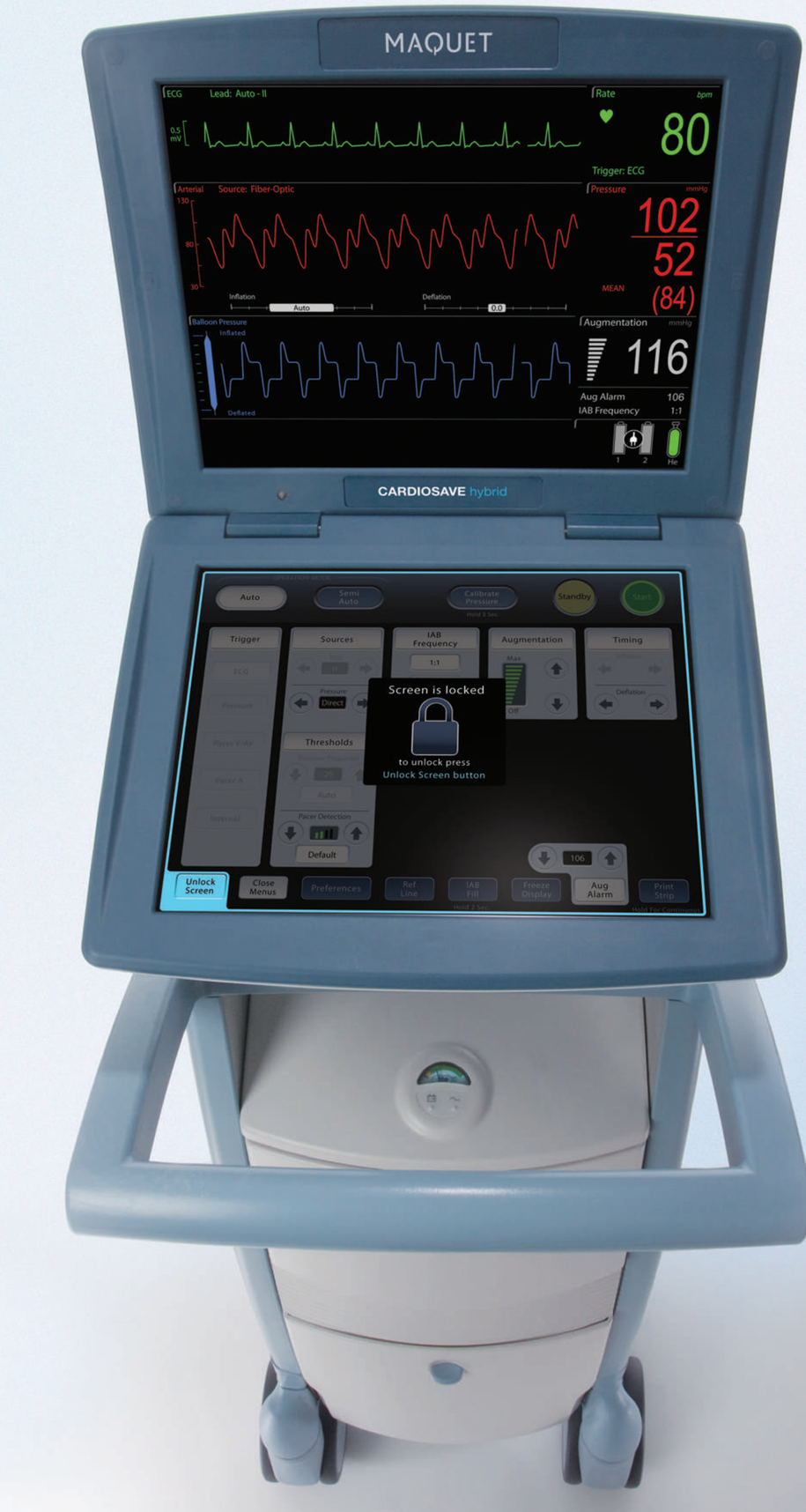
DIMENSIONS
Display Closed - Includes Rescue console and control monitor
57.2 cm high x 40.6 cm deep x 33.0 cm wide
22.5 in high x 16 in deep x 13 in wide
Display Open 90°- Includes Rescue console and control monitor
78.0 cm high x 40.6 cm deep x 33.0 cm wide
30.7 in high x 16 in deep x 13 in wide
* All dimensions ± 5%. Dimensions include the Pneumatic Module

CARDIOSAVE. Different from the first touch

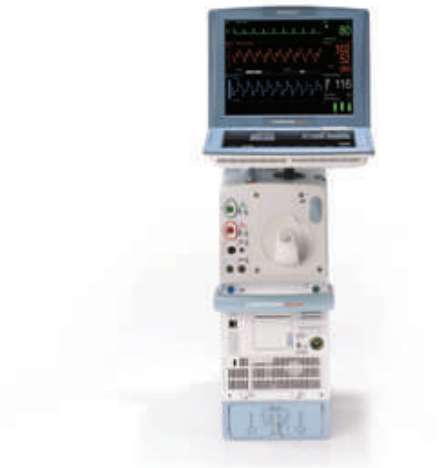
CARDIOSAVE incorporates a state-of-the-art liquid crystal display and touchscreen control. The large panel size, 24.58cm x 18.43cm (9.68in x 7.26in), 31cm (12.1in) diagonal, used for both the upper waveform display and lower touchscreen control allows for larger patient display parameters, improved help screen navigation and customizable control screens. The backlit screens allow visibility in varying lighting conditions with no alternate light source required.

CARDIOSAVE. Different from the first touch

CARDIOSAVE incorporates a state-of-the-art liquid crystal display and touchscreen control. The large panel size, 24.58cm x 18.43cm (9.68in x 7.26in), 31cm (12.1in) diagonal, used for both the upper waveform display and lower touch screen control allows for larger patient display parameters, improved help screen navigation and customizable control screens. The back-lit screens allow visibility in varying lighting conditions with no alternate light source required.

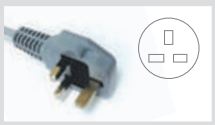


CARDIOSAVE™ hybrid



CARDIOSAVE™ rescue

ORDERING INFORMATION

Product		Part Number
CARDIOSAVE Hybrid - Type I Plug		0998-00-0800-45
CARDIOSAVE Hybrid - Type G Plug		0998-00-0800-52
CARDIOSAVE Hybrid - Type B Plug		0998-00-0800-53
CARDIOSAVE Hybrid - Type E/F Plug		0998-00-0800-55

ORDERING INFORMATION

Product	Part Number
CARDIOSAVE Rescue	0998-00-0800-83

MAQUET
GETINGE GROUP

For more information, please contact your local sales representative or visit: http://ca.maquet.com

MAQUET
GETINGE GROUP

Datascope Corp.
1300 MacArthur Blvd.
Mahwah, NJ 07430 USA
Phone: 1 800 777 4222 or
1 973 244 6100
Fax: 1 800 258 8762 or
1 973 244 6279
http://ca.maquet.com

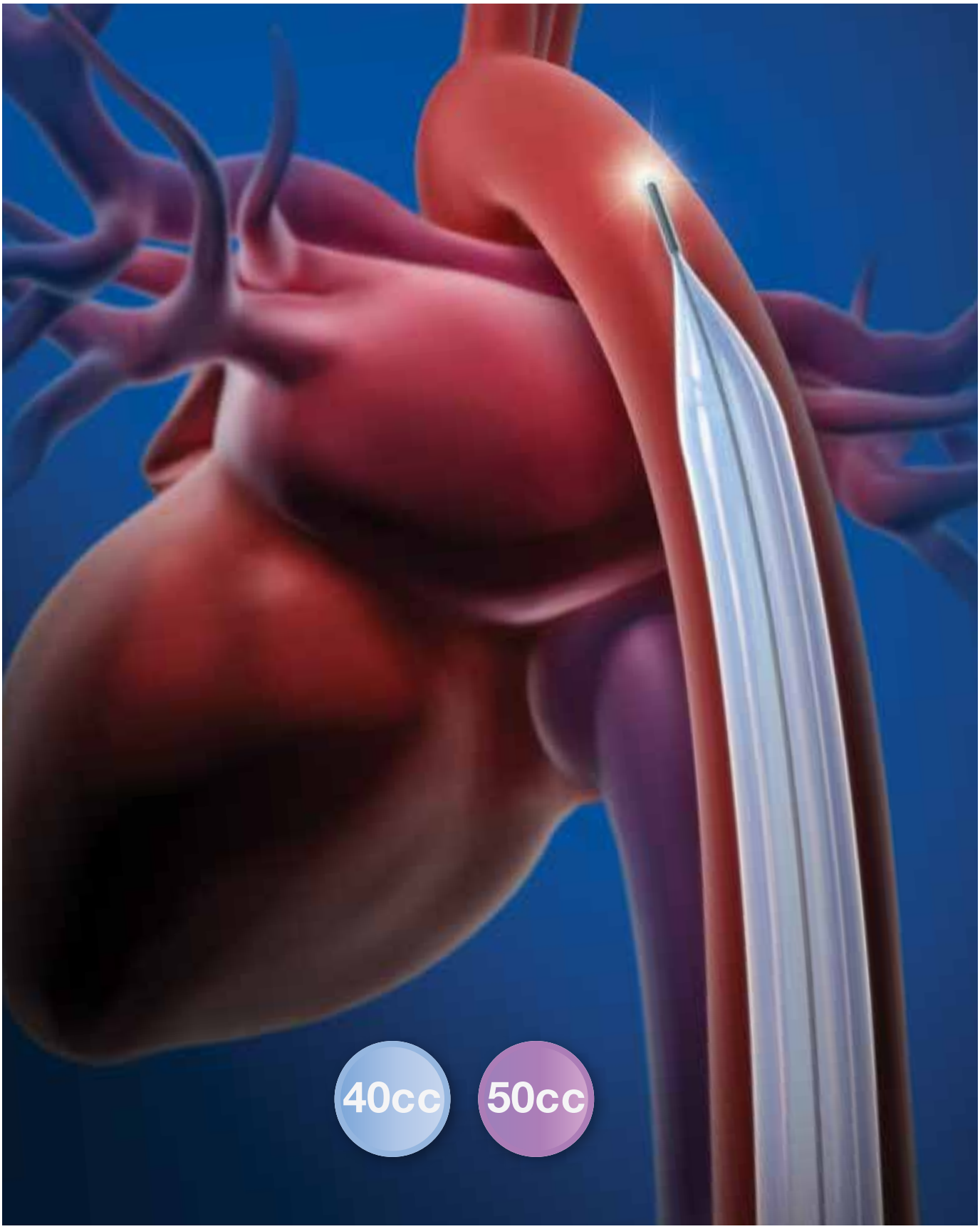
GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. ArjoHuntleigh focuses on patient mobility and wound management solutions. GETINGE provides solutions for infection control within healthcare and contamination prevention within life sciences. MAQUET specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

PN: 0002-08-1075 R0 MCV-BR-80000205-EN-01
△ Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician. Refer to Instructions for Use for current indications, warnings, contraindications, and precautions.

SENSATION PLUS®

Higher Efficacy Fiber-optic IABs

MAQUET
GETINGE GROUP



This document is intended to provide information to an international audience outside of the US.

Higher Efficacy Fiber-optic IABs

SENSATION PLUS® is a technological first in improved hemodynamic support, offering all the benefits of Maquet's easy-to-use IAB fiber-optic technology with the increased clinical effectiveness that larger volume IABs offer. Faster set-up and easier patient management come standard.

Unique automatic *in vivo* calibration:
Maquet offers a fiber-optic IABP and catheter system that automatically calibrates in the patient after insertion and automatically recalibrates *in vivo* every 2 hours or sooner should patient or environmental conditions change.

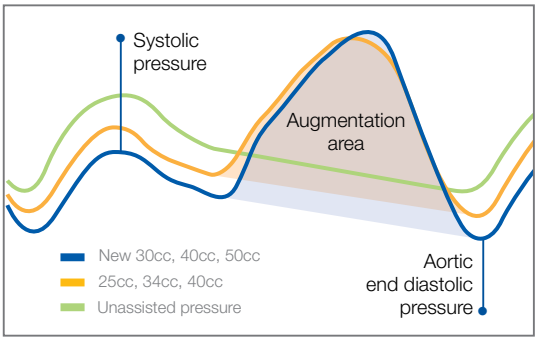
The result: faster time to therapy, ongoing consistency and accuracy of the arterial blood pressure waveform, and improved ease-of-use.

A new level of support.
A new standard of care.

Exceptional Benefits

Greater hemodynamic support

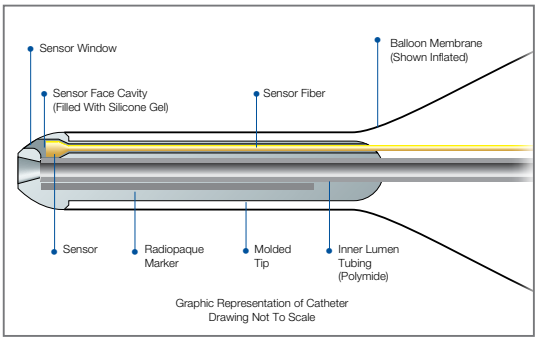
- More blood volume displacement
- More diastolic augmentation
- More systolic unloading



*Hemodynamic Comparison**

Fiber-optic Technology

- Faster time to therapy
- Automatic *in vivo* calibration
- Instantaneous signal transmission
- Crisp, clean arterial pressure waveform



Representation of Catheter tip

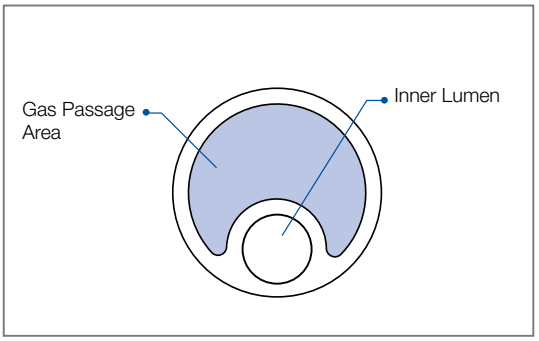
STATLOCK® IAB included

- Eliminates suture-securement needle sticks and suture-wound complications
- Patient comfort and safety
- Quick and easy application and removal

STATLOCK® IAB Stabilization Device

Advanced IAB design and membrane

- One guidewire (0.025") for sheathed or sheathless IAB catheter insertion
- No step-down due to unique balloon wrap
- Co-lumen design for optimal gas passage
- Large 0.027" inner lumen for a reliable pressure transducer signal
- Proprietary IAB membrane: 43% more abrasion resistance*, reduced insertion force and immediate inflation at start-up



Co-lumen design

** Bench testing completed by Maquet. Data on file. Bench test results are not necessarily predictive of clinical results.*

New Sizing Guidelines

Why are the NEW sizes better for my patient?

Larger volume balloons like SENSATION PLUS displace more blood in the aorta during diastole, resulting in improved augmentation and unloading.

With these new sizing guidelines, a larger patient population can benefit from greater hemodynamic support than ever before.

Thus, why not consider using a higher efficacy IAB as your **FIRST** choice when hemodynamic support is needed?

Comparison of Balloon Specifications

The larger volume SENSATION PLUS 40cc and 50cc balloons offer greater support when compared to 34cc and 40cc.

