pREBOA-PRO™ Catheter
Pressure Regulated Occlusion™

Instructions for Use

Instructions for Use (en)

pREBOA-PRO™ CATHETER

CAUTION

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

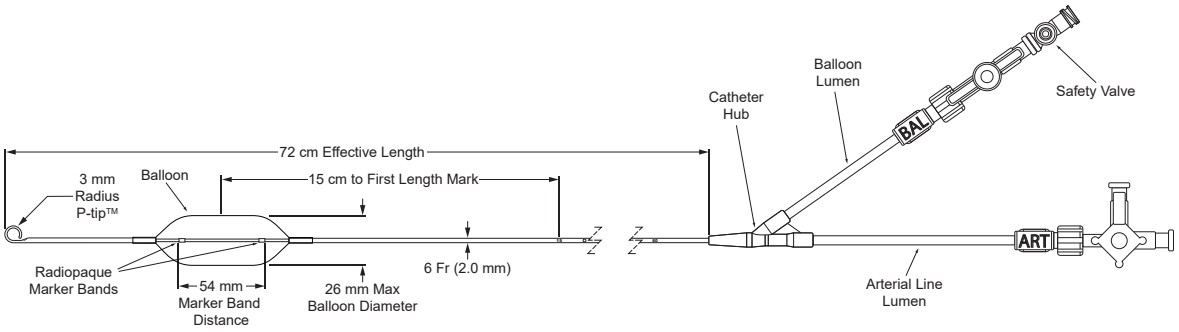
DEVICE DESCRIPTION

The pREBOA-PRO™ Catheter with Pressure Regulated Occlusion™ is a large vessel occlusion catheter with a dedicated lumen for pressure monitoring. The device consists of a semi-compliant balloon, in-line pressure relief valve (safety valve), atraumatic distal tip (P-tip™), dual lumen catheter shaft and a hub with extension lines to provide access to each lumen (details shown in Figure 1 below).

The pREBOA-PRO™ Catheter is designed with flow channels to enable precise, smooth control of inflation and deflation of the balloon. This ability to precisely control arterial flow enables the pREBOA-PRO™ Catheter to be used for complete as well as partial occlusion at the discretion of the clinician. Partial REBOA is intended to stabilize blood pressure and reduce blood loss while diminishing distal ischemia and detrimental reperfusion sequelae associated with prolonged occlusion times. This technique extends time for definitive hemorrhage control by increasing blood pressure above the balloon to improve cardiac and cerebral perfusion while permitting sustained low-volume aortic flow to perfuse organs and tissues below the balloon.

The device has an effective length of 72 cm and is compatible with 7 Fr introducer sheaths as shown in the compatibility section of the IFU. The catheter has a unibody design and is intended to be placed and advanced without a guidewire. In addition, the catheter is compatible with guidewires up to 0.025” that may be used to facilitate subsequent vascular procedures after a REBOA procedure. An orange peel-away sheath is preloaded on the catheter shaft covering the balloon to ease insertion of the catheter’s P-tip™ into an introducer sheath hemostasis valve. A catheter shaft provides appropriate stiffness with a distal tip (P-tip™) designed for atraumatic advancement of the catheter in a blood vessel. Pad printed marks on both sides of the outer catheter shaft indicate distance to the center of the balloon as well as average insertion depth ranges to the center of aortic Zones 1 and 3 to facilitate proper placement. Radiopaque platinum iridium marker bands are located at the functional ends of the balloon to facilitate and visualize accurate balloon placement when used with imaging. The proximal end of the catheter has a hub and extension lines. The arterial line lumen is used to monitor blood pressure above the balloon. The balloon lumen is used to inflate and deflate the balloon as needed. An in-line safety valve is connected to the balloon lumen stopcock and is designed to help prevent over-inflation of the balloon. The stopcocks provide control to each of the catheter’s two lumens. The orange peel-away sheath can be separated from the catheter shaft after insertion if needed. The device is a single-use, sterile device.

