Cambus Medical™

Our Dedication Shows

A Freudenberg Medical Joint Venture Company

Hypotube and Micro-component Solutions

CAPABILITIES

- Cutting
  - Straight
  - Skive
  - Spiral
- Laser Marking
- 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

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Baile an tSagairt, Spiddal Industrial Estate, Spiddal, County Galway, Ireland

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Cambus Coat™

"Simplicity is the ultimate sophistication"
– Leonardo Da Vinci

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Cambus Coat™

The Cambus Coat™ applicator system was created by Cambus 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 Cambus 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 Cambus Medical including our high-performance, PTFE enhanced Mμ-Coat and our newest coating – 'Rho Coat' which is an ultra smooth coating 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 Cambus Medical is based. All operations carried out by Cambus Medical are designed and operated 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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Mμ-Coat™

Confidently Consistent

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Mμ-Coat™

Mμ-Coat™ is a high performance PTFE enhanced coating material which is applied using our state of the art proprietary application technology – Cambus Coat™. When cured on the substrate, it forms a lubricious and non-stick matrix which is ideal for coating guidewires and hypotube-based products.

Benefits of Cambus Coat™

Superior Performance & Cost Efficient
- Virtually 'Zero' material wasted in the process
- Highly automated 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'

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

Technical Specifications

Coating
- Mμ-Coat™ (PFOA-free)

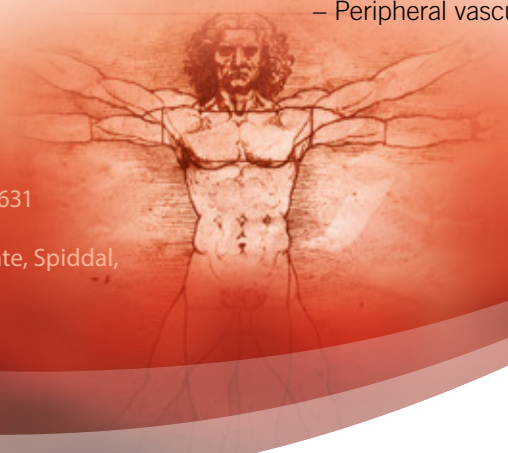
Base Materials
- Stainless Steel
- Nitinol (limitations apply)
- Other alloys on request

Tube/Wire Diameter Range
- OD: 0.010"~0.250" or 0.25mm~6.50mm

Coating Thickness
- 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)

Coating Colours
- Black
- Blue
- Green on request

Applications
- Guidewires
- Marker bands
- Coated Hypotube shafts for
  – Cardiovascular devices
  – Neurovascular devices
  – Peripheral vascular devices



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Rho-Coat™

Smooth and Refined

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Rho-Coat™

Rho-Coat™ is a PTFE-free coating material for guidewires and hypotube-based catheters. It is applied using our state of the art proprietary application technology – Cambus Coat™. Rho-Coat™ provides an ultra smooth coating with high 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.

Benefits of Cambus Coat™

Superior Performance & Cost Efficient
- Virtually 'Zero' material wasted in the process
- Highly automated 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'

Benefits of Rho-Coat™

- Ultra Smooth
- High Lubricity
- Conformal Coating
- Excellent Adhesion
- Tight Tolerances
- 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

Technical Specifications

Coating
- Rho-Coat™ (PTFE & PFOA free)

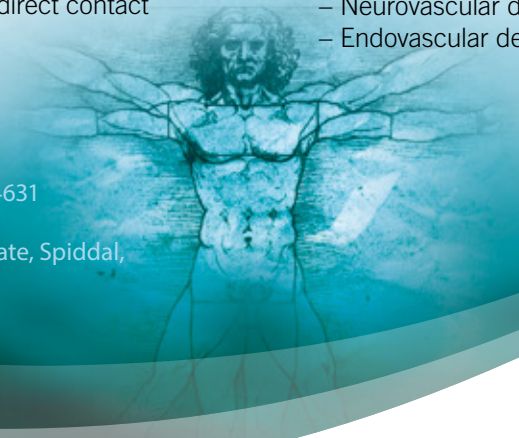
Base Materials
- Stainless Steel
- Nitinol (limitations apply)
- Other alloys on request

Tube/Wire Diameter Range
- OD: 0.010" ~ 0.255" or 0.254mm ~ 6.50mm

Coating Thickness
- Average coating thickness of 0.0002" (0.005mm) per side is consistently achieved
- Typical Range: 0.0002" – 0.0009" (0.005mm to 0.023 mm)

Coating Colours
- Black
- Blue
- Green on request

Applications
- Guidewires
- Marker bands
- Coated Hypotube shafts for
  – Cardiovascular devices
  – Neurovascular devices
  – Endovascular devices



