OsteoMed® FAST-FLAP™
Neuro Rigid Fixation System

Product Information and Instructions for Use

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EN **These instructions are intended for the Operating Surgeon and supporting Healthcare Professionals in the European Union only.**

Device 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.

Intended Purpose
The ***OSTEOMED*** **FAST-FLAP** is intended for fixation of craniomaxillofacial fractures or reconstruction as a result from trauma or genetic malformations of the craniomaxillofacial skeleton and bone.

Material
Auto-Drive Screws are made from titanium alloy (ASTM F-136). The plates are made from Titanium (ASTM F-67) or Titanium Alloy (ASTM F-136). The material composition of Acumed implants is described in detail in the available Metal Sensitivity Statement document "Metal Sensitivity Statement" which can be found at www.acumed.net/ifu.
The instruments are manufactured from various grades of titanium alloy, 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 intended clinical benefit of the ***OSTEOMED*** FAST-FLAP is to provide fracture fixation for patients with craniomaxillofacial fractures of the face and skull as a result from trauma or genetic malformations of the craniomaxillofacial skeleton and bone. The indirect clinical benefit of the encompassed instrumentation is to facilitate implantation protocols for fracture fixation.

Contraindications
- Active or latent infection or marked inflammation of the treatment area
- Sepsis
- Insufficient quantity or quality of bone, osteoporosis, or in patients with certain metabolic diseases
- Patients with confirmed material sensitivity
- Patients who are unwilling or incapable of following post-operative care instructions and/or the limitations of internal rigid fixation implants

Warnings
- Treatment or implant may fail, including sudden failure, because of:
  - Loose fixation and/or loosening
  - Stress, including stress from inappropriate bending of the implant during surgery
  - Stress concentrations
  - Stress of weight bearing, load bearing, or excessive activity

  Failure is more likely if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. Failure is more likely if the patient does not follow post-operative care instructions.
- Nerve or soft tissue damage may result from surgical trauma or the presence of an implant.
- Instrument breakage or damage, as well as tissue damage, may occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use, or unintended use.
- Devices of dissimilar material should not be used together in or near the implant site. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects.
- Fractured implants should be removed from the patient during surgery. If unable to remove, notify the patient.
- Implants may cause distortion and/or block the view of anatomic structures on radiographic images.

Caution
- Implants and instruments are intended only for professional use by a licensed physician.
- Use devices and instruments in accordance with the Instructions for Use.
- Do not use the sterile product past the use-by date. Refer to the device label.
- Do not use or re-sterilize an implant provided in sterile packaging if the package has been damaged. The sterility may be compromised, and the cleanliness of the implant may be uncertain. Report damaged packaging to your distributor or Acumed.
- Use of this system has not been evaluated in children or individuals that are not skeletally mature.
- Inspect all components preoperatively to ensure utility. Do not attempt a surgical procedure with faulty, damaged, or suspect instruments or implants. Alternate fixation methods should be available intraoperatively.
- Reprocessing and/or reuse of single use devices may result in infection/cross contamination, and/or sudden failure due to previous stresses.
- Use of implant components from different manufacturers has not been evaluated.
- Use of chemical disinfection may leave residues that adversely affect steam sterilization.
- Steam penetration and device sterilization may be negatively affected by labeling that block tray steam holes.
- Devices may be contaminated with biohazardous materials and/or sharp materials. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling of biohazardous material and disposal of sharp materials.
- Manipulation of maxillofacial bones or tissues can potentially result in cardiac complications such as but not limited to ectopic beats, atrioventricular block, bradycardia, syncope, vomiting, and asystole. These are known complications during maxillofacial surgery and are not specifically related to any device.

Potential Adverse Effects
- Pain, discomfort, or abnormal sensations, nerve or soft tissue damage, necrosis of bone or tissue, bone resorption, or inadequate healing from the presence of an implant or due to surgical trauma.
- Implant fracture due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur.
- Metal sensitivity, histological, allergic, or adverse foreign body reaction resulting from implantation of a foreign material. Consult our document "Metal Sensitivity Statement" at www.acumed.net/ifu.
- Injury to user.

