HYPOTUBE AND MICRO-COMPONENT SOLUTIONS

www.freudenbergmedical.com

FREUDENBERG MEDICAL

Freudenberg Medical partners with the world's top medical device companies to provide innovative design and manufacturing solutions, specializing in metal hypotube and micro components for catheter applications.

Our high precision and technologically advanced hypotubes, assemblies and micro-component solutions support our customers in the manufacturing of catheters, stent delivery systems, structural heart delivery systems and other minimally invasive devices used in diagnostic and therapeutic interventions.

We assist our customers from new product development through to full-scale manufacturing, delivering advanced materials and process manufacturing solutions, supported by deep expertise and knowledge of hypotube and micro-component products.

CAPABILITIES

- Cutting
  - Straight
  - Skive
  - Spiral
- Laser Marking
- PTFE & non-PTFE Coating
- Electrical Discharge Machining (EDM)
- Electrical Chemical Machining (ECM)
- Centreless Grinding
- Specialty Needle Grinding
- Laser Welding
- Passivation
- Electropolishing
- Overmoulding
- Assembly
- Cleaning
- Printing

MATERIALS

- Stainless Steel
- Nitinol
- Other Alloys

Do you have any questions?

Freudenberg Medical
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FREUDENBERG MEDICAL

CAMBUS COAT™ TECHNOLOGY

The Cambus Coat™ Technology applicator system was created by Freudenberg Medical Engineers to provide substantial competitive advantages over traditional coating methods such as dipping and spraying.

CAMBUS COAT™

The Cambus Coat™ system was inspired by the work of Leonardo Da Vinci (1452-1519) who was a renowned artist, inventor, engineer and one of the first people to quantitatively study and measure friction.

The precision design of the Cambus Coat™ process eliminates the high wastage associated with traditional coating methods, every cubic centimeter of coating material is used on the product, unlike other systems.

The Cambus Coat™ system uses 70% less labour than traditional coating methods. These savings in labour costs, coupled with efficient use of energy in the curing process ensures that Freudenberg Medical remains very cost competitive in comparison to other coating methods.

In addition to being PFOA free, hypotubes and wires finished using the Cambus Coat™ system present superior quality and safety advantages over other application methods. Components coated with Cambus Coat's™ proprietary application technology exhibit excellent adhesion and resistance to flaking under the most demanding performance tests.

The Cambus Coat™ system delivers its superior performance and efficiency advantages to all coatings applied by Freudenberg Medical including our high-performance, PTFE enhanced Mμ-Coat™ and Rho-Coat™, an ultra-smooth coating solution offering high lubricity in conjunction with a smooth glossy aesthetic feel.

ENVIRONMENTALLY SOUND

Surrounded by the natural, un-spoilt beauty of Connemara in County Galway, Ireland where Freudenberg Medical is based, all operations are designed and conducted under the strictest environmental controls.

Our location, our culture and our awareness of the delicate natural environment in which we operate have helped to inspire us to create the Cambus Coat™ system. It has become recognised, by our peers, as one of the most environmentally friendly coating processes available to our section of the medical device industry.

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FREUDENBERG MEDICAL

HYPOTUBE COATING SOLUTIONS

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FREUDENBERG MEDICAL

Mμ-COAT™

Confidently Consistent

Mμ-Coat™ is a high-performance PTFE-enhanced coating solution for hypotube and guidewire-based catheter shafts. Mμ-Coat™ is applied using Freudenberg Medical's state-of-the-art proprietary application technology – Cambus Coat™ – an environmentally friendly coating process.

When Mμ-Coat™ is cured on the substrate metal, it forms a lubricious and non-stick matrix which is ideal for coating hypotube-based products in the creation of catheter shafts. Mμ-Coat™ is applied to catheter shaft solutions for cardiovascular and neurovascular device applications.

