INDUSTRIAL SOLUTIONS LABORATORY

Company Information

Company Name	Structure Medical LLC	**Date Submitted**	11/4/2025
Project Title	Additive Manufacturing Artifact – Use for CMM Programming Verification (STRUCTURE_CMM)	**Planned Starting Semester**	*Spring 2026*

Senior Design Project Description

Personnel

Typical teams will have 4-6 students, with engineering disciplines assigned based on the anticipated Scope of the Project.

Please provide your estimate of staffing in the below table. The Senior Design Committee will adjust as appropriate based on scope and discipline skills.

Discipline	Number	Discipline	Number
Mechanical	5-6	Electrical	
Computer		Systems	

Company and Project Overview:

Structure Medical, LLC is a contract manufacturer that utilizes precision manufacturing equipment to produce medical devices for the orthopedic industry. These devices range from complex assemblies to standalone components designed to improve quality of life. The tolerances required in this industry are becoming increasingly stringent as innovative designs are developed to reduce healthcare costs and enhance patient outcomes.

Proposed Project:
Determine whether a 3D-printed implant, acting as a replica of the titanium implant to be manufactured, can achieve sufficient accuracy to validate the CMM program. Structure Medical uses Hexagon Metrology's Global 575 and creates programs using PC-DMIS.

Project Requirements:

The manufacturing model at Structure Medical closely follows the Toyota Manufacturing Principle of *continuous flow*. Small batches are produced with the goal of achieving near one-piece flow,

which requires medical device components to be manufactured within a cellular CNC machining layout, with deburring and CMM measuring integrated into the continuous flow.
The continuous flow process includes up to six different operations, which may include: SideAOp1, SideAOp2, SideB, Deburr, Clean, and CMM. If a challenge arises at any point within the value stream, the continuous flow stops immediately, and problem-solving begins. The speed of this process is critical due to the costs associated with cell downtime. Each robotic cell, equipped with five (5) CNC 5-axis machines, represents an annual opportunity value of over $3.0 million.

Over the past three years, we have identified that a significant contributor to downtime is related to the CMM process. The primary reasons include:

1. A new program must be tested and validated for the first time after the initial part has been produced. This means that a robotic cell has been set up, and the first part is completed, but it must remain idle until the CMM program is tested using the Hexagon Metrology Global 575.
2. A Gage R&R study may be required to verify the stability of both the program and the loading process.
3. Mechanical measurements may not always align with the results obtained from the CMM.
4. The most challenging tolerances include:
   a. True Position within .002” relative to three datums—particularly when the three datums are more than .500” apart or are not square and perpendicular to each other.
   b. Profile of a Surface within .003” relative to three datums—especially when the three datums are more than .300” apart or lack squareness and perpendicularity.

This project will research the current state of the art in additive manufacturing to determine if it would be possible to print (with sufficient accuracy) an additive manufacturing part prior to the production run and use that print to validate the CMM program. If it can, then the CMM program could be “pre-validated” so it’s ready when the first titanium piece is made. This would eliminate the time where productive production hours are non-productive while validating the CMM with the titanium first piece. The team would do a cost benefit analysis on this approach as well.

It is envisioned that this approach would be tested in the second semester on several parts and machines to validate. Additive parts would be purchased from subcontractors that possess the equipment being trialed. The final report would include an investment justification along with conclusions from the project.

Expected Deliverables/Results:

- Determine whether there is a 3D printer on the market capable of printing a replicated artifact.
- The artifact must be able to pass measurements on a Global 575 CMM while utilizing only a fraction of the printer’s tolerance.
- Surface finish is critical, as many medical device features require a 0.3 mm tip.

Inconsistent surface finish could negatively affect measurement accuracy.

- Structure Medical has an off-line Global 575 located in the quality lab. The addition of a precision artifact will allow CMM programmers to perform Gage R&R studies and make program edits prior to the robotic cell producing the first titanium part. This will ultimately help prevent costly downtime.
- Investment justification for selected printer.

Disposition of Deliverables at the End of the Project:

Students are graded based on their display and presentation of their team's work product. It is mandatory that they exhibit at the Expo, so if the work product was tested at the supporter's location, it must be returned to campus for the Expo. After the expo, the team and supporter should arrange the handover of the work product to the industry supporter. This handover must be concluded within 7 days of the Expo.

List here any specific skills, requirements, specific courses, knowledge needed or suggested (If none please state none):

- ASME Y14.5 GD&T knowledge
- Solid Modeling
- Metrology – mechanical inspection and verification
- 3D printing
- PCDMIS or other CMM Programming software
- Statistics – Gage R&R and Capabilities studies using Minitab software (standard deviation).
- Ability to travel to Structure Medical's Mooresville NC location as required. Mileage will be reimbursed IAW ISL procedures.