Da Vinci Xi Arm Drapes Manufacturing

Final Proposal

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Product Overview

Function:

- Provides a sterile barrier between the surgical robot and the patient.
- Attaches at key sites between robot arms and instruments.
- Ensures sufficient slack for movement while remaining form-fitting.

Attachment Components:

- **Clips**: Secure the drape to the "hand" side.
- **Magnets**: Attach to the robot's side.
- **Malleable Strips**: Minimize hanging drapes for better control.

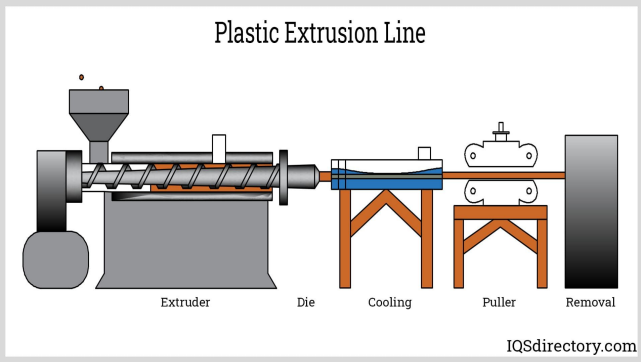
Material and Fit:

- **TPU Lining**: Customized to arm measurements to ensure a snug, sterile fit.

Regulatory Compliance

- Must follow:
  - **FDA Requirements**
  - **ISO 13485 Standards**

Material: Drapes Film

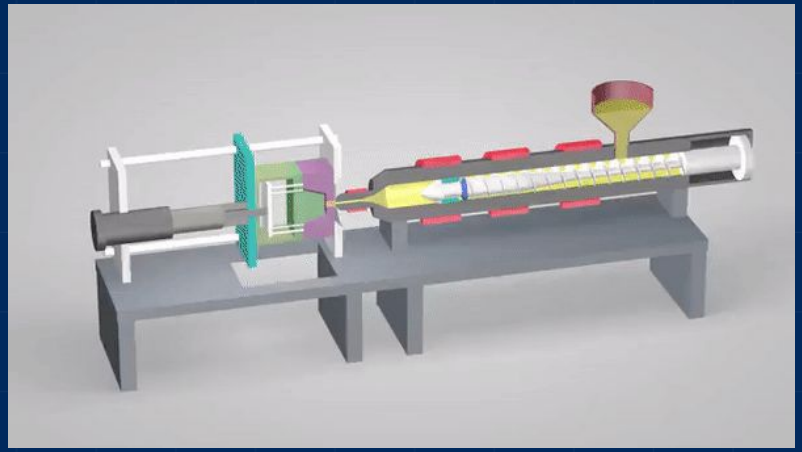


- Thermoplastic polyurethane (TPU)
- Supplier: UFP Med Tech
  - Biocompatibility ISO 10993
  - Disposable
  - Durability – ASTM D882 (Tensile Strength Testing)
  - Tear resistance – ASTM D882 (Tensile Strength Testing)
  - Elasticity resistance
  - Flexible – 3D complex shapes
  - Puncture resistance – ISO 7765 (determination of puncture impact properties of a plastic film)
- Challenges
  - Expensive
  - Heat resistance
- Yield strength: 24.7 – 33.4 MPa
- Ultimate Strength: 1.72 – 90.0 MPa

- Process: Barrel extrusion process
  - Dry TPU pellets (moisture 0.02% or less)
  - Dry temperature 80–110 °C for 2–4 hours
  - Barrel temperature 190–230 °C
  - Die 200–240 °C
  - Cooling rollers room temperature

Material: Injection Mold Part

- ABS – PC (acrylonitrile butadiene styrene – polycarbonate)
  - Supplier: Covestro – Bayblend T45 PG
- Advantages
  - High strength, high stiffness, high heat resistance, and high impact resistance
- Barrel injection molding
  - Temperatures 220-265 °C
  - Mold Temperature 70-90 °C
  - Dry Air Dying 90 °C, 4 hours
  - Hold Pressure: 50-70%
- Testing/Regulations:
  - ISO 180 – Izod impact test for determining the impact and notched impact strength on plastics
  - ISO 527-1,2 – tensile properties
  - ISO 294 – injection molding thermoplastic, check uniformity
  - ISO 1183-1 – determination of density of non-cellular plastics
  - ISO 62 – determining the amount of water absorbed by plastic specimens



