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INTRODUCTION

Background

- Cervical spondylosis = degeneration of the cervical spine, often caused by wear and tear of spine with age
 - 85% of those above 60 show evidence of such condition
- Severe cases require surgical intervention that consists of implantation of anterior cervical plates

Problem

- Bulkiness of the plate: high pressure around surrounding tissues can cause irritations
- Common complications include plate migration and swelling of the pharynx wall



Medtronic's predicate plate

Need Statement

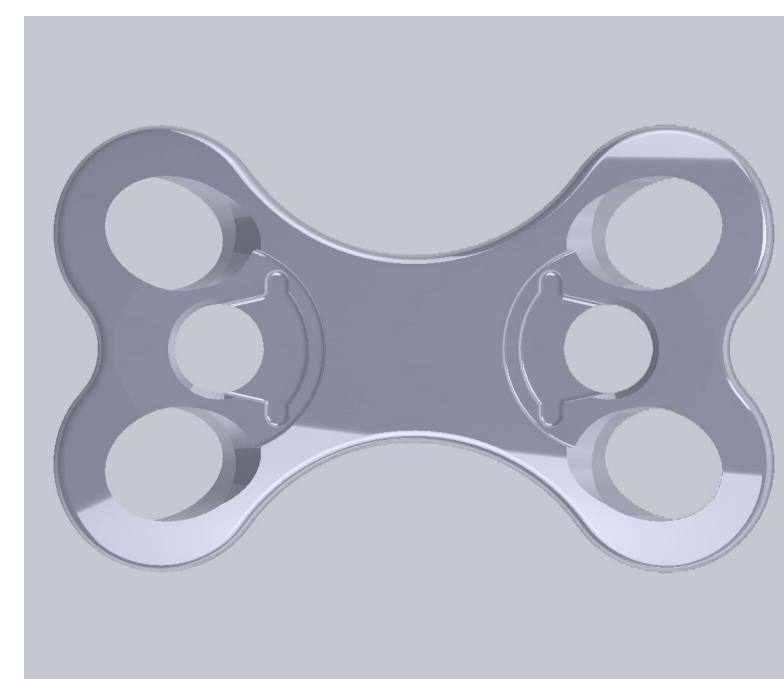
A modernized **low profile** anterior cervical plate that **meets the FDA-specified and in vivo load-bearing mechanical needs** of the patient requiring anterior cervical surgery while being cost-effective and efficient to manufacture.

PROPOSED SOLUTION

- Low-profile anterior cervical plate that maintains mechanical strength and durability of the predicate plate
- Maintain features from previous plates such as variable angle screw holes and viewing window for the spine

