

Unprecedented Control

Radiofrequency-Targeted Vertebral Augmentation™
(RF-TVA™) with the StabiliT® Vertebral Augmentation System



INNOVATION

Provide rapid and lasting back pain relief with the most advanced targeted therapy available for vertebral compression fractures

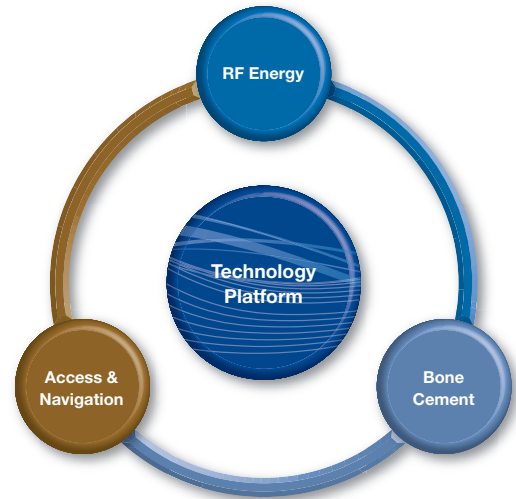
RF-TVA

Radiofrequency-Targeted Vertebral Augmentation™ (RF-TVA™), produced by DFINE, a developer of innovative, minimally invasive therapeutic devices used to treat pathologies of the vertebrae, has emerged as the leading edge spine fracture treatment available to physicians.

The StabiliT® System

RF-TVA with the StabiliT® Vertebral Augmentation System represents a generational advance in the treatment of vertebral compression fractures, providing physicians with unprecedented control over access, navigation, cement delivery, and radiation exposure.

DFINE Technology Platform



DFINE's unique technology platform delivers unprecedented results with the highest degree of control and consistency. Our platform is designed to combine leading-edge technologies into advanced solutions that enable physicians to relieve pain and improve the quality of life for patients suffering from vertebral pathologies.

CONTROL

Take Control of MI-VCF* procedures with the StabiliT Vertebral Augmentation System

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

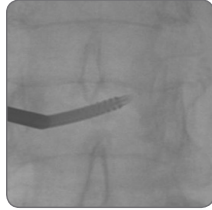
The StabiliT Vertebral Augmentation System is a fully integrated state-of-the-art system that provides unprecedented control over cement viscosity and delivery, leading to a consistent and more predictable vertebral augmentation.

*Minimally Invasive Vertebral Compression Fracture

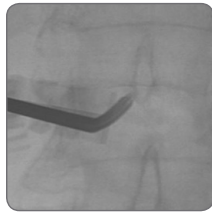
1. Lador R, Dreielang N, Ben-Galim PJ, and Hipp JA. A pictorial classification atlas of cement extravasation with vertebral augmentation. Spine J. 2010;10(12):1118-1127.



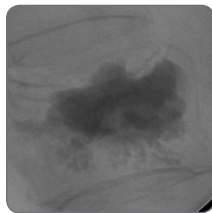
ACCESS



The VertecoR® MidLine Osteotome enables targeted vertebral access via a unipedicular approach.



Unlike conventional balloon systems, targeted cavity creation minimizes destruction of intact cancellous bone, while creating pathways for the preferential flow of ultra-high viscosity StabiliT® bone cement.



Targeted pathways maximize the exposed surface area available for cement interdigitation, resulting in an optimally filled and mechanically sound vertebra.

NAVIGATION

Greater control in cavity creation

The VertecoR MidLine Osteotome provides targeted vertebral access.

- Allows unipedicular access to vertebrae*
- Enables targeted cavity creation across the vertebral midline
- Spares cancellous bone
- Lessens the impact of fracture morphology on cement distribution by creating preferential pathways for the flow of ultra-high viscosity StabiliT bone cement
- Maximizes exposed surface area to facilitate interdigitation

*>85% of RF-TVA procedures to date have used the unipedicular technique to enter vertebrae²



INTELLIGENT ENERGY

Extended viscosity control

The MultiPlex Controller regulates the application of radio-frequency energy and controls the consistent delivery rate of bone cement. The display offers real-time instructions and information to assist the physician and staff throughout the procedure.



Viscosity adjusted in real-time

A proprietary “smart” algorithm continuously monitors ambient temperature and polymerization of StabiliT energy-responsive (ER) bone cements and adjusts RF energy delivery to provide consistent and predictable cement viscosity.

When StabiliT bone cement passes through the Activation Element, RF energy boosts the viscosity of the cement just prior to delivery into the vertebral body.

