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Design Output Document

**Preparation for Use**

Prior to use, thoroughly examine all equipment for defects. Inspect the PTCA catheter carefully for any bends, kinks, or damage and ensure that no defective equipment is used. Prepare the equipment according to the manufacturer's instructions or standard procedures. Follow these steps to prepare the PTCA catheter for use:

1. Remove the Protective Sheath: Gently slide the protective sheath off the balloon to expose the catheter.
2. Submerge the Catheter Tip: Dip the catheter tip/guidewire lumen into heparinized normal saline to ensure smooth navigation and prevent blood clotting.
3. Prepare the Inflation Device: Load the recommended contrast medium into an inflation device as per the manufacturer’s instructions.
4. Evacuate Air from the Balloon:
   a. Fill a 20-cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.
   b. Attach the syringe or inflation device to the catheter hub (balloon inflation lumen), ensuring the PTCA catheter's distal tip and balloon are oriented downward.
   c. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing the contrast medium to fill the catheter shaft.
   d. Disconnect the syringe or inflation device from the catheter hub.
   e. Ensure all air is removed from the syringe or inflation device barrel. Reconnect it to the catheter hub while maintaining negative pressure until no more air returns to the device.
   f. Slowly release the device pressure to neutral.
5. Connect the Inflation Device: Disconnect the 20-cc syringe (if used) and connect the inflation device to the catheter hub without introducing air into the system. Caution: Ensure all air is expelled from the balloon and replaced with a contrast medium before insertion into the body to avoid complications.

**Instructions for Use**

1. Insert the Guidewire: Insert a guidewire through the hemostatic valve as per the manufacturer's instructions.

2. Advance the Guidewire: Carefully advance the guidewire into and through the guiding catheter. Withdraw the guidewire introducer if used.
3. Attach Torque Device: If desired, attach a torque device to the guidewire. Under fluoroscopy, use accepted PTCA techniques to advance the guidewire to and across the lesion.
4. Backload the Catheter: Backload the distal tip of the PTCA catheter onto the guidewire, ensuring that the guidewire exits the catheter at the notch located distal to the balloon. Support the catheter to prevent the guidewire from wrapping around the balloon.
5. Advance to Hemostatic Valve: Advance the PTCA catheter over the guidewire until it approaches the hemostatic valve.
6. Insert into Hemostatic Valve: Open the hemostatic valve, insert the PTCA catheter while maintaining the guidewire's position, and tighten the hemostatic valve. Ensure the balloon is fully deflated to negative pressure to facilitate insertion.
7. Secure the Hemostatic Valve: Tighten the hemostatic valve to create a seal around the PTCA catheter without restricting contrast flow or guidewire movement.
8. Align Shaft Marker: Advance the PTCA catheter until the appropriate shaft marker aligns with the hemostatic valve hub, indicating that the catheter tip has reached the guiding catheter tip.
9. Position the Balloon: Advance the PTCA catheter over the guidewire and into the stenosis. Use fluoroscopy and the radiopaque marker band(s) to position the balloon within the stenosis correctly.
10. Dilate the Stenosis: Continue using accepted coronary angioplasty techniques to dilate the stenosis. Note: Do not exceed the rated burst pressure indicated on the package label. Maintain negative pressure on the balloon between inflations.
11. Withdraw and Discard: Withdraw the deflated PTCA catheter and guidewire into the guiding catheter. Use a chosen technique to remove the catheter, guidewire, and guiding catheter from the vasculature. Discard the used PTCA catheter, guidewire, and guiding catheter.

**List of Design Constraints and Assumptions**

The PTCA catheter must be designed to accommodate varying vessel diameters and insertion depths based on the access route. For jugular venous access, catheters must accommodate insertion depths of 16 cm for right-sided and 20 cm for left-sided access. For subclavian venous access, the respective depths are the same as jugular, while femoral venous catheters require lengths between 15 to 30 cm to ensure they can reach and treat the target site effectively

without causing trauma. This constraint ensures the catheter can be used safely across different patient anatomies and procedural requirements.

All materials used in the catheter, including those for the balloon, shaft, and coating, must be medical-grade to ensure biocompatibility and safety. Materials must withstand the chemical exposure and temperature conditions of Ethylene Oxide sterilization without degradation or toxic residue release. This requirement is critical to prevent any adverse reactions in patients and to comply with health and safety regulations.

The catheter's outer diameter must be carefully chosen to accommodate the typical range of vessel diameters it will enter. The average diameter for the femoral vein is 11.84mm at rest and 14.27 mm during the Valsalva maneuver.  Coronary arteries, where PTCA catheters are most commonly used, typically range from 2 mm to 4 mm in diameter. The catheter diameter must be small enough to navigate these vessels without causing damage but large enough to perform effective angioplasty and stenting.

The balloon must be capable of inflating and deflating quickly to allow for swift and efficient manipulation during angioplasty procedures.The catheter body must maintain structural integrity under operational pressures and not burst or split.

The catheter design must ensure that all components are compatible with Ethylene Oxide sterilization. This method is chosen for its effectiveness at sterilizing complex devices at low temperatures This is important for preserving the integrity and performance of temperature-sensitive materials like polyurethane and certain grades of nylon used in the catheter. The design must also account for sufficient aeration time post-sterilization to remove any residual EtO, ensuring the catheter is safe for patient exposure.

The design assumes that the catheter will be used in a standardized range of patient anatomies, as described for the different catheter placement depths and vessel sizes. This assumption simplifies design parameters and focuses on accommodating the majority of adult patients.

It is assumed that the catheter will be handled and operated by trained medical professionals familiar with PTCA procedures. This expertise is crucial for the safe and effective use of the catheter, ensuring that procedural risks are minimized.

The catheter's use is assumed to occur in a controlled medical environment, such as hospitals or specialized clinics, equipped with appropriate surgical and imaging equipment. This environment ensures that the catheter can be used under optimal conditions for both safety and efficacy.

