

F R O S T & S U L L I V A N

FROST & SULLIVAN BEST PRACTICES AWARD

BONE REGENERATION  
FIXATION DEVICES - NORTH AMERICA

New Product Innovation 2019

**OSSIO**<sup>®</sup>  
Restore. Regrow. Renew.

FROST & SULLIVAN

2019

BEST  
PRACTICES  
AWARD

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## Background and Company Performance

### *Industry Challenges*

Globally, osteoporosis causes approximately 9 million fractures annually, resulting in an osteoporotic fracture every three seconds.<sup>1</sup> According to the International Osteoporosis Foundation, the global incidence of hip fractures in men is projected to increase by 310% and in women by 240% by 2050.<sup>1</sup> Bone injuries or abnormalities that require treatment occur as a result of physical trauma (due to high-impact or crushing forces), non-union bone fractures (subsequent to severe bone fractures), bone voids, and disease such as osteoporosis. Treatment is bone fixation, which aims at stabilizing and supporting fractured bones until they get back to their natural strength through regeneration. To regenerate, bone tissue requires grafting part of a bone or bone-like material. Common bone graft fixation methods include autografts — using bone from the same individual receiving treatment; allografts — harvesting and grafting bone tissue from an individual other than the patient receiving the treatment; and xenografts — extracting bone tissue from an alternative species (such as bovine or porcine).

Frost & Sullivan notes that osteoporosis and osteoporotic fracture prevalence, as well as the increase in the global geriatric population, remain critical drivers of the bone fixation market. However, risk factors associated with bone graft fixation - including morbidity and cellular rejection - often hamper growth in this market. Substandard biomaterial may also spread communicable disease (such as Hepatitis B and Human Immunodeficiency Virus). Furthermore, Frost & Sullivan points out that the bone fixation procedure remains quite expensive. Novel products should seek to attenuate the number of operative interventions necessary for bone fixation procedures and should mitigate the risk of inherent complications using conventional techniques – all while considering cost.

Current research and development focus on more sterile bone fixation, prompting the acceptance of both internal and external fixation methods. Mainly used for fractures, external bone fixation devices are surgically placed using percutaneous methods to hold bones together with pins and wires, while internal fixation is a more invasive alternative involving nails, plates, screws, and wires.

### *New Product Attributes and Customer Impact*

Founded in Israel in 2014, Massachusetts headquartered OSSIO is a holistic orthopedic fixation company dedicated to transforming the orthopedic market through its first-of-its-kind bio-integrative bone fixation solution, OSSIOfiber™ — its flagship technology platform.

### **Breakthrough Intelligent Bone Regeneration Technology**

OSSIOfiber, a proprietary natural mineral fiber matrix custom made with a polymer that acts as glue, is a breakthrough in bone regeneration technology and is a new category of non-permanent fixation material. As such, OSSIOfiber is the first credible replacement for permanent fixation implants. The fiber matrix architecture used by OSSIO is two times stronger than polyetheretherketone (PEEK) and five times stronger than traditional bio-

<sup>1</sup> International Osteoporosis Foundation, <https://www.iofbonehealth.org/facts-statistics>.

resorbables, popular materials used by competitors. The bio-integrative material properties provide surgeons with a biologically-friendly means of restoring patient stability and mobility (while leaving nothing permanent behind).

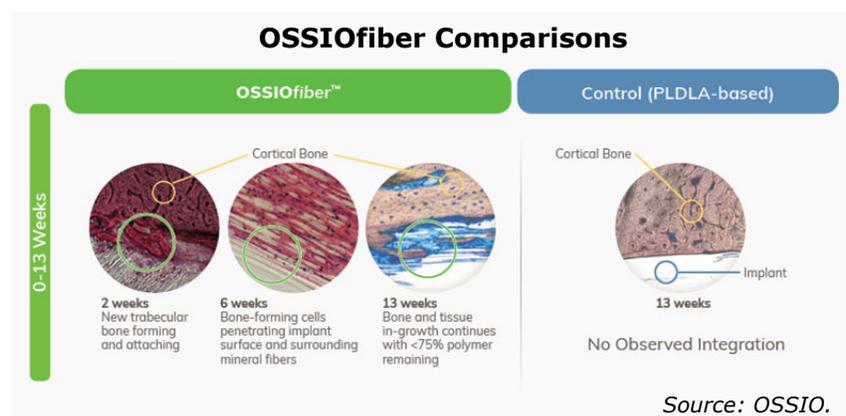
OSSIOfiber consists of 50% polymer and 50% natural mineral fiber, e.g., silica, calcium, magnesium, and other materials typically found in the bone. The proprietary bio-integrative mineral fibers are custom made to attain preeminent mechanical properties. For example, OSSIOfiber uses proven materials such as Poly Lactic Acid (PLDLA) and Poly (L-lactide-co-D, L-lactide) to bind the fibers into cohesive material.

