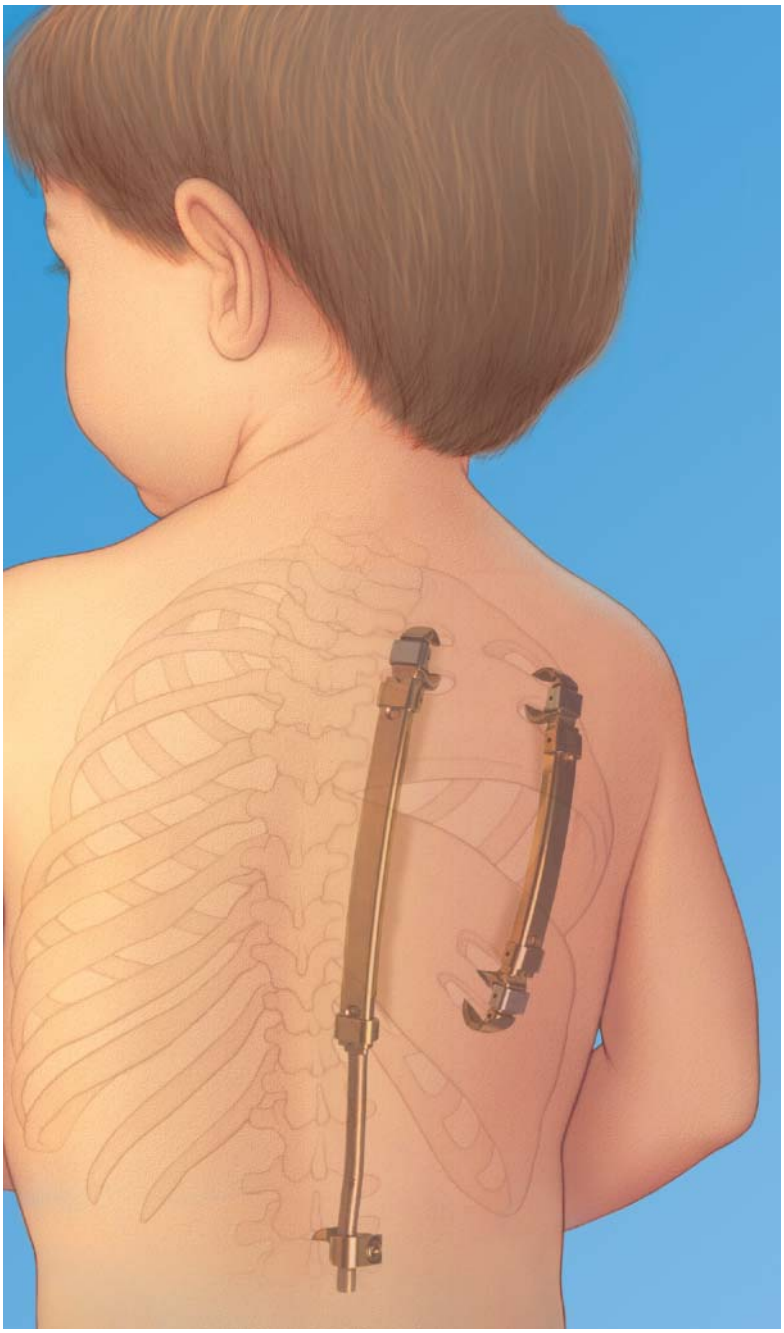
VEPTR. Vertical Expandable Prosthetic Titanium Rib.

Technique Guide



SYNTHES® Spine

Instruments and implants approved by the AO Foundation

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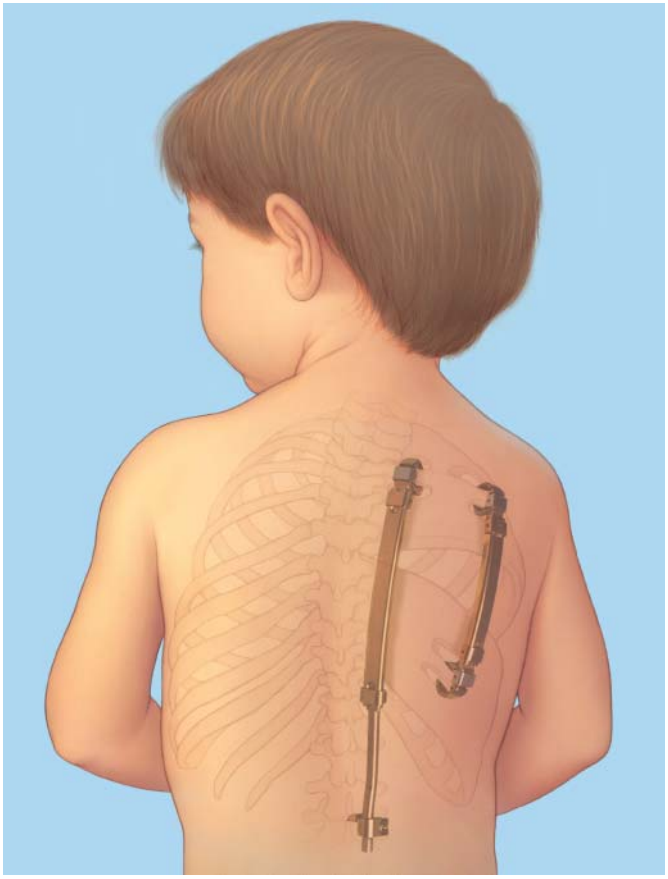
Image intensifier control

VEPTR. Vertical Expandable Prosthetic Titanium Rib.

The Vertical Expandable Prosthetic Titanium Rib (VEPTR) device is designed to mechanically stabilize and distract the thorax to correct three-dimensional thoracic deformities and provide improvement in volume for respiration and lung growth in infantile and juvenile patients diagnosed with thoracic insufficiency syndrome. The VEPTR devices are attached perpendicular to the patient's natural ribs, or to the lumbar vertebra or ilium. Once the VEPTR device is in place, its design allows expansion, anatomic distraction, and replacement of components through less-invasive surgery.

All components of the VEPTR system are manufactured from a titanium alloy, Ti-6Al-7Nb, with the exception of the S-Hook and the 2.0 mm Rod, which are manufactured from commercially pure titanium.

VEPTR implants are labeled MR Conditional according to the terminology specified in ASTM F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, and may be safely scanned only under certain conditions. Please refer to page 4 for further information about specific scan conditions.



Goals of treatment

- Increase thoracic volume
- Obtain thoracic symmetry
- Improve thoracic function
- Equilibrate the thorax by lengthening the concave, restricted hemithorax
- Avoid growth-inhibiting procedures
- Maintain these improvements throughout the patient's growth
- Maintain spinal alignment
- Allow spinal growth

Indications and Contraindications

Indications

The device is indicated for the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients. TIS is defined as the inability of the thorax to support normal respiration or lung growth. For the purpose of identifying potential TIS patients, the categories in which TIS patients fall are as follows:

- Flail chest syndrome
- Constrictive chest wall syndrome, including
  - Rib fusion and scoliosis
- Hypoplastic thorax syndrome, including
  - Jeune's syndrome
  - Achondroplasia
  - Jarcho-Levin syndrome
  - Ellis van Creveld syndrome
- Progressive scoliosis of congenital or neurogenic origin without rib anomaly

Contraindications

The VEPTR device should not be used under the following conditions:

- Inadequate strength of bone (ribs/spine) for attachment of the VEPTR device
- Absence of proximal and distal ribs for attachment of the VEPTR device
- Absent diaphragmatic function
- Inadequate soft tissue for coverage of the VEPTR device
- Age beyond skeletal maturity for uses of the VEPTR device
- Age less than 6 months
- Known allergy to any of the device materials
- Infection at the operative site

Humanitarian Use Device: Authorized by Federal law for use in the treatment of thoracic insufficiency syndrome in skeletally immature patients. The effectiveness of this device has not been demonstrated.

