



3DCERAM

Global Advanced Ceramics

New Harmony >> New Solutions™

CUSTOM CERAMIC IMPLANTS FOR CRANIOFACIAL SURGERY FCP BIOCRANIUM®



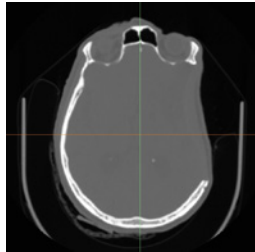


CERAMIC 3D PRINTING



CERAMIC 3D PRINTING DEDICATED TO BIOMEDICAL

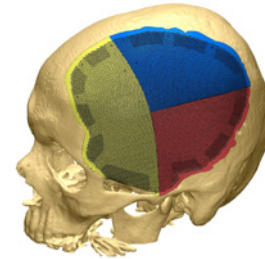
1 Image from hospital scanner



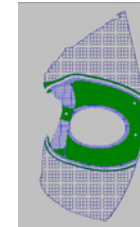
2 Three dimensionally reconstructed



3 CAD design of the implant in STL format



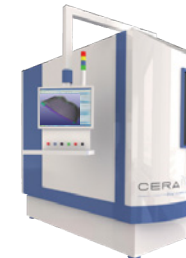
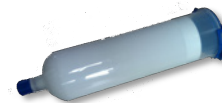
4 Slicing and calculation of the laser way



5 Making of ceramic paste



6 Stereolithography printing



10 Packaging and sterilisation



9 Checking of the geometry on the skull model



8 Debinding - Sintering



7 Cleaning



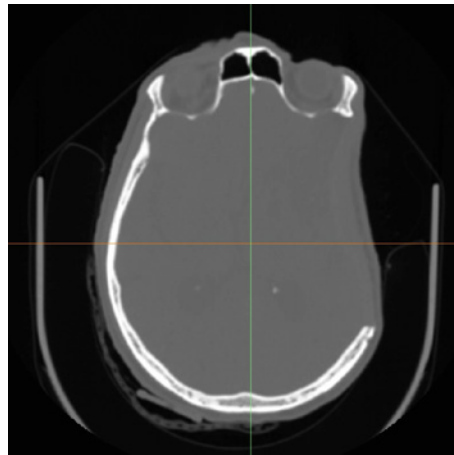
CAD WORKS

- From DICOM.
- Different steps to create the implant with specifications of surgeon.



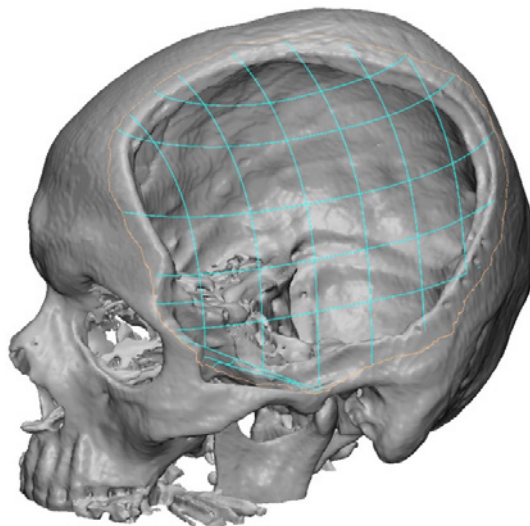
CAD WORKS – STEP 1

- Import DICOM.
- Export STL file of the skull.

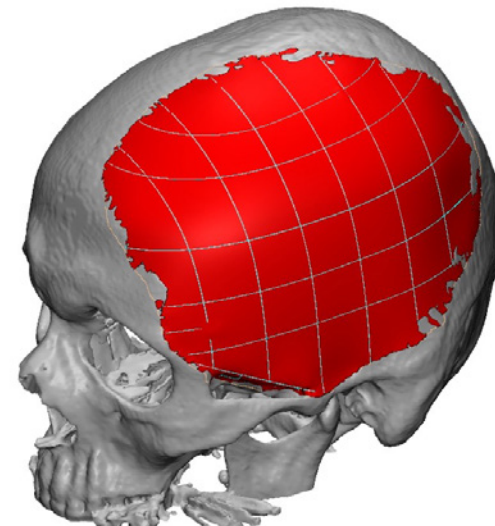


CAD WORKS – STEP 2

- Creation of guide lines.
- Generation of the surface and of the volume.

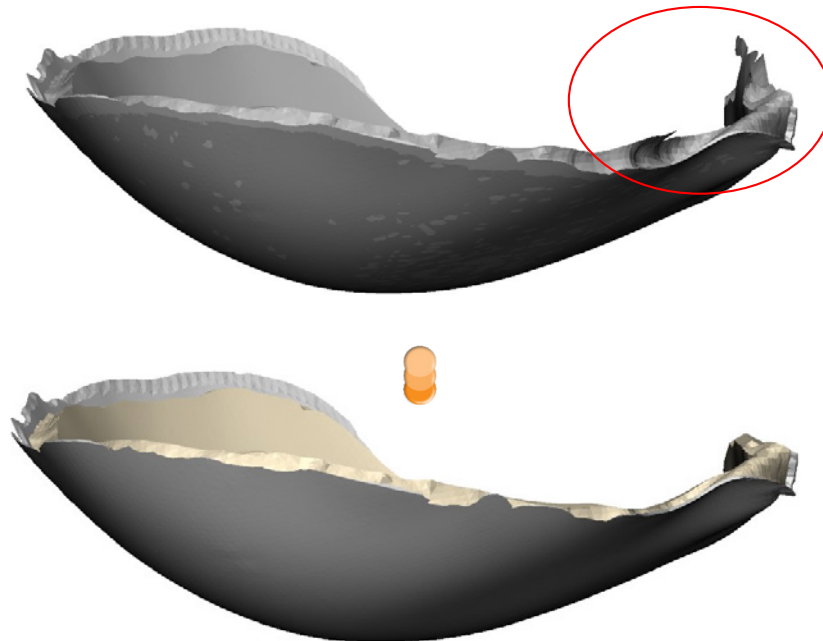
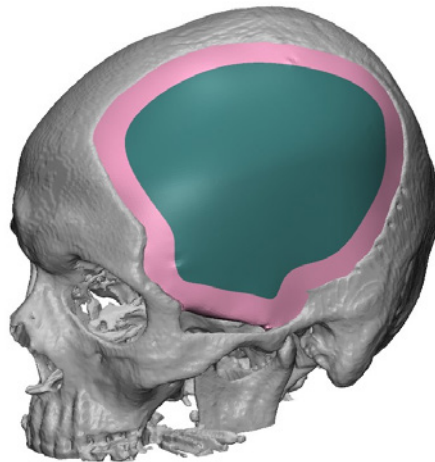


Defined with
specifications of
surgeon.



CAD WORKS – STEP 3

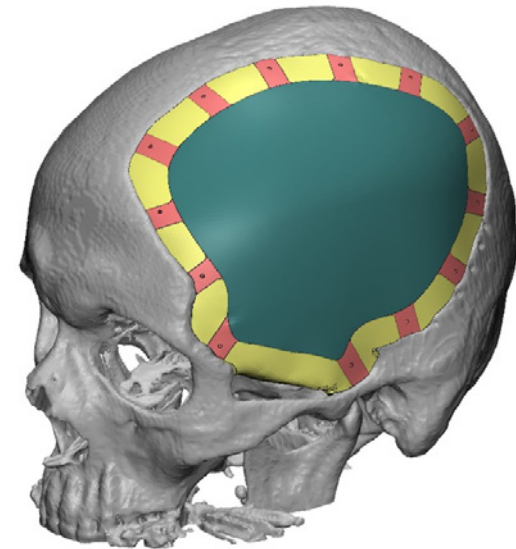
- Select of final volume of implant.
- Removal of undercuts.



CAD WORKS – STEP 4

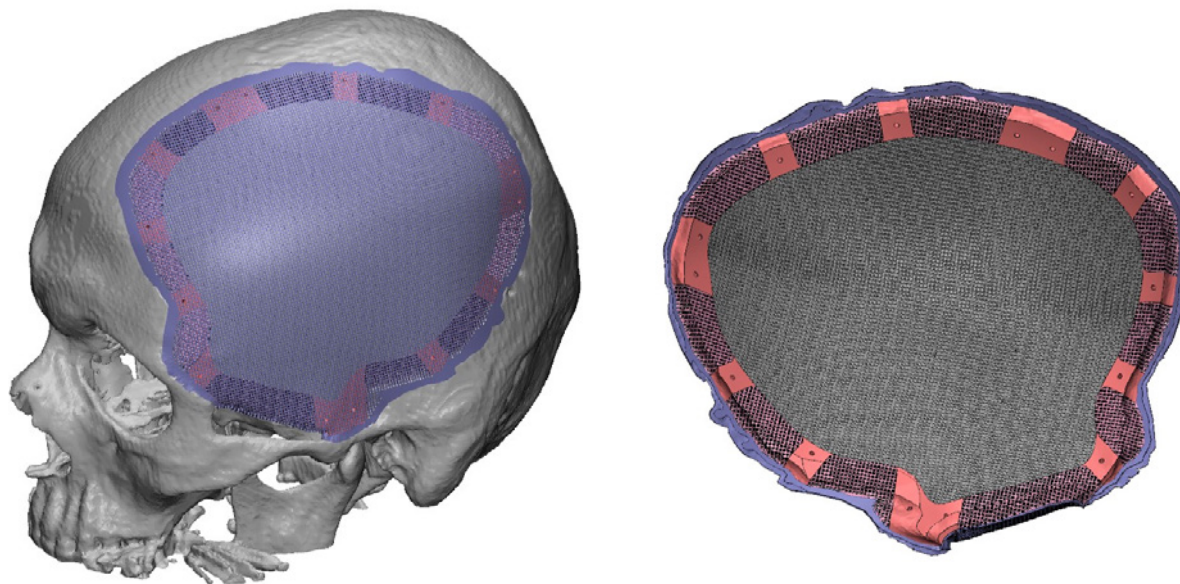


- Selection of porous (yellow) and dense (blue and pink) volumes.
- Creation of fixing holes (diameter 1,4 mm - spaced of ~25mm)



