

VEPTR II. Vertical Expandable Prosthetic Titanium Rib II.

Technique Guide



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VEPTR II

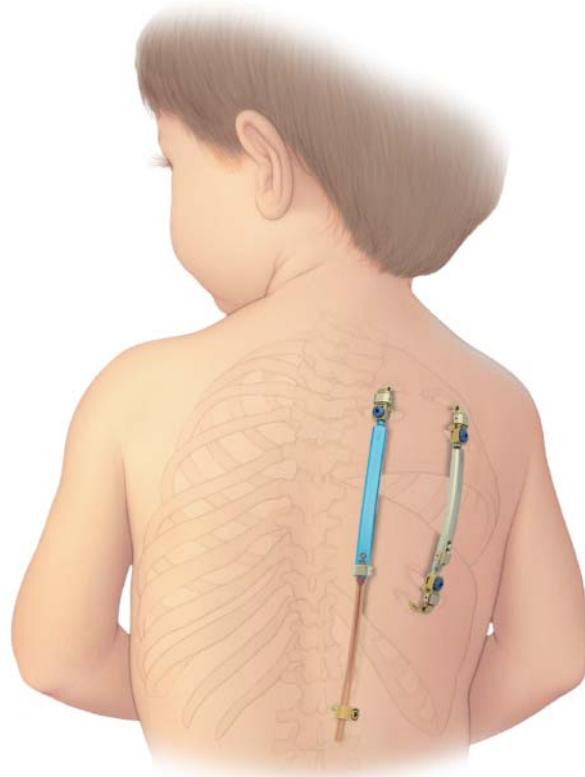
The Vertical Expandable Prosthetic Titanium Rib (VEPTR) device is designed to mechanically stabilize and distract the thorax to correct three-dimensional thoracic deformities and provide improvement in volume for respiration and lung growth in infantile and juvenile patients diagnosed with thoracic insufficiency 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 II system are manufactured from a titanium alloy (Ti-6Al-7Nb) with the exception of the S-hook and S-rod, which are manufactured from commercially pure titanium.

 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, and may be safely scanned only under certain conditions. Please refer to page 4 for further information about the specific scan conditions.

Goals of Treatment

1. Increase thoracic volume
2. Obtain thoracic symmetry
3. Improve thoracic function
4. Equilibrate the thorax by lengthening the concave, restricted hemithorax
5. Avoid growth-inhibiting procedures
6. Maintain these improvements throughout the patient's growth
7. Maintain spinal alignment
8. 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 below 6 months
- Known allergy to any of the device materials
- Infection at the operative site

Warnings and Precautions

Humanitarian 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 device 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

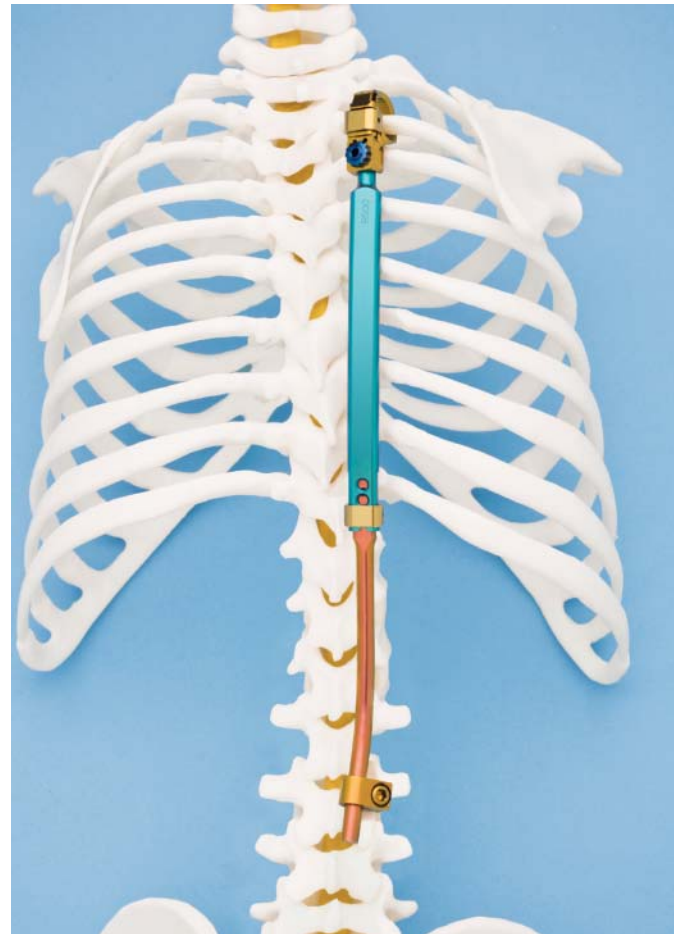
For SE sequence

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

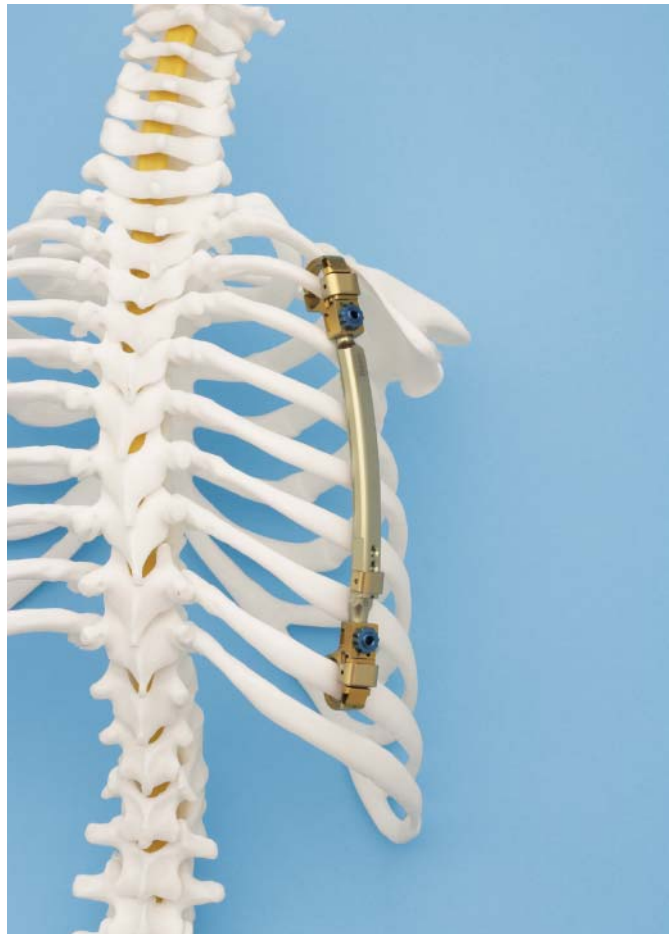
Rib-to-Lumbar Lamina

- Attaches to rib and to lumbar spine
- Components available in 220 mm or 500 mm radius



