ZIMMER BIOMET
Moving You Forward.™

Surgical Technique

UNITUS™ Staple System

UNITUS STAPLES

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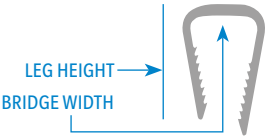
The UNITUS™ Staple System consists of sterile, single use orthopedic implants and instruments. The single use bone fixation compression staples are intended to be permanently implanted. The staples are made out of Nickel Titanium (Nitinol) available in multiple combinations of bridge width, leg lengths, 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 preloaded on a disposable inserter.

UNITUS Staple Kit Part Numbers



PART NUMBER	DECRIPTION	BRIDGE WIDTH	LEG LENGTH	LEG LENGTH	DRILL DIAMETER	LOCATING PIN DIAMETER
15ZB00102	8X8mm	8mm	8mm	8mm	2.0mm	1.8mm
15ZB00103	10X8mm	10mm	8mm	8mm	2.0mm	1.8mm
15ZB00105	15X12mm	15mm	12mm	12mm	2.0mm	1.8mm
15ZB00106	15X15mm	15mm	15mm	15mm	2.0mm	1.8mm
15ZB00108	18X18 mm	18mm	18mm	18mm	2.7mm	2.4mm
15ZB00109	20X18mm	20mm	18mm	18mm	2.7mm	2.4mm
15ZB00110	20X20mm	20mm	20mm	20mm	2.7mm	2.4mm
15ZB00111	25X20mm	25mm	20mm	20mm	2.7mm	2.4mm
15ZB00116	10X13X15mm	10mm	13mm	15mm	2.0mm	1.8mm
15ZB00117	15X15X18mm	15mm	15mm	18mm	2.0mm	1.8mm
15ZB00119	30X20mm	30mm	20mm	20mm	2.7mm	2.4mm

Every UNITUS Staple kit is provided sterile and contains all instruments necessary for a single staple implantation procedure:

- Inserter with preloaded staple implant
- Locating pins • Drill guide • Drill bit

Indications and Contraindications

Indications for Use

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- 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.

Contraindications

- 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 thepolycarbonate 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 and Tyber Medical have not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Prior to use of the system, the surgeon should refer to the product Instructions For Use for warnings, precautions, indications, contraindications and adverse effects. Instructions For Use are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique.

Preparation

Preparation

Make an incision and gain exposure to the desired area. Tarsometatarsal fusion is demonstrated in this surgical technique.

Step 1: Size and Select Implant

To determine the correct implant size, measure the implant size with a standard surgical ruler and select corresponding staple kit.

Step 2: Prepare Implant Site

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. The drill is laser marked with three 2-mm bands denoting 10, 15, and 20mm drill depth (Figure 1). Note: the drill uses a standard AO drill connection.

Figure 1

Insert a locating pin into the first hole and, while ensuring full reduction of the fracture site, repeat step for the second hole (Figures 2A and 2B).

Optional: Insert the additional locating pin into the second hole (Figures 3A and 3B). 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.