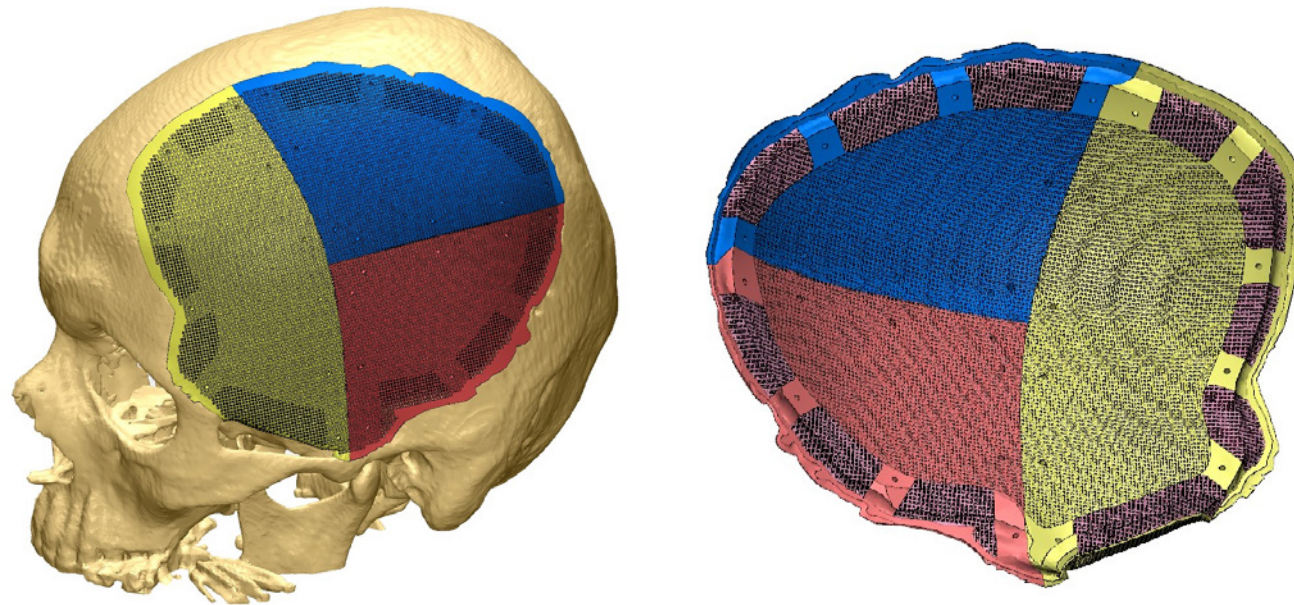
CAD WORKS – STEP 5

- Creation of surface porosity.
- Creation of 3D porous volume.



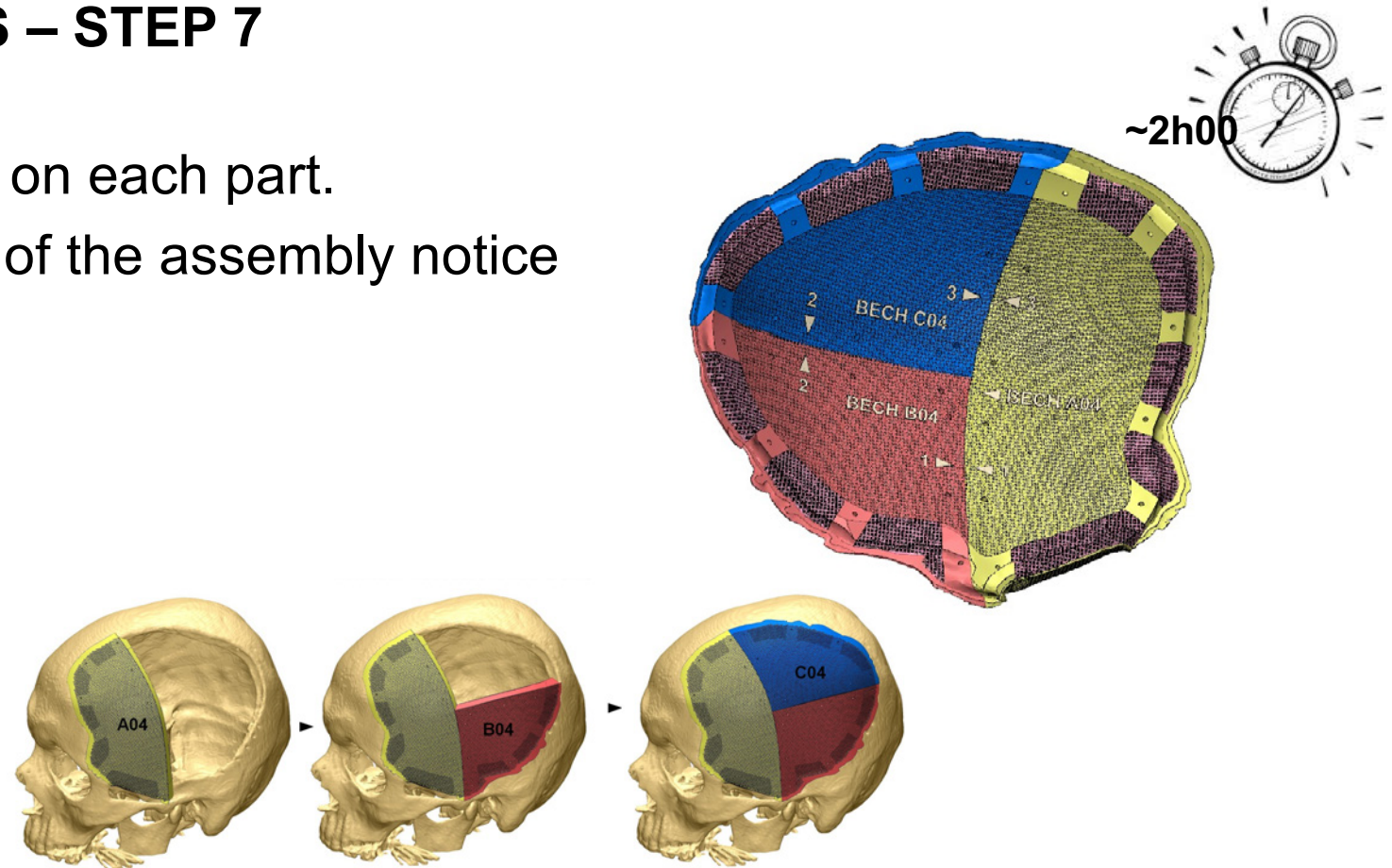
CAD WORKS – STEP 6

- For big size implant, cutting the implant.