Figure 1: pREBOA-PRO™ Catheter



INTENDED USE

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

INDICATIONS FOR USE

The pREBOA-PRO™ Catheter is intended for temporary partial or complete occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage.

CONTRAINDICATIONS

The pREBOA-PRO™ 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 introducer sheath
- have an aortic diameter larger than 26 mm
- are minors (younger than 18 years old)

The pREBOA-PRO™ Catheter is also contraindicated for use with incompatible introducer sheaths. For a list of incompatible introducer sheaths see the compatibility information below.

COMPATIBILITY

The pREBOA-PRO™ Catheter is compatible with a 0.025" diameter or smaller guidewire. Larger guidewires are not compatible.

The pREBOA-PRO™ Catheter is intended to be used with a 7 Fr or larger introducer sheath. The pREBOA-PRO™ Catheter has been confirmed to be compatible with the following 7 Fr introducer sheaths:

- Arrow Super Arrow-Flex® Sheath Introducer– 7 Fr
- Cordis Avanti®+ Sheath Introducer – 7 Fr
- Terumo Pinnacle® R/O II Radiopaque Marker Introducer Sheaths – 7 Fr
- Terumo Pinnacle® Precision Introducer Sheath – 7 Fr
- Merit Medical Prelude® Introducer Sheath – 7 Fr

For sheaths not listed in this IFU or on the Prytime Medical website, confirm compatibility with a selected introducer sheath before inserting the introducer sheath into a patient. Compatibility can be confirmed by first sliding the orange peel-away sheath towards the catheter distal tip to fully enclose and straighten the P-tip™, then inserting the orange peel-away sheath and catheter into the introducer valve. Once the sheath and catheter enter the valve, advance the catheter through the sheath and introducer about 15cm. If the catheter can be introduced and advanced through the sheath easily and without significant resistance, compatibility is confirmed. If the orange peel-away sheath and catheter cannot be introduced to the valve, or advancement of the catheter encounters resistance and requires significant force, the introducer sheath is not compatible.

The pREBOA-PRO™ Catheter has been confirmed to be ***incompatible*** with the following 7 Fr introducer sheaths:

- Arrow AK-09701 Arrow-Flex® Sheath Introducer - 7 Fr
- Cook Check Flo® Performer™ Introducer – 7 Fr
- St. Jude Fast-Cath™ Introducer with Cath-Lock and Guidewire – 7 Fr

Additional introducer sheath models that are confirmed for compatibility or non-compatibility will be updated on the Prytime Medical website at www.prytimemedical.com/introducer-sheath-compatibility.

WARNINGS

- Prime the safety valve with inflation media prior to initial use. Failure to prime the safety valve can cause the valve to open at a higher pressure than intended and result in over-inflation of the balloon.
- The arterial line lumen must be flushed prior to inserting the catheter 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.
- With orange peel-away sheath still in place, remove all air from the balloon and close the stopcock prior to inserting the catheter into the introducer sheath. Failure to do so may make it difficult to insert/advance the catheter and/or may cause an air embolism in the case of balloon rupture.
- Do not attempt to pass the catheter through an introducer sheath smaller than 7 Fr. Damage to the catheter and/or vessel may occur.
- If available, use of conventional x-ray or fluoroscopy is recommended to confirm desired catheter position. **Note:** Zone and length markings on the catheter shaft (cm) may be used to measure depth of insertion to middle of balloon to facilitate placement. For reference, numbered ranges with rectangle end-marks indicate the approximate centers of aortic Zone 1 and Zone 3. These marks should not be used as a substitute for measuring and confirming appropriate insertion depth for the specific patient being managed.
- The pREBOA-PRO™ Catheter may be used without the aid of medical imaging. If medical imaging is clinically required in pregnant patients, standard local institutional radiation mitigating measures should be utilized to minimize exposure to the fetus. Once the patient has delivered the baby, the warnings and precautions described in this IFU common to all bleeding patients apply.
- Use the recommended balloon inflation media (100% sodium chloride (saline)). If contrast is necessary, ensure that the dilution is 3:1 diluted contrast solution (75% sodium chloride (saline) / 25% contrast media). Do not use air or any gaseous media to inflate balloon. Doing so may cause an air embolism if the balloon were to rupture.
- Do not use full, undiluted contrast solution to inflate the balloon.
- Hand inflation 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.
- Do not exceed maximum inflation volume of 25 cc. Adhere to the balloon inflation parameters outlined in the Inflation Volume Table (Table 1) below. Over-inflation may result in damage to the vessel wall and/or vessel rupture, and/or balloon rupture.