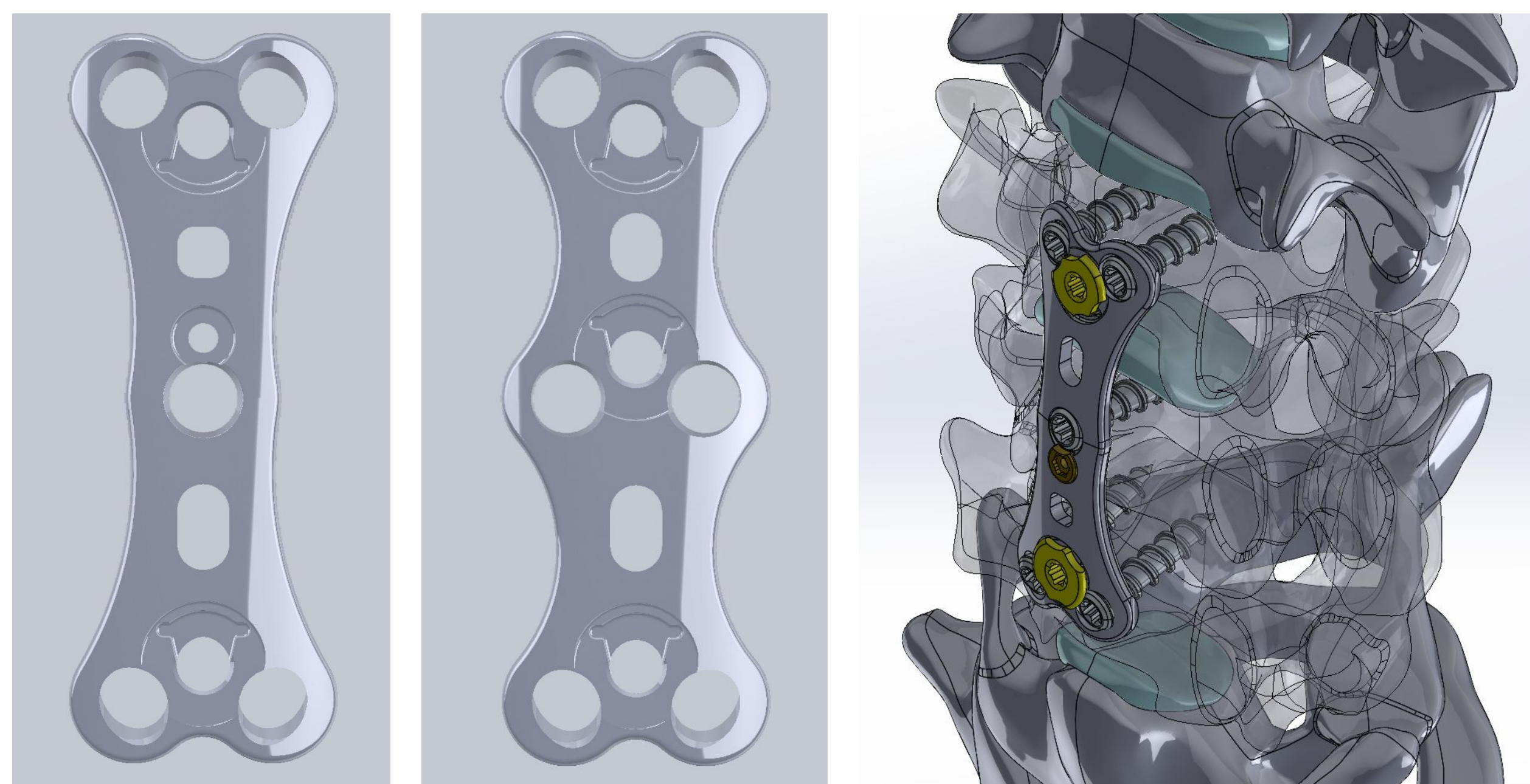
1 Level

- Spans one cervical disc
- Prototype reduces the area it takes up while still maintaining sightlines



