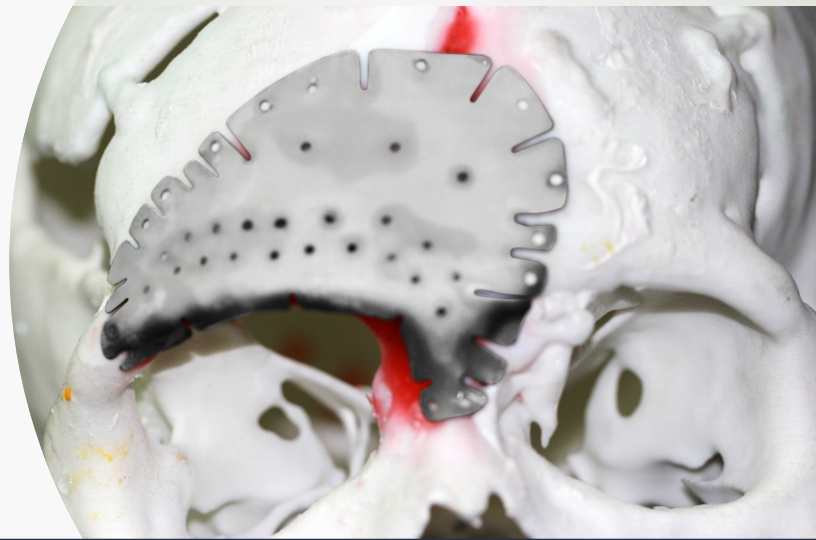


# Changing Faces India

*Concept to Change Life...*

TECHNOLOGY AT ITS PEAK...

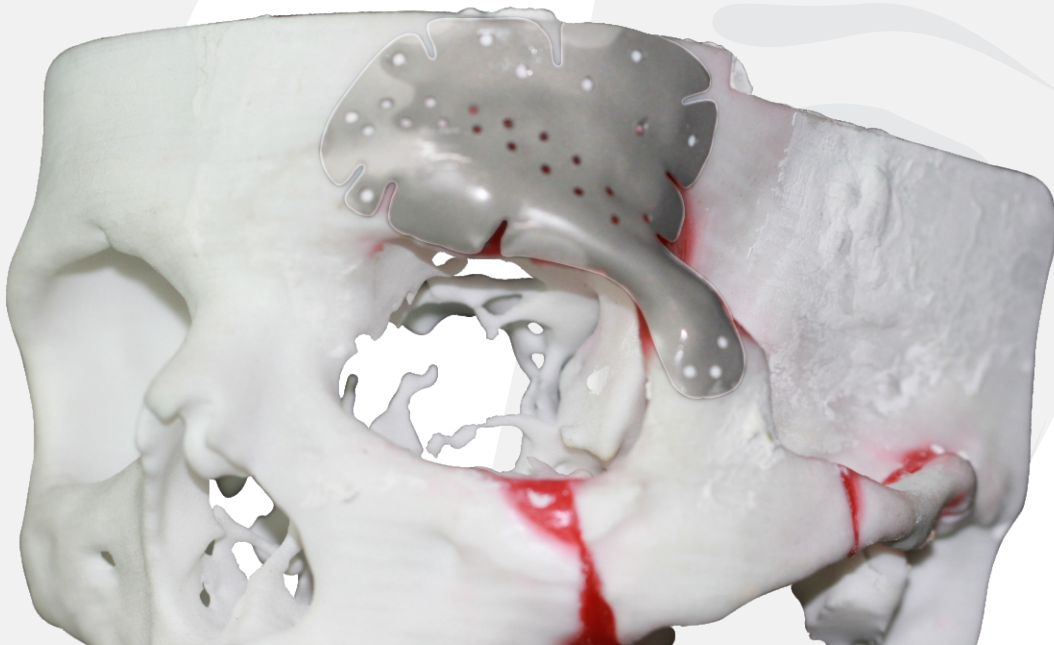


## PATIENT SPECIFIC IMPLANTS

BETTER ANATOMIC FIT  
REDUCED OPERATING TIME  
SUPERIOR ESTHETICS RESULTS

# Successful 10 Years

In field of reconstruction science, its all about improvement of quality of life....



Changing faces India, centre of advance maxillofacial defect reconstruction is working in this field since a decade. Our team is skilled and committed to provide best possible services in the field of maxillofacial reconstruction for upliftment of quality of life. With advent in technology, the reconstruction of acquired and congenital defects is clinically possible. Our centre excels in patient specific implant and has brought back smiles to many faces.

## ADVANTAGES

### ACCURATE & HIGHER COSMETIC OUTCOME

With use of modern technology such as accurate scan, CAD & 3D printing we provide accurate implant which has perfect for the patient's defect with good cosmetic results.

### STRENGTH & STABILITY

The Next-Generation design improves strength and removes the risk of local movement and flexing that may damage surrounding tissue and apply unnecessary force on screws.

### NONTOXIC TO LIVING TISSUE

Titanium is strong, biocompatible and has the lowest infection rate compared to ceramics, PMMA and autologous bone.

