

Modular Sternal Cable System.

Flexibility and strength in sternal closure and repair.

Technique Guide

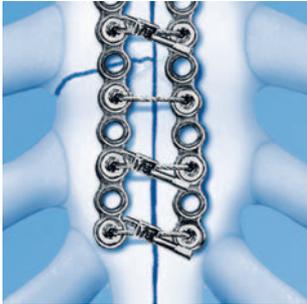


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Warning

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

Cleaning of instruments

For detailed information please refer to "Reprocessing, Care and Maintenance" of Synthes instruments in the section "Medical Community" on the international Synthes website www.synthes.com, and to "Care and Maintenance for Tensioner/Crimper/Cutter for Sternal Cable Ø 1.0 mm (391.291)", Art. No. 036.000.535.

Overview

The Synthes Modular Sternal Cable System is a set of stainless steel implants and instruments designed to facilitate sternal closure and repair.

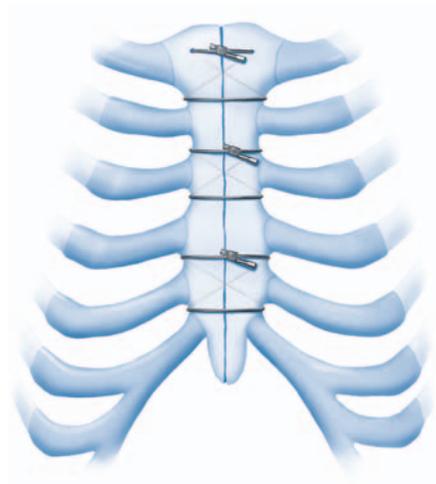
This system addresses the unique requirements of sternal closures. Implants can be combined to meet a specific patient need.

The Sternal Cable has been designed to be used alone (with needle), with cannulated screws (without needle) or with cannulated screws and plates (without needle).

The cable's flexibility and strength enable numerous closure options that provide stable fixation.

The benefits of each technique, the needs of the patient, and surgeon preference should be considered when selecting a method of closure. The chosen method will dictate the Sternal Cable Sets that need to be prepared for the surgical procedure.

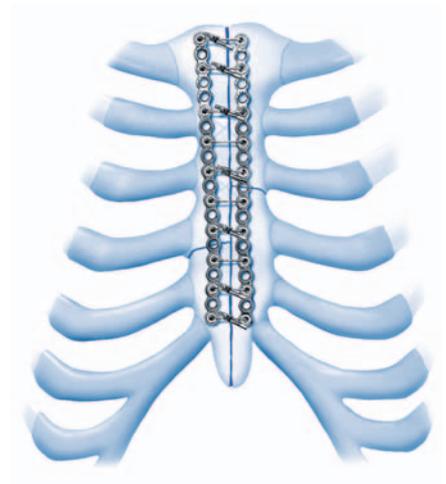
This guide outlines the three surgical techniques for using cable to close the sternum:



Peristernal (around the sternum) using cable with needle



Transsternal (through the sternum) using cable (without needle) and cannulated screws



Sternal Reconstruction using cable, cannulated screws and plates

Indications and Contraindications

-
- Sternal closure after sternotomy
 - Sternal repair and reconstruction of sternal transverse fractures

Note: Standard sternal precautions are recommended for six weeks after surgery, such as:

- Do not lift more than 4.5 kg.
- Do not pull or lift the patient by the arms.
- Do not raise arms greater than 90 degrees at shoulder level.
- Avoid trunk twisting.
- Patient should press a pillow against his chest if he has a strong cough.

Contraindications

The sternal reconstruction plates are not indicated for bridging a bony gap of the sternum

Warnings:

- Using the system in pediatric patients may result in pain and/or implant protrusions which may require ex-plantation.
 - Do not use this device in patients with known nickel allergy (stainless steel implant material 316L contains up to 15% nickel).
 - Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
-

A. Use of the Tensioning, Crimping and Cutting Device

The Tensioner/Crimper/Cutter for Sternal Cable (391.291) is used in all techniques to secure the sternal cables. Therefore the use of this instrument is described in the first chapter and referenced in the rest of this document.

1

Prepare device

Pulling back on the gold collar of the Tensioner/Crimper/Cutter place the fixation sleeve into the flat side of the nose of the instrument.

Release the gold collar to secure the fixation sleeve in the nose of the instrument.

Note: Handles must be completely open when placing the fixation sleeve in the nose or it will not fit.



2

Insert cable

Pass the cable through the fixation sleeve in the nose of the instrument.

Note: Make sure to pass it through the flat side of the nose first.

The gold collar may need to be pulled back slightly to pass the cable through the fixation sleeve. Make sure the fixation sleeve is facing up before pulling back on the collar, to ensure that it does not fall out of the instrument.



3a

Position instrument

Pass the cable through the fixation sleeve until it gets contact with the parallel end piece.

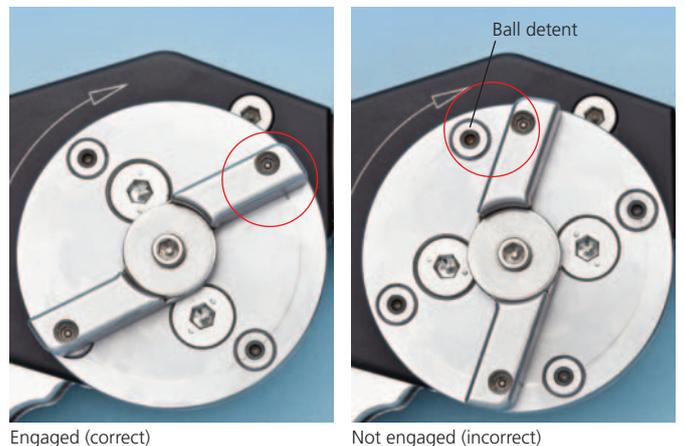
Note: The gold collar can be used to rotate the nose of the tool.



3b

Ensure tensioning wheel is set

Turn the wheel counterclockwise until the ball detent is engaged, if it is not already engaged.



4

Wrap the cable around the tensioning wheel

Wrap the cable clockwise (in the direction of the arrows) around the tensioning wheel on the instrument until it clicks once.

Note: Do not wrap the cable more than one click around the tensioning wheel to avoid a crossing of the cable during tensioning.



