English

DENTALSTUDIO

GBR Pin

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EC REP

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CE	● CE conformity marking		
	● Date of manufacture	LOT	● Batch code
NON STERILE	● Non-sterile		● Manufacturer
	● Single use		
	● Caution, consult accompanying documents		
Rx Only	● Federal law(USA) restricts this device to sale by or on the order of a licensed dentist		
	● Consult instructions for use		
EC REP	● Authorised representative in the european community		

IFU-DSE-GBT35-R00/ 2023-04-13

[Product name] GBR Pin
[Model name] GBT-35
[Weight or packaging unit] Own packaging unit
This product is a disposable medical device, so reuse is prohibited.

Purpose of use

Screws that are temporarily implanted in the alveolar bone to fix the periodontal tissue regeneration induction material.

Instruction for Use & Procedure

A. Preparations before use

1. Product inspection and precautions before use
   ① Check the packaging status of the product. Since the package is sealed, it cannot be used if the seal is torn, and it cannot be used if it is covered with foreign materials that interfere with use, such as impurities and foreign materials, or is opened.
   ② Select and prepare a model with specifications suitable for the surgical site and purpose.
   ③ Surgical techniques for implantation of this product require special and complex procedures. Formal training for product implantation is recommended.
   ④ After determining the suitability of the location to transplant this product and where to operate locally, it is necessary to establish a treatment plan through appropriate radiographic measurement before using the product, and to establish a treatment plan through visual inspection of the place to transplant the product.
   ⑤ The operator must be familiar with the surgical method, clinical indications, precautions, etc. using the surgical instruments of this product.
   ⑥ Confirm that there are no factors that may hinder the surgical result.
   ⑦ Since it is a non-sterilized product, sterilize it at 132℃ for 15 minutes with moist heat before use. After sterilization, dry for 30 minutes.

   When sterilizing, pay attention to the following points.
   · When sterilizing, follow the sterilization method and usage method of the facility manufacturer.
   · When sterilizing and drying, place the products so that they do not come into contact with each other, and use sterile cloth.

B. Establishment of patient's treatment plan

1. Medical evaluation
   ① Investigation of appropriate medical history
   ② Dentist re-examines the contents of the patient's investigation
   ③ Physical evaluation and therapeutic evaluation
   ④ If necessary, medical advice or clinical pathology examination

2. Establishment of radiological plan Establishment of periapical scan, occlusal image, panoramic image, cephalometric image, conventional tomography, CT scan, MRI scan, etc.

C. How to use

1. Placement procedure
   ① Considering the patient's oral condition, select a periodontal tissue regeneration guide material and a periodontal tissue regeneration guide material fixing screw (GBR Pin) of an appropriate size.
   ② Put the periodontal tissue regeneration inducing material to be used on the implantation site.
   ③ Fix the periodontal tissue regeneration guide material by fixing the periodontal tissue regeneration guide material fixing screw to the holder and then malleting (hit the rear part of the holder's handle in a vertical direction) to place the pin insertion part into the alveolar bone.
   ④ After the fixation of the periodontal tissue regeneration inducing material is completed, the treatment area is sutured according to the general suture procedure.

2. Removal procedure
   ① After treatment is completed, prepare a remover, an instrument for removing screws for fixing periodontal tissue regeneration induction materials.
   ② Push the remover into the head shoulder part of the inserted screw for fixing the periodontal tissue regeneration induction material and lift it in a lever manner in the opposite direction of the implantation direction to remove the screw for fixing the periodontal tissue regeneration induction material.
   ③ After removal, suture according to the usual suture procedure.

D. How to store and manage after use

This product is a disposable medical device, so reuse is prohibited.

Precautions for use

A. Caution

1. This product shall not be used for any purpose other than use.
2. This product should be used only by those who have been trained or have sufficient experience in related procedures such as periodontal tissue regeneration induction.
3. Surgical instruments used for the procedure of this product must be used after sterilization.
4. Be careful not to apply excessive force to the product.

B. Contraindications

1. Infection
2. If you have a disease that can affect bone or wound recovery
3. Patients who are mentally and physically difficult to treat after surgery
4. Hypersensitivity to titanium materials
5. Poor oral hygiene
6. Smoking
7. Substance abuse
8. Patients who need special attention compared to other patients such as infants, children, the elderly, pregnant women, lactating women, and childbearing women

C. Side effects

1. Damage to implant due to improper fixation
2. Implant migration and loosening
3. Common allergic reactions due to metal intolerance or foreign body implants

D. Warnings

1. Do not reuse implants or used screws.
2. Metal screws or other devices of heterogeneous material shall not be used together in or near the implantation site.
3. The surgical instrument should be used as a standard product and fit snugly, and should not be used excessively.
4. It should never be used except for experienced doctors and authorized persons, and it should only be used once during the procedure, and reuse in any form is prohibited.
5. This product is a non-sterile product, so it must be sterilized before use.
6. The safety and suitability of the GBR Pin in the magnetic resonance (MR) environment has not been evaluated. No tests were performed on fever, migration, and imaging defects in the magnetic resonance environment. Therefore, the safety of the GBR pin in a magnetic resonance environment is not known.
   In case of scanning a patient with this medical device inserted, the patient may be injured.

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