DePuy Synthes
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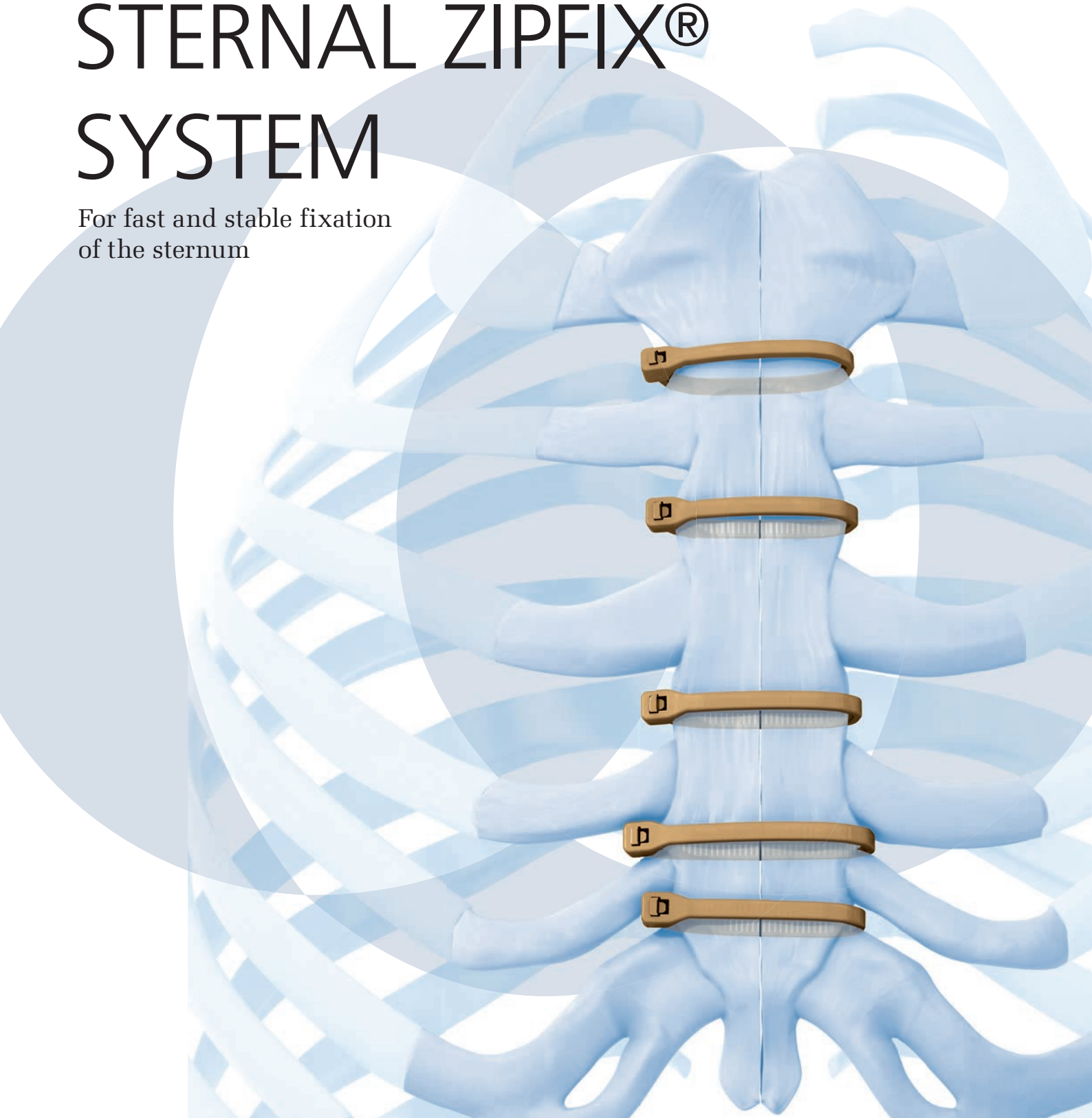
STERNAL ZIPFIX® SYSTEM

For fast and stable fixation of the sternum



This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

TABLE OF CONTENTS

Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please contact your local sales representative or refer to: www.synthes.com/reprocessing

STERNAL ZIPFIX SYSTEM

FOR FAST AND STABLE FIXATION OF THE STERNUM

The Sternal ZIPFIX System enables fast sternal closure with consistent tension along a sternotomy of the sternum.

The system primarily consists of PEEK (polyetheretherketone) implants and an application instrument.

- Flexible and easy to handle
- Excellent closure strength and stability
  – Made of PEEK for biocompatibility
  – MR safe after removal of stainless steel needle

Sternal ZIPFIX implant
- Can be cut using wire/pin cutter for quick emergent re-entry
- Rounded edges for less soft tissue irritation
- Less risk of glove puncture than wires
- MR Safe after removing stainless steel needle (see device specific insert for full instructions)

Caution: **The ZIPFIX with attached ferromagnetic needle cannot be placed in the vicinity of an MR scanner, anywhere in the MR procedure room, or used in an interventional MRI procedure.**

Removable stainless steel needle
- Blunt, stainless steel needle for peristernal application

Locking head
- Self-locking for easy implant application
- Flat-locking feature for low profile

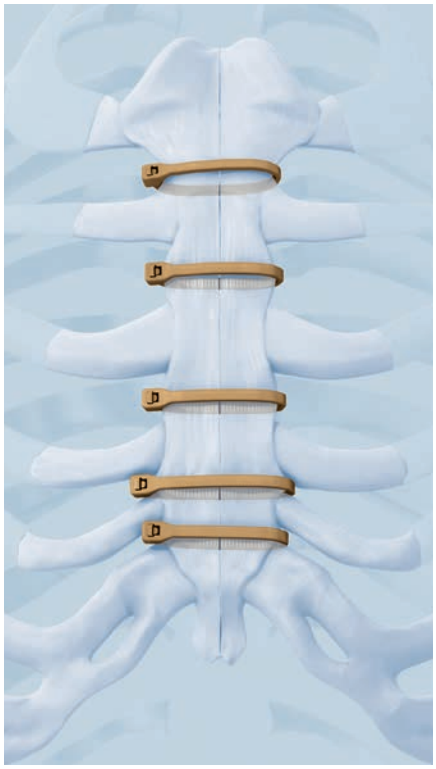
Application instrument
Multifunctional instrument to consistently tension and cut ZIPFIX implant.

