



BONASTRE
ENGINEERING AND ADVANCED MACHINING



WHO WE ARE

- **BONASTRE** is a Contract Development and Manufacturing Organization (**CDMO**) with extensive experience in **Design & Development, Engineering, Prototyping** and **Production** of high-quality surgical products and instrumentation.
- With **65+ years of expertise** in Engineering and Advanced Machining of complex parts, we deliver cutting-edge solutions for **Minimally Invasive Surgery, Odontology, Traumatology, Orthopedics, Neurosurgery, Surgical Robotics**, and **Thoracic Surgery**.
- Our passion for **precision, perfection**, and **innovation** drives the development of high-quality products, **adding value for clients** and positioning us as a **unique supplier**.



WHO WE ARE



- **MISSION:** BONASTRE offers advanced machining for those companies or projects that require a supplier able to provide them **added value** and a **total service**, working as **partners** of our clients.

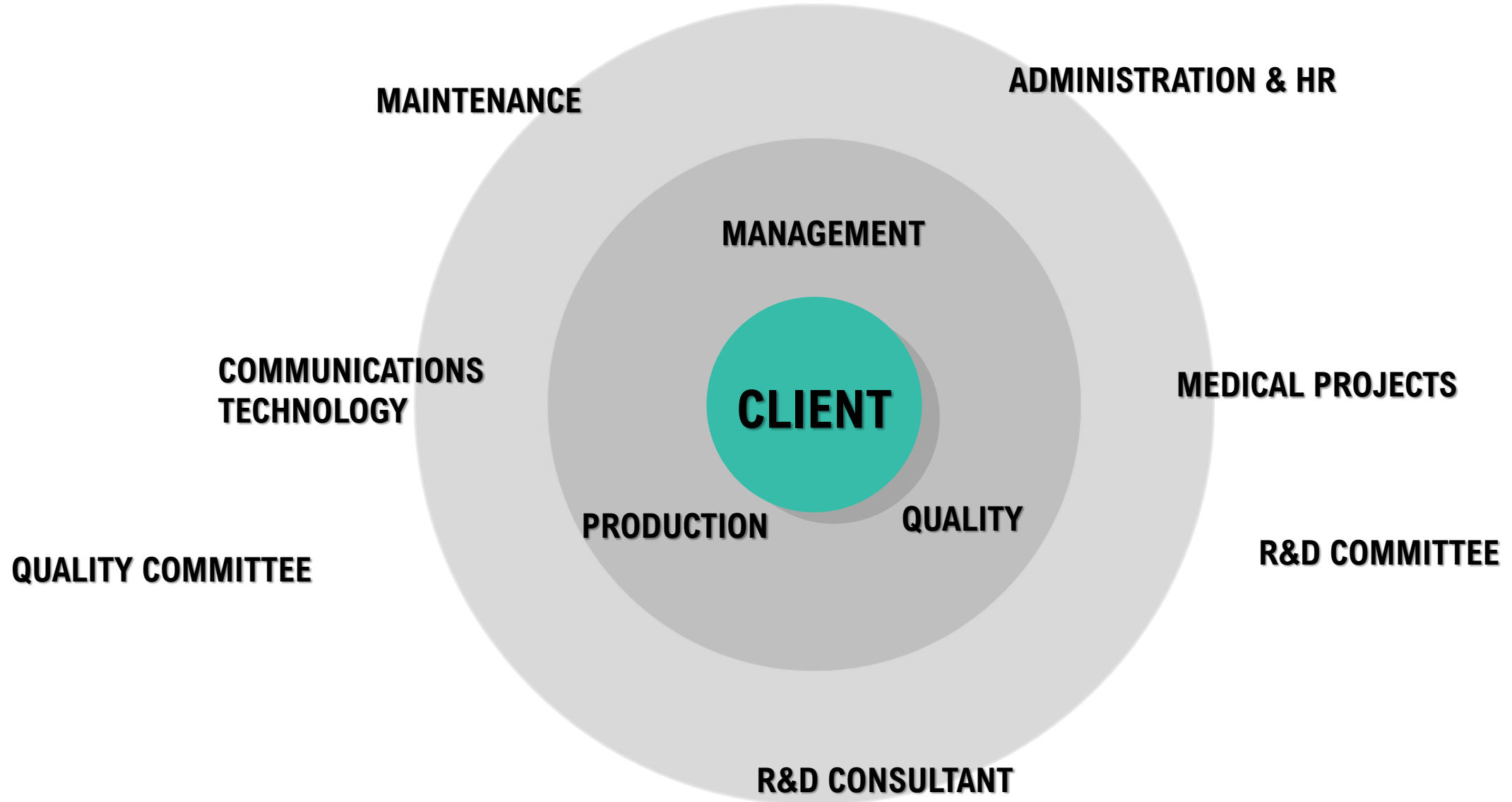
We can also offer the services from our **Engineering** department, helping in the development or improvement of those products or projects that require it.

- **VISION:** Our **spirit of innovation** and **continuous improvement**, lead us towards a constant production of products or devices of high quality and technical difficulty, creating **added value** and becoming a unique supplier for our clients.

We are highly-oriented towards the research of new ideas and medical projects from the beginning, transforming ideas into projects or devices, and developing its **technology transfer** and, afterwards, producing them in the role of suppliers OEM/CDM.

- Specialised in the **medical sector**, we produce almost 6.000 different references from fields such as odontology, traumatology, sports medicine, pneumology, surgery or surgical instruments.
- Over the years, we have designed, developed and produced different Medical Devices or components, dental implant lines, surgical instruments, etc.





MEDICAL AREAS



We provide medical solutions for the primary surgical areas



**MINIMALLY
INVASIVE SURGERY
(MIS)**



ODONTOLOGY



VASCULAR



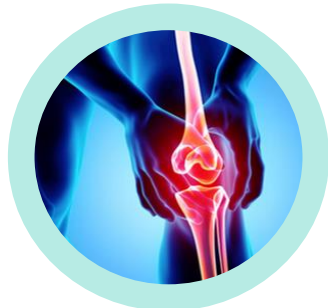
**ORTHOPEDICS
& TRAUMA**



THORACIC



**SURGICAL
ROBOTICS**



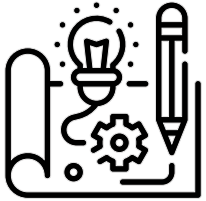
SPORTS MEDICINE



NEUROSURGERY



DESIGN, DEVELOPMENT & ENGINEERING



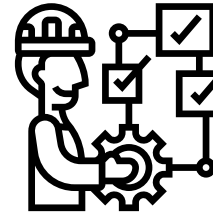
We support your project at **any stage** of the medical device development lifecycle to bring **your idea** from **initial concept** to **production**.

PROTOTYPING & TESTING



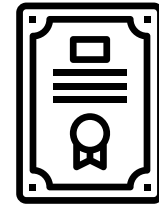
From **rapid prototyping** to **production-equivalent** prototypes, we conduct testing across the entire medical device development lifecycle to **Verify** and **Validate** the design.

MANUFACTURING



We excel in various manufacturing methods, with a **mastery in advanced machining** for your medical components. Our expertise extends to crafting **highly intricate parts** with **precision**.

QUALITY & REGULATORY COMPLIANCE



Certified to **ISO 13485**, **ISO 9001**, **UNE 166002**, and **ISO 14001**, our Integral Quality System ensures excellence. We offer **Technical Documentation packages** and **Regulatory support**.