Note: Any serious incident that has occurred in relation to the device should be reported to Acumed (through customercomplaints@acumed.net or +1.888.627.9957) and the competent authority of the Member State in which the user and/or patient is established.

Target Population and Intended Users

The ***OSTEOMED*** FAST-FLAP System is in intended for use by suitably trained and qualified surgeons in a hospital operating room setting to treat skeletally mature patients with craniomaxillofacial fractures or reconstruction as a result from trauma or genetic malformations of the craniomaxillofacial skeleton and bone.

MRI Status

Many Acumed implants have been evaluated for safety in the MR environment and are MR conditional. Consult our publication "Acumed Implants in the MR Environment" at www.acumed.net/ifu for more information.

Device Lifetime

Once installed, implants are expected to provide fixation and physiological support and have an effective life during bone healing. The implants are biocompatible and may remain implanted at the discretion of the surgeon or patient.

Multiple-use instruments have a lifetime that is affected by usage, handling, and processing. Assess multiple-use instruments for fitness during pre-sterilization inspection.

Summary of Safety and Clinical Performance (SSCP)

The SSCP for the implants may be obtained from the European database on medical devices (EUDAMED) at https://ec.europa.eu/tools/eudamed. Use the following search terms: 08456940BUDIO13NR.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.
- The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.Acumed devices should be used in an operating room environment.
- All Acumed plates, screws, and instrumentation may be required for each surgery. Failure to use dedicated, unique Acumed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure that could cause subsequent patient injury. Failed devices may require re-operation and removal.
- Inspect the Acumed implants prior to use. Do not attempt a surgical procedure with faulty, damaged, or suspected instruments or implants. Alternate fixation methods should be available intraoperatively.
- Instrument lifetime is affected by usage, handling, and processing. Assess multiple-use instruments for fitness before and after each procedure to confirm that they are in proper operating condition. Indications that a reusable instrument should not continue to be used include but are not limited to deformation, dulled sharps, cracks, breakage, missing components, corrosion, excessive wear, and restriction or seizure of moving parts. Instruments which are faulty, damaged, or suspected should not be used. They should be replaced or sent to Acumed for disposition and repair.
- 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, following the outlined procedures.

Instructions for Use – AutoDrive 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 degree 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.
- Implants are single-use only and must not be reused. Reuse of single-use devices may result in transmission of infectious material from one patient to another which could result in serious injury or death.
- Contaminated implants must not be cleaned/reprocessed and reused. Any implant that has been contaminated by blood, tissue, and/or other bodily fluids/matter should never be used again and should be handled according to hospital protocol.
- Implants which are new, unused, and have never been contaminated by blood, tissue, and/or other bodily fluids/matter may be cleaned.
- Acumed recommends the following cleaning and sterilization instructions for implants and instruments:

Manual Cleaning

IMPORTANT: Manual Cleaning steps are mandatory. Manual cleaning must be performed prior to performing automated cleaning.

1. Rinse the articles to be cleaned under running cool tap water to remove visible soil.
2. Use a syringe to flush water through any cracks, crevices, lumens, and hard to reach areas. During rinsing, actuate the articles to ensure thorough rinsing.
3. Prepare a neutral enzymatic cleaning solution per the manufacturer's instructions. Presoak soiled implants and instruments for a minimum of 1 minute in the enzymatic solution.
4. After soaking, thoroughly brush the articles beneath the surface of the cleaning solution using a soft bristled brush, paying close attention to all hard-to-reach areas until all evidence of soil is removed. Using a lumen brush or similar type brush, brush each lumen a minimum of 5 times, ensuring that the lumen brush is passed completely through or to the bottom of the entire lumen during brushing. Use twisting actions where possible. Actuate the articles while brushing to clean mated surfaces and movable parts.
5. Rinse implants and instruments under cool running water for at least 30 seconds to flush debris out of any tight spaces. Use a syringe to flush any lumen or mated surfaces.
6. Drain excess water from the article and dry using a clean, soft cloth and/or filtered pressurized air at ≤40 psi. Visually inspect each article without magnification for visible soil, deterioration, or loss of function. If soiled, repeat cleaning process. If the device is visibly deteriorated or is unable to function, return to Acumed.
7. Proceed to the automated cleaning steps -OR- Return the instruments to their sterilization case and steam sterilize according to Sterilization instructions.

