

**INTELiFUSE**™  
LLC  
*Fixation Using Smart Elements*

---

# **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**

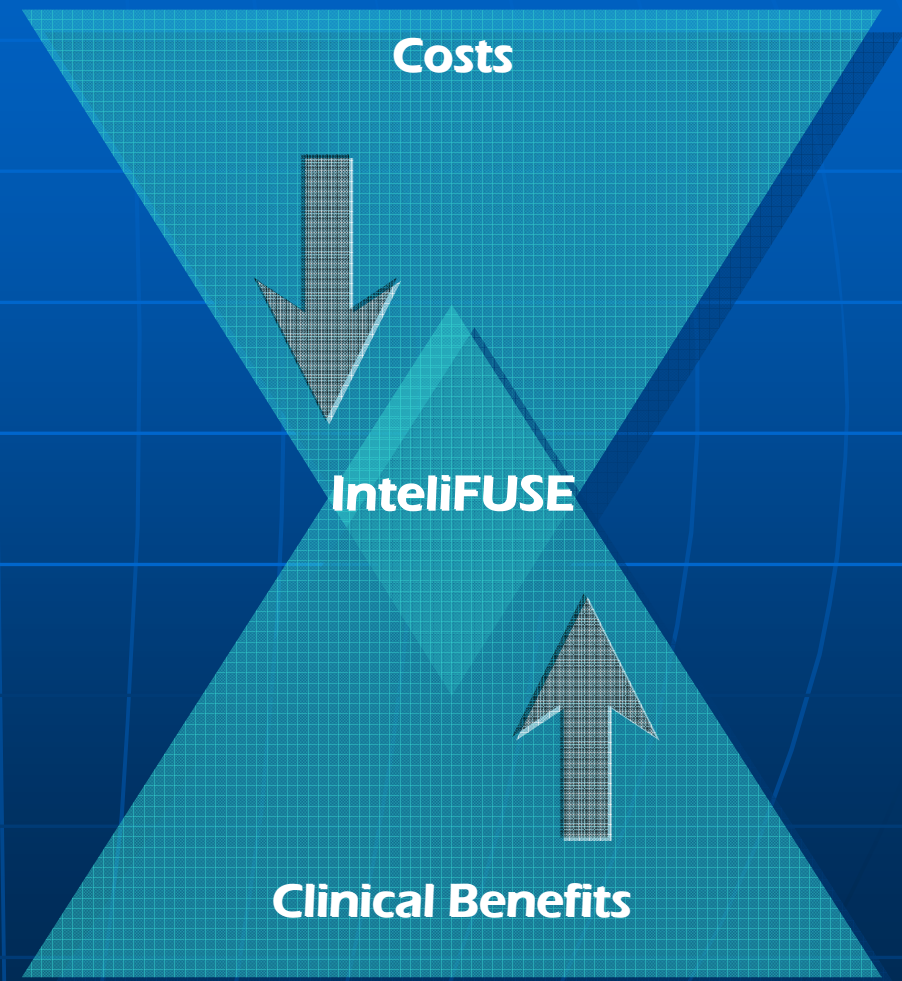
# Management Team

- *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*

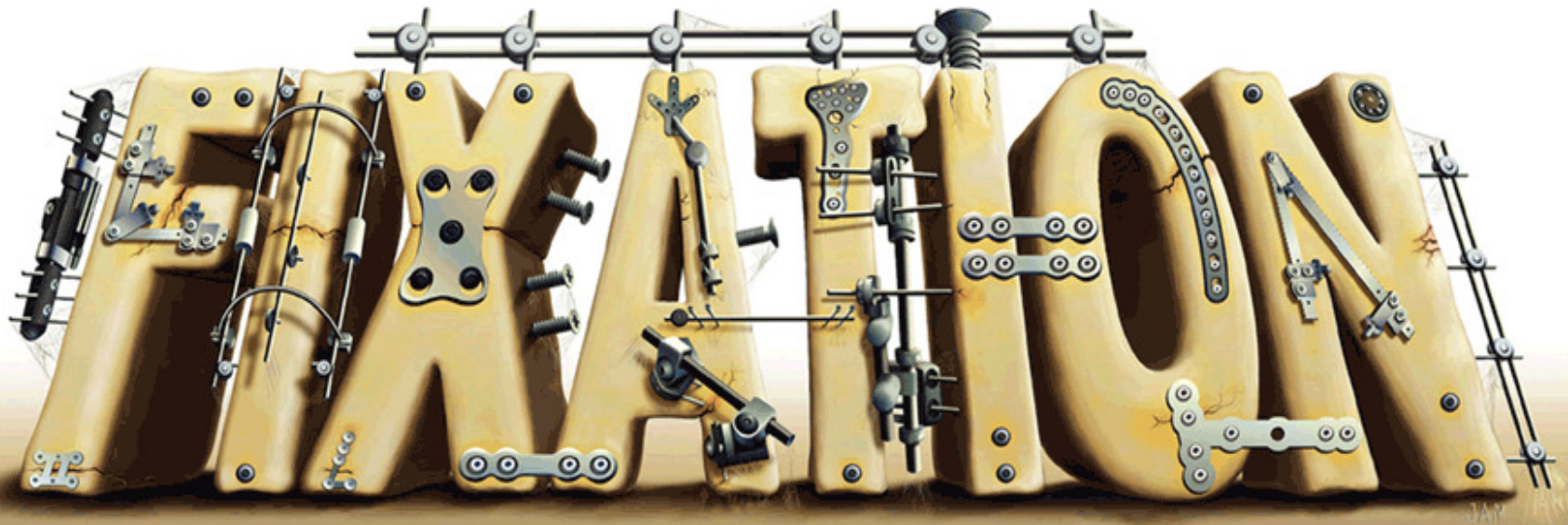
\* Profiles for each member of the executive team can be found at [www.intelifuse.com](http://www.intelifuse.com)

# Company Overview

- **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

# 2005 Global Market Opportunity

- **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

