Instructions for Use
VEPTR™ Implant and VEPTR II™ Implant

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Nov 28, 2023

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

SE_528806 AE 04/2023

Instructions for Use

VEPTR™ Implant and VEPTR II™ Implant
VEPTR and VEPTR ll (Vertical Expandable Prosthetic Titanium Rib) is based on a three-dimensional posterior thoracic approach to treat patients with complex chest wall and/or spinal deformities where the thorax is unable to support normal respiration or lung growth (Thoracic Insufficiency Syndrome).
The VEPTR and VEPTR II devices are attached perpendicularly to the subject's natural ribs and lumbar vertebra or pelvis. Once the VEPTR and VEPTR II device is in place, its design allows for expansion, anatomic distraction, and replacement of component parts through less invasive surgery.

The VEPTR and VEPTR II devices allow assembly in a number of different configurations. The configurations can be attached with either cradles or hooks. Components are selected and assembled to form a construct suitable to the individual patient needs.

All components of the VEPTR and VEPTR II system are manufactured from a titanium alloy (Ti-6Al-7Nb) with the exception of the ala-hook, rod ∅ 2.0 mm and s-rod, which are manufactured from commercially pure titanium.

These instructions for use contain information about the following products:

04.601.000S	04.641.003S	04.641.114S	497.128	04.641.056
04.601.001S	04.641.004S	04.641.115S	04.641.011	04.641.101
497.057S	04.641.005S	04.641.116S	04.641.080	497.108
497.061S	04.641.006S	04.641.117S	497.066	497.252
497.065S	04.641.007S	04.641.118S	497.129	04.641.057
497.066S	04.641.008S	04.641.119S	04.641.017	04.641.102
497.067S	04.641.009S	04.641.120S	04.641.081	497.109
497.068S	04.641.010S	04.641.121S	497.067	497.253
497.069S	04.641.011S	04.641.122S	497.131	04.641.058
497.085S	04.641.017S	04.641.123S	04.641.018	04.641.103
497.086S	04.641.018S	04.601.000	04.641.082	497.110
497.087S	04.641.019S	04.641.061	497.068	497.254
497.088S	04.641.021S	04.641.115	497.132	04.641.059
497.089S	04.641.022S	497.115	04.641.019	04.641.113
497.103S	04.641.023S	04.601.001	04.641.083	497.111
497.104S	04.641.025S	04.641.062	497.069	497.261
497.105S	04.641.030S	04.641.116	497.133	04.641.060
497.106S	04.641.035S	497.116	04.641.021	04.641.114
497.107S	04.641.040S	04.641.001	04.641.084	497.112
497.108S	04.641.053S	04.641.063	497.085	497.262
497.109S	04.641.054S	04.641.117	497.134	497.071
497.110S	04.641.055S	497.117	04.641.022	497.091
497.111S	04.641.056S	04.641.002	04.641.085	497.230
497.112S	04.641.057S	04.641.064	497.086	497.244
497.115S	04.641.058S	04.641.118	497.225	497.072
497.116S	04.641.059S	497.118	04.641.023	497.092
497.117S	04.641.060S	04.641.003	04.641.093	497.231
497.118S	04.641.061S	04.641.065	497.087	497.245
497.119S	04.641.062S	04.641.119	497.226	497.073
497.120S	04.641.063S	497.119	04.641.025	497.093
497.121S	04.641.064S	04.641.004	04.641.094	497.232
497.122S	04.641.065S	04.641.073	497.088	497.246
497.125S	04.641.073S	04.641.120	497.227	497.074
497.126S	04.641.074S	497.120	04.641.030	497.094
497.127S	04.641.075S	04.641.005	04.641.095	497.233
497.128S	04.641.076S	04.641.074	497.089	497.247
497.129S	04.641.077S	04.641.121	497.228	497.075
497.131S	04.641.078S	497.121	04.641.035	497.095
497.132S	04.641.079S	04.641.006	04.641.096	497.234
497.133S	04.641.080S	04.641.075	497.103	497.248
497.134S	04.641.081S	04.641.122	497.229	497.076
497.225S	04.641.082S	497.122	04.641.040	497.096
497.226S	04.641.083S	04.641.007	04.641.097	497.235
497.227S	04.641.084S	04.641.076	497.104	497.249
497.228S	04.641.085S	04.641.123	497.241	497.077
497.229S	04.641.093S	497.125	04.641.053	497.097
497.241S	04.641.094S	04.641.008	04.641.098	497.236
497.242S	04.641.095S	04.641.077	497.105	497.263
497.243S	04.641.096S	497.057	497.242	497.078
497.251S	04.641.097S	497.126	04.641.054	497.098
497.252S	04.641.098S	04.641.009	04.641.099	497.237
497.253S	04.641.099S	04.641.078	497.106	497.079
497.254S	04.641.100S	497.061	497.243	497.099
497.261S	04.641.101S	497.127	04.641.055	497.238
497.262S	04.641.102S	04.641.010	04.641.100	497.080
04.641.001S	04.641.103S	04.641.079	497.107	497.100
04.641.002S	04.641.113S	497.065	497.251	497.239