5

Tension cable

Turn the wheel clockwise (in the direction of the arrows) to tension the cable appropriately. The cable should fit snug to the bone.

Important: The instrument has a clutch mechanism which will slip, preventing overtensioning of the cable.

Note: Maximum tension is ensured when two audible clicks are heard. Avoid angling the ferrule during tensioning, as this may cut the cable prematurely.

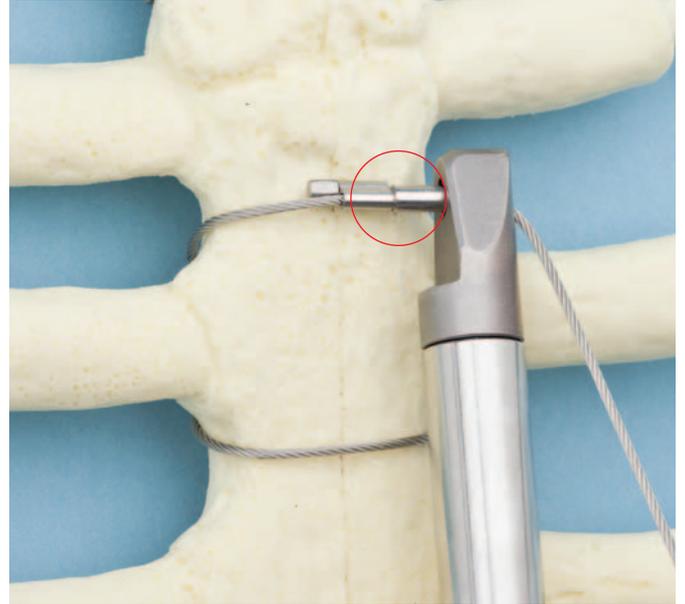


6

Verify cable positioning

Verify proper position of the instrument and the parallel end piece, as well as cable tension.

Important: Ensure the parallel end fitting and ferrule are positioned straight and along the line of the cable. The nose of the instrument should be square to the cable.



7

Crimp ferrule and cut cable

When correct position and tension have been achieved, squeeze the handles together completely to crimp and cut the cable, in one action.

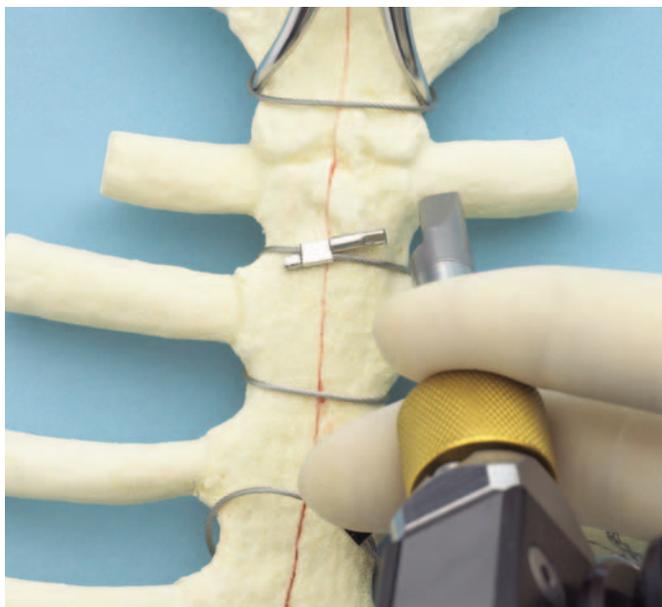
Note: Not squeezing the handles together completely will result in an incomplete crimp.



8

Release Cable

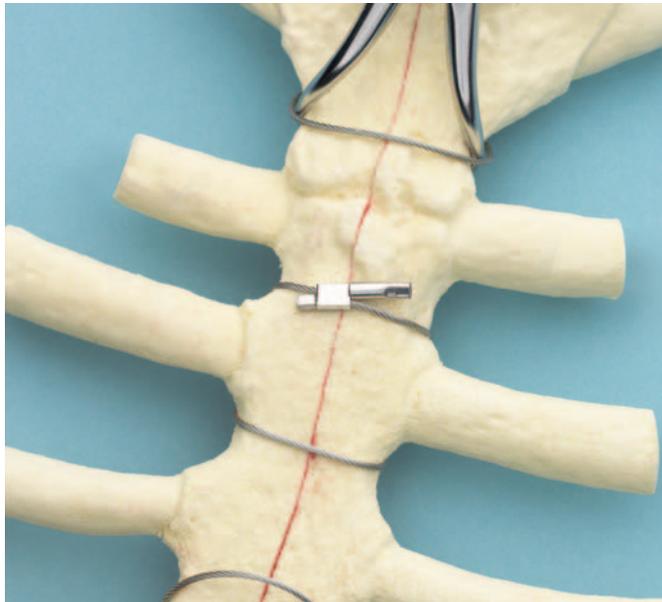
Pull back on the gold collar and remove the instrument from the crimped fixation sleeve.



9

Check appropriate fixation

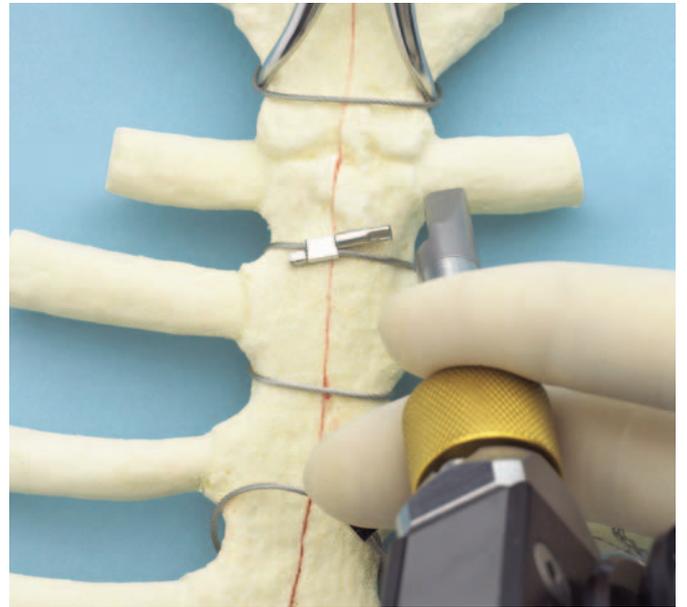
Verify visually that the cable is tight and that the sternal halves are correctly approximated.