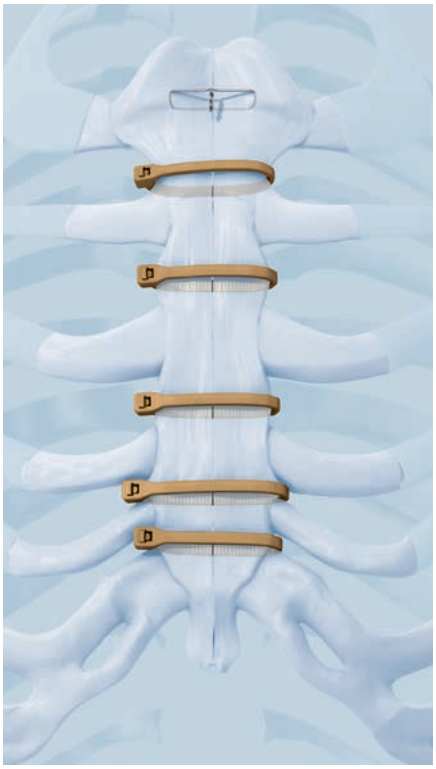
❶ Squeeze trigger to tension implant

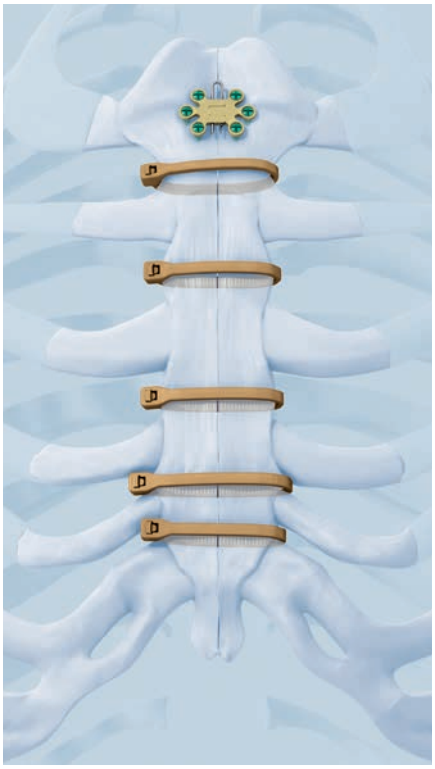
❷ Lift lever to cut implant

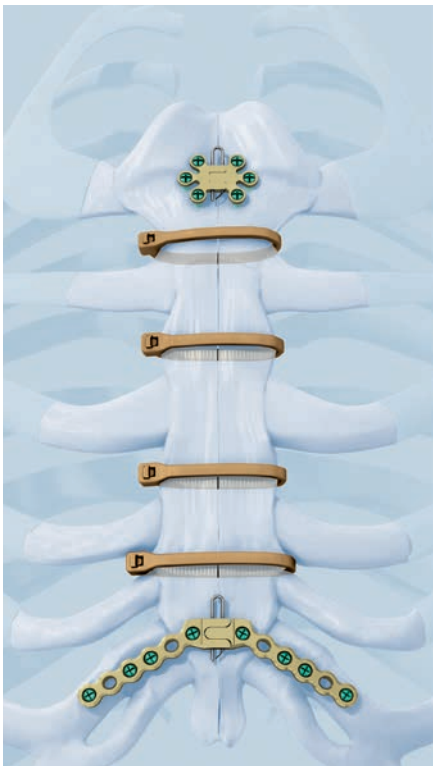
❸ Mechanism to prevent over tensioning of the implant

Multiple Closure Options



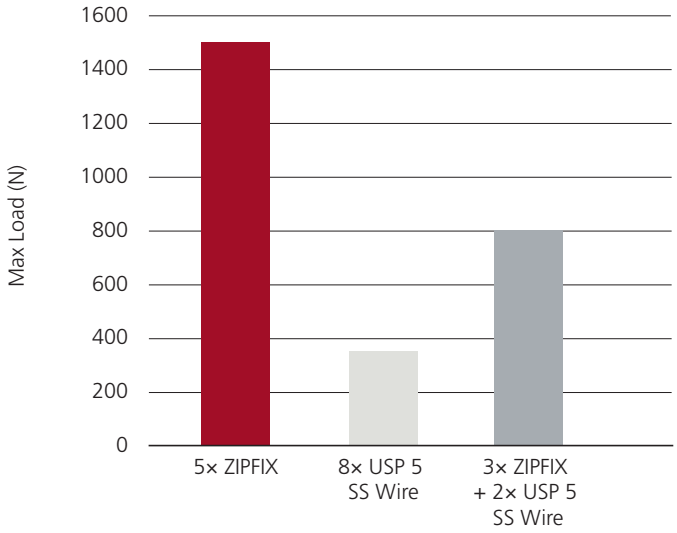






Construct strength comparison*
Dynamic Test[1]
Maximum load to reach 500,000 cycles (more than 3 weeks of bone healing†)

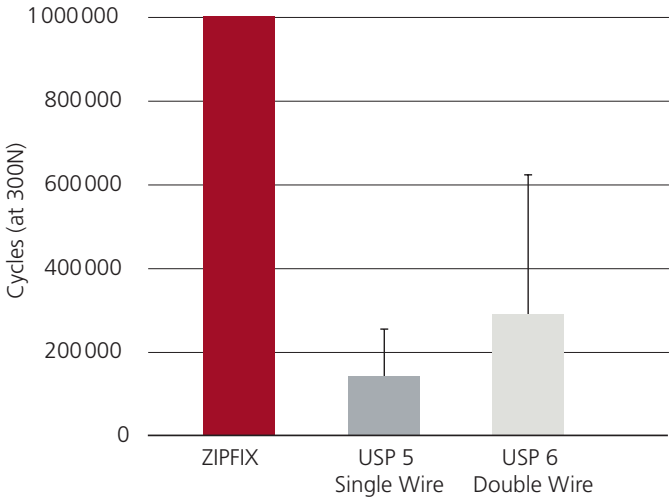
The ZIPFIX construct demonstrates a higher resistance to fatigue failure compared to stainless steel wire.