Material: Attachment Fasteners

Magnets:

- Supplier: Integrated Magnetics (IM)
- Neodymium iron boron
  - Strongest type of permanent magnet, ideal for securing components
- Coated with nickel plating
  - Help prevent flaking of raw magnet material
- Process: electroplating
  - Clean the magnet
  - Electroplating 55-65°C
  - Current density used during electroplating 2 A/dm² and 10 A/dm²
  - Plating time about 30 minutes to several hours

- ISO 10993 – evaluating the biocompatibility of medical devices to manage biological risk
- ASTM B117 or ISO 9227 – corrosion test, salt spray test

Twist tie:

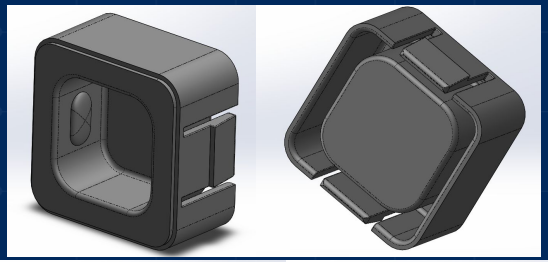
- Supplier: Hanscom Inc
- 2 wires of stainless steel
  - Strength and shape retention
- Coated with polyethylene (PE)
  - Durable
  - Flexible
- Process: extrusion
  - Wires into the extruder
  - Extruder heats/melts PE plastic (180-250 °C)
  - PE is forced through a die, coating the wire
  - Cool water, room temperature, 5-10 seconds
- Biocompatibility ISO 10993

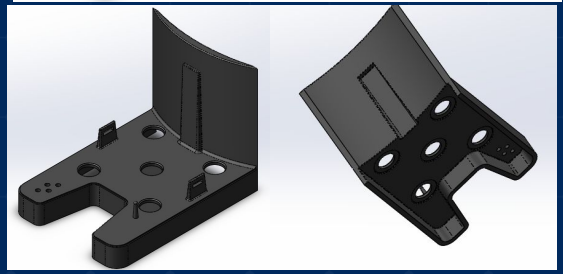
01

Make Parts

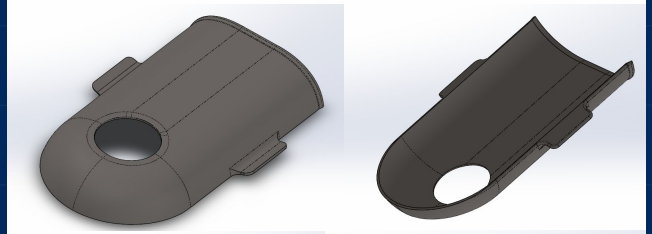
Clips (Injection Mold)

