



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

TESTING

DEVELOPMENT

MANUFACTURING



[www.rescoll-medical.com](http://www.rescoll-medical.com)



Accreditation N°1-1995.  
Scope available on [www.cofrac.fr](http://www.cofrac.fr)



BUREAU  
VERITAS

ISO 9001  
ISO 13485

Rescoll and Rescoll manufacturing are companies involved in medical activities

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.

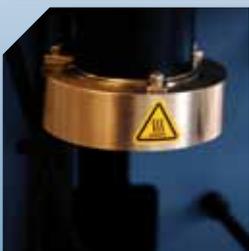
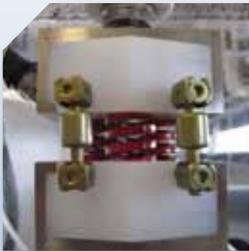
The combined expertise of RESCOLL and RESCOLL Manufacturing allows us to propose a unique offering in France and in Europe. To offer a wide range of tools to help you develop your innovative projects and reach your market as quickly and safely as possible.

## TESTING



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**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  
REVERSE ENGINEERING - RISK ANALYSIS & REGULATORY  
ISSUES - PROTOTYPING - SCALE-UP

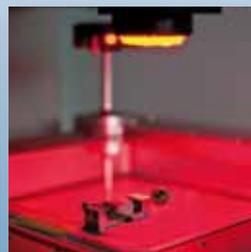


# MANUFACTURING

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



**BUREAU  
VERITAS**  
ISO 9001  
ISO 13485



# 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  
Neosteo  
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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.

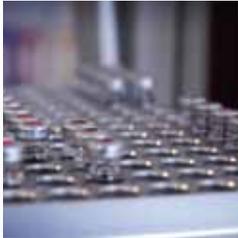
All experiments are conducted in ISO 17025 accredited laboratories.

# Rescoll Testing



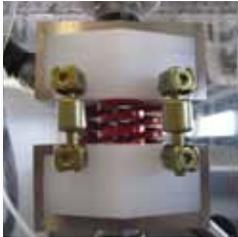
## MATERIALS AND PRODUCTS ANALYSIS

- 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

## Biomaterials & Medical devices



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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



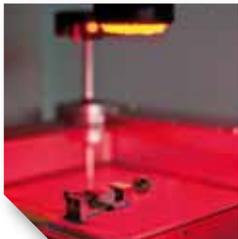
## PRODUCTS

- 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, Tantale, 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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