



FULL ENGINEERING SERVICES  
CONTRACT MANUFACTURING

Implants & Catheters  
Active medical devices

Your Partner For Advanced Medical Devices

## CONTRACT MANUFACTURING

From ramp up to full production, **STATICE** provides manufacturing services adapted to the customer's needs. Production management with ERP and MES ensures full traceability. All processes are controlled in cleanrooms class ISO 5 and ISO 7.

PURCHASE ORDER

SUPPLY AND SCHEDULING

MANUFACTURING

QUALITY CONTROL

CLEANING/ PACKAGING : ISO 5

LABELLING

RELEASE - READY TO BE STERILIZED :  
DHR, TRACEABILITY, COC

ERP / MES

## FULL ENGINEERING SERVICES

Since 1978, **STATICE** provides engineering services and contract manufacturing. The company has gathered a strong know-how in process engineering and design transfer. The engineering department with 25 people has strong experience in the development of implants, catheters and active medical devices. The team works according to customer specification and proposes breakthrough technologies for bespoke solutions. **STATICE** has access to advanced technologies thanks to its internal research activity.

### TECHNOLOGICAL RESEARCH

- Internal research activity
- European projects
- Biomaterial PhD

### DESIGN & PRODUCT DEVELOPMENT

CLINICAL FIELDS : Neurology | Cardiology | Urology | Ophthalmology | Orthopaedics & others

### DHF

Design  
History  
File

- Support for risk analysis & usability
- Specifications
- Investigation & justification of solutions
- Material selection
- Feasibility/Proof of concept: Early technical study, mock up, 3D printing, tests
- Mechanical and electronical design
- Software development
- Packaging design

- Prototyping
- In-house mechanical workshop (CNC, EDM) : components and tooling
- In-house electronic lab

- Respect of biocompatibility. (ISO 10993-1)
- Bench tests & validations in our laboratory
- Test reports

### PROCESS ENGINEERING & DESIGN TRANSFER

- Optimisation of manufacturing methods
- Process flowchart, work instructions, control instruction
- Packaging & labelling definition

ALL PARAMETERS IN ERP

OPERATORS TRAINING

PILOT RUN

### VMP + REPORTS

- Verification & Validation (V&V) of product performance
- Qualification (IQ/OQ/PQ) of special processes
- Qualification of Cleaning and Packaging (ISO 11607)
- Software Validation (EN 62304)
- PFMEA

DESIGN TRANSFER APPROVAL

### DMR

Device  
Master  
Record

## IMPLANTS & CATHETERS EXPERTISE

### TRANSFORMATION OF BIOCOMPATIBLE MATERIALS

- Liquid Silicone Rubber (LSR) injection
- Compression moulding with High Consistency Silicone
- Silicone over-moulding
- Silicone calendaring (sheeting w/o polyester meshes)
- Silicone dipping
- Bioresorbable polymers injection (PLLA, PGA, PCL, PDO,...)
- Thermoplastics injection or over-moulding (PEEK, PUR, PE...)



### INTEGRATION AND ASSEMBLY WITH

- Metallic parts (nitinol, platinum, titanium, stainless steel)
- Wires
- Ceramic
- Silicone parts
- Gold markers
- Plastic parts



### ASSEMBLY TECHNOLOGIES

- Plasma treatment + gluing: silicon, UV, epoxy
- Welding: laser, ultrasound, electrical, high frequency
- Mechanical assembly: Clipping, riveting, setting, forced bushing



### INNOVATIVE AND TECHNICAL CATHETERS

- Endovascular electrophysiology
- Active catheters RF, microwave
- Disposable endoscopes
- Delivery systems
- Neuro / Neurovascular



#### WITH:

- Ergonomic handle
- Steering capacity
- Plasma treatment + technical coatings
- Sensors embedding (ablation electrode, P<sup>o</sup>, T<sup>o</sup>, P<sup>o</sup>O<sub>2</sub>)
- Balloon & irrigation function (Multilumen tubes)



### ELECTROSPINNING TECHNOLOGIES

Polymer fibers created by electrospinning are used for:

- Tissue regeneration features such as patches, vessels, valves, scaffolds.
- New mechanical behaviors: bioresorbable and non-bioresorbable polymers
- Controlled drug release



20 μm



## ACTIVE MEDICAL DEVICES AND IVD EXPERTISE

### ACTIVE MEDICAL DEVICE

- Biomaterial interface with the body
- Integration of electronics
- Micromechanical systems (MEMS)
- Development of plastic housing
- Management of tightness
- Validation following IEC 60601
- Electromagnetical compatibility (EMC)
- Electrical safety



### ELECTRONICAL DESIGN

- Digital and analog electronics
- Microprocessor embedding
- Thermal regulation (Hot or Cold)
- Engine drivers
- RF generator
- RF et NFC communication
- Bluetooth, WIFI



### SOFTWARE

- Human Machine Interface (HMI)
- Database
- Embedded software (microprocessor)
- Traceability patient / product
- Development of applications on Windows, iOS, Android (tablet and PC)



### IVD

- Precision fluids movement, microfluidic manifolds
- Micromechanical systems
- Automation
- Optic, Electromagnetism



Since 1978 **STATICE** is one of the European leaders in the subcontracting medical device industry. **STATICE** is a regular partner in French and European research projects and is recognized in Europe for its innovation skills. The company is certified ISO 13485.



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