ARCADIA®

English

Balloon-Assisted Vertebral Augmentation System

INSTRUCTIONS FOR USE

Common information

Devices are sterile. Do not reuse and do not re-sterilize.

℞ ONLY CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

WARNINGS
- Dispose of used product per Local, State and Federal Blood borne pathogen controls including Biohazard sharps container and disposal procedures.
- Breakage of the device may require intervention or retrieval.
- This device should only be used by qualified physicians with training in the clinical procedure in which it is being used. Always use fluoroscopic guidance to avoid patient injury. Always use imaging guidance to avoid patient injury.
- It is essential to maintain strict sterile technique during all phases of handling and use of this product.
- Check packaging for damage prior to placing contents in sterile field.
- Remove product from package using standard sterile technique.
- 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.

PRECAUTIONS
- It is important to read the Instructions For Use and these precautions prior to device operation.
- Do not use damaged product. Before use, inspect each device and packaging to verify that no damage has occurred.
- Follow the Instructions For Use to create an access channel and a cement staging area in the bone.
- DO NOT use if package is opened or damaged. All devices are provided sterile.

HOW SUPPLIED
The Arcadia kit components are supplied sterile in peel-open packages.

STORAGE & HANDLING
Handle with care. Store in original packaging in a clean, cool, and dry location. Avoid extreme humidity and temperature.

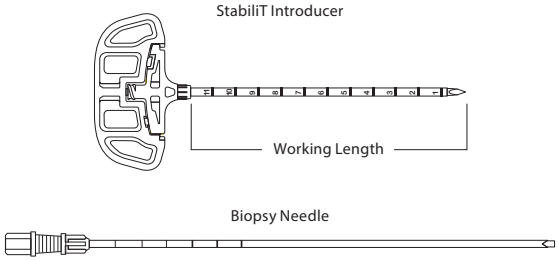
REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, 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.

StabiliT® Introducer and Biopsy Needle

INDICATION
The StabiliT® Introducer is indicated for percutaneous access to bone.

DESCRIPTION
The StabiliT Introducer is indicated for percutaneous access to bone and consists of a cannula with either a trocar or bevel tip stylet. The Introducer cannula is 3.6mm in outer diameter. See the chart below for the device length.

Device	Working Length
StabiliT Introducer (Short)	10 cm
StabiliT Introducer (Long)	12 cm



WARNINGS
1. For safe use of the StabiliT Introducer, the physician should have specific training, experience, and thorough familiarity with the use and application of this product.
2. It is essential to maintain strict sterile technique during all phases of handling and use of this product. The product is sterile. Do not use if package is opened or damaged.
3. Do NOT use this product in dense bone; device damage resulting in patient injury may occur. Breakage of the device may require intervention or retrieval.
4. The Introducer Stylet should be inserted and engaged with the Working Cannula during Introducer removal or manipulation.

PRECAUTIONS
1. Use the StabiliT Introducer prior to Use By Date noted on the package to verify no damage has occurred.
2. Physicians using the StabiliT Introducer should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.
3. The StabiliT Introducer should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images.

ADVERSE EVENTS
Adverse events potentially associated with use of the device include:
- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Embolism
- Hemorrhage
- Hemothorax or pneumothorax
- Hematoma
- Infection including deep or superficial wound infection
- Pain
- Unintended puncture wounds including vascular puncture and dural tear
- Fracture
- Incorrect placement possibly resulting in rupture of the aorta and/or nerve damage.
- Re-fracture of treated vertebral body

DIRECTIONS FOR USE
1. Make a skin incision over the selected area for access. Using fluoroscopic imaging guidance, manually advance the StabiliT Introducer to the selected bone surface checking AP/Lateral images to confirm proper placement. Do not advance the cannula without the stylet fully inserted into the cannula.
2. While holding the cannula in place, turn the stylet counter-clockwise to release and remove it from the cannula. The cannula is now ready to accept other instrumentation.

NOTE: Markings on the cannula may be used as reference markers only, they are not intended to replace the use of fluoroscopic observation.

