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Технические характеристики на катетеры, устройства стабилизации компании **GETINGE**

Statlock IAB Stabilization Device

Designed to securely attach both the sheath seal and "Y" suture pads of the Maquet Intra-Aortic Balloon Catheters to a patient's thigh when IAB therapy is indicated



Where patient and clinical safety matter most

The Statlock Stabilization Device for IAB is designed to securely attach both the sheath seal and "Y" suture pads of the Maquet Intra-Aortic Balloon Catheters to a patient's thigh when IAB therapy is indicated.



Dual Adhesive

- The slow set center adhesive pad allows for repositioning of the device. The hydrocolloid adhesive is more resistant to moisture.
- The fast set wing adhesive pads lock the device into position with an acrylic adhesive.
- Both adhesives must be removed with alcohol.



Patient Friendly Materials

- Tricot-woven polyester anchor pad
- Proven acrylic and hydrocolloid adhesive formula
- Molded polypropylene copolymer retainer
- No components or packaging contain latex

Suture Complications incurred with using suture can include the following:

Suture wound oozing and infection

Increased occurrence of catheter-related bloodstream infections

Possibility of Healthcare Provider needle

•

stick and resulting infection

Standards of Practice Compliance

CDC (2002 Guidelines) –
"Sutureless securement devices
can be advantageous over suture
in preventing catheter-related blood
stream infections
(CRBSI's)"

OSHA (2004 Fact Sheet) – "As part of their annual review of methods to reduce needle sticks, employers must review options for securing medical catheters and consider appropriate engineering and work practice controls"

INS (2006 Guidelines) –
"Whenever feasible, using a
manufactured catheter stabilization
device is preferred"

Benefits of using Statlock IAB Stabilization Device

- Eliminates suturewound complications
 - Increases patient
- comfort
 - Provides proactive
- healthcare provider safety
 - Reduces complications that
- may lead to catheterrelated blood stream infections

Linear 7.5Fr. IAB Catheter

Features an innovative membrane and a 7.5 Fr. size.



Easier to insert

The Linear IAB features an innovative membrane and a 7.5 Fr. size. This reduced size enables clinicians to deliver counterpulsation therapy to a broader range of patients, including those with smaller peripheral vasculature.

Bringing clarity to mechanical circulatory support

Recent debate regarding the IABP has centered on the discrepant results obtained from randomized, controlled trials (RCTs), versus the benefits observed by clinicians in decades of clinical practice.

Improved Sheath

- Improved Sheath to Introducer Transition
- Hemostasis Valve
- Twist Lock Introducer Hub
- · Universal Color Coding for Size

Potential For Reduced Complications*

All balloon and catheter materials meet FDA and ISO biocompatibility guidelines for devices and materials. LINEAR 7.5 Fr. IAB catheters and insertion kits do not contain latex.

Ideal for small adults, diabetics, and patients with PVD*

- Reduced catheter crosssection area by 12% vs. 8 Fr.
- Smaller catheter size has potential to increase distal limb flow
- Minimized size of arterial puncture

Proprietary
IAB
membrane
provides
better
performance*

- Abrasion resistance improved by 43%
- Immediate inflation at start-up
- Improved fatigue resistance

Faster inflation cycle times

- Faster
 gas
 shuttle
 performance
 allows
 support
 of rapid
 heart
 rates
 and
 arrhythmias
- 19%
 faster
 cycle
 time in
 80°
 bend
 test
 method
 when
 compared
 to
 competitor

T-Handle protector for balloon membrane

- Keeps the membrane tightly wrapped prior to insertion
- Helps to handle catheter prior to insertion

Mega 7.5Fr. & 8Fr. IAB Catheters

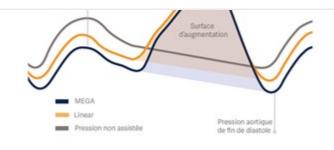


The Mega IAB family offers greater hemodynamic support and higher efficacy for every patient, at any height.

As the leader in counterpulsation therapy,
Maquet is committed to developing IABs that deliver greater hemodynamic support

That's why we've built on the exceptional track record of the Mega 8 Fr. 50 cc IAB to create an expanded Mega family. With the addition of the larger volume Mega 7.5 Fr. 30 cc and 40 cc IAB, there's now a balloon that delivers superior blood volume displacement for everyone, at any height.

Mega: Greater hemodynamic support and higher efficacy for every patient.





Greater hemodynamic support

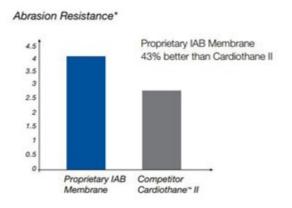
Larger volume balloons like Mega displace more blood in the aorta during diastole, resulting in improved augmentation and unloading.*

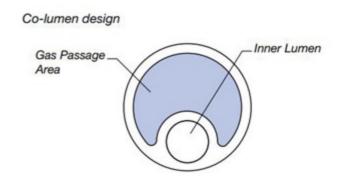
- · More blood volume displacement
- More diastolic augmentation
- More systolic unloading

Statlock® IAB Stabilization Device

All Mega IABs include two complete and ready-to-use Statlock® IAB Stabilization Devices for sutureless securement of IAB catheters, delivering safety and comfort to you and your patients.

