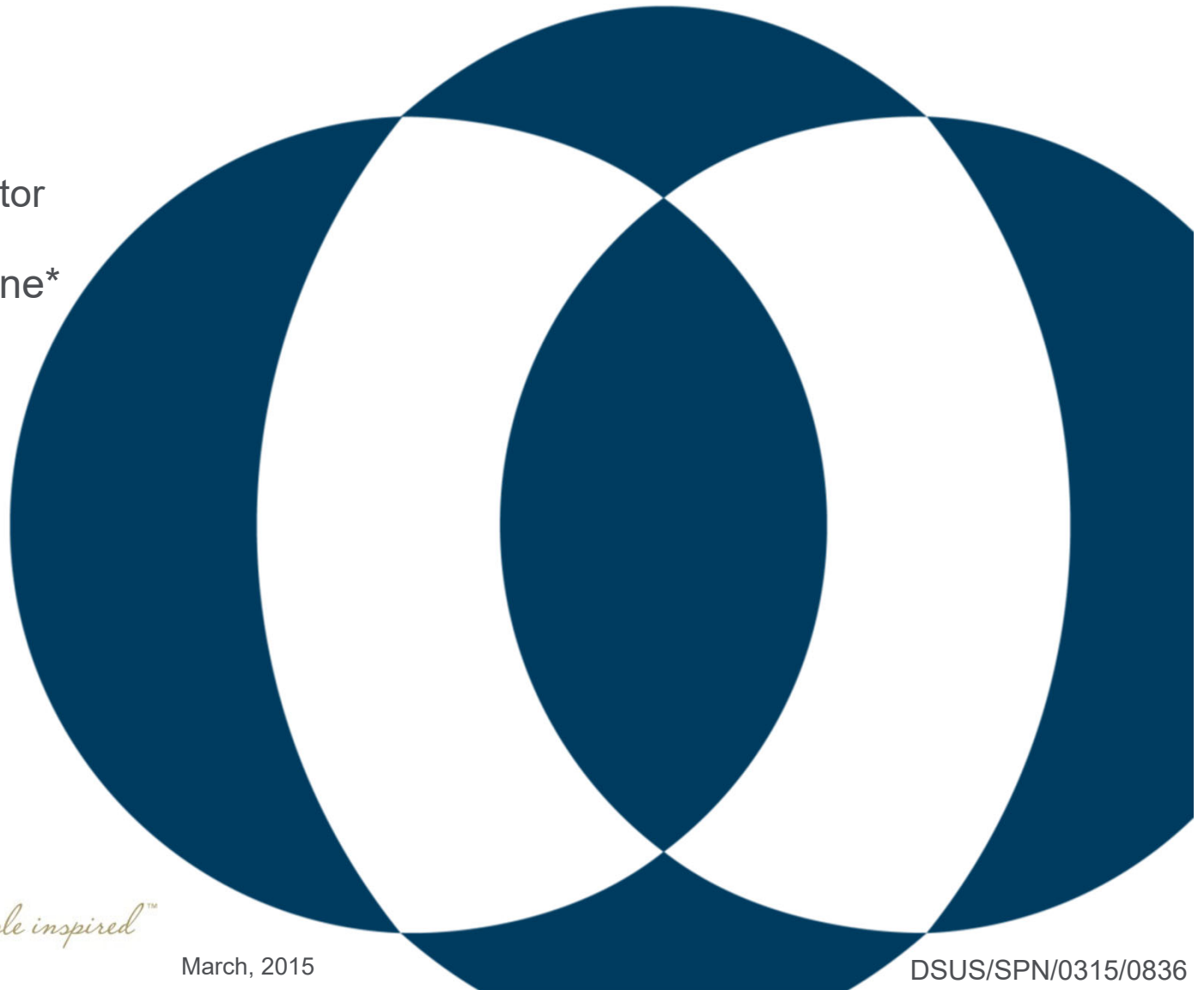
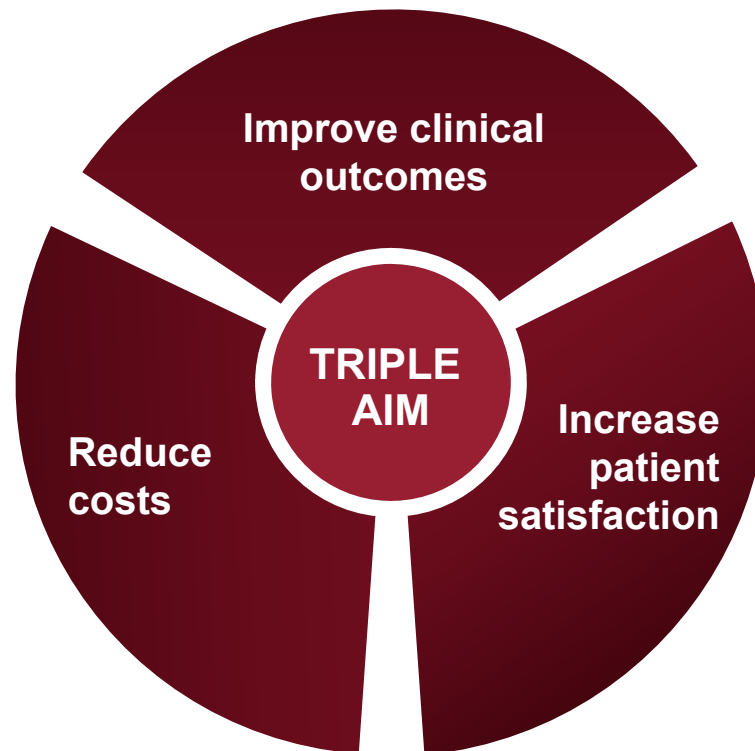


