Nordson MEDICAL

5 Characteristics to Consider

WHEN DESIGNING AN ENGINEERED SHAFT OR DELIVERY SYSTEM

5 Characteristics to Consider

When Designing an Engineered Shaft or Delivery System

Introduction:

The medical device industry is continuously advancing the standard of care for patients. As new procedures, devices, implants and therapeutics come to market, one of the primary objectives is to develop systems that are as minimally invasive as possible. Novel technologies require high-performance delivery systems today more than ever.

There are several factors to consider when designing reinforced catheters and delivery systems. Nordson MEDICAL has the capabilities, expertise, equipment, and systems to help guide the product development of complex delivery systems to ensure clinical performance and user requirements are consistently achieved.

Nordson MEDICAL utilizes engineering expertise along with a software platform, SimShaft™, to balance key characteristics to optimize the performance of delivery systems. Five key features to consider will be discussed in greater detail. These include:

1. Tensile Strength
2. Ovalization Resistance
3. Torsional Rigidity
4. Flexural Rigidity
5. Profile

Performance Feature #1:

TENSILE STRENGTH & COMPRESSION RESISTANCE

Many applications for implant delivery require the delivery system to resist very high tensile and compressive forces. It is common to utilize a push-pull mechanism to deploy an implant. As a result, tensile strength is needed to ensure the ID of the reinforced shaft avoids necking and allows for advancement of the implant. Compression strength is needed to avoid buckling of the shaft during deployment.

Nordson MEDICAL can maximize compression resistance and tensile strength of delivery systems by leveraging the following:

TRI-AXIAL REINFORCEMENT WITHIN THE BRAID:

All our braiders are set up to allow for a longitudinal wire or fiber to be woven within the braid. This allows for significant improvement in tensile resistance with additional positive impact on compression force.

MULTI-LAYER BRAIDING & COILING:

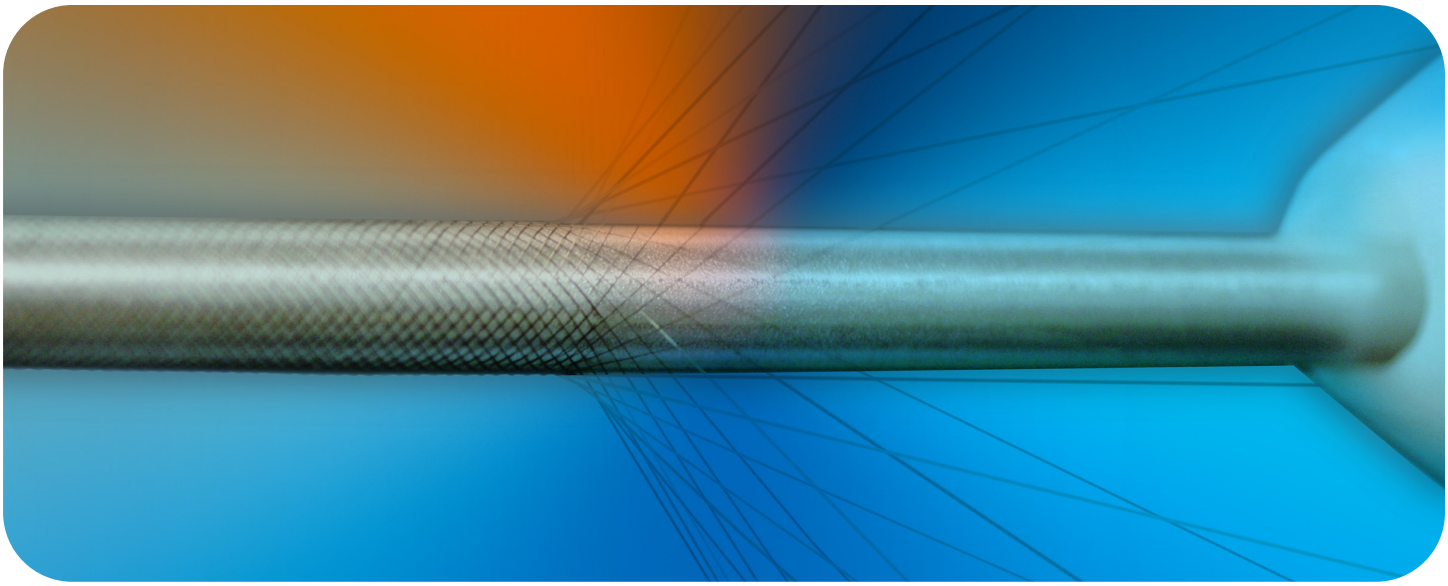
Utilizing our many coil winding capabilities along with our 16-, 32- and 48-carrier braiders, we can leverage multiple layers of reinforcement to significantly improve tensile resistance and compression force.

