

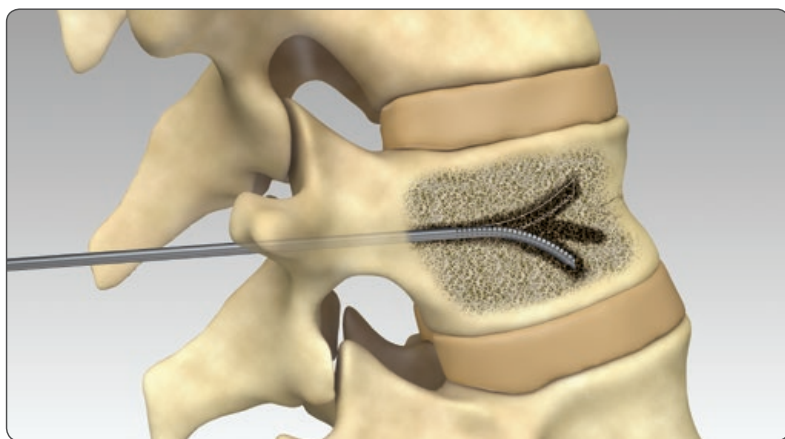
STABILIT[®]

Vertebral Augmentation System



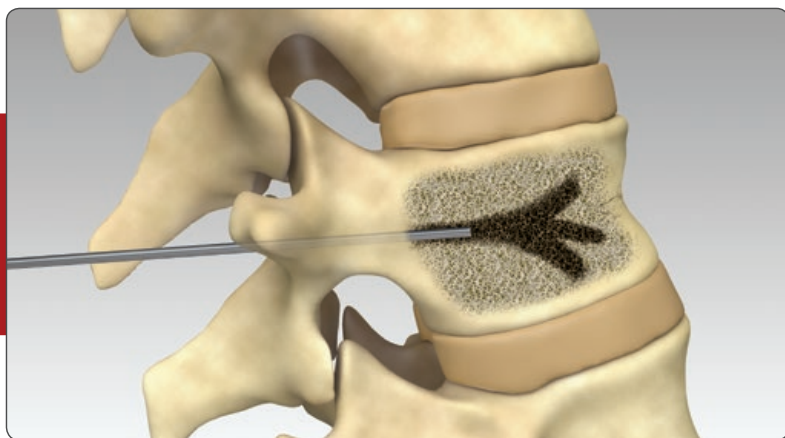
ACCESS + NAVIGATION + STABILIZATION

Merit Medical's intuitive platform is designed to treat vertebral compression fractures, and can provide rapid and lasting pain relief¹ with the most advanced targeted therapies. The StabiliT Vertebral Augmentation System is a minimally invasive procedure which provides physicians with a simple device that enables control over access, navigation, cement delivery, and radiation exposure.



The PowerCURVE[®] Navigating Osteotome enables targeted vertebral access across the midline via a unipedicular approach.*

Targeted cavity creation spares cancellous bone as it creates preferential pathways for the flow of ultra-high viscosity StabiliT ER² Bone Cement.



Targeted pathways maximize the exposed surface area available for cement interdigitation, resulting in a predictable fill and improved mechanical strength.



1. Pflugmacher, R. (2012, February). [Comparison of clinical and radiological data in the treatment of patients with osteoporotic vertebral compression fractures using radiofrequency kyphoplasty or balloon kyphoplasty]. Retrieved January 25, 2017, from <https://www.ncbi.nlm.nih.gov/pubmed/21993914>

* Data on file.

