

# MINIMALLY INVASIVE SOLUTION FOR TEMPORARY OCCLUSION OF LARGE BLOOD VESSELS



## ER-REBOA™ Catheter

### Value Analysis Committee – Product Information Kit

Resuscitative Endovascular Balloon Occlusion of the Aorta



# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

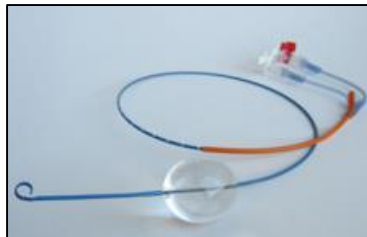
### EXECUTIVE SUMMARY

#### Clinical Need

- Hemorrhage is the leading cause of death in civilian and military trauma.<sup>3-8</sup>
- Bleeding is shown as a major contributor to trauma deaths and the leading cause of potentially preventable death.<sup>7,8</sup>
- REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta) is a method to temporarily occlude large blood vessels, however existing balloon catheters have many limitations.

#### Our Solution

- The ER-REBOA™ Catheter technology was designed by trauma surgeons for use in the Emergency and Critical Care environment to overcome limitations with existing techniques and technology.



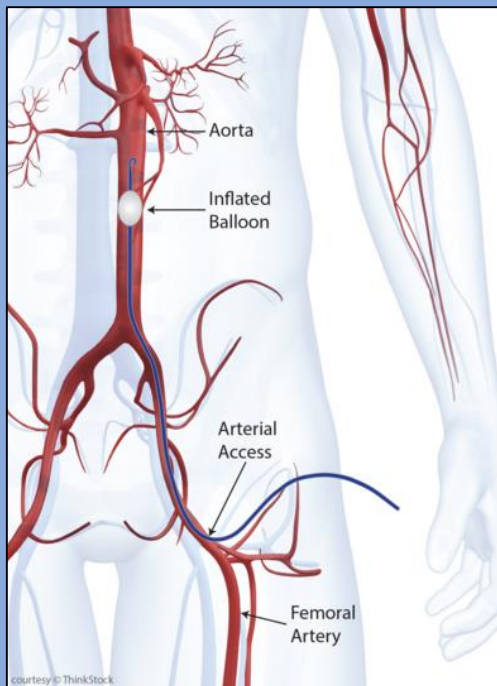
#### Potential Impact

- Small 7 Fr size, designed to eliminate the need for surgical repair at the access site when compared to larger catheters. This could result in less OR time needed for surgical closure, reduced patient morbidity, fewer access site complications, and better patient outcomes
- Designed for easy and fast placement of balloon, in fewer steps and with no need for guidewires.
- Designed to reduce amount of blood products needed.

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

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# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### CLINICAL NEED



- No one should bleed to death. Yet hemorrhage is the leading cause of potentially survivable death in civilian and military trauma.<sup>3-8</sup>
- As a particularly vexing example, Non Compressible Torso Hemorrhage (NCTH) is defined as hemorrhage arising from trauma to the torso vessels, pulmonary parenchyma, solid abdominal organs, and/or disruption of the bony pelvis resulting in hypotension or shock.<sup>1,2</sup> It is often called 'truncal hemorrhage' for brevity.
- Truncal hemorrhage is of particular interest, because there are limited clinical options to temporarily occlude large vessels during truncal hemorrhage.
- 70% of deaths in the military setting are caused by exsanguination from truncal injuries, of which 90% occur before hospital admission.<sup>6</sup> The civilian experience is similar.<sup>7,8</sup>
- Accordingly, there is significant clinical interest in devices and techniques which may eliminate these potentially survivable deaths.

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### Previous Solutions

For decades, open resuscitative aortic occlusion was used for temporary occlusion of large vessels in the setting of noncompressible torso hemorrhage. Open resuscitative aortic occlusion increases after-load and central aortic pressure until hemostasis can be achieved.

However, this maneuver is extremely invasive and has a very low survival rate. It requires thoracotomy and aortic clamping, which relegates it as a reactive, often last resort procedure performed after the loss of pulses.<sup>1</sup>

Recently, development of external clamping and compression devices for certain truncal injuries has occurred, and show promise.<sup>9</sup> However, these devices do not address the entire range of noncompressible torso hemorrhage injury patterns.

**"Save one life - that is all I ask."  
- Dr Lorne Blackbourne (Army Trauma Surgeon)**





# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### The Search for New Solutions



In an attempt to find a therapy of use in a broad range of hemorrhage situations, there has been a reappraisal of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an alternative to other methods.<sup>10</sup>

Unlike thoracotomy, REBOA is performed in a series of less invasive steps beginning with transfemoral arterial access and pressure monitoring. As such, REBOA provides a proactive and minimally invasive approach to temporarily occluding large vessels. Temporarily occluding hemorrhage can allow for aortic control to support the central circulation of patients at imminent risk of cardiovascular collapse.<sup>10,11</sup>

Emerging evidence demonstrates the benefits of REBOA during shock, with occlusion time of up to 60 minutes generating a significant but survivable metabolic penalty.<sup>12,13</sup>

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### REBOA PROCEDURE – USING EXISTING TECHNOLOGIES

#### Background

- Resuscitative aortic occlusion with a balloon was reported as early as the Korean War and has been described in more recent publications.<sup>15–18</sup>
- Despite potential advantages over thoracotomy with aortic clamping, resuscitative endovascular balloon occlusion of the aorta (REBOA) for trauma has not been widely adopted.
- Broader application of this procedure may have lagged because of latent technology, a poorly understood skill set, or anticipated ineffectiveness of the technique.

#### Potential Hazards with Existing Technologies<sup>19</sup>

- Existing catheters suitable for REBOA have large diameters which require surgical repair at the access site.
- They require multiple wire exchanges, costing precious time.
- They have long protruding wires which are not ideal for emergency situations. Wire movement after placement risks arterial injury, and maintaining sterility is difficult.
- They lack integrated above balloon pressure monitoring capability.
- Over inflation of balloon may cause damage to aortic wall.
- Migration of balloon, sheath, and wire.

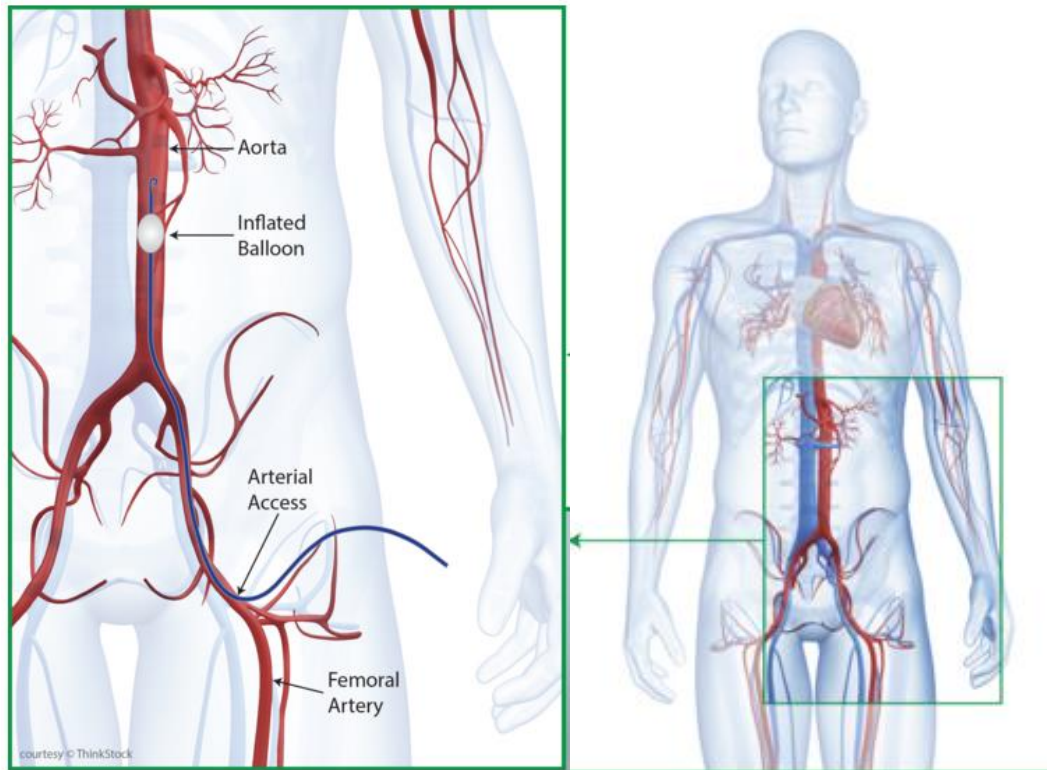
# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### REBOA PROCEDURE – USING ER-REBOA™



