EMBOLINER®

Embolic Protection System

REF **EPC-03**

1. R_x ONLY

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

2. REUSE WARNING STATEMENT

Contents are supplied STERILE using an irradiation process. Do not use if sterile barrier is damaged. If damage is found, contact the authorized representative listed on the labeling. For single patient use only. Do not reuse, reprocess, or re-sterilize as these may compromise the structural integrity of the device and/or lead to device failure, and may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infection disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

3. DEVICE DESCRIPTION

The Emboliner® Embolic Protection System ("Emboliner") is a sterile, short term use medical device. The Emboliner is a percutaneously delivered embolic protection filter, designed to capture and remove debris dislodged during transcatheter aortic valve replacement (TAVR). The Emboliner is comprised of the filter, its catheter, an integrated delivery sheath, and a balloon catheter. The system is also supplied with a filter loading tool (Figure 1). The Emboliner is delivered over a guidewire via femoral artery access. The filter is deployed via the integrated delivery sheath across the aortic arch to capture debris that would otherwise enter the cerebral branch vessels and descending aorta during transcatheter aortic valve replacement (TAVR). The Emboliner catheter and delivery sheath contain radiopaque markers to facilitate visualization during use. The filter is composed of a double-layer, heparin-coated, cylindrical nitinol mesh. The Emboliner catheter contains an integrated 6 Fr lumen to allow the introduction of procedural devices (e.g., angiography pigtail catheter, guidewire, etc.). At the completion of the procedure, the filter and debris are retrieved into the delivery sheath and removed from the patient.

System specifications and anatomical requirements for the target patient group are listed in Table 1.

Delivery profile	4.09 mm outer diameter
Working length	Delivery sheath: 79 cm Balloon Catheter: 1280 mm, Balloon tip: 3 cm
Angiography pigtail compatibility	6 Fr maximum, 125 cm minimum
Guidewire compatibility	Exchange length, 0.035 in (0.889 mm) stiff guide wire with j-tip
Ascending aorta diameter	48 mm maximum
Descending aorta diameter	33 mm maximum
Femoral access site to sinotubular junction (STJ) distance	80 cm maximum
Balloon Catheter Specifications	
Nominal size of balloon	4.45 mm diameter, 30 mm exposed length
Position of marker band	See item C in Figure 1
Rated burst pressure	20 atm (2026.5 kPa)
Ballon inflation pressure	16 atm (1621.2 kPa)
Device compatibility	Guidewire: 0.035 in (0.889 mm) exchange-length stiff guide wire with j-tip Introducer sheath: 4.33 mm minimum inside diameter or a 14 Fr sheath

Table 1.

Package Contents

One (1) Emboliner System

One (1) Filter Loading Tool

Materials

The Emboliner system consists of a deployable nitinol filter attached to a polymer catheter via stainless steel wire. The delivery sheath is a braid-reinforced polymer shaft. The retrieval lasso wire consists of nitinol wire.

Non-pyrogenic

The Emboliner system is non-pyrogenic.

4. TARGET PATIENT POPULATION

The Emboliner is intended for use in adult patients undergoing transcatheter intravascular procedures by trained physicians. Anatomical size limitations are listed in Table 1.

5. INTENDED USE/INDICATIONS FOR USE

The Emboliner Embolic Protection System is indicated for use as an embolic protection device to capture and remove embolic material during transcatheter aortic valve replacement (TAVR). Anatomical requirements for aortic diameters and femoral access site to sinotubular junction (STJ) distance should meet the requirement as specified in the Instructions for Use.

6. INTENDED USER

The Emboliner should only be used by physicians who have received training on Emboliner use, have experience with transcatheter procedures, and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with those procedures.