Specifications	SENSATION PLUS	SENSATION	SENSATION PLUS	SENSATION
Balloon Size	40cc	34cc	50cc	40cc
Patient Height	5'0" to 5'4" (152-162cm)	5'0" to 5'4" (152-162cm)	5'4" & taller (≥162cm)	5'4" to 6'0" (162-183cm)
Catheter/ Sheath Size	7.5Fr.	7Fr.	8Fr.	7Fr.
Balloon Diameter	16mm	15mm	17.4mm	15mm
Balloon Length	229mm	221mm	258mm	258mm
Guidewire	0.025"	0.018"/ 0.035"	0.025"	0.018"/ 0.035"
Inner Lumen	0.027"	0.020"	0.027"	0.020"

Note: This information is to be used as a guidance only. Clinical information and patient factors such as torso length should be considered when selecting the appropriate balloon size.

Ordering Information

Product	Part Number
SENSATION PLUS 7.5Fr. 40cc Fiber-Optic Balloon Catheter, Insertion Kit and Two STATLOCK® IAB devices	0684-00-0568-01
SENSATION PLUS 8Fr. 50cc Fiber-Optic Balloon Catheter, Insertion Kit and Two STATLOCK® IAB devices	0684-00-0576-01
Accessories	**Part Number**
SENSATION PLUS 7.5Fr. 40cc Insertion Kit ONLY SENSATION PLUS 8Fr. 50cc Insertion Kit ONLY *SENSATION PLUS Insertion Kits include:* - 6" (15cm) Reinforced Introducer Sheath with hemostasis valve - One Introducer Dilator - One Vessel Dilator - One 18 gauge Angiographic Needle - One 0.025" x 145cm 3mm J PTFE Stainless Steel Guidewire - One Male Luer Cap - One Three-Way Stopcock - Two 4' Pressure Tubings - One 6'0" Catheter Extender Tubing (40cc ONLY) - One 5'7" Catheter Extender Tubing (50cc ONLY)	0884-00-0019-22 0884-00-0019-23
0.025" x 145cm 3mm J PTFE Stainless Steel Guidewire (5 Pack) 0.025" x 175cm 3mm J PTFE Stainless Steel Guidewire (5 Pack) 0.025" x 260cm 3mm J PTFE Stainless Steel Guidewire (5 Pack)	0684-00-0254-09 0684-00-0254-14 0684-00-0254-15
7.5Fr. Sheath and Dilator Set 8Fr. Sheath and Dilator Set	0684-00-0403-05 0684-00-0403-10
6'0" Catheter Extender Tubing for 34cc and 40cc IABs (10 Pack) 5'7" Catheter Extender Tubing for 50cc IABs (10 Pack)	0684-00-0186 0684-00-0526
STATLOCK® for Maquet IAB Securement (1 Box contains 20 single pouches)	0684-00-0472
Arrow Pump Adapter for 25cc to 40cc IABs (5 pack) Arrow Pump Adapter for 50cc IABs (5 pack)	0684-00-0510-01 0684-00-0510-02

Configuration

Materials	Packaging	Cycle Life
All balloon catheters, insertion kits and STATLOCK® IAB Stabilization Devices meet FDA and ISO biocompatibility guidelines for devices and materials. SENSATION PLUS catheters, insertion kits and STATLOCK® IAB devices do not contain latex.	Every IAB catheter, insertion kit and STATLOCK® IAB device has been individually placed in a single pouch, sealed and sterilized.	1 procedure

MAQUET
GETINGE GROUP

Maquet
1300 MacArthur Blvd., Mahwah, NJ 07430, USA
Phone: +1 201 995 8700

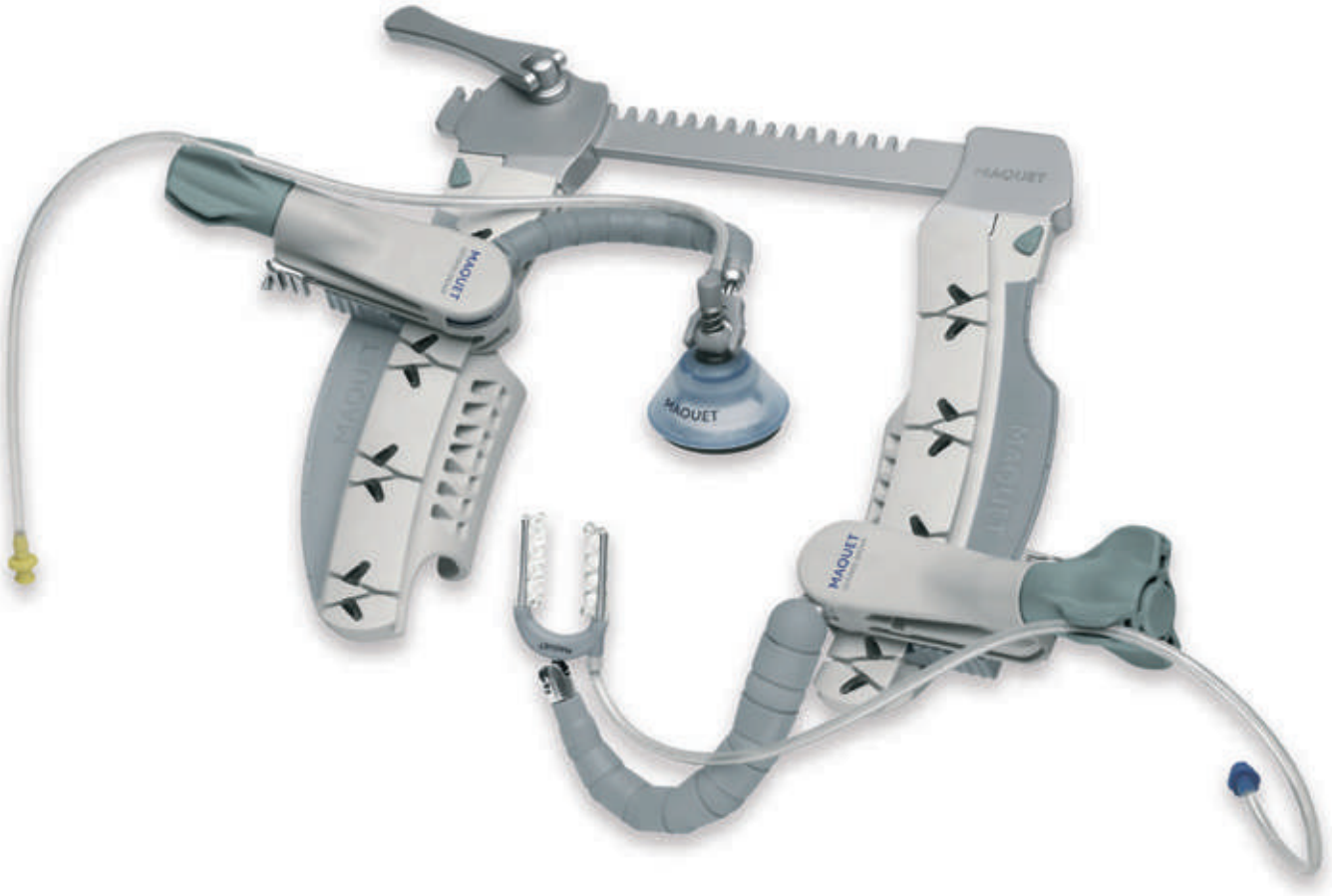
www.maquet.com

GETINGE GROUP

Getinge Group is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, Getinge and Maquet. ArjoHuntleigh focuses on patient mobility and wound management solutions. Getinge provides solutions for infection control within healthcare and contamination prevention within life sciences. Maquet specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

This document is intended to provide information to an international audience outside of the US.

OFF-PUMP PRODUCTS



Acrobat-i Off-Pump System

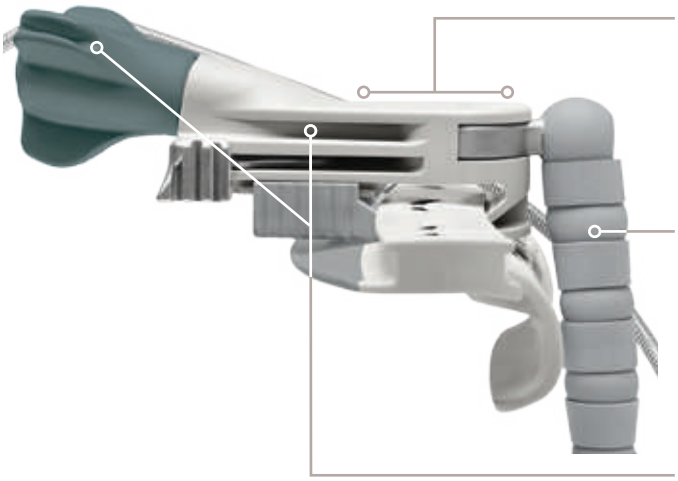
Enhance visibility and control in beating heart surgery

GETINGE

Sleek form and superb function

Improving clinical outcomes

Off-pump coronary artery bypass (OPCAB) surgery can offer patients benefits like reduced stroke in high-risk patients[1], reduced bleeding in diabetics[2] and reduced in-hospital death with patients with low ejection fractions[3].



Optimize the work area with a low-profile mount

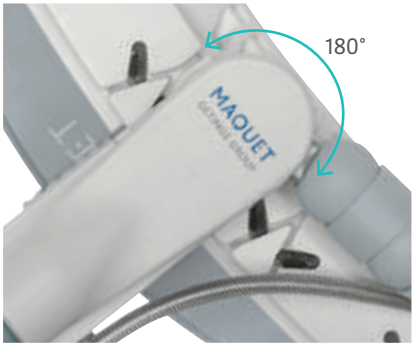
- Thin stabilizer mount maintains a constant low profile, even at extreme arm positions.
- Locking lever is streamlined and out of the way.

Flexlink arm technology delivers proven strength and reliability

- Stabilizer allows a vertical drop of the Flexlink arm into the chest cavity.
- Delivers proven Getinge Acrobat strength and flexibility.

Tubing management system removes work area clutter

- Integrated channels secure the tubing from movement.
- Maintains an organized working space.
- Improved vacuum tubing flexibility.



Revolutionary Getinge Acrobat-i swivel

- Proprietary technology provides 180º side-to-side range of motion of the arm.
- Exceptional arm maneuverability for both the stabilizer and positioner.
- Improves visibility and access to the surgical field.

Improve patient outcomes

Delivers dependable performance

The Getinge Acrobat-i off-pump system incorporates practice-proven features from the Getinge Acrobat and Getinge Xpose product families. Utilizing OPCAB surgery can lead to fewer cognitive and neurological effects, shorter hospital stays, and fewer wound complications.[4]

Getinge Acrobat-i Stabilizer

- Suction pods provide ideal stabilization and superb vessel presentation.
- Malleable foot conforms to the heart for optimal placement.

Getinge Acrobat-i Tri-Slot Socket

- Flexible access to challenging vessels with “toes-up” and “toes-down” positioning.

Getinge Acrobat-i Positioner

- Proprietary active suspension technology allows normal cardiac motion and maintains stable hemodynamics.
- The tissue-conforming suction cup uses a gentle vacuum to securely lift and hold the heart.
- Designed for apical or nonapical placement.

Description	Code
Acrobat-i Vacuum Stabilizer System*	OM-10000
Acrobat-i Vacuum Positioner System	XP-5000
Acrobat-i Off-Pump System (Stabilizer + Positioner)*	XO5-10000

*Includes Accessrail Platform (standard blades).

References
1. Kowalewski M, Pawliszak W, Malvindi PG, Bokszanski MP, Perlinski D, Raffa GM, et al. Off-pump coronary artery bypass grafting improves short-term outcomes in high-risk patients compared with on-pump coronary artery bypass grafting: Meta-analysis. *J Thorac Cardiovasc Surg*. 2016 Jan;151(1):60-77.
2. Wang Y, Shi X, Du R, Chen Y, Zhang Q. Off-pump versus on-pump coronary artery bypass grafting in patients with diabetes: a meta-analysis. *Acta Diabetol*. 2017 Mar;54(3):283-292.
3. Keeling WB, Williams ML, Slaughter MS, Zhao Y, Puskas JD. Off-pump and on-pump coronary revascularization in patients with low ejection fraction: a report from the society of thoracic surgeons national database. *Ann Thorac Surg*. 2013 Jul;96(1):83-8: discussion 88-9.
4. Puskas JD, Martin J, Cheng DC, Benussi S, Bonatti JO, Diegeler A, et al. ISMICS Consensus Conference and Statements of Randomized Controlled Trials of Off-Pump Versus Conventional Coronary Artery Bypass Surgery. *Innovations (Phila)*. 2015 Jul-Aug;10(4):219-29.

GETINGE

Sales Office · 45 Barbour Pond Drive · Wayne, NJ 07470 · USA · 888 627 8383

www.getinge.com

MCV00005107 REVE
EXP03/20

Beating heart surgery

Product family

GETINGE

A comprehensive solution

Designed to help optimize outcomes

Acrobat-i Stabilizer

Acrobat-i Positioner

Seal loader and delivery device

Seal

Aortic cutter

Acrobat-i® Off-Pump System

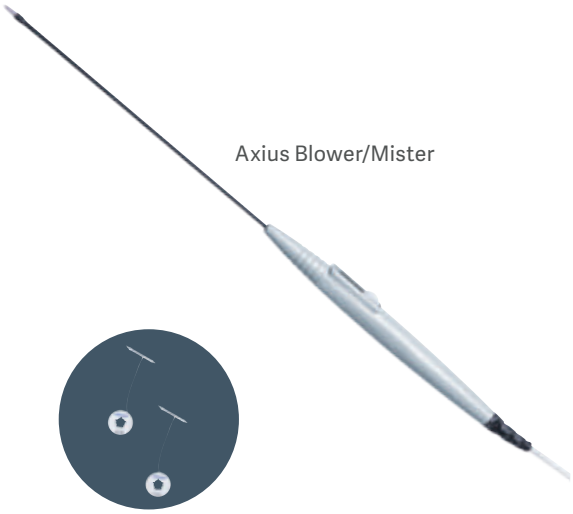
Acrobat-i combines sleek form with superb function and enables surgeons to easily and confidently deliver the benefits of beating heart surgery. It incorporates the preferred features from the Acrobat and Xpose product family: proven stability, strength and flexibility.

- Low profile mount: stabilizer mount maintains a constant low profile even at extreme arm positions for an optimized work area.
- Increased visibility: stabilizer allows a vertical drop into the chest cavity and provides 180° side-to-side range of motion of the arm.
- Increased workspace: streamlined locking lever and Integrated channels secure tubing and decrease workspace cluttering.

Heartstring® III Proximal Seal System

Heartstring III brings proximal anastomotic technology into the future. A hemostatic seal enables surgeons to eliminate partial occlusion clamps and minimize aortic manipulation that can lead to complications.

- Benefits: Minimizing the manipulation of the ascending aorta reduces the risk of neurologic complications. In patients with minimal aortic diseases the cerebral emboli number is significantly reduced when the Heartstring device is used.[1]
- Patency: allows use of the surgeon's own hand-suturing technique for optimal anastomotic quality and procedural flexibility.
- Ease-of-use: the innovative loading device makes Heartstring III seal placement fast and easy.



Axius Blower/Mister

Coronary shunts

Activator II Drive Mechanism

Axius® beating heart accessories

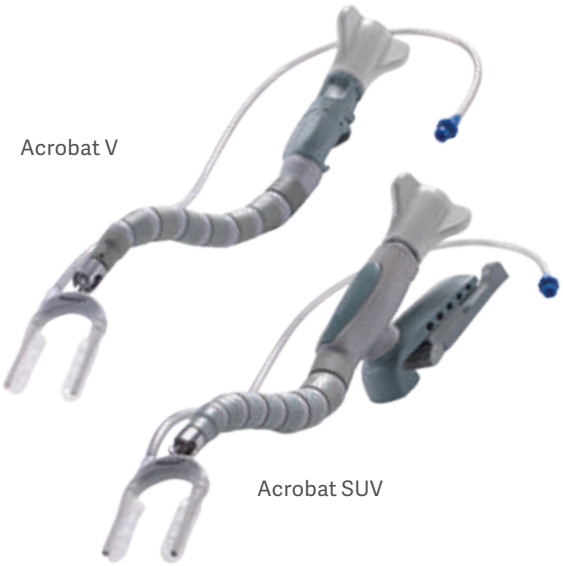
The Axius Coronary Shunt and Blower/Mister help to optimize operative conditions during coronary revascularization procedures.

