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STABILIT™ VERTEBRAL AUGMENTATION SYSTEM WITH ULTRA-HIGH VISCOSITY STABILIT ER BONE CEMENT

The Power and Control to Treat Vertebral Compression Fractures

The **StabiliT™ Vertebral Augmentation System** by **DFine, Inc. (San Jose, CA)**, now offers physicians a unique, ultra-high viscosity bone cement with an on-demand delivery system that may redefine the treatment of vertebral compression fractures (VCFs). The **StabiliT Vertebral Augmentation System** features a streamlined process for access and delivery of its proprietary **StabiliT ER Bone Cement**, specially formulated to work at an ultra-high viscosity with an extended working time of more than 25 minutes—longer than any other product on the market. As the cement is warmed with carefully controlled radiofrequency (RF) energy, it forms ultra-high viscous cement for delivery into the vertebral body. The ultra-high viscosity minimizes the potential for extravasation, a common problem that can lead to complications.¹ DFine's **StabiliT MultiPlex Controller** allow real-time monitoring and remote delivery of **StabiliT ER Bone cement**, giving physicians full and steady control of the delivery and viscosity of the bone cement for optimal vertebral body augmentation. During bone cement delivery, a remote hand switch allows physicians to maintain a distance from the radiation source unparalleled in the industry, and significantly reduces the manipulation required in conventional delivery systems.

DFine's **StabiliT ER Bone Cement** is a proprietary, energy-responsive polymethyl-methacrylate (PMMA)-based cement. The ultra-high viscosity enables it to simultaneously create and fill a cavity, achieving site-specific repair of areas comprised of cancellous bone. Whereas other similar systems have working times of eight or nine minutes (at 22 degrees Celsius), the **StabiliT ER Bone Cement** has a working time of approximately 25 minutes* after mixing, and achieves ultra-high viscosity just prior to delivery into the fracture site when delivered through the **StabiliT Vertebral Augmentation System**. Injection of this bone cement will form an internal cast for stabilizing fractures—reducing micro-motion—which may help eliminate pain. Injection of the **StabiliT ER Bone Cement** may also be used



StabiliT Vertebral Augmentation System.

to apply mechanical forces in vertebral augmentation in an effort to maintain and restore spinal function, and to address fractures with greater specificity by localizing cement deposition in a vertebra.

Robert D. Poser, Vice President of Scientific and Medical Affairs at DFine, Inc., notes that what differentiates this product from others is that, “**StabiliT** energy responsive proprietary bone cement has an extremely long working time—yet when delivered through our innovative RF-based, remote hydraulic delivery system—provides the physician the ability to deliver an ultra-high viscosity cement on demand at a distance from the imaging-related radiation. The application of RF energy to only that portion of bone cement about to enter the patient allows the remaining cement to stay at ambient temperature for extended periods of time. Accelerating polymerization of cement immediately prior to entering the patient increases its viscosity to a level not yet seen in the industry, but requires a unique hydraulic delivery system for minimally invasive delivery into the fractured vertebra. The **StabiliT Vertebral Augmentation System** carefully synchronizes the amount of energy applied to the cement with the delivery rate, in order to optimize cement viscosity and provide controlled delivery.” Dr. Poser further notes that, “As viscosity is directly related to leakage, the higher the viscosity the less likely the cement is to leak. Leakage of cement outside the vertebral body can cause

complications.” Current vertebroplasty and kyphoplasty procedures for treating VCFs utilize standard bone cement of relatively low viscosity. Bone cement of such viscosities can leak from the vertebral body before the cement hardens. Complications from leakage include extravasation to the perivertebral venous plexus, epidural veins, or intervertebral disc space; nerve root compression; paralysis; and pulmonary embolization.

