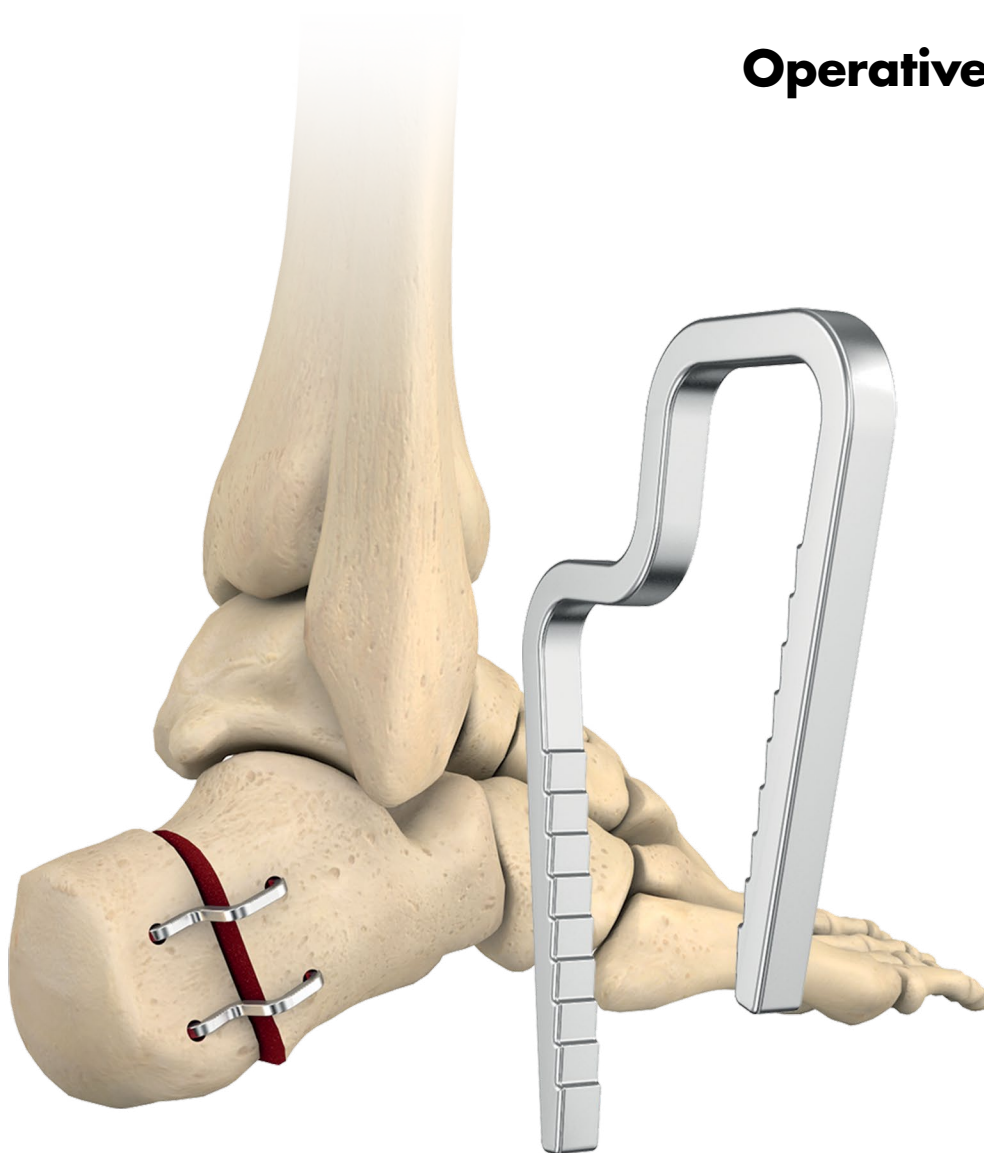


EasyStep™

Operative technique



EasyStep

EasyStep - Step staple

This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions (ES-ADI-1 and ES-ADI-2).

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See package insert (Instruction for Use instruments: V15011 and Implant: V15103) for a complete list of potential adverse effects, contraindications, warnings and precautions.

The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

The EasyStep system should only be used for the fixation of bone fragments or osteotomies in which there is an offset ranging from 4 to 12 mm

Warning information:

- Never re-sterilize EasyStep implants. Any application of extensive heat would compromise the biomechanical features of the devices possibly resulting in implant failure.