Step 2. Prepare Implant Site

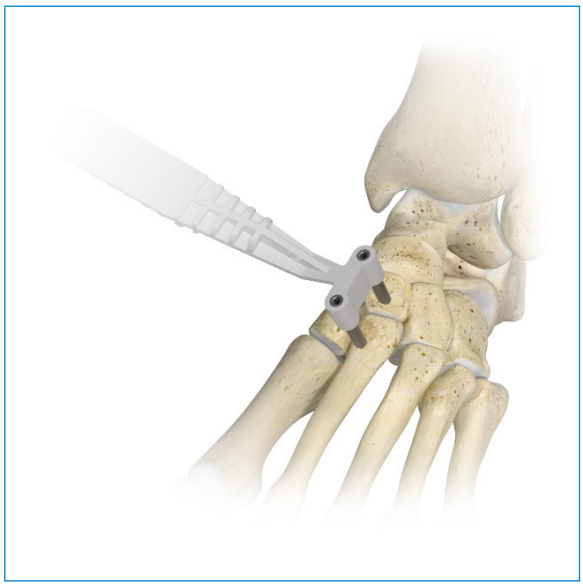


Figure 2a

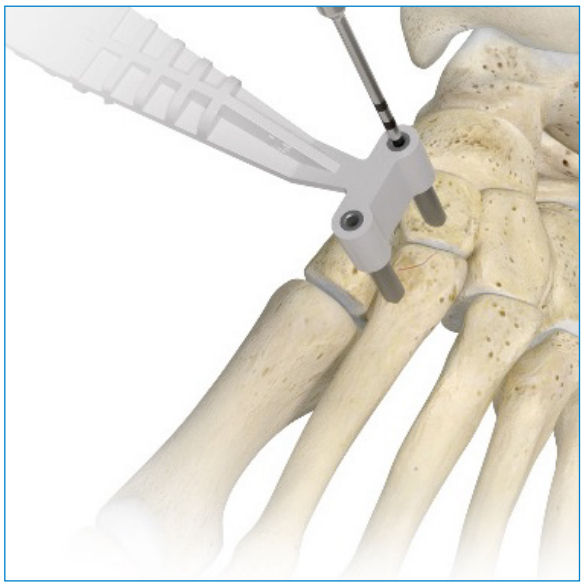


Figure 2b

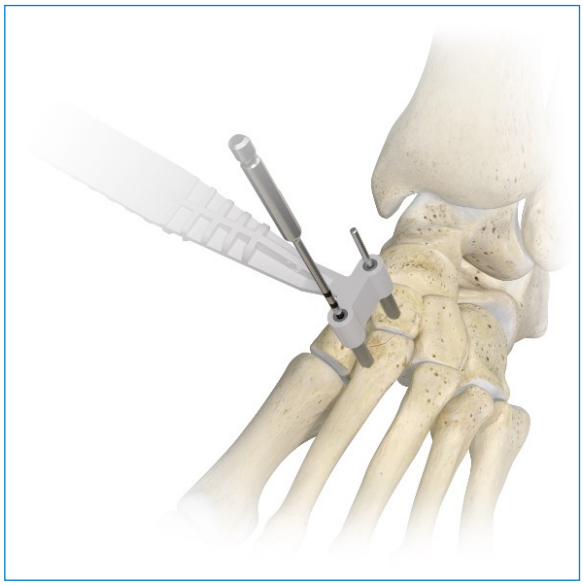


Figure 3a

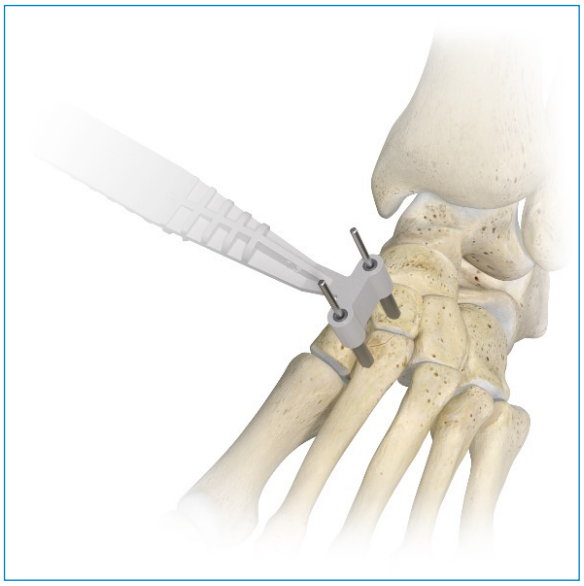


Figure 3b

Step 3: Implantation

Remove the drill guide, locating pins, and drill and align the preattached implant and inserter over the implant site.

Insert the implant as far as possible into the predrilled holes (Figure 4). **Note:** to ensure proper placement, fluoroscopy may be used prior to releasing the implant.

Pull the inserter slide back (proximal) while maintaining the inserter/staple position to disengage the implant and slide the inserter off the implant (move inserter perpendicular to implant bridge)(Figures 5a and 5b).