**Component and Assembly drawings for each part**

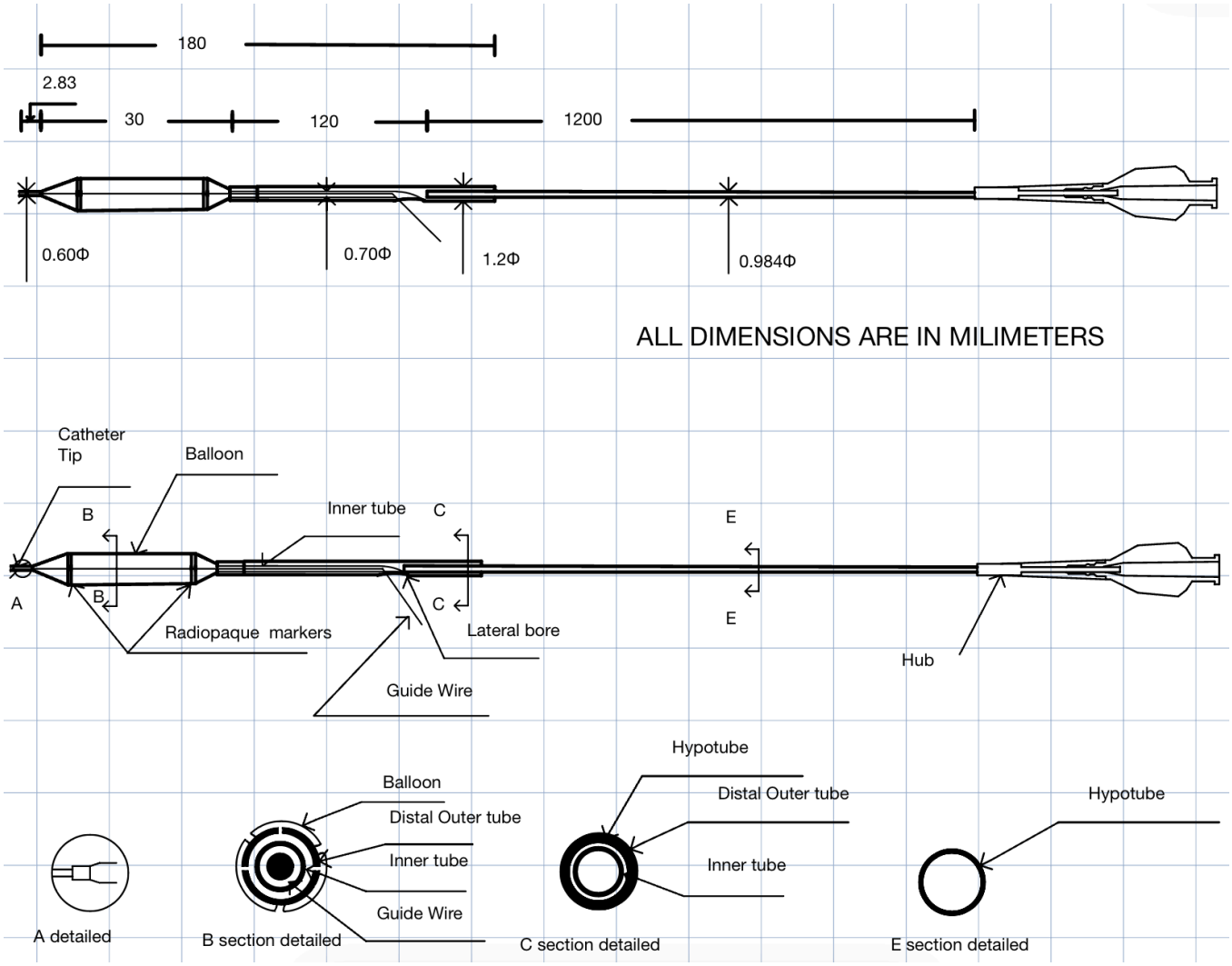


Figure 1. Assembly design of the PTCA Catheter.

