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BIOMEDICAL ENGINEERING
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MDR CERTIFIED
DESIGN AND PRODUCTION
comply with Regulation (UE) 2017/745

ROSE-TMJ PROSTHETIC SYSTEM

- CUSTOM-MADE 3D PRINTED
- MAXIMUM PRECISION
- RAPID MANUFACTURING

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SUMMARY

THE INFORMATION PROVIDED HEREIN IS INTENDED FOR PROFESSIONALS WORKING IN THE HEALTHCARE SECTOR ONLY

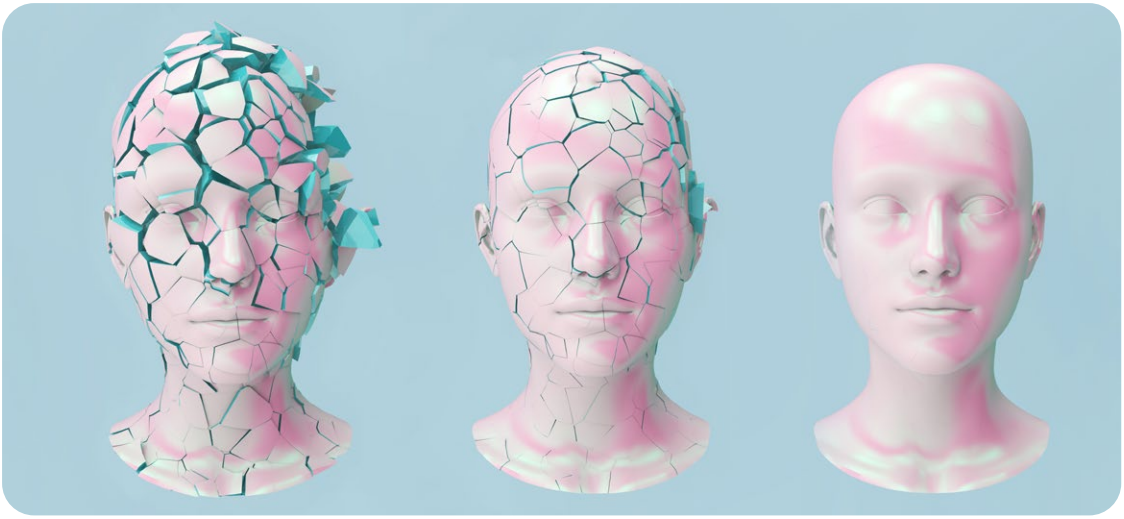
SINTAC BIOMEDICAL ENGINEERING

Restoring the patient's facial features following a serious illness or trauma, thus recovering one of the fundamental aspects of their identity.

This is the ongoing commitment of the Sintac team, the GPI Group business unit that offers biomedical engineering services and designs and manufactures custom-made prostheses.

In 2011, Sintac began building expertise in maxillofacial surgery - one of the most difficult areas of all due to its complex anatomy and the psychological implications for the patient.

As a result of a few years of collaboration with major Italian and foreign universities, Sintac is now setting the standard in maxillofacial surgery, and the skills acquired have enabled it to expand into other segments of the custom-made reconstruction sector.



THE GPI **GROUP**

GPI is the reference partner for software, technology and services dedicated to healthcare, welfare and public administration. Founded in Trento in 1988, GPI has grown as a result of significant investment in M&A (in Italy and abroad), and of research and development projects run in partnership with the main universities and research centres, for the purpose of transferring scientific, technological, functional and process knowledge to the e-health, e-welfare, and well-being sectors.

Also strengthened by solutions and skills acquired by companies that have become part of its ecosystem, the Group has succeeded in translating emerging needs of the healthcare world into cutting-edge technological solutions and new service models, thereby optimising the processes of prevention, diagnosis and treatment and improving people's quality of life. The offer combines specialist IT, consulting and design skills that allow the GPI Group to operate in different business areas: Software, Care, Automation, ICT and Pay.

GPI
The Healthcare Partner

MAIN ADVANTAGES OF THE SINTAC PROSTHESES

Sintac custom-made 3D prostheses have many advantages over standard prostheses. They result from major innovation in clinical process due to the introduction of the most advanced CAD-CAM (computer-aided design and manufacturing) technology.

CUSTOM-MADE, 3D PRINTED
ultra-precise prostheses that adapt perfectly to the patient's morphology

VERY QUICK MANUFACTURING TIME
5-7 days in Italy, 2-3 weeks overseas as confirmed by a doctor

MDR CERTIFIED
design and production process comply with Regulation (UE) 2017/745 on Medical Devices

INCREASED SURGICAL PRECISION
due to the positioning system with guides

REDUCED TIME IN THE OPERATING THEATRE
with both economic and safety implications

THE ROSE-TMJ PROSTHETIC SYSTEM

ROSE-TMJ is a customised, innovative prosthetic system obtained by **3D printing,** for reconstruction of the temporomandibular joint.

The ROSE-TMJ prosthetic system consists of **a ramus-condyle component and a fossa component**.

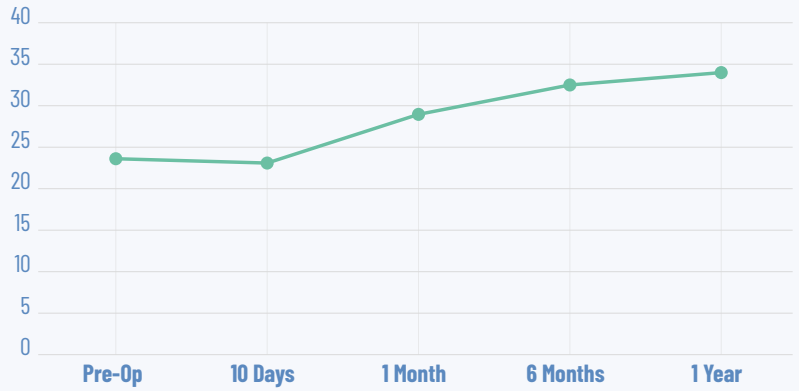
The design of the surgery and prosthesis is entirely **virtual and computer-guided**.

The innovative **cutting/positioning guides** are designed to ensure an **ultra-precise** procedure and insertion of the prosthesis.

CLINICAL EXPERIENCE

ROSE-TMJ emerged from a project conducted by the Maxillofacial Surgery Clinic of the University of Udine, which obtained the approval of the regional ethics committee to launch a multicentre (University of Udine, University of Verona, & University of Milan) clinical trial in **2018.**

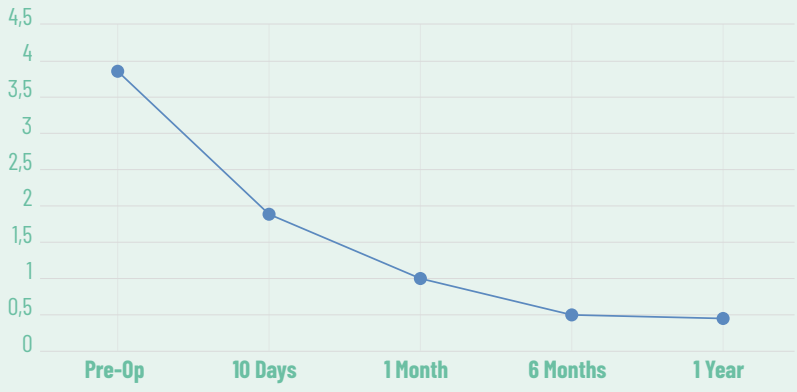
44 ROSE-TMJ prostheses were implanted in 27 patients. The results show a **96% success rate**. No prostheses were removed. The following graphs show the average improvement in maximum mandibular opening and pain reduction in the 27 patients treated:



MAXIMUM INTERINCISAL OPENING (MIO)

