NEUROSURGERY

# Cranioplasty Line

TECRES

ADVANCING HIGH TECHNOLOGY

“Knowing
that our products
every day improve
the lives of many people.
This is our ambition.
This is our reward.”

Giovanni Faccioli, President.

# TECRES

Cutting-edge technologies and constant research to improve the lives of many people. This is the vision of Tecres since 1981, operating in sinergy with surgeons, Universities and Research Institutes in order to invent, realize and provide the market with safe, effective and innovative products.
We are specialized in acrylic resins since 1986 with medical applications in fields such as orthopaedics, spinal surgery and neurosurgery. Our excellence and reliability are recognized in more than 70 Countries around the world.

# CRANIOPLASTY LINE

Our range of products for cranial reconstruction is based on our clinical expertise and experience in the acrylic resin sector. Tecres has been developing medical-grade PMMA resins since 1986.
Mendec® Cranio is the result of our vast experience in orthopaedics. This product is a PMMA resin developed to repair small cranial defects.
For complex cases, Tecres provides Cranos, a customised PMMA implant also available in the antibiotic version.
Cranos perfectly adapts to the cranial defect, providing optimal functional and aesthetic results.

# CRANIOPLASTY

Cranioplasty is a neurosurgical procedure used to repair cranial defects. This procedure restores cranial function and the aesthetics of the skull, while protecting the brain. Patients will be relieved even psychologically and will see their social skills improved.[1] Tecres provides two cranioplasty solutions:


**Mendec® Cranio:** malleable PMMA resin developed to repair skull holes, craniotomy cuts, and other cranial defects.

**Cranos:** customised PMMA implant created based on CT scans, for reconstructing even large bone defects. Available also in two antibiotic versions.

# MENDEC® CRANIO

## RADIOPAQUE PMMA RESIN

Mendec® Cranio is an acrylic resin developed for cranioplasty procedures.
It is a safe and reliable solution for repairing skull holes, craniotomy cuts, and other cranial defects.
This resin is extremely malleable and perfectly adapts to the cranial defect.
Once the resin has hardened, it can be drilled and milled. It can also be used for fixation by means of plates and screws or suture threads.
The formula includes barium sulphate, which makes resin radiopaque and thus perfectly visible on X-rays.


Scan the QR code and discover how to prepare Mendec® Cranio

**THE PACKAGING INCLUDES:**
- 20 g of powder
- 6.65 g of liquid

CODE 1220/D

## ADVANTAGES:

**Malleability:** shortly after mixing, Mendec® Cranio becomes extremely malleable, allowing for prolonged surgical manipulation. Mendec® Cranio remains malleable for a long time, allowing the reconstruction of the bone defect. Once the resin has hardened, it can be drilled and milled. It can also be used for fixation by means of plates and screws or suture threads.

**Perfect reconstruction:** thanks to its malleability, Mendec® Cranio can reconstruct the cranial defect, achieving excellent aesthetics. Its texture keeps the given shape even before the resin hardens. Therefore, exothermic polymerisation must occur on an external medium, away from the meninges.

**Safety:** PMMA is a biocompatible material with excellent mechanical properties: elasticity, resistance and lightness. PMMA is widely used in clinical applications. Its safety has been reliably demonstrated.

**Reduced toxicity:** thanks to our special production process, Mendec® Cranio needs less liquid (MMA). This means reduced toxicity and lower polymerisation temperature.

### WORKING TIMES A 23°C

| MIX | WAITING | HANDLING & MOULDING | HARDENING |
|---|---|---|---|
| 45" ±15" | 1'45" ±30" | 5'30" ±1'00" | 3'00" ±2'00" |