Patients implanted with the VEPTR should not be braced. The VEPTR device is designed to allow for thoracic cavity growth and the restrictive nature of a brace would not help the condition, but defeat its purpose.

Patients may require additional wound protection to prevent inadvertent rubbing or bumping of the wound.

Patients with a diagnosis of spina bifida should have an occlusive dressing over the wound site to keep the site dry.

MRI Information

Synthes Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II) implants are labeled *MR Conditional* according to the terminology specified in ASTM F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Non-clinical testing of the VEPTR/VEPTR II demonstrated that the implant is *MR Conditional*. A patient with a VEPTR/VEPTR II implant may be scanned safely under the following conditions:

- **Static magnetic field** of 1.5-Tesla and 3.0-Tesla at Normal Operating Mode
- **Highest spatial gradient magnetic field** of 3,000 Gauss/cm (30 T/m) or less
- **Maximum MR system** reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode for 15 minutes of scanning

To minimize heating, the scan time should be as short as possible, and the SAR as low as possible.

Note: In non-clinical testing, Synthes shortest, longest, and two intermediate VEPTR/VEPTR II implant construct lengths were assembled and tested for heating and results showed a maximum observed heating of 3.4° C for 1.5T and a maximum observable heating of 4.2° C for 3.0T with a machine reported whole body averaged SAR of 2 W/kg as assessed by calorimetry.

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal expected temperature rise is less than 4.2° C. To minimize heating, the scan time should be as short as possible and the SAR as low as possible. Temperature rise values obtained were based upon a scan time of 15 minutes.

The above field conditions tested in a 1.5T and a 3.0T Philips Achieva (Philips Healthcare, software release 2.6.3 SP4) MR scanner should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. Synthes *MR Conditional* VEPTR/VEPTR II implants may have the potential to cause artifact in the diagnostic imaging.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the VEPTR/VEPTR II implants and it may be necessary to optimize MR imaging parameters in order to compensate for the presence of the implants.

Representative constructs have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by VEPTR/VEPTR II implants may present issues if the MR imaging area of interest is in or near the area where the implant is located.

For FFE sequence

Scan duration: 3 min, TR 100 ms, TE 15 ms, flip angle 15°

- Worst-case artifact will extend approximately 1.5 cm from the ends of the implant and central lock and less than 0.5 cm around the rest of the implant

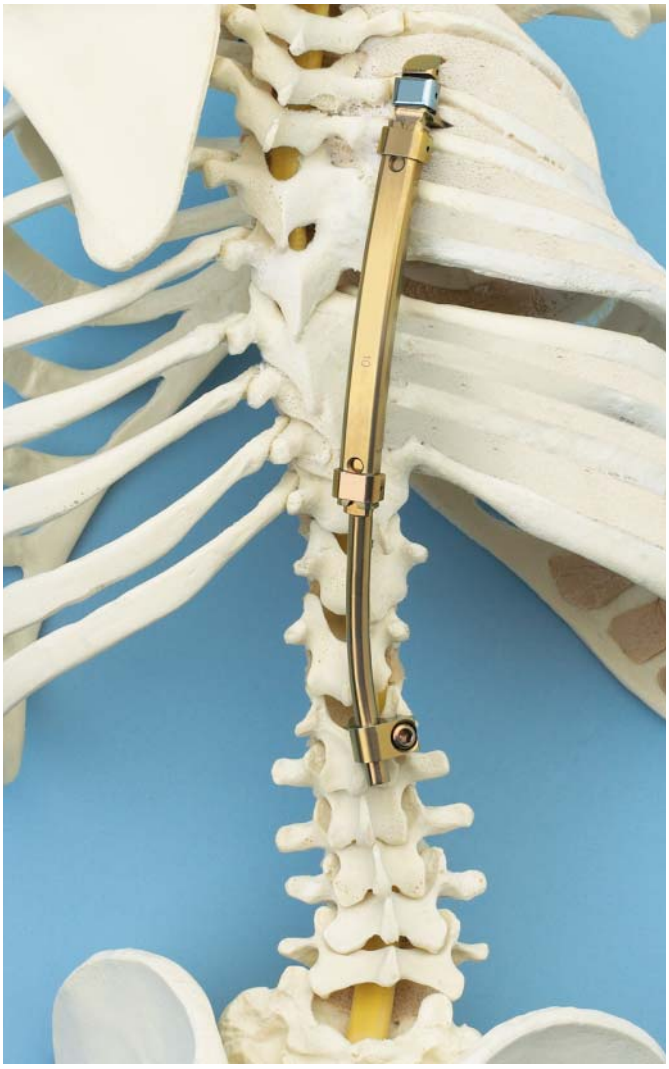
For SE sequence

Scan duration: 4 min, TR 500 ms, TE 20 ms, flip angle 70°

- Worst-case artifact will extend approximately 1.5 cm from the ends of the implant and central lock and less than 0.5 cm around the rest of the implant

Construct Options

Rib-to-Lumbar Lamina
- Attaches to rib and to lumbar spine
- Components available in 220 mm radius



Rib-to-Rib

– Attaches to the superior rib and to the inferior rib
– Components available in 70 mm or 220 mm radius

220 mm radius

70 mm radius

Rib-to-Ilium

– Attaches to the rib and to the ilium
– Components available in 220 mm radius

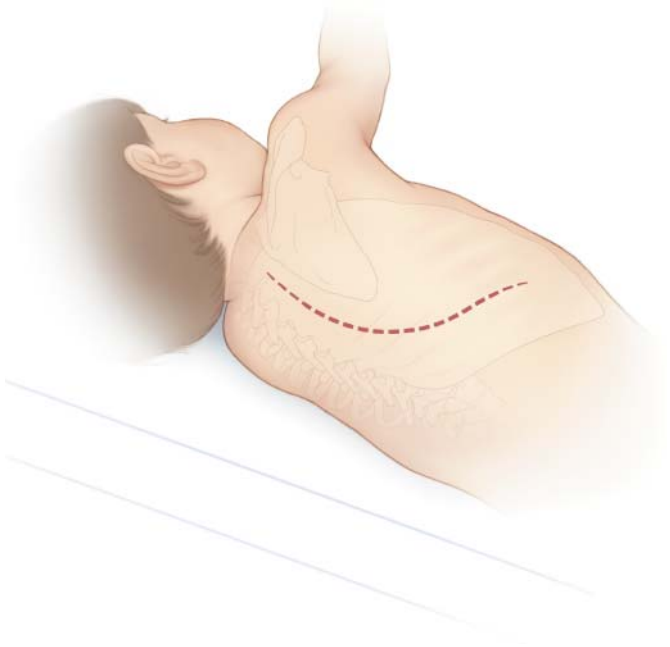
1

Patient positioning

Place the patient in a lateral decubitus position similar to that required for a standard thoracotomy.

To protect against brachial plexus injury, do not extend the shoulder more than 90°.

Note: Patient positioning and superior exposure remain the same regardless of the construct being implanted.

