MERIT MEDICAL®

STABILIT®

Vertebral Augmentation System

IOS

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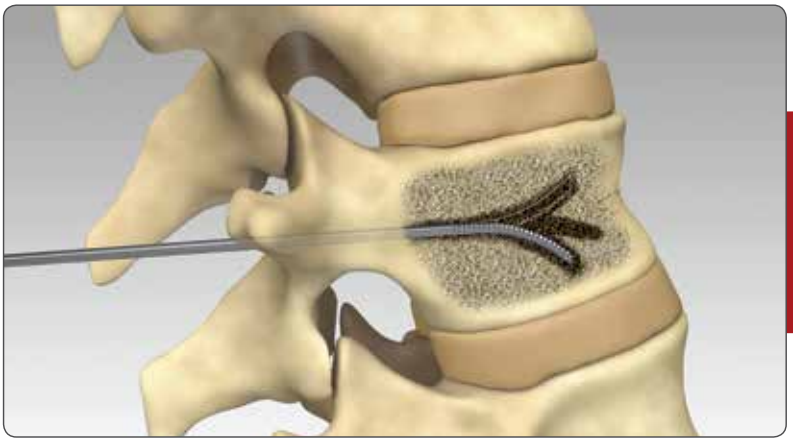
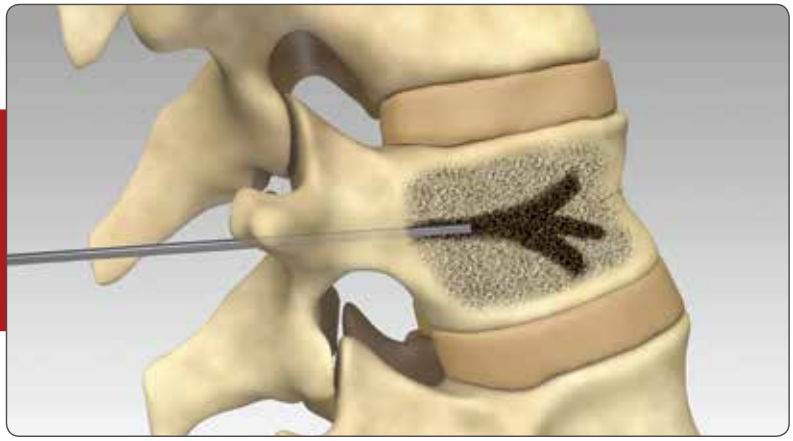
ACCESS + NAVIGATION + STABILIZATION

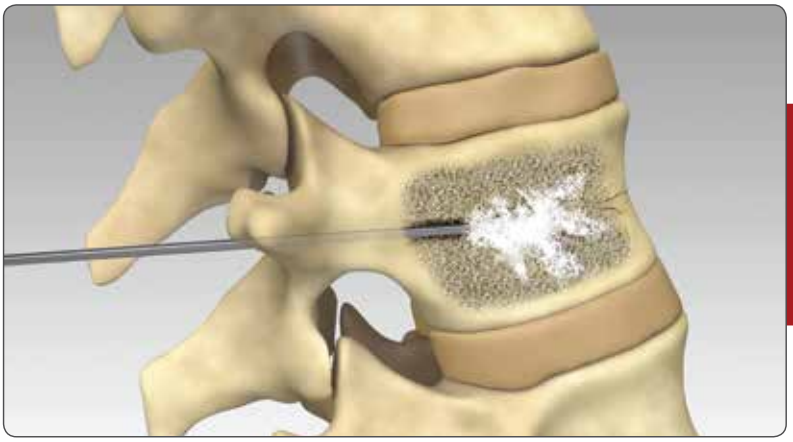
Merit Medical's intuitive platform is designed to treat vertebral compressions fractures, and can provide rapid and lasting pain relief[1] with the most advanced targeted therapies. The StabiliT Vertebral Augmentation System is a minimally invasive procedure which provides physicians with a simple device 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 ER[2] 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™