DESIGN, DEVELOPMENT & ENGINEERING

LEADING ENGINEERING

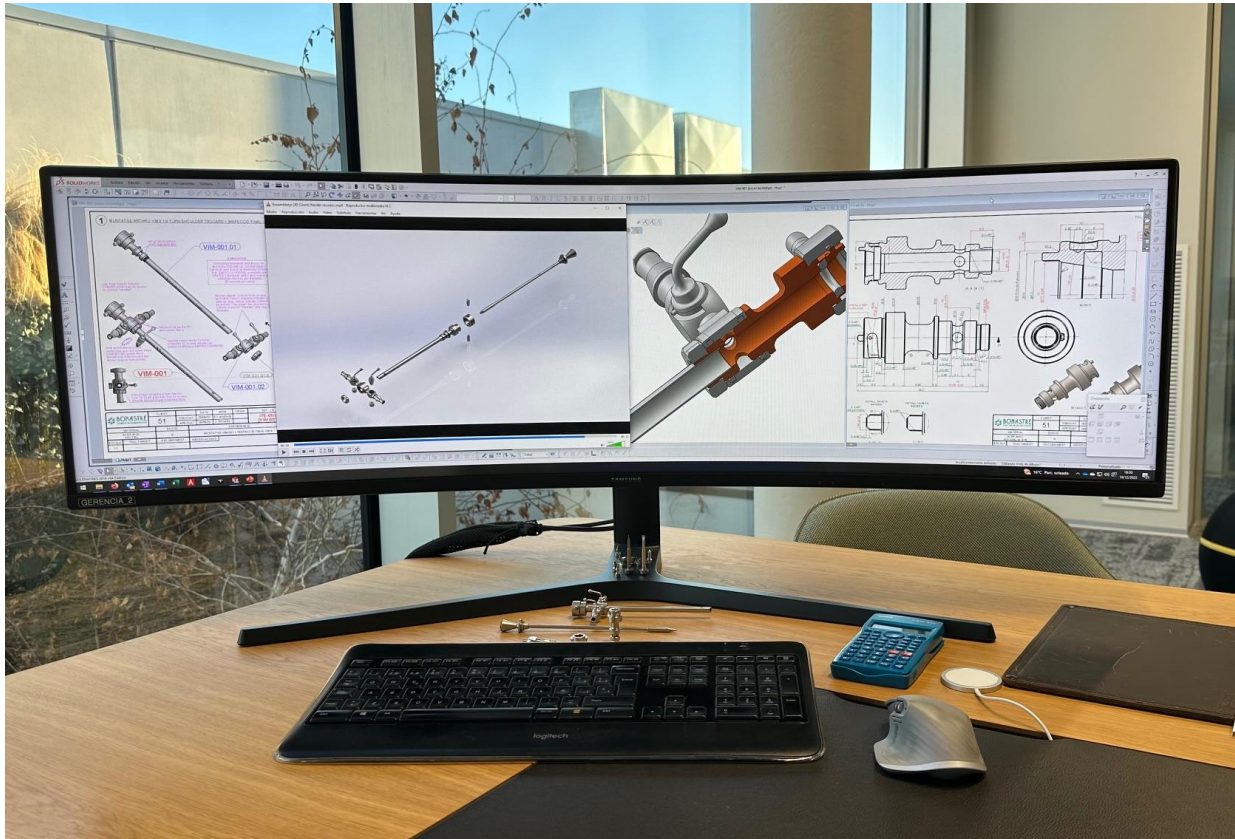
Certified R+D+I management system (UNE 166002) powered by the most robust fully automated Technology Forecasting and Competitive Intelligence system.

EXTENSIVE KNOW-HOW

Our diverse skills, expertise, and knowledge across various medical domains empower us to create effective designs and innovative solutions.



DESIGN, DEVELOPMENT & ENGINEERING



DESIGN FOR MANUFACTURING (DFM) & DESIGN FOR ASSEMBLY (DFA)

Our engineers and top-notch setters meticulously craft our own manufacturing drawings, applying our key strengths in **DFM** and **DFA**. This ensures **seamless alignment of design and manufacturing**, expediting industrialization and reducing Time to Market.

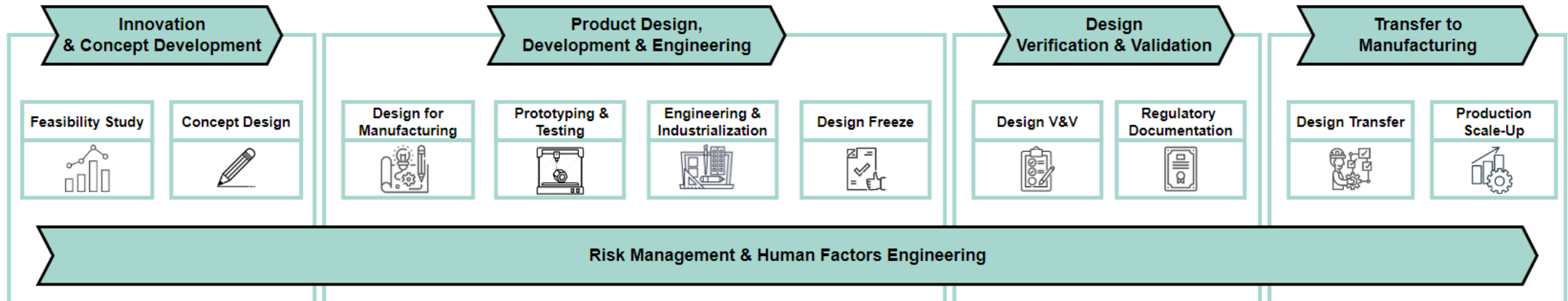
TOOLING DESIGN

The inherent technical complexity of certain projects demands the creation of custom tools and specialized tooling tailored to meet each unique requirement.

DESIGN, DEVELOPMENT & ENGINEERING

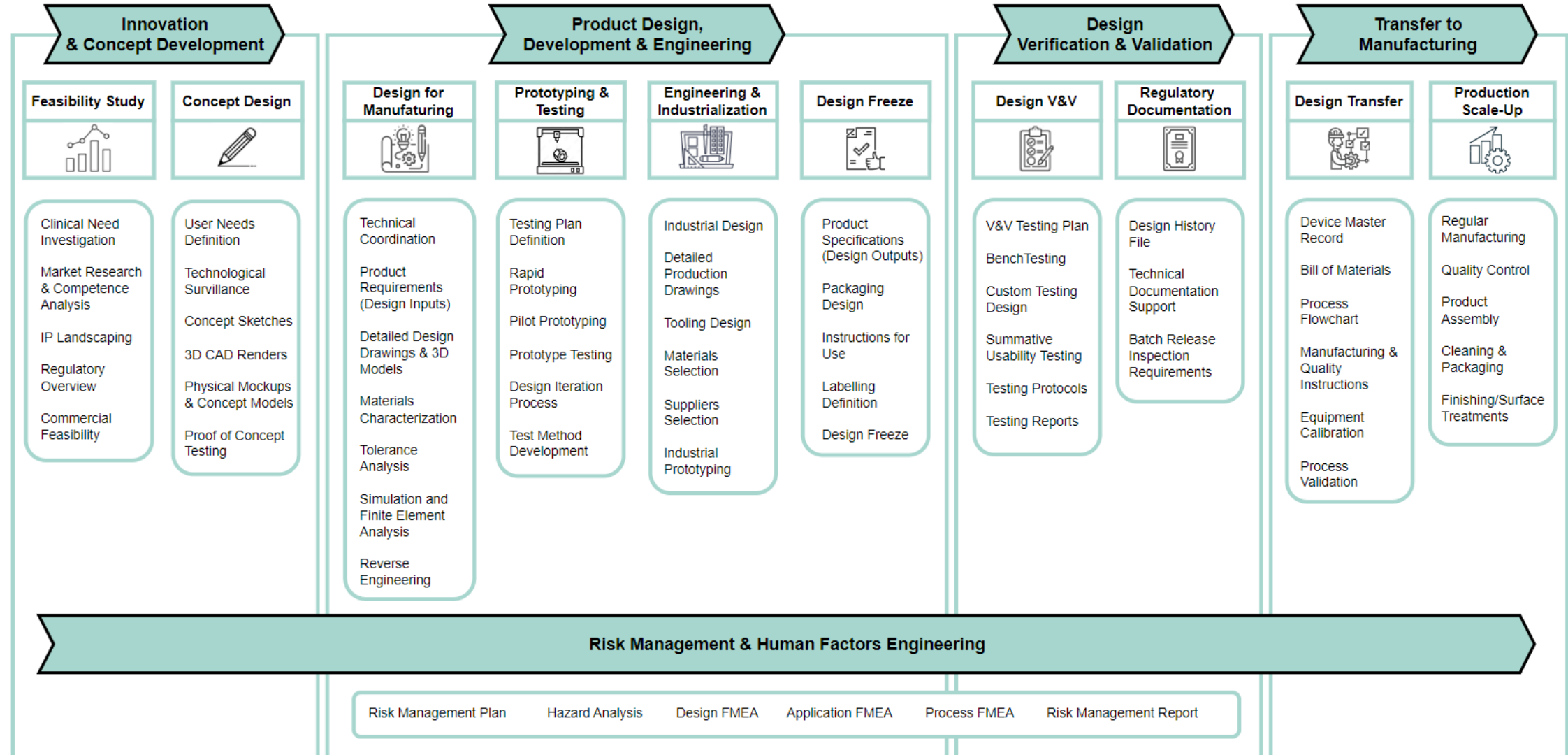
PRODUCT DESIGN & DEVELOPMENT

We support your project at any stage of the medical device development lifecycle to bring your idea from initial concept to production.