MRI safety information:

Non-clinical testing has demonstrated EasyStep is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 T
- Maximum spatial field gradient of 3000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, EasyStep is expected to produce a maximum temperature rise of less than 2.8 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 17.5 mm from EasyStep when imaged with a spin echo pulse sequence and a 3 T MRI system.



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Indications, precautions & contraindications

Indications

The EasyStep system is intended for bone fragment and osteotomy fixation of the foot in adult patients. Indications include:

- Bone fragment fixation
- Osteotomy fixation

Precautions

Implant selection and sizing: the correct selection of the bone fixation appliance is extremely important. Failure to use the appropriate appliance may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

Never resterilize EasyStep Step Staple. Single use devices cannot be reused, as they are not designed to perform as intended after the first usage. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization may compromise the integrity of the design and/or materials leading to diminished safety, performance and/or compliance with relevant specifications.

See package insert for warnings, precautions, adverse effects and other essential product information.

Contraindications

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

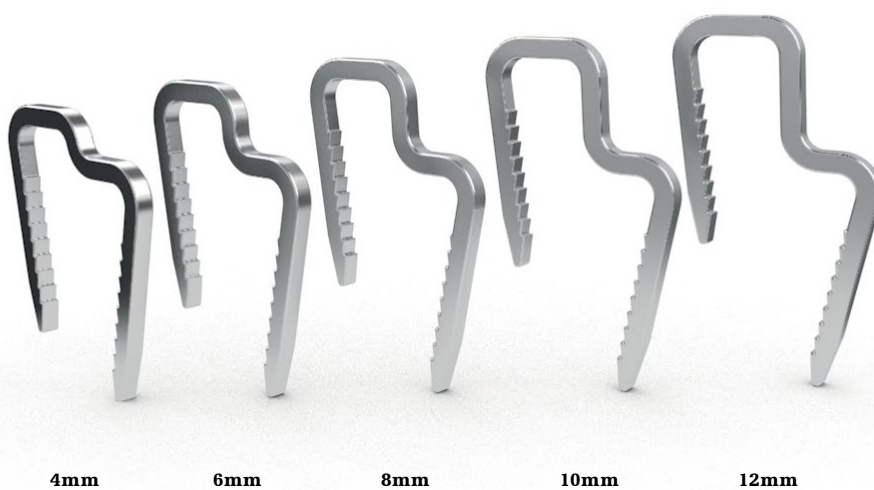
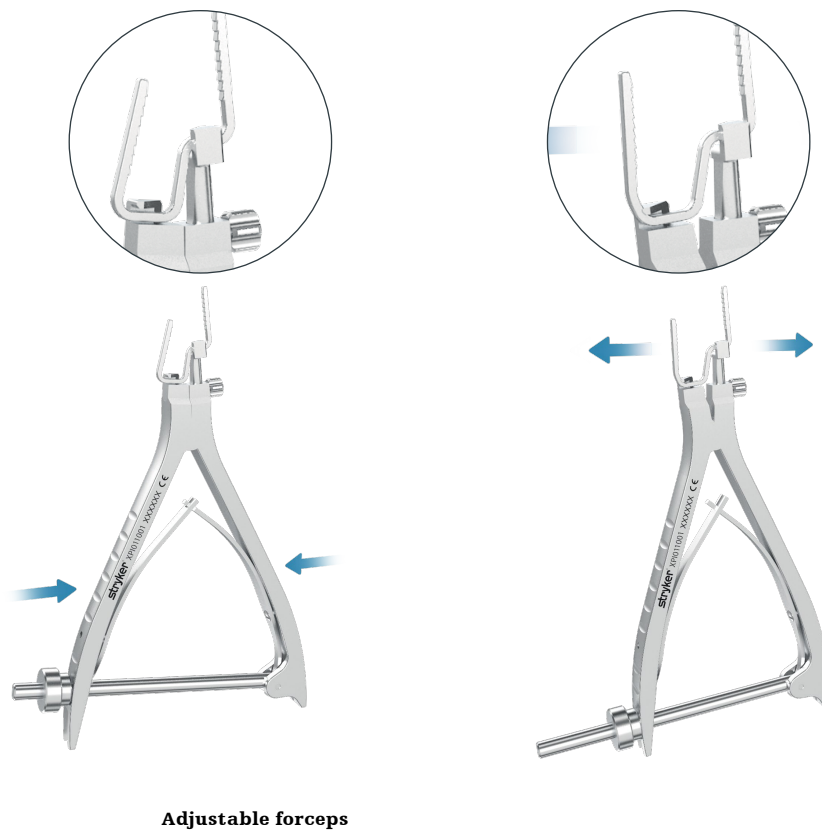
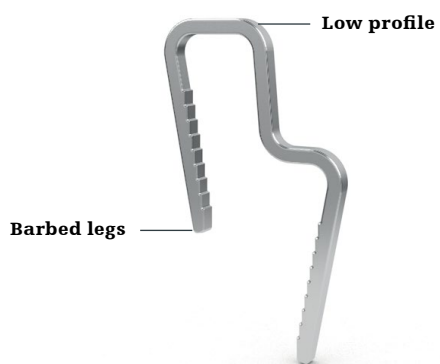
- Any active or suspected latent infection or marked local inflammation in or around the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with the anatomical structures or physiology performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical condition which would preclude the potential benefit of surgery.