### LIGHT WEIGHT

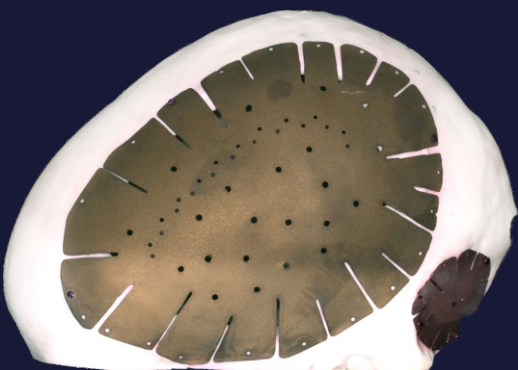
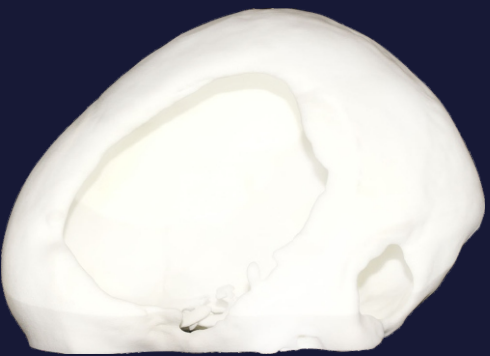
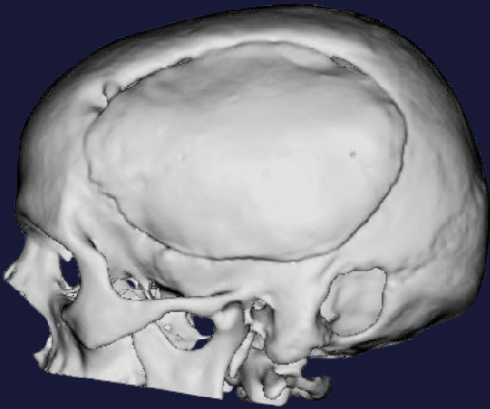
Pressed-sheet titanium minimizes the amount of alloplastic material (e.g. less than 20% the material in titanium implants that mimic bone thickness) without any strength disadvantage.

### AUTOCLAVABLE

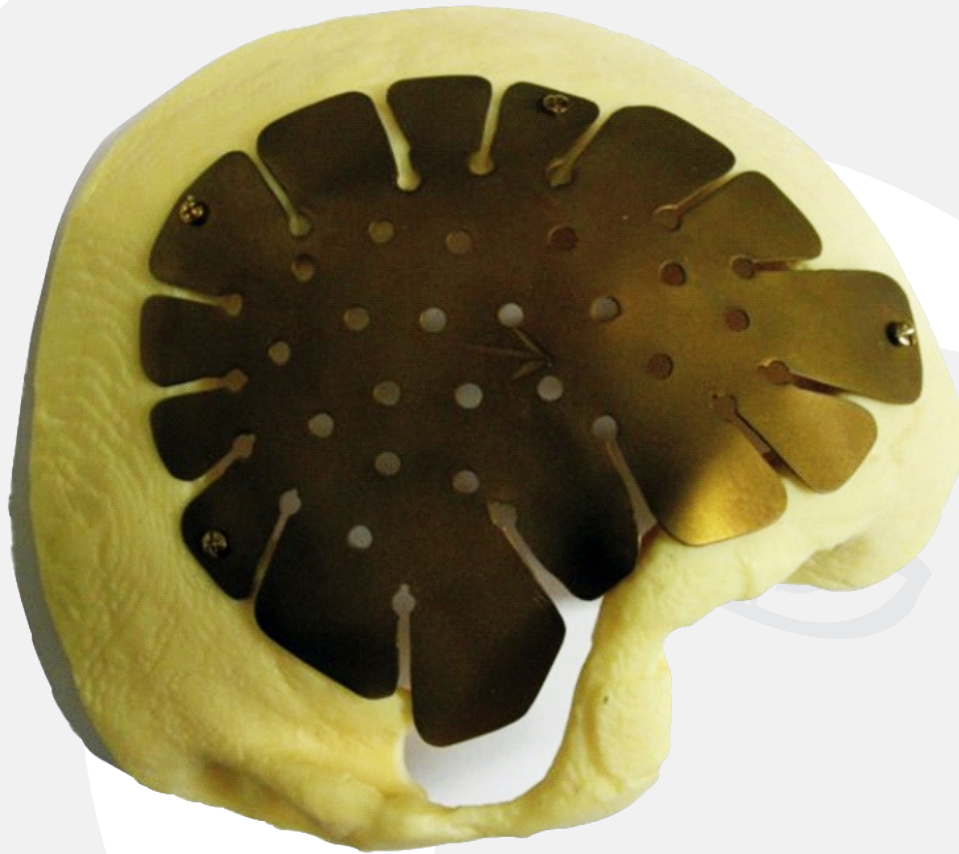
Titanium implants can withstand repeated sterilization without deformation

### EASY TO ACQUIRE

Fast production turnaround, which facilitates enormously your planning, logistics and stock management, hence reducing costs and potential waste.



## CRANIOTITE



Reconstruction of cranial defect is important for protection of vital tissue, function & also aesthetics. Custom implants for the reconstruction of craniofacial defects have gained importance due to better performance over their generic counterparts.

