Vitale™

OCCLUSION BALLOON CATHETER

INSTRUCTIONS FOR USE

STERILE EO

Contents sterile unless enclosed package has been opened or damaged. Sterilized by Ethylene Oxide (EO).

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

QXMédical, LLC
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English

Vitale™

Occlusion Balloon Catheter

INSTRUCTIONS FOR USE

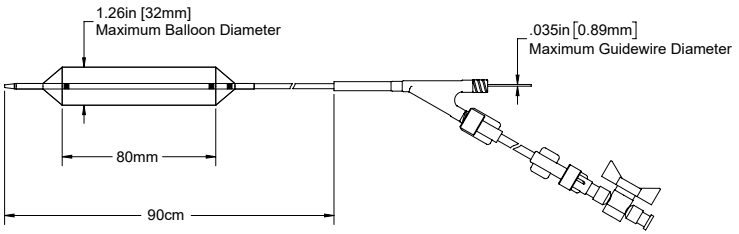
1. DEVICE DESCRIPTION

The Occlusion Balloon Catheter is designed for temporary occlusion of large vessels, including the superior vena cava (SVC). The catheter may be used for perioperative occlusion and emergency control of hemorrhage associated with vascular tears that may occur during Lead Extraction procedures.

The Occlusion Balloon Catheter is an over-the-wire (OTW) tri-lumen catheter with a compliant polyurethane balloon having a maximum diameter of 32mm at 60cc. Two lumens inflate and deflate the balloon while one lumen is reserved for guidewire passage. The catheter has a usable length of 90 cm.

This device is designed to accommodate a 0.035" diameter guidewire. Three (3) radiopaque marker bands are placed within the balloon to facilitate balloon placement prior to inflation. The catheter is available in two (2) sizes; each compatible with different sized introducer sheaths as outlined in the table below. The catheter has an extension tube with a stopcock in order to facilitate handling and fluid control. The device model information is outlined below:

Catalogue Number	Minimum Introducer Sheath Diameter	Maximum Outer Diameter (Crossing Profile)
VITB08	8 Fr	2.67mm (0.105")
VITB10	10 Fr	3.33mm (0.131")



There are risks involved with any medical procedure. Both physician and patient should fully understand those risks associated with surgery, and additional new risks associated specifically with the use of this endoluminal device.

CAUTION: This device is intended for use by interventionalists and endovascular specialists who are familiar with the complications, side effects, and dangers associated with using this device.

CAUTION: Read the entire Instructions for Use manual prior to using the device.

2. INDICATIONS FOR USE

The occlusion balloon catheter is indicated for temporary occlusion of large vessels, including the superior vena cava, in applications including perioperative occlusion and emergency control of hemorrhage.

3. CONTRAINDICATIONS

The Occlusion Balloon Catheter is contraindicated in patients who:

- Are contraindicated to contrast media or anticoagulants
- Have an vascular entry site that cannot accommodate the required introducer sheath
- Are minors <18 years old
- Are pregnant

4. WARNINGS

- The Occlusion Balloon Catheter is supplied STERILE and for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and of compromised device performance.
- The catheter should only be manipulated and inflated/deflated while observing under fluoroscopy.
- If resistance is encountered at any time during the insertion procedure, do not force passage or torque the catheter. Resistance may cause damage to device or vessel. Carefully withdraw the catheter.
- Do not torque or twist the catheter during insertion or withdrawal.
- The catheter should only be advanced or withdrawn over a guidewire.
- Maintain guidewire position throughout the procedure; do not remove the guidewire while the balloon is inflated.
- Adhere to balloon inflation parameters outlined in the **Balloon Compliance Chart (Table 1)**. Do not exceed a balloon diameter of 32mm and do not exceed 60cc inflation volume at 32mm balloon diameter. Rupture of balloon may occur. Over-inflation may result in damage to vessel wall, vessel rupture, balloon rupture or introduction of air emboli.
- Balloon rupture may occur under certain anatomical, procedural, and/or clinical circumstances. It is therefore recommended to have back-up Occlusion Balloon Catheters on hand.
- Ensure that the balloon is fully deflated (under vacuum) before moving the Occlusion Balloon Catheter.
- Studies indicate that the danger of micro-embolization increases with increased manipulation and/or duration of the procedure.
- Over inflation of the balloon can cause vessel rupture. Care should be taken when inflating the balloon in vessels, particularly in calcified, stenotic, and/or otherwise diseased vessels.
- Do not use in the heart or coronary arteries.
- Hand injections using a 60cc syringe are recommended. Do not use a pressure inflation device for balloon inflation.
- Do not use a power injector for injection of contrast medium through distal catheter lumen. Rupture may occur.

