

Instructions for Use (IFU)

1. BEFORE USING PRODUCT

This booklet has been made to assist in using the Field Orthopaedics (FO) Bony Trauma Extremity System (BTES). It should not be used as a reference for surgical technique.

2. CAUTION

US Federal Law restricts this device to sale and use by, or on the order of, a physician.

3. GENERAL DESCRIPTION

The FO BTES is an extremity trauma system consisting of an Expanded Screw System, NX Extremity Nails, and a Hand Plating System.

3.1 Expanded Screw System

Comprises a range of implants and instruments for use in the fixation of fractures, osteotomies and arthrodesis, appropriate for the device. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate variations in patient size and sites of application.

3.2 NX Extremity Nail System

Comprises a range of threaded intermedullary nails and instruments for use in the fixation of fractures, osteotomies and arthrodesis, appropriate for the device. Variation in the implant size and diameter are intended to allow the implants to accommodate variations in patient size and site of application.

3.3. Hand Plating System

Is a rigid fixation system consisting of plates and screws in various configurations, shapes and sizes. These devices are to be used in the fixation of fractures, osteotomies and arthrodesis of the hand and other small bones. Plates are provided in a variety of shapes and sizes, and offer surgeons compression and locking hole designs. Key features of the plate range include anatomical contouring, locking screw, rotational correction, and compression holes. The Plate screws are offered in different diameters and lengths, with locking and non-locking designs.

3.4 Implant Materials

- All screws in the screw range are made with Titanium ELI (as per ASTM F136).
- All nails in the NX Extremity Nail range are made with Titanium ELI (as per ASTM F136).
- All plates are available as identical configurations in both Titanium ELI (as per ASTM F136) and CP Titanium (ISO 5832-2).
- The instrumentation is made from medical grade stainless steel, anodized aluminium and marked with epoxy resin.

Refer to the package label for the materials.

3.5 Implant colour

All implants are colour anodized for the purpose of distinguishing sizes of designs. The table below describes the colour scheme in relation to screw and plate size.

Colour Anodised	Headed Screw Diameter	Headless Screw Diameter	Nail Diameter	Plate Thickness
Silver	1.2 mm	-	-	0.6 mm
Seafoam	-	1.5 mm	-	1.0 mm
Light Blue	1.5 mm	-	-	1.2 mm
Gold	2.0 mm	2.0 mm	2.0 mm	
Magenta	2.5 mm	2.5 mm	2.5 mm	
Teal	3.0 mm	3.0 mm	3.0 mm	
Purple	3.5 mm	3.5 mm	3.5 mm	
Bronze	4.0 mm	4.0 mm	4.0 mm	
Green	4.5 mm	4.5 mm	-	
Grey	5.0 mm	5.0 mm	5.0 mm	
Grey	7.0 mm	7.0 mm	-	

4. INDICATIONS FOR USE

The FO BTES Screw and NX Extremity Nail range are intended for use in the fixation of fractures, osteotomies, and arthrodesis, appropriate for the size of the device, in adults and in both, children (2-12 years) and adolescents (12-21 years), in which growth plates have fused or in which growth plates will not be crossed by screw fixation. The FO Fenestrated Screws are not for the delivery of tissue bone graft, bone cement or bone void filler.

The FO BTES Plate Range and Plate Screws are intended for use in the fixation of fractures, osteotomies and arthrodesis of the hand and other small bones. The system may be used in both adults and paediatric patients.

4.1 CE Marked Regions Indications for Use*

The FO BTES Screw and NX Extremity Nail range has the following indications in CE Marked Regions:

- The FO BTES Screw and NX Extremity Nail range is intended for fixation of fractures and osteotomies of small bones in the foot and hand.