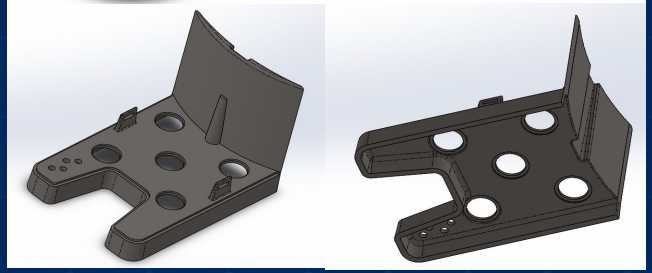
Initial Designs

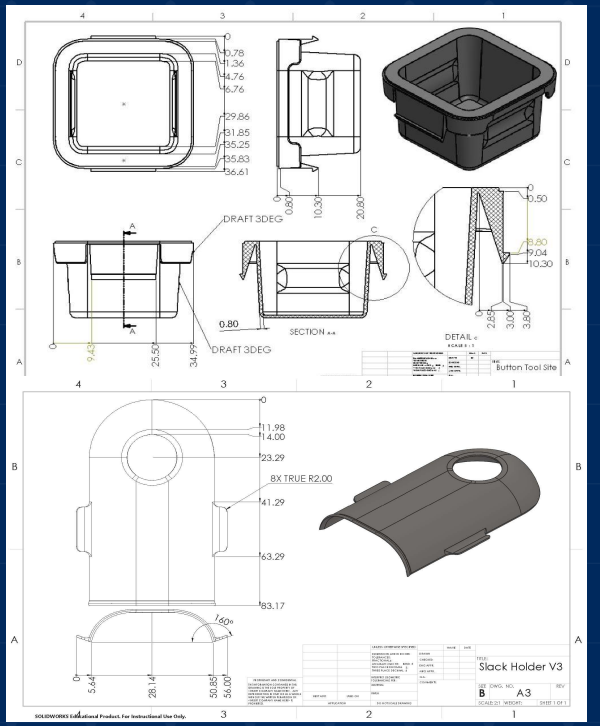


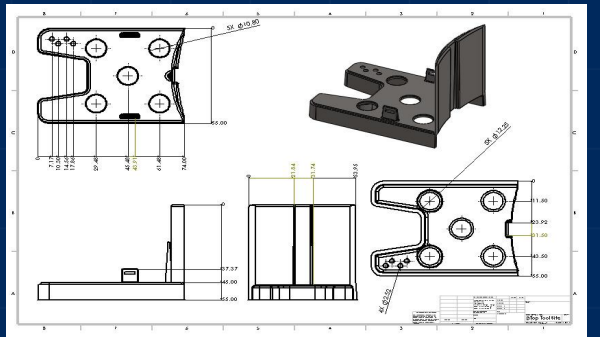


Final Designs





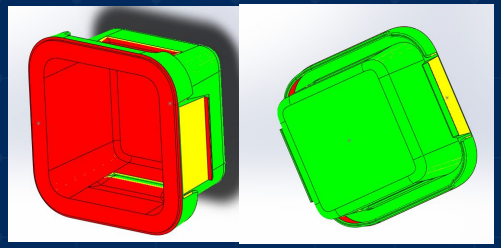




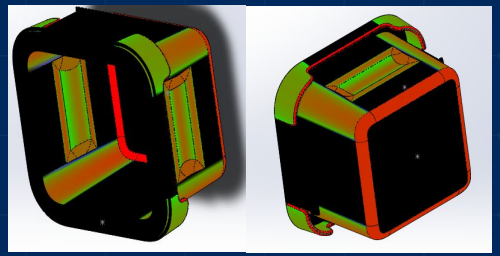
+ Difference: Surface Modeling, Consistent Wall Thickness, Draft Angle, Ribs, Using Splines for all Curves Injection Molding DFM

