cyberbone

Instructions for using personalized implants

PRODUCT DESCRIPTION

The medical device - CYBERBONE - is an individualized product, precisely tailored to the anatomical structures of a particular patient. The medical device is bioresorbable, bone-forming and non-toxic to the body.
Customized - the geometric form of the implant is precisely adapted to the anatomical structure of the patient's defect.
Bioresorbable - degrades into basic chemical compounds that are inert to the human body, and then after a certain period of time is expelled.
Bone-forming - the patient's defect is replaced with new, natural bone, mimicking the shape of the implant.
In addition, it reduces a risk of inflammation at the implant site.

The medical device CYBERBONE is a composite material that consists of polylactide (PLDLLA) and a filler in the form of hydroxyaptatite (HAp). The PLDLLA has a masterfile of the US FDA confirming its medical usability. Hydroxyapatite, on the other hand, is a natural component of human bones.

The types and ratios between polymer matrix and the filler in the implant are selected according to the needs of the patient, i.e. it exhibits characteristics of high biocompatibility and resorbs within a certain time while initiating bone reconstruction. This solution allows to adjust the time of material decomposition individually for each case. Each time at the design stage, the forces acting on the implant and its location are also analyzed in the body, so as to ensure optimal mechanical properties of the device during usage.

The geometric form of the implant is matched to the patient's anatomical structures, its functionality, the doctor's guidelines and the method of implantation. A virtual model of the patient's bone loss is constructed (in specialized software) based on medical imaging studies such as computed tomography and/or magnetic resonance imaging.
Functionality and the defect location affect the geometric form of the implant due to the forces and loads it will have to bear. Functionality is understood as the reconstruction of anatomical structures to restore proper body function and/or aesthetic improvement.
The method and location of implant fixation each time are consulted with the physician in charge of the case. In addition, it is advisable to ensure the presence of an engineer during the surgery/procedure, who can consult on an ongoing basis on the method of implant fixation (taking into account e.g., the forces acting on it at different periods of implant life).
Obtaining personalized anatomical geometric forms each time is possible thanks to additive manufacturing - 3D

printing, using FDM (fused deposition modelling) technology. The implants are printed in a specialized laminar chamber ensuring ISO class 3 purity. The implants are additionally subjected to radiation sterilization (safe for this type of material). The product delivered to the customer is always properly protected in a packaging system, which consists of a double sterile barrier system (paper / foil bags) and protective packaging (cardboard box).

The product is intended for the exclusive use of qualified healthcare professionals/professional users.

INDICATIONS FOR USE

CYBERBONE medical device is intended for filling bone defects resulting from trauma, resorption or removal of degenerative tissues, in orthopedics, traumatology, neurosurgery, maxillofacial surgery, etc. This solution allows to repair the defect/damage to the anatomical structure of the patient's tissue and restore the anatomically correct bone structure with parallel resorption of the implant. The products fully reflect the anatomical shape of the sites indicated for regeneration and are adapted to the needs of reconstruction of bone defects.

CONTRAINDICATIONS TO USE

- Infection.
- Patients with mental or neurological disorders who refuse or are incapable of adhering to postoperative recovery behavioral recommendations.
- The patient's condition including: blood supply restrictions, insufficient quantity or quality of operated bone, or hidden infection.
- Pathological tissue changes that prevent the use of implants for reunion of the operated bone.

HANDLING OF THE PRODUCT

Store under refrigerated conditions +4° C. Short-term storage at a maximum temperature of +30° C is permissible, e.g. for the time of transport or before surgery in the operating room. Protect from direct light and moisture. Handle the implant gently and carefully, so that it does not undergo mechanical damage.

It is essential to verify the device's identification data before implantation.

The bone defect before implantation should be properly prepared, according to the principles accepted in bone surgery and the arrangements made at the design stage. During the preoperative and intraoperative phases, the implant should be handled with the implant with great care, avoiding any activity that could damage or contaminate the device. It is essential to ensure that the implant remains in direct contact with the patient's bone.