DESIGN, DEVELOPMENT & ENGINEERING





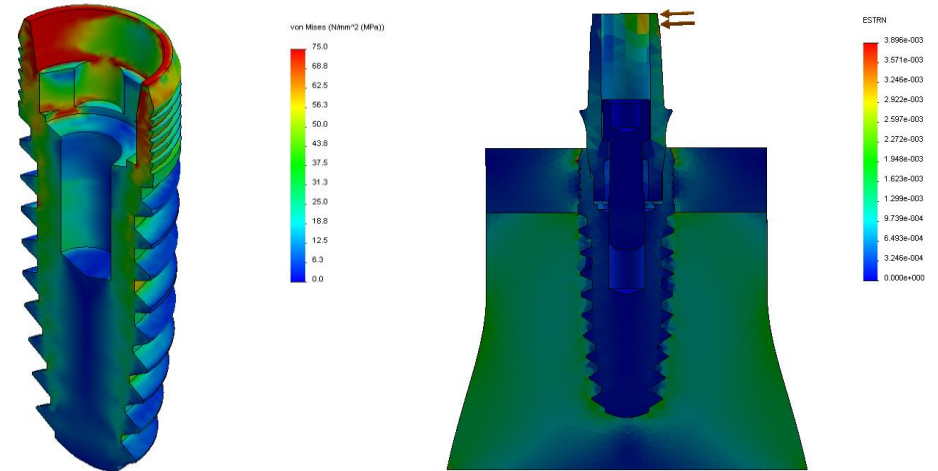
DESIGN, DEVELOPMENT & ENGINEERING

FINITE ELEMENT ANALYSIS (FEA)

We provide cost-effective FEA services by using advanced simulation software to predict, optimize and validate our designs. The analysis (FEA) also enables the streamlining of the process, **reducing** the need for numerous **prototypes**, and **cutting** testing **costs**, thus optimizing your design journey with precision and affordability.

REVERSE ENGINEERING

Employing **Reverse Engineering techniques**, we extract valuable design information from comparable benchmark products. The **extracted data** serves as a crucial input for new product development initiatives and to enhance existing designs.





DESIGN, DEVELOPMENT & ENGINEERING



USABILITY / HUMAN FACTORS ENGINEERING (IEC 62366)

We specialize in developing user-friendly products and devices, prioritizing usability, safety, and enhanced functionality. Our human factors and usability engineering approach is dedicated to meeting user needs and elevating safety standards.

RISK MANAGEMENT (ISO 14971)

We consistently integrate Risk Management into design and manufacturing, ensuring final products meet essential safety controls and effectiveness. Employing robust risk management tools, we systematically evaluate, control, and reduce identified risks.



PROTOTYPING & TESTING

PROTOTYPES

We offer prototyping capabilities at every stage of development, allowing to swiftly deliver low-volume prototypes for concept testing, customer feedback, material selection, performance and usability testing. This accelerates your device's time to market in a cost-effective manner.

- **Rapid Prototype:** Used to test shape and compatibility using rapid prototyping methods. While not fully functional, these prototypes provide essential insights.
- **Pilot Prototype:** Created to assess functional designs and manufacturability processes, typically during non-regulatory phases.
- **Production Prototype:** Prototypes closely resembling the final product, incorporating exact design, packaging, and material specifications. They are intended for use in verification and validation testing.





MANUFACTURING



ADVANCED MACHINING

With over 60 years of manufacturing expertise and know-how, we adeptly meet the most demanding requirements. Specializing in complex part production, we tackle intricate morphologies, tight tolerances, and challenging raw materials.

INDUSTRIALIZATION

As specialists in industrialization, we meticulously attend to every detail across production phases, crucial for meeting high-quality standards. Proficiency in diverse manufacturing technologies, with machining as our core strength, ensures a controlled industrialized process.



MANUFACTURING

HIGHLY QUALIFIED STAFF

Outstanding setters empower us to consistently meet challenging technical requirements. Our Training Program for New Setters ensures they become top-notch specialists, maintaining our commitment to excellence.

EQUIPMENT

Our state-of-the-art facilities feature cutting-edge machinery for seamless adaptation to various components. Prioritizing optimal efficiency, flexibility, and scalable production is at the core of our operation.





MANUFACTURING

FINISHING/SURFACE TREATMENTS

We offer finishing and surface treatment services, including polishing, deburring, passivation, laser marking, anodizing, etc.

CLEANING AND PACKAGING

We can effectively remove production residues in a process-capable manner, offering the right cleaning methods for various types of applications.

Products final assembly and packaging can be conducted in our ISO-7 clean room.



MANUFACTURING



MANUFACTURING





QUALITY & REGULATORY COMPLIANCE



QUALITY, BONASTRE'S TRADEMARK

Our meticulous approach ensures an exceptional quality in our products. Validated processes guarantee attention to every detail across all manufacturing phases, allowing us to proactively anticipate and resolve potential issues during production. 100% Visual Inspection of medical products.

CERTIFICATIONS



We are prepared to meet any requirement for products intended for subsequent **CE** marking or FDA approval.



