CYBERBONE

GENERAL DESCRIPTION OF THE PRODUCT AND ITS OPERATION

Personalized implants designed on the basis of CT images and physician-operator guidelines and manufactured from biomaterials via FDM 3D printing using a bone-forming filament.

The product is "triple" personalized — (1) in terms of the shape being adapted to the bone defect of a given patient, with careful consideration of the degree of correction of the limb axis, (2) in terms of the internal structure of the print being adapted to the site of implantation and specific guidelines in osteodegeneration, (3) in terms of the composition of the bone-forming filament adapted to the bone structure of a given patient (the proportion of components and possible additives agreed upon with the doctor-operator).

Materials used:

Matrix — PLDLLA is a bioresorbable polymer and in a biological environment is hydrolyzed to lactic acid in the first phase. Lactic acid in the reactions of the so-called Krebs cycle (natural metabolic changes), breaks down into water and carbon dioxide, which are excreted from the body. That is, PLDLLA will undergo gradual biodegradation and metabolic absorption by the body.

Fillers — hydroxyapatite (a mineral composed of calcium hydroxyphosphate. It is a mineral scaffolding of connective tissue, responsible for the mechanical strength of bone), calcium triphosphate — (inorganic chemical compound, calcium salt of phosphoric acid, it is characterized by better solubility than hydroxyapatite. Included in ceramic biomaterials, resorbable), BCP — (biphasic calcium phosphate is a bone substitute that is a mixture of hydroxyapatite and β-tricalcium phosphate in fixed proportions. Studies have shown the osteoconductive potential of this composition).

PLDLLA, hydroxyapatite, BCP, and calcium triphosphate have approvals for medical use. No other material will be used.

The implant is vacuum-packed in a foil-foil or paper-foil packaging set protected by additional packaging in transport. Sterilization is performed via the free-electron beam radiation method in accordance with a validated method of such sterilization. This validation was obtained by Syntplant sp. z o.o. for such biomaterials (the sterility testing was conducted at Wroclaw Medical University).

Features of the implant solution:

1. Variable porosity of the implant (thanks to the 3D printing technology), which, during the procedure, allows for optimal indentation conditions, enabling osteoinductive and targeted biodegradation processes that will allow restoration close to the natural bone structure of a given patient.

2. Simple implant composition — a biodegradable and bioresorbable copolymer based on PLDLLA with long-standing medical approval (matrix) and hydroxyapatite (which on average accounts for 80% of the composition of human bone), calcium triphosphate, BCP (filler).

3. Biomimetics — achieving the optimal structure of the implant for bone tissue overgrowth, which will affect the process of osseointegration and achieve a balance between resorption of the polymer structure of the implant and restoration of the natural (or close to natural) bone structure. Moreover, implants with PLDLLA/HAp, TCP, or BCP have the ability to nucleate calcium phosphate from body fluids, which accelerates mineralization (calcification) of the newly formed bone.

4. Perfectly obtain a shape corresponding to the anatomy of the defect — necessary for further processing — thanks to the use of geometric reconstruction of bone outlines (3D printing) from the visualization of data from diagnostic imaging, i.e. computed tomography (CT) and magnetic resonance imaging (MRI). In addition to the main aesthetic effect, this will also result in the absence of the need to pre-fit the implant (before and/or during surgery) and will have a beneficial effect of shortening the duration of the surgical procedure, lowering the number of complications related to, among others, the presence of bacterial endotoxins (preoperative fitting) or infections (intraoperative fitting).

5. Development of a bone defect model — modeling of objects with forms that do not contain any standard geometric elements (i.e., plane, analytical surface lobe, sphere, cylinder, cone, etc.) will be carried out using contemporary surface modeling systems.

6. The speed of obtaining the final product due to the use of "fast prototyping" technology — haptic modeling speeds up obtaining the model compared to other methods. The use of this type of modeling will allow to obtain synergistic effects of increased capabilities, as well as quality and efficiency of the modeling process. The haptic-prepared model is sent to a 3D printer, which produces the product.