DFM Analysis Example

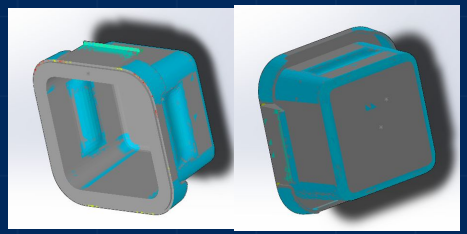
Mold Release



DRAFT

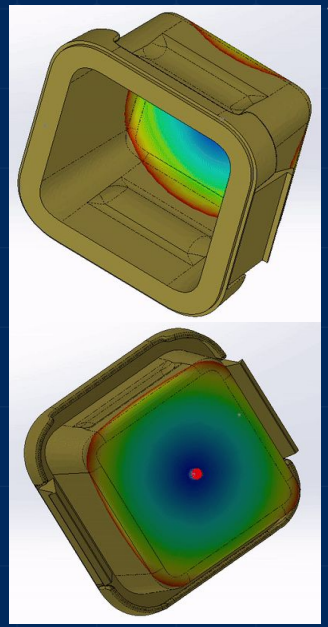


CURVATURE



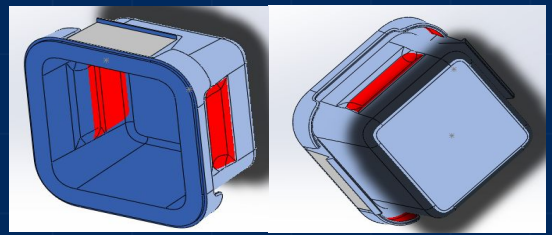
WALL THICKNESS

Plastic Flow



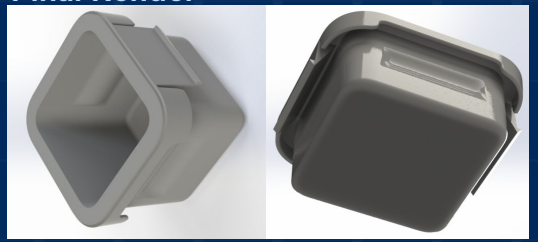
Simulation Summary

- ✅ Injection Pressure: 45.5 MPa (66% of max).
- ✅ Shear Rate: Within safe limits.
- ✅ Cooling Time: 0.98 sec.
- ✅ Residual Stress: 13.23 MPa.
- ✅ Filling Time: 0.245 sec.
- ✅ Material Integrity: No degradation.
- ✅ Clamping Force: 3.85 tonnes.
- ✅ Bulk Temp at Fill End: Within range.
- ✅ Ease of Fill: Smooth flow.
- ✅ Sink Marks: Minimal.
- ✅ Frozen Layer: Optimized.
- ✅ Volumetric Shrinkage: Controlled.



UNDERCUT

Final Render



Magnets and Twist Ties

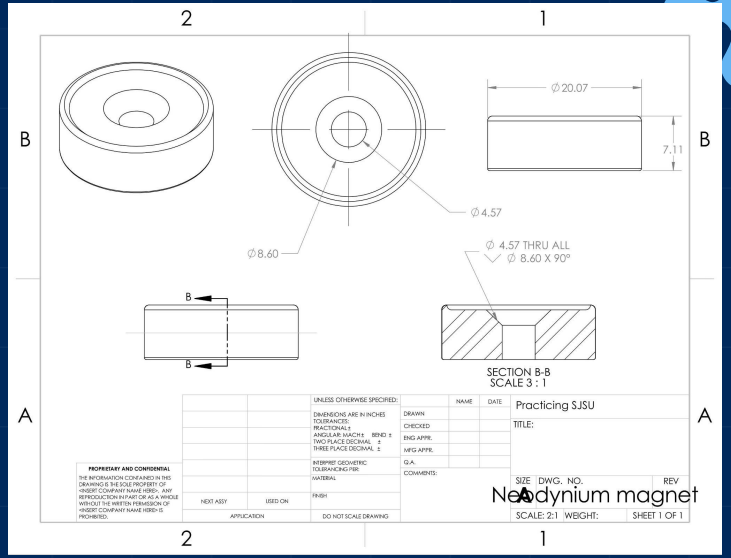
Magnets
Supplier – Integrated Magnetics (IM)

