MOD*fix*/UNI*fix* Bone Fixation System

INSTRUCTION FOR USE

A. Description

The **MOD*fix*** (modular fixation) and (**UNI*fix*** universal fixation) systems are comprised of various sizes of modular fixation screws and complementary abutments, designed for oral and maxillofacial bone regeneration. The system also includes the instrumentation required for the installation of fixation screws and abutments, as well as a cassette used for organization and sterilization of the components.

B. Material

MOD*fix*/UNI*fix* fixation screws and abutments are comprised of medical grade Titanium alloy (ASTM F136). Drivers and drills are composed of surgical grade stainless steel.

C. Order Information and Dimensions

See current product catalog for updated and detailed order information of different sizes and dimensions of the **MOD*fix*/UNI*fix*** fixation systems screws and abutments.

D. Indications for Use

MOD*fix*/UNI*fix* fixation system is used for stabilization of bone (particulate or block bone), barrier membranes (resorbable or non-resorbable) or titanium mesh in the oral cavity.

E. Contra-indications

There are no absolute contra-indications for application of **MOD*fix*/UNI*fix*** fixation system other than those applicable for oral surgery in general, including, but not limited to:

- Current or recent history of bisphosphonates
- Radiation therapy of the jaws
- Active infection
- Smoking, alcohol or drug abuse
- Poor oral hygiene
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate consultation and test(s) may be conducted to rule out this possibility prior to implantation
- Conditions which tend to limit the patient's ability and/or willingness to cooperate and follow instructions during the healing
- Any degenerative disease, the progress of which could adversely affect the placement of the implant.
- Inadequate bone quantity/quality for secure anchorage of fixation screws.
- Compromised blood supply
- Inadequate coverage by healthy tissue
- Conditions which compromise the sterility of the site, i.e open cavities, such as sinuses

F. How Supplied

The **MOD*fix*/UNI*fix*** Bone Fixation Screws are provided **NON-STERILE**. They are intended for **SINGLE USE ONLY**. All non-sterile products **MUST be sterilized prior to use**. Sterilize according to the suggested protocol described below. Do not use if package has been previously opened or damaged.

G. Cleaning and Sterilization Instructions

The fixation screws and abutments are provided clean and **NON-STERILE** (requiring sterilization) and are for **SINGLE USE** only.

The instrumentation (drivers, drills and handles) are also provided **NON-STERILE** and need to be sterilized before use. The drivers may be used several times, but need to be cleaned and sterilized before each use. The following steps are recommended:

1. Remove all new components (fixation screws and abutments) out of packaging and place in designation slots in the organizer wheel (**MOD*fix*/UNI*fix*** kit) or **UNI*fix*** cassette.
2. Completely disassemble instruments (drivers, swivel handle, latch adaptor, etc)
3. Any screws or abutments that have been contaminated with blood or bodily fluids should be discarded.
4. Remove any visible debris from the instruments, using a soft non-metallic bristle brush and an appropriate detergent. Rinse thoroughly. Allow all components to dry.
5. Once cleaned and inspected, the drivers, drills and other instruments should be placed into the **MOD*fix*/UNI*fix*** cassette.

6.The drivers should be sterilized with moist heat using the following validated steam sterilization guidelines.

Caution: Do not exceed single sterilization pouch to ensure adequate sterilization by following validated parameters. The **MOD*fix*/UNI*fix*** bone fixation screws and instrumentation should be sterilized with moist heat, using the following validated steam sterilization guidelines.

Method	Cycle	Temperature	Exposure Time
Steam	Pre-vacuum	132°C 270°F	4 Minutes Steam 20 minutes dry time

H. Patient education

It is the physician's responsibility to educate the patient and/or their representatives regarding oral maxillofacial surgery. This should include a description of associated complications and potential alternative therapy.

I. Possible adverse effects

All of the complications associated with surgery are possible. Complications and possible adverse effects associated with implants may, in addition, include the following:

- Decreased bone density and/or bone necrosis due to stress shielding
- Vascular Changes
- Allergic reaction or metal sensitivity to the fixation devices
- Nerve damage due to surgical trauma
- Breakage of the fixation device due to non-union or delayed bony tissue union
- Bending or fracture of the fixation devices
- Migration or loosening of the fixation devices
- Pain, discomfort, and/or abnormal sensation due to the presence of the fixation devices
- Superficial and/or deep infection
- Growth restriction
- Passive transmigration of fixation devices
- Tissue Staining

J. Warnings and Precautions

The physician is responsible for describing and explaining the following warnings, precautions and complications to the patient and/or their representative prior to proceeding with surgical procedures:

- Lint, fingerprints, talc and other surface contaminants or residues from latex gloves can cause foreign body or allergic reactions.
- Care must be taken to ensure that particulate contaminants are not introduced into components during the implantation or handling. These could result in improper performance of the devices.
- An implanted device should never be reused.
- Leftover screws and abutments which have been contaminated with blood or body fluids should be discarded.
- Until bone healing is complete, the fixation provided by the system should be considered temporary and may not withstand extraordinary unsupported stress.
- The patient should be provided with detailed instructions on the use, limitations, and possible complications of the system.
- Any decision to remove the system should take into consideration the potential risk to the patient of a second surgical procedure.
- Preoperative and operative procedures, including knowledge of surgical techniques and proper selection and placement of the fixation devices are important considerations in the successful utilization of the system.
- Careful pre-operative clinical and radiographic assessment and planning is required to avoid impingement of the fixation devices on anatomic structures, such as teeth, neuromuscular structures, etc.
- Radiation therapy has been shown to decrease the chance of successful results.

K. Warranty

All products are warranted to be free of defects in material and workmanship. No warranty is made for any purpose other than in the product specifications and labeling.

Caution: Federal law (USA) restricts this device to sold by or on the order of a physician or dentist.

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