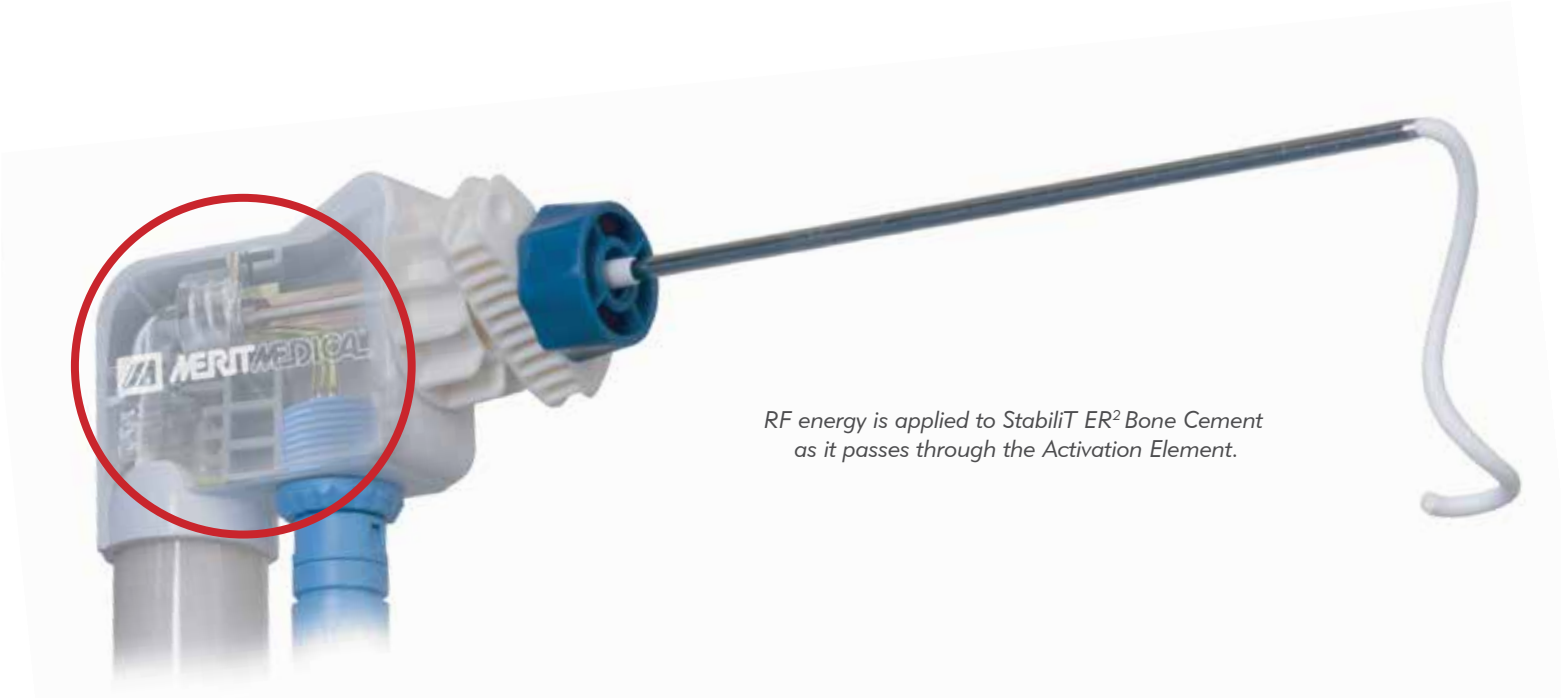
Extended viscosity control

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 ER^2 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 (High <=> Low) to tailor cement viscosity to user's preference and case specific requirements.



RF energy is applied to StabiliT ER^2 Bone Cement as it passes through the Activation Element.

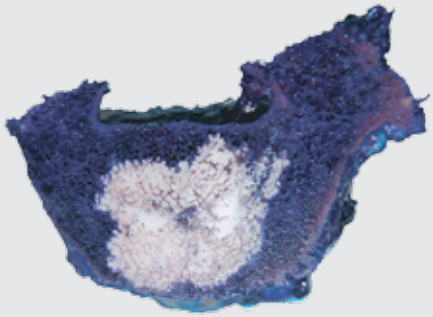
BONE CEMENT

Energy-responsive (ER)

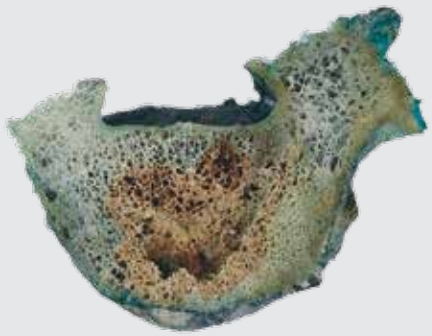
The StabiliT System utilizes proprietary energy-responsive StabiliT ER^2 bone cement that provides consistent, ultra-high viscosity properties over an extended working time.

Superior interdigitation

Vertebral augmentation with ultra-high viscosity StabiliT ER^2 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 ER^2 Bone Cement has a working time of at least 35 minutes for a longer, more controlled delivery.*

