Staples Instead of Screws

Rich Ashman
Chief Science Officer
InteliFUSE Inc.
New Orleans LA
InteliFUSE Inc.

- New Orleans Based FDA and CE Regulated Orthopedic Device Company-

  - Purchased the controlling patented technology for orthopedic implants using ABOVE BODY TEMPERATURE Nitinol, a shape memory alloy
  - Developing new patented orthopedic products based on this superior technology
Management Team

- Eugene A. Antoine, Jr., CEO, President and Co Founder
- Charles R. Strand, Executive Vice President and Co Founder
- Richard B. Ashman, Ph.D., Chief Science Officer
- Megan Ohar, M.S., Director of Regulatory and Quality
- Richard Kilgus, Vice President, Sales and Marketing

* Profiles for each member of the executive team can be found at www.intelifuse.com
Our mission is to change the standard of care by replacing current fixation devices with lower cost, more clinically reliable, InteliFUSE Shape Memory Alloy (SMA) FUSION devices.
Replace

with

FUSION
There are currently 2 existing markets:

- Fracture Fixation Market
  $5 Billion, with a 9% Compound Annual Growth Rate

- Bone Growth Stimulation Market
  $1 Billion, with a 10% CAGR

3 Million procedures annually

- For repair of foot, hand, long bone, craniomaxillofacial, and spine
2006 US + Europe Procedures

- Long Bone 1,189,886
- Hand/Wrist 200,322
- Foot/Ankle 897,720
- Craniomaxillofacial 416,333
- Spine 1,226,516

- Ortho Fact Book 5th ed., Knowledge Enterprises
Current Fixation Opportunity

- Two necessary elements for bone fractures to heal quickly and completely:
  - Bone fragment stabilization
  - Osteogenic Response
- Current “static” fixation modalities only accomplish initial stabilization
  - Resulting non-fusion rate is between 10% - 50%
  - Non-fusion routinely requires 2nd surgical procedure
Wolff’s Law

“In 1892, Julius Wolff published his seminal thesis on bone remodeling.

Simply stated, bone grows in response to mechanical stress so as to produce an anatomical structure best able to resist the applied stress.

The application of SMA to bone fracture repair is the advancement that takes bone fracture fixation to bone fracture fusion.
Examples of Competitors’ Fixation Devices
Current InteliFUSE Product Offering

StimuLINK™ Fixation Devices
Nitinol, Shape Memory Material
Warmed After Insertion
Maintain Significant Long Term Compression
FDA and CE Cleared
Nitinol Shape Memory Alloy

- Nitinol (Nickel Titanium Naval Ordnance Laboratory)
- Ability to "remember" original shape
- "Martensite to Austenite" Transformation
Phase Transformation of Nitinol SMA

Austenite

Martensite

Room Temperature 25°C

Body Temperature 37°C

Safe Threshold 55°C
Current InteliFUSE Product Offering

- InteliFUSER™ Warming System
  - Disposable / Reusable Models
  - Ergonomic Design
  - Patented and Pat Pending
  - FDA and CE Cleared
InteliFUSER™ Disposable Warmers
Competition

- **Direct Competition**
  - Cold Nitinol Products
  - Warm Nitinol

- **Static Fixation Devices**
  - Wire / Pins
  - Static Staple Devices
  - Screws
  - Plates
<table>
<thead>
<tr>
<th>Competitor</th>
<th>Trauma</th>
<th>Spine</th>
<th>CMF</th>
<th>Totals</th>
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</thead>
<tbody>
<tr>
<td>Synthes</td>
<td>$640</td>
<td>$334</td>
<td>$63</td>
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<td>Medtronic Sofamor Danek</td>
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<td>J&amp;J (Depuy, ACE, Mitek)</td>
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<td>Zimmer</td>
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<td>Biomet</td>
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<td>Orthofix</td>
<td>$74</td>
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<tr>
<td><strong>Totals</strong></td>
<td><strong>$1,855</strong></td>
<td><strong>$2,031</strong></td>
<td><strong>$161</strong></td>
<td><strong>$4,047</strong></td>
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## Competitive Advantage Summary

<table>
<thead>
<tr>
<th>Features</th>
<th>InteliFUSE&lt;sup&gt;™&lt;/sup&gt;</th>
<th>Competition</th>
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<tbody>
<tr>
<td>Provides bone fragment fixation</td>
<td>✓</td>
<td>n</td>
</tr>
<tr>
<td>Long term dynamic stress stimulates response to grow and fuse bone</td>
<td>✓</td>
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</tr>
<tr>
<td>Patent pending presterile disposable activation device, provides surgeon with maximum implant control (no capital equipment outlay).</td>
<td>✓</td>
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<tr>
<td>Patented implant technology replaces bulky implant hardware</td>
<td>✓</td>
<td></td>
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<tr>
<td>Elegant implant designs enable smaller incisions and shorter procedure times, leading to reduced trauma to patient and faster recovery</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Lower price compared to traditional “plates &amp; screws”</td>
<td>✓</td>
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</table>
InteliFUSE™ proprietary technology yields longer term compression, thus reduced healing times while increasing the success rate of fusion by enabling surgeons to apply Wolff’s Law on command.

StimuLINK™ replaces plates, screws, wires and nails.
InteliFUSE™
New Product Developments

- Spine (Fusion / Deformity applications)
- Long Bone Fixation
- Distal Radius Fixation
- Cranial Flap Closure
- Sternum Closure
- On-going design enhancements to current product line
Marketing & Sales Strategies

- Contract with major distributor to achieve initial sales goals in U.S.
- Conduct and publish animal studies to verify superior clinical benefits
- Reduce manufacturing costs to allow pricing of “FUSION” devices below existing fixation devices
- Build strong clinical alliances leading to technology and product development
• US / Canadian Distribution Agreement
  Current product line only
• Extremity / Reconstruction Sales Org
  Lower / Upper Extremity Fixation
  AEON™
• Shipments > $1M
  Shipments began July 2007

Continuous, Dynamic Compression
IP and Regulatory Milestones

- Intellectual Property Platform and Existing Products covered under current US and International Patents
  - Additional Patents Pending
- Multiple 510(k) Regulatory Clearances in place covering entire skeleton (except spine) and soft tissue fixation.
  - Clearance for Spine expected 2008
- ISO 13485 Certification
- CE Mark European Device Certification
- Canadian Certification (Anticipated 2Q 2008)
Medical Device Industry in New Orleans

**Pros**
- Underutilized pool of Bioengineering talent
- Accessibility to two Medical Schools
- Tulane Dept of Biomedical Engineering
- State tax credits and other incentives

**Cons**
- Lack of local VC market
- Medical device industry not understood by local banking
- Perception that NO is or will be underwater
In Summary...

- InteliFUSE™ will revolutionize the way bone fractures and bone deformities are healed, strengthened and corrected.

- By 2010, InteliFUSE™ will be the leading provider of “FUSION” devices to the orthopedic industry and its technology will be the “Gold Standard” for bone fusion and remodeling.