Our custom implants are made of pressed-sheet titanium. These are Next-Generation implants which combine accurate design with state-of-the-art pressing technology. Craniotite are stronger implants with a better fit to the defect and remove the

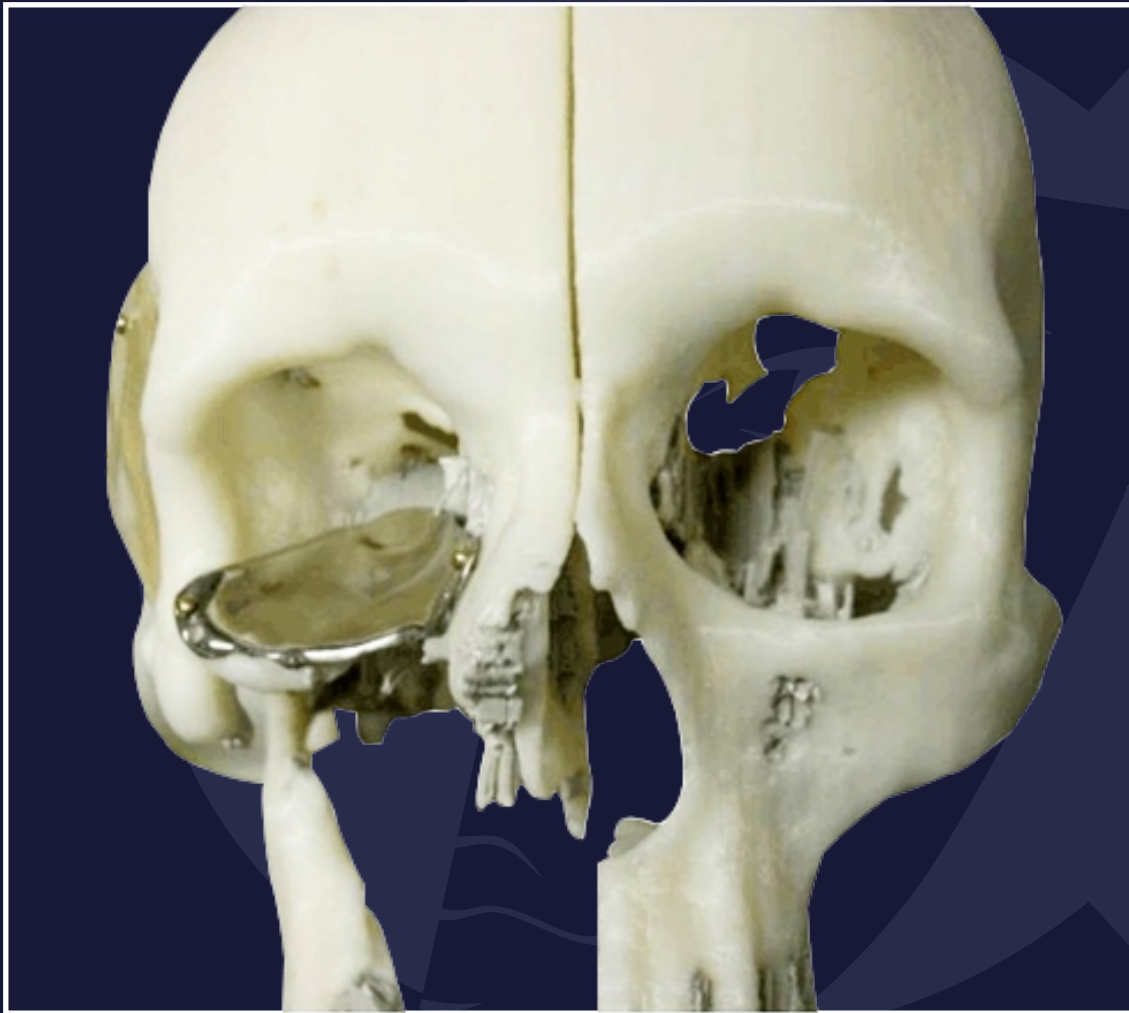
need for the surgeon to contour and adapt in theater. Thus, craniotite not just reduce intra-operative time, but also provide superior esthetics and post-surgical outcome. Indeed, we can press implant for large cranial defect. Production of the craniotite implants are also much quicker, which allows us to give surgeons and patients a swift service.

Our temporal Implants provide a means for temporalis suspension to improve cosmetic outcomes.



# ORBITITE

Simplification of Complexity...



Orbital Floor & wall repairs are notoriously difficult because their shape is critical to the visual function. There is not one fit to different shapes as every orbit is different. The anatomy, extent & contour of the defect also varies. Hence a functional repair needs to restore the original contour and therefore should be customized. It is also important that the orbitite implant is physically able to be fitted and can be accurately positioned in the orbit, while avoiding the critical structures.

## PRODUCT DETAILS

<b>BRAND NAME</b>	<b>CRANIOTITE / ORBITITE</b>
<b>DIMENSION</b>	Defect Customized in 2mm thickness
<b>PLACE OF ORIGIN</b>	India
<b>MATERIAL</b>	Medical Grade Titanium (Passive Annealed, Micro Surfaced)
<b>USAGE</b>	Cranial Defect, Orbital Defect, Zygomatic Defect
<b>RETAINED WITH</b>	Titanium Screw of 2mm X 3mm or with Titanium wire (16gauge)
<b>STATUS OF IMPLANT AT TIME OF DELIVERY</b>	Unsterilized

## PAYMENT & SHIPPING TERMS

<b>PRICE</b> SIZE LESS THAN OR EQUAL TO 2 SQUARE INCH SIZE MORE THAN 2 SQUARE INCH	Contact for Updated Price
<b>MINIMUM ORDER QUANTITY:</b>	1 Piece
<b>PORT:</b>	Mumbai
<b>PACKAGING DETAILS:</b>	Poly Bag, and then in Carton also as per your Requirement
<b>DELIVERY TIME:</b>	7 -10 Working Days (After Patient CT Data is Received)
<b>PAYMENT TERMS:</b>	Delivery on Payment
<b>SUPPLY ABILITY:</b>	200Pieces/ Per Month

