MERITMEDICAL® | SPINE

STEERABLE SPINE SOLUTIONS

Steerable Spinal Augmentation and Ablative Therapies

AT THE FOREFRONT OF SPINAL THERAPY INNOVATIONS

The Merit SPINE Advantage

Discover a more targeted therapy using the first and only steerable portfolio for Vertebral Augmentation and Radiofrequency Ablation. Merit SPINE's unique cutting-edge steerable technology, enables clinicians to target and treat spinal pathologies with precision and control. These latest advancements allow for navigation of complex anatomies, enhanced procedural flexibility, and optimized clinical outcomes. Choose from a broad product offering intended for targeted cavity creation, fracture stabilization, and radiofrequency tumor ablation.

Merit SPINE's mission and continued commitment is to help improve patient quality-of-life by innovating minimally invasive techniques that deliver rapid and lasting pain relief.

STEERABLE SPINE SOLUTIONS

Channel Creation

PowerCURVE®
Navigating Osteotome

Create preferential pathways for targeted therapy using the only steerable osteotome for vertebral pathologies. This intuitive design allows for minimally invasive VCF stabilization via unipedicular access, while preserving intact cancellous bone.

Cavity Creation

ARCADIA®
Steerable Balloon Catheter

Create a bipedicular footprint via unipedicular access using the revolutionary ARCADIA Steerable Balloon Catheter. This innovative balloon catheter allows for a targeted cavity creation in the coronal plane, providing optimal cement fill and limited morbidity associated with multiple access points.

Tumor Ablation

STAR™
Tumor Ablation System

Confidently target and treat metastatic spinal tumors with the STAR System. Steerable bipolar probes allow modification of trajectory within the vertebral body. Thermocouples, embedded along the shaft, provide real-time feedback to quantify, adjust, and confirm the ablation zone intra-operatively.

MERIT SPINE'S CUTTING-EDGE STEERABLE TECHNOLOGY ALLOWS FOR A MORE TARGETED THERAPY, YIELDING PREDICTABLE OUTCOMES.

1. **UNIPEDICULAR ACCESS:**

- Minimize incision and access-related morbidity.[1,2,3]
- Reduce procedure and imaging time.[2]

2. **STEERABLE CAVITY CREATION AND RF ABLATION:**

- Navigate complex anatomies.
- Change trajectory past the pedicle-body junction.[3, 4]
- Reach anterior and posterior regions of the vertebral body.[3, 4]