LASER-CUT HYPOTUBE ENCAPSULATION:

Nordson MEDICAL can laminate a laser-cut hypotube with cut features designed to optimize tensile strength and compression resistance between polymeric layers.

MULTI-FILAR BRAID REINFORCEMENT:

We are able to run multiple wires off of each bobbin. This capability allows us to increase tensile performance without compromising other performance features such as flexibility or torque.



Performance Feature #2:

OVALIZATION RESISTANCE

Ovalization resistance is a critical feature that needs to be considered when there are multiple components closely mated together within a delivery system. Often the forces to deploy an implant will be significantly increased if the system is not designed to minimize ovalization. There are several variables to be considered to avoid ovalization.

BRAID CONFIGURATION:

All of Nordson MEDICAL's braiders are capable of running variable pitch braid. This means the delivery system can have multiple segments that exhibit unique performance characteristics. For instance, the proximal end of the shaft could be reinforced with a very open braid pattern to increase the rigidity of the system while the distal end could have a very dense braid coverage profile to minimize ovalization and to increase flexibility.

COIL REINFORCEMENT:

Nordson MEDICAL has several different coil winders. Utilizing a coil reinforcement can significantly improve the ovalization resistance of a catheter. Coiling can be done continuously through the full length of the catheter, or in a discrete section where ovalization resistance is critical. Nordson MEDICAL also has point winding capabilities, which can be leveraged to eliminate the spring-back of the coil in discrete cases. This helps to ensure the coil is wound tightly over the substrate. Nordson MEDICAL can use variable-pitch coiling to optimize performance for various sections along the length of a single reinforced shaft.

WIRE/FIBER OPTIONS:

Several different reinforcement options exist to help achieve performance characteristics while minimizing impact to profile. Nordson MEDICAL can utilize round or flat wires, varying grades of SS, Tungsten or various types of fibers such as UHMWPE.

Performance Feature #3:

TORSIONAL RIGIDITY

Alignment and orientation of the delivery system can be of paramount importance for allowing the system to navigate to the target anatomy and to allow for a successful procedure. Nordson MEDICAL has a wide range of material options that can be utilized to optimize the torque response of a reinforced catheter in addition to the various reinforcement elements. We manufacture extrusions with various grades of Pebax, Nylon, Polyurethane, Polyester, Polyethylene, Polyimide and PEEK (in addition to several other less common materials).

In addition to selecting the right material for the outer jacket, it can be equally as beneficial to ensure the right liner is utilized. Nordson MEDICAL has a unique offering that includes liners with a strike layer of polymer to enable the reinforcement layer to be more fully encapsulated by the two layers of thermoplastic. This can significantly improve the torque response of the system.

WHAT IS A STRIKE LAYER?:

Using the film-cast process to apply a microthin layer of thermoplastic over an etched PTFE surface can optimize thermal or adhesive bonding. This thermoplastic "strike layer" adds up to 60% more bond strength between the etched PTFE liner and the catheter assembly, compared with bond strength without a strike layer.

Why does an etched PTFE liner with a thermoplastic strike layer produce such high thermal bond strength? In the film-cast process, the thermoplastic strike layer is applied to the etched PTFE surface as a liquid coating. This enables the material to flow completely into the microtexture of the surface, resulting in more surface area contact and hence a higher adhesive bond than an etched PTFE surface without a strike layer. Adding a film-cast strike layer to an extruded PTFE liner tube is not possible.