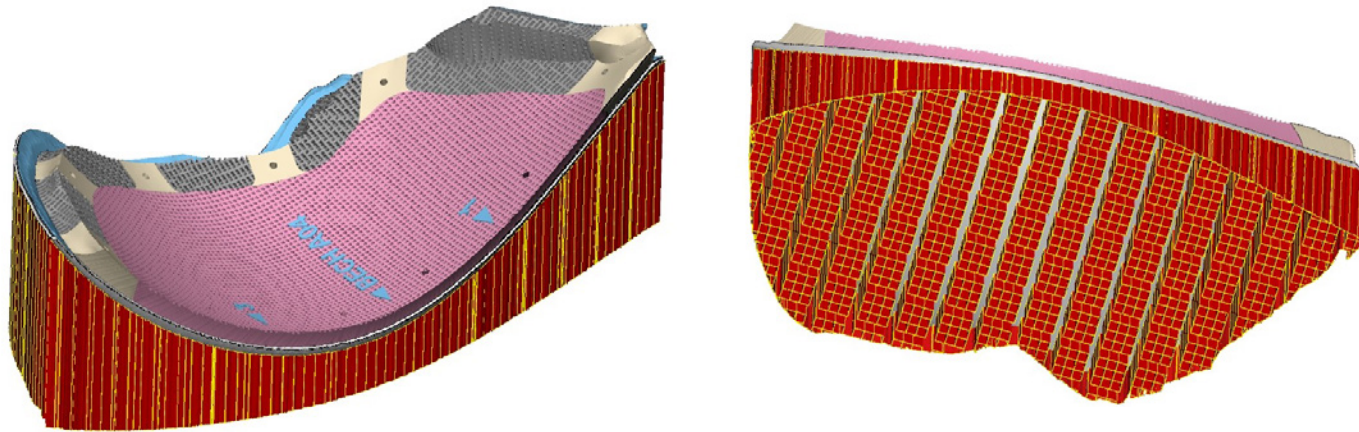
CAD WORKS – STEP 7

- Reference on each part.
- Redaction of the assembly notice



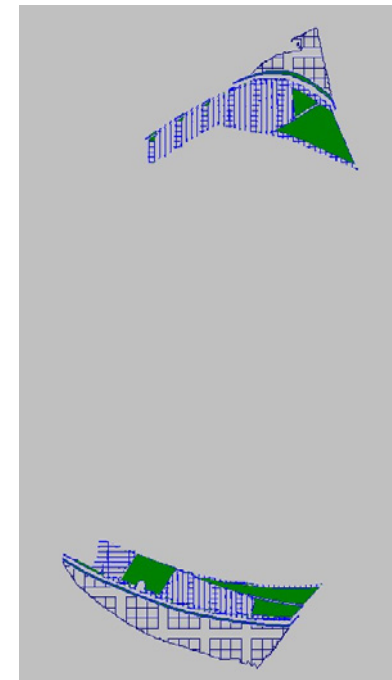
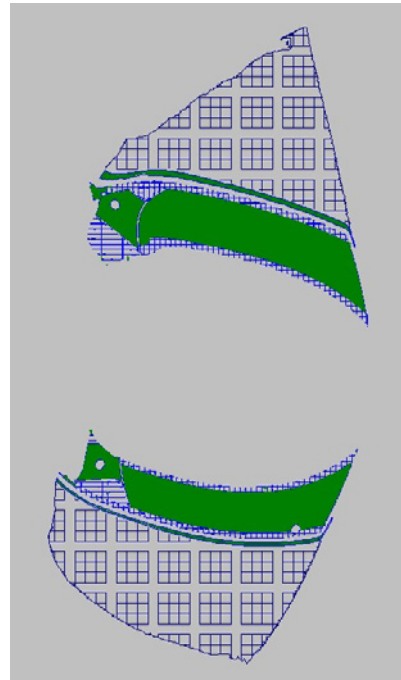
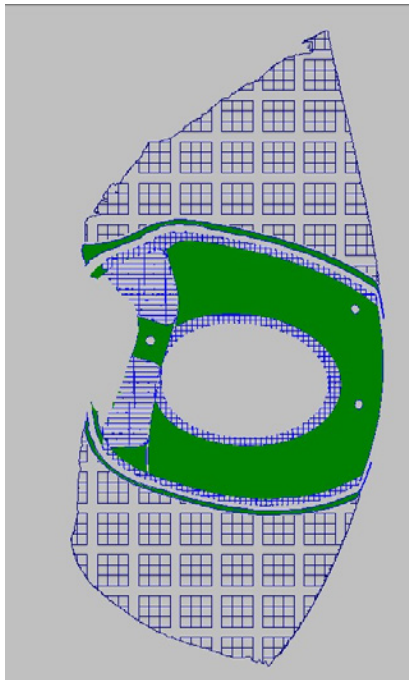
CAD WORKS – STEP 8

- Creation of printing supports for each part.



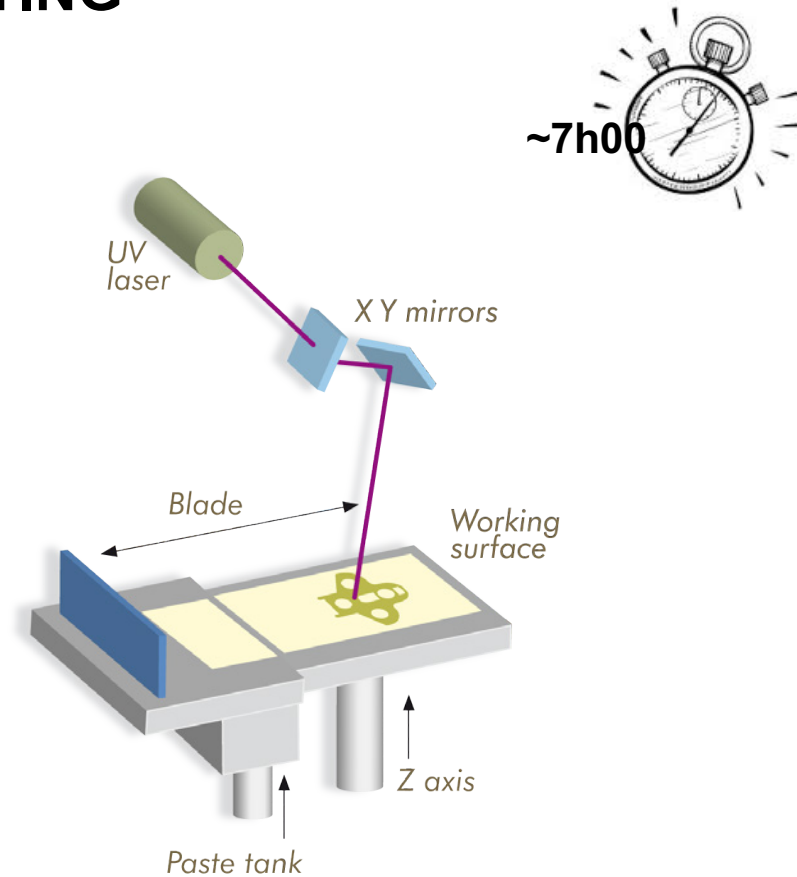
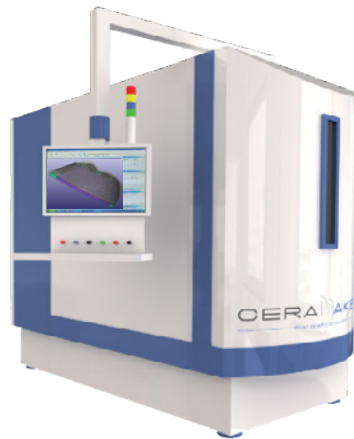
CAD WORKS – STEP 9

- Check the slicing file (laser path)



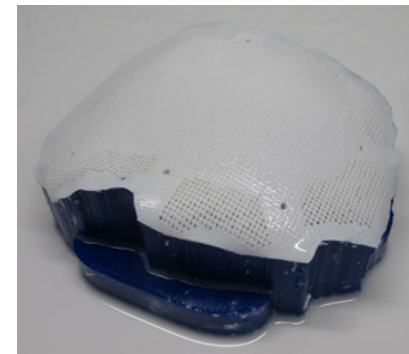
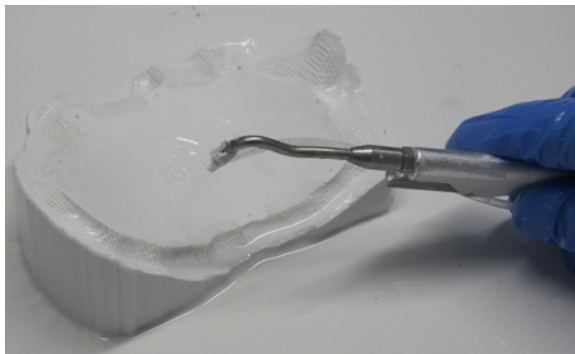
STEREOLITHOGRAPHY PRINTING

- Production in successive layers
- The UV laser polymerises the paste.



CLEANING OF THE IMPLANT

- Removal of the unpolymerised paste
- Removal of printing supports
- Cleaning with specific solvents
- Using of cleaning supports



DEBINDING - SINTERING

- Debinding : Heat treatment to eliminate the resin.
- Sintering : Ceramic powder densification to 98-99 %.
- Shrinkage : ~20%



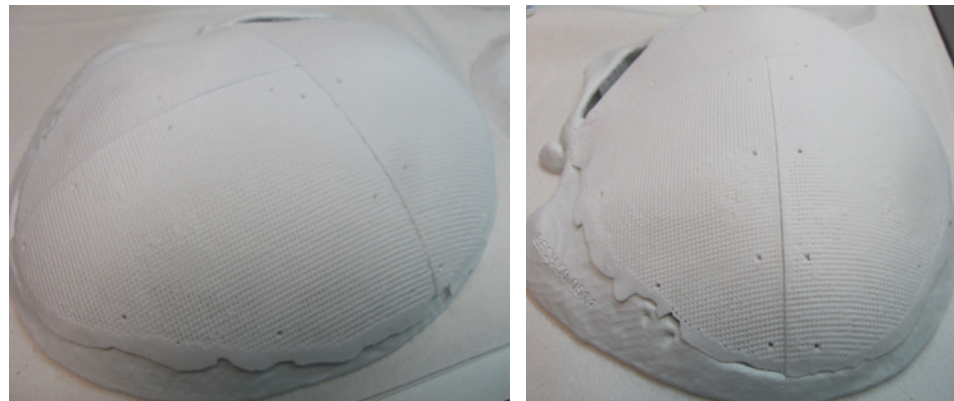
Green part



Sintered part

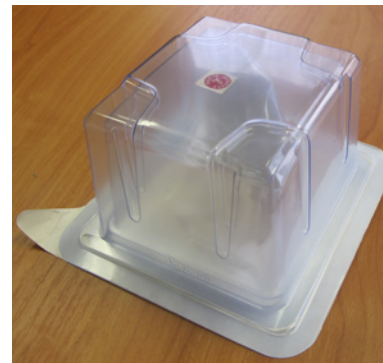
CHECKING OF THE IMPLANT

- Under clean atmosphere
- Measure dimensions and shape on skull model
- In case of several parts, check the assembly
- Checking chemical composition and strength according standards



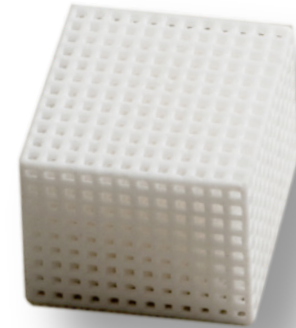
PACKAGING AND STERILISATION

- Under double blister
- Gamma sterilization (25 kGy)
- Delivered with assembly notice, declaration of conformity according standards



