Made for GDT Implants
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GBR Bone Screw & Titanium Mesh Membrane

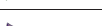
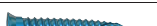
Bone Fixation System

INSTRUCTIONS FOR USE

DESCRIPTION:

1. GBR System is comprised of bone screws and plates that are used for bone fixation surgery. The bone screws and plates are not reusable. The bone screws are composed of the titanium alloy (ASTM F136) the bone plates are composed of titanium (ASTM F67 Grade1). The screws are offered in the following range; diameter (1.4, 1.6, 2.0 mm) and length (3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0 mm). Also the tip of screw has single type; the self-drilling and self-tapping available type and the type that require the pre-drilling (Surgeon's option). The bone plate is offered in 0.1 mm thickness and in length 22x15 mm, 36x22 mm and 44x44 mm. The each device is provided non-sterile. Stem sterilization is recommended. This system could be used with the following instruments; Pilot drill, Bone Collector drill with Stopper, Driver, Driver Handle, Mallet and Tac Applicator.

- **GBR Bone Fixation Screw**

Type	Length	Ø 1.4 mm	Ø 1.6 mm	Ø 2.0 mm
	3.0 mm	GS1403	GS1603	GS2003
	4.0 mm	GS1404	GS1604	GS2004
	6.0 mm	GS1406	GS1606	GS2006
	8.0 mm	GS1408	GS1608	GS2008
	10.0 mm	GS1410	GS1610	GS2010
	12.0 mm	GS1412	GS1612	GS2012

- **GBR Bone Tac Screw**

Tac	Color	Diameter	Length	Code
	Purple	Ø2.0 / 0.85 mm	3.5 mm	GBTC35
	Blue	Ø2.0 / 0.85 mm	5.0 mm	GBTC50

- **Titanium Mesh**

Number of pore	Pore Ø	Width	Length	Code
24 X 16	0.6	15 mm	22 mm	TMS101
40 X 24	0.6	22 mm	36 mm	TMS102
48 X 48	0.6	44 mm	44 mm	TMS103
6 X 4	1.4	15 mm	22 mm	TMS201
10 X 6	1.4	22 mm	36 mm	TMS202
12 X 12	1.4	44 mm	44 mm	TMS203

** Thickness : 0.1 mm.*

2. Micro Implants are devices installed by a simplified surgical procedure, through the gum with topical or infiltrative anaesthesia, temporarily fixed to the maxillary or mandibular bone, with the purpose of:

- Create stable anchorage points;
- Allow the application of continuous forces;
- Substitute the traditional anchorage systems, or those requiring the patient collaboration, also enabling the performance of more complex orthodontic movements with accurately and in shorter time.

- Micro Implants Ø 1.5 mm

Type	Transmucosal Margin	Blade length	CODE
	1.0 mm	6.0 mm	ORT106
	1.0 mm	8.0 mm	ORT108
	2.0 mm	6.0 mm	ORT206

	2.0 mm	8.0 mm	ORT208
	2.0 mm	10.0 mm	ORT210
	2.0 mm	12.0 mm	ORT212
	2.0 mm	14.0 mm	ORT214

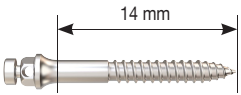
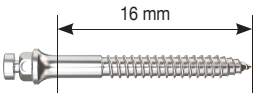
3. The Orthodontic Micro Implants with Cross Head is commercialized with installation threads with Clockwise insertion with anchoring of accessories in the 0.021 “x0.025” slots.

• Micro Implants Ø 1.5 mm with Cross Head

Type	Transmucosal Margin	Blade length	CODE
	1.0 mm	6.0 mm	ORT316
	1.0 mm	8.0 mm	ORT318

4. Micro Implants are single-use implantable medical and dental devices, temporarily fi xed to the maxila or mandible bone in extra-alveolar areas such as the Buccal Shelf and Zigomatic Crest to create stable anchor points that are unable to move by applying the clinical forces necessary for orthodontic treatment.
This anchorage, called skeletal anchorage, allows the application of continuous forces and replaces traditional anchor systems or those that require patient collaboration, as well as enabling more complex orthodontic movements with precision and in less time.

• Buccal Shelf Micro Implant Ø 2.0 mm

Type	Transmucosal Margin	Blade length	CODE
	4.0 mm	10.0 mm	ORT216
	4.0 mm	12.0 mm	ORT215

- Zygomatic Bone Micro Implant Ø 2.0 mm

Type	Transmucosal Margin	Blade length	CODE
	8.0 mm	9.0 mm	ORT217

PRINCIPLE OF OPERATION:
The function of GBR System is use in applications for maintaining the relative position of bone grafts in reconstruction of maxillary and/or mandibular areas.

INDICATIONS FOR USE:
The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.

HOW TO USE:

1. Selection of plate and screw:
Selection of plate and screw size to use is at the discretion of the operating surgeon. The tip of screw is available for self-drilling and self-tapping.
In case of high density bone surgery, pre-drilling is recommended prior to inserting Bone Screw.
The bone screws and plates are offered in various sizes as follows:

2. Titanium Mesh (bone plate)
Handling: The Titanium Mesh is grasped using the forceps or finger.

3. Titanium Mesh (bone plate)
Cutting Titanium Mesh plate can be cut using medical scissors. Exercise care while cutting plates to avoid producing flying plate fragments that can enter the surgical site. The edge made by breaking off a plate section can be easily smoothed using a round burr.