### COMMERCIALLY PURE MEDICAL GRADE TITANIUM

- Ultra-high strength
- Radiopaque
- Excellent biocompatibility
- Autoclavable – withstand repeated sterilization

### TITANIUM MECHANICAL PROPERTIES

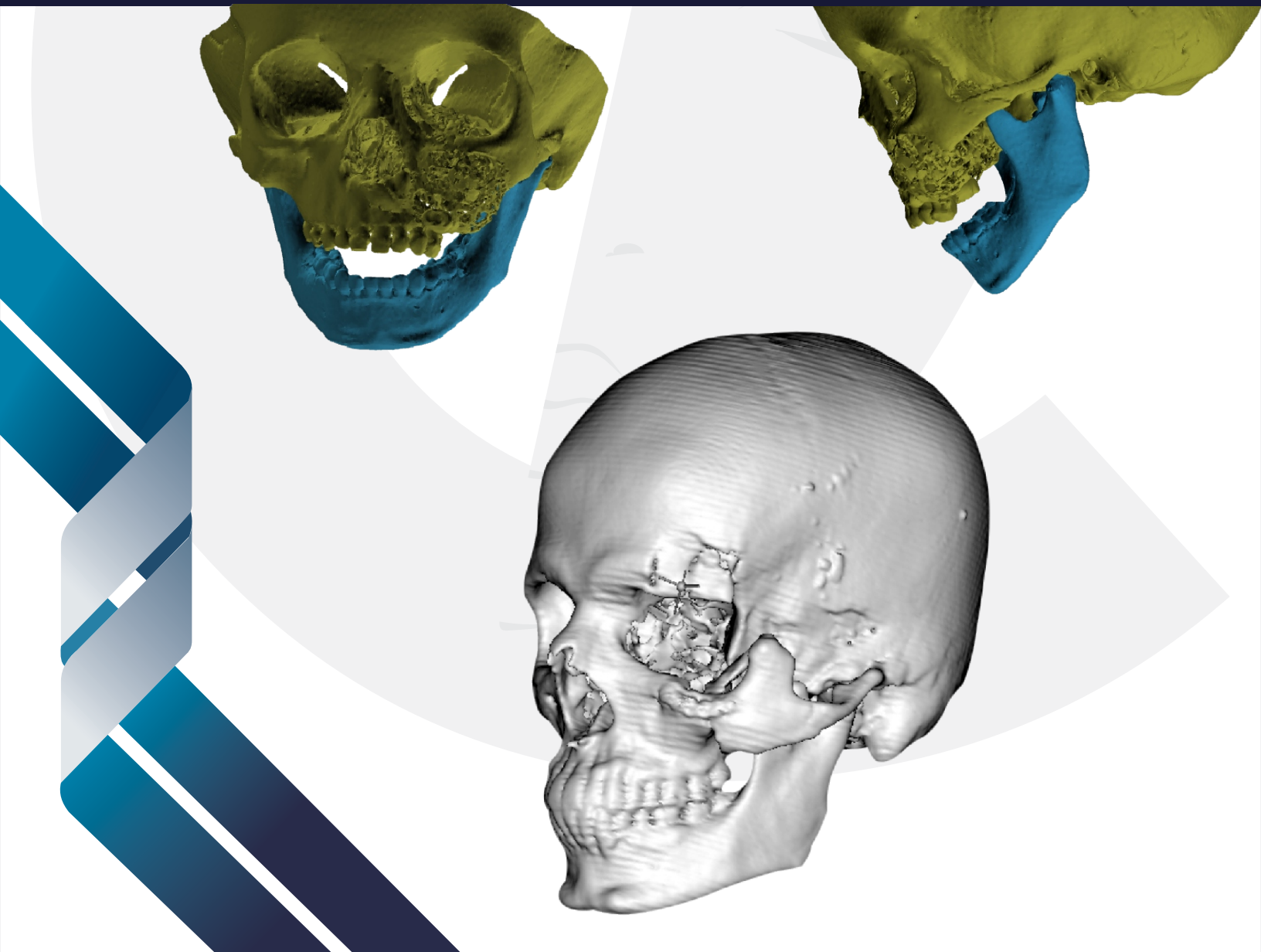
- Grade II titanium
- Yield strength – 65 Ksi
- Tensile strength – 50 Ksi

Note- Titanium specific implants cannot be modified. If there is minor fit adjustment required, surgeon must modify the patient's bone.

## Recommended Scanning Protocol for Implant and Maxillofacial Implants

Position the patient's head in the CT scanner headrest making sure that the patient does not move during the scan (this is to avoid movement artefacts in the scan). Metallic object such as jewelry, dental prosthesis, so as to prevent metallic artifact. And Scan the defect and at least 2cm of the surrounding tissue, using contiguous sequential 1mm-thick or less than 1mm-thick slices. If using a CBCT scanner for scanning a one-sided defect, please ensure that the field of view is large enough to include both sides of the head (this is to achieve as good an outcome as possible post-operatively) If possible, do not use gantry tilt, unless to avoid

critical structures that do not need imaging For orbital floor or wall defect, it is very important to use very thin contiguous slices to be able to image correctly the bone still present in this area. Export the raw data with a bone filter into a DICOM - format (Digital Imaging and Communications in Medicine). Send us the scan via our FTP server or on a DICOM CD. On your request, it is also possible for us to collect the data from your IT network. Your IT manager can contact us directly regarding this facility. Do not hesitate to contact us if you have any queries about scanning or data transfer - better before the patient is scanned but never too late!



