



smartbone[®] on demand[™]

Custom made graft for oral and maxillo-facial reconstructive surgery



 **swiss made**



smartbone® on demand™

Dear Doctor,
we sincerely thank you for your interest in our custom made graft. As you requested, here you can find detailed information about SmartBone® On Demand™ procedure.

What is SMARTBONE® ON DEMAND™?

SmartBone® On Demand™ is a service provided by Industrie Biomediche Insubri SA according to the 93/42/CEE Legislation regarding custom-made medical devices, and following three different ways, described in the next page.

HOW TO GET YOUR GRAFT?



Step 1

Take a CT Scan in DICOM format of the Patient concentrating on the defect. Please check on our website the guidelines.

Step 2

Send the CT Scan to IBI-SA with a brief clinical description.

IBI's trained Engineers will get in contact with you, discuss the plan and share with you the economical offer as well.

Step 3

You will receive a confirmation document that must be sent signed to IBI referring your unique case, in order to approve the project and let's start the production

IBI's trained Engineers, in conformity with your indications and suggestions, will design the graft until your approval.

Step 4

3 weeks later you will receive your graft ready for the surgical operation. No sterilization or extra shaping required.

Modes of supply

1 If you choose to send us the patient's DICOM file, together with his clinical prescription, IBI is able to plan the custom-made piece.

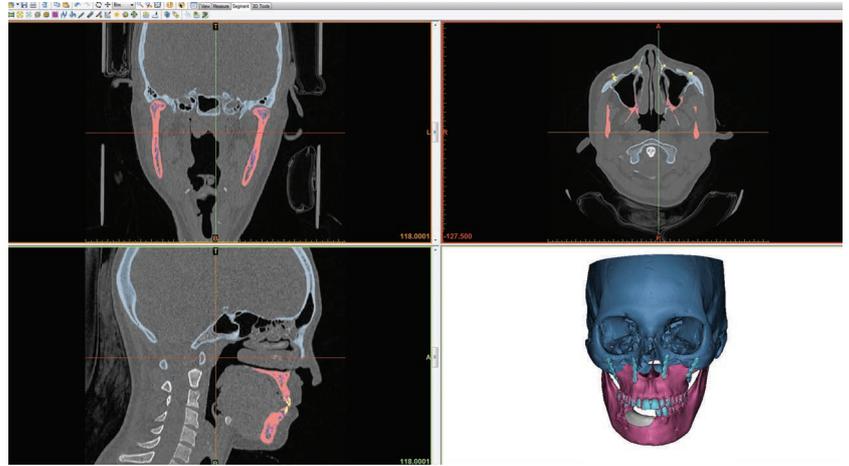


Figure 1 : Design Software

2 You can choose to send us the stereolithographic model directly, reproducing a plastic model of the missing piece of bone (usually the doctors rely on an external laboratory). IBI can use the stereolithographic model to reconstruct the custom-made piece, by previous HD scan.

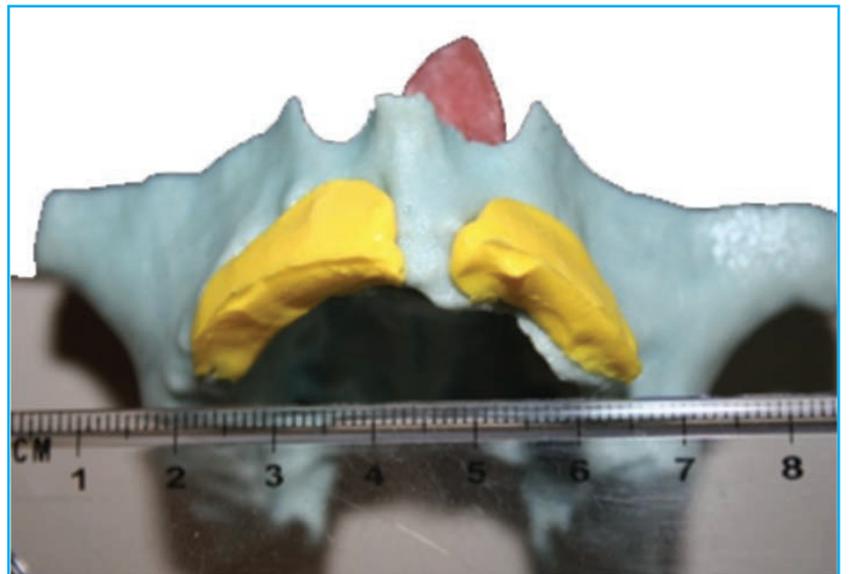


Figure 2 : Stereolithographic mode

3 If you send the design file (.STL), IBI can produce directly the piece, without additional costs.



Figure 3 : .STL model, output of the design software



Request

HOW TO ORDER A SMARTBONE® ON DEMAND™?