- Create a clear work area: shunt provides a bloodless field at the anastomotic site.
- Minimize ischemia: shunt helps maintain distal perfusion.
- Maintain moisture: Blower/Mister helps prevent dessication of graft.
- Increase visibility: Blower/Mister gently displaces blood with a controlled flow of saline and CO_2.

Activator® II Drive Mechanism

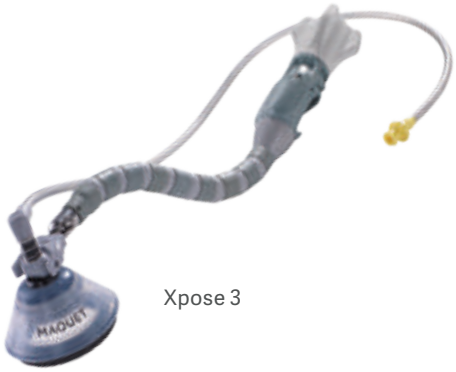
The Activator II Drive Mechanism is a reusable, stainless steel retractor used in combination with the Accessrail Platform to open the sternum, providing access and direct visualization into the thoracic cavity.

- Flexibility: choose between standard blades or deep blades to accommodate different anatomies which easily attach to the Activator II Drive Mechanism.
- Clear workspace: enables clean organization of pericardial sutures and also accommodates the stabilizers and positioners used on the beating heart.



Acrobat V

Acrobat SUV



Xpose 3

Acrobat® Off-Pump System

The Acrobat Off-Pump System provides the strength, visibility, and the stability necessary in a variety of surgical situations.

- Excellent stabilization: malleable feet provide ideal stabilization and superb vessel presentation; tri-slot socket wrist design provides access to difficult vessels in “toes-up” position, for maximum visibility.
- Strength and flexibility: low-profile arm is designed for increased strength, and innovative FlexLink™ technology features interlocking links that enable greater maneuverability.

Xpose® Access Device

The Xpose Access Device is designed for apical or non-apical placement, and securely lifts the heart for access to vessels in any location.

- Maintain stable hemodynamics: active suspension technology allows normal cardiac motion.
- Ensure secure contact: tissue-conforming suction cup uses gentle vacuum to stay in place.
- Reveal hard-to-reach vessels: low-profile arm makes it easy to see and gain access to any target vessel.

Ordering information

Description	Code
Heartstring III Proximal Seal System	
Heartsrtring III Seal, Delivery Device, Loader, and 3.8 mm Aortic Cutter	HSK-3038
Heartsrtring III Seal, Delivery Device, Loader, and 4.3 mm Aortic Cutter	HSK-3043
Heartsrtring III Seal, Delivery Device, and Loader	HS-3045
Aortic Cutter, 3.8 mm	AC-3038
Aortic Cutter, 4.3 mm	AC-3043
Xpose Access Devices	
Xpose 3 Positioner	XP-3000
Acrobat-i Positioner	XP-5000
Acrobat Off-Pump Systems and Ultima OPCAB System	
Acrobat-i Stabilizer	OM-10000
Acrobat SUV Stabilizer	OM-9000S
Acrobat V Stabilizer	OM-9100S
Acrobat-i Positioner and Stabilizer	XO5-10000
Xpose 3 + Acrobat SUV Stabilizer	XO3-9000S
Xpose 3 + Acrobat V Stabilizer	XO3-9100S

Beating heart accessories	Code
Activator® II Drive Mechanism	
Activator II Drive Mechanism	UA-5001
Accessrail Platform Standard Blades	SB-1000
Accessrail Platform Deep Blades	DB-1000
Axius® Blower/Mister	
Axius Blower/Mister	CB-1000

Axius Coronary Shunt

Tip Diameter (mm)	Standard Length (mm)	Long Length (mm)	Code
1.00	16.25	–	OF-1000
1.25	16.25	–	OF-1250
1.50	16.25	– 20.25	OF-1500/ OF-1500L
1.75	17.50	–	OF-1750
2.00	18.00	– 22.00	OF-2000/ OF2000L
2.25	18.00	–	OF-2250
2.50	19.00	–	OF-2500
2.75	19.50	–	OF-2750
3.00	20.00	–	OF-3000
3.50	24.00	–	OF-3500

Reference
1. El Zayat H, Puskus JD, Hwang S, et al. Avoiding the clamp during off-pump coronary artery bypass reduces cerebral embolic events: results of a prospective randomized trial. *Interactive CardioVascular and Thoracic Surgery*. 2012; 14(1): 12-16.

GETINGE

Sales Office · 45 Barbour Pond Drive · Wayne, NJ 07470 · USA · 888 627 8383

www.getinge.com

MCV00020165 REVB
EXP02/20

SURGICAL ADHESIVE

Surgery

GRENA Think Medical

NEXGlue®

Surgical Adhesive

Your Safety Net

Full strength in 2 minutes

PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

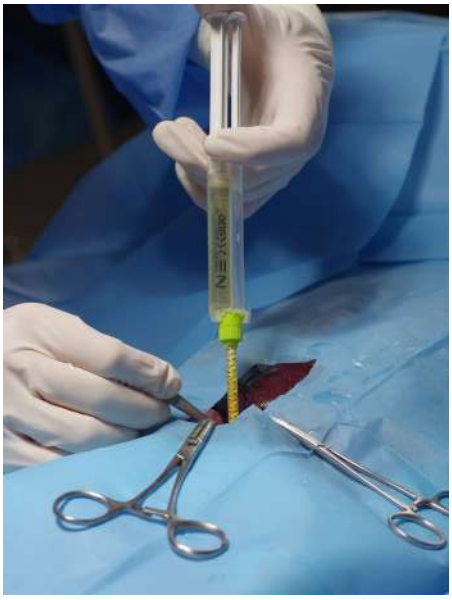
WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

NE'X Glue® Surgical Adhesive

NE'X Glue® is two component surgical adhesive which covalently bonds with tissue and takes a form of flexible hydrogel. It also mechanically binds with synthetic materials. Such features allow for strong tissue - tissue or tissue - synthetic material connections.
Combination of purified albumin and aldehyde in optimal ratio with precise mixing inside the applicator of the delivery device allows for full consumption of aldehyde during the polymerisation. As a result, absolutely biocompatible flexible hydrogel is created.

KEY FEATURES:

- Variety of available volumes – 2, 5 and 10 ml
- Standard and spreader applicator tips
- Room temperature storage
- Ready for use in seconds
- Easy to use
- Full polymerization in 20-30 seconds
- Full strength in 2 minutes
- Works independently of the coagulopathic state of the patient
- Stronger than sealants based on fibrin or poly-ethylene glycols

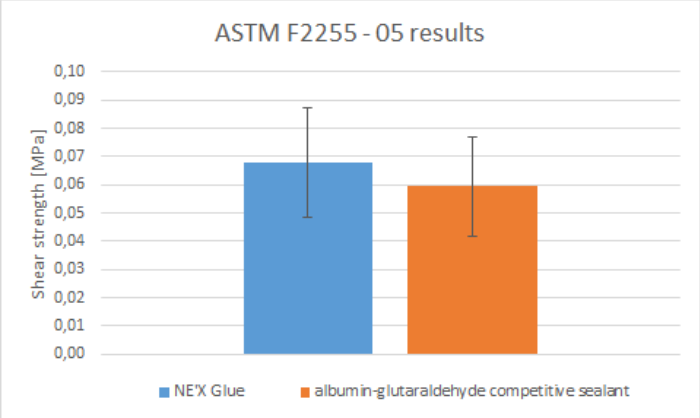


CLINICAL APPLICATIONS:

NE'X Glue® is used as an adjunct to standard methods of repair such as sutures, staples, electrocautery and patches to seal, bond and reinforce tissue. Can be applied alone to fix surgical meshes, reinforce, repair or seal damaged parenchyma as a replacement of ineffective or impractical techniques.

- VASCULAR SURGERY
- CARDIAC SURGERY
- THORACIC SURGERY
- GENERAL SURGERY
- GENITOURINARY SURGERY
- NEUROSURGERY
- ENT SURGERY
- SPINAL SURGERY

REF	PRODUCT	CONTAINS
0206-NX2	NE'X Glue® Surgical Adhesive 2 ml	5 single packs - each contains: 1 syringe (2 ml) & syringe plunger, 4 syringe applicator tips
0206-NX5	NE'X Glue® Surgical Adhesive 5 ml	5 single packs - each contains: 1 syringe (5 ml) & syringe plunger, 4 syringe applicator tips
0206-NX10	NE'X Glue® Surgical Adhesive 10 ml	5 single packs - each contains: 1 syringe (10 ml) & syringe plunger, 4 syringe applicator tips, 3 spreader tips (12 mm)
0206-NX4SM	Syringe applicator tip	5 single packs - each contains 4 syringe applicator tips
0206-NX3WM12	Syringe 12 mm spreader tip	5 single packs - each contains 3 syringe 12 mm spreader tips
0206-NX3WM16	Syringe 16 mm spreader tip	5 single packs - each contains 3 syringe 16 mm spreader tips



Endotoxin content in the whole extract [EU]	NE'X Glue® Surgical Adhesive	Albumin-glutaral-dehyde competitive sealant
	0,290	0,535

Grena Biomed Ltd.
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP, United Kingdom

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 07/01.07.2022

NE'X Glue® Surgical Adhesive

Instructions for use

Ref. no.: 0206-NX2, 0206-NX5, 0206-NX10, 0206-NX4SM, 0206-NX3WM12, 0206-NX3WM16

GRENA **Grena Biomed Limited,** Chelsea House, Chelsea Street, Nottingham, NG7 7HP, United Kingdom	**Contact information:** Phone/Fax: + 44 115 9704 800	EC REP **MDML INTL LTD**. 10 McCurtain Hill Clonakilty, Co. Cork, P85 K230, Republic of Ireland	CE 1434	**ENG** IFU-NX-ENG_06

Caution:

This instruction cannot be used as a manual for surgical techniques used during the work with Surgical Adhesive. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of experienced surgeon. Before use we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious surgical consequences such as patient injury, contamination, infection, cross-infection, inappropriate sealing / bonding / reinforcing strength or death.

Indications:

NE'X Glue® Surgical Adhesive is indicated to bond, seal and/or reinforce soft tissue. Can be applied as an adjunct to staples, sutures, electrocautery or patches as well as alone for sealing or reinforcing parenchymal organs when other standard methods are impractical or ineffective. Another application is surgical mesh fixation in hernia surgery. Soft tissues where NE'X Glue® is effective are vascular, cardiac, pulmonary, dural, esophageal, gastric, intestinal, colorectal, pancreatic, splenic, biliary, hepatic and genitourinary. NE'X Glue® can be applied prophylactically or after a leak is detected. NE'X Glue® Syringe Applicator Tips and Spreaders are intended to thoroughly mix the NE'X Glue® Surgical Adhesive components and to apply adhesive to the tissue.

Patient target group – adult and young patients, males and females.

Intended users: product is intended to be used exclusively by qualified medical staff.

Contraindications:

DO NOT use in cerebrovascular procedures.
DO NOT use on exposed nerves or in a closed locations that are in immediate proximity to nerve structures.
DO NOT use on eyes.
DO NOT use intra-luminally.
DO NOT use intra-vasculary or in contact with circulating blood.
DO NOT use in case of known sensitivity to materials of bovine origin.
DO NOT use as a substitute for sutures or staples in tissue approximations.
DO NOT use on infected or contaminated areas.

Side effects:

Possible side effects may include, but are not limited to: failure of glue to adhere to tissue, inflammatory response, immune response, allergic reaction, application to tissue not targeted for the procedure, tissue necrosis, vessel obstruction, bronchus obstruction, luminal obstruction, tissue mineralization, thrombosis and thromboembolism, pulmonary emboli, injury to vessels or tissue, transmission of infectious agents of animal origin.

Description of the device:

NE'X Glue® Surgical Adhesive is two component product composed of bovine serum albumin and glutaraldehyde. Each component is closed in separate chamber of the syringe and they are mixed in the applicator tip during application to the tissue. Polymerization starts immediately after application and final strength is reached after 2 minutes. Delivery system consists of prefilled syringe, plunger and applicator tips. Applicator tips are delivered in sets together with Surgical Adhesive (Ref 0206-NX2, 0206-NX5, 0206-NX10) and are also available separately. Product is sterile and non-pyrogenic. It is intended for single-patient use only.

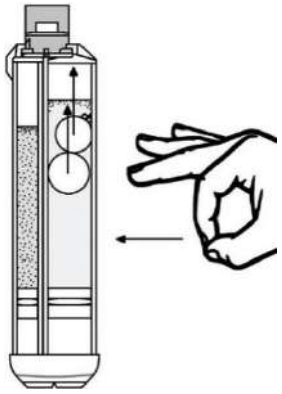
Single package content:

Surgical Adhesive		Applicator Tips			Remarks
REF	**Volume**	**Type**	**REF**	**pcs**	
0206-NX2	2 ml	Pinpoint	0206-NX4SM	4	Applicator Tips **also** available **separately** in sets of 4 pcs
0206-NX5	5 ml				
0206-NX10	10 ml				
		Spreader 12 mm	0206-NX3WM12	3	Applicator Tips **also** available **separately** in sets of 3 pcs
		Spreader 16 mm	0206-NX3WM16		Applicator Tips available **separately only** in sets of 3 pcs

Instructions for use:

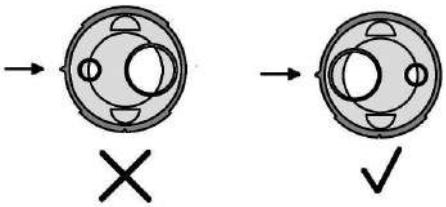
DEVICE PREPARATION:

1. Remove syringe with a glue, plunger and applicator tips from the packaging. Hold the syringe tip upright and tap the syringe chambers few times to let air bubbles in the solutions to rise upto the top of the syringe (pic.1).
   NOTE: It is important to move all the air bubbles to the top of the syringe to remove air prior to priming of the applicator tip. Omitting this step may result in the components not being mixed in the right proportions, which may weaken the effect of the adhesive or cause an irritating effect. Take care to keep holding of the syringe upright during entire assembly procedure.



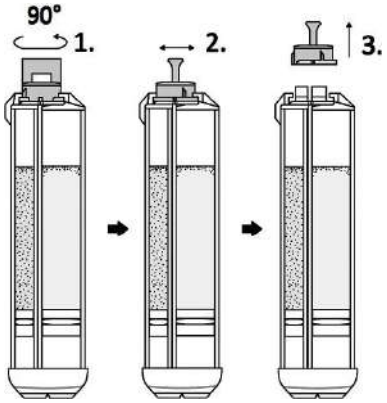
Pic. 1

2. Check if triangle projection of the nut of the applicator tip is located directly over the larger port (pic. 2). If not, hold the shaft of the applicator tip and rotate the nut to locate triangle projection over the larger port. Improper position of the projection relative to the large port will prevent the applicator tip from connecting to the syringe.