10

Tensioning of the remaining cables

Repeat steps 1–9 to secure additional cables.



B. Peristernal Technique Using Cable with Needle



1

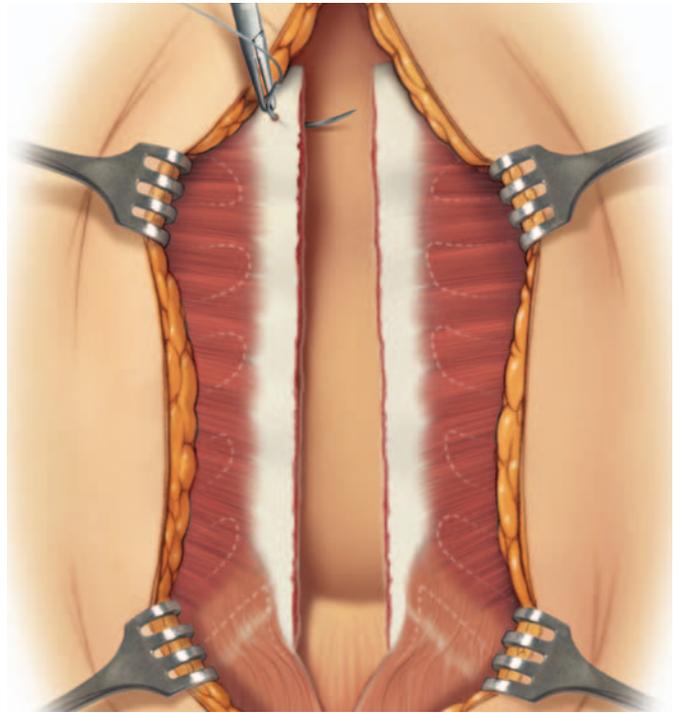
Suture cable

Suture the cable around the two halves of the sternum, using the attached cutting needle. The needle can be sutured through the manubrium and the intercostal spaces around the sternal body and xyphoid area.

Precaution: Take care to avoid damaging vessels or the soft tissue beneath the sternum.

Note: Always pull the cable completely through before going on with further suturing.

Precaution: A transsternal wiring in the sternal body and xyphoid with the cable alone is not recommended. The multifilament structure of the cable could lead to post-operative bleeding.



2

Release needle

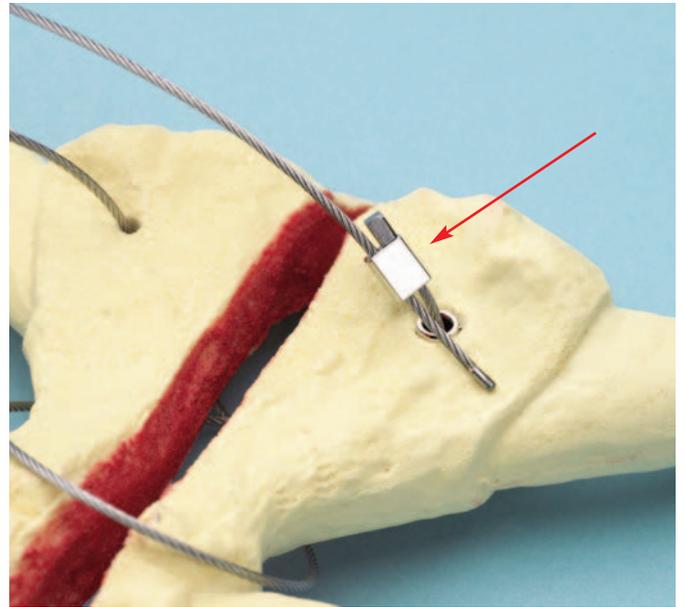
After weaving the cable, remove the quick-release needle from the end of the cable by holding the cable with one hand and pulling sharply on the needle with forceps.



3

Secure cable

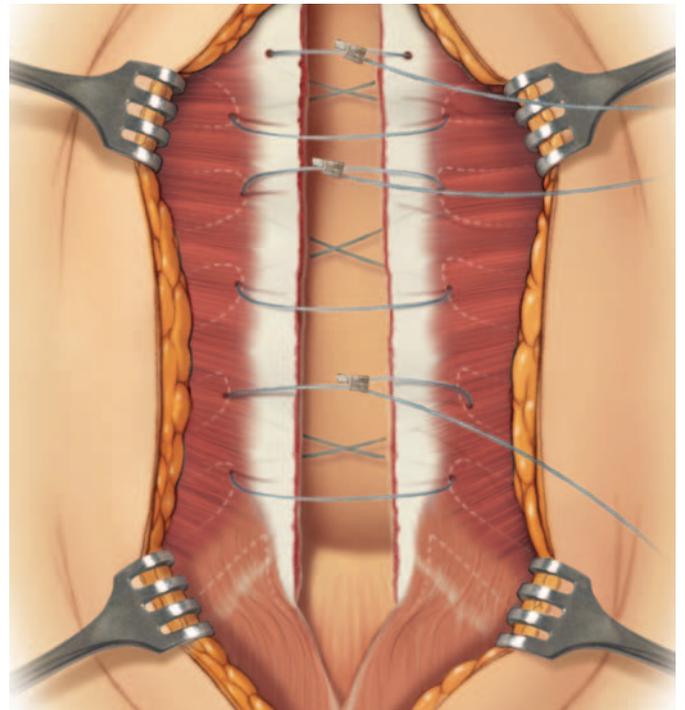
Pass the end of the cable through the parallel end piece and leave for the moment.



4

Place remaining cables

Continue with placement of additional cables as needed for the desired closure.



