

CRITICAL DESIGN
CONSIDERATIONS IN
THE DEVELOPMENT
OF CATHETERS
AND DELIVERY
SYSTEMS

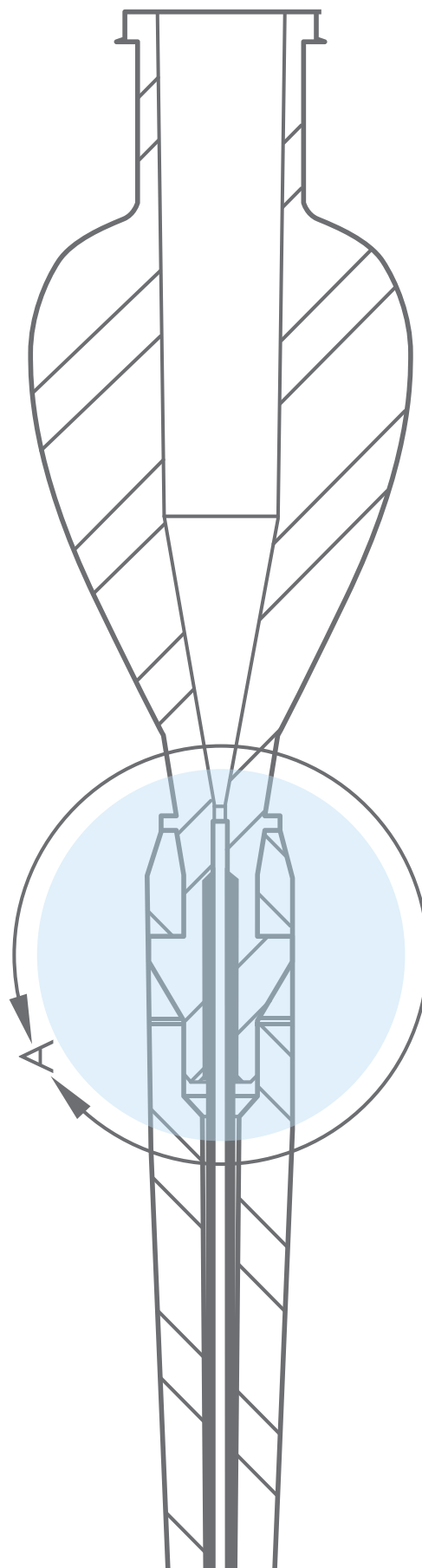
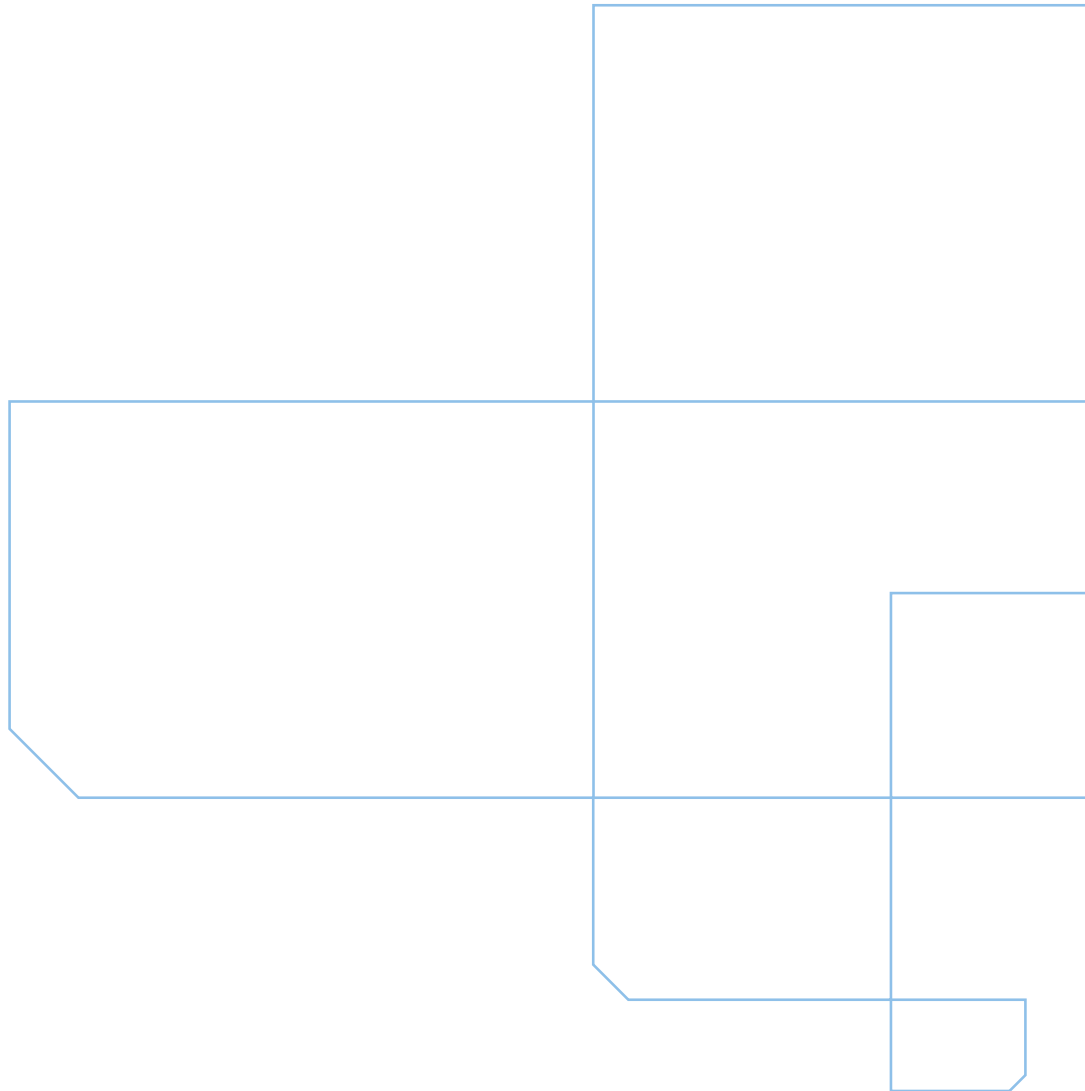


