Implantize *hybrid*

Custom-made titanium maxilofacial implant

Implantize *hybrid* is a custom-made medical device, manufactured specifically under medical prescription and under the responsibility of the prescriber, with specific design features intended exclusively for use in a particular patient. Implantize *hybrid* medical device should only be used by a qualified clinician with in-depth knowledge of the specific surgical techniques of oral surgery procedures. Before using a BoneEasy (Resdevmed Lda.) branded product, the responsible surgeon/physician should carefully review all information provided by the manufacturer, including indications, contraindications, warnings, instructions and other relevant information. Detailed instructions other than those contained herein may be obtained by contacting the manufacturer or its representative.

Implantize *hybrid* should be used at the discretion of the clinician, who has an obligation to determine if the product is appropriate for the patient and to evaluate all relevant circumstances. The clinician is responsible for any direct, indirect complications or detrimental situations that may result from erroneous indication or surgical technique, misuse of material, overload, lack of asepsis, or failure to follow explicit safety instructions in the instructions for use. The manufacturer or representative of Resdevmed Lda. cannot be held responsible for complications associated with use by the physician as described above or to the patient, including the patient's anatomy and general habits. Resdevmed Lda. disclaims any liability, express or implied. It is also the surgeon/doctor's responsibility to adequately inform the patient about the necessary function and care, as well as the known risks associated with the product.

Description

Implantize *hybrid* is a custom-made grade 5 titanium maxilofacial implant (Ti6Al4V). It is developed based on files from computed tomography, using computer aided design and segmentation software, and manufactured by laser sintering (SLM Selective Laser Melting).

The medical device should be stabilized with fixation screws and with bone retentions in non-atrophic regions. The necessary screws are provided with the medical device as well as case-specific anatomical models.

Indications

Implantize *hybrid* is a long-term implantable medical device for use in dental rehabilitation procedures where endosseous implants are not advised.

Contraindications

Implantize *hybrid* should only be used if the cortical bone volume allows implant stabilization. Poor bone quality, difficulty in anchoring screws, systemic diseases (diabetes, etc.), reduced immunity, alcoholism, smoking, drug dependence and psychological instability may all contribute to the lack of integration and/or subsequent implant failure. Misuse of the implant or improper fixation can lead to screw relaxation, fractures and/or implant failure. Radiation exposure and chemotherapy may affect implant functionality.

Warnings

Inadequate surgical techniques can result in bone loss, patient damage, pain, and partial or complete medical device failure.

Implantize *hybrid* should not be used in conjunction with standard screws. Provided screws must be used for implant fixation, as planning has been done based on these.

When using Implantize *hybrid* with any type of bone substitute, all indications given for each material should be considered.

Steroid or anticoagulant treatments may affect the surgical site and impact the patient's ability to integrate the medical device.

Long-term exposure or use of bisphosphonate-based drugs, especially with chemotherapy, may have a negative impact on implant functionality. A detailed study of the patient's history, including consultation with the attending physician, is recommended before opting for any solution offered by Resdevmed Lda.

Mobility, bone loss or infection may be indications of implant failure. The decision on the best course of action should be carefully evaluated by the doctor.

Due to the conductivity of the metal, electrosurgery can result in tissue damage, patient injury, and implant failure and should be used with caution.

See also Contraindications.

Precautions

Proper case planning is crucial for the long-term success of the medical device.

During surgery aseptic rules must be respected. Direct handling of the medical device should be avoided.

Implantize *hybrid* can be used in load situations. However, micro-movements must be avoided as they lead to bone resorption, so effective fixation is essential.

Implantize *hybrid* is a custom-made medical device for a particular patient, so it should not be used on a patient other than the one for which it is manufactured.

Implantize *hybrid* was developed for single use only. It must not be reused, reprocessed or resterilized. Failure to follow these instructions can compromise the structural integrity of the device and/or lead to device failure, with consequent patient damage.

