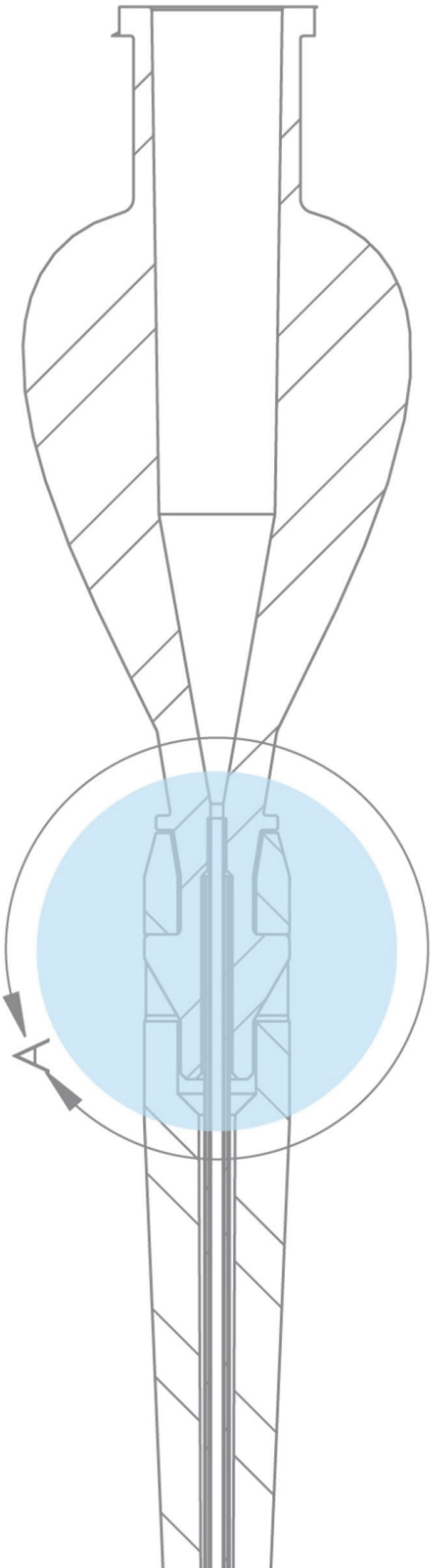
Heraeus

medevio

CRITICAL DESIGN CONSIDERATIONS IN DEVELOPMENT OF CATHETERS AND DELIVERY SYSTEMS



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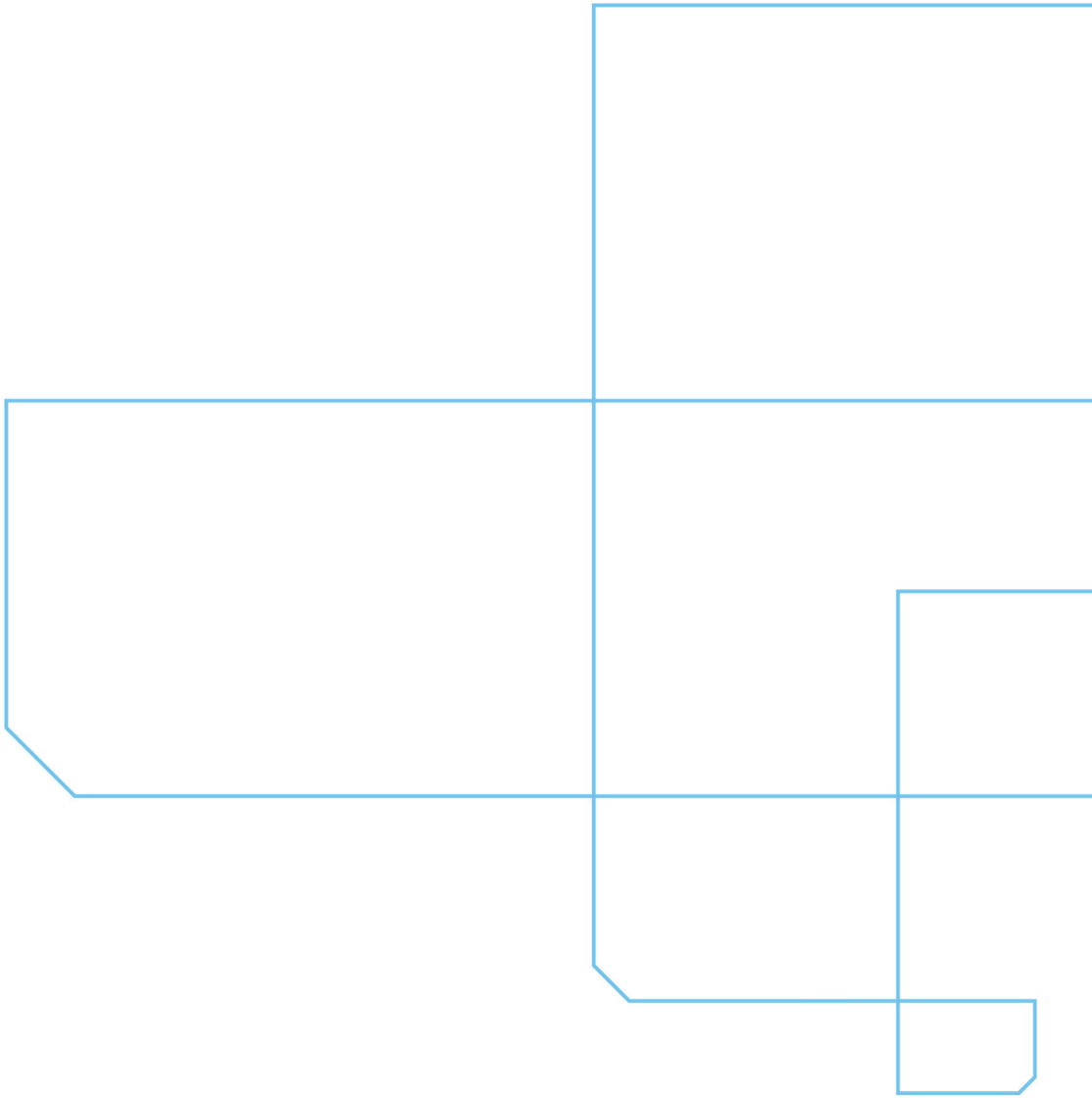