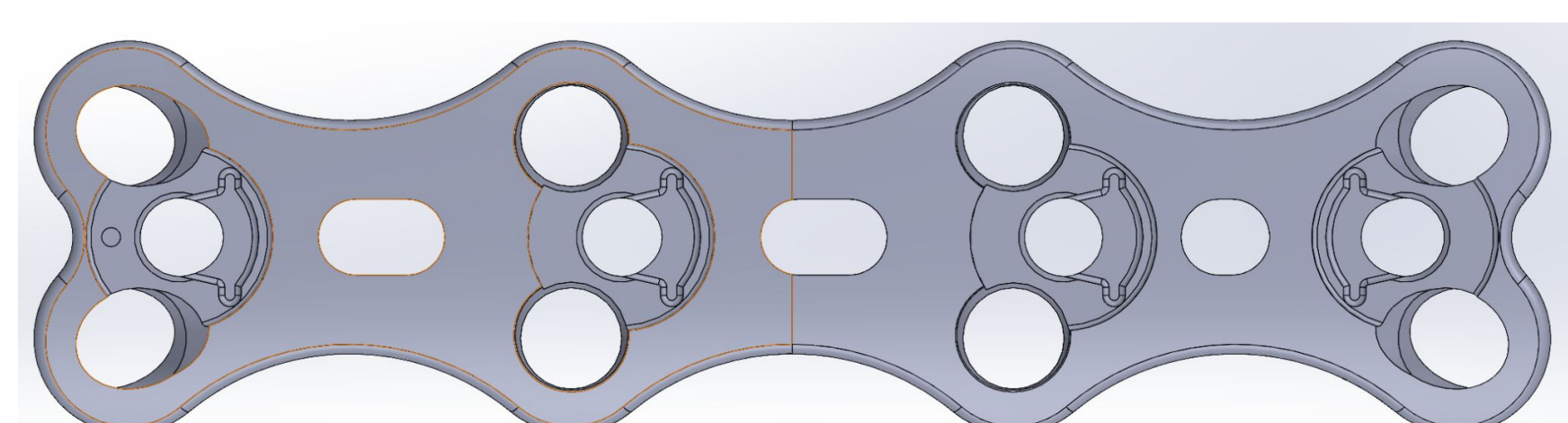
2 Level

- Designed two 2 Level Plates to cater to patients with more degeneration where more fixation points are required



3 Level

- CAD model of larger plate created for patients with more severe degeneration



FEA TESTING

- Modeled the ASTM-F1717 Setup in ANSYS Static Structural
- **Testing methods:** Compression, Tension, and Torsion

Table 1: Percentage comparison between prototype to predicate plate

	Equivalent Stress (MPa)	Principal Stress (MPa)	Directional Displacement (mm)
Tension			
Final Prototype	-1.439%	-0.388%	13.878%
Compression			
Final Prototype	-1.693%	-28.607%	25.594%
Torsion			
Final Prototype	3.323%	3.136%	102.554%

Topology Optimization

- **Goal:** Optimize Material layout of the plate
- **Constraints:** Minimize compliance, Minimize mass by 90%, Global Von-Mises Stress, Displacement Constraint
- **Result:** Provided reference to minimizing mass around the top and bottom screw holes