You need to send your request to carlo.grottoli@ibi-sa.com, adding patient's and doctor's name/ surname and a brief description of the clinical case. If the .STL file is not available, please send the DICOM file for our feasibility evaluation. In case of a positive evaluation, IBI's staff promptly generates a univocal identification code.

The formal request for custom made grafts **MUST** be signed, dated and on the doctor's letterhead; patient's name and clinical needs must be indicated. You can find the request form on [our website](#).

Request form on demand bone grafts
On the letterhead of the Customer

Industrie Biomediche Insubri SA – I.B.I. SA
Via Cantonale 67
CH-6805 Mezzovico-Vira
Svizzera

Place....., Date.....

Re: RFP for supply of on demand bone substitutes

Dear I.B.I. SA

We hereby request an offer for the supply of n. on demand bone substitutes (Custom Made Medical Devices, ex Directive 93/42/EEC and subsequent amendments), made with your technology, intended for grafting purposes as necessary in our clinical case no., patient Mr. / Mrs. for the use in, with geometric shapes as contained in the mathematical. .stl files attached (n. files attached), and under the personal responsibility of the undersigned requesting doctor who hereby confirms the accuracy and conformity of the geometric shapes and related mathematical files to the clinical needs of the case, confirming the final use of such medical devices.

We ask you to kindly confirm the technical feasibility and to provide a commercial offer with the supply conditions (technical information, payment methods and delivery time).

Best regards,

(The requesting doctor, (name and sign)
Dr.....

Attachments: n. stl files on CD identified with the clinical case number:



Order confirmation

After the technical approval, IBI will send a form that must be completed in its entirety and then signed in order to proceed with the production order.

Mezzovico, xx/xx/20xx

Re: offer For bone substitutes tailored For Case IBI-xxxx-xxxxx

Dear XXX,

Upon your request submitted On xx/xx/20xx, we hereby confirm that your order has been taken In charge by our company And was assigned the unique Case code BI-xxxx-xxxxx.

Please always refer To this code In any further communication With us regarding your clinical Case.

We have successfully verified the technical feasibility Of your request which can be accomplished using SmartBone, a bone substitute Of bovine origin, equipped With all the required certifications In accordance With the law For human use, shaped accordingly To the geometry Of the shape provided by you In the .stl files sent To us On xx/xx/20xx, which will be kept In our archives In accordance With the law.

The conditions For the service are the following:

- economic conditions, time Of delivery And payment, As In the attached offer n.;
- the responsibility Of the Requesting Doctor For the use Of On demand bone substitutes;

We remain at your disposal For any further information. Please use this document To confirm your acceptance, completing And signing the field below And returning this form To IBI.

Sincerely

FOR ACCEPTANCE OF:

- THE OFFER
- THE CONDITIONS REPORTED HEREIN
- AND FOR THE ASSUMPTION OF RESPONSIBILITY BY THE APPLICANT DOCTOR CONFIRMING:
- THE ACCURACY AND COMPLIANCE OF THE GEOMETRIC SHAPES AND THEIR MATHEMATICAL FILES TO THE REQUIREMENTS OF THE CASE,
- THE FINAL USE OF THE ON-DEMAND MEDICAL DEVICES SHAPED As REQUESTED BY ME ON xx/xx/20xx.