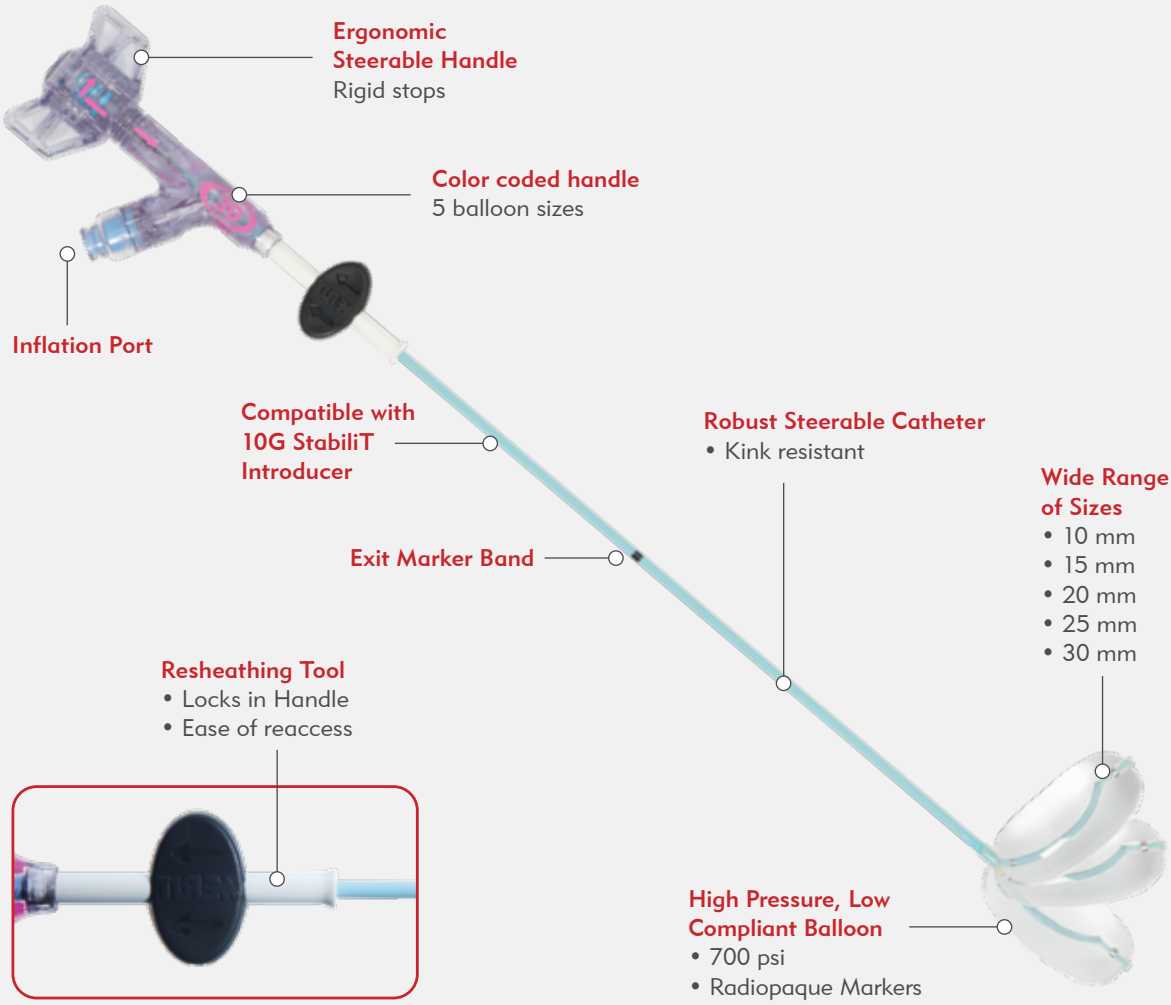
3. **CEMENT DELIVERY:**

- Optimize targeted cement deposition and volume.[6]
- Deliver ultra-high viscosity cement with an extended working time.[7]

ARCADIA®
Balloon Assisted Vertebral Augmentation System

CAVITY CREATION

ARCADIA® STEERABLE BALLOON CATHETER is designed to achieve controlled, targeted cavity creation in vertebral augmentation procedures, followed by targeted cement delivery for optimal fracture stabilization. This articulating, low-compliant balloon, enables a change of trajectory inside the vertebral body,allowing for unipedicular access and targeted balloon placement. Steerable technology helps limit morbidity associated with multiple access points and yields more predictable outcomes.[2, 5]



ARCADIA® STRAIGHT BALLOON CATHETER is designed for consistent, predictable, and precise cavity creation when compacting cancellous bone in the treatment of vertebral compression fractures via bipedicular approach.

ARCADIA® BALLOON KITS

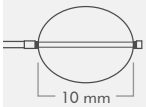
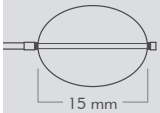
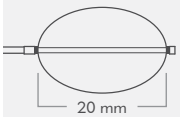
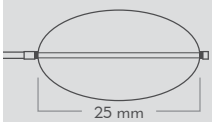
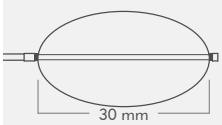
Providing comprehensive vertebral augmentation solutions for a more efficient and straightforward procedural setup and approach.

ARCADIA® Steerable Balloon Kit

StabiliT® Introducer Trocar-tip and Beveled-tip Stylet) | ARCADIA® biopsy needle | PowerCURVE® Navigating Osteotome | ARCADIA® Steerable Balloon Catheter | ARCADIA® 20mL VacLok | ARCADIA® Inflation Syringe | Locking Cement Delivery Cannula (11G) with Trocar-Tip Stylet | StabiliT® Bone Cement & Saturate Mixing System | Master Syringe/Elbow/Coupler | DiamondTOUCH™ Inflation Syringe

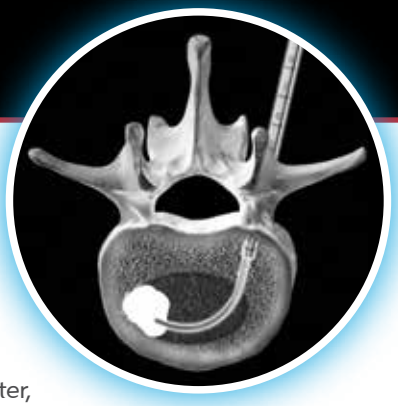
ARCADIA® Straight Balloon Kit

StabiliT® Introducer Trocar-tip and Beveled-tip Stylet) | ARCADIA® biopsy needle | VertecoR® Bone Drill | ARCADIA® Straight Balloon Catheters | ARCADIA® 20mL VacLok | ARCADIA® Inflation Syringes | Locking Cement Delivery Cannula (11G) with Trocar-Tip Stylet | StabiliT® Bone Cement & Saturate Mixing System | Master Syringe/Elbow/Coupler | DiamondTOUCH™ Inflation Syringe

Pre-Inflation Length	Product Number		Color Code	Max Inflation Volume	Volume	Diameter (D)	Length (L)
	Steerable	Straight					
	ARC10SB-LK	ARC10ST-LK		3 cc	2 cc	14 mm	16 mm
					3 cc	16 mm	20 mm
	ARC15SB-LK	ARC15ST-LK		4 cc	2 cc	14 mm	18 mm
					4 cc	17 mm	23 mm
	ARC20SB-LK	ARC20ST-LK		5 cc	2 cc	13 mm	21 mm
					5 cc	18 mm	27 mm
	ARC25SB-LK			7 cc	2 cc	13 mm	25 mm
					7 cc	19 mm	34 mm
	ARC30SB-LK			8 cc	2 cc	13 mm	26 mm
					8 cc	20 mm	36 mm