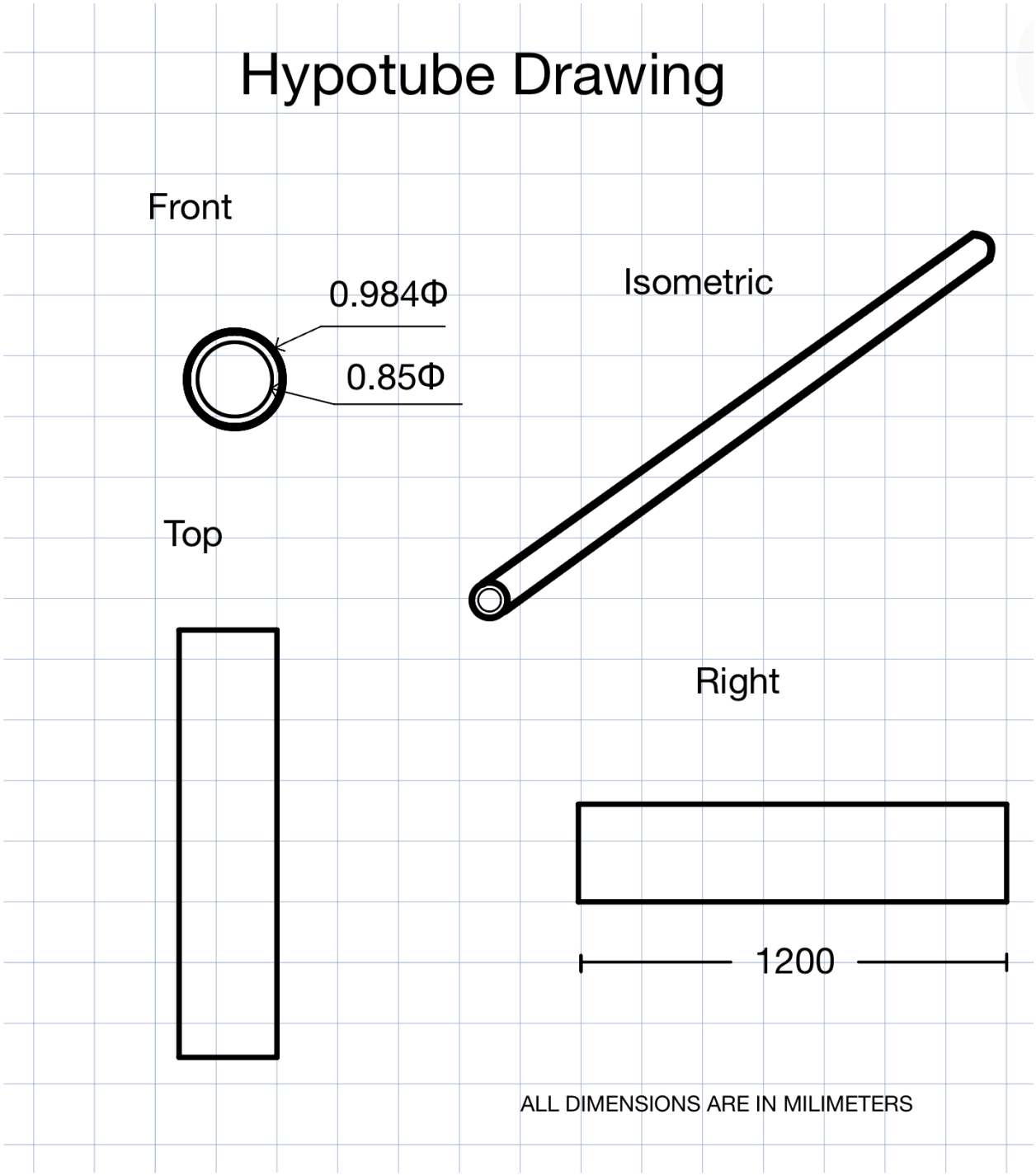


Figure 2. Drawing of the isometric, front, top and right views of the hypotube.

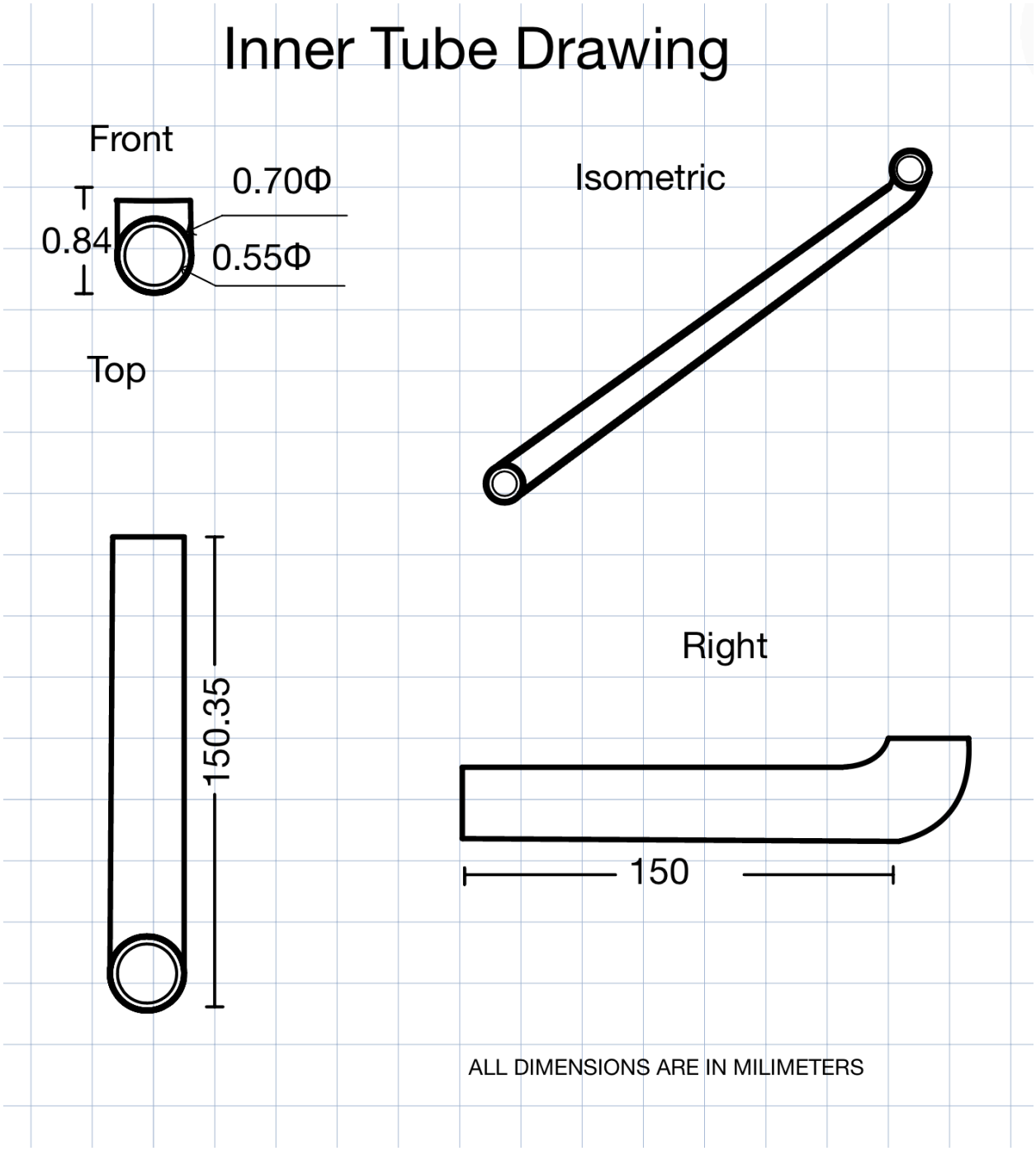


Figure 3. Drawing of the isometric, front, top and right views of the inner tube.