- Designed by trauma and vascular surgeons for the emergency and critical care setting to overcome limitations with existing techniques and technology
- A rapidly deployable, low-profile aortic occlusion system
- Small 7 Fr size, designed to preclude the need for additional surgical repair at the access site<sup>19</sup>





# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### PRODUCT OVERVIEW



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

Designed by trauma and vascular surgeons for the emergency and critical care settings to overcome limitations with existing techniques and technology.


ER-REBOA is a rapidly deployable, low-profile aortic occlusion system covering multiple attractive performance characteristics:

- ✓ Integrated A-line for above balloon pressure monitoring
- ✓ Soft, atraumatic P-Tip™ (Patent Pending)
- ✓ One pass, guidewire-free
- ✓ Compliant balloon
- ✓ 7 Fr sheath compatible

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### 510(k) Clearance and Indications For Use

	DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service Food and Drug Administration 10903 New Hampshire Avenue Document Control Center - N056-G009 Silver Spring, MD 20993-0002
October 23, 2015	
Pryor Medical Devices, Inc % Semih Oktay, PhD President CardioMed Device Consultants, LLC 5523 Research Park Dr #205 Catonsville, MD 21228	
Re: K151821 Trade/Device Name: ER-REBOA Catheter Regulation Number: 21 CFR 870.1250 Regulation Name: Percutaneous Catheter Regulatory Class: Class II Product Code: DQY, DQO Dated: September 22, 2015 Received: September 23, 2015	
Dear Dr. Oktay:	
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.	
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <a href="#">Federal Register</a> .	
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR	

Page 2 - Semih Oktay
Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a> . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.
You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a> .
Sincerely yours,  Kenneth J. Cavanaugh -S for Bram D. Zuckerman, M.D. Director Division of Cardiovascular Devices Office of Device Evaluation Center for Devices and Radiological Health
Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES Food and Drug Administration	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
Indications for Use	
510(k) Number (if known) K151821	
Device Name ER-REBOA Catheter	
Indications for Use (Describe) The ER-REBOA Catheter is intended for temporary occlusion of large vessels and monitoring of blood pressure.	
Type of Use (Select one or both, as applicable) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
CONTINUE ON A SEPARATE PAGE IF NEEDED.	
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FORM FDA 3881 (8/14)	Page 1 of 1

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### INSTRUCTIONS FOR USE



#### ER-REBOA™ Catheter

#### Instructions for Use

Pryor Medical Devices, Inc.  
229 N. Main Street  
Boerne, TX 78006, USA  
[feedback@pryormedical.com](mailto:feedback@pryormedical.com)  
[www.pryormedical.com](http://www.pryormedical.com)

US 1-210-340-0116

U.S. and Foreign Patents Pending

P/N 7001-01 Rev A

Nov. 3, 2015

#### 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

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##### 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 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.

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# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### INSTRUCTIONS FOR USE - Continued

#### 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

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#### 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.

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#### 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.

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# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### INSTRUCTIONS FOR USE - Continued

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

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

#### Balloon Deflation, Withdrawal and Removal

- 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).

- Disengage or detach the method/device used to secure the catheter to the patient.
- 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.

- Remove introducer sheath and close access site using standard techniques.
- 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.

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Do not re-sterilize this product.



Do not reuse this product.

STERILE EO

This product has been sterilized using Ethylene Oxide.

**Rx 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.

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# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### HOSPITAL ECONOMICS – OVERVIEW

Improving care for patients needing temporary occlusion of large vessels has many potential clinical benefits and also potential cost-offsets to the hospital. Below are some potential categories of cost to consider when evaluating ER-REBOA.

#### Supply costs

- Existing technologies requires a balloon, guidewires, sheaths, A-Line, sutures, and closure devices or surgical repair at the access site<sup>19</sup>

#### Blood product costs

- Hemorrhage can result in significant blood loss, speed when stopping bleeding is critical. Studies show blood product costs can range from \$200 to 300 per unit.<sup>20</sup> Massive transfusion patients can require upwards of 50 units of blood products<sup>22</sup>

#### Access site repair

- Surgical site repair of large femoral access openings can require significant operating room time and increase risk for complications.<sup>21</sup>

#### Access site complications

- Large bore femoral access sites have major complication rates of 6% to 10%<sup>21</sup>

#### Trauma team & ER costs

- Trauma teams are highly skilled and costly. Average charges to activate a trauma team can range from \$800 to \$24,000<sup>23</sup> Throughput and ER utility improves with reduced time required.

#### Trauma team training time

- Training trauma teams on existing technologies can be costly



# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### ER-REBOA COST EFFECTIVENESS – SAVINGS WORKSHEET

Actual	Typical	Calculations	Backup / Assumptions***
			Key Assumption: Stopping bleeding sooner is better.
	\$ 450	Cost of off label / alternate catheter	Assume 8 REBOA cases per month = 96 per year
	\$ 45	+ Cost of current guidewire	Assume improved speed will reduce blood use, incidence of MT, and reduce patient morbidity and mortality. <sup>8,24</sup>
	\$ 25	+ Cost of A-Line	Assume reduced catheter size will reduce access site repair entirely compared to larger catheters, thereby reduce morbidity at access site <sup>19</sup>
	\$ 25	+ Sutures for access site repair	
	\$ 125	+ Closure devices and/or vascular patch for access site	
	\$ 670	<b>= SAVINGS per procedure</b>	
		Fewer blood products used:	Type/amount of blood products used varies clinically, assume \$250 per
	\$ 250	Whole blood, PRBCs, FFP, Cryo precip, Factor VII, TXA, etc	Assume ave 1 less unit of blood product per patient. <sup>25, 26</sup>
			Additionally, assume 1 less MT every 48 REBOA procedures (6 months).
	\$ 260	+ Less blood required for Massive Transfusion (MT):	Extreme MT can require 50+ units <sup>22</sup> . 50 units*\$250*2/98 REBOA per yr = \$260 saved per procedure on MT blood.
	\$ 510	<b>= SAVINGS per procedure</b>	
	\$ 400	Reduction in operating room time	Assume Fully loaded cost per minute of OR time = \$20 <sup>19</sup> . Assume average operative arteriotomy/repair = 20 min 20 min X \$20/hr = \$400
	\$ 180	+ Reduced off hour vascular surgery consults	After hours Vascular consult @300/hr * min 1 hr @ 60% of REBOA cases occurring during peak trauma times (off hours) = \$300 *.6 = \$180
	\$ 580	<b>= SAVINGS per procedure</b>	
		Reduction in major access complications	REBOA-ER designed for no need for access site closure. Access site closure major complications range from 6-10% <sup>21</sup> . Assume 96 REBOA cases per year (8 per mo), avoid 6% x 96 = 5.76 infections or other complication x 3 ICU days @ \$8500 per day <sup>23</sup> = \$25,500 *5.76 / 96 = \$1530
		X Cost per Complication	
		/ total cases	
	\$ 1,530	<b>= SAVINGS per procedure</b>	
		Reduction in training hours	Assume REBOA with old technology requires more Trauma team training.
		X Cost per Hour / total cases	Assume 1 hr of training reduces x 10 staff x \$100/hr div by 98 cases per year = \$10.20
	\$ 10	<b>= SAVINGS per procedure</b>	
		Reduction in massive transfusion rate means less TRALI	Avoiding even one case of TRALI saves entire cost of new catheters <sup>24</sup> . Calculate as % of total REBOA cases. Assume 2 MT cases per year avoided. 1 in 4 MT cases have additional major complications = 1 less TRALI per every 2 years. = \$50,000 / 2 / 98 cases = \$255 per case
	\$ 255	<b>= SAVINGS per procedure</b>	
	\$ 3,555	<b>= Cumulative SAVINGS per procedure</b>	<b>A + B + C + D + E + F</b>
	\$ 350	<b>Cost per new catheter</b>	
	\$ 1,560	<b>TOTAL savings using new catheter per procedure</b>	