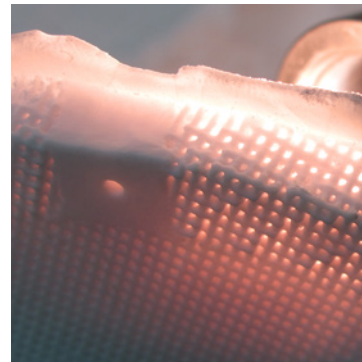
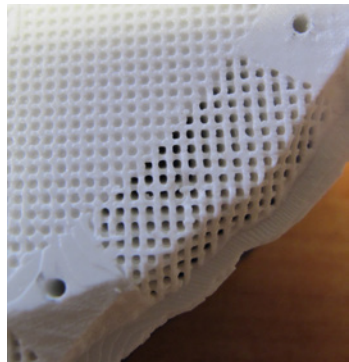
ADAPTATIVE TECHNOLOGY

- No limitation in design of the implant
- Strictly adhere to the tolerances set out in customer's specifications
- The surgeon or the specialist keeps full control of the operations
- Eliminate residue or contaminant linked to production process



UNIQUE 3D POROSITY CONTROL

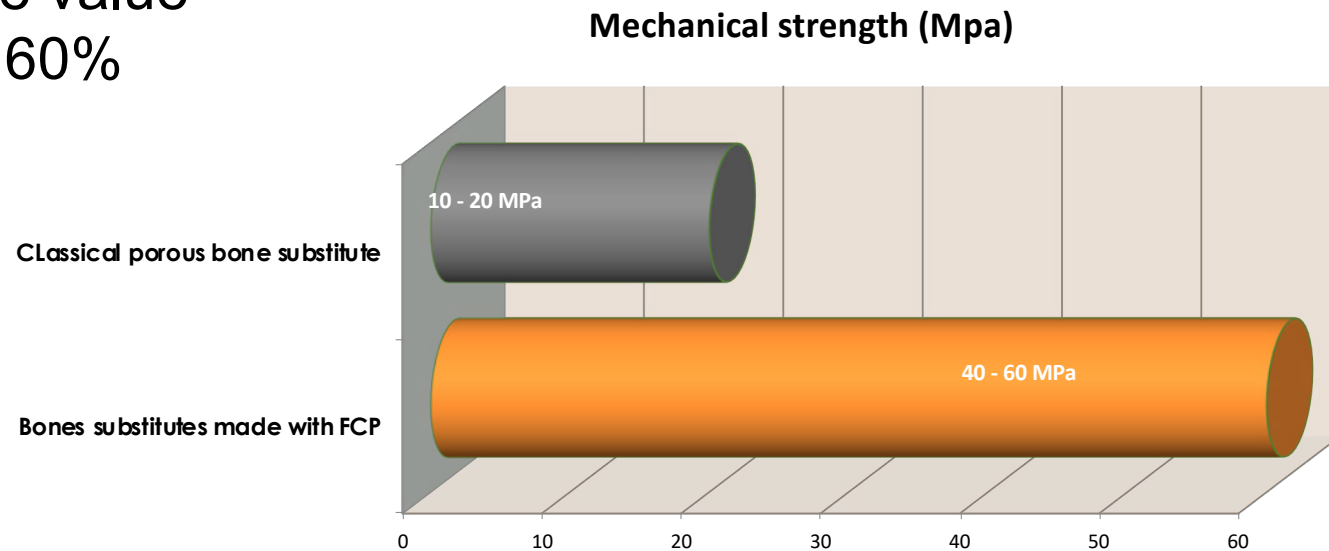
- 3DCERAM enables to control the location and geometry of porous areas of substitutes.
- Porosity structured in 3 dimensions.
- Define a consistent diameter of pores.
- Ensure a complete interconnection of pores



Porous and
dense areas
combined on the
same implant

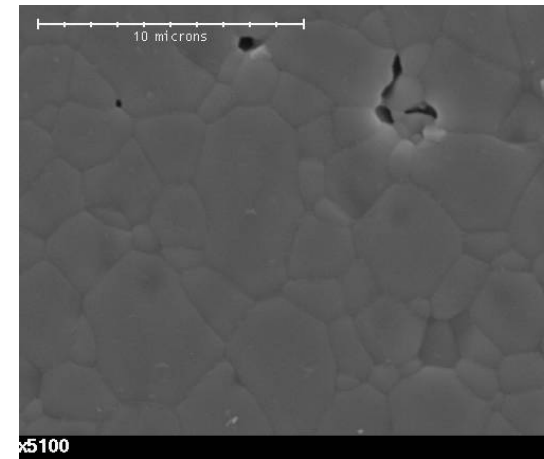
COMPRESSIVE MECHANICAL STRENGTH 3 TO 5 TIMES HIGHER

For the same value
of porosity : 60%



CARACTERISTICS OF HYDROXYAPATITE

- Densification rate = 98-99%/dth
- Density = 3,2
- Microstructure : grain size 1-5 μm .
- Flexural strength : 80-100 MPa.
- Chemical properties :



	Controls	STANDARD	3DCERAM HYDROXYAPATITE
HAP material according standards ISO 13 779-1 : 2008	Hydroxyapatite cristallinity	$\geq 95 \%$	96 %
	Total of other phases	$\leq 5 \%$	4 %
	Ca/P ratio	1,65 à 1,82	1,705

BIOCRANUIM®
MADE-TO-MEASURE IMPLANTS
FOR MAXILLO FACIAL APPLICATIONS

**CLINICAL STUDY
2005 – 2009**



OBJECTIVES

- Assess implants osteointegration
- Assess **aesthetic and functional results**
- Determine **any adverse impact** under normal conditions and assess risks in relation to devices performances

EVALUATION CRITERIA

Primary :

- ➔ Implants osteointegration evaluation : scanner data et post-operative radiography
- ➔ Implants tolerance evaluation : clinical local exam

Secondary :

- ➔ Implants tolerance evaluation : patients interview and clinical exam (pains, heaviness, itching and burning)
- ➔ Functionnal consequences : patient interview (Folstein Mini Mental State)
- ➔ Aesthetical consequences: pictures.



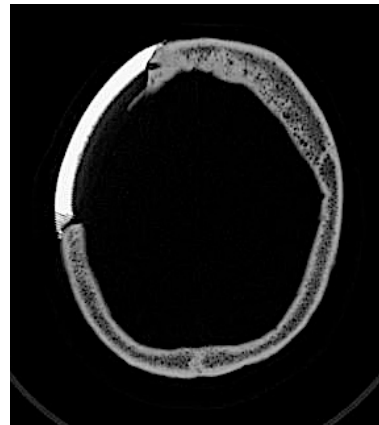
PATIENTS CHARACTERISTICS

- 8 patients (2 women and 6 men)
- 27 to 62 years of age
- Affected with a cranial bone defect between 35 and 109 cm²

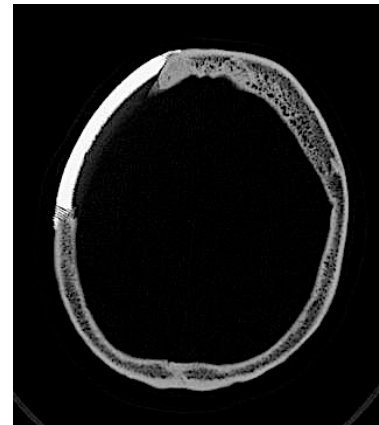
OSSEOINTEGRATION

- Examinations of the patients' skull showed **a perfect integration** of implants in the skeletons. The implants showed **no sign of deterioration**. **No encapsulating membrane** was observed.

➔ Example case #6 :



1 month after surgery



12 months after surgery

IMPLANTS TOLERANCE

- **No signs of inflammation** (warmth or redness), and **no flow** have been observed in various examinations of surgical wounds.
- **No patient had any fever episode** during the postoperative period
- **Pain, burning, heaviness and itching low to moderate** disappeared during the postoperative period



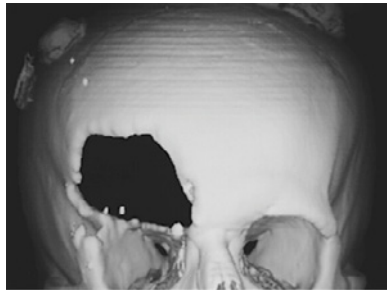
FUNCTIONAL CONSEQUENCE

- MMSE test results showed that the implantation of the device **does not affect the higher functions** of the patient and may even improve them.

AESTHETIC RESULTS

- All the patients **were satisfied with the esthetic result**. The different cases show an improvement in the result quality.