The clinical situation of the patient should be carefully monitored.

Do not use the medical device if its original packaging is open, damaged or showing signs of deterioration.

See also Contraindications.

Recommendations

An oral hygiene plan should be prescribed by the clinician, which may include mechanical and chemical control of plaque and instructions for brushing and flossing.

Antibiotic therapy is recommended at the discretion of the clinician.

During the first week, at least one visit is recommended for patient monitoring and prophylaxis.

X-rays may be taken after surgery to assess tissue and medical device status, unless complications from implantation require early screening.

Medical device removal should be considered in case of exposure, complications that cannot be controlled by standard postoperative treatments, tissue inflammation or evidence of infection, but always at the discretion of the clinician.

Possible adverse effects

Complications that may occur from the use of this medical device include (but are not limited to): pain, discomfort, edema, bruising, inflammation, thermal sensitivity, infection, exfoliation, perforation or abscess formation, hyperplasia, gingival irregularities, complications associated with anesthesia, mechanical implant failure or exposure. Other adverse effects may also occur as a result of iatrogenic factors or patient response.

Implant removal should be considered whenever the location of the implant shows signs of impairment, which cannot be controlled by postoperative treatment.

Report to the manufacturer any adverse events recorded and not shown in this document.

Technical information

Implantize *hybrid* is an implantable medical device that requires proper planning.

The following considerations are proposed by Resdevmed Lda. However, it is important to remember that the implantation of Implantize *hybrid* should only be performed by qualified clinicians, with thorough knowledge and mastery of the specific surgical techniques for oral implantation procedures.

For Implantize *hybrid* placement during surgery:

1.Keep the sterile field throughout the procedure.

2.Minimize saliva or any other source of contamination of material and surgical site.

3.After exposure of the jawbone, the bone should be cut if necessary.

4.Adapt and secure the supplied surgical guide.

5. Make bone preparations for Implantize hybrid.

6.Test implant adaptation.

7.After validation of the previous steps, the implant should be fixed with the provided fixation screws.

8.In case of loss of screw stability, the retaining screws should be replaced with the emergency screws also provided with the implant.

Note: In case of damage to the screws or bone where the screw is to be fixed, and being an important fixation point for implant success, a device may be designed by BoneEasy to stabilize the implant at new fixation points in a future intervention.

Sterilization

Implantize *hybrid* is sterilized by ethylene oxide. The packaging will serve as a sterilization barrier until the expiration date indicated on the box. This medical device is designed for single use only and should not be resterilized.

Single use

Implantize hybrid should not be reused. Reuse of a single use medical device that has been in contact with blood, bone, tissues, body fluids or other contaminants may lead to damage to the user. Possible risks associated with reusing a single use device include, but are not limited to, mechanical failure and transmission of infectious agents. Implantize *hybrid* is a custom-made medical device for a particular patient, so it should not be used on a patient other than the one on which it is manufactured.

Packaging

Implantize hybrid has been cleaned and packaged in a controlled environment. It is supplied in multiple packaging. The outer label contains information about the batch number that should be recorded on the patient's clinical record to ensure complete traceability of the product. The manufacturer also makes extra labels available on the packaging which can be placed on the medical record for the same purpose. One of the extra labels provided must be given to the patient.

Storage

Implantize *hybrid* should be stored at room temperature and protected from external damage.

Disposal, in the case of post-surgical removal, must follow rules for disposal of contaminants with blood.

Disposal of produced parts, without contact with biological contamination, must follow titanium disposal rules.

Patient Information

It is the surgeon/physician's responsibility to adequately inform the patient of the necessary function and care as well as the known risks associated with the product.

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Information on symbology used:

	Batch code
	Use by
	Do not reuse
	Manufacturer
	Sterilized using ethilene oxide
	Date of Manufacture
	Caution
	Do not resterilize
	Do not use if package is damaged
	The law restricts the sale of this device to a doctor or under his demand