EXTREMITY® MEDICAL

**METAFORE™ SMALL SCREW SYSTEM**

**PACKAGE INSERT**

***CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.***

## DESCRIPTION OF THE MEDICAL DEVICE:

The MetaFore Small Screw System consists of implantable screws, and instruments for use in fracture repair and arthrodesis procedures of the hand and forefoot. The screws are available in various diameters and lengths, 2.0mm snap-off, 2.5 and 3.0mm cannulated headless and 3.0 and 4.0mm cannulated beveled available in various overall lengths and thread lengths.

**Materials:**

Screws are manufactured from Titanium alloy (Ti 6Al-4V ELI) in compliance with ASTM F136 standards.

The specialized instruments are made primarily of surgical grade stainless steel and titanium.

## INDICATIONS FOR USE

The MetaFore Small Screw System is indicated for the fixation of bone fractures and for bone reconstruction in hand and forefoot surgery.

## HOW SUPPLIED

The MetaFore screws are sterilized using gamma irradiation within a dose range of 25 to 42 kGy.

Instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

## CONTRAINDICATIONS

The MetaFore screws should not be used in a patient who has currently, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance.

## WARNINGS and POTENTIAL RISKS

The MetaFore screws are designed for **single patient use only and must never be reused.** As with all other orthopedic implants, the Extremity Medical screws should never be re-implanted under any circumstances.

The screws can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the screws in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

## PRECAUTIONS

The implantation of screws should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Screws that have already been in contact with body fluids or body tissues must not be resterilized.

Pre-operative assessment of the suitability of the patient's anatomy for accepting screws is made on the basis of x-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected.

**Correct selection of the screw is extremely important**. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

**Proper screw handling before and during the operation is crucial**. Handle the implant components properly. Ensure packaging integrity. Do not allow the screw surfaces to be damaged.

All screws and some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used.
Possible risks associated with re-use of single use devices include:

- Mechanical malfunction
- Transmission of infectious agents

**Adequately instruct the patient**. The physician should inform the patient about orthopedic screw advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of the screws.

**IMPORTANT:** The Guidewires included in the MetaFore Small Screw System are not intended as implants. The Guidewires are only intended for use as instruments to facilitate screw insertion.

The MetaFore screws have not been evaluated for safety and compatibility in the MR environment. MetaFore screws have not been tested for heating or migration in the MR environment.

## POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening and/or breakage of any or all screws;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone nonunion or delayed union;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.

## DIRECTIONS FOR USE

To implant the MetaFore screws, use only the specialized MetaFore screw system instrumentation. Do not use implants or instruments from any other system or manufacturer.

The MetaFore screw instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document. All MetaFore system components should be carefully inspected to ensure proper working condition. Critical areas should be checked for wear, damage or irregularities. Damaged or broken MetaFore devices must not be used or processed and should be returned to Extremity Medical for evaluation.

Before using the MetaFore Small Screw System for the first time, the surgeon should be thoroughly familiar with the MetaFore Small Screw System Surgical Technique Manual as well as the functionality of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all MetaFore screws and instruments, please refer to the MetaFore Smalll Screw System Surgical Technique Manual (available at no charge upon request).

### Limitations on Processing

Repeated processing has a minimal effect on these implants and instruments. End of life for instruments and tray is normally determined by wear and damage to due to use.

### Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated devices.

Reprocessing begins at the point of use, which includes initial cleaning measures to prevent drying of the soil and contaminants in and on the devices. Soiled instruments must be removed from trays.

### Containment and Transportation

It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Do not clean soiled instruments while in trays. Instrument trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use.

### Preparation for Cleaning

- If possible, it is recommended that devices be reprocessed promptly after use.
- Where instruments interface with other devices, disassemble prior to cleaning.
- Remove gross soil with a clean, disposable, absorbent Kimwipe or equivalent.
- Soak and/or rinse cannulated and multi-component assemblies with neutral or mild alkaline cleaning agent solution. Follow the cleaning agent manufacturer's instructions for correct exposure time, temperature, water quality, and concentration.
- Ensure debris are cleared from cannulations/lumens via cleaning brush or equivalent, where applicable.
- Repeat soak/rinse step followed by cleaning via cleaning brush or equivalent until visibly clean
- Extremity Medical devices must be cleaned separately from Extremity Medical instrument trays/cases.
- Instruments and trays must be thoroughly cleaned.