CLINICAL CASE #1



Ref : Case #1
Age : 27 years
Sex : Male
Surgery date : 07 January 2005
Surgery duration : 180 min
Implant surface : 7 x 5 cm
Implant thickness : 5 mm
Fixation holes : 4
Topography : Orbitofrontal

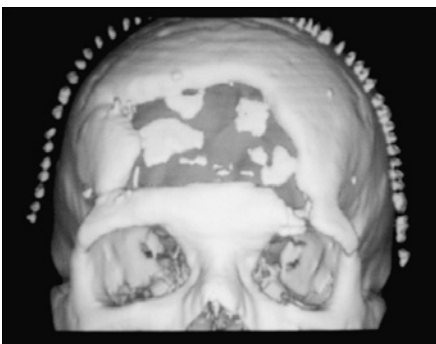


M1

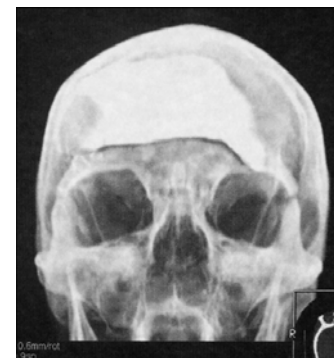


M12

CLINICAL CASE #2



Ref : Case #2
Age : 54 years
Sex : Male
Surgery date : 30 September 2005
Surgery duration : 150 min
Implant surface : 9 x 7 cm
Implant thickness : 5 mm
Fixation holes : 7
Topography : Frontal



M1

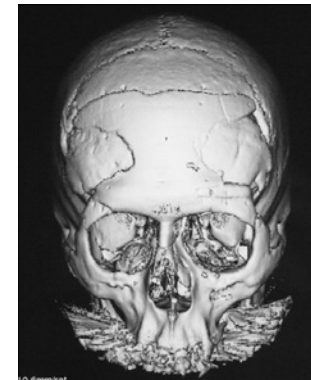


M12

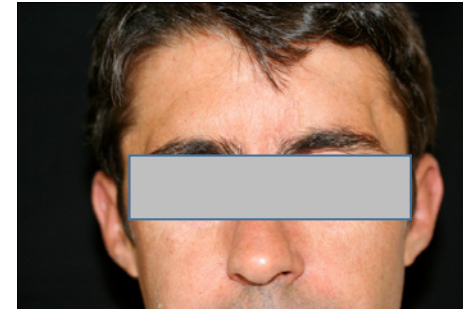
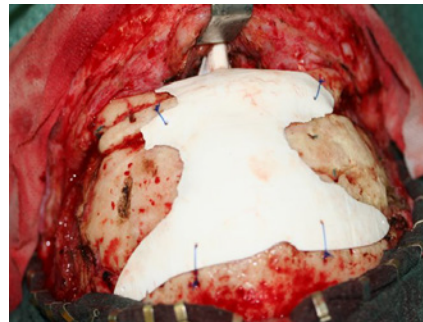
CLINICAL CASE #3



Ref : SOL 68 1005 A10
Age : 38 years
Sex : Male
Surgery date : 28 April 2006
Surgery duration : 90 min
Implant surface : 11,5 x 9,5 cm
Implant thickness : 5 mm
Fixation holes : 13
Topography : Nasofrontal

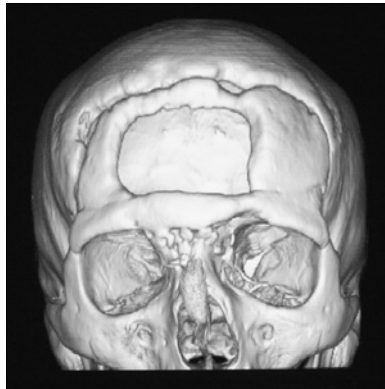


M1

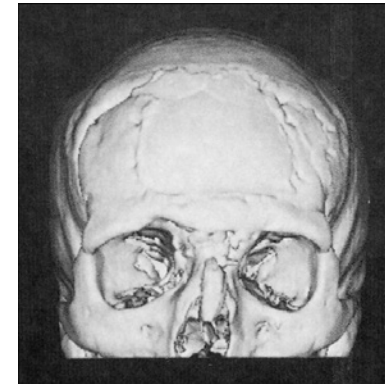


M12

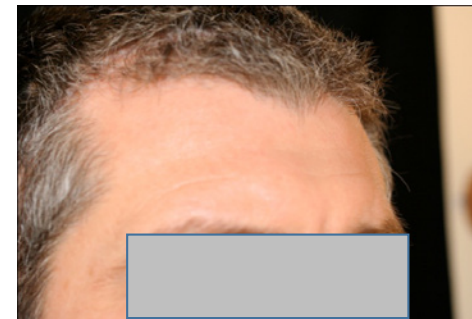
CLINICAL CASE #4



Ref : TUE 69 0106 A04 +
TUE 690106 B04
Age : 40 years
Sex : Male
Surgery date : 09 June 2006
Surgery duration : 120 min
Implant surface : 9 x 7 cm
Implant thickness : 5 mm
Fixation holes : 8 + 3
Topography : Frontal



M1

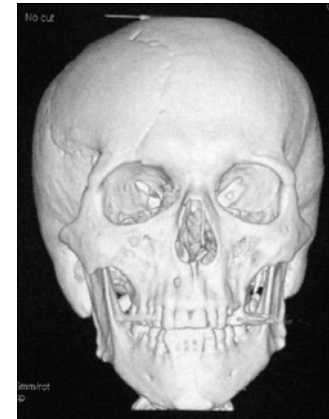


M12

CLINICAL CASE #5



Ref : COD 72 0107 A05
Age : 35 years
Sex : Male
Surgery date : 30 August 2007
Surgery duration: 105 min
Implant surface : 11 x 8,5 cm
Implant thickness : 5 mm
Fixation holes : 7
Topography : Temporal

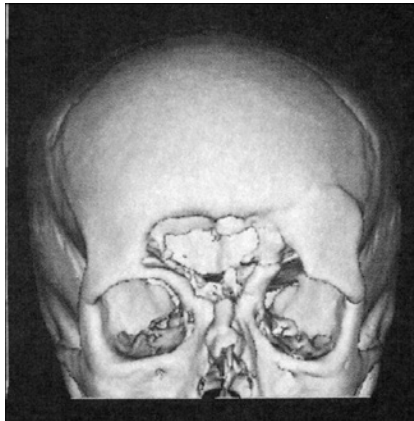


M1

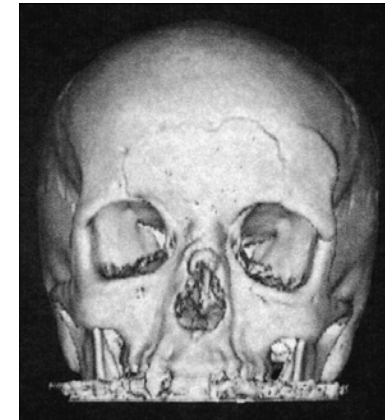


M12

CLINICAL CASE #6



Ref : ERM 63 0107 A04
Age : 44 years
Sex : Female
Surgery date : 05 December 2007
Surgery duration : 120 min
Implant surface : 7 x 5,5 cm
Implant thickness : 5 mm
Fixation holes : 6
Topography : Frontonasal



M1

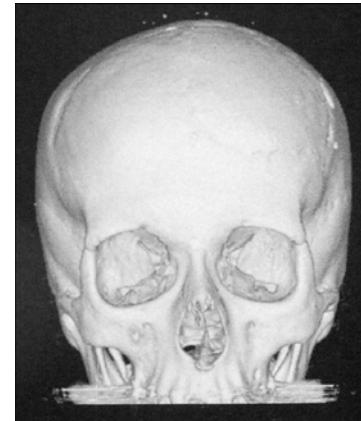


M12

CLINICAL CASE #7



Ref : BOM 56 0807 A02
Age : 52 years
Sex : Female
Surgery date : 22 February 2008
Surgery duration : 75 min
Implant Surface : 9 x 8 cm
Implant thickness : 5 mm
Fixation holes : 9
Topography : Parietal



M1

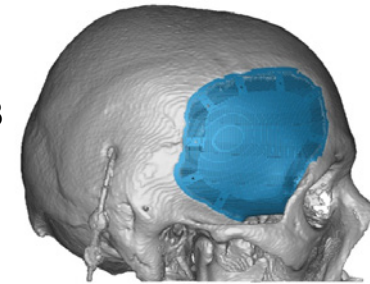


M12

CLINICAL CASE #8



Ref : MIC 45 0807 A03
Age : 63 years
Sex : Male
Surgery date: 21 November 2008
Surgery duration : 90 min
Implant Surface : 10 x 9 cm
Implant thickness : 5 mm
Fixation holes : 8
Topography : Temporal



M1



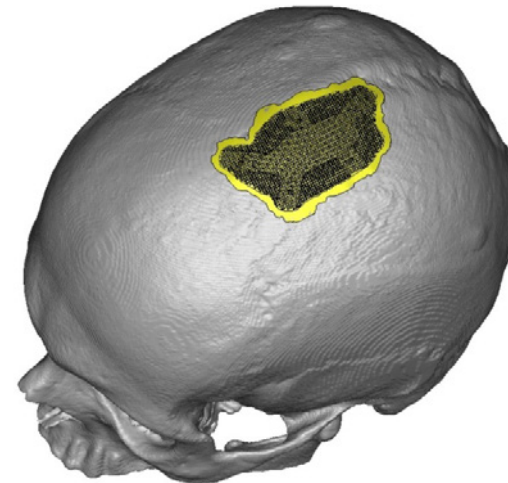
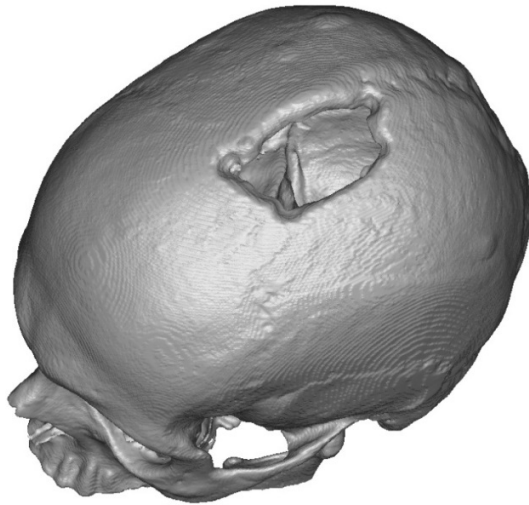
M12



PER FRENCH LAW, THE CLINICAL STUDY RESULTS HAVE TO BE VALIDATED ONE YEAR AFTER THE LAST PATIENT SURGERY , HENCE NO IMPLANT SURGERY IN 2009.