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium)
according to ISO 5832-11
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2

Intended Use
The VEPTR and VEPTR II system is intended to mechanically stabilize and distract the thorax in skeletally immature patients. It is intended to be expanded through subsequent surgeries.

VEPTR and VEPTR II may be configured for use in supporting rib-based expansion thoracoplasty operations.

Indications
VEPTR and VEPTR II system is indicated for patients with severe, progressive spinal deformities and/or three-dimensional deformity of the thorax associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth. This would include patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis.

Contraindications
The VEPTR and VEPTR II system should not be used under the following conditions:
– Inadequate strength of bone (e.g. ribs/spine) for attachment of the VEPTR
– Absence of proximal and distal ribs for attachment of the VEPTR
– Absence of diaphragmatic function
– Inadequate soft tissue for coverage of the VEPTR
– Age beyond skeletal maturity for uses of the VEPTR
– Age below 6 months
– Known allergy to any of the device materials
– Infection at the operative site

Patient Target Group
The VEPTR and VEPTR II system is intended for use in skeletally immature patients above 6 months. The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
When the VEPTR and VEPTR II system is used as intended and according to the instructions for use and labeling, the device allows for improvement in respiration and lung growth secondary to expansion of thorax.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
The VEPTR and VEPTR II system is a vertical expandable prosthetic rib system, designed to provide mechanical stability and distract the thorax to support normal respiration and lung growth.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; respiratory/pulmonary complications; neural and vascular injury; death, stroke; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; decrease in bone density due to stress shielding; ongoing pain or neurological symptoms; damage to bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device displacement.

Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
- It is strongly advised that the VEPTR and VEPTR II Implant is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place as per the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, hardware prominence, skin coverage and pleural tear, the limitations of treatment methods, or inadequate asepsis.

VEPTR
- 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.

Primary Procedure

Position patient
Place the patient in a lateral decubitus position similar to that required for a standard thoracotomy.
Patient positioning and superior exposure remain the same regardless of the construct being implanted.
- To protect against brachial plexus injury, do not extend the shoulder more than 90 degrees.

Perform superior exposure
Make a J-shaped thoracotomy incision and retract the skin flaps.
- Avoid disrupting the periosteum overlying the ribs.

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

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

Insert closing half-ring
- Using the holding forceps for closing half-ring, insert the closing half-ring into the intercostal space above the opposite side of the rib, with the open end facing laterally to protect the great vessels. Rotate it distally to mate with the cranial rib support.

Insert lock for rib support
Load a blue lock into the inserter for rib support lock. Insert the lock into the aligned holes of the cranial rib support and the closing half-ring. Using a hammer, firmly tap the inserter to seat the lock.
- The lateral lock inserter should always be used to ensure the lock is fully seated.

Distract chest wall
Assemble two feet to the longitudinal retractor. Distract ribs using the rib retractor assembly as needed. 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.
- Only resect visible bone adjacent to the spine. Be aware of anomalous segmental arteries due to abnormal anatomy.

Lumbar extension assembly
(Use for rib-to-lumbar lamina, or rib-to-ilium constructs)
Determine contour and cut to length, if necessary
Use the trial rod to determine the contour of the rod portion of the lumbar extension. Using the bending pliers, contour the rod portion only to match the anatomy. As an alternative, the USS bending irons can be used for contouring.
- Do not bend the T-section of the lumbar extension which mates with the extension bar.

Insert caudal closure for extension bar
Prior to insertion, connect the extension bar with the lumbar extension by sliding the lumbar extension rod into the extension bar. Align the most caudal hole in the extension bar with the most caudal hole in the lumbar extension rod. The implants should overlap completely to maximize future expansion capacity.
- The lock crimper should always be used to ensure the closure is fully seated

Insert caudal implant
Lamina hook (Use for rib-to-lumbar lamina construct)
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 unilaterally.
- Do not disturb the facet joints.

Insert closure for extension bar
Insert a golden closure for extension bar using the inserter for rib support lock to fix the extension bar to the cranial rib support.
- The lock crimper should always be used to ensure the lock is fully seated.

