



EasyClip® Osteosynthesis Compression Staples

Operative Technique



Foot & Ankle

EasyClip Osteosynthesis Compression Staples

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 appropriate instructions for use (IFU). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

See package insert 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.

Warning Information:

- Never re-sterilize EasyClip implants. Any application of extensive heat would compromise the biomechanical features of the devices possibly resulting in implant failure.
- EasyClip implants are not intended for immediate postoperative weight bearing. Be sure that the postoperative loading of the internal fixation is reduced to a minimum (e.g. with application of a Forefoot Off-loading Shoe) until bone consolidation is confirmed by follow up X-Ray examination (normally after 4-6 weeks).

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Indications, Precautions & Contraindications

Indications

The EasyClip staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

Contraindictions

The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon.

- Acute or chronic infections, local or systemic.
- Surgical procedures other than those mentioned in the Indications section.
- Do not use on patients allergic to the components of the product (Titanium-Nickel) or having known allergies.

Precautions

Stryker Osteosynthesis systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling. Detailed information is included in the instructions for use being attached to every implant.

See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.









Potential Advantages & Features

The EasyClip is designed to facilitate fast and easy fixation in a variety of applications.

- No Heat activation required
- Controlled compression due to the specific forceps
- Large range for a variety of sizes 8-25mm
- Biocompatible
- Symmetric or asymmetric leg lengths to fit the anatomy



Forceps for secure insertion and controlled compressive force.



Memometal Nitinol Features: Superelasticity Effect

Manufactured of Nitinol Alloy the EasyClip Staples potential benefits from the Superelasticity Effect:

After Stress deformation, the Superelastic alloys, made approximately of 50% nickel and 50% titanium, have the ability to return to their original shape, immediately after unloading.

The Superelastic effect is acquired during the manufacturing process which is all integrated for precise shape recovery. The load developed by each implant has been specifically set to deliver anchorage and compression.

The Superelastic alloys react only to mechanical stress, no change in temperature is needed for the alloy to recover its initial shape. Removal of the implant is at surgeon's discretion.

Overview

EasyClip Range

Main surgical procedures and their associated EasyClip references are presented for informational purposes. Each surgeon must assess the relevance of the procedure and the EasyClip references, in light of his own training and experience.



Instrumentation

EasyClip Forceps

Each staple reference can be inserted with the two different forceps designs (Adjustable or Single Size), for a secure insertion and controlled compressive forceps.

Adjustable Forceps

- 1 First nut: Size Selection
- Second Nut: Staple opening adjustment
- 3 EasyClip holding bits
- 4 Graduation of the EasyClip sizes

References

- 1. For EasyClip size 08 to size 12 (XPI006001)
- 2. For EasyClip size 15 to size 18 (XPI006002)
- 3. For EasyClip size 20 to size 25 (XPI006003)



Single Size Forceps*

- 1 Notch
- 2 Stop
- BasyClip holding bits

References

- 1. EasyClip Forceps for EZ10 (XPI002001)
- 2. EasyClip Forceps for EZ12 (XPI002002)
- 3. EasyClip Forceps for EZ15 (XPI002007)
- 4. EasyClip Forceps for EZ18 (XPI002005)

*Custom order



The following operative technique is based on MTP arthrodesis which illustrates a common procedure for EasyClip staples insertion and EasyClip Instrumentation use. Each indication has its own specificities in terms of bone preparation, tissue approach, suture etc.

Arthrodesis of the first metatarsophalangeal joint

1. Incision & Joint preparation

A medial longitudinal incision is commonly used to expose the joint.

The surfaces are prepared with flat cuts or a Cup-and-Cone configuration.

The amount of bone resection depends upon the size of the dorsal bone proliferation, the amount of damaged cartilage and the desired length of the 1st metatarsal.

Metatarsal Preparation

Option 1: Flat cuts technique

Proceed to the metatarsal head resection with an oscillating saw. The bone of the proximal phalange is resected perpendicularly to the phalanx axis.

Option 2: Cup and Cone technique

Displace the phalanx laterally to expose the metatarsal head. Using a power tool, place a 1.6mm guide wire (AGK16100) proximally through the center of the metatarsal head and into the diaphysis.