Rib-to-Rib

- Attaches to the superior rib and to the inferior rib
- Components available in 220 mm or 500 mm radius



Rib-to-ilium

- Attaches to rib and to ilium
- Components available in 220 mm or 500 mm radius



Technique—Primary Procedure

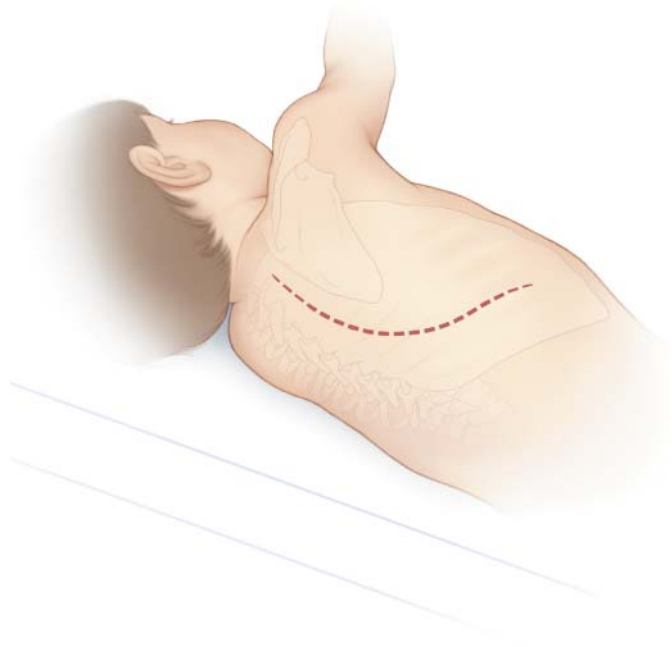
1

Position patient

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.

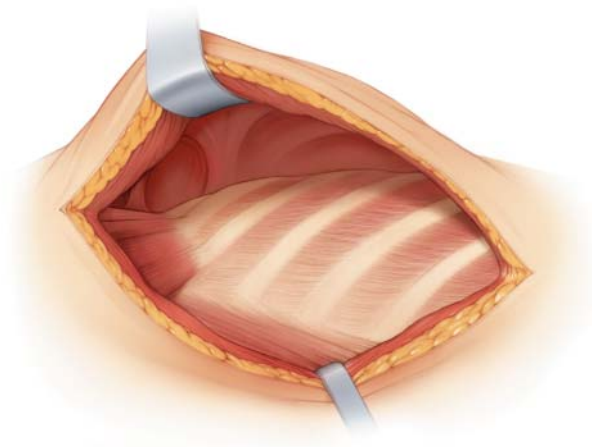


2

Perform 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.



3

Insert superior implants

A. Identify superior rib

- 1 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.

B. Prepare rib for implants

Instruments

03.641.001 Small Rib Hook Trial

03.641.012 Rib Hook Trial

U44-483-20 Double-Ended Elevator

Make a 1 cm incision into the intercostal muscles above and below the rib where the superior cradle will attach. Insert 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.

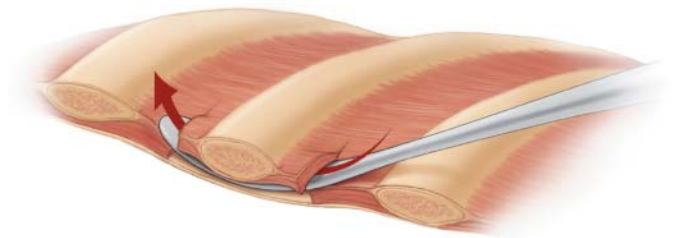
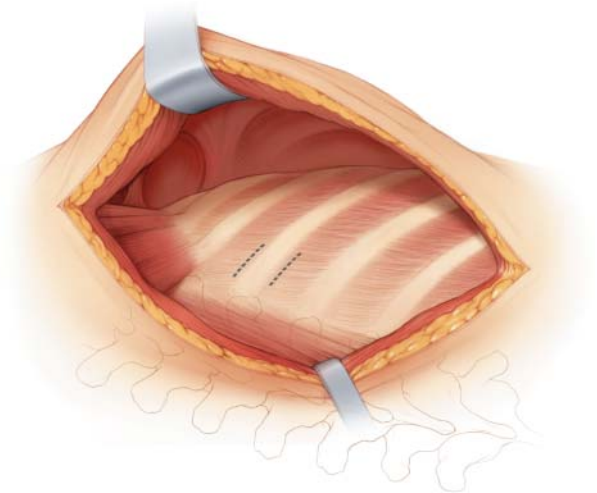
Use the rib hook trial to prepare the rib for the rib hook and rib hook cap.

For a smaller patient where the small rib hook may be used, use the small rib hook trial to prepare the rib.

Note: The rib hook trial and small rib hook trial may also be used to determine the appropriate rib hook size.

C. Select proper rib hook size

After using the rib hook trial and the small rib hook trial, select the appropriate size rib hook.



3. Insert superior implants

D. Seat the rib hook

Instrument

03.641.005 Rib Hook Holder

Using the rib hook holder, seat the underside of the rib hook 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.

Tip: For ease of grasping the rib hook with the rib hook holder, seat one tip of the rib hook holder first rather than simultaneously closing the tips onto the rib hook.

