

Steerable Balloon and Straight Balloon Catheter

INSTRUCTIONS FOR USE

Device is sterile. Do not reuse and do not re-sterilize.

INTENDED PURPOSE/INTENDED USE

The Arcadia™ steerable and straight balloon catheters are intended to be used for creation of a void in bone.

INDICATIONS FOR USE

The Arcadia™ steerable and straight balloon catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. These balloon catheters are to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement for use during percutaneous vertebral augmentation, such as kyphoplasty.

DEVICE DESCRIPTION

The Arcadia balloon catheters consist of a Y-Adapter with a dual-lumen catheter shaft and a balloon. The inner shaft lumen contains a stylet (either straight or articulating), the outer lumen is an inflation conduit for the balloon. The marker band is printed on the shaft and serve as an indicator of when the distal tip of the balloon catheter has reached the distal end of the working cannula of the StabiliT™ Introducer. A resheathing tool protects the balloon portion of the device during shipping. It should be slid proximally to uncover the balloon and locked in the handle prior to preparing the balloon.

The Arcadia steerable balloon catheter features a steerable mechanism that enables the steering of the device. The steerable mechanism assists the clinician in directing the balloon catheter through a pre-existing channel by turning the steering handle clockwise to articulate the distal portion of the device.

Figure 1: Arcadia Steerable Balloon Catheter

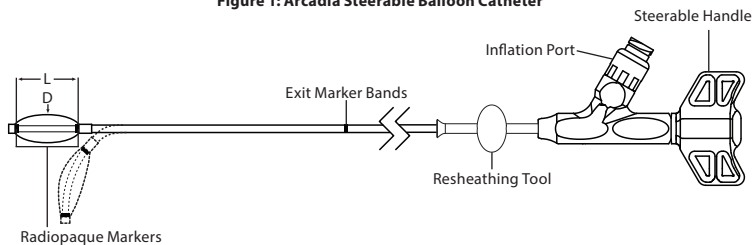
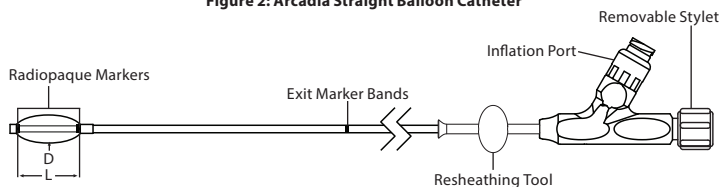


Figure 2: Arcadia Straight Balloon Catheter



CONTRAINDICATIONS

- Instability of posterior wall and/or pedicles.
- Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon.
- Infection.
- Bleeding disorder or treatment that increases the chance of excessive bleeding.
- Any known allergy to bone cement.
- Any known allergy to contrast material.
- Pregnancy.

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

WARNINGS

- Use the device prior to the "Use By" date noted on the package. Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date.
- Inflating the balloon beyond the maximum inflation volume may cause the balloon to rupture before reaching the maximum inflation pressure of 700 psi.
- Inflating the balloon beyond the maximum inflation pressure may cause the balloon to rupture before reaching the maximum inflation volume.
- The balloon may rupture due to contact with bone splinters, bone cement, and/or surgical instruments.
- Do not inflate the balloon until it has been fully deployed in the vertebral body. Inflating the balloon prior to full deployment may result in balloon failure due to contact between the balloon and the working cannula.
- Breakage of the device may require intervention and/or retrieval.
- Never use any air or any gaseous medium to inflate the Arcadia balloons. Use only the recommended minimum 60% contrast medium.
- For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur.
- Complications that may occur during a parapetacular approach include pneumothorax and bleeding.
- The exit marker band on the balloon catheter is for reference only and is not intended to replace the use of fluoroscopic guidance.

PRECAUTIONS

- It is important to read the Instructions For Use carefully prior to use.
- For safe and effective use, this device should only be used by qualified physicians with training in the clinical procedure in which it is being used. The physician should have specific training, experience, and thorough familiarity with the use and application of this product.
- The balloons should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images.
- It is essential to maintain a strict sterile technique during the procedure and during all phases of handling this product.