BENEFITS OF Mμ-COAT™

- Conformal coating
- Low coefficient of friction – improves hypotube trackability
- Excellent adhesion
- Tight tolerances
- Perfluorooctanoic Acid (PFOA) - free
- Passed stringent biocompatibility testing in accordance with ISO standard 10993-1 for short-term contact of less than 24 hours with human body,
  - Cytotoxicity
  - Hemocompatibility: direct & In-direct contact

BENEFITS OF CAMBUS COAT™

Superior performance & cost efficiency

- Virtually 'zero' material wasted in the process
- Highly automated process resulting in significantly less handling than traditional coating methods
- Efficient use of energy

Product consistency

- Comparative & destructive tests are carried out to ensure reliability

Environmentally friendly coating technology

- Does not contain Perfluorooctanoic Acid, the materials are 'PFOA – free'

TECHNICAL SPECIFICATIONS

Tube/Wire Diameter Range	Coating Thickness	Base Materials	Coating Colours
OD: 0.012"~0.080" or 0.30mm~2.00mm	Average coating thickness of 0.0002" (0.005mm) per side is consistently achieved Typical range: 0.0002"–0.0009" (0.005 µm to 0.023 µm)	Mμ-Coat™ can be applied to all major metal catheter shaft substrates including: • Stainless Steel • Other alloys on request	Black Blue Green on request

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FREUDENBERG MEDICAL

Rho-COAT™

Smooth and Refined

Rho-Coat™ is a PTFE-free coating material for hypotube and guidewire-based catheters. It is applied using our state-of-the-art proprietary application technology – Cambus Coat™.

Rho-Coat™ provides an ultra-smooth coating with optimum lubricity for easy insertion and removal of the wire or catheter. Rho-Coat™ produces products with a finish similar in performance to a polymer jacket.

Rho-Coat™ can be applied to hypotubes in the creation of coated catheter shafts deployed in cardiovascular and neurovascular applications.

BENEFITS OF RHO-COAT™

- Ultra-smooth
- High lubricity
- Conformal coating
- Excellent adhesion
- Tight tolerances
- PTFE & PFOA-free
- Passes stringent biocompatibility testing in accordance with ISO standard 10993-1 for short-term contact of less than 24 hours with human body:
  - Cytotoxicity
  - Hemocompatibility: Direct & In-direct contact

BENEFITS OF CAMBUS COAT™

Superior performance & cost efficiency

- Virtually 'zero' material wasted in the process
- Highly automated process resulting in significantly less handling than traditional coating methods
- Efficient use of energy

Product consistency

- Comparative & destructive tests are carried out to ensure reliability

Environmentally friendly coating technology

- Does not contain Perfluorooctanoic Acid, the materials are 'PFOA – free'

TECHNICAL SPECIFICATIONS

Tube/Wire Diameter Range	Coating Thickness	Base Materials	Coating Colours
OD: 0.012"~0.080" or 0.30mm~2.00mm	Average coating thickness of 0.0002" (0.005mm) per side is consistently achieved Typical range: 0.0002"–0.0009" (0.005 µm to 0.023 µm)	Rho-Coat™ can be applied to all major metal catheter shaft substrates including: • Stainless Steel • Other alloys on request	Black

Do you have any questions?

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E-PRO®

The Strength to Deliver

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FREUDENBERG MEDICAL

E-Pro® is an advanced metallurgical hypotube solution offering superior kink resistance over traditional '304 stainless steel', making navigation through tortuous anatomies safer. In thin-walled tube applications, E-Pro's® high kink resistance allows for larger internal diameters thus delivering reduced deflation times leading to a better product.

E-PRO® BENEFITS

Optimize For Procedure Safety

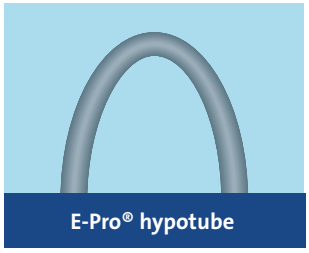
- Potential to reduce procedure time, contributing to patient safety
- High kink resistance reduces risk of failure
- Reduced inflation/deflation times

Improved Confidence

- Increased kink resistance makes navigation through tortuous anatomies safer and easier
- Allows physicians to use higher forces to deliver solution

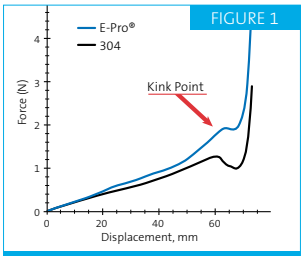
Technical Data

- Medical grade stainless steel hypotube
- Greater kink resistance without compromising pushability, trackability and torqueability
- Enhanced kink resistance enables:
  – Increase in inner diameter for better inflation/deflation time
  – Thinner walls to maximise trackability
  – Greater push and torque forces for better manoeuvrability
- More flexibility improves the 'feel' of the hypotube
- Improved package set properties



Higher kink resistance allows for an increase in inner diameter improving inflation/deflation time.