*All sizes rated at 700 psi

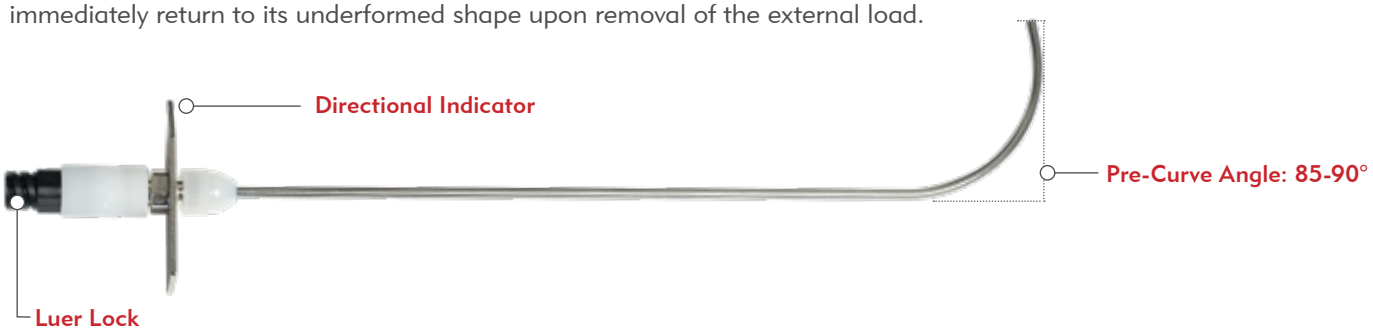
ARCADIA®
Curved Delivery Cannula



TARGETED CEMENT DELIVERY

The ARCADIA® Curved Delivery Cannula complements the steerable capabilities of the PowerCURVE® Navigating Osteotome and ARCADIA® Steerable Balloon Catheter, providing you with the trifecta of treatment for targeted cement delivery. The pre-curved nitinol cannula allows for predictable cement deposition across midline of the vertebral body, optimizing cement volume, while potentially reducing the need for bipedicular access.

Nitinol Curved Delivery Cannula: Able to undergo large deformations and immediately return to its underformed shape upon removal of the external load.



Flexible Stylet: Can be used when placing ARCADIA Curved Delivery Cannula to avoid obstruction at distal tip.

Stainless Steel Obturator: Used to clear obstructions or express cement within the cannula.

ORDERING INFORMATION

Product Number	Gauge	Length
ARC13CDC	13G	19 cm

Specifications	
Cannula Length	19 cm
Cannula length that protrudes beyond Merit Introducer	5.1 cm
Cannula OD	0.0913"
Cannula ID	0.0668"
Pre-Curved Angle	85-90°
Flexible Stylet Length	22.5 cm
Stainless Dilator Length	23.3 cm
Directional Indicator	Yes

STABILIT® VP
Vertebroplasty System

SIMPLIFIED VERTEBROPLASTY

The StabiliT® VP Vertebroplasty System combines Merit's patented simple cement preparation with the controlled delivery of high-viscosity cement.

SIMPLE CEMENT PREPARATION

- No blending, shaking, squeezing, or stirring
- Mixing cartridge used for delivery; no need to transfer cement

EXCELLENT CONTROL

- Up to 2x viscosity of standard PMMA cements*; designed for consistent filling and interdigitation
- Extended working time ~35 minutes for procedural flexibility*
- Barium sulfate radiopacifier

CONTROLLED DELIVERY

- Precise cement delivery and stoppage for predictable results
- Reduced radiation exposure with 36-inch delivery line

STABILIT® VP VERTEBROPLASTY KIT

Product Number	Description
VP-1110L	**StabiliT® VP Vertebroplasty Kit** StabiliT® Introducer (10G) with Diamond-tip Stylet | Locking Cement Delivery Cannula (11G) with Diamond-tip Stylet | StabiliT® Bone Cement & Saturate Mixing System | StabiliT® Touch Syringe
VP-0010A	**StabiliT® VP Vertebroplasty Kit (Without Needles)** StabiliT® Bone Cement & Saturate Mixing System | StabiliT® Touch Syringe

* Tests performed and data on file at Merit Medical Systems, Inc.