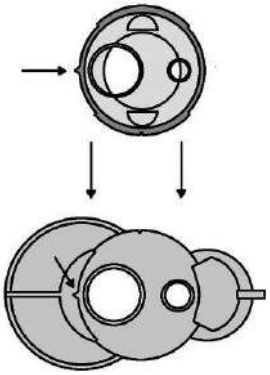


Pic. 2

3. Grasp syringe firmly nose upwards, turn the cap 90° counterclockwise and remove the cap by rocking it side-to side (pic. 3).
4. Align position of the applicator tip with the syringe looking at the triangle projection on the applicator tip and corresponding notch on the syringe and place the applicator tip on the syringe (pic. 4).
   CAUTION: Take care not to spill solutions from the syringe during assembly.

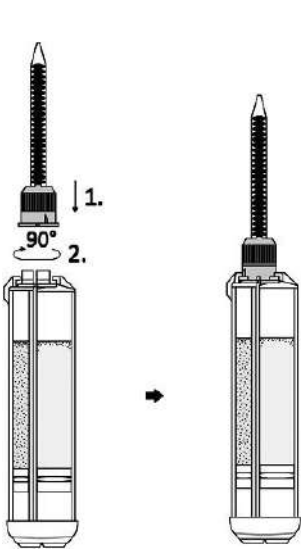


Pic. 3

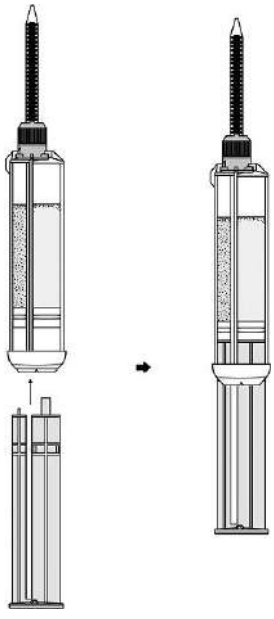


Pic. 4

5. Push the applicator tip firmly towards the syringe and rotate the applicator tip nut 90° clockwise to lock the tip on the syringe (pic. 5). If the cap is not rotated, the application tip will not be locked and may fall off the syringe before/during application, and leaking glutardehyde unreacted with albumin may lead to tissue damage.
6. Keep the syringe upright and insert double plunger into the back of corresponding syringe chambers until resistance from the silicone plungers is felt (pic. 6).
   CAUTION: DO NOT lay the assembled device on its side.
   CAUTION: DO NOT remove air from above solutions in the syringe and DO NOT prime applicator tip at this stage. Air removal and priming should be done after application site is prepared for immediate NE'X Glue® use. Early air removal and applicator tip priming would block applicator tip.



Pic. 5



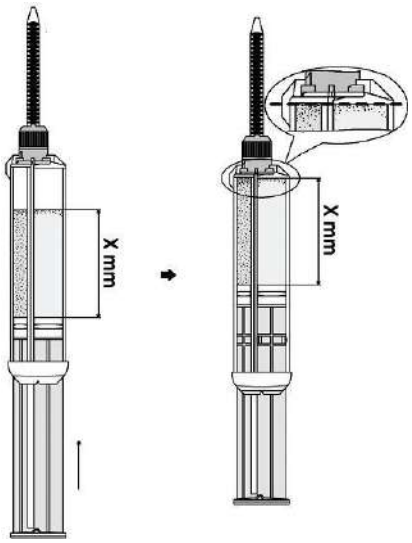
Pic. 6

SITE PREPARATION:

7. Prepare patient according to standard hospital procedures and secure unrestricted and convenient access to the application site.
8. Protect the tissue surrounding the surgical site from the undesired application of NE'X Glue® by placing moist sterile gauze pads in these areas. These pads should be removed immediately after application, while adhesive is still soft. Otherwise, the gauze pads will stick to the tissue. Any excess of adhesive residues should be wiped away from around the site.
9. Take care that application site is dry what can be described as a field that does not restain with blood within 4-5 seconds after wiping dry with a surgical sponge.
   CAUTION: Application of NE'X Glue® on a wet field may result in a failure to adhere.

AIR REMOVAL:

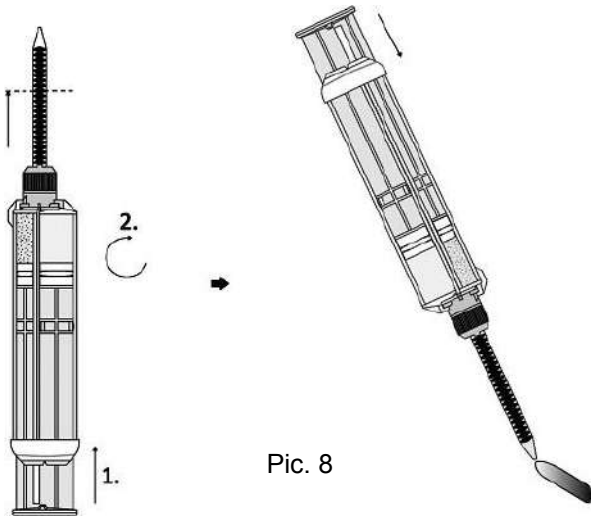
10. Continue to keep syringe upright and make sure that the air bubbles in the solutions are located at the top of the syringe.
11. Compress the plunger until the solutions are even with the top of the syringe body (pic. 7). Once the residual air space has been removed delivery device is ready for applicator tip priming.
    CAUTION: If at this stage solutions enter base of the applicator tip, tip will be occluded with polymerized NE'X Glue® and replacement with a new one before priming will be necessary. To remove occluded applicator tip, grasp the applicator tip nut, rotate the tip nut counterclockwise, and lift the tip off the syringe by rocking it side to side.
    NOTE: Air removal is necessary prior to initial use only.



Pic. 7

APPLICATOR TIP PRIMING:

12. Prime applicator tip by compressing the plunger until Applicator tip will be filled with solutions and approximately 3 cm long ribbon of NE'X Glue® will be expelled onto a sterile disposable surface (e.g. gauze pad). It is recommended to start priming with syringe in the upright position until half of applicator tip is filled with solutions. When solutions fills about half of applicator tip continue compressing the plunger and aim the tip down at an angle to a sterile surface to expel ribbon of NE'X Glue® (pic. 8).
13. Examine the material expelled during priming and ensure that its colour is uniform light yellow to amber and free of air bubbles.
    If expelled material is colourless or contains bubbles expel longer ribbon of NE'X Glue or repeat priming procedurę until the device delivers a uniform light yellow to amber liquid with no bubbles.
    CAUTION: Avoid direct contact of any tissue with material expelled during priming as it may have an irritating effect.
14. After the applicator tip has been properly primed proceed immediately to application.
    CAUTION: NE'X Glue polymerizes rapidly. Pausing between priming and application can lead to polymerization of NE'X Glue® inside the applicator tip. Should this occur, replace the blocked tip and repeat priming procedure. Do not apply pressure to the plunger once the tip has occluded.



Pic. 8

CAUTION: If surgeon needs to stop application, applicator tip will be occluded with polymerized NE'X Glue®.
To use remaining solutions after application was paused, applicator tip must be replaced with a new one and priming procedure must be performed again.

General techniques for the use of NE'X Glue®:

1. As proper and smooth device preparation, air removal and priming is critical for good results, it is highly recommended to practice all the steps with the product prior to initial use in the surgical site.
2. Clamp and depressurise vessels prior to applying NE'X Glue® to targeted anastomoses. This will reduce bleeding, which would weaken the effect of the adhesive.
3. For vessel repair apply an even adhesive coating 1,2 – 3,0 mm thick for anastomosis of vessels/grafts greater than 2,5 cm in diameter; apply an even adhesive coating 0,5 – 1,0 mm for vessels/grafts less than 2,5 cm in diameter.
4. For parenchymal repair apply an even adhesive coating 1,5 – 3,0 mm thick.
5. Do not apply thicker layers of adhesive than required, as it does not increase its effectiveness and only limits the elasticity of the layer.
6. The area of adhesive application should **NOT** be compressed or subjected to an extra pressure, which would stiffen the anastomosis in a non-anatomical shape and disturb function of the anastomosed structures.
7. After adhesive polymerizes, trim away excess or irregular adhesive edges with scissors and pickups.

Specific Techniques for the use of NE'X Glue® in aortic dissection repair:

1. The dissected layers of the aorta should be initially cleared of blood and thrombus material and should be dried with surgical sponges to the extent possible.
2. For the distal end of the dissection repair, insert a balloon catheter into the true lumen to define the distal terminus for the application of NE'X Glue®. In addition, the dissected layers of the aorta should be closely approximated by inserting a dilator, sponge, or catheter into the true lumen to preserve the natural architecture of the vessel. NE'X Glue® should then be dispensed into the false lumen as far distally as the distal balloon catheter will allow. Filling the false lumen should proceed from distal to proximal with a spiralling out motion for smooth application. Completely fill the false lumen with NE'X Glue®; avoid overfilling the false lumen and spilling NE'X Glue® into the true lumen or surrounding tissue.
3. For the proximal end of the dissection repair, the dissected layers of the aorta should also be closely approximated by using a dilator, sponge, or catheter. If necessary, moist gauze pads should be placed over the aortic valve leaflets to protect them from inadvertent application of NE'X Glue®. NE'X Glue® should then be dispensed to fill the false lumen. Graft material may be sutured directly onto the tissues adhered and reinforced with NE'X Glue® at both the proximal and distal aspects of the dissection repair. Allow NE'X Glue® to completely polymerize without any manipulations for a full two minutes prior to suturing through the adhered tissue layers.

NE'X Glue® in lung surgery:
NE'X Glue® can be applied to a deflated or inflated lung.

Warnings and precautions measures:

1. Any surgical and minimally invasive procedures should be performed only by persons having adequate training and familiarity with those techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.
2. It is recommended that surgical gloves, sterile gauze pads/towels, and surgical instruments be maintained moist to minimize the potential for NE'X Glue® inadvertently adhering to these surfaces.
3. Use only the applicator tips indicated in this manual. The use of similar-looking tips from other manufacturers may result in glue leaks, reduced adhesion and necrotic changes.
4. Take care not to spill contents of the syringe because glutardehyde present in the smaller chamber of the syringe, if unreacted with albumine, has an irritating effect on tissues.
5. Do not press plunger while attaching it to the syringe as this will compress the air above the level of the fluids in the syringe, which can lead to leakage from the syringe when the cap is removed.
6. Apply NE'X Glue® onto dry surface as too wet field may result in poor adherence.
7. Do not use blood saving devices when suctioning excess of NE'X Glue® from the surgical field.
8. Avoid any negative pressure during application and polymerization of NE'X Glue® to prevent the entrance of NE'X Glue® into the cardiovascular system. For example, left ventricular vents should be turned off prior to the application of NE'X Glue® as it could be suctioned into the aorta and impeding heart valve function when used in conjunction with an active left ventricular vent.
9. Circumferential application of adhesive may restrict dilatation on growing tissue what suggests caution with the circumferential use of NE'X Glue® in children.
10. Ineffective sealing may be observed when NE'X Glue® is used in the translabyrinthine approach for acoustic neuroma repairs; its use with this surgical approach is not recommended. Recommended for acoustic neuroma repair is the middle fossa or retrosigmoid approach.
11. Excessive application of NE'X Glue® in lung surgery can increase residual air space and cause atelectasis.
12. Do not allow NE'X Glue® to contact or obstruct circulating blood flow during or after application as it could result in local or embolic vascular obstruction.
13. Do not allow NE'X Glue® to obstruct air pathways or any other luminal fluid flow during or after application.
14. Protect tissue not intended for application from contact with NE'X Glue®. If NE'X Glue® adheres to undesired area, allow adhesive to polymerize and then gently dissect the adhesive away from the unintended area with forceps and scissors. Never attempt to peel away adhesive as this could lead to tissue damage. Leaving NE'X Glue in undesired places may lead to serious consequences depending on the location and amount of adhesive left. The consequences may include, but are not limited to: perforation, necrotic changes, ischemia, hemorrhage, myocardial infarction, nerve conduction disorders, tissue mineralization, and adhesions.
15. Direct application of NE'X Glue® to the exposed phrenic nerve can cause acute nerve injury. Direct application of NE'X Glue® to the surface of the sinoatrial node (SAN) of the heart can cause coagulation necrosis that extends into the myocardium, which could reach underlying conduction tissue and may cause acute, focal SAN degeneration. Chlorhexidine gluconate gel (e.g., Surgilube®) can protect the phrenic nerve, the myocardium, and the underlying SAN from potential injury from NE'X Glue® use.
16. Do not use NE'X Glue® if staff is not adequately protected (e.g., wearing gloves, mask, protective clothing, and safety glasses). Unreacted glutaraldehyde may cause irritation to eye, nose, throat, or skin; induce respiratory distress; and cause local tissue necrosis. Prolonged exposure to unreacted glutaraldehyde may cause central nervous system or cardiac pathology. If contact occurs, flush affected areas immediately with water and seek medical attention.
17. Exercise caution with repeated exposure of the patient to NE'X Glue® as hypersensitivity reactions are possible.
18. NE'X Glue® contains material of animal origin, which potentially may be capable of transmitting infectious agents, but strictly controlled manufacturing proces minimized such possibility.
19. Always inspect the site for hemostasis before procedure is finished. Bleeding can be controlled by electrocautery, surgical sutures or additional NE'X Glue® application.
20. No available literature data indicate the need to quantitatively restrict the use of NE'X Glue during the procedure, however, the recommendations of this manual should be strictly followed in relation to the thickness of the applied layers and applications in unintended areas.
21. Dispose of all opened syringes with NE'X Glue® or applicator tips no matter if they were used or not to prevent accidental use of a contaminated device.
22. Store below 25°C, but do not freeze.
23. Use immediately after opening. Storage of the device after package opening leads to its contamination and creates a risk of an infection to the patient.
24. The product requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
25. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
26. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

	Do not re-use		Keep dry	eIFU indicator www.grena.co.uk/IFU	Consult electronic instructions for use		Manufacturer
STERILE EO 1	Sterilized using ethylene oxide	STERILE R 2	Sterilized using irradiation		Do not resterilize		Do not use if package is damaged and consult instructions for use
MD	Medical device	REF	Catalogue number	LOT	Batch code		Use-by date
	Double sterile barrier system		Caution, consult accompanying documents	BIO	Contains biological material of animal origin		Quantity in package
	Date of manufacture	25°C 0°C	Temperature limit	EC REP	Authorized representative in the European Community		

1– refers to applicator tips
2– refers to syringes with solutions

The hard copies of instructions for use delivered with Grena products are always in English language.
If you require a hard copy of IFU in other language, you can contact Grena Ltd.
*at **ifu@grena.co.uk** or **+ 44 115 9704 800.***

Please scan the below QR code with the appropriate application.
It will connect you with Grena Ltd. website where you can choose eIFU in your preferable language.

You can enter the website directly by typing in www.grena.co.uk/IFU in your browser.
Make sure that paper version of IFU in your possession is in the latest revision prior to use of the device.
Always use the IFU in the latest revision.