BIOPSY PROCEDURE (OPTIONAL)
WARNING: Do not use for a sternal procedure. Due to the needle length, internal thoracic organs or blood vessels may be punctured or otherwise damaged.
- Remove obturator from biopsy needle. Insert biopsy needle into the access cannula.
- Advance the biopsy needle to the appropriate depth according to clinical judgment.

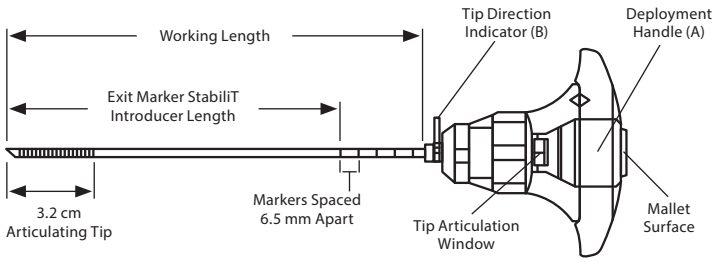
CAUTION: Use appropriate techniques to confirm the position of the access cannula and biopsy needle tip. Be aware of the anatomical considerations for positioning.
- After the appropriate depth has been reached, rotate the biopsy needle clockwise and counterclockwise sufficiently to dislodge the specimen from the surrounding tissue.
- Remove the needle from the patient and carefully eject the specimen from the needle using obturator.

PowerCURVE® Navigating Osteotome

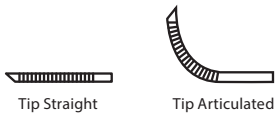
INDICATIONS FOR USE
The PowerCURVE® Navigating Osteotome is intended for scraping or coring of bone in the spine.

DESCRIPTION
The PowerCURVE Navigating Osteotome is a sterile single use osteotome device for scraping or coring of bone to create an area in which cement delivery can be initiated in the treatment of vertebral compression fractures. It is to be used with the StabiliT Introducer. The Shaft is 3.0 mm in outer diameter and the working length is 17.1 cm.

The Deployment Handle (A) is the rotating portion that articulates the distal tip of the device. The Tip Direction Indicator (B) indicates the direction in which the tip will articulate.



DEVICE	Working Length	Distal Exit Marker
PowerCurve Osteotome (Short)	15.1cm	12.0 cm
PowerCurve Osteotome (Long)	17.1cm	14.0cm



WARNING
1. For safe use of the PowerCURVE Navigating Osteotome, the physician should have specific training, experience, and thorough familiarity with the use and application of this product.
2. Do NOT use the device in fractures due to pararenal or prostatic cancer metastasis to the spine.
3. Do NOT use a device to scrape or core in more than one vertebra.
4. Dispose used product per Local, State and Federal Bloodborne pathogen controls including Biohazard sharps container and disposal procedures.
5. The product is sterilized by gamma radiation. Do not use if package is opened or damaged.
6. Do NOT use this product in dense bone including traumatic fractures; device damage resulting in patient injury may occur.

PRECAUTIONS
1. Use the PowerCURVE Navigating Osteotome prior to Use By Date noted on the package.
2. Physicians using the PowerCURVE Navigating Osteotome should be familiar with the physiology and pathology of xthe selected anatomy, and be trained in the performance of the chosen surgical technique.
3. The PowerCURVE Navigating Osteotome should be manipulated only while under image guidance observation with radiographic equipment that provides high quality images.
4. The location of the StabiliT Introducer's Working Cannula in the vertebra should be monitored under image guidance before and during advancement as well as after removal of the PowerCURVE Navigating Osteotome.