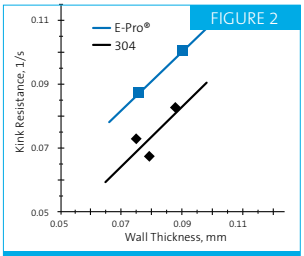
FIGURE 1



Force & displacement of E-Pro® material & conventional 304 material. The hypotubes had similar WT/OD ratios and comparable yield strengths.

E-Pro® has higher kink point than 304 material allowing physicians to confidently use greater push and torque forces to progress the catheter.

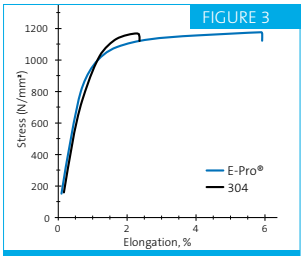
FIGURE 2



Kink resistance as a function of wall thickness. Wall thickness effects pushability, trackability, torqueability and kink resistance.

The kink space, s, is the distance between the plates when the force drops significantly. 1/s represents the resistance of the hypotube material kinking.

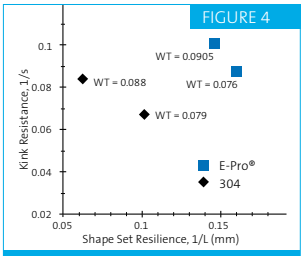
FIGURE 3



Tensile strength & elongation of E-Pro® material & conventional 304 material. The hypotubes had similar WT/OD ratios and comparable yield strengths.

E-Pro® exhibits higher elongation after yielding, preventing failure for longer so that the hypotube can be removed without undue trauma to the patient.

FIGURE 4



Shape set resilience & kink resistance of E-Pro® & conventional 304 material. L is the distance between a rule and the highest point of an arched hypotube after being stored for 2 hours in a 6 inch diameter coil.

Improved resilience means E-Pro® is less likely to retain shape of storage coil than 304 material.

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FREUDENBERG MEDICAL

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STANDARD & CUSTOM
OVER-MOULDED HUBS

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FREUDENBERG
MEDICAL

Freudenberg Medical can accelerate your next product launch with our cost efficient standard and customisable over-moulded hub and strain relief. We offer an ergonomically designed, ISO compliant, high-pressure hub in a variety of colours and materials which can incorporate your company logo. If a customised shape design is required, our modular mould designs allow for quick turnaround of your finished parts at a fraction of the cost and time required to build dedicated mould tooling.

TECHNICAL SPECIFICATIONS

- Rapid exchange style hub and strain relief designs
- ISO 594-1, ISO 594-2 & ISO 80369 compliant
- High burst pressure capabilities (>20atm)
- Ergonomically styled
- Resin may be as specified by the customer
- Materials can be selected for required sterilisation method
- Range of colours available
- Company logo can be incorporated
- Range of hypotube ID/OD's accommodated
- Strain relief design can be altered to the customer's specifications
- Can be designed to fit specific hooping/packaging requirements

COMMERCIAL ADVANTAGES

- Rapid time to market (6-8 weeks)
- Low cost of entry
- Designed to match the customer's hypotube ID/OD dimensions
- Multiple strain relief design options available
- All production volumes catered for
- Product identity and branding opportunities
- Flexible aesthetic design options