Beginning with the largest diameter reamer (XFR004122) (22mm), place the reamer over the Guide Wire (K-Wire) and gently ream the metatarsal head until bleeding subchondral bone becomes visible

on the joint surface. To ensure proper sizing, it is advisable to begin by using the largest size reamer, and then downsizing to match the diameter of the metatarsal head.

Once reaming is complete, the K-Wire can be held to elevate the metatarsal head to enable the removal of the bone on the plantar aspect.





Note:

Make sure to protect the sesamoids, and check the progress of the reamer frequently to prevent excessive shortening of the metatarsal. Take note of the last reamer size used.

Phalangeal Preparation

The proximal phalanx is plantar flexed using a curved McGlamry or Hohman retractor. The 1.6mm K-Wire (AGK16100) is again placed in the center of the articular cartilage and directed through the diaphysis. Care should be taken not to penetrate the interphalangeal joint.

Reaming should begin by using the smallest size of phalangeal reamer (XFR004214) (14mm) and must end with the same diameter size as the last reamer used on the metatarsal head.

Example, if the metatarsal reaming stopped at 18mm, the last and largest reamer used on the phalanx will be 18mm.

Note:

The metatarsal head should be protected when reaming.



2 Provisional Placement

The cup and cone shaped surfaces make it possible to rotate the joint and set the dorsal flexion and valgus angles to the desired position.

Once this is determined a provisional Guide Wire should be placed across the joint, aligning it in the final arthrodesis position.

The position of the phalange is verified by placing a support against the platform surface of the foot.



3 Drill guide positioning

Choose the appropriate drill guide and drill bit 2mm according to the identified staple width (from 8 to 18 mm) or drill bit 3mm according to the identified staple width (from 20 to 25mm).

The drill guide is positioned dorsally, over the osteotomy line. Each drill hole should be seated on the opposite sides of the osteotomy line (asymmetric position to avoid any conflicts with the second staple).





After drilling the first hole, insert a positioning pin (AGB200) to stabilize the guide on the bony surface.

Proceed to drill the second hole through the drill guide.



4 Measurement

After removing the drill guide, insert the gauge (XJA002004) through each hole to determine the appropriate staple reference.



Staple Size Identification

Always select the staple leg reference 2mm longer than the gauge measurement to take into account the staple back thickness and ensure good bicortical penetration.

Note:

Between the four EZ18 staple references select the EZ 18-19-17 to consider the back of the staple.

- Ø EZ18-12-12
- Ø EZ18-14-14
- ✓ EZ18-17-15

EZ18-19-17



5 Staple Insertion

5.1 Forceps identification

Choose the appropriate Forceps and adjust the first nut to the EZ size laser mark.



5.2 Staple set-up

Remove the staple from its sterile package and set the staple into the EasyClip holding bits of the forceps.





Press the forceps to put the handle in contact with the first nut. The EasyClip staple is then over opened.

Note:

This over opening step is essential to obtain the right compression rate after the implantation.





Once over opening is completed proceed to adjust the EasyClip legs to be parallel by screwing or unscrewing the second nut.



Note:

For a Single Size Forceps* utilization press the handle until the stop. Then release pressure and the forceps will automatically bring the legs to a parallel stance.



5.3 Staple insertion

Insert the staple into the holes until the forceps bits touch the bone surface.



5.4 Forceps removal

Simultaneously release the adjustment rod and turn the forceps handle.

Note:

In Bicortical cases, ensure the legs have correctly reached the second cortex before you remove the forceps.



Smart Toe Product Range

5.5 Impaction

Use the impactor and a mallet to flush the staple with the bone surface.



6 Second Staple Insertion

The second staple is inserted following the previous step 3-6.



7 Imaging

Check staples position to avoid any risk of joint injuries.