ADVERSE EVENTS
- Adverse events potentially associated with use of the device include:
- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pulmonary embolism
- Hemothorax or pneumothorax
- Pain

- Hemorrhage
- Hematoma
- Infection including deep or superficial wound infection
- Unintended puncture wounds including vascular puncture and dural tear

DIRECTIONS FOR USE

1. The Articulating Tip is the distal portion of the PowerCURVE Navigating Osteotome. The Tip Direction Indicator points in the direction that the Articulating Tip bends.
2. The Deployment Handle is the rotating portion of the PowerCURVE Navigating Osteotome Handle.
   a. Turning the Deployment Handle one (1) full 360° turn clockwise will cause the Articulating Tip to fully bend.
   b. Turning the Deployment Handle counter-clockwise will cause the Articulating Tip to straighten.
   c. Do not deploy the Deployment Handle greater than one (1) full 360°turn clockwise.
3. Ensure the Articulating Tip is fully extended in the straight position prior to insertion into the Working Cannula.
4. Remove the Stylet from the Working Cannula.
5. Insert the PowerCURVE Navigating Osteotome into the Working Cannula until the first laser mark on the shaft is even with the proximal end of the luer on the Working Cannula. Confirm by image guidance that the distal end of the PowerCURVE Navigating Osteotome is at the distal end of the Working Cannula before proceeding. When fully inserted into Working Cannula, the shaft extends approximately 31 mm beyond the distal end of the Working Cannula.
6. As the Articulating Tip exits the Working Cannula turn the Deployment Handle in a clockwise direction to bend the Articulating Tip.
7. The PowerCURVE Navigating Osteotome can be advanced to the desired position using image guidance.
8. Care should be taken at all times to NEVER strike the arms of the Deployment Handle, especially when rotated from its starting position.
9. Using image guidance (and stabilizing the Working Cannula), the PowerCURVE Navigating Osteotome can be carefully withdrawn and advanced multiple times to scrape or core bone until the desired cavity (size and location) is created.
10. When the Articulating Tip is substantially articulated, the PowerCURVE Navigating Osteotome should not be rotated. The rotation limiting mechanism will slip if the large handle is rotated while the Articulating Tip is substantially articulated and it meets substantial resistance.
    CAUTION: The location of the Working Cannula in the vertebra should be monitored before, and during advancement of the PowerCURVE Navigating Osteotome through the Working Cannula.
11. When cavity creation is complete, using imaging guidance, straighten the Articulating Tip and return the Deployment Handle to its starting position.
    CAUTION: Straightening of the Articulating Tip should be done slowly and under imaging guidance while carefully monitoring the position of the tip of the device. Straighten the device by turning the Deployment Handle counter-clockwise.
12. Under imaging guidance, remove the PowerCURVE Navigating Osteotome from the StabiliT Introducer's Working Cannula.
13. The location of the StabiliT Introducer Working Cannula in the vertebra should be monitored and adjusted if necessary after removal of the PowerCURVE Navigating Osteotome.

VertecoR® Bone Drill, 3.0

INDICATIONS FOR USE

The VertecoR® Bone Drill is intended for percutaneous access to bone in the spine.

DESCRIPTION

The VertecoR Bone Drill is a sterile single use device used for coring of bone. This device must be used with the StabiliT® Introducer.

WARNING

1. This device is for use with TWO lengths of StabiliT Introducers. Directions for Use on how it should be used with each length should be strictly adhered to.
2. For safe use of the VertecoR Bone Drill, the physician should have thorough familiarity with the use and application of this product.
3. The product is sterilized by gamma radiation. Do NOT use if package is opened or damaged.
4. Do NOT hammer or bend the device during use. Breakage of the device may occur requiring intervention or retrieval.
5. Shaft marks on the drill may be used only as reference marks. Shaft marks are not intended to replace the use of imaging guidance.
6. Do NOT use the device without the StabiliT Introducer.

PRECAUTIONS

1. Use the VertecoR Bone Drill prior to Use By Date noted on the package.
2. Physicians using the VertecoR Bone Drill should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.
3. The VertecoR Bone Drill should be manipulated only while under imaging guidance.