7. CONTRAINDICATIONS

- Patients whose access anatomy is unable to accommodate a 4.09 mm outer diameter sheath
- Patients whose aortic anatomy is unable to accommodate both the Emboliner and other procedural devices together
- Contraindicated in patients where allergy or hypersensitivity to aspirin, heparin products, clopidogrel or ticlopidine, nitinol, and/or contrast agents cannot be pre-medicated
- Patients with uncorrected bleeding disorders or Type 2 heparin-induced thrombocytopenia
- Patients with significant suprarenal aortic tortuosity with kinking that cannot be straightened with other procedural devices

8. PRECAUTIONS

- If the filter is not pulled far enough into the delivery sheath during loading, the filter may damage the balloon.
- If excessive force is required to pull the filter into the delivery sheath during loading, the filter may not be loaded properly in the filter loading tool. If so, carefully push the filter out of the delivery sheath and repeat the loading process. If difficulty persists, load a new Emboliner.
- The Emboliner is compatible with a 0.035" exchange-length guidewire.
- The Emboliner is compatible with a 125-cm minimum length and a maximum 6 Fr angiography pigtail catheter.
- The Emboliner is not designed to be used with a power injector.
- The Emboliner filter is coated with heparin, which is an animal-derived medicinal material.
- Arterial access for the Emboliner should be prepared to accommodate a sheath with an outer diameter of 4.09mm.

9. WARNINGS

- For single use only. Do not reuse, reprocess, or re-sterilize.
- Do not use the device if the Use By date has elapsed.
- Do not use if the packaging or device is damaged.
- For use only by physicians who have received Emboliner device training.
- Administer antiplatelet/anticoagulation therapy pre- and post-procedure in accordance with standard medical practice.
- Do not deploy or retrieve the Emboliner with procedural devices in the aortic arch.
- Do not twist the Emboliner catheter or delivery sheath during filter loading, insertion into arteriotomy, or filter deployment.
- Do not exceed balloon rated burst pressure of 20 atm.
- Before withdrawing the balloon, visually confirm complete deflation by fluoroscopy.
- Do not cross the access port with a bare guidewire.
- Ensure that procedural devices pass through the access port, and not between the filter and the aortic wall, or through the wall of the filter.
- Ensure that procedural devices do not wrap around the Emboliner sheath or catheter.
- If excessive resistance is encountered when advancing a device through the access port, withdraw the device, confirm centering of procedural device in the aorta, and re-cross the access port.
- If the filter becomes twisted or incorrectly positioned during use, remove all procedural devices, retrieve the filter and insert a new Emboliner.
- Maintaining the guidewire or long angiography pigtail on the outer curvature of the arch with the distal end in the NCC ensures static placement of the filter during the treatment procedure.
- Do not exert high forces during loading, delivery, or retrieval of the filter. If high forces are encountered or high resistance is felt, stop and address the cause before proceeding.
- Do not advance the delivery sheath after the balloon has been deflated or once it has been removed.

10. ADVERSE EVENTS

This Emboliner is used during therapeutic endovascular procedures of which all have risk of adverse events. Refer to the specific IFU of those endovascular devices for a complete list of their potential adverse events. Possible adverse events associated with Emboliner use and endovascular procedures include, but are not limited to, the following:

- Access site complications
- Arrhythmia
- Arteriovenous fistula
- Bleeding or hemorrhage
- Cardiac tamponade
- Death
- Emboli (including air, tissue, thrombus or device materials)
- Valve embolism
- Hematoma
- Immune system response (local or systemic)
- Infection (local or systemic)
- Ischemic stroke
- Localized inflammation
- Mural thrombus formation
- Pseudoaneurysm
- Surgical intervention
- Vessel injury (including spasm, trauma, dissection, and perforation)