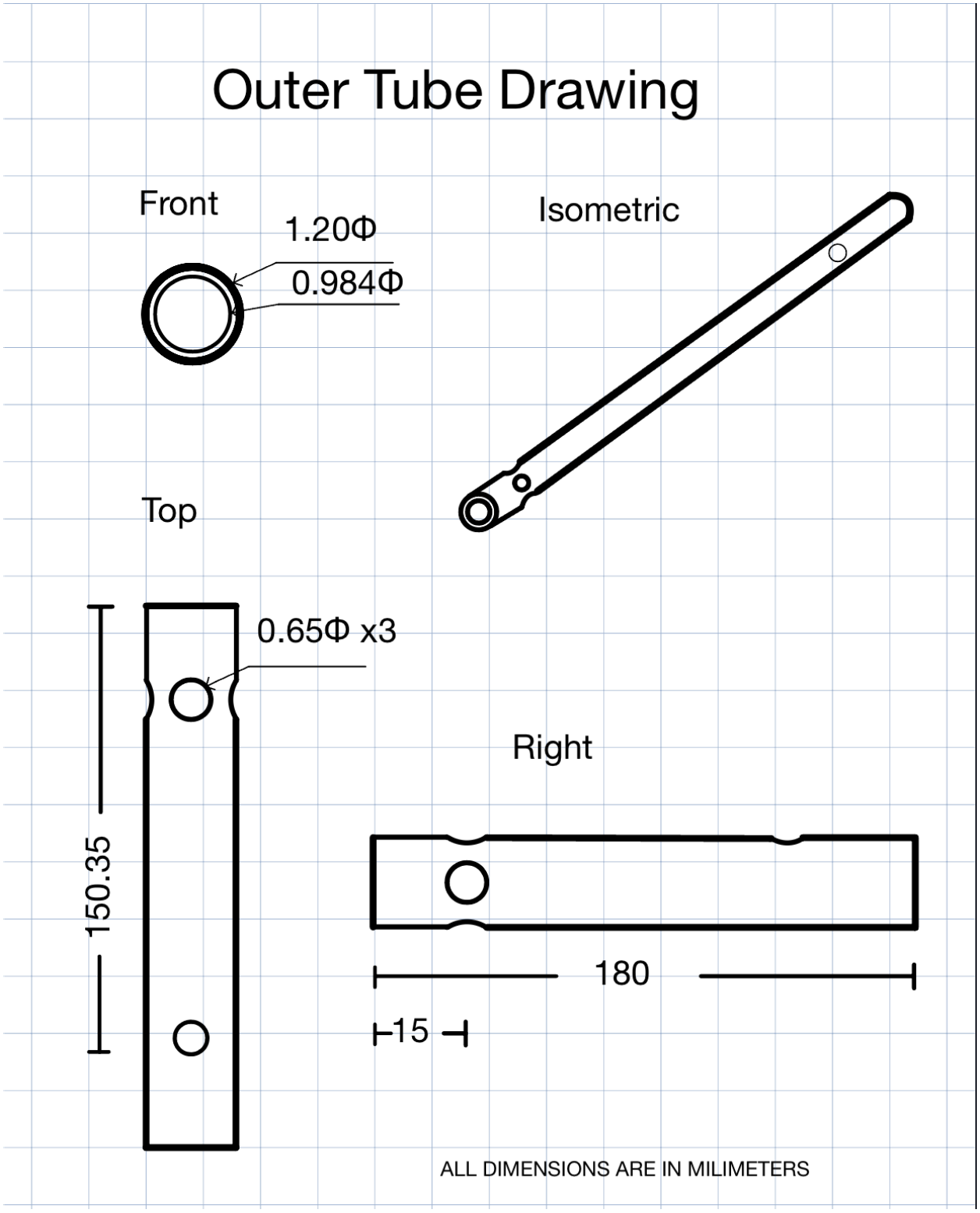


Figure 4. Drawing of the isometric, front, top and right views of the outer tube.

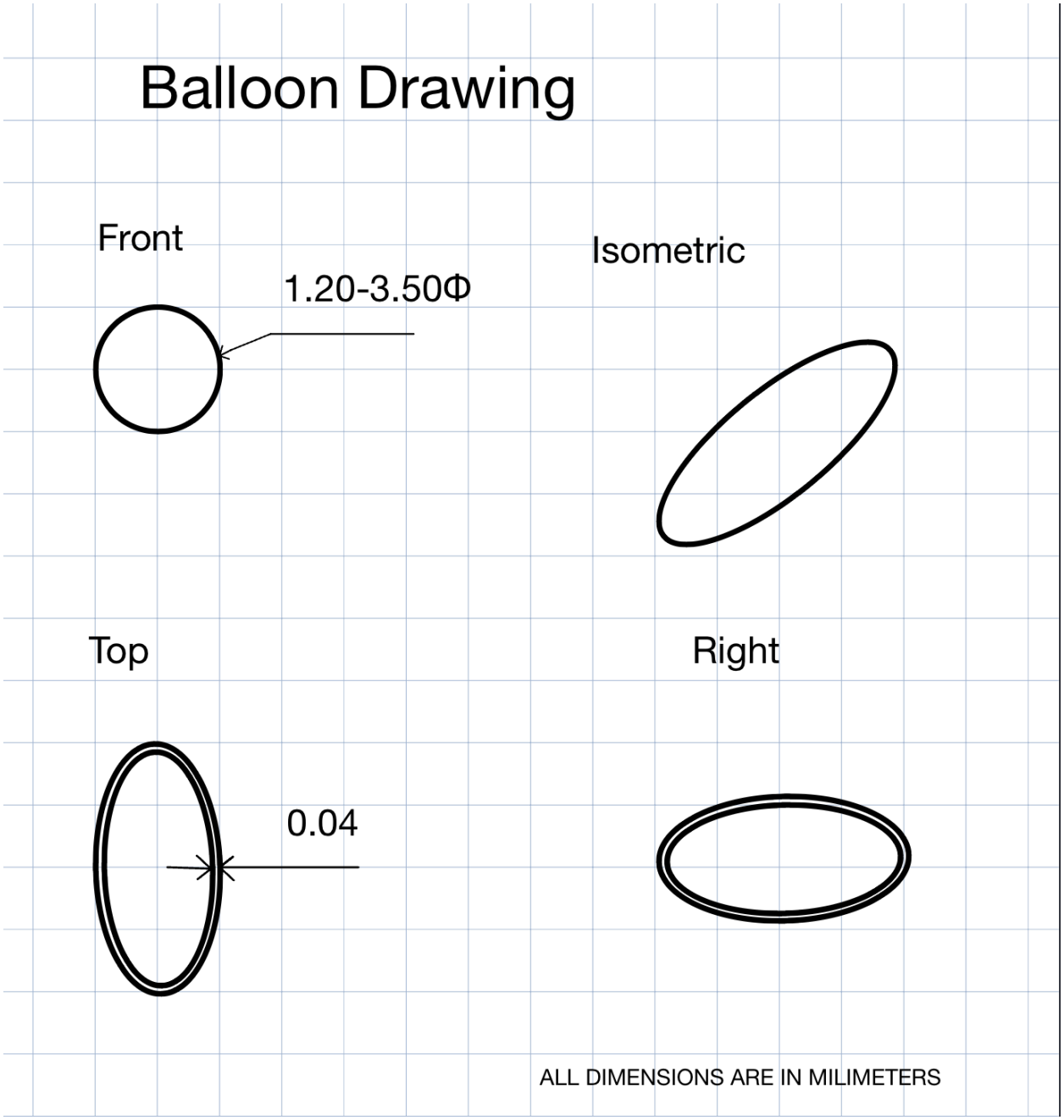


Figure 5. Drawing of the isometric, front, top and right views of the balloon.