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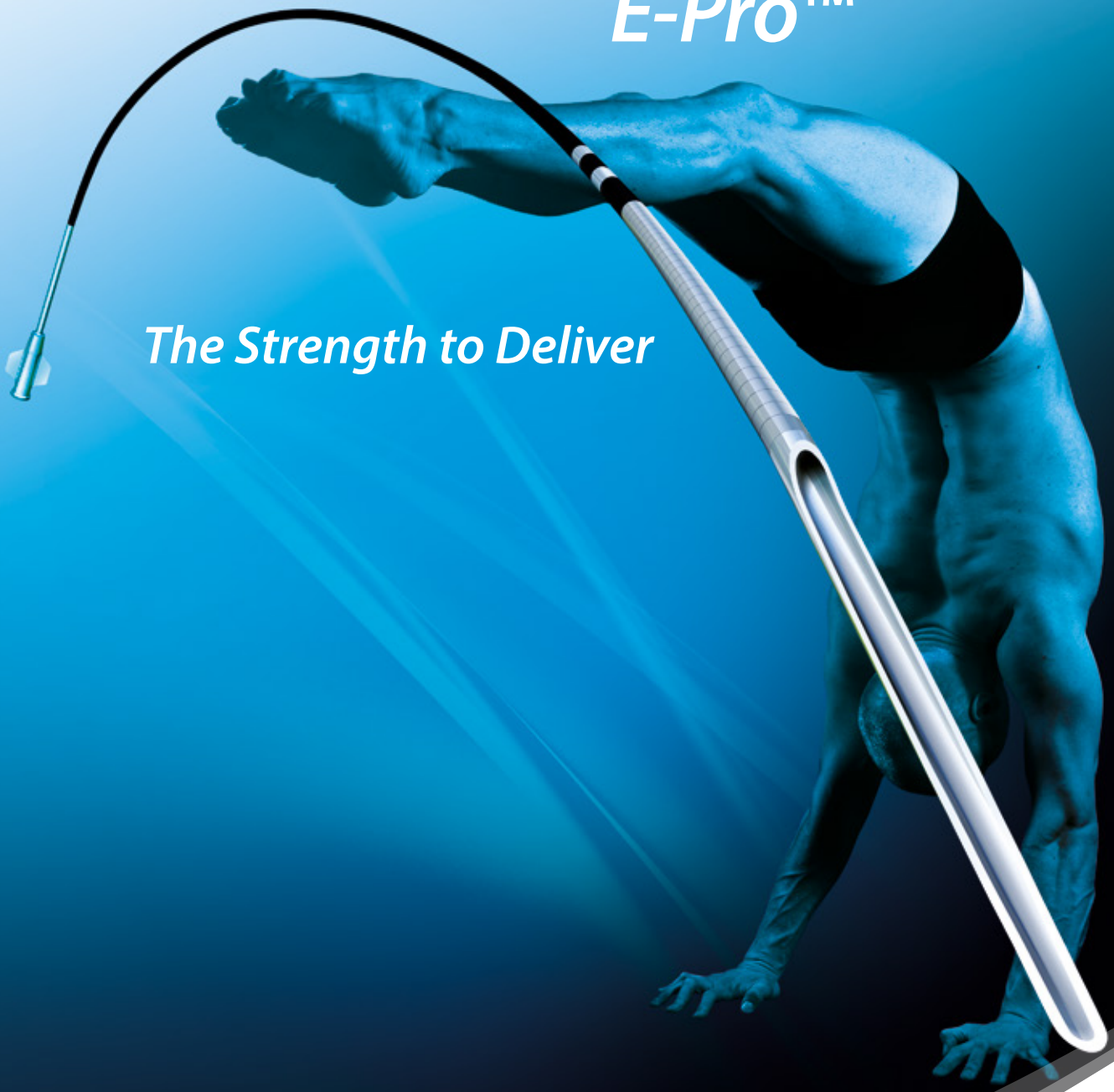
E-Pro™



The Strength to Deliver

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E-Pro™

E-Pro™ is an advanced metallurgical 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

Minimise Patient Trauma

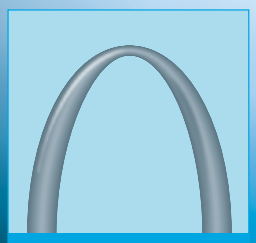
- Potential to reduce procedure time, improving patient safety
- High kink resistance reduces risk of failure
- Reduced inflation/deflation times

Improved Confidence

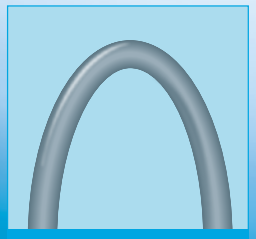
- Increased kink resistance makes navigation through tortuous anatomies safer and easier
- Allows physicians to use higher forces to deliver solution
- Improved package set properties