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- QXMedical is not responsible for mis-sizing, misuse or misplacement of the device.
- Lead Extraction should be performed at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. It is strongly suggested that the recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) be followed for best results.
- Prior to initiating a Lead Extraction procedure, a guidewire should be placed through a venous access site and across the length of the SVC. Attempting to place a guidewire after a venous tear occurs may:
  - Result in an inability to traverse the SVC with the guidewire
  - Result in the guidewire exiting the vasculature at the tear site
  - Result in an inability to place the Occlusion Balloon Catheter
  - Delay or prevent the ability to achieve occlusion
- Do not position the Occlusion Balloon Catheter in a manner that would obstruct the right atrium. Obstruction of the atrium could lead to arrhythmias and/or hemodynamic compromise.
- Occlusion of the SVC beyond 30 minutes is not recommended as this may increase the risk of adverse physiologic or neurologic complications.

5. PRECAUTIONS

- **Preparations should be made and a trained vascular surgical team available in the event conversion to open surgery is required.**
- Carefully inspect the package and catheter prior to use to verify no damage occurred during shipment. Do not use if the package or catheter is damaged since the sterility or integrity of the device may be compromised and thus increasing the risk of patient infection and device malfunction.
- Use the catheter prior to the **Use By** date specified on the package.
- Do not attempt to pass the catheter through a smaller than recommended introducer sheath. Damage to the device may occur.
- 0.035" diameter stiff or super-stiff guidewires are recommended.
- To avoid damage to the catheter or vessel, do not advance or withdraw the device without a guidewire in place.
- Catheter should not be advanced into a vessel having a diameter smaller than the catheter outer diameter. Damage to the device or vessel may occur.
- Carefully monitor the patient's blood pressure and other vital signs throughout the procedure.
- If an obstruction in the vessel (e.g., a tortuous bend, stenosis, calcification, etc.) prevents advancement of the catheter, use standard techniques to try to dilate and/or straighten the vessel before continuing to advance the catheter.
- It is recommended that back-up Occlusion Balloon Catheters are made available.
- Balloon is highly compliant. Inflate slowly. Do not over-inflate in vessels. Operator should visualize the balloon at all times during inflation to detect any movement. Use special care in areas of diseased vessels to avoid rupture or vessel trauma.
- The Occlusion Balloon Catheter is not intended for use as an angioplasty or dilatation balloon.
- The Occlusion Balloon Catheter is not intended for use as an infusion catheter.
- When aligning the position of the catheter so that the balloon is in proper position for expansion within vessel, pay careful attention to the fluoroscope location in order to avoid parallax or other sources of visualization error.
- Do not use the Occlusion Balloon Catheter for more than 20 inflation/deflation cycles.
- Do not exceed 32mm balloon diameter and do not exceed 60cc inflation volume at 32mm balloon diameter. Adhere to the balloon inflation guidelines outlined in Table 1.
- To avoid balloon damage or rupture, lead extraction tools (such as extraction sheaths) should be removed from the SVC area prior to placing the Occlusion Balloon Catheter.
- If surgical repair of a venous tear requires suturing, use caution to avoid puncturing the balloon.

6. POTENTIAL COMPLICATIONS/ADVERSE EFFECTS

Complications may occur with the use of any occlusion balloon catheter or during any catheterization procedure. Therefore, only physicians trained in electrophysiology, vascular surgery, interventional radiology or cardiology, and who have completed training or have experience with balloon catheters and associated devices should consider using this device. Possible complications associated with this type of procedure include but are not limited to the following:

CLINICALLY RELATED:

- Allergic reaction
- Hemodynamic deterioration
- Thromboembolic episode
- Sepsis/infection
- Vessel perforation, dissection, rupture or injury
- Occlusion at some locations may cause arrhythmia
- Paresthesia
- Drug reactions
- Entry site infection
- Entry site hematoma
- Cardiac events
- Respiratory failure
- General malaise
- Arterial thrombosis and/or embolism
- Hemorrhage
- Stroke
- Aneurysm rupture
- Renal complications
- Death

DEVICE RELATED:

- Balloon rupture
- Inability to inflate/deflate balloon
- Inability to insert guidewire
- Inability to withdraw catheter from introducer

7. PACKAGING, STERILIZATION AND STORAGE

The device has been sterilized using ethylene oxide (EO) and is supplied sterile and non-pyrogenic. The package label indicates the **Use By** date.

Do not use the device <u>after</u> the **Use By** date. The device sterility and integrity may be compromised and possibly result in patient infection and device malfunction.

The device should be stored in cool dry place.

8. RECOMMENDED ITEMS

Each Occlusion Balloon Catheter package includes the following:

- Single-use sterile disposable catheter with extension tube and stopcock mounted on a paperboard card.

Materials required but not provided are:

- Compatible Introducer Sheaths with hemostasis valve
- Guidewires, 0.035" diameter, Stiff or Super Stiff

- 60cc syringes
- Diluted contrast solution (80% sodium chloride / 20% renographin) is recommended for balloon inflation/deflation
- Additional Occlusion Balloon Catheters

It is also recommended that a freely-angled C-Arm with high resolution fluoroscopy, high quality angiography and Digital Subtraction Angiography (DSA) be used during the procedure.

9. DEVICE PREPARATION

9.1 Carefully inspect the package and catheter prior to use to verify no damage occurred during shipment. Do not use catheter if either the catheter or packaging is damaged or compromised.