IMPLANT CARD INFORMATION

Implant card (IC) is delivered with the product, one IC for each device.
Implant card is supposed to be completed by a implanting healthcare institution or healthcare provider and should be handed over to the patient who has been implanted.
The instructions on how to complete the implant card (IC) in your preferable language you can find on our website
www.grena-biomed.com/ic

LIGATING CLIPS & CLIP APPLIERS

Surgery

GRENA Think Medical

Titanium Ligation System

LigaV® Ligating Clips & Clip Appliers

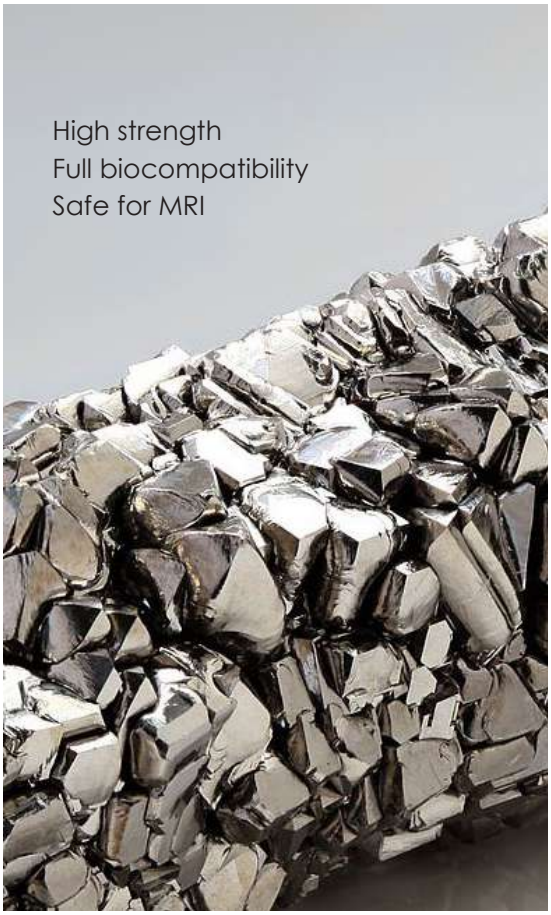
Reliable Ligation

PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

LigaV® ligating clips

LigaV® Ligating Clips are implantable medical devices. They are widely used in surgery for marking and ligating purposes. Medical practitioners value the product for its hemostatic features. LigaV® manufactured by Grena Ltd., comes with inner and outer serration which enhances its function. The outer serration helps to grip the clip in the applier's jaws; the inner serration enables its proper nourishment. The product is offered in 4 standard sizes ensuring every user will be able to find appropriate clip for the given tissue. The LigaV® clips are delivered in colour coded cartridges to ensure easy and intuitive identification. A cartridge includes 4 or 6 clips that ensure economical and comfortable use. The product is disposable, EO sterilized.
Clip appliers with proper sized jaws depending on the clip should be used.
Clip appliers are made of highest quality surgical grade steel. Handle rings are color coded matching cartridge hue.



KEY FEATURES:

- 4 sizes available: S, M, ML, L
- 4 or 6 clips per cartridge
- V-shaped
- Made of a medical grade titanium,
- Color-coded cartridges for easy identification
- Compatible with corresponding Vclip® Appliers

Liga2®

REF	CLIP SIZE	COLOUR	COMPATIBLE WITH APPLIERS (JAWS GRIP) (MM)	PRODUCT	PCS PER CARTRIDGE/ BOX
0301-01S	S	●	0,59-0,75	V-shaped titanium ligating clips	6/50
0301-01M	M	○	0,84-1,00	V-shaped titanium ligating clips	6/50
0301-01ML	ML	●	1,16-1,32	V-shaped titanium ligating clips	6/20
0301-01ML04	ML	●	1,16-1,32	V-shaped titanium ligating clips	4/20
0301-01L	L	●	1,26-1,42	V-shaped titanium ligating clips	6/20

4 CLIPS PER CARTRIDGE
Cost-effective alternative for simple procedures

LigaV® open surgery clip appliers

LigaV® open surgery appliers are available in a wide range of sizes and applier lengths. Made of the highest quality surgical stainless steel to meet the requirements of the most demanding professionals. Handle rings are color-coded matching cartridge hues.

KEY FEATURES:

- Available for S, M, ML and L non-absorbable LigaV® clips to be used on large spectrum of tissue sizes
- 3 lengths available: 15 cm, 20 cm and 28 cm
- Made of high quality surgical stainless steel
- Colour-coded rings matching cartridge hue

REF	CLIP SIZE	COLOUR	TYPE	APPLIER LENGTH (CM)	PCS PER BOX
0301-02S15*	S	●	Open Surgery	15	1
0301-02S20	S	●	Open Surgery	20	1
0301-02S28*	S	●	Open Surgery	28	1
0301-02M15*	M	○	Open Surgery	15	1
0301-02M20	M	○	Open Surgery	20	1
0301-02M28*	M	○	Open Surgery	28	1
0301-02ML20	ML	●	Open Surgery	20	1
0301-02ML28	ML	●	Open Surgery	28	1
0301-02L20	L	●	Open Surgery	20	1
0301-02L28	L	●	Open Surgery	28	1

* Manufactured on request

Other lengths and jaw's angles available on request

Omnifinger® articulating endoscopic clip appliers

OmniFinger® is an outstanding articulating endoscopic clip applier designed to deal with challenging cases. This innovative tool offers some unique features that can help surgeons to open the doors to new operating techniques.

KEY FEATURES:

- 60° of total angulation
- Articulation and 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel

REF	CLIP SIZE	COLOUR	LOCK	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-02MEOMN	M	○	YES	36	10	1
0301-02MEOMNB	M	○	YES	47	10	1
0301-02MLEOMN	ML	●	YES	36	10	1
0301-02MLEOMNB	ML	●	YES	47	10	1
0301-02LEOMN	L	●	YES	36	10	1
0301-02LEOMNB	L	●	YES	47	10	1

LigaV® endoscopic clip appliers

LigaV® endoscopic clip appliers are available in a wide range of sizes. Made of the highest quality surgical stainless steel Grena appliers guarantees ergonomic and effective approach in endoscopic procedures.
Handle rings are color-coded matching cartridge hues. Precise performance makes Grena appliers the leading choice for surgeons performing endoscopic procedures.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality stainless steel
- Non-detachable design for easier maintenance and durability

REF	CLIP SIZE	COLOUR	TYPE	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-02ME	M	○	Endoscopic	33	10	1
0301-02MLE	ML	●	Endoscopic	33	10	1
0301-02LE	L	●	Endoscopic	33	10	1

LigaV® endoscopic clip appliers 45 cm

In order to carry out bariatric procedures safely, Grena offeres extra length endoscopic clip applliers for bariatric surgery.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality stainless steel
- Non-detachable design for easier maintenance and durability
- Colour-coded rings matching cartridge hue
- Available length: 45 cm

REF	CLIP SIZE	COLOUR	TYPE	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-02MEB	M	○	Endoscopic	45	10	1
0301-02MLEB	ML	●	Endoscopic	45	10	1
0301-02LEB	L	●	Endoscopic	45	10	1

LigaV® endoscopic clip appliers 25°

LigaV® endoscopic applier, angled at 25 degrees, designed to provide precision and ease during surgical procedures. Our applier is made with high-quality materials to ensure durability and reliability in the operating room.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability
- Colour-coded rings matching cartridge hue
- Jaws angle 25°

REF	CLIP SIZE	COLOUR	TYPE	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-02MLEA25	ML		Endoscopic	33	10	1

Grena Ltd.
1000 Great West Road, Brentford,
London TW8 9HH, United Kingdom

EC REP **MDML INTL LTD.**
10 McCurtain Hill, Clonakilty, Co. Cork,
P85 K230, Republic of Ireland

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 06/11.04.2023

GRENA Think Medical

Titanium Ligation System

Vclip® Ligating Clips & Clip Appliers

Reliable Ligation

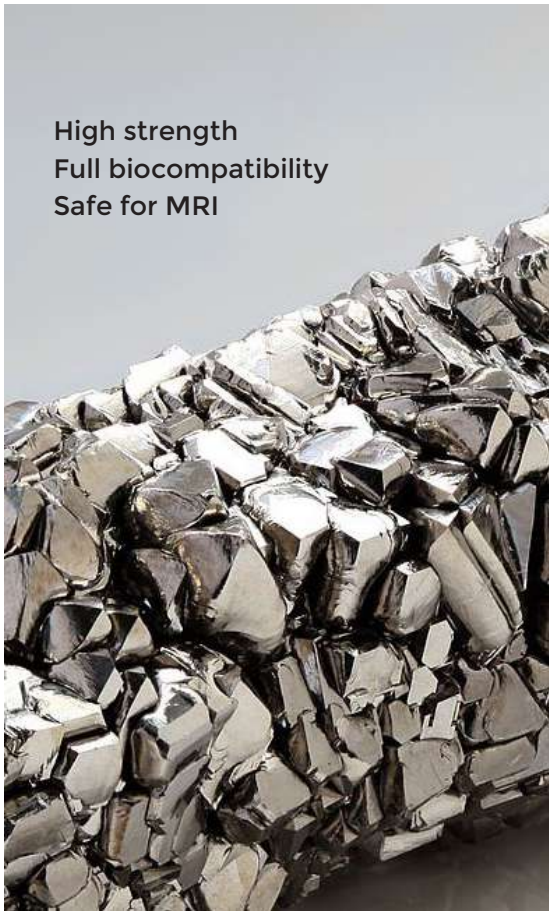
PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

Vclip® ligating clips

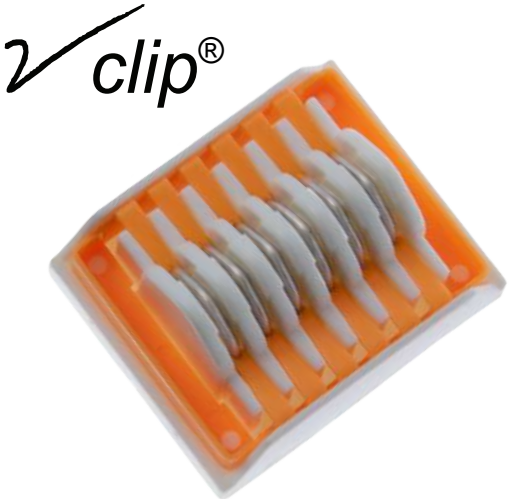
Vclip® Ligating Clips are implantable medical devices. They are widely used in surgery for marking and ligating purposes. Medical practitioners value the product for its hemostatic features. The product offered by Grena is supplied with inner surreys that shall enhance its functions by assuring proper grip on the tissue and enabling its proper nourishment. Microstructural outer surface of clip legs and their divergence improves affixing of the clip in the applier. Vclip® Ligating Clips are manufactured of a medical grade titanium which ensures proper level of biocompatibility. The applied technology guarantees the product meets the requirements of even the most demanding clinical institutes.

Vclip® Ligating Clips are delivered in colour-coded cartridges to ensure easy identification. A cartridge includes 4, 6 or 10 clips that ensure economical and comfortable use. Product details necessary for its identification are also located on tracking labels. They can be placed in patient's history form The product is disposable, EO sterilized.

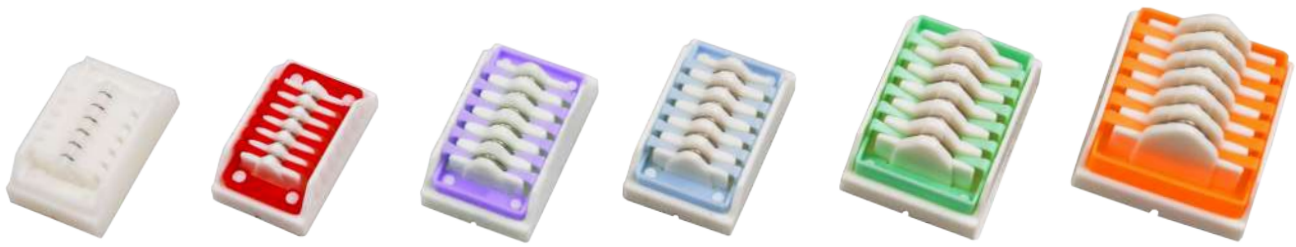


KEY FEATURES:

- 6 sizes available: XS, S, SM, M, ML, L
- 4, 6 or 10 clips per cartridge
- Chevron-shaped
- Made of a medical grade titanium,
- Color-coded cartridges for easy identification
- Compatible with corresponding Vclip® Appliers
- Adhesive backing of the cartridge



REF	CLIP SIZE	COLOUR	COMPATIBLE WITH APPLIERS	PRODUCT	PCS PER CARTRIDGE/ BOX
0301-06XS	XS	○	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	6/30
0301-06S	S	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	6/30
0301-06S10	S	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	10/20
0301-06SM	SM	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	6/30
0301-06M	M	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	6/30
0301-06M10	M	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	10/20
0301-06ML	ML	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	6/20
0301-06ML04	ML	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	4/20
0301-06ML10	ML	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	10/15
0301-06L	L	●	50° - 60° V-shaped jaws cross-section	chevron-shaped titanium	6/20



10 CLIPS PER CARTRIDGE
Cost-effective alternative if you need more clips

4 CLIPS PER CARTRIDGE
Cost-effective alternative for simple procedures

Vclip® open surgery clip appliers

Vclip® open surgery appliers are available in a wide range of sizes and applier lengths. Made of the highest quality surgical stainless steel to meet the requirements of the most demanding professionals. Handle rings are color-coded matching cartridge hues.

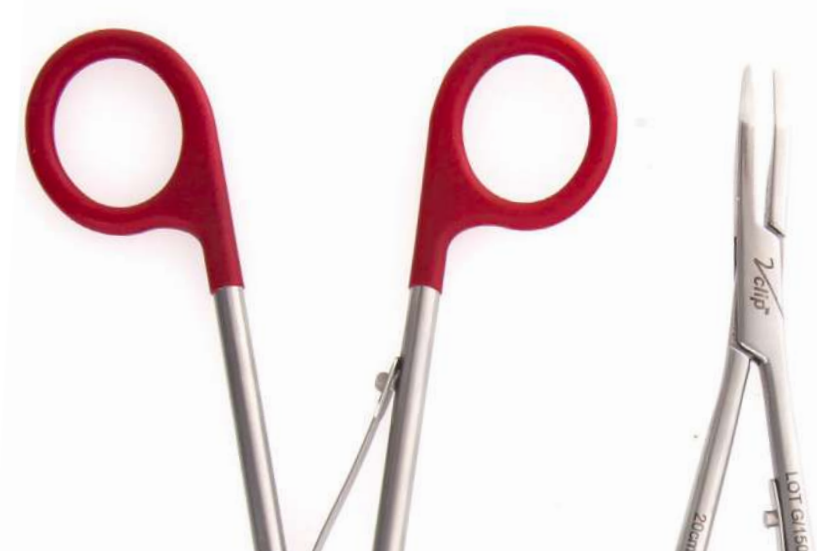
KEY FEATURES:

- Available for XS, S, SM, M, ML and L non-absorbable Vclip® clips to be used on large spectrum of tissue sizes
- 3 lengths available: 15 mm, 20 mm and 28 mm
- Made of high quality stainless steel
- Colour-coded rings matching cartridge hue

REF	CLIP SIZE	COLOUR	TYPE	APPLIER LENGTH (CM)	PCS PER BOX
0301-07XS15*	XS	○	Open Surgery	15	1
0301-07XS20	XS	○	Open Surgery	20	1
0301-07XS28*	XS	○	Open Surgery	28	1
0301-07S15*	S	●	Open Surgery	15	1
0301-07S20	S	●	Open Surgery	20	1
0301-07S28*	S	●	Open Surgery	28	1
0301-07SM15*	SM	●	Open Surgery	15	1
0301-07SM20	SM	●	Open Surgery	20	1
0301-07SM28*	SM	●	Open Surgery	28	1
0301-07M15*	M	●	Open Surgery	15	1
0301-07M20	M	●	Open Surgery	20	1
0301-07M28*	M	●	Open Surgery	28	1
0301-07ML20	ML	●	Open Surgery	20	1
0301-07ML28	ML	●	Open Surgery	28	1
0301-07L20	L	●	Open Surgery	20	1
0301-07L28	L	●	Open Surgery	28	1

* Manufactured on request

Other lengths and jaw's angles available on request



Vclip® endoscopic clip appliers

Vclip® endoscopic clip appliers are available in a wide range of sizes. Made of the highest quality surgical stainless steel Grena appliers guarantees ergonomic and effective approach in endoscopic procedures. Handle rings are color-coded matching cartridge hues. Precise performance makes Grena appliers the leading choice for surgeons performing endoscopic procedures.

