SentreHEART
An AtriCure Company

AtriCure

ENDOCATH®
LARGE OCCLUSION BALLOON

15mm x 12mm x 90cm

20-06

Carefully Read All Instructions Prior to Use.

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

Packaging and Storage

The EndoCATH Large Occlusion Balloon Catheter is sterile (using ethylene oxide gas) and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

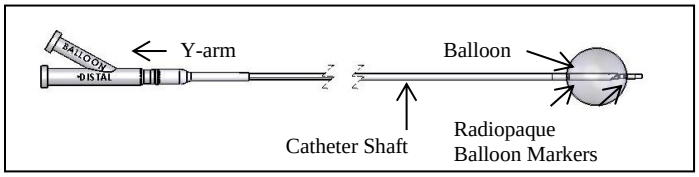
Handle with care. Do not store in excessive heat. Prolonged exposure to ultraviolet light may cause discoloration and changes in the physical characteristics of the catheter. After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Indications

The EndoCATH Large Occlusion Balloon Catheter is intended for temporary occlusion of large vessels in applications such as arteriography, preoperative occlusion, and emergency controlled hemorrhage procedures.

Description

The EndoCATH Large Occlusion Balloon Catheter consists of a catheter shaft with two independent lumens upon which an expandable balloon material is bonded. The "Distal" lumen extends the length of the catheter and is used for placement of a guide wire. The "Balloon" lumen is used to inflate and deflate the balloon. Radiopaque markers at the location of the balloon provide fluoroscopic visualization of balloon during placement. To increase ease of introduction, the balloon is coated with a thin layer of lubricant.



Large Occlusion Balloon Catheter

Potential Adverse Events

Potential adverse effects associated with the use of an occlusion balloon catheter include:

- Vessel dissection, perforation, rupture or injury
- Occlusion at some locations may cause arrhythmia
- Drug reactions
- Arterial thrombosis and/or embolism
- Infection and irritation at insertion site
- Vessel spasm
- Hemorrhage
- Hematoma
- Hypotension
- Short-term hemodynamic deterioration
- Allergic reactions to contrast media
- Pyrogenic reaction
- Arteriovenous fistula

⚠Warnings

- Do not exceed maximum inflation volume. Over inflation may cause the balloon to rupture or fragment, or cause damage to vessel wall and/or vessel rupture.
- Do not use a pressure inflation device as it may cause the balloon or catheter to rupture or fragment, or cause damage to vessel wall and/or vessel rupture.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

⚠Precautions

- Do not heat or attempt to shape the catheter tip.
- Use only the recommended inflation medium. Never use air or gaseous medium to inflate balloon.
- Do not attempt to advance catheter through an occlusion or extreme tortuous anatomy. Doing so may damage the catheter.

Instructions for Use

Preparation

1. Carefully inspect all devices and their packaging prior to use to verify size, shape, and condition. Do not use a device that is damaged in any way or if its packaging is damaged.
2. Reference Table 1 for recommended introducer sheaths, guide wires, and syringes specific to the balloon catheter being used.

Table 1 - Recommended Accessories

Balloon Size	Introducer Sheath	Syringe	Guide Wire
15mm x 12mm	8.5F	10 cc	.035" max.

Catheter Aspiration

3. Remove protective balloon sleeve and attach a stopcock to the balloon lumen on the catheter's Y-arm.
4. Remove all air from balloon and balloon lumen by aspirating using standard technique:
   - Attach empty syringe to stopcock
   - Draw back on syringe to deflate balloon
   - Close stopcock and remove syringe
   - Fill syringe with 1:1 saline and contrast mixture
   - Attach syringe to opened stopcock
   - Hold catheter with tip and balloon pointing down
   - Inject just enough contrast material to partially inflate balloon
   - Draw back on syringe deflating balloon
   - Repeat process until all the air has been aspirated from the balloon.
5. Completely deflate balloon and close stopcock.

Catheter Introduction & Inflation

6. Flush the distal lumen with heparinized saline solution.
7. Reference Table 2 for recommended vessel sizes. Note: The recommended vessel sizes are based on the balloon inflation parameters provided in Figure 1 on page 2.

Table 2 - Recommended Vessel Sizes

Balloon Size	Minimum	Maximum
15mm	13mm	15mm

8. Advance balloon catheter over the pre-positioned guide wire utilizing the introducer sheath recommended in Table 1. The exact method of insertion depends largely on the nature of the procedure and physician preference.

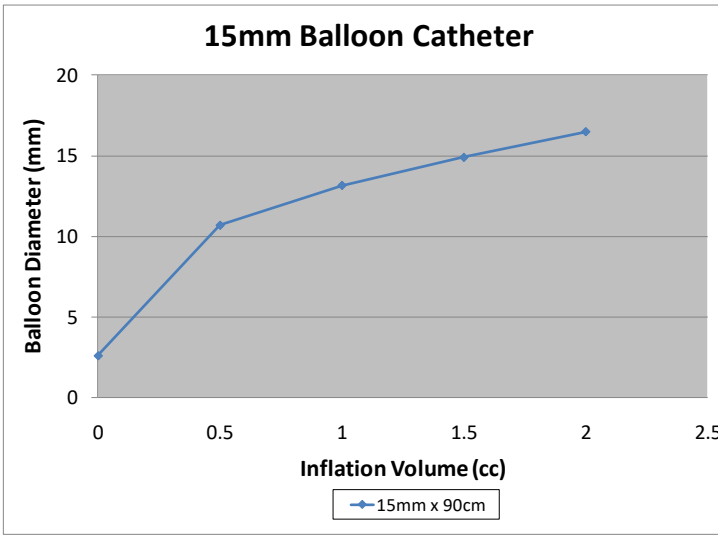
NOTE: If resistance is met while advancing the balloon catheter, determine the cause prior to proceeding.

9. Under fluoroscopy, advance the balloon to the desired position using the balloon's radiopaque markers.

10. Prior to inflation determine the amount of standard 1:1 saline and contrast mixture needed to inflate the balloon to the desired inflation diameter. Refer to the Balloon Inflation Parameter charts in Figure 1, below.

11. Prior to inflation verify balloon is positioned clear of any calcified plaque, stents, or any other sharp object/material.

Figure 1 - Balloon Inflation Parameters



12. Open stopcock and inflate the balloon with standard 1:1 saline and contrast mixture using the recommended size syringe in Table 1. Adhere to the recommended maximum inflation volumes in Table 3. When inflating the balloon always inflate slowly. Monitor balloon manipulations and inflation using fluoroscopy at all times.

Table 3 - Maximum Inflation Volumes

Balloon x Catheter	Max. Volume
15mm x 12mm x 90cm	1.5 cc

The Large Occlusion Balloon Catheter is recommended for a maximum of five inflations/deflations.

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

Balloon Deflation and Withdrawal

14. Completely deflate balloon by pulling vacuum on the inflation syringe. Allow adequate time for balloon to deflate.

15. Maintain vacuum on the balloon and withdraw the catheter.

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

Catalog Number:	REF
Batch Code:	LOT
Use By:	
Contents of the package:	CONTENTS
Do Not Reuse:	
Do Not Resterilize:	
Do not use if packaging is damaged:	
Keep Away From Sunlight:	
Keep Dry:	
CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician:	Rx only
Caution	
Consult Instructions For Use:	
Sterilized using ethylene oxide:	STERILE EO

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