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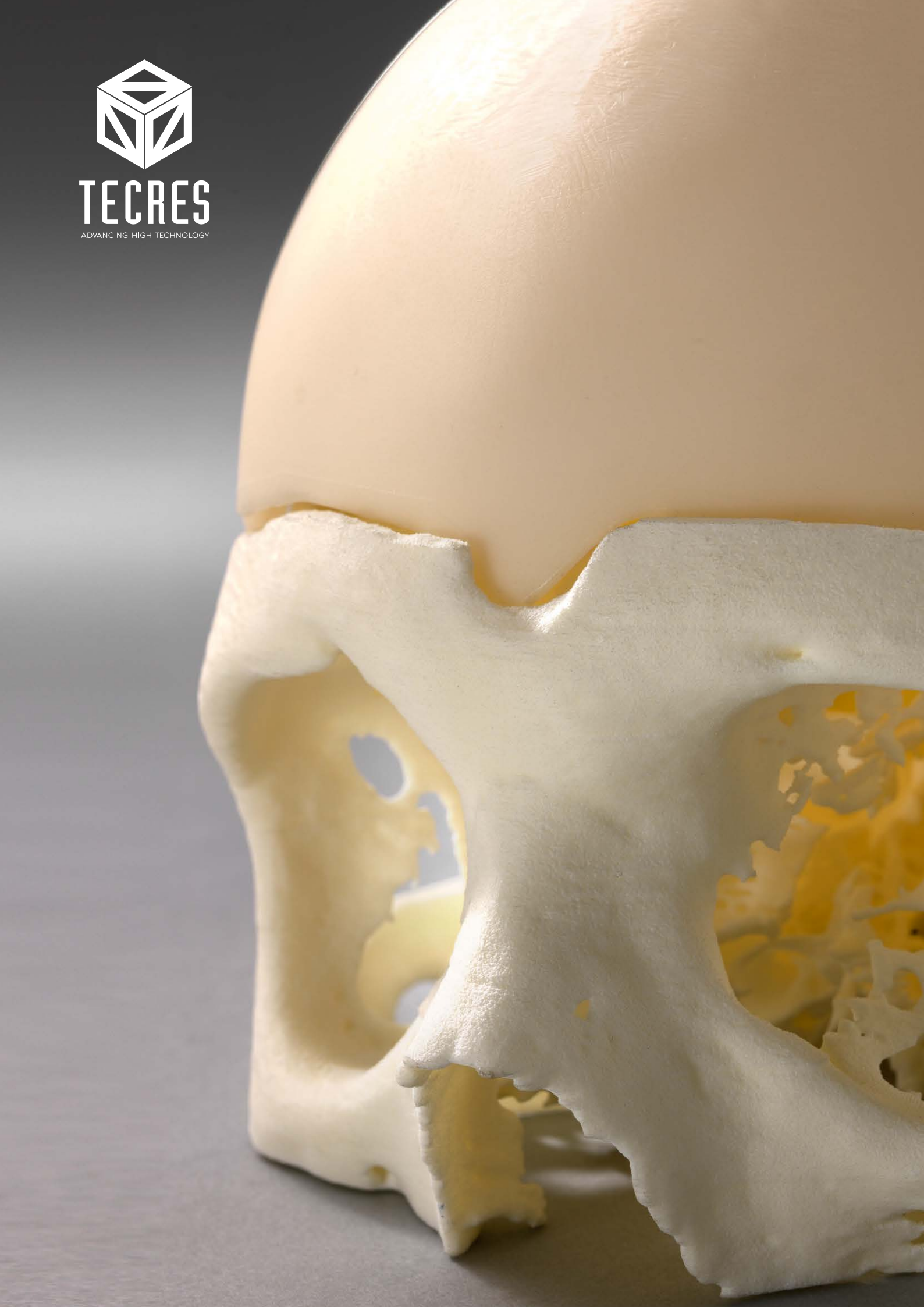


# Cranos

**Custom-made PMMA implants.**
**Also available in the antibiotic version.**

# CRANOS

## CUSTOM-MADE PMMA IMPLANTS FOR PERFECT CRANIAL RECONSTRUCTION

Cranos is a custom-made PMMA implant made by a highly specialised team. Thanks to our expertise in the clinical application of PMMA, we can develop custom-made implants that perfectly adapt to the bone defect, even large ones.

## ADVANTAGES:

**A customised solution:** Cranos implants are designed based on patients' tomographic images. That's why they perfectly adapt to the bone defect, protecting the anatomical thickness of the skull.

**Strong and resistant:** Cranos implants are made of Polymethyl methacrylate (PMMA), an acrylic resin widely used for clinical applications. PMMA is safe, biocompatible, and highly resistant. It's also elastic and withstands small shocks without breaking or deforming. Cranos implants are perfectly visible on X-rays, since PMMA is added with barium sulphate, a common radiopaque agent. Moreover, Cranos is compatible with Magnetic Resonance Imaging (MRI).

**Infection control:** infections are a serious threat for patients. Cranioplasty infection rates can even exceed 25%[2].
That's why Cranos also comes in the antibiotic version with Gentamicin alone or in combination with Vancomycin. The implant slowly releases the antibiotic locally to reduce the risk of infection.

**CRANOS IS AVAILABLE IN 3 VERSIONS:**

- **Cranos (CRN01)**
- **Cranos with Gentamicin (CRN02)**
- **Cranos with Gentamicin and Vancomycin (CRN03)**

## THE RISK OF INFECTION IN CRANIOPLASTY

Cranioplasty is associated with significant post-surgery infection rates that can even exceed 25%[2]. Thanks to its clinical experience in the world of orthopaedic infections, Tecres has created the antibiotic version of Cranos implants.