POTENTIAL ADVERSE EVENTS

- Deep or superficial wound infection
- Pain
- Unintended puncture wounds including vascular puncture and dural tear
- Hemorrhage
- Hemothorax or pneumothorax
- Bleeding or Hematoma
- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism
- Nerve injury including puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis

DIRECTIONS FOR USE

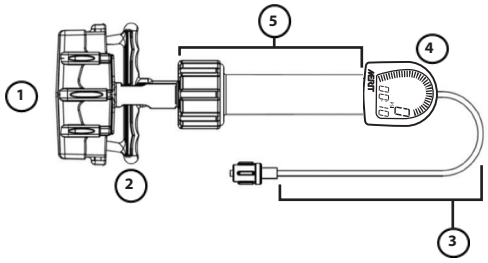
1. Create an access channel into the vertebral body using the StabiliT Introducer.
2. Remove the Stylet from the StabiliT Introducer and insert the VertecoR Bone Drill into the Working Cannula.
3. Using imaging guidance and the THICK shaft marks on the proximal portion of the shaft, advance the distal end of the VertecoR® Bone Drill to the distal end of the Working Cannula:
   a. When using the StabiliT Introducer 3.6-11.5, advance the VertecoR Bone Drill to the DISTAL THICK shaft mark.
   b. When using the StabiliT Introducer 3.6 advance the VertecoR Bone Drill to the PROXIMAL THICK shaft mark.
   c. PRIOR to proceeding, confirm this position using imaging guidance.
4. Using manual control and imaging guidance, rotate the drill clockwise and advance to the desired depth.
5. Remove the VertecoR Bone Drill from the Working Cannula of the StabiliT Introducer using a clockwise rotation.

CAUTION: The location of the Working Cannula in the vertebra should be intermittently monitored before and during advancement of the VertecoR Bone Drill through the Working Cannula.

DiamondTOUCH™ Syringe

DESCRIPTION

The DiamondTOUCH™ Syringe is a 30mL disposable device with a threaded plunger assembly and a flexible high pressure extension tube. The DiamondTOUCH Syringe is designed to generate positive and negative pressure, and monitor positive pressures over a range of zero to 514 PSI (zero to +35ATM/BAR).



1. Handle
2. Clutch
3. Extension Tube
4. Pressure Gauge
5. Barrel (contains plunger)

INDICATIONS FOR USE

The DiamondTOUCH Syringe is intended for percutaneous delivery of bone cement. The device can also be used for inflating and deflating interventional devices, and to measure pressure.

PREPARATION AND USE

1. Press the blue button behind the DiamondTOUCH Syringe LCD display near the tubing to power the device on. The LCD will display "Zero" for two seconds and then the device will be ready for use. At this point the syringe will begin its incremental time keeping.
   NOTES:
   a. The syringe will default to PSI mode when initially turned on. To change the pressure display to read ATM/BAR, press and hold the blue button until "ATM/BAR" flashes four times. The display is now in "ATM/BAR" mode. To change back to PSI, press and hold the blue button once again.

   b. When in PSI mode, the tick marks on the left of the display that represent pressure will be limited to 350 PSI (23.8 ATM). If the DiamondTOUCH is pressurized past 350 PSI, the grouping of tick marks on the left will flash. The numerical digits in the center of the display will continue to show actual pressure throughout the device's pressure range (-6 to 514 PSI) After pressure reading has been taken, a graph bar or tick mark will remain to mark the highest point of pressure. Pressing the blue button once quickly will display last pressure reading information and a "↺" indicator on the display. After the next pressure reading has started, the last tick mark will disappear.
   c. To conserve power the backlight will automatically turn off after ten minutes of inactivity. However, the microprocessor will continue to monitor the pressure. Pressing the blue button will reactivate the backlight. The device will power itself off after 90 consecutive minutes at zero pressure.