Caudal rib support (Use for rib-to-rib constructs)
Choose appropriate caudal rib
The proper caudal 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.

Insert caudal implants
Using the holding forceps for rib support, seat the caudal rib support into the space between the periosteum and the rib. Rotate it into the correct position around the rib.
– The lock crimper should always be used to ensure the lock is fully seated.

Expansion procedure
– When performing an expansion procedure on patients implanted with a VEPTR device, the decision to distract the implanted VEPTR device should consider the risk/benefit of lengthening the device further versus alternative options including replacement of cranial and/or caudal construct components to longer ones. Remaining vigilant and closely monitoring patients for any device breakage with careful interpretation of this area on post-op imaging is recommended.

VEPTR II
– 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.

Primary Procedure

Patient positioning
Place the patient in a lateral decubitus position similar to that required for a standard thoracotomy. Patient positioning and superior exposure remain the same, regardless of the construct being implanted.
– To protect against brachial plexus injury, do not extend the shoulder more than 90 degrees.

Perform superior exposure
Make a J-shaped thoracotomy incision and retract the skin flaps.
– Avoid disrupting the periosteum overlying the ribs.

Insert superior implants
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.
– Due to the risk of brachial plexus impingement, do not choose the first rib as the superior point of attachment.

Prepare rib for implants
Make a 1 cm incision into the intercostal muscles above and below the rib where the cranial rib support will attach. Insert a periosteal elevator to 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.

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 areas of ribs, or multiple ribs.
– If using the small rib hook, it is necessary to use one of the small rib hook caps (light blue).

Insert closure for extension bar
Load a closure for extension bar into the 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 closure for extension bar. Using a hammer, firmly tap the impactor to seat the closure for extension bar.
– The lock crimper should always be used to ensure the closure for extension bar is fully seated.

Distract chest wall (if necessary)
Assemble the two feet for rib distractor 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 thoracostomy.
– Only resect visible bone adjacent to the spine. Be aware of anomalous segmental arteries due to abnormal anatomy.

Assemble distal portion of construct
Determine contour and cut to length, if necessary
Use the trial rod 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 extension bar.

Insert closure for extension bar
Prior to 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.
– The lock crimper should always be used to ensure the closure for extension bar is fully seated.

Insert inferior implant
Lamina hook (for rib-to-lumbar lamina construct)
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.

Alternative implant usage
Using the rib hook extensions (series attachment)
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).
– If using the rib hook extensions, the most inferiorly placed rib hook should be the long rib hook (red).

Expansion Procedure

– When performing an expansion procedure on patients implanted with a VEPTR II device, the decision to distract the implanted VEPTR II device should consider the risk/benefit of lengthening the device further versus alternative options including replacement of cranial and/or caudal construct components to longer ones. Remaining vigilant and closely monitoring patients for any device breakage with careful interpretation of this area on post-op imaging is recommended.

Final locking
Insert a new closure for extension bar using the offset lock impactor to fix the proximal extension in its distracted position. Using a hammer, firmly tap the impactor to seat the closure.
– Check to ensure the closure is fully seated using the lock crimper.

Replacement of components
VEPTR II component replacement
– Make sure to lock the extensions before insertion.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
The VEPTR and VEPTR II Implants are applied using associated VEPTR Instruments. Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

The VEPTR consists of three main segments: an upper rib support/hook that is meant to attach to the superior rib, a caudal fixation point, and an extension bar (attaches the cranial rib support to the caudal rib support or lumbar extension rod) separating the upper and lower attachment points. This extension bar is connected by a removable closure for extension bar to lock the construct; the construct can be distracted to accommodate a growing child and maintain deformity correction through adolescence.

Several rib supports are available to encircle single or multiple ribs, as well as different sized (i.e., fused) ribs. Variations are also available in extension rod length, radius and diameter. The "rod" portion of the proximal and distal extension rods may be manipulated (shortened or bent) to accommodate various patient anatomies.

Construct Options

VEPTR	VEPTR II
Rib-to-Rib – Attaches to the superior rib and to the inferior rib – Components available in 70 mm or 220 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-Lumbar Lamina – Attaches to rib and to lumbar spine – Components available in 220 mm radius	Rib-to-Lumbar Lamina – Attaches to rib and to lumbar spine – Components available in 220 mm or 500 mm radius
Rib-to-Ilium – Attaches to the rib and to the ilium – Components available in 220 mm radius	Rib-to-Ilium – Attaches to rib and to ilium – Components available in 220 mm or 500 mm radius

The VEPTR and VEPTR II device is comprised of a combination of the following component(s):