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

### COST EFFECTIVENESS – SAVINGS WORKSHEET

#### ER-REBOA Additional potential savings not calculated above:

##### Value Driver:

##### Value Details:

##### Clinical Value

Reduced need for fluoroscopy	No guidewire, so less fluoro for placement
Reduce downstream ischemia	Reduce ischemia in major arteries
Reduced guidewire movement injury	Reduce potential adverse events from guidewire movement
Reduce access site pain	Patient recovery / satisfaction from smaller access site

##### Staff Value

Reduce need for Fluoroscopy	Potential impact on physicians and staff
ER Workflow	Reduce long wire hassle / Improve ER workflow and throughput
Trauma Team	Improve solutions available to trauma team
Physician preference	Staff satisfaction

##### Strategic Value

Trauma center image	Adopting latest technology offers marketing opportunity for trauma centers
ER Workflow	Reduce ER wait times for other patients / improve utilization
Simplify procedure	Less skilled staff able to perform / support procedure



# ER-REBOA™ Catheter

Future of Care for Temporary Occlusion of Large Vessels

## ORDERING INFORMATION

Product Name:	ER-REBOA™ Catheter
Product Code/ Catalog Number:	ER7232A
List Price:	\$1995

### For Ordering Info:

Phone 210.340.0116

Email [sales@prytimemedical.com](mailto:sales@prytimemedical.com)

# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

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# ER-REBOA™ Catheter

## Future of Care for Temporary Occlusion of Large Vessels

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## **ER-REBOA™ Catheter**

### **Instructions for Use**



Pryor Medical Devices, Inc.  
229 N. Main Street  
Boerne, TX 78006, USA



[feedback@pryormedical.com](mailto:feedback@pryormedical.com)  
[www.pryormedical.com](http://www.pryormedical.com)



US 1-210-340-0116

U.S. and Foreign Patents Pending

# ER-REBOA™ CATHETER

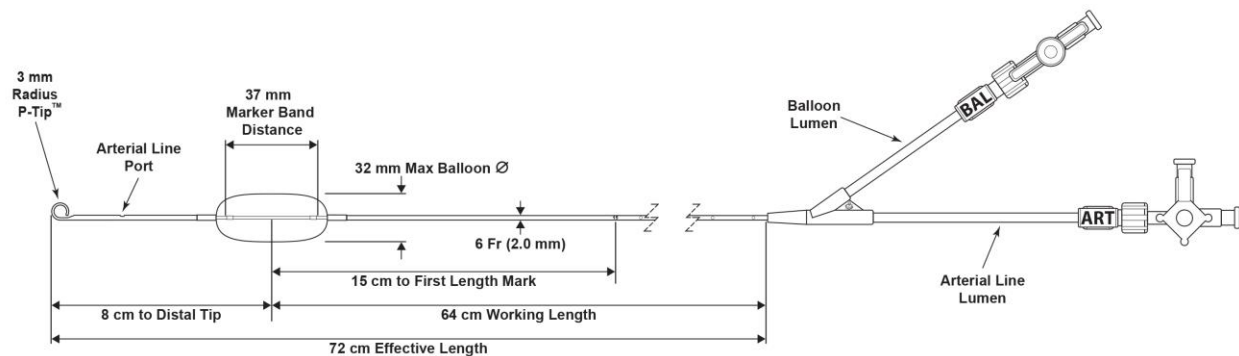
## CAUTION:

- 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<sub>x</sub> ONLY**

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

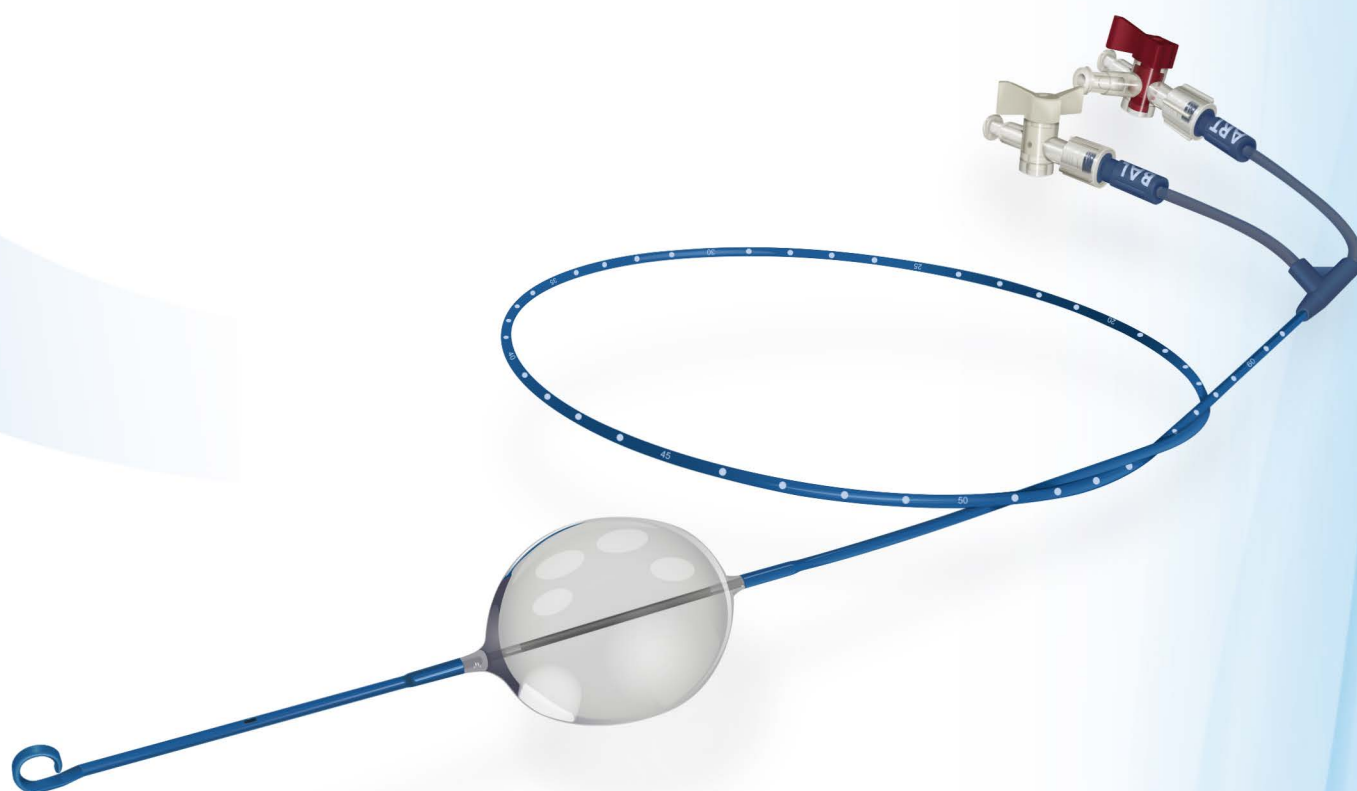


The content is sterile if the package is unopened or undamaged. Do not use if package is damaged.