- DO NOT use if package is opened or damaged. All devices are provided sterile. All devices are sterilized using gamma radiation.
- Do not use damaged products. Prior to use, inspect the packaging and product to verify that no damage has occurred.
- For single patient 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.
- The Arcadia balloon catheters should only be inflated using an inflation device such as the DiamondTOUCH™ Syringe or the StabiliT Touch™ Syringe.
- Only inflate the balloons with liquid contrast media: a 60% solution is recommended. Follow manufacturer's instructions for contrast medium indications, usage, warnings, precautions, and contraindications.
- Steerable balloon catheters should only be deployed in curved access channels previously created by the PowerCURVE® Navigating Osteotome to prevent balloon damage.
- Risk of balloon rupture increases if the balloon comes in contact with bone cement when balloon volume has not been decreased by 1cc from inflated volume.
- The inflation characteristics of the balloon may be altered when inflated inside bone.
- Use the inflation device to withdraw contrast from the balloon and deflate the balloon completely before removal.
- If using the Arcadia steerable balloon catheter, return the steering mechanism to the starting position by turning the steering handle counter-clockwise until the hard stop is detected, prior to balloon catheter removal.
- Dispose of used product per local, state and federal blood borne pathogen controls including biohazard sharps container and disposal procedures.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the use of the balloons include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae.
- Rupture with fragmentation of the inflatable portion of the (device) resulting in retention of a fragment within the vertebral body.
- Rupture of the balloon causing contrast medium exposure, possibly resulting in an allergic reaction or anaphylaxis.
- Deep or superficial wound infection.
- Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis.
- Fracture of the end plate and/or sidewall of the vertebral body due to over inflation of a nonmobile fracture.
- Re-fracture of treated vertebral body
- Bleeding or hematoma.
- Pneumothorax.
- Pedicle fracture.

CLINICAL BENEFITS

The Arcadia™ steerable and straight balloon catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. These balloon catheters are to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement for use during percutaneous vertebral augmentation, such as kyphoplasty.

DIRECTIONS FOR USE

CAUTION: Follow the manufacturer's Instructions For Use for the inflation device.

CAUTION: Contrast media may have different viscosity and precipitation levels that may cause slower inflation and deflation times. For this reason, the use of at least a 60% contrast medium is recommended.

- Select the Arcadia balloon catheter size and type based on the site and treatment goal. Table 1 defines the inflated diameter (D) and the inflated length (L) of the Arcadia balloon in 37°C water at 2mL and the maximum inflation volume.
- The dimensions below may vary during product use due to variation in bone structure.

Table 1: Inflated dimensions in 37°C water

Note: All Arcadia balloon catheters are 10G compatible with a maximum inflation pressure of 700psi.

Catalog #	Balloon Configuration	Pre-Inflation Length	Max Inflation Volume	Volume	Diameter (D)	Length (L)
ARC10SB	Steerable	10mm	3cc	2cc	14mm	16mm
				3cc	16mm	20mm
ARC15SB	Steerable	15mm	4cc	2cc	14mm	18mm
				4cc	17mm	23mm
ARC20SB	Steerable	20mm	5cc	2cc	13mm	21mm
				5cc	18mm	27mm
ARC25SB	Steerable	25mm	7cc	2cc	13mm	25mm
				7cc	19mm	34mm
ARC30SB	Steerable	30mm	8cc	2cc	13mm	26mm
				8cc	20mm	36mm
ARC10ST	Straight	10mm	3cc	2cc	14mm	16mm
				3cc	16mm	20mm
ARC15ST	Straight	15mm	4cc	2cc	14mm	18mm
				4cc	17mm	23mm
ARC20ST	Straight	20mm	5cc	2cc	13mm	21mm
				5cc	18mm	27mm
ARC25ST	Straight	25mm	7cc	2cc	13mm	25mm
				7cc	19mm	34mm
ARC30ST	Straight	30mm	8cc	2cc	13mm	26mm
				8cc	20mm	36mm

PREPARATION OF THE ARCADIA BALLOON CATHETER

- Remove the resheathing tool from the balloon by sliding it proximally until locks in the handle prior to preparing the balloon.
- Push plunger all the way into locking syringe. Attach locking syringe to the inflation port of the Arcadia balloon catheter and pull the plunger back to remove air from the balloon. Turn plunger to lock it in position on the last slot in the syringe.
- Detach the locking syringe and set balloon aside.

- Prepare inflation device with contrast media according to inflation device manufacturer's Instructions For Use.
- Attach the luer connecting port on the inflation device tubing to the inflation port on the Arcadia balloon catheter. The balloon catheter is now ready to use.