   CAUTION: If the DiamondTOUCH Syringe LCD displays anything besides the pressure and time windows as shown above, the syringe is defective. Please return the syringe to Merit Medical for credit.
2. Prepare the DiamondTOUCH Syringe:
   a. Squeeze the clutch and advance the plunger with enough force to completely remove any air present in the syringe.
   b. Submerge the end of the extension tube in sterile water (or saline) when used for cement delivery or liquid contrast media for inflation and deflation of interventional devices.
   c. Squeeze the clutch on the DiamondTOUCH Syringe and pull back the handle to develop a negative pressure and fill the syringe with fluid. Do so until the entire syringe is filled.
   d. While holding vertical, push handle against table or other solid surface to remove any air in syringe and extension tube.
   e. If additional fluid is needed in the DiamondTOUCH Syringe, squeeze the clutch and pull back fully to aspirate with sterile water (or saline), or liquid contrast media.
   f. Optional device stickers are included to be attached to the DiamondTOUCH Syringe to identify the fluid being used in the syringe. The white sticker may be used to identify sterile water, the blue sticker for saline, and the yellow sticker for contrast.

PRECAUTIONS

When using for inflatable bone tamps only use liquid contrast media (a 60% solution is recommended). Follow manufacturer's instructions for contrast media indications, usage, and cautions.

CAUTION: Inspect the DiamondTOUCH Syringe tubing to ensure that there is no air in the system prior to cement delivery.

CEMENT DELIVERY

1. Assemble cement and delivery system components per IFU.
2. After inserting needle into patient, begin delivery of bone cement by rotating the DiamondTOUCH Syringe handle in the CLOCKWISE direction. Once bone cement exits the needle tip, stop cement flow by squeezing and releasing the clutch on the syringe. Wipe needle tip clean.
3. Under image guidance, deliver bone cement by rotating the handle in the CLOCKWISE direction.
4. To stop bone cement delivery, squeeze and release the clutch on the DiamondTOUCH Syringe. To re-engage (if necessary), squeeze the clutch and push the handle forward until resistance is met, then release clutch. Continue delivering bone cement by rotating the handle in the CLOCKWISE direction.

CAUTION: To protect the threads of the lock release handle, the quick release mechanism should be used to stop flow and relieve pressure when the gauge indicates 367 PSI (25 ATM) or lower.

BALLOON INFLATION AND DEFLATION

To inflate the balloon, squeeze the clutch and advance the plunger until resistance is met. Release grip on the clutch, locking the plunger in position.

To increase pressure, while assessing balloon inflation under image guidance, rotate the handle clockwise until the desired inflation pressure or size of the balloon is reached. The lock mechanism maintains the pressure. **NOTE:** Loss of pressure may indicate a leak in the system.

To deflate the balloon, rotate the handle counterclockwise to release pressure to 25 ATM or lower. Squeeze the clutch and pull back to generate a negative pressure. Release grip on the clutch to lock the plunger in the negative pressure position.

CAUTION: The quick release clutch mechanism will activate (signaled by a clicking sound) if the operator exceeds the maximum pressure for the DiamondTOUCH Syringe. Once this has occurred, the clutch mechanism may disengage at lower pressures during subsequent attempts to increase pressure.

CAUTION: The volume change of fluid dispensed may not be accurate due to compliance of the plastic components as pressure changes.
CAUTION: If applied pressure does not indicate on gauge/ digital display, discontinue use immediately and replace it with a new unit.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RADIO FREQUENCY (RF) COMMUNICATIONS EQUIPMENT AND THE DIAMONDTOUCH SYRINGE
The DiamondTOUCH Syringe is intended for use in an electromagnetic environment in which RF radiated disturbances are controlled. The user of the DiamondTOUCH Syringe can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DiamondTOUCH Syringe as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (in meters) m		
Rated maximum output power of transmitter (in watts) W	**150 kHz to 80 MHz** $d=[1.2]\sqrt{P}$	**80 MHz to 800 MHz** $d=[1.2]\sqrt{P}$	**800 MHz to 2.5 GHz** $d=[2.3]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.

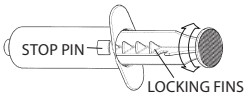
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-20	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Increasing relative humidity will reduce the potential for ESD related difficulties

Users should follow local guidelines and practices regulating the disposal of infected waste products.