4. Pre-drilling:
GBR System Bone Screws are self-tapping and self-drilling. In case of high density bone like mandibular molar region, consider pre-drilling using pilot drill, connected to a dental handpiece, is recommended prior to insertion of Bone Screw to prevent fracture of screw thread.
Fault drilling causes that screws will not fit tightly into the bone. To reduce potential for thermal necrosis, all pilot drills should be used at minimal RPM.

5. Bone Screws and Bone Plate Fixation:
For screw and plate fixation, the surgeon can use driver shafts (Tac Remover Driver). When using a driver manually, it is used with a driver handle. Use it to pick up a screw then drive it to fixate the screw in the surgical site until the screw head is seat. Do not over torque the screw.
In case of Bone tac (Bone screw) fixation, in order to insert bone tac the surgeon can use a tac applicator and mallet manually. Use the tac applicator to pick up Bone tac, and hammer the bone tac using the mallet at the surgical site until the bone tac head is fixed.

WARNING:

- The type and size of Bone Screw and Bone Plate should be carefully considered by the operating surgeon taking into account ossein, bone geometry, functional load, post-operation adaptability

of the patient, etc.

- For efficient and safe use for GBR System, the surgeon should be sufficiently trained and have enough experience in the operating method related to this product.
- The surgeon should be able to make a reasonable judgment when deciding which Bone Screw and Bone plate type to use for a special purpose.
- GBR System Bone screw and plate are not intended to endure excessive abnormal functional stresses.
- Use of an under sized plate or screw in areas of high functional stress may lead to implant fracture and failure.
- It should not be used together or in vicinity of other medical instrument such as metal plate, screw, wire, etc.
- Imperfect fixing of the product may cause damage or rupture of this product.
- The GBR System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of GBR System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Do not subject the Micro Implant to forces greater than for 300gf (for Buccal Shelf/Zygomatic Screw
  – 450gf).
- Do not exceed the maximum torque of 25 N/cm (55 N/cm) during installation. Literatures report that fractures can occur due to flexion efforts during application. It is up to the practitioner to decide on the removal of the implant fragment or to install another Micro Implant.
- In case of immediate loading in this device, the application must be made perpendicular to the long axis of the Micro Implant.
- Use a drill up to Ø 1 mm for pre-drilling. In case of high bone density, use drill up to Ø 1.5 mm for pre-drilling.
- Keep the minimum distance of 1mm between the dental root and the Micro Implant.
- Observe the installation direction of the Micro Implant to avoid unscrewing during mechanical application with orthodontic wires.
- This product hasn't been evaluated for compatibility and safety in Magnetic Resonance environment, the patient should be advised of this condition.

CAUTIONS:

- The surgeon should be well acquainted with suitable precautions against problems that may occur during an operation.
- Always follow appropriate safety precautions.
- Select the appropriate size of plate and screw for the patient.
- Selection of the bone screw and plate, the operation method suitable for the patient and the judgment on the removal time are the responsibilities of the operator.
- Once applied, never reuse bone screws and plates.
- Excessive driving torque may cause fracture of the screw tip.
- Delay in conglutination, non-conglutination, incidental bone resorption, or an external injury may cause excessive stress to this device which result in rupture or loosening of the device.

PRECAUTIONS:

- The physician should inform the patient of risks associated with surgery.
- Inspect each device to ensure they are not bent or damaged.
- Bone screws, plates and instruments must be sterilized prior to use.

POSSIBLE ADVERSE EFFECTS:

- If an operation is done for a patient who lacks occification due to osteoporosis or because vascular transplantation is suppressed, the product may become loose, bent, broken or ruptured.
- An early removal operation after the transplantation may cause failure in fixing the product to the bone and that results in imperfect osteosynthesis.
- Inappropriate alignment or arrangement may cause delay or failure in bone articulation.
- It should not be used for the patients who are sensitive to a metallic material such as titanium.

CONTRAINDICATIONS:

- Do not use for patients with active or suspected infection, immune deficiency history, steroid treatment, bleeding disorder, endocrine diseases, osteomyelitis or other acute diseases.
- Do not use for patients receiving radiation therapy on the cranium or having gingival diseases or oral hygiene problems.
- Do not use for any patients who is not suitable for surgery including titanium-sensitive patients.

MATERIAL:

Bone screw (Bone Screw, Bone Tac): Titanium Alloy (ASTM F 136).
Bone screw (Micro Implant): Grade 23 Titanium Alloy.
Bone plate (Titanium Mesh): Titanium (ASTM F 67 Grade1).

STERILIZATION

GBR System & Bone screw is supplied **NON-STERILE**.
The screws, plates and drills must be sterilized by dental clinics prior to use.

PACKAGING:

GBR System devices are packaged individually.
This device is manufactured made for GDT Implants

Consult instructions for use		Manufacturer	
Caution		Reference / Article number	REF
Non-sterile product		Batch Code	LOT
Temperature limitation		Date of manufacture	
Keep away from rain		Symbol for "Use by Prescription only"	Rx Only
Keep away from sunlight			

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.