

# R&D and RA Production

*Our MISSION :*

*To offer our expertise in R&D and in the production of personalized and innovative microtechnical systems to the Medical, Aeronautics and Food markets.*



## Our story

- STATICE was founded in 1978 by watchmaking engineers. The company's reputation has been built on its strong expertise in microtechnology, which is put to work on innovative projects.
- We work on over 200 projects per year.
- We have 800m<sup>2</sup> of clean room and are **ISO13485** certified.
- 3 activities :
  - **From designing to manufacturing of medical devices divided into 2 areas of expertise, biomaterials and mechatronics: catheters, silicone implants, single-use DM, DM incorporating electronics, In Vitro Diagnostic Devices,**
  - Non-Destructive Testing based on historic know-how at Statice: precision micro-winding,
  - More recently, our know-how has been extended to the field of chocolate for professionals (machines to reduce tempering time...).

# The group

Besançon  
Mauritius



R&D  
32 people

Contract  
Manufacturing  
70 people

Production  
*Mauritius*  
12 people

Turnover  
11M€



# Our team

R&D Invasive Medical Devices Department

R&D Equipements Department

Electronics and Software Development Department

Regulatory Affairs and Validation Department

Prototyping workshop

Our customers

Major groups

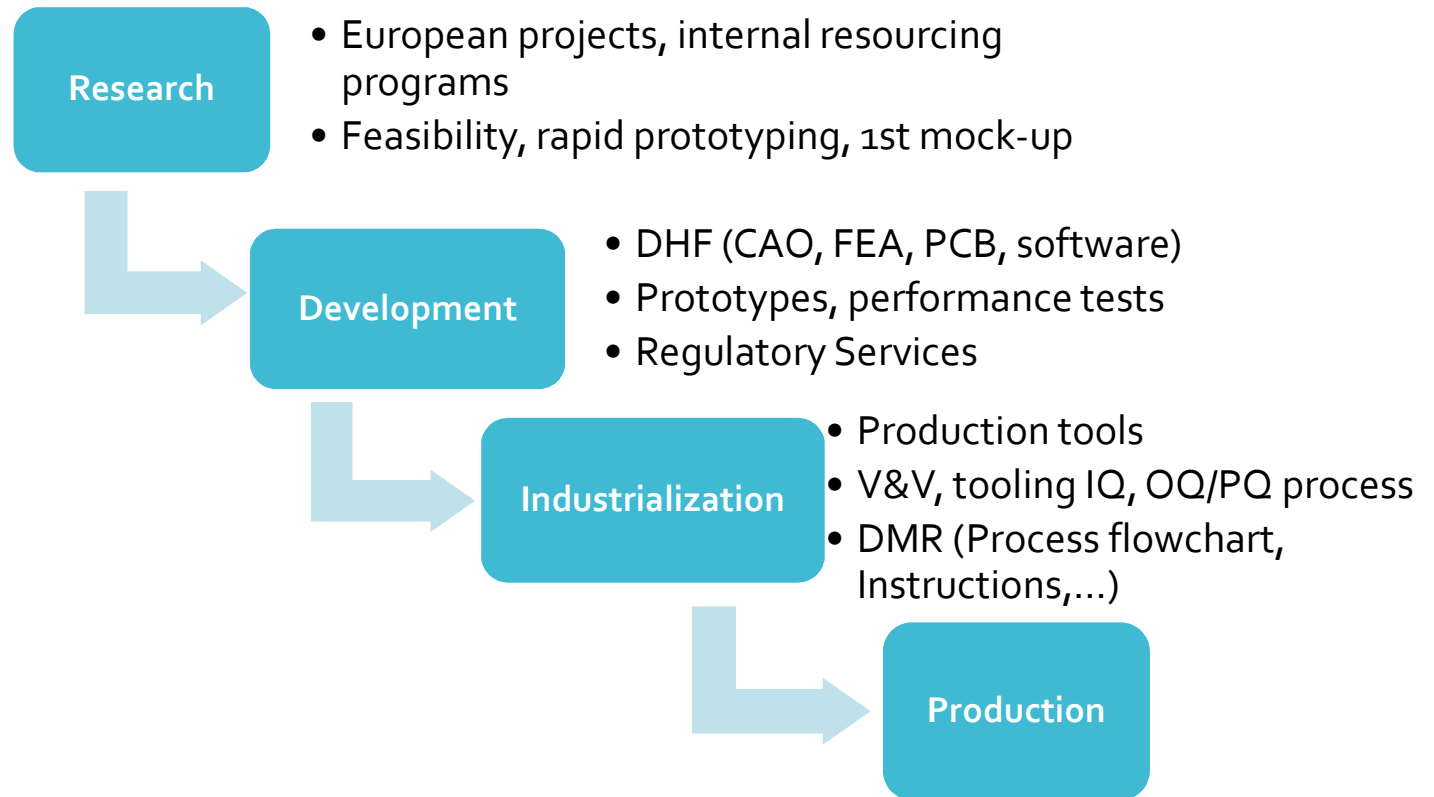
SME

Start-up or doctors

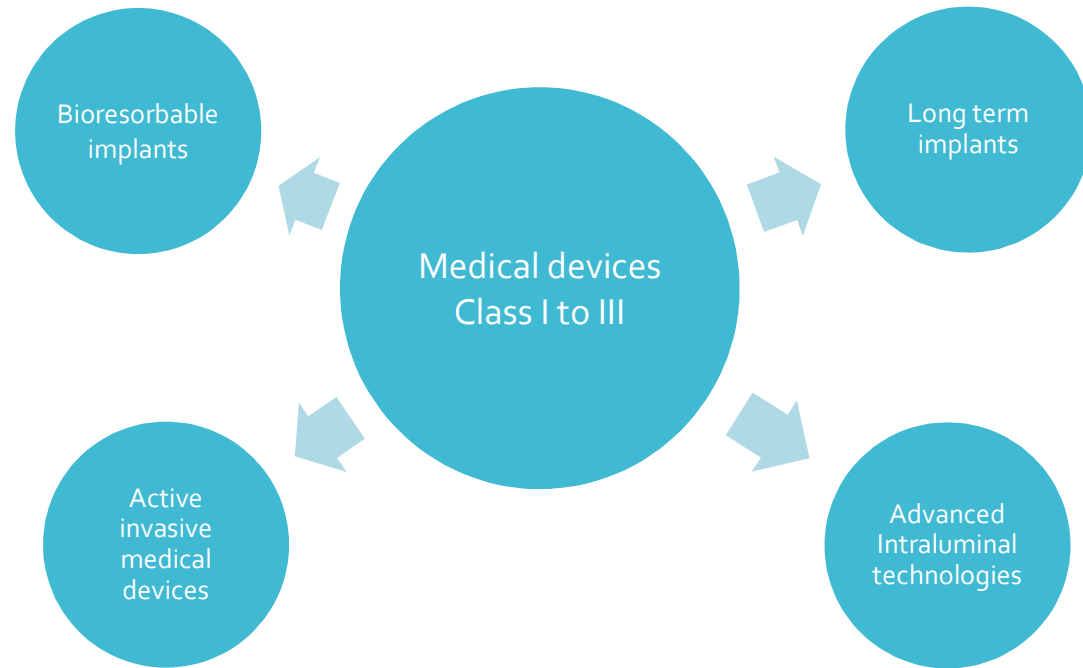
Laboratories

# From idea to production

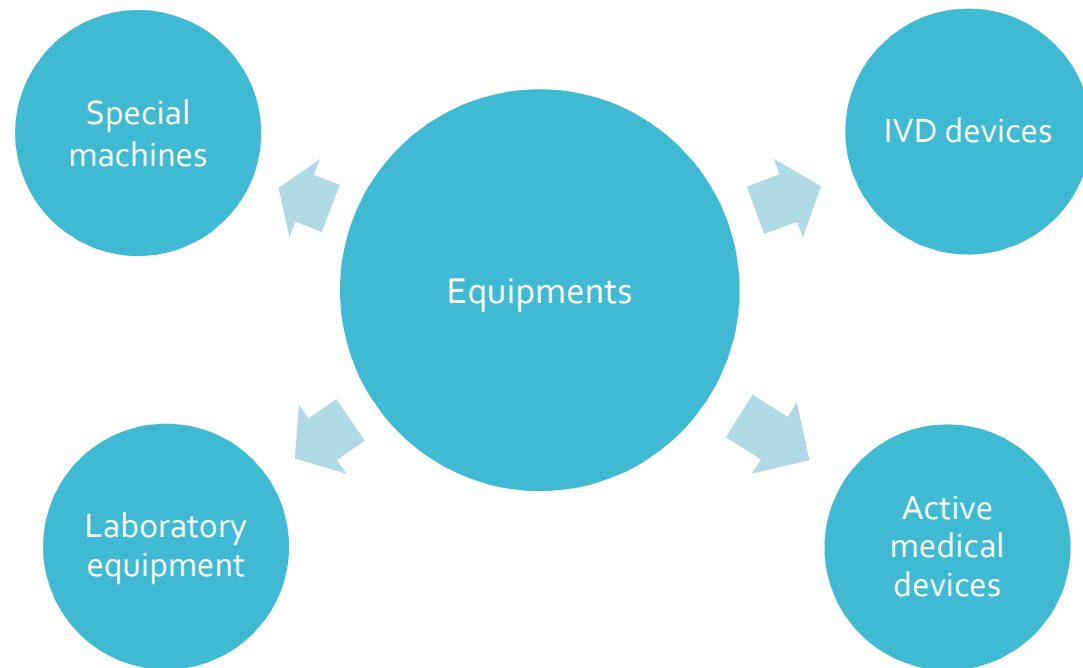
While granting the customer full and complete intellectual property rights



