Background

Current System
- Medtronic’s reference frame maps tools in space for image guided spinal surgery
- Current reference frame has 1 degree of freedom

Medical Significance
- 266 million individuals worldwide have degenerative disc disease
- Surgery needed for extreme cases of back pain

Problem
- Frame gets in the way of the surgeon
- Increases cost of surgery due to 25 minute delay ($62 per minute)

Needs Statement
A way to utilize a reference frame during image-guided spinal surgery such that equipment does not hinder the execution of the procedure, while offering improvements in efficiency for the benefit of healthcare providers.

Proposed Solution

Design 1: Rail
- 4 degrees of freedom
- Telescoping joint
- Vertical translation - 1 inch
- Rotation about vertical axis - 360°
- 12 discrete positions possible
- Held in place with screw

Design 2: Ball and Socket
- 4 degrees of freedom
- Telescoping joint
- See above
- Swivel fixture
- Locking ball and socket joint
- Cone of angulation covers full hemisphere
- Starburst adapter
- See above

Mechanical Testing
- Torque Testing
  - Simulate a potential bump
- Cyclic Loading
  - Ensures no fouling between components
  - 120 cycles
  - Indicative of the normal product lifespan

FEA Bump Testing
- Simulate 12 N load on reference frames
  - Rail Mechanism
    - Max deflection ~ 0.35 mm
  - Swivel Fixture
    - Max deflection ~ 0.40 mm

Functionality Verification / Testing

Regulatory Pathway
- Updated reference frame considered a Class II Device
- Requires a 510(k) Pathway for approval
- Must be approved by the Center for Devices and Radiological Health (CDRH)

Patent Information
- Medtronic is submitting a patent for this design
- Medtronic already owns patents surrounding this system

Reimbursement
- Will be covered by Medicare Part A and Medicaid
- Deductibles will vary

Manufacturing Cost

<table>
<thead>
<tr>
<th>Part</th>
<th>Supplier</th>
<th>Manufacturing Process</th>
<th>Cost Per Component (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ball and Socket</td>
<td>Protolabs</td>
<td>Machined</td>
<td>$898</td>
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<tr>
<td>Telescope</td>
<td>Protolabs</td>
<td>Machined</td>
<td>$224</td>
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<tr>
<td>Rail Component</td>
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<tr>
<td>Alligator Clamp</td>
<td>Medtronic</td>
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<td>$230</td>
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<td>Air Frame</td>
<td>Medtronic</td>
<td>Machined</td>
<td>$634</td>
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<tr>
<td>Starburst Adapter</td>
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</tbody>
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References
2. Medtronic Internal

Acknowledgements
Thank you to entire BME Design class and TA’s for providing thoughtful feedback on all of our designs and presentations. Also, thank you to our designers Dani, Joel, and Emily for their graphics and advice. A huge thanks goes to Dr. Zapanta and Erica Comber for believing in our project and pushing us to put out our best work. Lastly, thank you to Jerald Redmond, who advised our project and dedicated tons of his time to providing us with resources and tools to set up our team for success.