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

11. INSTRUCTIONS FOR USE

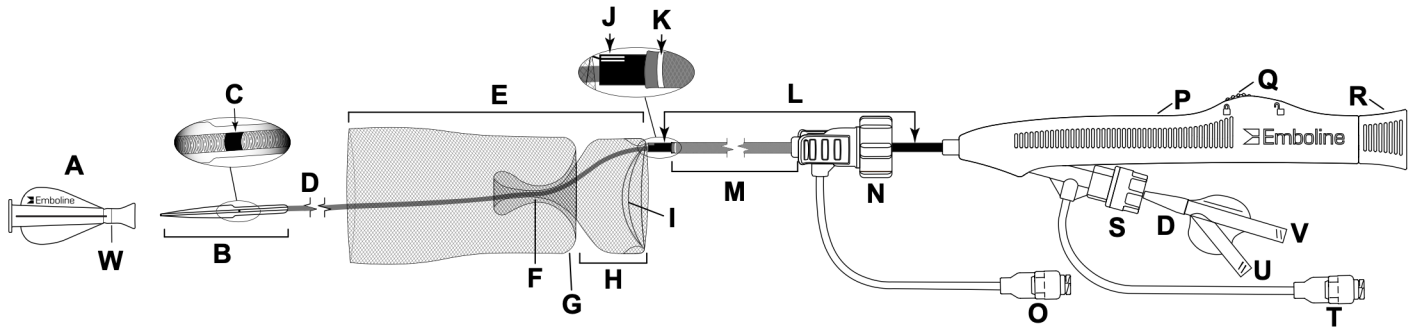


Figure 1.

A. Filter loading tool
B. Balloon
C. Balloon loading marker
D. Balloon catheter
E. Filter
F. Access port
G. Shoulder
H. Vestibule
I. Lasso
J. Emboliner catheter radiopaque markers (2)
K. Sheath radiopaque marker
L. Emboliner catheter
M. Sheath
N. Sheath Tuohy valve
O. Sheath flush port
P. Handle
Q. Rachet lock
R. Rachet knob
S. Emboliner catheter Tuohy valve
T. Emboliner catheter flush port
U. Balloon inflation port
V. Balloon guidewire lumen
W. Filter loading tool alignment mark

11.1. Additional Items for Safe Use

The following supplies are not provided and need to be available and prepped prior to use of the Emboliner:

- Balloon inflation device with manometer with minimum range of 20 atm
- Diluted radiopaque contrast medium (50:50 medium to saline dilution)
- Exchange length, 0.035 in (0.889 mm) stiff guidewire with j-tip
- 5 or 6 Fr long angiography pigtail catheter, minimum 125 cm
- 5 or 6 Fr standard angiography pigtail catheter, 110 cm
- 1 L heparinized normal saline solution (HS)
- 1 syringe with Luer lock, approximately 20 cc
- Sterile bowl (large)
- 9 Fr short sheath

11.2. Device Preparation

11.2.1. Inspect the package for damage. Remove the Emboliner and filter loading tool from the package and inspect the device for damage.

11.2.2. Push the balloon catheter into the handle until the inflation port abuts the Tuohy valve.

11.2.3. Flush the sheath and Emboliner catheter flush ports. **NOTE**: Use heparinized saline for all flush steps.

11.2.4. Confirm that the ratchet lock is in the locked position by noting the lock and unlock symbols on the handle.

11.2.5. Pull the ratchet knob on the handle until resistance is felt to fully collapse the vestibule.

11.2.6. Pin the sheath and slowly pull the handle until approximately 1cm of filter remains outside the sheath.

11.2.7. Reverse the previous step by pinning the sheath and pushing the Emboliner catheter until the entire filter exits the sheath and the handle abuts the sheath Tuohy valve.

11.2.8. Release the lasso by unlocking the ratchet lock and pushing the ratchet knob fully into the handle. Confirm that the lasso is fully expanded in the vestibule. Lock the ratchet lock.

11.2.9. Submerge filter in heparinized saline and remove. Radially compress the distal end of the filter.

11.2.10. Orient the filter loading tool so that the arrow points towards the filter, as shown on Figure 1.

11.2.11. Insert the compressed end of the filter into the filter loading tool. Continue to pass the compressed filter through the filter loading tool until the filter loading tool reaches the port.

11.2.12. Elongate the port, continue to advance the filter through the filter loading tool and stop before the filter loading tool reaches the vestibule.

11.2.13. Radially compress the proximal end of the filter. **CAUTION:** If the lasso wire loop protrudes from the filter mesh, allow the vestibule to expand, ensure that the lasso wire remains inside the mesh layers, and then re-compress.

11.2.14. Hold the compressed end of the filter and continue to slide the filter loading tool over the filter until the the distal end of the black Emboliner catheter is aligned with the most proximal line on the filter loading tool, as shown as item W on Figure 1. **CAUTION:** Do not force the filter beyond this point.

11.2.15. Hold the Emboliner handle and advance the sheath until the sheath tip reaches the internal stop inside the filter loading tool.

