



Your Partner for the development,  
manufacturing and approval of  
your medical devices



## Laser Welding and Laser Marking Technologies on Implantable Active Medical Devices

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## From Idea to use

### Our mission

Cisteo MEDICAL supports, under contract, **medical device manufacturers** in their **conception, development, approval and manufacturing** through its **microtechnical and regulatory Expertise**

### A global offer for medical device manufacturers...

Conception

Industrialisation

Manufacturing

Homologation

Training

### ...that meets regulatory requirements



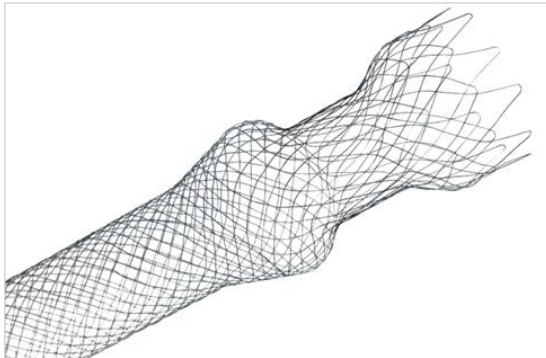
## A wide field of medical application in R&D

We cover all stages of R&D projects

### Experience particularly in :

- **Neurosurgery**
- **Cardiac surgery**
- **Cardiology**
- **Urology**

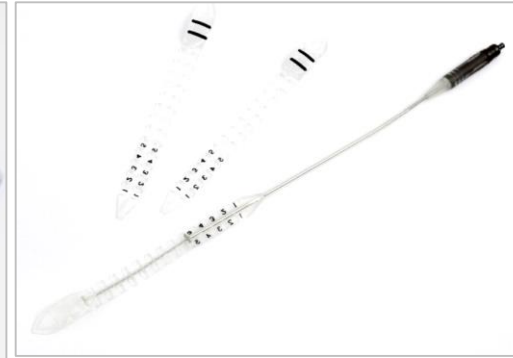
Expertise in minimally invasive surgery thanks to the mastery of micromechanics and materials with hyper-elastic properties (nitinol and silicone)



Cardiovascular Stent



AMD – Titanium Casing and packaging



Silicone Component



Clean room

## Manufacturing and assembly of MD under controlled environment

Equipped with many clean room equipment, Cisteo MEDICAL can carry out tailor-made services to meet your needs.

Many services are offered :

- Cleaning
- Laser marking
- Metallographic section
- Gluing
- Electronic component assembly
- Helium leaking control
- Design Verification Testing
- Accelerated aging tests
- Plasma treatment, crimping
- Micro soldering of electronic components
- Resistance micro-welding
- ...

➤ **Complete integration, from assembly to packaging, in a clean room**

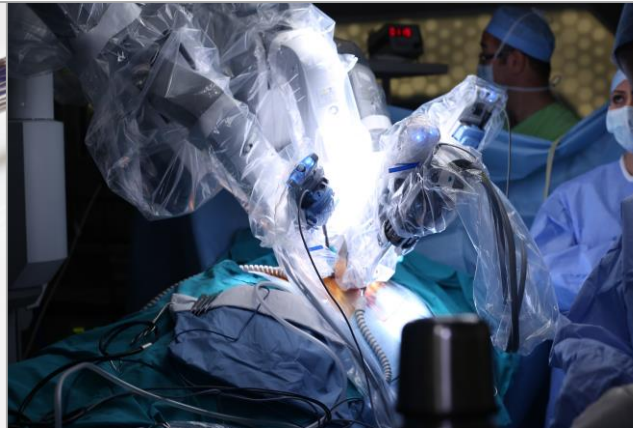
**Expertise in critical medical devices**