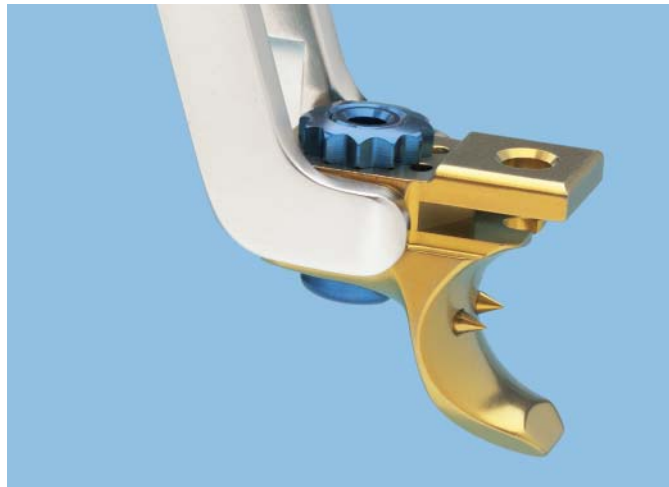


Figure 1

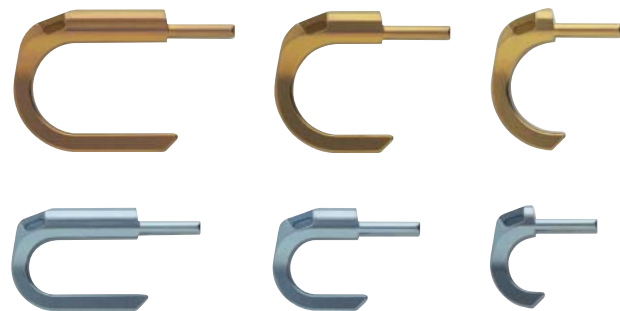


Figure 2

E. Select proper rib hook cap size

Based on the patient's anatomy, select the appropriate rib hook cap (standard, extended, or extra long). The larger sizes can be used to encircle large ribs, large areas of fused ribs, or multiple ribs.

Note: If using the small rib hook, it is necessary to use one of the small rib hook caps.



F. Insert rib hook cap

Instrument

03.641.006 Cap Holding Forceps

Using the cap holding forceps, insert the rib hook cap into the intercostal space superior to the rib (Figure 3). Rotate it distally to mate with the cradle (Figure 4).



Figure 3

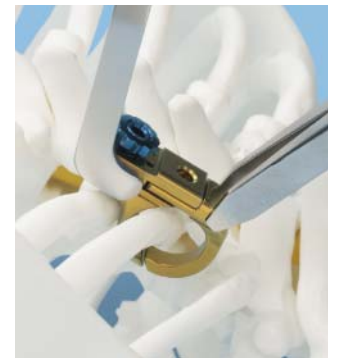


Figure 4

3. Insert superior implants

G. Insert distraction lock

Instruments

03.641.009 Offset Lock Impactor

388.474 Lock Crimper

Load a distraction lock into the offset lock impactor. To lock the rib hook/rib hook cap assembly, align the holes of the rib hook and rib hook cap and insert the distraction lock. Using a mallet, firmly tap the impactor to seat the lock. The lock crimper should always be used to ensure the lock is fully seated.

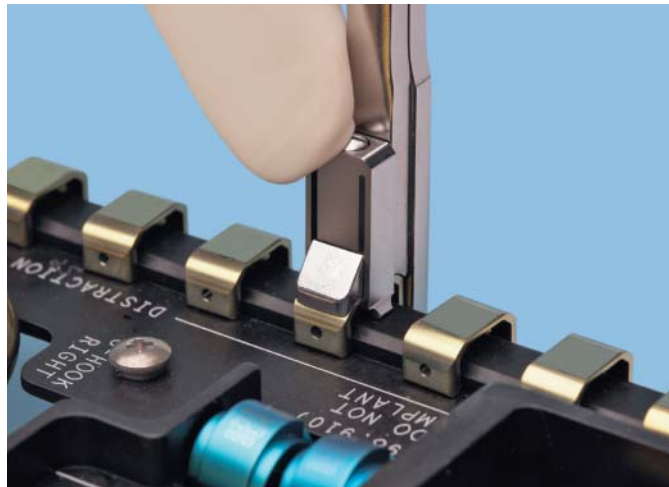


Alternative instrument

03.641.010 Sure-Lock

Alternatively, the sure-lock can be used to place the lock and ensure it is fully seated.

Tip: To facilitate loading a distraction lock onto the sure-lock, press the sure-lock onto the lock while the lock remains in the case. Pushing on the top of the sure-lock tip will facilitate grasping the lock.



4

Distract chest wall

Instruments

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

Assemble two rib blades to the longitudinal retractor. Distract the ribs using the rib retractor assembly as needed. A bone spreader may also be used to gently distract the chest wall at the site of the 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.



5

Select length of proximal extension

A. Measure expandable portion

Instrument

388.905	Coated Rod Template
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Using the coated rod template, measure the distance for the expandable portion of the construct to determine the appropriate proximal extension size.

The measurement in centimeters will correspond to the correct proximal extension size. For example, if the distance is determined to be 7 cm, use a proximal extension marked with a 7. Implant sizes are identified from 3–15 in 1 cm increments for the 500 mm radius implants, and from 3–13 in 1 cm increments for the 220 mm radius implants.



5

Select length of proximal extension

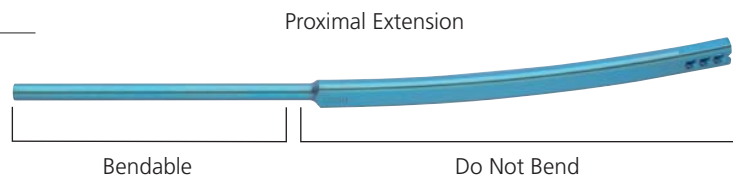
B. Cut and contour proximal extension, if necessary

Instruments

03.641.014 Extension Measuring Guide

03.620.020 Rod Bender

388.751* Handheld Rod Cutter



Approximately 11 mm of rod must remain on the proximal extension to allow the rod to fully seat within the rib hook. The extension measuring guide can be placed on the proximal extension to ensure enough rod is left on the extension to fully seat in the rib hook. Any remaining rod can be cut and/or contoured to match patient anatomy.



Optional instruments

03.622.061 Coronal Rod Bender, left

03.622.062 Coronal Rod Bender, right

329.052 Bending Iron, right

329.053 Bending Iron, left



Using the rod bender, contour only the rod portion of the proximal extension. As an alternative, the bending irons and coronal rod benders can be used to contour the rod. The rod portion of the extension can be cut using the handheld rod cutter.

