

# Concept Prototyping Manufacturing Regulatory



Specialising in the design &  
manufacture of minimally  
invasive catheter-based  
medical devices



# Concept Development: Design

At ARROTEK, we pride ourselves on our design capabilities.

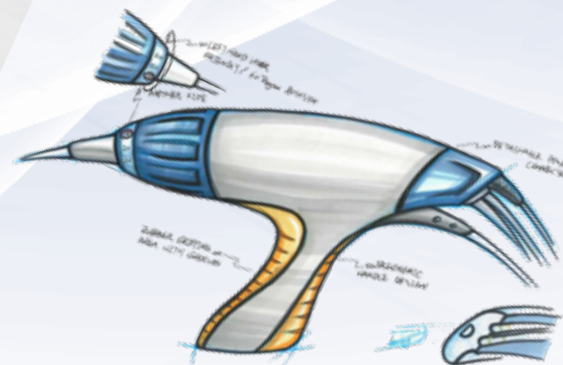
These capabilities enable us to offer a full service with an experienced team of designers who will take your ideas from concept to finished product, ready for scale-up manufacturing.

Using our design experience and dedication to quality, we have developed a six-step design process.



This now proven method takes a holistic approach to your idea, viewing it as a complete project, not just a product. Furthermore, we are unique in that we have our own production facility – we create what we have imagined.

During the design phase, we produce multiple prototypes. Following the design phase, we can upscale the process suitable for manufacturing, enabling the production of qualified medical devices.

All our medical device design and prototyping services are carried out under our ISO 13485:2016 & EN ISO 13485:2016 accredited quality management system.



## Six Step Process

-  **01. SPECIFICATION**  
DEVELOP DESIGN BRIEF
-  **02. CONCEPTS**  
VISUALISATION, EXPLORATION
-  **03. DEVELOPMENT**  
DEVELOP 3D CAD MODELS & DESIGN DIRECTION
-  **04. PROTOTYPE A**  
STAGE 1 PROTOTYPES REFLECTING DEVELOPMENT WORK
-  **05. REFINEMENT**  
CONCEPT ENHANCEMENT BASED ON PROTOTYPE A
-  **06. PROTOTYPE B**  
STAGE 2 PROTOTYPES FOR FUNCTION EVALUATIONS





# Manufacturing

ARROTEK's on-site cleanroom manufacturing area supports our commitment to providing a successful finished product ready for the clinic or hospital. ARROTEK offers both pilot and full-scale production services to meet your outsourcing needs.

Our manufacturing capabilities include, but are not limited to, the following:

- Balloon Blowing
- Tipping
- Laser Welding
- Moulding

- Micro Moulding
- Film Welding
- Bonding
- Printing

- Tube forming
- Drilling / Punching
- Finished Assembly
- Packaging

All medical device manufacturing is carried out in our validated Class 7 (10,000) cleanroom for assembly and packaging and our Class 8 (100,000) cleanroom for moulding in accordance with our ISO 13485:2016 & EN ISO 13485:2016 accredited quality management system.



## Balloon Blowing

ARROTEK has in-house capabilities to manufacture compliant, semi-compliant, and non-compliant balloons. We have experience manufacturing balloons with materials such as PU, nylon, and PEEK. Balloons are tailor-made to meet your requirements.



## Tipping

With many years of experience utilising induction heating processes, ARROTEK is capable of tipping tip lengths up to 100mm in materials including nylon, PE, PU, PEEK, and fluoropolymers. Tooling is designed in house which reduces lead time offering our customers a faster turnaround time.



## Laser Welding

ARROTEK technology includes in-house laser welding of various materials including Nitinol and Stainless Steel.



## Inject/Insert Moulding

ARROTEK has modern and efficient equipment in our class 10,000 cleanroom that is suitable for both prototype and production builds. We also work with local toolmakers, reducing turnaround times to meet the demands of our customers.



## Bonding

With our experience, we'll select the correct bonding method for your product. Whether this is through heat welding of two similar materials or through the use of an adhesive, ARROTEK will tailor-make a process suitable to your requirements.



## Printing

Using a closed cup pad printing system, we offer consistent print detail and can print graduation marks and logos. We have developed a biocompatible surface treatment process which allows us to print on a wide range of materials.



## Film Welding

ARROTEK has developed in-house film welding techniques. With our experience, we have the capability to create large volume balloons to suit your application.



## Finished Product Assembly

By combining the above-mentioned processes, ARROTEK can offer you a fully assembled finished device. Should you require additional services, ARROTEK has in-house capabilities for tray and pouch sealing, fully packing your device, and co-ordinating sterilisation and logistics to make your device ready for distribution.



# Quality & Regulatory

## Quality

At ARROTEK, we value and understand the importance of using dependable suppliers for both the product supplied and the service provided. This is why everything we do at ARROTEK is carried out in accordance with our ISO 13485:2016 & EN ISO 13485:2016 accredited quality management system. We are an FDA registered company.

## Regulatory

Our team includes experts in medical device regulation who can guide you through CE marking, FDA submission and other regulatory needs for your product.



## Our regulatory services include:

- Process validation
- Sterilisation validation
- Age testing for shelf life
- Transportation testing
- Bench testing of transport and aging units
- Clinical language verification for instructions for use
- Testing to ISO standards
- Label design
- File compilation and submissions for regulatory approvals

If you would like us to provide you with a regulatory evaluation, contact us now at [sales@ARROTEK.com](mailto:sales@ARROTEK.com) with questions, or phone us on +353 71 91 15111.





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