Improvement in the mandibular opening

MIO



VISUAL ANALOGIC SCALE (VAS) 0-10

Reduction in pain

VAS

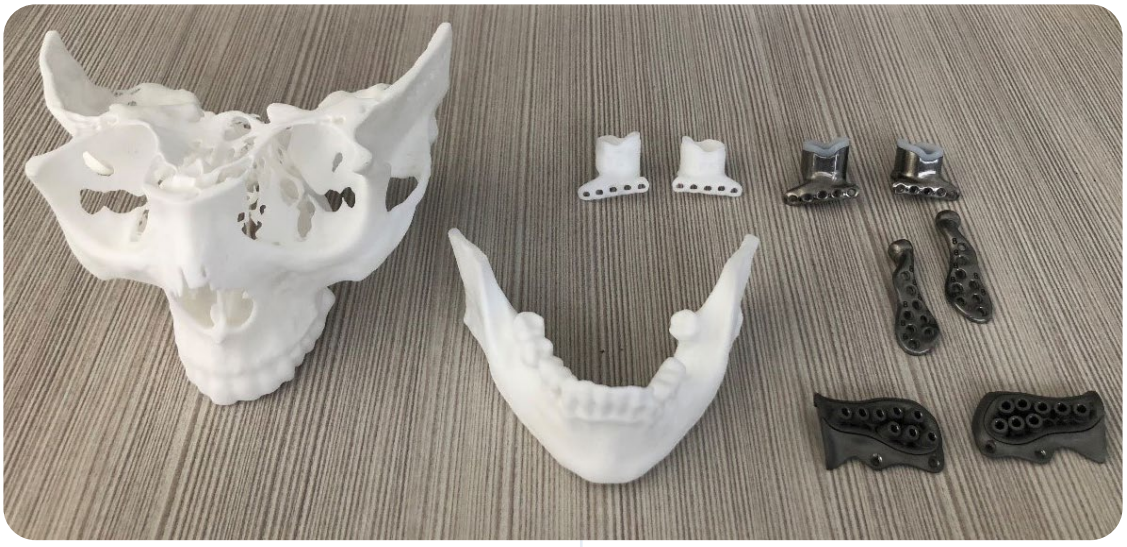
COMPONENTS OF THE PROSTHETIC SYSTEM

The ROSE-TMJ prosthesis system consists of two components obtained by 3D printing and mechanical processing:

1. **RAMUS-CONDYLE COMPONENT**
   made of Ti64 Titanium alloy
2. **GLENOID FOSSA**
   in Ti64 Titanium alloy and UHMWPE Polyethylene coupled under pressure (interlocking)

WHAT IS INCLUDED IN THE ROSE-TMJ PROSTHETIC SYSTEM KIT

1. **PROSTHESES**
2. **TITANIUM CUTTING/POSITIONING GUIDES**
   (to ensure maximum adhesion to the bone and therefore maximum precision)
3. **ANATOMICAL REPLICAS**
   of the skull and jaw in Polyamide



Example of the ROSE-TMJ prosthetic system kit

DESIGN

1 IMAGE ACQUISITION FROM CT SCAN

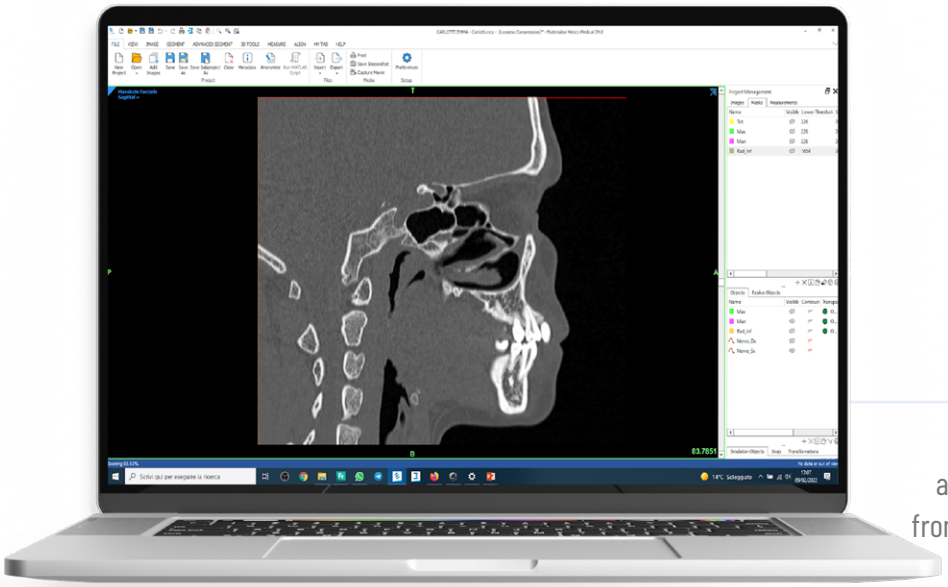


Image acquisition from CT scan

PARAMETERS FOR CORRECT SCANNING

- **IMAGE FORMAT:** DICOM
- **SCANNING AREA:** scan the relevant part of the anatomy only
- **ACQUISITION ALGORITHM:** use standard algorithms without filters (soft tissue or bone)
- **CONTRAST:** scan without contrast
- **PITCH:** 1:1
- **GANTRY TILT ANGLE:** 0°
- **INTERVAL BETWEEN SLICES:** 0.5 mm / 1.0 mm; do not reformat
- **THICKNESS OF SLICES:** equal to resolution parameter

BEFORE SCANNING

It is recommended that, where possible, all objects, prostheses or metal structures that could create artefacts that disturb, cover or cancel the affected part of the anatomy are removed before performing the scan.

WHILE SCANNING

- Use axial scanning only.
- The head must be positioned symmetrically with respect to the acquisition field.
- Field of acquisition: from vertex to neck (including the whole mandible).
- Position the patient such that the occlusal plane is parallel to the plane of the sections (tooth arches not in contact).
- The area to be scanned must be immobilised throughout the acquisition. If any disturbance due to movement is detected, repeat the acquisition.
- Scans with slice intervals greater than 1 mm should not be provided. Optimal value of slices 0.625 mm.

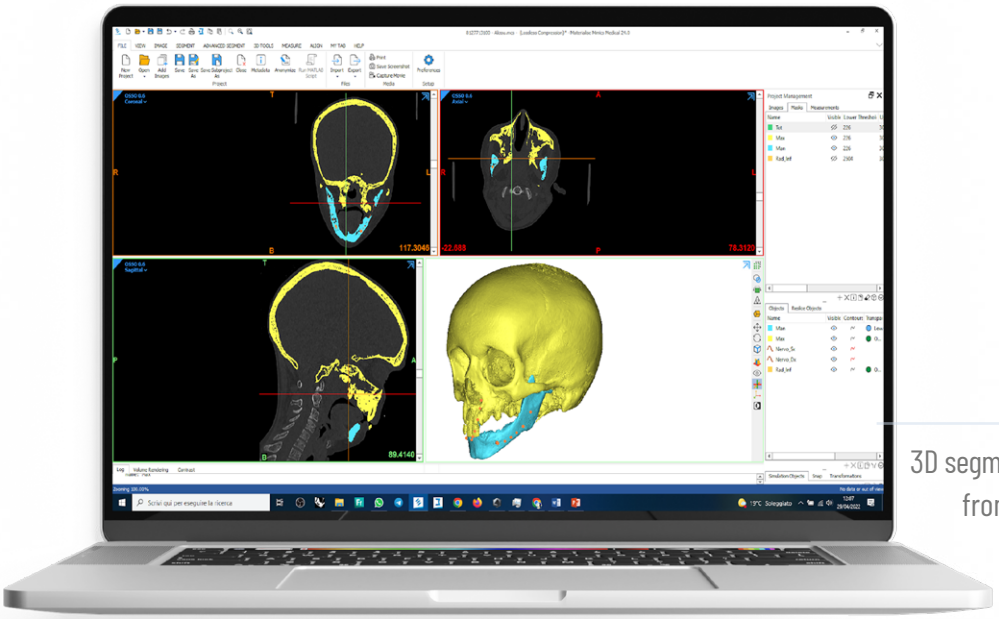
AFTER SCANNING

The data must be stored on a CD in an uncompressed DICOM format using a standard/bone algorithm.

The data can be physically sent via CD or FTP.

2 3D SEGMENTATION FROM THE CT SCAN

The DICOM files from the CT scan are imported and processed in certified imaging software. Individual bone elements are exported in 3D, identifying the nerves, roots of the teeth and any other structures required. The three-dimensional model of the relevant part of the anatomy is imported into the design software.