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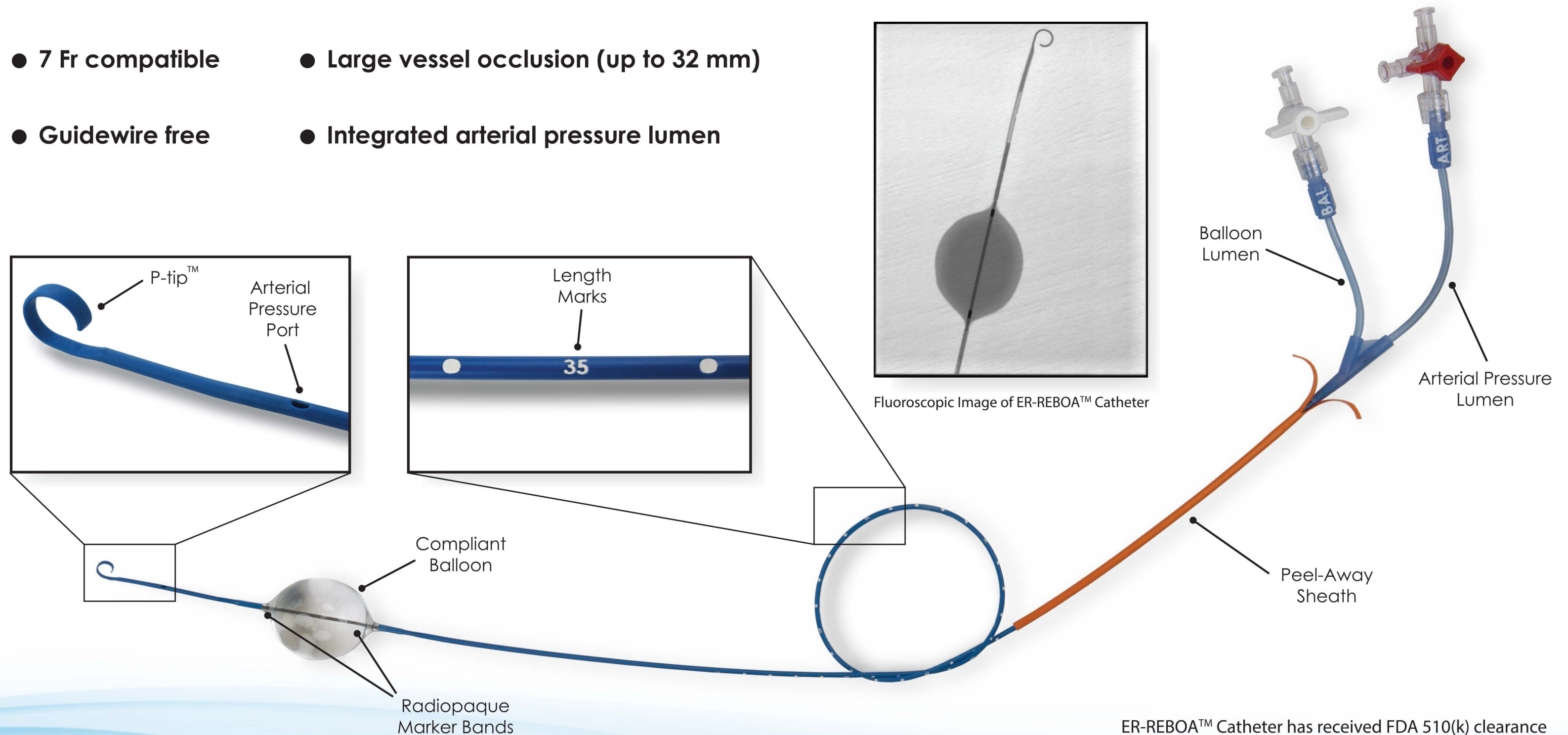
**ER-REBOA™**  
CATHETER

[www.prytimemedical.com](http://www.prytimemedical.com)



# ER-REBOA™ CATHETER

- 7 Fr compatible
- Large vessel occlusion (up to 32 mm)
- Guidewire free
- Integrated arterial pressure lumen



ER-REBOA™ Catheter has received FDA 510(k) clearance

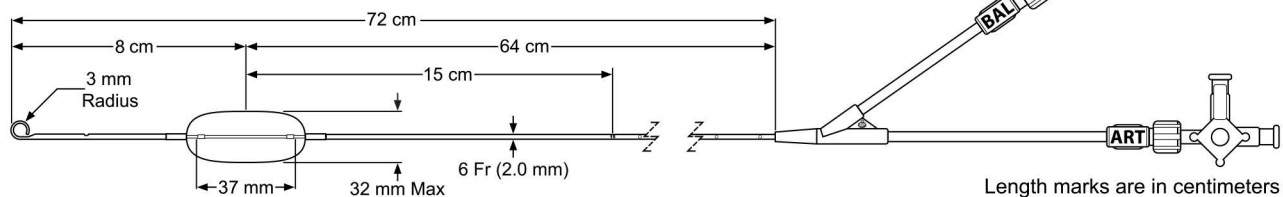


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Contact us at **1-210-340-0116** or [info@prytimemedical.com](mailto:info@prytimemedical.com)

## ER-REBOA™ Catheter



**US and Foreign Patents Pending**



**PRYTIME**MEDICAL™

The REBOA Company™

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# Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock

REBOA is used for temporary aortic occlusion in traumatic hemorrhagic shock. REBOA supports proximal aortic pressure and minimizes hemorrhage until hemorrhage control and definitive hemostasis are obtained.