# HOW TO ORDER

1. The completed Request for quote (RQF) form and the CT scan (according to the CT Scanning Protocol) are both send together to:

**Changing Faces India**

**Beside Axis bank, Near new bus stand**

**Pandri, Raipur**

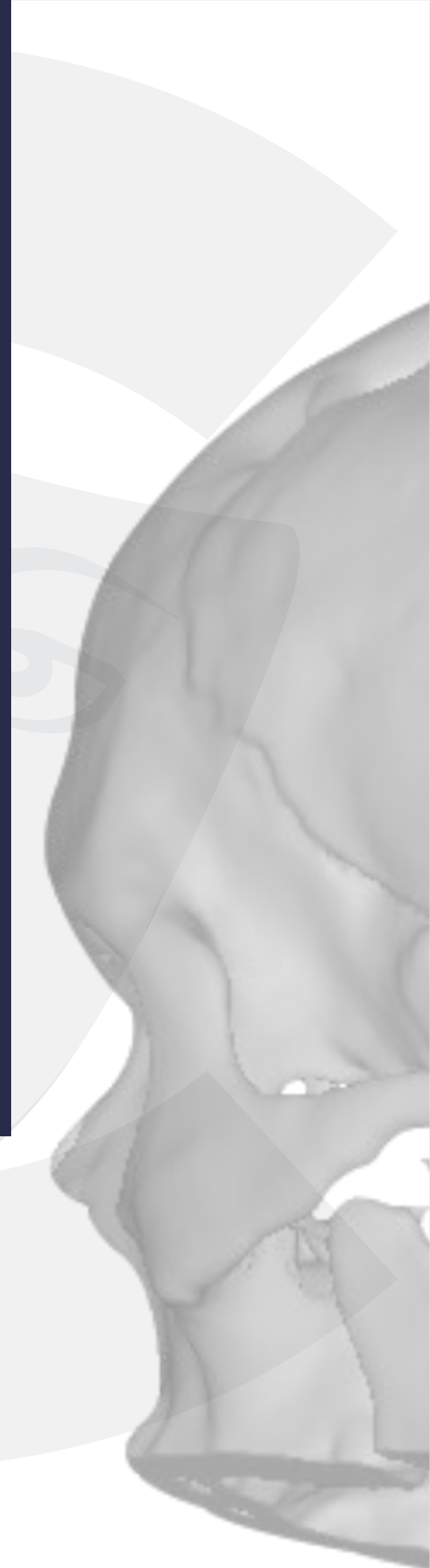
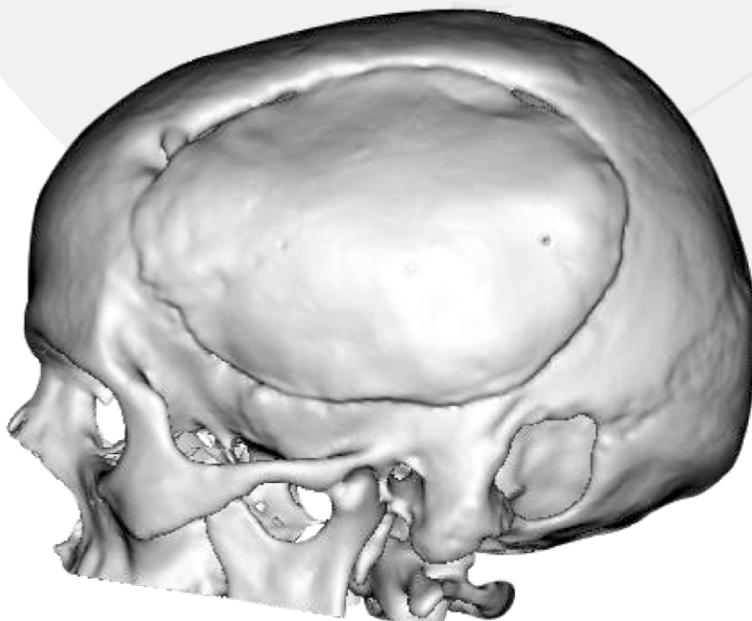
**Chhattisgarh -492001**

**India**

or upload to our secure server or upload it online data storage portal such as google drive, dropboxand send the download link to us. Please call us for access to this FREE service.

There is no charge for sending us your data for discussion of what you would need or how we can help you. Your data will be secure and will not be shared with other parties.

2. We design the implant and provide you images in different view and/ or skull model will be sent to the surgeon for review and approval.
3. Surgeon approves the design. (Prompt approval of the design is required for the implant to be manufactured in a timely fashion. If changes are required at this stage, the model will be modified, reviewed and approved by the surgeon again. This will delay the start of implant manufacture.
4. When the purchase order and the design approval are received. We manufacture the implant. After manufacturing, nonsterile implant will be shipped to the surgeon.