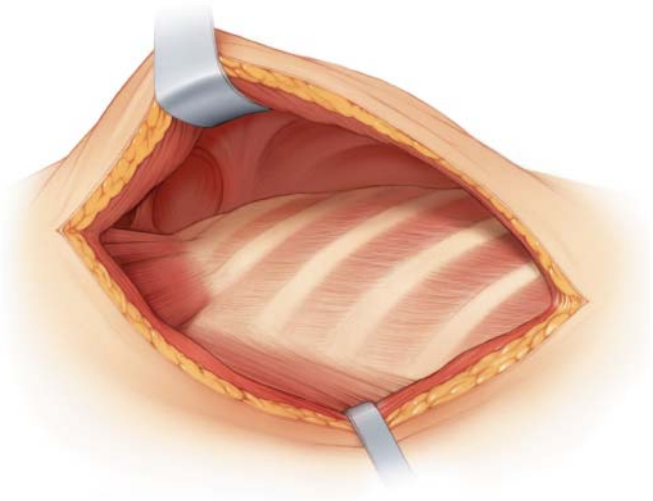


2

Superior exposure

Make a J-shaped thoracotomy incision without disrupting the periosteum overlying the ribs.

Retract the skin flaps. Continue the incision and elevate the paraspinal muscles medially only to the tips of the transverse processes. Gently elevate the scapula to expose the middle posterior scalene muscle.

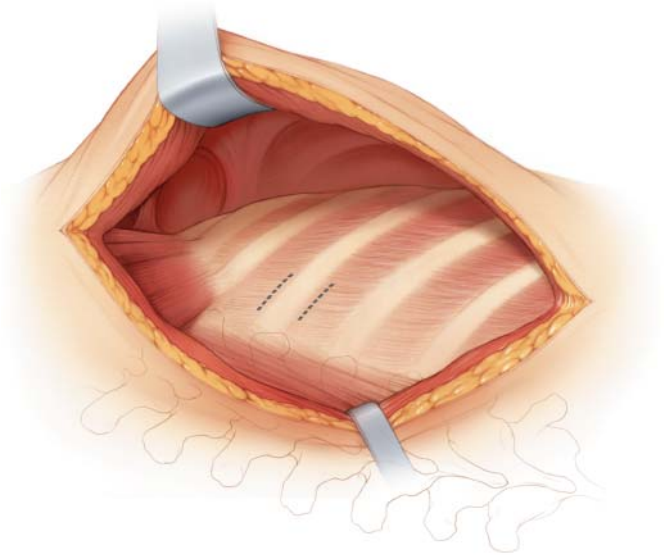


1

Identify superior rib

Identify the superior rib to be used as the superior point of attachment. Mark this point and confirm location using radiographic imaging.

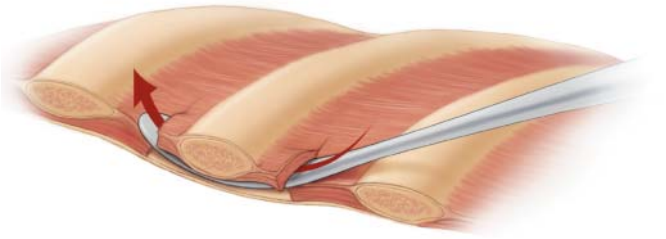
Because of the risk of brachial plexus impingement, do not choose the first rib as the superior point of attachment.



2

Prepare rib for implants

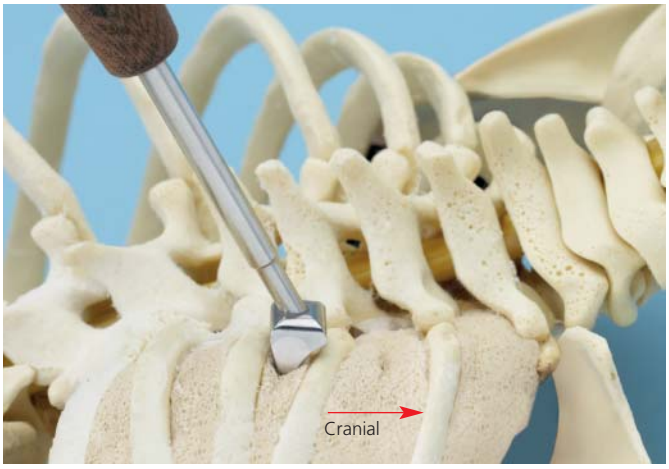
Instruments	
388.467	Cradle Trial
398.408	Freer Elevator
U44-483-20	Double-Ended Elevator



Make a one centimeter incision into the intercostal muscles above and below the rib where the superior cradle will attach. Insert a freer elevator or a double-ended elevator to carefully elevate the periosteum adjacent to the lung.

Take care to preserve the soft tissue surrounding the rib to protect rib vascularity and the neurovascular bundle.

Use the cradle trial to prepare the rib for the superior cradle and the cradle end half.



3

Select proper superior cradle angulation and radius

Assess the patient's thoracic anatomy in order to determine the required superior cradle angulation (neutral, right, or left).

Choose either a 70 mm or 220 mm radius superior cradle. A 220 mm cradle is used with either a lumbar extension or a 220 mm radius inferior cradle. A 70 mm cradle is used solely with the 70 mm inferior cradle.

The corresponding rib sleeve should match the contour of the thorax when the proper angulation is chosen.

4

Seat superior cradle

Instrument	
388.461	Cradle Holding Forceps

Using the cradle holding forceps, seat the underside of the superior cradle into the space between the periosteum and the rib (Figure 1). Rotate it into the correct position (Figure 2). For the medial construct, seat as medial as possible to the transverse process.

Figure 1

Figure 2

5

Select proper cradle end half size

Based on the patient's anatomy, select the appropriate cradle end half (standard or extended). The extended cradle end half is used to encircle large areas of fused rib or two ribs.

6

Insert cradle end half

Instruments	
388.453*	Cradle End Half Forceps
388.465	Clamp, for Cradle End Half

Using the clamp for cradle end half, insert the cradle end half into the intercostal space above the contralateral side of the rib, with the open end facing laterally to protect the great vessels (Figure 1). Rotate it distally to mate with the superior cradle (Figure 2).

Figure 1

Figure 2

7

Align superior cradle and end half

Instruments	
388.488	Cradle Jaw
388.489	End Half Jaw
388.494	Parallel Compressor Body

If the cradle end half and superior cradle are not aligned, prepare the cradle assembly forceps. Affix the end half jaw and the cradle jaw to the parallel compressor body. This assembly is referred to as the cradle assembly forceps.

Align the superior cradle with the cradle end half using the cradle assembly forceps (Figure 1).

Figure 1

* Also available

8
Insert cradle lock

Instruments	
388.456*	Lock Inserter
388.474	Lock Crimper
388.475	Lateral Lock Inserter
388.493	Lock Impactor
399.41	Hammer

Load a cradle lock into the lock impactor (Figure 1). Lock the superior cradle-cradle end half assembly by inserting the cradle lock into the aligned holes of the superior cradle and the cradle end half (Figure 2). Using the hammer, firmly tap the impactor to seat the lock.

The lock crimper should always be used to ensure the lock is fully seated (Figure 3).

Alternatively, the lock inserter or the lateral lock inserter can be used to seat the lock.

The implants now encircle the rib (Figure 4).

