EXTREMITY® MEDICAL

Omni Foot and Ankle Plating System

PACKAGE INSERT

DESCRIPTION OF THE MEDICAL DEVICE:

The implants, delivered non sterile, are:

- Plates in multiple sizes
- 2.3mm, 2.8mm and 3.5mm locking and non-locking solid screws
- 3.5mm headed and headless cannulated screws
- 4.0mm solid cortical screws
- Compression Posts
- Washers

MATERIAL

Plates: Unalloyed Titanium (ASTM F67)
Screws: Titanium alloy (ASTM F136)

The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899 and A564).

INDICATIONS FOR USE

The Omni Foot and Ankle Plating System is intended for use in internal fixation of arthrodeses, osteotomies, fractures and nonunions of the small bones of the foot & ankle including the fore-, mid-, and hind foot and ankle applications.

HOW SUPPLIED

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

CONTRAINDICATIONS

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

The Extremity Medical implants 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. Screws placed across the syndesmosis have a higher probability of fatigue failure of screws due to the repetitive motion across the syndesmosis.

Serious post-operative complications may occur from the implant 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.

LABEL SYMBOLS

REF	Catalog Number
LOT	Lot Number
QTY	Quantity
	Consult instructions for use
	Non-Sterile
	Do Not Re-Use
	Manufacturer
	Date of Manufacture
	Prescription Only

PRECAUTIONS

The implantation of screw and plate systems should be performed only by experienced surgeons with specific training in the use of this plate and 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. Implants 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 implants 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 implant is extremely important. The morbidity as well as patient weight, height, occupation and/or degree of physical activity should be considered.

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

All implants 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 implant 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 orthopedic prostheses.

IMPORTANT: The guidewires included in the Omni Foot and Ankle Plating System are not intended as implants. The guidewires are only intended for use as instruments to facilitate screw insertion.

MRI SAFETY INFORMATION

The Omni Foot and Ankle Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Omni Foot and Ankle Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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, disassembly and/or breakage of any or all implants;
- 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 non-union 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 Omni Foot and Ankle Plating System implants, use only the specialized Omni Foot and Ankle Plating System instrumentation. Do not use implants or instruments from any other System or manufacturer.

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

Before using Omni Foot and Ankle Plating System for the first time, the surgeon should be thoroughly familiar with the Omni Foot and Ankle Plating System Surgical Technique Manual as well as the functionality and assembly 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 Omni Foot and Ankle Plating

System implants and instruments, please refer to the Omni Foot and Ankle Plating System Surgical Technique Manual.

CARE AND HANDLING

Omni Foot and Ankle Plating System **implants and instruments are provided non-sterile** and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing

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

Point of Use

Warning: The following Extremity Medical instruments are intended for single use: guidewires, threaded wires and cannulated drills.

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 and soil and contaminants in and on the devices.

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 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 for complete removal of any debris. If the device 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 samples 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 until all traces of cleaning solution are removed.
- Pat dry the instruments with a clean, disposable, absorbent Kimwipe or equivalent.
- Inspect instruments to make sure they are visually clean.
- If the device is not visually clean, repeat manual cleaning cycle.

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, Repair and Servicing

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 or service any Extremity Medical instrument.

If your Extremity Medical instrument requires maintenance, repair or servicing, 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 or servicing.

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

Extremity Medical 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/Resterilization Procedure

In conformity with the requirements of standards ISO 17664, ISO 17665 and AAMI TIR12 the following sterilization procedures have been validated:

	U.S. Cycle	EU Cycle
Sterilizer Type	Pre-Vacuum	Pre-Vacuum
Minimum Temp.	132°C	134°C
Exposure*	4 min	3 min
Dry Time	30 minutes	

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

LIABILITY

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

CUSTOMER SERVICE

For further information regarding the Omni Foot and Ankle Plating System or a copy of the Omni Foot and Ankle Plating System Surgical Technique Manual, please contact Extremity Medical, LLC or your local Extremity Medical Distributor.

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