3D segmentation from the CT scan

3 DESIGN

The procedure, which includes both resection (osteotomy with cutting guides) and reconstruction (with positioning guides), is planned on STL format files by a designer using certified medical software, who works in close collaboration with the surgeon.

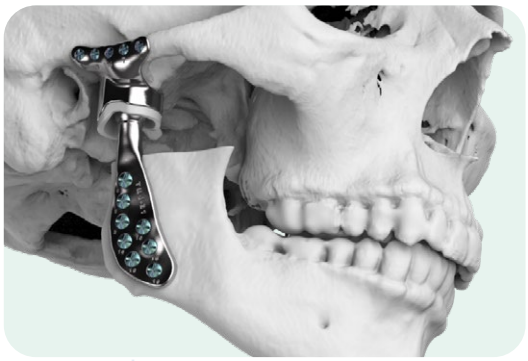
At this stage, the branch/condyle and fossa components of the prosthesis, and cutting and positioning guides, are designed according to the anatomy of the patient, and anatomical replicas are created to allow the surgeon to undergo suitable pre-operative training.

TITANIUM/POLYETHYLENE PROSTHESIS

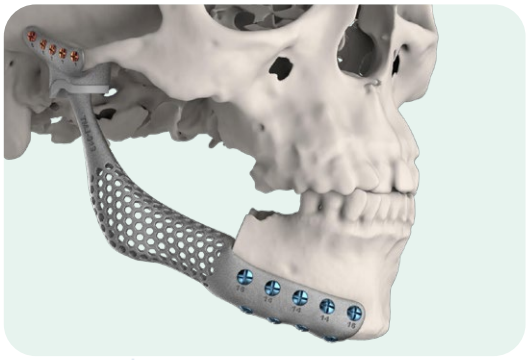
- The branch/condyle prostheses are made from Ti6Al4V Titanium alloy and contain holes for screws of a 2.7 mm-diameter.
- The fossa prostheses have holes for 2.3mm-diameter screws. The component in contact with the bone is made of Ti6Al4V Titanium alloy, while that in contact with the prosthetic condyle is Ultra High Molecular Weight Polyethylene (UHMWPE).

As planned, numbering that indicates the optimum length of the screws is **laser printed on the Titanium prosthetic components**.

In some cases, the shape and size of the prosthesis may vary according to the extent of the defect to be reconstructed. In such cases, special "extended prostheses" are designed.



Titanium prosthetic components



Example of "extended prosthesis"

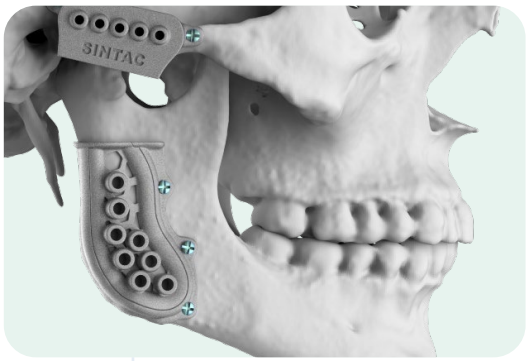
TITANIUM CUTTING AND POSITIONING GUIDES

The cutting guides are made of Ti6Al4V Titanium alloy. They are designed to adapt to the bone resection **margin, adhere in a** specific position and can be fixed by pressure to a suitably skeletonised bone surface.

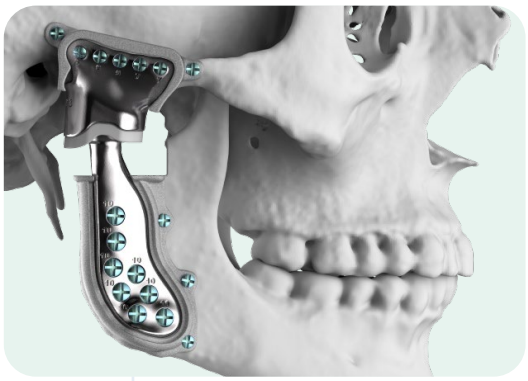
The guides have two components, a “core” and a “rim”, with a particular geometry that enables the two units to be connected together. The “core” has holes for the respective 2.7 mm screws for the mandible and 2.3 mm for the fossa. The "rim" component, on the other hand, contains 2.0 mm holes for fixing to the bone.

The guides make it possible to:

1. Pre-drill the bone where the fixing screws will be inserted.
2. Perform osteotomies with great precision.
3. Act as a guide by removing the "core" and leaving only the "rim" for the positioning of prostheses.



Cutting guides for osteotomy

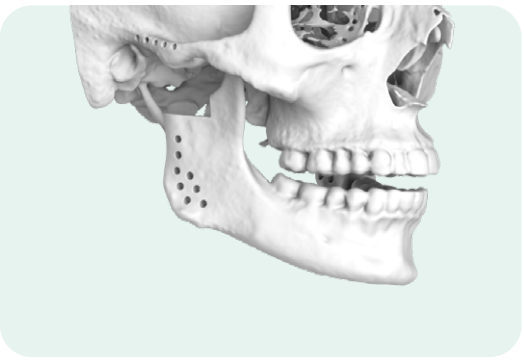


Positioning guides

ANATOMICAL REPLICAS IN POLYAMIDE

The replicas **enable suitable pre-operative training**: the surgeon can rehearse the correct insertion of the prosthesis according to the patient's anatomy (adaptability), before and after resection.

The designer provides the surgeon with a digital version of the entire planned process for checking and validation.
We then move on to the production phase.



Anatomical replicas in Polyamide

4 PRODUCTION AND MATERIALS

The metal and polyamide components are produced using 3D printers for medical production, in accordance with rigorous GPI quality procedures.
The working principle of these particular machines is based on the **direct sintering of metal and plastic** (Direct Metal Laser Sintering - DMLS). A laser beam melts the pulverised metallic and/or plastic material, thus creating solid parts of various morphologies, layer by layer.
The ultra-high molecular weight polyethylene (UHMWPE) components are manufactured using **numerically controlled milling machines**.

TITANIUM

The material used for the reconstructive plates is Ti6Al4V ELI Titanium alloy for surgical implants: a metallic super-alloy with excellent mechanical and corrosion resistance combined with a low specific weight and high biocompatibility. It can be sterilised in an autoclave. As regards the Titanium metal components, **2 types of finishing can be used**: polishing and sandblasting

ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE)

This is a highly resistant, implantable, certified polymer that is highly biocompatible with skin, blood and tissues. Due to its low heat resistance it cannot be sterilised in an autoclave. It requires low-temperature sterilisation cycles.

POLYAMIDES

The material used for the anatomical replicas is Polyamide, an inert, sterilisable polymer that is subsequently used during surgery.
The parts produced are fully functional, with quality by design. It can be exposed to high thermal or mechanical stresses and can therefore be sterilised in an autoclave

MECHANICAL MICROSTRUCTURAL CHARACTERISATION

In support of the clinical study, the University of Udine Engineering Department subjected the ROSE-TMJ prosthesis to microstructural and mechanical characterization (hardness and tensile tests).

A supporting tribological characterisation of the polyethylene/titanium contact was carried out. A finite element method (FEM) analysis completed the study. The ROSE-TMJ prosthesis demonstrated excellent behaviour in the analyses performed, with compliant results.

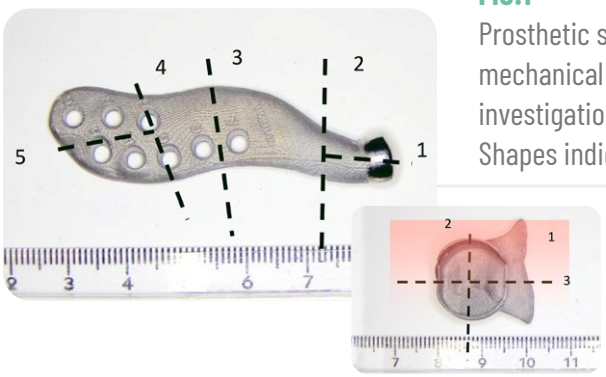


FIG.1
Prosthetic samples subjected to microstructural and mechanical
investigation. The straight lines indicate cutting lines. Shapes indicate cutting planes.