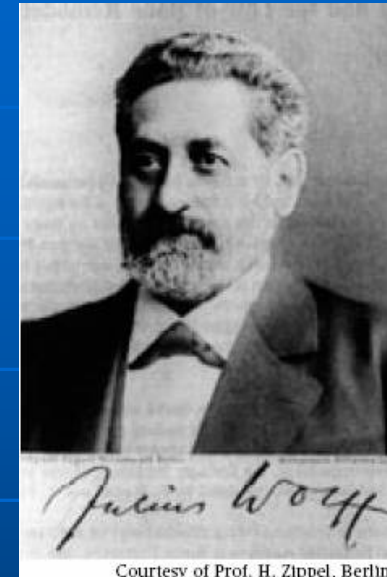


# Current Fixation Opportunity

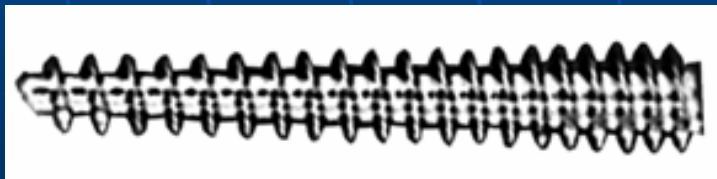
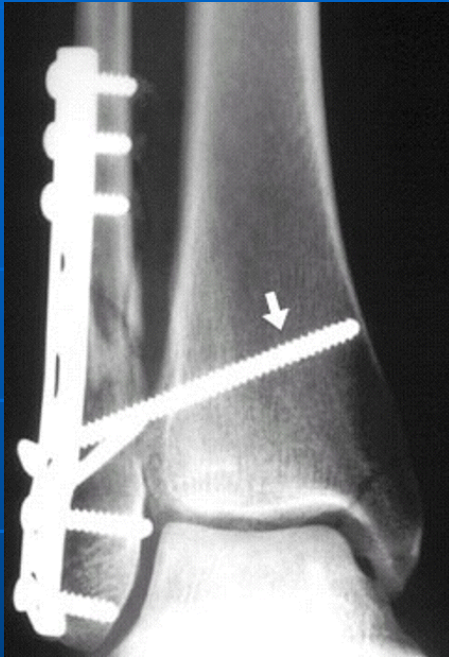
- **Two necessary elements for bone fractures to heal quickly and completely:**
  - **Bone fragment stabilization**
  - **Osteogenic Response**
- **Current “static” fixation modalities only accomplish initial stabilization**
  - **Resulting non-fusion rate is between 10% - 50%**
  - **Non-fusion routinely 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***