ARCADIA BALLOON CATHETER INSERTION

- An access channel is required for the Arcadia balloon catheter placement.
- Follow the Instructions For Use for the chosen Merit access instruments to create the access channel in the bone.
- The steerable balloon catheters will require a channel previously created by the PowerCURVE Navigating Osteotome.
- Insert the deflated Arcadia balloon catheter into the access channel and position it under fluoroscopic image guidance using the radiopaque markers. A gentle twisting motion with the forward push can aid insertion.
- When using the long StabiliT Introducer, the distal tip of the deflated balloon has reached the distal end of the working cannula when the proximal marker band on the balloon shaft aligns with the proximal end of the cannula.
- Straight Balloons:
 - While holding the balloon catheter in place, inflate to 44psi (3atm) to secure balloon in position. Remove the stylet in the straight balloon catheter if desired.
- Steerable Balloons:
 - The Arcadia steerable balloon catheter has a steering handle that enables the steerable feature of the balloon. The arrow printed on the steerable handle indicates the directionality of the steerable handle turning (clockwise) to increase articulation.
 - Begin turning the steering handle on the Arcadia steerable balloon catheter clockwise to aid in directing the distal portion of the device when the distal radiopaque marker of the balloon has exited the working cannula. Continue advancing the balloon catheter and turning the steering handle simultaneously to follow the access channel.
 - The steering mechanism features a detectable hard stop when the maximum articulation has been reached.
 - While holding the balloon catheter in place, inflate to 44psi (3atm) to secure balloon in position.

ARCADIA BALLOON CATHETER INFLATION

- Inflate the Arcadia balloon under continuous fluoroscopic image guidance.
- Increase the volume in small increments (0.25 – 0.5cc). Assess balloon position in lateral and AP views before proceeding to further volume increase.
- Stop balloon inflation when the treatment goal is achieved, any part of the inflated balloon contacts cortical bone, or the maximum inflation volume and/or maximum inflation pressure have been reached (see Table 1).

ARCADIA BALLOON CATHETER REMOVAL

- Deflate the balloon before removal by pulling the inflation device plunger all the way back and removing all contrast medium from the balloon. Confirm using imaging that all contrast is removed from the balloon before continuing.
- If using the Arcadia steerable balloon catheter, return the steering mechanism to the starting position by turning the steering handle counter-clockwise before removal until the hard stop is detected.
- If there is resistance, connect the locking syringe to the inflation port, pull the syringe plunger back, locking it to create a vacuum, confirm using imaging there is no contrast in the balloon, and resume the balloon catheter removal.
- Do not withdraw the balloon catheter unless it is fully deflated. Never withdraw the balloon catheter against resistance. Determine the cause of resistance under fluoroscopy and take the necessary remedial actions.
- Remove the Arcadia balloon catheter from the bone with a gentle motion.
- If unable to remove balloon, simultaneously remove balloon catheter and working cannula through which the balloon was inserted.

COMPLETION OF VERTEBRAL AUGMENTATION OR BALLOON KYPHOPLASTY PROCEDURE

Following void creation in a pathological fracture of the vertebral body, StabiliT® Bone Cement may be introduced. Please refer to appropriate Instructions For Use for cement delivery.

CEMENT RESISTANCE TECHNIQUE

If leaving an inflated balloon inside the vertebral body during cement fill on the contra-lateral side, prior to injection of cement, ensure balloon volume is reduced by 1.0cc. It is recommended that the balloon is not placed in contact with the bone cement for more than 5 minutes.

STERILIZATION

Sterilized by Gamma Irradiation.

HOW SUPPLIED

The Arcadia balloon catheter package is supplied sterile in a peel-open package. A locking syringe is also provided in a separate sterile, peel-open package. In the event of damage to packaging, do not use and notify the manufacturer.

MATERIALS NOT SUPPLIED

- Inflation Syringe
- Contrast Media
- StabiliT Introducers
- PowerCURVE Navigating Osteotome
- VertecoR® Bone Drill
- StabiliT Bone Cement

NOTE: Inflation Syringe, StabiliT Introducers, PowerCURVE Navigating Osteotome, VertecoR Bone Drill and StabiliT Bone Cement are available from Merit Medical.


















STORAGE

The Arcadia balloon catheter should be stored in its original shipping materials. Proper care should be taken to ensure that the devices will not be damaged. Store in a clean, cool, dry place. Avoid extreme humidity and temperature.

SINGLE USE DEVICE

For single patient 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.

The Basic UDI-DI for the Arcadia Balloon Catheter is 088445048829ED.

	Sterilized using irradiation
	Caution: Consult accompanying documents
	Use-by date: YYYY-MM-DD
	Manufacturer
	Date of Manufacture: YYYY-MM-DD
	Do Not Use If Package Is Damaged
	Single Use Device, DO NOT REUSE
	Authorized Representative in the European Community
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Catalog Number
	Lot Number
	Consult instructions for use. For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service.
	Do not resterilize
	Medical Device
	Single Sterile Barrier System
	Unique Device Identifier
	Maximum Inflation Pressure
Maximum Inflation Volume	Maximum Inflation Volume
Pre-Inflation Length	Pre-Inflation Length
Straight Balloon Catheter	Straight Balloon Catheter
Steerable Balloon Catheter	Steerable Balloon Catheter
Part A	Part A
Part B	Part B
Made in U.S.A.	Made in U.S.A.



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