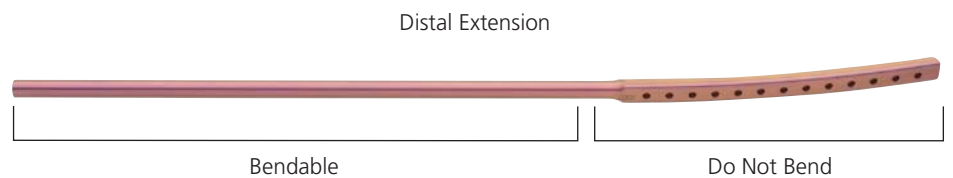
* Also available

6

Assemble distal portion of construct

A. Select the appropriate distal extension

Distal extension sizes correspond to the proximal extension sizes. For example, if the selected proximal extension is a size 7, the correct distal extension will also be a size 7. The radius of the distal extension must match the radius of the proximal extension.



6. Assemble distal portion of construct

B. Determine contour and cut to length, if necessary**Instruments**

03.620.020	Rod Bender
388.905	Coated Rod Template
388.751*	Handheld Rod Cutter

Optional instruments

03.622.061	Coronal Rod Bender, left
03.622.062	Coronal Rod Bender, right
03.641.014	Extension Measuring Guide
329.052	Bending Iron, right
329.053	Bending Iron, left

Use the coated rod template to determine the contour of the rod portion of the distal extension. Do not bend the T-section of the distal extension which mates with the proximal extension.

Using the rod bender, contour only the rod portion of the distal extension. As an alternative, the bending irons and coronal rod benders can be used to contour the rod. The rod portion of the extension can be cut using the handheld rod cutter.

Note: If implanting a rib-to-rib construct, approximately 11 mm of rod must remain on the proximal and distal extensions to allow the rod to fully seat within the rib hook. The extension measuring guide can be placed on the extensions to ensure enough rod is left on the extensions to fully seat in the corresponding rib hooks. Any remaining rod can be cut and/or contoured to match patient anatomy.

Tip: When using a lamina hook or S-hook with parallel connector, an additional length of 1.5 cm should be left on the rod portion of the distal extension to allow distraction.

* Also available

C. Insert distraction lock

Instruments

03.641.009 Offset Lock Impactor

388.474 Lock Crimper

Before insertion, slide the distal extension into the proximal extension. Align the most inferior hole in the proximal extension with the most inferior hole in the distal extension. The implants should overlap completely to maximize expansion over time.

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

Alternative instrument

03.641.010 Sure-Lock

Alternatively, the sure-lock can be used to place the lock and ensure it is fully seated.



6. Assemble distal portion of construct

D. Insert inferior implant

1. Offset lamina hook (use for rib-to-lumbar lamina construct)

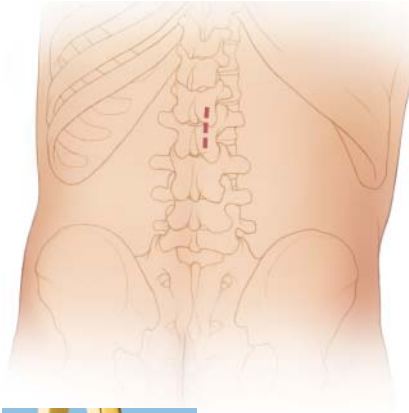
Instrument

03.641.008 Lamina Hook Holding Forceps

Make a 4 cm, 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.

Choose the appropriate offset lamina hook (right or left). Use the lamina hook holding forceps to place the hook in the desired location on the lumbar vertebra. Place the hook downward-facing with the setscrew most lateral.

The hook can be further secured with a heavy, nonabsorbable suture around the spinous process.



2. S-hook or S-rod (use for rib-to-iliac construct)

Instruments

03.641.013 Rod Holder

03.641.015 Small Hexagonal Screwdriver

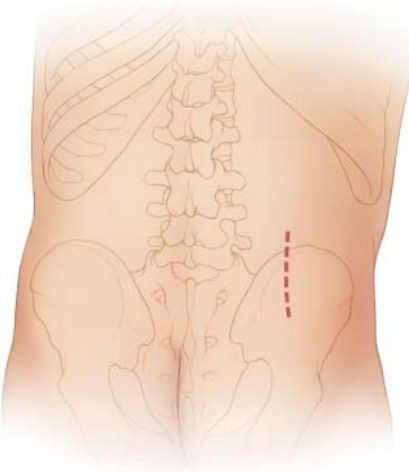
Make a 4 cm incision just lateral to the posterior superior iliac spine. Identify the posterior third and middle third of the iliac crest.

Choose the appropriate S-hook or S-rod. If using the S-rod, cut it to the appropriate length and contour as necessary.

Attach an extension connector or parallel connector to the S-hook or S-rod using the small hexagonal screwdriver.

The 5.0 mm/6.0 mm extension connector or 5.0 mm/6.0 mm parallel connector should be used with the S-hooks, and the 6.0 mm/6.0 mm extension connector or 6.0 mm/6.0 mm parallel connector should be used with the S-rods.

Insert the S-hook or S-rod, using the rod holder, over the top of the iliac crest and medial to the inner table of the iliac wing.



D. Insert inferior implant continued**3. Rib hook (use for rib-to-rib construct)**

Use the same procedure and instrumentation as described earlier for placement of the rib hook and rib hook cap.

E. Align the distal extension to the inferior implant**1. Placement using the offset lamina hook (use for rib-to-lumbar lamina construct) or S-hook or S-rod (use for rib-to-iliac construct)**

Instruments

03.641.013 Rod Holder

03.641.015 Small Hexagonal Screwdriver

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

If attaching to a lamina hook (for rib-to-spine construct), guide the distal extension into the lamina hook.

If using an S-hook or S-rod (for rib-to-iliac construct), guide the distal extension into the opposing side of the extension or parallel connector. Tighten the setscrews in the connector using the small hexagonal screwdriver.

2. Placement using the rib hook (use for rib-to-rib construct)

Instruments

03.641.002 5 Nm Torque Limiting Handle

03.641.003 VEPTR Nut Driver Shaft

03.641.007 Sleeve Holder

Guide the distal extension into the rib hook using the sleeve holder. Ensure that the rod portion of the distal extension is visible through the view holes. Insert the nut driver shaft into the torque limiting handle. Use the torque limiting handle and shaft to tighten the nut onto the rib hook, connecting the distal extension.