5

Reduce sternal halves

Instruments

398.903	Sternal Reduction Forceps, angled, with ratchet lock
398.985	Reduction Forceps

Optional instruments

351.026	Awl Ø 2.7 mm with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling
398.902	Sternal Reduction Forceps

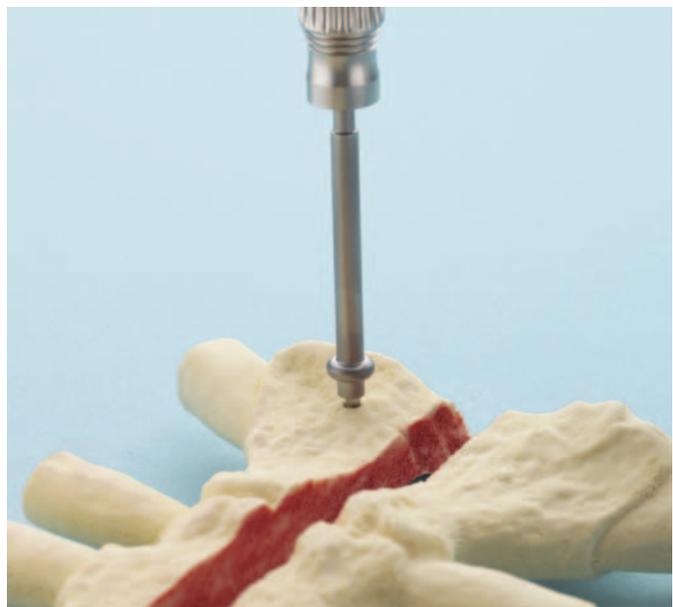
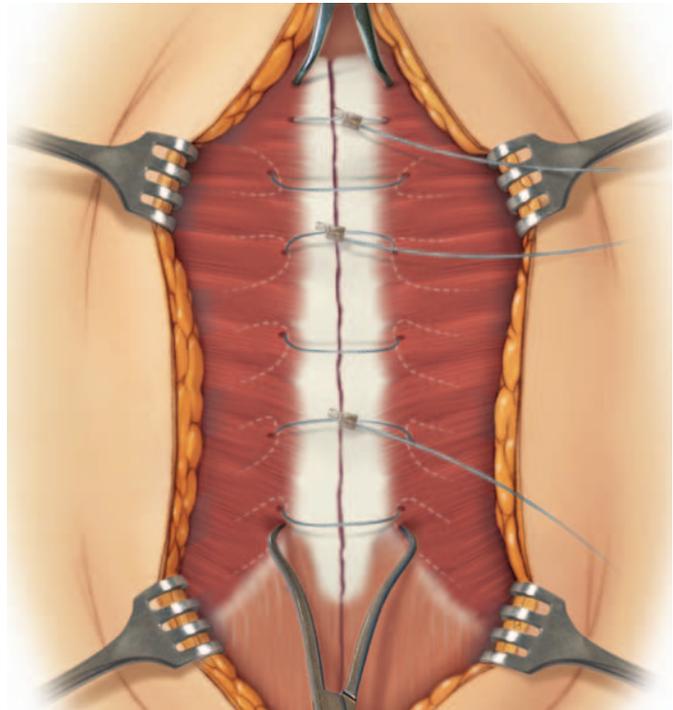
To achieve anatomical reduction of the sternum, the use of reduction forceps to approximate the sternal halves is recommended.

After the forceps are placed, tighten them to align the sternal halves into the correct anatomic position.

Note: The tips of the reduction forceps can be placed intercostally. Or if necessary, the 2.7 mm awl can be used to create pilot holes in the body of the sternum.

The tips of the forceps should not be placed against the cable during reduction.

Precaution: Take care to avoid damaging the vessels or any soft tissue while placing the forceps.



6

Secure Cables

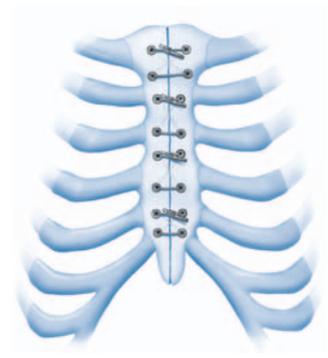
Tighten all cables by hand.

7

Tension Cables

Tension, crimp and cut the cables as described in chapter A (page 4–9).

C. Transsternal Technique Using Cable (without Needle) and Cannulated Sternal Screws



1

Position screws

Using a marking pen, identify locations for screw placement in the manubrium and sternal body.

2

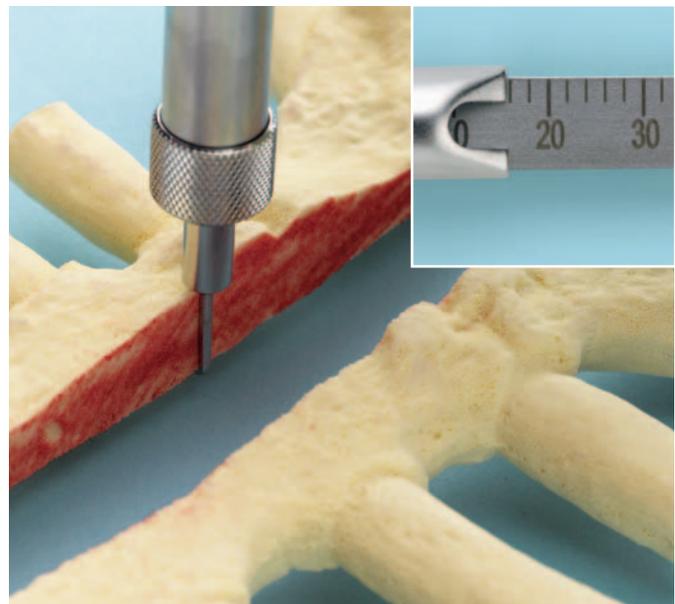
Measure sternal edges

Instruments

03.501.001 Depth Gauge for Sternal Cable

Using the Depth Gauge, determine the thickness of the sternum medial to the planned screw location.

Note: Bicortical screw insertion is critical for maximum effectiveness. Careful measurement and screw selection is necessary.



3

Select appropriate screw length

Select the appropriate length screw based on the depth-gauge reading.

4

Pick up cannulated screw

Instruments

351.034	Screwdriver Shaft, hexagonal, adjustable with Blade with spade point, for Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

Insert the 4.5 mm Hexagonal Adjustable Screwdriver Blade with spade point into the Screwdriver Handle.

Turn the adjustable sleeve on the screwdriver blade until the screw length determined in step 2 is indicated. Insert the tip of the screwdriver into the recess of the screw and press down to secure the screw to the blade.

Note: The tip of the blade should protrude approximately 2 mm beyond the tip of the screw.