R&D expertise

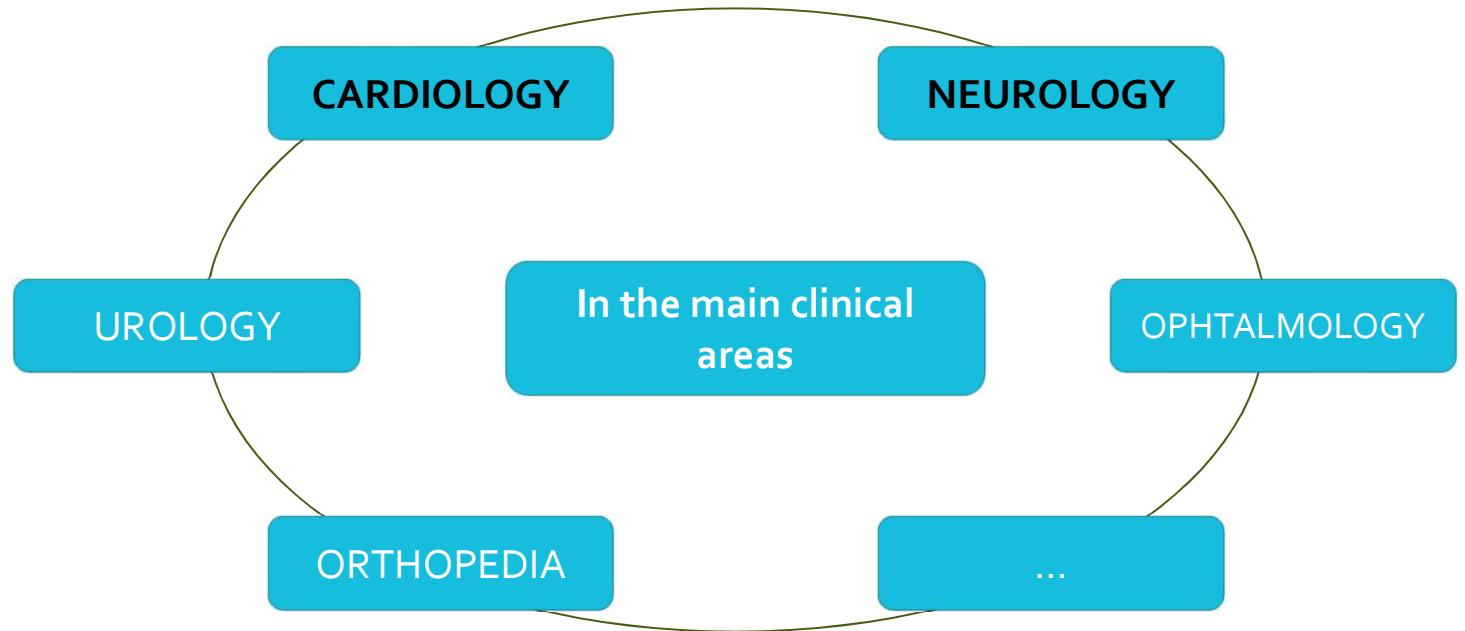


R&D expertise





R&D expertise



# Biomaterials The silicone (LSR, HCR,...)



# Biomaterials Silicone


## Application in neurology

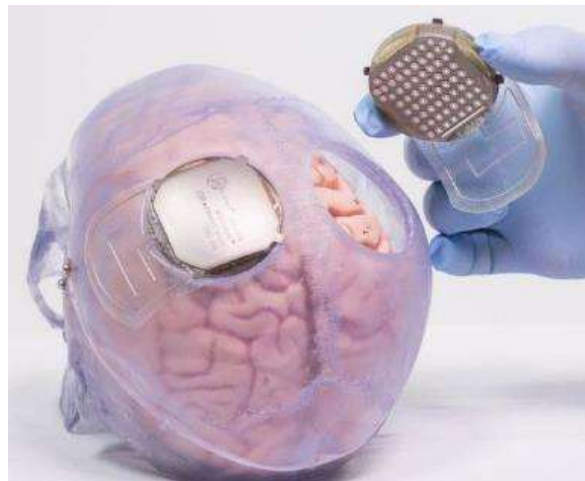
THE LANCET  
Neurology

ARTICLES | ONLINE FIRST

< An exoskeleton controlled by an epidural wireless brain-machine interface in a tetraplegic patient: a proof-of-concept demonstration

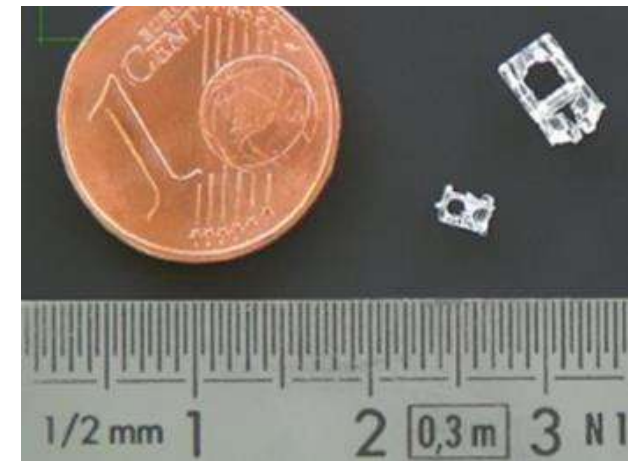
Prof Alim Louis Benabid, MD   • Thomas Costecalde, PhD • Andrey Eliseyev, PhD • Guillaume Charvet • Alexandre Verney • Serpil Karakas • et al. [Show all authors](#)

Published: October 03, 2019 • DOI: [https://doi.org/10.1016/S1474-4422\(19\)30321-7](https://doi.org/10.1016/S1474-4422(19)30321-7)  Check for updates