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

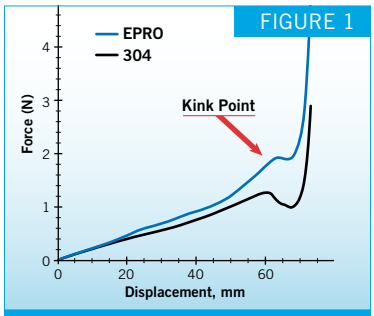


Conventional 304 hypotube



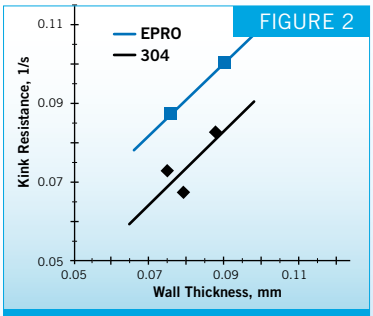
E-PRO™ hypotube

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



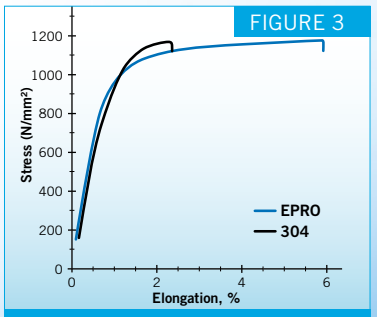
Force & Displacement of E-PRO material & conventional 304 material. The hypotubes had similar WT/OD ratios and comparable yield strengths.

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



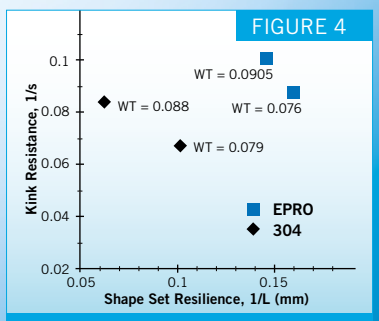
Kink resistance as a function of wall thickness. Wall thickness effects pushability, trackability, torqueability and kink resistance.

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.



Tensile Strength & % elongation of E-PRO material & conventional 304 material. The hypotubes had similar WT/OD ratios and comparable yield strengths.

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



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 EPRO is less likely to retain shape of storage coil than 304 material.

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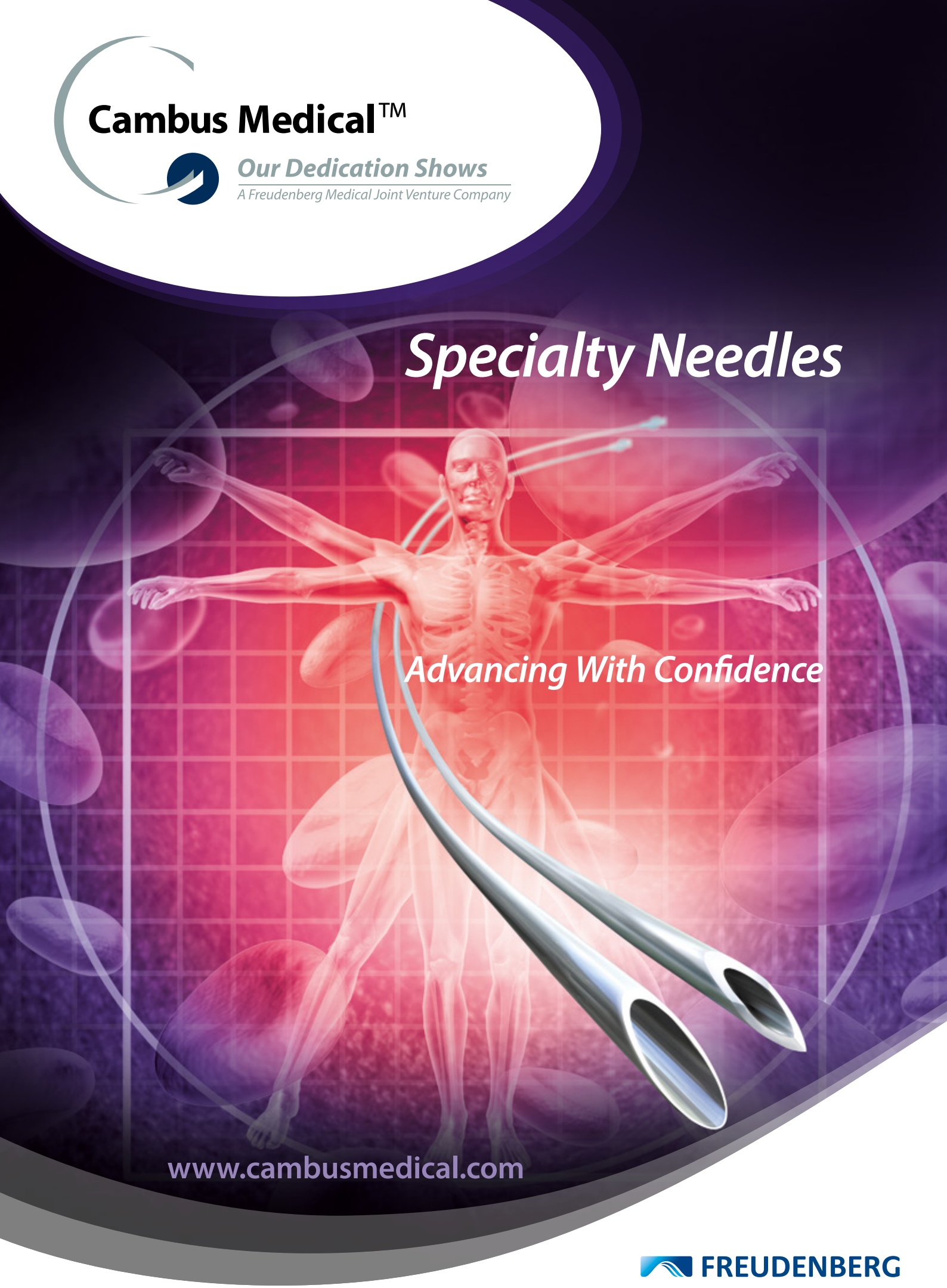
Specialty Needles