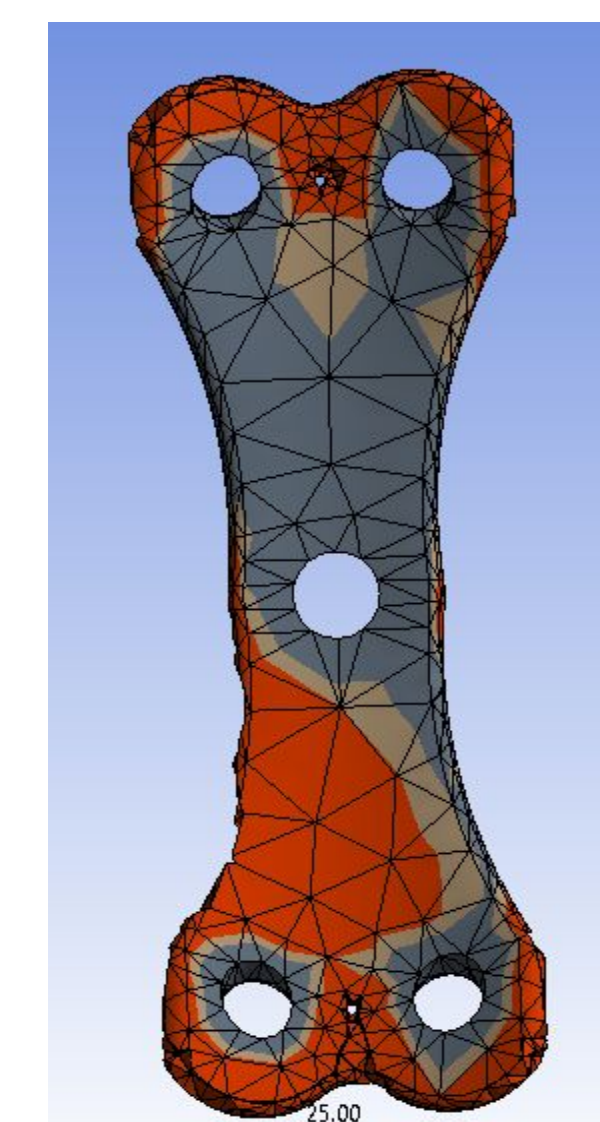
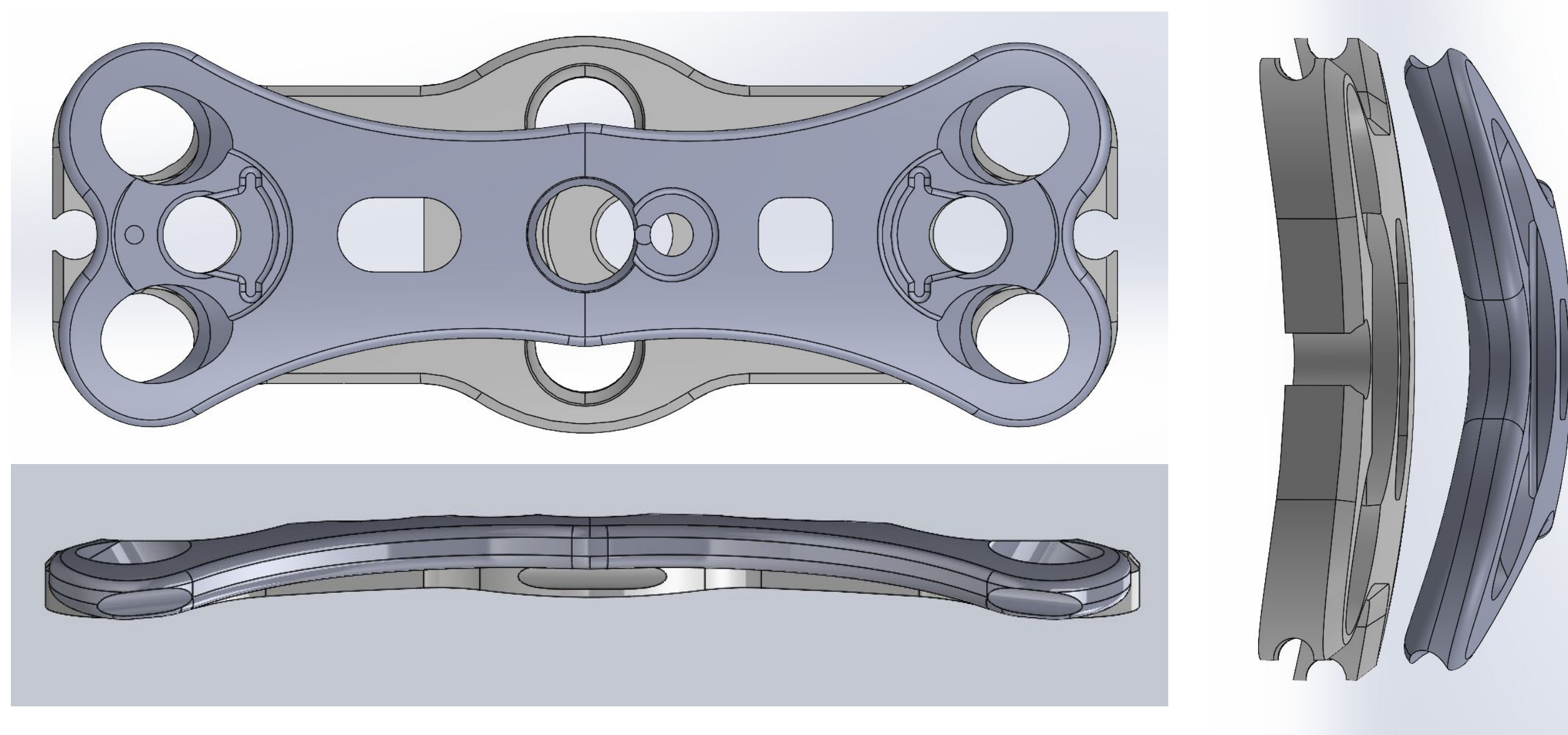


Plate Design



Predicate plate (bottom, left) compared to our design (top, right)

- Mass reduction of ~20%
- Thickness reduced to 1.5mm at the ends and 1.7mm in the middle