- Failure to fully deflate the balloon and close the stopcock before removing catheter may make it difficult or impossible to remove the catheter from the introducer sheath and/or vessel.
- Do not attempt to insert a guidewire greater than 0.025" into catheter. Damage to catheter and/or vessel may occur.
- Do not use the pREBOA-PRO™ Catheter for dilation of vascular prostheses. Damage to the vessel and/or balloon rupture may occur.
- Do not use the pREBOA-PRO™ Catheter as a valvuloplasty/angioplasty balloon catheter.
- The pREBOA-PRO™ 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.
- Prolonged duration of occlusion may result in serious injury or death. Device is intended for temporary applications. Long term or permanent application of this device may cause harm.
- Ensure that proximal and distal blood pressure goals can be achieved when performing partial occlusion. Use complete occlusion only when necessary.

PRECAUTIONS

- 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.
- Inflating too quickly can cause a pressure spike at the catheter hub that can result in premature opening of the safety valve. If this occurs, decrease the rate of balloon inflation.
- The safety valve is a safety feature designed to prevent over-inflation of the balloon. The user should cease balloon inflation once there is clinical evidence of occlusion, e.g., a blood pressure response, and not rely solely on the safety valve to open. Further inflation increases stress on the blood vessel/balloon and does not provide additional occlusion. Do not inflate the balloon if the safety valve is not in place.
- Do not cut, trim or modify catheter or components prior to placement.
- Care should be taken to avoid damage to balloon when handling catheter near medical instruments.
- Training and experience in endovascular techniques is recommended for users of 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 inserting and inflating the balloon in the vessel, particularly when inflating in calcified, stenotic, and/or otherwise diseased vessels. Calcified lesions may damage balloon.
- 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.
- Zone and length markings on the catheter shaft (cm) may be used to measure depth of insertion to middle of balloon to facilitate placement. For reference, numbered ranges with rectangle end-marks indicate the approximate centers of aortic Zone 1 and Zone 3. These marks should not be used as a substitute for measuring and confirming appropriate insertion depth for the specific patient being managed.
- The pREBOA-PRO™ Catheter has not been tested for use with MRI (Magnetic Resonance Imaging). The patient should not receive and MRI exam while using the pREBOA-PRO™ Catheter.
- Do not exceed more than 10 complete inflation/deflation cycles of the balloon.
- 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.
- Limited clinical data[1] and animal studies[2,3,4] suggest that partial occlusion durations of up to two hours in Zone 1 can be tolerated without increasing the risk of life-threatening ischemic injury. Consider complete occlusion only in cases where the patient is not capable of maintaining partial occlusion targets, i.e., above the balloon SBP 90-110 mmHg and below the balloon SBP > 20 mmHg with pulsatile waveform. Evidence based guidelines[5] suggest that increased caution should be exercised when complete aortic occlusion times approach 30 minutes in Zone 1 and 60 minutes in Zone 3. Individual patient tolerance to partial and complete occlusion may vary and clinical judgement is necessary when determining duration and degree of occlusion. It is advised to resuscitate and deflate the catheter as soon as the patient's hemodynamics allow; the maximum safe occlusion time remains undefined and needs additional exploration

MATERIALS

- The pREBOA-PRO™ Catheter is not made with natural rubber latex.