Figure 1

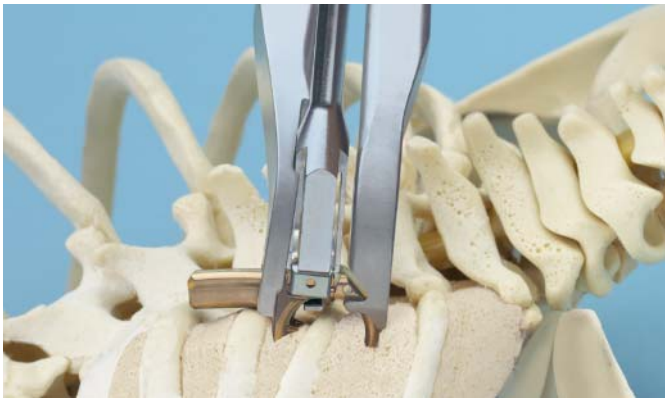


Figure 2

Figure 3

Figure 4

* Also available

1

Distract chest wall

Instruments	
388.486	Rib Blade
389.501	Vein Retractor
399.13	Bone Spreader
U22-640-10	Longitudinal Retractor

Assemble two rib blades to the longitudinal retractor. Distract ribs using the rib retractor assembly as needed (Figure 1). Bone spreaders in conjunction with vein retractors can also be used to gently distract the chest wall at the site of an opening wedge thoracotomy.

Additional resection of medial fused ribs may be required if distraction is difficult. Only resect visible bone adjacent to the spine. Be aware of anomalous segmental arteries due to abnormal anatomy.

Figure 1

388.486 U22-640-10

2

Select appropriate rib sleeve

Instrument	
388.902	Coated Rod Template

Using the coated rod template, measure the distance between the superior rib and either the thoracolumbar junction or the chosen inferior rib to determine the appropriate rib sleeve size.

– Measure to the thoracolumbar junction when planning a rib-to-ilium or rib-to-lumbar lamina construct.
– Measure to the inferior rib when using a rib-to-rib construct.

The measurement in centimeters will correspond to the correct rib sleeve size. For example, if the distance is determined to be 7 cm, use a rib sleeve marked with a 7. Implant sizes are identified from 4 to 13 in 1 cm increments.

Lumbar extension
(Use for rib-to-lumbar lamina or rib-to-ilium constructs)

1

Select appropriate lumbar extension

Lumbar extension sizes correspond to the rib sleeve sizes. For example, if the selected rib sleeve is a size 9, the correct lumbar extension will also be a 9.

2

Determine contour and cut to length, if necessary

Instruments	
388.750*	Table Top Rod Cutter and Bender
388.961	Rod Bender

Alternative instruments	
329.052, 329.053	Bending Irons, for 6.0 mm rods, right and left

Use the coated rod template to determine the contour of the rod portion of the lumbar extension. Do not bend the T-section of the lumbar extension which mates with the rib sleeve. Using the rod bender, contour only the rod portion to match the anatomy. As an alternative, the bending irons for 6.0 mm rods can be used for contouring.

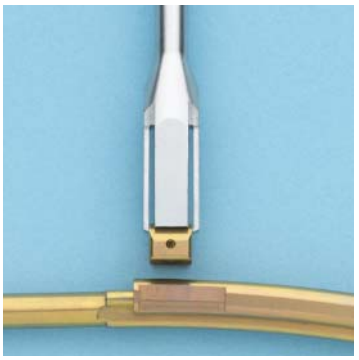
If necessary, cut the rod portion of the lumbar extension to the correct length using the table top rod cutter. The length of the rod portion of the lumbar extension should be at least equal to the distance between the thoracolumbar junction and the planned inferior implant. When using a lamina hook, an additional length of 1.5 cm should be left to allow for distraction.

* Also available

Lumbar extension
(Use for rib-to-lumbar lamina or rib-to-ilium constructs)

1

Insert inferior distraction lock



Instruments	
388.456*	Lock Inserter
388.474	Lock Crimper
388.493	Lock Impactor
399.41	Hammer

Prior to insertion, connect the rib sleeve with the lumbar extension by sliding the lumbar extension into the rib sleeve. Align the most inferior hole in the rib sleeve with the most inferior hole in the lumbar extension. The implants should overlap completely to maximize expansion over time.

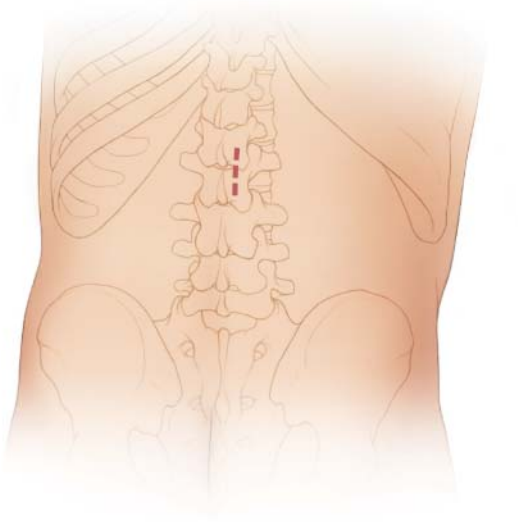
Place a distraction lock in this position using the lock impactor. Using the hammer, firmly tap the impactor to seat the lock. The lock crimper should always be used to ensure the lock is fully seated.

Alternatively, the lock inserter or the lateral lock inserter can be used to seat the lock.

2

Insert inferior implant

Option 1
Offset lamina hook (Use for rib-to-lumbar lamina construct)



Instruments	
388.495	Hook Holding Forceps
388.521	Lamina Finder

Make a four-centimeter, longitudinal, paraspinal skin incision on the concave side of the curve at the lumbar interspace that was selected preoperatively. Retract the paraspinal muscles laterally. Do not disturb the facet joints.

* Also available

Lumbar extension
(Use for rib-to-lumbar lamina or rib-to-ilium constructs)

2. Insert inferior implant

Use the lamina finder to separate the ligamentum flavum unilaterally from the underside of the lamina to ensure good bony contact with the lamina hook, leaving the interspinous ligament intact. Resect enough ligamentum flavum for the hook to pass.

388.495

Choose the appropriate offset lamina hook (right or left). The hook will be placed downward-facing and the setscrew will be lateral.

Use the hook holding forceps to place the hook in the desired location on the lumbar vertebra (Figure 1). The hook can be further secured by using a heavy, non-absorbable suture around the spinous process.


Figure 1

Option 2
S-Hook (Use for rib-to-ilium construct)

Make a four-centimeter incision just lateral to the posterior superior iliac spine (Figure 2). Identify the posterior third and middle third of the iliac crest. Incise the apophysis transversely to create a tunnel for the S-hook.

Choose the appropriate S-hook. The correct S-hook should have the upper end lying medial to the downward pointed end.