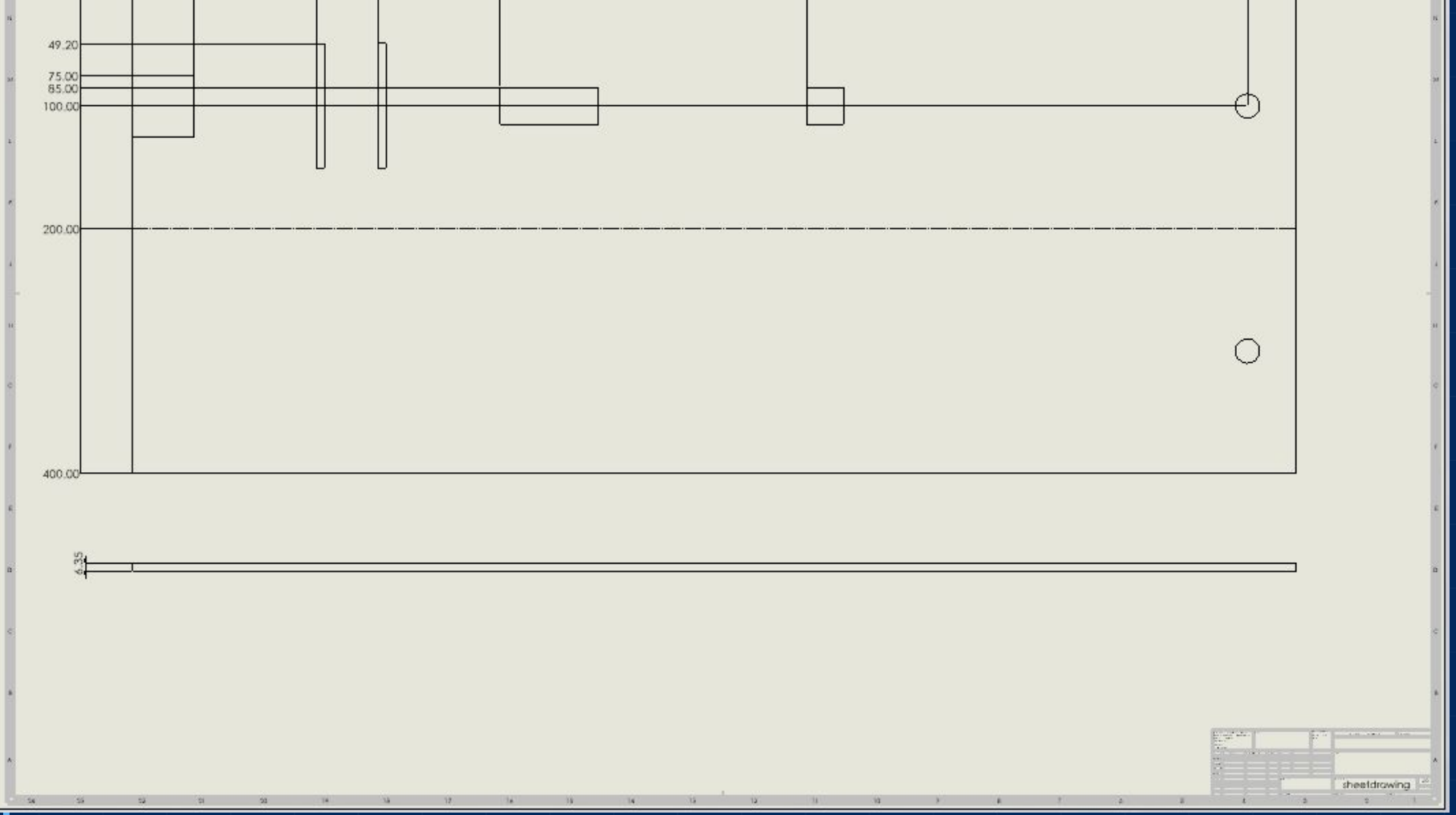
- Quick and easy application and removal
- Repeatable action: Metal disc on drape attaches to magnetic socket on column
- Same magnet on column used consistently leaving less room for user error

Twist Ties – Hanscom Inc

- Prevents excess drape material from interfering with robotic arm
- Dual Stainless steel wire
  - Strength and shape retention
- Coated with polyethylene (PE)
  - Durable
  - Flexible

Both parts are common and can be sourced directly from suppliers.




49.20
75.00
85.00
100.00
200.00
400.00
4.35
sheetdrawing

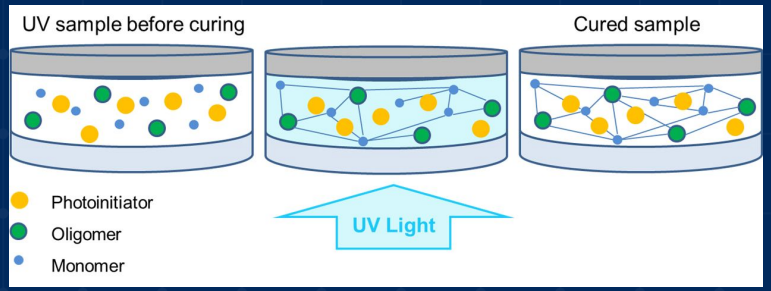
02

Assemble

Assembly process

Assembly Process Overview

- **Environment**:
  - Components are assembled in-house in a **clean room environment** to prevent contamination.
- **Bonding Methods**:
  - **Glue Application**: Used for precision bonding of components.
  - **UV Curing**: Provides fast, reliable bonding for permanent assembly.