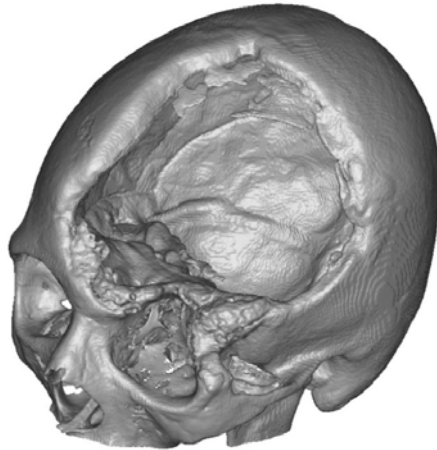
- Since 2010 → commercialisation

CASE TAF



Ref : TAF 56 1010 U01
Age : 55 years
Sex : Male
Surgery date : 25/02/2011
Implant surface : 25 cm²
Implant thickness : 5 mm
Fixation holes : 5
Topography : Parietal

CASE ARB



Ref : ARB 54 0610 A03 + B03 + C03

Age : 59 years

Sex : Female

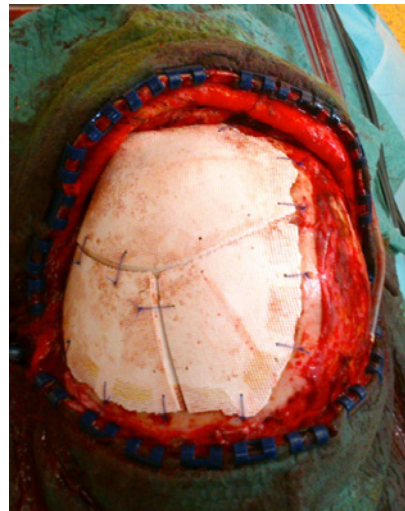
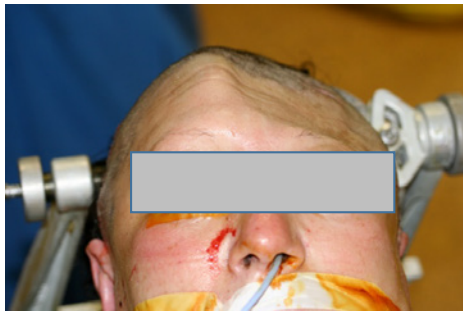
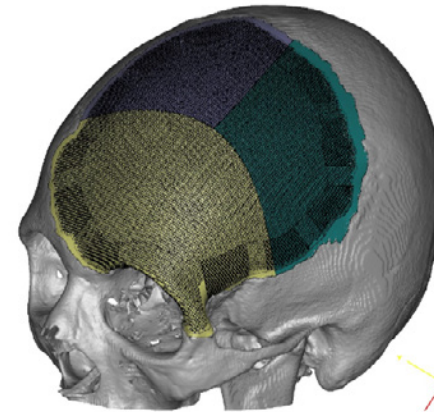
Surgery date : 15/02/2013

Implant surface : 150 cm²

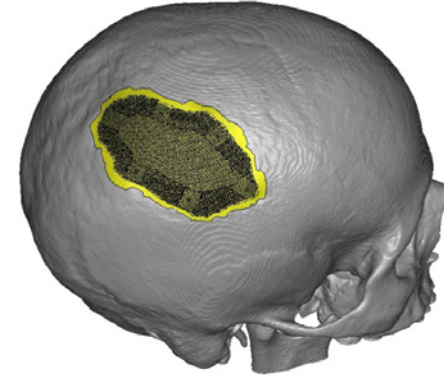
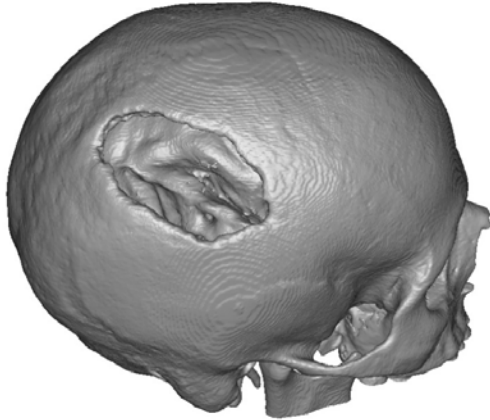
Implant thickness : 5 mm

Fixation holes : 12

Topography : Orbitofrontal

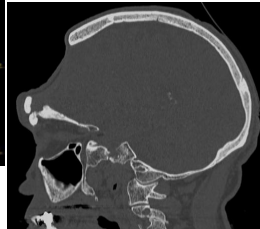


CASE ARD



Ref : ARD 88 0111 U01
Age : 23 years
Sex : Male
Surgery date : 06/06/2011
Implant surface : 35 cm²
Implant thickness : 5 mm
Fixation holes : 6
Topography : Parietal

CASE DEJO



Ref:DEJO 37 1111 A01 + B01 + C01

Age : 76 years

Sex : Male

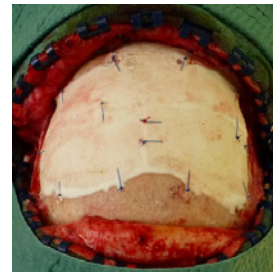
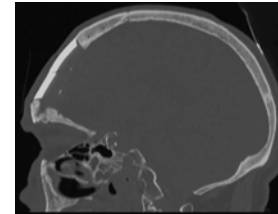
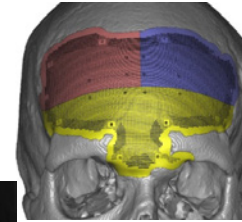
Surgery date : 15/03/2013

Implant surface : 106cm²

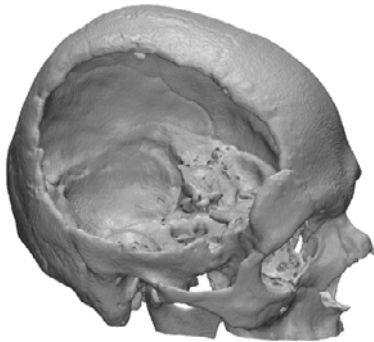
Implant thickness : 5mm

Fixation holes : 12

Topography : Frontal



CASE PHMA



Ref: PHMA 83 1111 A02 + B02

Age: 29 years

Sex: Male

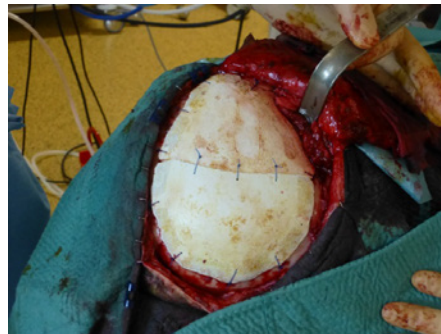
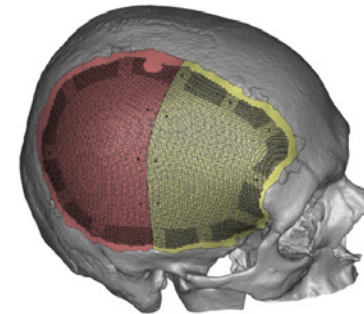
Surgery date: 22/02/2013

Implant surface: 149 cm²

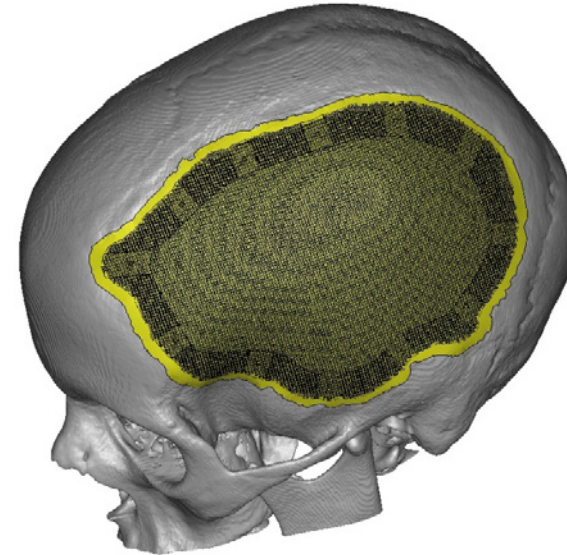
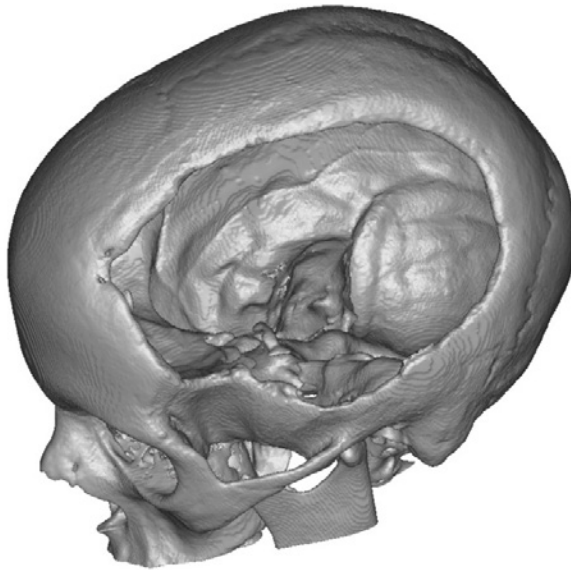
Implant thickness: 5mm