KEY FEATURES:

- Jaws activated by front handle for better stability,
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability

REF	CLIP SIZE	COLOUR	TYPE	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-07ME	M		Endoscopic	33	10	1
0301-07MLE	ML		Endoscopic	33	10	1
0301-07LE	L		Endoscopic	33	12	1

Omnifinger™ articulating endoscopic clip appliers

OmniFinger™ is an outstanding articulating endoscopic clip applier designed to deal with challenging cases. This innovative tool offers some unique features that can help surgeons to open the doors to new operating techniques.

KEY FEATURES:

- 60° of total angulation
- Articulation and 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel

REF	CLIP SIZE	COLOUR	LOCK	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-07MEOMN	M	●	YES	36	10	1
0301-07MEOMNB	M	●	YES	47	10	1
0301-07MLEOMN	ML	●	YES	36	10	1
0301-07MLEOMNB	ML	●	YES	47	10	1

Vclip® endoscopic clip appliers 25°

Vclip® endoscopic applier, angled at 25 degrees, designed to provide precision and ease during surgical procedures. Our applier is made with high-quality materials to ensure durability and reliability in the operating room.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability
- Colour-coded rings matching cartridge hue

REF	CLIP SIZE	COLOUR	TYPE	WORKING LENGTH (CM)	TROCAR DIAMETER (MM)	PCS PER BOX
0301-07MLEA25	ML	●	Endoscopic	33	10	1

Grena Ltd.
1000 Great West Road, Brentford,
London TW8 9HH, United Kingdom

EC REP **MDML INTL LTD.**
10 McCurtain Hill, Clonakilty, Co. Cork,
P85 K230, Republic of Ireland

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 07/11.04.2023

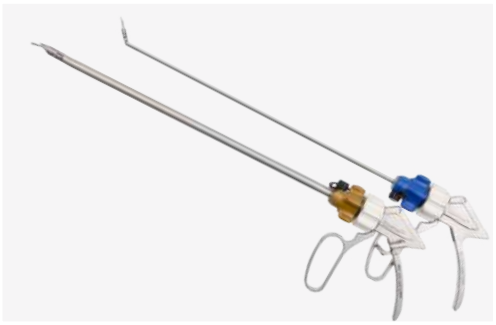
Surgery

GRENA Think Medical

Polymer Ligation System

Click'aV® Ligating Clips & Clip Appliers

Safe and minimally invasive solution even for the most challenging cases



Inspired by Diego Gonzalez Rivas

PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

Click'aV Plus™ Ligating Clips

The second generation Click'aV Plus™ is a unique ligating clip equipped with **patented teeth** that significantly increase the patient safety thanks to:

- **Bi-directional tissue stabilization**
- **Increased transverse stability – eliminates tendency to slide off the vessel due to blood pressure or manipulation in the operation field**
- **Atraumatic stabilization of vessels**

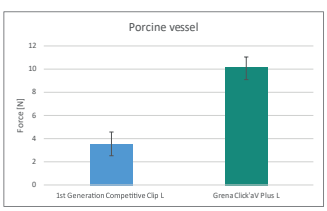
In a number of procedures, Click'aV Plus™ ligating clips successfully replace endostaplers or the harmonic scalpel, combining highest security level with cost savings. Equally important is the low interference with CT scanning, radiolucency in X-rays and the great safety in MRIs resulting in the lack of artifacts. Every clips is fitted with the hinge and the latch tested in thousands of procedures.

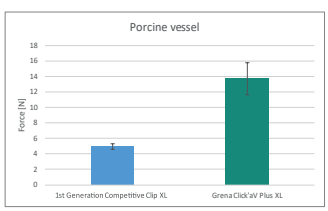
Click'aV Plus™ clips were specifically designed for:

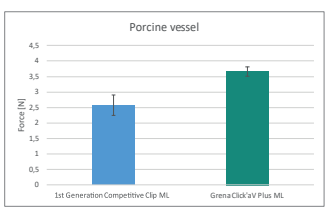
- large vessels with increased pressure
- locations with difficult access or reduced visibility
- locations where manipulation in the operation field results in higher risk of mechanical clips displacement

More than double the slip resistance compared to the 1st generation competitive polymer clip.

Transverse stability is a major factor protecting against clip slipping off. Our main objective during the design work on Click'aV Plus™ was to protect the patient from the possibility of clip displacement off the vessel. Result of Grena's Team efforts is the second generation polymer clip - the first clip in the world with ABS built-in.







GRENA Think Medical

Click'aV Plus™

Patent No. 10,265,079

KEY FEATURES:

- 2, 3, 4 or 6 clips per cartridge
- 4 sizes available: ML, L, XL, XXL
- Atraumatic 2-ways stabilization
- Color-coded cartridges for easy identification
- Compatible with corresponding Click'aV® appliers
- Adhesive backing of the cartridge

REF	CLIP SIZE	TISSUE BUNDLE SIZE RANGE (MM)	COLOUR	PCS (per cartridge/ cartridges per box)
0301-10ML	ML	3-10		6/20
0301-10ML04	ML	3-10		4/20
0301-10ML02	ML	3-10		2/20
0301-10L	L	5-13		6/20
0301-10L04	L	5-13		4/20
0301-10L02	L	5-13		2/20
0301-10XL	XL	7-16		6/20
0301-10XL04	XL	7-16		4/20
0301-10XL02	XL	7-16		2/20
0301-10XXL04	XXL	10-22		4/8
0301-10XXL03	XXL	10-22		3/8
0301-10XXL02	XXL	10-22		2/8

NEW

XXL Click'aV Plus™ Ligating Clips

With Click'aV Plus™ XXL size surgeon can extend the range of economical benefits in procedures performed on extremely thick tissues by replacing expensive endostaplers or harmonic scalpel with the same safe, but cost effective technique.

Unique size

New possibilities

Click'aV® Ligating Clips

Click'aV® ligating clips are implantable medical devices made of an advanced polymer to ensure a high level of biocompatibility along with the structural and dimensional stability over time, necessary for long-lasting patient safety. They are designed to combine the speed of the metal clip with outstanding security comparable to 2.0 suture. This combination leads to extreme time savings.

Click'aV®

KEY FEATURES:

- 2, 4, or 6 clips per cartridge
- 4 sizes available: M, ML, L, XL
- Color-coded cartridges for easy identification
- Compatible with corresponding Click'aV® Appliers
- Adhesive backing of the cartridge

REF	CLIP SIZE	TISSUE BUNDLE SIZE RANGE (MM)	COLOUR	PCS (per cartridge/ cartridges per box)
0301-03M	M	2-7		6/20
0301-03M04	M	2-7		4/20
0301-03ML	ML	3-10		6/20
0301-03ML04	ML	3-10		4/20
0301-03ML02	ML	3-10		2/20
0301-03L	L	5-13		6/20
0301-03L04	L	5-13		4/20
0301-03L02	L	5-13		2/20
0301-03XL	XL	7-16		6/20
0301-03XL04	XL	7-16		4/20
0301-03XL02	XL	7-16		2/20

Click'aV® Open Surgery Clip Appliers

Click'aV® open surgery appliers are available in a wide range of sizes and applier lengths. Made of the highest quality surgical stainless steel to meet the requirements of the most demanding professionals. Handle rings are color-coded matching cartridge hues.

KEY FEATURES:

- Available for M, ML, L and XL ClickaV® & Click'aV Plus™ clips
- 2 lengths available: 20 cm and 27 cm
- Made of high quality surgical stainless steel

REF	CLIP SIZE	TIP STYLE	APPLIER LENGTH (CM)	COLOUR	PCS PER BOX
0301-04M20	M	Curved	20		1
0301-04M27	M	Curved	27		1
0301-04M27A70	M	Right Angled 70°	27		1
0301-04ML20	ML	Curved	20		1
0301-04ML27	ML	Curved	27		1
0301-04ML27A70	ML	Right Angled 70°	27		1
0301-04L20	L	Curved	20		1
0301-04L27	L	Curved	27		1
0301-04L27A70	L	Right Angled 70°	27		1
0301-04XL20	XL	Curved	20		1
0301-04XL27	XL	Curved	27		1
0301-04XL27A70	XL	Right Angled 70°	27		1

Click'aV® Endoscopic Clip Appliers

Click'aV® endoscopic clip appliers are available in a wide range of sizes. Made of the highest quality surgical stainless steel Grena appliers guarantees ergonomic and effective approach in endoscopic procedures. Handle rings are color-coded matching cartridge hues. Precise performance makes Grena appliers the leading choice for surgeons performing endoscopic procedures.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability

REF	CLIP SIZE	TYPE	WORKING LENGTH (CM)	SHAFT/TROCAR DIAMETER (MM)	COLOUR	PCS PER BOX
0301-04ME	M	Endoscopic	33	5/5		1
0301-04MLE	ML	Endoscopic	33	5/5		1
0301-04LE	L	Endoscopic	33	10/10		1
0301-04XLE	XL	Endoscopic	33	10/10		1

Click'aV® Endoscopic Clip Appliers 45 cm

In order to carry out bariatric procedures safely, Grena offeres extra length endoscopic clip applliers for bariatric surgery.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability

REF	CLIP SIZE	TYPE	WORKING LENGTH (CM)	SHAFT/TRO-CAR DIAME-TER (MM)	COLOUR	PCS PER BOX
0301-04MEB	M	Endoscopic	45	5/5		1
0301-04MLEB	ML	Endoscopic	45	5/5		1
0301-04LEB	L	Endoscopic	45	10/10		1
0301-04XLEB	XL	Endoscopic	45	10/10		1

GRENA Think Medical

Click'aV® Endoscopic Clip Appliers 20°

20° endoscopic clip appliers were specifically designed for better access in difficult anatomical conditions.

KEY FEATURES:

- Jaws activated by front handle for better stability
- 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- Non-detachable design for easier maintenance and durability

REF	CLIP SIZE	TYPE	WORKING LENGTH (CM)	SHAFT/TROCAR DIAMETER (MM)	COLOUR	PCS PER BOX
0301-04MEA20	M	Endoscopic	33	5/10		1
0301-04MLEA20	ML	Endoscopic	33	5/10		1
0301-04LEA20	L	Endoscopic	33	10/12		1
0301-04XLEA20	XL	Endoscopic	33	10/12		1

Click'aV® Detachable Endoscopic Clip Appliers

This products line is offered for users with the highest hygienic regimes. The device can be disassembled to allow medical personnel to clean and disinfect it according to the applicable local requirements without any compromise. The other advantage of this development is very high flexibility and compatibility across the components.

REF	CLIP SIZE	PRODUCT	WORKING LENGTH (CM)	SHAFT/TROCAR DIAMETER (MM)	COLOUR	PCS PER BOX
0301-04MMLEHS	M/ML	Handle with shaft	33	5/5		1
0301-04LXLEHS	L/XL	Handle with shaft	33	10/10		1

REF	CLIP SIZE	PRODUCT	FITS	PCS PER BOX
0301-04MEI	M	Insert	0301-04MMLEHS	10
0301-04MLEI	ML	Insert	0301-04MMLEHS	10
0301-04LEI	L	Insert	0301-04LXLEHS	10
0301-04XLEI	XL	Insert	0301-04LXLEHS	10

Click'aV® Universal Endoscopic Clip Appliers

Listening to the suggestions of surgeons we designed a universal clip applier (Patent Pending) that can be used to load either L or XL polymer clips. With an easy switch of a lever the operator decides what clip size is to be used with the device. The concept helps to reduce the number of appliers held by the hospital as well as reduce the environmental footprint related to cleaning, disinfection and sterilization of appliers.

REF	CLIP SIZE	TYPE	WORKING LENGTH (CM)	SHAFT/TROCAR DIAMETER (MM)	COLOUR	PCS PER BOX
0301-04LXLUNE	L/ XL	Endoscopic	33	10/10		1

Gonzalez Rivas Endoscopic Clip Appliers 45°

The 45° endoscopic clip applier is the unique device designed in collaboration with Dr. Diego Gonzales Rivas to allow better access in VATS surgery. It facilitates clip application in the most challenging VATS cases, especially in single access port procedures.

Dr. Diego Gonzalez Rivas

Degree in Medicine and Surgery by the Universidad de Santiago de Compostela (1992-1998). Resident at the Thoracic Surgery Unit at Juan Canalejo hospital in La Coruna from 1999 to 2004. Medical doctor in Thoracic Surgery since July 2004, with medical practice at the Thoracic Surgery Unit at Complexo Hospitalario Universitario in Santiago de Compostela until April 2005 and from then in the Thoracic Surgery Unit at Complexo Hospitalario Universitario de A Coruna.

45° Endosconpic Appliers fit Grena's disposable wound protectors/ retractors RingProtect™ Gonzalez Rivas modified.
REF 0221-070070035NA

REF	CLIP SIZE	TYPE	WORKING LENGTH (CM)	SHAFT/ TROCAR DIAMETER (MM)	RETRACTOR (recommended)	COLOUR	PCS PER BOX
0301-04MEA45	M	Endoscopic	33	5/10	RingProtect™ Gonzalez Rivas modified		1
0301-04MLEA45	ML	Endoscopic	33	5/10	RingProtect™ Gonzalez Rivas modified		1
0301-04LEA45	L	Endoscopic	33	10/NA	RingProtect™ Gonzalez Rivas modified		1
0301-04XLEA45	XL	Endoscopic	33	10/NA	RingProtect™ Gonzalez Rivas modified		1

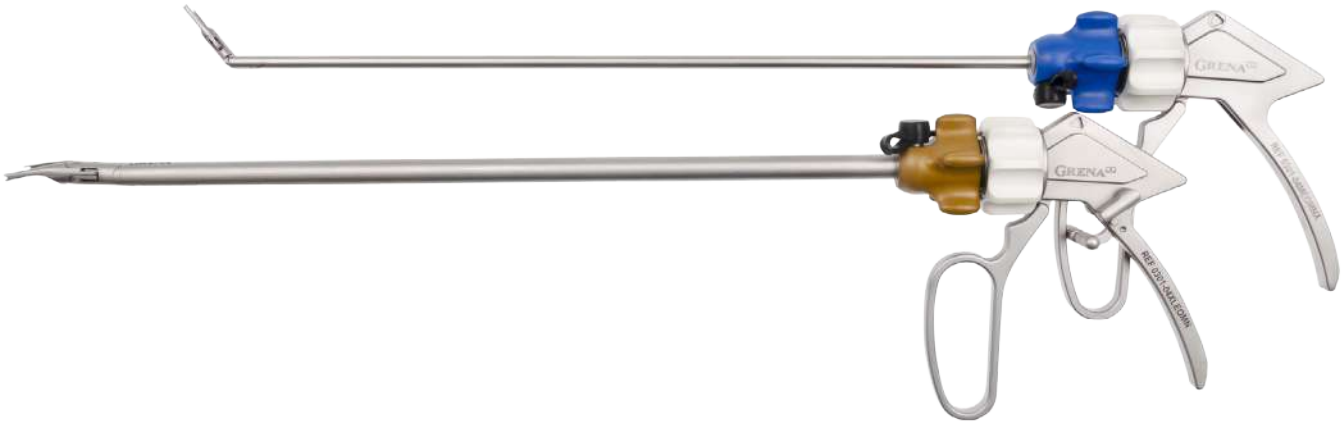
Omnifinger™ Articulating Endoscopic Clip Appliers

OmniFinger™ is a unique articulating endoscopic clip applier designed in collaboration with Dr. Diego Gonzales Rivas. It was specifically developed to deal with challenging cases.