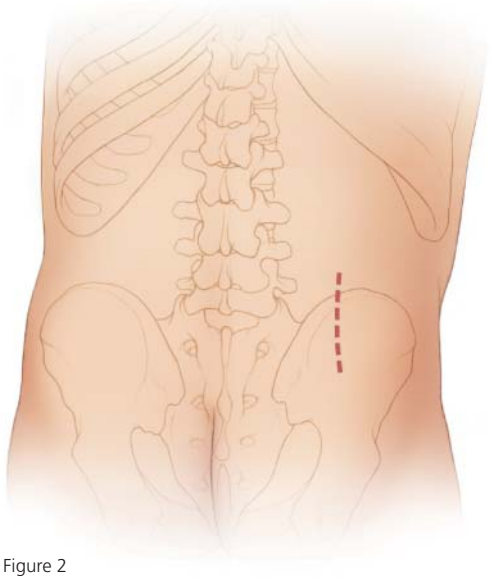
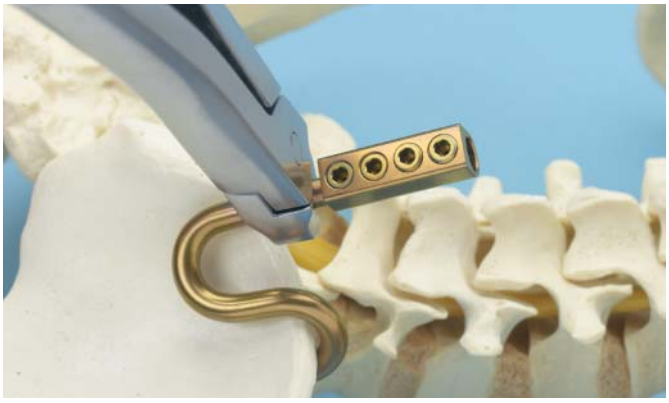


Figure 2

Instruments

314.070	Small Hexagonal Screwdriver, 2.5 mm width across flats
388.441	Rod Holding Forceps
388.911, 388.922	Bending Irons, for 5.0 mm rods, left and right

Attach an extension connector to the S-hook using the 2.5 mm small hexagonal screwdriver. Ensure the 5.0 mm opening in the extension connector is mated with the S-hook.



Use the 5.0 mm bending irons to contour the S-hook to fit the ilium. Insert the S-hook, pointed end downward, using the rod holding forceps over the top of the iliac crest and medial to the inner table of the iliac wing.

Lumbar extension
(Use for rib-to-lumbar lamina or rib-to-ilium constructs)

1

Align lumbar extension to inferior implant

Create a tunnel through the paraspinal muscles from the proximal incision to just above the inferior attachment point. Place the lumbar extension into the tip of a #20 chest tube and thread safely proximal-to-distal, to the inferior attachment point.

If using an S-hook (for rib-to-ilium construct), guide the lumbar extension into the opposing side of the extension connector. Tighten the setscrews in the connector using the 2.5 mm small hexagonal screwdriver (Figure 1).

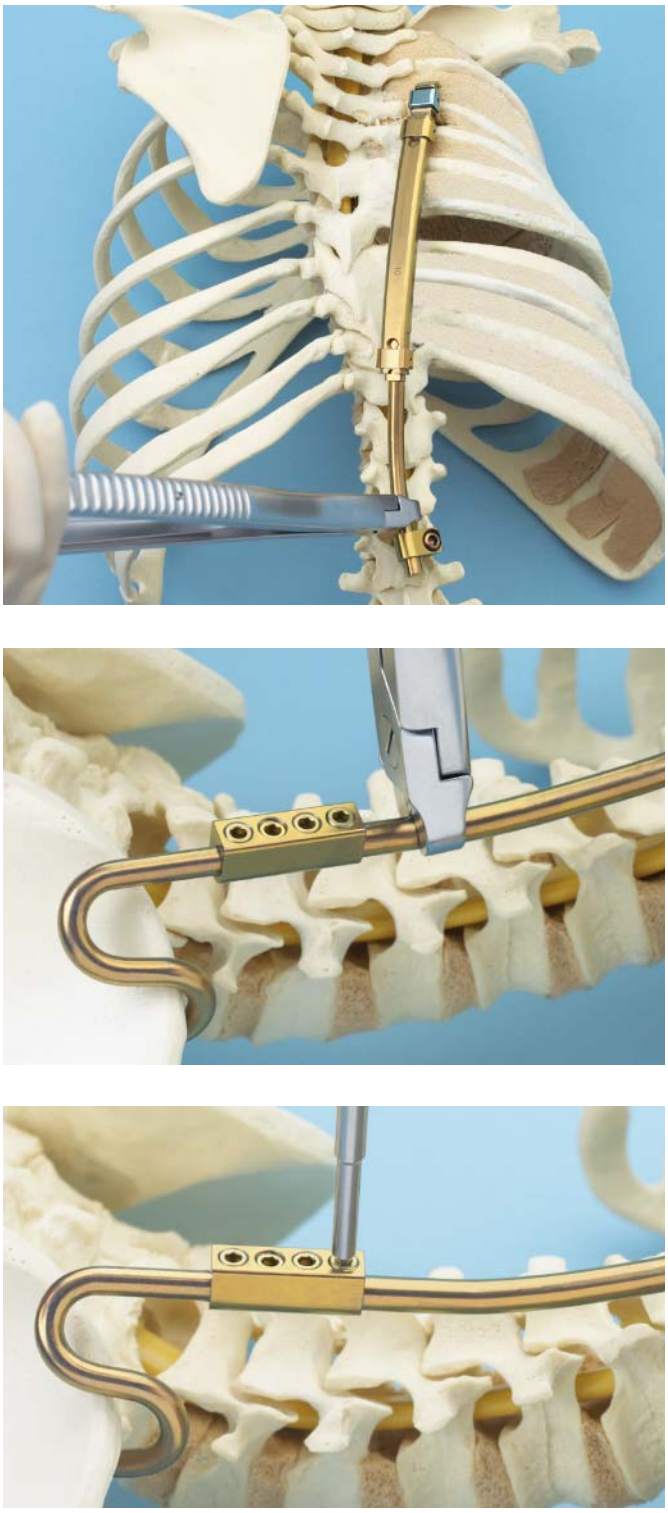


Figure 1

2
Align rib sleeve to superior cradle

Instruments	
388.461	Cradle Holding Forceps
388.468	Rib Sleeve Holding Forceps

Use the rib sleeve holding forceps and the cradle holding forceps to slide the superior end of the rib sleeve over the superior cradle (Figure 1).

Alternative instruments	
388.458	Cradle Iron
388.459	Rib Sleeve Iron
388.466	Cradle Introducer

Alternatively, the rib sleeve iron and the cradle iron can be used to align the two implants (Figure 2). The cradle introducer can also facilitate alignment.

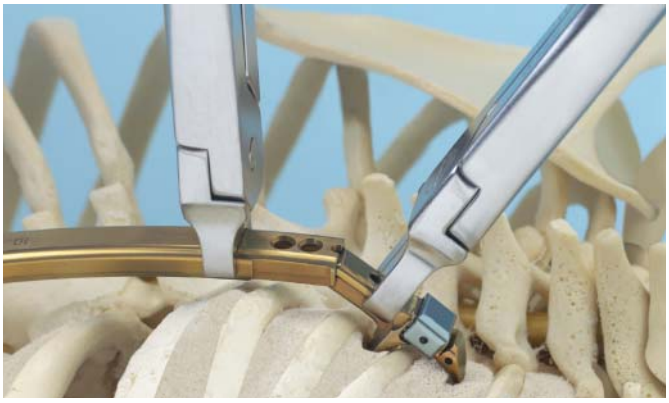


Figure 1

Figure 2

Lumbar extension
(Use for rib-to-lumbar lamina or rib-to-ilium constructs)

3
Insert superior distraction lock

Instruments	
388.456*	Lock Inserter
388.464	Rib Sleeve Positioning Fork
388.474	Lock Crimper
388.475	Lateral Lock Inserter
388.493	Lock Impactor
399.41	Hammer

Insert a distraction lock using the lock impactor (Figure 1) to fix the rib sleeve to the superior cradle.

Note: If necessary, the rib sleeve positioning fork can be used to align the holes.

Using the hammer, firmly tap the impactor to seat the lock.

The lock crimper should always be used to ensure the lock is fully seated.

Alternatively, the lock inserter or the lateral lock inserter can be used to seat the lock.