INTELLIGENT ENERGY™

Extended viscosity control

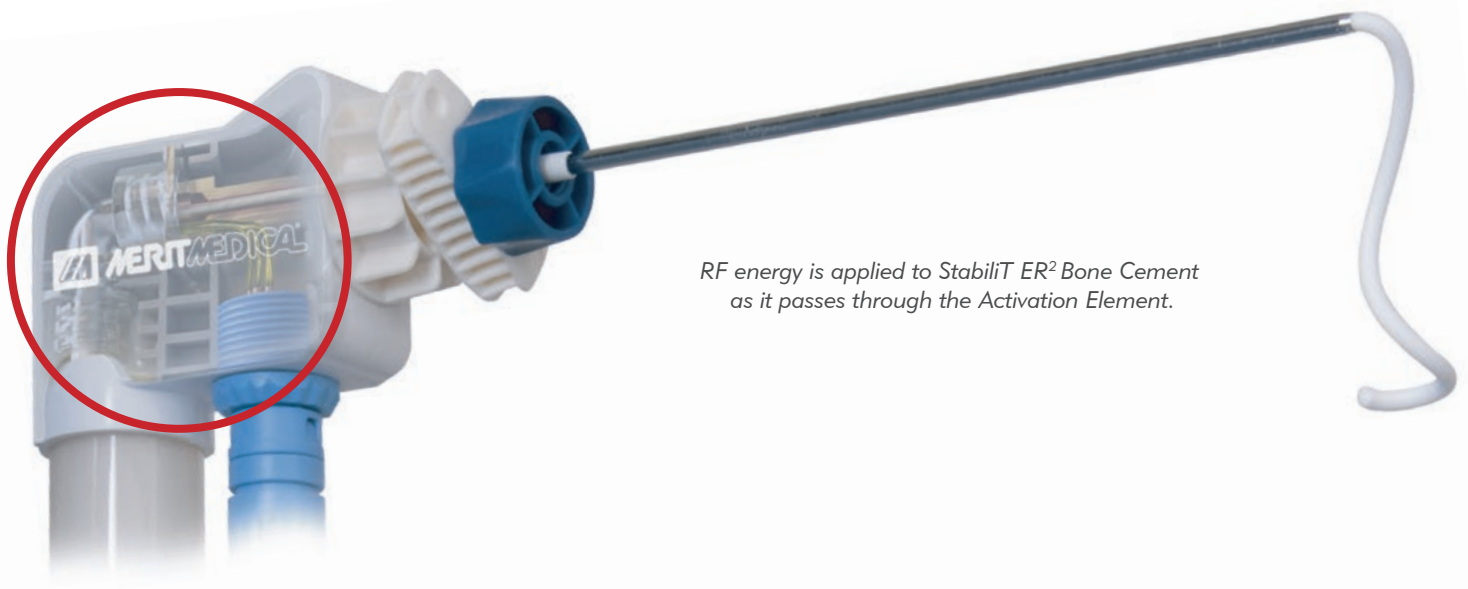
The MultiPlex II Controller with Variable Viscosity modulates the application of radio-frequency energy and controls the consistent delivery rate of bone cement.



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 polymerization 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 (High \leftrightarrow Low) 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.

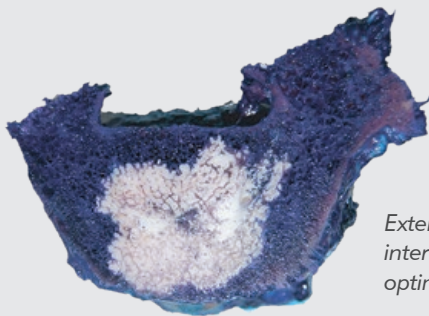
BONE CEMENT

Energy-responsive (ER)

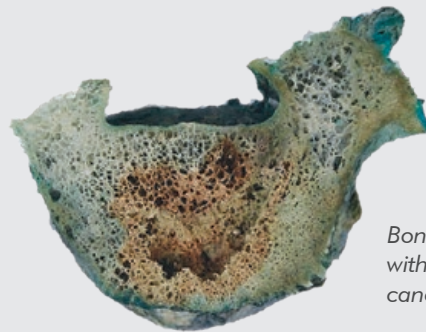
The StabiliT System utilizes proprietary energy-responsive StabiliT ER² bone cement that provides consistent, ultra-high viscosity properties over an extended working time.