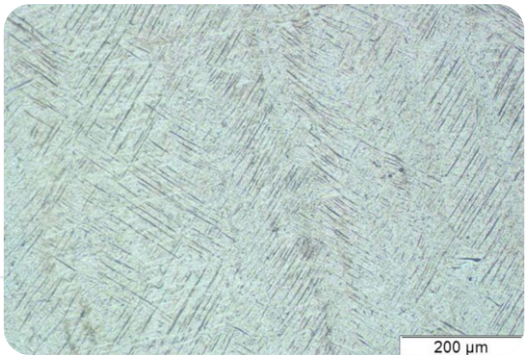


FIG.2
Microstructural characterisation of the prostheses in one of the representative points shown in Fig. 1

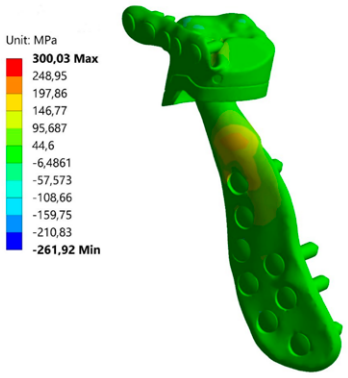


FIG.3
FEM simulation: distribution of maximum main stress on the entire prosthetic assembly

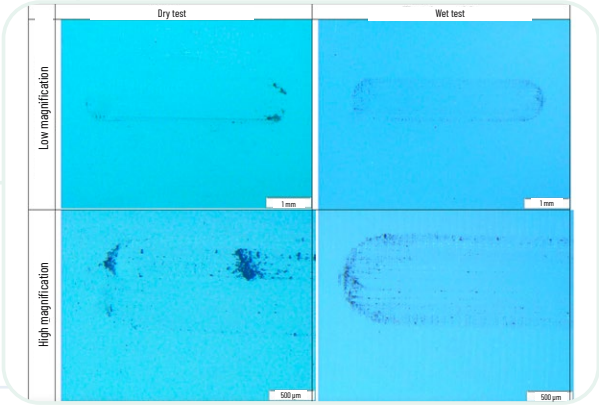


FIG.4
Representative stereomicroscope images of polyethylene samples following wear test

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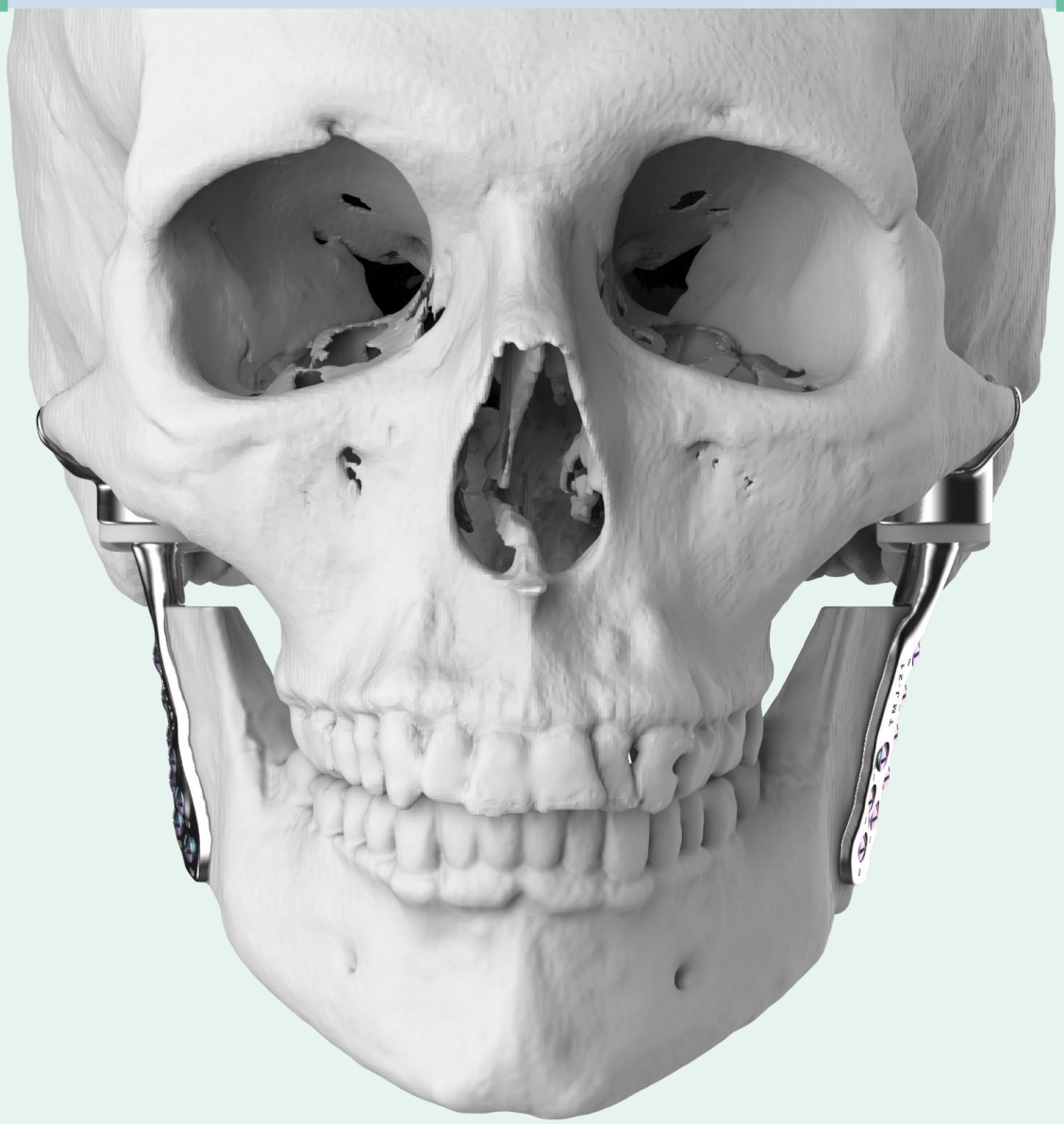


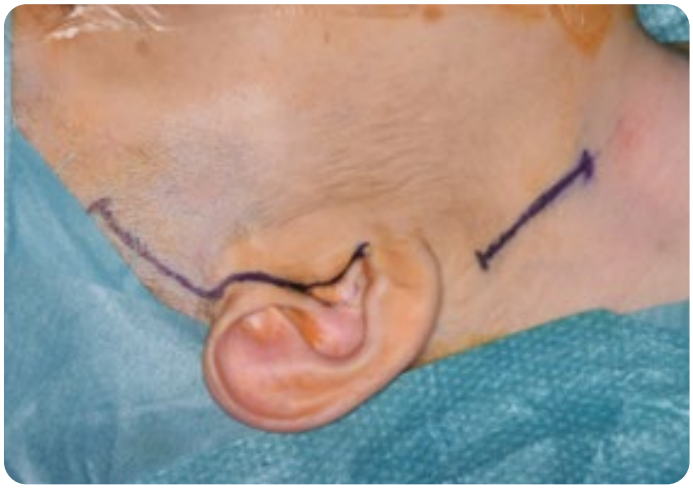
ROSE-TMJ PROSTHETIC SYSTEM

SURGICAL TECHNIQUE

SURGICAL TECHNIQUE

SURGICAL APPROACHES

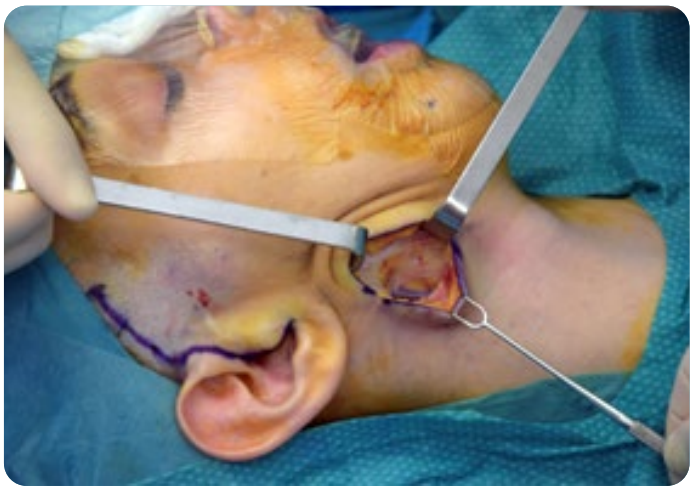
The surgical accesses for positioning the Rose-TMJ prosthesis are: retro-submandibular and preauricular.