7

Final assembly

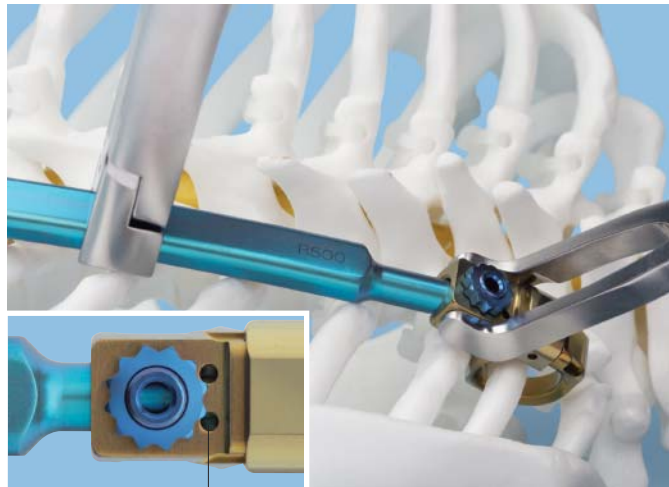
A. Assemble the proximal extension to the rib hook

Instruments

03.641.005 Rib Hook Holder

03.641.007 Sleeve Holder

Use the sleeve holder and the rib hook holder to slide the rod end of the proximal extension into the rib hook. Ensure that the rod portion of the proximal extension is visible through the view holes.



B. Tighten the nut on the rib hook

Instruments

03.641.002 5 Nm Torque Limiting Handle

03.641.003 VEPTR Nut Driver Shaft

03.641.005 Rib Hook Holder

Insert the nut driver shaft into the torque limiting handle. Use the torque limiting handle and shaft to tighten the nut onto the cradle, connecting the proximal extension. The Rib Hook Holder should be used to provide counter torque.



Optional instrument

03.641.004 Socket Wrench for VEPTR Nut



The Socket Wrench for VEPTR Nut can be used when there is limited access to the rib hook nut. For example, in a rib-to-rib construct for placement of the rib hook under the scapula.

C. If using a lamina hook, distract if necessary and tighten

Instruments

03.641.015 Small Hexagonal Screwdriver

03.641.016 Large Hexagonal Screwdriver

388.472 Rib Sleeve Distraction Forceps

498.910 Half Ring

Using the small hexagonal screwdriver, place a half ring superior to the lamina hook onto the rod portion of the distal extension.

Using the rib sleeve distraction forceps against the half ring, gently distract to further seat the hook (Figure 5). Use the large hexagonal screwdriver to tighten the setscrew in the hook (Figure 6).

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

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.

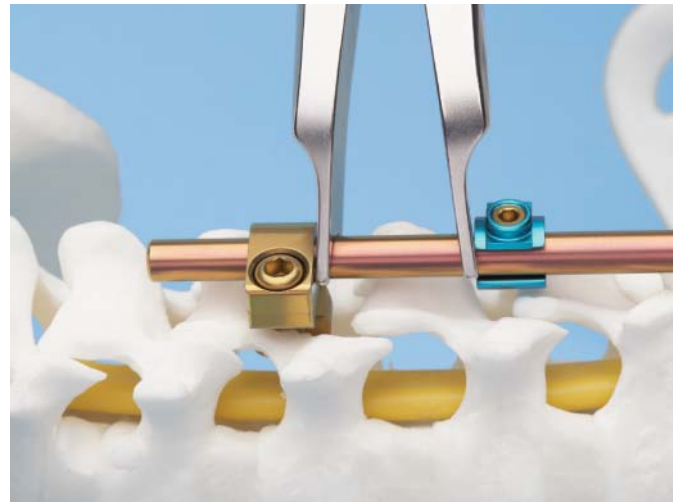


Figure 5

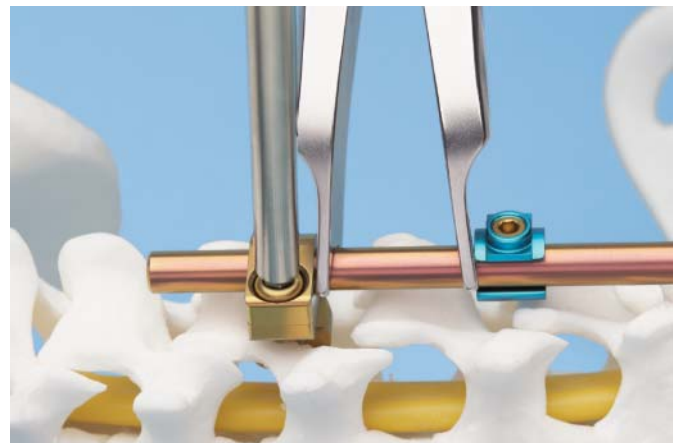


Figure 6

8

Alternative implant usage

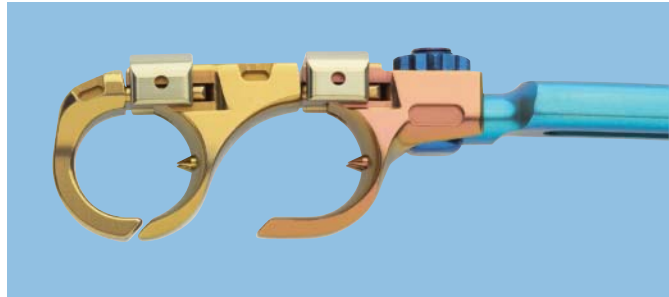
A. Using the rib hook extensions

Instrument

03.641.006 Cap Holding Forceps

The rib hook extensions can be used when multiple rib attachment is desired. Based on the patient's anatomy, select the appropriate length rib hook extension (20 mm, 30 mm, or 40 mm). Rib hook extensions are connected to a rib hook cap (proximally) and a rib hook (distally) with a distraction lock.

Tip: If using the rib hook extensions, the most inferiorly-placed rib hook should be the long rib hook.