Fixation holes: 12

Topography: Temporal



CASE TRJ



Ref : TRJ 94 0111 U02

Age : 17 years

Sex : Female

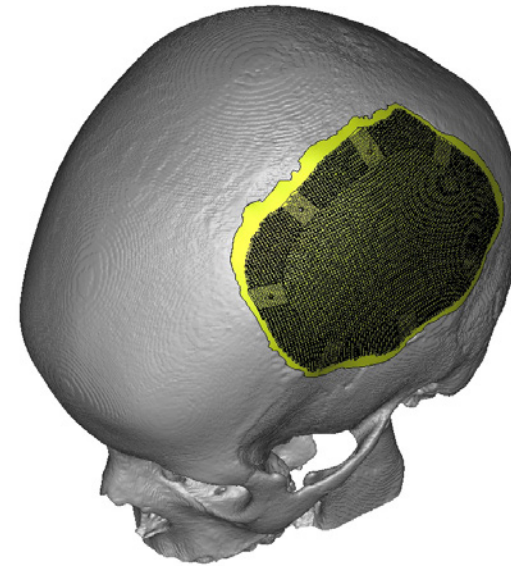
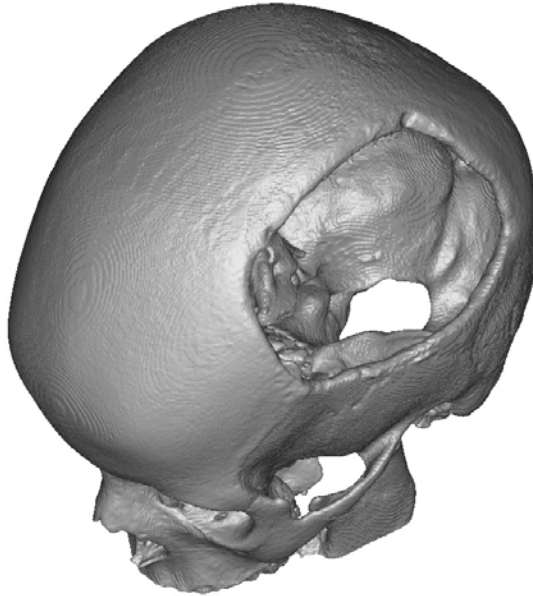
Implant surface : 125 cm²

Implant thickness : 5 mm

Fixation holes : 12

Topography : Parietal

CASE WIC



Ref : WIC 99 0610 U01

Age : 12 years

Sex : Male

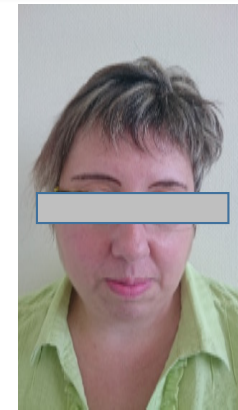
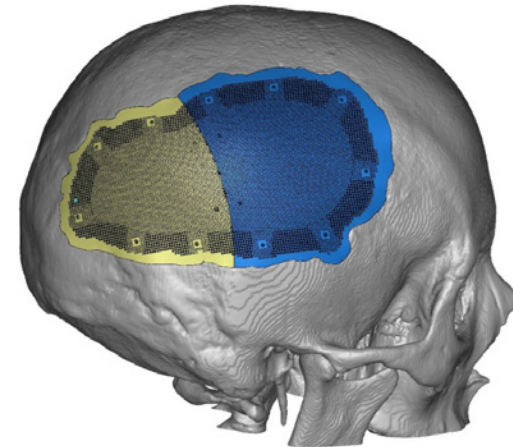
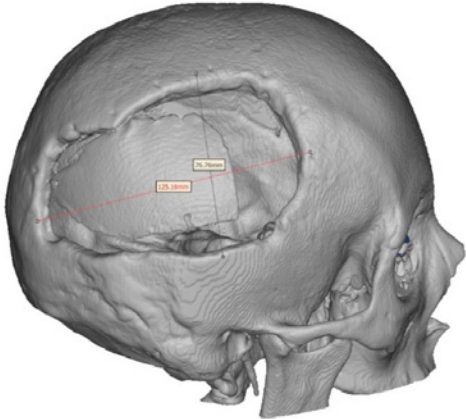
Implant surface : 80 cm²

Implant thickness : 5 mm

Fixation holes : 8

Topography : Parietal

CASE THIS



Ref : THIS 68 0912 A01 + B

Age : 45 ans

Sex : Female

Surgery date : 08/11/2013

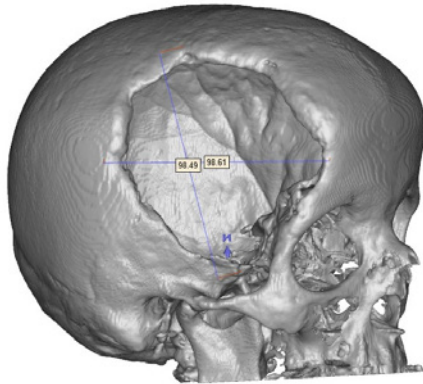
Implant surface : 97 cm²

Implant thickness : 5 mm

Fixation holes : 11

Topography : Parietal

CASE LABE



Ref :LABE 39 1112 A03 + B03

Age : 74 ans

Sex : Female

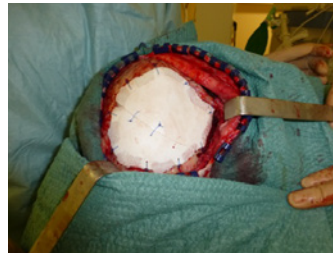
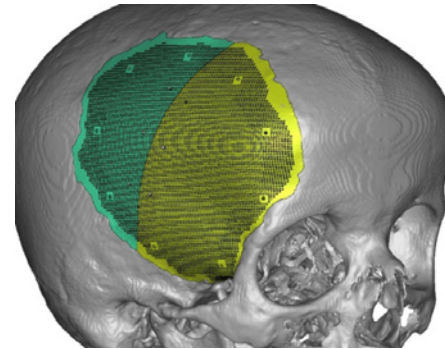
Surgery date : 22/03/2013

Implant surface : 83 cm²

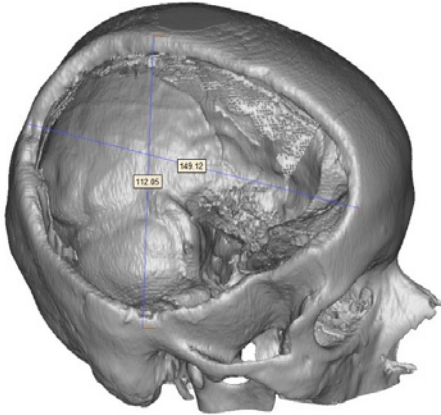
Implant thickness : 5mm

Fixation holes : 9

Topography : Temporal



CASE BAMA



Ref : BAMA 63 1112A01 + B01 + C0

Age : 50 ans

Sex : Female

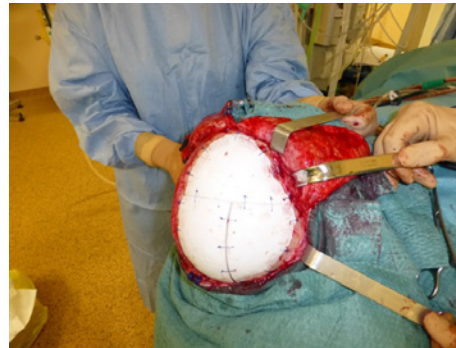
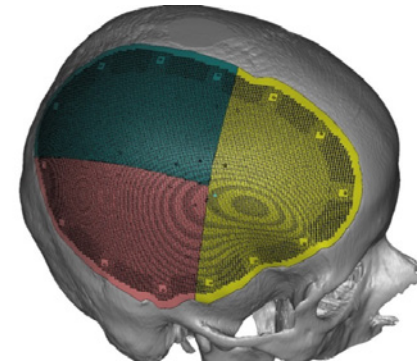
Surgery date : 24/05/2013

Implant surface : 157 cm²

Implant thickness : 5 mm

Fixation holes : 14

Topography : Temporal



CASE GAS1



Ref: GAS1 42 0414A01 + B01 + C01

Age: 72 ans

Sex: Female

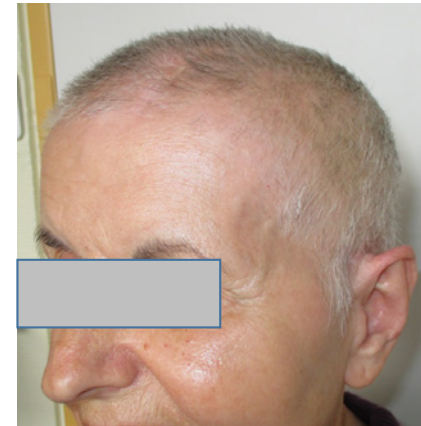
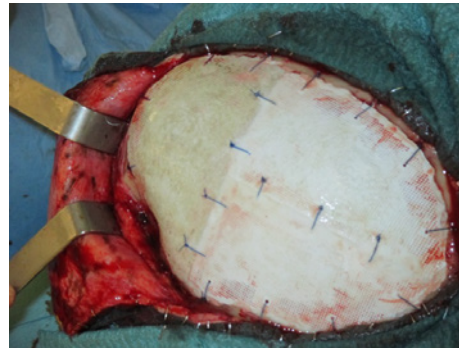
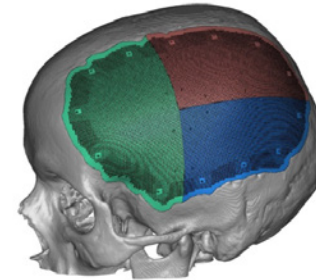
Surgery date: 25/07/2014

