

IMAGING REQUIREMENTS FOR CUSTOM MADE SERVICE

This document provides you some indications on how a CT/CBCT scan has to be taken and other important indications for the purpose of getting custom made medical device provided by Industrie Biomediche Insubri SA according to the Medical Device Directive 93/42/EEC.

GUIDELINES:

- Patient is at least 18 years old;
- Patient CBCT/CT scan is no older than 4 months;
- Prevent as many artefacts as possible in the surgical area in the resulting images;
- Movements of the patient while scanning must be strictly avoided;
- Scan all slices of the study in the same directions;
- Provide scan data (CT/CBCT) in DICOM* multislices format (i.e. 200 files .dcm) or provide STL file of the graft by email or the stereolithographic model of the graft needed by using tracked shipment;
- DICOM files can be sent in CD, DVD or USB memory by using tracked shipment. It is recommended to prefer web transmission platform;
- Do not send DICOM files inserted in proprietary software;
- It's important to attach the requesting form with a brief clinical description of the medical regenerative intention;
- Do not use web exchange platforms such as DropBox or GDrive;

*DICOM: Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems. DICOM files can be exchanged between two entities that are capable of receiving image and patient data in DICOM format.

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