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 (Figure 6).

Repeat steps 1-3 for each additional implant used.
Tip: If implants are placed at 90-degrees to each other, stagger them to ensure unobstructed insertion.

Figure 4

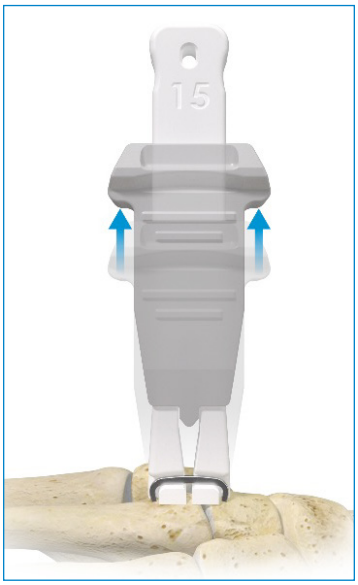


Figure 5a

Figure 5b

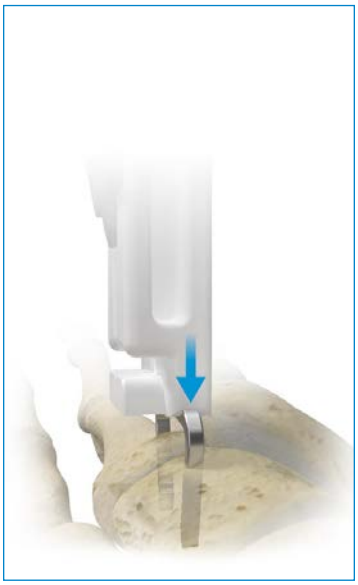


Figure 6

Optional: Implant Reattachment and Removal

Optional: Implant Reattachment to Inserter

Ensure the inserter slide is fully proximal allowing the inserter legs to collapse fully (Figure 7A). Place the distal prongs of the inserter underneath the staple bridge as shown(Figure 7B).

Before proceeding, ensure the staple is held securely either in bone or grip with fingers to ensure staple does not spring out during reattachment. Push the inserter slide distal until the implant is fully seated, with legs splayed out parallel (Figure 8).

Optional: Implant Removal

Using forceps grasp the center of the implant and pull up. If possible, reattach the inserter using the **Implant Reattachment to Inserter** step defined in the technique guide to expand the staple legs parallel and then remove. Alternatively, 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.

Figure 7a

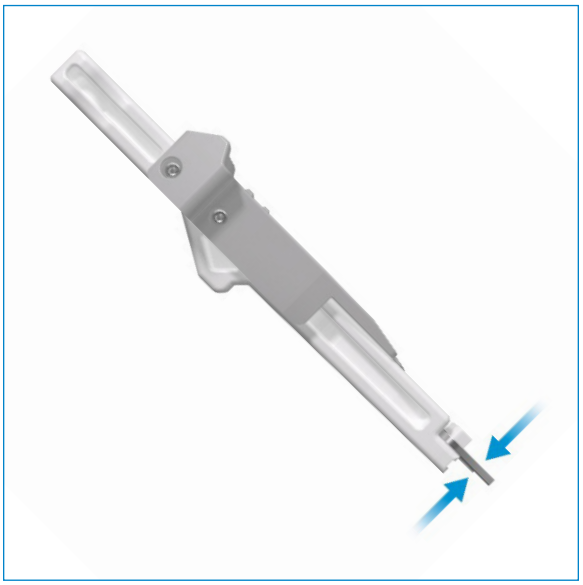


Figure 7b

Figure 8

This material is intended for health care professionals. For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit zimmerbiomet.com for additional product information.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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Legal Manufacturer
Tyber Medical LLC
83 South Commerce Way, Ste. 310
Bethlehem, PA 18017
Phone: (866) 761-0933
Fax: (866) 889-9914
www.tybermedical.com

Zimmer Biomet, Inc.
1800 W. Center Street
Warsaw, IN 46580 USA
Tel: 1-800-348-2759
Fax: 574-372-3968
www.zimmerbiomet.com