Part No. **030-1999**
Rev. A
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OSTEOMED
EXTREMIFIX MID & LARGE SCREW SYSTEM
RIGID FIXATION SYSTEM
Product Information and Instructions for Use

Description
The ***OSTEOMED ExtremiFix Mid & Large Screw System*** is comprised of screws in diameters of 4.5mm, 5.5mm, 6.5mm, and 7.0mm in headed and headless options with various thread types and lengths. The system includes washers for use with 4.5mm, 5.5mm, 6.5mm and 7.0mm headed screws. The system also includes instruments to facilitate the placement of screws.

Material
Screws and washers are made from titanium alloy (ASTM F-136). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymers.

Clinical Indications
The ***OSTEOMED ExtremiFix Mid & Large Screw System*** is indicated for use in bone reconstruction, osteotomy, arthrodesis, and fracture fixation of foot, ankle, and long bones (upper and lower extremity). The screws are intended for single use only. The system drills and guide wires are single use instruments.

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/instrument 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 uses, OsteoMed cannot guarantee the safety and effectiveness of the single use device/instrument if it is used on more than one patient.

Contraindications
Use of the ***OSTEOMED ExtremiFix Mid & Large Screw System*** 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 physician's pre- and/or post-operative instructions and/or the limitations of internal rigid fixation implants.

Warnings
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
3. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Instruments, guide wires and screws are to be treated as sharps.
5. It is recommended to remove any fractured implants and/or instruments from patients during surgery. If unable to remove, notify patient.
6. Use of screws in high density bone may result in implant and/or instrument fracture or failure upon insertion.
7. The OSTEOMED ExtremiFix Mid & Large Screw System is recommended for use in patients with sufficient bone quality to sustain effectiveness and benefits of rigid fixation.
8. The user should be aware of possible allergic reactions to materials used in the device. The patient should be informed on this matter by the user.
9. Failure to follow instructions may result in device not operating as intended.
10. Failure to follow sterilization parameters may result in device not operating as intended.

MRI Safety Information
The ***OSTEOMED ExtremiFix Mid & Large Screw System*** has not been evaluated for safety and compatibility in the MR environment. It has not been tested for radio frequency (RF) heating, migration due to magnetically induced displacement, or image artifact in the MR environment. The safety of the implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of bone screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The ***OSTEOMED ExtremiFix Mid & Large Screws*** are not intended to endure excessive abnormal functional stresses.
4. The ***OSTEOMED ExtremiFix Mid & Large Screws*** are intended for temporary fixation only until osteogenesis occurs.
5. All ***OSTEOMED ExtremiFix mid and large size 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.
8. Depth Gauge marking tolerance: ± 0.13mm for Midsize, ± 0.25mm for Large.

Instructions for Use, Mid and Large Size Screws and Washers
1. Secure proper placement of bone segments to be joined.
   Note: This step is very important if the bone is very dense or in arthrodesis, as the axial force necessary for insertion could temporarily distract the fragments at the fracture/arthrodesis line. Using a wire driver, insert the guide wire toward the distal cortex.
2. CAUTION: Intra-operative imaging should be used to verify proper placement. Verify that guide wire is not bent. When placing more than one screw, ensure that subsequent guide wires do not interfere with other implants.
3. Using the appropriate depth gauge, determine screw length. Subtract any anticipated interfragmentary compression resulting from screw insertion.
   4.1 Pre-drilling and proximal cortex drilling:
   4.1.1 On softer bone, screws may be inserted without any pre-drilling or proximal cortex drilling.
   4.1.2 Pre-drilling is recommended when working with high density bone, especially in a bi-cortical application, using the drill.
   NOTE: If significant resistance is felt while inserting the screw, back out the screw and use a drill per the table below. Bone taps are also available. Remember to use irrigation when pilot drilling.

Screw Size	Recommended Drill Size
4.5mm	Ø3.1mm Pilot Drill
5.5mm	Ø3.7mm Pilot Drill
6.5mm	Ø4.8mm Pilot Drill
7.0mm	Ø4.8mm Pilot Drill

   4.1.3 Use of the proximal cortex drill to skim the proximal cortical surface is recommended when using headless screws. Be sure to accurately measure with the depth gauge or the screw may not purchase and the length of the screw may be too long or too short.
   4.1.4 When inserting the headless screw in an oblique orientation it may be necessary to drive screw a little further to prevent a portion of the screw from remaining exposed. Note: Use of proximal cortex drill may aid in countersinking the screw.
5. Remove desired screw from screw block. Verify length of screw with screw length gauge.
6. When placing headed screws, a washer may be used to provide additional contact with the bone. Washers are lasermarked to indicate which side must be in contact with the screw head.
7. Place screw over guide wire and drive screw until fully seated.
8. Check that screw is seated flush with the surface of the bone.
9. Remove guide wire and discard.

Instructions for use, Reduction Tool
Controlled reduction and closure of fracture gap using the headless screw Reduction Tool

Step 1: Screw engagement
Place the reduction tool over the screw head to engage screw. Once engaged, hold Reduction Tool Sleeve stationary and rotate Reduction Tool Driver Shaft counterclockwise to secure the head of screw within the distal end of the Tool.

Step 2: Screw insertion
Insert the screw into the bone until the distal tip of the Reduction Tool comes into contact with the bone.

Step 3: Closure of gap (lag screw technique)
Once the tip of the reduction tool lies on the bone, continue driving the screw (using a lag screw technique) until the fracture gap is closed.

