Pro-fix Precision Fixation System Instructions

Contents

Pro-fix Precision Fixation System

Product Information

Product Specifications:

- **Method:** Steam
- **Cycle:** Pre-vacuum, Gravity
- **Temperature:** Not specified
- **Exposure Time:** 30 minutes, 60 minutes
- **SAR:** 2 W/kg (Normal Operating Mode)

Product Usage Instructions

- **Method of Use:**
  The product is designed to be used with a steam sterilization method, specifically pre-vacuum or gravity cycles.
- **Exposure Time:**
  Ensure that the product is exposed to steam for the specified times of either 30 minutes or 60 minutes depending on the cycle selected.
- **Screw Removal:**
  The screws included are not meant to be permanent implants and should be removed after the bone regeneration procedure.
- **Warranty Information:**
  All products are warranted against defects in material and workmanship. Refer to the product specifications and labeling for warranty details.
- **Caution:**
  According to federal law (USA), the device should only be sold by or on the order of a physician or dentist.
- **Labeling Symbols:**
  Pay attention to the labeling symbols on the package for easy identification, including caution, do not reuse, and manufacturer symbols.
- **MR Conditional:**
  The product is MR Conditional, and specific guidelines should be followed for use in magnetic resonance environments.

Frequently Asked Questions (FAQ):

- **Q: Are the screws included in the product intended for permanent implantation?**
  A: No, the screws are not meant to remain as permanent implants and should be removed after the bone regeneration procedure.
- **Q: What is the warranty coverage for the product?**
  A: The product is warranted against defects in material and workmanship. Refer to the product specifications and labeling for warranty details.

Introduction

The user of Osteogenics Biomedical products must determine whether or not any product is suitable for the particular patient and circumstances. Osteogenics Biomedical disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use or installation of Osteogenics Biomedical products.

IMPORTANT:
Read this entire package insert before use and follow all instructions carefully.

Description

The Pro-Fix™ Precision Fixation System consists of screws of various sizes, the instrumentation that is used to place the screws, and the sterilization container.

Indications:
The Pro-Fix™ Precision Fixation System is used to stabilize, fixate, and/or support bone grafts, bone-filling materials, and/or barrier membranes used for the regeneration of bone in the oral cavity.

Instructions for Use

A variety of surgical techniques may be used during the placement and fixation of the devices. The placement sites and techniques used are at the discretion of the surgeon. Ensure that the appropriate instrumentation is available before surgery. Instrumentation includes Pro-Fix™ blades that fit the Pro-Fix™ handle or contra-angle handpieces. These blades specifically fit all of the Pro-Fix™ screws.

- Note: Use Pro-Fix™ screwdriver only with Pro-Fix™ screws.
- Note: To preserve the surface finish, these implants should be handled with clean instruments dedicated to titanium, or a talc-free gloved hand.
- Note: To disengage the Pro-Fix™ screwdriver from the screw tilt the screwdriver at a 45-degree angle to loosen and release the friction-fit connection between the driver and screw.
- Note: when using Pro-Fix™ blades designed to fit contra-angle handpieces, use the manufacturer’s speed recommendations to produce the best results.

CAUTION:
THIS PRODUCT IS NOT INTENDED TO BE THE SOLE MEANS OF SUPPORT. NO SUCH IMPLANT CAN WITHSTAND BODY LOADS WITHOUT THE SUPPORT OF BONE. IN THIS EVENT, BENDING, LOOSENING, DISASSEMBLY, AND/OR BREAKAGE OF THE IMPLANTS WILL EVENTUALLY OCCUR.

Material Specifications

The screws are made of medical-grade titanium alloy (ASTM F136) and are expressly warranted as being

fabricated from the foregoing material specifications.

Cleaning and Sterilization Instructions

The fixation screws are provided clean and NON-STERILE (requiring sterilization), and can withstand multiple sterilizations. The fixation screws are for single-patient use only. The instrumentation (screwdriver blade and handle) is also provided clean and NON-STERILE (requiring sterilization), and can withstand multiple sterilizations. The instrumentation can be utilized repeatedly to insert the screws, but only after being cleaned and sterilized before every use. Instruments should soak in water or disinfectant/detergent as soon as possible after use to prevent the drying of debris. Manual cleaning is preferred. To clean, rinse the blade and handle with warm running water for a minimum of one (1) minute. Prepare neutral enzymatic detergent according to the manufacturer's recommendations. Fully immerse the devices in the prepared detergent, paying attention to all hard-to-reach areas, and then allow the device to soak for a minimum of two (2) minutes. After soaking, brush the devices thoroughly using a soft-bristled brush beneath the surface of the prepared detergent until all visible soil has been removed. Pay special attention to hard-to-reach areas. Remove the devices from the detergent solution and thoroughly rinse under running tap water until all detergent residues are removed. During rinsing, thoroughly brush the devices using a soft-bristled brush, paying special attention to hard-to-reach areas. Dry the devices using a clean, soft cloth. Visually inspect the devices for cleanliness. Both the instruments and screws must be sterilized in the Pro-Fix™ sterilization container before use.