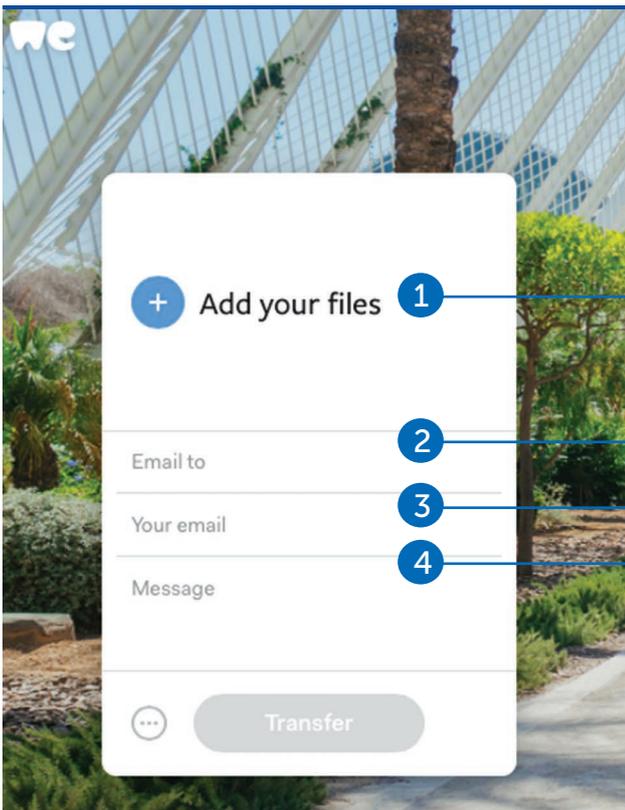
Place....., Date.....

The requesting Doctor,

Sending the DICOM file

HOW TO SEND US THE DICOM FILE?

You can send the DICOM files using an online file-transferring platform such as <https://wetransfer.com>



1 You can upload your file

2 just adding `carlo.grottoli@ibi-sa.com` as the receiver's email address

3 your email address

4 and a brief description of the type of intervention you need from us

6

As soon as we get the file, we make an offer on the basis of the estimated graft volume. Once you accept the offer, we get in touch within 72h to start the design project of the custom made graft together, that will end only once you approve it.

After completing the design project, we send the responsibility documentation, stating that the project itself accomplish your prescription. The documentation needs to be signed from you, then we confirm the order and the estimated shipment date.

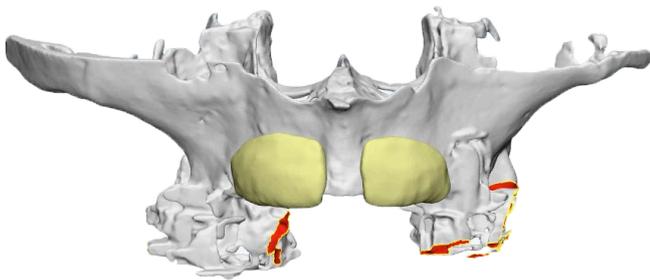
If it is easier for you, you can send the file on DVD together with your prescription to :

Industrie Biomediche Insubri SA – IBI SA
c/o Grottoli Carlo Francesco

Via Cantonale 67
CH-6805 Mezzovico
Switzerland

Clinical Cases design

Hereunder you can find some grafts of clinical cases designed with SmartBone® On Demand™.