Implant

technical specifications

The EasyStep Step Staple, incorporates several features:

- No heat activation required
- Comprehensive step size range; from 4 mm to 12 mm
- Low profile
- Barbed legs for anchorage
- Superelastic nickel-titanium (Ni-Ti) alloy

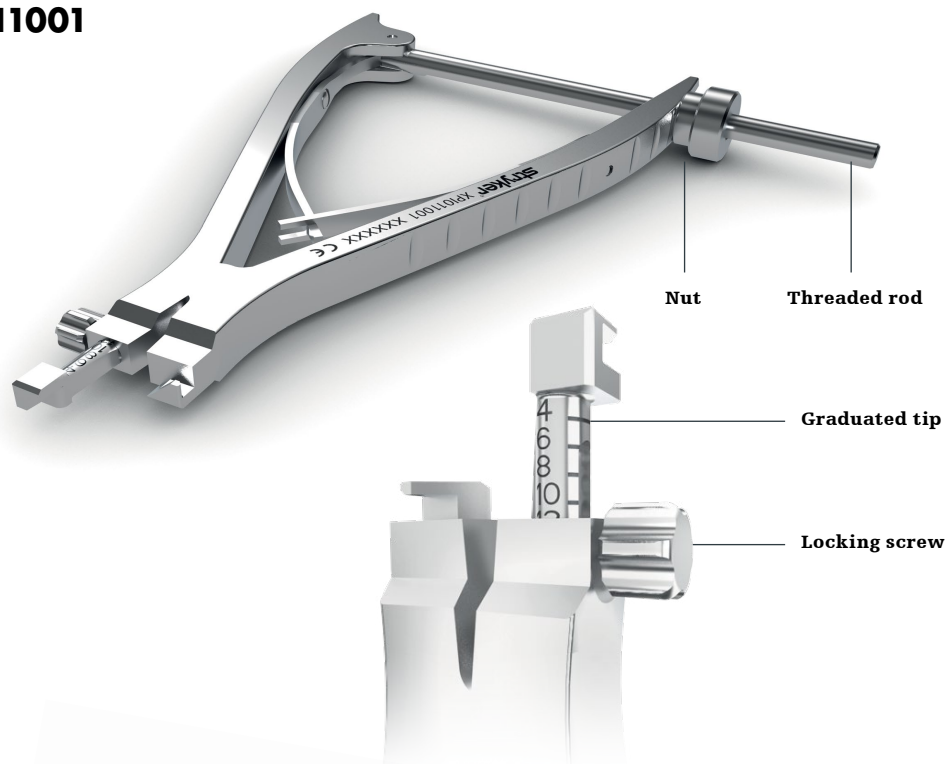


Instrumentation

technical specifications

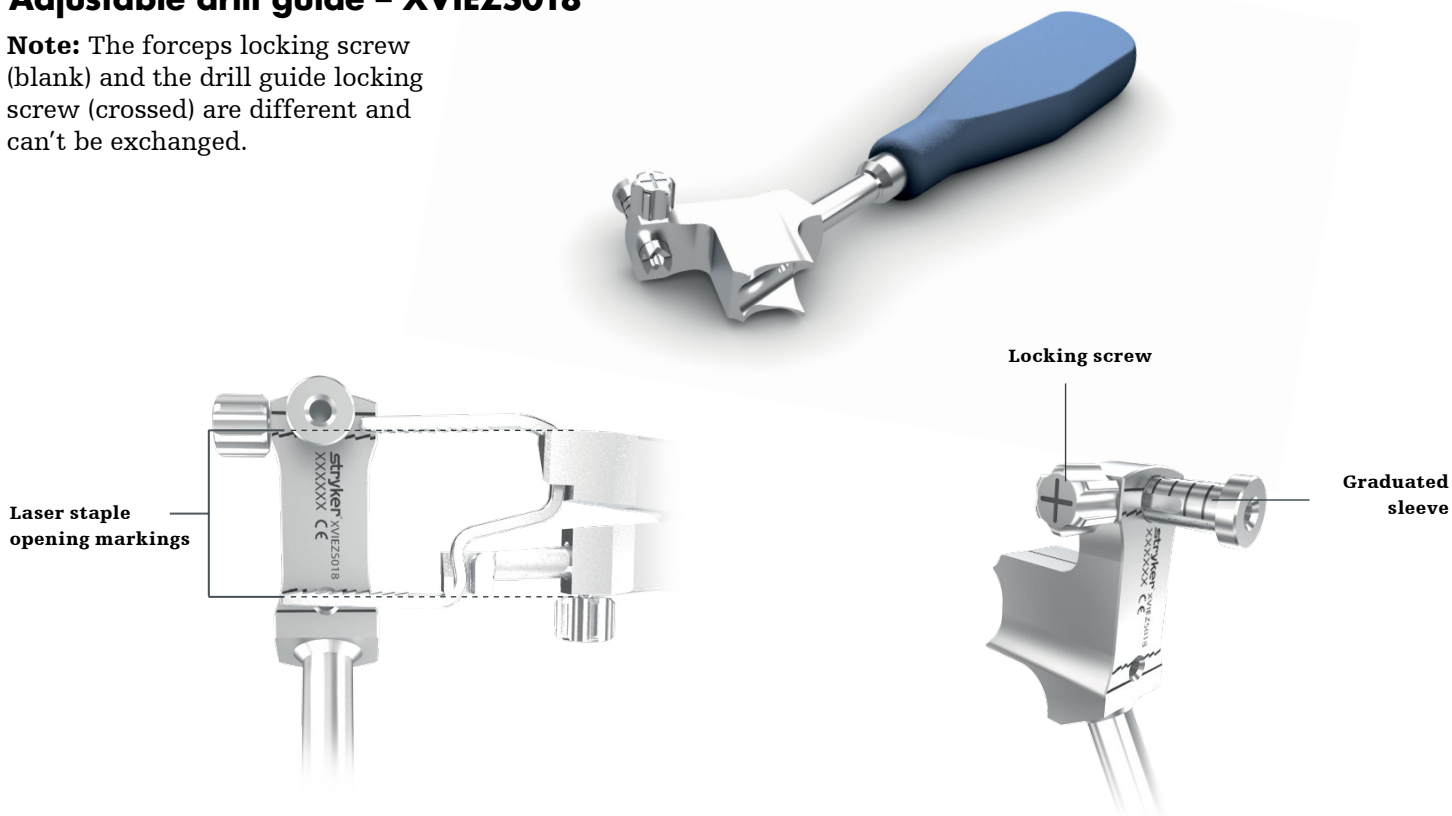
Adjustable forceps – XPI011001

The forceps and the drill guide are designed with an adjustable graduated tip or sleeve to be used with the entire staple range from 4 to 12mm.



Adjustable drill guide – XVIEZS018

Note: The forceps locking screw (blank) and the drill guide locking screw (crossed) are different and can't be exchanged.



Positioning pins - AGB2120



Drill bit with stop - XFO130022

Ø2.2mm

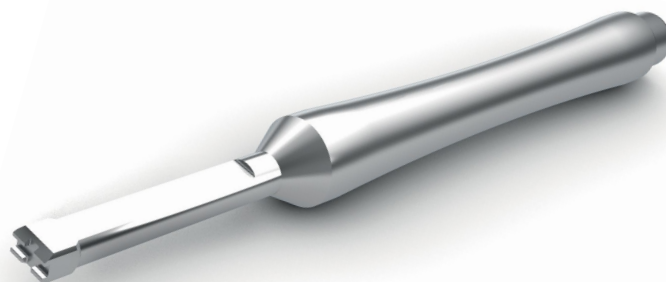


Kirschner wires - 390192

Ø2.0mm × 150mm



Impactor - XIM008001



Operative technique

Calcaneal displacement osteotomy

1. Incision and calcaneal preparation

The incision is placed lateral to the calcaneus, parallel to the peroneal tendons.