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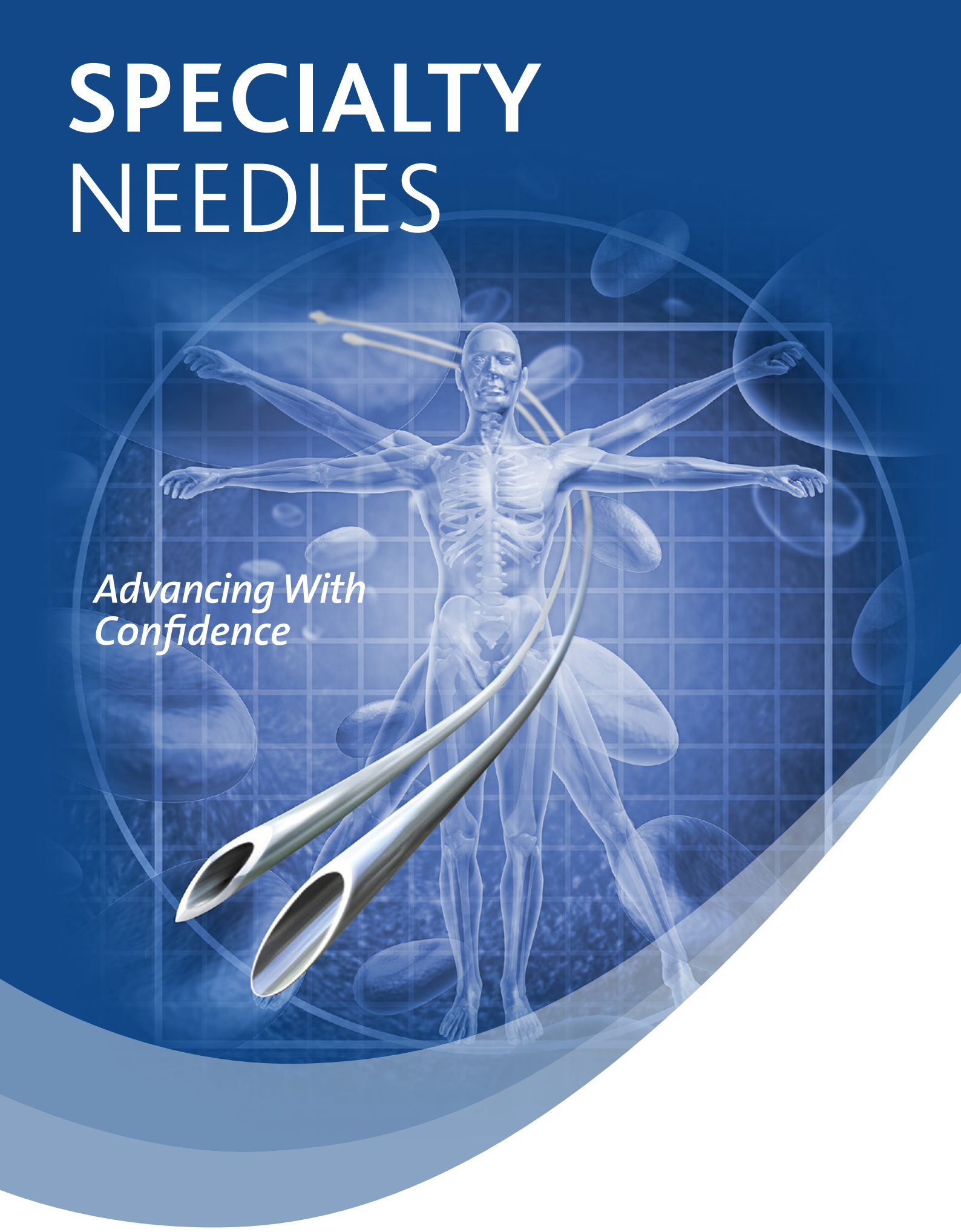
SPECIALTY NEEDLES



Advancing With Confidence

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FREUDENBERG MEDICAL

Freudenberg Medical offers high precision needle assemblies manufactured to customer specification with profiles ranging from standard needle points to complex multi-faceted designs. Our specialty needle capabilities include needle point, cannula and stylet design and manufacture, needle shaft marking, needle shaping, echogenic enhancement and hub mechanisms.

To enhance performance, all tips are precision ground for uniform sharpness. For the most demanding clinical applications, our advanced manufacturing technologies deliver sophisticated point geometries and custom features.

TECHNICAL SPECIFICATIONS

Diameter
From 27Ga to 7Ga - 0.0162" (0.413mm) to 0.180" (4.572mm)

Length
Up to 1800mm

Wall Thickness
Regular wall / thin wall / ultra-thin wall

Material
Medical grade Stainless Steel
Advanced alloys and exotic metals

Needle Points
Wide range of bevel types available; single bevel, multi-bevel & multi-facet needle points.

Designs include; Lancet, Menghini, Whitacre, Cournand, Backcut Bevel, Bias Grind, Diamond Point, Pencil Point, Razor Edge, Pro Point, Trocar, Sharkcore or custom designs.

Echogenic Enhancement
Echogenic enhancement technologies available to enhance the visibility of needles used under ultrasound guidance.