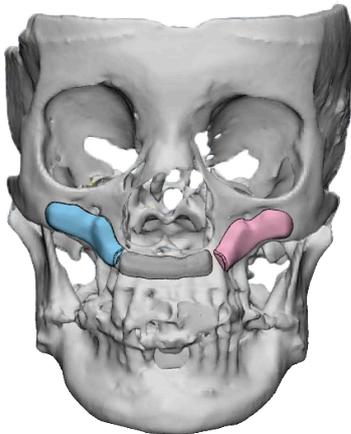


Vertical and horizontal maxillary augmentation

*Courtesy of Dr. R. Ghiretti,
Private Dentistry Practice, Mantova*

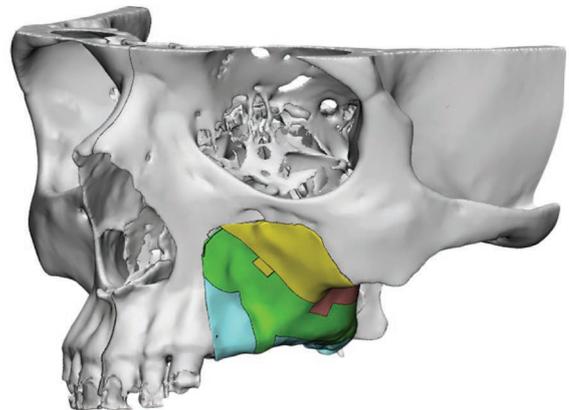


J-shape reconstruction for vertical and horizontal mandibular augmentation



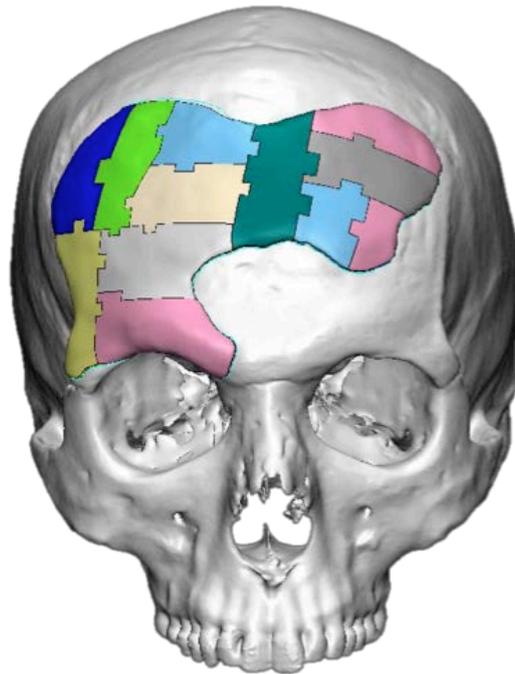
Zygomatic reconstruction with 3 grafts

*Courtesy of Prof. Dr. P. Cascone / Dr. V. Ramieri,
Policlinico Umberto I, Roma*



Zygomatic, crestal and hemipalatin reconstruction with 4 grafts

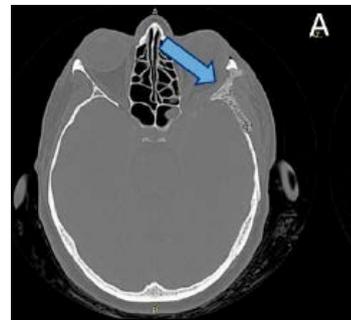
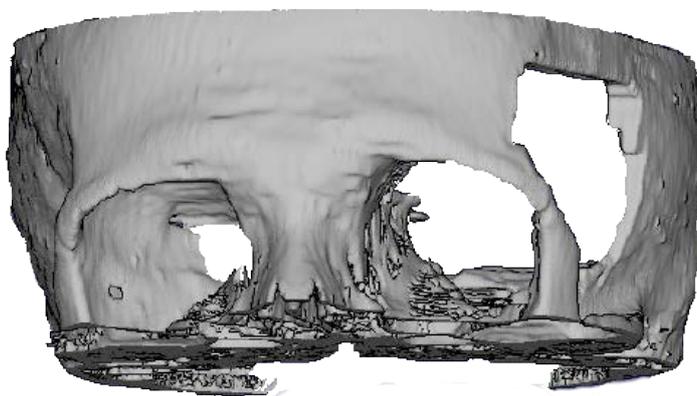
*Courtesy of Prof. Dr. M. Innocenti / Dr. M. Squadrelli,
Azienda Ospedaliera Universitaria, Firenze*