**Note: The limited indications only should be considered for the use of the FO BTES Screw and NX Extremity Nail range in CE marked regions.*

5. CONTRAINDICATIONS

Use of the FO BTES is contraindicated in the following,

- Cases of inflammation,
- Cases of active or suspected sepsis / infection and osteomyelitis,
- Patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

1. Acute or chronic infections, local or systemic.
2. Vascular, muscular or neurological pathologies that compromise the concerned extremity.
3. All concomitant pathologies that could affect the function of the implant.
4. Patients with insufficient bone/inadequate bone quantity.
5. Osteopathies with reduced bone substance that could affect the function of the implant.
6. Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.
7. Patients with metal allergies and foreign body sensitivity or having known allergies that may cause adverse events both peri- and post-operatively.
8. Patients with limited blood supply.
9. Whenever the use of the implant comes into conflict with the anatomical structures of physiological status.
10. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt unfused growth plate.
11. Patients with unstable physical and/ or mental health conditions.
12. Combination of this implant with implants of another origin is contraindicated.

Other Medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

1. The presence of tumors.
2. Congenital abnormalities.
3. Immunosuppressive pathologies.
4. Increased sedimentation rates that cannot be explained by other pathologies.
5. Increased leukocyte (WBC) count.
6. Pronounced left shift in the differential leukocyte count.

6. POTENTIAL COMPLICATIONS & ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

1. Loosening, deformation or fracture of the implant.
2. Acute post-operative wound infections and late infections with possible sepsis.
3. Thrombosis and embolism.
4. Wound hematoma and delayed wound healing.
5. Temporary and protracted functional neurological perturbation.
6. Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
7. Corrosion with localized tissue reaction and pain.

All possible complications listed here are not typical of the FO BTES but are in principle observed with any implant. Promptly inform FO as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide FO with the extracted implant(s) in a cleaned, disinfected and sterile condition. FO cannot accept any other returns of used implants.

It is the responsibility of the surgeon to ensure patients have adequate post-operative management. Surgeon's postoperative care instructions must be strictly adhered to by the patient to avoid adverse loads on the implant/s that may lead to loosening, migration, or failure of the implant.

In the case of complications, it might be necessary to remove the implants. For removal follow the surgical technique using the indicated screwdriver. Make sure that the screwdriver/screw head connection is precisely aligned in the axial direction.

All implant components are intended for one single application in a single patient. Implants that were used in a patient and removed, must be discarded following the local requirements.

7. WARNINGS AND PRECAUTIONS

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. The FO Micro Screws, FO Pins and K-Wires, and FO drill bits are intended for single use only; re-use may cause product failure and could lead to disease transmission.
5. Instruments, guide wires and screws are to be treated as sharps.
6. Do not use other manufacturer's instruments or implants in conjunction with the FO BTES.

8. MRI SAFETY INFORMATION

- These devices have not been evaluated for safety and compatibility in the MR environment.
- They have not been tested for heating, migration or image artefact in the MR environment.
- The safety of the FO BTES in the MR Environment is unknown.
- Scanning a patient who has these devices may result in patient injury.

9. MAINTAINING DEVICE EFFECTIVENESS

1. The surgeon should have specific training, experience, and thorough familiarity with the use of screws, fixation pins and wires.
2. The surgeon must exercise reasonable judgment when deciding which type to use for specific indications
3. *The* FO BTES is not intended to endure excessive abnormal functional stresses.
4. The FO BTES is intended for temporary fixation only until osteogenesis occurs.
5. Failure to use dedicated, unique FO BTES 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 screws, fixation pins and wires prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
7. FO recommends the use of FO products in a sterile environment.

10. CLEANING & DECONTAMINATION

Before being used for the first time and each use thereafter (if reusable), all devices and instruments must be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field.

The instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents.

It is the user's responsibility to ensure that:

1. The implants and instruments are completely sterile when used.
2. User sterilizers and sterilization processes are validated according to applicable Standards, regularly serviced and inspected, including all instruments and accessories used in combination, according to manufacturer's specifications.
3. Manufacturer's recommended parameters are maintained for each cycle. Refer to the FO document RPIN00001 Reprocessing Instructions - USA for validated, in-depth cleaning, disinfecting, and sterilization instructions.

Download the most up-to-date version available at www.fieldorthopaedics.com/brochures.

10.1 Point of Use

The cleaning of instruments should begin at the point of use and continue during the surgical procedure to prevent drying of blood, soil, and debris on the surface and within lumens.