For the State of California, U.S.A. only
Perchlorate Material: special handling may apply.
See www.dtsc.ca.gov/hazardouswaste/perchlorate
Perchlorate Material: Lithium battery contains perchlorate.

VacLok® Syringe

PRODUCT DESCRIPTION
A vacuum pressure syringe (locking syringe).

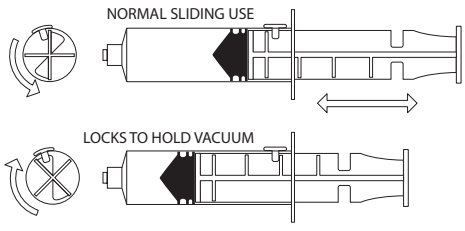


INTENDED USE
The VacLok® Syringe is intended to be used by a cardiologist or radiologist during angiographic or radiologic procedures.

PRECAUTIONS
- This device is sterile and non-pyrogenic.

INSTRUCTIONS FOR USE
Inspect the device prior to use to verify that no damage has occurred during shipping.
1. To setup the syringe to lock, move the plunger completely forward or completely back and turn the plunger so that the locking fins can engage the stop pin.
2. To create and maintain vacuum, withdraw the syringe plunger to the desired position and rotate the plunger clockwise to position one of the locking fins behind the stop pin.
3. Turn the plunger counterclockwise to release.
4. To aspirate fluids without locking the syringe, move the plunger completely forward or completely back, turn the plunger so that the locking fins will not interfere with the stop pin.

Device is sterilized as stated on the package label. Accuracy = ± 4%



Arcadia® Steerable Balloon and Straight Balloon Catheter

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

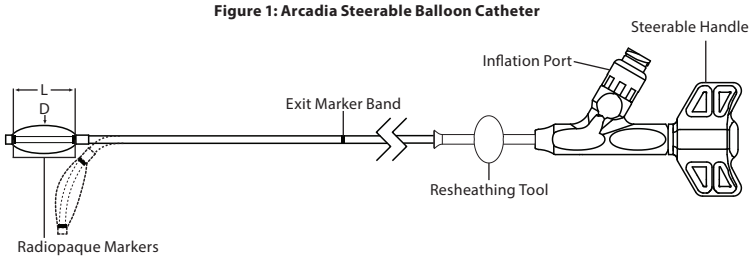
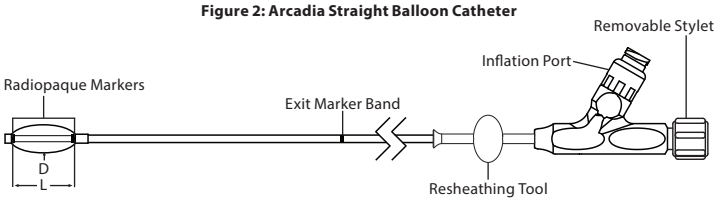


Figure 2: Arcadia Straight Balloon Catheter



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 parapedicular 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 intended clinical benefit of the Arcadia Balloon Catheters is to create targeted void(s) in bone for subsequent augmentation by using bone cement.

PATIENT POPULATION

The Arcadia Balloon Catheters are intended for the treatment of adult patients.

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 catheter 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 marker band on the catheter shaft aligns with the proximal end of the cannula.
- Straight Balloons:
  - o 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:
  - o 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.
  - o 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.
  - o The steering mechanism features a detectable hard stop when the maximum articulation has been reached.
  - o 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.

Master Syringe Assembly

INDICATIONS FOR USE

The Master Syringe Assembly is intended for the delivery of StabiliT® Bone Cement.
(For a complete listing of Indication for Use, Contraindications, Warnings, Precautions and Adverse Events reference the relevant StabiliT® Bone Cement and StabiliT® Delivery System instructions for use.)

DESCRIPTION

The Master Syringe Assembly consists of three components:

- Hydraulic Coupler: The Hydraulic Coupler is used to connect the StabiliT® Delivery Syringe extension tube to the Master Syringe.
- Master Syringe: The Master Syringe is connected between the Hydraulic Coupler and the Cement Syringe to translate hydraulic force to physical force for delivery of bone cement.
- Cement Delivery Elbow: The Cement Delivery Elbow is used to connect the Cement Syringe to the Access Needle or Locking Delivery Cannula at a 90° angle.