STABILIT® MX
Vertebral Augmentation System

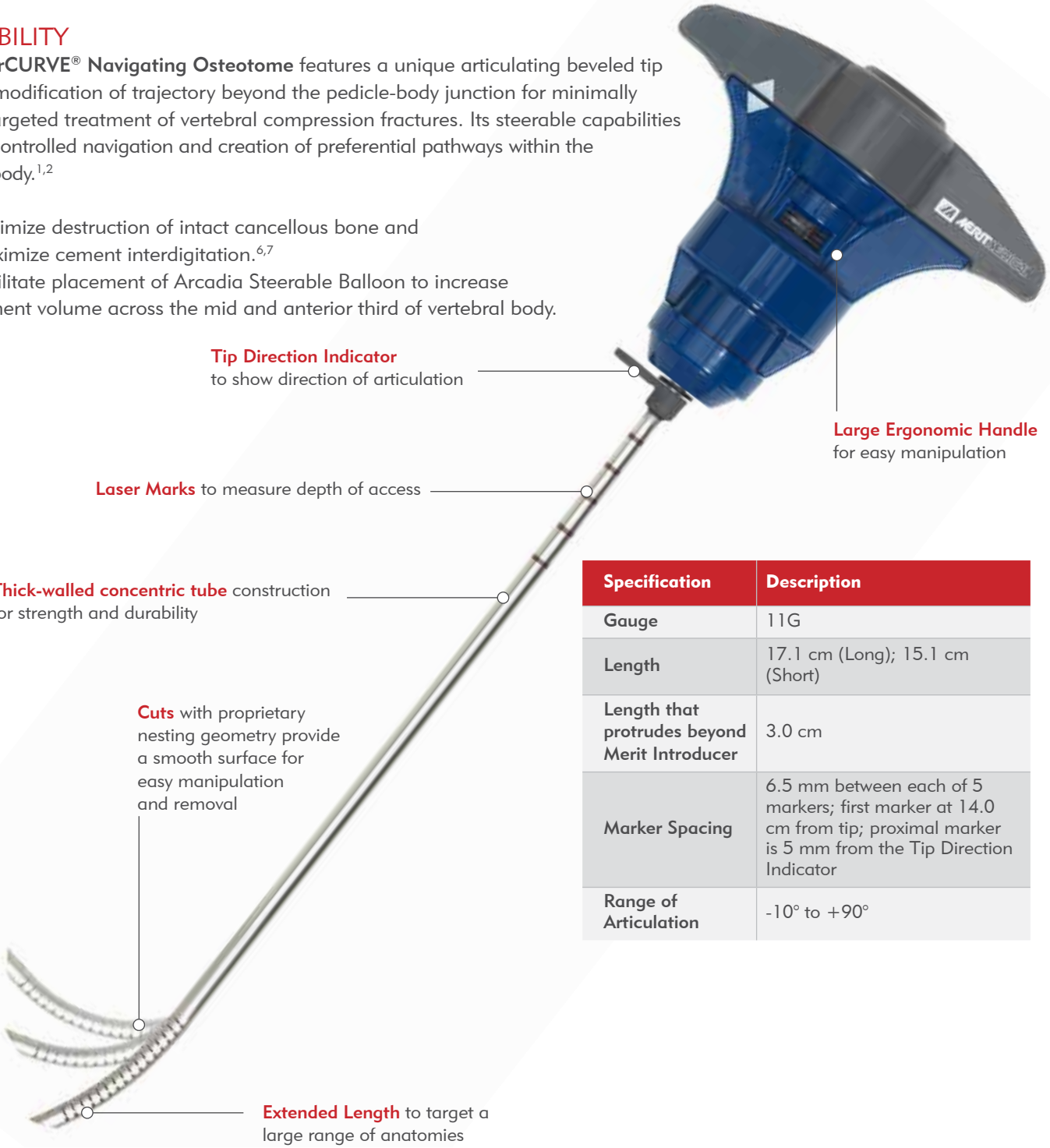
STEERABLE CHANNEL CREATION

The StabiliT® MX system is your solution for targeted, bone-sparing vertebral augmentation. Create preferential paths using steerable technology for the controlled delivery of high-viscosity cement in various fracture morphologies.

STEERABILITY

The **PowerCURVE® Navigating Osteotome** features a unique articulating beveled tip enabling modification of trajectory beyond the pedicle-body junction for minimally invasive targeted treatment of vertebral compression fractures. Its steerable capabilities allow for controlled navigation and creation of preferential pathways within the vertebral body.[1,2]

1. Minimize destruction of intact cancellous bone and maximize cement interdigitation.[6,7]
2. Facilitate placement of Arcadia Steerable Balloon to increase cement volume across the mid and anterior third of vertebral body.

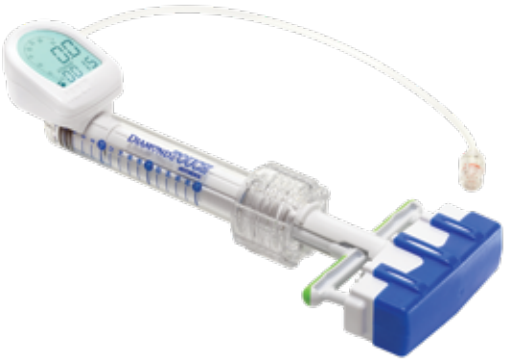


Specification	Description
Gauge	11G
Length	17.1 cm (Long); 15.1 cm (Short)
Length that protrudes beyond Merit Introducer	3.0 cm
Marker Spacing	6.5 mm between each of 5 markers; first marker at 14.0 cm from tip; proximal marker is 5 mm from the Tip Direction Indicator
Range of Articulation	-10° to +90°

DEXTERITY

DiamondTOUCH™ Syringe

- Clutch mechanism enables quick release
- Bright LCD gauge with highly visible, easy to read numbers
- 36-inch delivery line allows operation of syringe away from radiation source



CONTROL

StabiliT® Bone Cement

- High viscosity cement for a controlled cement delivery
- Extended working time ~35 minutes provides procedural flexibility*