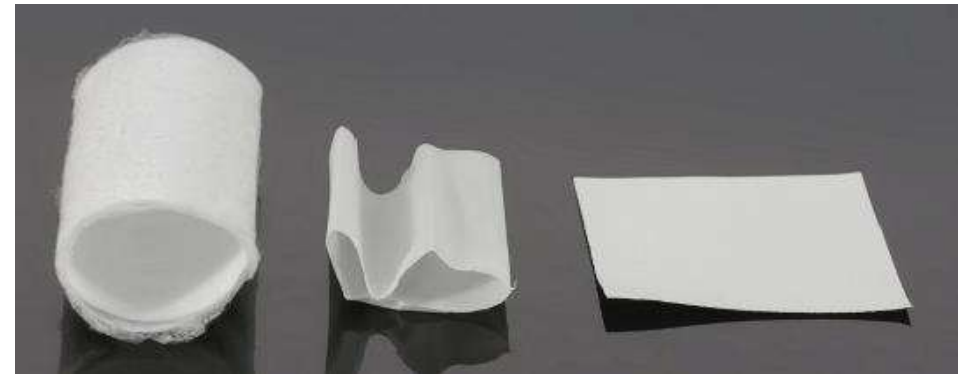
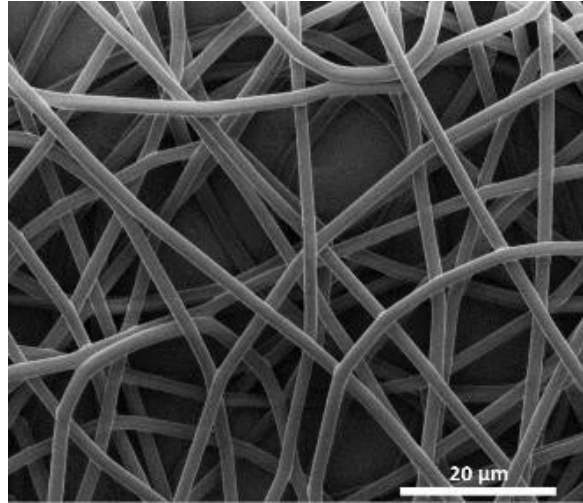