The peroneal tendons are reflected proximally to gain access to the lateral aspect of the calcaneus tubercle.

A one inch osteotome or saw is used to make the osteotomy across the calcaneus to the opposite cortex.

Note: While exposing the calcaneus, make sure not to injure the sural nerve.

2. Osteotomy and displacement fixation

Slide the posterior bone fragment medially until the necessary correction is achieved.

Make sure that the proximal and distal bone fragments are in close contact by pushing on the posterior fragment or plantarflexing the foot. The bone fragment is fixed with two temporary K-Wires (390192).

3. Staple identification

Position the drill guide (XVIEZS018) against the proximal bone fragment. Make sure screw is loosened first. Push the graduated sleeve until flush with the bone surface. Select the appropriate implant size according to the graduation.

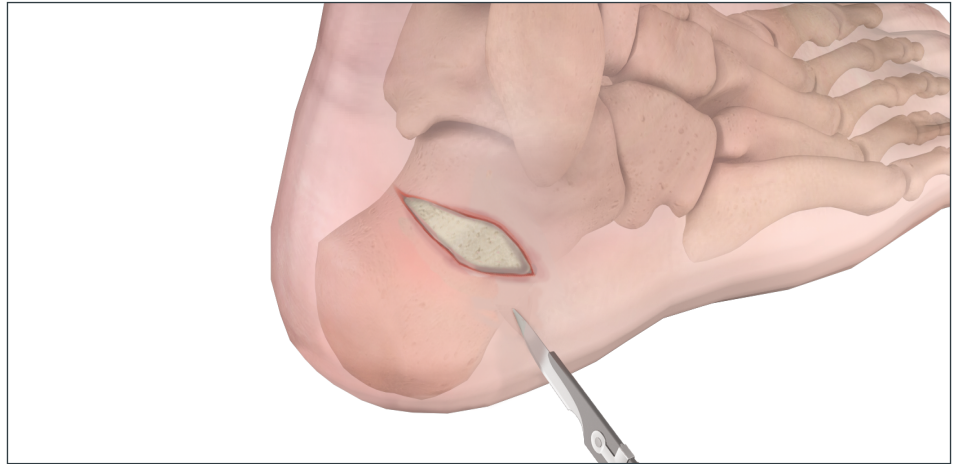


Figure 1

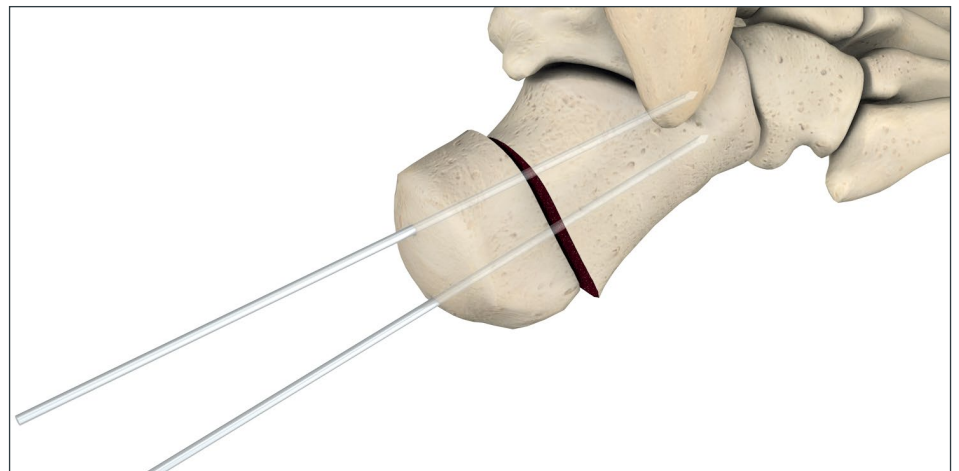


Figure 2

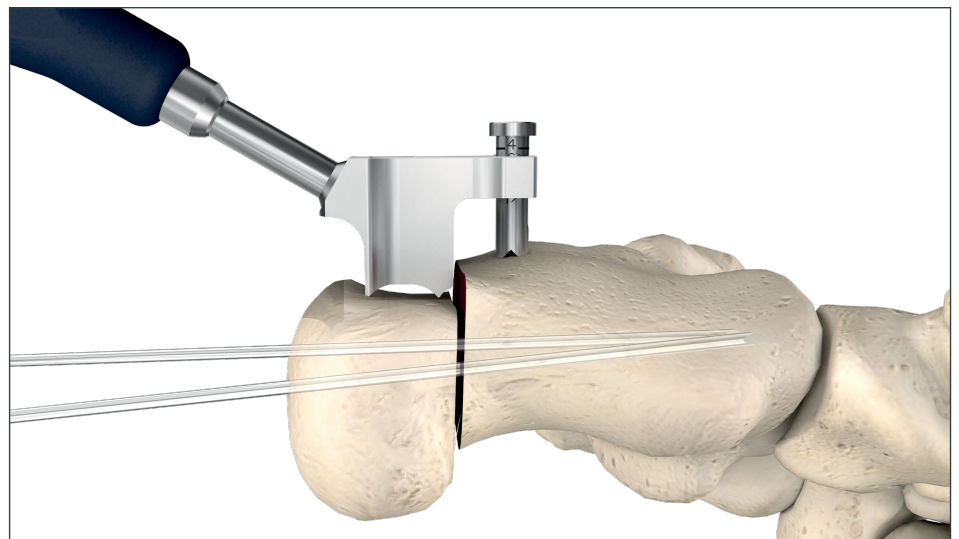


Figure 3

4. Drilling

Prior to drilling, lock the drill guide with the locking screw. Place the drill guide (XVIEZS018) onto the osteotomy. Begin with the anterior drilling, until the stop of the drill bit makes contact with the drill guide (Fig. 4a). Place the positioning pin (AGB2120) into the hole.