STABILIT® MX VERTEBRAL AUGMENTATION FRACTURE KIT

Product Number	Description
MX-1100L-01 (Long)	**StabiliT® MX Fracture Kit (Base) with PowerCURVE®** StabiliT® Introducer (10G) with Diamond-tip Stylet | PowerCURVE® Navigating Osteotome | Locking Cement Delivery Cannula (11G) with Diamond-tip Stylet | StabiliT® Bone Cement & Saturate Mixing System | DiamondTOUCH™ Syringe | Master Syringe With Coupler and Elbow
MX-2100L-01 (Long)	**StabiliT MX Fracture Kit (Full) with PowerCURVE** StabiliT® Introducer (10G) with Diamond-tip and Beveled-tip Stylet | VertecoR® StraightLine Osteotome | PowerCURVE® Navigating Osteotome | Locking Cement Delivery Cannula (11G) with Diamond-tip Stylet | StabiliT® Bone Cement & Saturate Mixing System | DiamondTOUCH™ Syringe | Master Syringe With Coupler and Elbow

* Tests performed and data on file at Merit Medical Systems, Inc.

STABILIT®
Vertebral Augmentation System

VARIABLE VISCOSITY WITH REMOTE DELIVERY

Studies suggest that fracture morphology, cement viscosity, and the rate of cement injection may influence the likelihood of cement extravasation during vertebral augmentation.[8] The StabiliT® Vertebral Augmentation System provides physicians with a simple device that enables control over access, navigation, cement delivery, and radiation exposure.

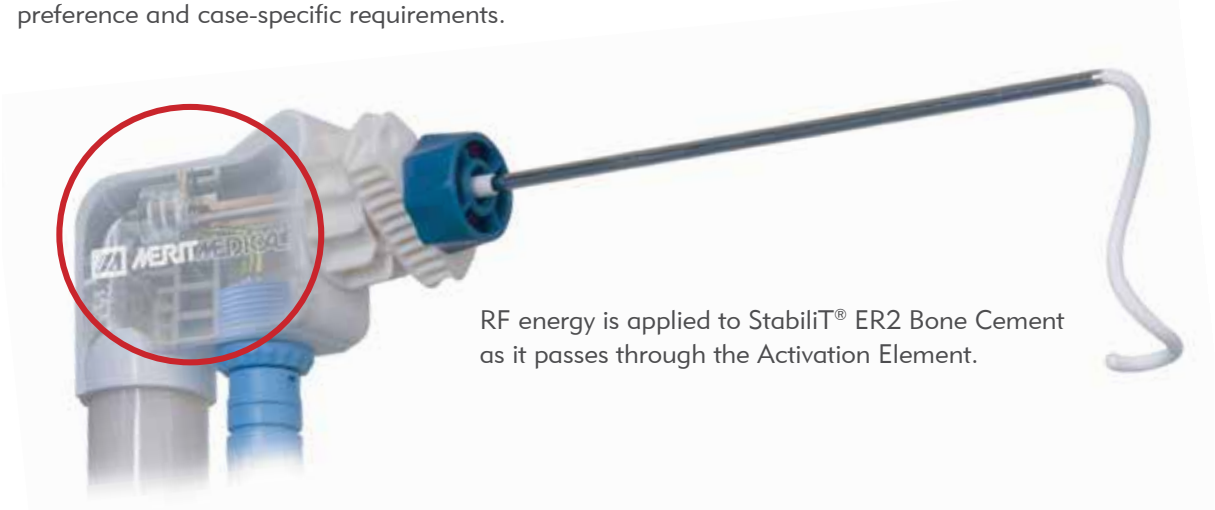
ENHANCED VISCOSITY CONTROL

The MultiPlex II Controller with Variable Viscosity modulates the application of radio-frequency energy and controls the consistent delivery rate of bone cement.

VISCOSITY ADJUSTED IN REAL-TIME

The exclusive cement viscosity algorithm continuously monitors cement viscosity and adjusts polymerization of ER2 bone cement, by adjusting RF energy delivery to provide consistent and predictable viscosity. As bone cement passes through the Activation Element, RF energy accelerates polymerzation to increase the viscosity of the cement prior to delivery into the vertebral body. The Multiplex II Controller responds to changing conditions in real-time in order to maintain control over cement viscosity and delivery.

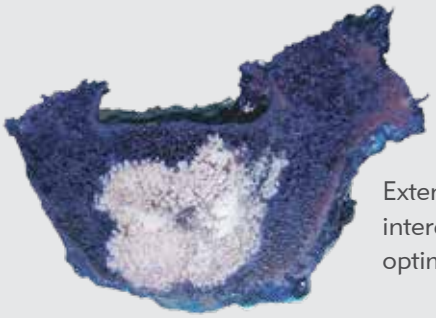
The Variable Viscosity feature allows the user to adjust cement viscosity intraoperatively to tailor cement viscosity to user's preference and case-specific requirements.



RF energy is applied to StabiliT® ER2 Bone Cement as it passes through the Activation Element.