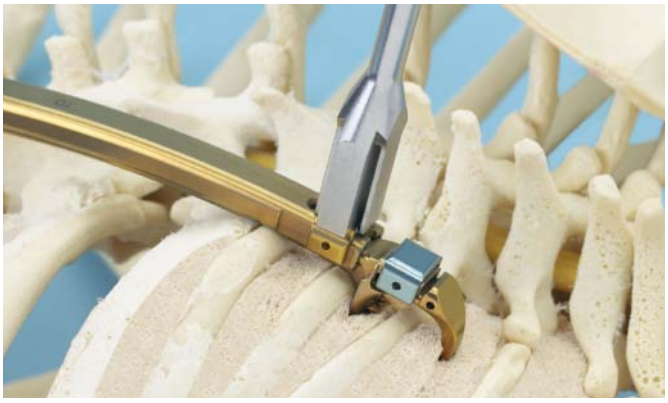


Figure 1

* Also available

4

If using lamina hook, distract if necessary and tighten

Instruments	
314.070	Small Hexagonal Screwdriver, 2.5 mm width across flats
314.27	Large Hexagonal Screwdriver, 3.5 mm width across flats
388.410	Distraction Forceps, curved
498.910	Half Ring

Using the 2.5 mm small hexagonal screwdriver, place a half ring superior to the hook onto the rod portion of the lumbar extension.

Using the distraction forceps, gently distract to further seat the hook (Figure 1). Use the large hexagonal screwdriver to tighten the setscrew in the hook (Figure 2).

Remove the half ring following distraction, using the 2.5 mm small hexagonal screwdriver.

Figure 1

Figure 2

Inferior cradle
(Use for rib-to-rib constructs)

1

Choose appropriate inferior rib

The proper inferior rib for attachment of the rib-to-rib device should be transverse in orientation and of adequate width. Do not choose an oblique rib, such as rib 11 or 12.

2

Select appropriate inferior cradle

Inferior cradle sizes correspond to rib sleeve sizes. For example, if the selected rib sleeve is a size 7, the correct inferior cradle will also be a size 7 (see "Select appropriate rib sleeve," page 13).

Note: If a 70 mm radius rib sleeve is used, a 70 mm radius inferior cradle must be used. If a 220 mm radius rib sleeve is used, a 220 mm radius inferior cradle must be used.

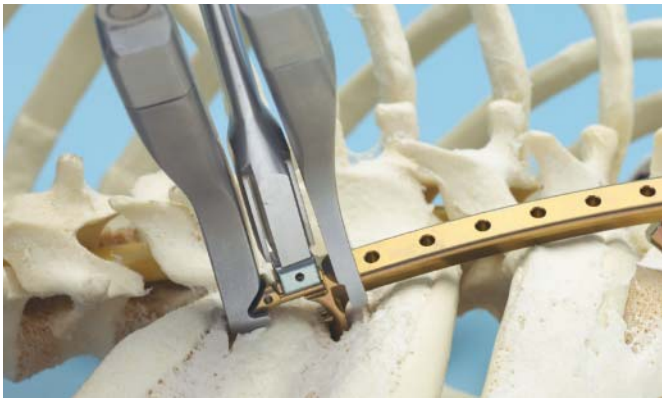
Inferior cradle, size 7, 220 mm radius

Rib sleeve, size 7, 220 mm radius

3

Insert inferior implants

Instruments	
388.453*	Cradle End Half Forceps
388.456*	Lock Inserter
388.461	Cradle Holding Forceps
388.465	Clamp, for Cradle End Half
388.474	Lock Crimper
388.475	Lateral Lock Inserter
388.493	Lock Impactor
399.41	Hammer



Using the cradle holding forceps, seat the inferior cradle into the space between the periosteum and the rib. Rotate it into the correct position around the rib.

Based on the patient's anatomy, select the appropriate cradle end half (standard or extended).

Using the clamp for cradle end half, seat the cradle end half over the contralateral side of the rib.

Align the inferior cradle and cradle end half using the cradle assembly forceps, the cradle jaw, end half jaw and parallel compressor body assembly.

Load a cradle lock into the lock impactor. Lock the assembly by inserting the cradle lock into the aligned holes of the inferior cradle and the cradle end half. Using the hammer, firmly tap the impactor to seat the lock.

The lock crimper should always be used to ensure the lock is fully seated.

Alternatively, the lock inserter or the lateral lock inserter can be used to seat the lock.

The implants now encircle the rib.

* Also available

Inferior cradle
(Use for rib-to-rib constructs)

1

Assemble construct

Instruments	
388.458	Cradle Iron
388.459	Rib Sleeve Iron
388.464	Rib Sleeve Positioning Fork
388.466	Cradle Introducer
388.468	Rib Sleeve Holding Forceps
388.472	Rib Sleeve Distraction Forceps

Use the rib sleeve holding forceps to slide the selected rib sleeve over the inferior cradle.

Slide the rib sleeve onto the superior cradle. The rib sleeve iron and cradle iron can be used to align the two implants (Figure 1). The cradle introducer can also help with alignment.

Place a distraction lock in the superior end of the rib sleeve using the lock impactor. Using the hammer, firmly tap the impactor to seat the lock.

Use the rib sleeve distraction forceps or the rib sleeve positioning fork to distract the device (Figure 2) until the inferior hole in the rib sleeve is aligned with an inferior hole in the inferior cradle. Both the superior and inferior cradles should be seated against the ribs.

Figure 1

Figure 2

2
Lock construct

Instruments	
388.456*	Lock Inserter
388.474	Lock Crimper
388.475	Lateral Lock Inserter
388.493	Lock Impactor

Using the lock impactor, place a distraction lock in the inferior end of the rib sleeve to lock the assembly in place. Check to ensure both locks are fully seated, using the lock crimper.

Alternatively, the lock inserter or the lateral lock inserter can be used to seat the lock.

Note: If the patient is older than 18 months and of adequate body size, a second device (rib-to-rib construct) may be added posterolaterally in the midaxillary line to further expand the constricted hemithorax.

* Also available

Fused ribs and scoliosis

After the superior cradle and inferior point of attachment have been chosen, perform an opening wedge thoracotomy through the fused ribs at the apex of the thoracic deformity from the tip of the transverse process to the costochondral junction, in the general orientation of the ribs.

Separate the fusion mass. Ensure the continuity between the anterior and posterior attachments of the newly separated ribs.

Continue the procedure using the appropriate construct technique.

For a detailed description of a thoracostomy, see Robert M. Campbell Jr., MD; Melvin D. Smith, MD; Anna K. Hell-Vocke, MD. "Expansion Thoracoplasty: The Surgical Technique of Opening-Wedge Thoracostomy." *Journal of Bone and Joint Surgery*–American Volume. 86-A Supplement 1:51–64, 2004.

Hypoplastic thorax

Instrument	
391.82	Wire-Bending Pliers

A hypoplastic, low volume thorax (as seen with Jeune's syndrome) requires the use of a 70 mm radius rib-to-rib construct (70 mm radius implants include: superior cradle, inferior cradle, rib sleeve). These constructs are placed bilaterally in separate procedures.

After inserting both the superior and inferior cradles, free the central segment of the selected hemithorax by making transverse incisions in the periosteum to enable anterior and posterior osteotomies.

Perform anterior and posterior osteotomies from ribs 3 through 8. Distract the mobilized chest segment posterolaterally.

Place retractors subperiosteally to protect the underlying lung.

Choose 2–3 sites in the central portion of the mobilized segment to insert the 2.0 mm titanium rod, which will hold the ribs to the construct. Bend the rod to form a gentle curve, using the wire-bending pliers.