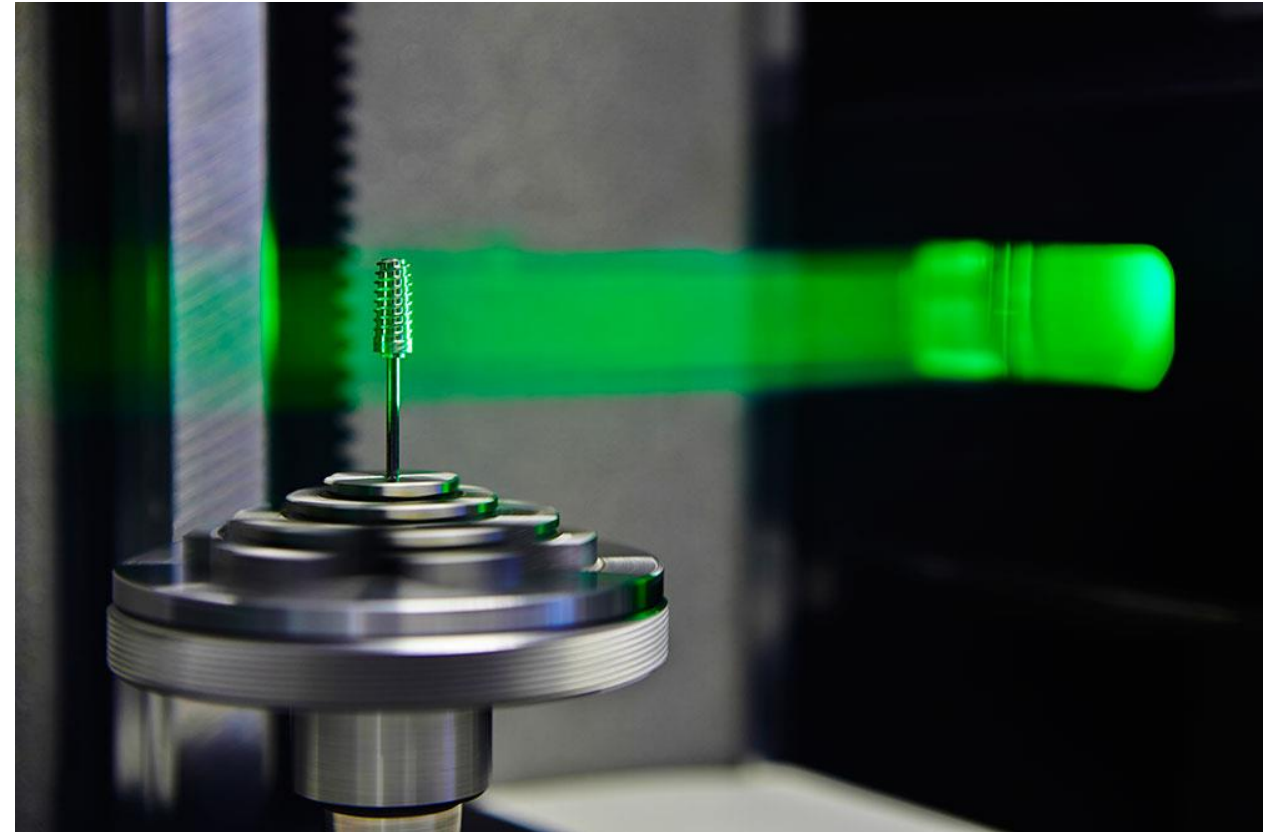
QUALITY & REGULATORY COMPLIANCE

QUALIFIED STAFF

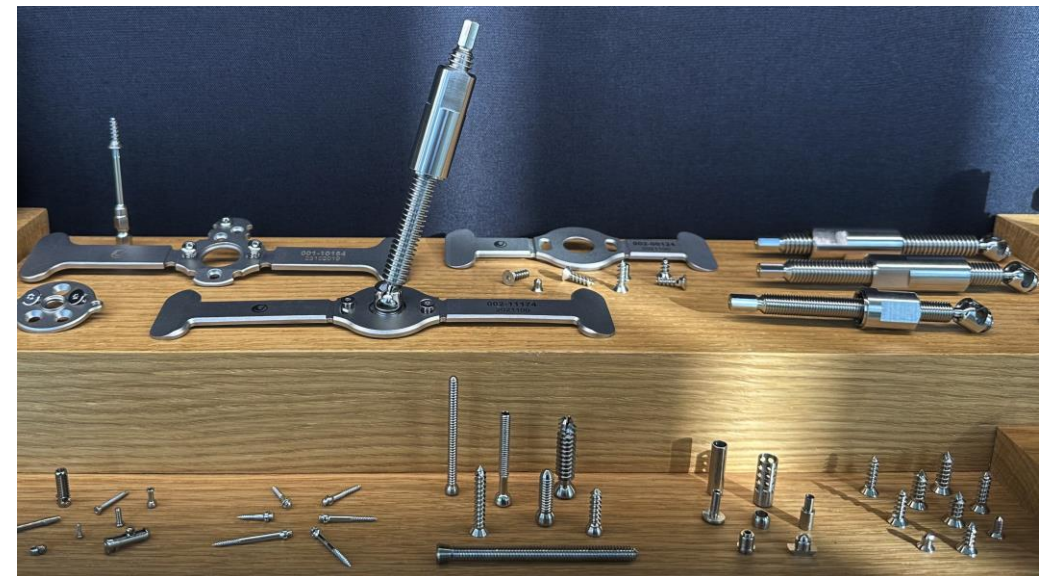
Producing intricate parts, at times more demanding to inspect than create, calls for a team of qualified staff. Our highly skilled personnel thrive in meeting varied requirements, ensuring thorough verification of any product or device.

METROLOGY

Ensuring the quality of intricate parts demands not only skilled personnel but also advanced metrology equipment. We have at our disposal modern facilities, including a temperature-controlled room at 20°C, to certify the most restrictive tolerances.



MEDICAL PRODUCTS



MEDICAL PRODUCTS

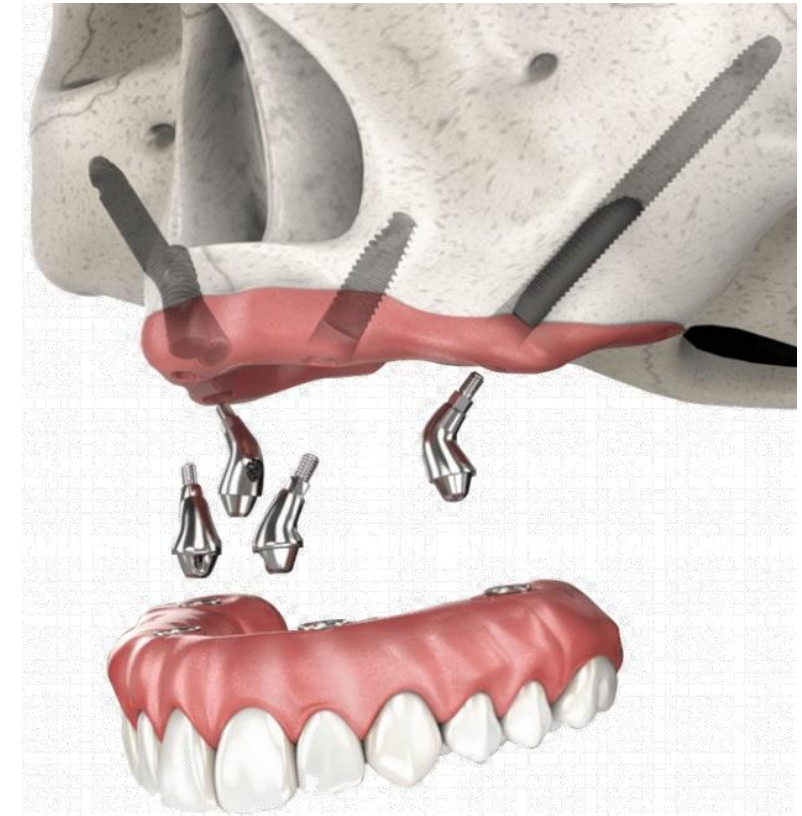
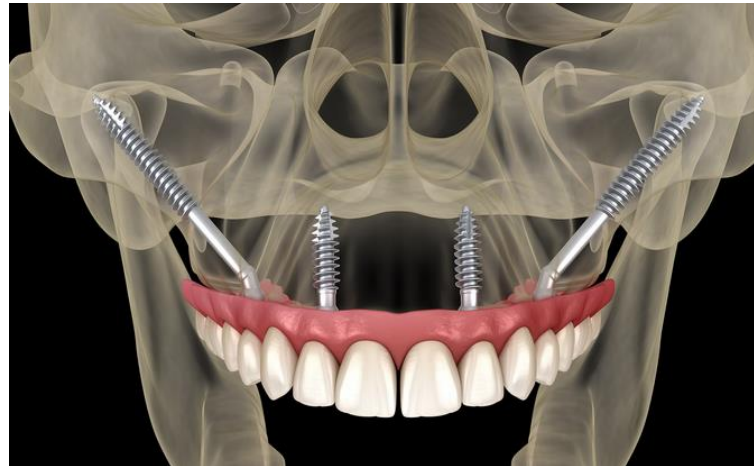
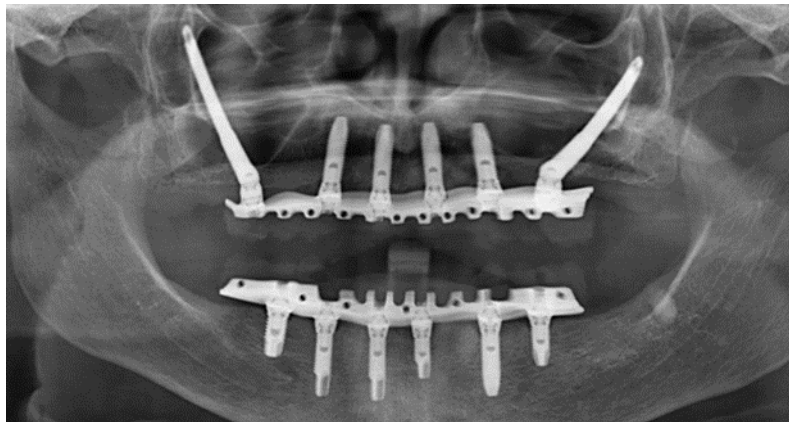




■ ZYGOMATIC IMPLANTS

Design, Development, and Industrialization of the Zygomatic Implant System.