Automated Cleaning

The following automated cleaning steps are optional. Automated cleaning using a washer/disinfector, according to the following steps, may be performed following the manual cleaning steps listed above.

8. Prepare a cleaning neutral enzymatic solution with the nominal detergent concentration per the washer/disinfector manufacturer's instructions.
9. Place implants within the appropriate Acumed organizer. Remove all trays from their cases prior to processing. Place the organizers and implants in a suitable washer/disinfector basket. Place instruments in a suitable washer/disinfector basket. Minimally invasive surgery (MIS) injector or irrigation ports may be affixed to cannulated instruments so cleaning spray forces water through the instrument lumens. Using the cleaning solution, process implants and instruments through a standard washer/disinfector cycle in compliance to EN ISO 15883-1 and EN ISO 15883-2 or equivalent national standards. Dry for the nominal time recommended by the washer/disinfector manufacturer. Do not use a lubrication phase.
10. Visually inspect each article under normal lighting and without magnification for residual water in blind holes, visible deterioration, or loss of function. Pay particular attention to all challenging areas. If the device is visibly deteriorated or is unable to function, return it to Acumed.
11. Return the implants and instruments to their sterilization case and steam sterilize according to Sterilization instructions.

Thermal Disinfection:

For thermal disinfection, remove trays from the outer case and place separately in the washer/disinfector's rack during automated cleaning and thermal disinfection. Utilize a thermal disinfection program consistent with an A0 value > 3000 or perform thermal disinfection at 90°C (maximum temperature 95°C) for at least 5 minutes.

Pre-Sterilization Inspection

- Visually inspect all devices under normal lighting to ensure that cleaning was effective. Pay close attention to all challenging areas. Reprocess instruments that are not clean and replace instruments that cannot be cleaned.
- Inspect the implants and instruments for surface damage, such as nicks, scratches, and cracks. Replace affected devices.
- Assess the instruments for proper use. Operate all parts and connecting mechanisms. Give careful attention to drivers, drill bits and reamers, and instruments used for cutting or implant insertion. Critically assess them for wear, sharpness, straightness, and corrosion. Replace any instrument that does not perform as intended.

- Inspect cutting edges under magnification. Replace worn instruments e.g., dull, chipped, cracked, rolled, or otherwise deformed. Run a cotton cloth over the edge to help detect chipping and cracking.
- Verify the legibility of all markings and reference scales. Replace any device that is unreadable.
- Repair, replace, and/or repeat the cleaning of instruments as needed to ensure proper operation before proceeding with sterilization.
- Lubricate (instrument milk) surgical instruments to increase useful life. Do not use silicone-based lubricants, oil, or grease, as these will interfere with steam sterilization. Use a water-based lubricant intended for use on surgical instruments and with steam sterilization. Use the lubricant as directed by the manufacturer. Use critical water if dilution is required.
- Fully replenish the system trays and caddies.

Sterility

- Product is supplied **NON-STERILE unless expressly labeled as STERILE.**
- Select plates and screws are available sterile packaged (Gamma Sterilized)**. DO NOT USE IF THE 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 dry devices prior to sterilization per standard hospital procedures.
- Follow current industry best practice guidelines such as ANSI/AAMI ST79:2017, the Association for the Advancement of Medical Instrumentation's (AAMI's) "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of Acumed implant systems, the following parameters in the table below should be used. The table shows the minimum parameters validated to achieve a required Sterility Assurance Level (SAL) of 10^{-6} for the system.