Fatigue load*
Dynamic Test[2]

The ZIPFIX survives over 1 million cycles (more than 6 weeks of bone healing†) at exaggerated loading.

The ZIPFIX survives a higher number of loading cycles at 300N than stainless steel wires.

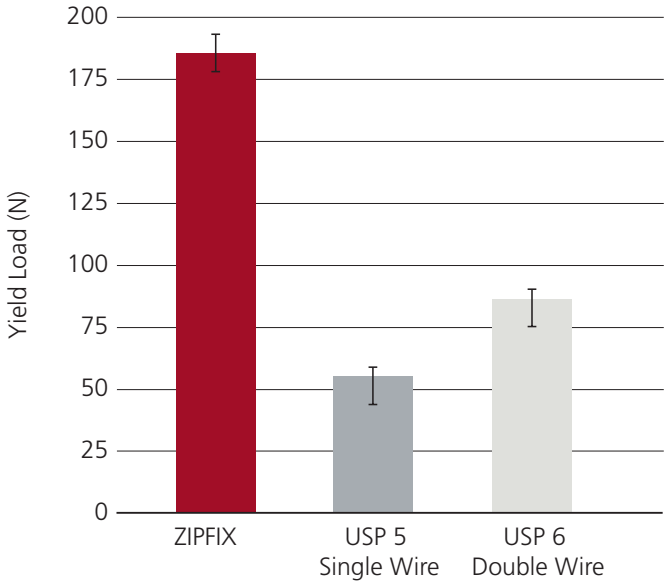


1 Constructs loaded cyclically in tension in lateral direction. All tests were performed on stainless steel pins to simulate the sternum.
2 Implant loaded cyclically in tension in lateral direction. All tests were performed in polyoxymethylene (copolymer) blocks to simulate the sternum.
† The estimate for the amount of cycles at 300N represents fracture healing based on 14.1 breaths per minute. 300N represents the maximum load on a single implant during an aggressive cough.
Casha AR, Yang L, Kay PH, Saleh M, Cooper GJ. A biomechanical study of median sternotomy closure techniques. *Eur J Cardio-Thorac Surg* 1999; 15:365-369.
* Mechanical test data on file at Synthes. Mechanical test results may not necessarily be indicative of clinical performance.

Cut-through test*
Yield load in "poor-quality bone" until cut through[3]

The ZIPFIX provides increased resistance to implant cut-through in the sternum compared to stainless steel wire.

The ZIPFIX has larger implant-to-bone contact area compared to stainless steel wire to reduce risk of bone cut-through.



3 Implants loaded in tension in lateral direction. All tests were performed in 12 mm thick polyurethane foam blocks of 10 lb/ft³.
* Mechanical test data on file at Synthes. Mechanical test results may not necessarily be indicative of clinical performance.

AO PRINCIPLES

In 1958, the AO formulated 4 basic principles, which have become the guidelines for internal fixation.[4,5] Those principles are:

Anatomic reduction
Fracture reduction and fixation to restore anatomical relationships.

Stable fixation
Stability by fixation, as the personality of the fracture and the injury requires.

Preservation of blood supply
Preservation of the blood supply to soft tissue and bone by careful handling.

Early, active mobilization
Early, active mobilization of the part and patient.

4 Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991.
5 Rüedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

INDICATIONS AND CONTRAINDICATIONS

Indications
Closure of the sternum folowing sternotomy to stabilize the sternum and promote fusion.

Contraindications
Patients under 12 years of age.

Warnings:
- **Cannot be used in location of transverse fracture.**
- **Using the system in pediatric patients may result in pain and/or implant protrusion which may require explantation.**
- **Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.**

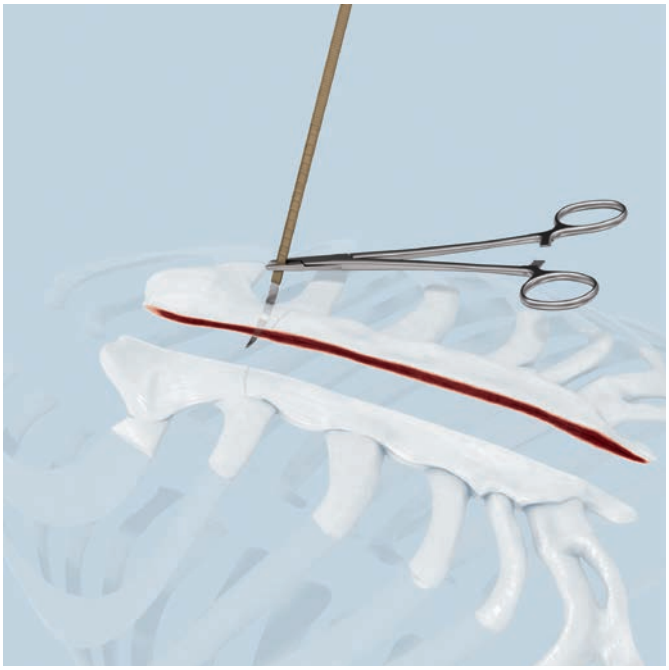
1

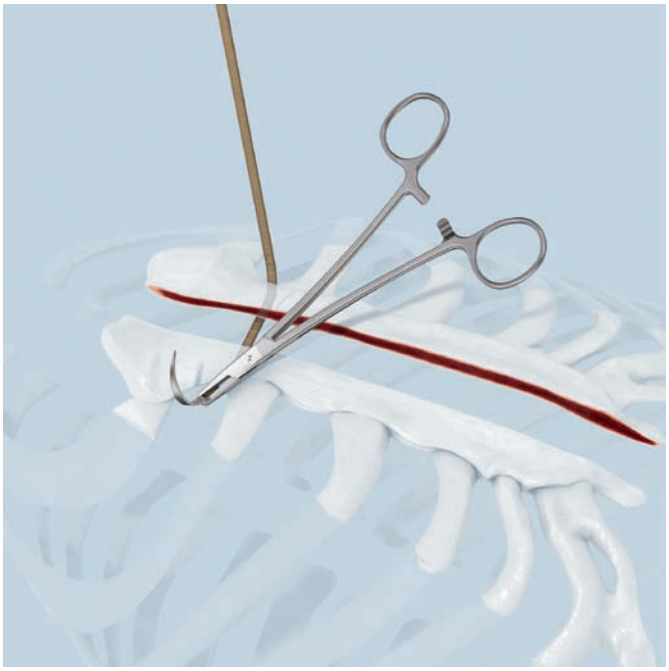
Insert Sternal ZIPFIX implant

Using a needle holder, pass the ZIPFIX through the intercostal space and around the sternal halves.