MAJOR INDUSTRY: SUCCESS METRICS FOR DEVELOPMENT IN PEDIATRIC SPINE

Andrea Light
Group Product Director
DePuy Synthes Spine*



WHAT IS SUCCESS FOR ANY PROJECT?

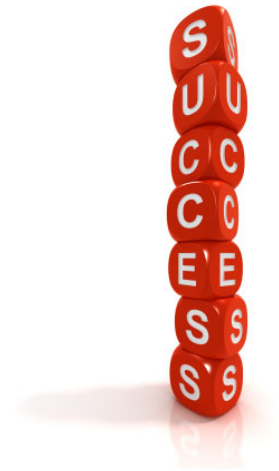


WHAT IS SUCCESS FOR ANY PROJECT?

- Key Stakeholders: “The 5 P’s”

What are the Barriers to Entry with Each of These?

- **Patient**
 - Is there a true clinical need?
 - Can we develop a solution to address the need?
- **Physician**
 - What are the needs of the physician and how can our solution address those?
- **Provider**
 - What are the requirements of hospital administration?
- **Policy Maker**
 - Regulatory requirements
- **Payer**
 - Will this product be reimbursed by major payers?



WHAT IS SUCCESS FOR ANY PROJECT?



WHAT IS SUCCESS FOR ANY PROJECT?



Revenue

Pull through Sales

Complete Product Offering

People Resources

Development Time

Manufacturing Cost

Cannibalization

Study costs

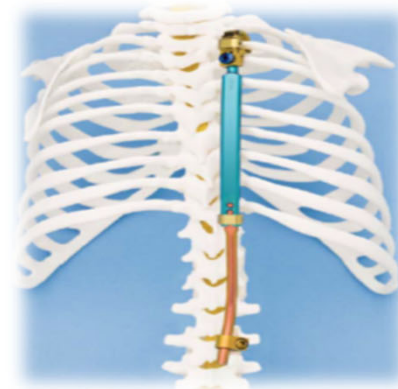


NOVEL & INNOVATIVE TECHNOLOGIES

Bulletin of the Hospital for Joint Diseases 2013;71(1):49-53 49

Fusionless Surgery for Scoliosis

Stuart H. Hershman, M.D., Justin J. Park, M.D., and Baron S. Lonner, M.D.