- **Process**:
  - UV adhesive is applied to the joint.
  - A **UV light source** activates the adhesive, initiating polymerization for a secure and durable bond.
  - Typically completes in seconds, offering strong and clean results.
- **Advantages**:
  - Precise control over bond location and strength.
  - Reduces curing time compared to traditional methods.
  - Ideal for medical applications due to minimal thermal stress.

03

Package & Sterilize

Package Process

Folding Method:

- Drapes folded with the **sterile side facing up**.
- Folded upward repeatedly to form a compact packet.

Design Features:

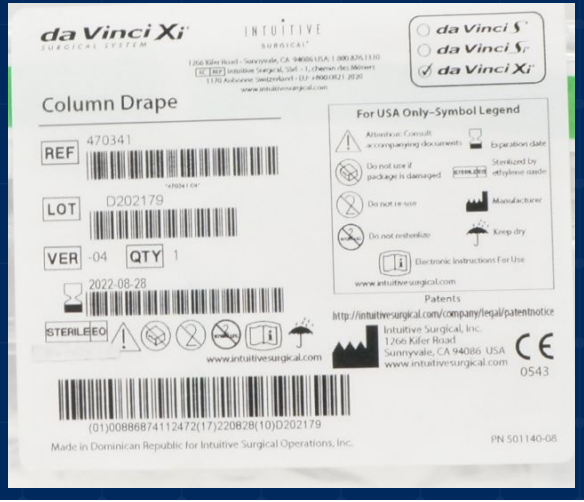
- **Pocket flaps (cuffs)** at the proximal section enable sterile handling.
- Staff insert hands into cuffs to position drapes without touching non-sterile surfaces.

Sterility Protocol:

- Touching areas outside cuffs or sterile side **breaches sterility**.

Label Information:

- Includes **Lot#**, **Part#**, and **Expiration Date** for traceability.