Ordering Information – Implants

А		А	
P1	P2	PI	P2



REF	A Width (mm)	P1 - P2 Legs Length (mm)	Thickness (mm)BxC	Drilling Diameter (mm)
EZM08-08-08	8	8-8	1.5mm x 1.2mm	2
EZM10-10-10	10	10-10	1.5mm x 1.2mm	2
EZB10-15-13	10	15-13	1.5mm x 1.2mm	2
EZB10-17-15	10	17-15	1.5mm x 1.2mm	2
EZB10-19-16	10	19-16	1.5mm x 1.2mm	2
EZM12-10-10	12	10-10	1.5mm x 1.2mm	2
EZB12-15-13	12	15-13	1.5mm x 1.2mm	2
EZB12-17-15	12	17-15	1.5mm x 1.2mm	2
EZB12-19-16	12	19-16	1.5mm x 1.2mm	2
EZ15-12-12	15	12-12	1.8mm x 1.3mm	2
EZ15-15-15	15	15-15	1.8mm x 1.3mm	2
EZ18-12-12	18	12-12	1.8mm x 1.3mm	2
EZ18-14-14	18	14-14	1.8mm x 1.3mm	2
EZ18-17-15	18	17-15	1.8mm x 1.3mm	2
EZ18-19-17	18	19-17	1.8mm x 1.3mm	2
EZ20-16-16	20	16-16	2.5mm x 1.6mm	3
EZ20-20-20	20	20-20	2.5mm x 1.6mm	3
EZ25-22-22	25	22-22	2.5mm x 1.6mm	3

Ordering Information – Instruments

	REF	Description
	XPL01400101	Tray for EasyClip EZ08 to EZ25
	460168R0001	Handle
	460016P 2008	Drill guide head for FasyClip 08 (02mm)
• •	460016R2000	Drill guide head for EasyClip 10 (Ø2mm)
	460016R2012	Drill guide head for EasyClip 12 (Ø2mm)
	460016R2015	Drill guide head for EasyClip 12 (02mm)
	460016R2018	Drill guide head for EasyClip 18 (Ø2mm)
	460016R3020	Drill guide head for EasyClip 20 (Ø3mm)
	460016R3025	Drill guide head for EasyClip 25 (Ø3mm)
	XFO012002	Drill bit AO (Ø2mm)
	AGB200	Positioning Pin (Ø2mm)
	XFO013002	Drill bit AO (Ø3mm)
	AGB300	Positioning Pin (Ø3mm)
	XJA002004	Gauge
	XPI006001	Adjustable Forceps (EZ08, EZ10 & EZ12)
	XPI006002	Adjustable Forceps (EZ15 & EZ18)
	XPI006003	Adjustable Forceps (EZ20 & EZ25)
	AGR104	Impactor

Ordering Information – Optional Instrumentation

		REF	Description
(@			
@		XTU001002	Tube for K-Wire/Length 17cm without hole
@		AGK16100	K-Wire Trocar-Ig 100mm - Ø1.6mm
		XFR004114	Concave reamer Ø14
@		XFR004116	Concave reamer Ø16
		XFR004118	Concave reamer Ø18
		XFR004120	Concave reamer Ø20
		XFR004122	Concave reamer Ø22
	¢	XFR004214	Convex reamer Ø14
	¢	XFR004216	Convex reamer Ø16
		XFR004218	Convex reamer Ø18
	¢	XFR004220	Convex reamer Ø20
		XFR004222	Convex reamer Ø22
		AGV2008	
		AGV2010	
		AGV2012	
		AGV2015	
		AGV2018	
	l		
		XPI002001	Single Size Forceps for EZ10
	Tor	XPI002002	Single Size Forceps for EZ12
	Ter I	XPI002005	Single Size Forceps for EZ18
	A	XPI002007	Single Size Forceps for EZ15

Ordering Information

Standard Tray Composition





REF	Description
XSEEZ090101	Instrumentation for EZ08 to EZ25 with MTP arthrodesis reamers and adjustable forceps
XSEEZ130001	Instrumentation for EZ08, EZ10 & EZ12 with adjustable forceps

Kits for fore-foot surgery with Fixos screw and EasyClip staple are available according to the surgeon's technique. Refer to Foot & Ankle Catalog for ordering.

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Manufactured by:

Stryker GmbH Bohnackerweg 1 CH - 2545 Selzach Switzerland

www.stryker.com

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