Shaft Marking
Needle shaft markers assist the physician in navigation and placement of the device. We offer a range of marker solutions for needle shafts from laser and mechanical processing to surface roughening.

Hub Technologies
Freudenberg Medical has a range of capabilities to design, manufacture, assemble and test proximal needle hub components. Our hub offerings are compliant with ISO 594-1, ISO 954-2 and ISO 80369.

Hub Offerings:
- Injection moulded components
- Welded / soldered micro machined metal components

Quality
All of our manufacturing processes are fully accredited to ISO13485.

Freudenberg Medical has a range of test capabilities for our specialty needle production which include; leak testing, tensile testing and puncture force testing.

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NAVIGATE®

Steering you through the design and development process

Seafaring has shaped our world and the history of mankind like no other field of exploration. From the discovery of the Americas to navigating the North West Passage and races at speed across the world's oceans, each have pushed the limits of human and engineering capabilities. It is this same vision, this desire to conquer the unknown that drives the Freudenberg Medical Navigate® team. With our passion, commitment and expertise we will help you steer a course that will open a world of possibilities.

WHAT IS NAVIGATE®?

Navigate® is a unique Freudenberg Medical programme to drive innovation and speed through our customers' design process. Our team of professional medical device engineers have a proven track record in charting the course of new product development through the most testing and extreme conditions.

We invite you to explore this technology and the expertise housed in our Navigate® centre to support and accelerate your next product launch.

OUR LOCATION

Situated in Galway, Ireland, on Europe's most westerly shoreline we are inspired by a proud history in maritime achievement. We operate from a state of the art product research and development laboratory equipped with dedicated manufacturing and test equipment.

OUR SERVICES

- Design for Manufacture & Assembly (DFMA)
- Materials analysis
- Advanced materials selection & development
- Fluoropolymer coatings development
- Project management
- Project costing
- Failure Mode & Effect Analysis (FMEA)
- Dedicated manufacturing & test equipment for prototyping
- Process development & validation
- Biocompatibility testing

HOW THE NAVIGATE® DESIGN & DEVELOPMENT PROCESS WORKS

Idea Generation

We begin by 'laying-out' the ideas which have been explored. This evaluation is led by our engineering team and often involves face-to-face meetings with our customers to gain a complete understanding of the project. Ideas that have failed are identified along with the reasons for their failure. Some ideas may be noted for their contribution to the project and retained for further investigation.

Building on the advances already made, our team begins the process of developing new ideas. Drawing on their extensive experience in the field of medical device engineering our team will develop credible alternatives. Working closely with our customers through this research and testing phase we ensure there is a good flow of information in both directions. The protection of our customers' intellectual property is a high priority, and we always endeavour to steer away from areas of sensitivity.

Concept Testing

Ideas will be assessed on their merits and potential to be successfully advanced through each development stage right through to launch. Prototypes may be produced at this stage to test basic functionality for some deliverables. We encourage our customers to visit our facility at this point so that they can be on hand to make minor adjustments to the concept ideas. This is normally carried out in a day with the support of our Navigate® team.

Prototype Development

Following rigorous testing, we typically will have uncovered several ideas that we can now progress through to the next development phases. Before we proceed further, we include our operations teams in the Navigate® process to assess the manufacturability of the product ideas. Their engagement at an early stage ensures that there will be a smooth transition to manufacturing later, saving time and cost. All equipment used at this point is mirrored in production so that validations will be able to rely on data captured at the prototype stage.

Design for Manufacture

The input of our operations team ensures that product solutions can be manufactured efficiently and effectively at scale. Navigate® team members have all worked in operations and understand what can and cannot be done. We employ the simple philosophy "to generate the best possible methods in the least overall time." This stage can be cyclical and may require compromises to develop the most cost-effective solutions.

Validation

Once the method of manufacture has been agreed with our customer input, we continue the validation of the product through our processes. Our internal risk analysis and validation procedures will identify any areas of concern that are then addressed with input from the customer.

The timeline here is shortened due to the earlier evaluative work. In addition, the equipment used has been previously validated and therefore much of the framework and risk analysis has been undertaken.

Launch

All steps in this process can be treated as stand-alone services or a complete project deliverable from the Navigate® Team. The output from the previous steps can be a comprehensive report for a regulatory body right through to a completed assembly. With an unwavering commitment to both the project and our customers, we steer a course through all challenges and strive to deliver results that exceed our customer's expectations.

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