# Biomaterials

## The resorbables



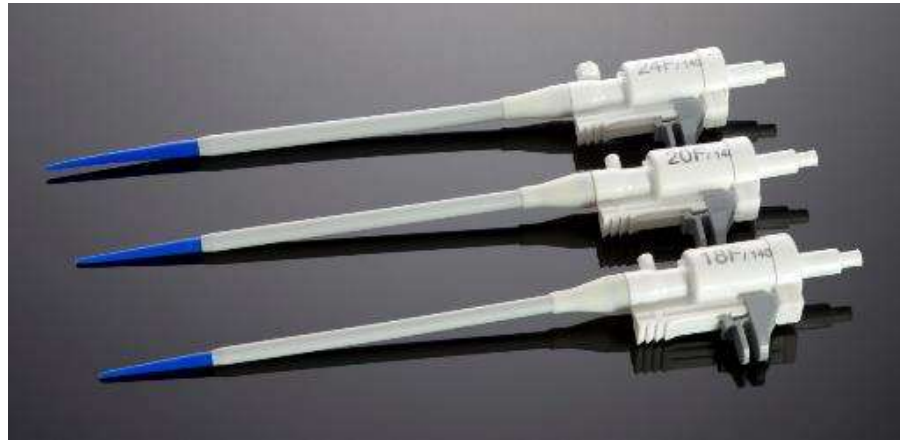
# Biomaterials Electrospinning



# Complex catheter assemblies



# Micromechanics Plasturgy



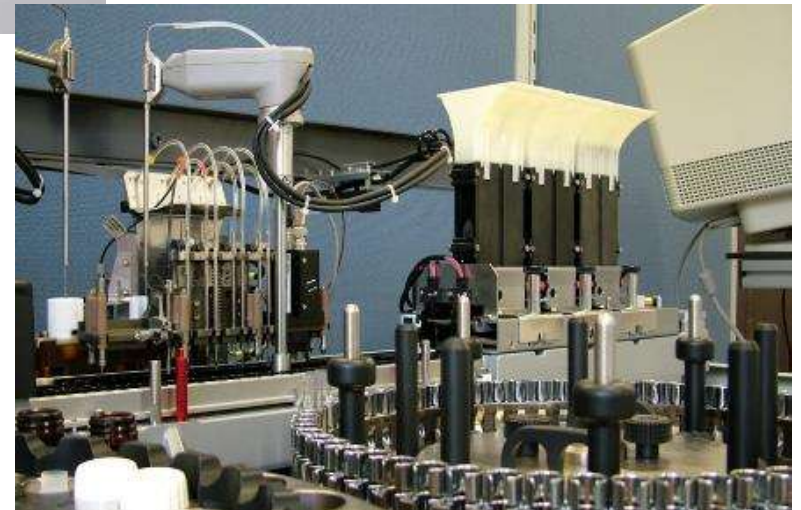
# Active Medical Devices





# In Vitro Diagnostic Devices

$\mu$ -Fluidics  
Optical control  
Automation



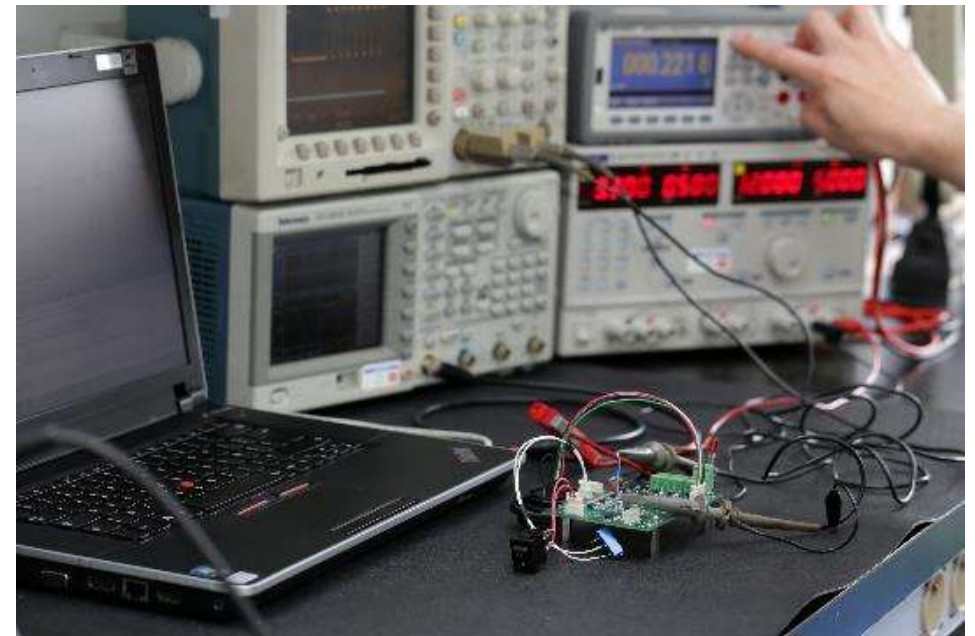
# Mechanical workshop

Numerical control  
Electroerosion



# Electronic workshop

Micro-winding  
Micro-wiring  
CMS PCBs



# Regulatory Affairs Services



## Regulatory strategy

- Evaluating and defining the different regulatory routes to access the European and international market

## Technical or homologation file

- Drafting or support with a view to CE marking and international approvals

## Validation

- Process validation (molding, assembly, packaging ISO11607)
- Electrical validation (IEC 60601)
- Software validation (IEC 62304)
- Fitness for use file (ISO62366)
- Biological evaluation (ISO 10993)
- Validation of sterilisation

## QMS: Deployment and improvement

- Implementation / optimisation of your QMS (ISO 13485, 21CFR Part820, ...)
- Support in communication with notified bodies and/or competent authorities
- Audit of your QMS

# Design Transfert:

Process Qualification

Assembly

Cleaning

Packaging

Labelling

Technical documentation



# Contract Manufacturing

ERP (Traceability)



# Clean Room

800 m<sup>2</sup>  
ISO 7 & ISO 5





Contact us!



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