Throughout the procedure, the StabiliT System responds to changing conditions in real time, ensuring the physician is able to maintain complete control over cement targeting and delivery.



RF energy is applied to StabiliT bone cement as it passes through the Activation Element.



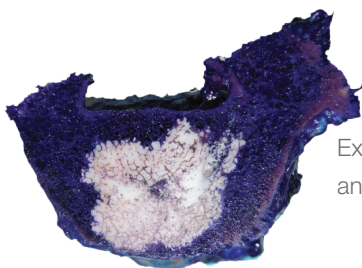
BONE CEMENT

Energy-responsive (ER) Bone Cements

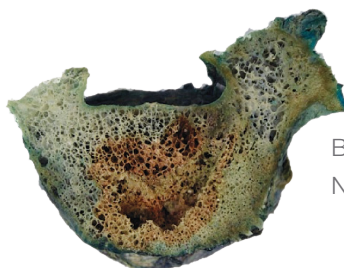
RF-TVA with the StabiliT System utilizes DFINE's proprietary energy-responsive StabiliT ER² and StabiliT ER^x bone cements that provide consistent, ultra-high viscosity properties over an extended working time. ER² is ideal for more routine VCF procedures while ER^x is for more difficult and complex cases where even greater control and radiopacity is desirable.

Superior interdigitation

RF-TVA with ultra-high viscosity StabiliT ER bone cements deliver superior interdigitation.

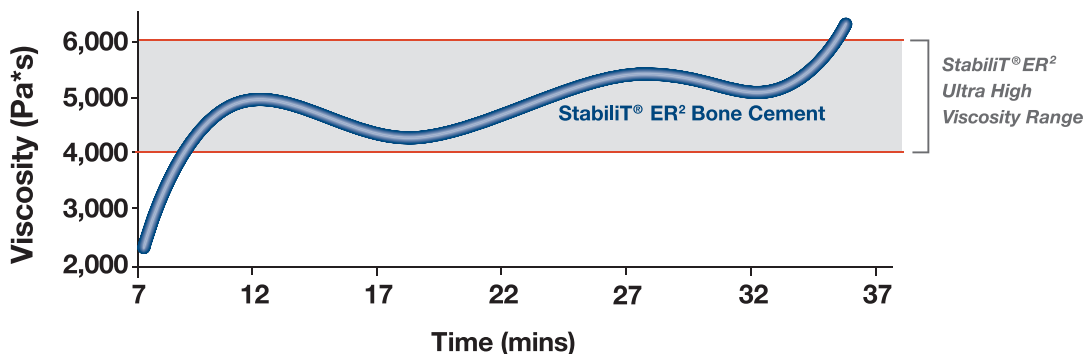


Extensive cement interdigitation and optimized fill.



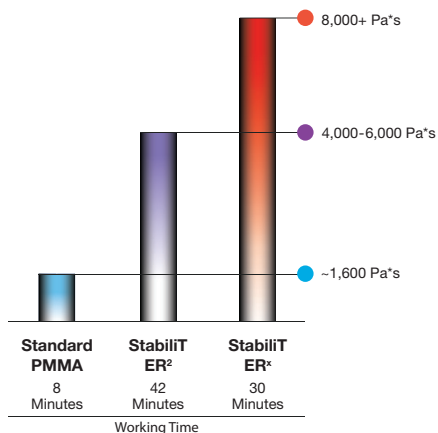
Bone cement removed with acid. Note the intact cancellous bone.

Significantly extended working time

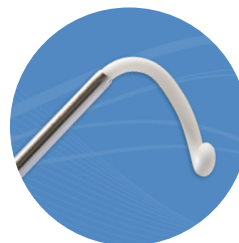


StabiliT ER² Bone Cement quickly reaches and stabilizes in the ultra-high viscosity range for delivery over an extended period of time.

StabiliT ER^x Bone Cement Xtreme Performance. Xceptional Control.



All cements tested at 68° Fahrenheit.



StabiliT ER^x Bone Cement is up to 5X the viscosity of standard PMMA bone cements. It has a working time of at least 30 minutes for a longer, more controlled delivery.

