Part No. 030-1726
Rev .F

OSTEOMED
OSTEOMED Profile Zero System
Low Profile Neuro Fixation System

Product Information and Instructions for Use

Description

The *OSTEOMED Profile Zero System* is comprised of plates, screws and instrumentation. The system features various plates and meshes with a low profile thickness of 0.25mm, and 1.6mm diameter Low Profile Auto-Drive screws in 3.5mm to 6.0mm lengths and 1.9mm Low Profile Safety standard screw in 3.0 and 4.0mm lengths.

The instruments include drill bits, plate holding forceps, plate cutters, and screwdrivers to facilitate the placement of screws and modification of plates.

Material

The screws are made from Titanium Alloy (ASTM F-136). The plates are made from Titanium Alloy (ASTM F-136) or commercially pure Titanium (ASTM F-67). The instrumentation is made from various grades of surgical grade stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications

The *OSTEOMED Profile Zero System* is indicated for osteotomies, fractures or reconstruction of the cranial bones.

The *OSTEOMED Profile Zero System* implants and drills are intended for single use only. System instruments are reusable. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications

- Use of the *OSTEOMED Profile Zero System* is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium or stainless steel; or in patients with certain metabolic diseases.
- It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation plate and screw implants and/or in patients where there is insufficient bone or poor bone quality.

Warnings

1. Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Multiple bending may weaken the plate and could result in implant fracture and failure.
4. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
5. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient.
6. Use of excessive torque during insertion of screws may lead to implant failure.
7. When placing additional screws, ensure that subsequent screw placement does not interfere with the other screws.
8. The *OSTEOMED Profile Zero System* implants have not been evaluated for safety and compatibility in the MR environment.
9. The *OSTEOMED Profile Zero System* implants have not been tested for heating or migration in the MR environment
10. The cranial plates and meshes are intended for non-load bearing applications.
11. It is recommended to cut with fragment trajectory away from patient and personnel.
12. The *OSTEOMED Profile Zero System* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
13. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.
3. The *OSTEOMED Profile Zero System* plates and screws are not intended to endure excessive abnormal functional stresses.
4. When loading a screw onto driver, apply a perpendicular force to engage screw cruciform with driver. The surgeon should avoid multiple insertions of driver into the same screw to maintain self-retention feature of screw to driver.
5. The *OSTEOMED Profile Zero System* is intended for temporary fixation only until osteogenesis occurs.
6. All *OSTEOMED* plates, screws, and instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
7. Carefully inspect the *OSTEOMED* implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to *OSTEOMED* for disposition and repair. NOTE: The implants are color anodized. Slight color changes may occur after repeated autoclave cycles, this does not affect the quality of the implant.
8. When placing more than one screw, ensure that subsequent screw placement does not interfere with other screws. Insert the second screw on the opposite side of the fracture or osteotomy site, and then all remaining screws.
9. *OSTEOMED* recommends the use of OsteoMed products in a sterile environment.
10. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance to the Power System Instruction for Use. Use irrigation when pilot drilling.
11. When using plate cutters, face away from the patient and personnel.

Instructions for Use, Auto-Drive® screws

The Auto-Drive® screws are self drilling and can be inserted in one step. Insert the screw in a TaperLock™ screwdriver and drive into the bone at a 90° angle using moderate pressure until the head is flush with the surface of the bone/plate. Higher torque may be required to fully engage the threads than when using a normal screw with a pilot drill.
Note: In high density bone pilot drilling may be necessary.

Cleaning

- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- *OSTEOMED* recommends the following cleaning and sterilization instructions for Instrumentation:

1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
2. Thoroughly rinse all instruments and the sterilization tray with water.
3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
4. Steam Autoclave per the following Sterilization Instructions.

Sterility

- Product is supplied STERILE (Gamma Sterilized) and NON-STERILE. DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- NON-STERILE implants and instruments MUST be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED* implant systems, the following parameters should be used.

Pre-Vacuum Steam Sterilization	*OSTEOMED Profile 0 System: Profile Zero System*
Minimum Temperature:	270°F (132°C)
Full Cycle Time:	4 minutes
Minimum Dry Time:	40 minutes
Configuration:	Wrapped tray in two layers of 1-ply polypropylene wrap (Kimguard KC600 - 510(k) K082554) using sequential envelope techniques
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.	
Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.	

Storage

Sterile packaged implants should be stored at controlled room temperature out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering.

Caution

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

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CE 0086

Symbols and Definitions

Single Use Only	
REF	Catalogue Number
Use By (Date)	
	Do not use if sterile package is damaged
LOT — Batch Code (Lot Number)	
	Consult Instructions for Use
Date of Manufacture	
	Manufacturer
Attention, See Instructions for Use Caution, Consult Accompanying Documents	
	EC REP — Authorized Representative in the European Community
Rx ONLY — Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.	
	STERILE R — Sterile, Method of Sterilization Using Irradiation

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