Precaution: Take care to avoid damaging the soft tissue beneath the sternum.



5

Insert screw

Instruments

351.034	Screwdriver Shaft, hexagonal, adjustable with Blade with spade point, for Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

Insert the screw into the sternum.
When the screw is properly seated, remove the screwdriver blade by pulling straight back.

Precaution: To prevent any deeper injury, the cannulated screw should not be longer than necessary to engage the posterior cortex.



Proper insertion – anterior cortex



Proper insertion – posterior cortex

Optional instruments

351.026	Awl Ø 2.7 mm with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

In dense cortical bone, use the 2.7 mm Awl with the Screwdriver Handle to pierce the outer cortex of the sternum in the desired screw location.



6**Insert remaining screws**

Instruments

351.034	Screwdriver Shaft, hexagonal, adjustable with Blade with spade point, for Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

Repeat steps 3–5 to implant additional screws.

7

Insert cables

Instruments

351.027	Obturator for Sternal Cable Passer
351.028	Cable Passer for Sternal Cable Ø 1.0 mm

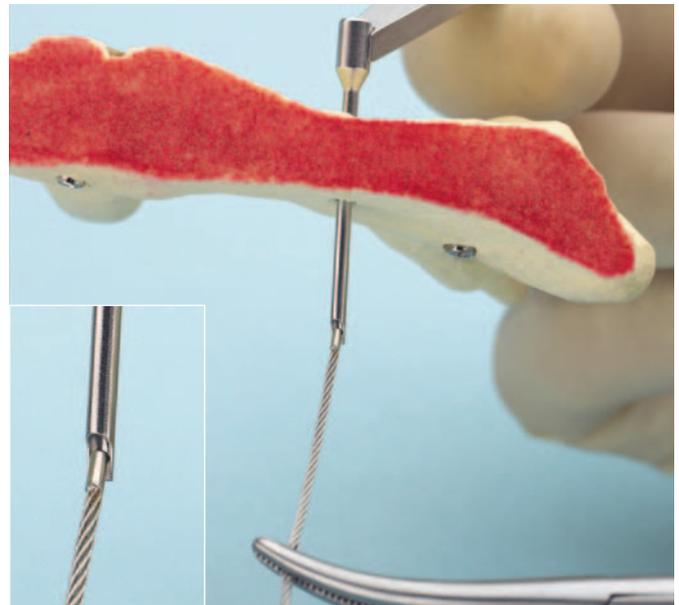
Insert the cable anterior to posterior through the first cannulated screw.



Insert the Cable Passer with Obturator into a screw in the opposite hemisternum. Remove the Obturator. Pass the cable through the Cable Passer from the posterior aspect of the sternum.

After pushing the end of the cable through the top of the Cable Passer, remove the Cable Passer while holding onto the cable. Continue by passing the cable through additional screws.

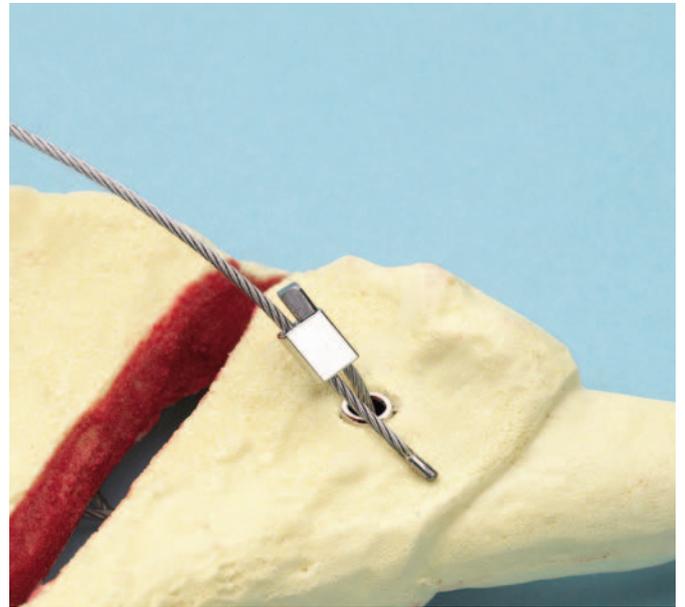
Note: The Cable Passer can also be used to pass the cable through the intercostal space.



8

Secure cable

Pass the end of the cable through the parallel end piece and leave for the moment.



9

Place remaining cables

Continue with placement of additional cables as needed for the desired closure.

10

Reduce sternal halves

Instruments

398.903	Sternal Reduction Forceps, angled, with ratchet lock
398.985	Reduction Forceps

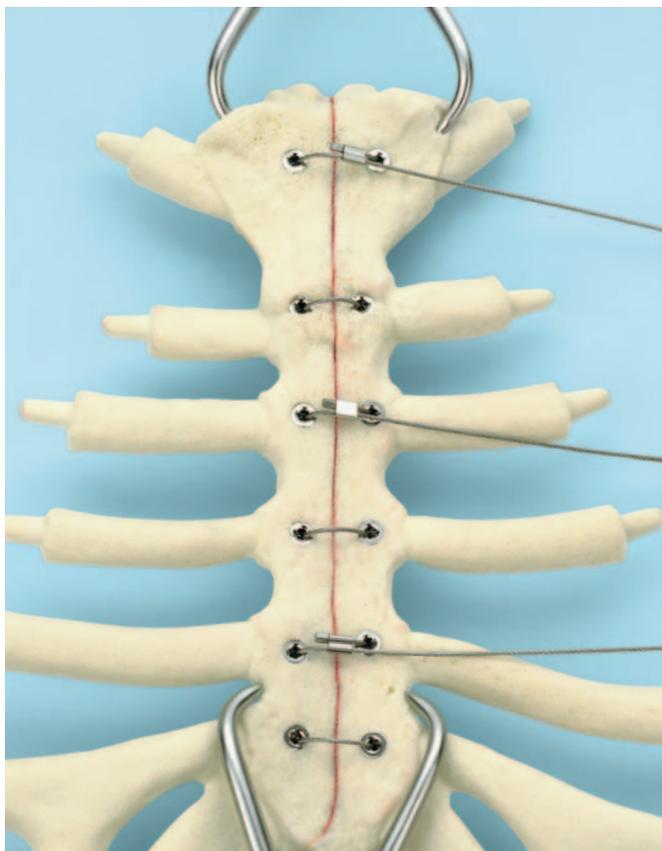
To achieve anatomical reduction of the sternum, the use of reduction forceps to approximate the sternal halves is recommended.