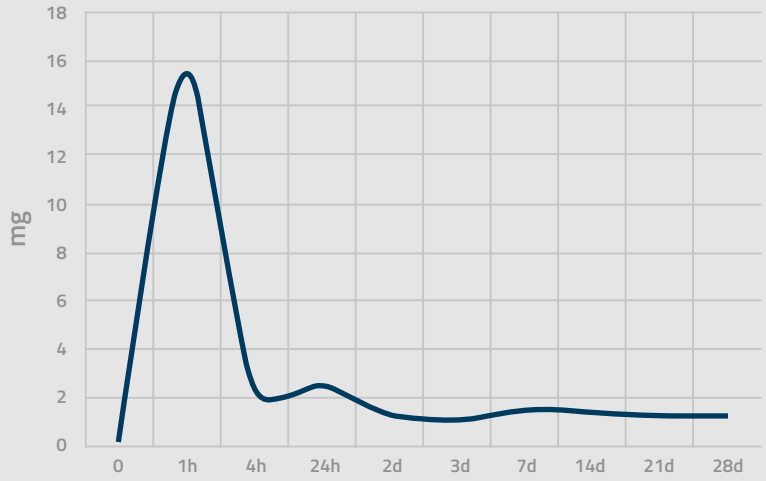
## ANTIBIOTIC LOADED CRANOS

Cranos is also available in two antibiotic versions: with Gentamicin alone and in combination with Vancomycin. The antibiotic versions aim at preventing infections. The antibiotic is integrated into the PMMA and is released locally as soon as the implant comes into contact with body fluids. Most of the antibiotic is released during the first few hours after implantation and then gradually reduces in the subsequent weeks.

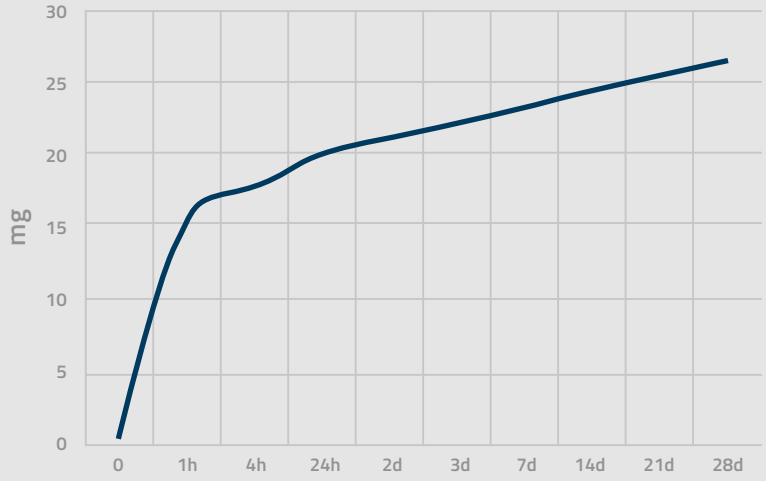
## CRANOS WITH GENTAMICIN

Cranos is available in the version with Gentamicin, a broad-spectrum antibiotic. Cranos with Gentamicin is the ideal solution for preventing post-surgery infection caused by Gentamicin-sensitive bacteria.

### ANTIBIOTIC RELEASE




Release of Gentamicin from a 25 cm2 Cranos implant over a 4-week period. Below the cumulative release.



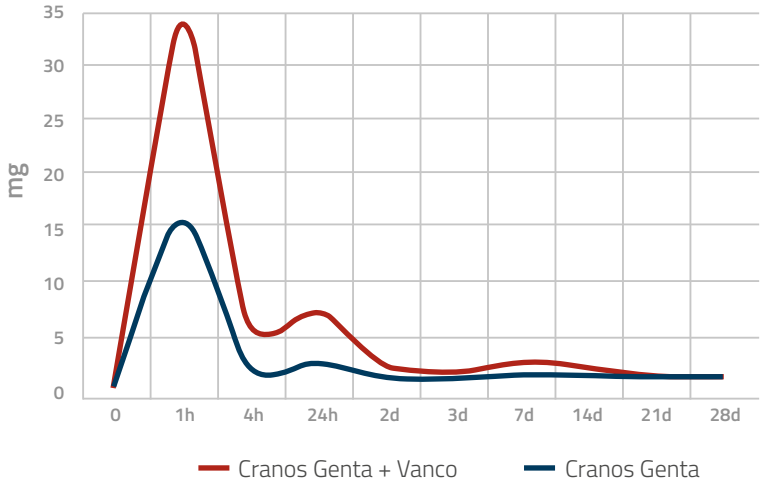
## CRANOS WITH GENTAMICIN AND VANCOMYCIN

MRSA (Methicillin Resistant Staphylococcus Aureus) and MRSE (Methicillin Resistant Staphylococcus Epidermidis) infections are still a serious and difficult problem. That's why Cranos also comes in a version with Gentamicin and Vancomycin. These antibiotics work synergistically against bacteria.[3,4,5]. Their range of action covers approximately 90% of isolated pathogens in surgical site infections[5,6].

