ARROW®

MRI Labeling Information for Arrow® IAB and IABP Systems

Teleflex®

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The following document is a summary of the MRI information for the Arrow® IAB and IABP Systems from Teleflex. Overall, the use of MRI on IABP patients is NOT recommended because the Intra-aortic Balloon Pump (IABP) is MRI Unsafe and should never be used during an MRI procedure. This requires that IABP therapy be discontinued during the MRI procedure, which may increase the risk of hemodynamic instability or thrombus on the IAB components, such as the membrane, catheter or sheath. Even patients who are anti-coagulated may have an increased risk of thrombus due to the IAB remaining dormant during the MRI examination.

The information contained in this document is supplemental to the Operation Manual and Instructions for Use (IFU) provided with IAB and IABP system products. Please follow all instructions contained in the manual for safe system operation.

MRI INFORMATION: **ARROW® IABP SYSTEMS**

Non-clinical testing has demonstrated that all Arrow® Intra-aortic Balloon Pumps (IABP) are **MR Unsafe**. There are no MRI scanning conditions that can be performed safely in the presence of the IABP system.

If the physician determines that an MRI is necessary, IABP pumping must be stopped and all cables, such as the ECG cable, AP transducer cable and slave cables for ECG and/or AP, should be disconnected from the patient and *never allowed in the MRI suite*. NOTE: The IAB catheter should be disconnected from the IABP but NOT be removed from the patient. The driveline tubing should be disconnected at the quick connect and the driveline tubing with the IAB catheter volume connector should be removed from the MRI suite with the ECG, AP transducer and slave cables.

The IABP system **MUST NOT** go into the MRI system room so as to prevent the pump from coming in contact with the MRI system. In addition, it is very important that the IAB catheter be properly secured by sutures, tape, dressings and/or other means to reduce the risk of the IAB position changing during the MRI procedure.

Careful consideration of the patient's condition must be given because of the loss of hemodynamic support during the MRI. Consider the following warnings from the IABP Operation Manual regarding the safe length of time that IABP support may be discontinued. If the MRI procedure will take longer than 15–30 minutes an increased risk to the patient may occur:

WARNING: If balloon pumping is interrupted and cannot be continued within 15–30 minutes, connect a 50/60cc syringe to the balloon connector and inflate and deflate the balloon manually. Thrombus formation may result from blood becoming trapped in the folds of a dormant balloon.

WARNING: Pump shutdown requires immediate staff action. Note the time and call knowledgeable maintenance personnel. If pumping cannot be restored within 15–30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation. Consider removing the balloon. Arrow International recommends that you have a back-up IABP system available.

MRI INFORMATION: **Arrow® IAB Catheters**

While the Arrow® IABP systems are MRI Unsafe, Arrow® IAB catheters are MRI Conditional except when the RediGuard® IAB Catheter is used with Super Arrow-Flex® Sheath. The following sections provide specific information on each IAB catheter by product line. The information for each product line applies to all IAB's in that product line.

FOR ARROW® IAB CATHETERS INSERTED WITH SUPER ARROW-FLEX® SHEATH

WARNING: The Super Arrow-Flex® Sheath (wire-reinforced) provided with the RediGuard® IAB Catheter is MRI unsafe. If the Super Arrow-Flex® Sheath has been used for RediGuard® IAB Catheter insertion, MRI scanning should not be performed.

NOTE: The RediGuard® IAB Catheter is MRI Unsafe if inserted with the Super Arrow-Flex® Sheath. The RediGuard® IAB Catheter is MRI Conditional if a PTFE sheath is used for insertion or if inserted without a sheath as described in the chart below.

Non-clinical testing has demonstrated that the **5800 Series (Ultra 8®), RediGuard®, and 6800 Series (UltraFlex™) Catheters are MR Conditional.**

The UltraFlex™,RediGuard®, and Ultra 8® catheters can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla
- Spatial gradient field of 720-Gauss/cm or less

The table below provides the MRI information for each IAB product line. In non-clinical testing, the IAB catheters produced a temperature rise of less than 6.7°C at a maximum and <64° induced forces, or moderate torque. The induced forces are mitigated by stabilization devices such as sutures, tape or bandages and pose no risk. The RediGuard® IAB Catheter may be more susceptible to movement during the MRI, so it is imperative that stabilization and anchoring devices are secure prior to scanning.

