Titanium Usage and Demand Drivers in the Medical Device Industry

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Agenda

- Who is Synthes
- Core Competencies of Titanium
- Demand Drivers
- Effects of Uncertain Supply
- Effects of Regulatory Environment
Synthes at a Glance

- Synthes is a leading global company in the medical device industry and market leader in traumatology
- American group with meaningful Swiss history
- Sales 2010: US$ 3.7 billion
- 11,400 employees (Dec 31, 2010)
- Listed on the Swiss stock exchange since 1996 (SYST.VX)
Core Competencies of Titanium

- Corrosion Resistance
- Biocompatibility
- Mechanical and Physical Properties
- Fatigue
- MRI Compatibility
- Ability to Color Code

Dependent on specific device design and MR compatibility testing
Demand Drivers
Cranial Maxillofacial (CMF)

- Primarily Titanium
- Low “Tonnage” Opportunities
- Mainly Sheet
- Mainly CP

- Product Requirements
  - High Purity
  - Tight Gage Tolerance
  - Excellent Surface Quality
  - Small lots

- Market
  - US$ 700 – 750m
  - Growth Rate 7%-8%
Spine

- Primarily Titanium
- Larger “Tonnage” Opportunities
- Bar, Wire and Plate
- Alloy and CP

- Product Requirements
  - Precision Bar
  - Stress Free Bars
  - Excellent Surface Finish

- Market
  - US$ 6.7 – 7.2 bn
  - Growth 2%-4%
Trauma

- US – Primarily Stainless
  - But…IM Nails are Titanium
- EU – Primarily Titanium
- High “Tonnage” Opportunities
- Most Product Forms
  - Bar, Wire, Sheet, Plate

- Product Requirements
  - Precision Bar
  - Low Stress Bar

- Market
  - US$ 4.4 - 4.8 bn
  - Growth Rate 5% - 7%
Hip Fractures By The Numbers (2008)

- #1 Hospitalized Fracture
  - 18.8% of All Hospitalizations
  - 355,938 Hospitalizations
- 87% Resulted in Operations
- 87% of Patients Were Over 64 Years Old
  - Vs. 48% Overall
- 94% Due to Falls

With the Aging Population, Hospitalizations for Hip Fractures Should Continue to Grow

Source: Orthopedic Network News Vol. 22, Number 2
Change in Treatment of Hip Fractures

Results in an increased need for titanium precision round bar

Source: Orthopedic Network News Volume 22, Number 2
Growth - Units not Market Value ($)


Source: Millennium Research Group

CAGR '07-'13

7.4%
Product Changes Affect Raw Material

- Anatomic Plating on the Increase
- Changes Materials Needs
  - Reduces Sheet, Plate and Profiles
  - Increases Forgings, Large Rectangles

Plate and Screw Procedures by Type, US 2007-2013

Source: Millennium Research
Material Needs During Development Process

- Sample Material
- Small Quantities
- Size and Shape Not Critical
- Non-Standard Processes - Material and Production
Material Needs During Development Process

- Small Size Lots
- Size and Shape Critical
- Developing Standard Production Processes
- Last Chance for New Alloys
- Final “Production Equivalent” Parts for Regulatory Filing Requires Fully Qualified Raw Material
Material Needs During Development Process

- Standard Lot Size
- Production Quantities
- Size and Shape Critical
- **Standard Production Processes Locked**
- Design Locked
- **Regulatory Clearances/Approvals Sought**
Material Needs During Development Process

- Standard Lot Size
- **Demand “Bubble”**
- Size and Shape Critical
- Standard Production Processes Locked
- Design Locked
Material Needs During Development Process

– Standard Lot Size

– Replacement Quantities

– Market Growth Should Increase Quantities

– On to the Next Project!
Materials Needs During Development Phases – An Example

![Bar Chart]

- **Prototypes**
- **Proof of Concept**
- **Build For Market Evaluation**
- **Post Launch**
- **Build for Launch + Phased Launch**

**Lbs**

- 0
- 2000
- 4000
- 6000
- 8000
- 10000
- 12000
- 14000
- 16000
- 18000

**Months**

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39

**Regulatory Clearances/Approvals Sought**

**Market Evaluation**
Effects of Supply Uncertainty
Effects of Supply Uncertainty (Product Design)

- Design with Alternate Materials
  - Will not compromise timeline
- Slows Adoption of New Materials
  - Will work around new materials with design changes and process changes
- Slows Product Development Timelines
  - Everyone needs to get to market faster
Effects of Supply Uncertainty (Manufacturing)

- Manufacture with Alternate Product Forms
  - Forgings vs. Special Shapes or Flats/Strip
  - Machining From Larger Sizes
  - Adoption of Alternate Technologies
    - MIM
    - Additive Manufacturing
- Pressure Purchasing for Larger Safety Stocks
- Overestimate Needs
- Slow Down Product Timelines
Effects of Supply Uncertainty (Purchasing)

- Defensive Buying
  - Speculative Buying
  - Overbuying
  - SWAG Buying
- Loyalty to Niche Suppliers
  - Stay loyal to loyal suppliers
- Increase the Supply Base
  - Requires multiple sources to be developed
  - Requires additional resources at supplier and OEM
  - Results in low penetration for most suppliers

Distorts the Market!
Regulatory Effects
Regulatory Effects

- Device Maker Responsible for Supplier’s Quality
  - FDA does not regulate materials suppliers
  - FDA does regulate the device maker
- FDA Adoption of Consensus Specifications such as ASTM
- Additional OEM Requirements Typical
- ISO Certificate Won’t Exempt Supplier from Site Audits
- Paperwork Must Be Accurate
- Slow Adoption of New Materials
Biocompatibility for New Materials

- Regulators Require Biocompatibility Profile
- ISO 10993 Describes Tests and Decision Matrix
- Device Manufacturer is Responsible
- But, Metal Producer Can Help
- Typical Cost $75-100K
- Typical time – 6 to 12 months
  - Plus up to 2 years for implantation studies

Time to market based on Regulatory time line
Regulatory Pathways - Submission Levels

- 510k
  - Substantial Equivalence to Predicate
  - 30-90 days
- Investigational Device Exemption / Humanitarian Device Exemption
  - Design Lock During Clinical Trials
  - 2-5 years
- Pre-Market Approval
  - Increased Change Control
- US vs. EU vs. Asia
  - Differences in Requirements
  - Differences in Approved Materials
Summary

- Anatomy Distinguishes Market Size and Product Requirements
- Growth in Procedures, not Sales, Distinguishes Opportunities
- Changes in Care Drives Changes in Titanium Usage
- Titanium Suppliers Need to Support the Design Cycle to Succeed
- Titanium Suppliers Need to Support Device Makers During all Portions of the Aerospace Cycle to Succeed
- Regulatory Requirements Are Driven Down to the Supply Base
- Regulatory Requirements Slow the Adoption of New Materials
Thank You!

Technical references for this material presentation are documented at the Synthes Technical Center.