**Active implantable medical devices**



**Implants**



**Robotic Surgical Instrumentation**



**Surgical Instrumentation**

**Exemples**

Neurostimulation device



Incontinence treatment device



Electrocardiograph



Neurostimulation device



## Laser welding processes in controlled environments (ISO 7)

### Medical device welding process

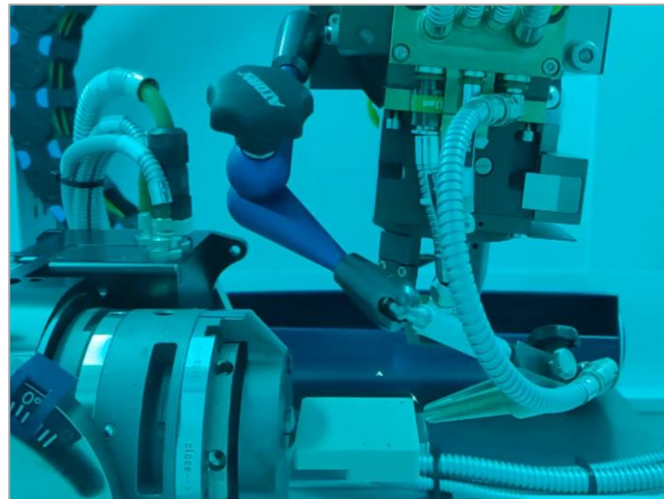
- 5-axis titanium casing laser welding under inert gases (Ar/He) with:
  - leaking control (Mil-Std 883)
  - analysis of residual gases
- Laser micro welding

A complete integration of assembly steps

- **Assembly of electronic components** in an ISO 7 cleanroom
- **Drying electronics** by reducing the humidity level
- Integration of electronics into titanium shells
- **Welding** titanium shells on complex geometries
- Injection of helium inside the case for the **preservation of electronics**
- Making **the implant waterproof and testing its tightness**
- Control of welding by **metallographic cutting**



Example of a titanium casing welding

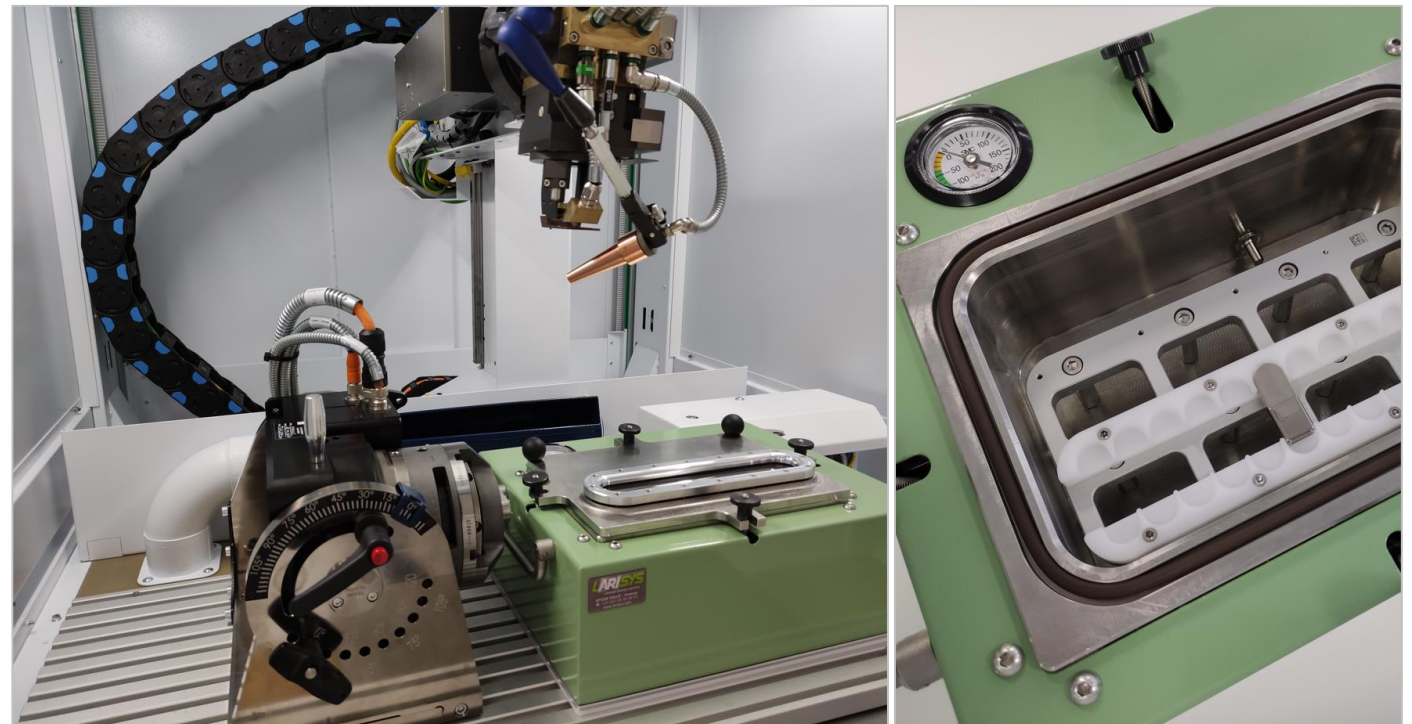


## Sealing and hermeticity following welding

### Sealing, welding and hermeticity

According to standards:

- MIL-STD-202G Method 112E
- MIL-STD-883J Method 1014-14
  
- Drying bench: Helium/Argon filling (which allows us to dry the electronics before sealing and fill the implant with an inert gas).
- Consideration of the sensitivity of components to helium
- Bombing
- Leak detection and measurement



## Laser marking

### Goal

Meeting the UDI (Unique Device Identification) required under the European Regulation MDR 2017/745

### Means implemented

- Implementation of software to generate the data matrix or barcode
- Laser marking on medical devices

### Result

Ensuring quality, readability and durability of marking on medical devices.



## Presentation of the processes controlled internally under controlled environment in connection with your device

### Cleaning process in ISO 7 and packaging in ISO 5

- Ultrasonic tank cleaning
- Heat sealing
  - Packing in blisters (with mastery of packaging and tool design)
  - Placing in bags

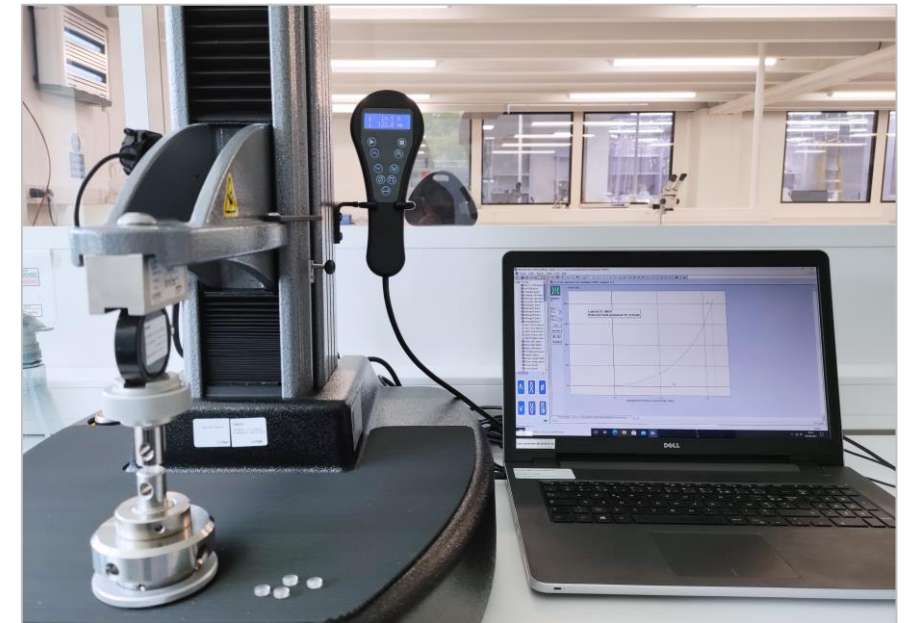
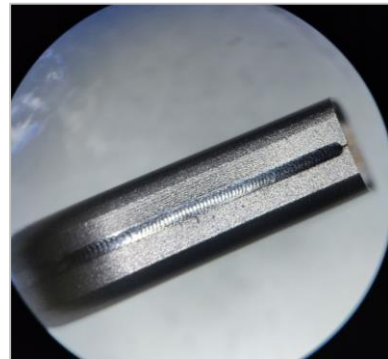




## Presentation of the processes controlled internally in a controlled environment in connection with your device

### Qualification of critical processes according to GHTF-SG3-N99-10.2004

- Qualification of welding processes
- Qualification of cleaning processes by bath or manual (Method based on NF EN ISO 19227:2018)
- Qualification of packaging processes according to NF EN ISO 11607-1:2020 and NF EN ISO 11607-2:2020 and associated standards and guides
- Drafting of the validation master plan in consultation with the client
- Achievement of operational and performance qualifications
- Performing internal and/or external tests if necessary (e.g., transport test according to ASTM D4169)



At your disposal, thank you for your attention.



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