Advancing With Confidence

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Specialty Needles

Cambus Medical offer 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 30Ga to 10Ga – 0.010" (0.254mm) to 0.102" (2.59mm)

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 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
Cambus Medical have a range of capabilities to design, manufacture, assemble and test proximal needle hub components. Our hub offerings are compliant with ISO594-1 & ISO594-2.
Hub Offerings:

- Injection Moulded Components
- Welded / Soldered Micro Machined Metal Components

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

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

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Standard & Custom Over-moulded Hubs

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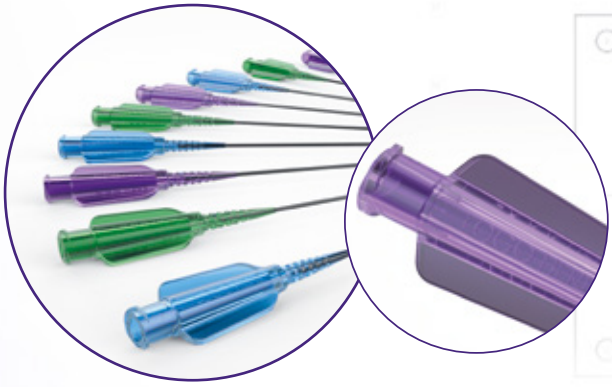
Standard & Custom Over-moulded Hubs

Cambus 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, 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 and ISO594-2 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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Navigate™

speed

experience

dedication

responsiveness

Steering you through the design and development process

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Navigate™

steering you through

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 Cambus 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 Cambus Medical's newest initiative in driving 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 and more recently with the world famous Volvo Ocean Race visiting our shores. We operate from a 3000sq ft 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
- Design Control Services
- Failure Mode & Effect Analysis
- Dedicated manufacturing & test equipment for prototyping
- Process Development & Validation
- Biocompatibility Testing

the design and development process

Idea Generation

We begin by 'laying-out' the ideas which have been explored. This evaluation is led by our CTO 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 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 endeavour at all times to steer away from areas of sensitivity.

Concept Testing

Ideas will be assessed on their merits and potential to be developed through each of the following stages right through to launch. Prototypes may be produced here to test basic functionality for some deliverables.

We encourage our customers to visit our plant 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 may end up with a few ideas which are now moving towards becoming designs. At this stage we bring in the operations team to assist with the manufacturability of the products. Their engagement at an early stage ensures that there will be a smooth transition to manufacturing later.

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

Operations are involved at an early stage to ensure we design a solution that can be made efficiently and effectively. Our Navigate™ team have all worked in operations and understand what can and cannot be done.

A simple philosophy is used "to generate the best possible methods in the least overall time." This stage may be cyclical and some compromises may be necessary as we work with you to develop the best cost effective solutions.

Validation

Once the method of manufacture has been agreed, we continue the validation of the product through our processes.

Our internal risk analysis and validation procedures will identify the areas of concern, these are addressed along with input at every stage 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 unwavering commitment to both the project and our customers we steer a course through all challenges and strive to deliver results that exceed our customers expectations.

"The greater difficulty, the more glory in surmounting it. Skillful pilots gain their reputation from storms and tempests."

– Epicurus, Greek philosopher, BC 341-270)

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