The implants are designed for the specific patient in accordance with the indications of the attending physician, so the geometry of the device should not be changed in any way. Any modifications to be carried on the implant can be made only in consultation with Syntplant Sp. z o.o. designers. Any independent action will be performed under the sole responsibility of the attending physician.

The implant should be fixed in the manner established at the design stage. Any necessary modifications should always be consulted with Syntplant Ltd. designers.

PRECAUTIONS

Cyberbone is a sterile device if the packaging has not been opened or damaged. The packaging along with with the device has been radiation sterilized.

Before use, check that the immediate packaging is not damaged. If you notice damage to the packaging, **the product is not suitable for use.**
The double sterile barrier system (paper / foil bags) with the device should be opened immediately before the procedure in accordance with aseptic principles.

The expiration date is indicated on the outer packaging and direct packaging of the product. Do not use after the expiration date.
Single-use product. Leftover unused material is not reusable. They must be disposed, in accordance as recommended by local regulations. Do not re-sterilize.

Due to the unique design of the device - shape and material - the implant may have sharp edges. Care should be taken to avoid cuts.
Keep in mind that the device is relatively fragile and during implantation it can be damaged by applying too much force.

It is strictly forbidden, to clean the device. If the above situation occurs, the intended function of the implant may be disrupted.

REQUIRED MEDICAL INSTRUMENTATION

Standard equipment and sterile surgical instruments may be used for CYBERBONE implantation.

POSSIBLE SIDE EFFECTS

Side effects that may occur in connection with with the use of this product or any surgical procedure include infection, excessive bleeding in the surgical field, destruction of the device during implantation. Wound infection can cause the procedure to fail. The surgical procedure can cause neurovascular damage.
Inadequate anastomosis of large bone defects can result in the destruction of the implant before the bone healing process is complete.
Implantation of foreign material can cause limited local inflammation, fading progressively as resorption progresses.

Professional medical personnel should report any suspected adverse reactions related to the use of personalized CYBERBONE implants manufactured by Syntplant sp. z o.o. (custom medical device) in accordance with the rules for reporting adverse reactions through the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, 181 C Jerozolimskie Avenue, 02-222 Warsaw, tel: ndl@urpl.gov.pl.
The adverse reaction report form is available at: www.urpl.gov.pl or directly from Syntplant Ltd.

POST-OPERATIVE MEASURES

Clinical follow-up every 7 days for the first four weeks after surgery is recommended, as well as a medical imaging study (CT scan or MRI) at 3, 6 and 12 months.

CAUTIONS

The indications and warnings given to the patient by the attending physician in the post-operative period are extremely important. Thus, the patient should be advised to avoid direct trauma to the area of the implant after the procedure, and that the effectiveness of the procedure may be reduced by abuse of alcohol, drugs or in patients suffering from mental illness.
It is also important to remember that:

- The implant may resorb prematurely if there is inadequate or delayed healing of the defect due to improper bone anastomosis.
- The quality of the patient's bone can affect the healing process and should be assessed during surgery. Healing may be slower in the case of osteoporotic bone.
- Exercising appropriate post-operative care for the duration of cavity healing is part of the medical procedure.
- Do not use simultaneously other bioresorbable implants manufactured by other manufacturers, whose resorption times may differ from each other.

Failure to follow the above recommendations may lead to failure of the procedure or other complications.

Expiration date: The expiration date is indicated on the outer and immediate packaging of the product.

Do not use after the expiration date.

CE MARKING

CE marking is not required for custom-made medical devices referred to in Article 20 of Regulation (EU) 2017/745.

SYMBOLS USED

	Manufacturer/developer
	Production date
	Use before
	Do not reuse
	Do not use if the packaging has been damaged
	Do not re-sterilize
	Check in the instructions for use or check in the electronic instructions for use
	Sterilized by radiation
	Plasma sterilized
	Storage temperature range
	Store in a dry place
	Protect from sunlight
	Medical device
	Patient information website
	Serial number

MANUFACTURER'S DATA

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The instruction is effective as of 26.05.2023.