INTRODUCTION

Medical catheters are made with a variety of materials and designs to serve a broad range of functions in healthcare areas including cardiology, neurovascular, peripheral vascular, and more. Proper design and quality standards are critical to patient outcomes, and there are many elements to consider when starting a new project. This eBook will outline the five critical elements for optimal catheter design and how you can employ them.

Choosing an experienced partner who understands these crucial factors when outsourcing catheter development can determine the success and speed of your project. Learn how Heraeus Medevio can serve as an extension of your engineering team to bring high-quality products to market quickly.

CRITICAL DESIGN CONSIDERATIONS

When starting a new catheter development project, there are three critical factors to consider in the design phase that affect ease of introduction and placement. If your team will be outsourcing all or part of this project, evaluating vendors based on their expertise in these areas can produce better results and get your product to market faster.

LUBRICITY

Lubricity is critical in reducing friction while introducing and positioning the catheter, reducing procedure time, and improving patient outcomes.

The inner lumen is one area where lubricity is key. Typically ram extruded PTFE liners are used for this application. However, supply chain challenges have made it difficult to obtain PTFE liners. In this case, other materials can be leveraged, such as high durometer polymers with lubricious additives. With in-house extrusion capabilities, Heraeus Medevio can help to develop the catheter liner for optimal lubricity and long-term supply chain stability.

Catheter coatings can also support proper lubricity. The two primary coatings used are hydrophilic and hydrophobic. Hydrophobic coatings allow similar, more durable gliding properties in wet and dry conditions. However, Hydrophilic coatings typically have an overall superior lubricity with less friction and better performance. Heraeus Medevio offers hydrophobic, hydrophilic, and proprietary coatings to improve the performance of your device.

Heraeus Medevio co-developed a new coating, combining market-leading lubricity performance with highly effective anti-fouling technology. Using a proprietary technology inspired by surfaces in nature, this coating prevents the adhesion of bacteria and blood proteins without the potential side effects of pharmaceuticals or metal particles. The coating can be applied using existing manufacturing methods to a wide variety of commonly used medical device materials. Coating performance can be tuned to adapt to different applications within the interventional market. This technology is ideal where low device friction, biofilm formation prevention, and non-thrombotic responses are desired. The business model is adaptable to fit the unique needs of the customer.

FLEXIBILITY & PUSHABILITY

Designers should evaluate the intended placement of the catheter to determine how much flexibility will be required for a successful procedure. Flexibility must be balanced with pushability for optimal placement and positioning. Physicians have to exert enough force to overcome points of friction while advancing the catheter, and the catheter needs to be able to navigate through the vessels.

Often a catheter will require varying flexibility along the length. Many designs incorporate a stiffer main body for improved pushability and a more flexible and atraumatic distal tip for navigating tortuous anatomy. Optimization of catheter and introducer sheath performance can be achieved through:

- Combining flexibility and kink resistance while maintaining a round shape assuring an easier passage of inserted devices
- Selective braid and coil density
- Material and pattern
- Varying the durometer of the outer jacket material

TORQUE TRANSFER AND STEERABILITY

The amount of torque transfer determines the catheter's ability to apply twisting motions throughout its length, or it's steerability. When steering the catheter into place, buckling can occur due to the force applied or friction within the vessels.