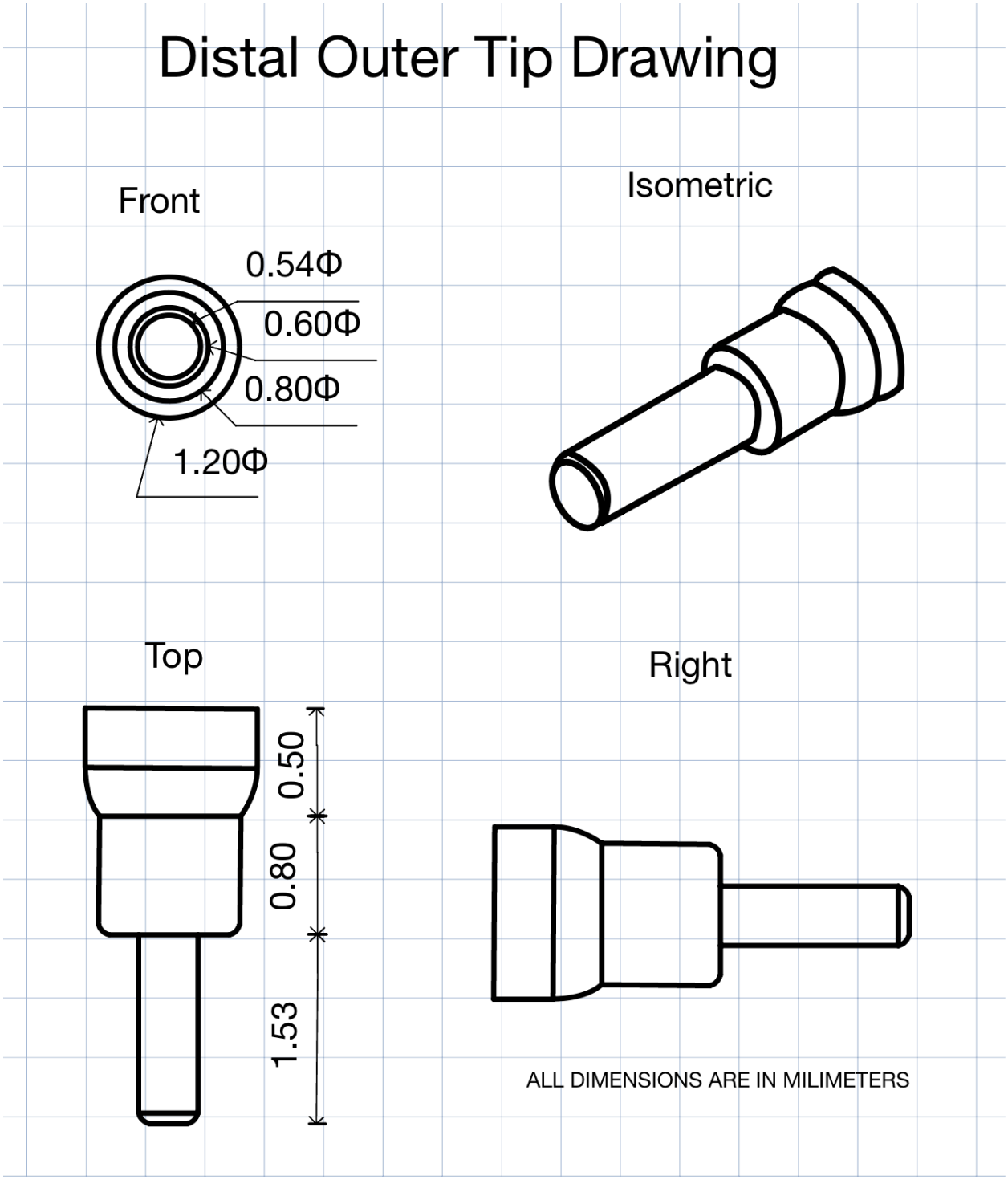


Figure 6. Drawing of the isometric, front, top and right views of the distal outer tip.

**Bill of Materials**

| PART | Material | DESCRIPTION | QTY. |
|---|---|---|---|
| Catheter Tip | Silicone Rubber | Minimizes vascular trauma during insertion with its soft, flexible design. | 1 |
| Distal Outer Tube | Polyurethane | Transports fluid to the balloon, made from flexible material to facilitate expansion. | 1 |
| Hypotube | 316 Stainless Steel | Provides structural support and transmits torque for navigation through vessels. | 1 |
| RadioPaque Markers | Platinum | Enhances visibility under imaging to aid precise placement of the catheter. | 2 |
| Balloon | Nylon 12 | Expands during angioplasty to dilate stenotic or occluded vessels. | 1 |
| Inner Tube | Polyurethane | Houses the guidewire, enhancing navigational flexibility within the catheter. | 1 |
| Guide Wire | Stainless Steel | The thin, flexible wire used to guide the catheter into position within blood vessels. | 1 |

**Analysis of stress in the wall of the catheter and balloon**

In the catheter design the burst pressure of the balloon cannot break the catheter shaft. Therefore, we must ensure the thickness of the balloon and catheter shaft are rated for each respective pressure. We can determine the thickness with the equation below:

$$\sigma_{balloon} = \frac{P_{nominal} r_{balloon}}{t_{ballon}} \Rightarrow t_{ballon} = \frac{P_{nominal} r_{balloon}}{\sigma_{balloon}} \qquad \text{eq 1.}$$

where:

$P_{nominal}$ is the nominal pressure at 8 atm.

$r_{balloon}$ is the radius of the balloon inflated which is 1.75mm.

$t_{ballon}$ is the thickness of the balloon that is iterated for.