Hydraulic Coupler | Master Syringe | Cement Delivery Elbow

WARNING

1. This device should only be used by qualified physicians with training in the clinical procedure in which it is being used and have thorough familiarity with the use and application of this product. Physicians using the Master Syringe Assembly should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.
2. It is essential to maintain strict sterile technique during all phases of handling and use of this product. The product is sterilized by gamma radiation. Do not use if package is opened or damaged.
3. This device is only for use with Merit products.

DIRECTIONS FOR USE

1. Thread the Master Syringe onto the Cement Syringe.
   CAUTION: Ensure that the Cement Syringe is FULLY threaded onto the Master Syringe before proceeding. Not doing so may cause device malfunction.
2. Confirm that the StabiliT® Delivery Syringe extension tube is securely connected to the Hydraulic Coupler and Master Syringe.
3. The Cement Syringe is then connected to the Cement Delivery Elbow, which is used to connect to the Cement Syringe to the Access Needle or Locking Delivery Cannula.

Locking Delivery Cannula 3.0-11.5-ED and Locking Delivery Cannula 3.0

INDICATIONS FOR USE

The StabiliT Vertebral Augmentation System is intended for percutaneous delivery of StabiliT ER2 Bone Cement in kyphoplasty procedures in the treatment of pathological fractures of the vertebrae. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

DESCRIPTION
The Locking Delivery Cannula (LDC) is packaged with a diamond tip stylet and cannula with a threaded luer adaptor and wheel hub. The cannula is 3.0mm in outer diameter. See the chart below for the device length.

Device	Working Length
Locking Delivery Cannula 3.0-11.5-ED (Short)	13 cm
Locking Delivery Cannula 3.0 (Long)	15 cm

WARNING
1. LDC must be utilized only with the working cannula properly positioned in the vertebral body under fluoroscopic guidance using on demand radiographic imaging equipment.
2. Following completion of cement delivery the pressure in the system should be relieved and the LDC removed within 1 minute of completing cement delivery.

PRECAUTIONS
1. Use the LDC prior to Use By Date noted on the package and verify product is undamaged.
2. Physicians using the LDC should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.

ADVERSE EVENTS
Adverse events potentially associated with use of the device include:
- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Pulmonary embolism
- Hemorrhage
- Hemothorax or pneumothorax
- Hematoma
- Infection including deep or superficial wound infection
- Pain
- Unintended puncture wounds including vascular puncture and dural tear

DIRECTIONS FOR USE
1. Separate the LDC stylet from the LDC cannula and attach the cement delivery elbow to the LDC cannula hub.
2. Properly prepare, mix and deliver bone cement through the LDC following the StabiliT Bone Cement and Saturate Mixing System IFU and the StabiliT MX Vertebral Augmentation System IFU.
   CAUTION: Never deliver cement through the LDC without fluoroscopic guidance to confirm cement position.

	Caution
	Use by date: YYYY-MM-DD
	Manufacturer
	Date of Manufacture: YYYY-MM-DD
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single Use Device, DO NOT REUSE
EC REP	Authorized Representative in the European Community
℞ ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.
REF	Catalog Number
LOT	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
MD	Medical Device
	Single sterile barrier system with protective packaging inside
STERILE	Sterilized
STERILE R	Sterilized using Irradiation
STERILE EO	Sterilized using Ethylene Oxide
	Interference may occur in the vicinity of equipment marked with this symbol
	Contains Batteries - Do Not Remove
UDI	Unique Device Identifier
LATEX	No Latex
QTY	Quantity
	Bevel Tip
	Trocar Tip
LEN 17.1 CM	Shaft length 17.1cm
L	Longer Length instrument
	Keep Dry
	Keep away from sunlight
	Temperature Limitations
	Maximum 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.

MERITMEDICAL®

CE 2797

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