Pre-Vacuum Steam Sterilization	Fast Flap System in Blue Metal Tray (222-0200)	Fast Flap System in BLUE Metal Tray (222-0200)	Profile Plus Tray P/N 220-0270 with Mesh Drawer	Profile Plus Tray P/N 220-0270 without Mesh Drawer	Profile Plus Tray P/N 220-0270 without Mesh Drawer
Temperature	270°F (132°C)	273°F (134°C)	273°F (134°C)	270°F (132°C)	273°F (134°C)
Time	4 minutes	3 minutes	3 minutes	4 minutes	3 minutes
Dry Time	40 minutes	40 minutes	65 minutes	40 minutes	40 minutes
Configuration:	Wrapped Tray	Wrapped tray	Wrapped tray	Wrapped tray	Wrapped tray
Wrapping Technique	Wrap tray in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential envelope folding technique.				
Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.					

Do not exceed 135°C, to avoid compromising functions of polymeric instrumentation.

Post-Sterilization Inspection

- Do not store or use sterile devices if they are not dry.
- Inspect the sterile barrier for signs of damage. Do not use the product if the sterile barrier has been compromised.

Storage

After steam sterilization, sets should be stored under controlled conditions in a manner that minimizes the potential for contamination per ANSI/AAMI ST79:2017. Refer to sterilization wrap or rigid container manufacturer's IFU for limits on sterile product storage time and storage requirements for temperature and humidity. Devices should be stored in an area that provides protection from dust, pests, and temperature/humidity extremes.

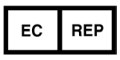
Sterile packaged implants should be stored at controlled room temperature out of direct sunlight and should be stored in an area that provides protection from dust and pests. Product package should be inspected prior to use for signs of damage or tampering.

Safe Disposal

Devices may be contaminated with biohazardous materials and/or sharp materials. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling biohazardous material and disposal of sharp materials.

Symbols and Definitions

Note: This is a general list of symbols. Not all symbols apply to all systems.

Symbol	Description	ISO 15223-1	Symbol	Description	ISO 15223-1
	Manufacturer	5.1.1		Authorized Representative in the European Community	5.1.2
	Date of Manufacture	5.1.3		Use-by Date	5.1.4
	Batch Code (Lot Number)	5.1.5		Catalogue Number	5.1.6
	Serial number	5.1.7		Sterilized using irradiation	5.2.4
	Do Not Resterilize	5.2.6		Non-Sterile	5.2.7
	Do not use if sterile package is damaged	5.2.8		Single Sterile barrier System	5.2.11
	Double Sterile barrier System	5.2.12		Single Sterile barrier System with Protective packaging inside	5.2.13
	Single Sterile barrier System with Protective packaging inside	5.2.14		Single Use Only	5.4.2
	Medical Device	5.7.7		Consult Instructions for Use	5.4.3
	MR Conditional (ASTM F2503)			CE marking of conformity, Article 17 of EU Directive 93/42/EEC or Article 20 of Regulation (EU) 2017/745. CE marking may be accompanied by the identification number of the notified body responsible for conformity assessment	
	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician. (U.S. 21 CFR 801.109)				

ACUMED, LLC
5885 NE CORNELIUS PASS ROAD
HILLSBORO, OR 97124
CUSTOMER SERVICE (OUTSIDE USA):
+1.888.627.9957

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Subsidiaries:

Acumed Ltd
Huebner House
The Fairground
Andover
Hampshire UK SP11 0QN
Tel: +44 1264 774450

Acumed GmbH
Fuhlsbuttler Stasse 300
22307 Hamburg
Deutschland
Tel: +49-40 947 82 093

Acumed Iberica C/
Procion 1 Edificio
Oficor 28023
Madrid-Spain Tel:
+34 913516357

EC REP

EMERGO EUROPE
WESTERVOORTSEDIJK 60
6827 AT ARNHEM
THE NETHERLANDS

CE
2797