**Cleaning (Automated)**

- Ensure all gross soil is removed from the device and that all preparation for cleaning steps are complete.
- For devices that have cannulations/lumens or present complexity, a preliminary manual cleaning may be required.
- Use a validated, properly maintained, and calibrated washer disinfector.
    - Equipment: Washer Disinfectant/ Decontaminator (Hydrim L110W) and detergent (HIP Cleaning Solution L110W) or equivalent.
- Place the device(s) in a washer basket or equivalent for loading into washer disinfector
    - Ensure that the devices are oriented in a way that allows devices to drain
    - Ensure device orientation aligns with manufacturer's orientation recommendations.
- It is recommended that a pH-neutral enzymatic solution is used. If using an alkaline solution, a neutralizer must be added. Please follow manufacturer's datasheet for concentration of solution, time of use, and temperature.
- Rinse devices using sterile or freshly prepared purified water
- Use automated drying cycle to dry devices or hand dry using absorbent, non-shedding cloth.
- The following cycle will be selected (at a minimum):

| | |
|---|---|
| **Prewash** | Cold Water + Hot Water for 2 minutes (tap water) |
| **Pulsed Enzyme** | Hot water for 11 minutes (tap water) with Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner (1/8oz of detergent/gallon of water) |
| **Rinse** | Purified water for 2 minutes |
| **Thermal Disinfection** | 90°C for 5 minutes |
| **Dry** | High Temperature for 30 minutes |

- Inspection: When unloading, visually inspect the devices and trays for complete removal of any debris. If the device or tray is not visually clean, repeat the automated cleaning cycle or use manual cleaning.
- Remove instruments from the Washer/Disinfector and wrap devices with sterilization wrap or place instrument in a sterilization pouch.

**Cleaning (Manual)**

***Warning: Movable components and blind holes require particular attention during cleaning.***

All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Manual Cleaning Instructions:

- Alcohol wipe the instruments.
- Bathe the instruments in an enzymatic solution for 20 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft brush.
- Rinse the instruments in cold water.
- Submerge the instruments in cleaning/ disinfection solution and sonicate for 15 min at 40°C (104°F).
- Scrub the instruments with a soft brush.
- Rinse the instruments in deionized water.
- Pat dry the instruments with a clean, disposable, absorbent Kimwipe or equivalent.
- Visually inspect the instruments for complete removal of any debris. If the device is not visually clean, repeat manual cleaning.

**Disinfection**

Disinfection solution may be used in accordance with the label instructions.

If automated cleaning is employed, a final rinse at 60° C for 20 minutes may be used to affect thermal disinfection.

**Maintenance and Repair**

***Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.***

***Warning: Do not attempt to repair any Extremity Medical instrument.***

If your Extremity Medical instrument requires repair or maintenance, return the instrument in the Extremity Medical box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Extremity Medical, LLC
300 Interpace Parkway
Building A, 2nd Floor
Parsippany, NJ 07054
**Attn: Extremity Medical Technical Services**

**Note**: Instruments returned to Extremity Medical must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

**Inspection and Function Testing**

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

**Packaging**

Instruments may be loaded into dedicated instrument trays, or in general-purpose trays. Wrap the trays using an appropriate method.

**Storage**

Implants should be stored in their original, undamaged packaging in a clean, dry environment at room temperature. Additionally, they should be kept away from direct sunlight, excessive heat, and moisture.

Instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

**Sterilization**

**Screws:**
Screws are intended for single-use only and are supplied sterile, packaged in double-blister packaging for optimal safety and sterility.

**Do not resterilize.**

**Instruments:**
Cleaned and inspected devices should be placed into the tray in their corresponding labeled locations as provided.

The total weight of the tray should not exceed 25 lbs.

Note: Only FDA-cleared sterilization barriers (e.g., wraps, pouches, or containers) should be used by the end-user for packaging terminally sterilized devices.

To achieve a sterility assurance level of SAL $10^{-6}$, Extremity Medical recommends the following parameters for the instruments:

Cycle: pre-vacuumed autoclave
- Temperature : 132 °C
- Time : 4 minutes exposure
- Drying : 30 minutes

Extremity Medical recommends following the recommendations of AAMI Guideline for Steam Sterilization ST79 which includes: physical monitoring of the cycle, including a chemical indicator external and internal of the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

**Do not** stack trays during sterilization. Stacking of trays may adversely affect sterilization and drying effectiveness.

**LIABILITY**
Extremity Medical declines all responsibility in case of deviation from the above mentioned directions.

**CUSTOMER SERVICE**
For further information regarding the MetaFore Small Screw System or a copy of the MetaFore Small Screw System Surgical Technique Manual, please contact Extremity Medical, LLC. or your local Extremity Medical Distributor.

**Manufactured For:**

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