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



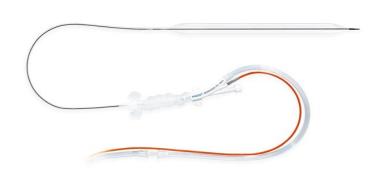


Proprietary IAB Membrane

Advanced IAB Design

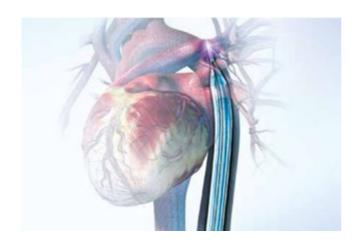
ensation 7Fr. IAB Catheter

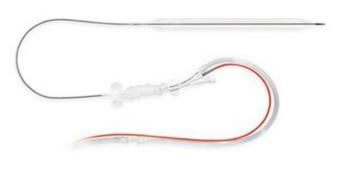
The smallest IAB catheter, combined with innovative fiber-optic technology that automatically calibrates in vivo.



Smaller is better for patient and clinician

Sensation 7Fr. is the smallest IAB catheter available today, combined with innovative fiber-optic technology that automatically calibrates in vivo. Smaller is better for the patient, potentially reducing vascular complications.





7Fr. size without sacrificing performance

- The 7Fr. catheter is made possible by fiber-optic technology, allowing more patients with smaller, compromised vessels to benefit from IABP therapy
- Potential for smaller arteriotomy
- Potential for reduced limb ischemia

New IAB tray and insertion kit packaging: Innovative tray design for faster, easier setup and improved membrane protection.

The Sensation 7Fr. Catheter. Smaller is Better

- Potential for smaller arteriotomy
- Potential for reduced limb ischemia
- 15% increase in the amount of distal flow vs. 8Fr.*
- 23% reduction on the cross-sectional area

Fiber-optic Sensor

The fiber-optic sensor instantaneously transmits a precise pressure signal to the Cardiosave (Hybrid, Rescue) or CS300:

- Reduced signal transfer delay vs. fluid-filled column
 - Maximizes helium gas
- shuttle lumen
 - Speeds and standardizes pressure
- set-up

Proprietary IAB Membrane

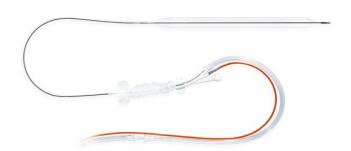
A patented, blow-molded polyurethane IAB material developed to withstand the constant abrasion of even the most calcified aortas*:

- 43% more abrasion resistance
 Reduced insertion force
- Immediate inflation at start-up
- Improved fatigue resistance
- *Bench testing completed by Maquet. Data o file. Bench test results are not necessarily predictive of clinical results.

Unique T-handle Balloon Retainer

- Ensures smallest balloon membrane profile
 - Protects balloon
- membrane during set-up

Sensation Plus 7.5 Fr. & 8Fr. IAB Catheters



Higher Efficacy Fiber-optic IABs

A technological first in improved hemodynamic support, easy-to-use IAB fiber-optic technology.

Higher Efficacy Fiber-optic IABs

Sensation Plus is a technological first in improved hemodynamic support, offering all the benefits of the Getinge easy-to-use IAB fiber-optic technology with the increased clinical effectiveness that larger volume IABs offer. With the introduction of the new fiber-optic Sensation Plus 7.5Fr. 40cc IAB, counterpulsation therapy using fiber-optic technology is now also available for patients from 5'0" to 5'4" (152-162cm).

Unique automatic in vivo calibration: Getinge offers a fiber-optic IABP and catheter system automatically calibrates to the patient after insertion and automatically recalibrates in viv every two hours or sooner, should patient or environmental conditions change. The result: faster time to therapy, ongoing consistency an accuracy of the arterial blood pressure wavef and improved ease-of-use.

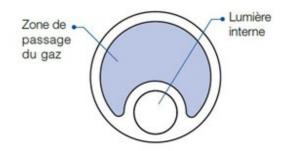
The new Sensation Plus IABs represent state of the art IAB catheter design, with greater patient support, comfort and ease-of-use than any IAB catheter Getinge has ever offered. Faster set-up and easier patient management come standard.

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

Ease-of-Use, Advanced IAB Design And Membrane

Only one 0.025" guidewire is used for inserting the sheath and IAB catheter, so there is no need to switch wires. With only one wire, insertion and application is quick and easy.

- One guidewire (0.025") for sheathed or sheathless IAB catheter insertion No step-down due to unique balloon wrap
- Co-lumen with 0.027" inner diameter for a reliable pressure transducer signal

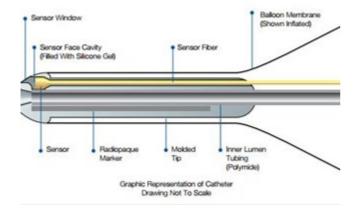


Bringing clarity to mechanical circulatory support

Recent debate regarding the IABP has centered on the discrepant results obtained from randomized, controlled trials (RCTs), versus the benefits observed by clinicians in decades of clinical practice.

This series of educational programs reviews the physiological principles behind current circulatory support therapies.

Watch Drs. Redwood, Perea and Pijls in a new video series



Fiber-optic Technology

The Sensation Plus is the newest Getinge catheter that utilizes the benefits of fiber-optic technology. These benefits translate to faster initiation of therapy, easier patient management, crisp, clean arterial pressure waveform and automatic in vivo calibration.

- Faster time to therapy
- Automatic in vivo calibration
- Instantaneous signal transmission
- Crisp, clean arterial pressure waveform
- Low-level output capability

Greater Hemodynamic Support

Larger volume balloons like Sensation Plus displace more blood in the aorta during diastole, resulting in improved augmentation and unloading.*

- · More blood volume
 - More diastolic augmentation
 - More systolic unloading
 - 40cc for patients 5'0" to 5'4" (152-162cm)
 - 50cc for patients 5'4" (162cm) and taller.

Statlock® IAB Stabilization Device Included

Sensation Plus includes two complete, and ready-to-use Statlock® IAB Stabilization Devices that deliver sutureless securement benefits and comfort to you and your patients.

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

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