Superior interdigitation

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



Extensive cement interdigitation and optimized fill.



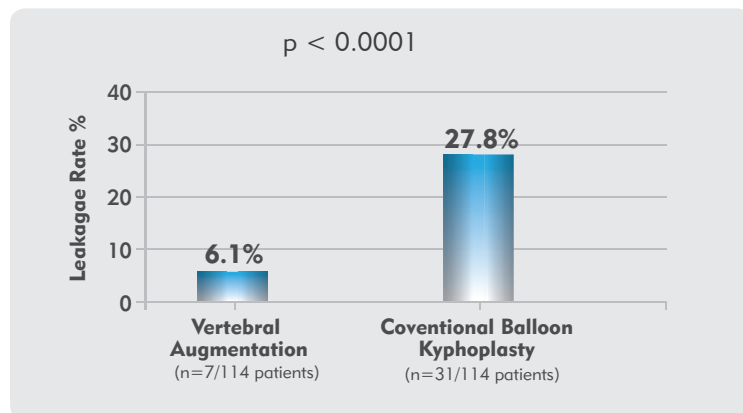
Bone cement removed with acid. Note the intact cancellous bone.

Extended working time

StabiliT ER² Bone Cement has a working time of at least 35 minutes for a longer, more controlled delivery.*

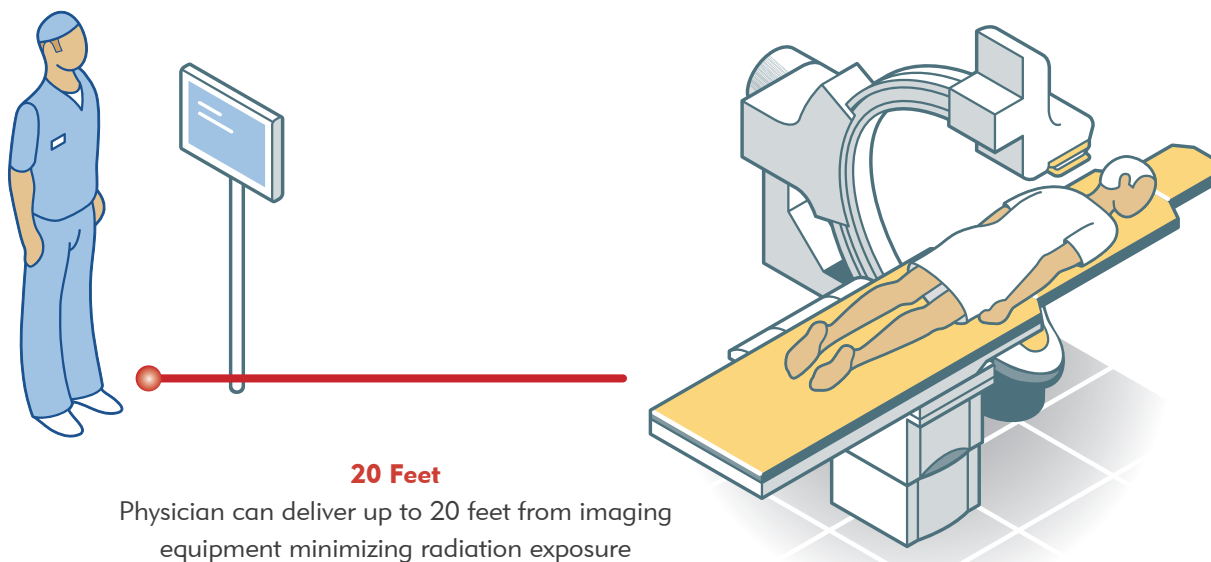


Reduced extravasation with vertebral augmentation (VA)



Studies suggest that fracture morphology, cement viscosity, and the rate of cement injection may influence the likelihood of cement extravasation during vertebral augmentation.^{2,3}

Reduced radiation exposure



The intensity of radiation exposure dissipates exponentially as the distance from the radiation source increases. The StabiliT System Hand Switch Cable allows a physician to work up to 20-feet away from the source of radiation during StabiliT ER² Bone Cement delivery.

