



Leading to competitiveness through innovation
in **MEDICAL DEVICES**,
Biomaterials,
Surfaces Treatments and
Processes

TESTING

DEVELOPMENT

MANUFACTURING



www.rescoll-medical.com



Accreditation N°1-1995.
Scope available on www.cofrac.fr



Rescoll and Rescoll manufacturing are companies involved in medical activities

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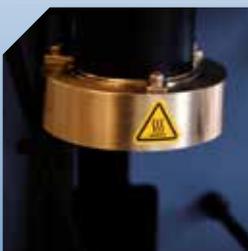
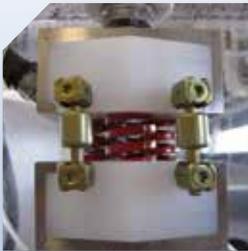
With more than 20 years of experience in the study of polymers, composites, advanced materials and surface treatments as well as over 50 patents to its credit, RESCOLL plays a major role in national and international research and innovation.

The combined expertise of RESCOLL and RESCOLL Manufacturing allows us to propose a unique offering in France and in Europe. To offer a wide range of tools to help you develop your innovative projects and reach your market as quickly and safely as possible.

TESTING



**MATERIALS AND PRODUCTS ANALYSIS - VALIDATION
CLEANING VALIDATION - PACKAGING AND STABILITY
VALIDATION - HEAVY METALS - RESIDUAL SOLVENT AND
MONOMER - ENDOCRINE DISRUPTORS - MECHANICAL
TESTING AND VALIDATION - STATIC AND FATIGUE TESTING
EXPERTISE**



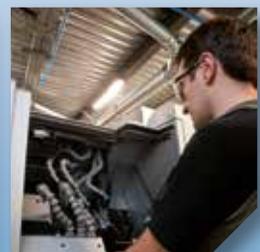
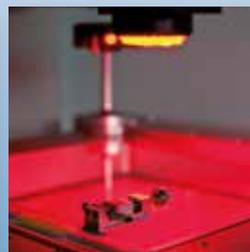
DEVELOPMENT

BIOMATERIALS DEVELOPMENT - PRODUCTS DEVELOPMENT
LITERATURE REVIEW - GEL FORMULATION - COMPOSITE
FORMULATION - ADHESIVE FORMULATION - SURFACE
TREATMENT AND BIOACTIVE COATING - CLEAN ROOM RE-
VERSE ENGINEERING - RISK ANALYSIS & REGULATORY
ISSUES - PROTOTYPING - SCALE-UP



MANUFACTURING

PROTOTYPING - MANUFACTURING - SWISS TURNING
MILLING - POLISHING - LASER MARKING - CLEANING
CLEAN ROOM PACKAGING - METROLOGY - TITANIUM STAIN-
LESS STEEL REFRACTORY - PEEK - ERTACETAL TEFLON -
POM - PROPYLUX - RADEL - PEEK CARBON FIBER



Example of innovation study

HOBBIT : Innovative composite material (organic /bioactive ceramic) with gradients of mechanical properties and resorption to develop resorbable implants.

Project supported by FUI 8, 092906353

RIBIO : Development of homogenous and adhesive surface coating using polymer on titanium in order to enhance healing and antiseptic properties.

Project supported by FUI 11, F1106038V

SPIDIMAN : Development of new surface treatment and glucose sensitive fluorescent coating technology applied onto a standard insulin catheter and incorporated into a single port artificial pancreas system.

Project co-funded under the FP7 : 305343



ANASTOMOSEAL : Development of biomaterials with adhesion properties for implantable medical device. Perform mechanical characterization of adhesion over inert and biological substrates.

Project co-funded under the FP7 : 280929



TEH-TUBE : Tissue Engineering of the right Heart outflow tract by a biofunctionalized bioresorbable polymeric valved TUBE.

Project co-funded under the FP7 : 604049



NEWBONE : Development of load fiber reinforced composite based non-metallic biomimetic bone implants.

Project supported by FP6, 026279



References

Depuy
Creaspine
Implanet
S14 Implant
Medicrea
Teknimed
Biomet
BBRaun
Noraker
Medacta
ConMed
Global-D
Septodont
Statrice Santé
Tecknoflex
Fx Solutions
Hexabio
Ascuelab
Galenix
développement
L'Oréal recherche
Laboratoires
Santé beauté
Cardio3
Ceva
Cardial
Cousin Biotech
Acteon
Ellipse
Pierre fabre
Médicaments
Textile Hi-Tec
ART
LDR Medical
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Rescoll Development

With 20 years of experience, Rescoll has become the reference as the innovative partner for biomaterials and medical devices development. With a team of over 50 doctors, engineers and technicians, RESCOLL is in charged or is involved in medical devices development for orthopedic, ophthalmic, cardiovascular, dental, intestinal implants sectors and skin compatible adhesives.

