

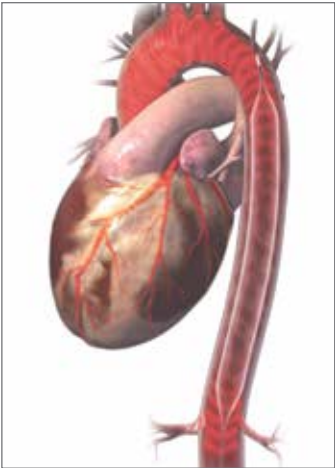
New sizing guidelines

Why are the NEW sizes better for my patient?

Larger volume balloons like MEGA 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 MEGA 30cc, 40cc and 50cc balloons offer greater support when compared to 25cc, 34cc and 40cc.

Specifications	MEGA	LINEAR	MEGA	LINEAR	MEGA	LINEAR
Balloon Size						
Patient Height	< 5'0" (<152cm)	< 5'0" (<152cm)	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.	7.5Fr.	7.5Fr.	7.5Fr.	8Fr.	7.5Fr.
Balloon Diameter	16mm	15mm	16mm	15mm	17.4mm	15mm
Balloon Length	178mm	165mm	229mm	221mm	258mm	258mm

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
MEGA 7.5Fr. 30cc Balloon Catheter, Insertion Kit & Two STATLOCK® IABs	0684-00-0294-01
MEGA 7.5Fr. 30cc Balloon Catheter, Insertion Kit & Two STATLOCK® IABs, with APA*	0684-00-0294-02
MEGA 7.5Fr. 40cc Balloon Catheter, Insertion Kit & Two STATLOCK® IABs	0684-00-0295-01
MEGA 7.5Fr. 40cc Balloon Catheter, Insertion Kit & Two STATLOCK® IABs, with APA*	0684-00-0295-02
MEGA 8Fr. 50cc Balloon Catheter, Insertion Kit & Two STATLOCK® IABs	0684-00-0296-01
MEGA 8Fr. 50cc Balloon Catheter, Insertion Kit & Two STATLOCK® IABs, with APA*	0684-00-0296-02
*Arrow Pump Adapter	
Accessories	Part Number
MEGA 7.5Fr. 30cc/40cc Insertion Kit only	0884-00-0019-21
MEGA 8Fr. 50cc Insertion Kit only	0884-00-0019-17
<i>MEGA Insertion Kits include:</i>	
<ul style="list-style-type: none">- One 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 Ft (122cm) Pressure Tubings- One 5'6" Catheter Extender Tubing (30cc/40cc ONLY)- One 5'7" Catheter Extender Tubing (50cc ONLY)	
0.025" x 145cm 3mm J PTFE Stainless Steel Guidewire (5 Pack)	0684-00-0254-09
0.025" x 175cm 3mm J PTFE Stainless Steel Guidewire (5 Pack)	0684-00-0254-14
0.025" x 260cm 3mm J PTFE Stainless Steel Guidewire (5 Pack)	0684-00-0254-15
7.5Fr. Sheath & Dilator Set	0684-00-0403-05
8Fr. Sheath & Dilator Set	0684-00-0403-10
5'6" Catheter Extender Tubing for 30cc/40cc IABs (10 Pack)	0684-00-0275
5'7" Catheter Extender Tubing for 50cc IABs (10 Pack)	0684-00-0526
STATLOCK® for Maquet IAB Securement (1 Box contains 20 single pouches)	0684-00-0472
Arrow Pump Adapter for 25cc-40cc IABs (5 Pack)	0684-00-0510-01
Arrow Pump Adapter for 50cc IABs (5 Pack)	0684-00-0510-02

Configuration

Materials	Packaging	Cycle & Shelf Life
All balloon catheters, insertion kits and STATLOCK® IAB Stabilization Devices meet FDA and ISO biocompatibility guidelines for devices and materials. MEGA catheters, insertion kits and STATLOCK® IAB devices do not contain latex.	Every IAB catheter, insertion kit, APA and STATLOCK® IAB device has been individually placed in a single pouch, sealed and sterilized.	Cycle Life: 1 procedure Shelf Life: 3 years from date of sterilization. All parameters specified at 25°C ambient temperature. We maintain a policy of continual product improvement and reserve the right to change materials and specifications without notice.

Technical Specifications

Linear 7.5 Fr. IAB Catheter with Insertion Kit

Part Number	Balloon					
	Nominal Volume (cc)	Nominal Length (mm)	Balloon Dia. at 2 psi (mm)	Insertable Length (mm)	Pressure Lumen ID Size (in.)	Guidewire Size (in.)
0684-00-0480-01	40	258	15.0	723	0.027	0.025
0684-00-0479-01	34	221	15.0	723	0.027	0.025
0684-00-0478-01	25	165	15.0	723	0.027	0.025

Ordering Information

Product	Part Number
40 cc Linear 7.5 Fr. IAB Catheter with Catheter Extender	0684-00-0480-01
40 cc Linear 7.5 Fr. IAB Catheter with Arrow Pump Adapter	0684-00-0480-02
34 cc Linear 7.5 Fr. IAB Catheter with Catheter Extender	0684-00-0479-01
34 cc Linear 7.5 Fr. IAB Catheter with Arrow Pump Adapter	0684-00-0479-02
25 cc Linear 7.5 Fr. IAB Catheter with Catheter Extender	0684-00-0478-01
25 cc Linear 7.5 Fr. Catheter with Arrow Pump Adapter	0684-00-0478-02
Linear 7.5 Fr. 40 cc and 34 cc Insertion Kit includes:	0884-00-0019-13
<ul style="list-style-type: none"> • 6" (15 cm) Reinforced Sheath Introducer with hemostasis valve and Introducer Dilator • One 18 gauge Angiographic Needle, one Vessel Dilator • One 0.025" X 145 cm 3 mm J PTFE Stainless Steel Guidewire • One 6' Catheter Extender (40 cc and 34 cc only) • One Male Luer Cap • One Three-Way Stopcock • Two 4' (122 cm) Pressure Tubings 	
25 cc Insertion Kit includes: Above contents and one 5' Catheter Extender	0884-00-0019-12
0.025" X 145 cm 3 mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-09
0.025" X 175 cm 3 mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-14
0.025" X 260 cm 3 mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-15
Arrow Pump Adapter 5 Pack (25 cc to 40 cc)	0684-00-0510-01
7.5 Fr. Sheath and Dilator Set	0684-00-0403-05
Catheter Extender for 40 cc and 34 cc IABs only (10 Pack)	0684-00-0186
Catheter Extender for 25 cc only (10 Pack)	0684-00-0335

Configuration

Materials
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.
Packaging
Single Pouch, Corner Peel
Cycle Life
One procedure
Shelf Life
3 years from date of sterilization. All parameters specified at 25°C ambient temperature. Getinge maintains a policy of continual product improvement and reserves the right to change materials and specifications without notice.



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 102541 0003 Rev. 00

Manufacturer:

Datascope Corp.

1300 MacArthur Blvd
Mahwah NJ 07430
USA

Product Category(ies): Intra-Aortic Balloon Pumps and accessories.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Valid from: 2020-05-28

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Date, 2020-05-28

Christoph Dicks
Head of Certification/Notified Body