IAB MODEL	INDUCED FORCES (ASTM REQ. < 45°)	TORQUE MEASUREMENT	INDUCED TEMPERATURE 1.5T/3.0T	ARTIFACTING
5800 SERIES (ULTRA 8)	19° (Pass)	NA	1.8°/2.2° C	Moderate
6800 SERIES (ULTRAFLEX)	42° (Pass)	NA	2.1°/6.1° C	Moderate
REDIGUARD	64° (Fail)	Moderate	1.9°/2.3° C	Moderate

1.5-Tesla/64-MHz MR system (Excite, Software HDx, Software)
14X.M5, General Electric Healthcare, Milwaukee, WI) reported whole body averaged SAR value of 2.9-W/kg was associated with a calculated whole body averaged SAR value of 2.1 -W/kg.

3-Tesla/128-MHz MR system (Excite, Software HDx, Software)
14X.M5, General Electric Healthcare, Milwaukee, WI) reported whole body averaged SAR value of 2.9-W/kg was associated with a calculated whole body averaged SAR value of 2.7 -W/kg.

MR System 2: (Heating Tests)
1.5-Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner. The transmit/received head radiofrequency (RF) coil was used to transmit and receive RF energy.

References:

1 ASTM Standards Followed for testing:

A. F2052-06: American Society for Testing and Materials International. Designation: ASTM F2213-06, Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment. In: Annual Book of ASTM Standards, Section 13, Medical Devices and Services, Volume 13.01 Medical Devices; Emergency Medical Services. West Conshohocken, PA, pp; 1576-1580, 2006.

B. F2119-07: American Society for Testing and Materials International. Designation: ASTM F2119-07, standard test method for evaluation of MR image artifacts from passive implants. West Conshohocken, Pa: American Society for Testing and Materials International, 2007.

C. F2182-09: American Society for Testing and Materials International. Designation: ASTM F2182- 09, standard test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging. West Conshohocken, Pa: American Society for Testing and Materials International, 2009.

D. F2213-06 American Society for Testing and Materials International. Designation: ASTM F2213-06, standard test method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment. West Conshohocken, Pa: American Society for Testing and Materials International, 2009

2 Shellock FG. Biomedical implants and devices: assessment of magnetic field Interactions with a 3.0-Tesla MR system. Journal of Magnetic Resonance Imaging. 16:721-732; 2002.

3 Shellock FG. Biomedical implants and devices: assessment of magnetic field Interactions with a 3.0-Tesla MR system. Journal of Magnetic Resonance Imaging.16:721-732; 2002.

4 Shellock FG, Woods. T., Crues, J. MRI Labeling for Implants and Devices: Explanation of Terminology. Radiology: 253:26-30; 2009.

5 Guidance for industry and FDA staff: establishing safety and compatibility of passive implants in the magnetic resonance (MR) environment. U.S. Food and Drug Administration Web site. http://www.fda.gov/cdrh/osel/guidance/1685.html. Published August 21, 2008.

6 MRISafety Web site. http://www.mrisafety.com/ Accessed June 2011.

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

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Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Information in this material is not a substitute for the product Instructions for Use. Not all products may be available in all countries. Please contact your local representative. Revised: 08/2019.