The zygomatic implants must be designed to insert into the cheekbone and address mandibular atrophy

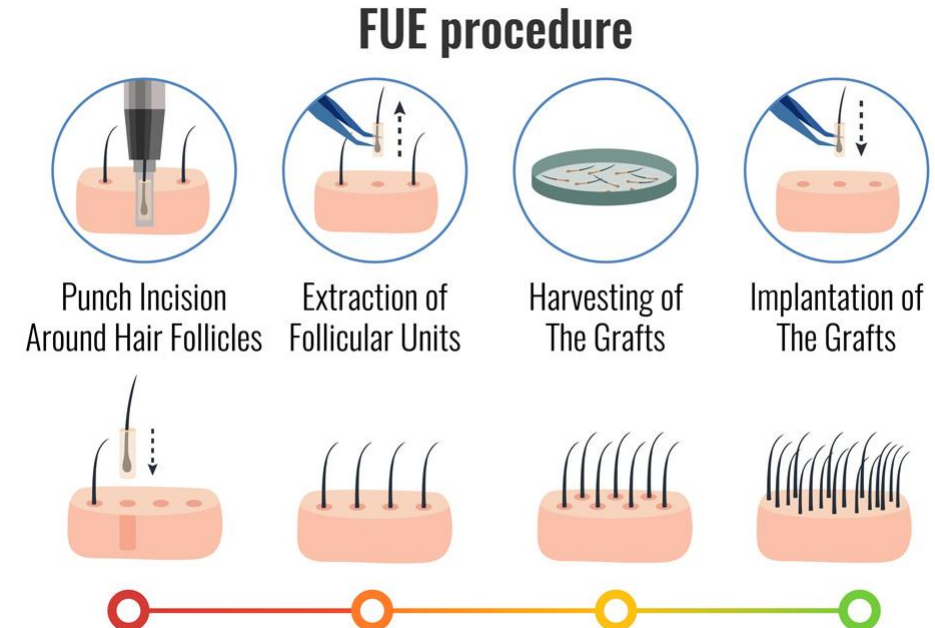




■ HAIR FUE PUNCH

Design, Development, Industrialization, and CE Certification of the Needle Range for Follicular Extraction using the FUE (Follicular Unit Extraction) Method

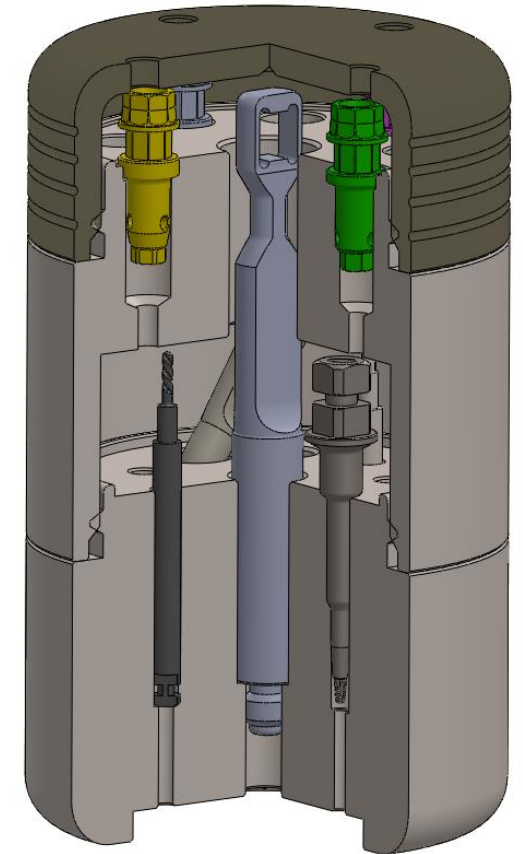
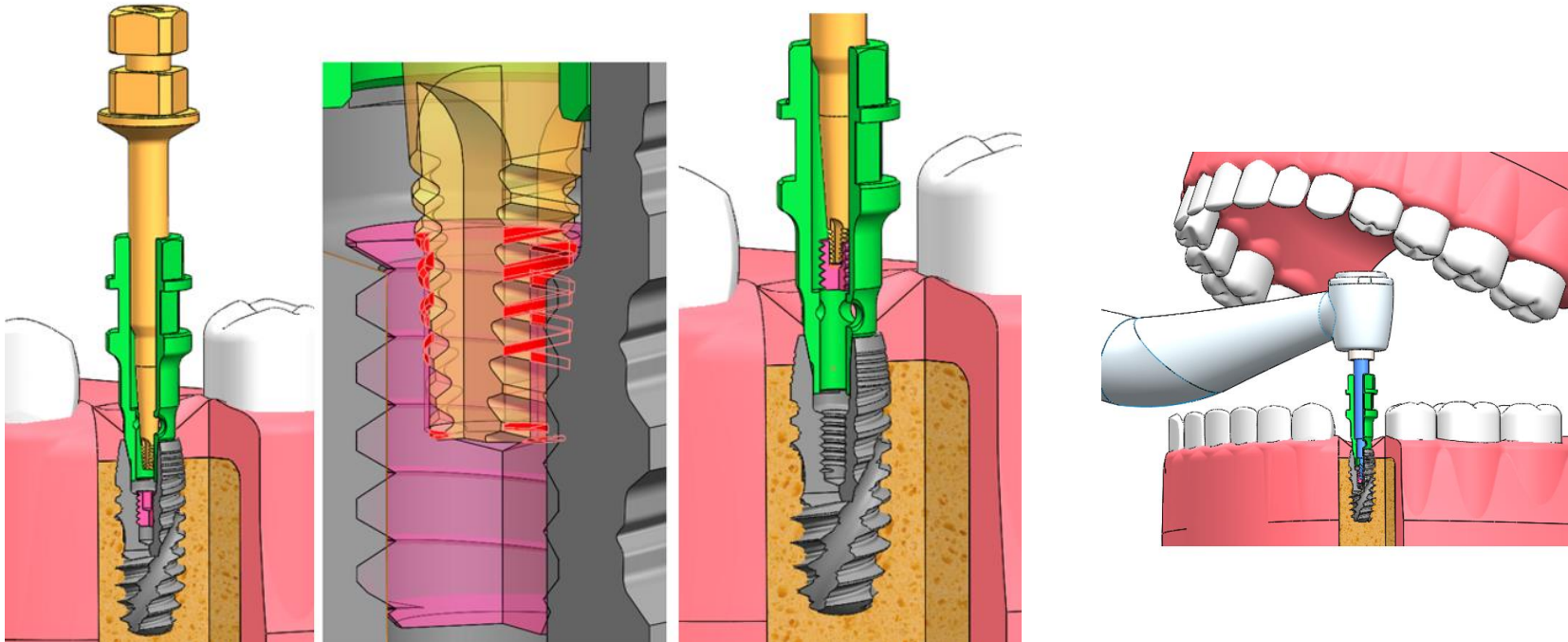
The experimentation and creation of hair extraction needles require high precision in cutting and follicle preservation. Therefore, it is essential to design and determine the optimal geometry for the various types of needle tips





■ BROKEN SCREW KIT

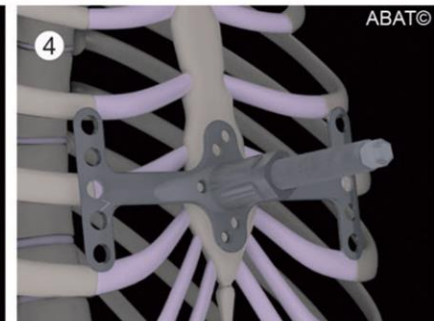
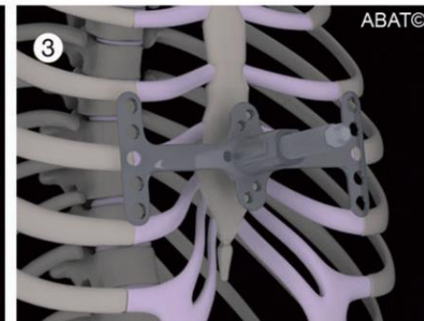
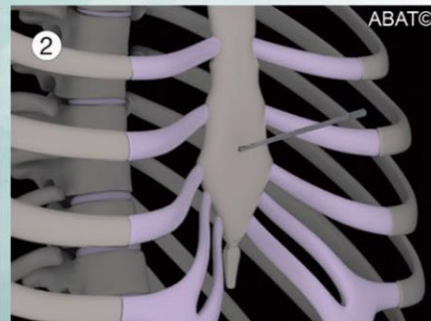
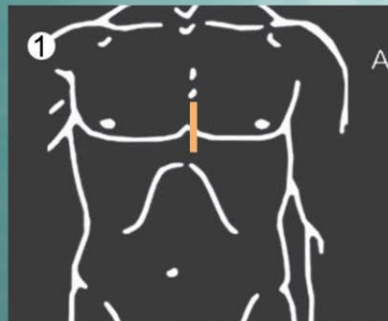
Design, Development, and Industrialization of a Broken Screw Rescue Kit, adaptable to various work settings and capable of addressing the most common breakage points in prosthetic screws