Frost & Sullivan notes that PLDLA has been the generally accepted bio-resorbable material for decades, as it is naturally cleared by the body by hydrolysis and dissolves, letting the bone fill the gap. However, OSSIOfiber's matrix is clearly superior to PLDLA, as it includes a polymer and natural bone fibers — making it much stronger than cortical bone. As it integrates with the bone, OSSIOfiber provides stability and secures the bone fixation during the healing process, leaving no permanent hardware behind.

While metal and PEEK have been the generally accepted bone fixation techniques throughout the years, both are foreign objects and thus carry a risk of rejection or issues with the bone implant interacting during the healing process. These materials can also cause stress shielding and weakening of the bone over time and break due to low ossification. Previous companies struggled to develop a fixation method that led to complete calcification of the bone while supporting the bone's natural regeneration. Similar to allografts, OSSIO's technique completely incorporates into the native bone, while eliminating some the risks associated with using donor bone.

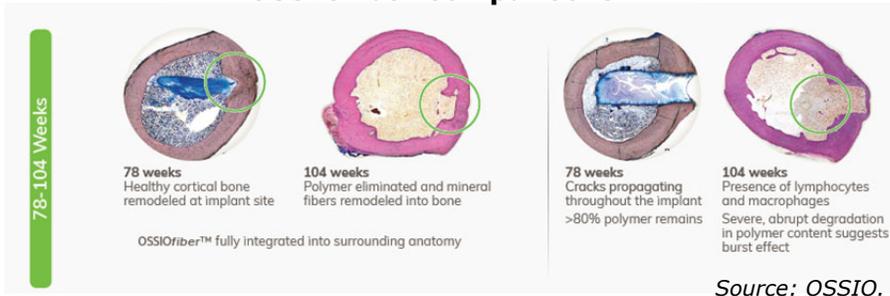
### A First-of-its-Kind in Bio-integrative Orthobiologics

OSSIO's implant method offers a myriad of opportunities for the fixation market. OSSIOfiber's strength and durability enable improved and faster motion as well as rehabilitation. The bio-integrative method also removes the need for hardware removal, which can be quite time-consuming - as well as potentially expose patients to possible infection. As a result, Frost & Sullivan believes that OSSIOfiber is uniquely cost-effective.



In January 2019, OSSIO received 510(K) clearance from the United States (US) Food and Drug Administration (FDA) for its OSSIOfiber™ Bone Pin Family. The company notes that this is a major milestone, raising the bar for competing medical device manufacturers. The clearance comes after the company conducted a 104-week pre-clinical animal study to prove safety, biocompatibility, and long-term degradation profiles of the material. Specifically, an in-bone implantation study in rabbit femurs showed that full integration into the surrounding anatomy takes place within approximately 18 to 24 months, leaving only the native bone and no residual hardware behind. The pre-clinical study showed early bone attachment and in-growth, as well as gradual integration with surrounding anatomy without any adverse inflammation.

### OSSIOfiber Comparisons



The OSSIOfiber results differ from similar trials with other fixation materials, which could not achieve integration in the first 78 weeks and prone to late, abrupt polymer degradation, which may result in adverse

inflammation and cyst formation. The study not only raises the bar for orthopedic and fixation developers, but also for medical device manufacturers in general, as the clinical trials provided in-depth research and results over a two-year period - as opposed to the standard 26 week period that it usually takes for companies to garner for FDA clearance.

