Made for GDT Implants
Yitzhak Ben Zvi 9/64
Beer Sheva, Israel
info@gdt-implants.com
1-800-390-115

Instrument Kit

Membrane Standard kit

INSTRUCTIONS FOR USE

DESCRIPTION:
The device is intended for use in inserting and removing dental bone screws for guided bone regeneration in dental implant surgery.

COMPOSITION:
GBR Screws Motor Mount/ Driver: MMGB20 (Ø2.3 X 20) / MMGB26 (Ø2.3 X 26).
Mallet: GMT. **Tac Applicator:** GTA . **Bone Tac Case:** GB35 /GB50

HOW TO USE:

No	Product	How to Use
1	GBR Screws Motor Mount/ Driver	Connect Tac Remover Driver to a dental handpiece and tight or remove bone screws.
2	Tac Applicator	With a tip of Tac Applicator, grasp Bone Tac and place it on the surgical site.
3	Mallet	Insert Bone Tac into the surgical site by malleting Tac Applicator.

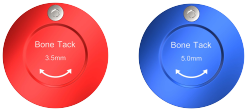
- **GBR Screw driver**

Type	Size	Code
	20.0 mm	MMGB20
	26.0 mm	MMGB26

- **Tools**

Type	Code
	GTA
	GMT

- **Bone Tac**

Type	Type	Code
	for Tac 3.5 mm	GB35
	for Tac 5.0 mm	GB50

STORAGE AND TRANSPORTATION CONDITIONS:
The device should be kept during storage and transportation at room temperature in dry place. Keep the device out of direct sunlight and avoid heavy materials placing on the device.

MATERIAL: Stainless Steel, Aluminium, Acetal copolymer, Trimrite.

WARNING:
- For efficient and safe use of this device, the surgeon should be sufficiently trained and have enough experience in surgical operation technique related to these instruments.
- The surgeon is responsible for making reasonable judgement on deciding which instrument and surgical technique to use for a special purpose considering condition of individual patient.

CAUTIONS:

- The surgeon should be well acquainted with suitable precautions against problems that may occur during an operation.
- Excessive drilling can cause injury during surgical operation.

PRECAUTIONS:

- The surgeon should inform the patient of the risks associated with surgery.
- Inspect each device to ensure they are not damaged.
- All instruments must be sterilized prior to use.
- The device should be used by sufficiently trained surgeon.
- The device should not be modified or used against the [Indications for Use] stated in this document.

POSSIBLE ADVERSE EFFECTS:

Allergy to metallic material, inflammation and/or infection caused by carelessness.

CONTRAINDICATION:

- Do not use for the patients with active or suspected infection, immune deficiency history, steroid treatment, bleeding disorder, endocrine diseases, osteomyelitis or other acute diseases and the patients receiving radiation therapy on the cranium or having gingival diseases or severe oral hygiene problems unless the surgeon make reasonable judgement that the surgery with the device is safe for the patients under appropriate control.
- Do not use for any patient who is not suitable for surgery including the patients with allergy to metallic material.

CLEANING & STERILIZATION:

The subject devices, surgical instruments, are reusable after cleaning and sterilizing. They must be cleaned before reuse. Following these recommended instructions for cleaning.

1) Cleaning:

① Disassemble the device where possible.
② Remove body fluids or blood with flowing water.
③ Cleanse the device thoroughly using suitable brushes in flowing water until foreign substances are removed. (do not use metal brushes or steel wool).
④ Cleanse the device with surgical instrument cleaner according to the instructions provided by the manufacturer of the cleaner.
⑤ Rinse the device in flowing water or distilled water for 20 seconds three times.
⑥ Air-dry or wipe the device with clean cloth and alcohol to prevent from water spot.

2) Pre-Cleaning:

① Follow the same instructions from ④ to ⑥ of Cleaning.

3) Sterilization:
Dental Surgical Instruments is supplied **NON-STERILE**.
They must be sterilized by the end user after and prior to use.
Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps or pouches) should be used.

PACKAGING:
The device is packaged in KIT.
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.