CAUTION:
Do not exceed double wrapping to ensure adequate sterilization by the following validated parameters. The Pro-Fix™ fixation screws and instrumentation should be sterilized with moist heat, using either of the following validated steam sterilization guidelines.

Method	Cycle	Temperature	Exposure Time
Steam	Pre-vacuum	270°F 132°C	30 minutes
Steam	Gravity	250°F 121°C	60 minutes

How Supplied

Unless provided sterile and clearly labeled as such, Pro-Fix™ Precision Fixation System screws are supplied NON-STERILE. They are intended for SINGLE USE ONLY. NON-STERILE products must be sterilized before use. Sterilize according to the suggested protocol described above. Do not use it if the package has been previously opened or damaged.

Patient Education

It is the physician's responsibility to educate the patient and/or their representative(s) regarding oral-maxillofacial surgery. This should include a description of associated complications and an explanation of potential alternative products and treatments.

MRI Safety Information

Non-clinical testing has demonstrated that Profix Precision Fixation System Screws are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T.
- Maximum spatial gradient of 3,000 gauss/cm (30 T/m).
- Maximum MR system reported a whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Under the scan conditions defined above, the Profix Precision Fixation System Screws are expected to produce a maximum temperature rise of less than 2.3°C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the device extends approximately 3 mm from the implant when imaged with a gradient echo pulse sequence and a 3.0 T MR system.

Contraindications

- Contraindications include, but are not limited to, the following:
- Active infections.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be done to rule out this possibility prior to implantation.
- Conditions that tend to limit the patient's ability and/or willingness to cooperate and follow instructions during the healing period.
- Any degenerative disease, the progress of which could adversely affect the placement of the implant.
- Insufficient quantity of bone to securely anchor the implant.
- Blood supply limitations, radiation therapy, and/or previous infections may tend to retard healing and increase the possibility of infection and/or rejection of the implant.
- Inadequate coverage with healthy tissue.
- Procedures in which a non-sterile environment exists, i.e. open cavities, such as sinuses.

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 density of bone and/or necrosis of bone 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 a nonunion or delayed union of bony tissue.
- 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 the fixation devices.
- Tissue staining.

Warnings and Precautions

The physician is responsible for describing and explaining the following warnings, precautions, and complications

to the patient and/or his representative(s) before proceeding with the 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 onto components during implantation or handling. This could result in improper performance of the system.
- An implanted device should never be re-used; re-use of a device could cause cross-contamination.
- Leftover implants which have been contaminated with blood or body fluids should be discarded as medical waste.
- Until bone healing is complete, the fixation provided by the system should be considered temporary and may not withstand extraordinary unsupported stresses.
- Detailed instructions on the use, limitations, and possible complications of the system should be given to the patient.
- Any decision to remove the system should take into consideration the potential risk to the patient of a second surgical procedure.
- Preoperative and operation procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are important considerations in the successful utilization of the system.
- Radiation therapy has been shown to decrease the chance of successful results.
- Postoperatively as a precaution, before patients with implants receive any further surgery (such as dental procedures) prophylactic antibiotics may be considered, especially in high-risk patients.

Screw Removal:
The screws are not intended to remain in place as a permanent implant and should therefore be removed following the bone regeneration procedure.

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 sale by or on the order of a physician or dentist.

Labeling Symbols

Symbols may be used on package labeling for easy identification.

-  Caution
-  Do Not Reuse
-  Manufacturer
-  Manufactured Date
-  Lot Number

- REF Catalog Number
- NON STERILE Not Sterile Product
- QTY Quantity
- EC REP Authorized Representative in the European Community
- Consult instructions for use
- MR MR Conditional

Contact Information

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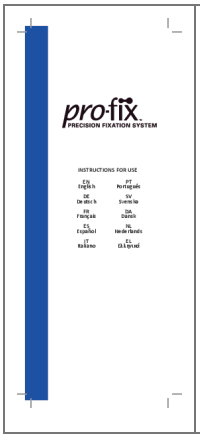
- www.osteogenics.com.
- **Emergo Europe BV**
  Westervoortsedijk 60 6827 AT Arnhem The Netherlands

Documents / Resources

	Pro-fix Precision Fixation System [pdf] Instructions Precision Fixation System, Precision Fixation System, Fixation System, System

References

- User Manual