



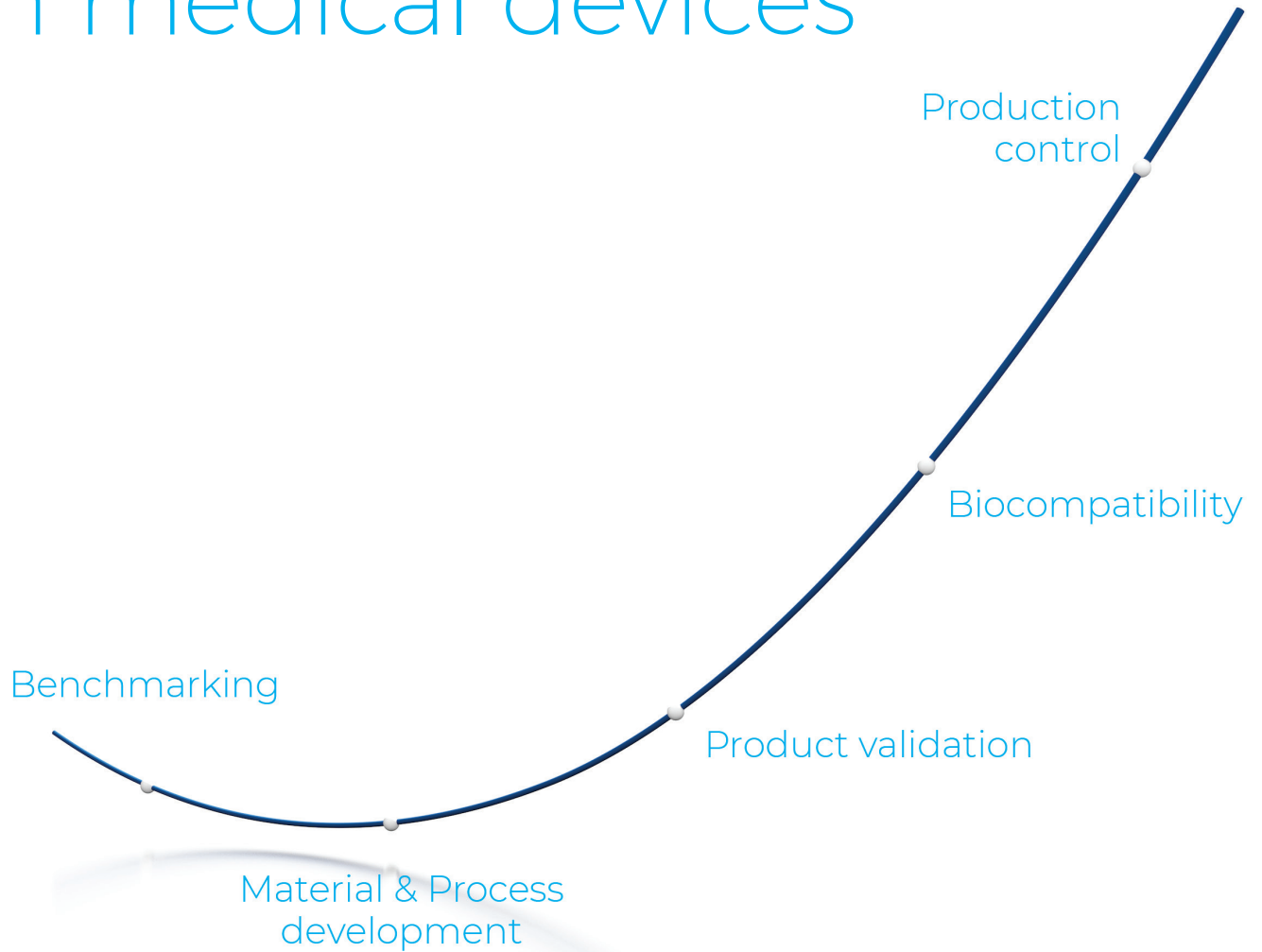
RESCOLL

# EXPERTISE & TESTING OF BIOMATERIALS AND MEDICAL DEVICES



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# A global offer in medical devices





## Our Company

With more than 20 years expertise in materials science, Rescoll offers services in testing, development and manufacturing in accordance with the highest quality standards.