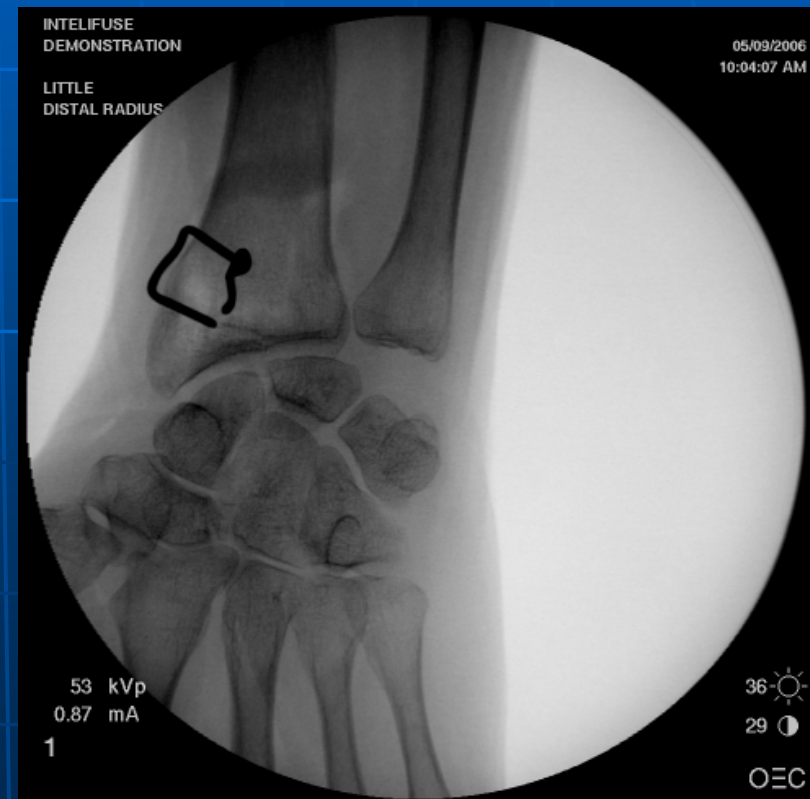
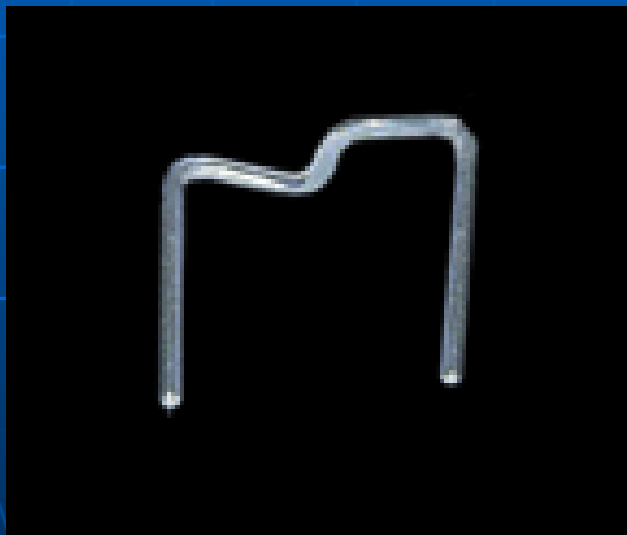


