Proof Of Concept Validation of a Self Actuated Natural Growth Driven Growing Rod Technology for EOS

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Clinical Problem: Early Onset Scoliosis

**EOS Definition**

- S shaped spinal deformity affecting children in age group 1 - 9 years.

**EOS Symptoms**

- Reduction in thoracic cavity space
- Severely compromised lung growth and function and consequently Quality of Life.
- Increased risk of early death due to lung and heart disease.
- Strong psychologically painful effect on the children as well as parents.

*Fig 1: Standing X-Ray of a 4 year old suffering from EOS*
Goal of the Technology

- Improve Quality of Life by reducing / eliminating repeat lengthening.
- Reduce complications associated with surgical lengthening.
- Eliminate or reduce tissue necrosis.
- Reduce skin infections and implant protrusion.
- Reduce rod breakage.
- Enable increased access of technology to all patients due to cost efficient pricing.
Testing

Assembly Hydraulic Testing

- Rod – Cylinder arrangement was connected to a hydraulic power pack and pressurized up to twice the working pressure
- The test was conducted to ensure that the system is leak-proof and can sustain higher loads than those intended.

Fig 3: Schematic of Assembly Used for Testing

Fig 4: Hydraulic Testing of the Assembly: Load Graphs
Simulated Hydraulic Testing
When connected to the growing rod, the PCD gives gradual distraction & holds the distraction force till the test setup (simulated spine) further expands to simulate natural growth thus making the process a quasistatic one.

Fig 5: Hydraulic Testing of the Assembly
Testing

Mechanical Testing

Successfully tested the Growing Rod system in a modified F1717 construct. Yield load observed was 5 times the load acting on an adult lumbar spine, which is substantially higher force than predicate testing of standard Pedicle Screw Rod construct.

Fig 6: Mechanical Testing of the Assembly
Technology Value Addition

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<tr>
<th>CONSIDERATIONS</th>
<th>SOLUTION</th>
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<tr>
<td>Avoid / Eliminate invasive externally controlled distraction</td>
<td>Natural – Growth Driven, Self-Actuating Quasi-static distraction of the system</td>
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<td>Continuous Active Distraction Force</td>
<td>Staged PCDs which supply increasing force as growth occurs</td>
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<td>Prevent implant protrusion and thus subsequent skin infection</td>
<td>Sub – muscular implantation</td>
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<td>Prevent metallosis and thus tissue necrosis</td>
<td>Ensure no metal-on-metal wear interface and contain any debris within the system through seals</td>
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<td>Efficient Healthcare Economics</td>
<td>Reduce / eliminate multiple invasive procedures</td>
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*Fig 7: Implantation on a Scoliotic Sawbone Model*
INDIUS Patent Portfolio (Patents Pending)

1. USPTO Application
2. PCT International Application
3. INDIA Application
Future Plan

- Proof of Concept to DFM (Design For Manufacturability)

- Any design modifications based on Laboratory Testing

- Preclinical Testing:
  - Mechanical Testing
  - Animal Studies
  - Biocompatibility Studies
THANK YOU!

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