

SBS HEAT SEALING PROCESS DESIGN

Project Description

Dexcom develops Continuous Glucose Monitoring (CGM) systems, and the next iteration of their device requires a new packaging system. Our team has designed and produced a **Sterile Barrier System (SBS)**, sealing fixture, and heat sealing recipe that is used to seal a Tyvek lid to the top of the SBS, forming a package.

Requirements and Constraints

Sterile Barrier System (SBS)

- SBS shall be safe for users to handle and open when sealed.

Heat Sealing Recipe

- Temperature, pressure, and time variables shall be optimized for the heat sealing of the SBS with the Tyvek lid.

Heat Sealing Fixture

- Sealing fixture shall maximize the number of SBS's sealed with each pass through the heat sealer.

Adhesive Peel Test Fixture

- Peel test fixture shall be able to securely hold the SBS while conducting the adhesive peel test per ASTM F88/88M.

Sterile Barrier System (SBS)



Team



Team members, from left to right: David Bell, Sarah Gomez, Iliana Douraghi, Daniel Brandes

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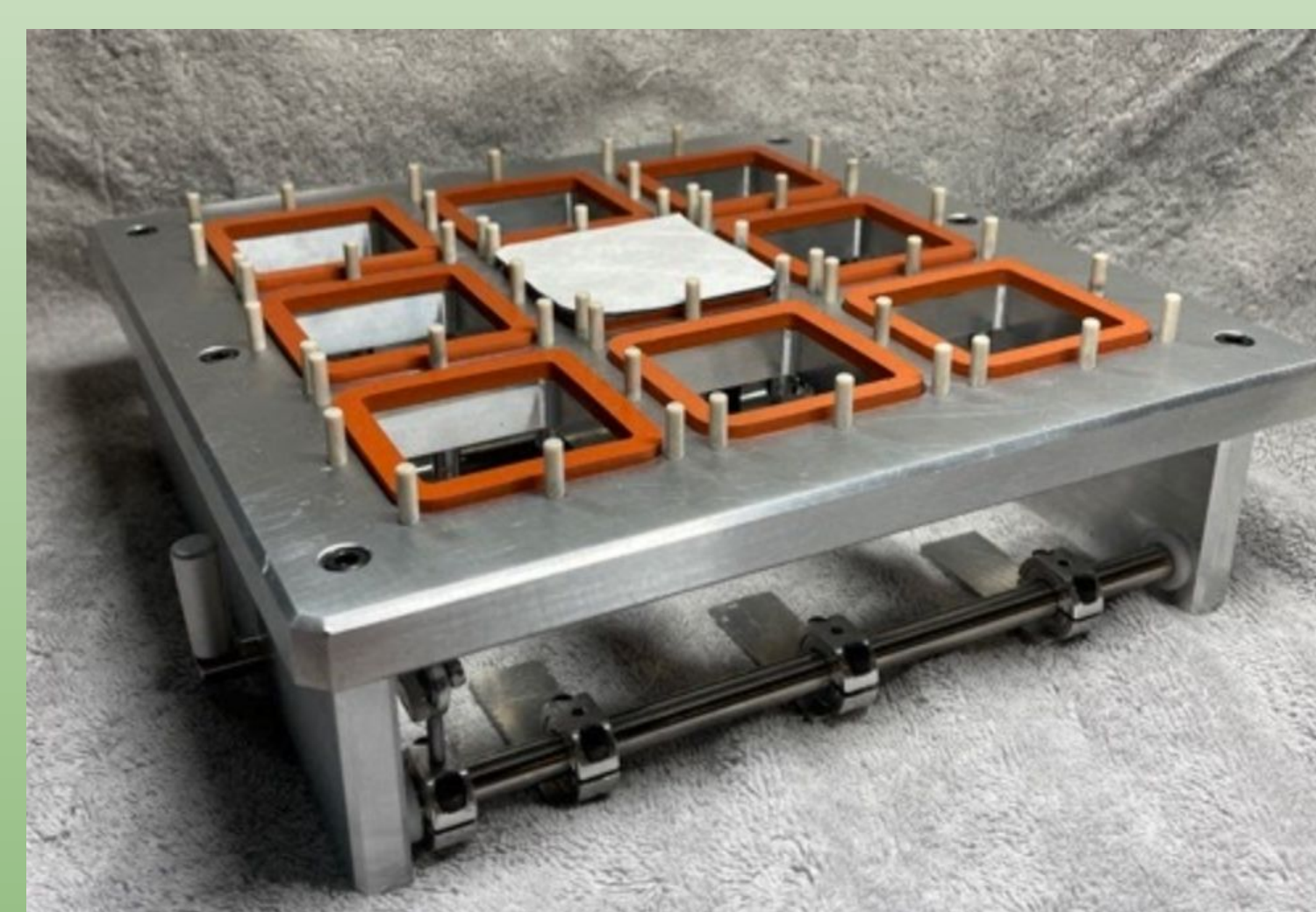
Manufacturing

The SBS design was 3D printed in PETG due to the high costs associated with the traditional SBS thermoforming process.