1. The instruments should be kept free of debris and blood during the surgical procedure. If possible, the instruments should be wiped clean using a sterile, water-moistened sponge. Care must be taken that the sponge is not used on the tissues of the patient.
2. Instruments with lumens should be cleared using the FO cleaning stylet and flushed with a sterile, water-filled syringe to remove blood and debris and prevent drying of the gross soil.
3. Instruments that may not be used for the remainder of the procedure must be immediately soaked in a basin containing sterile water.
4. Prolonged exposure to saline should be avoided to minimize the potential for corrosion.

10.2 Pre-Soaking

1. Pre-soak the instruments with an enzymatic solution, such as Enzol[®] by Advanced Sterilization Products[®], for a minimum of 1 minute to moisten and loosen the soil, thus making the cleaning step more efficient.
2. Rinse thoroughly to ensure the removal of any potentially harmful residue from the soaking solution.
3. When pre-soaking the instruments, refer to the solution manufacturer's written instructions for the correct dilution, temperature, and soak time.

10.3 Sorting and Disassembling

Upon arrival in the decontamination area, remove the contaminated items from their transport containers and prepare for cleaning. Check all instruments for damage and corrosion prior to cleaning. If a component is lost, damaged, or corroded, contact FO directly or your local representative for a replacement.

If the device consists of more than one component and is designed to be disassembled, this device must be disassembled prior to cleaning and disinfection. Keep non-interchangeable components of assemblies together to ensure correct

reassembly.

10.4 Cleaning

For reusable medical devices, the most important step in decontamination is thorough cleaning and rinsing. Cleaning primarily removes rather than kills microorganisms. The factors that contribute to cleanliness are:

1. Quality of water.
2. Quality, concentration, and type of cleaner.
3. Washing method.
4. Rinsing and drying.
5. Preparation of the contaminated devices.
6. The time, temperature, load capacity of the equipment being used.
7. Operator performance.

Many types of soil could be present on a device, but dried blood is especially difficult to remove. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to clean. It must be rehydrated and then washed.

When using ultrasonic cleaning, to prevent coagulation do not exceed temperatures of 140°F (60°C) and conduct for a period of 10 minutes. Instruments are optimally cleaned in water and detergent solutions at temperatures between 80°F and 110°F (27°C to 44°C), but not to exceed 140°F (60°C).

When cleaning instruments, use a brush, cloth, or sponge, and a low foaming, pH neutral detergent solution, such as Renu Klenz™, or equivalent. Use a soft bristle brush to remove all traces of blood and debris; pay close attention to textured areas, crevices, blind holes, hinges, joints, and cannulated parts.

When cleaning an articulating instrument, fully immerse the instrument in the detergent and remove traces of blood and debris with a soft bristle brush. If the instrument can be articulated, retract and open the instrument in the detergent repeatedly.

Heavy instruments should not be placed on top of delicate instruments and small components should be placed in baskets.

Rinse components under warm or hot flowing water for at least one minute, with direct contact of each surface for a minimum of 10 seconds. Repeat this step using purified water.

Dry the internal areas of instruments using compressed air. When drying instruments with concave features, place the concave surface down to facilitate draining.

On completion of cleaning, it is advised to reassemble any devices that were disassembled prior to placing back in the tray

When reassembling and stocking the tray it is important to take note and ensure that all implants and instruments are put in the correct locations and are not sitting proud. Prior to closing the lid of the tray it is a requirement to review the placement and position of all devices and if any product is not residing in the correct location it is corrected. When closing the tray lid, if the operator feels resistance, it is important to stop, gently remove the lid and review the placement of the tray contents. If any devices are in the incorrect position or sitting proud this is to be corrected prior to attempting to close the lid again. If after all products are placed in the correct position there is ongoing issues with lid closure, please contact a FO representative.

10.5 Cleaning Verification

Inspect all instruments before sterilizing to ensure the complete removal of all soil from surfaces, tubes, holes, and moveable parts. The ANSI/AAMI ST79 acceptance standard for cleanliness is visibly clean.