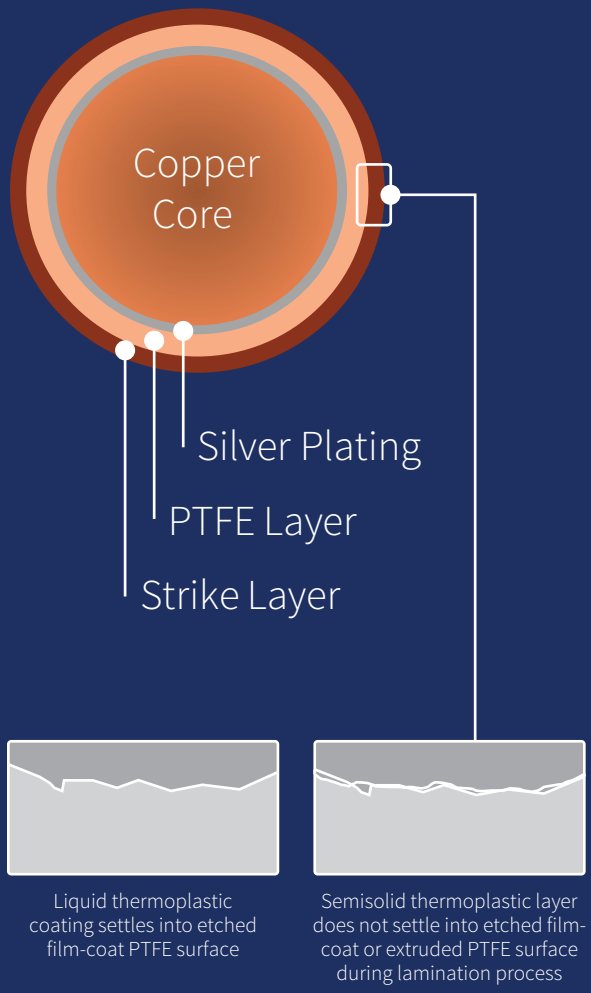


Fig. 1: A Comparison of Liquid vs. Semisolid Thermoplastic Adhesion During Lamination

By coupling material selection with reinforcement selection, Nordson MEDICAL is able to produce reinforced catheters that exhibit high degrees of torsional rigidity. However, torsional rigidity of a reinforced shaft can also have an inverse effect on flexural rigidity. Balancing these performance features is critical.

Performance Feature #4:

FLEXURAL RIGIDITY/FORCE TO FLEX

Flexural rigidity is a very important feature to consider when designing a delivery system to navigate through very tortuous anatomy. This also becomes extremely important when developing steerable/deflectable catheters. Nordson MEDICAL utilizes SimShaft™ software as a platform tool to enable our engineers to predict the impact of reinforcement and material selections. This allows for the balance of torsional rigidity and flexural rigidity to be evaluated early in the design process.