*Data on file

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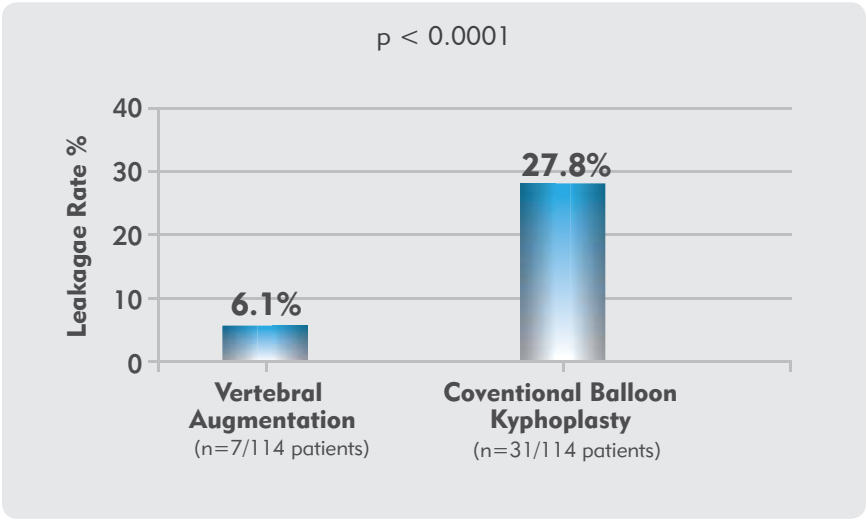
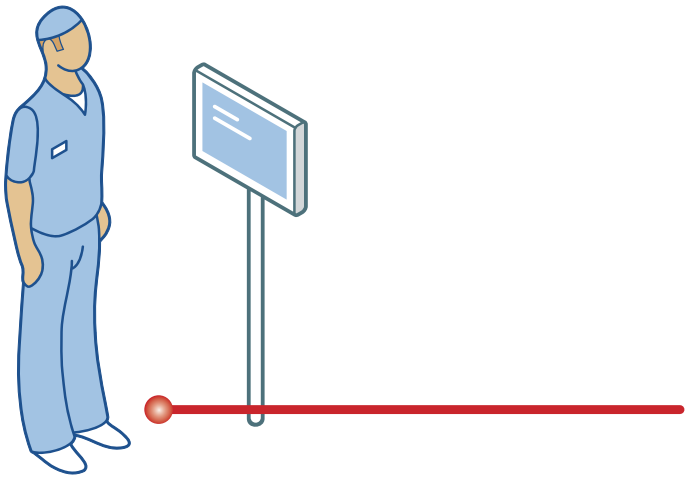
Reduced extravasation with vertebral augmentation (VA)



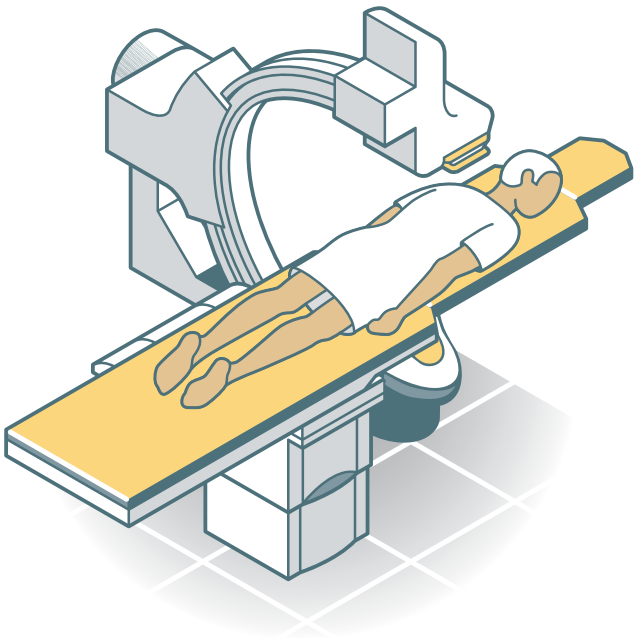
Studies suggest that fracture morphology, cement viscosity, and the rate of cement injection may influence the likelihood of cement extravasation during vertebral augmentation.[1,2]

Reduced radiation exposure



20 Feet

Physician can deliver up to 20 feet from imaging equipment minimizing 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.

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
2. 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.

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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, vertebral augmentation (VA) procedures using the StabiliT System involve risks, some of which may be serious or even fatal. Patients undergoing VA are subject to risks associated with surgery including, but not limited to, complications from anesthesia/sedation as well as bleeding, bruising, pain, infection, blood clots, myocardial infarction, cardiac arrest, stroke, pulmonary embolism, cardiac embolism, as well as damage to normal tissue, nerves, the spinal cord or other structures, which could result in injuries, including paralysis. Not every patient is a good candidate for VA. The StabiliT System is contraindicated for patients with coagulation disorders, severe pulmonary insufficiency, and certain spinal conditions, or patients who are sensitive to components of StabiliT Bone Cement. Please review the Instructions for Use for a more detailed description of risks and contraindications.

Catalog No.	Description
3610	MultiPlex II Controller with Variable Viscosity
KIT CONFIGURATIONS	
2003-01	StabiliT First Fracture Kit with PowerCURVE (Long)
3353-01	StabiliT First Fracture Kit with PowerCURVE (Short)
A LA CARTE (SHORT/LONG)	
1488/1467	StabiliT Introducer (Bevel)
1493/1472	StabiliT Introducer (Diamond)
0975/1426	Locking Delivery Cannula
1011/1545	VertecoR® StraightLine Cement Staging Osteotome
2011S/2011L	PowerCURVE Navigating Osteotome
2224	VertecoR Bone Drill
1688	StabiliT ER² Bone Cement and Saturate Mixing System
1402	Hydraulic Assembly
1155	Activation Element (AE)
0860	AE Cable
0856	Hand Switch Cable

MERIT MEDICAL®

Understand. Innovate. Deliver.™

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