POTENTIAL ADVERSE EVENTS

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

- Vessel dissection, perforation, pseudoaneurysm, rupture or injury
- Occlusion at some locations may cause arrhythmia
- Paresthesia
- Contrast reactions
- Infection, bleeding, hematoma and/or pain at insertion site
- Cardiac events
- Hemorrhage
- Stroke
- Aneurysm rupture
- Renal complications
- Arterial thrombosis and/or embolism
- Paralysis
- Ischemia
- Balloon rupture
- Malpositioning of the balloon
- Exacerbation of proximal bleeding
- Loss of a lower extremity
- Death

PACKAGING CONTENTS, RECOMMENDED, AND REQUIRED ITEMS

Each pREBOA-PRO™ Catheter package includes a single-use, sterile, disposable balloon catheter and a pre-installed orange peel-away sheath on the catheter shaft covering the balloon. The orange peel-away sheath is used to straighten the P-tip™ for insertion into the introducer sheath. The package also includes a removable tag with priming instructions which may be used to document procedure information such as insertion depth, inflation volume and occlusion time/duration.

Note: The pREBOA-PRO™ Catheter is designed to be advanced WITHOUT a guidewire. The catheter is compatible with guidewires up to 0.025" should guidewire use be desired by clinician.

Materials required but not provided are:

- Needle (Seldinger type)
- Introducer sheath (7 Fr minimum)
- 30 cc syringe
- Inflation media
  - sodium chloride (saline) recommended, or
  - contrast solution (required dilution of 3:1 (75% sodium chloride (saline) / 25% contrast media))
- Method/device for securing sheath and catheter to patient's leg
- Vital signs monitor with external pressure monitoring sensor and appropriate pressure monitoring extension tubing or other means of measuring arterial blood pressure

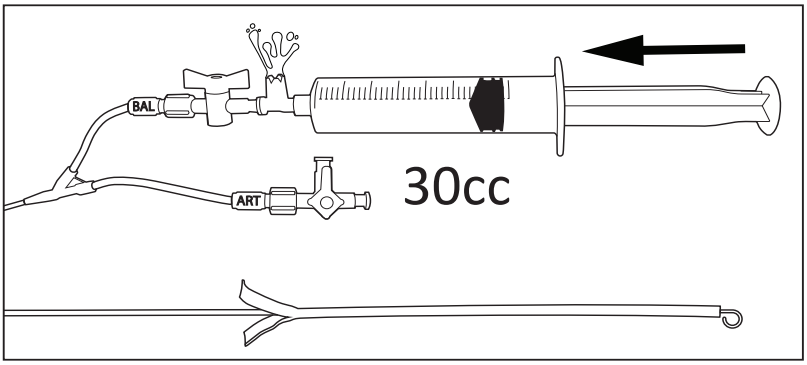
INSTRUCTIONS FOR USE

Balloon Lumen Preparation

Note: Even with the peel-away sheath covering the balloon, the balloon and balloon lumen of the pREBOA-PRO™ Catheter may contain air. Air should be removed from the balloon and balloon lumen prior to insertion using standard techniques.

1. Prime the safety valve and prepare the balloon lumen (BAL) with inflation media (see Figure 2) as follows:
   a. Attach syringe with approximately 30 cc of inflation media and ensure balloon lumen stopcock is open.
   b. Leave the orange peel-away sheath in place covering the balloon.
   c. Flush inflation media into the balloon lumen until the safety valve opens, leaving approximately 25 cc in the syringe. This primes the safety valve.
   d. Pull a vacuum on the syringe plunger for at least 5 seconds and close the balloon stopcock while holding the vacuum to make sure as much media and air is removed from the balloon/balloon lumen as possible.
   e. Disconnect the syringe and purge air from the syringe.

Figure 2: Preparing Balloon Lumen



Note: Failure to prime the safety valve can cause the valve to open at a higher pressure than intended. Do not inflate the balloon if the safety valve is not in place.

Pressure Monitoring Lumen Preparation

2. Slide the orange peel-away sheath towards the catheter distal tip to fully enclose and straighten the P-tip™ which will facilitate insertion into the introducer sheath.