After the forceps are placed, tighten them to align the sternal halves into the correct anatomic position.

Optional instruments

398.902	Sternal Reduction Forceps
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Precaution: Take care to avoid damaging the vessels or any soft tissue while placing the forceps.



11

Secure Cables

Tighten all cables by hand.

12

Tension Cables

Tension, crimp and cut the cables as described in chapter A (page 4–9).

D. Sternal Reconstruction using Cable, Cannulated Screws and Plates



4.5 mm Sternal Reconstruction Plates can be used to fixate transverse fractures of the sternum. Plate implantation should be performed in conjunction with muscle flap advancement to ensure adequate blood supply, and to provide additional soft tissue coverage to the region.

1

Select plate

Select the plate of appropriate length.



2

Contour bending template

Instrument

329.400 Bending Template

Using the Bending Template, determine the contour of the hemisternum



3

Contour plate

Instrument

329.142 Bending Pliers with Nose

With the Bending Template as a guide, use the Combination Bending Pliers to contour the plate, in the following sequence:

In-plane bend

Place the plate into the jaws of the bender. Squeeze the handles together to bend the plate.



Out-of-plane bend

Place the plate into the jaws of the bender. Squeeze the handles together to bend the plate.



Or:

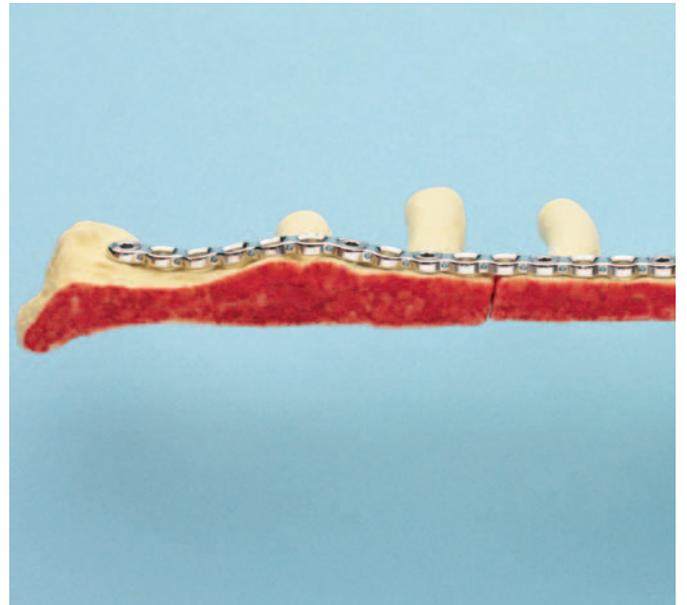
Place the plate into the “duckbill” end of the bender. Squeeze the handles together to bend the plate.



4

Place plate

Place the plate on the sternum to verify contour accuracy.



Profile of plate on the sternum

5

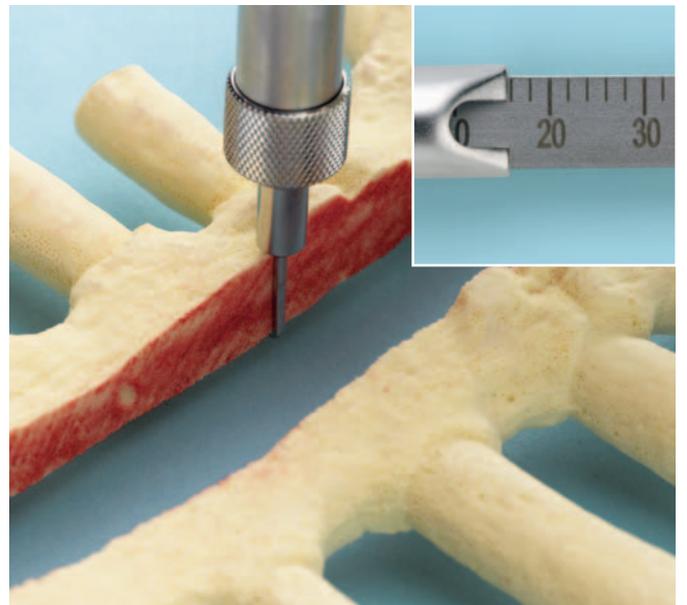
Measure sternal edges

Instruments

03.501.001 Depth Gauge for Sternal Cable

Using the Depth Gauge, determine the thickness of the sternum medial to the planned screw location.

Precaution: Bicortical screw insertion is critical for maximum effectiveness. Careful measurement and screw selection is necessary.



6

Select appropriate screw

Select the appropriate length screw based on the depth gauge reading, adding **3 mm** to allow for plate thickness.

7

Pick up cannulated screw

Instruments

351.034	Screwdriver Shaft, hexagonal, adjustable with Blade with spade point, for Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

Insert the 4.5 mm Hexagonal Adjustable Screwdriver Blade with spade point into the Screwdriver Handle. Turn the adjustable sleeve on the screwdriver blade until the screw length determined in step 6 is indicated. Insert the tip of the screwdriver into the recess of the screw and press down to secure the screw to the blade.

Note: The tip of the blade should protrude approximately 2 mm beyond the tip of the screw.



8

Attach plate to the sternum

Instruments

351.034	Screwdriver Shaft, hexagonal, adjustable with Blade with spade point, for Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

Using 4.5 mm Sternal Cannulated Screws, attach the plate to the sternum. Placing screws every two to three plate holes is recommended.

