

# **Polymer Solution Casting:**

ENHANCED PERFORMANCE FROM A SINGLE-PIECE DEVICE

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## Enhanced Performance from a Single-Piece Device

#### 1.0 Introduction:

Nordson MEDICAL is the world's leading contract manufacturer of cardiopulmonary vascular cannulae, catheters, and specialized medical tubing for a wide range of clinical applications. The key is our Avalon polymer solution casting technology, which allows us to design and manufacture custom tubing with features not achievable by conventional extrusion, injection molding, or common layup techniques. Our technology results in feature rich devices with single-piece construction and seamless transitions.

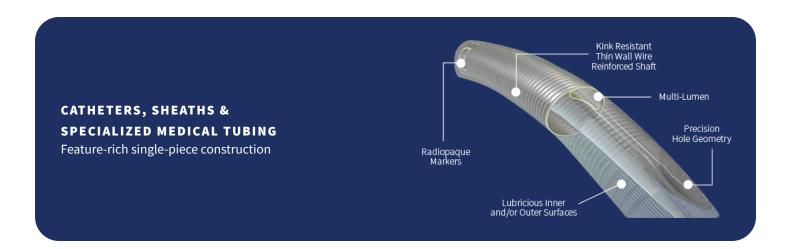
Cannula are used in cardiovascular and cardiopulmonary applications to create a continuous circuit for blood oxygenation and/or C02 removal. One cannula each can be used in arterial and venous access points, or a dual-lumen cannula can be used to create a circuit with a single device.

Polymer solution casting can achieve both flexibility and pushability along a catheter shaft by encapsulating multiple components and reinforcements such as braids, coils, and hypotubes within polymer layers. This technology lends itself to varying wall thicknesses and diameters along the length of the device in a single-piece construction while maintaining tight tolerances.

### 2.0 The Polymer Solution Casting Process:

#### 2.1 PROCESS:

A mandrel, rigid structure, or inner diameter mold is immersed in a tank of liquid plastic, or polymer solution, which forms a film of desired thickness on the mold. After the first layer cures, secondary features, such as coiled reinforcements, radio opaque markers, malleable wires, or any variety of embedded features can be added. Additional layers of polymer solution can be added around the reinforcements to achieve desired strength and profiles. The materials can be varied between layers or along the length of the cannula to achieve the desired strength and flexibility. The wall thicknesses and diameters can be varied along the length of the device in a single-piece construction, while maintaining tight tolerances. This allows for the creation of tapered features while maintaining a single-piece construction without bonded components.



#### 2.2 MATERIALS:

The primary materials used in Polymer Solution Casting are polyurethanes (PU) and polyvinyl chloride (PVC). We can also create custom blends to achieve different flexural properties.

#### 2.3 EMBEDDED COMPONENTS:

There are several types of embedded components that can be added after the first layer of polymer is applied to the mandrel or inner diameter mold. These include:

- 1. Baskets: Single-piece etched metal plates for punched holes.
- 2. Springs/Coils: Flat or round wire wound throughout the tube or small sections.
- 3. Hypotubes: Long metal tubes with or without micro-engineered features along the length.
- 4. Malleable Wires: Wires that hold their shape when bent and do not break. They are used to add a curve or bend into the cannula during the procedure. They can be bent as needed based on the application.
- 5. Radiopaque/Imaging Targets: Marker bands or dots can be added for visibility during the medical procedure.
- 6. Compatible with many metals and polymers.



## 3.0 Common Applications:

#### 3.1 CANNULA:

Cannulae are used in cardiopulmonary vascular applications to deliver or remove blood from the body. They are typically inserted through arteries, veins, or directly into the heart.

Depending on the application, the cannula can be configured to customer specifications. Typical operations include punching holes in reinforcements or cutting the tip to form a straight hole to allow blood to flow, bonding other features like injection molded connectors onto the back end, gluing on hard molded tips, or printing onto the cannula either pad print logos or depth indicators along the length.

#### 3.2 DELIVERY OR RETRIEVAL SHEATHS:

The same process can be applied to rigid structures including laser-cut hypotubes or other metallic structures such as nitinol components.

The hypotube functions in place of a coiled wire. Laser-cutting into the tube with a spiral pattern results in a slightly more rigid structure than a coil or a braid, and depending on the pattern cut into the hypotube, you can achieve directionality for flexibility in one direction, not all directions. Ultimately the device may only require one dip to add a layer 0.002" – 0.004" thick.

In applications such as sheaths, a PTFE liner can be used on the ID of the metallic structure to allow ease of delivery/retrieval without damaging other devices. The assembly process would be similar to a typical lay-up process to construct the liner, hypotube, then other marker-bands onto the PTFE. The polymer solution casting process allows for our materials to bond to the PTFE liner through the interdigitation in the metallic structures.

#### 3.3 THIN WEBBING ON ACTIVE GEOMETRIES:

The polymer solution casting process can be used to provide webbed or membrane features on active components such as nitinol baskets that allow for the final geometry to be a webbed structure. It can then be collapsed and delivered through a sheath returning to its final geometry upon delivery into the vasculature.

#### 4.0 Conclusion:

Nordson MEDICAL removes some of the barriers of extrusion technology for custom catheters, shafts and assemblies without compromising on product quality, features and functionality. Polymer solution casting results in thin single-piece construction, seamless transitions between diameters, high flow, and superior column strength for enhanced performance. Our technology provides a multitude of design options while streamlining manufacturing processes for improving manufacturability and reliability.

#### **About Nordson MEDICAL**

Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market.

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