$\sigma_{balloon}$ is the stress of the balloon that is half of the tensile yield stress for a conservative safety factor 0.5(690.83)atm.

$$\Rightarrow t_{ballon} = \frac{8(1.75)}{0.5(690.83)} 0.04mm$$

We can determine the radius the of the balloon at the burst using the equation:

$$r_{balloon} = \frac{\sigma_{tensile} t_{balloon}}{P_{burst}} \qquad \text{eq 2.}$$

Where:

$\sigma_{tensile}$ is the stress of the balloon tensile yield stress at 690.83 atm.

$P_{burst}$ is the burst pressure at 14 atm.

$$\Rightarrow r_{balloon} = \frac{690.83(0.04)}{14} = 2mm$$

The outer distal tube must have a thickness that can withstand the burst pressure, but it will be conservatively higher than the minimum thickness the tube can handle.

$$\sigma_{tensile} = \frac{P_{burst} r_{outer\ tube}}{2t_{outer\ tube}} \Rightarrow t_{min\ outer\ tube} = \frac{P_{burst} r_{outer\ tube}}{2\sigma_{tensile}} \qquad \text{eq 3.}$$

Where:

$P_{burst}$ is the burst pressure at 14 atm.

$r_{outer\ tube}$ is the radius of the outer tube which is 0.6mm.

$t_{min\ outer\ tube}$ is the thickness of the outer tube that is the smallest possible thickness for the burst and tensile yield stress.

$\sigma_{outer\ tube}$ is the stress of the outer tube's tensile yield stress 148.035atm.

$$\Rightarrow t_{min\ outer\ tube} = \frac{14(0.6)}{2(148.035)} = 0.057mm$$

I chose a thickness that is 0.216mm for a better torqueability and with this thickness, the pressure it bursts at will yield 106.59 atm which is 7.61 times larger than the burst pressure of the balloon.

*Flexibility*

To determine the total flexibility of the catheter; determine the flexibility of the hypotube and the distal outer tube and then add them in series. To determine the modulus of elasticity and shear modulus I did the upper boundary minus the lower boundary divided by two to get the middle value for a conservative approach on the material.

$$K_{flex} = \frac{3EI}{L^3} \qquad \text{eq 4.}$$

Where:

$E$ is the young's modulus for the material.

$L$ is the length of the material.

$I$ is the moment of inertia.

$$I = \frac{\pi}{64}(d_o^4 - d_I^4) \qquad \text{eq 5.}$$

Where:

$d_o$ is the outer diameter.

$d_I$ is the inner diameter.

The hypotube flexibility was calculated as follows:

$$I = \frac{\pi}{64}(0.000984^4 - 0.00085^4) = 2.04 \times 10^{-14} m^4$$

$$K_{flex\ hypotube} = \frac{3(1770\times10^6)\ 2.04\times10^{-14}}{1.20^3} = 6.27 \times 10^{-5} \frac{N}{m}$$

The distal outer tubes flexibility was calculated as follows:

$$I = \frac{\pi}{64}(0.0012^4 - 0.000984^4) = 5.58 \times 10^{-14} m^4$$

$$K_{flex\ outer\ tube} = \frac{3(1.95\times10^{11})\ 5.58\times10^{-14}}{0.18^3} = 5.59 \frac{N}{m}$$

Then to calculate the total flexibility we can use the equation:

$$K_{total\ flex} = \left(\frac{\Sigma\left(\frac{L_i}{k_i}\right)}{\Sigma(L_i)}\right)^{-1} \quad \text{eq 6.}$$

$$\Rightarrow K_{total\ flex} = \left(\frac{\frac{0.18}{5.59}+\frac{1.2}{6.27\times10^{-5}}}{0.18+1.2}\right)^{-1} = 0.00007\frac{N}{m}$$

*Torqueability*

Determine the torqueability of each component by using the following equation:

$$K_{torq} = \frac{GJ}{L} \quad \text{eq 7.}$$

Where:

$G$ is the Shear modulus for the material.

$L$ is the length of the material.

$J$ is the polar moment of inertia.

$$J = \frac{\pi}{2}(r_o^4 - r_I^4) \quad \text{eq 8.}$$

Where:

$r_o$ is the outer radius 0.000492m.

$r_I$ is the inner radius 0.000425m.

The hypotube torqueability was calculated as follows:

$$J = \frac{\pi}{2}(0.000492^4 - 0.000425^4) = 4.08 \times 10^{-14} m^4$$

$$K_{torq\ hypotube} = \frac{(82\times10^9)\ 4.08\times10^{-14}}{1.20} = 2.79 \times 10^{-3} Nm$$

The distal outer tubes torqueability was calculated as follows:

$$J = \frac{\pi}{2}(0.0006^4 - 0.000492^4) = 1.12 \times 10^{-13} m^4$$

To determine the total torqueability of the catheter; calculate the torqueability

$$K_{torq\ outer\ tube} = \frac{(0.102\times10^9)\ 1.12\times10^{-13}}{0.18} = 6.32 \times 10^{-5} Nm$$

$$K_{total\ torq} = \frac{1}{\frac{1}{K_{torq\ hypotube}} + \frac{1}{K_{torq\ outer\ tube}}}$$ eq 9.

$$\Rightarrow K_{total\ torq} = \frac{1}{\frac{1}{2.79\times10^{-3}} + \frac{1}{6.32\times10^{-5}}} = 6.2 \times 10^{-5} Nm$$

*Pushability*

Determine the pushability of each component by using the following equation:

$$K_{push} = \frac{EA}{L}$$ eq 10.

Where:

$E$ is the Young's modulus for the material.

$L$ is the length of the material.

$A$ is the Area.

$$A = \frac{\pi}{4}(d_o^2 - d_I^2)$$ eq 11.

Where:

$d_o$ is the outer diameter.

$d_I$ is the inner diameter.