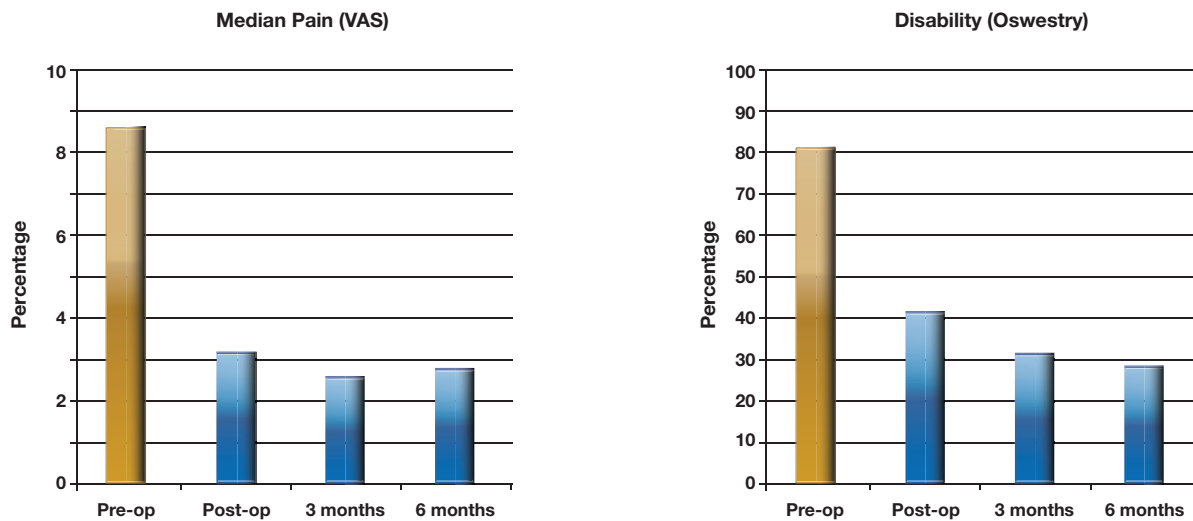
RESULTS

Significant and sustainable pain reduction

Vertebral compression fractures have a debilitating effect on patients, including chronic pain, limited mobility, and reduced quality of life.

Improved Median Pain and Disability Scores⁴

$p < 0.001$



Pre- and post-RF-TVA visual analog scale (VAS) median pain scores and Oswestry disability scores at 3 and 6 months. (n = 63 patients/116 osteolytic vertebral compression fractures treated).

4. Pflugmacher R, Randau T, Kabir K, and Wirtz DC. Radiofrequency (RF) Kyphoplasty in treatment of osteolytic vertebral fractures. IOF WCO-ECCE010 2010.

SAFETY

Studies demonstrate the StabiliT Vertebral Augmentation System reduces extravasation⁵

	Patients Treated	Total Fractures Treated	Fractures with Cement Leakage	Incidence of Cement Leakage	Symptomatic Cement Leakage*
RF-TVA	60	90	5	5.4%	0.0%
VERTEBROPLASTY**	39	52	31	59.6%	5.1%

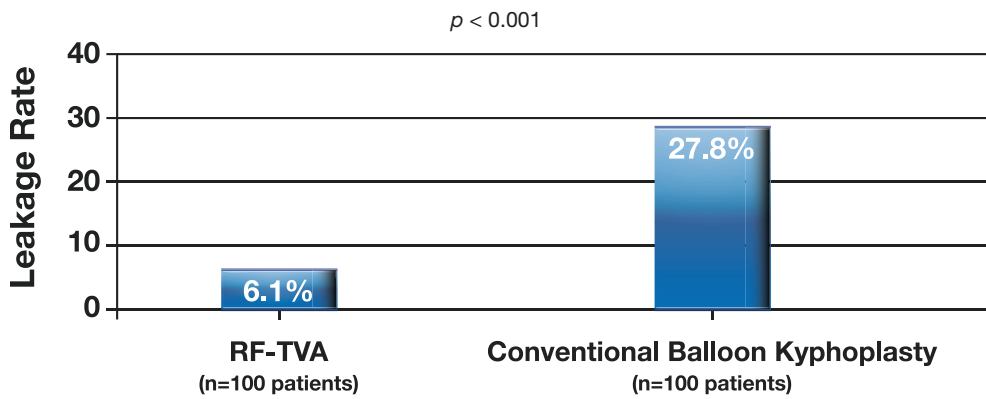
*Measured as a percentage of total patients treated.

**Two patients experienced cement pulmonary embolism.

Control group: Vertebroplasty patients, two of which experienced cement pulmonary embolisms during the study.