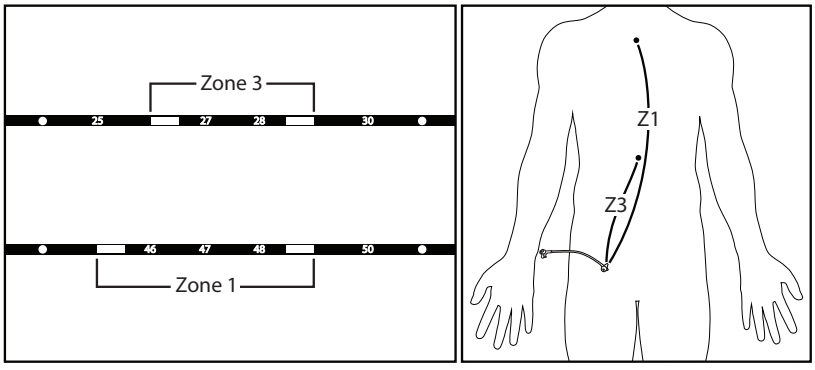
3. Connect the pressure sensor and extension tubing (optimal length 48" (122 cm) or shorter) using standard techniques to the catheter's arterial (ART) line 3-way stopcock. Flush the extension tubing and pREBOA-PRO™ Catheter arterial line with saline (not contrast solution) using standard techniques, readying the device for pressure transduction.

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

Balloon Introduction

4. Determine desired depth for catheter placement (Figure 3). External landmarks such as the sternal notch and xyphoid process may be used as an aid to determine approximate placement depth. Zone and length markings on the catheter shaft (cm) may be used to measure depth of insertion to middle of balloon to facilitate placement. For reference, numbered ranges with rectangle end-marks indicate the approximate centers of aortic Zone 1 and Zone 3. These marks should not be used as a substitute for measuring and confirming appropriate insertion depth for the specific patient being managed.

Figure 3: Zone 1 and Zone 3 approximate center ranges and bony landmarks for measuring



5. Insert the orange peel-away sheath and catheter into the 7 Fr (or larger) introducer sheath approximately 5mm or until the orange peel-away sheath hits a stop. Do not advance the orange peel-away sheath any further. Advance the catheter approximately 15 cm (indicated by first marking on shaft) into the introducer sheath, then slide the orange peel-away sheath toward the catheter hub. If necessary for full advancement, pull tabs to separate the orange peel-away sheath from the catheter shaft.

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

   Note: Flush ART line(s) again after placement.

6. An additional arterial line should be placed below the balloon to measure distal (below balloon) blood pressure.

7. Using standard technique, advance the catheter to the desired position. If available, use of conventional x-ray or fluoroscopy is recommended to confirm position using radiopaque markers.

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

Balloon Inflation

Note: The pREBOA-PRO™ Catheter is capable of precise adjustments to arterial flow. The clinician determines which level of occlusion (complete or partial) is appropriate based on individual patient needs and clinical circumstances following the guidelines below.

8. Open balloon stopcock and slowly and carefully inflate the balloon with inflation media (Figure 4) while maintaining control of catheter at the sheath to avoid migration.

9. To achieve partial occlusion, target ***both*** of the following and close the stopcock:

   Proximal (above balloon) systolic blood pressure: 90 - 110 mmHg

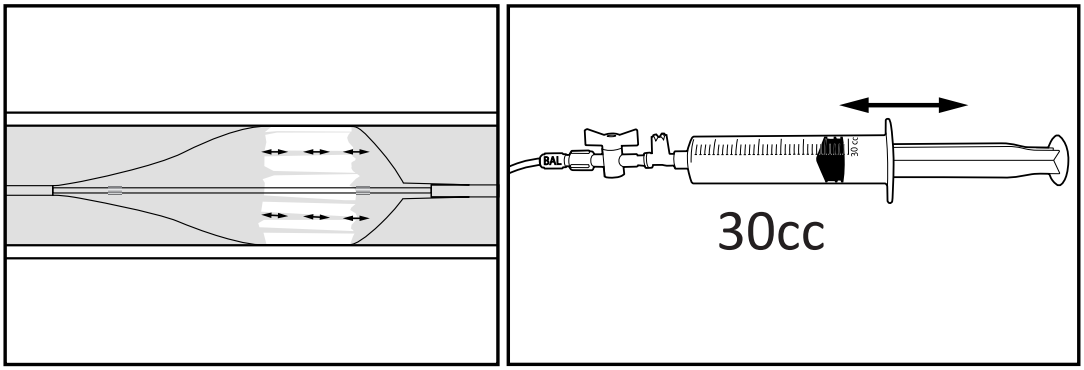
   Distal (below balloon) systolic blood pressure: > 20 mmHg with pulsatile waveform