KEY FEATURES:

- 60° of total angulation
- 2 shaft diameter available: 5 mm and 10 mm
- 2 lengths available: 36 cm and 47 cm
- Articulation and 360° shaft rotation by index finger allows one-hand operation
- Flushing port facilitates easy cleaning, thus eliminating potential contamination
- Made of high quality surgical stainless steel
- By default without lock, version with lock available for special order

Patent pending



REF	SIZE	LOCK	COLOUR	SHAFT DIAMETER (MM)	TROCAR DIAMETER (MM)	WORKING LENGTH (CM)	BOX QUANTITY (PCS)
0301-04MEOMN	M	YES		5	5	36	1
0301-04MEOMNX	M	NO		5	5	36	1
0301-04MLEOMN	ML	YES		5	5	36	1
0301-04MLEOMNX	ML	NO		5	5	36	1
0301-04LEOMN	L	YES		10	10	36	1
0301-04LEOMNX	L	NO		10	10	36	1
0301-04XLEOMN	XL	YES		10	10	36	1
0301-04XLEOMNX	XL	NO		10	10	36	1
0301-04MEOMNB	M	YES		5	5	47	1
0301-04MEOMNBX	M	NO		5	5	47	1
0301-04MLEOMNB	ML	YES		5	5	47	1
0301-04MLEOMNBX	ML	NO		5	5	47	1
0301-04LEOMNB	L	YES		10	10	47	1
0301-04LEOMNBX	L	NO		10	10	47	1
0301-04XLEOMNB	XL	YES		10	10	47	1
0301-04XLEOMNBX	XL	NO		10	10	47	1

Clip Removers

REF	CLIP SIZE	PRODUCT	TIPS	PCS PER BOX
0301-R804MMLL	M, ML, L	Open Surgery Clip Remover	-	1
0301-R804XL	XL	Open Surgery Clip Remover	-	1
0301-R804MLLE	M, ML, L	Endoscopic Clip Remover	-	1
0301-R804LXLE	L, XL	Endoscopic Clip Remover	Recommended for L	1
0301-R804MLLEB	M, ML, L	Endoscopic Clip Remover Bariatric	-	1
0301-R804LXLEB	L, XL	Endoscopic Clip Remover Bariatric	Recommended for L	1

INDEX

Extensive list of the available clip appliers and clip removers

REF	PRODUCT
0301-04L20	Click'aV® Ligating Clip Applier L, 20cm, open surg
0301-04L27	Click'aV® Ligating Clip Applier L, 27cm, open surg
0301-04L27A70	Click'aV® Ligating Clip Applier L, 27cm, 70°, open surg
0301-04LE	Click'aV® Ligating Clip Applier L, endo
0301-04LEA20	Click'aV® Ligating Clip Applier L, endo, angled 20°
0301-04LEA20B	Click'aV® Ligating Clip Applier L, endo, angled 20°, bariatric
0301-04LEA20I	Click'aV® Ligating Clip Applier Insert, L, endo, angled 20°
0301-04LEA20IB	Click'aV® Ligating Clip Applier Insert, L, endo, angled 20°, bariatric
0301-04LEA45	Click'aV® Ligating Clip Applier L, endo, Gonzalez Rivas
0301-04LEA45I	Click'aV® Ligating Clip Applier Insert, L, endo, Gonzalez Rivas
0301-04LEA45IB	Click'aV® Ligating Clip Applier Insert, L, endo, Gonzalez Rivas, bariatric
0301-04LEB	Click'aV® Ligating Clip Applier L, endo, 45 cm, bariatric
0301-04LEI	Click'aV® Ligating Clip Applier Insert, L, endo
0301-04LEIB	Click'aV® Ligating Clip Applier Insert, L, endo, bariatric
0301-04LEOMN	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, L, endo
0301-04LEOMNB	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, L, endo, bariatic
0301-04LEOMNBX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, L, endo, bariatic, without lock
0301-04LEOMNX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, L, endo, without lock
0301-04LXLEHS	Click'aV® Ligating Clip Applier Handle with Shaft, L, XL, endo
0301-04LXLEHSB	Click'aV® Ligating Clip Applier Handle with Shaft, L, XL, endo, 45 cm (bariatric)
0301-04M20	Click'aV® Ligating Clip Applier M, 20cm, open surg
0301-04M27	Click'aV® Ligating Clip Applier M, 27cm, open surg,
0301-04M27A70	Click'aV® Ligating Clip Applier M, 27cm, 70°, open surg,
0301-04ME	Click'aV® Ligating Clip Applier M, endo
0301-04MEA20	Click'aV® Ligating Clip Applier M, endo, angled 20°
0301-04MEA20B	Click'aV® Ligating Clip Applier M, endo, angled 20°, bariatric
0301-04MEA20I	Click'aV® Ligating Clip Applier Insert, M, endo, angled 20°
0301-04MEA20IB	Click'aV® Ligating Clip Applier Insert, M, endo, angled 20°, bariatric
0301-04MEA45	Click'aV® Ligating Clip Applier M, endo, Gonzalez Rivas
0301-04MEA45I	Click'aV® Ligating Clip Applier Insert, M, endo, Gonzalez Rivas
0301-04MEA45IB	Click'aV® Ligating Clip Applier Insert, M, endo, Gonzalez Rivas, bariatric

REF	PRODUCT
0301-04MEB	Click'aV® Ligating Clip Applier M, endo, bariatric
0301-04MEHS	Click'aV® Ligating Clip Applier Handle with Shaft, M endo
0301-04MEI	Click'aV® Ligating Clip Applier Insert, M, endo
0301-04MEIB	Click'aV® Ligating Clip Applier Insert, M, endo, bariatric
0301-04MEOMN	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, M, endo
0301-04MEOMNB	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, M, endo, bariatic
0301-04MEOMNBX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, M, endo, bariatic, without lock
0301-04MEOMNX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, M, endo, without lock
0301-04ML20	Click'aV® Ligating Clip Applier ML, 20cm, open surg
0301-04ML27	Click'aV® Ligating Clip Applier ML, 27cm, open surg
0301-04ML27A70	Click'aV® Ligating Clip Applier ML, 27cm, 70°, open surg
0301-04MLE	Click'aV® Ligating Clip Applier ML, endo
0301-04MLEA20	Click'aV® Ligating Clip Applier ML, endo, angled 20°
0301-04MLEA20B	Click'aV® Ligating Clip Applier ML, endo, angled 20°, bariatric
0301-04MLEA20I	Click'aV® Ligating Clip Applier Insert, ML, endo, angled 20°
0301-04MLEA20IB	Click'aV® Ligating Clip Applier Insert, ML, endo, angled 20°, bariatric
0301-04MLEA45	Click'aV® Ligating Clip Applier ML, endo, Gonzalez Rivas
0301-04MLEA45I	Click'aV® Ligating Clip Applier Insert, ML, endo, Gonzalez Rivas
0301-04MLEA45IB	Click'aV® Ligating Clip Applier Insert, ML, endo, Gonzalez Rivas, bariatric
0301-04MLEB	Click'aV® Ligating Clip Applier ML, endo, 45 cm, bariatric
0301-04MLEHS	Click'aV® Ligating Clip Applier Handle with Shaft, ML endo
0301-04MLEI	Click'aV® Ligating Clip Applier Insert, ML, endo
0301-04MLEIB	Click'aV® Ligating Clip Applier Insert, ML, endo, bariatric
0301-04MLEOMN	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, ML, endo
0301-04MLEOMNB	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, ML, endo, bariatic
0301-04MLEOMNBX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, ML, endo, bariatic, without lock
0301-04MLEOMNX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, ML, endo, without lock
0301-04MMLEHS	Click'aV® Ligating Clip Applier Handle with Shaft, M, ML, endo
0301-04MMLEHSB	Click'aV® Ligating Clip Applier Handle with Shaft, M, ML, endo, 45 cm (bariatric)
0301-04XL20	Click'aV® Ligating Clip Applier XL, 20cm, open surg
0301-04XL27	Click'aV® Ligating Clip Applier XL, 27cm, open surg

REF	PRODUCT
0301-04XL27A70	Click'aV® Ligating Clip Applier XL, 27cm, 70°, open surg
0301-04XLE	Click'aV® Ligating Clip Applier XL, endo
0301-04XLEA20	Click'aV® Ligating Clip Applier XL, endo, angled 20°
0301-04XLEA20B	Click'aV® Ligating Clip Applier XL, endo, angled 20°, bariatric
0301-04XLEA20I	Click'aV® Ligating Clip Applier Insert, XL, endo, angled 20°
0301-04XLEA20IB	Click'aV® Ligating Clip Applier Insert, XL, endo, angled 20°, bariatric
0301-04XLEA45	Click'aV® Ligating Clip Applier XL, endo, Gonzalez Rivas
0301-04XLEA45I	Click'aV® Ligating Clip Applier Insert, XL, endo, Gonzalez Rivas
0301-04XLEA45IB	Click'aV® Ligating Clip Applier Insert, XL, endo, Gonzalez Rivas, bariatric
0301-04XLEB	Click'aV Ligating Clip Applier XL, endo, 45 cm, bariatric
0301-04XLEHS	Click'aV Ligating Clip Applier Handle with Shaft, XL endo
0301-04XLEI	Click'aV® Ligating Clip Applier Insert, XL, endo
0301-04XLEIB	Click'aV® Ligating Clip Applier Insert, XL, endo, bariatric
0301-04XLEOMN	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, XL, endo
0301-04XLEOMNB	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, XL, endo, bariatic
0301-04XLEOMNBX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, XL, endo, bariatic, without lock
0301-04XLEOMNX	OMNIFinger™ Articulating Click'aV® Ligating Clip Applier, XL, endo , without lock
0301-04LXLUNE	Universal Click'aV® Ligating Clip Applier, L/XL, endo
0301-04MLEN	Click'aV® Ligating Clip Applier ML, endo
0301-04MEN	Click'aV® Ligating Clip Applier M, endo
0301-04MEA20N	Click'aV® Ligating Clip Applier M, endo, angled 20°
0301-04MEA45N	Click'aV® Ligating Clip Applier M, endo, angled 45°
0301-04MEA20BN	Click'aV® Ligating Clip Applier M, endo, angled 20°, bariatric
0301-04MEA45BN	Click'aV® Ligating Clip Applier M, endo, angled 45°, bariatric
0301-04MEBN	Click'aV® Ligating Clip Applier M, endo, bariatric
0301-04MLEA20N	Click'aV® Ligating Clip Applier ML, endo, angled 20°
0301-04MLEA45N	Click'aV® Ligating Clip Applier ML, endo, angled 45°
0301-04MLEBN	Click'aV® Ligating Clip Applier ML, endo, bariatric
0301-04MLEA20BN	Click'aV® Ligating Clip Applier ML, endo, angled 20°, bariatric
0301-04MLEA45BN	Click'aV® Ligating Clip Applier ML, endo, angled 45°, bariatric

REF	PRODUCT
0301-04LEN	Click'aV® Ligating Clip Applier L, endo
0301-04LEBN	Click'aV® Ligating Clip Applier L, endo, bariatric
0301-04XLEN	Click'aV® Ligating Clip Applier XL, endo
0301-04XLEBN	Click'aV® Ligating Clip Applier XL, endo, bariatric
0301-04XXLEN	Click'aV® Ligating Clip Applier XXL, endo
0301-04XXLEBN	Click'aV® Ligating Clip Applier XXL, endo, bariatric
0301-04XXL20	Click'aV® Ligating Clip Applier XXL, 20 cm, open surgery
0301-R804LXLE	Click'aV® Ligating Clip Remover, L, XL, endo
0301-R804LXLEB	Click'aV® Ligating Clip Remover, L, XL, endo, bariatric
0301-R804LXLEHS	Click'aV® Ligating Clip Remover Handle with Shaft, L, XL, endo
0301-R804LXLEHSB	Click'aV® Ligating Clip Remover Handle with Shaft, L, XL, endo, 45 cm (bariatric)
0301-R804LXLEI	Click'aV® Ligating Clip Remover Insert, endo, L, XL,
0301-R804LXLEIB	Click'aV® Ligating Clip Remover Insert, endo, L, XL, bariatric
0301-R804MLLE	Click'aV® Ligating Clip Remover, M, ML, L, endo
0301-R804MLLEB	Click'aV® Ligating Clip Remover, M, ML, L, endo, bariatric
0301-R804MLLEHS	Click'aV® Ligating Clip Remover Handle with Shaft, M, ML,L endo
0301-R804MLLEHSB	Click'aV® Ligating Clip Remover Handle with Shaft, M, ML,L endo, 45 cm (bariatric)
0301-R804MLLEI	Click'aV® Ligating Clip Remover Insert, endo, M, ML, L
0301-R804MLLEIB	Click'aV® Ligating Clip Remover Insert, endo, M, ML, L, bariatric
0301-R804MMLL	Click'aV® Ligating Clip Remover M, ML, L, open surgery
0301-R804XL	Click'aV® Ligating Clip Remover XL, open surgery

Grena Ltd.
1000 Great West Road,
Brentford, London TW8 9HH,
United Kingdom

LONDON CHAMBER of COMMERCE AND INDUSTRY

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 11/25.01.2022

SCISSORS, DISSECTORS, GRASPERS

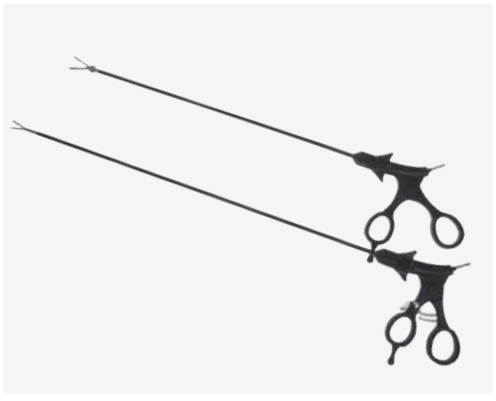
Surgery

GRENA Think Medical

Reusable Endoscopic Instruments

Scissors, Dissectors, Graspers

Precision and ergonomy in your hand



PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

Reusable Endoscopic Detachable Instruments

Grena offers an extensive selection of reusable detachable monopolar endoscopic instruments. Variety of jaw patterns of reusable inserts of scissors, graspers and dissectors makes the most complicated minimally invasive procedures possible.
These include such specialities like General, Colorectal, Urological and Gynaecological surgery. Precise performance makes Grena endoscopic instruments the leading choice for surgeons performing minimally invasive surgery.