*



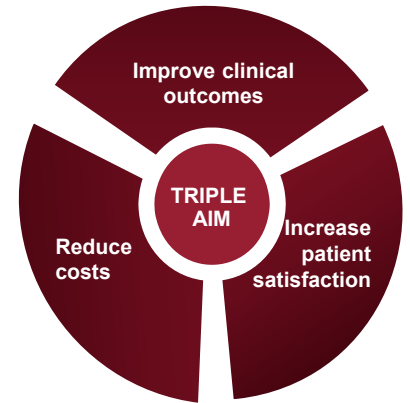
Next Generation of Growth-Sparing Techniques

Preliminary Clinical Results of a Magnetically Controlled Growing Rod in 14 Patients With Early-Onset Scoliosis

Behrooz A. Akbarnia, MD,*† Kenneth Cheung, MD,‡ Hilali Noordeen, FRCS, (Orth),§
Hazem Elsebaie, MD, FRCS,¶ Muharrem Yazici, MD,|| Zaher Dannawi, FRCS(Orth),§ and Nima Kabirian, MD*

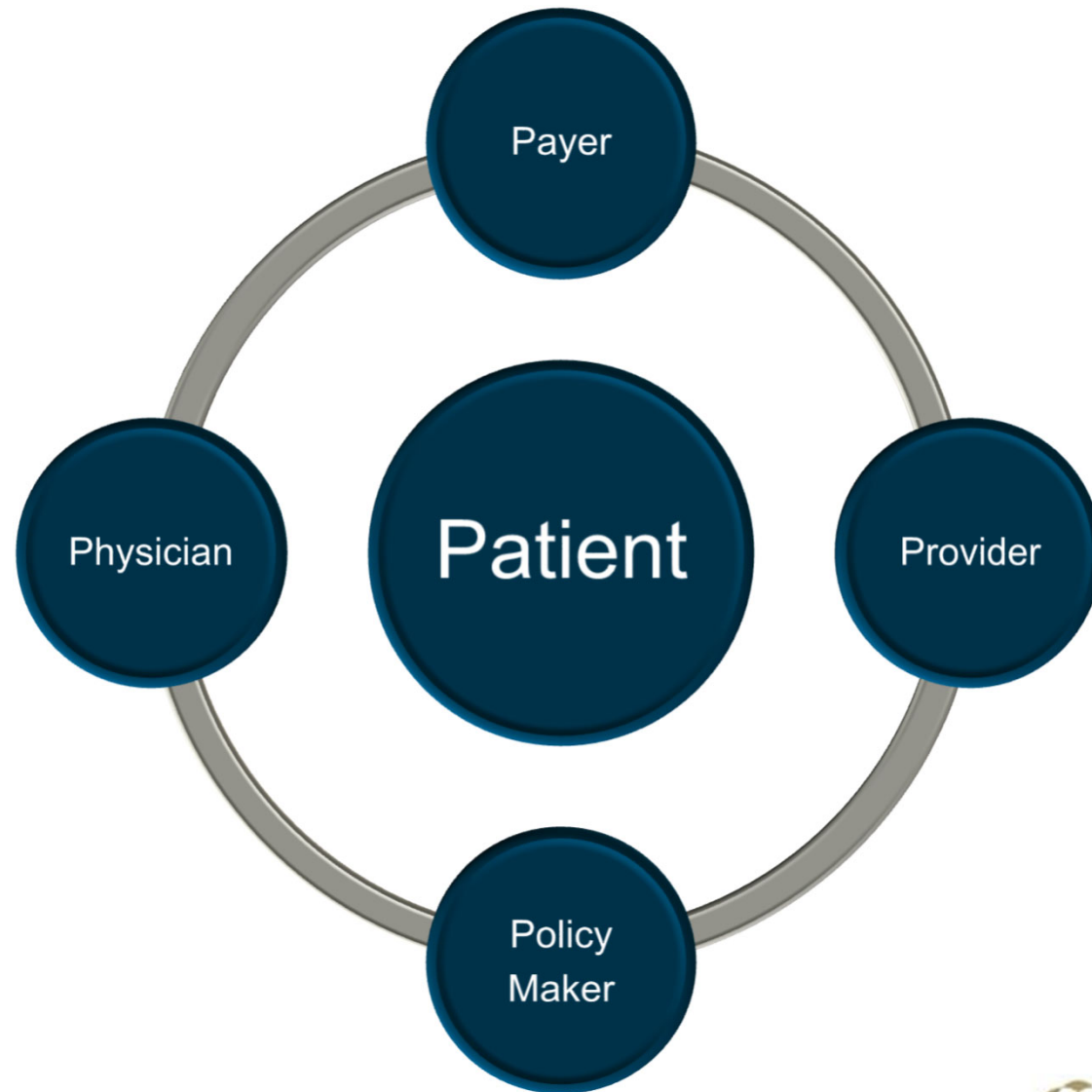


IS THIS ACHIEVABLE IN PEDIATRICS?



- **Improve Clinical Outcomes**
 - A different norm exists with sick children
- **Increase Patient Satisfaction**
 - Morbidity and complication rates are significantly higher
- **Reduce Costs**
 - Often these are some of the most expensive cases, with significant hospital stay and care required.

IS THIS ACHIEVABLE IN PEDIATRICS?



PATIENT

Clinical need is high in pediatric patient population



- Disease state can often be life threatening or at best, associated with reduced quality of life
- Relatively few implant options to choose from
- Current systems are often designed for adults
- The size of the patient population, however, is relatively small in number



Ability to address clinical need is moderate



- Significantly higher complication rates
- Spine deformity is often linked to other etiologies



PHYSICIAN & PROVIDER

Physician: Positive Surgeon Environment



- Surgeons are dedicated to advancing musculoskeletal & spinal care for children
- Supportive & collaborative society relationships

AAOS
American Academy of Orthopedic Surgeons

POSNA

Provider: Mixed Environment



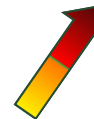
- Also dedicated to the care of pediatric patients