   Note: Target pressures were developed for trauma. Target pressures for obstetric hemorrhage may vary, e.g., require higher below balloon pressure, due to physiological changes of gestation.

10. Continue to monitor blood pressure and titrate the balloon as needed to maintain these targets to ensure adequate proximal and distal blood pressure. If patient hemodynamics do not permit both proximal and distal blood pressure targets to be sustained, prioritize the proximal pressure target range and consider additional fluid resuscitation to enable both pressure targets to be achieved. A distal pressure of less than 20 mmHg SBP should be considered complete occlusion.

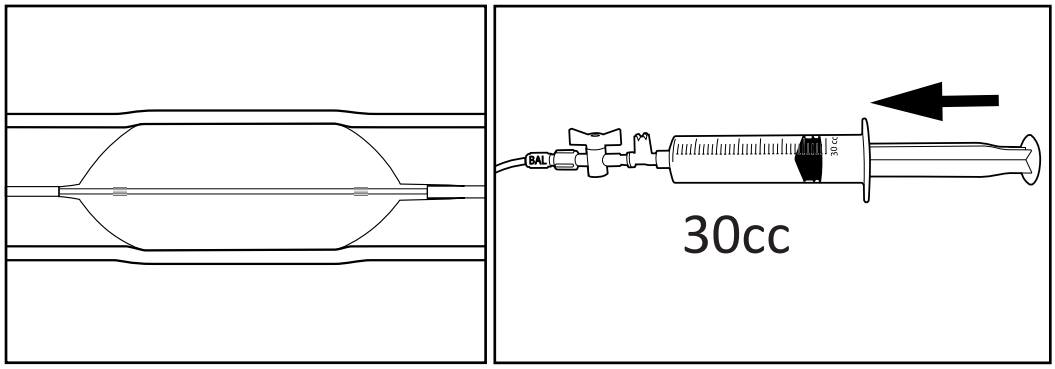
    Note: Limited clinical data[1] and animal studies[2,3,4] suggest that partial occlusion of up to 2 hours in Zone 1 can be tolerated without risk of life-threatening ischemic injury if both the proximal and distal pressure targets are maintained. Evidence based guidelines[5] suggest that increased caution should be exercised when complete aortic occlusion times approach 30 minutes in Zone 1 and 60 minutes in Zone 3. Individual patient tolerance to partial and complete occlusion may vary and clinical judgement is necessary when determining duration and degree of occlusion. It is advised to resuscitate and deflate the catheter as soon as the patient's hemodynamics allow; the maximum safe occlusion time remains undefined and needs additional exploration.

Figure 4: Titrating balloon for partial occlusion



11. If complete occlusion is appropriate, vessel occlusion can be confirmed by an increase and leveling off of proximal blood pressure, a distal pressure of less than 20 mmHg SBP, loss of distal pulses, or tactile feedback on the syringe plunger. Once desired inflation is achieved, close stopcock. Balloon inflation may also be confirmed using appropriate medical imaging, i.e. conventional x-ray or fluoroscopy.

Figure 5: Inflating balloon to complete occlusion



Note: Inflating too quickly can cause a pressure spike at the catheter hub that can result in premature opening of the safety valve. If this occurs, decrease the rate of balloon inflation.

