Thorne Liquid Whole Blood Project Handoff Documentation

Email: sarah.glomski@duke.edu

Phone: 480-340-3068

File Locations

- C:\Symbient Vault\11044\CAD\Phase 2\Design Concepts\Concept 6 Capillary
- "THT C6 Big Part Plastic" is the most recent CAD
- Thorne_Drawbridge > Liquid Whole Blood > Capillary Tube > Capillary v3

CAD Background/Naming

- "Cartridge tab hack", "Microtainer capillary adapter", and "Capillary shell" used to be made separately and assembled with glue—now they are combined into one body in "THT C6 Big Part" and 3D printed as one part
- "V2" and "V3" parts are designs that were developed in parallel for the glass capillary (ignore these)
- "- Plastic" parts are for the most recent design using a larger plastic capillary tube (can be used for .07" glass capillary tubes as well)

Current Status

- "THT C6 Big Part Plastic" is the most recent design; it uses a .07" plastic capillary tube (heparin coated) taken from an OTS part
 - Has been used in 3 successful tests so far
 - Moving away from OTS vial, will be ordering capillary tubes directly from Fisher Sci <u>https://www.fishersci.com/shop/products/plastic-blood-gas-capillary-tubes-</u> <u>additives/22757134?keyword=true</u> (will not arrive until December)
- Moving away from the .04" glass capillary tubes due to failed tests and low volumes
- Continuing with one large 3D printed part with a flange for gluing in place
 - Flange thickness was increased to prevent breakage
- Continuing with tapered PP tip (taken from OneDraw insert)
 - Must be drilled out for large plastic capillary tubes
- Continuing with rectangular hole that vents to the side of shell
- Continuing with microtainer adaptor o-ring
 - O-ring groove was increased in diameter to create a tighter seal
- Continuing with pressure gauge screening, use PSA to seal cup
 - May increase from –4psi to –10psi based on customer feedback
- Potentially decreasing the length of microtainer adapter to allow for more blood volume in vial
 - Increases dead volume as a tradeoff, should be done gradually

Past Attempts

• "Cartridge tab hack" taken from OneDraw insert

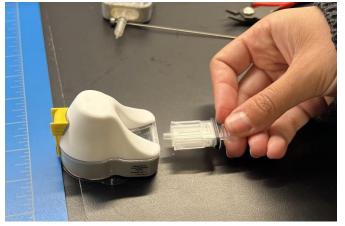
- Overmold was successful in providing a good seal, but assembly took much longer and introduced potential seal failures from gluing together parts
- "Cartridge tab hack" printed with an o-ring groove
 - O-ring provided poor sealing and required lots of lubricant
- Venting by the PP tapered part resulted in blood collection inside the shell
- Concentric venting was less efficient at reducing dead volume than the rectangular cutout
- Shorter capillary tubes resulted in poor droplet formation/collection in vial, and sometimes resulted in wicking back up the outside of the capillary tube
- Flexing arm muscles increases circulation but can create a diaphragm that sucks blood back into capillary tube and cup

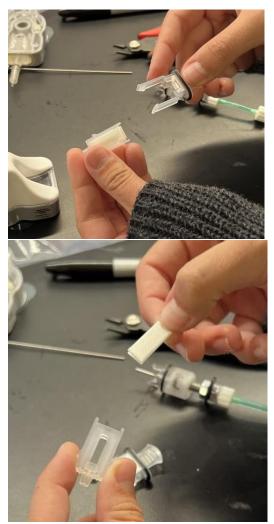
Next Steps

- Ordering .07" glass capillary tubes to determine whether the increase in size or change in material is responsible for larger volumes
 - When using glass capillary tubes, must score with a file and snap to be ~9cm in length
 - Must also be careful not to break capillary tubes during gluing
- "Cartridge tab hack" printed with an o-ring groove and a flange
 - Provides backup options for sealing, but likely not worth it if the flange continues to work with glue
- Testing on more subjects to see if high volumes are consistent with this design
 - Averaging ~380 uL on the first 3 test draws
- Printing big part + PP tip as one part in a PP-like material (outsourced)

Assembly Procedure

1. Open a OneDraw (make sure it isn't expired), remove the PP insert and isolate the tapered tip.





Cut down the insert to only be the tapered piece on top. Sand down with a dremel to be ~2.75mm tall and wide enough to fit snug at the top of the shell.





Then drill out the hole with the ~2.1mm drill bit in the 11044 bin. This widens the part and makes a tighter seal in the OneDraw. Ideally, there will be a ~2mm gap between the bottom of the female gray part and the flat face of the PP tapered part. You can feel the snug fit when inserting the part.



2. Slide the plastic capillary tube into the PP taper (want a very snug fit) and into the 3D printed shell. Use Dymax glue to attach the taper onto the shell (once between the two faces, then in the cracks on either side). The Dymax takes about 20 seconds to cure and turns orange. Slide capillary tube so it sticks out by ~1mm above the taper, then apply a ring of Dymax around the tip to create a slim donut shape—do not get glue on the sides of the tapered part or it will not fit into the OneDraw hole. If this happens, use fine sandpaper to get the glue off the sides of the taper.



- 3. Test the fit inside the OneDraw (note the asymmetric design--the vent hole should be facing towards the clear window). When pushed in, the flange should just barely reach the outside surface of the OneDraw. Apply regular UV curing glue around the outside of the shell as well as the inside of the flange—may need to reapply to fill any visible cracks.
- Add small o-ring onto groove and apply ample Vaseline. Apply a 1.5cm x 1.5cm square of PSA onto the inside of the cup and reapply the plastic. Slide the test vial onto the microtainer adapter and test if pressure holds steady at –4psi. Make sure to remove the PSA before recording masses.



5. Record the mass of the vial. Reapply Vaseline to the adapter o-ring and then slide the vial on and record the mass of the whole device (including plastic cover and vial, but not including the PSA). When calculating the volume collected, assume a density of 1 g/mL and calculate both the total volume collected by the device (which includes blood left inside the capillary and the cup) and the volume collected just by the vial.