Catheter design can ease this process by using materials with precise flexural modulus, tailored shaft reinforcement (coil or braid), and lubricious coatings. Also, Heraeus Medevio's patented torque coils provide excellent torque transmission, with 1:1 responsiveness, while maintaining maximum pushability and flexibility. Heraeus Medevio also supports the design of single or multi-direction steerable shafts and custom handles.

CASE STUDY: DURASHEATH INTRODUCER SHEATH

GOAL

Serve as an extension of your development and engineering teams to increase speed to market with market ready catheter solutions.

DURASHEATH OVERVIEW

Indications for Use

DuraSheath can be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

General Design Range

- 4 Fr – 8 Fr
- 15 cm, 45 cm, 60 cm, 90 cm, & 130 cm
- Shaped Tips and Sheaths for Specific Applications, including Hockey Stick, Renal Double Curve, Multi-Purpose, Left Internal Mammary Artery

Key Performance Attributes

- Superior kink resistance and non-ovaling due to a larger inner diameter
- Atraumatic Tip for smooth insertion
- Hydrophobic and Hydrophilic coatings for multiple applications

Clinical Testing and Regulatory

- Product is 510(k) cleared & CE Mark
- ROW registrations can be pursued upon request

Summary & Outcomes

Heraeus offers fully integrated solutions with capabilities across the full spectrum of design, product/process development and documentation, Regulatory Affairs, and high volume/low-cost manufacturing.

In a post-market surveillance study of DuraSheath conducted with interventional cardiologists, interventional radiologists, and vascular surgeons in 31 cases at nine facilities in the US and Europe, the following key findings were reported:

- The majority of cases were performed via femoral artery access, with mix of ipsilateral and contralateral approaches. Access via the jugular vein was also accomplished.
- A variety of therapies are supported, including angioplasty, atherectomy, thrombectomy, stenting, IVUS, and embolization.
- Target vessels treated during evaluations:
  - Iliac
  - Superficial femoral
  - Popliteal
  - Anterior tibial
  - Posterior tibial
  - Peroneal
  - Subclavian
  - Genicular
  - Gonadal vein
- In 97.6% of cases, physicians found DuraSheath performed better or equal to their preferred guide sheath.
- No serious adverse or reportable events occurred during testing.

PARTNERING WITH HERAEUS

Heraeus Medevio employs teams steeped in medical device expertise spanning contract design, development and large-scale manufacturing of advanced catheters and delivery systems. Partnering with Heraeus can drastically reduce your time to market with a full range of in-house product performance testing, assisting you in securing regulatory clearances and approvals.

The Heraeus team offers unique design capabilities and uses comprehensive, proprietary manufacturing processes to develop and manufacture a wide range of high-quality catheters. The following illustrates Heraeus' processes and technology expertise:

PROCESSES

- Extrusion
- Braiding / coiling
- Balloon blowing
- Laser welding / soldering
- Lamination / reflow
- Injection molding
- Over-molding
- Grinding
- Adhesive bonding
- Swaging / crimping
- Swiss machine
- Laser marking / pad printing
- 3D printing
- Tipping / flaring / tip shaping
- HPC coating
- Label printing
- Sterile packaging
- Sterilization

TECHNOLOGIES

- Ablation Catheters
- Aspiration Catheters
- Balloon Occlusion Catheters
- Electrophysiology Diagnostic and Mapping Catheters
- Guide Catheters
- Micro-catheters (Coronary chronic total occlusion (CTO), Peripheral, Neurovascular, Oncology)
- Support Catheters
- Steerable Catheters
- Implant Delivery Systems and Introducers for:
    - o Transcatheter aortic valve replacement (TAVR)
    - o Left atrial appendage (LAA) Stent Delivery Systems

TESTING & REGULATORY SUPPORT

REGULATORY SERVICES

- FDA device clearance (510(k), PMA, etc.)
- CE Conformity Assessment Procedures (technical file preparation, post market activities, etc.)
- Support in clinical trial approvals, clinical trial support and set-up and maintenance of quality management systems

PERFORMANCE TESTING

Creation and execution of performance test plans to support development activities and regulatory submissions are determined for each device manufactured by Heraeus Medevio.

Testing is performed according to ISO, EN, DIN, ASTM and applicable regulatory standards, including FDA requirements (e.g., 510(k) submissions, IDE applications, etc.). Testing pathway is supported by in-house Subject Matter Experts for various areas such as:

- Biocompatibility
- Hazardous Substances
- Particulate Matter
- Clinical Evaluations
- Sterilization method
- Usability
- Package Integrity
- Risk Management
- Acitve Devices

Additional performance testing includes:
- Torque-ability (1 to 1 rotation through tortuous anatomy)
- Simulated use/trackability
- Rail support (guidewires)
- Tip shape retention
- Lubricity and durability of coatings
- Prolapse resistance/tip resiliency

LET'S CONNECT

Schedule your free consultation today to go over your concepts and requirements and create a plan tailored to your project.