Screw Angle Variability

- **Sagittal Plane Degrees of Freedom:** -4°-33° from Vertical

Locking Mechanism

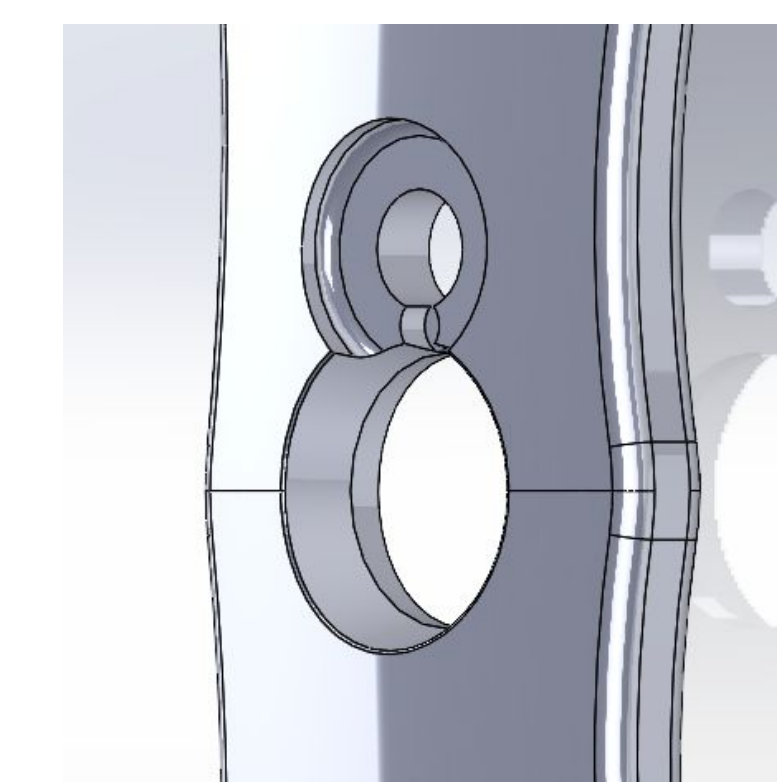
Role: Secure the screws in place

Double fixation point

- Utilized predicate plate's locking mechanism

Single fixation point

- Compatible with Medtronic's current surgical instrument



MANUFACTURING COST, REIMBURSEMENT

Table 2: Manufacturing quotes from different sources

	Avg current cost	Protolabs		Xometry		
		3 units	20+ units	3 units	50 units	1000 units
One-level	48.55	236.19	166.14	1233.12	179.29	32.1
Two-level	68.34	427.4	343.98	1,417.43	208.88	38.46
Alt. two-level		426.71	343.98	1620.13	253.35	51.03

*all given costs are price per unit based on the order quantity
Avg. price difference (between current cost and Xometry mass quote): 40.48% decrease

ICD-10-CM Diagnosis code: **M47.012** (Spondylosis, anterior spinal compression, cervical region)

Reimbursement codes: **CPT 22853 and 22845:** Under Spinal Instrumentation Procedures on the Spine (Vertebral Column)

MARKET ANALYSIS

The ACDF market is stimulated by the aging population and positive clinical outcomes

- ACDF is performed approximately 132,000/year + estimated penetration rate = 30% for Medtronic products
 - Therefore, market size of 39,600 plates/year, with a mean price for an anterior cervical plate of \$1200 → **Potential Market Value: \$43,560,000**

PATENTS

Due to the complexity around the patent space for cervical plates, legal evaluation by Medtronic would be required to determine if patent protection for the plate is feasible.

CONCLUSIONS

- **Reduced plate profile and mass** while maintaining FDA specified and in vivo load-bearing mechanical needs of the patient requiring anterior cervical surgery, reducing the likelihood of post surgery complications
- **Optimized the material layout** of the plate by minimizing mass while maintaining the structural integrity
- Incorporated essential features of anterior cervical plates compatible with existing Medtronic surgical instruments
- Developed **1 and 2 level plates** for varying degrees of cervical spondylosis
- Final prototype compared to Medtronic's predicate plate **decreased the mass by 20%**

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