Franklin G. Moser, MD, of Cedar Sinai Medical Center (Los Angeles, CA), finds the StabiliT system provides him the control he needs to deliver the cement with greater precision. “Not only will this optimize results, but it will reduce the risk of extravasation. You don’t want the cement to leak into the spinal canal, so the ability to minimize this risk is an important safety factor. As we know, traditional bone cement can be more difficult to control in that the lower viscosity and the irregular flow rate make for inconsistent delivery. The DFine system prevents this.”

Thomas J. Raley, Jr., MD, of the Minimally Invasive Spine Institute (Washington, DC and Arlington, VA), agrees with Dr. Moser. “The DFine technology offers a highly controlled delivery system that gives me an ultra-viscous, yet highly workable, cement. Because I have more control, I can do things that I might not be able to do with other cements, such as perform a uniportal procedure or stabilize burst fractures.” Dr. Raley also notes that the DFine system reduces operator radiation exposure, making it safer to use. “Other vertebral augmentation procedures require extended periods



Bone cement with no RF energy applied.

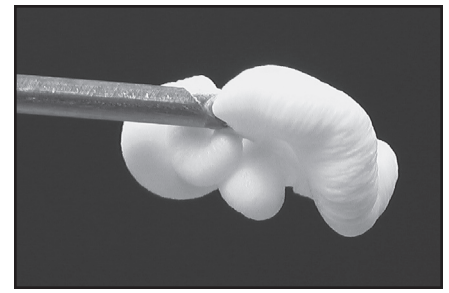
of fluoroscopic guidance, which can lead to substantial radiation dose exposure.” The DFine system’s remote hand switch allows for optimized cement delivery from up to 10 feet away from the radiation source. “You can step away during the procedure, which will limit your radiation exposure.”

“I think the DFine system is a technological advance that addresses a number of challenges surgeons face,” notes Paul J. Slosar, MD, President of the Spine Care Medical Group (Daly City, CA). “Not only does DFine’s activation system allow the cement to be delivered with a reliable consistency and a longer working time, DFine has also created a cement that stabilizes the vertebrae at a cooler temperature than traditional cement. This further increases its safety profile.” Dr. Slosar explains, “Traditional bone cement becomes quite hot and if it were to leak outside the vertebra and come into contact with other important structures, such as the spinal cord, there is concern that the exothermic, or heat reaction, could burn a nerve or the cord. The DFine cement greatly decreases the likelihood of extravasation; but in the unlikely event there is extravasation, you’ve reduced the possibility of a heat-related complication.”

Osteoporosis is a major public health threat in the United States, and today it is estimated that more than 10 million individuals already have the disease; and 34 million more are estimated to have low bone mass, which places them at risk for osteoporosis.² Every year, 1.5 million fractures attributable to osteoporosis occur in the United States,^{3,4-6} and of these, *half* are VCFs.² In 2005, osteoporosis-related fractures accounted for approximately \$19 billion in costs. With the increases in life expectancy and the aging baby-boomer generation, experts foresee costs rising to approximately \$25.3 billion by 2025.²

About DFine, Inc.

DFine, Inc., founded in 2004, was formed to develop new technologies to provide precise means of delivering bone cement



Bone cement with RF energy applied.

or other materials to fractures of the spine in an effort to restore normal function. “We are a diverse group, accomplished in various disciplines, brought together to create innovative products for the minimally invasive treatment of VCFs,” notes Dr. Poser.

“Our technology combines RF energy, hydraulic delivery system, and polymer chemistry, the combination of which has resulted in a system that supplies the highest viscosity cement available through what could be the most controlled delivery system on the market. It is an eclectic approach that provides a very simple answer for both the physician and the patient.” The company’s research and development efforts are overseen by experts in the field of interventional neuroradiology, neurosurgery and orthopedics. DFine’s corporate headquarters are in San Jose, CA. ◆

To Learn More

For more information about the StabiliT Vertebral Augmentation System, please visit the Web site at www.dfineinc.com, or call 1-866-96DFINE (1-866-963-3463) to find a DFine sales representative near you.

*All cements tested at 20 degrees Celsius room temperature.

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