Step 4: Countersinking and compression
Once the closure of the fracture gap is achieved, press the PUSH button, hold the Reduction Tool Sleeve, and continue to advance the screw until the screw is flush with the bone surface**.**

Screw Removal: (if necessary)
1. Locate implant with intraoperative imaging.
2. Palpate screw and remove surrounding soft tissue to gain maximum exposure.
3. Insert appropriate guide wire through cannula if possible.
4. Engage screw with driver and rotate counterclockwise until screw is removed.
5. If screw cannot be removed, use screw extractor.

Cleaning
OsteoMed recommends the following cleaning instructions for the OsteoMed reusable instrumentation:
1. Rinse the articles to be cleaned under running cool tap water to remove gross soil.
2. Use a sterile 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 an enzymatic cleaner such as Enzol® per manufacturer's recommendations at 1oz/gal using lukewarm tap water. Using a clean soft cloth that has been soaked in the solution, wipe the entire article. Use a sterile syringe to flush at least 50mL of enzymatic cleaner through any cracks, crevices, lumens, and hard to reach areas. Actuate the articles while immersed to ensure complete penetration of cleaning solution. Allow the articles to soak in the solution for a minimum of 15 minutes.
4. After soaking, thoroughly brush the articles beneath the surface of the prepared cleaner using a soft bristled brush, paying close attention to all hard to reach areas until all evidence of soil is removed. Actuate the articles while brushing in order to clean matted surfaces and movable parts. 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 the entire lumen during brushing. Use a syringe to flush any lumen or matted surface with at least 50mL of solution.
5. Rinse the articles in RO/DI (reverse-osmosis/deionized) water until all visible evidence of detergent is removed. Flush any lumens or matted surfaces with the RO/DI water. Once all evidence of detergent is removed continue to rinse for an additional 30 seconds.
6. Drain excess water from the article and dry using a clean soft cloth or filtered pressurized air.
7. Prepare a non-enzymatic detergent such as MetriWashTM per manufacturer's recommendations at ¼ oz/gal of lukewarm tap water.
8. Fully immerse the articles and flush all lumens with at least 50mL of the detergent.
9. Allow the articles to soak in the solution for a minimum of 15 minutes.
10. Thoroughly brush the exterior of the articles beneath the surface of the prepared cleaner using a soft bristled brush. 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 the entire lumen during brushing. Flush all lumens with 50mL of solution after brushing.
11. Use a mild detergent such as MetriwashTM and prepare per manufacturer's recommendations of ¼ oz/gal using lukewarm tap water in a sonication unit. Fully immerse the articles in the prepared detergent. Use a sterile syringe to flush at least 50mL of the prepared detergent through any cracks, crevices, lumens, and hard to reach areas. Actuate the articles while immersed to ensure complete penetration of the cleaning solution. Sonicate the articles for a minimum of 10 minutes.
12. Remove the articles from the sonicator and rinse under RO/DI water for a minimum of 2 minutes. While rinsing, actuate the articles to ensure a thorough rinsing until all visible evidence of detergent is removed. Use a sterile syringe to rinse any lumens or other hard to reach areas with a minimum of 60mL of RO/DI water.
13. Drain excess water and dry the articles using a clean soft cloth and 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 device is visibly deteriorated or is unable to function, device shall be returned to OsteoMed.

Sterility
- Implants may be provided **non-sterile** or **sterile** packaged (Gamma Sterilized). **DO NOT USE IF IMPLANT STERILE PACKAGE IS DAMAGED. DO NOT USE IMPLANTS AFTER EXPIRATION DATE**.
- Implants and instruments supplied **non-sterile** must be sterilized prior to use. Instruments must be sterilized in an open and unlocked position.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures and OsteoMed cleaning instructions.
- Non-sterile devices and instrumentation are sterilizable by steam sterilization (autoclaving). For sterilization of ***OSTEOMED ExtremiFix Mid & Large Screw System***, the following parameters should be used.

Pre-vacuum Steam Sterilizer	**The OsteoMed ExtremiFix Mid & Large Screw System**	
Wrap Configuration	Wrapped Tray	Wrapped Tray
Temperature	270°F (132°)	273°F (134°)*
Sterilization Time	4 minutes	3 minutes
Minimum Dry Time	30 minutes	30 minutes
Open Door Time	15 minutes	15 minutes
Cool-Down Time	30 minutes outside of chamber on a wire rack	30 minutes outside of chamber on a wire rack
Wrapping Technique	Individually wrap in two layers of 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		

For US customers:
***Note**: The 134°C with 3 minute exposure and 30 minute dry time sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).
****NOTE**: If specified wrap is not available, only FDA cleared wraps should be used to wrap the subject device.
Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.

The OsteoMed ExtremiFix Mid & Large Screw System implants are non-pyrogenic. This labeling claim has been validated to the endotoxin limit of no more than 20.0 EU per device

Storage
- ***OsteoMed*** *ExtremiFix Mid & Large Screw System* should be stored at controlled room temperature, away from moisture and direct sunlight.
- Sterile packaged devices must be stored according to the labeled storage instructions. Do not use sterile packaged devices if the package has been damaged or otherwise tampered.
- Prior to each use, inspect the contents of ***OsteoMed*** *ExtremiFix Mid & Large Screw System* for signs of damage and/or defects.

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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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 (MFG Date)		Manufacturer (MFR)
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
	Keep Away from Sunlight	STERILE R	Sterile, Method of Sterilization Using Irradiation
30°C 86°F 15°C 59°F	Storage Temperature 15°C to 30°C 59°F to 86°F	Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.
	Keep Dry		

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