11.2.16. Immerse the sheath tip and filter. Flush the sheath. Agitate the filter to remove bubbles.

11.2.17. Continue to immerse the filter and sheath tip. Maintain sheath position in-line with the filter loading tool. Pin the sheath and slowly pull the handle to draw the filter into the sheath until 2 cm the filter remains outside of the sheath. Remove the filter loading tool. **CAUTION:** If excessive force is felt during this step, stop, push the filter out of the sheath, inspect the filter and sheath tip for damage, and repeat the loading steps.

11.2.18. Prepare the inflation device per manufacturer's IFU. Fill with 5 cc of 50:50 contrast mixture. Purge air from the tubing.

11.2.19. Connect the inflation device directly to the balloon catheter inflation port. Hold inflation device with nozzle pointing down. Pull vacuum with the inflation device to purge air from the balloon catheter.

11.2.20. Inflate the balloon to 4 atm and inspect for air bubbles. If air bubbles are found, repeat vacuum and inflation steps.

11.2.21. Pull the balloon catheter until the distal filter edge is aligned with the balloon loading marker as shown on Figure 1.

11.2.22. Immerse balloon, filter, and sheath tip. Flush the catheter until no bubbles are visible.

11.2.23. Complete filter loading by pinning the sheath and pulling the handle or catheter, stopping when the balloon shoulder abuts the sheath tip and the sheath tip and balloon create a smooth transition.

11.2.24. Increase balloon pressure to 16 atm. Keep balloon inflation device attached to balloon inflation port during device handoff.

11.2.25. Flush guidewire lumen. Verify that the ratchet lock is in the locked position. THE DEVICE IS READY TO USE.

11.3. Procedure Delay — Perform these steps if > 30 minutes have elapsed between device preparation and use

11.3.1. Deflate the balloon.

11.3.2. Immerse balloon and sheath tip; partially unsheathe the filter by advancing the Emboliner Catheter ~5 cm

11.3.3. Flush the sheath.

11.3.4. Repeat steps 11.2.20 through 11.2.25.

11.4. Device Procedure —Deployment of filter

11.4.1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Anticoagulant therapy sufficient to maintain an Activated Clotting Time of at least 250 seconds for the duration of the procedure is recommended.

11.4.2. Ensure the aortic arch is free of all devices.

11.4.3. Confirm the stiff 0.035" guidewire has a curved tip and advance to the non-coronary cusp. Monitor and maintain guidewire position throughout the Emboliner deployment process. Maintain adequate tension on the guidewire to straighten anatomy and ensure smooth delivery of the Emboliner.

11.4.4. Advance the Emboliner through the arteriotomy and over the aortic arch until the radiopaque marker on the sheath is near the sinotubular junction (STJ). **CAUTION:** During advancement, maintain device orientation with the ratchet lock facing away from the operator. The second operator should pin the balloon catheter at the Emboliner catheter Tuohy valve to ensure the balloon does not move out of the sheath tip during the insertion process. **CAUTION:** Monitor the balloon during insertion and stop if the balloon becomes dislodged from the sheath tip. If this happens, carefully remove the entire system, and repeat step 11.3. to flush and insert the balloon into the sheath. **CAUTION:** Do not twist the Emboliner during advancement.

11.4.5. Deflate the balloon. Carefully withdraw the balloon catheter from the Emboliner catheter, maintaining wire position. If difficulty is experienced during removal, verify that the balloon is fully deflated. **WARNING:** Do not advance the sheath after the balloon has been deflated.

11.4.6. Introduce the long pigtail catheter over the guidewire and advance until resistance is felt.

11.4.7. Pin the Emboliner catheter and pull the sheath, deploying the filter. Continue until the shoulder appears. **CAUTION:** Do not use excessive force when deploying the filter. If force is excessive, remove the device and replace with a new device.

11.4.8. Pin the sheath and advance the Emboliner catheter to form the access port.

11.4.9. Return to pinning the Emboliner catheter, pull the sheath until the vestibule is fully formed and the sheath abuts the control handle.

11.4.10. Advance the long pigtail catheter over the guidewire and into the non-coronary cusp. Maintain the guidewire on the outer curvature of the aortic arch to support the Emboliner filter.

