ZIMMER BIOMET
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Titanium AccuraMesh ™
Custom-made **Titanium** implant for guided bone regeneration

Titanium AccuraMesh is a custom-made medical device, manufactured specifically under medical prescription and under the responsibility of the prescriber, with specific design features intended for use exclusively in a particular patient. **Titanium AccuraMesh** should only be used by a qualified clinician with thorough knowledge and mastery of the specific surgical techniques of guided bone regeneration procedures. Before using a Zimmer Biomet branded product, the responsible surgeon/physician should carefully review all information provided by the manufacturer, including indications, contraindications, warnings, instructions for use and other relevant information. Detailed instructions other than those contained herein may be obtained by contacting the manufacturer or its representative.
Titanium AccuraMesh should be used at the discretion of the clinician, who has an obligation to determine if the product is suitable for the patient and to evaluate all relevant circumstances. The clinician is responsible for any direct and/or 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 Zimmer Biomet 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. Zimmer Biomet disclaims any liability, express or implied. It is also the surgeon/doctor's responsibility to adequately inform the patient about the function and necessary care, as well as the known risks associated with the product.

1 | Description
Titanium AccuraMesh is a custom-made barrier mesh made of medical grade material. It is developed based on files from computed tomography, using computer aided design and segmentation software, and manufactured by 3D-printing techniques.
Titanium AccuraMesh must be stabilized with screws (not included with this device).

2 | Indications
Titanium AccuraMesh is a long-term implantable medical device suitable for guided bone regeneration surgical procedures.

3 | Contraindications
The clinician should be careful in selecting the patients indicated for guided bone regeneration procedures, in selecting the most appropriate postoperative treatments and should also be critical during the **Titanium AccuraMesh** design process. **Titanium AccuraMesh** is not designed to handle high loads. For this reason the load on the individualized mesh should be minimized, with removable prosthesis resting on the tissues that cover it to avoid its collapse and not to compromise the healing process. **Titanium AccuraMesh** can be designed with pillars for provisionalization, for aesthetic use only and not for loading. This medical device was not designed for joints (e.g., mandibular temporal joint reconstruction). The long-term effectiveness and safety of combining **Titanium AccuraMesh** with bone substitutes is not yet established, so when performed in combination, the clinician should follow individual material bone substitutes indications.
The following should not be subjected to bone regeneration **Titanium AccuraMesh** procedures: patients with poor oral health, deficient oral hygiene, or who have previously undergone organ transplants, patients with cardiovascular disease, hypertension, thyroid or parathyroid disease, malignant tumors detected within 5 years prior to intervention or nodular augmentation.
The following psychophysiology problems may increase the risks of the procedure: cardiovascular failure, coronary disorders, arrhythmia, chronic pulmonary or respiratory diseases, gastrointestinal disorders, hepatitis, intestinal inflammation, chronic renal failure and urinary system disorders, endocrine disorders, haematological problems, anemia, leukemia, clotting problems, osteoporosis or musculoskeletal arthritis, stroke, neurological disorders, mental retardation or paralysis. Chemotherapy reduces or nullifies bone regeneration capacity, so patients undergoing such treatments should be carefully evaluated prior to intervention.
In case of bisphosphonate administration (especially orally and intravenously), cases of osteonecrosis have been reported in oral surgeries. The presence of periodontal disease may lead to diffuse infections at the treated site level, and patients with periodontal syndromes must be previously treated and recovered. Contraindications also include:Chronic subacute maxillary osteitis, systemic diseases, endocrine disorders, pregnancy, lactation, renal failure, fibrous dysplasia, hemophilia, neutropenia, steroid use and diabetic disease. Patients with over-sensitivity to materials and foreign-body reaction (Pre implantation tests must be carried out even if such over-sensitivity or reaction are suspected). General contraindications common to all oral surgery interventions should also be considered.
It is the clinician responsibility to evaluate the risk-benefit for the surgery performance, accordingly with patient clinical records.