Note: The safety valve is a safety feature designed to prevent over-inflation of the balloon. The user should cease balloon inflation once there is clinical evidence of complete occlusion, e.g., a blood pressure response, and not rely solely on the safety valve to open. Further inflation increases stress on the blood vessel/balloon and does not provide additional occlusion. Do not inflate the balloon if the safety valve is not in place.

Note: It is recommended that use parameters be recorded for balloon inflation, deflation or partial cycles per institutional requirements. A removable tag is provided on the catheter shaft as a convenience to record the depth of insertion (cm), volume of inflation media used (cc), time of occlusion or balloon inflation(s), and blood pressure (BP) after balloon inflation and aortic occlusion.

Note: If balloon pressure is lost and/or balloon rupture occurs, deflate the balloon and remove the catheter and introducer sheath as a unit. A 0.025" or smaller guidewire can be advanced through the catheter arterial line prior to removal to retain the access site. Consider removing arterial line stopcock if needed. Fluoroscopic imaging must be used in association with guidewire use.
Note: Clinical judgment, preferably with the appropriate vital sign monitoring (e.g., above and below balloon blood pressure monitoring), is required when establishing and maintaining the degree of partial occlusion.

12. Verify and monitor appropriate level of occlusion by monitoring blood pressure response. As reference for complete occlusion, the balloon Inflation Volume Table (Table 1) may be a guide for starting volumes in Aortic Zones 1 and 3. Start small, then check. Do not exceed 25 cc occlusion volume. Over-inflation of the balloon may result in damage to vessel wall and/or vessel rupture and/or balloon rupture and/or catheter damage.

Table 1: Inflation Volume Table for complete occlusion

Aortic Zone	Inflation Volume
Zone 3*	Start with 4 cc
Zone 1*	Start with 11 cc
MAX	25 cc

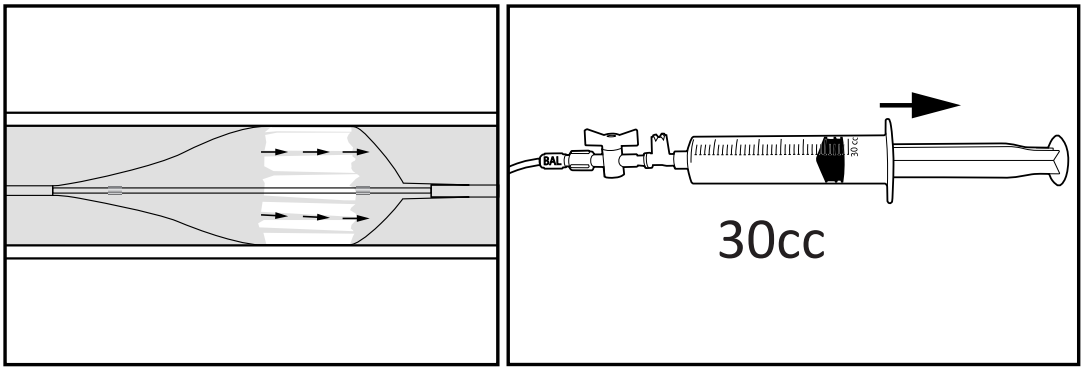
*Based on aortic diameter in Aortic Zone 1 and Zone 3 from CT scans of 1789 male and female trauma patients. Data on file.

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

Balloon Deflation and Removal

14. Slowly deflate the balloon by opening the BAL lumen stopcock and drawing a vacuum using a 30 cc syringe (**must be a 30 cc syringe or larger, Figure 6**) until the balloon is completely deflated. The balloon is fully deflated when no more fluid movement is seen in the BAL lumen of the catheter (bubbles) and full vacuum has been held for an additional 5 seconds after that fluid movement has ceased. After all inflation media is removed, empty syringe and reattach to BAL lumen, pull full vacuum for a second time holding for at least 5 seconds to ensure any residual fluid is removed. While still holding full vacuum, close the BAL lumen stopcock. If contrast media is used to inflate the balloon, complete deflation may be confirmed using appropriate medical imaging, i.e. conventional x-ray or fluoroscopy.