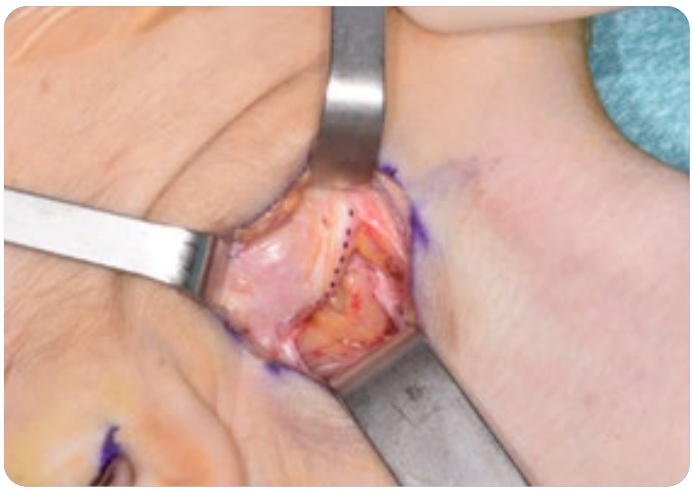


1

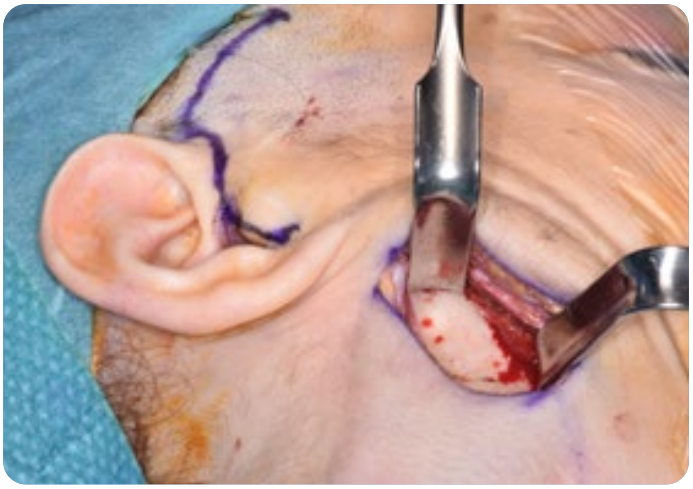
RETRO-SUBMANDIBULAR INCISION

The mandibular angle is found through the retro-submandibular approach and the periosteum is incised to expose the mandibular ramus.





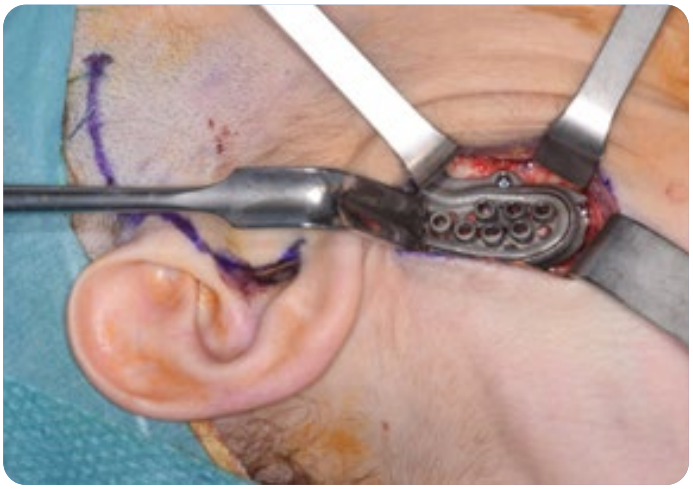
SURGICAL TECHNIQUE

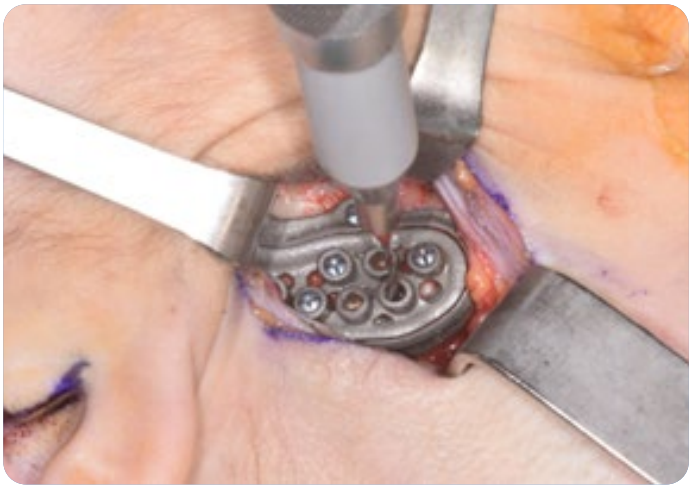


2

EXPOSURE OF THE MANDIBULAR RAMUS

Skeletonisation of the mandibular ramus.





3

USE OF THE CUTTING/ POSITIONING GUIDE ON THE RAMUS

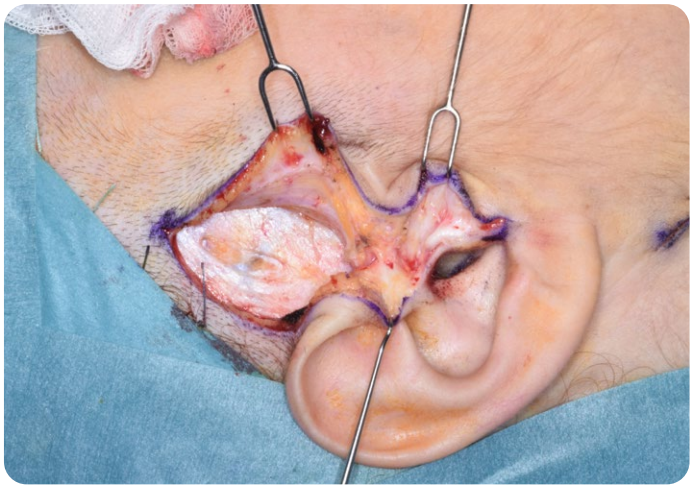
The cutting/positioning guide is carefully adhered to the bone and fixed to the ramus of the mandible using special screws in both the peripheral and central components. Holes for fixing the final prosthesis are also made.

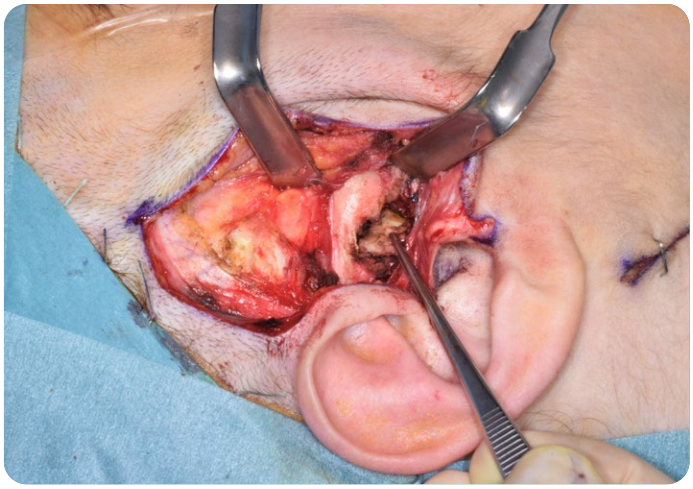
SURGICAL TECHNIQUE

4

PREAURICULAR INCISION WITH TEMPORAL EXTENSION

The zygomatic arch and temporomandibular joint are exposed through the deep subfascial approach.