Precautions:

- **Take care to avoid injury to, or impingement upon, the internal mammary artery and intercostal vessel and nerve bundles.**
- **There may be a risk of bleeding when used transsternally.**
- **Transsternal application may be inhibited by hard bone.**
- **Avoid clamping of implant in the area of the teeth or excessive bending/twisting of the implant, as this may lead to implant failure.**





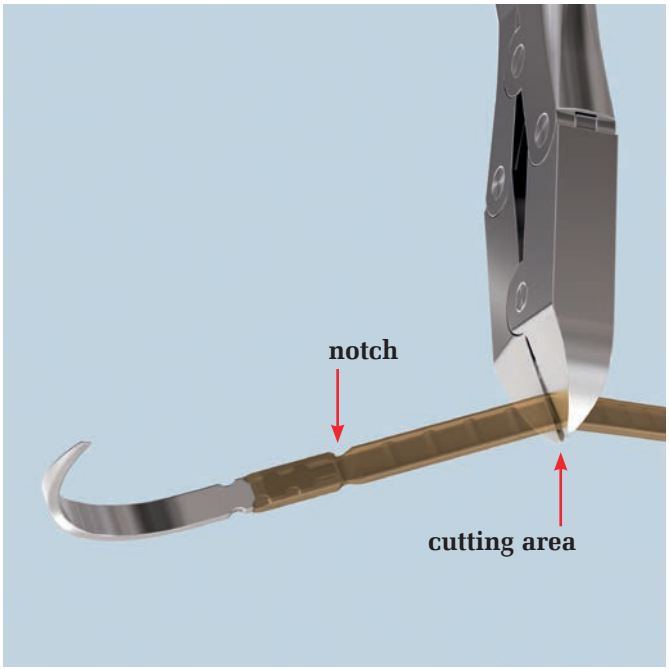
2
Remove Sternal ZIPFIX needle

Instrument	
391.905	Cable Cutter, standard

Cut needle off the ZIPFIX below the notch, using the cable cutter.

Precautions:
- **Do not cut the implant directly at the notch.**
- **Removing the needle by bending or twisting will cause a deformed end that may damage the locking head during insertion. Always ensure that the implant end is cut and not deformed. If the implant is not cut, implant failure may occur.**

Note: **Needle can also be removed using a wire/pin cutter.**



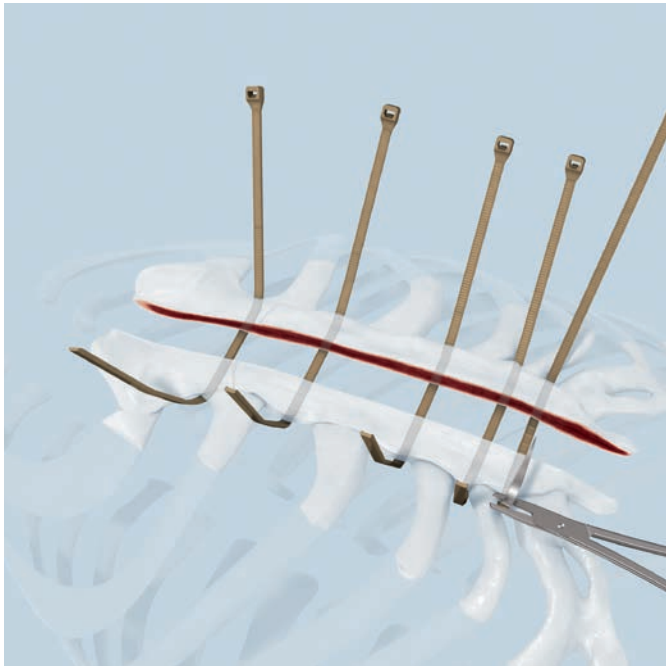
3

Insert remaining Sternal ZIPFIX implants and remove needles

Insert the remaining ZIPFIX and remove needles as described in Steps 1 and 2.

Use 5 ZIPFIX to achieve stable fixation in a full midline sternotomy. ZIPFIX can be used with plates and/or wires or where ZIPFIX insertion is inhibited by patient anatomy.

Notes:
- **Stainless steel wires may be applied to the manubrium and xyphoid regions if desired.**
- **The number of ZIPFIX used in partial sternotomy is according to patient anatomy.**



4

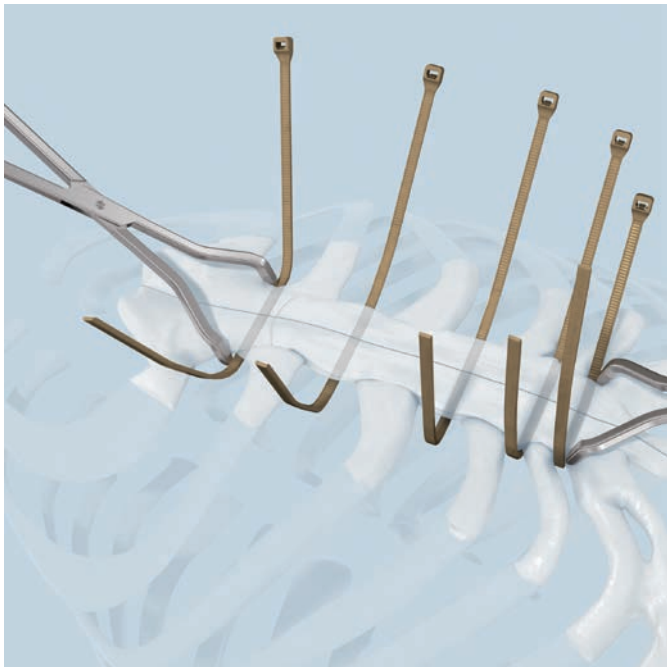
Reduce sternal halves

Instrument	
398.903	Sternal Reduction Forceps, angled, with ratchet lock

Optional instruments	
398.902	Sternal Reduction Forceps
398.980	Reduction Forceps with Points, ratchet lock, length 180 mm

Reduce the sternal halves by using reduction forceps on both the superior and inferior aspects or by securing the ZIPFIX as in Step 5.