## REBOA Steps:

### 1. Arterial access and Sheath Placement

- Ultrasound-guided common femoral arterial access with Micropuncture kit (21 gauge needle, 4 or 5 French catheter and dilator, 0.018 inch guidewire)
- Or Cook single lumen arterial line; or Femoral artery cut-down, proximal/distal control for direct puncture
- Insert 7-French Sheath (can upsize arterial line)

### 2. Balloon selection and positioning

- ER-REBOA catheter (32mm max balloon diameter)
- Flush ER-REBOA catheter with saline; connect arterial line to transduce while inserting
- Measure **sheath to P-tip distance** in cm REBOA:  
**Zone 1 approx 46 cm; Zone 3 approx 27cm**
- Zone 1 P-tip sternal notch, balloon mid-sternum; Zone 3 P-tip xiphoid, balloon at umbilicus**
- Insert ER-REBOA to pre-measured distance
- Digital Xray to confirm REBOA balloon location**

### 3. Balloon inflation

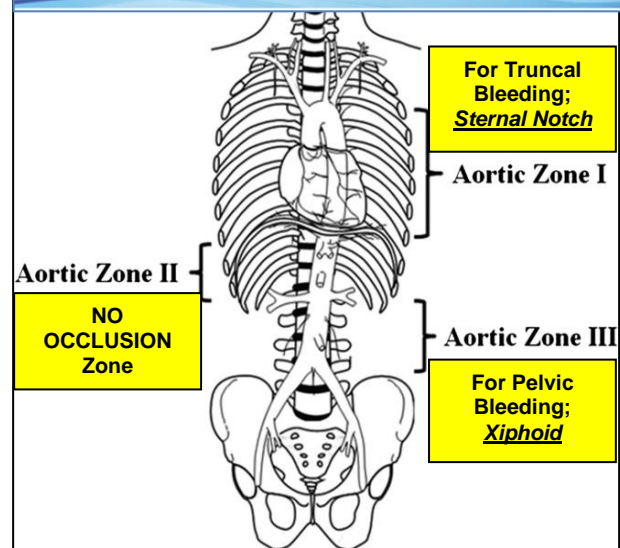
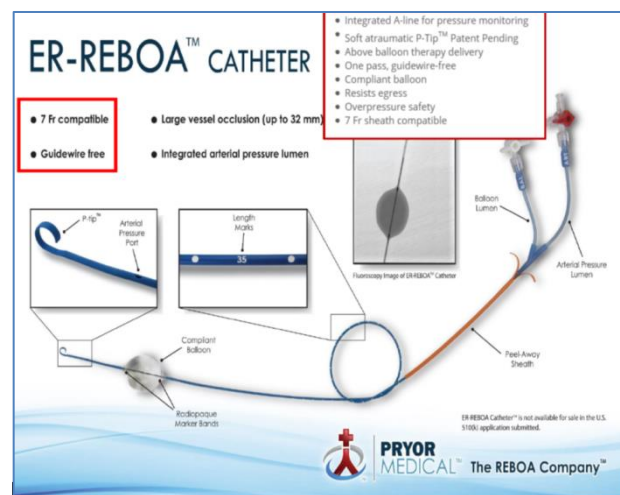
- Inflate balloon, tactile feedback
- Zone 1 8cc; Zone 3 2cc "2 or 8, don't overinflate"**
- 30cc syringe; NS or ½ NS/Contrast; Max 24cc
- Mark Inflation time**; Minimize balloon inflation time
- Suture catheter and sheath; transduce arterial line
- Go to OR or IR for definitive hemorrhage control**

### 4. Balloon deflation – Partial REBOA

- Intermittent deflation of REBOA (Partial-REBOA) can be used to optimize visceral perfusion, goal SBP > 90 mm Hg

### 5. Femoral Artery Sheath removal

- HD stable, normal coagulation, withdraw balloon saline w/ 30cc empty syringe
- 30 min digital pressure at sheath site, keep patient supine for 6 hrs, no hip flexion
- Femoral arterial duplex at 24-72 hrs to evaluate patency of femoral artery



## REBOA Intra-Aortic Balloon Placement for Hemorrhagic Shock

Balloon placement determined by injury/hemorrhage location:

**Zone 1** Descending Thoracic Aorta (origin of left subclavian to celiac) for truncal hemorrhage

**Zone 2** Para-visceral Aorta (celiac artery to lowest renal artery): **NO-OCCLUSION ZONE**

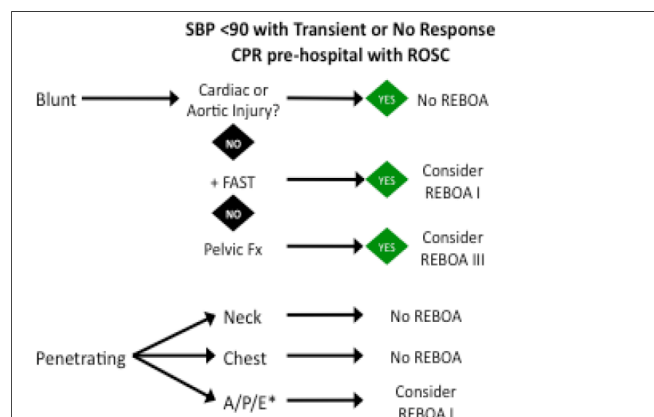
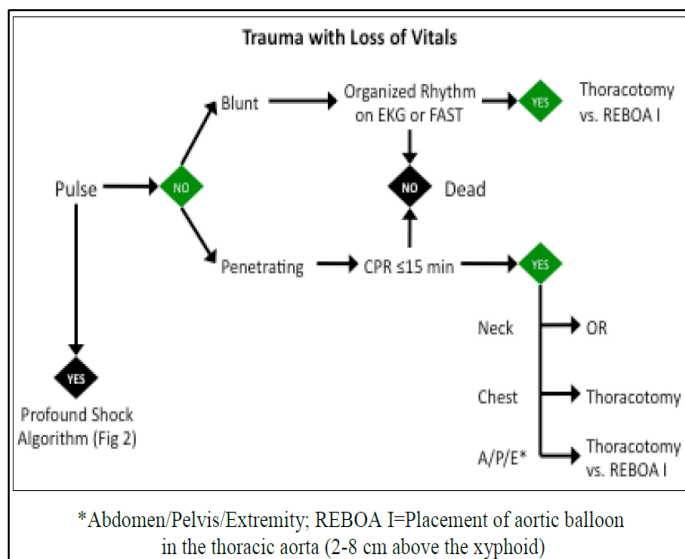
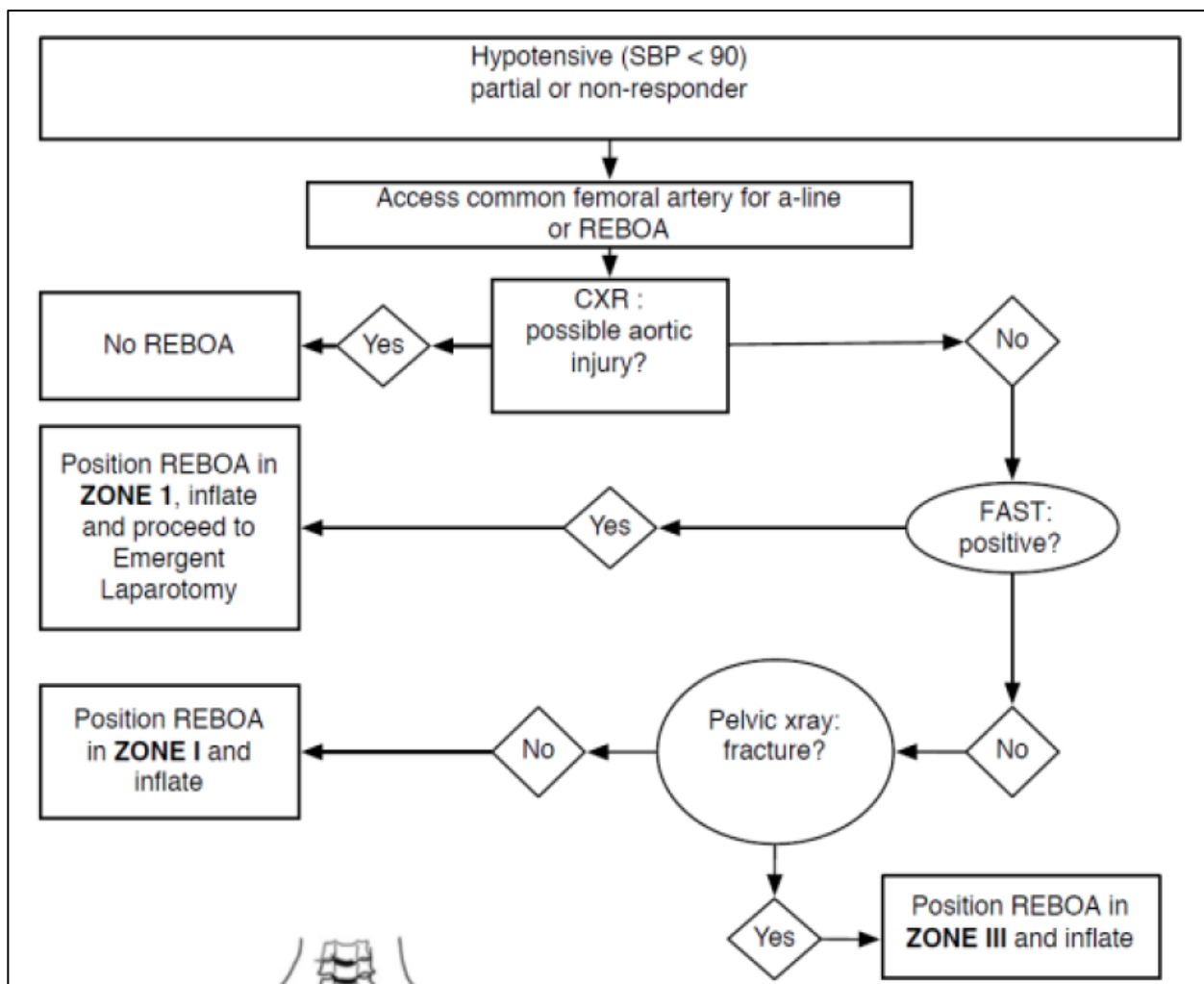
**Zone 3** Infra-renal Aorta (lowest renal artery to aortic bifurcation) for pelvic/junctional bleeding.