■ EXTRATHORACIC SURGERY FOR THE PECTUS EXCAVATUM TREATMENT

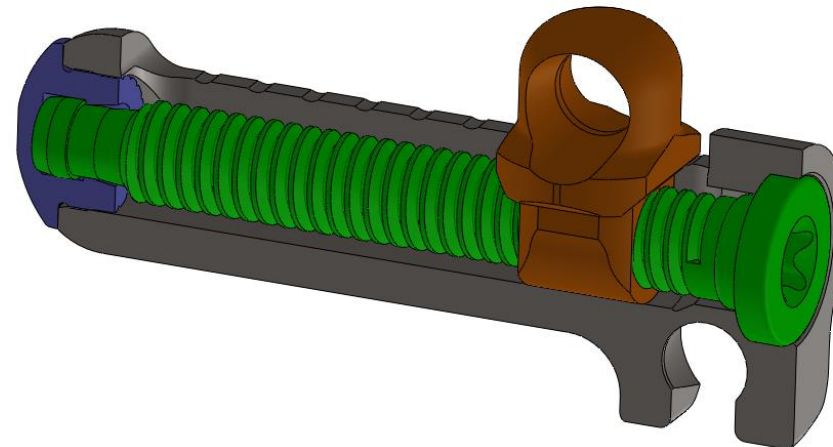
Industrialization and Manufacturing of a System to Correct Pectus Excavatum, a genetic chest deformity that causes several ribs and the sternum to grow abnormally





■ APNEA

Design, development, and manufacturing of a medical device for the treatment of sleep apnea. The solution consists of an activation and locking mechanism for mandibular advancement splints to prevent the closure of the airways





- **MODULAR SYSTEM FOR INTRAMEDULLARY IMPLANTS**

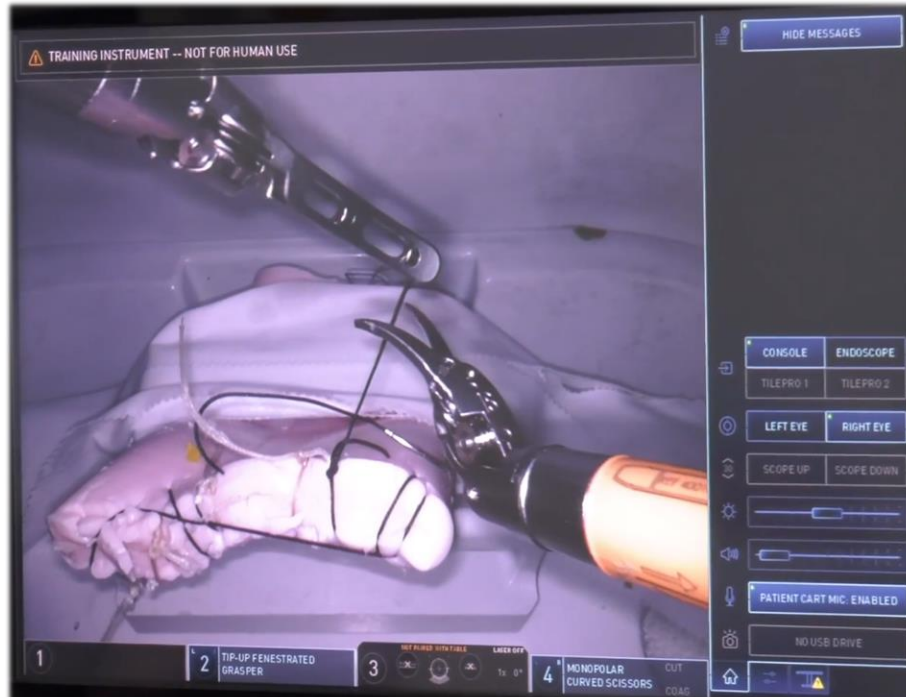
Prototyping of the NELA Modular Implant System intended to provide a customized fit for each patient, avoiding conventional techniques that rely on impact press-fit or the use of bone cement for fixation





■ HIGH PRECISION ROBOTIC SURGERY

Design, development, manufacturing, and assembly of components for a surgical robotic arm, aimed at improving precision, surgical dexterity, and maneuverability during minimally invasive procedures





■ STEAM CURE

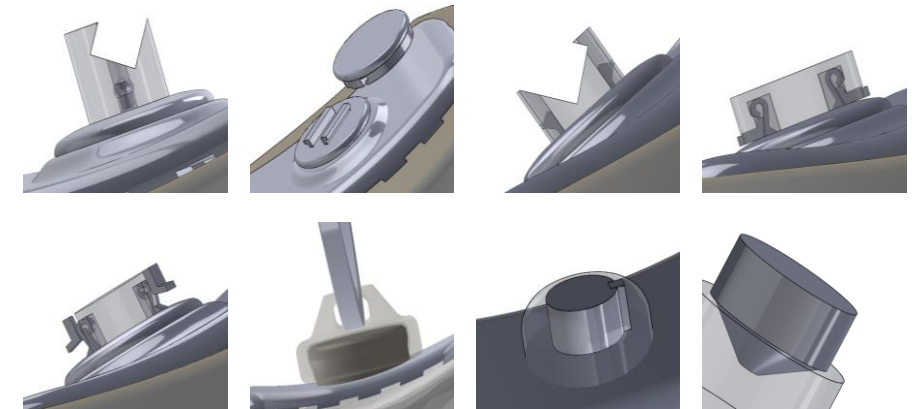
Design and Development of a medical vaporizer for delivering substances for therapeutic purposes via inhalation. This device allows users to monitor and control the active ingredients in the inhaled dosage.





■ MIXED LINGUAL ORTHODONTIC SYSTEM

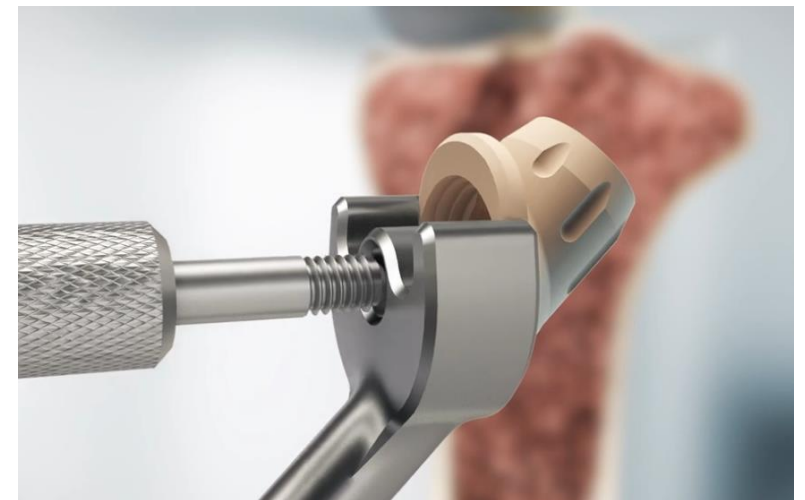
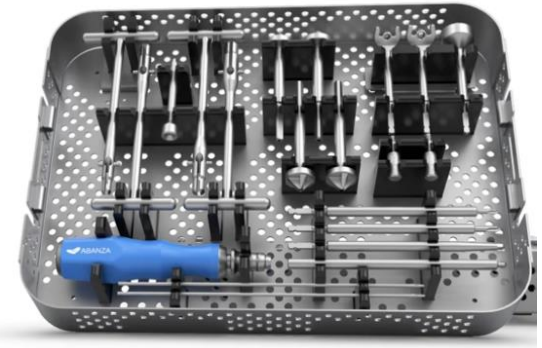
Design, Development and Industrialization of a mixed lingual orthodontic system, a project that combines the dental movement capabilities of brackets with those of invisible aligners. The system includes a fixed part attached to the tooth and a removable part that incorporates the aligner, the wire, and the brackets.





