Orthopedic Medical Device Precision Contract Manufacturing Trends

Structure Medical
Naples, FL
Mooresville, NC

Bob Fletcher, Vice President of Procurement & Facilities
Sept. 25-28, 2016 • JW Marriott Desert Ridge Resort • Phoenix, Arizona
Structure Medical

• Structure Medical was founded in Naples, FL in 2004 and established a second facility in Mooresville, NC two years later. The company uses the most advanced machine tools available around the world to produce products that meet the highest quality standards.

• Structure Medical is a leading tier-one manufacturer of medical implant products that are used by orthopedic surgeons to treat disorders of the musculoskeletal system. Orthopedic surgeons use these medical devices to treat trauma, sports injuries, degenerative diseases, tumor and congenital conditions. Structure Medical’s Vision is to be the leader in technology driven medical manufacturing by applying our innate expertise and by utilizing and committing to the world’s most sophisticated machine equipment. We recognize our responsibility to our customers is to provide products true to their design and meet the expectation that these products will be manufactured with the highest quality standards.
Facilities

Milling Center of Excellence – Mooresville, NC

Turning Center of Excellence – Naples, FL

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- Additive Manufacturing/Laser Sintering
- 5-Axis Machining
- Raw Material Input Stock
- Sterile Packaging
- Delivery – Quality – Cost
- Outsourcing
Additive Manufacturing/Laser Sintering

- FDA has published new requirements pertaining to the validation of the laser sintering process

- OEM’s gaining traction internally and starting to outsource

- To handle the precision tolerances within the industry parts still would need to be finished on a CNC machining center
5-Axis Machining

• Increasing price pressures from changes in healthcare
  — Reduce cost/Increase throughput/reduce lead-time
    = Reduce Overall Cost!
• We must invest in the latest technology on the market – reduce setup time/utilization is crucial
Raw Material Input Stock - Titanium

- OEM’s through creativity and innovation are understanding material properties down to the KSI to provide product that better adapts to the human anatomy.
  - Alloys fabrication of precision machined components to bend and adapt to anyone’s anatomy.
  - Material science at the purchasing level
Sterile Packaging

• Viable distribution process within the trauma market including extremities both upper and lower. There has been some traction in the spinal market but it hasn’t been proven yet.
  • Trauma has been able to develop a template that builds confidence with surgeons that the part number needed during surgery will be present when he opens the kit.
  • Spine needs so much variety in a kit that it’s hard to predict the exact sizes and part numbers needed. Current cases are already large and extensive.
Delivery – Quality - Cost

- We need access to readily available quality titanium that meets the specs., tolerances, and mechanical properties required.
- We pursue quality by constantly investing in the latest technology and equipment (5-Axis, Swiss turn, Additive) on the market which allows us to reduce cost, reduce lead-time and continue pursuing innovation.
Outsourcing

• Healthcare/OEM consolidation are driving press pressures
• Contract manufactures planning to grow at the highest level and strategically partner with OEM’s will need to look at offshore strategic manufacturing to support international sales.
  • OEM’s that are on the cutting edge of innovation want that innovation and development to start here in the U.S.
  • The VA requires U.S. made products
  • As product life cycles come to an end and are retired in the U.S., they are sold overseas. Offshore lower cost manufacturing will help support international price points
• THANK YOU!