Implant surface: 154 cm²

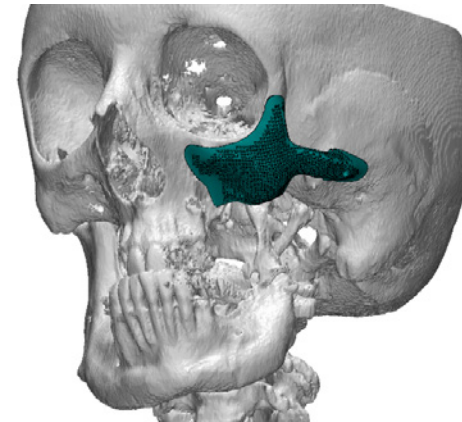
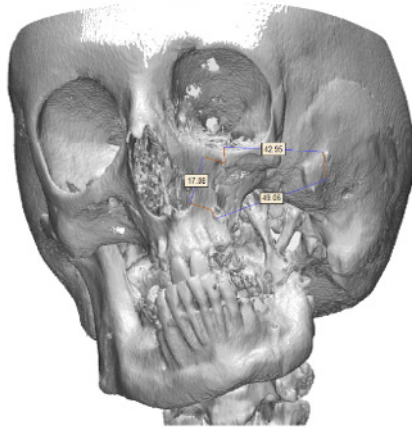
Implant thickness: 5mm

Fixation holes: 13

Topography: Parietal

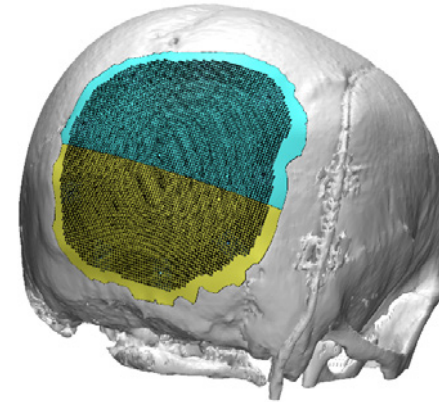
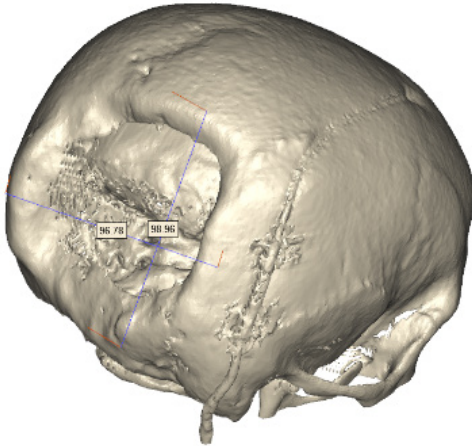


CASE TIAN



Ref :TIAN 42 0814 U04
Age : 72 ans
Sex : Female
Implant surface : 14,5 cm²
Implant thickness : 5mm
Fixation holes : 6
Topography : Facial

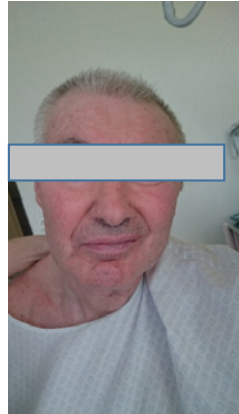
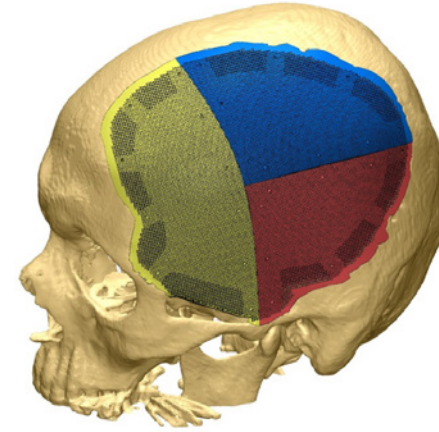
CASE LAGE



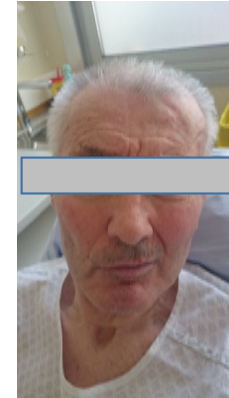
Ref : LAGE 70 0514 A02 + B02
Age : 45 years
Sex : Male
Surgery date : 10/04/2015
Implant surface : 92 cm²
Implant thickness : 5 mm
Fixation holes : 9
Topography : Parietal



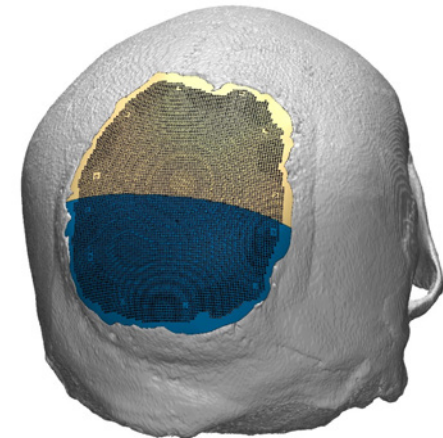
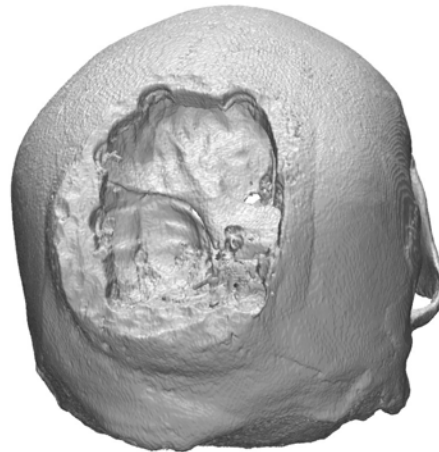
CASE BECH



Ref : BECH 50 0514 A04 + B04 + C04
Age : 66 years
Sex : Male
Surgery date : 13/03/2015
Implant surface : 159 cm²
Implant thickness : 5mm
Fixation holes : 14
Topography : Temporal



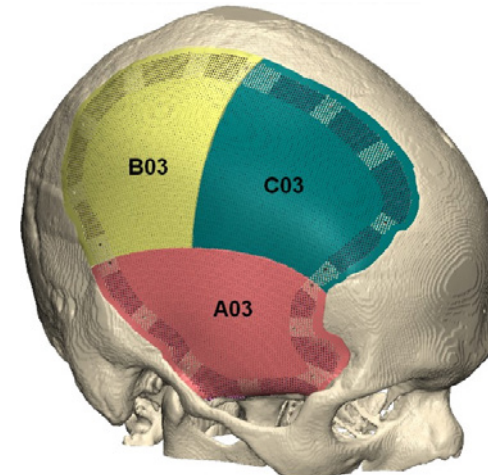
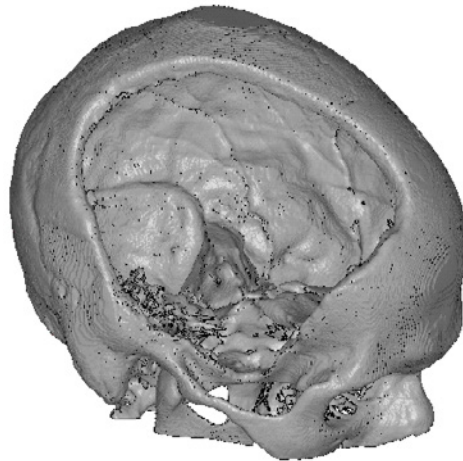
CASE RODO



Ref : RODO 56 0115 A02 + B02
Age : 60 years
Sex : Male
Surgery date : 22/01/2016
Implant surface : 96 cm²
Implant thickness : 5mm
Fixation holes : 12
Topography : Parietal

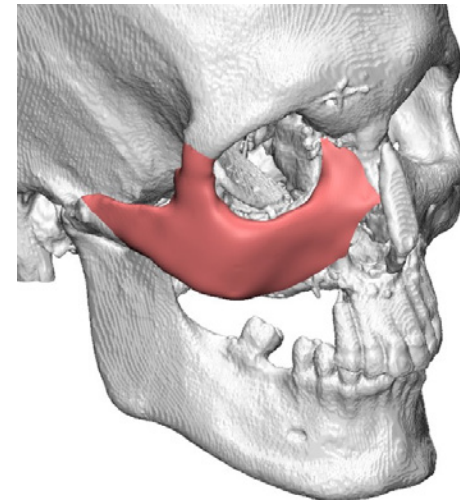


CASE KRPA



Ref : KRPA 81 0915 A03
Age : 35 years
Sex : Male
Implant surface : 162 cm²
Implant thickness : 5mm
Fixation holes : 18
Topography : Temporal

CASE ANMA



Ref : ANMA 89 0815 A03

Age : 27 years

Sex : Male

Implant surface : 35 cm²

Implant thickness : 5mm

Fixation holes : 4

Topography : Facial

NEW CASES IN PROGRESS...