Some surfaces of an instrument can be visually obstructed which prevents this verification. If a borescope is not available for inspection, checking for blood can be accomplished by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, then blood is present, and cleaning must be repeated.

Rinse instruments thoroughly after using hydrogen peroxide solution.

11. STERILIZATION AND HANDLING

All FO BTES implants and instruments are supplied CLEAN and NONSTERILE and MUST be sterilized prior to use.

FO recommends the use of steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle after removal of all protective packaging and labelling. Instruments shall be sterilized in the mounting condition as stored on the tray (i.e. if the brackets or recessions in the tray are designed to accommodate multi-component instruments in their assembled state) there is no need to disassemble these instruments for sterilization. The use of an FDA cleared sterilization wrap, such as the KimGuard® Sterilization Wrap, is recommended. DO NOT stack the FO supplied trays.

Instruments that do not have a designated place in FO supplied trays can be placed in a standard sterilisation tray as per local sterilisation procedure for loose tools and accessories.

Autoclaves should comply with the requirements of, and be validated, maintained and checked in accordance with EN 285/ EN 13060, EN ISO 17665, and ANSI AAMI ST79.

Method*	<ul style="list-style-type: none">Moist heat sterilization according to EN ISO 17665 and ANSI/AAMI ST79
Cycle Type	<ul style="list-style-type: none">Pre-Vacuum (Pre-Vac)
Cycle Temp.**	<ul style="list-style-type: none">132°C-138°C (270°F-280°F)
Exposure Time**	<ul style="list-style-type: none">3-4 minutesExposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc.
Dry Time*	<ul style="list-style-type: none">40 minutes (minimum, in chamber)
Cool Time	<ul style="list-style-type: none">60 minutes (minimum, at room temperature)

*FO has validated the above sterilization cycle per ISO17665-1 and has the data on file. The validated sterilization parameters meet the minimum requirements per AAMI ST79. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

**The worst case autoclave cycle has been validated by FO as being capable of achieving sterile medical devices; however autoclave design and performance can affect the efficacy of the process. Healthcare facilities should validate the process that they use, employing the actual equipment and operators that routinely process the devices.

***The drying time varies due to load configuration, wrapping method and material. It is the hospital's responsibility to validate the appropriate drying time with the sterilization equipment used.

The following FO BTES implants and instruments are for SINGLE USE ONLY, and not reusable:

- ALL FO Screws, FO Plates, FO Pins and Wires, and FO Drill bits.

All other FO BTES instruments are reusable.

The epoxy coated components of the FO BTES have been validated to be safe for up to 10 sterilization cycles. FO cannot guarantee the safety and efficacy of the components past this limit.

12. RECEIVAL, INSPECTION & FUNCTIONAL TESTING

Upon receipt, FO recommends that the kits be inspected for damage and dislodgement of any individual parts for the system. Any implants or instruments in the kit found to be damaged or displaced during transport should be discarded and replacements ordered. The rejected goods must be returned to FO Pty Ltd. or their distribution partner within ten working days.

- Instruments should be inspected for damage and wear before use.
- Check for smooth movement of assemblies without excessive play.
- Locking mechanisms should attach and detach easily.
- Cutting edges should be free of nicks and have a continuous edge.
- Long slender instruments should be straight and free of distortion.
- If resistance is met when closing the lid, cease usage and contact a FO Representative

End of functional life is normally determined by wear and damage due to use.

13. PACKAGING

FO devices should be accepted only if the factory packaging and labelling arrive intact. Contact Customer Service if the package has been opened or altered.

14. SURGICAL TECHNIQUE

FO Screws, NX Nails, Plates, Pins and K-Wires should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Surgeons are advised to review the product specific surgical technique prior to performing any surgery.

FO provides detailed surgical techniques in print and electronic formats. Refer to the FO *product specific Surgical Technique* for illustrated procedural instructions.

Download the most up-to-date version available at www.fieldorthopaedics.com/brochures.

15. STORAGE CONDITIONS.

Store away from moisture and direct heat.

16. PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labelling, or performance to FO immediately. FO should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact FO (info@fieldorthopaedics.com) for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

17. SYMBOLS



Authorised Representative

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Manufacturer

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