



Bone Solutions, Inc.: Recipient of the
North American Bone Graft Technology Leadership of the Year Award

“We accelerate growth.”

North American Bone Graft Technology Innovation of the Year Award

Award Description

The Frost & Sullivan Technology Leadership of the Year Award is bestowed each year upon the company that has demonstrated excellence in technology leadership within their industry. The recipient company has demonstrated technology leadership by excelling in all stages of the technology life cycle—incubation, adaptation, take-up, and maturity—to ensure a continuous flow of improvements. By innovating leading-edge concepts, the company has pioneered client applications.

Research Methodology

To choose the recipient of this Award, the analyst team tracks all emerging technologies and ongoing research and development projects within the industry. This process includes interviews with all the market participants and extensive secondary and technology research. The technologies and research projects are then compared according to customer base demands. Also considered are elements such as feasibility of product launch, likelihood of customer acceptance and acceptance rates, and estimated time to market. Competitors are then compared and ranked for relative position. The company chosen to receive the Award received the number one industry ranking.

Measurement Criteria

In addition to the methodology described above, there are specific criteria used in determining the final ranking of competitors in this industry. The recipient of this Award has excelled based on one or more of the following criteria:

- Significance of the technology in the industry
- Number of competitors having similar industry technology (competitive factor)
- The technology refinement process meets changing end-user needs (addresses research and development efforts by vendors)
- Value-added technology and services to the customers
- Adoption rate by each of the industry participants (denotes responsiveness of the vendors)
- New product innovation

Frost & Sullivan is proud to recognize Bone Solutions Inc. (BSI) with the Technology Leadership of the Year Award for their development of OsteoCrete™. OsteoCrete™ represents a revolutionary solution to attaching ligaments and tendons to bone, and bone-to-bone, creating an entirely new category in the bone graft market. The OsteoCrete™ is unprecedented magnesium oriented grafting material for orthopedic surgical operations, aiding bone and ligament orthopedic surgical operations for both human and animal applications. To date, the world has products that are 99% oriented from a calcium based compound, and magnesium opens up a new world of healing possibilities for BSI's newly approved product, OsteoCrete, by the FDA. OsteoCrete received FDA 510(k) clearance on May 21, 2009 as a bone void filler for long bone and pelvis applications.

BSI, a privately held Texas medical device company, commercialized the first adhesive or binder oriented solution from its co-industry experience when this patented binder solution was successfully introduced in the road repair industry. The powerful binding qualities were then applied to the medical industry. This disruptive high strength but osteoconductive technology has lucrative potential in human markets, as it potentially represents the first compound that can attach bone to bone in trauma injuries as well ligaments and tendons to bone. BSI's first product, OsteoCrete,™ for human use as bone void filler is the first product to spin out of its technology platform.

Current Bone Graft Solutions Offer Limited Advantages for Bone Healing

Historically, bone graft and demineralized bone matrices have been used to augment fracture repair, bone replacement, fusions, or substantial bone loss. In human medicine, bone grafting has become the second most common transplantation procedure, with approximately 2.2 million bone grafts procedures performed annually worldwide. Traditionally, these grafts enhanced bone healing via their osteogenic, osteoinductive, osteoconductive capacity, but provided little mechanical support. Additionally, donor site morbidity and limited availability sparked the search for appropriate alternatives and led to the development of biocompatible bone fillers and cements.

In the last decade, the clinical application of these bone fillers/cements as bone substitutes in trauma and orthopedic surgery has increased exponentially in acceptance. Particularly, calcium (Ca)-phosphate compounds, including tricalcium phosphates, Ca sulfates, and hydroxyapatite, have been intensively investigated over the last decade. Injectable Ca-based pastes are in the exploratory stage as delivery vehicles for proteins, such as BMP 2, into fractures. However, their slow absorption rate and non-adhesive qualities do not offer any advantage to bone healing other than to serve as a carrier for other materials that may promote bone formation and to provide a scaffold for bony ingrowth. Biomechanically, cements do not offer adhesive properties and are weak under tension.

Increasing evidence shows that magnesium (Mg) based implants promotes bone healing (osteoconductive) and also bone formation (osteogenesis), and Mg-based alloys are being studied as orthopedic biomaterials. Bone Solutions is also investigating use of Mg as the principal component of bone cement. Mg-based bone void filler may also be less prone to other complications associated with Ca-based biomaterials, such as the activation of clotting and its resorbability.

OsteoCrete™ Promotes Bone Formation and Provides Strong Binder Properties

Now cleared by the FDA 510 (k) process, OsteoCrete™ is a magnesium-based, injectable, and moldable bone binder. This product is composed of magnesium oxide, monopotassium phosphate and a very small percentage of tricalcium phosphaste.. The magnesium gives the cement a binder quality that theoretically allows it to resist tensile forces at time zero, thereby potentially limiting graft-tunnel motion. Most commercially available bone cements are calcium based, with limited adhesive properties, and exhibit little or no biodegradability. OsteoCrete™ has been shown in studies to have a peak tensile load to failure three times that of calcium-based bone cements in both bone-bone and tendon-bone attachments in cadaver models, and it resorbs in 26 weeks.

OsteoCrete® has been used in several animal studies that have convincingly shown:

<ul style="list-style-type: none">• OsteoCrete™ is biocompatible in vivo.
<ul style="list-style-type: none">• OsteoCrete™ is absorbed in a time frame compatible with bone healing and faster than the notoriously long Calcium phosphates.
<ul style="list-style-type: none">• OsteoCrete™ adheres bone fragments to parent bone in vivo.
<ul style="list-style-type: none">• OsteoCrete™ adheres stainless steel screws to bone in vivo and is stronger than other cements.
<ul style="list-style-type: none">• OsteoCrete®, by itself, is expected to affirm in future additional research that is may be as potent as recombinant BMP-2 in Ca-based cement in both bone healing in an ACL tunnel and in the mechanical strength of the ACL repair after healing

A Focus on Bringing Innovative Solutions to Orthopedic Industry Likely to Drive Success for BSI

The Bone Solutions technology could potentially revolutionize sports medicine injury repair, as well as several key segments of orthopedics and orthobiologics. BSI is exploring licensing or joint venturing for various orthopedic applications, including trauma for synthetic bone grafts, sports medicine, extremities, maxillofacial/cranial, and dental among others. As a result of the application breadth, BSI has large addressable markets that are fragmented, totaling \$3.0 billion globally.

Having received its first FDA 510 (k) clearance, BSI plans to complete a series of four additional 510(k) approvals as filler for cranial, and maxillofacial, and non-load bearing spine, and as a bone anchor to broaden its use across many orthopedic applications. The availability of OsteoCrete™ for human sale is expected to be in 1Q 2010. BSI's planning for marketing, distribution, and potential strategic relationships with certain key orthopedic companies are now underway.

BSI's strategy is to rapidly deploy its platform technology across a spectrum of surgical procedures, such as ACL/rotator cuff/extremities, shoulder repair, and cementless knee and hip, maxillofacial/cranial applications, and dental implants. At a minimum, the quality of the BSI technology may fully replace screws and plates now used for major knee and shoulder surgeries, allowing for more rapid recoveries. In rotator cuff surgeries it may augment the current use of sutures. It could also be used to augment bio-absorbable screws.

Conclusion

Due to the innovative properties afforded by their approach, the BioHesive platform is likely to generate great interest for the use of this technology in various applications. For its ingenuity in developing this unique platform in the industry, Frost & Sullivan presents the Technology Leadership of the Year Award to Bone Solutions Inc.

About Frost & Sullivan

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