Aesthetic cranial reconstruction with 12 grafts

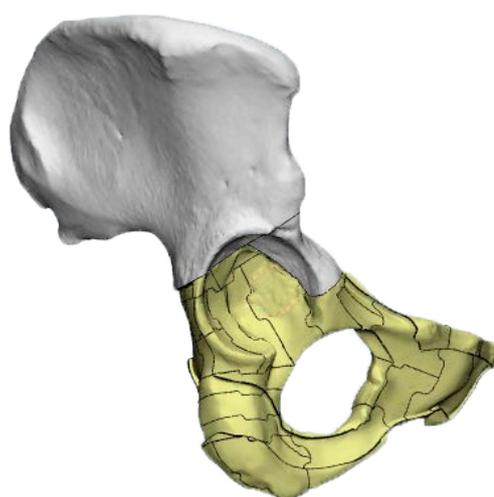
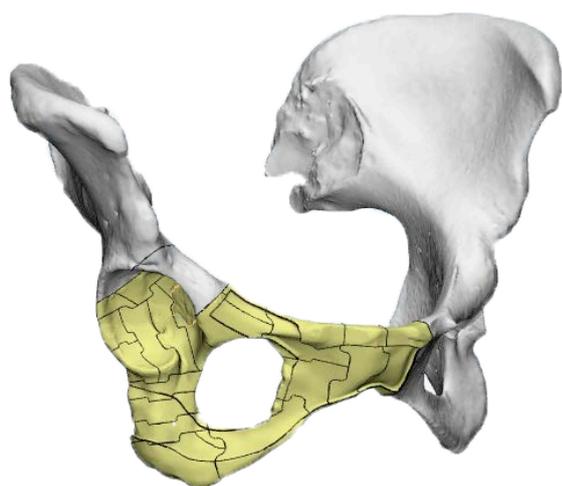
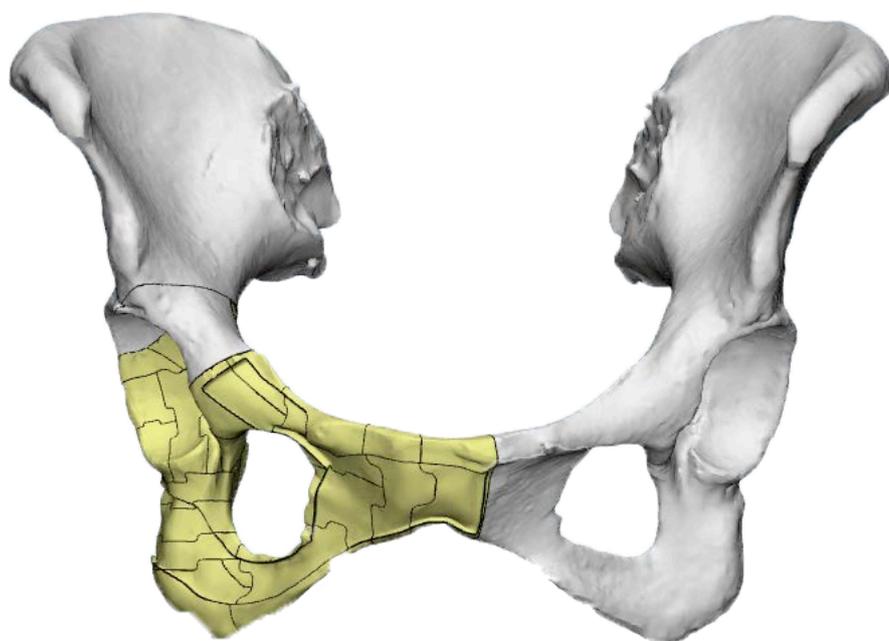
Courtesy of Dr. E. Facciuto,
Azienda Ospedaliera "A. CARDARELLI", Napoli

8



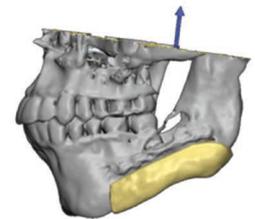
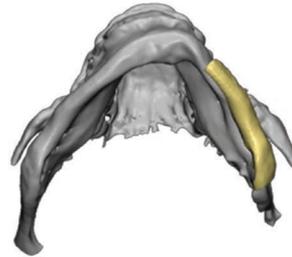
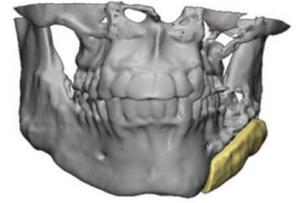
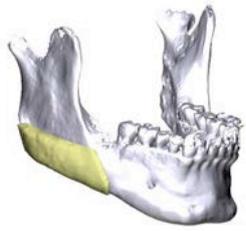
Cranio temporal reconstruction

Courtesy of Prof. Dr. L. Chiarini / Dr. A. Anesi,
Università degli Studi di Modena e Reggio Emilia, Modena



Oncological hip reconstruction with 21 grafts

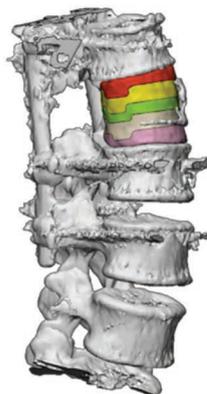
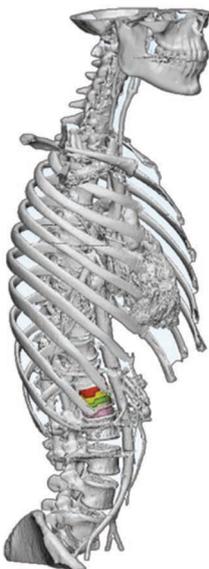
*Courtesy of Prof. Dr. R. Biagini / Dr. C. Zoccali,
Istituto Regina Elena, Roma*