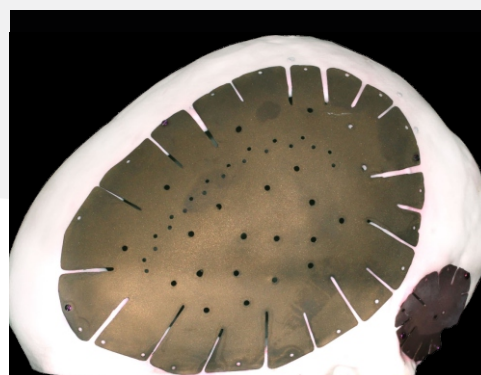
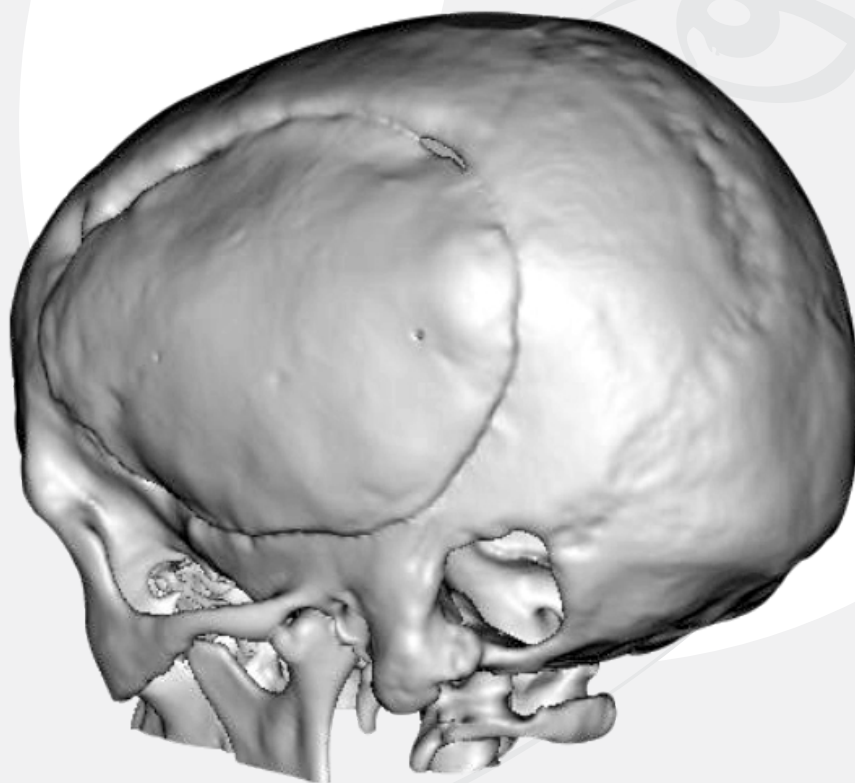




## Recommended Sterilization Protocol for Maxillofacial Implants

All our Products are delivered NON-STERILE. Implants should always be cleaned with detergent and then steam-sterilized using an autoclave operating within the parameters set in HTM 2010 with the sterilization hold time of 134-137 degrees centigrade for 3-3.5 minutes in a porous load sterilizer. The implant must not be used if the package was opened or damaged during delivery. If sterility of Templates or Models of the defect is required, you must use 25-35kGy gamma irradiation, unless specified differently in the documentation that comes with the Product. Re-sterilization: If re-

sterilization is required, ensure that the Product is 1) not damaged or contaminated and 2) still fits the model of the defect and does not contain sharp edges before re-sterilizing it using the methods described above. It is not our responsibility to ensure sterilization and validation of sterilization equipment's. Your sterilization manager can contact us directly if they have any question that we may be able to help with.



# REQUEST FOR QUOTE

**Craniotite<sup>®</sup>**  
*Patient specific implant*

**Changing Faces India**  
*Concept to Change Life...*

For questions please call and ask for Craniotite/Orbitite - Changing Faces India, Implant Department (+91 - 09752995399).

Surgeon Name

Hospital Name

Postal Address (With City, Territory and Postal Code)

Phone Number

Alternate Phone Number

E-mail Address

Patient Name

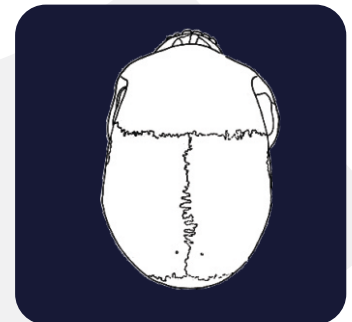
Age

Sex

Date of Planned Surgery

Review Methods

Appropriate Defect Location (With Schematic Location)



CD – ROM of CT include with marked Patient details attached -

- ☐ Yes  
☐ NO

Date

Signature

## **General Terms and Conditions CFI**

### **1. General**

1.1 The present terms and conditions shall apply to each and every offer, sale and delivery by Changing Faces India (CFI), Raipur, C.G. India of goods and services to Client.

1.2 The present terms and conditions shall also apply to all agreements between CFI and the Client, the execution of which calls for the services of third parties.

1.3 Possible deviations from the present general terms and conditions shall only be valid provided they have been explicitly agreed upon in writing.

1.4 The applicability of Client's possible purchase or other conditions is explicitly rejected.

### **2. Agreement, Offers and Confirmation**

2.1 Offers shall be free of obligation. They shall be valid for a period of thirty (30) days.

2.2 An agreement exists only after it has been signed by CFI and Client. Further oral understandings are only binding to CFI after they have been confirmed in writing by CFI and Client.

2.3 The agreement between CFI and the Client shall be entered into for an indefinite period of time unless the nature of the agreement dictates otherwise or if CFI and the Client have agreed otherwise.