Assemble the construct as stated in the rib-to-rib construct section.

After the construct has been completely assembled and locked, use the wire-bending pliers to again grasp the rods and contour around the implanted rib-to-rib construct, leaving space available to remove the locks and expand the construct.

2.0 mm Rod

Expansion Procedure

1

Patient Positioning

Place the patient in a lateral decubitus or prone position.

2

Exposure

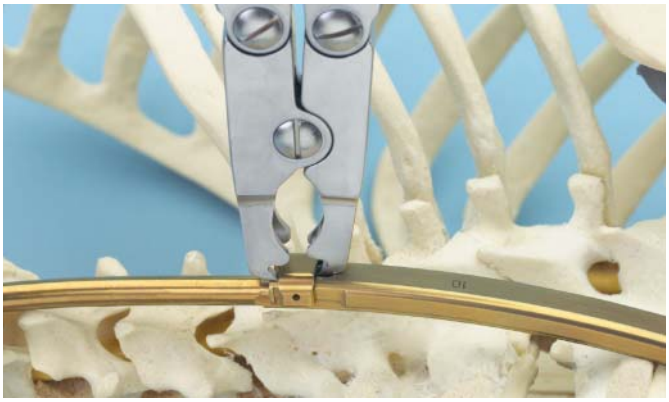
Identify the approximate location of the inferior distraction lock through palpation and/or radiographic marker. Make a transverse or longitudinal incision over the inferior distraction lock.

3

Remove lock

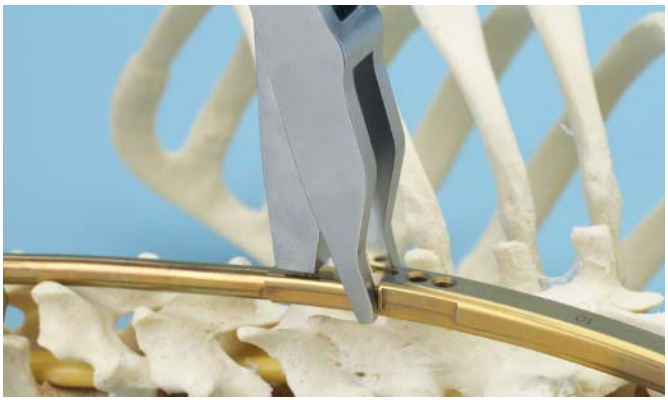
Instruments	
388.452	Lock Removal Pliers
388.462	Distraction Lock Removal Bar

Remove the distraction lock using the lock removal pliers or the distraction lock removal bar.



4
Distraction

Instruments	
388.457	Temporary Distraction Pins
388.471	Rib Expansion Pliers
388.472	Rib Sleeve Distraction Forceps
498.910	Half Ring



Use the rib expansion pliers, or the rib sleeve distraction forceps in conjunction with a half ring, to gently distract the implanted device until the device is adequately lengthened. Use the temporary distraction pins as placeholders to assist distraction.

5
Final locking

Instruments	
388.456*	Lock Inserter
388.474	Lock Crimper
388.475	Lateral Lock Inserter
388.493	Lock Impactor
399.41	Hammer

Insert a new distraction lock using the lock impactor to fix the rib sleeve in its distracted position. Using the hammer, firmly tap the impactor to seat the lock.

Check to ensure the lock is fully seated, using the lock crimper.

Alternatively, the lock inserter or the lateral lock inserter can be used to seat the lock.

* Also available

Replacement of Components

Replacement of components	
Instrument	
388.452	Lock Removal Pliers

For replacement of the rib sleeve, inferior cradle or lumbar extension, make three transverse incisions, one at the midportion of the implanted construct and others along the distal and proximal portions. A portion of the previous thoracotomy incision may be used.

Unlock the device by removing the distraction lock(s) using the lock removal pliers.

Remove the required components and insert the new components through the fibrous canal surrounding the old devices.

Install new distraction lock(s).

Refer to detailed instructions within this technique guide to install specific components.

Implants

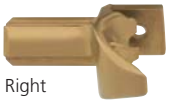
Superior Cradle
- Attaches to the cradle end half and rib sleeve to support the superior rib
- Available in 220 mm and 70 mm radii
- Available in neutral, right and left angulations


220 mm radius


70 mm radius


Left


Neutral


Right

Inferior Cradle
- Attaches to the cradle end half and rib sleeve to support the inferior rib
- 220 mm radius, in ten lengths, sizes 4–13, in neutral, right and left angulations
- 70 mm radius, in eight lengths, sizes 4–11, in neutral, right and left angulations


220 mm radius


70 mm radius

Left

Neutral

Right

Cradle End Half
- Attaches to the superior cradle or inferior cradle to encircle the superior or inferior rib(s)
- Two sizes, standard and extended


Standard


Extended

Locks
- Cradle lock (blue) connects the cradle end half to the superior cradle or the inferior cradle
- Distraction lock (gold) connects the rib sleeve to the superior cradle, inferior cradle, or lumbar extension


Cradle lock (blue)


Distraction lock (gold)

Rib Sleeves
- Attach the superior cradle to the inferior cradle or lumbar extension
- 220 mm radius in ten lengths, sizes 4–13
- 70 mm radius in eight lengths, sizes 4–11

220 mm radius

70 mm radius

Lumbar Extension
- Attaches the rib sleeve to the offset hook or the extension connector
- Eight lengths, sizes 6–13, to correspond with 220 mm radius rib sleeves

With 220 mm radius rib sleeve

Offset Lamina Hook
- Right or left offset
- Low profile minimizes soft tissue interference
- Opening captures 6.0 mm rod and permits longitudinal adjustments along the rod before tightening
- 3.5 mm setscrew secures the placement

Top view

Side view

S-Hook
- Used with the lumbar extension and extension connector to attach to the ilium
- Left or right contours
- Available in standard 45° or 90° angulations

Top view 90°

Top view 45°

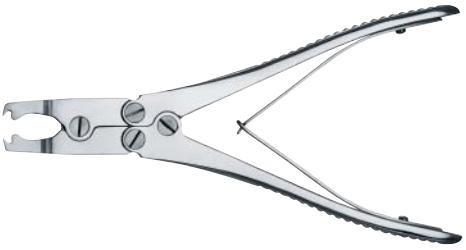
Extension Connector

– Connects the S-hook (5.0 mm rod) to the lumbar extension (6.0 mm rod)

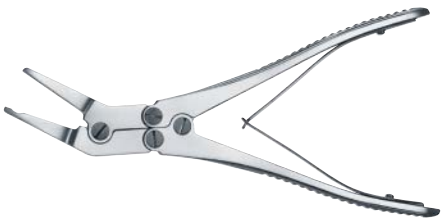
2.0 mm Rod

– Holds osteotomized ribs against the construct

Instruments

314.070	Small Hexagonal Screwdriver, 2.5 mm width across flats	
314.27	Large Hexagonal Screwdriver, 3.5 mm width across flats	
329.052	Bending Iron, right, for 6.0 mm rod	
329.053	Bending Iron, left, for 6.0 mm rod	
388.410	Distraction Forceps, curved	
388.441	Rod Holding Forceps	
388.452	Lock Removal Pliers	

388.457	Temporary Distraction Pin	
388.458	Cradle Iron	
388.459	Rib Sleeve Iron	
388.461	Cradle Holding Forceps	
388.462	Distraction Lock Removal Bar	
388.464	Rib Sleeve Positioning Fork	
388.465	Clamp, for Cradle End Half	
388.466	Cradle Introducer	