- ◆ Since 2001
- ◆ More than 150 employees
- ◆ More than 20 PhD and engineers in materials science
- ◆ More than 1000 customers
- ◆ Over 60 patents
- ◆ Over 12,000 m<sup>2</sup> facilities



Accréditation  
N°1-1995 et 1-6323  
Liste des sites et portées  
disponibles sur  
[www.cofrac.fr](http://www.cofrac.fr)





## Biocompatibility testing according to ISO 10993

Biocompatibility assessment of a medical device is conducted in accordance with ISO 10993-1. RESCOLL will help you choose the right ones to validate your medical devices.

Main tests proposed by Rescoll and its partners:

- ◆ In vitro and in vivo studies according to ISO 10993-5, ISO 10993-10 and ISO 10993-11, etc.
- ◆ Preparation of samples and reference materials according to ISO 10993-12
- ◆ Identification and quantification of degradation products of polymer-based medical devices according to ISO 10993-13
- ◆ Identification and quantification of degradation products of ceramics according to standard ISO 10993-14
- ◆ Physicochemical, morphological and topographical characterization of materials according to ISO 10993-19
- ◆ Physicochemical analyses according to ISO 10993-18



## Cleaning validation

RESCOLL performs the following tests under ISO 10993-18 standard:

- ◆ Metallic and mineral elements analysis by ICP - OES spectroscopy (quantitative multi-element analysis)
- ◆ Gas and liquid chromatography coupled with a mass spectrometer (GCMS), LC-QTOF-MS
- ◆ Ionic species (anions and cations) and weak acids analyses by ion chromatography...

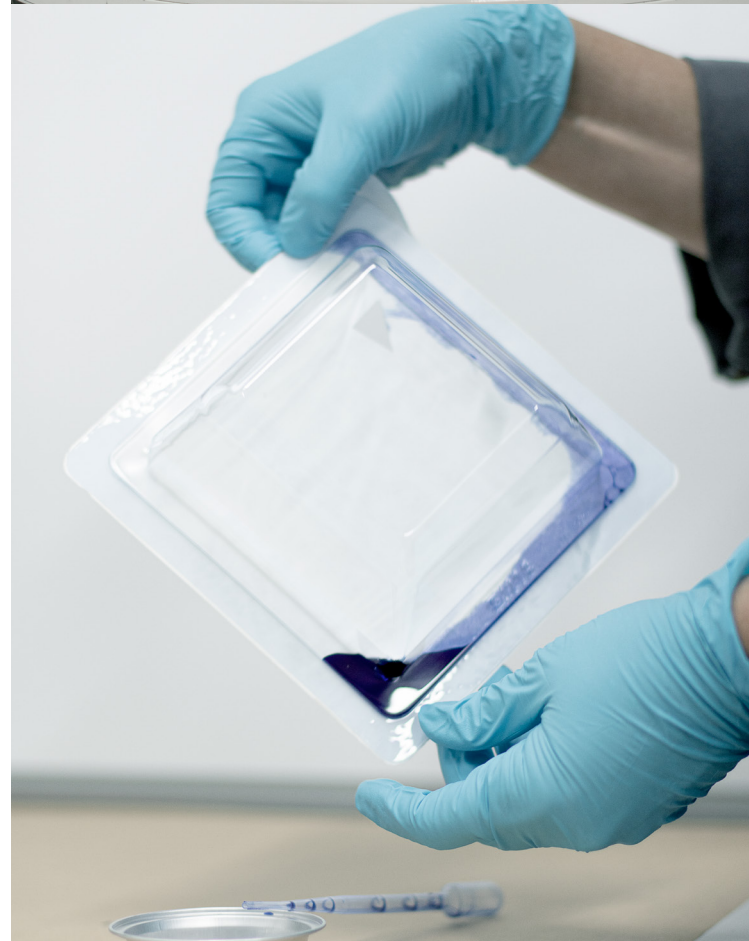
Routine analysis for cleaning validation according to ISO 19227 standard include the following tests:

- ◆ HCT/TOC analysis according to NF EN 1484 and NF EN ISO 9377-2 standards
- ◆ Analysis by ICP or ion chromatography for inorganic pollutants measurement

## Packaging validation

RESCOLL laboratories have implemented major test methods according to NF EN ISO 11607-1 standard to assess the performance of sterile packaging, including:

- ◆ Visual inspection of seals according to ASTM F1886
- ◆ Manual peeling and seal strength tests according to EN 868-5
- ◆ Integrity testing by dye penetration according to ASTM F1929
- ◆ Accelerated ageing tests according to ASTM F1980
- ◆ Transport tests simulation according to ISTA and ASTM D4169 standards







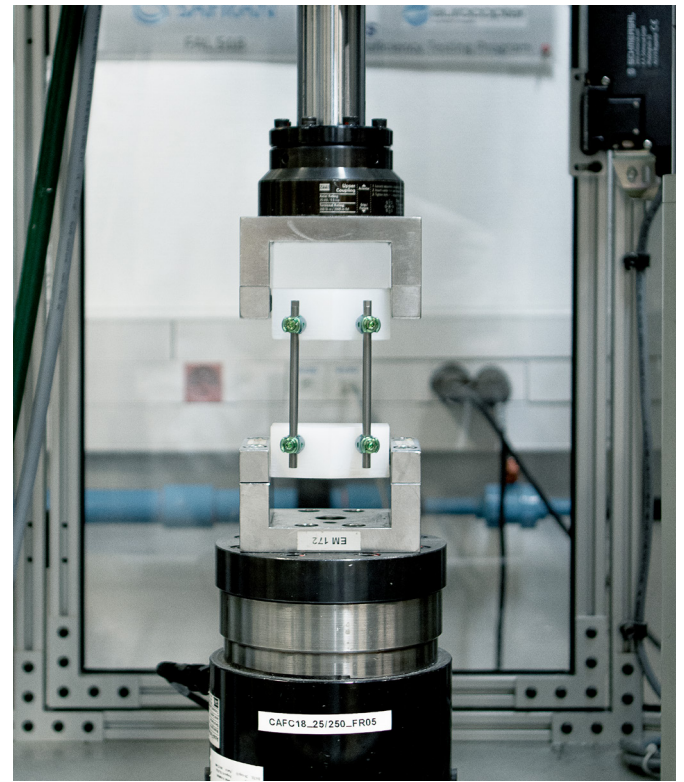
## Stability validation

Natural & Accelerated ageing test (ASTM F1980) can be conducted to assess the stability over time and during storage of your medical devices.

- ◆ Development and validation of “on demand” method of stability test and released product quantification (antibiotics, degradation product, etc.)
- ◆ Product performance stability during lifetime
- ◆ Storage stability

### Examples:

- ◆ Analyses of the kinetics of degradation according to ISO 13781 on resorbable implants in PLA
- ◆ Stability tests on bone cements and associated analyses (Gentamicin dosage)
- ◆ ISO 10993 Part 13: Identification and quantification of degradation products from polymeric medical devices



## Mechanical tests on implants and biomaterials

Rescoll supports you in the characterization of device integrity according to standard tests or custom designed tests. Most of these tests are ISO 17025 accredited.

All tests can be performed in environmental condition, physiological bath or at specific temperature.

### Testing capacities:

- ◆ Static / Fatigue / Creep / Relaxation
- ◆ Traction / Compression / Flexion
- ◆ Shear test
- ◆ Torsion / Rotation
- ◆ Impact

### Static and dynamic mechanical test on spinal and orthopedic implant and assemblies:

- ◆ Compression, shear and torsion test
  - Bone screw (ASTM F 543)
  - Intervertebral Body Fusion Devices (ASTM F2077)
  - Nucleus device (ASTM F2789 et ASTM F2346)
  - Spinal implant (ASTM F1717 et ASTM F1798)
- ◆ Subsidence test and expulsion (ASTM F 2267)
- ◆ Fatigue test: bone cement (ASTM F2118)





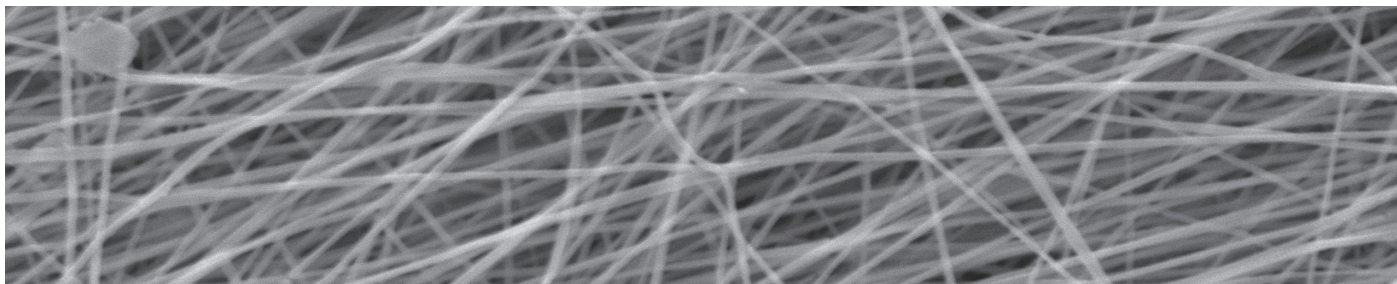
## Materials and medical devices chemical characterization