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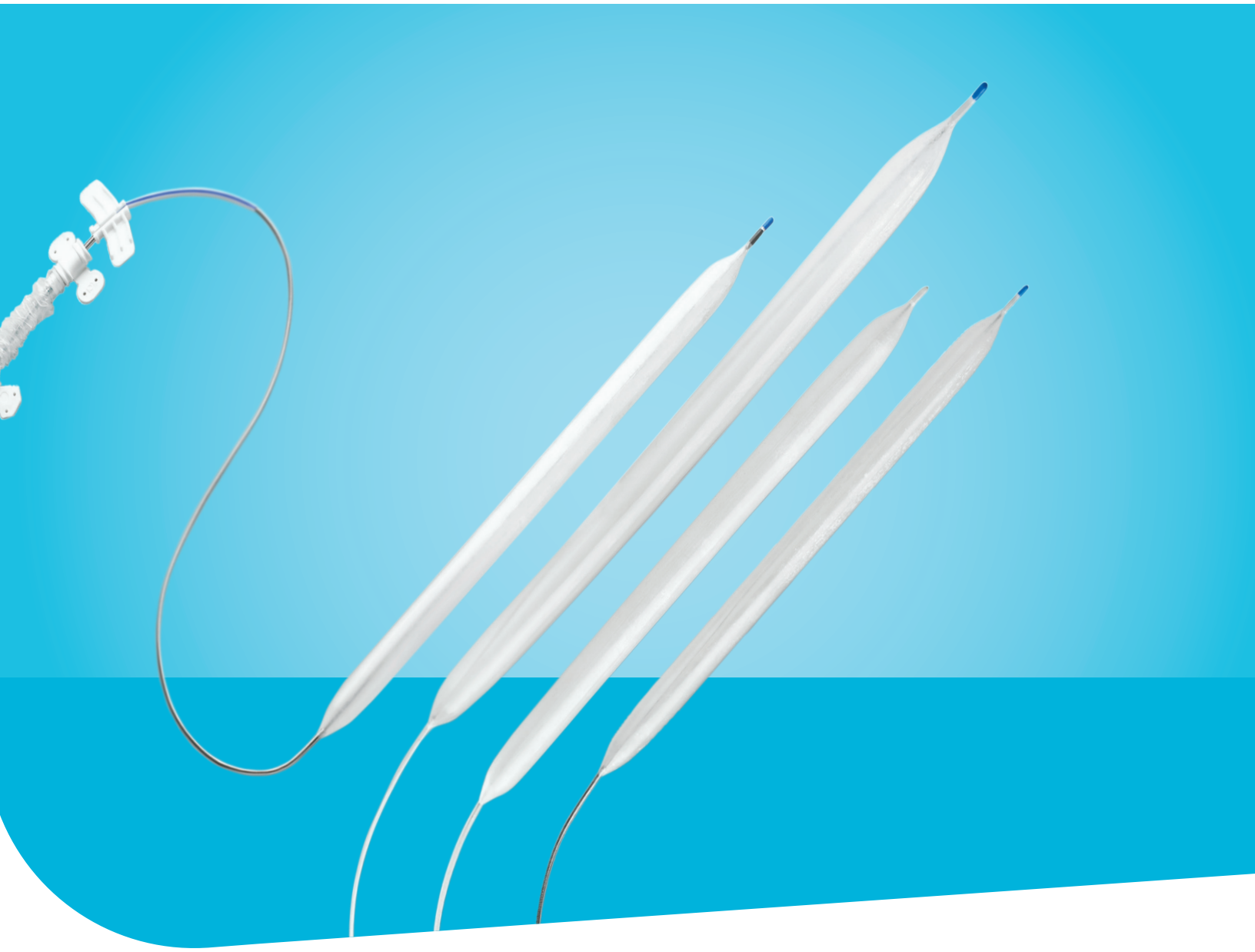

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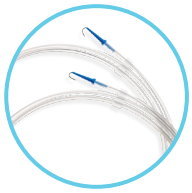
Intra-Aortic Balloon Catheter Options

Proactively meeting your counterpulsation needs



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Ultra 8® Fiber-Optic IAB Catheter Features

- Fits through 8 Fr. sheath
- 0.025" guidewire for trackability
- Large 0.027" central lumen design
  – Designed to minimize the risk of central lumen clotting
- Stainless steel tip
- Captures and transmits the high-fidelity AP signal at the speed of light
  – Works with unique components of the AutoCAT2WAVE® and AC3 Optimus™ IABPs to deliver ProActive CounterPulsation® Technology

Fiber-Optic IAB Catheter

Ultra 8® Fluid-Filled IAB Catheter Features

- Fits through 8 Fr. sheath
- 0.025" guidewire for trackability
- Large 0.027" central lumen design
  – Designed to minimize the risk of central lumen clotting
- Soft, atraumatic blue bumper tip

UltraFlex™ 7.5 IAB Catheter Features

- Kink-resistant, wire-reinforced catheter body
  – Strong, flexible catheter body resists kinking for optimal gas exchange
  – Soft, atraumatic blue bumper tip
  – Maintains the circular shape of the gas lumen to help ensure consistent patient support
- The smallest wire-reinforced 30 cc and 40 cc IAB catheter
  – Maximizes arterial blood flow and helps reduce limb ischemia due to 7.5 Fr. catheter size
- Crisp, clear AP waveforms
  – High performance without the need for frequent flushings

RediGuard® IAB Catheter Features

- Flexible, soft catheter design
- Smallest IAB catheter available – 7 Fr. 30 cc
- Soft, atraumatic blue bumper tips on 50 cc catheter
- 0.027" reinforced central lumen design
- Flexible, soft central lumen design
  – Pliable, reinforced central lumen; accepts 0.025" guidewire
- Centimeter markings on catheter body for placement
- 7 Fr. 30 cc IAB catheter
  – Available for patients under 5'4" (162 cm) in height
- Wide range of flexible IAB catheters
  – 7 Fr. 30 cc
  – 8 Fr. 40 cc
  – 9 Fr. 50 cc