B. Using the transverse rib hooks and transverse bars

Instrument

03.641.015 Small Hexagonal Screwdriver

The transverse rib hooks and the transverse bars can be used when multiple rib attachment is desired. Insert the transverse rib hook and appropriately sized rib hook cap onto the selected rib. Based on the patient's anatomy, select the appropriate length transverse bar (15 mm, 20 mm, 25 mm, or 30 mm) to connect the transverse rib hook to the rod portion of the proximal extension on the medial construct. Guide the rod of the transverse bar into the transverse rib hook. Attach the transverse bar to the rod portion of the proximal extension using the small hexagonal screwdriver.

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



Fused ribs and scoliosis

After the superior and inferior points 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.

Technique—Expansion Procedure

1

Patient positioning

Place the patient in a lateral decubitus or prone position.

2

Exposure

Identify the approximate location of the distraction lock, locating the proximal and distal extension through palpation and/or radiographic marker. Make a transverse or longitudinal incision over the distraction lock.

3

Remove the lock

Instruments

388.452	Lock Removal Pliers
388.462	Distraction Lock Removal Bar

Remove the distraction lock using the lock removal pliers (Figure 7) or the distraction lock removal bar.

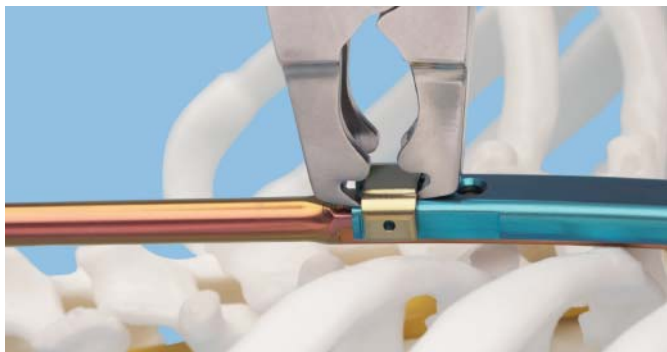


Figure 7

4

Distraction

Instruments

03.641.011	Temporary Distraction Peg
388.471	Rib Expansion Pliers
388.472	Rib Sleeve Distraction Forceps
498.910	Half Ring

Use the rib expansion pliers (Figure 8), 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 pegs as placeholders to assist distraction (see Figure 9 on next page).



Figure 8

Tip: For the initial expansion (when the rib expansion pliers cannot be used), the temporary distraction pegs can be used to assist distraction (Figure 9). Use the rib sleeve distraction forceps with the half ring to distract the proximal extension. When the desired hole location is reached, place the round tip of the first temporary distraction peg in the desired hole of the proximal extension. Remove the rib sleeve distraction forceps and place the rectangular end of the second temporary distraction peg in the distal extension to prevent the proximal extension from slipping (the “foot” on the peg may need to be rotated 90° depending on the desired hole location). Remove the first temporary distraction peg to allow final locking.

Note: The hole spacing in the VEPTR II device will allow for incremental lengthening of 2.5 mm (minimum).

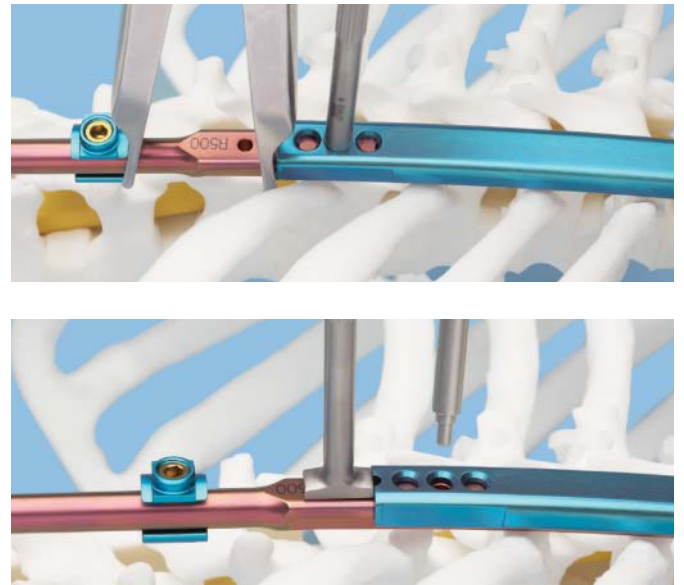


Figure 9

5 Final locking

Instruments

03.641.009 Offset Lock Impactor

388.474 Lock Crimper

498.910 Half Ring

Insert a new distraction lock using the offset lock impactor to fix the proximal extension in its distracted position. Using a mallet, firmly tap the impactor to seat the lock.

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

Alternative instrument

03.641.010 Sure-Lock

Alternatively, the sure-lock can be used to both place the lock and ensure it is fully seated.

Technique—Replacement of Components

A. VEPTR II component replacement

For replacement of proximal extension and distal 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.

To disconnect the proximal extension, unlock the device by loosening the nut on the rib hook using the torque limiting handle and nut driver shaft. To disconnect the distal extension, loosen the nut on the rib hook (for rib-to-rib construct), loosen the setscrew on the lamina hook (for rib-to-spine construct) or loosen the setscrews on the extension or parallel connector (for rib-to-iliac construct).

Note: Loosen the nut until a tactile release is felt. Do not disassemble.

Remove the proximal and distal extension and insert the new components through the fibrous canal surrounding the old devices. Make sure to lock the extensions before insertion.

B. VEPTR component replacement (conversion of existing VEPTR to VEPTR II)

For replacement of an original VEPTR construct (rib sleeve/lumbar extension or rib sleeve/inferior cradle) without removing the implanted VEPTR superior cradle, use the VEPTR adapter. Detach and remove the original VEPTR rib sleeve/lumbar extension or rib sleeve/inferior cradle from the superior cradle(s). Attach the VEPTR adapter to the original VEPTR superior cradle using a distraction lock (Figure 10). Now a VEPTR II proximal or distal extension can be used to replace the original VEPTR rib sleeve construct.

