Part No. 030-1128
Rev.W

OSTEOMED
Neuro Rigid Fixation System
FAST-FLAP™

Product Information and Instructions for Use

Description

The *OSTEOMED* FAST-FLAP™ is comprised of 1.2mm and 1.6mm diameter screws and plates used for fixation of craniofacial and maxillofacial skeleton, fractures, and reconstructions. The system features Auto-Drive™ screws, 1.6mm in diameter with lengths from 3.5mm to 6.0mm, 1.2mm in diameter with lengths from 3.0mm to 5.0mm, safety screws 1.9mm in diameter and 3mm and 4mm in length, and 0.25mm to 0.7mm thick plates and meshes. The instruments include drill bits and screwdrivers to facilitate the placement of screws.

Material

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

Clinical Indications

The *OSTEOMED* FAST-FLAP™ System is indicated for fixation secondary to trauma or reconstruction of craniofacial and maxillofacial skeleton. The *OSTEOMED* FAST-FLAP™ screws, plates, meshes, and drills are intended for single use only. 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. Other system instruments are reusable.

Contraindications

The *OSTEOMED* FAST-FLAP™ is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; 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.

Warnings

1. Use of an undersized screw or plate 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. Use of excessive torque during insertion of screws may lead to implant failure.
6. 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.
7. The *OSTEOMED* FAST-FLAP™ 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.

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 screws and plates to use for specific indications.
3. The *OSTEOMED* FAST-FLAP™ screws and plates are not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED* FAST-FLAP™ is intended for temporary fixation only until osteogenesis occurs.
5. 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.
6. 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.
7. *OSTEOMED* recommends the use of *OSTEOMED* products in a sterile environment.

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 NON-STERILE unless expressly labeled as STERILE.
- Select plates are available sterile packaged (Gamma Sterilized) in 5-packs. DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- A sterile packed (Gamma Sterilized) kit is available and includes screws and plates. OsteoForm Mesh is also available sterile packaged (Gamma Sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- 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.

BLUE METAL TRAY SYSTEM:

Pre-Vacuum Steam Sterilization

Temperature:	270°F (132°C)
Time:	15 minutes
Dry Time:	20 minutes
Configuration:	Individually wrap in 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping 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. Refer to product label on package for shelf life.

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.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001 USA
Customer Service: 800/456-7779
Outside USA: 972/677-4600

EC REP
Shotwell & Carr, LLC
2 St. Paul's Road
Clifton Bristol
BS8 1LT, U.K.
Tel: +44 (0) 117 9738944

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

Printed in U.S.A.
OSTEOMED August 2014