# Examples of Competitors' Fixation Devices



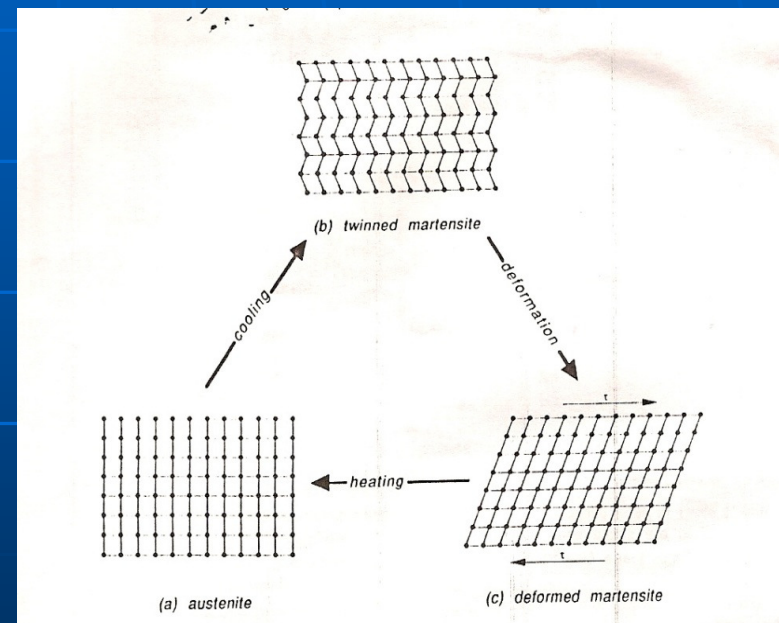
# Current InteliFUSE Product Offering

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

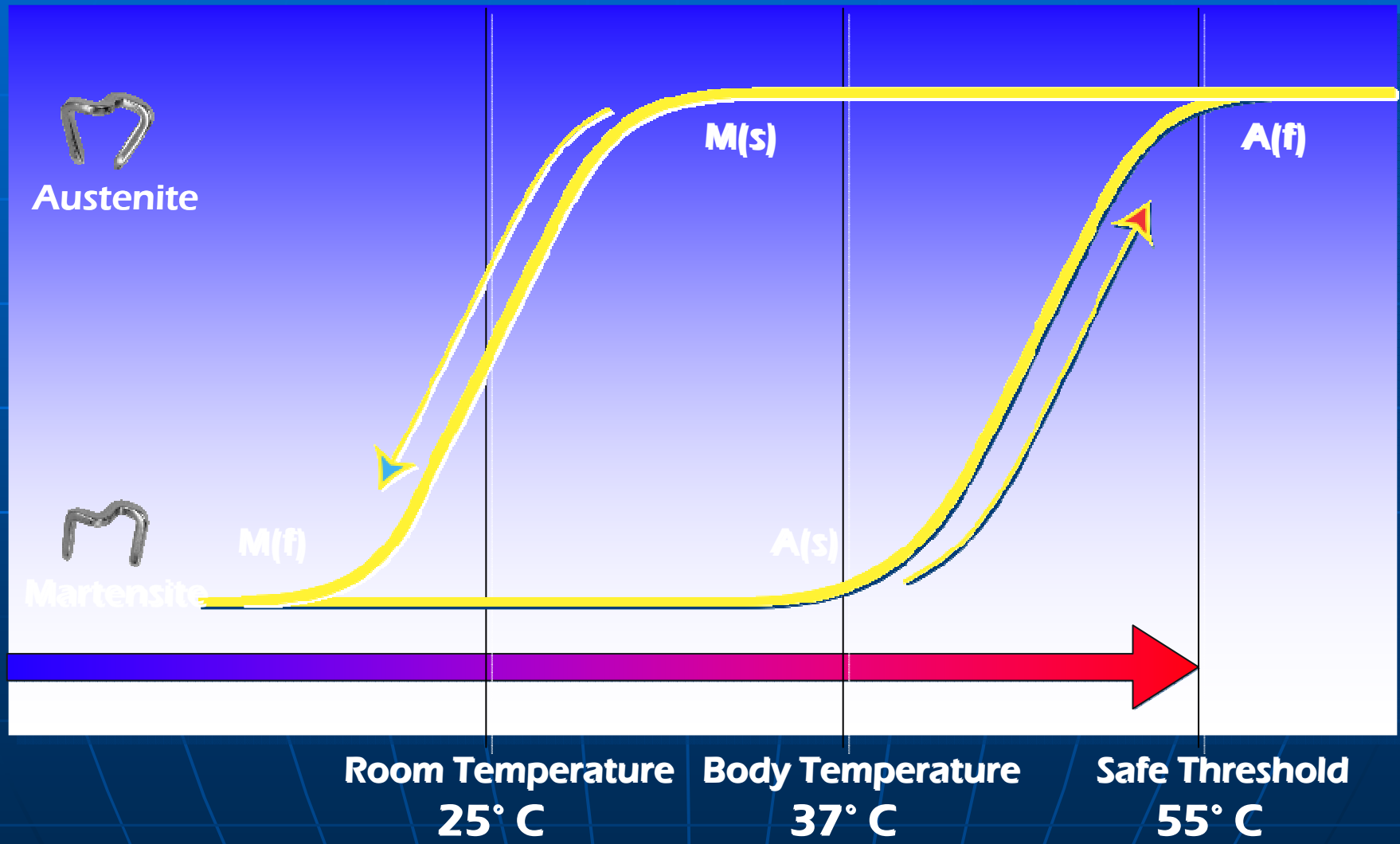


# Nitinol Shape Memory Alloy

- Nitinol (Nickel Titanium Naval Ordnance Laboratory)
- Ability to “remember” original shape
- “Martensite to Austenite” Transformation