OSSIO identified the foot and ankle market as a habitually untapped market. With the aging population on the rise, arthritis and osteoporosis are set to increase, as well as injuries such as metatarsophalangeal joint injuries, cross ankle ligament sprains, syndesmotic sprains, and ankle dislocations requiring minor surgeries. The US has a particularly significant foot and ankle market share due to geriatric issues and sports-related injuries. Frost & Sullivan firmly believes that OSSIO's 510 (K) FDA approval puts the company at an ideal position to enter the segment.

### Conclusion

*Technology and innovation continue to transform the healthcare sector daily. However, innovation needs to improve the overall quality of life, while taking both safety and quality into consideration.*

*OSSIO's bone fixation device is a one-of-a-kind solution that considers and integrates all of these elements. OSSIOfiber is the first fully bio-integrative fixation device that does not compromise quality, as it uses fiber that is twice as strong as traditional material used within fixation devices market (e.g., PEEK). OSSIOfiber incorporates its material with the bone over time, removing the need for additional hardware removal surgery. The company is at the sweet spot of innovative orthopedic design, and its bio-integrative solution earns the 2019 Frost & Sullivan New Product Innovation Award.*

## Significance of New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



## Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity — for consistently translating ideas into high-quality products that have a profound impact on the customer.

## *Key Benchmarking Criteria*

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

### **New Product Attributes**

- Criterion 1: Match to Needs
- Criterion 2: Reliability
- Criterion 3: Quality
- Criterion 4: Positioning
- Criterion 5: Design

### **Customer Impact**

- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

## Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 <b>Monitor, target, and screen</b>	Identify Award recipient candidates from around the globe	<ul style="list-style-type: none"> <li>• Conduct in-depth industry research</li> <li>• Identify emerging sectors</li> <li>• Scan multiple geographies</li> </ul>	Pipeline of candidates who potentially meet all best-practice criteria
2 <b>Perform 360-degree research</b>	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> <li>• Interview thought leaders and industry practitioners</li> <li>• Assess candidates' fit with best-practice criteria</li> <li>• Rank all candidates</li> </ul>	Matrix positioning of all candidates' performance relative to one another
3 <b>Invite thought leadership in best practices</b>	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> <li>• Confirm best-practice criteria</li> <li>• Examine eligibility of all candidates</li> <li>• Identify any information gaps</li> </ul>	Detailed profiles of all ranked candidates
4 <b>Initiate research director review</b>	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> <li>• Brainstorm ranking options</li> <li>• Invite multiple perspectives on candidates' performance</li> <li>• Update candidate profiles</li> </ul>	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 <b>Assemble panel of industry experts</b>	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> <li>• Share findings</li> <li>• Strengthen cases for candidate eligibility</li> <li>• Prioritize candidates</li> </ul>	Refined list of prioritized Award candidates
6 <b>Conduct global industry review</b>	Build consensus on Award candidates' eligibility	<ul style="list-style-type: none"> <li>• Hold global team meeting to review all candidates</li> <li>• Pressure-test fit with criteria</li> <li>• Confirm inclusion of all eligible candidates</li> </ul>	Final list of eligible Award candidates, representing success stories worldwide
7 <b>Perform quality check</b>	Develop official Award consideration materials	<ul style="list-style-type: none"> <li>• Perform final performance benchmarking activities</li> <li>• Write nominations</li> <li>• Perform quality review</li> </ul>	High-quality, accurate, and creative presentation of nominees' successes
8 <b>Reconnect with panel of industry experts</b>	Finalize the selection of the best-practice Award recipient	<ul style="list-style-type: none"> <li>• Review analysis with panel</li> <li>• Build consensus</li> <li>• Select recipient</li> </ul>	Decision on which company performs best against all best-practice criteria
9 <b>Communicate recognition</b>	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> <li>• Present Award to the CEO</li> <li>• Inspire the organization for continued success</li> <li>• Celebrate the recipient's performance</li> </ul>	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 <b>Take strategic action</b>	Upon licensing, company is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> <li>• Coordinate media outreach</li> <li>• Design a marketing plan</li> <li>• Assess Award's role in future strategic planning</li> </ul>	Widespread awareness of recipient's Award status among investors, media personnel, and employees

## The Intersection between 360-Degree Research and Best Practices Awards

### Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

### 360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



### About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.