388.467	Cradle Trial	
388.468	Rib Sleeve Holding Forceps	
388.471	Rib Expansion Pliers	
388.472	Rib Sleeve Distraction Forceps	
388.474	Lock Crimper	
388.475	Lateral Lock Inserter	

388.486	Rib Blade	
388.488	Cradle Jaw, for parallel compressor body	
388.489	End Half Jaw, for parallel compressor body	
388.493	Lock Impactor	
388.494	Parallel Compressor Body	
388.495	Hook Holding Forceps, for offset lamina hook	
388.521	Lamina Finder	

388.902	Coated Rod Template, for 6.0 mm rod, 150 mm	
388.911	Bending Iron, left, for 5.0 mm rod	
388.922	Bending Iron, right, for 5.0 mm rod	
388.94	Rod Pusher	
388.961	Rod Bender, with bend radius adjustment	
389.501	Vein Retractor, 13 mm width	
391.82	Wire-Bending Pliers	

398.408	Freer Elevator, 195 mm	
399.13	Bone Spreader, 12 mm beak width	
399.41	Hammer	
498.910	Titanium Half Ring	
U22-640-10	Longitudinal Retractor, spreader only	
U44-483-20	Double-Ended Elevator, 20 cm, size 2	

VEPTR (Vertical Expandable Prosthetic Titanium Rib) Instrument and Titanium Implant Set (146.995)

Graphic Cases

690.068	Graphic Case, for VEPTR Basic Implant Set
690.069	Graphic Case, for VEPTR 70 mm Radius Implant Set
690.088	Graphic Case, for VEPTR Basic Instrument Set
690.089	Graphic Case, for VEPTR Lumbar Extension Instrument Set

690.068

Instruments

314.070	Small Hexagonal Screwdriver, 2.5 mm width across flats
314.27	Large Hexagonal Screwdriver, 3.5 mm width across flats
329.052	Bending Iron, right, for 6.0 mm rod
329.053	Bending Iron, left, for 6.0 mm rod
388.410	Distraction Forceps, curved
388.441	Rod Holding Forceps
388.452	Lock Removal Pliers, 2 ea.
388.457	Temporary Distraction Pin, 2 ea.
388.458	Cradle Iron
388.459	Rib Sleeve Iron
388.461	Cradle Holding Forceps
388.462	Distraction Lock Removal Bar
388.464	Rib Sleeve Positioning Fork
388.465	Clamp, for Cradle End Half, 2 ea.
388.466	Cradle Introducer
388.467	Cradle Trial
388.468	Rib Sleeve Holding Forceps
388.471	Rib Expansion Pliers
388.472	Rib Sleeve Distraction Forceps
388.474	Lock Crimper
388.475	Lateral Lock Inserter
388.486	Rib Blade, 4 ea.
388.488	Cradle Jaw, for parallel compressor body
388.489	End Half Jaw, for parallel compressor body
388.493	Lock Impactor, 2 ea.

690.069

690.088

690.089

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions, please refer to
http://www.synthes.com/sites/NA/MedicalCommunity/cleaning-sterilization/Pages/default.aspx
or to the below listed inserts, which will be included in the shipping container:
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– Processing Non-sterile Synthes Implants—DJ1304

Instruments

388.494	Parallel Compressor Body
388.495	Hook Holding Forceps, for offset lamina hook
388.521	Lamina Finder
388.902	Coated Rod Template, for 6.0 mm rod, 150 mm
388.911	Bending Iron, left, for 5.0 mm rod
388.922	Bending Iron, right, for 5.0 mm rod
388.94	Rod Pusher
388.961	Rod Bender, with bend radius adjustment
389.501	Vein Retractor, 13 mm width, 2 ea.
391.82	Wire-Bending Pliers, 2 ea.
398.408	Freer Elevator, 195 mm
399.13	Bone Spreader, 12 mm, 2 ea.
399.41	Hammer
498.910	Titanium Half Ring, 2 ea.
690.856	Label Sheet for Lock Crimper
U22-640-10	Longitudinal Retractor, spreader only, 2 ea.
U44-483-20	Double-Ended Elevator, 20 cm, size 2

Implants

04.601.000	90° Titanium S-Hook, right, 2 ea.
04.601.001	90° Titanium S-Hook, left, 2 ea.
497.125	Titanium Distraction Lock, 10 ea.
497.126	Titanium Cradle End Half, 6 ea.
497.127	2.0 mm Titanium Rod, 150 mm, 6 ea.
497.128	Titanium Cradle Lock, 10 ea.
497.129	Titanium Extended Cradle End Half, 4 ea.
497.256	Titanium Extension Connector, 4 ea.
497.257	Titanium S-Hook, left, 2 ea.
497.258	Titanium S-Hook, right, 2 ea.
497.261	Titanium Offset Lamina Hook, low profile, left, 2 ea.
497.262	Titanium Offset Lamina Hook, low profile, right, 2 ea.

Titanium Lumbar Extensions, 220 mm radius, 2 ea.

	Size		Size
497.131	6	497.251	10
497.132	7	497.252	11
497.133	8	497.253	12
497.134	9	497.254	13

Titanium Superior Cradles

497.057	220 mm radius, 6 ea.
497.058	220 mm radius, right
497.059	220 mm radius, left

Titanium Rib Sleeves, 220 mm radius, 4 ea.

	Size		Size
497.103	4	497.108	9
497.104	5	497.109	10
497.105	6	497.110	11
497.106	7	497.111	12
497.107	8	497.112	13

Titanium Inferior Cradles, 220 mm radius, 4 ea.

	Size		Size
497.065	4	497.225	9
497.066	5	497.226	10
497.067	6	497.227	11
497.068	7	497.228	12
497.069	8	497.229	13

Titanium Inferior Cradles, right, 220 mm radius

	Size		Size
497.071	4	497.230	9
497.072	5	497.231	10
497.073	6	497.232	11
497.074	7	497.233	12
497.075	8	497.234	13

Titanium Inferior Cradles, left, 220 mm radius

	Size		Size
497.076	4	497.235	9
497.077	5	497.236	10
497.078	6	497.237	11
497.079	7	497.238	12
497.080	8	497.239	13

Titanium Inferior Cradles, left, 70 mm radius

	Size		Size
497.096	4	497.100	8
497.097	5	497.247	9
497.098	6	497.248	10
497.099	7	497.249	11

Titanium Superior Cradles

497.061	70 mm radius
497.062	70 mm radius, right
497.063	70 mm radius, left

Titanium Rib Sleeves, 70 mm radius

	Size		Size
497.115	4	497.119	8
497.116	5	497.120	9
497.117	6	497.121	10
497.118	7	497.122	11

Titanium Inferior Cradles, 70 mm radius

	Size		Size
497.085	4	497.089	8
497.086	5	497.241	9
497.087	6	497.242	10
497.088	7	497.243	11

Titanium Inferior Cradles, right, 70 mm radius

	Size		Size
497.091	4	497.095	8
497.092	5	497.244	9
497.093	6	497.245	10
497.094	7	497.246	11

Also Available

Sets

146.996	VEPTR Lengthening Set
146.997	VEPTR 70 mm Implant Set
146.998	VEPTR Basic Implant Set

Instruments

388.453	Cradle End Half Forceps
388.456	Lock Inserter
388.750	Table Top Rod Cutter and Bender
388.751	Handheld Rod Cutter, for 4.0 mm, 5.0 mm and 6.0 mm rods

Graphic Case

690.116	Graphic Case for VEPTR Lengthening Set

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