

*INTREPID ORTHOPEDICS*

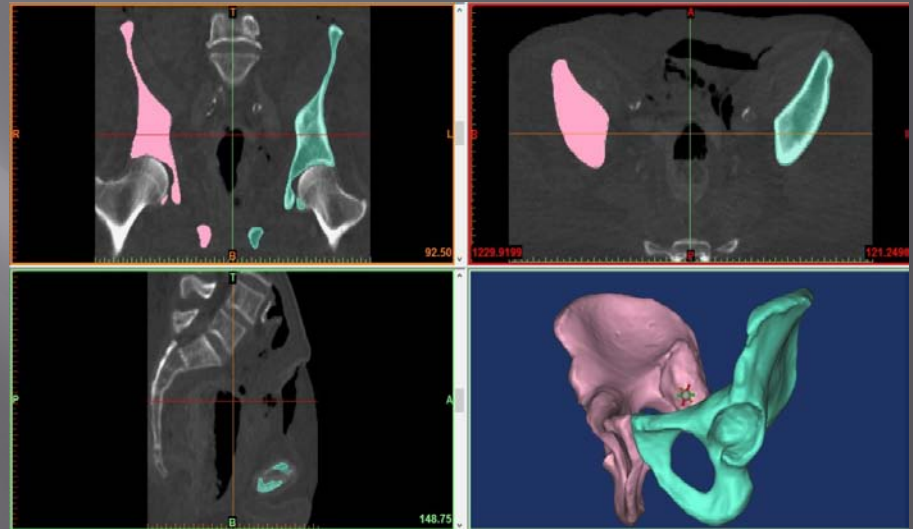
*MEDICAL DEVICE  
EXPERTS*

# Management Team

	<b>Title</b>	<b>Experience</b>
<b>Lee Strnad</b>	<b>President</b>	<i>25 years in Orthopedics (R&amp;D, Operations, and Regulatory)</i>
<b>Chuck Birchall</b>	<b>Vice President</b>	<i>25 years in Orthopedics (Business Development, Marketing and Sales)</i>
<b>Al Ernst</b>	<b>Prototype Manager</b>	<i>30 years in Manufacturing (Medical devices, Aerospace, and Automotive)</i>

# Development

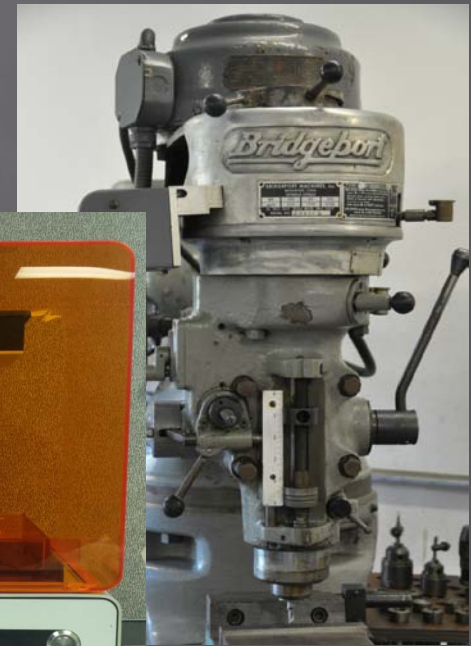
- ▣ Mimics
  - Patient-specific models and anatomical engineering
  - Mimics provides the ability to design patient-specific implants or instruments based on CT or MRI data





# Prototype Manufacturing

- ▣ Rapid Prototyping
  - SLA (3D plastic models)
  - DMLS rapid prototypes (direct metal laser sintering)
- ▣ Conventional Prototyping
  - Turning, milling, EDM, ect