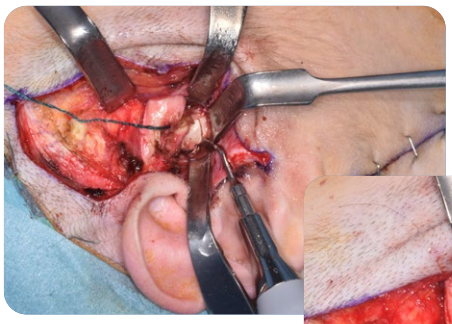


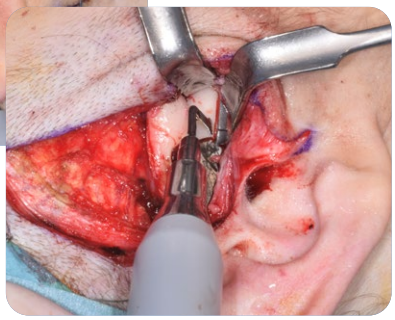


5

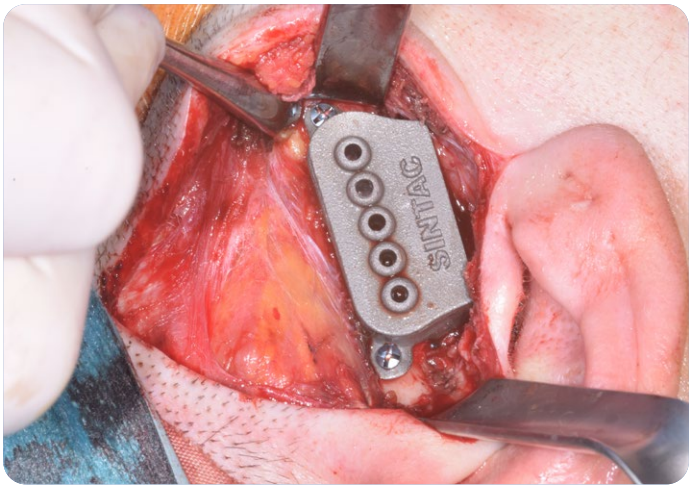
OSTEOTOMIES

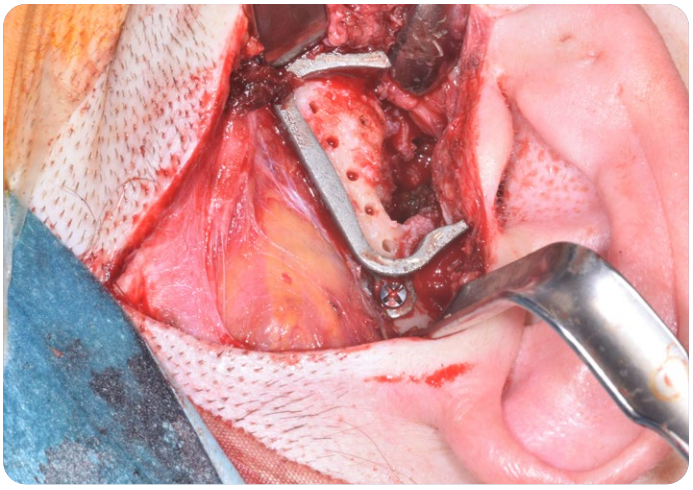
An initial osteotomy of the condylar head is performed using a piezoelectric instrument. A second osteotomy is then carried out on the mandibular ramus using the previously positioned cutting guide.





SURGICAL TECHNIQUE

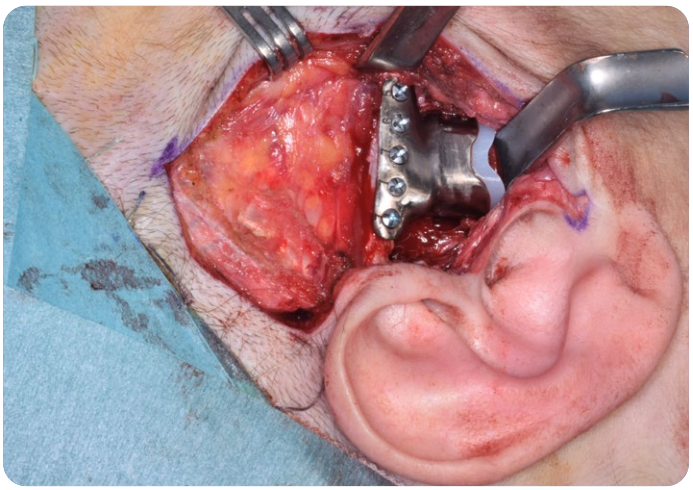




6

USE OF THE CUTTING/ POSITIONING GUIDE ON THE FOSSA

The cutting/positioning guide is carefully adhered to the bone and fixed to the zygomatic arch using special 2.0 system screws in the peripheral section; if necessary (as in cases of ankylosis), the osteotomy is performed with the cutting guide; holes for fixing the final prosthesis are also made in the central section. The central part is then removed to make room for the fossa component of the prosthesis.



7

POSITIONING OF THE FOSSA PROSTHESIS

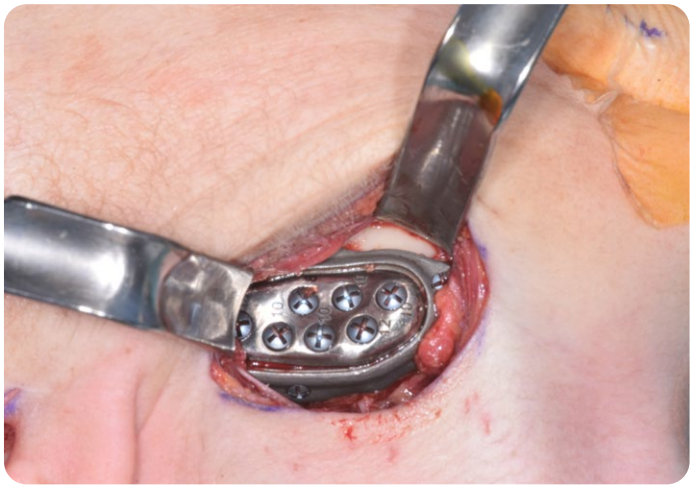
The final fossa prosthesis is fixed to the zygomatic arch using 2.3 system screws of a pre-determined, pre-specified length.

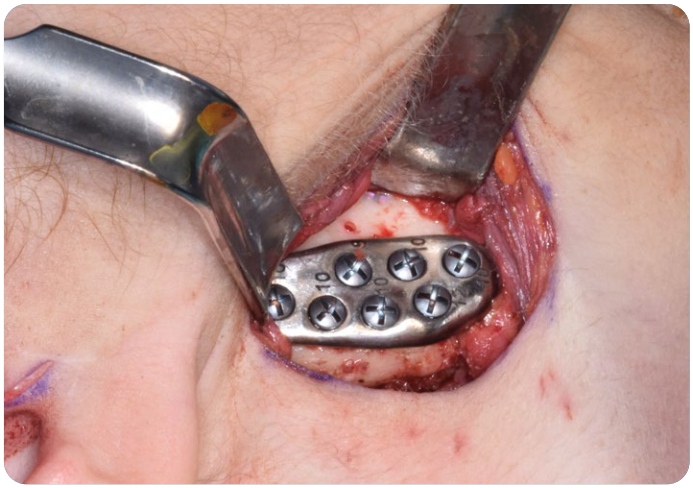
SURGICAL TECHNIQUE

8

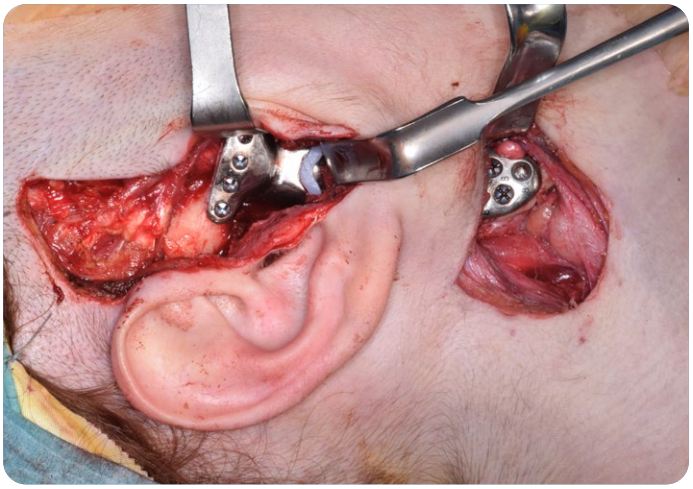
POSITIONING OF THE RAMUS/CONDYLE PROSTHESIS