With the help of our team of experts, we can offer you:

- ◆ Routine analysis
- ◆ Suppliers qualification or QC your material
- ◆ Identification of organic and inorganic contamination
  - Identification origin of failure or unmet specifications
  - Identification of causes (degradation, ageing, wrong operations..)
- ◆ Identification of change in the product or process
- ◆ Reverse engineering
- ◆ Audit

Thanks to our cutting-edge equipment, we offer a large range of analyses for chemical composition and materials properties:

- ◆ Residual solvent, residual monomer,
- ◆ Residual hydrogen peroxide
- ◆ Elemental analysis/metal traces
- ◆ SEM Microscopy coupled with elemental analysis
- ◆ Thermodynamic properties (DSC, DMA)
- ◆ Polymer molecular weight (SEC)
- ◆ Particle size characterization
- ◆ Surface analysis (roughness, wear, corrosion,..)



# Materials & process development

Based on your specifications and user needs, we will offer you a feasibility study of the right process followed by - if necessary - the definition of an experimental plan and its undertaking.

## Benchmarking

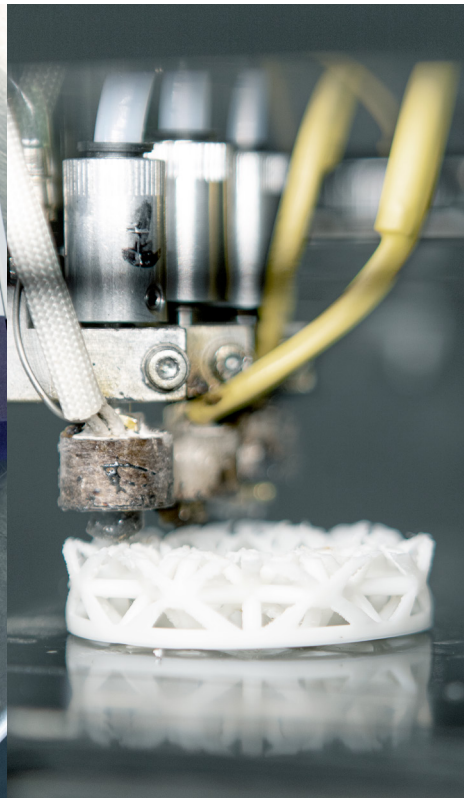
- ◆ Identification of material for securing supply
- ◆ Identification of material for new product development or process optimization
- ◆ Conformity assessment to applicable regulations

## Formulation

- ◆ Custom-made thermoplastic compounds
- ◆ Formulation of hydrogels and adhesives
- ◆ Development of functionalized coatings & surfaces

## Process & Prototyping

- ◆ Development of electro-spinning process
- ◆ FFF additive manufacturing
- ◆ Scale-up of adhesive and coating process
- ◆ Custom-made filament for additive manufacturing







## CMO manufacturing

Rescoll Manufacturing is a CMO specialized in high-precision machining of technical parts and plastic injection in prototyping and mass production with an all-inclusive offer for the medical sector.

- ◆ **Manufacturing**  
Equipped with swiss turning, milling and multi-axis CNC Milling machines, Rescoll Manufacturing has the capacity of producing up to 100,000 products/year in different materials (PEEK, POM, Ti, Cobalt, etc.) in a perfectly controlled ISO 13485 environment...
- ◆ **Finishing and Assembling**  
After dimensional control, complex implants can be assembled in house.
- ◆ **Cleaning and packaging**  
RESCOLL Manufacturing can take charge of the laser marking, cleaning and packaging thanks to its clean room (ISO 7) facilities.





## CONTACT

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