Note: **The sternum can also be reduced with sternal wires.**



5
Secure Sternal ZIPFIX implants

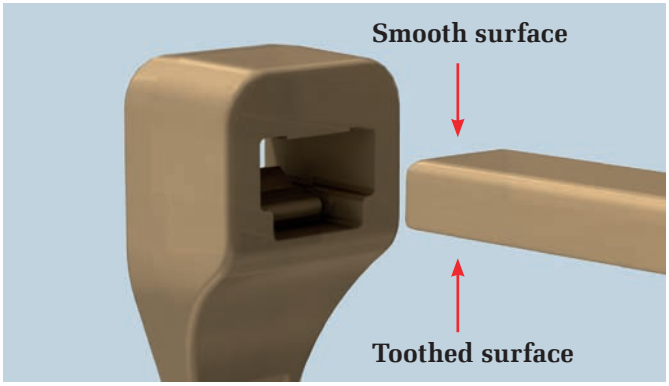
Pass the cut end through the locking head and tighten manually.

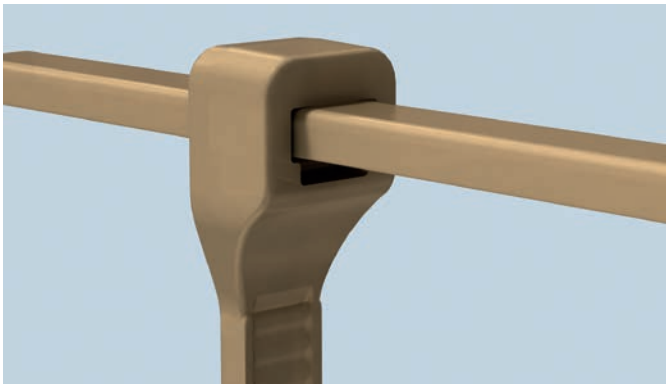
Repeat for the remaining ZIPFIX.

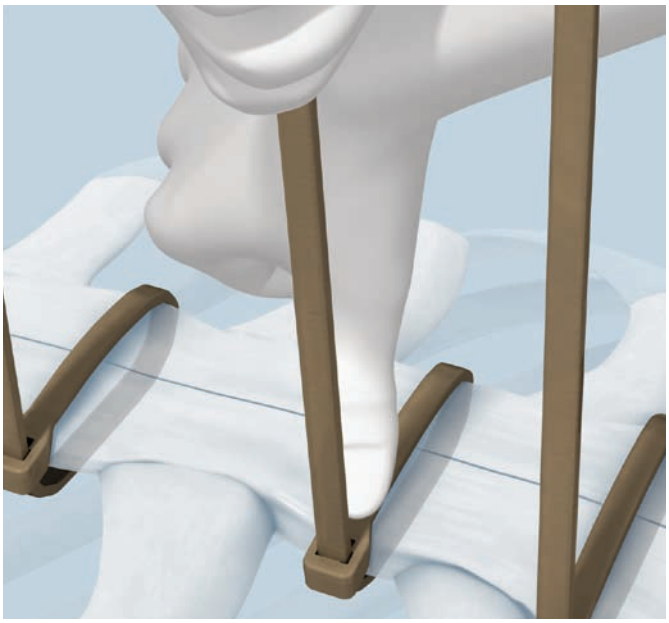
Remove forceps, if used.

Cautions:
To avoid damage to the locking head:
- **Stainless steel needles must be removed before closing the ZIPFIX.**
- **Prior to insertion of the cut end, ensure the ZIPFIX is properly oriented such that the toothed surface contacts the sternum.**
- **Align the cut end with the locking head during insertion. Do not insert at an angle.**
- **Avoid excessive force when tightening implant. Do not use forceps to tighten implant. Damage resulting from excessive force or forceps may cause implant failure.**

Note:
- **Secure the locking mechanism in the intercostal space to minimize implant profile.**







6
Tension Sternal ZIPFIX implants

Instrument	
03.501.080	Application Instrument for Sternal ZIPFIX

Ensure the cutting lever is in the locked position. The cutting lever is locked when the lever is snapped into the latch.

Insert the cut end of the implant into the front portion of the application instrument and slide the application instrument down to the locking head.

Squeeze the trigger to tension the ZIPFIX.

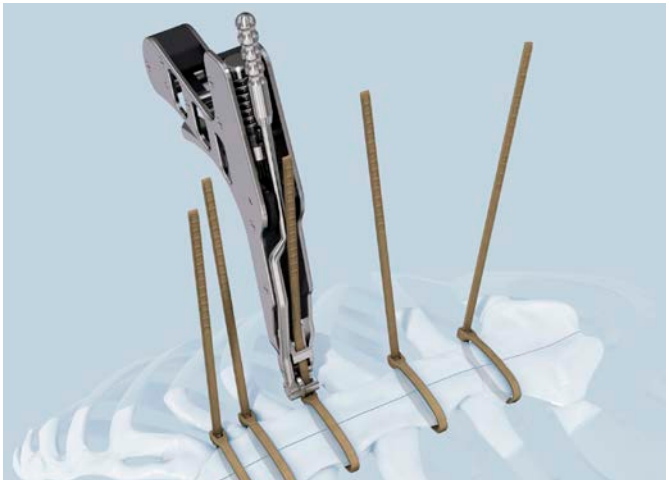
Tension remaining ZIPFIX.

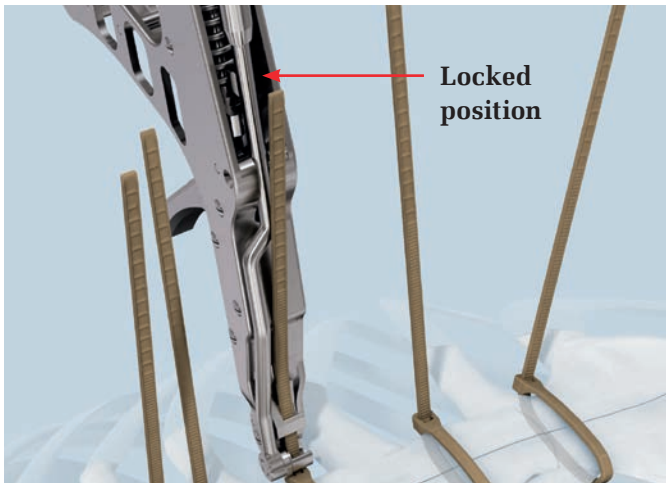
If required, the ZIPFIX can be tensioned again to achieve the desired stability.