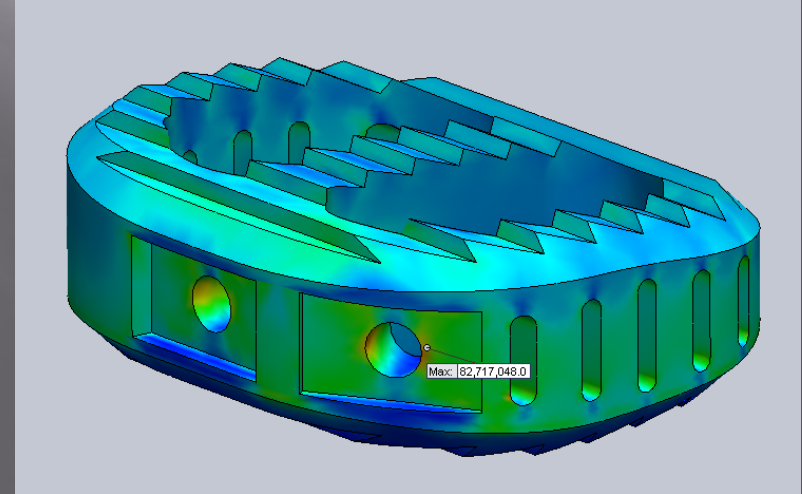
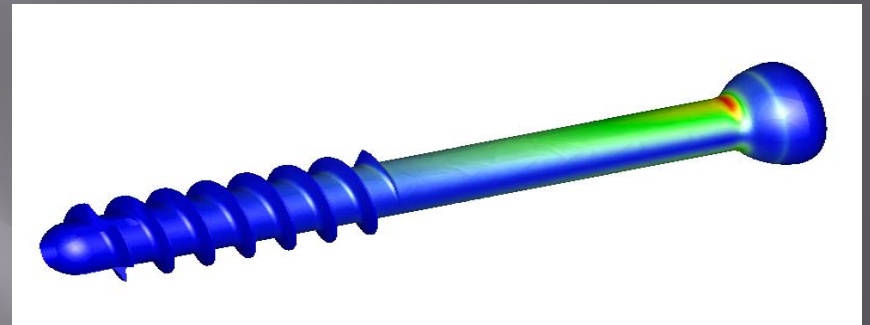
# Intellectual Property

- ▣ 30+ patent applications submitted over the past 20 years
- ▣ Companies owning patent rights include:
  - J&J/Depuy/Acromed
  - Zimmer/Biomet
  - Tornier/OrthoHelix
  - Spinal Frontier/Axiomed
  - Intrepid Orthopedics



# Verification and Testing (Finite Element Analysis)

- ▣ SolidWorks Simulation (FEA)
  - ▣ Provides extra confidence that the design will meet testing standards before any prototypes are made
  - ▣ Component and Assembly FEA
  - ▣ Experienced in static, buckling, thermal, frequency, drop test, and fatigue FEAs



# *Verification and Testing (Mechanical Testing)*

- ▣ Create verification and validation plans
- ▣ Preliminary testing
- ▣ Pre-production and 510k testing
- ▣ Create cleaning and sterilization protocols
- ▣ Manage cleaning and sterilization validation





# *Supply Chain Management*

- ▣ 25 yrs of relationships with leading suppliers in the orthopedic field
- ▣ Create and maintain
  - Supplier qualification, assessment, and surveys
  - Master device documentation
  - Purchase orders



# Quality Assurance

- ▣ Create and maintain inspection plans
- ▣ Manage all inspection activities from outside vendors
- ▣ Receive and inspect implants and instruments
- ▣ Document and control non-conforming material and deviations



# *Supply Chain Management Inventory Management*

- ▣ Handle and store prototype, production, and demo product
- ▣ Control and maintain accurate counts of all inventory
- ▣ Replenish loaner sets and ship replenishment inventory to customers



# *Compliance and Regulatory*

- Create and maintain
  - QSP System
  - Quality records
  - Design control documentation
  - Product complaints
  - Corrective and preventative action
  - MDR's, recalls, and removals & corrections
- Assemble and submit 510k documentation
- Perform management reviews
- Document employee training records



# Marketing and Sales

- ▣ Create and maintain
  - Marketing strategies
  - Surgical techniques and IFU's
  - Brochures and sell sheets
  - Ads and mailers
  - Price lists, charge sheets, and commission rates
  - Target customer list
  - Sales forecast and distribution plan
  - Sales training



# *INTREPID ORTHOPEDICS*

- ▣ Superior knowledge of the orthopedic market
- ▣ Extensive experience of the development process
- ▣ Novel IP portfolio with cutting edge technology
- ▣ Track record of executing on-time product launches
- ▣ Proven marketing and business development strategies
- ▣ Excellent and hard working employees

# *INTREPID ORTHOPEDICS*

*THANK YOU!*