Objective

- Develop a tool or system to optimize the loading of CorInnova’s CAD into a tube used for device deployment.
- The system must decrease loading time, maintain the CAD’s outer carbothane layer positioning without damaging it, and allow the CAD to open fully during deployment.

Background

- CorInnova’s CAD is a biventricular, non-blood contacting heart assist device intended to increase cardiac output in the acutely failing heart.
- The loading method has a high impact on successful deployment. Failed deployment can result in bodily harm or unsuccessful placement.

Methods

- CAD is compressed into a deployment tube used for device deployment.
- The system consists of three primary components: the loading system, loading funnel, and deployment tube.
- The loading tool has a high impact on successful deployment.
- Our loading tool system is able to successfully navigate the CAD into the deployment tube while significantly reducing the loading time.
- Loading forces for each prototype were lower without the use of saline. The lowest forces, or easiest loading, was with a handle of 1/2” diameter and no saline.

Results

- Loading tool:
  - Most significant part of the loading system.
  - Used to navigate the CAD through a funnel into the deployment tube.
  - Polycarbonate (PC) handle allows insertion into the CAD and force application to guide CAD.
  - Nitinol frame mimics CAD shape, holding the carbothane layer in place.
  - Frame is covered with a polypropylene (PP) cone to prevent carbothane pinching.

- Loading funnel:
  - Conical shape supports the outer wall of the CAD slowly compressing and guiding it into the deployment tube.
  - Temporarily connected to the deployment tube with a rubber adapter.

- Deployment tube:
  - Where the device is loaded into and be deployed from.
  - Retained CorInnova’s 1” PTFE tube design for its low friction properties.

Conclusions

- Our loading tool is able to successfully navigate the CAD into the deployment tube while significantly reducing the loading time.
- Loading forces for each loading tool prototype were lower without the use of saline. The lowest forces, or easiest loading, was with a handle of 1/2” diameter and no saline.
- The loading path was divided into 3 zones and the maximum force measured for each zone.
- Loading forces decreased with decreasing tool handle diameter and were lower without the use of saline.
- The lowest forces, or easiest loading, was with a handle of 1/2” diameter and no saline.

Table 1: Carbothane Layer Leak Testing

<table>
<thead>
<tr>
<th>d</th>
<th>Saline</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>1/2”, No Saline</td>
<td>PASS</td>
<td></td>
</tr>
<tr>
<td>3/4”, No Saline</td>
<td>FAIL</td>
<td></td>
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</tbody>
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Figure 1: Device deployment
- The device is deployed through a small incision in the apex of the pericardium to self-expand around the ventricles within the pericardial sac.
- The loading method has a high impact on successful deployment. Failed deployment can result in bodily harm or unsuccessful placement.

Figure 2: CAD compressed into deployment tube
- The device is fabricated from delicate thin-film polyurethane and super elastic shape memory Nitinol wire.
- The CAD’s outer carbothane layer was checked for leaks.
- The plastic was filled with air, placed in a water bath, and inspected for the formation of bubbles. Observed bubbles indicate leaking and a failed test.
- Only the tool with the 1/2” handle failed.

Figure 3: Loading System Components
- The loading system consists of three primary components: the loading tool, loading funnel, and deployment tube.

Figure 4: Loading tool
- Handle: 3D printed PC rod with rounded end. Twelve holes are placed near the rounded tip for the placement of Nitinol wire ends.
- Nitinol wire: Twelve compressible Nitinol wires bent in the shape of the Nitinol frame of the CAD. Free wire ends are placed into the respective holes on the handle.
- Suture Mesh: Reinforces links between wires to provide stability.
- Crimps: Placed on lower bend of wires to link them together.
- PP cone: Surround wires to protect containment layer of CAD from damage.

Figure 5: Funnel and deployment tube components
- Connector clamp secures funnel and deployment tube together for device loading.
- Once loading is complete, components are disconnected and the CAD is ready for surgical implantation.

Figure 6: Loading Forces for each prototype
- The loading path was divided into 3 zones and the maximum force measured for each zone.
- Loading forces decreased with decreasing tool handle diameter and were lower without the use of saline.
- The lowest forces, or easiest loading, was with a handle of 1/2” diameter and no saline.

Table 1: Carbothane Layer Leak Testing
- Following testing of loading forces for each loading tool prototype, the CAD’s outer carbothane layer was checked for leaks.
- The plastic was filled with air, placed in a water bath, and inspected for the formation of bubbles. Observed bubbles indicate leaking and a failed test.
- Only the tool with the 1/2” handle failed.

Conclusions
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