9.2 If the packaging is free of damage, carefully open the outer pouch and introduce the inner pouch (with catheter) to the sterile field using sterile techniques.

9.3 Open the inner pouch and carefully disengage the catheter, manifold and extension tube assembly from the paperboard card. Carefully inspect the catheter for any signs of damage. If damaged, please discard and use another catheter.

NOTE: Patient and entry site preparation should be performed prior to device preparation. Prepare patient in accordance with standard techniques; including proper administration of anticoagulation and antiplatelet medication. Using standard techniques prepare entry site, including placement of the introducer sheath.

NOTE: Prior to initiating a Lead Extraction procedure, the guidewire should be advanced through the introducer sheath and across the length of the SVC. Do not attempt to place the guidewire after a venous tear occurs.

9.4 Fill 60cc syringe with 10cc to 15cc of heparinized saline solution.

9.5 Attach the syringe to the guidewire lumen port and flush the guidewire lumen.

9.6 Remove the syringe from the guidewire lumen port, fill with 15cc of heparinized saline solution and connect it to the stopcock. Ensure that the stopcock is OPEN and draw vacuum. Do not introduce any solution into the balloon during the preparation.

9.7 While maintaining the balloon under vacuum, gently remove the protective sleeve from the balloon by twisting the sleeve in one direction and pulling it off the balloon.

9.8 Observe the syringe for a continuing stream of air bubbles as this may indicate a catheter leak. If a leak is observed, please discard the catheter and use a new one.

9.9 While under vacuum, turn the stopcock OFF and remove the syringe. Set the catheter aside until needed.

10. DEVICE USAGE

10.1 Prior to introducing the catheter, fill a 60cc syringe with **diluted contrast** (80% sodium chloride / 20% renographin) needed to inflate the balloon. Reference the balloon inflation parameters outlined in the **Balloon Compliance Chart (Table 1)** for guidance.

WARNING: Over-inflation may result in damage to vessel wall, vessel rupture, balloon rupture or introduction of air emboli.

10.2 Place the prepared catheter over the previously inserted guidewire by threading the end of the guidewire through the tip of the catheter. Advance the catheter until the guidewire exits the proximal port and position the tip of the catheter proximal of the introducer sheath.

10.3 Verify that the balloon is completely deflated and under vacuum.

10.4 If required, advance the balloon catheter through the introducer sheath. Using fluoroscopic imaging, carefully advance the catheter to the desired location in the vasculature using the markerbands for visual guidance.

NOTE: For a Lead Extraction procedure, advance the catheter until the proximal marker band is located at the junction of the SVC and right atrium.

CAUTION: When aligning the position of the catheter so that the balloon is in proper position for expansion within vessel, pay careful attention to the fluoroscope location in order to avoid parallax or other sources of visualization error.

10.5 Fill the 60cc syringe with diluted contrast solution and attach it to the stopcock ensuring that no air is introduced into the balloon catheter. Open the stopcock and inflate the balloon at the target location. Continuously monitor fluoroscope screen, watching for balloon movement. **Table 1** (below) is a guideline for determining the volume of diluted contrast solution required to obtain a given balloon expansion diameter. Close the stopcock once the desired balloon inflation is achieved.

Table 1: Balloon Compliance Chart

Recommended Inflation Volume	Balloon Diameter
20 cc	18 mm
25 cc	20 mm
30 cc	22 mm
35 cc	24 mm
40 cc	26 mm
45 cc	28 mm
50 cc	30 mm
55 cc	31 mm
60 cc	32 mm

* Maximum Inflation Diameter -- DO NOT EXCEED 32mm Balloon Diameter and DO NOT EXCEED 60cc inflation at 32mm balloon diameter.

CAUTION: The above chart is only a guide. Inflate the balloon until vessel occlusion is achieved. Balloon expansion should be carefully monitored with the use of fluoroscopy.

CAUTION: Balloon is highly compliant. Operator should visualize the balloon at all times during inflation to detect any movement. If balloon needs to be repositioned, completely deflate the balloon prior to repositioning.

CAUTION: Use special care in areas of diseased vessels to avoid rupture or vessel trauma.

10.6 If balloon pressure is lost and/or balloon rupture occurs, deflate the balloon and remove balloon. If required, replace with a new Occlusion Balloon Catheter.

10.7 When balloon inflation is complete, draw a vacuum in the balloon and verify that the balloon is fully deflated.

10.8 Maintain vacuum on the balloon and withdraw the Occlusion Balloon Catheter back through the introducer sheath. Use fluoroscopic imaging to track the movement of the Occlusion Balloon Catheter throughout the withdrawal.

10.9 If resistance is met during withdrawal, apply negative pressure with a larger syringe before proceeding. If resistance continues, remove balloon and sheath as a unit.

10.10 Remove introducer sheath and close entry site with standard surgical closure technique.

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DISPOSAL

After use, this product is a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable hospital, local, state and federal laws and regulations.

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