Do not remove the drill guide and repeat the operation for the posterior drill hole (Fig. 4b). Remove the drill guide when the two positioning pins are inserted.

Note: Make sure that the drill bit does not interfere with the k-wire.

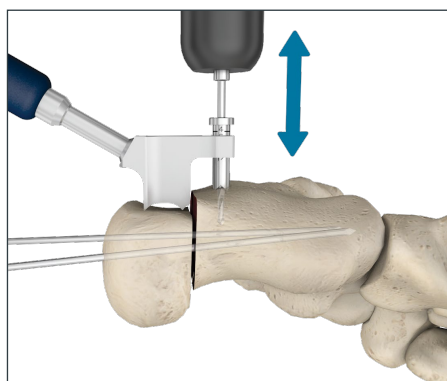


Figure 4a

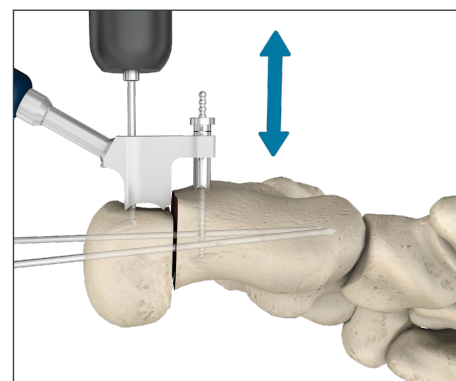


Figure 4b

5. Implant opening

Make sure to manipulate the implants above a sterile field.

Slightly loosen the forceps locking screw (XPI011001), in order to adapt the position of the tip to the implant size (Fig. 5), and lock the position.

Loosen the nut on the forceps threaded rod in order to make sure the forceps are in unconstrained position.

Place the implant between the tips of the forceps (Fig. 6). Make a quarter turn in order to fit the implant into the jaws (Fig. 7). Slightly press the forceps arms in order to maintain the staple.

Open, until the implant legs are in parallel position (Fig. 8). Spin the nut along the threaded rod in order to maintain the position.

Note: Avoid excessive widening of the implant, in order to keep the same interaxis distance between the implant legs and the drill holes.