## References:

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- Johnson MA, Neff LP, Williams TK, DuBose JJ, et al. P-REBOA: Clinical technique & rationale. J Trauma 2016 Nov;92:S133.



# Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock



\*Abdomen/Pelvis/Extremity; ROSC, Return of Spontaneous Circulation; REBOA I Placement of aortic balloon in the thoracic aorta (2-8 cm above the xyphoid); REBOA III Placement of aortic balloon directly above the aortic bifurcation (1-2 cm above the umbilicus)

Joint Theater Trauma System Clinical Practice Guideline: REBOA for Hemorrhagic Shock.

[http://www.usaisr.amedd.army.mil/assets/cpgs/REBOA\\_for\\_Hemorrhagic\\_Shock\\_16Jun2014.pdf](http://www.usaisr.amedd.army.mil/assets/cpgs/REBOA_for_Hemorrhagic_Shock_16Jun2014.pdf)

# **REBOA**

## **Resuscitative Endovascular Balloon Occlusion of the Aorta**

- 11 blade – Disposable
- 30cc syringe
- 100ml bag .9NS
- Bag Decanter 10-102
- Conray 50ml
- Micropuncture Introducer Set 21g/4fr/.018 G47946
- Cordis Avanti 7fr Introducer sheath kit 402-607A
- Central Venous Catheter Set G01916
- ER-REBOA Catheter ER7232A
- 0 Silk #678
- Arrow 5fr Catheter Clamp with Fastener

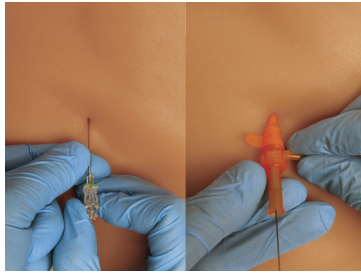
### **Nursing Instructions:**

1. Call Radiology 8-3636 or page 2465 for stat digital XRAY films of Chest/Abdomen.
2. Open all of the above items.
3. Decant Conray & .9NS – May use just .9NS or 1:1 Conray with .9NS
4. Replace Reboa kit with backup kit from POD III service lead office, between OR 18 and OR 19.  
Call Rochelle Crow 4-2531 or email [rkraus@med.umich.edu](mailto:rkraus@med.umich.edu) to replenish.

# The ER-REBOA™ Catheter Quick Reference Guide

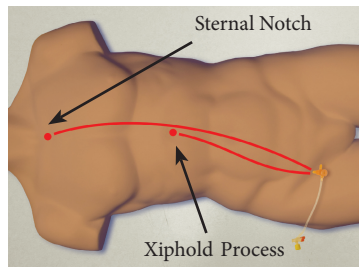
## 6 REBOA Steps: ME-FIIS (Pronounced ME-FIZZ)

### Get Access Early



Obtain access using standard techniques

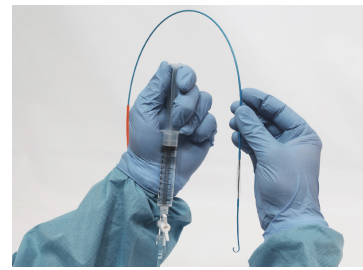
### 1. Measure



**Placement depth**<sup>1,2,3,4,5,6</sup>

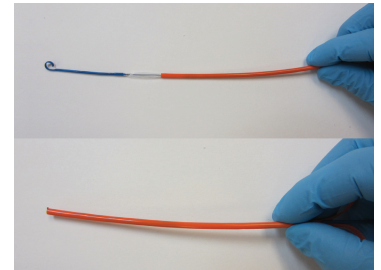
- Zone 1: Approximately 46 cm
- Zone 3 : Approximately 28 cm

### 2. Empty



**Flush & deflate balloon**

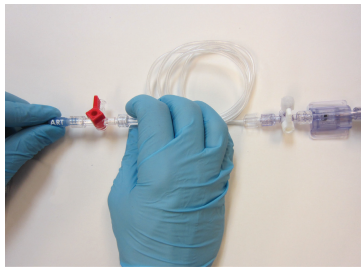
- Ensure balloon is fully deflated
- Hold vacuum for **5 seconds**
- Close stopcock with vacuum held



**Advance & twist peel-away to cover P-tip®**

- Ensure the balloon and P-tip® are captured

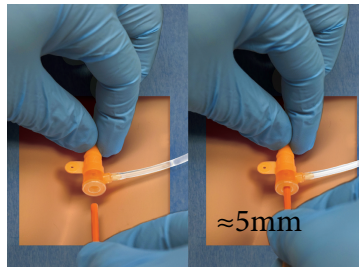
### 3. Flush



**Attach & flush arterial line**

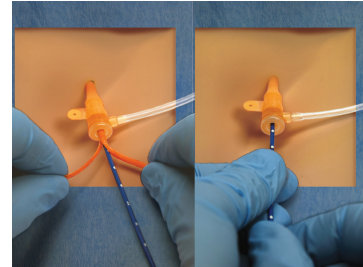
- Use standard techniques
- Ensure all air is purged

### 4. Insert



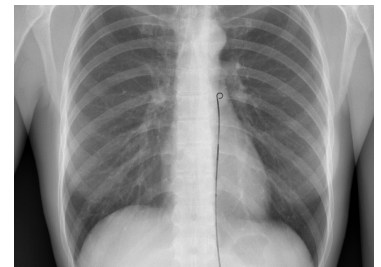
**Insert sheath into valve**

- Approximately 5 mm
- Insert into the common femoral artery



**Advance catheter into vessel**

- Hold orange sheath
- Advance blue Catheter
- Remove sheath after balloon passes valve