TABLE OF CONTENTS

Introduction	2
Critical Design Considerations	3
Lubricity	3
Flexibility and Pushability	4
Torque Transfer and Steerability	4
Partnering with Heraeus Medevio	5
Design + Development	6
Complex Transfers	7
Case Study	8
Testing + Regulatory Support	9



INTRODUCTION

Medical catheters are made with a variety of materials and designs to serve a broad range of functions in healthcare areas, including electrophysiology, interventional cardiology, neurovascular, peripheral vascular, structural heart, and more. Proper design and world-class quality standards are critical to patient outcomes, and there are many elements to consider when starting a new project.

Choosing an experienced partner who understands these crucial design factors when outsourcing catheter development is critical to the success and speed of your project. Learn how Heraeus Medevio's end-to-end support and expertise can help you bring high-quality catheters 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 is 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 AND 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 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.



PARTNERING WITH HERAEUS MEDEVIO

There are many additional factors to consider when choosing a design, development, and manufacturing partner. Heraeus Medevio understands this and employs in-house subject matter experts to help its customers bring world-class catheters to market faster with:

- End-to-end design, development, and large-scale manufacturing support
- Innovative solutions tailored to your needs, including in-house product performance testing, regulatory clearance expertise, and more
- A vertically integrated supply chain, enabling simplification and risk reduction
- Precious metals and coatings backward integration
- Expertise in scaling and transferring
- A commitment to forward investment in the manufacturing footprint

As a vertically integrated CDMO partner, Heraeus Medevio offers support from extrusions and molded components to precious and non-metals components, all the way through completed assemblies and finished devices.

DEVICES

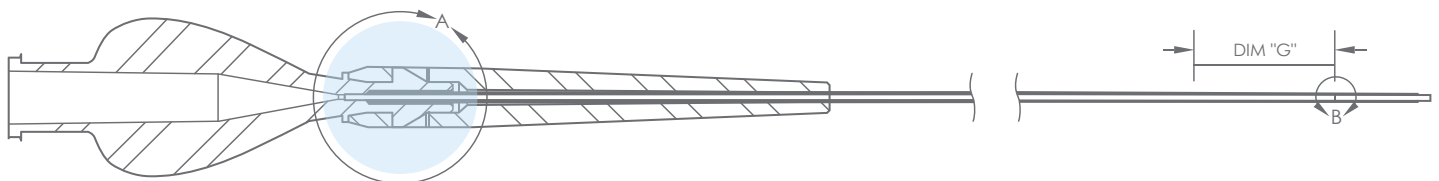
- Introducer sheaths
- Ablation catheters
- Aspiration catheters
- Balloon catheters
- Guide catheters
- Microcatheters
- Support catheters
- Steerable catheters
- Thrombectomy catheters
- Implant delivery systems and introducers for:
 - Transcatheter Aortic Valve Replacement (TAVR)
 - Left Atrial Appendage (LAA) implant delivery system

VERTICAL INTEGRATION

- Transseptal needles
- Marker bands
- Pull-wire assemblies
- Micromachined components
- Coils / torque coils
- Laser-cut hypotubes
- Complex catheter tooling
- Custom handles
- Balloons (compliant, semi-compliant, non-compliant)
- Proprietary coatings (hydrophilic, hydrophobic, Amplicat®)
- Hemostasis valves
- Finished goods packaging