Mandibular reconstruction

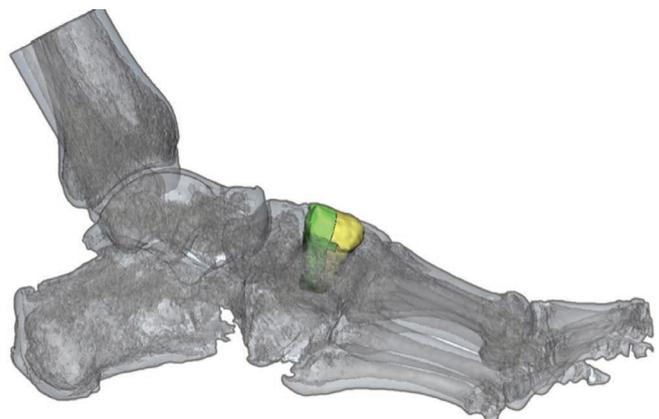
Courtesy of Prof. Dr. P. Cascone / Dr. V. Ramieri,
Policlinico Umberto I, Roma

10



Replacement with vertebral fusion T12/L1

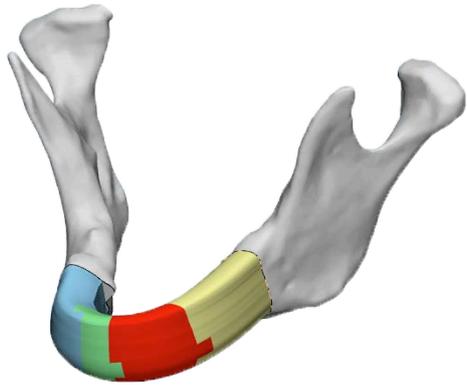
Courtesy of Prof. Dr. A. Gasbarrini,
Istituto Ortopedico Rizzoli, Bologna



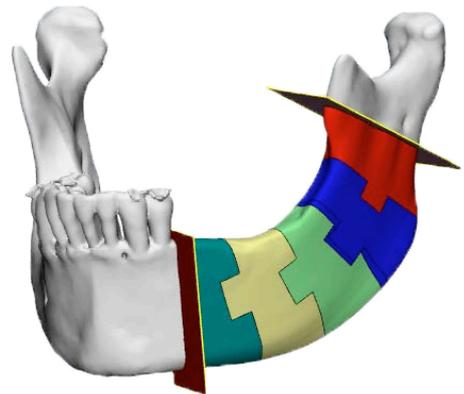
Reconstruction of the 3rd cuneiform of the foot

Courtesy of Prof. Dr. D. A. Campanacci,
Azienda ospedaliera universitaria, Firenze

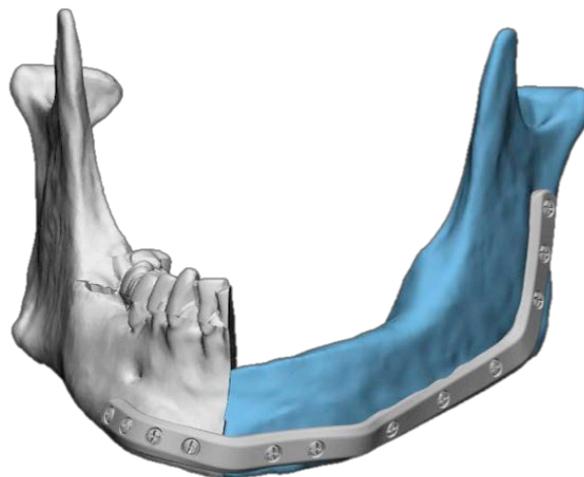
Design samples



Total mandibular reconstruction



Hemimandibular reconstruction





ibi SA
industrie
biomediche
insubri

**Industrie Biomediche
Insubri SA**

Via Cantonale, 67
Mezzovico-Vira
CH-6805
Switzerland
Ph. +41 91 93 06 640

www.ibi-sa.com

info@ibi-sa.com