### **3. Execution of the Agreement**

3.1 CFI shall execute the agreement to the best of its knowledge and ability and in accordance with the requirements of good craftsmanship.

3.2 If and in so far required for the proper execution of the agreement, CFI shall have the right to have certain work done by third parties.

3.3 The Client shall see to it that CFI shall be provided in due time with all data and materials which are reasonably necessary or desirable for the timely and appropriate execution of the agreement by CFI.

3.4 CFI shall not be liable for damage of whatever nature caused by the fact that CFI worked on the basis of incorrect and/or incomplete data provided by the Client, unless Client should have been aware of said incorrectness or incompleteness.

3.5 If CFI and the Client have agreed that the agreement will be executed in stages, CFI can suspend the execution of the parts belonging to a following stage until the Client has approved in writing the results of the stage prior to it.

3.6 Unless expressly stated otherwise in the agreement, any times or dates for delivery by CFI are estimates and shall not be of the essence.

### **4. Changes to the Agreement**

4.1 If it is shown during the execution of the agreement that the work to be done needs to be changed and supplemented in order to ensure its proper execution, CFI and the Client shall adapt the agreement accordingly in due time and in mutual consultation.

4.2 If a fixed fee has been agreed upon then CFI shall indicate the degree to which the change or supplement to the agreement will result in an increase of said fee.

### **5. Secrecy**

5.1 CFI and the Client shall be bound to secrecy of all confidential information they have received within the scope of the agreement from the other party. Information shall be considered to be confidential if the other party has indicated so or if the confidential character results from the nature of the information.

5.2 If a statutory provision or a judicial decision compels CFI to convey confidential information to third parties designated by law or by the court and CFI cannot for that purpose invoke a legal right to refuse to give evidence or such a right acknowledged or allowed by the competent court, CFI shall not be held to pay damages or compensation and the Client shall not be entitled to demand the dissolution of the agreement on the ground of any damage resulting from said circumstance.

### **6. Intellectual Property and Copyrights**

6.1 Unless expressly stated otherwise in the agreement, all intellectual

property rights resulting from the execution of the agreement –including the patent right, the design right and the copy right, shall belong to CFI. To the extent such right can only be obtained by a filing, only CFI is entitled to do so.

6.2 Unless expressly stated otherwise in the agreement, CFI has no obligation to implement an investigation to the existence of third party rights, as patent rights, trademark rights, design rights, copyrights or portrait rights or to implement an investigation to the possibility to develop such protection in favor of Client.

6.3 CFI is entitled to mention or to remove its name on or at goods.

6.4 All documents, such as reports, advice, agreements, designs, sketches, drawings, software and prototypes etc., provided by CFI, shall not be reproduced, made public, or brought to the notice of third parties by Client, unless the nature of the documents and goods dictates otherwise.

### **7. Fee and Price**

7.1 CFI and the Client can agree upon a fixed price or fee the moment the agreement is concluded.

7.2 If no fixed price or fee has been agreed upon, the price or fee for services of CFI shall be determined on the basis of the number of hours actually spent on the work, calculated in accordance with CFI's usual hourly rates unless a deviating hourly rate has been agreed upon.

7.3 The price or the fee and all other costs and expenses shall be exclusive VAT and other charges levied by the government.

### **8. Payment**

8.1 CFI is entitled to invoice on a monthly basis for work implemented and costs made in connection with the agreement.

8.2 Payment must be made within fourteen (14) days from the date of invoice by transfer to a bank account designated on the invoice.

8.3 Payments shall be made without discount or set-off excluding the settlement with pre-payments made to CFI in accordance with the agreement.

8.4 If after the elapse of the payment term CFI has not received the (full) payment, then Client shall be in default by operation of law. In that event, Client shall owe an interest equal to the Indian legal trade interest.

8.5 All costs and expenses incurred by CFI, as litigation costs and extrajudicial and judicial costs and expenses, including the costs for legal assistance, bailiff and debt-collection agencies shall be borne by the Client. The extrajudicial costs are deemed to be at least ten (10) % of the amount of the invoice.

8.6 Claims with respect to an invoice shall be submitted within eight (8) days after the date of the invoice. Thereafter the Client shall be deemed to have approved the invoice.

### **9. Non-Employment of Personnel**

9.1 Throughout the duration of the agreement and for one year following termination thereof, the Client shall not hire or employ in any other way, be it directly or indirectly, staff of CFI or of enterprises that CFI has engaged to execute the present agreement and who are or were involved in the execution of the agreement.

### **10. Retention of Title**

10.1 All goods delivered by CFI, possibly also including designs, sketches, drawings, films, software, (electronic) files, etc., shall remain CFI's property until Client has fulfilled all of his obligations under all agreements concluded with CFI.

10.2 Client shall not be authorized to pledge or encumber in any way the goods falling under the retention of title.

10.3 If third parties seize goods delivered subject to retention of title or wish to establish or assert a right to them, Client shall be held to inform CFI promptly thereof.

10.4 The Client shall undertake to insure the goods delivered subject to retention of title and to keep them insured against damage caused by fire, theft, explosion and water and make this insurance policy available for inspection on first demand.

10.5 Goods delivered by CFI falling under the retention of title by virtue of the present article, may only be sold on within the framework of normal business activities and must never be used as instrument of payment.

10.6 In the event that CFI wishes to exercise his ownership rights mentioned in the present article, Client shall give CFI or third parties to be appointed by CFI, now for then, unconditional and irrevocable permission to access all sites and locations where CFI's property might be found and to take these goods back.