Figure 6: Deflating balloon



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

Note: It is recommended that use parameters be recorded for balloon inflation, deflation or partial cycles per institutional requirements.

15. If desired, a 0.025” or smaller guidewire can be advanced through the arterial line lumen of the catheter shaft to facilitate subsequent procedures. Consider removing arterial line stopcock if needed. Fluoroscopic imaging must be used in association with guidewire use.
16. Disengage or detach the method/device used to secure the catheter to the patient.
17. Carefully remove catheter by grasping near the insertion sheath hub. Pull slowly straight back until 20 cm depth marking is visible at sheath hub. Grasp catheter at 20 cm marking near sheath hub and continue to pull while turning catheter in unilateral direction to assist balloon with collapse and entry into access sheath end. Continue to pull until entire catheter is removed from access sheath.

    Note: Never twist the catheter back and forth. Never withdraw REBOA catheter by holding from catheter hub.

    Note: Never pull harder if unexpected resistance is felt. If difficulty is encountered when removing the catheter, stop and reinsert to Zone 3, fully inflate balloon, then repeat deflation Step 14. If removal issues persist, remove the catheter and introducer sheath as a unit.
18. 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 (applicable local, national and EU laws and regulations for CE use).
19. Manage introducer sheath and access site using hospital protocols.

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 and undamaged. Do not use this product if there is doubt as to whether the product is sterile. Store in a dark and dry 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.		Do not reuse this product.
	Store the product appropriately in dry location.		This product has been sterilized using Ethylene Oxide.
	Store the product in a location out of direct sunlight.		This product uses a single sterile barrier system.
	Product is non-pyrogenic.		The pREBOA-PRO™ Catheter is not made with natural rubber latex.
	Do not re-sterilize this product.		The content is sterile if the package is unopened and undamaged. Do not use if package is damaged.
R_x ONLY	USA Federal Law restricts this device to sale by or on the order of a physician (or properly licensed healthcare practitioner).		Warning. The instructions on tag for the Safety Valve are there to warn users to prime the valve before use. Step 1 above describes the procedure to prime the valve.
MD	This item is a medical device.		

REFERENCES AND NOTES

1. These best practices guidelines are based on limited published data and only represent the experience of 12 clinicians currently practicing in REBOA programs with pREBOA-PRO:
   Nguyen J, Spalding MC, Meyer CH, Beckett A, Smith A, Kundi R, Raza SS, Radomski M, Dennis B, Mukherjee K, Akrish E, Raley J, Fox C, Moore EE. A DELPHI CONSENSUS ALGORITHM FOR MODERN REBOA PROGRAMS: EMPLOYING A TITRATABLE CATHETER AND PARTIAL AORTIC OCCLUSION TO ADVANCE THE PROCEDURE. Shock. 2025 Aug 1;64(2):176-186. doi: 10.1097/SHK.0000000000002622. Epub 2025 Apr 30. PMID: 40341373.
2. Kemp et. al., A Novel Partial Resuscitative Endovascular Balloon Aortic Occlusion (pREBOA) Device That Can Be Deployed in Zone 1 for more than 2 hours with Minimal Provider Titration, J Trauma Acute Care Surg. 2020; 90(3): 426-433
3. Ho et. al., Prolonging the zone 1 aortic occlusion time to 4 hours using a partial resuscitative endovascular balloon in a swine model, J Trauma Acute Care Surg. 2023; 95(S2): S129-S136
4. Ho et. al., Finding the right balance: Partial REBOA in a swine model of uncontrolled vascular injury, J Am Coll Surg. 2024 Jan 1;238(1):32-40
5. J. Glaser, Stigall, K., Cannon, J., Jensen, S., Morrison, J. J., Snyder, S., Russo, R., Manley, J., Becker, T., Dubose, J., Rasmussen, T., Graybill, J., Gurney, J., & Shackelford., S, Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock (CPG ID:38), (2020)

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