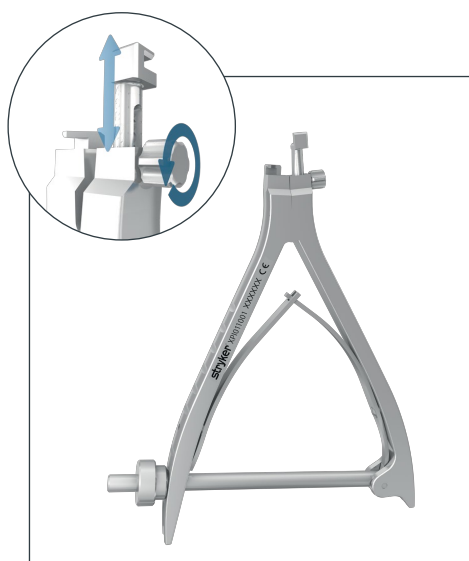


Figure 5

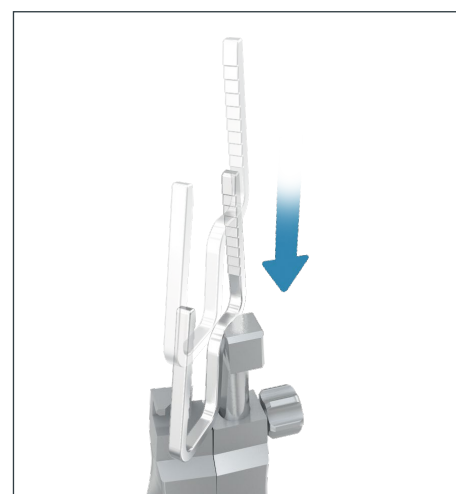


Figure 6

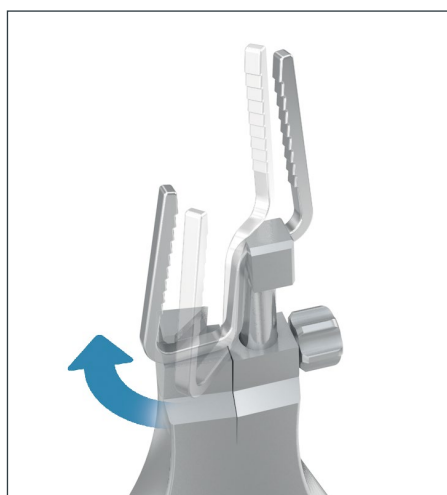


Figure 7

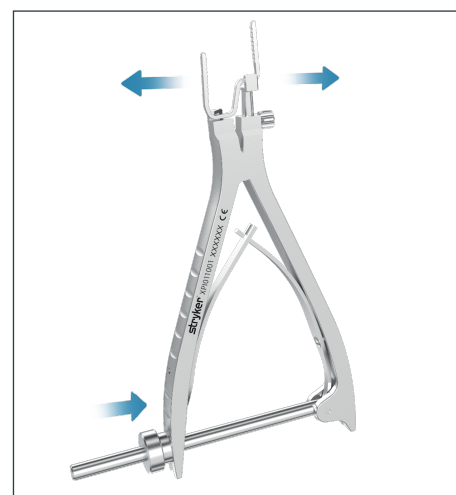


Figure 8

Confirm the position by placing the implant legs over the drill guide markings (Fig. 10).

The implant legs must fit in between the lines.

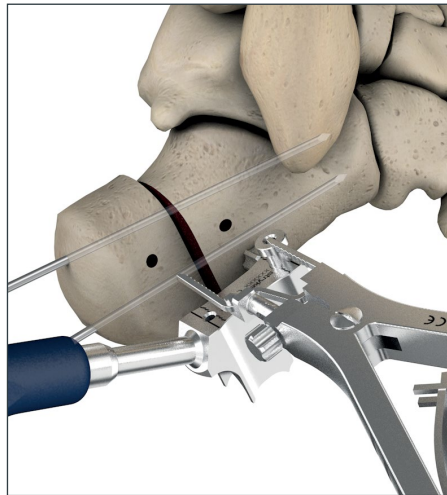


Figure 9

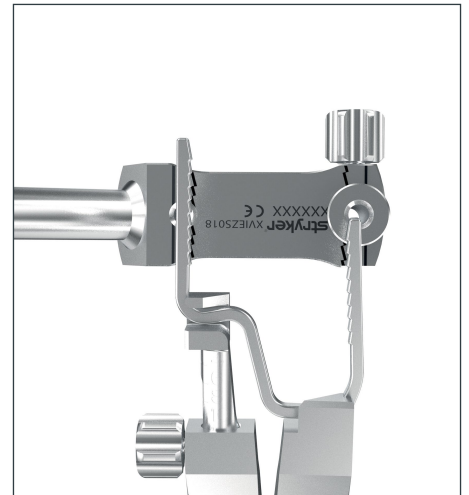


Figure 10

6. Implant insertion

Remove the positioning pin(s). Place the implant over the osteotomy. Insert the implant into the drill holes until the tips of the forceps are flush with the bone surface (Fig. 11). Loosen the nut on the threaded rod.

