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.

*RF-TVA is formerly known as RF Kyphoplasty.

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 injection 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 injection, leading to a consistent and more predictive vertebral augmentation.

*Minimally Invasive Vertebral Compression Fracture

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® ER² 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 ER² Bone Cement
- Maximizes exposed surface area to facilitate interdigitation

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

². DFINE international data score. Data on file.
Extended viscosity control

The MultiPlex Controller regulates the application of radio-frequency energy and controls the automatic delivery 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 the StabiliT ER² Bone Cement and adjusts RF energy delivery to provide consistent and predictable cement viscosity.

When StabiliT ER² Bone Cement passes through the StabiliT System Activation Element, RF energy boosts the viscosity of the cement to between 4,000 and 6,000 pascal seconds (Pa*s).

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.
Superior interdigitation with StabiliT ER² Bone Cement

RF-TVA with ultra-high viscosity StabiliT ER² Bone Cement delivers superior interdigitation.

This cross section of a vertebral body demonstrates extensive cement interdigitation and optimized fill.

Exceptional fill control

Studies have shown that high-viscosity cement significantly enhances uniformity of cement filling in MI VCF procedures. The MultiPlex Controller ensures a controlled delivery rate of StabiliT ER² ultra-high viscosity bone cement to maximize interdigitation, fill uniformity and fracture stability.

The orange area indicates where ultra-high viscosity StabiliT ER² Bone Cement penetrated the trabeculae. Note the high degree of remaining intact cancellous bone and the relative size of the targeted cavity versus the high degree of cement interdigitation.

Significantly extended delivery time

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

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 Scores

\( p < 0.001 \)

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.


SAFETY

Studies demonstrate the StabiliT Vertebral Augmentation System reduces extravasation

<table>
<thead>
<tr>
<th></th>
<th>Patients Treated</th>
<th>Total Fractures Treated</th>
<th>Fractures with Cement Leakage</th>
<th>Incidence of Cement Leakage</th>
<th>Symptomatic Cement Leakage*</th>
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</thead>
<tbody>
<tr>
<td>RF-TVA</td>
<td>60</td>
<td>90</td>
<td>5</td>
<td>5.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>VERTEBROPLASTY</strong> **</td>
<td>39</td>
<td>52</td>
<td>31</td>
<td>59.6%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

*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.

The volume of radiation exposure dissipates exponentially as the distance from the radiation source increases. The StabiIT System Hand Switch Cable allows a physician to work up to 10-feet away from the source of X-ray radiation during StabiIT ER Bone Cement delivery.

Reduced extravasation with RF-TVA

\[ p < 0.001 \]

<table>
<thead>
<tr>
<th>Leakage Rate</th>
<th>RF-TVA (n=100 patients)</th>
<th>Conventional Balloon Kyphoplasty (n=100 patients)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>6.1%</td>
<td>27.8%</td>
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</table>


Controlled radiation exposure

Physician executes delivery up to 10 feet from patient side. Low Radiation Exposure.
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 radiofrequency (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.

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>0867</td>
<td>MultiPlex Controller</td>
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**Kit Configurations**

<table>
<thead>
<tr>
<th>Kit Configurations</th>
<th>Description</th>
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<tr>
<td>2003</td>
<td>StabiliT® First Fracture Kit (Long)</td>
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<tr>
<td>3353</td>
<td>StabiliT® First Fracture Kit (Short)</td>
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**A La Carte**

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<tr>
<th>A La Carte</th>
<th>Description</th>
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<tr>
<td>1488/1467</td>
<td>StabiliT® Introducer (Bevel)</td>
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<tr>
<td>1493/1472</td>
<td>StabiliT® Introducer (Diamond)</td>
</tr>
<tr>
<td>0975/1426</td>
<td>Locking Delivery Cannula</td>
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<tr>
<td>1011/1545</td>
<td>VertecoR® StraightLine Cement Staging Osteotome</td>
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<tr>
<td>0987/1620</td>
<td>VertecoR® MidLine Osteotome</td>
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<tr>
<td>2224</td>
<td>VertecoR® Bone Drill</td>
</tr>
<tr>
<td>1688</td>
<td>StabiliT® ER2 Bone Cement and Saturate Mixing System</td>
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<tr>
<td>1402</td>
<td>Hydraulic Assembly</td>
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<td>1155</td>
<td>Activation Element (AE)</td>
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<td>0860</td>
<td>AE Cable</td>
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<tr>
<td>0856</td>
<td>Hand Switch Cable</td>
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**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.