#### **11. Guarantee**

11.1 CFI solely guarantees construction and functioning of the parts of the goods delivered. This guarantee is valid for a period of twelve (12) months from delivery, unless differently agreed in writing.

11.2 The guarantee is only applicable if the fault is not attributable to the Client. The guarantee is at the option of CFI limited to repairing by or on behalf of CFI or replacement of the relevant part or good.

11.3 The Client needs to send the goods which qualify for repair or replacement at his own risk and expense to the address designated by CFI. CFI is entitled to invoice Client for transport charges for sending repaired or replacing goods to him.

#### **12. Complaints**

12.1 The Client must notify CFI in writing of complaints about the work done within eight (8) days following their detection, but no later than within fourteen (14) days following completion of the work concerned.

12.2 If a complaint proves to be well-founded, CFI shall do the work as agreed upon, unless such has become demonstrably useless in the meantime to the Client and such has been notified by Client to CFI in writing.

#### **13. Liability**

13.1 CFI cannot be held liable for results which are not reached, because pursuant to the agreement it will only have an obligation to use best endeavors.

13.2 CFI shall never be liable for damages caused by loss of profit or lost savings and indirect and consequential damage.

13.3 If CFI is liable for direct damage, then said liability shall be limited to a maximum of the invoiced amounts. CFI's liability shall at all times be limited to a maximum equaling the amount of the payment to be made by CFI's professional liability insurer in the occurring event.

13.4 In the event of an assignment with a duration of more than 6 months, the liability shall, contrary to the stipulations under 3. of the present article, furthermore be limited to the part of the price or fee due for the last six months.

#### **14. Indemnification and Guarantee Client**

14.1 The Client shall indemnify and hold CFI harmless for claims of third parties with respect to the use of the results of the services of CFI and the use of the goods delivered.

14.2 The Client shall indemnify and hold CFI harmless against claims filed by third parties concerning intellectual property rights on material or data provided by the Client, which shall be used for and during the execution of the agreement.

14.3 If the Client provides CFI with information carriers, electronic files or software etc., the former shall guarantee that said information carriers, electronic files or software are free of viruses and defects.

#### **15. Force Majeure**

15.1 CFI and the Client shall not be held to fulfil any of their obligations if they are hindered to do so by force majeure.

15.2 In addition to the provisions of the law and the judge-made law in this respect, force majeure shall in the present general terms and conditions furthermore be understood to be any external circumstance, be it envisaged or not, on which CFI cannot have any influence but which prevents CFI from fulfilling his obligations. Strikes at CFI's company shall also be understood to be a circumstance of force majeure.

#### **16. Cancellation**

16.1 CFI and the Client shall be entitled to cancel the agreement at all

times.

16.2 If the agreement is terminated prematurely by Client, CFI shall be entitled to compensation of the loss of capacity utilization to be demonstrated caused by said premature termination and committed external costs, unless the termination is based on facts and circumstances which can be attributed to CFI. Client shall furthermore be held in that event to pay the invoices for the work done up till that moment and related costs and expenses.

16.3 If the agreement is terminated prematurely by CFI, it shall see to it in conjunction with Client that the work still to be done be transferred to third parties, unless the termination is based on facts and circumstances which can be attributed to Client. If the transfer of the work still to be done entails extra costs for CFI, said costs shall be charged to Client.

#### **17. Suspension and Dissolution**

17.1 CFI shall be authorized to suspend the fulfilment of the obligations under the agreement or to dissolve the agreement, in the event that :- Client does not fulfil or does not fully fulfil his obligations resulting from the agreement ; - After the agreement has been concluded, CFI learns of circumstances giving good ground to fear that the Client will not fulfil his obligations and the shortcoming justifies suspension or dissolution; - Other circumstances arise of such a nature that the unaltered maintenance of the agreement can no longer be demanded in all reasonableness.

17.2 If the agreement is dissolved, CFI's claims against the Client shall be forthwith due and payable.

17.3 CFI shall always retain the right to claim damages.

#### **18. Limitation of Action**

18.1 No action by Client shall be brought unless Client first provides written notice to CFI of any claim alleged to exist against CFI within thirty (30) days after the event complained of first becomes known to Client and an 18.2 action is commenced by Client within twelve (12) months after such notice.

#### **19. Applicable Law and Jurisdiction**

19.1 The laws of The India apply to this agreement excluding principles of conflict of laws. The applicability of the United Nations Convention on Contracts for the International Sale of Goods (CISG) is excluded.

19.2 The court in Raipur, Chhattisgarh, India have exclusive jurisdiction to hear actions. Nevertheless, CFI shall be entitled to submit the dispute to the court deemed competent by the law.

#### **20. Patient Data Regulation**

20.1 Patient data delivered by the Client. Privacy: all efforts are undertaken to guarantee privacy of the patient's information in the framework of the ISO 13485 quality system and other NEN which apply.

20.2 Personal information will be identified by assigning a unique case number.

20.3 By providing the patient data, Client confirms that the disclosure of any information is done in accordance with applicable privacy regulations and legislation and written acceptance of the patient for charging patients data with a third party.

#### **21. Support devices**

21.1 The supplied (electronic) devices are intended to support the design and validation process of CFI's products. Support devices will be delivered after the first patient-specific implant order, if necessary. The devices remain the property of CFI at all time. CFI reserves the right to recall these devices at any time. CFI cannot be held responsible for possible damage caused to or by these devices.