STABILIT Vertebral Augmentation System Indications and Risks

The StabiliT Vertebral Augmentation System is intended for percutaneous delivery of StabiliT Bone Cement in vertebral augmentation (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).

As with most surgical procedures, there are risks associated with the StabiliT procedure, including serious complications. For complete information regarding risks, contraindications, warnings, precautions, and adverse events please review the System's Instructions for Use.

2. Pflugmacher, R. (2012, February). [Comparison of clinical and radiological data in the treatment of patients with osteoporotic vertebral compression fractures using radiofrequency kyphoplasty or balloon kyphoplasty]. Retrieved January 25, 2017, from <https://www.ncbi.nlm.nih.gov/pubmed/21993914>

3. Lador, R., Dreiangel, N., Ben-Galim, P.J., Hipp, J.A. (2010). A pictorial classification atlas of cement extravasation with vertebral augmentation. *The Spine Journal*, 10(2010), 1118-1127. [doi: 10.1016/j.spinee.2010.09.020](https://doi.org/10.1016/j.spinee.2010.09.020).

Capital Equipment Options	
Product Number	Description
3610	MultiPlex II Controller with Variable Viscosity
R3610	Daily Rental - Multiplex II Controller with Variable Viscosity

A LA CARTE OPTIONS		
Product Number		Description
Long	Short	
1467	1488	StabiliT Introducer with Bevel-tipped Stylet
1472	1493	StabiliT Introducer with Diamond-tipped Stylet
1426	0975	Locking Delivery Cannula with Diamond-tipped Stylet
1545	1011	VertecoR [®] StraightLine Osteotome
PWR-2011L	PWR-2011S	PowerCURVE Navigating Osteotome
2224		VertecoR [®] Bone Drill
1688		StabiliT ER ² Bone Cement and Saturate Mixing System (10cc)
3366		StabiliT ER ² Bone Cement and Saturate Mixing System (7cc)
3427		Hydraulic Master Syringe Assembly
DF-5000A		Master Syringe Assembly (Master Syringe, Coupler and Elbow)
1155		Activation Element (AE)
0860		AE Cable
0856		Handswitch Cable
3119		Purge Assist

Kit Options		
Product Number		Description
Long	Short	
2003-01	3353-01	StabiliT First Fracture Kit with PowerCURVE <ul style="list-style-type: none"> • StabiliT Introducer (10G) with Diamond-tipped Stylet • StabiliT Introducer (10G) with Bevel-tipped Stylet • PowerCURVE Navigating Osteotome • VectecoR[®] StraightLine Osteotome • Locking Cement Delivery Cannula (11G) with Diamond-tipped Stylet • StabiliT ER² Bone Cement & Saturate Mixing System (10 cc) • Activation Element • AE Cable • Handswitch Cable • Hydraulic Syringe • Master Syringe
1666-01	1436-01	StabiliT Second Fracture Kit with PowerCURVE <ul style="list-style-type: none"> • StabiliT Introducer (10G) with Diamond-tipped Stylet • StabiliT Introducer (10G) with Bevel-tipped Stylet • PowerCURVE Navigating Osteotome • Locking Cement Delivery Cannula (11G) with Diamond-tipped Stylet • StabiliT ER Bone Cement & Saturate Mixing System (10 cc) • Activation Element • Hydraulic Syringe • Master Syringe
3506-01	3512-01	StabiliT Complete Fracture Kit with PowerCURVE <ul style="list-style-type: none"> • StabiliT Introducer (10G) with Diamond-tipped Stylet • PowerCURVE Navigating Osteotome • Locking Cement Delivery Cannula (11G) with Diamond-tipped Stylet • StabiliT ER² Bone Cement & Saturate Mixing System (7cc) • Activation Element • AE Cable • Handswitch Cable • Hydraulic Syringe • Master Syringe



Understand. Innovate. Deliver.™

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