The hypotube pushability was calculated as follows:

$$A = \frac{\pi}{4}(0.000984^2 - 0.00085^2) = 1.93 \times 10^{-7} m^2$$

$$K_{push\ hypotube} = \frac{(1770\times10^6)1.93\times10^{-7}}{1.20} = 284.70\ Nm$$

The distal outer tubes pushability was calculated as follows:

$$A = \frac{\pi}{4}(0.00126^2 - 0.000984^2) = 3.71 \times 10^{-7} m^2$$

To determine the total pushability of the catheter; calculate the pushability in the outer tube and then add each tube's pushability in series.

$$K_{push\ outer\ tube} = \frac{(1.95\times10^{11})\ 1.12\times10^{-13}}{0.18} = 4.01 \times 10^5\ Nm$$

$$K_{total\ push} = \frac{1}{\frac{1}{K_{push\ hypotube}} + \frac{1}{K_{push\ outer\ tube}}}$$ eq 12.

$$\Rightarrow K_{total\ push} = \frac{1}{\frac{1}{284.70}+\frac{1}{4.01\times10^5}} = 284.50\ Nm$$

**Analysis of time of deflation of balloon**

For the Deflation and inflation of the balloon; determine the flow rate of the fluid in the catheter. Next determine the volume where the fluid will be flowing through. Finally we can calculate the inflation and deflation time.

$$Q_{proximal} = \frac{\Delta P \pi R^4}{8L\mu} \qquad \text{eq 13.}$$

Where

$\Delta P$ is the pressure change in the catheter for our case it is 405,309pa because the nominal pressure it gets to is 810,619pa, however this is a linear inflation rate that averages about 405,309pa.

$R$ is the smallest radius the fluid, for the catheters case it's the hypotubes radius at 0.425mm

$L_{proximal}$ is the length the hypotube at 1200mm

$\mu$ is the viscosity of the fluid traveling through the catheter, for our case Optiray 350 in a 1:1 solution with saline water which has a value of

$$\mu = 0.0089(0.5) + 0.001(0.5) = 0.005 pa \cdot s$$

$$\Rightarrow Q_{proximal} = \frac{405{,}309\pi(0.425)^4}{8(1200)(0.005)} = 865.47\frac{mm^3}{s}$$

The distal tube has a different flow where the pressure and the viscosity of the fluid is the same:

$$Q_{distal} = \frac{\Delta P \pi}{8L\mu}\left[R_2^4 - R_1^4 - \frac{(R_2^2 - R_1^2)^2}{ln(\frac{R_2}{R_1})}\right] \qquad \text{eq 14.}$$

$R_1$ is the inner tube's outer radius of 0.35mm.

$R_2$ is the outer tube's inner radius of 0.492mm.

$L_{distal}$ is the length of the distal outer tube at 180mm.

$$\Rightarrow Q_{distal} = \frac{405{,}309\pi}{8(1350)(0.005)}\left[0.492^4 - 0.35^4 - \frac{(0.492^2 - 0.35^2)^2}{ln(\frac{0.492}{0.35})}\right] = 284.79\frac{mm^3}{s}$$

The flow is in series so we can use the equation derived from the conservation of mass to determine the total flow for the inflation:

$$\frac{1}{Q_{total}} = \frac{1}{Q_{proximal}} + \frac{1}{Q_{distal}} \qquad \text{eq 15.}$$

$$\Rightarrow Q_{total} = \frac{1}{\frac{1}{Q_{proximal}} + \frac{1}{Q_{distal}}} \Rightarrow Q_{total} = \frac{1}{\frac{1}{865.47} + \frac{1}{284.79}} = 214.28\frac{mm^3}{s}$$

To solve for the volume going through the catheter we can add the volumes together.

$$V_{total} = V_{hypotube} + V_{outer\ tube} + V_{balloon} \qquad \text{eq 16.}$$

$$V_{total} = \pi((R_{hypotube})^2 L_{hypotube} + ((R_{outer\ tube})^2 - (R_{inner\ tube})^2)L_{outer\ tube} + (\frac{3}{4})(R_{balloon})^3 L_{balloon})$$

$$V_{total} = \pi((0.425)^2 1200 + ((0.492)^2 - (0.35)^2)180 + (\frac{3}{4})(1.75)^3 30)) = 761.18mm$$

To solve for the Inflation time, we can divide the volume by the flow rate:

$$t_{inflation} = \frac{V_{total}}{Q_{total}} \qquad \text{eq 16.}$$

$$\Rightarrow t_{inflation} = \frac{761.18mm^3}{214.28\frac{mm^3}{s}} = 3.55\,s$$

To solve for the deflation time we can use the same values for all variables but assume the pressure difference will be half the pressure of the inflation time because the pressure decreases linearly going down at a slower rate. Therefore, equation 13 and 14 will be changed:

$$\Rightarrow Q_{proximal} = \frac{202{,}654.8\pi(0.425)^4}{8(1200)(0.005)} = 432.73\frac{mm^3}{s}$$

$$\Rightarrow Q_{distal} = \frac{202{,}654.8\pi}{8(1350)(0.005)}\left[0.492^4 - 0.35^4 - \frac{(0.492^2 - 0.35^2)^2}{ln(\frac{0.492}{0.35})}\right] = 142.40\frac{mm^3}{s}$$

We can then determine the total flow using equation 15 and deflation time using equation 16:

$$Q_{total} = \frac{1}{\frac{1}{432.73}+\frac{1}{142.40}} = 107.14\frac{mm^3}{s}$$

$$t_{deflation} = \frac{761.18mm^3}{107.14\frac{mm^3}{s}} = 7.10s$$

This deflation time is well below 30 seconds which is the maximum time it should be.

## Manufacturing, Assembly and Bonding Methods

Tip (Silicone Rubber)

The tip of the catheter is manufactured using liquid silicone rubber (LSR) injection molding. This process allows for precision in shaping the silicone to ensure the tip is flexible and has a smooth surface, reducing the risk of vascular trauma during insertion. The tip is bonded to the catheter distal outer tube and inner tube using medical-grade adhesives techniques, which provide a durable and seamless connection for the catheter's performance.

Balloon (Nylon 12)

The balloon component is manufactured through a blow molding process using Nylon 12. This method heats the Nylon 12 until it is molten and then inflates it within a mold to achieve the desired balloon shape, ensuring uniform wall thickness and robust performance. The balloon is thermally bonded at its proximal and distal ends to the catheter’s polyurethane distal outer tube, creating airtight seals that are critical for its inflation and deflation during the procedure. Thermal bonding involves applying heat to the nylon ends of both the balloon and the tube, causing them to melt slightly. When they cool and solidify, they form a durable joint that ensures the balloon is securely attached at both its proximal and distal ends.