11.5. Device Procedure — Primary endovascular procedure

11.5.1. Contralateral to the Emboliner, insert a pigtail catheter and advance it toward the vestibule of the Emboliner. Utilizing fluoroscopy, observe its advancement from the abdominal bifurcation toward the vestibule confirming the pigtail does not wrap around the Emboliner. Advance a guidewire into the pigtail to provide support for port crossing. **CAUTION:** If wrapping is observed with the Emboliner catheter, retract the operative pigtail to the abdominal aorta bifurcation and, while observing under fluoroscopy, re-advance toward the vestibule, confirming the pigtail does not wrap around the Emboliner.

11.5.2. Advance the standard pigtail into the vestibule and through the port. Confirm port crossing by gently pulling the pigtail until the curl of the pigtail engages with and slightly deflects the proximal opening of the access port.

11.5.3. Advance the pigtail and exchange with a guidewire needed for the endovascular procedure. When crossing through the Emboliner filter with the endovascular delivery system, advance slowly through the vestibule and port. If significant interaction is observed, withdraw the endovascular delivery system from the vestibule, re-center and re-attempt crossing.

11.5.4. After completion of procedure, withdraw the endovascular delivery system slowly through the Emboliner filter.

11.6. Device Procedure — Emboliner retrieval

11.6.1. Confirm that all devices from the operative side are removed from the filter.

11.6.2. Confirm the Emboliner Catheter radiopaque markers are at the edge of the vestibule, and the sheath still abuts the control handle.

11.6.3. Confirm that the ratchet lock is in the locked position.

11.6.4. Pull the ratchet knob until the lasso compresses around the pigtail catheter and slight resistance is felt.

11.6.5. Retract the pigtail catheter so it is within the Emboliner Catheter

11.6.6. Pull the ratchet knob to achieve complete, uniform, and symmetrical collapse of the vestibule.

11.6.7. Pin the sheath and pull the handle to fully retrieve the filter into the sheath. Continue to pull the handle until the filter is removed from the sheath.