- Significant focus on profitability resulting in price erosion, contracting, etc. for industry

U.S. Hospitals are in the Leading
Edge of an Economic Storm

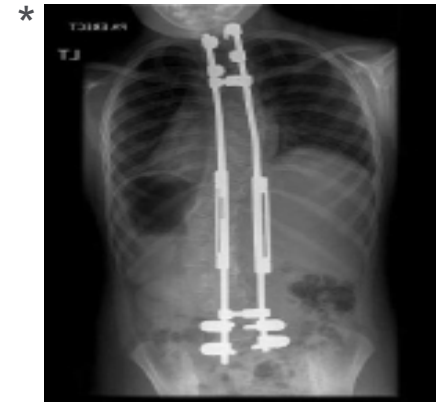
POLICY MAKER



Positive Evolving Regulatory Environment



- FDA is encouraging innovation for Pediatric pathologies
- Previously required FDA pathways
 - Humanitarian Device Exemption (HDE) – i.e. VEPTR® Vertical Expandable Prosthetic Titanium Rib
 - Class III PMA / IDE requiring long term clinical study – i.e. future growth modulation innovation
- Recent alternative FDA pathways
 - 510k with clinical data – biomechanically equivalent to predicate device
 - Accelerated PMA / IDE pathway



PAYER

Mixed Reimbursement Environment →

- Traditional technologies & procedures gain positive reimbursement
 - Traditional rods & screws
 - Fusion
- New, novel technologies receive significant scrutiny
 - Novel flexible materials
 - Growth modulation
- Payers burden of proof is high
 - Clinical superiority
 - Economic superiority
- With the pediatric population, this burden of proof may be unachievable



RETURN ON INVESTMENT IN PEDIATRICS



SO WHY DO WE DO IT?

- Inherent Ethical Obligation
- Must provide a complete portfolio to remain competitive
- Opportunity for differentiation
- The Patient



SUMMARY

- Success metrics for pediatric spine development are consistent with non-pediatric development initiatives
- Our ability to score highly in the metrics is arguably more difficult to achieve
 - Regulatory challenges
 - Complex patient pathology
 - High burden of proof
 - Challenging economic pressures
- The clinical need of the pediatric patient and desire to serve all our customers outweighs the challenges.

THANK YOU