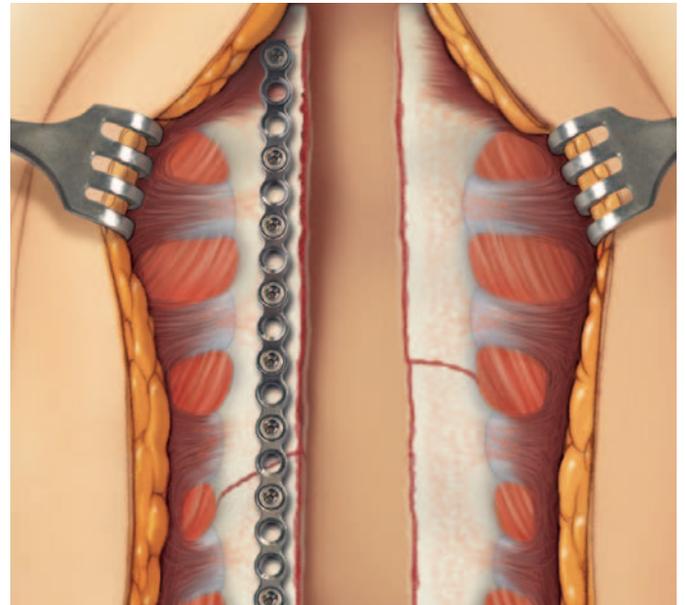
Note: If spanning a transverse fracture, placing screws adjacent to (but not in) the fracture is also recommended.

Precaution: To prevent any deeper injury, the cannulated screw should not be longer than necessary to engage the posterior cortex.

Optional instruments

351.026	Awl Ø 2.7 mm with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling

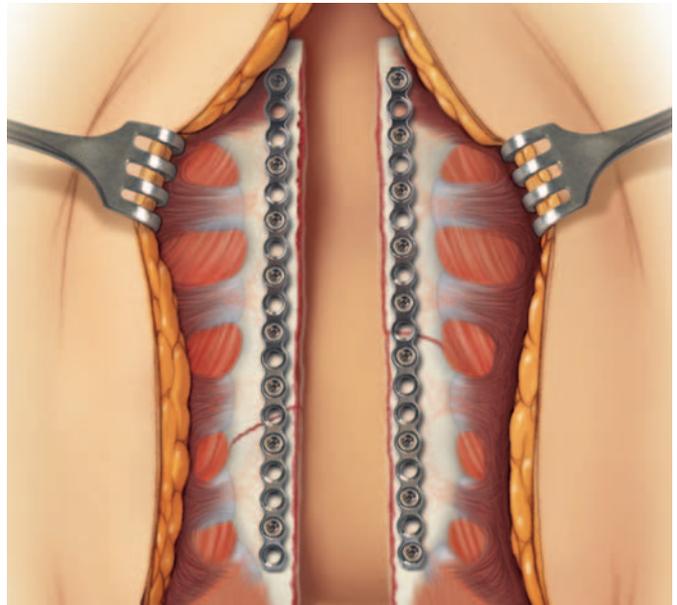
In dense cortical bone, use the 2.7 mm Awl with the Screwdriver Handle to pierce the outer cortex of the sternum in the desired screw location.



9

Attach remaining plates

Repeat this process with the other hemisternum as needed.



10

Secure cable

Instruments

351.027	Obturator for Sternal Cable Passer
351.028	Cable Passer for Sternal Cable Ø 1.0 mm

Insert the cable anterior to posterior through the first cannulated screw.

Insert the Cable Passer with Obturator into a screw in the opposite hemisternum. Remove the Obturator. Pass the cable through the Cable Passer from the posterior aspect of the sternum.

After pushing the end of the cable through the top of the Cable Passer, remove the Cable Passer while holding onto the cable. Continue by passing the cable through additional screws.



11

Secure Cables

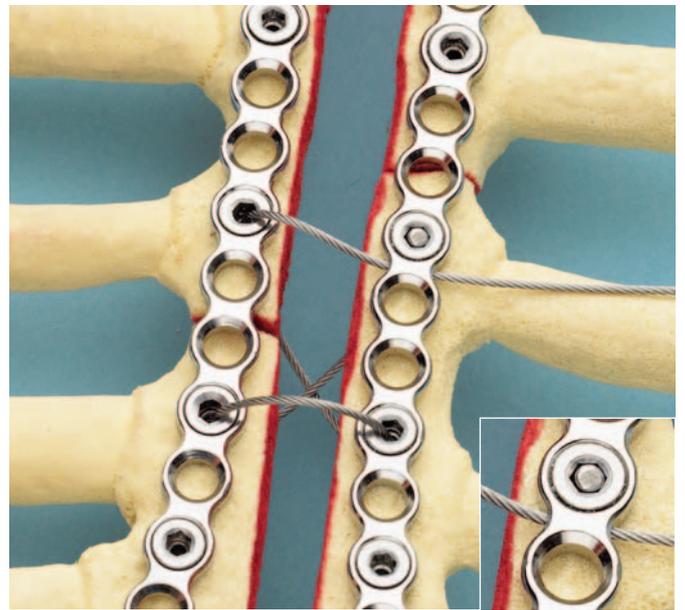
Pass the end of the cable through the parallel end fitting.

12

Alternative: Secure cables through transverse holes

The cable may be used without the parallel end fitting and terminated with a ferrule after passing it through a side hole in the plate.

To use this technique, first remove the parallel end fitting from the cable. Pass the cable through the first cannulated screw from anterior to posterior. The finished end of the cable will sit flush in the head of the screw, as shown.



When finished weaving the cable, pass it through a side hole in the plate.



13

Place remaining cables

Continue with placement of additional cables as needed for the desired closure.

Precaution: It is recommended that a minimum of ten total loops be used for closure with plates and screws, either using ten single loops, five figure of eight loops (two loops each), or a combination of each totaling ten loops.

14

Reduce sternal halves

Instruments

398.903	Sternal Reduction Forceps, angled, with ratchet lock
398.985	Reduction Forceps

To achieve anatomical reduction of the sternum, the use of reduction forceps to approximate the sternal halves is recommended.