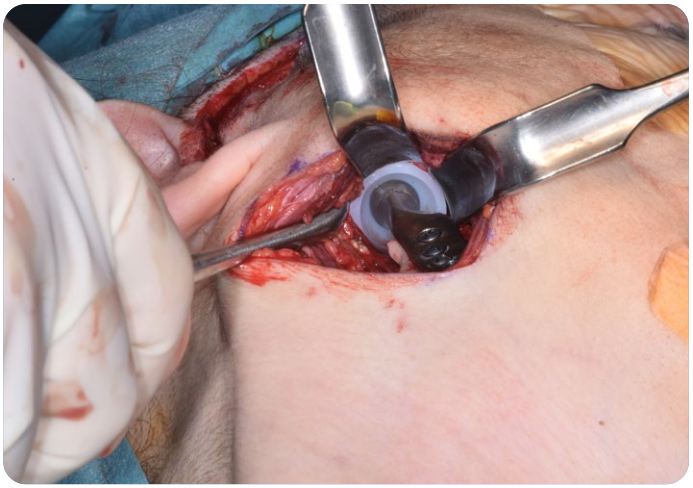
The central part of the cutting/positioning guide is removed through the retro-submandibular approach to accommodate the final ramus/condyle prosthesis, which is fixed by 2.7 screws of pre-determined, pre-specified length. The peripheral section of the guide is then removed.





SURGICAL TECHNIQUE

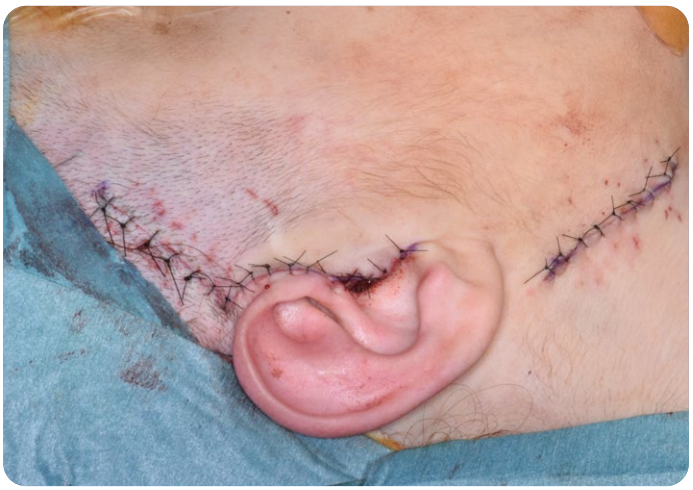




9

CHECKING

The correct positioning of the condyle in the fossa and the prosthesis function (mandibular movements) are checked.



10

SUTURES

LEGISLATION

The design and production of custom-made implantable joint prosthesis of GPI (EUDAMED SRN: IT-MF-000020127) comply with Regulation (EU) 2017/745 on Medical Devices.
The Quality Management System of GPI complies with Standard ISO 13485:2021 for design and management of the manufacture of implantable non-active orthopedic and articular custom-made devices and of non-active instruments associated with them.

REGULATORY REFERENCES

MDR 745/2017	EU Regulation on Medical Device
EN ISO 9001:2015	Quality Management Systems - Requirements
EN ISO 13485:2021	Medical devices – Quality Management Systems – Requirements for Regulatory Purposes
UNI EN ISO 14971:2019	Medical devices - Application of Risk Management to Medical Devices
EN ISO 14155:2020	Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice
UNI EN ISO 16061:2021	Instrumentation for Use in Association with Non-active Surgical Implants - General Requirements
UNI EN ISO 14630:2013	Non-active Surgical Implants - General Requirements
UNI EN ISO 21534:2009	Non-active Surgical Implants - Specific Requirements
UNI EN ISO 10993-1:2021	Biological Assessment of Medical Devices
UNI EN ISO 5832-3:2022	Surgical Implants - Metallic Materials - Part 3: Titanium 6 - Aluminium 4 - Vanadium alloy
ISO 5834-2:2019	Surgical Implants - Part 2: Ultra high molecular weight polyethylene
ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements
UNI CEI EN ISO 15223-1:2021	Medical Devices - Symbols to be used on Labels for Medical Devices, and in the Labelling and Information to be Provided - Part 1: General requirements
STERILIZATION	The sterilization procedure has been validated by testing according to ISO 17665-1:2006 for Ti6Al4V and PA samples and ISO 14937:2009 for UHMWPE samples.
BIOCOMPATIBILITY	Manufacturing materials are carefully selected and controlled during the production process based on chemical and mechanical characterization tests to confirm EN ISO 5832-3:2022, ASTM F136-13 and ASTM F3001-14 for TI6Al4V-ELI grade 23 and ISO 5834-2:2019 and ASTM F648-21 for UHMWPE.

The prostheses have specific design features; they are provided under the responsibility of a requesting practitioner who is authorised by national law by virtue of their professional qualifications.

Due to their personalised features and materials, the prostheses are for the individual, exclusive use of the patient.

INDICATIONS

The ROSE-TMJ alloplastic prosthetic system is indicated for reconstruction of the temporomandibular joint in the final stage of joint disease in the following pathological conditions:

- Arthritis/arthritic conditions involving the temporomandibular joint which are not responding to other methods of treatment.
- Bone/fibrous ankylosis (patients still growing or at end of growth).
- Revision procedures in cases where other treatments have failed (e.g. functional surgery, bone/cartilage grafts).
- Fractures not otherwise treatable by reduction or osteosynthesis.
- Benign/malignant neoplasms.
- Loss of mandibular vertical height caused by resorption and developmental disorders.
- Failure of previous alloplastic reconstruction.

CONTRAINDICATIONS

- Active/chronic infections.
- Conditions in which the bone is not of sufficient quantity/quality to support prosthetic components.
- Systemic diseases that increase susceptibility to infections.
- Documented allergy to the materials in prosthetic components.

DELIVERY

GPI SPA medical devices are supplied in NON-STERILE conditions. To ensure safe clinical use, the recommended specified sequence should be followed:

CLEANING

STERILISATION

PACKAGING

CLEANING INSTRUCTIONS

- REMOVE THE PRODUCTS FROM THE PACKAGING
- DISASSEMBLE THE MEDICAL DEVICE INTO ITS COMPONENT PARTS
- CHECK THAT IT IS IN GOOD WORKING ORDER
- CHECK THAT THERE ARE NO RESIDUES/DUST; IF NECESSARY: CLEAN/UNBLOCK/WASH THE HOLES BEFORE STERILISATION
- WASH USING A NEUTRAL DETERGENT (MUST NOT BE ACIDIC) AND LUKEWARM WATER
- DRY USING AN ABSORBENT FABRIC THAT LEAVES NO RESIDUES, OR USE AN INDUSTRIAL DRYER OR DRYING CABINET

Highly alkaline detergents (pH ≥ 12) are not recommended.
Avoid prolonged exposure to acidic or alkaline solutions or those containing chlorides, bromides or iodine.

STERILISATION INSTRUCTIONS

The following process parameters have been shown to produce a product with a SAL level of 10-6 log in accordance with UNI EN ISO 17665 and UNI EN ISO 14937. Other similar loops can be used but have not been evaluated. It is the responsibility of the user to demonstrate the adequacy of the sterilization cycle used if it should vary from the following indications.

- **TITANIUM ALLOY (Ti6Al4V) PROSTHESES AND COMPONENTS**
  Steam sterilisation: Steam autoclave sterilisation at a temperature of 134 ºC for a minimum of 5 minutes.

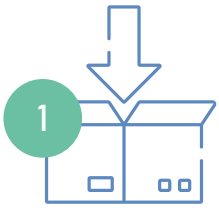
- **POLYAMIDE (PA) ANATOMICAL REPLICAS AND SURGICAL TEMPLATES**
  Steam sterilisation: Steam autoclave sterilisation at a temperature of 134 ºC for a minimum of 5 minutes.