Make a quarter turn to the left to release the implant from the forceps (XPI011001) tips.

Note: If there is a misfit between the implant legs and the drill holes, you can still adjust the opening.

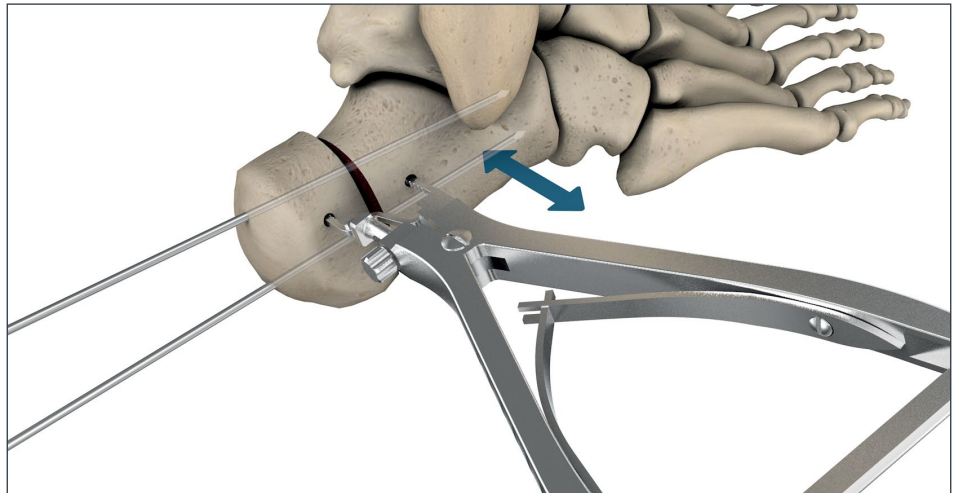


Figure 11

7. Implant impaction

Impact the implant with the impactor (XIM008001) and a mallet until the staple back is in contact with the bone surfaces (Fig. 12).

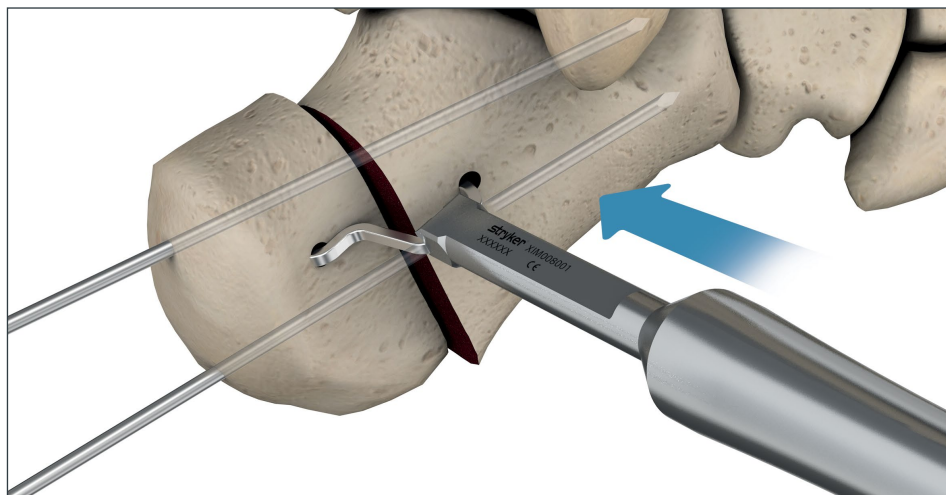


Figure 12

8. Second implant placement

Repeat procedure; including drilling, implant opening, insertion, and impaction (Fig. 13). Depending on the morphology of the calcaneus, you may have to use implants with different step sizes. Remove the K-Wire temporary fixation.

Note: Make sure that maximum distance exists between the two implants.



Figure 13

9. Imaging

Correct positioning of the implants can be checked using X-Ray imaging.

10. Staple removal

If staple removal is required, the EasyStep forceps can be used to re-engage and decompress the staple. Once decompressed, the EasyStep staple can be lifted and removed from the bone. If the forceps cannot be engaged due to osseous integration around the staple, a thin elevator can be used to clear the area and partially lift the staple. This will allow for clearance to reintroduce the EasyStep forceps.

Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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