# Phase Transformation of Nitinol SMA

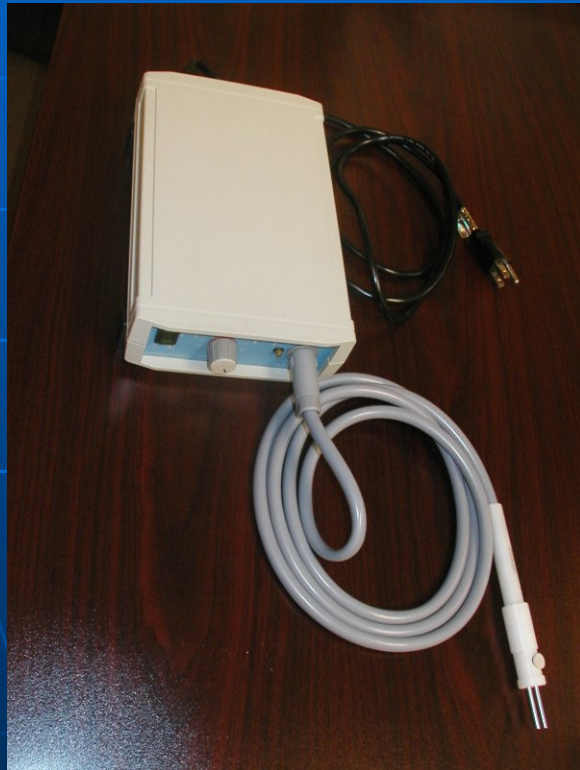


# Current InteliFUSE Product Offering

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



# InteliFUSER™ Disposable Warmers





# Competition

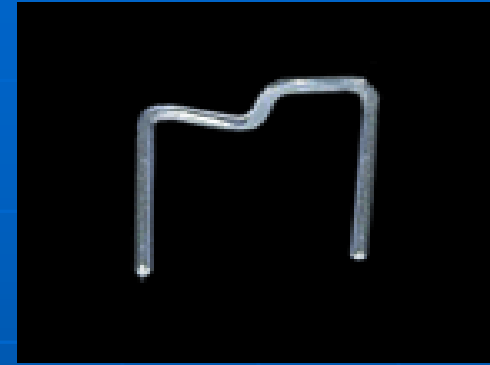
- **Direct Competition**
  - **Cold Nitinol Products**
  - **Warm Nitinol**
- **Static Fixation Devices**
  - **Wire / Pins**
  - **Static Staple Devices**
  - **Screws**
  - **Plates**



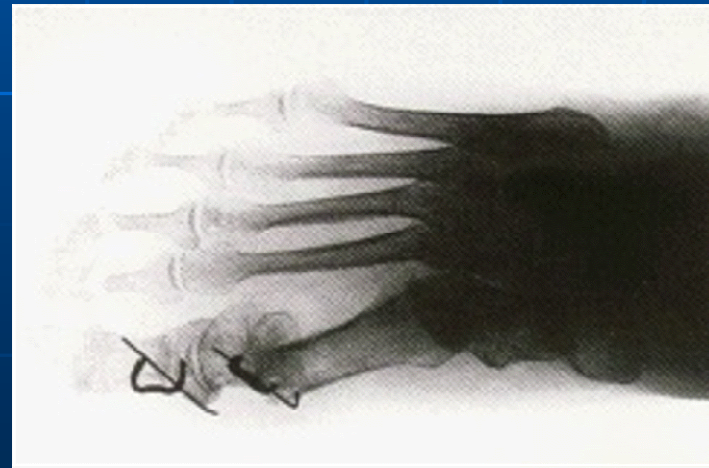
# Competitive Advantage Summary

<b>Features</b>	<b>InteliFUSE™</b>	<b>Competitio</b>
<b>Provides bone fragment fixation</b>	✓	n ✓
<b>Long term dynamic stress stimulates response to grow and fuse bone</b>	✓	
<b>Patent pending presterile disposable activation device, provides surgeon with maximum implant control (no capital equipment outlay)</b>	✓	
<b>Patented implant technology replaces bulky implant hardware</b>	✓	
<b>Elegant implant designs enable smaller incisions and shorter procedure times, leading to reduced trauma to patient and faster recovery</b>	✓	
<b>Lower price compared to traditional "plates &amp; screws"</b>	✓	

**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 2005**



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