11.6.8. The sheath may remain in place to be used for additional access if needed.

12. PROTECT THE HEAD TO HEAD CLINICAL STUDY SUMMARY

Study Title	Protect the Head to Head: A Safety and Efficacy Assessment of the Emboliner® Embolic Protection Device, referred to as Protect H2H Study
Sponsor:	Emboline, Inc.
ClinicalTrials.gov ID	NCT05684146
Investigation Device	Emboliner® Embolic Protection Catheter (EPC-03), referred to as Emboliner
Study Phase	Pivotal (Safety and Efficacy)
Study Design	Prospective, randomized, multicenter, 2-arm, safety and efficacy study
Study Centers	18 centers: 11 in the United States, 2 in Brazil, 5 in Germany
Study Initiation Date	04 May 2023 (first subject treated)
Study Completion Date	12 December 2025 (last subject completed)
Population:	Subjects with symptomatic severe aortic stenosis undergoing transcatheter aortic valve replacement (TAVR) with an FDA-approved valve in conjunction with the use of embolic protection
Total Subjects Enrolled	The study was planned to enroll up to 540 randomized subjects and up to 40 roll-in subjects (total: up to 580 enrolled subjects) A total of 557 subjects were enrolled (522 randomized + 35 roll-in)
Primary Analysis Population (mITT)	The study was powered to include a minimum of 236 evaluable subjects in the modified intent-to-treat (mITT) population in each treatment arm The final mITT population includes 485 subjects (Emboliner n=244; Sentinel n=241)
Study Objective	The primary objective of Protect The Head To Head study was to evaluate the safety and efficacy of Emboliner by demonstrating non-inferiority to the control device (Sentinel CPS) with respect to the incidence of 30-day (±7 days) composite major adverse cardiac and cerebrovascular events (MACCE) following the TAVR procedure
Primary Endpoint	Combined safety and efficacy: 30-day composite of MACCE, defined as all-cause death, stroke, and stage 3 acute kidney injury (AKI)
Non-inferiority Margin	7% absolute difference; one-sided alpha = 2.3% (after alpha spending at interim analysis)
Primary Endpoint Result	Emboliner 4.5% (11/244) vs. Sentinel 5.0% (12/241); 95% CI upper bound 3.51% <7%; P(NI) = 0.0004
MACCE Components	23 total MACCE events: Emboliner 11 (4.5%) vs. Sentinel 12 (5.0%), comprising all-cause death: Emboliner 5 (2.0%) vs. Sentinel 5 (2.1%), stroke Emboliner 5 (2.0%) vs. Sentinel 5 (2.1%), and Stage 3 AKI Emboliner 1 (0.4%) vs. Sentinel 3 (1.2%)
Timing of Endpoint Events	Cardiovascular deaths: Emboliner 4 (1.6%) vs. Sentinel 3 (1.2%) occurred earlier in the follow-up period in both arms (POD 0-17, median POD 2) and non-cardiovascular deaths: Emboliner 1 (0.4%) vs. Sentinel 2 (0.8%) occurred later in the follow-up period in both arms (POD 18-26, median POD 22); Stage 3 AKI occurred early (2–3 days) in both arms; stroke timing presented below
Stroke (Secondary Endpoint #1)	Incidence of all stroke events (VARC-2 defined) occurring within 30 days following the procedure, adjudicated by the independent DMC/CEC (Emboliner 2.0% [5/244] vs. Sentinel 2.1% [5/241]; 95% CI upper bound 2.88% <7%; P[NI] = 0.0001)
Stroke Severity and Timing	Disabling stroke: Emboliner 4 (1.6%) vs. Sentinel 1 (0.4%); Non-disabling stroke: Emboliner 1 (0.4%); vs. Sentinel 4 (1.7%); Onset ≤72 hours Emboliner 3 (1.2%) vs. Sentinel 4 (1.7%); onset >72 hours Emboliner 2 (0.8%) vs. Sentinel 1 (0.4%) All events ischemic except one hemorrhagic stroke (Emboliner, POD 17)
Debris Capture (Secondary Endpoint #2)	Total count of embolic debris particles >150 µm captured in the first 100 consecutive, evaluable filters (50 Emboliner + 50 Sentinel) - analyzed by CVPath Institute histopathology core laboratory (Emboliner median 93 particles ≥150 µm vs. Sentinel 31 [p<0.0001]; 3-fold superior capture)
Technical Success	Vessel coverage maintained throughout the procedure with no device-related SAE at OR/cath lab exit: Emboliner 95.9% (234/244) vs. Sentinel 87.1% (210/241)
Conclusion	Non-inferiority of the Emboliner vs. Sentinel demonstrated for both MACCE and stroke.

13. DEVICE DISPOSAL

Dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

- Device and accessories are biologically hazardous due to the contact with patient's blood
- Packaging card is made of HDPE
- Pouch is made of Tyvek
- External box is made of carton paper

14. WARRANTY

Emboline, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of, and excludes, all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning, and sterilization of this instrument as well as other factors relating to the patient diagnosis, treatment, surgical procedures, and other matters beyond the direct control of Emboline affect the instrument and the results obtained from its use. The obligation of Emboline under this warranty is limited to the repair or replacement of this instrument and Emboline shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Emboline neither assumes, nor authorizes, any other person to assume for it any other or additional liability or responsibility in connection with this instrument. Emboline assumes no liability with respect to instruments reused, reprocessed or resterilized, and makes no warranties, express or implied, including but not limited to, merchantability or fitness for a particular purpose, with respect to such instruments.

15. SYMBOLS

REF	Catalog number
LOT	Lot number
MD	Medical device
QTY	Quantity in package
UDI	Unique device identifier
	Use by date
	Manufacture date
	Read instructions for use
Rx	By prescription only
2	Single use only
2 STERILIZE	Do not re-sterilize
	Do not use if package is damaged
	Non-pyrogenic
	Store in a cool, dry place
STERILE R	Sterilized by radiation (shelf box)
STERILE R	Sterilized by radiation (pouch)
	Inside diameter
MAX GW	Maximum recommended guidewire
	Manufacturer
EU REP	EU authorized representative
	Contains a medicinal substance
BIO	Contains a biological substance
	Maximum guide wire diameter
DEHP	Does not contain DEHP
	Contents of packaging
RBP	Rated Burst Pressure
NP	Nominal Inflation Pressure
IS R	Minimum inside diameter of compatible introducer sheath

16. MANUFACTURER

Manufacturer

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