Radiopaque Markers (Platinum)

Platinum radiopaque markers are produced via precision machining or laser cutting to achieve exact dimensions. These markers are embedded into the balloon or the catheter shaft using adhesives or mechanical fixation in predetermined recesses, which are crucial for enhancing visibility under imaging during the catheterization procedure. The platinum radiopaque markers are bonded to the Nylon balloon using an adhesive. For this process, a biocompatible adhesive specifically designed for medical use is applied to the markers. Once the adhesive is in place, the markers are positioned on the balloon. The adhesive then cures, forming a permanent bond that keeps the markers fixed during the catheter's operation.

Distal Outer Tube (Polyurethane)

The distal outer tube of the catheter is extruded from polyurethane. The extrusion process allows for the production of continuous lengths of tubing with consistent diameter and wall thickness. The lateral bore is engineered during the extrusion process for the guide wire. It is strategically positioned to facilitate the transition of the inner tube at its junction, allowing for the effective passage of guide wires and other necessary medical instruments.

Inner Tube (Polyurethane)

The inner tube of the catheter is designed to serve as the lumen for the guide wire. It's manufactured using precision extrusion from thermoplastic polyurethane, known for its optimal balance of flexibility and strength. This tube is then thermally bonded to the outer distal tube at the point of the lateral bore, ensuring a secure and durable connection crucial for maintaining integrity under the dynamic conditions of medical procedures. The distal tip has a specially formulated silicone adhesive to bond the extruded inner tube to the silicone rubber tip. This ensures that the catheter tip remains securely attached and functional throughout its use. Each assembly step is performed under controlled conditions to maintain the highest standards of quality and safety.

Hypotube (Stainless Steel 316)

The hypotube is manufactured using a tube drawing process that refines the diameter and enhances the length of stainless steel 316. This process also improves the tube's strength and surface finish. The hypotube provides structural support and rigidity; it's encased by the polyurethane layers with a polyurethane adhesive bonding to the distal outer tube to contain the fluid for the balloon expansion. The hypotube will go through the hub into the distal outer tube to give support.

**Sterilization Procedure**

Preparation:

- Cleaning: The catheter must be thoroughly cleaned to remove any residues from manufacturing processes such as oils, lubricants, and particulates. This ensures that the sterilization agent, ethylene oxide, can effectively contact all surfaces of the device.
- Drying: After cleaning, the catheter must be completely dried. Moisture can react with ethylene oxide, which can affect the sterilization efficacy and potentially produce harmful byproducts.

Packaging:

- Material Selection: The catheter is packaged in breathable materials that allow ethylene oxide gas to penetrate but maintain sterility once the sterilization process is complete. Common materials include Tyvek® and medical-grade paper.
- Sealing: The packaging is sealed to prevent contamination after sterilization while allowing the ethylene oxide gas to escape during the aeration phase.

Sterilization Chamber Loading:

- Loading: The packaged catheters are placed in a sterilization chamber. The load is arranged to ensure that gas circulation is unobstructed so that all items are uniformly exposed to ethylene oxide gas.

Sterilization Cycle:

- Humidity and Temperature: The chamber is conditioned to reach the necessary humidity and temperature to enhance the effectiveness of the ethylene oxide. Typical conditions might include temperatures around 37-55°C and relative humidity about 40-80%.
- Gas Introduction: Ethylene oxide gas is introduced into the chamber at a controlled rate and concentration. The specific concentration, temperature, and humidity are maintained for a predetermined time to ensure complete sterilization, typically several hours.
- Dwell Time: The exact conditions and dwell time depend on the device's configuration, material properties, and the specific EtO sterilization cycle parameters validated for your product.

Aeration:

- Removing Residual Gas: After the sterilization cycle, the catheter remains in the chamber or is transferred to a separate aeration room to allow any absorbed ethylene

oxide to dissipate. This phase is critical as ethylene oxide is toxic, and sufficient aeration ensures that residuals are reduced to safe levels.
- Duration: Aeration time can vary from several hours to days, depending on the materials' ability to absorb and release ethylene oxide.

Quality Control and Testing:

- Sterility Testing: Random samples from each sterilization batch are tested to ensure they meet the required sterility assurance levels.
- Residual Testing: Additional testing for ethylene oxide residuals is performed to ensure they are below the limits specified by international safety standards such as ISO 10993-7.

Documentation and Release:

- Record Keeping: Detailed records of each sterilization cycle, including parameters like gas concentration, temperature, humidity, and exposure time, are maintained.
- Release: After passing all quality checks, the sterilized catheters are cleared for distribution.

Ethylene Oxide (EtO) sterilization is a widely utilized method for sterilizing medical devices that are sensitive to heat and moisture. This low-temperature sterilization technique involves exposing devices to ethylene oxide gas in a controlled environment, which effectively eradicates all known microorganisms, including bacteria, viruses, fungi, and spores. The process leverages EtO's alkylation ability to disrupt the DNA of microorganisms, thereby preventing them from reproducing and causing infection. Due to its efficacy at lower temperatures, EtO is particularly suitable for medical devices made from materials like plastics, resins, and metals that might degrade or lose functionality under the high temperatures of steam sterilization. However, post-sterilization, devices require thorough aeration to remove any residual EtO, due to its potential toxicity to humans. This sterilization method is critical for ensuring that complex medical devices are both sterile and functional upon delivery for clinical use, making it an indispensable tool in the healthcare industry.

Ethylene Oxide (EtO) sterilization is particularly favorable for complex medical devices such as PTCA catheters that incorporate diverse materials, each reacting distinctively to the sterilization

process. For the Nylon 12 used in the balloon, EtO sterilization ensures effective microbial eradication without compromising the material's mechanical properties, as Nylon 12 is resistant to the low temperatures and chemical exposure involved in the process. Polyurethane, utilized in the inner tube and Distal Outer tube, also benefits from EtO's mild conditions, maintaining its integrity and elasticity as it is not subjected to the degradative effects of heat or moisture. Platinum, used in the radiopaque markers, remains unaffected by EtO due to its inert nature, ensuring that its functionality and visibility under imaging are preserved. Lastly, Stainless Steel 316 in the tip and hypotube retains its corrosion resistance and structural integrity under EtO exposure, unaffected by the chemical environment due to its robust metallurgical properties. EtO's compatibility with these materials ensures that the catheter remains sterile and fully functional, maintaining all physical and mechanical properties essential for safe and effective clinical use.

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