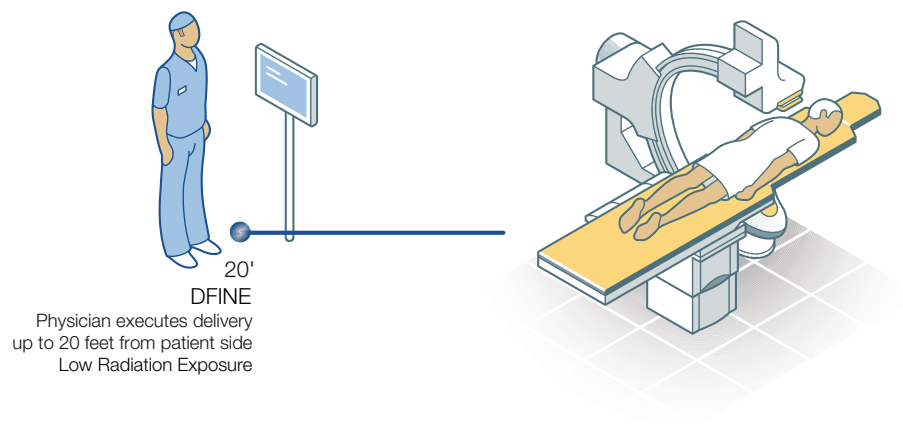
5. Pflugmacher R, Randau T, Kabir K, and Wirtz DC. Radiofrequency (RF) Kyphoplasty in comparison to in Vertebroplasty (VP) A prospective evaluation. IOF WCO-ECCE010 2010.

Reduced extravasation with RF-TVA⁶



6. Comparison of Clinical and Radiological Data in the Treatment of Patients with Osteoporotic Vertebral Compression Fractures Using Radiofrequency Kyphoplasty or Balloon Kyphoplasty. Pflugmacher R, Bornemann R, Koch EM, Randau TM, Müller-Broich J, Lehmann U, Weber O, Wirtz DC, Kabir K. Z Orthop Unfall. 2011 Oct 12.

Controlled radiation exposure



The volume 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 X-ray radiation during StabiliT bone cement delivery.

DFINE

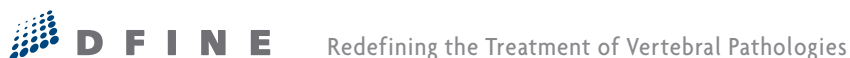
DFINE is the developer of minimally invasive radiofrequency (RF) targeted therapies for the treatment of vertebral pathologies. Our devices are built on an extensible RF platform that currently covers two procedural applications: The StabiliT Vertebral Augmentation System – the most advanced technology to treat vertebral compression fractures (VCFs), and the STAR™ Tumor Ablation System for the palliative treatment of spinal tumors.

DFINE is dedicated to relieving pain and improving the quality of life for patients suffering from vertebral pathologies through innovative, minimally invasive therapies.

Catalog No.	Description
0867	MultiPlex Controller
Kit Configurations	
2003/3353	StabiliT® First Fracture Kit (Long, Short)
3772/3773	StabiliT® ER ^x Fracture Kit (Long, Short)
A La Carte	
1488/1467	StabiliT® Introducer (Bevel) (Short, Long)
1493/1472	StabiliT® Introducer (Diamond) (Short, Long)
0975/1426	Locking Delivery Cannula (Short, Long)
1011/1545	VertecoR® StraightLine Cement Staging Osteotome (Short, Long)
0987/1620	VertecoR® MidLine Osteotome (Short, Long)
2224	VertecoR® Bone Drill
1688	StabiliT® ER ² Bone Cement and Saturate Mixing System
1136	StabiliT® ER ^x Bone Cement and Saturate Mixing System
3427	Hydraulic Master Syringe Assembly
1155	Activation Element (AE)
0860	AE Cable
0856	Hand Switch Cable

Risks Statement

As with most surgical procedures, serious adverse events can occur, some of which can be fatal. RF-TVA is designed to minimize these risks as much as possible. However, potential serious adverse events that can occur include: Myocardial infarction (heart attack), Pulmonary embolism (cement leakage that migrates to the lungs), Cerebrovascular accident (stroke), Cardiac arrest (heart stops beating), Paralysis or muscle weakness, Death. A prescription is required. Consult your patients to determine if this procedure is right for them and to discuss other potential concerns, including their current physical condition, age of the fracture, a treatment timetable, and RF-TVA (RF Kyphoplasty) risks and complications.



WORLD HEADQUARTERS

3047 Orchard Parkway, San Jose, CA 95134 | www.dfineinc.com

T 1.866.96DFINE (1.866.963.3463) | F 1.408.321.9401 | info@dfineinc.com