4 | Warnings
Inadequate surgical techniques can result in bone loss, harm to the patient, pain, and partial or complete medical device failure.
Steroid or anticoagulant treatments may affect the surgical site and impact the patient's ability to integrate.
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 use of any solution available at Zimmer Biomet. The clinical condition of all patients should be continuously monitored and, if necessary, the medical device removed.
Titanium AccuraMesh should not be used in conjunction with unstable endosseous implants.
When combining **Titanium AccuraMesh** with any type of bone defect replacement bone substitutes, all indications for each material should be considered individually.
Electrosurgery must be used with caution in the presence of metallic items, such as metal implants or screws.
See also Contraindications.

5 | 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.
Titanium AccuraMesh should not be used under load situations.
Titanium AccuraMesh is a custom-made medical device for a particular patient, so it should not be used on a patient other than the one for whom it is manufactured.
Titanium AccuraMesh is designed for single use only. It must not be reused, reprocessed or re-sterilized. 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.
See also Contraindications.

6 | 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 post surgery, 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.

7 | 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 failure of the medical device or exposure. Other adverse effects may also occur as a result of iatrogenic factors or patient response.
Removal of the mesh should be considered whenever the site where it is placed shows signs of compromise in such a way that it cannot be controlled by postoperative treatments.
Report to the manufacturer and/or the responsible authorities of any adverse events recorded and not shown in this document.

8 | Technical information
Titanium AccuraMesh is an implantable medical device that requires proper planning.
The following considerations are proposed by Zimmer Biomet. However, it is important to remember that **Titanium AccuraMesh** implantation should only be performed by qualified clinicians, with thorough knowledge of the specific surgical techniques of guided bone regeneration procedures.
For **Titanium AccuraMesh** placement during surgery:
1.Keep the sterile field throughout the procedure.
2.Minimize saliva or any other source of contamination to material and surgical site.
3.Gently open the outer blister and remove the inner blister containing the sterile **Titanium AccuraMesh** into the sterile field. Carefully remove the medical device from the internal blister.
4.Place the medical device in the area to be treated.
5.The stability of the medical device is ensured by fixing with suitable screws.
6. To aid in the regenerative process, the medical device should be combined with bone substitutes and covered with a resorbable membrane, if applicable.
Removal of the medical device is the clinician's discretion: depending on the type of application, different time windows may be recommended for removal of implanted materials: four to nine months or until bone regeneration is complete to place the implants; four to twelve weeks for transgingival healing.

9 | Sterilization
Titanium AccuraMesh 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 re-sterilized.

10 | Single use
Titanium AccuraMesh 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. Titanium AccuraMesh is a custom-made medical device for a particular patient, so it should not be used on a patient other than the one on for which it is manufactured.

11 | Packaging
Titanium AccuraMesh has been cleaned and packed 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 provides extra labels, available on the package, which can be placed on the medical record for the same purpose. One of the extra labels provided must be given to the patient.
Do not use the medical device if its original packaging is open, damaged or showing signs of deterioration.

12 | Storage
Titanium AccuraMesh 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 raw material disposal rules.

13 | 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 medical device.

Manufacturer:
Resdevmed Lda.
Travessa do Navega, 436 C, Arada, 3885-183, Ovar, Portugal
Contact: (351) 256782047
www.boneeasy.com

Distributed by:
Biomet 3i Dental Iberica, S.L.U.
C/ Tirso de Molina, 40
WTC Almeda Park - Edificio 4, planta 2
08940 Cornellá de Llobregat
Barcelona, Spain

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Information on symbology used:

	Batch code
	Use by
	Do not reuse
	Manufacturer
	Sterilized using ethylene oxide
	Date of Manufacture
	Caution
	Do not re-sterilize
	Do not use if package is damaged
	Product code
	Medical device
	Distributor
	Consult instructions for use