**Position catheter**

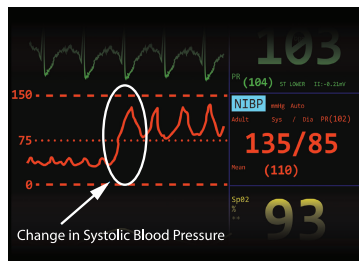
If available, use conventional x-ray or fluoroscopy to confirm position using radiopaque markers

### 5. Inflate<sup>1,2,3,4,5,6</sup>

Inflation Volume

**Zone 1** Start with 8 cc

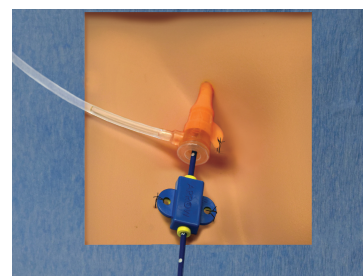
**Zone 3** Start with 2 cc



**Monitor arterial waveform feedback**

- Look for change in blood pressure above balloon
- Use other standard techniques

### 6. Secure



**Secure Catheter close to the introducer sheath**

### Provide Definitive Treatment



**Provide definitive hemorrhage control**

- Mark time of inflation
- The clock is ticking!
- Move quickly to definitive control

**Start small then check**

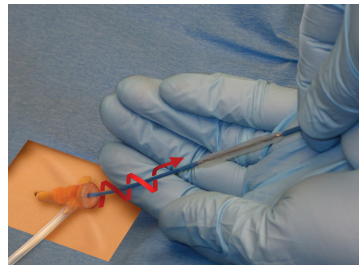
**"2 or 8, don't overinflate."**

### Remove



**Fully deflate balloon**

- Hold vacuum for **5 seconds**
- Close stopcock with vacuum held



**Remove catheter**

- Corkscrew twist the catheter to facilitate removal
- If necessary, remove catheter and introducer sheath as a unit

### Caution



**Check for full and equal pulse in each leg using your standard technique**


**PRYTME MEDICAL™**  
**The REBOA Company™**  
[www.prytimemedical.com](http://www.prytimemedical.com)

This instruction is not a replacement for the instruction for use (IFU). The ER-REBOA™ Catheter IFU should be read in its entirety before using the device

1. Joint Trauma System Clinical Practice Guideline (JTS CP) REBOA for Hemorrhagic Shock (CPG ID: 38)
2. Peay P, Flaris AN, Post NJ, Cotton F, Lundberg PW, Callot JL, David JS, Voiglio EJ. Fixed-Distance Model for Balloon Placement During Fluoroscopy-Free Resuscitative Endovascular Balloon Occlusion of the Aorta in a Civilian Population. JAMA Surg. 2016 Dec 14.
3. Linnebur M, Inaba K, Halmeier T, Rasmussen TE, Smith J, Mendelberg R, Grabo D, Demetriades D. Emergent non-image-guided resuscitative endovascular balloon occlusion of the aorta (REBOA) catheter placement: A cadaver-based study. J Trauma Acute Care Surg. 2016 Sep;81(3):453-7.
4. MacTaggart JN, Poulton WE, Akhtar M, Sees A, Thorson K, Phillips NY, Deyagova AS, Samensky AV. Morphometric roadmaps to improve accurate device delivery for fluoroscopy-free resuscitative endovascular balloon occlusion of the aorta. J Trauma Acute Care Surg. 2016 Jun;80(5):941-6.
5. Morrison JJ, Stannard A, Midwinter MJ, Sharon DJ, Eliaison JL, Rasmussen TE. Prospective evaluation of the correlation between torso height and aortic anatomy in respect of a fluoroscopy free aortic balloon occlusion system. Surgery. 2014 Jun;155(6):1044-51.
6. Stannard A, Morrison JJ, Sharon DJ, Eliaison JL, Rasmussen TE. Morphometric analysis of torso arterial anatomy with implications for resuscitative aortic occlusion. J Trauma Acute Care Surg. 2013 Aug;75(2 Suppl 2):S169-72.



## Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock

REBOA is used for temporary aortic occlusion in traumatic hemorrhagic shock. REBOA supports proximal aortic pressure and minimizes hemorrhage until hemorrhage control and definitive hemostasis are obtained.

### REBOA Steps:

#### 1. Arterial access and Sheath Placement

- Ultrasound-guided common femoral arterial access with Micropuncture kit (21 gauge needle, 4 or 5 French catheter and dilator, 0.018 inch guidewire)
- Or Cook single lumen arterial line; or Femoral artery cut-down, proximal/distal control for direct puncture
- Insert 7-French Sheath (can upsize arterial line)

#### 2. Balloon selection and positioning

- ER-REBOA catheter (32mm max balloon diameter)
- Flush ER-REBOA catheter with saline; connect arterial line to transduce while inserting
- Measure **sheath to P-tip distance** in cm REBOA:  
**Zone 1** approx 46 cm; **Zone 3** approx 27cm
- Zone 1** P-tip sternal notch, balloon mid-sternum;  
**Zone 3** P-tip xiphoid, balloon at umbilicus
- Insert ER-REBOA to pre-measured distance
- Digital Xray to confirm REBOA balloon location**

#### 3. Balloon Inflation

- Inflate balloon, tactile feedback
- Zone 1 8cc; Zone 3 2cc "2 or 8, don't overinflate"**
- 30cc syringe; NS or 1/4 NS/Contrast; Max 24cc
- Mark Inflation time**; Minimize balloon inflation time
- Suture catheter and sheath; transduce arterial line
- Go to OR or IR for definitive hemorrhage control**

#### 4. Balloon deflation - Partial REBOA

- Intermittent deflation of REBOA (Partial-REBOA) can be used to optimize visceral perfusion, goal SBP > 90 mm Hg

#### 5. Femoral Artery Sheath removal

- HD stable, normal coagulation, withdraw balloon saline w/ 30cc empty syringe
- 30 min digital pressure at sheath site, keep patient supine for 6 hrs, no hip flexion
- Femoral arterial duplex at 24-72 hrs to evaluate patency of femoral artery

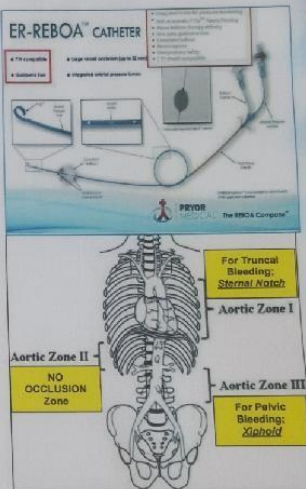
### REBOA Intra-Aortic Balloon Placement for Hemorrhagic Shock

Balloon placement determined by injury/hemorrhage location:

**Zone 1** Descending Thoracic Aorta (origin of left subclavian to celiac) for truncal hemorrhage

**Zone 2** Para-visceral Aorta (celiac artery to lowest renal artery): **NO-OCCLUSION ZONE**

**Zone 3** Infra-renal Aorta (lowest renal artery to aortic bifurcation) for pelvic/junctional bleeding.

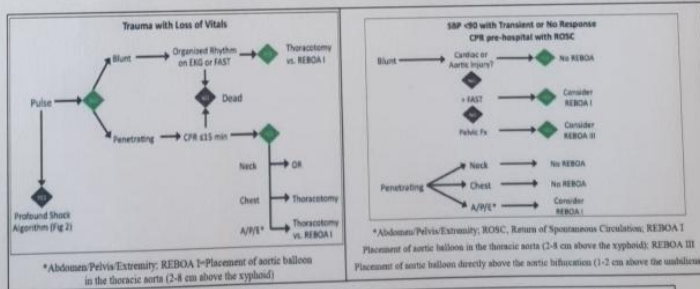
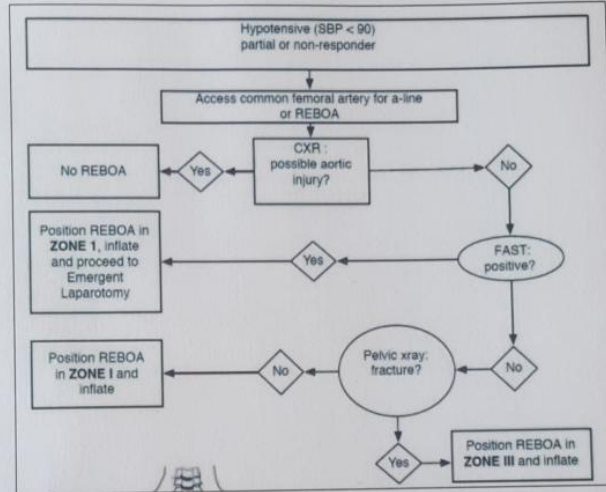


### References:

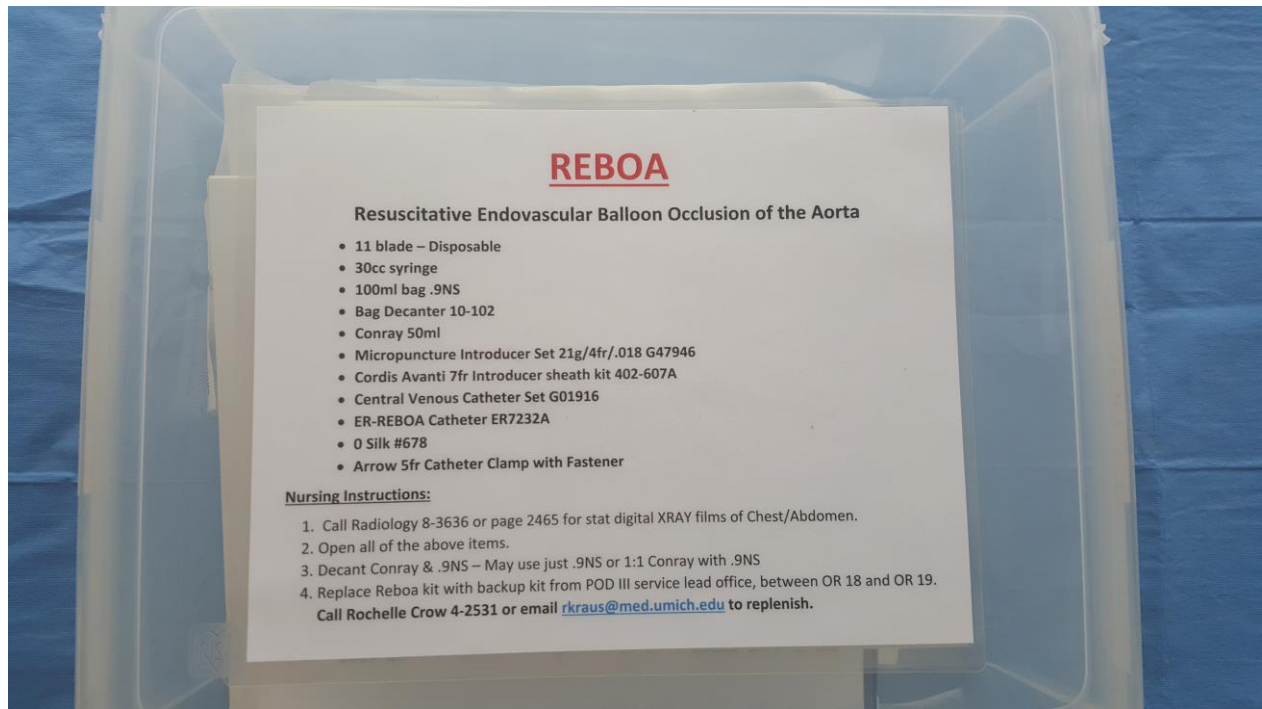
- Stannard A, Eliason JL, Rasmussen TE. REBOA as an adjunct for hemorrhagic shock. J Trauma. 2011 Dec;71(6):1869-72.
- Brenner ML, Moore LJ, Dubose JJ, Tyson GH, et al. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. J Trauma Acute Care Surg. 2013 Sep;75(3):506-511.
- Villamaria CY, Eliason JL, Napolitano LM, Stansfield B, Spencer JR, Rasmussen TE. An Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS™) Course: Curriculum Development, Content Validation and Program Assessment. American Association for the Surgery of Trauma. J Trauma Acute Care Surg. 2014 Apr;76(4):929-35.
- Dubose JJ, Scalea TM, Brenner M, et al. AAST AORTA Registry: Utilization/outcomes of REBOA. J Trauma 2016 Sep;81(3):409.
- Johnson MA, Neff LP, Williams TK, DuBose JJ, et al. P-REBOA: Clinical technique & rationale. J Trauma 2016 Nov;82:S133.



# Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock



Joint Theater Trauma System Clinical Practice Guideline: REBOA for Hemorrhagic Shock.  
[http://www.usaisr.amedd.army.mil/assets/cpgs/REBOA\\_for\\_Hemorrhagic\\_Shock\\_16Jun2014.pdf](http://www.usaisr.amedd.army.mil/assets/cpgs/REBOA_for_Hemorrhagic_Shock_16Jun2014.pdf)







# The ER-REBOA™ Catheter Quick Reference Guide

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Placement depth:  
• Zone 1: Approximately 46 cm  
• Zone 3: Approximately 28 cm

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Flush & deflate balloon  
• Ensure balloon is fully deflated  
• Hold vacuum for 5 seconds  
• Close stopcock with vacuum held



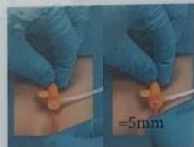
Advance & twist peel-away to cover P-tip!  
• Ensure the balloon and P-tip are captured

### 3. Flush



Attach & flush arterial line  
• Use standard techniques  
• Ensure all air is purged

### 4. Insert



Insert sheath into valve  
• Approximately 5 mm  
• Insert into the common femoral artery



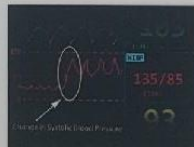
Advance catheter into vessel  
• Hold orange sheath  
• Advance blue Catheter  
• Remove sheath after balloon passes valve



Position catheter  
If available, use conventional x-ray or fluoroscopy to confirm position using radiopaque markers

### 5. Inflate

Inflation Volume	
Zone 1	Start with 8 cc
Zone 3	Start with 2 cc



Start small then check

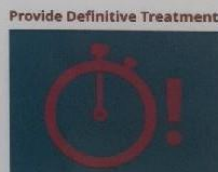
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Fully deflate balloon  
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Remove catheter  
• Corkscrew twist the catheter to facilitate removal  
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### Caution



Check for full and equal pulse in each leg using your standard technique



The REBOA Company™  
www.prytimemedical.com

This instruction is not a replacement for the instruction for use (IFU). The ER-REBOA™ Catheter IFU should be read in its entirety before using the device.

1. Adult Trauma Society Clinical Practice Guidelines: Pelvic Fracture Management Page 10  
2. Prytime Medical, Inc. The REBOA Catheter: A Novel Device for Hemorrhage Control  
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Advise | Revision F