Fluid-Filled IAB Catheter

Ordering Information

Ultra 8® Fiber-Optic IAB Catheters

PRODUCT NUMBER	CATHETER SIZE	BALLOON VOLUME	INSERTABLE LENGTH	SHEATH LENGTH	CENTRAL LUMEN I.D.	MAXIMUM GUIDEWIRE	CATHETER MATERIAL	BALLOON MEMBRANE LENGTH	INFLATED DIAMETER
IAB-05830-LWS	8 Fr.	30 cc	23.8" (60.5 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane/ Pebax	9.1" (230 mm)	13.9 mm
IAB-05840-LWS	8 Fr.	40 cc	26" (66.0 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane/ Pebax	10.2" (260 mm)	15 mm

Ultra 8® Fluid-Filled IAB Catheters

PRODUCT NUMBER	CATHETER SIZE	BALLOON VOLUME	INSERTABLE LENGTH	SHEATH LENGTH	CENTRAL LUMEN I.D.	MAXIMUM GUIDEWIRE	CATHETER MATERIAL	BALLOON MEMBRANE LENGTH	INFLATED DIAMETER
IAB-05830-U	8 Fr.	30 cc	23.8" (60.5 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane/ Pebax	9.1" (230 mm)	13.9 mm
IAB-05840-U	8 Fr.	40 cc	26" (66.0 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane/ Pebax	10.2" (260 mm)	15 mm

UltraFlex™ 7.5 IAB Catheters

PRODUCT NUMBER	CATHETER SIZE	BALLOON VOLUME	INSERTABLE LENGTH	SHEATH LENGTH	CENTRAL LUMEN I.D.	MAXIMUM GUIDEWIRE	CATHETER MATERIAL	BALLOON MEMBRANE LENGTH	INFLATED DIAMETER
IAB-06830-U	7.5 Fr.	30 cc	23.8" (60.5 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane Stainless Steel*	9.1" (230 mm)	13.9 mm
IAB-06840-U	7.5 Fr.	40 cc	26.0" (66.0 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane Stainless Steel*	10.2" (260 mm)	15 mm

RediGuard® IAB Catheters

PRODUCT NUMBER	CATHETER SIZE	BALLOON VOLUME	INSERTABLE LENGTH	SHEATH LENGTH	CENTRAL LUMEN I.D.	MAXIMUM GUIDEWIRE	CATHETER MATERIAL	BALLOON MEMBRANE LENGTH	INFLATED DIAMETER
IAB-S730C	7 Fr.	30 cc	26.8" (68.1 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane	9.1" (230 mm)	13.9 mm
IAB-S840C	8 Fr.	40 cc	26.0" (66.0 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane	10.2" (260 mm)	15 mm
IAB-R950-U	9 Fr.	50 cc	26.0" (66.0 cm)	6" (15 cm)	0.027"	0.025"	Polyurethane	10.3" (262 mm)	16 mm

Replacement Insertion Kits

PRODUCT NUMBER	DESCRIPTION
IAK-06845	Replacement insertion kit for use with UltraFlex 7.5, Ultra 8 fiber-optic and fluid-filled IAB catheters
IAK-S7IT	Replacement insertion kit for use with RediGuard 30 cc IAB catheters
IAK-S8IT	Replacement insertion kit for use with RediGuard 40 cc IAB catheters
IAK-02691	Driveline tubing with pre-attached Arrow® 30 cc pump connector for use with Arrow pump consoles, fiber-optic, and fluid-filled 30 cc IAB catheters
IAK-02692	Driveline tubing with pre-attached Arrow 40 cc pump connector for use with Arrow pump consoles, fiber-optic, and fluid-filled 40 cc IAB catheters
IAK-02693	Driveline tubing with pre-attached Arrow 50 cc pump connector for use with Arrow pump consoles and 50 cc RediGuard IAB catheters
IAK-02263	Driveline tubing for use with Datascope® Balloon Pumps and Arrow 30 cc and 40 cc IAB catheters
IAK-02271	Driveline tubing for use with Datascope® Balloon Pumps and Arrow 50 cc IAB catheters

** Wire-reinforced catheter body*
Note: All Arrow IAB catheters are latex-free

Caution: Federal law restricts this device to sale by or on order of a physician. Contents of unopened, undamaged package are sterile. Disposable. Refer to package insert for current warnings, indications, contraindications, precautions, and Instructions For Use.

References:

1. Winters KJ, Smith SC, Cohen M, et al. Reduction in ischemic vascular complications with hydrophilic-coated intra-aortic balloon catheter. *Cath and Cardiovasc Interven.* 1999; 46(3): 357-362.

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

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