Superior Interdigitation

Vertebral augmentation with ultra-high viscosity StabiliT ER2 bone cement delivers superior interdigitation.*

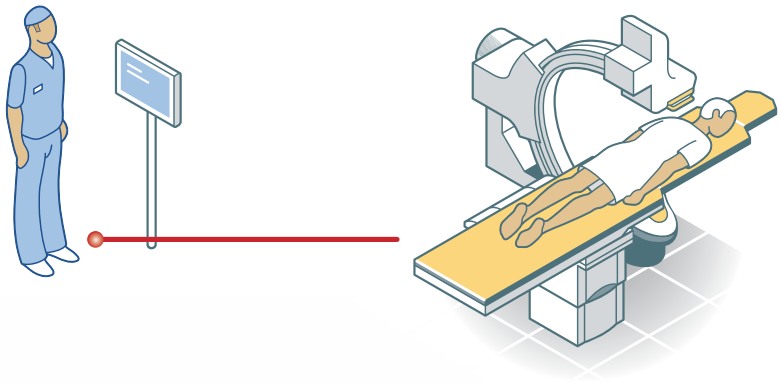


Extensive cement interdigitation and optimized fill.

Cement dissolved to demonstrate initial cavity and extent of interdigitation.

REDUCED RADIATION EXPOSURE

The intensity of radiation exposure dissipates exponentially as the distance from the radiation source increases. The StabiliT System's remote delivery allows a physician to deliver bone cement up to 20-feet away from the source of radiation.



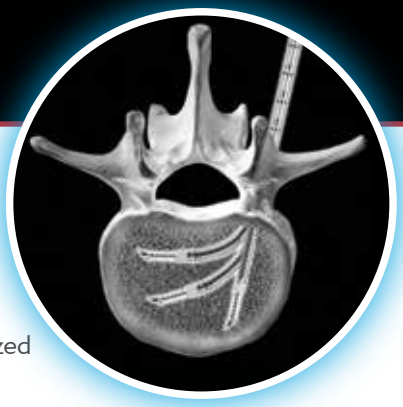
STABILIT® FIRST FRACTURE KIT

STABILIT® VERTEBRAL AUGMENTATION SYSTEM ORDERING INFORMATION

Product Number	Product Descriptions/Components
KIT OPTIONS	
2003-01	**StabiliT First Fracture Kit with PowerCURVE** StabiliT® Introducer (10G) with Diamond-tip and Beveled-tip Stylet | VectecoR® StraightLine Osteotome | PowerCURVE® Navigating Osteotome | StabiliT® ER² Bone Cement & Saturate Mixing System (10 cc) | Master Syringe | Locking Cement Delivery Cannula (11G) with Diamond-tip Stylet | Hydraulic Syringe | Activation Element | Hand Switch Cable | AE Cable
3506-01	**StabiliT Complete Fracture Kit with PowerCURVE** StabiliT® Introducer (10G) with Diamond-tip Stylet | PowerCURVE® Navigating Osteotome | StabiliT® ER² Bone Cement & Saturate Mixing System (7cc) | Master Syringe | Locking Cement Delivery Cannula (11G) with Diamond-tip Stylet | Hydraulic Syringe | Activation Element | Hand Switch Cable | AE Cable
1666-01	**StabiliT Second Fracture Kit with PowerCURVE** StabiliT® Introducer (10G) with Diamond-tip and Beveled-tip Stylet | PowerCURVE® Navigating Osteotome | StabiliT® ER² Bone Cement & Saturate Mixing System (10 cc) | Master Syringe | Locking Cement Delivery Cannula (11G) with Diamond-tip Stylet | Hydraulic Syringe

*Data on file

STAR™
Tumor Ablation System



TARGETED RF ABLATION

The STAR™ Tumor Ablation System delivers meaningful, rapid pain relief and localized destruction of metastatic malignant lesions within the vertebral body.[3, 9-12] It consists of the steerable bipolar SpineSTAR® Ablation Instrument for navigation within the vertebral body and the MetaSTAR® RF Generator to confirm and quantify ablation zones during treatment.[3, 4]

MetaSTAR RF GENERATOR

Real-time thermocouple temperature display

Multiple Power Levels

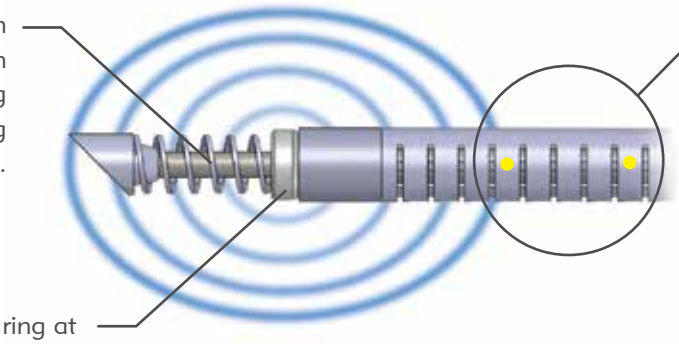
- 3W, 5W, 7.5W, and 10W
- Efficiently deliver radiofrequency (RF) energy to tissue while reducing impedance errors

SPINESTAR ABLATION INSTRUMENT

Embedded Thermocouples Along Length of Electrode
Provide real-time feedback to quantify, adjust, and confirm the ablation zone intra-operatively, and to assist in preventing damage to neural elements.[10, 12]