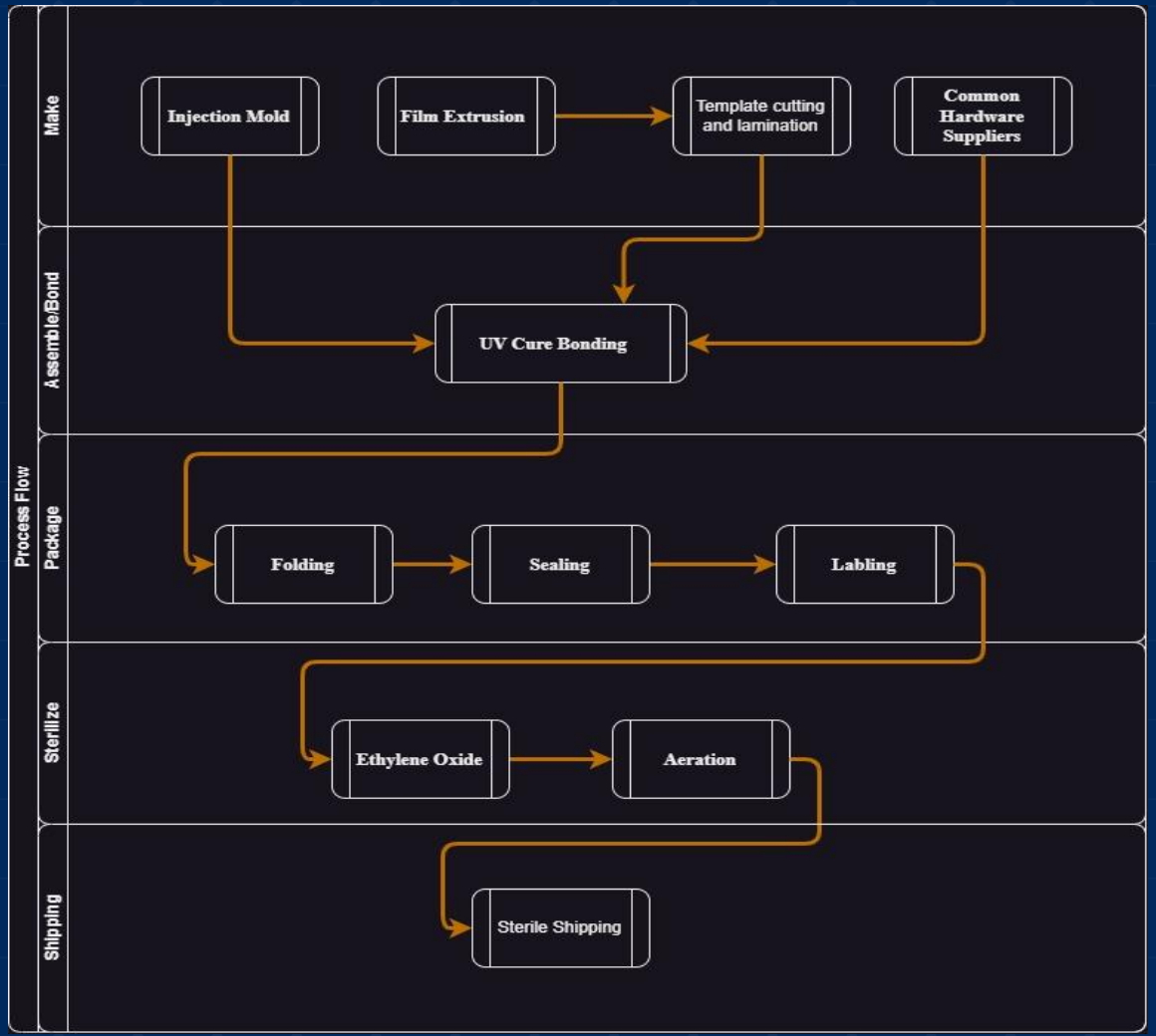


Da Vinci Xi drapes

	Product description	Qty/ box	Uses	Part number
	Arm drape (box of 20)	20	1 procedure	**470015**
	Column drape (box of 20)	20	1 procedure	**470341**

Sterilize Process

- **Packaging Process**:
  - Drapes individually sealed in sterile pouches (similar to autoclave pouches).
  - Packaged pouches placed in another sterile bag, tied, and boxed.
- **Box Sterilization**
  - Entire box sterilized by the pallet (multiple boxes per pallet).
  - Pallets shipped and remain sealed until opened in the OR by non-sterile staff, with sterile staff handling contents.
- **Sterilization Method**:
  - **Ethylene Oxide (EtO)** gas used for heat-sensitive materials.
  - Effectively penetrates materials to eliminate microorganisms.
  - Items aerated post-sterilization to dissipate toxic gas.


Process Flow
Make
Assemble/Bond
Package
Sterilize
Shipping
Injection Mold
Film Extrusion
Template cutting and lamination
Common Hardware Suppliers
UV Cure Bonding
Folding
Sealing
Labling
Ethylene Oxide
Aeration
Sterile Shipping

Risk Management

Type Of Risk	Risk	Risk Intensity	Action to Minimize	Risk Intensity Post Action
User Risk	Risk of contamination as sterile field is compromised leaving chance for infection (Hazard)		• Implement strict sterile protocols • Provide proper training on how to assemble drapes to staff	
User Risk	Incorrect placement or application of attachment causing parts of arm to be exposed (Hazard)		• Provide proper training on how to assemble drapes to staff • Develop standardized procedures	
User Risk	Obstruction - Drape is incorrectly placed interfering with robot's movement (Harm)		• Conduct simulations to identify potential issues prior to surgery • Provide Proper Training	
Process Risk	Instability - Drapes glued incorrectly with plastic clips / magnets (Hazard)		• Train staff to use both magnet and twist ties	
Process Risk	Packaging seal break causes non sterility (Hazard)		• Ensure proper transportation / storage	
Design Risk	Material Failure - Drape tearing / degrading during use (Harm)		• Regular Quality Check • Use of Reinforced Material • Proper Storage	
Design Risk	Plastic Clips interfere with instrument gearbox (Harm)		• Extensive Design Reviews • Tolerance/Clearance Analysis	

Thanks!

Do you have any questions?