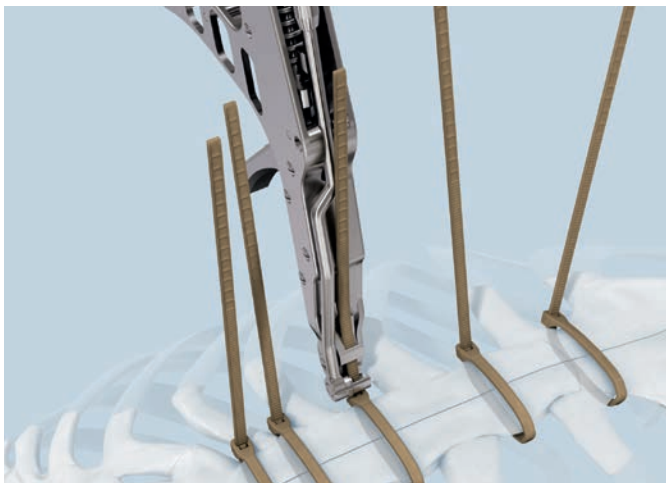
Warning: **Do not cut the implant until all implants have been fully tensioned. Implants cannot be tensioned once cut. Do not cut implants under tension.**

Precautions:
- **The application instrument has a mechanism to prevent overtensioning of the ZIPFIX implant. Do not apply additional force to overtension the implant.**
- **Care should be taken to control ZIPFIX tension in patients with poor bone quality to prevent additional injuries.**
- **Refer to "Maintenance of Application Instrument" section (page 22) for proper care instructions for the application instrument. Failure to lubricate the application instrument may result in instrument failure.**
- **Ensure that the application instrument is placed perpendicular to and is touching the locking head during tensioning.**

Note:
- **The application instrument may not tension if the cutting lever is not in the locked position.**







7
Remove excess material

Instrument	
03.501.080	Application Instrument for Sternal ZIPFIX

Optional Instrument	
391.905	Cable Cutter, standard

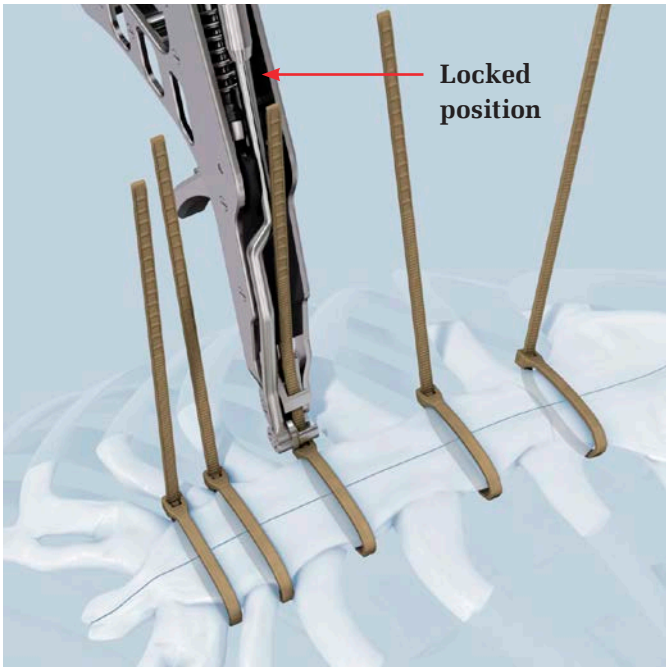
Insert the cut end of the implant into the front portion of the application instrument and slide the application instrument down to the locking head.

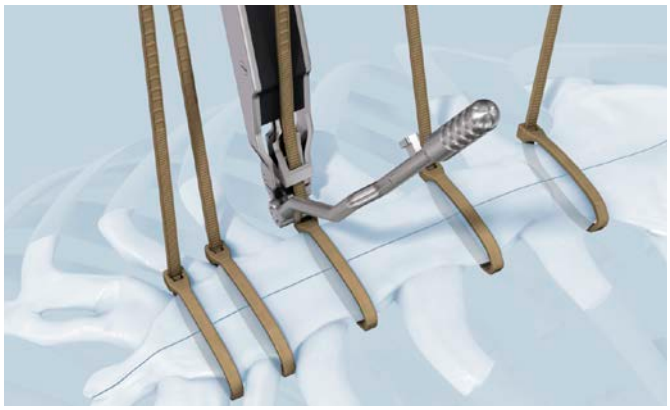
Fully extend the lever to cut the implant.

Return the cutting lever to the locked position before cutting subsequent implants.

Warning: **The tensioning trigger must be completely released before and during implant cutting. Cutting the implant while tensioning with the application instrument could compromise the implant lock and lead to implant failure. Do not cut the implant under tension.**

Precautions:
- **Ensure that the application instrument is placed perpendicular to and is touching the locking head during cutting to avoid sharp edges. The excess material can also be removed with a wire/pin cutter.**
- **The Sternal ZIPFIX implant cannot be tensioned after it is cut.**



