BONY TRAUMA EXTREMITY SYSTEM (BTES)

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 a Screw Range (Expanded Screw System, NX Nail System) and Plate Range and Plate Screws (Hand Plating System).

Products listed may not be available in all markets. Please contact Field Orthopaedics if you have any questions about the availability of products in your area.

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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. Variations 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 Nail System

Comprises a range of threaded intramedullary nails and instruments for use in the fixation of fractures, osteotomies and arthrodesis, appropriate for the device. Variations in the implant size and diameter are intended to allow the implants to accommodate variations in patient size and site of application. The NX Nail implants include a Sterile and Non-sterile option.

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 Materials

- All screws in the screw range are made with Titanium ELI (as per ASTM F136).
- All nails in the NX Nail System range are made with Titanium ELI (as per ASTM F136).
- All plates are made 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	-

4. INDICATIONS FOR USE

The Field Orthopaedics BTES Screw Range is 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 bone graft, bone cement or bone void filler.

The Field Orthopaedics 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.

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 tumours.
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 exists. 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 in the event a complication occurs or in the event of a complaint or adverse event in order to report the occurrence and to determine appropriate next steps. To assist with investigation of the event, where practicable, please retain the device and its packaging. Further processing may impact the device and the quality of the investigation and should not be undertaken without prior consultation with FO.

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 in accordance with 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/nail 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 Screws, NX Nails, Plates, 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/nails are to be treated as sharps.
6. FO branded instrumentation is recommended for use in conjunction with FO BTES Implants.

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 fixation until osteogenesis occurs.
5. Failure to use appropriate FO 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. Sterile product should be carefully inspected for package integrity and expiry date prior to use. Sterile packaging should not have rips or tears, and the seal should be intact. Product that is defective, damaged or where the sterile barrier has been compromised should not be used.
7. Carefully inspect the FO Screws, NX Nails, Plates, Pins and K-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.
8. FO recommends the use of FO products in a sterile environment.

10. RECEIVAL, INSPECTION & FUNCTIONAL TESTING

Upon receival, inspect the product for damage and dislodgement of any individual parts from the system. Any implants or instruments in the kit found to be damaged or displaced during transport should be discarded and replacements ordered.

For sterile products, do not use if the seal has been broken or prematurely opened. Do not use past the use by date indicated on the label.

Devices should only be accepted if the factory packaging and labelling arrive intact. The rejected goods must be returned to FO. Instruments should be inspected for damage and wear before use.

1. Check for smooth movement of assemblies without excessive play.
2. Locking mechanisms should attach and detach easily.
3. Cutting edges should be free of nicks and have a continuous edge.
4. Long slender instruments should be straight and free of distortion.
5. 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.

11. PACKAGING

FO devices should be accepted only if the factory packaging and labelling arrive intact. Sterile product should be inspected before use and product should not be used if seal has been broken or prematurely opened. Contact Customer Service if the package has been opened or altered.

12. NON-STERILE DEVICE: STERILIZATION AND HANDLING

All Non-sterile FO BTES implants and instruments are supplied CLEAN 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*	• Moist heat sterilization according to EN ISO 17665 and ANSI/AAMI ST79
Cycle Type	• Pre-Vacuum (Pre-Vac)
Cycle Temp.**	• 132°C-138°C (270°F-280°F)
Exposure Time**	• 3-4 minutes • Exposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc.
Dry Time*	• 40 minutes (minimum, in chamber)
Cool Time	• 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 pro cess 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, NX Nails, Plates, Pins and K-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.

13. NON-STERILE DEVICE: 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 current version available at www.fieldorthopaedics.com/brochures.

13.1 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.

13.2 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.

13.3 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, it must be disassembled prior to cleaning & disinfection. Keep non-interchangeable components of assemblies together to ensure correct reassembly.

13.4 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° 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.

13.5 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.

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 product specific Surgical Technique for illustrated procedural instructions.

Download the current version available at www.fieldorthopaedics.com/brochures.

15. STORAGE CONDITIONS.

Store away from moisture and direct heat.

16. CONTACT

Please contact the FO commercial team for product inquiries, cleaning instructions and surgical techniques, or to report a complaint or adverse event.

Commercial Team: sales@fieldorthopaedics.com

17. GLOSSARY OF SYMBOLS

Symbol	Standard	Ref & Title	Description
	ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements	5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
		5.1.6 Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified
		5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information
		5.7.7 Medical Device	Indicates the item is a medical device
		5.4.2 Do Not Re-use	Indicates a medical device that is intended for one single use only
		5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
		5.2.4 Sterilized	Indicates a medical device

		using irradiation	that has been sterilized using irradiation
		5.2.8 Do Not Use if Package is Damaged and Consult Instruction for Use.	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
		5.4.3 Consult Electronic Instructions for use	Indicates the need for the user to consult the instructions for use
		5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured
		5.1.1 Manufacturer	Indicates the medical device manufacturer
		5.1.9 Distributor	Indicates the entity distributing the medical device into the locale
		5.1.4 Use by Date	Indicates the date after which the medical device is not to be used
		5.3.4 Keep Dry	Indicates a medical device that needs to be protected from moisture
		5.2.12 Double Sterile Barrier System	Indicates two sterile barrier systems
QTY	N/A	N/A	Quantity
℞ Only	21 CFR 801.109 - Code of Federal Regulations Title 21	(b)(1) Prescription Only	United States Federal Law restricts this device to sale and use by, or on the order of, a physician.

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