MODULAR DESIGN

- the instrument may be customized for each user as well as easily completely disassembled for effective cleaning and decontamination by the sterile processing staff
- sterilization of fully assembled instrument provides he OR staff with ready to use instrument

COMFORT AND PERFORMANCE

- ergonomic handle for greater dexterity
- high quality components superbly crafted using the latest computer-controlled machine technology for smooth operation
- easy to reach rotation knob for easy one-handed 360° rotation
- excellent tissue and grip control
- ratcheted and non ratcheted handle to eliminate surgeon fatigue
- easy assembling and disassembling
- lock on the ratchet

COST EFFECTIVE

- compatibility and interchangability of all handles, shafts and inserts allow for long term cost savings by replacing or repair only necessary, less costly components, instead of the entire instrument

INSULATION

- shaft insulation ensures durability, longer instrument life, increased patient safety and reduced maintenance costs
- robust material maintains integrity during multiple sterilization cycles

OTHER FEATURES

- 5 mm shaft
- 4 mm standard HF connector

Handles & Shafts

REF	PRODUCT	TYPE	PCS PER BOX
0207-HR	Reusable Detachable Endoscopic Instrument – Handle		1
0207-HX	Reusable Detachable Endoscopic Instrument – Handle w/o ratchet		1

REF	PRODUCT	TYPE	PCS PER BOX
0207-S05UN	Reusable Detachable Endoscopic Instrument – Shaft for all types		1

Scissors

REF	PRODUCT	TYPE	SIZE	TIP	PCS PER BOX
0207-IS01	Endoscopic instrument Insert scissors	Metzenbaum Curved	5 mm		10
0207-IS02	Endoscopic instrument Insert scissors	Straight	5 mm		10
0207-IS03	Endoscopic instrument Insert scissors	Hook	5 mm		10

Dissectors

REF	PRODUCT	TYPE	SIZE	TIP	PCS PER BOX
0207-ID01	Endoscopic instrument Insert dissector	Maryland	5 mm		10

Graspers

REF	PRODUCT	TYPE	SIZE	TIP	PCS PER BOX
0207-IG01	Endoscopic instrument Insert grasper	Atraumatic Fenestrated	5 mm		10
0207-IG02	Endoscopic instrument Insert grasper	Allis	5 mm		10
0207-IG03	Endoscopic instrument Insert grasper	Maxi Grip	5 mm		10
0207-IG04	Endoscopic instrument Insert grasper	Toothed	5 mm		10
0207-IG05	Endoscopic instrument Insert grasper	Babcock	5 mm		10

Grena Ltd.
1000 Great West Road, Brentford,
London TW8 9HH, United Kingdom

EC REP **MDML INTL LTD.**
10 McCurtain Hill, Clonakilty, Co. Cork,
P85 K230, Republic of Ireland

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 05/05.05.2022

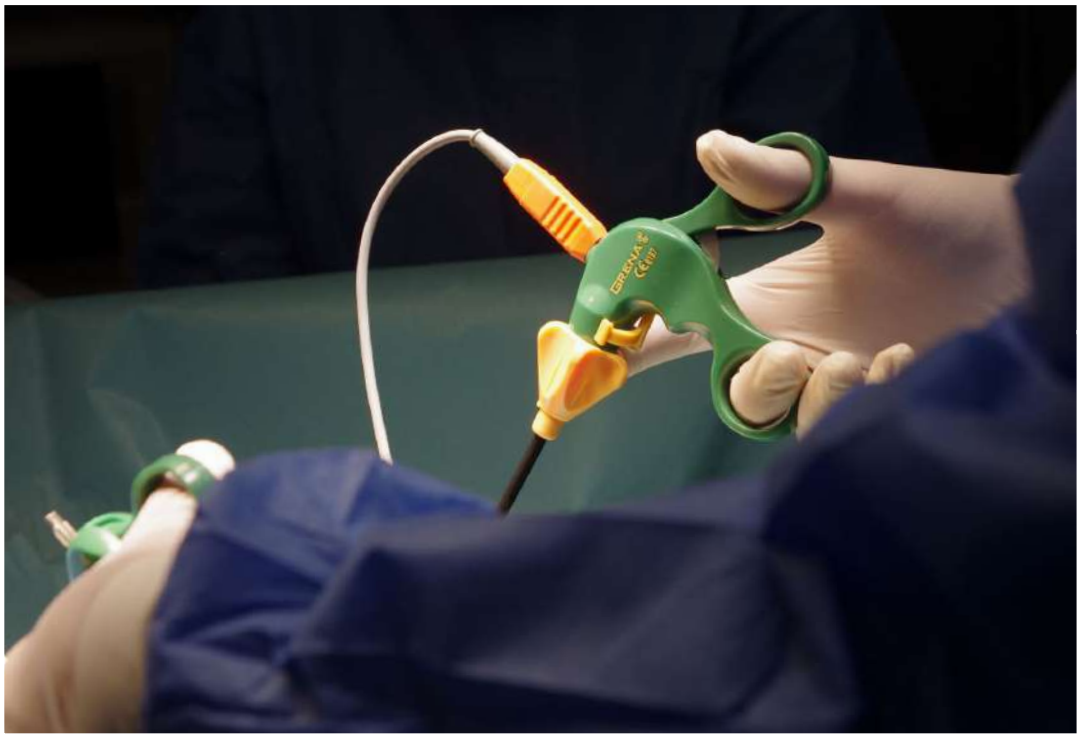
Surgery

GRENA Think Medical

Disposable Endoscopic Instruments

Scissors, Dissectors, Graspers

Precision and ergonomy in your hand



PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

Disposable Endoscopic Instruments

Our complete range of lightweight disposable mono-polar endoscopic instruments designed to fulfill all the crucial requirements of endo-surgens is now put on the market. The full range includes graspers, scissors and dissectors.
We also offer bariatric endoscopic instruments.
The devices were designed to be precise and sharp to offer comfort cutting.
The dissectors are made available both with a non-ratcheted handle and a switchable ratcheted one.
The range of graspers equipped with a switchable ratchet is there to facilitate surgery on any tissue.
The product is EO sterilized.

KEY FEATURES:

- ergonomic handle
- with ratchet/ without ratchet
- comfortable access to rotating knob
- wide jaws opening
- reliable insulation for increased safety
- consistent and precise performance
- 4mm mono-polar connector compatible with majority of HF-cables on the market

With Ratchet

Without Ratchet

Scissors

REF	PRODUCT	TIP	TYPE/ COLOUR	SIZE	PCS PER BOX
0208-DS01XX	Metzenbaum scissors - curved		Standard ●	5 mm	4
0208-DS02XX	Metzenbaum scissors - straight		Standard ●	5 mm	4
0208-DS03XX	Scissors - hook		Standard ●	5 mm	4

Dissectors

REF	PRODUCT	TIP	TYPE/ COLOUR	SIZE	PCS PER BOX
0208-DD01XX	Dissector – Maryland		Standard ●	5 mm	4
0208-DD01RX	Dissector with ratchet – Maryland		Standard ●	5 mm	4

Graspers

REF	PRODUCT	TIP	TYPE/ COLOUR	SIZE	PCS PER BOX
0208-DG01RX	Grasper with ratchet – atraumatic fenestrated		Standard	5 mm	4
0208-DG02RX	Grasper with ratchet - Allis		Standard	5 mm	4
0208-DG03RX	Grasper with ratchet – MaxiGrip		Standard	5 mm	4
0208-DG04RX	Toothed grasper with ratchet		Standard	5 mm	4
0208-DG05RX	Grasper with ratchet - Babcock		Standard	5 mm	4
0208-DG02RXB	Grasper with ratchet - Allis		Bariatric	5 mm	4
0208-DG04RXB	Toothed grasper with ratchet		Bariatric	5 mm	4
0208-DG05RXB	Grasper with ratchet - Babcock		Bariatric	5 mm	4

Grena Ltd.
1000 Great West Road, Brentford,
London TW8 9HH, United Kingdom

EC REP **MDML INTL LTD.**
10 McCurtain Hill, Clonakilty, Co. Cork,
P85 K230, Republic of Ireland

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 05/20.04.2022

Surgery

GRENA Think Medical

Reusable ‚Limited Use' Endoscopic Instruments

Scissors, Dissectors, Graspers

Precision and ergonomy in your hand

Limited use™

Up to 10 uses

PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

Reusable Limited-use endoscopic instruments

Our complete range of Limited-use™ lightweight disposable mono-polar endoscopic instruments designed to fulfill all the crucial requirements of endo-surgens. The full range includes graspers, scissors and dissectors.
The main advantage of the reusable limited-use™ instruments is the fact they are intended for up to 10 uses. The product is delivered sterile (EO) and can be re-sterilized up to 9 times. This combines the benefit of short lifetime of the product and economy of use. There is no hassle in taking care of the service of the reusable device and there is no concern of sharpness and functionality after certain number of reuses.
The scissors were designed to be precise and sharp to offer comfort cutting.
The dissectors are made available both with a non-ratcheted handle and a switchable ratcheted one.
The range of graspers equipped with a switchable ratchet is there to facilitate surgery on any tissue.
The reusable limited-use™ instruments are equipped with flushing channel that allows proper cleaning after each use.

Limited use™

Up to 10 uses

With Ratchet

Without Ratchet

Scissors

REF	PRODUCT	TIP	TYPE/ COLOUR	SIZE	PCS PER BOX
0207-LS01XF	Metzenbaum scissors - curved		Standard ●	5 mm	4
0207-LS02XF	Metzenbaum scissors - straight		Standard ●	5 mm	4
0207-LS03XF	Scissors - hook		Standard ●	5 mm	4
0207-LS03XFB	Scissors - hook		Bariatric ●	5 mm	4

Dissectors

REF	PRODUCT	TIP	TYPE/ COLOUR	SIZE	PCS PER BOX
0207-LD01XF	Dissector – Maryland		Standard ●	5 mm	4
0207-LD01RF	Dissector with ratchet – Maryland		Standard ●	5 mm	4
0207-LD01RFB	Dissector with ratchet – Maryland		Bariatric ●	5 mm	4

Graspers

REF	PRODUCT	TIP	TYPE/ COLOUR	SIZE	PCS PER BOX
0207-LG01RF	Grasper with ratchet – atraumatic fenestrated		Standard ○	5 mm	4
0207-LG02RF	Grasper with ratchet - Allis		Standard	5 mm	4
0207-LG03RF	Grasper with ratchet – MaxiGrip		Standard	5 mm	4
0207-LG04RF	Toothed grasper with ratchet		Standard	5 mm	4
0207-LG05RF	Grasper with ratchet - Babcock		Standard	5 mm	4
0207-LG04RFB	Toothed grasper with ratchet		Bariatric	5 mm	4
0207-LG05RFB	Grasper with ratchet - Babcock		Bariatric	5 mm	4

Grena Ltd.
1000 Great West Road, Brentford,
London TW8 9HH, United Kingdom

EC REP **MDML INTL LTD.**
10 McCurtain Hill, Clonakilty, Co. Cork,
P85 K230, Republic of Ireland

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 05/20.04.2022

Surgery

GRENA Think Medical

4seal®

Hemostatic Powder

Rapid hemostasis at hand

PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

4SEAL® Hemostatic Powder

4SEAL® Hemostatic Powder is ready to use, a plant-based, ultra-hydrophilic polysaccharide that effectively and quickly stops bleeding. Furthermore, 4SEAL® Hemostatic Powder also may be used for postoperative adhesion prevention.
4SEAL® Hemostatic Powder absorbs rapidly water from the blood. The dehydration process increases the concentration of red blood cells, platelets, and coagulation proteins at the bleeding site and thus accelerates the natural blood clotting process.
4SEAL® Hemostatic Powder is available in 1g, 3g, and 5g in comprehensive bellow bottles with an applicator, which are delivered to the sterile filed in a double barrier. Extended and laparoscopic applicators (from an external manufacturer) 14 and 38 cm long, respectively, matching the integrated applicator of the bellow bottle are also available in Grena offer. 4SEAL® Hemostatic Powder contains no animal nor human components and is resorbed in the body within a few days.

KEY FEATURES:

- Biocompatible, ultra-hydrophilic, pure plant-based technology
- Extremely quick and effective in bleeding control
- Easy to use and precise application
- Easy to store
- Ready to use instantly
- Long shelf life
- Hemostasis in 2-3 min

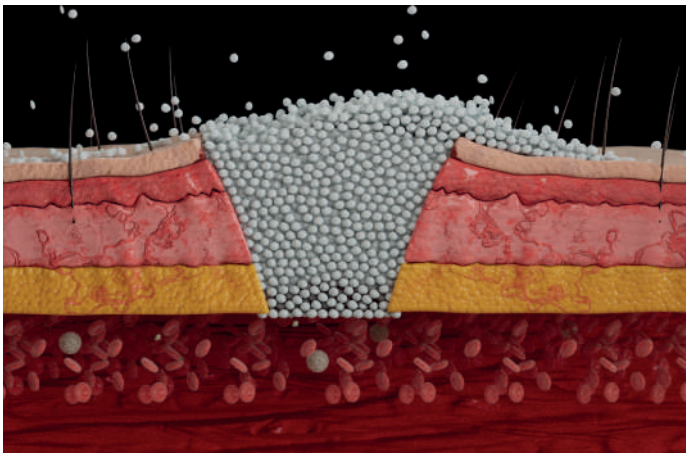
CLINICAL APPLICATIONS:

4SEAL® Hemostatic Powder is intended for use in surgical procedures or injuries as an adjunct hemostat when control of bleeding from capillary venous, or arteriolar vessel by pressure, ligature and other conventional means is either ineffective or impractical. 4SEAL® Hemostatic Powder can be successfully used in many surgical specialties:

- GENERAL SURGERY
- THORACIC SURGERY
- CARDIOVASCULAR SURGERY
- COLON AND RECTAL SURGERY
- GYNECOLOGY
- NEUROSURGERY
- ORAL AND MAXILLOFACIAL SURGERY
- ORTHOPEDIC SURGERY
- OTOLARYNGOLOGY
- PLASTIC AND MAXILLOFACIAL SURGERY
- UROLOGY

REF	PRODUCT	DIMENSIONS	PCS PER BOX
1203-HP001	4SEAL® Hemostatic powder	4SEAL® Hemostatic powder 1 g	5
1203-HP003	4SEAL® Hemostatic powder	4SEAL® Hemostatic powder 3 g	5
1203-HP005	4SEAL® Hemostatic powder	4SEAL® Hemostatic powder 5 g	5

REF	PRODUCT	LENGTH (CM)		PCS PER BOX
1206-40700003	Extended Applicator	14		15
1206-40700002	Laparoscopic Applicator	38		15



Grena Biomed Ltd.
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

MDML INTL LTD.
10 McCurtain Hill, Clonakilty, Co.
Cork,P85 K230, Republic of Ireland

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 08/01.12.2022

GRENA®
Think Medical

Retrieval Bag

For easy collection and flexible extraction of tissue specimens

PROVIDING SPECIALISTS WITH
INNOVATIVE
HEALTHCARE SOLUTIONS

WITH THE CENTRAL FOCUS ON
PATIENTS' SAFETY AND USERS' COMFORT

Retrieval Bag

The Retrieval Bag is a disposable device used as a receptacle for the collection and extraction of tissue specimens, such as the appendix, gallbladder, ovaries, fibroid tumors, other tissues and calculi during laparoscopic surgical procedures. The Retrieval Bag is comprised of a flexible plastic bag slipped on the shape memory wire, which facilitates opening after deployment in the body cavity and maintaining in a fully open position. The bag is located in a plastic deployment tube but not permanently attached to it that does not block the trocar and allows to use it after the bag deployment. The bag can stay inside the body cavity and be filled with tissue a few times during surgical procedure and removed just before surgery is completed.

REF	COLOUR	VOLUME	TROCAR DIAMETER	PCS PER BOX
0208-RBM200		200 ml	10 mm	5
0208-RBM400		400 ml	10 mm	5
0208-RBM800		800 ml	10 mm	5
0208-RBM1200		1200 ml	10 mm	5
0208-RBM1500		1500 ml	10 mm	5

Grena Ltd.
1000 Great West Road,
Brentford, London TW8 9HH,
United Kingdom

LONDON of CHAMBER COMMERCE AND INDUSTRY

CUSTOMER SERVICE CENTER
NOTTINGHAM OFFICE, UK
+ 44 115 9704 800
+ 44 115 9704 800
export@grena.co.uk
www.grena.co.uk

Rev. 05/01.02.2021


ONE TEAM ONE DREAM