

ER-REBOA™ Catheter

Instructions for Use

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U.S. and Foreign Patents Pending

ER-REBOA™ CATHETER

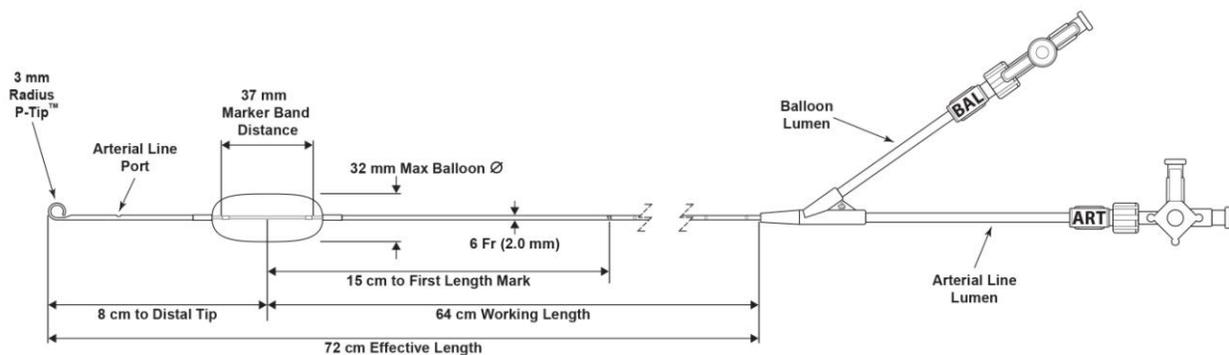
CAUTION:

- USA Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- Prior to use, read this entire Instructions for Use.

DEVICE DESCRIPTION:

The ER-REBOA™ Catheter is a large vessel occlusion catheter. The device consists of an atraumatic distal tip (P-tip™), a compliant occlusion balloon and catheter shaft with a built-in central lumen for blood pressure monitoring. The catheter has a uni-body design and is not compatible with a guidewire. The catheter contains two lumens which traverse the length of the catheter and connect to extension lines with stopcocks. The balloon lumen is used to inflate and deflate the balloon. The arterial line lumen is used to monitor blood pressure. Radiopaque marker bands are located on the catheter at the balloon to assist with positioning under fluoroscopy. A peel-away sheath is pre-loaded on the catheter shaft to ease insertion of the catheter's P-tip™ into an introducer sheath hemostasis valve.

Figure 1: ER-REBOA™ Catheter



INTENDED USE:

The ER-REBOA™ Catheter is intended for temporary occlusion of large vessels and monitoring of blood pressure.

CONTRAINDICATIONS:

The ER-REBOA™ Catheter is contraindicated for patients who:

- have known allergic reactions to contrast media
- do not have a femoral arterial access site that can accommodate a 7 Fr (minimum) introducer sheath
- have an aortic diameter larger than 32 mm
- are minors (younger than 18 years old)
- are pregnant

COMPATIBILITY:

The ER-REBOA™ Catheter is intended to be used with a 7 Fr or larger introducer sheath. Confirm compatibility with a selected introducer sheath before inserting the introducer sheath into a patient. The ER-REBOA™ Catheter has been confirmed to be compatible with the following 7 Fr introducer sheaths:

- Medtronic Input® Introducer Sheath – 7 Fr
- Cordis Avanti®+ Sheath Introducer – 7 Fr
- Terumo® Pinnacle R/O II Radiopaque Marker Introducer Sheaths – 7 Fr
- Arrow Super Arrow-Flex® Sheath Introducer – 7 Fr

WARNINGS:

- Do not exceed maximum inflation volume. Adhere to the balloon inflation parameters outlined in the Balloon Compliance Chart (Table 1). Over-inflation may result in damage to the vessel wall and/or vessel rupture, and/or balloon rupture.
- Hand inflation using a 30 cc syringe is recommended. Do not use a pressure inflation device to inflate the balloon. Use of such a device may result in damage to the vessel wall and/or vessel rupture, and/or balloon rupture.
- Do not use a power injector to inject fluid through the arterial line lumen. Damage to the catheter and/or vessel may occur.
- The arterial line lumen must be flushed prior to inserting into the introducer sheath. Failure to flush the arterial line may result in air embolism and/or poor arterial pressure monitoring. If arterial line lumen becomes occluded, do not force injection or withdrawal of fluids.
- Do not attempt to pass the catheter through an introducer sheath smaller than 7 Fr. Damage to the catheter and/or vessel may occur.
- Do not attempt to insert a guidewire into the catheter. Damage to the catheter and/or vessel may occur.
- The balloon must be flushed prior to inserting into the introducer sheath. Failure to do so may cause an air embolism in the case of balloon rupture.
- The balloon must be fully deflated and the stopcock closed prior to inserting the catheter into the introducer sheath. Failure to do so may make it difficult to insert/advance the catheter.
- The balloon must be fully deflated with the stopcock closed before removing the catheter. Failure to do so may make it difficult or impossible to remove the catheter from the introducer sheath and/or vessel.
- Do not use the ER-REBOA™ Catheter for dilation of vascular prostheses. Damage to the vessel and/or balloon rupture may occur.
- Do not use the ER-REBOA™ Catheter as a valvuloplasty/angioplasty balloon catheter.
- The ER-REBOA™ Catheter is supplied sterile and for single use only. Do not reprocess or re-sterilize. Attempting to re-sterilize and/or reuse may increase the risk of patient infection and may compromise the integrity of the device.
- Use fluoroscopy when manipulating (i.e. advancing, positioning, inflating, deflating, or removing) the catheter.
- Use the recommended balloon inflation medium. Do not use air or any gaseous medium to inflate balloon.
- Device is intended for temporary applications. Long term or permanent application of this device may cause harm.

PRECAUTIONS:

- Prolonged duration of occlusion may result in serious injury or death.
- Do not cut, trim or modify catheter or components prior to placement.
- Only physicians who are trained in vessel occlusion with compliant balloon catheters and have training or experience with balloon catheters and invasive blood pressure monitoring should consider using this device.
- Balloon rupture may occur under certain anatomical, procedural and/or clinical circumstances.
- Do not use the catheter for the treatment of dissections.
- Care should be taken when inflating the balloon in the vessel, particularly when inflating in calcified, stenotic, and/or otherwise diseased vessels.
- Carefully inspect the package and catheter prior to use to verify no damage occurred during shipment or storage. Do not use the catheter if the package or catheter is damaged as the sterility or integrity of the device may be compromised and thus increases the risk of patient infection and device malfunction.
- Do not use after labeled expiration date.
- If an obstruction in the vessel prevents or resists advancement of the catheter, do not force catheter past the obstruction. Remove the catheter and use an alternative treatment.
- Do not exceed more than 10 inflation/deflation cycles of the balloon.
- The balloon is highly compliant. Inflate the balloon slowly to avoid over-inflation.
- The balloon should be observed using fluoroscopy at all times during balloon inflation.
- Carefully monitor the patient's blood pressure throughout the procedure.
- Preparations should be made and a trained surgical team should be available in the event that conversion to open surgery is required.

POTENTIAL ADVERSE EVENTS:

Possible clinical complications associated with this type of procedure include, but are not limited to, the following:

- Vessel dissection, perforation, rupture or injury
- Occlusion at some locations may cause arrhythmia
- Paresthesia
- Contrast reactions
- Infection, hematoma and/or pain at insertion site
- Insertion site infection/hematoma
- Cardiac events
- Respiratory failure
- Hemorrhage
- Stroke
- Aneurysm rupture
- Renal complications
- Arterial thrombosis and/or embolism
- Paralysis
- Ischemia
- Death

RECOMMENDED ITEMS:

Each ER-REBOA™ Catheter package includes a single-use, sterile, disposable balloon catheter and a pre-installed peel-away sheath on the catheter shaft. The peel-away sheath is used to straighten the P-Tip™ for insertion into the introducer sheath.

Note: The ER-REBOA™ Catheter is designed to be used WITHOUT a guidewire.

Note: Length marks on the catheter shaft are measurements in centimeters from the middle of the balloon.

Materials required but not provided are:

- Introducer sheath (7 Fr minimum)
- 20-35 cc syringe (30 cc suggested)
- Inflation medium
 - 3:1 diluted contrast solution (75% sodium chloride (saline) / 25% contrast media (recommended)), or
 - Sodium Chloride (saline)
- Method/device for securing catheter to patient's leg
- Vital signs monitor with external pressure monitoring sensor and appropriate pressure monitoring extension tubing

Note: It is also recommended that a freely-angled C-arm or fixed imaging system with high resolution fluoroscopy be used during the procedure.

INSTRUCTIONS FOR USE:

Balloon Preparation

Note: The balloon and balloon lumen of the ER-REBOA™ Catheter contain air. Air must be removed from the balloon and balloon lumen prior to insertion using standard techniques.