- **HIGH DENSITY POLYETHYLENE (UHMWPE) PROSTHESES AND COMPONENTS**
  Hydrogen peroxide sterilization: with operating temperature range at 50-55 ºC, with a minimum residence cycle of 37 minutes + 3 minutes of initialization.

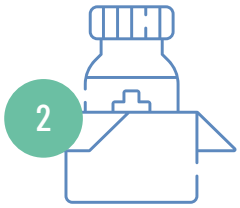
- **HIGH DENSITY POLYETHYLENE AND TITANIUM ALLOY COUPLING (UHMWPE+ Ti6Al4V) PROSTHESES AND COMPONENTS**
  Hydrogen peroxide sterilization: with operating temperature range at 50-55 ºC, with a minimum residence cycle of 37 minutes + 3 minutes of initialization.

At the end of the sterilization cycle, check the change of the SBS (sterile barrier system) indicators, the integrity of both the packaging system and the product. In case of anomalies or doubts consider the product non-compliant and therefore do not make it available to the user, as the safety for the patient cannot be guaranteed.

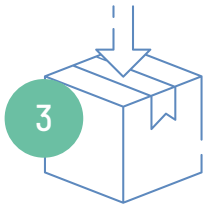
PACKAGING



After the sterilisation procedure, the customised device must be packaged such that its sterility is maintained and the risk of damage before use is avoided.



Only packaging material of suitable medical grade should be used.



Check that the packaging is a suitable size to contain the medical device without causing stress to the seal.

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CERTIFICATES

ITALCERT

Certificato UE di Sistema di Gestione della Qualità

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

061-00-00-MDR

in accordo all'Allegato IX CAPO I del Regolamento UE 2017/745
according to Annex IX Chapter I of EU Regulation 2017/745

ITALCERT S.r.l.

Organismo Notificato n°0426 / *Notified Body n°0426*
viale Sarca, 336 - 20126 MILANO (MI) - ITALIA

certifica che il / *certifies that the*

Sistema di Gestione della Qualità / *Quality Assurance System*

del Fabbricante / *of the Manufacturer*

GPI S.p.A.

(SRN: IT-MF-000020127)

via Ragazzi del '99, 13 – 38123 TRENTO (TN) – ITALIA

nella Sede Operativa di / *in the headquarter located in*

via Ragazzi del '99, 13 – 38123 TRENTO (TN) – ITALIA

è conforme ai requisiti previsti dal / *complies with the requirements stated in*

Regolamento UE 2017/745 Allegato IX CAPO I
Regulation UE 2017/745 Annex IX Chapter I

per i dispositivi medici di cui all'Allegato 1 del presente certificato
for the medical devices listed in the attached Annex I

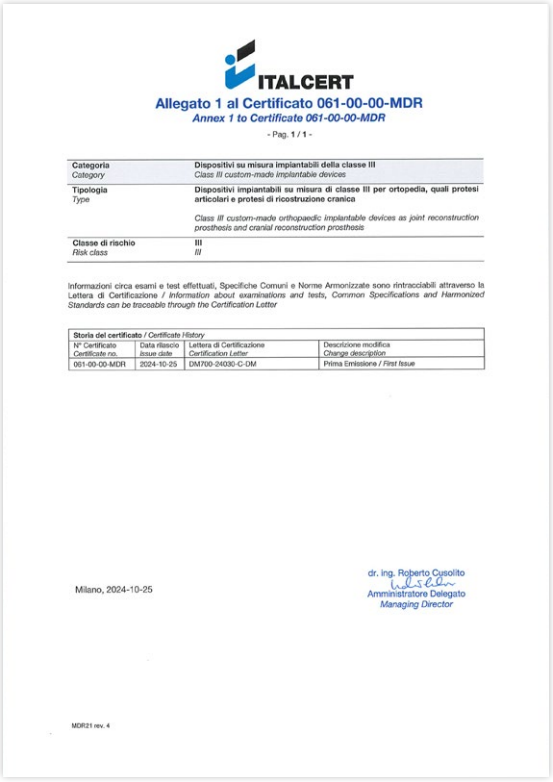
- Identificativo del rapporto di audit di certificazione/ *certification audit report ID:* RRC-MDR 5201/2024
- Il sistema di gestione della qualità del fabbricante è soggetto ad audit di sorveglianza annuale in conformità a quanto previsto dal comma 3 dell'allegato IX CAPO I del Regolamento UE 2017/745 / *The manufacturer's quality management system is subject to annual surveillance audit in accordance with the provisions of Annex IX CHAPTER I §3 of the EU regulation 2017/745*
- Il presente certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1 / *This certificate must made publicly available complete with Annex I*
- Informazioni riguardo esami e test (Allegato XII, punto 10 - Regolamento UE 2017/745) sono a disposizione su richiesta, da inoltrare a italcert@italcert.it / *Information about examinations and tests (Annex XII, point 10 - EU Regulation 2017/745) is available upon request from italcert@italcert.it*

dr. ing. Roberto Cusolito
AMMINISTRATORE DELEGATO / *MANAGING DIRECTOR*

Data di rilascio
First Issue
2024-10-25

Data di scadenza
Expiry Date
2029-10-24

MDR21 rev. 4



ITALCERT

Allegato 1 al Certificato 061-00-00-MDR

Annex 1 to Certificate 061-00-00-MDR

- Pag. 1 / 1 -

Categoria *Category*	**Dispositivi su misura impiantabili della classe III** *Class III custom-made implantable devices*
Tipologia *Type*	**Dispositivi impiantabili su misura di classe III per ortopedia, quali protesi articolari e protesi di ricostruzione cranica** *Class III custom-made orthopaedic implantable devices as joint reconstruction prosthesis and cranial reconstruction prosthesis*
Classe di rischio *Risk class*	**III** *III*

Informazioni circa esami e test effettuati, Specifiche Comuni e Norme Armonizzate sono rintracciabili attraverso la Lettera di Certificazione / *Information about examinations and tests, Common Specifications and Harmonized Standards can be traceable through the Certification Letter*

Storia del certificato / *Certificate History*

N° Certificato *Certificate no.*	Data rilascio *Issue date*	Lettera di Certificazione *Certification Letter*	Descrizione modifica *Change description*
061-00-00-MDR	2024-10-25	DM700-24030-C-DM	Prima Emissione / *First Issue*

Milano, 2024-10-25

dr. ing. Roberto Cusolito
Amministratore Delegato
Managing Director

MDR21 rev. 4

ITALCERT

CERTIFICATO N° 810DM00

CERTIFICATE N° 810DM00

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità
Quality Management System

messo in atto da
implemented by

GPI S.p.A.
Via Ragazzi del '99, 13 – IT 38123 Trento (TN)

nella Sede Operativa di
Operative Unit
Via Ragazzi del '99, 13 – IT 38123 Trento (TN)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Progettazione, sviluppo, installazione, manutenzione e gestione di software medicali ed erogazione dei relativi servizi di assistenza, consulenza e formazione.
Commercializzazione di apparecchiature elettromedicali.
Progettazione e gestione della fabbricazione di dispositivi su misura ortopedici e articolari non attivi impiantabili e di strumenti non attivi ad essi associati.

Design, development, installation, maintenance and management of medical software and provision of related assistance, consultancy and training services. Marketing of electromedical equipment. Design and management of the manufacturing of custom-made orthopaedic and joint devices non-active implantable and non-active instruments associated with them.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In case of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date
2014-11-07

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2024-08-05

Data di Scadenza
Expiry Date
2025-07-27

ACCREDIA

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

NOTE

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BIOMEDICAL ENGINEERING
a brand of GPI

MANUFACTURER

GPI S.p.a.
via Ragazzi del '99, 13 - 38123 Trento (TN)
Tel.: +39 0461 381515
Fax: +39 0461 381599
info.sintac@gpi.it
www.gpigroup.com

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VER SAN & Dafne m.d. S.r.l
Viale Archimede 25 - 37059 Campagnola di Zevio (VR)
Tel.: +39 045 569949
Fax: +39 045 568190
info@versandafne.it
www.versandafne.it

Registration No. of the Ministry of Health database
for manufacturers of customised medical devices: ITCA01042818