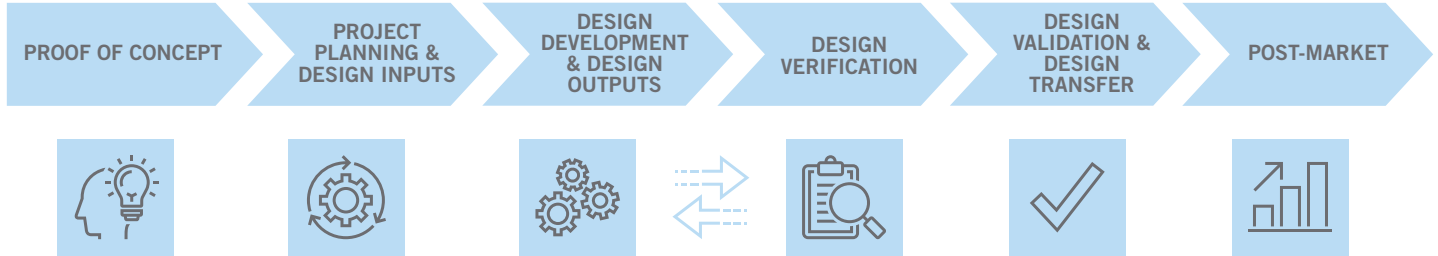
PROCESSES

- Complex extrusions
- Braiding / coiling
- Insert molding + overmolding
- Grinding
- Tipping / flaring / tip shaping
- Balloon blowing (compliant, semi, and non)
- Lamination / reflow
- Crimping / swaging
- Adhesive bonding
- Soldering
- Welding (laser, plasma, resistance, ultrasonic)
- Swiss machining
- Laser cutting
- Sensor integration
- Laser marking / pad printing
- Complex handle assembly



DESIGN + DEVELOPMENT

With an end-to-end design and development process and tailored solutions, you can leverage Heraeus Medevio's support based on your unique needs.



RAPID PROTOTYPING, DESIGN, AND CONCEPT CREATION

Successfully bringing a product to market and manufacturing it at scale starts at the very beginning with design. This must also be kept in mind throughout the development process to ensure long-term success.

CONCEPT DESIGN	DESIGN FOR ASSEMBLY	DESIGN FOR MANUFACTURABILITY
<ul style="list-style-type: none"> • Optimize design for part count and assembly • Design to fulfill application requirements 	<ul style="list-style-type: none"> • Product simplification • Minimize number of parts • Optimize for assembly 	<ul style="list-style-type: none"> • Optimize design and processes for product readiness • Customized for Heraeus Medevio serial manufacturing • Design for supply chain

Heraeus Medevio's Rapid Concept Creation (RCC) team brings customers' market-ready device visions to life with expertise in the early concept phase.



Mario Heintze, Rapid Concept Creation Manager, states, "Our team is committed to understanding our customers' needs and developing concepts into high-performing products. We quickly turn ideas into concepts and prototypes to create an initial Proof of Concept (PoC), laying the foundation for the next phases of long-term development projects."

With a dedicated RCC team, customers can overcome complex challenges by leveraging its breadth of experience and key capabilities:

- Initial concept creation of complex catheter systems, handle, and implant designs
- Improvement of concepts, patents, and ideas
- Cooperative collaboration and further development of existing concepts
- Prototype development and manufacturing
- Simulated use testing and iterative concept finding
- Fast and reactive processing through vertical integration (internal capabilities)
- Fast turn-around times through internal material stock
- Rapid material procurement through strong external supplier network

COMPLEX TRANSFERS

Complex transfers have become part of Heraeus Medevio's daily business and are executed based on a proven formal methodology, which is tailored based on the customers' needs. As the demand for expertise in this area increases, the team provides innovative solutions for several types, including:

- Lift and shifts, offering cost-effective manufacturing excellence
- New product transfers, providing R&D expertise and manufacturing excellence
- Transfers for process improvements, such as when a product is acquired and requires DFM to achieve scaled pricing and volume targets

In 2024, Heraeus Medevio ran 87 total transfer projects simultaneously across its global Manufacturing Centers of Excellence, spanning from early planning to ramp-up stages.

To manage these projects and best serve its customers, Heraeus Medevio also has a global Quality Management System and dedicated NPI team, who ensure successful transfers with a global transfer process:



CASE STUDY

CHALLENGE

An OEM partner acquired a kitting and sterilized therapy catheter with a braided introducer. Heraeus Medevio was asked to develop the manufacturing line with critical process improvements to meet 400k units/year in production.

Key Manufacturing Processes:

- Injection molding
- Braiding
- Catheter reflow
- Catheter tipping
- Shape forming
- Coating
- Port-hole cutting
- HPC valve
- Laser cutting
- Soldering
- Automated adhesive bonding
- Complex handle assembly
- Pouch sealing
- Sterilization

SOLUTION

A project team was assigned between the Minneapolis R+D and Costa Rica manufacturing sites. Following the Heraeus Medevio Global Transfer Process, they immediately made progress on the line setup and process improvements.

OUTCOME

The OEM partner's ramp volumes increased mid-project due to soaring market demand. The project team successfully executed to efficiently ramp and meet the target timeline.

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 setup 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
- Active 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 discuss your concepts and requirements with our experts and create a plan tailored to your project.