■ SURGICAL INSTRUMENTATION FOR ARTHROSCOPIC SOFT TISSUE REPAIR PROCEDURE

Industrialization and Manufacturing of Instruments for the Arthroscopic Procedure of Knee Soft Tissue Repair. This procedure provides a combination of strength and stiffness to ensure proper osteointegration of the graft while preserving its biomechanical properties, particularly for anterior cruciate ligament injuries.





■ ORTHODONTIC SYSTEMS KIT

Design, Development, and Industrialization of an orthodontic micro-screw application kit. The project includes the development of a manual screwdriver handle, instruments for orthodontic micro-screw insertion, and the complete surgical kit.





■ ARTHROSCOPIC TROCARS

Engineering, Development, and Industrialization of an Arthroscopic Trocar. The primary function of arthroscopic trocars is to facilitate the insertion of surgical instruments during arthroscopic procedures, enabling precise access to joints while minimizing tissue damage.



ARTHROSCOPY TROCAR





- **Robotic Retractor System for Endoscopic Transorbital surgery**

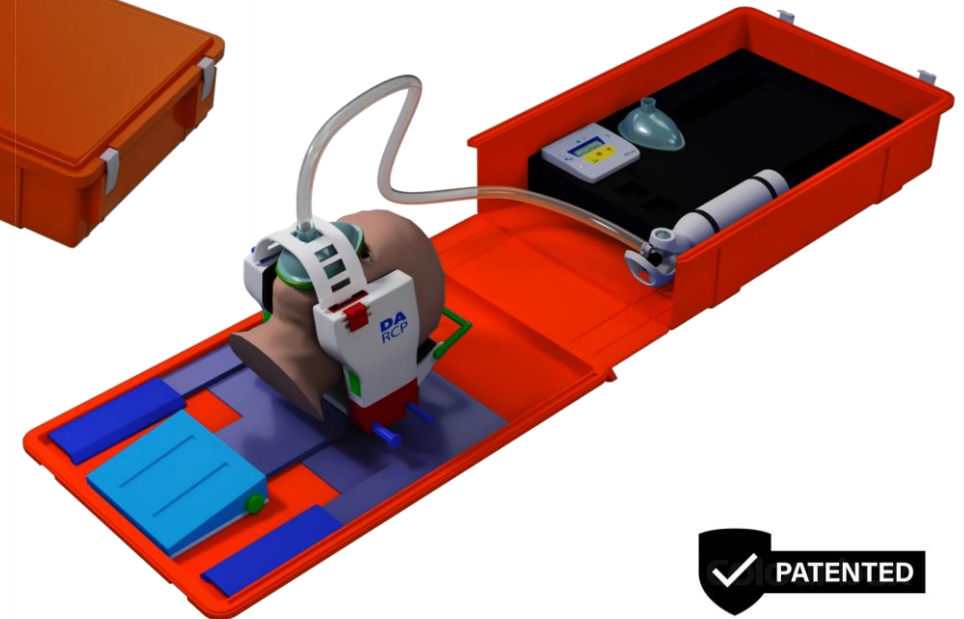
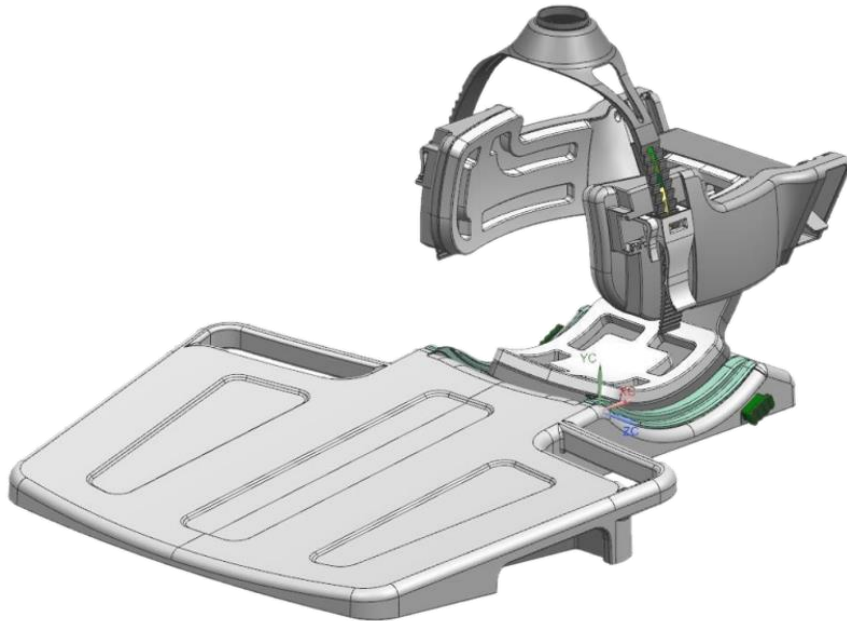
Design, Development, and Prototyping of the ROBORETO Device, a surgical instrument used in transorbital endoscopic surgery procedures with the aim of creating the necessary working space during the different phases of the intervention, while simultaneously measuring the intraorbital pressure in real-time to ensure the condition of the optic nerve





■ **Cardiopulmonary Resuscitation Support Device (DARCP)**

Engineering and advisory support in the development, industrialization, and certification of the DARCP Device - an innovative solution that enables a single operator, with just 8 hours of training, to complete the basic life support protocol in under one minute. This mobile, compact CPR emergency unit operates without the need for electrical power or software, significantly enhancing the efficiency and effectiveness of the survival chain.





▪ **Adjustable Needle Holder**

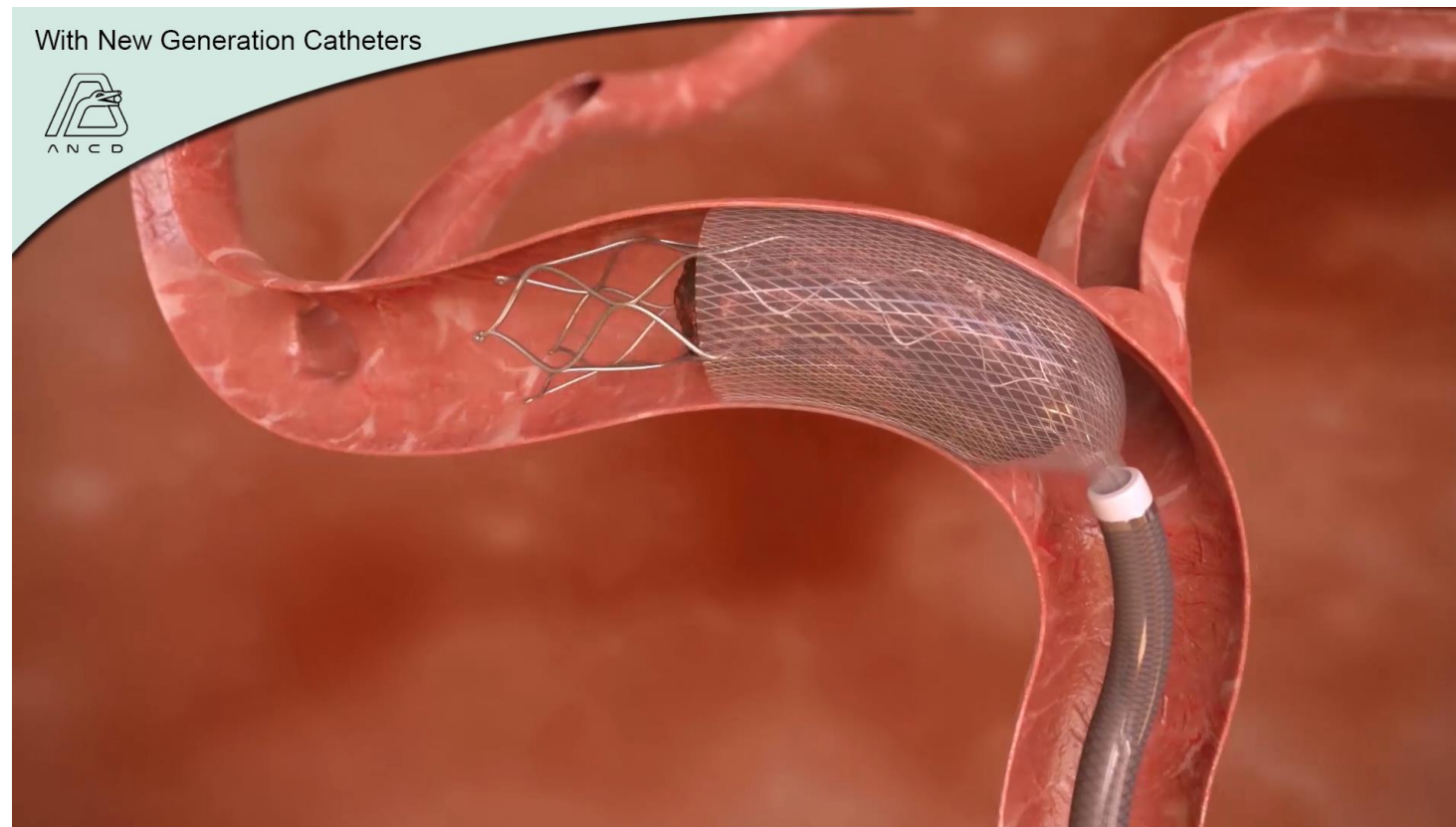
Design and industrialization of a versatile needle holder. The device is engineered to accommodate various needle sizes and references, enhancing usability and adaptability in diverse applications