Articulating Electrodes
Offer steerability and control to achieve and maintain the optimal location within the vertebral body, including the posterior central regions.[3]

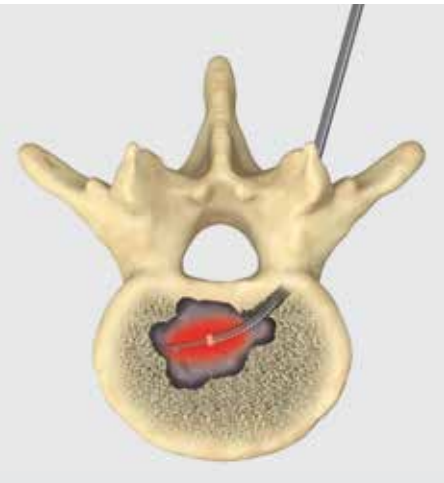
The unique bipolar ablation electrode bevel-tip design assists in directional targeting of the device and resulting ablation zone.

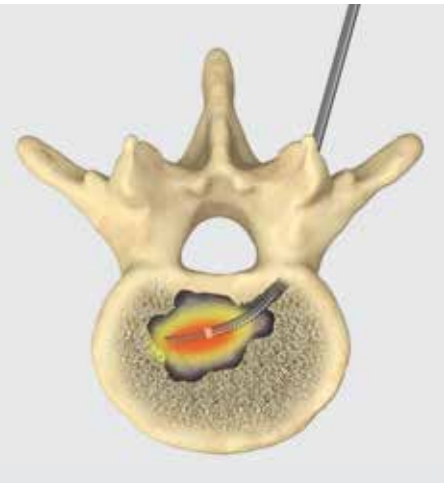


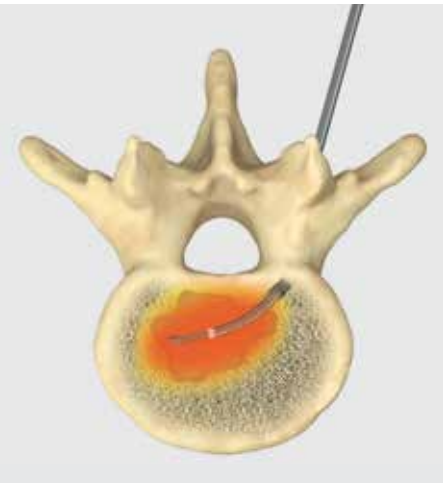
Radiolucent insulative ring at center of ablation zone.

Thermocouples embedded along the shaft of the electrode permit real-time monitoring of temperatures at the periphery of the developing ablation zone, allowing accurate, intraprocedural assessment of the ablation zone size and providing passive thermal protection.[12]

RF energy heats and destroys metastatic tumor cells, while thermocouples within the SpineSTAR continuously monitor the ablation zone progress to minimize patient risk.







STAR™ TUMOR ABLATION KIT

STAR™ TUMOR ABLATION SYSTEM ORDERING INFORMATION

Product Number	Product Descriptions	Specifications/Components	
RF-0510L-01 **RF-1015L-01**	STAR™ TUMOR ABLATION KIT	StabiliT® Introducer (Beveled-tip and Diamond-tip) | VertecoR® Straightline Cement Staging Osteotome | PowerCURVE® Navigational Osteotome | SpineSTAR® Ablation Instrument (5/10mm or 10/15mm Thermocouple configuration) | Hand Switch Cable (approx. 10 feet) | AE Cable (approx. 10 feet)	
3195	METASTAR® RF GENERATOR	**Power Input:**	Universal 100-240VAC, 50-60Hz
		Power Outputs:	3W, 5W, 7.5W, and 10W | Frequency of 480kHz | 20Ω-1000Ω impedance load
		Weight:	6.6 lbs
		Dimensions:	18"(L) x 11"(W) x 6"(H)

ACCESSORIES & A LA CARTE

StabiliT® Introducers - 10G

Diamond-tip Stylet

Version C

1493 *(Short)*

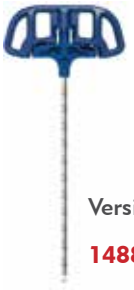
1472 *(Long)*

Version F

1493 *(Short)*

1472 *(Long)*

Beveled-tip Stylet



Version C

1488 *(Short)*

1467 *(Long)*

Version F

1488 *(Short)*

1467 *(Long)*

Short = 10 cm working length *Long* = 12 cm working length

VertecoR® Bone Drill (11G)

2224
compatible with short and long introducers

VertecoR® StraightLine Osteotome (11G)

1011
compatible with short introducer

1545
compatible with long introducer

PowerCURVE® Navigating Osteotome (11G)