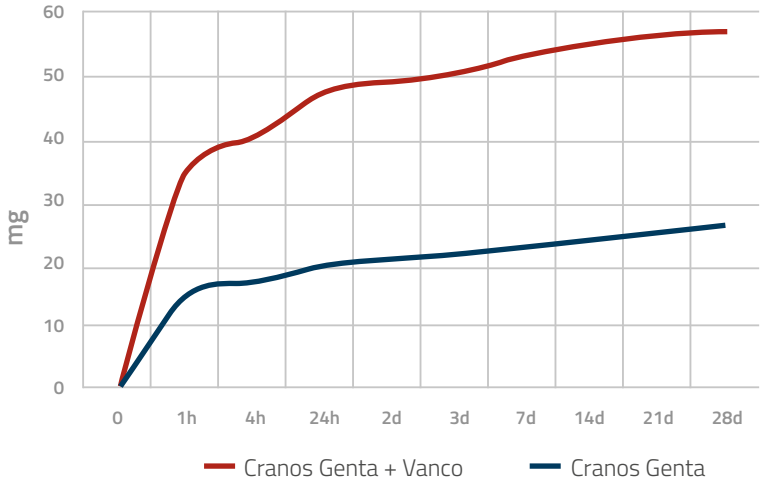
| | GRAM+ | | | | | GRAM- | |
|---|---|---|---|---|---|---|---|
| | MR-5 | MS-5 | ENTEROCOCCHI | STREPTOCOCCHI | PROPIONIBACTERIA | ENTEROBACTERIA | PSEUDOMONA SPP |
| **Gentamicin** | Medium | Low | Medium | | - | Medium | |
| **Vancomycin** | HIGH | | | | Medium | - | - |
| **Gentamicin + Vancomycin** | SYNERGIC | | | HIGH | MEDIUM | | |

Gentamicin combined with Vancomycin prevents bacterial adherence to the implant[5].
Cranos with Gentamicin and Vancomycin is the ideal solution for preventing post-surgery infection caused by Gentamicin- or Vancomycin-sensitive bacteria.

## ANTIBIOTIC RELEASE




A comparison between the antibiotic release of two 25 $cm^2$ Cranos implants, one with Gentamicin and Vancomycin and the other with Gentamicin alone. Below the cumulative release.



## REQUEST PROCEDURE

### REQUEST FORM:
fill out the Cranos request form and send it to Tecres with the CT images taken based on the indicated parameters. X-ray images should not be more than two months old. Please indicate any request for antibiotic implants, fixation or suspension holes.

### IMPLANT DESIGN:
Tecres designs the implant after verifying its technical feasibility. 3D images and a demo video show the implant on the bone defect.

### PROJECT APPROVAL:
the project is shared with the surgeon. If changes are not necessary, the surgeon signs and approves the project.

### PRODUCTION, STERILISATION AND DELIVERY:
Cranos is manufactured and delivered sterile. Each packaging contains two kits, one for the implant and the other for the backup. Delivery occurs within 15 days after we receive the signed project. We recommend implanting Cranos within a short time to ensure perfect results when repairing the bone defect.

## IMAGE PROTOCOL

| Image acquisition parameters |
|---|
| Scan scout: lateral |
| Scan angle: 0° |
| Orientation: head/backward |
| Scout length: enough to cover all the skull |
| Matrix resolution dimensions: 512x512 |
| Field of View = +/- 30 cm for an adult |
| Reconstruction algorithm: standard |
| Gantry tilt: 0° |
| Thickness and step slice max - 1.5 mm |
| Scan mA: 175. (not binding) |
| Scan kV: 130. (not binding) |
| **CT images must be exported in DICOM format** |

Any metal object must be removed before performing the CT scan

# ORDER REFERENCES

| MENDEC® CRANIO | | |
|---|---|---|
| **CODE** | **PRODUCT** | **DETAILS** |
| 1220/D | Mendec® Cranio Radiopaque | 20 g |
| CPSP-02 | Bowl and spatula | |
| CRN01 | Cranos | Custom-made cranial implant |
| CRN02 | Cranos with Gentamicin | Custom-made cranial implant with Gentamicin |
| CRN03 | Cranos with Gentamicin and Vancomycin | Custom-made cranial implant with Gentamicin and Vancomycin |

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6. Trampuz A, Zimmerli W. **Prosthetic joint infections: update in diagnosis and treatment.** *Swiss Med Wkly. 2005 Apr 30;135(17-18):243-51. Review.*

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