

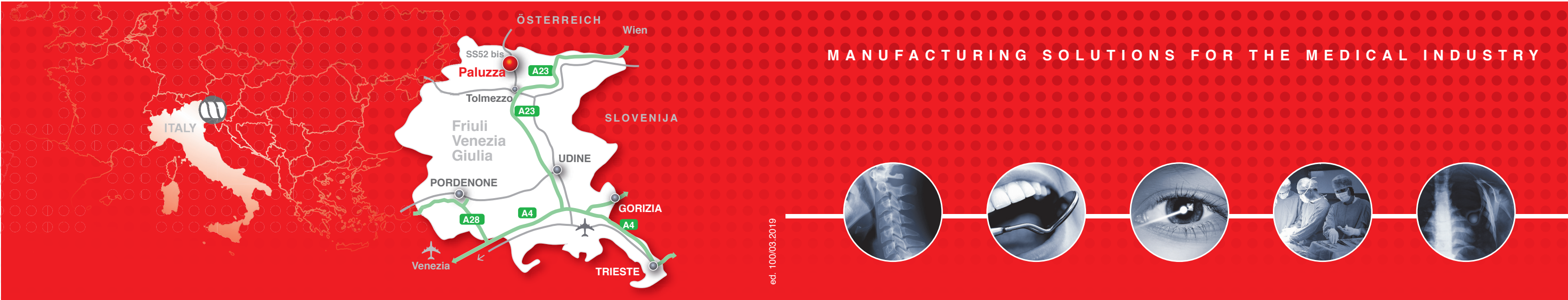
Lean manufacturing implementation

- **5s** philosophy:
 - **Sort**: all unneeded tools, parts and supplies are removed from the work space
 - **Set** in Order: a place for everything and everything is in its place
 - **Shine**: the work area is cleaned regularly (on a daily base)
 - **Standardize**:work processes, 5s activities and tasks are defined and standardized
 - **Sustain**: 5S is a habit of the organization and is continually improved
- **RTS-SMED** (Rapid Tool Setting):
 - Set-up time reduction and monitoring
 - Continuous tool setting time improvement
 - Key to implement the Just In Time methodology
 - Reduce costs and Lead Times
 - Improve flexibility (prototype – small serie production - high volume production)

Our Philosophy

- Continuous Improvement throughout our company structure
- Improve Quality, EN **ISO 13485** and **ISO 9001** certified manufacturing process
- Improve Quality environmental management system **ISO 14001** and occupational health and safety management system **BS OHSAS 18001**
- Reduce Time To Market
- Reduce Lead Time (production time) with high production flexibility
- Reduce cost and waste
- Proactive customer oriented approach
- Use always the latest technology available and state-of-the-art machines
- Full production traceability (30 years)
- Add value to contract manufacturing and engineering services

MANUFACTURING SOLUTIONS FOR THE MEDICAL INDUSTRY



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ORTHOPEDICS
TRAUMA
SPINE SURGERY

DENTAL
IMPLANTOLOGY

OPHTHALMOLOGY

MIS & MEDICAL
INSTRUMENTS

IMPLANTABLE
PORT SYSTEMS



ISO 9001 - ISO 13485



ISO 45001

www.carniaflex.com

Introduction

Since 2000 **Carniaflex manufactures** on customer's design, tiny high precision and complex mechanical parts, in **Titanium** (and other metals) for **non-active Medical Devices**.

The products, manufactured on customer's project, are parts of implant systems and accessories, components and parts for fractures locking systems, intramedullary nails and screws, cortical, cancellous and cannulated screws, polyaxial head screws, micro components for maxillofacial surgery, multi threaded dental implants and angled abutments with complex geometries, surgical instruments, implantable venous vascular access systems, flexible biopsy forceps and retrievers, etc.

Design and product Engineering

- Product design and development
- Feasibility check
- 2D Technical-Drawing
- 3D Modelling
- CAM development
- Prototyping
- Design improvement
- Production set up

MACHINING and Assembling

- **CNC High-Precision Turning:**
 - 10-axis Swiss single-spindle, with counter-spindle, sliding headstock lathes
 - From Ø0.5mm up to Ø32mm
 - Max Length: 500mm
- **CNC High-Precision Milling/Turning:**
 - 5-axis simultaneous machining centres
 - 3D complex parts
 - Micromachining down to Ø0.5mm
- **CNC Milling:**
 - 4-axis vertical machining centres
 - High-Rigidity/Precision Milling
 - Max Length/Width: 500/500mm
 - Fast set-up
- **Deep Hole Drilling:**
 - High-performance Gun drill bits
 - Temperature controlled cutting oil
 - Up to 500mm hole length, up to 150 x Hole Diameter
 - Cannulation of all grade Titanium, Stainless Steels and other hard materials
 - Applications: Intramedullary Nails, Medical Instruments
- Accurate Assembling of Orthopedic, Medical Instruments, Implantable Port Systems
- Micro-assembling of accessories for Endoscopic-Laparoscopic applications: Biopsy forceps, Foreign body retrievers...
- High level craftsmanship with long experience to provide outstanding quality at reasonable price

Quality inspection

- Material certification
- Full dimensional check at production start, report available upon request
- In-production continuous critical dimensional check and surface finish visual inspection to provide quality early warning
- Final random dimensional check and 100% visual quality inspection
- Custom inspections and reports available upon request
- High precision gaging systems: Computer assisted Optical Systems, profile-measurement projectors
- Product documentation traceability available for 30 years

Finishing and packaging

- In-house and through external long term qualified partners
- Micro EDM, Electro-Discharge Machining
- Surface finishing
- Deburring
- Polishing and Electropolishing
- Sand Blasting
- Surface Treatments
- Passivation
- Decontamination
- Color and type II (per AMS 2488) Titanium Anodization
- Laser Welding and Marking
- Vacuum Ultrasonic Washing
- Clean Room Class 10.000 / ISO 7 packaging