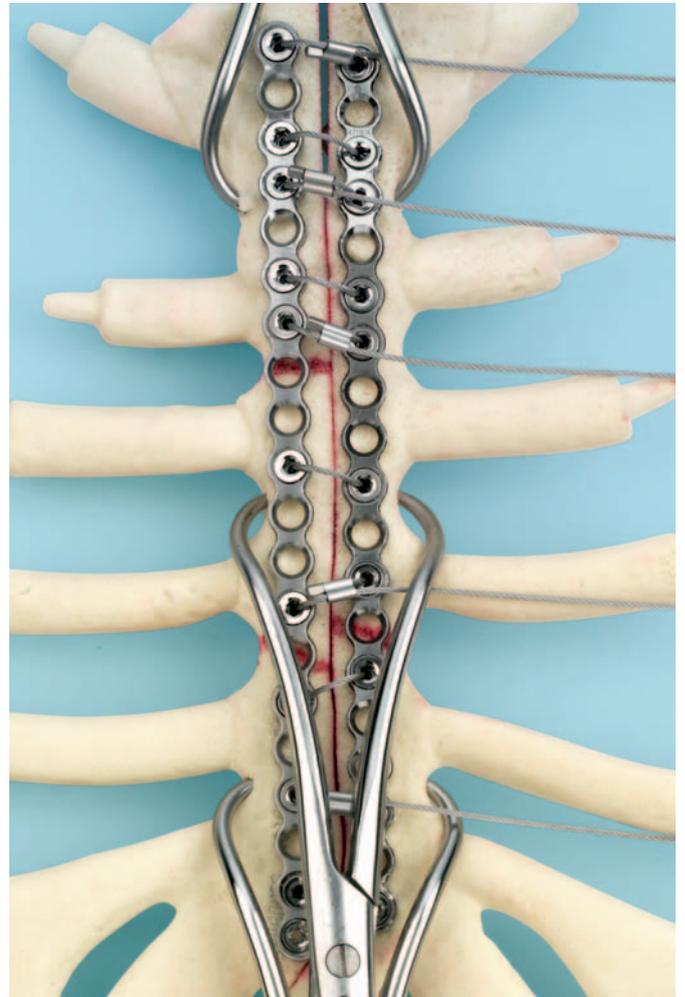
After the forceps are placed, tighten them to align the sternal halves into the correct anatomic position.

Note: The tips of the forceps should not be placed against the plates, screws or cables during reduction.

Optional instruments

398.902	Sternal Reduction Forceps
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Precaution: Take care to avoid damaging the vessels or any soft tissue while placing the forceps.



15

Secure Cables

Tighten all cables by hand.

16

Tension Cables

Tension, crimp and cut the cables as described in chapter A
(page 4–9).

E. Emergency Removal

1

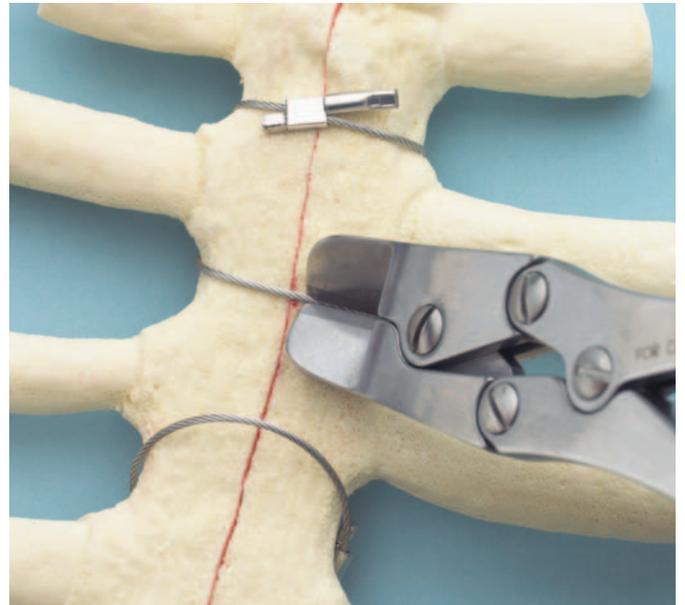
Cut cable

Instruments

391.905	Cable Cutter standard
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In case of emergency, the cable can be cut using standard wire cutters; however, using the Cable Cutter is recommended.

Note: If cannulated screws have been used, they may be left in the sternum and used again as a channel for cable passage.



Implants

291.911.01S Sternal Cable \varnothing 1.0 mm, with Fixation Sleeve and Parallel End Piece, Stainless Steel, sterile



291.916.01S Sternal Cable \varnothing 1.0 mm, with Needle, Fixation Sleeve, and Parallel Endpiece, Stainless Steel, sterile



291.906.05 Fixation Sleeve for Sternal Cable



291.907.05 Parallel End Piece for Sternal Cable



Cannulated Sternal Screw \varnothing 4.5 mm
 Lengths: 8 mm – 24 mm (1 mm increments)



Length	Non-sterile	sterile
8 mm	213.508	213.508S
9 mm	213.509	213.509S
10 mm	213.510	213.510S
11 mm	213.511	213.511S
12 mm	213.512	213.512S
13 mm	213.513	213.513S
14 mm	213.514	213.514S
15 mm	213.515	213.515S
16 mm	213.516	213.516S
17 mm	213.517	213.517S
18 mm	213.518	213.518S
19 mm	213.519	213.519S
20 mm	213.520	213.520S
21 mm	213.521	213.521S
22 mm	213.522	213.522S
23 mm	213.523	213.523S
24 mm	213.524	213.524S
25 mm	213.525	213.525S
26 mm	213.526	213.526S

Sternal Reconstruction Plate 4.5, Stainless Steel
 Lengths: 80 mm – 192 mm (16 mm increments)



Holes	Length	Non-sterile	sterile
10	80 mm	260.060	260.060S
12	96 mm	260.062	260.062S
14	112 mm	260.064	260.064S
16	128 mm	260.066	260.066S
18	144 mm	260.068	260.068S
20	160 mm	260.070	260.070S
22	176 mm	260.072	260.072S
24	192 mm	260.074	260.074S

Instruments

311.006 Handle, medium, with Hexagonal Coupling



03.501.001 Depth Gauge for Sternal Cable



329.400 Bending Template



329.142 Bending Pliers with Nose



351.026 Awl Ø 2.7 mm with Hexagonal Coupling



351.027 Obturator for Sternal Cable Passer



351.028 Cable Passer for Sternal Cable Ø 1.0 mm



351.034 Screwdriver Shaft, hexagonal, adjustable
with Blade with spade point, for
Hexagonal Coupling



351.035 Spare Blade for Screwdriver Shaft,
hexagonal, adjustable, for No. 351.034



391.291 Tensioner/Crimper/Cutter for Sternal Cable



391.905 Cable Cutter standard



398.903 Sternal Reduction Forceps, angled,
with ratchet lock



398.985 Reduction Forceps





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