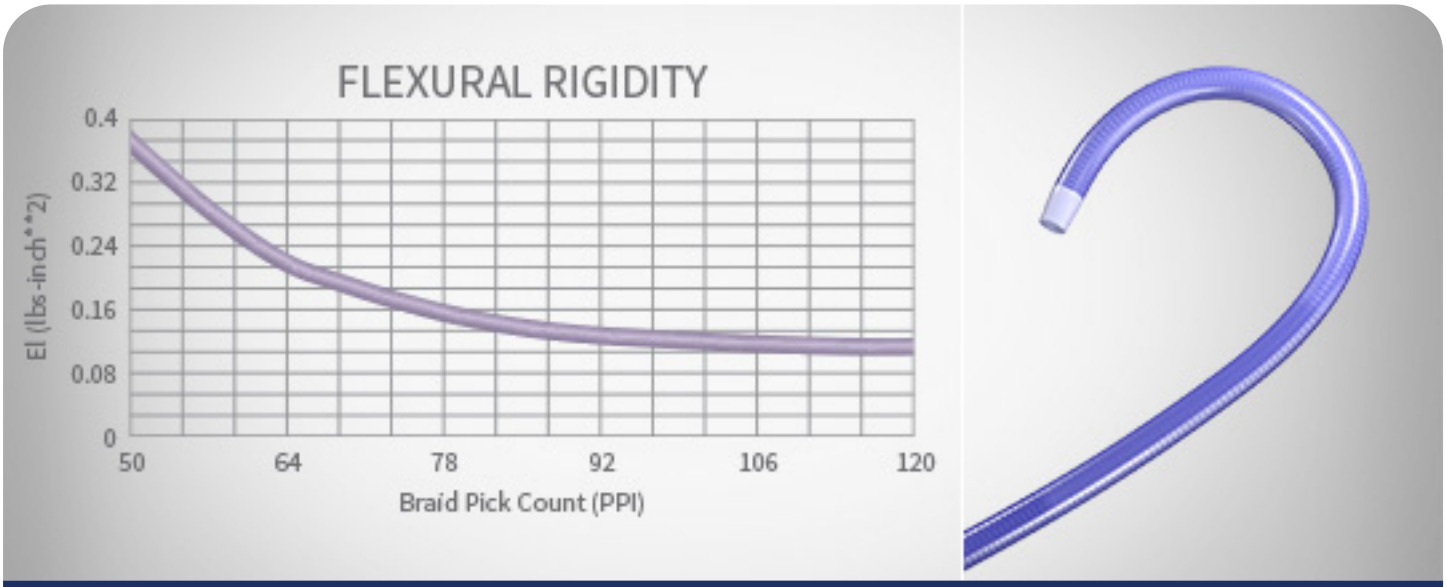


Fig. 2: SimShaft™ Simulated Shaft Performance Characteristics

Another factor that plays heavily into the force to flex is pull wire orientation. Nordson MEDICAL is able to embed pull wires in a number of different configurations that can be tailored to meet our customer's design intent. Pull wires can be aligned within a groove in the ID of the device, between the liner and the reinforcement layer, within an additional lumen in a multi-lumen configuration, over the reinforcement layer, or within the braid using a tri-axial approach. Additionally, we can design steerable systems with round pull wire assemblies, flat pull wire assemblies or even with fibers utilized as the pull mechanism. Nordson MEDICAL also manufactures film-cast PTFE liners which can be utilized to help reduce the force to flex for a system.

CONFIGURATIONS OF PULL WIRES FOR SINGLE STEERABLE ENGINEERED SHAFTS:

Performance Feature #5:

PROFILE

Minimally invasive systems continue to have more and more demanding requirements for minimizing profile. Nordson MEDICAL understands this demand and has put a high level of focus on pushing the boundaries of process capability for all of the components utilized in reinforced shaft construction. We have state-of-the-art capabilities for extrusion tolerances. Film-cast tubing exhibits wall thickness tolerances down to two tenths of a thousandth of an inch (0.0002”).

A LOOK AT THE FILM-CAST MANUFACTURING PROCESS: PTFE LINER TUBING

A liquid coating is created using water, PTFE particles or powder and a wetting-agent to keep the PTFE suspended in the water. This coating is applied to the outer surface of a silver-plated copper wire. Heat is applied to the coated wire, which causes the water and surfactant to vaporize, leaving only a thin coating of PTFE powder. Higher heat is then applied to sinter the individual particles of PTFE together into a homogenous film. Film-cast PTFE is supplied in straightened cut lengths or continuous spooled lengths. The wire on which the PTFE was fabricated can be left in place and used as a mandrel for the catheter assembly process. Once the mandrel is removed, ultrathin-wall PTFE tubing remains.

Nordson MEDICAL is able to push the limits on system profile by balancing all performance features in accordance with the design intent and clinical requirements.

Conclusion

When designing an engineered shaft, there are several factors to consider in order to meet clinical performance and user requirements. These include tensile strength, ovalization resistance, torsional rigidity, and flexural rigidity, all while maintaining a low profile.

Nordson MEDICAL is uniquely positioned to help you best balance these factors. Our vertically-integrated offering includes ultra-thin PTFE liner tubing, extrusions in a range of materials, and in-house design, development, and manufacturing. We will ensure that you get to market efficiently and with the highest quality.

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.

Visit Nordson MEDICAL at **nordsonmedical.com**

Nordson MEDICAL