PWR-2011S
compatible with short introducer

PWR-2011L
compatible with long introducer

ARCADIA® Balloon Catheter

Steerable
ARC10SB
ARC15SB
ARC20SB
ARC25SB
ARC30SB

Straight
ARC10ST
ARC15ST
ARC20ST
ARC25ST

ARCADIA® High-pressure Inflation Device - 55ATM | 14cc

IN55VCF

Locking Delivery Cannula (11G) with Diamond-tipped Stylet

0975
compatible with short introducer

1426
compatible with long introducer

StabiliT® Touch Syringe - 30ATM | 30cc

IN8VCF
2′ tubing

DiamondTOUCH™ Syringe - 30ATM | 30cc

IN9VCF
3′ tubing

StabiliT® Bone Cement & Saturate Mixing System 10cc

4457 StabiliT Bone Cement

1688 StabiliT ER² Bone Cement
(For use with MultiPlex II Controller)

Master Syringe Assembly

DF-5000A

- Master Syringe
- Coupler
- Elbow

Hydraulic-Master Syringe Assembly

(For use with MultiPlex II Controller)

- Hydraulic Syringe & Line
- Master Syringe

3427

Activation Element

1155

Spine Procedure Pack

K12T-09368A

- Standard OR Scissors, Straight, 5 ½ in, Sharp-Blunt Points (1)
- Rochester-Pean Hemostatic Forceps, Straight, 8 in (1)
- Drape, 75 x 125 in (with 6 x 12-in aperture and 2 windows (1)
- ShortStop® Temporary Sharps Holder (1)
- Gown, XLG Non-Reinforced(1)
- Towel Clamp (2)
- Medicine Cup, 2 oz (1)
- Bandbag, 36 x 48 in (2)
- #11 Futura® Safety Scalpel (1)
- ChloraPrep™,10.5 mL, Clear (1)
- Blue OR Towel (8)
- L/L Syringe, 10 cc (2)
- L/L Syringe, 20 cc (1)
- Needle, 18G x 1 ½ in, Reg Bev (1)
- Needle, 22G x 1 ½ in, Reg Bev (1)
- Spinal Needle, 22G x 3 ½ in (1)
- Tray, 9 x 5 x 2 in (1)
- Sponge Gauze, 4 x 4 in, 12-ply (10)
- Mallet (Lucae), 8 in (1)

OSSEOFLEX® SN Steerable Needle - 10G compatible

- Osseoflex SN Steerable Needle
- Needle Removal Tool

OF-0231

OSSEOFLEX® Bone Filler Device - 4 pack

OF-0298

OSSEOFLEX® CD-H Hydraulic Cement Delivery System

OF-0348

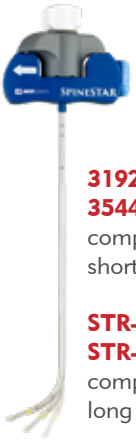
BonOs Inject 1x24g PMMA Cement

OP-0003

Bone Cement Mixer

OP-0005

SpineSTAR® Ablation Instrument



3192 *(1015 Short)*
3544 *(0510 Short)*
compatible with short introducer

STR-1015L
STR-0510L
compatible with long introducer

AE Cable (approx. 10 feet)

0860

Hand Switch Cable (approx. 10 feet)

0856

MetaSTAR® RF Generator

3195

R3195
Daily Rental

W3195-1Y
Extended Warranty, 1 year

W3195-2Y
Extended Warranty, 2 year

MultiPlex II Controller with Variable Viscosity

3610

R3610
Daily Rental

RETHINK YOUR SPINAL THERAPY STRATEGY

CHANNEL CREATION

PowerCURVE® Navigating Osteotome

Create preferential pathways for targeted therapy using the only steerable osteotome for vertebral pathologies. This intuitive design allows for minimally invasive VCF stabilization via unipedicular access, while preserving intact cancellous bone.

CAVITY CREATION

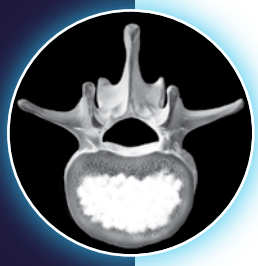
ARCADIA® Steerable Balloon Catheter

A revolutionary procedural solution, the ARCADIA Steerable Balloon Catheter offers steerable technology to create a bipedicular footprint via unipedicular access, while a large volume balloon enables superior cavity creation in the coronal plane for optimal cement fill. Low-compliance helps maintain balloon shape and reduce potential for balloon rupture.

CEMENT DELIVERY

ARCADIA® Curved Delivery Cannula

Complements the steerable capabilities of the PowerCURVE Navigating Osteotome and ARCADIA Steerable Balloon Catheter, providing the trifecta of treatment for targeted cement delivery. The pre-curved nitinol cannula allows for predictable cement deposition across midline, optimizing cement volume, while potentially reducing the need for bipedicular access.



FRACTURE STABILIZATION

StabiliT® Bone Cement

StabiliT high-viscosity bone cement with an extended working time of >30 minutes, provides procedural flexibility and controlled delivery. The proprietary vacuum-based Saturate Mixing System allows for quick and simple set-up.

RADIOFREQUENCY ABLATION

STAR™ Tumor Ablation System

Confidently target and treat metastatic spinal tumors with the STAR System. Steerable articulating bipolar probes allow modification of trajectory within the vertebral body. Thermocouples, embedded along the shaft, provide real-time feedback to quantify, adjust, and confirm the ablation zone intra-operatively.

EXPLORE MORE

Access additional product benefits, safety information, and instructions for use.

REFERENCES

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Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

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