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

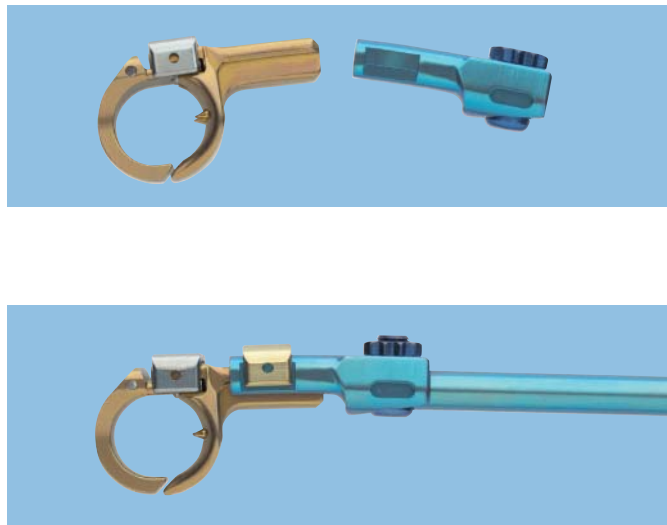
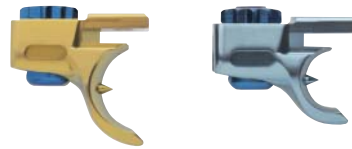


Figure 10

Implants

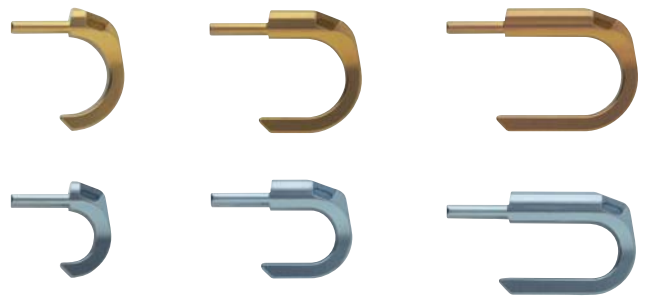
Rib Hooks

- Attach to the rib hook cap and proximal extension to support the superior rib, or the distal extension and rib hook cap to support the inferior rib
- Available in two sizes, standard and small



Rib Hook Caps

- Attach to the rib hook to encircle the superior or inferior rib(s)
- Two sizes, standard and small
- Each size is available in three lengths, standard, extended, and extra long



Distraction Lock

- Connects the rib hook to the rib hook cap, rib hook to proximal or distal extension, and proximal extension to distal extension



Proximal Extension

- Attaches the superior attachment point (rib hook) to the distal extension
- 220 mm radius in eleven lengths, sizes 3–13
- 500 mm radius in thirteen lengths, sizes 3–15



Distal Extension

- Attaches the proximal extension to the inferior attachment point (rib hook, lamina hook, or connector)
- 220 mm radius in eleven lengths, sizes 3–13
- 500 mm radius in thirteen lengths, sizes 3–15

Lamina Hooks

- 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



S-Hooks

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



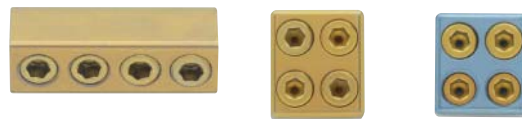
S-Rods

- Used with the distal extension and connector to attach to the ilium
- Left or right contours
- Available in standard 45° angulations
- 400 mm rod allows cutting to appropriate length



Extension and Parallel Connectors

- Connect the S-hook or S-rod to the distal extension
- Available as 5.0 mm/6.0 mm for attachment to S-hook and 6.0 mm/6.0 mm for attachment to S-rod



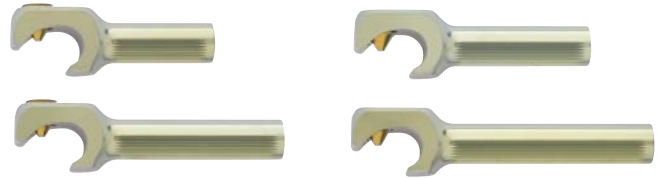
Rib Hook Extensions

- Connect to rib hook by distraction lock to allow for attachment to multiple ribs in a linear fashion
- Available in three sizes: 20 mm, 30 mm, 40 mm



Transverse Bars

- Connect to rod portion of distal or proximal extension and transverse rib hook to allow attachment to multiple ribs, or the same rib in multiple locations in an offset fashion
- Available in four lengths: 15 mm, 20 mm, 25 mm, 30 mm

**Transverse Rib Hook**

- Connects with transverse bar to allow attachment to multiple ribs, or the same rib in multiple locations in an offset fashion
- Attaches to standard sizes of rib hook caps with a distraction lock to encircle the rib

**Long Rib Hook**

- Attaches to the rib hook cap for long rib hook and proximal extension to support the superior rib or the distal extension and rib hook cap for long rib hook to support the inferior rib
- Longer shovel than standard rib hook allows better fit to patient anatomy

**Rib Hook Cap for Long Rib Hook**

- Attaches to long rib hook with a distraction lock to encircle the rib

**VEPTR Adapter (for conversion of VEPTR to VEPTR II)**

- Attaches to superior cradle from VEPTR system and proximal or distal extension of VEPTR II system
- Attaches with distraction lock and nut/barrel



Instruments

03.620.020 Rod Bender with radius adjustment and spring opening



03.622.061 Coronal Bender, left



03.622.062 Coronal Bender, right



03.641.001 Small Rib Hook Trial



03.641.002 5 Nm Torque Limiting Handle, 6 mm hex coupling



03.641.003 VEPTR Nut Driver Shaft, 6 mm hex coupling



03.641.004 Socket Wrench for VEPTR Nut



03.641.005 Rib Hook Holder



03.641.006 Cap Holding Forceps



03.641.007 Sleeve Holder



03.641.008 Lamina Hook Holding Forceps



03.641.009 Offset Lock Impactor



03.641.010 Sure-Lock



03.641.011 Temporary Distraction Peg



03.641.012 Rib Hook Trial



03.641.013 Rod Holder



03.641.014 Extension Measuring Guide



03.641.015 Small Hexagonal Screwdriver



03.641.016 Large Hexagonal Screwdriver



329.052 Bending Iron, right



329.053 Bending Iron, left



388.422 Compression Forceps



388.452 Lock Removal Pliers



388.462 Distraction Lock Removal Bar



388.464 Rib Sleeve Positioning Fork



388.471 Rib Expansion Pliers



388.472 Rib Sleeve Distraction Forceps



388.474 Lock Crimper



388.486 Rib Blade



388.905 Coated Rod Template



398.408 Freer Elevator, 195 mm



399.13 Bone Spreader, 12 mm



498.910 Half Ring



U22-640-10 Longitudinal Retractor



U44-483-20 Double-Ended Elevator, 20 cm



VEPTR II Instrument and Implant Set (01.641.001)

