ZIMMER BIOMET

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UNITUS 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 UNITUS Staple System consists of sterile, single use orthopedic implants and instruments. The single use bone fixation compression staples are intended to be permanently implanted. The staples are made out of Nickel Titanium (Nitinol) available in two or four legged designs with multiple combinations of bridge width, leg lengths, and cross sections to accommodate various anatomies. The staple implant applies compression across the bone segments when the staple implant legs are released from an insertion system that applies opposing forces to the staple legs to keep them parallel during implantation. The staple is provided pre-loaded on a disposable inserter.

The sterile staple kit contains all the instruments necessary for a single staple implantation procedure. These instruments include: an inserter with a preloaded staple implant, locating pin, drill guide for creating appropriately spaced holes, and drill bits to create appropriately sized holes in the bone for staple implantation. These components will be provided in a sterilized package to accommodate a range of anatomical sites and are discarded after the procedure is complete, removing the need for any facility reprocessing.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Intended Use
The implants are intended for bone fixation and management of fracture and reconstructive surgery.

Indications for Use
The UNITUS Staple System is indicated for:
- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small fragments of bone (i.e., small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and in flat bone such as the pelvis and scapula.

Material
Nitinol

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g., surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly

Contraindications
General contraindications for the use of these implants include:
- Comminuted bone surface that would militate against staple placement.
- Pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Do not use for surgeries other than those indicated

Warnings and Potential Risks
The surgeon should be aware of the following:
- The implants cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods (casting, splints, etc.) be maintained until bone healing has occurred (4–6 weeks).
- Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of a fracture line.
- Any additional processing or reprocessing of the implant may affect the shape memory properties of the nitinol, changing or otherwise reducing the effectiveness of the implant.
- Reprocessing of any instrument may affect its compatibility with other instruments and the usability of the reprocessed instrument.
- If sterilization is compromised prior to insertion, a different sterile implant or associated instrument(s) will need to be used. Product cannot be re-sterilized due to the heat lability of the polycarbonate materials.
- Prior to use, check the product expiration date and verify the packaging integrity. Product with damaged packaging should be discarded and must not be used, as sterility cannot be assured.
- Zimmer Biomet has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances

Possible Adverse Effects
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, malunion, non-union, bone damage and damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/ hypersensitivity reactions, and side effects associated with implant failure and hardware prominence.

MRI Safety Information

A patient with the Zimmer Biomet Nitinol Staples may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Zimmer Biomet Nitinol Staples
Nominal value(s) of Static Magnetic Field (T)	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-received coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 22 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

An MR Patient Implant Card is available and can be found on https://zb-eifu.info/

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Special Operating Instructions
1. Determine the correct implant size by measuring with a standard surgical ruler.
2. Open the corresponding implant and instrument kit.
3. While ensuring full reduction, place the drill guide across the fusion site with all prongs touching bone. Drill the first hole using the drill bit provided in the kit until the appropriate depth is reached, using fluoroscopy to monitor depth if needed.
4. Insert a locating pin into the first hole and, while ensuring full reduction, repeat step 3 for the second hole. Optional: Insert another locating pin into the second hole. The drill guide can be removed leaving the locating pins in place to mark the position of the drill holes. If desired, create a 1.0–1.5 mm trough in line with the two drill holes so that the implant can be recessed.
5. Remove the drill guide, locating pins, and drill and align the preattached implant and inserter over the implant site.
6. Insert the implant as far as possible into the predrilled holes. Note: to ensure proper placement, fluoroscopy may be used prior to releasing the implant.
7. Pull the inserter slide back (proximal) to disengage the implant and slide the inserter off the implant (move inserter perpendicular to implant bridge).
8. Align the tamp at the distal end of the inserter with the bridge of the implant and lightly tamp as needed to fully seat the implant.
9. Repeat steps 1-8 for each additional implant used. Tip: if implants are placed at 90-degrees to each other, stagger them to ensure unobstructed insertion.

For complete instructions regarding the proper use and application of all UNITUS Staple System, please refer to the Surgical Technique Manual (provided with the system).

Sterile device
STERILE R Sterilized using irradiation

Single-Use Device
Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g., cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, re-use or reprocessing of single-use devices may create a risk of contamination e.g., due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Storage
Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used if the expiration date. Sterile devices should be carefully examined prior to opening to ensure that packaging integrity has not been compromised. If the sterile packaging has been compromised, do not use.

Retrieval and Analysis of Removed Implants
The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Zimmer Biomet customer service for return of removed implants.

Implant Removal
- Expose the site and the bridge of the implant.
- Using forceps grasp the center of the implant and remove. If the implant is recessed, then use an elevator to lift the implant bridge and then use forceps to remove the implant. If the implant is solidly connected, cut the bridge with wire cutters and twist and remove each staple leg.

Customer Service
For further information regarding the UNITUS Staple System or a copy of the Surgical Technique Manual, please contact Zimmer Biomet, LLC or your local Zimmer Biomet Distributor.

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Symbols Glossary		
Symbol	**Title/Standard**	**Meaning**
REF	ISO 15223-1 5.1.6 Catalogue Number	Indicates the *manufacturer's catalogue number* so that the *medical device* can be identified
LOT	ISO 15223-1 5.1.5 Batch Code	Indicates the *manufacturer's* batch code so that the batch or lot can be identified
	ISO 15223-1 5.1.3 Date of Manufacture	Indicates the date when the *medical device* was manufactured
	ISO 15223-1 5.1.4 Use-by date	Indicates the date after which the *medical device* is not to be used
STERILE R	ISO 15223-1 5.2.4 Sterilized using irradiation	Indicates a *medical device* has been sterilized using irradiation
	ISO 15223-1 5.4.2 Do not re-use	Indicates a *medical device* that is intended for one *single use* only
	ISO 15223-1 5.2.8 Do not use if package is damaged and consult instructions 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
	ISO 15223-1 5.4.3 Consult instructions for use	Indicates the need for the user to consult the *instructions for use*
	ISO 15223-1 5.1.1 Manufacturer	Indicates the *medical device manufacturer*
UDI	ISO 15223-1 5.7.10 Unique device identifier	Indicates a carrier that contains unique device identifier information
CC	ISO 15223-1 5.1.11 Country of manufacture	To identify the country of manufacture of products
	ISO 15223-1 5.2.12 Double sterile barrier system	Indicates two *sterile* barrier systems
Rx only	21 CFR 801.109b Prescription Only	Indicates that a practitioner licensed by the law of the state in which the practitioner practices to use or order the use of the device
QTY	Quantity	Indicates the quantity of devices
MATL	Material	Indicates the material of the device
	ISO 15223-1 5.1.9 Distributor	Indicates the entity distributing the medical device into the locale
NON STERILE	ISO 15223-1 5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	ISO 15223-1 5.7.3 Patient Identification	Indicates the identification data of the patient
	ISO 15223-1 5.7.4 Patient Information Website	Indicates a website where a patient can obtain additional information on the medical product
	ISO 15223-1 5.7.5 Health care centre or doctor	Indicates the address of the health care centre or doctor where medical information about the patient may be found
31	ISO 15223-1 5.7.6 Date	Indicates the date that information was entered or a medical procedure took place