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	Investigator: Jan B. Markowski	Location:	Revision: 00

1.0 PURPOSE:

The creation of arterial models for ultrasound purposes requires the use of materials that will mimic the ultrasound properties of real vascular structures.

2.0 SCOPE:

2.1 This document will only outline how to create the silicon wall for a particular arterial model.

2.2 This SOP will not outline the use of the silicon wall, how to remove the metal core from the silicon wall, or any other subsequent procedures or related tasks.

2.3 Procedure is to be performed in a containment level 1 (CL1) laboratory.

3.0 RESPONSIBILITIES:

3.1 Someone trained by a qualified individual should perform this procedure.

4.0 DEFINITIONS:

Casting – the process of making a solid object by pouring a liquid plastic into a mould and allowing it to solidify.

Luer-lok - the threaded tip on a syringe that can be twisted into certain ports.

Mould – a symmetrical two-piece plastic encasement of a specific shape.

Plastic centering cup – white cups that hold the metal core securely within the plastic mould.

Trace – etched groove on the plastic mould.

5.0 REFERENCES:

[Reference to be provided by Hristo. (Tamie's paper?)]

6.0 MATERIALS AND EQUIPMENT:

6.1 MATERIALS

- Sylgard ® 184 Silicone Elastomer Kit
 - Silicone elastomer base
 - Silicone elastomer curing agent
- Sigmacell Cellulose (Type 50, 50µ average particle size)
- Silicon sealant

6.2 EQUIPMENT

The metal core of a particular arterial shape must have an accompanying plastic mould.

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- 10mL syringe
- 150mL plastic cup
- Exacto knife
- Metal core
- Plastic centering cups
- Plastic mould

7.0 PROCEDURES:

7.0.1 PREPARE THE MOULD

The following steps are performed assuming a carotid model.

1. Clean the metal core and plastic mould with ????
2. Attach plastic centering cups on all ends of the metal core. One adjustable plastic centering cup (has a screw) should be attached to the bottom end of the metal core.
3. Place the metal core with the plastic centering cups into the plastic mould.
4. **Precautionary alignment step: (optional)**
The metal core is usually a soft metal, and it might not exactly be centered inside the plastic mould, Silicon spacers may be placed inside between the plastic mould and the metal core to help center the metal core with a uniform 1mm space between the metal core and the plastic mould wall.
 - a. Place several 1mm thick silicon spacers between the metal core and the mould traces.
 - b. Use 1¼-20 screws to lock the two plastic mould pieces tightly together enclosing the metal core with the silicon spacers.
 - c. Stand the conjoined mould vertically. Leave for 3-4 hours.
 - d. Remove the spacers.
 - e. Inspect the mould with the metal core under a light to verify that there is a uniform 1mm gap between the plastic mould and the metal core.
5. Use 1 ¼-20 screws to lock the two plastic mould pieces tightly together enclosing the metal core with the plastic centering cups.
6. On the bottom of the conjoined mould, apply a thin layer of silicon sealant to any visible boundaries between the plastic centering cup(s) and the plastic mould pieces.
7. Wait 30min for the silicon sealant to dry.

7.0.2 PREPARE THE ELASTOMER MIX

The following steps are performed assuming a carotid model.

1. Mix 20mL of silicone elastomer base with 10% by volume of curing agent (2mL) into a 150mL plastic cup. Mix well for a few minutes.
2. Add Sigmacell cellulose to the mixture. For ultrasound purposes, add either (a) or (b):
 - a. Add 3% of Sigmacell cellulose by weight (Dr. Dan Rickey)
 - b. Add 0.5% of Sigmacell cellulose by weight (Dr. Tamie Poepping)

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- Mix well for 5 minutes.

7.0.3 DEGAS THE ELASTOMER MIX

- Place the plastic cup with the elastomer mix into the vacuum chamber.
- Turn both blue valves OPEN (Both *vent valve* and *pump vacuum valve* levers point parallel to the tube)
- Turn ON the pump. The switch is located on the power cable.
- Close the *pump vacuum valve* FIRST.

△CAUTION: DO NOT make the mistake of closing the *vent valve* first. Doing so will cause the contents of the container to explode because of the large internal pressure. Adjusting the pressure over 50mmHg will have a similar result.

- Close the *vent valve*.
- Use both valves to carefully adjust for the desired pressure. Opening the *pump vacuum valve* will increase the pressure. Opening the *vent valve* will decrease the pressure.
- Set the pressure to 10 mmHg.
- Turn OFF pump. Let it degas for 30 minutes.
- Open the *vent valve*.
- Open the *pump vacuum valve*.
- Remove plastic cup with mixture contents.

7.0.3 INJECT THE ELASTOMER MIX INTO THE MOULD

- Remove the luer-lok on a 10mL syringe.
- Slowly* draw in the elastomer mix into the syringe to avoid causing air bubbles.
- Align the plastic mould containing the metal core vertical so the metal core does not sag to one side.
- Insert the syringe into the injection hole on the plastic mould.
- Fill the mould by slowly dispensing the elastomer mix from the syringe.
- Leave to dry for 24 hrs. Do not remove the syringe from the injection hole during this process.

7.0.4 INSPECT THE SILICON WALL

- Unscrew the plastic mould.
- Remove the metal core with the silicon. Use an exacto knife to cut and free the silicon that is attached to the plastic centering cups.
- Place the metal core back into the mould.
- Holding the thick silicon wall for support, slowly twist off the plastic centering cups from the metal core.
- Rub off any excess silicon that formed at the interface of the plastic mould.

7.0.4 CLEANUP

- Remove the syringe from the injection hole.
- Step one. Complete any additional cleaning steps with the use of soap and water.
- Step two. There are two types of cleaning agents available. Use the one that is the least abrasive to the plastic mould.

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4. Etc. Place all the materials and pieces back to where they belong.
5. The syringe cannot be reused.

7.2 SAMPLE STORAGE AND HOLDING TIMES:

None.

7.3 RISKS TO PERSONNEL AND PRECAUTIONS FOR RISK REDUCTION:

7.3.1 Refer to *section 7: Basic Safety* of the *Robarts Research Laboratory Health and Safety Manual* for standard lab safety practices.

7.3.2 Wear impervious (preferably non-latex) gloves and safety glasses during the mixing procedure. If there is contact of any material in the eyes, flush for 15 minutes with water at an eye wash station.

7.7 CONTINGENCIES:

7.7.1 SPILLS

A. SILICONE ELASTOMER BASE

Use absorbent material to collect and contain for salvage or disposal.

B. SILICONE ELASTOMER CURING AGENT

Use absorbent material to collect and contain for salvage or disposal.

8.0 REPORTING AND DOCUMENTATION:

N/A

9.0 REVIEWS AND REVISIONS:

This procedure shall be reviewed for compliance and effectiveness and revised as necessary.

10.0 ATTACHMENTS and REFERENCE FORMS:

None.

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