Graphic Cases

- 60.641.001 Graphic Case, for VEPTR II Basic Implants
- 60.641.003 Graphic Case, for VEPTR II Instruments
- 60.641.004 Graphic Case, for VEPTR II Rod Instruments

Instruments

- 03.620.020 Rod Bender with radius adjustment and spring opening
- 03.622.061 Coronal Bender, left
- 03.622.062 Coronal Bender, right
- 03.641.001 Small Rib Hook Trial
- 03.641.002 5 Nm Torque Limiting Handle, 6 mm hex coupling
- 03.641.003 VEPTR Nut Driver Shaft, 6 mm hex coupling
- 03.641.004 Socket Wrench for VEPTR Nut
- 03.641.005 Rib Hook Holder, 2 ea.
- 03.641.006 Cap Holding Forceps, 2 ea.
- 03.641.007 Sleeve Holder
- 03.641.008 Lamina Hook Holding Forceps
- 03.641.009 Offset Lock Impactor
- 03.641.010 Sure-Lock
- 03.641.011 Temporary Distraction Peg, 2 ea.
- 03.641.012 Rib Hook Trial
- 03.641.013 Rod Holder
- 03.641.014 Extension Measuring Guide
- 03.641.015 Small Hexagonal Screwdriver
- 03.641.016 Large Hexagonal Screwdriver
- 329.052 Bending Iron, right
- 329.053 Bending Iron, left
- 388.422 Compression Forceps
- 388.452 Lock Removal Pliers
- 388.462 Distraction Lock Removal Bar
- 388.464 Rib Sleeve Positioning Fork
- 388.471 Rib Expansion Pliers
- 388.472 Rib Sleeve Distraction Forceps



- 388.474 Lock Crimper
- 388.486 Rib Blade, 2 ea.
- 388.905 Coated Rod Template
- 398.408 Freer Elevator, 195 mm
- 399.13 Bone Spreader, 12 mm
- 498.910 Half Ring, 2 ea.
- U22-640-10 Longitudinal Retractor
- U44-483-20 Double-Ended Elevator, 20 cm

Implants

- 04.601.000 90° Titanium S-Hook, right
- 04.601.001 90° Titanium S-Hook, left
- 04.641.001 Titanium Rib Hook, 4 ea.
- 04.641.002 Small Titanium Rib Hook, 4 ea.
- 04.641.003 Titanium Transverse Rib Hook, 2 ea.
- 04.641.004 Titanium Rib Hook Cap, standard, 6 ea.
- 04.641.005 Titanium Rib Hook Cap, extended, 4 ea.
- 04.641.006 Titanium Rib Hook Cap, extra long, 2 ea.
- 04.641.007 Small Titanium Rib Hook Cap, standard, 4 ea.
- 04.641.008 Small Titanium Rib Hook Cap, extended, 2 ea.

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:
– Processing Synthes Reusable Medical Devices - Instruments, Instrument Trays and Graphic Cases—DJ1305
– Processing Non-sterile Synthes Implants—DJ1304

04.641.009	Small Titanium Rib Hook Cap, extra long, 2 ea.	Titanium Proximal Extensions, 500 mm radius, 2 ea.
04.641.010	Long Titanium Rib Hook, 2 ea.	04.641.053 Size 3
04.641.011	Titanium Rib Hook Cap, for Long Rib Hook, 2 ea.	04.641.054 Size 4
04.641.015	Titanium Parallel Connector, 5.0 mm/ 6.0 mm, 2 ea.	04.641.055 Size 5
04.641.016	Titanium Parallel Connector, 6.0 mm/ 6.0 mm, 2 ea.	04.641.056 Size 6
04.641.017	6.0 mm/45° Titanium S-Rod, left	04.641.057 Size 7
04.641.018	6.0 mm/45° Titanium S-Rod, right	04.641.058 Size 8
04.641.019	Titanium VEPTR Adapter, 2 ea.	04.641.059 Size 9
04.641.130	Titanium Extension Connector, 6.0 mm/ 6.0 mm, 2 ea.	04.641.060 Size 10
497.125	Titanium Distraction Lock, 15 ea.	04.641.061 Size 11
497.256	Titanium Extension Connector, 5.0 mm/ 6.0 mm, 2 ea.	04.641.062 Size 12
497.257	Titanium S-Hook, left	04.641.063 Size 13
497.258	Titanium S-Hook, right	04.641.064 Size 14
497.261	Titanium Offset Lamina Hook, low profile, left	04.641.065 Size 15
497.262	Titanium Offset Lamina Hook, low profile, right	
	Titanium Rib Hook Extensions, 2 ea.	Titanium Distal Extensions, 500 mm radius, 2 ea.
04.641.021	20 mm	04.641.073 Size 3
04.641.022	30 mm	04.641.074 Size 4
04.641.023	40 mm	04.641.075 Size 5
	6.0 mm Titanium Transverse Bars, 2 ea	04.641.076 Size 6
04.641.025	15 mm	04.641.077 Size 7
04.641.030	20 mm	04.641.078 Size 8
04.641.035	25 mm	04.641.079 Size 9
04.641.040	30 mm	04.641.080 Size 10
		04.641.081 Size 11
		04.641.082 Size 12
		04.641.083 Size 13
		04.641.084 Size 14
		04.641.085 Size 15

Titanium Proximal Extensions, 220 mm radius

04.641.093	Size 3
04.641.094	Size 4
04.641.095	Size 5
04.641.096	Size 6
04.641.097	Size 7
04.641.098	Size 8
04.641.099	Size 9
04.641.100	Size 10
04.641.101	Size 11
04.641.102	Size 12
04.641.103	Size 13

Titanium Distal Extensions, 220 mm radius

04.641.113	Size 3
04.641.114	Size 4
04.641.115	Size 5
04.641.116	Size 6
04.641.117	Size 7
04.641.118	Size 8
04.641.119	Size 9
04.641.120	Size 10
04.641.121	Size 11
04.641.122	Size 12
04.641.123	Size 13

Also Available

388.751	Handheld Rod Cutter
60.641.002	Graphic Case for VEPTR II Additional Implants
60.641.005	Module for VEPTR II 500 mm Implants
60.641.006	Module for VEPTR II 220 mm Implants
60.641.007	Module for VEPTR II Basic Implants



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