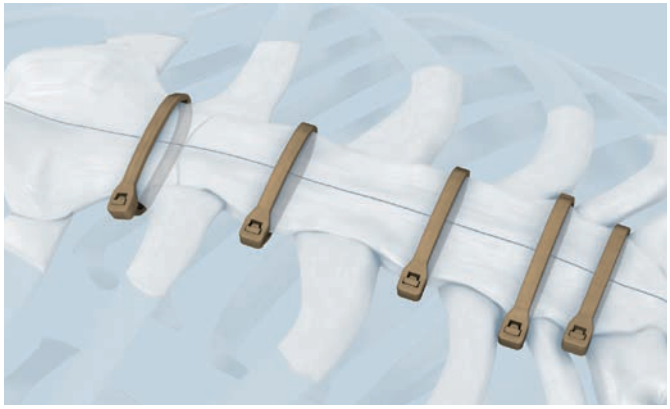


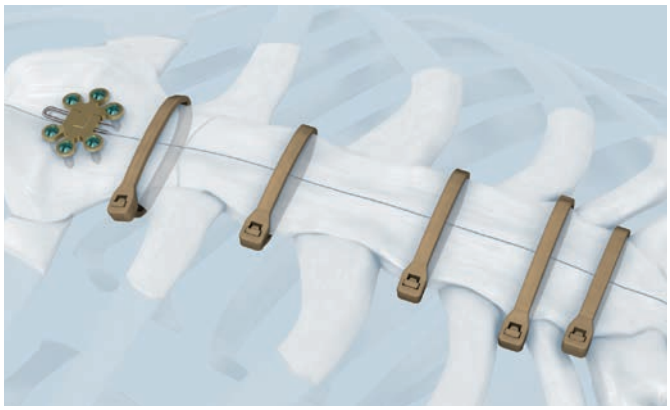
8

Confirm integrity of final construct

Confirm the integrity of the sternum.

Note: A manubrium plate can be added if additional stability in the manubrium is desired. Refer to the *Synthes Titanium Sternal Fixation System Surgical Technique* for additional information.





9

Postoperative considerations

Standard sternal precautions are recommended for 6 weeks after surgery, including:

- Patient should not lift more than 10 lbs (4.5 kg).
- Patient should not raise arms greater than 90°.
- Patient should press a pillow against his/her chest in the event of a strong cough.
- Do not pull or lift the patient by the arms.
- Avoid trunk twisting.

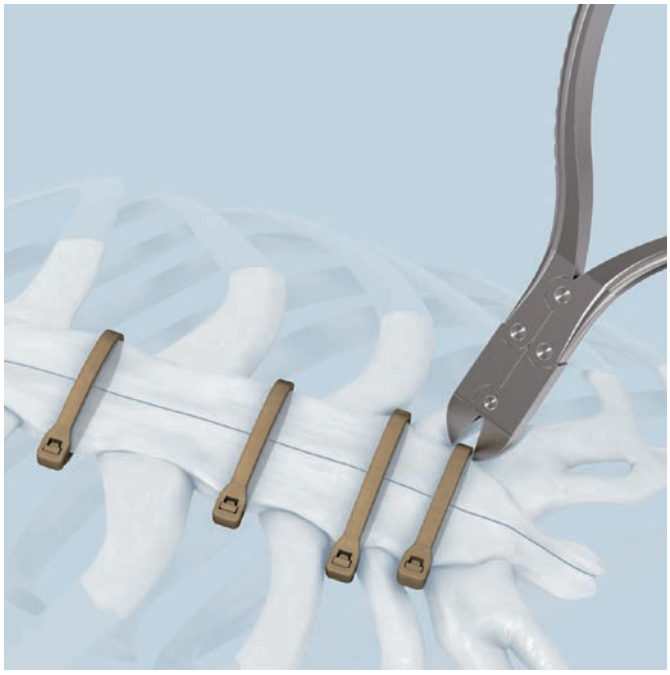
IMPLANT REMOVAL

1
Cut Sternal ZIPFIX implants

Instrument	
391.905	Cable Cutter, standard

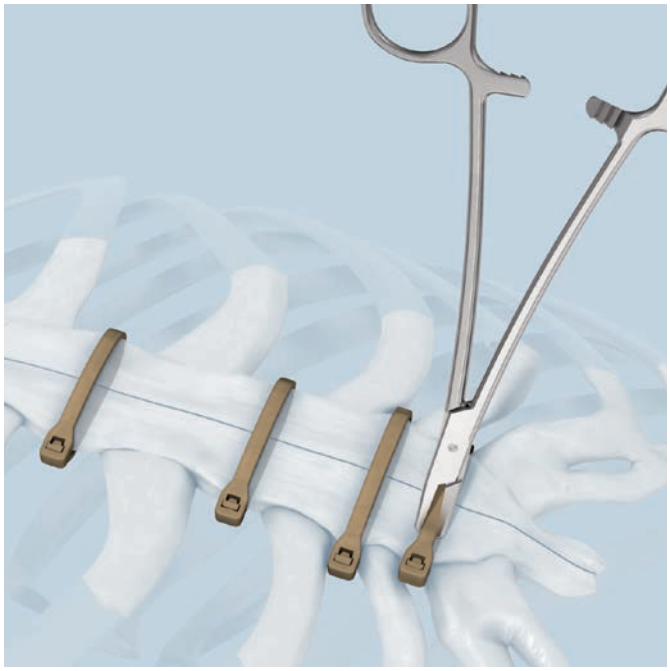
Cut all ZIPFIX with the cable cutter.

Note: **The ZIPFIX can also be cut with wire/pin cutters.**



2
Remove Sternal ZIPFIX implants

Carefully remove the ZIPFIX by pulling on the implant body.



IMPLANTS

Sternal ZIPFIX

08.501.001.01S	Sternal ZIPFIX with Needle, PEEK, sterile, single pack
08.501.001.05S	Sternal ZIPFIX with Needle, PEEK, sterile, pack of 5 units
08.501.001.20S	Sternal ZIPFIX with Needle, PEEK, sterile, pack of 20 units

INSTRUMENTS

03.501.080	Application Instrument for Sternal ZIPFIX	
03.503.072	Screwdriver Shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling*	
03.503.073	MatrixMANDIBLE Screwdriver, self-holding*	
311.023	Ratcheting Screwdriver Handle, with Hexagonal Coupling*	