All activities are conducted under ISO 9001 and/or ISO 17025 quality system. Prototyping could be achieved under clean room.



Rescoll Development



BIOMATERIALS DEVELOPMENT

- Literature Review
- Gel Formulation
- Composite Formulation
- Adhesive Formulation
- Surface Treatment and Bioactive Coating
- Reverse Engineering
- Risk Analysis & Regulatory Issues



PRODUCTS DEVELOPMENT

- Literature Review
- Polymeric Resorbable Implants
- Polymeric Non-Resorbable Implants
- Composite Implants
- Metallic Implants
- Reverse Engineering
- Risk Analysis & Regulatory Issues



EQUIPEMENTS

- Injection
- Extrusion
- Freeze Drying
- Supercritical Carbon Dioxide
- Coating
- Machining
- Clean Room



Biomaterials & Medical devices



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Rescoll Manufacturing

can help you to solve your issue or meet your needs in prototyping, manufacturing, finishing and controls.

All stages are conducted in an ISO 13485 certified environment. Final cleaning and Packaging are achieved under clean room.



Rescoll Manufacturing



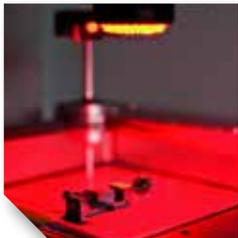
PRODUCTS

- Spine
- Knee
- Hip
- Maxillofacial
- Cardiac
- Dental
- Ancillary



PROCESS

- Swiss Turning
- Milling
- Turning/ Milling Multiaxis
- Polishing
- Laser Marking
- Cleaning
- Packaging
- Clean Room (ISO 7)
- Metrology



MATERIALS

- Metal : Titanium (TA6V4 ELI, T40/T60, Tantalé, Stainless steel (316LVM), Steel for instrument (316L, 17.4PH, X30CR13, CUSTOM 455), Refractory (CoCr, PHYNOX)
- Polymer : PEEK, ERTACETAL, TEFLON, POM, PROPYLUX, RADEL
- Composite : PEEK CARBON FIBER



Medical devices and Instruments



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Rescoll Testing

provides analysis services for evaluating **biomaterials and medical devices** concerning physico-chemical, chemical, physical and morphological properties. RESCOLL can help you to meet your needs for product stability, packaging and cleaning validation. More RESCOLL provides mechanical testing and expertise.

All experiments are conducted in ISO 17025 accredited laboratories.

Rescoll Testing



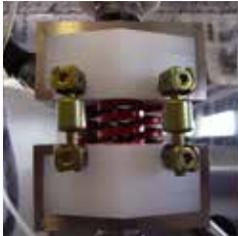
MATERIALS AND PRODUCTS ANALYSIS

- Chromatographic Analysis • Spectroscopic Analysis • Surface Analysis
- Chemical and Physical Analysis • Aging Study
- Thermo-mechanical Analysis



PRODUCTS AND PACKAGING VALIDATION

- Degradation of products analysis (ISO 10993-13)
- Chemical characterization of materials (ISO 10993-18)
- Morphological and Topographical analysis of materials (ISO 10993-19)
- Cleaning validation (XP Pr NF S 94-091)
- Packaging and stability validation (NF EN ISO 11607 -09, ASTM F1929 & EN 868-5, ASTM F1980-07)
- Analysis for heavy metals (USP< 232> ; USP< 233>; ICH Q3D)
- Residual solvent content & residual monomer content (USP <467> ; ICH Q3C)
- Identification and quantifying endocrine disruptors chemicals
- Performance testing of shipping containers and systems (NF H00-060, ASTM D4169, Test methods ISTA)



MECHANICAL TESTING AND VALIDATION

- STATIC AND FATIGUE TESTING
- SPECIMENS : Tensile, Compression, Shear, Peeling, Torsion, Rotation, Abrasion...
- PRODUCTS : Spine, Knee, Hip, Shoulder, Dental, ...
- BIOLOGICAL MATERIAL AND Implanted devices



EXPERTISE

- Failures analysis, aging, defects prematurely encountered in products or materials
- Analysis and comparison of materials used
- Process validation
- Purity validation

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