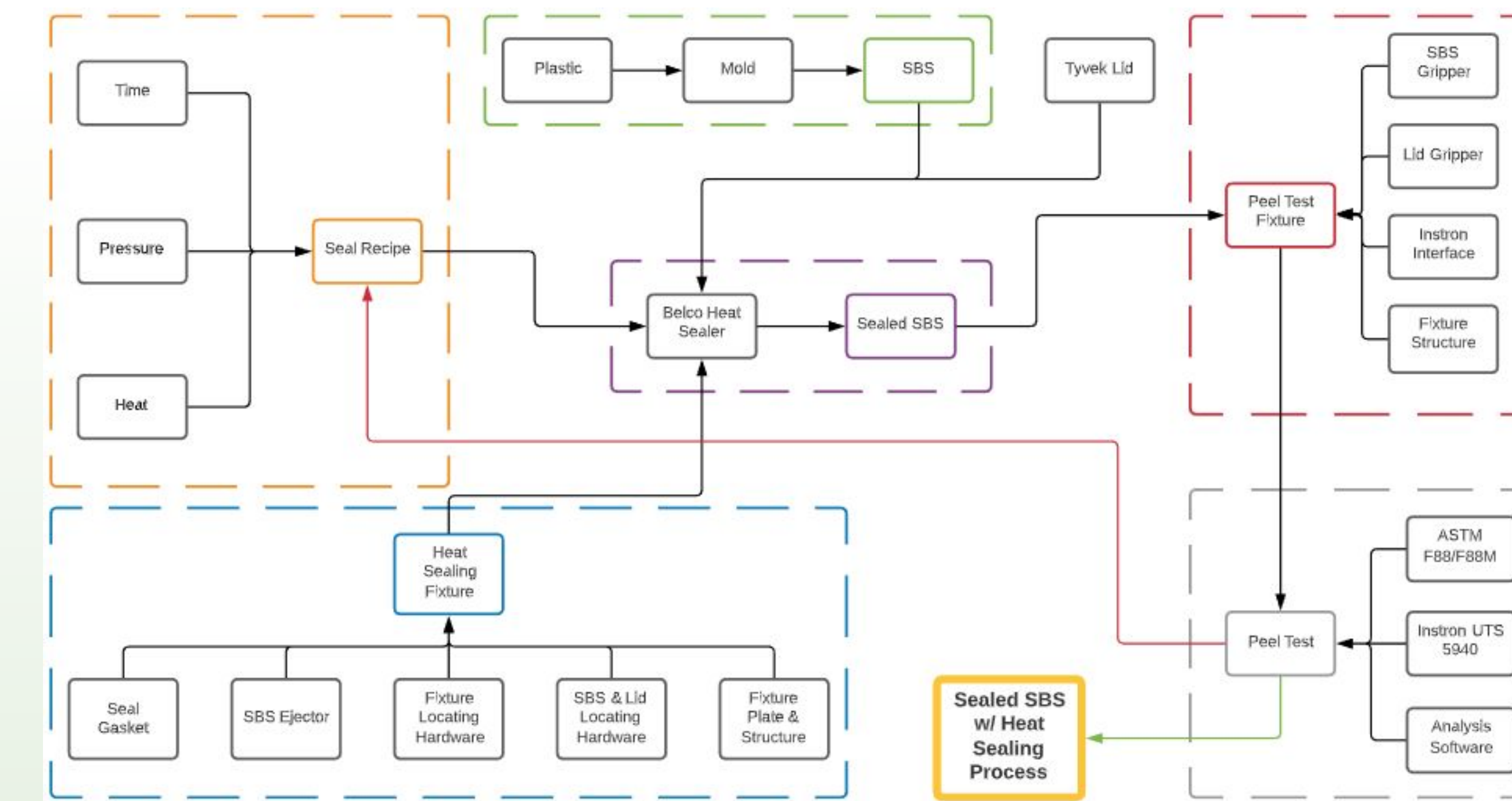
For the fixtures, most of the manufacturing was finished by using SDSU Machine Shop tools and equipment. The parts were first waterjetted and cut using the vertical band saw, then features were machined using the Haas CNC and ProtoTRAK mill.



Heat Sealing Fixture



System Level Diagram



Testing

The heat sealing recipe was validated and optimized through multiple trials at Dexcom. For each trial, the SBS was first sealed with a Tyvek lid based on the set recipe parameters with a Belco heat sealer. Then, the seal strength of the sealed SBS was measured by doing a peel test using an Instron 5900 per ASTM F88/F88M, Standard Test Method for Seal Strength of Flexible Barrier Materials.



Adhesive Peel Test Fixture