*Optional

391.905 Cable Cutter, standard

398.902 Sternal Reduction Forceps*

398.903 Sternal Reduction Forceps, angled, with ratchet lock

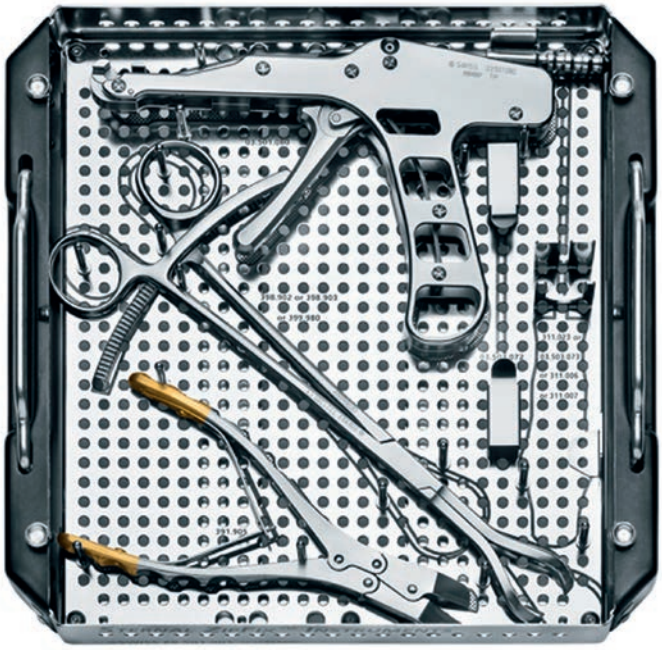
398.985 Reduction Forceps with Points, ratchet lock, length 180 mm*

*Optional

SET LIST

Sternal ZIPFIX System (01.501.006)

Instruments	
68.501.001	Instrument Tray for Sternal ZIPFIX Instruments
03.501.080	Application Instrument for Sternal ZIPFIX
398.903	Sternal Reduction Forceps, angled, with ratchet lock
391.905	Cable Cutter, standard



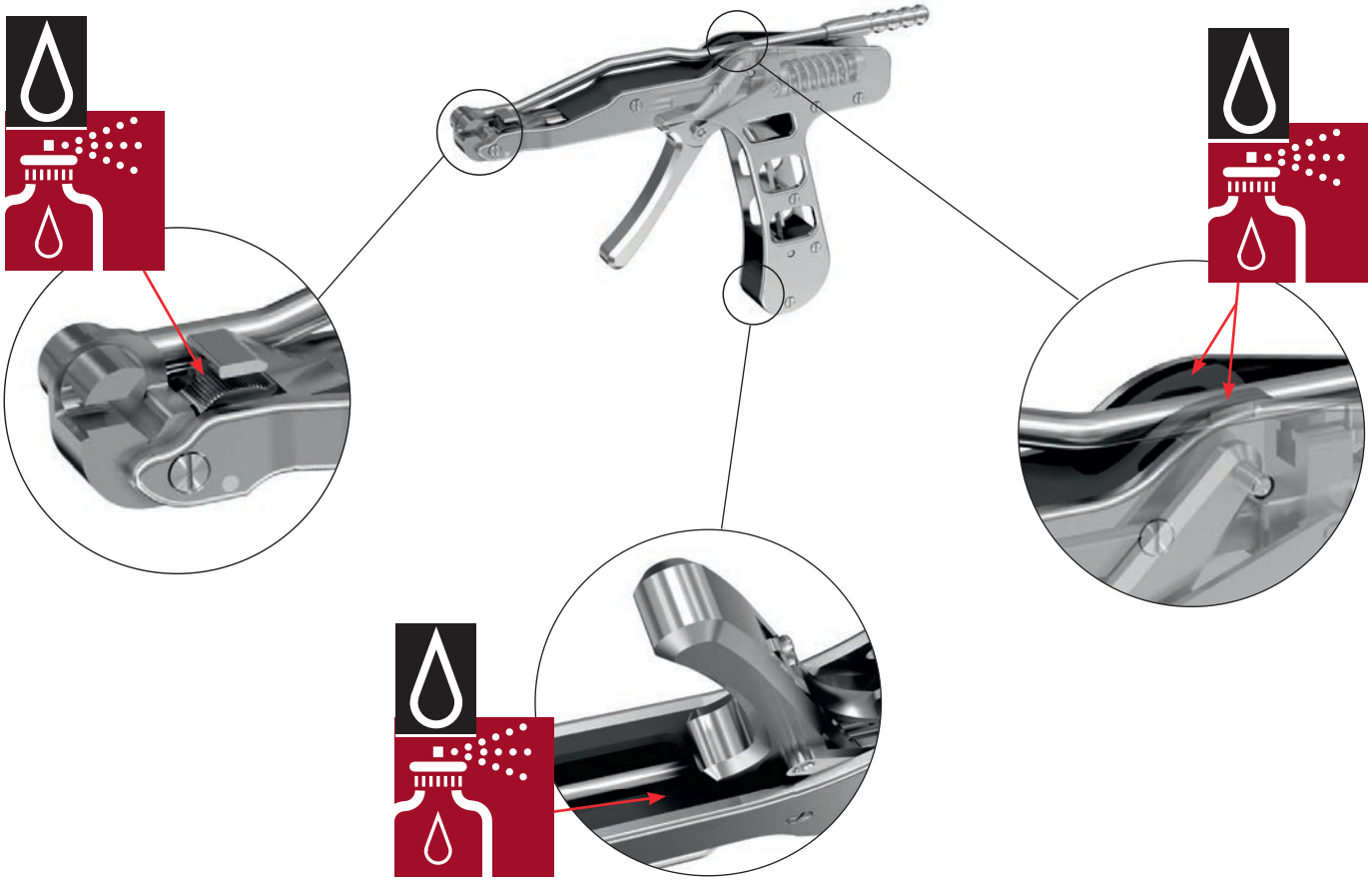
Optional instruments

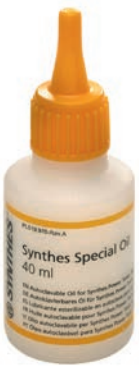
398.902	Sternal Reduction Forceps
398.985	Reduction Forceps with Points, ratchet lock, length 180 mm
399.980	Reduction Forceps, large, with Points, length 200 mm
311.006	Handle, medium, with Hexagonal Coupling
311.007	Handle, large, with Hexagonal Coupling
311.023	Ratcheting Screwdriver Handle, with Hexagonal Coupling
03.503.072	Screwdriver Shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling
03.503.073	MatrixMANDIBLE Screwdriver, self-holding

MAINTENANCE OF APPLICATION INSTRUMENT (03.501.080)

The Sternal ZIPFIX application instrument must be lubricated prior to sterilization.

Apply oil directly to the areas indicated.



519.970	Synthes Special Oil, 40 ml	

05.001.098 Synthes Maintenance Spray, 400 ml

05.001.095 Synthes Maintenance Oil, 40 ml, for EPD and APD

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 036.001.285 AE 03/2014