1. Prepare the balloon lumen with inflation medium as follows:
 - a. Attach syringe with appropriate amount inflation medium and open the stopcock on balloon lumen.
 - b. Purge all air from the balloon using standard techniques.
 - c. Completely deflate the balloon and close the stopcock.
 - d. Disconnect the syringe and purge air from the syringe. Refill the syringe with up to 24 cc (maximum inflation volume) of inflation medium and reconnect the syringe.
2. Slide the peel-away sheath towards the catheter distal tip to fully enclose and straighten the P-tip™.

Note: The outside of the balloon may be wetted with saline to facilitate advancement of the peel-away sheath over the balloon. The peel-away sheath may also be rotated as it is slid over the balloon.

Note: The entire P-tip™ should be contained within the peel-away sheath to facilitate insertion into the introducer sheath.

Pressure Monitoring Lumen Preparation

3. Connect the pressure sensor and extension tubing (optimal length 48" (122 cm) or shorter) using standard techniques to the catheter's arterial line 3-way stopcock. Flush the ER-REBOA™ arterial line with saline using standard techniques, readying the device for pressure transduction.

Note: The pressure monitoring lumen should only be flushed AFTER the peel-away sheath is slid distally to straighten the P-tip™.

Note: Pressure monitoring capability of the ER-REBOA™ Catheter is independent of balloon function.

Balloon Introduction and Inflation

4. Insert the peel-away sheath and catheter into the 7 Fr (or larger) introducer sheath approximately 5mm or until the peel-away sheath hits a stop. Do not advance the peel-away sheath any further. Advance the catheter 10-20 cm into the introducer sheath, then slide the peel-away sheath toward the catheter hub. If necessary for full advancement, pull tabs to separate the peel-away sheath from the catheter shaft.

Note: Do not allow the entire peel-away sheath to enter into the introducer sheath. The peel-away sheath is intended only to temporarily open the valve of the introducer sheath to facilitate introduction of the catheter tip.

5. Under fluoroscopy and using standard technique, advance the catheter to the desired position using radiopaque indicators.

Note: If resistance is encountered when advancing the catheter, do not advance the catheter any further. Withdraw the catheter and pursue alternate treatment.

6. Refer to the balloon inflation parameters table (Table 1) as a guide. Do not exceed maximum inflation volume. Over-inflation of the balloon may result in damage to vessel wall and/or vessel rupture and/or balloon rupture.

Table 1: Balloon Inflation Parameters

Balloon Diameter	Inflation Volume
15 mm	5 cc
20 mm	8 cc
25 mm	13 cc
30 mm	20 cc
32 mm (MAX)	24 cc (MAX)

7. Under fluoroscopy, carefully inflate the balloon with inflation media. Monitor the pressure feedback on the syringe plunger while inflating the balloon. Do not force excessive fluid into the balloon as this may cause the balloon to become over-inflated. Over-inflation of the balloon may result in damage to vessel wall and/or vessel rupture and/or balloon rupture.

Note: If balloon pressure is lost and/or balloon rupture occurs, deflate the balloon and remove the catheter and introducer sheath as a unit.

8. Secure the catheter to the patient appropriately using standard techniques to prevent device migration.

Balloon Deflation, Withdrawal and Removal

9. Completely deflate the balloon by opening the balloon stopcock and drawing a vacuum using the syringe. Verify that the balloon is fully deflated using fluoroscopy. Close the stopcock.

Note: Allow adequate time for the balloon to completely deflate (i.e. confirm that inflation medium is no longer re-entering the syringe before closing the stopcock and releasing the vacuum).

10. Disengage or detach the method/device used to secure the catheter to the patient.
11. Carefully withdraw the catheter until the catheter has been completely removed from the introducer sheath using standard techniques. The catheter may be rotated during withdrawal to ease removal through the introducer sheath.

Note: If difficulty is encountered when removing the catheter, remove the catheter and sheath as a unit.

12. Remove introducer sheath and close access site using standard techniques.
13. After use, the device may be a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

HOW SUPPLIED

This catheter is supplied sterile by ethylene oxide gas in a peel-open package. It is intended for single use only. Package is sterile if unopened or undamaged. Do not use this product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

DEFINITIONS



Read the Instructions for Use before using this product.



Store the product appropriately in a cool, dry location.



Product is non-pyrogenic.



Do not re-sterilize this product.



Do not reuse this product.



This product has been sterilized using Ethylene Oxide.

R_x ONLY

USA Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).



The content is sterile if the package is unopened or undamaged. Do not use if package is damaged.