■ **ADVANCED THROMBECTOMY SYSTEM: ANACONDA BIOMED**

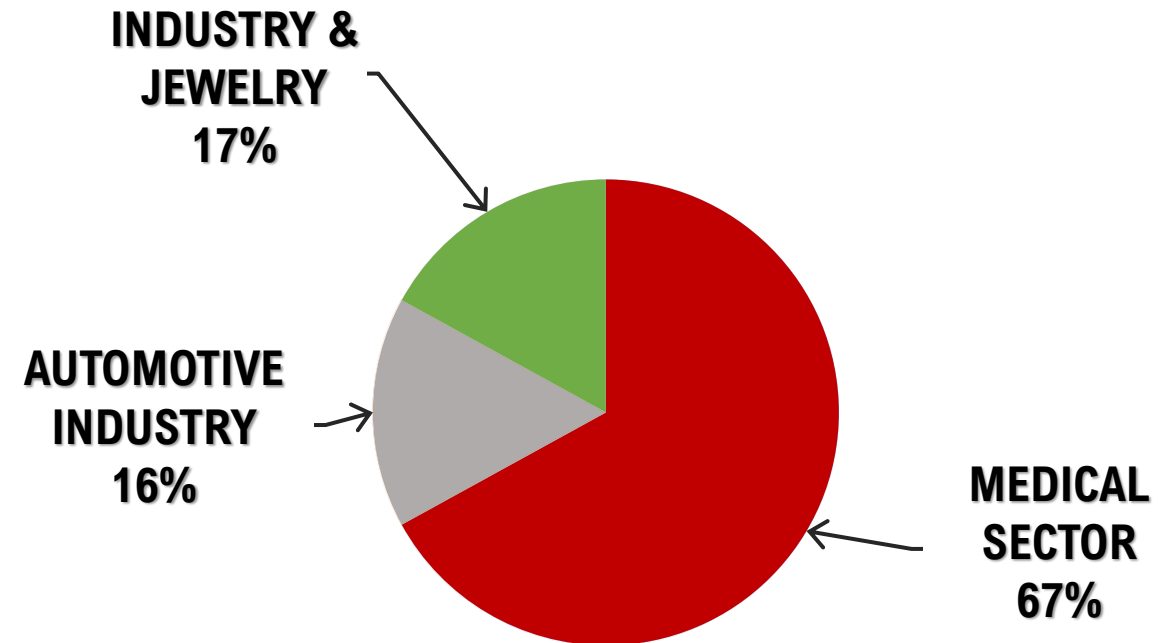
Bonastre has actively participated in the product and process engineering of the Anaconda project since 2015. Anaconda Biomed is developing the next generation of catheters to perform safely and efficiently mechanical thrombectomies. The Anaconda device is intended to restore blood flow in patients experiencing acute ischemic stroke due to a large vessel neurovascular occlusion.



PARAMETERS OF INTEREST



Clean Room ISO-7 of 25m²
[prepared for ISO-6]





FACILITIES TO PROMOTE WELL-BEING AT WORK:

A pleasant working atmosphere is an influencing factor to the final product's quality



**Healthy and gratifying
environment**

**Oil mist suction centralized system, and air
renewal**

Natural light

Courtyard gardens, terrace

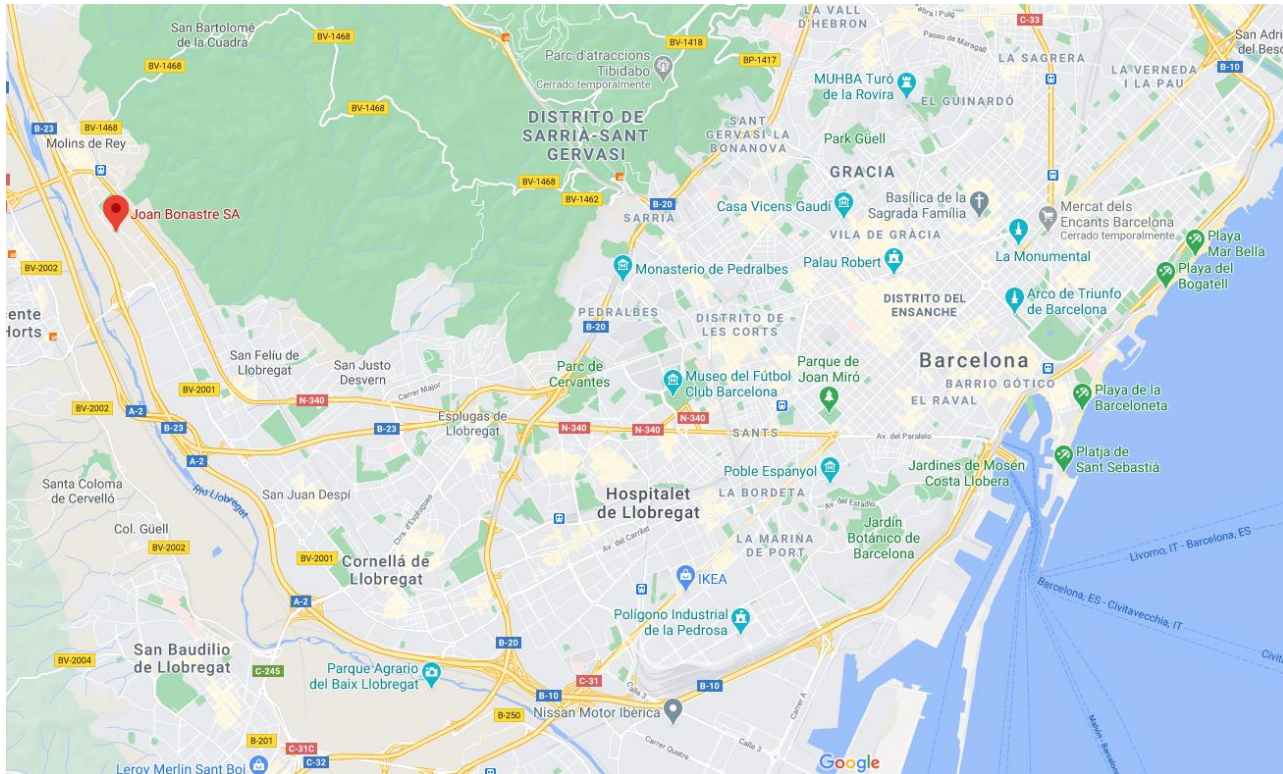
Comfortable meeting and training rooms

Gym

SYNTHESIS



CONTACT



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**THANK YOU FOR
YOUR ATTENTION**