VEPTR Components	VEPTR II Components
Rib Hooks and Caps	
Cranial Rib Support – Attaches to the closing half-ring and extension bar to support the cranial rib.	Rib Hook – 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
Closing Half-Ring – Attaches to the cranial or caudal rib support to encircle the cranial or caudal rib(s)	Rib Hook Cap – Attach to the rib hook to encircle the superior or inferior rib(s)
Rods and Connectors	
Closure for Extension Bar – Closure for extension bar (gold) connects the extension bar to the cranial rib support, caudal rib support or lumbar extension rod	Closure for Extension Bar – Closure for extension bar (gold) connects the extension bar to the cranial rib support, caudal rib support or lumbar extension rod
Lock for Rib Support – Lock for rib support (blue) connects the closing half-ring to the cranial rib support or the caudal rib support	This device is not part of the VEPTR II.
Extension Bar	Proximal Extension – Attaches the superior attachment point (rib hook) to the distal extension
Lumbar Extension Rod	Distal Extension – Attaches the proximal extension to the inferior attachment point (rib hook, lamina hook, or connector)
Extension Connector – Connects the ala hook to the lumbar extension rod – Accepts 5.0 mm/6.0 mm rods	Extension Connector – Connects the ala hook or s-rod to the distal extension – 5.0 mm/6.0 mm (for use with ala hooks) – 6.0 mm/6.0 mm (for use with s-rods)
This device is not part of the VEPTR.	Parallel Connector – Connects the ala hook or s-rod to the distal extension – 5.0 mm/6.0 mm (for use with ala hooks) – 6.0 mm/6.0 mm (for use with s-rods)
Caudal Anchors	
Lamina Hook – Right/Left – 3.5 mm setscrew secures the placement	Lamina Hook – Right/Left – 3.5 mm setscrew secures the placement
Ala Hook – Used with the distal extension and extension connector to attach to the ilium – Left or right contours – 90 degrees	Ala Hook – Used with the distal extension and extension connector to attach to the ilium – Left or right contours – 90 degrees
Caudal Rib Support – Attaches to the distal extension and closing half ring to support the inferior rib – Available in 70 mm or 220 mm radius configurations	VEPTR II utilizes the same rib hook and rib hook cap for cranial and caudal fixation
This device is not part of the VEPTR.	S-Rods – Used with the distal extension and connector to attach to the ilium – Left or right contours – Available in 45° angulation – 400 mm rod allows cutting to appropriate length
Rod 2.0 mm, Pure Titanium – Holds osteotomized ribs against the construct	This device is not part of the VEPTR II.

Magnetic Resonance Environment

VEPTR

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the VEPTR system are MR conditional. These articles can be scanned safely under the following conditions:

– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the VEPTR implant will produce a temperature rise not greater than 4.2 °C at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the VEPTR device.

VEPTR II

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the VEPTR II system are MR conditional. These articles can be scanned safely under the following conditions:

– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the VEPTR II implant will produce a temperature rise not greater than 4.2 °C at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the VEPTR II device.

Treatment before Device is Used

Sterile Device:

The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging.

Do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:

– Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
– Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.

Do not use if the package is damaged or expired.

Non-Sterile Device:

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Implant Removal

The VEPTR and VEPTR II is intended for long-term implantation. Any decision to remove the device must be made by the surgeon and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of an additional surgical procedure.

If a VEPTR and VEPTR II Implant must be removed, the following technique is recommended:

VEPTR

Position patient

– Place the patient in a lateral decubitus or prone position.

Exposure

– Identify the approximate location of the cranial and caudal location of the rib support and the closure for extension bar through palpation and/or X-ray. Make transverse or longitudinal incision over the cranial and caudal rib support and the closure for extension bar as required. A portion of the previous thoracotomy incision may be used.

Remove locks

– Remove the golden closure for extension bar using the lock removal pliers or the lock removal device.
– Remove the locks for the cranial and caudal rib supports.

Remove extension bar, rib support and closing half-ring
– Remove the proximal and distal extension with the holding forceps for extension bar. Remove the closing half ring and the rib support with the holding forceps for closing half-ring or rib support.

Removal of the lamina hook
– Remove the extension connector from the lamina hook using the 2.5 mm screwdriver. Remove the lamina hook using the holding forceps for hooks, for VEPTR.

Removal of ala hook (rib-to-ilium construct)
– Remove the extension connector from the ala hook using the 2.5 mm screwdriver.
– Remove the ala hook using the holding forceps for USS paediatric rods 5.0 mm.

VEPTR II
Position patient
– Place the patient in a lateral decubitus or prone position.

Exposure
– Identify the approximate location of the cranial and caudal location of the rib support and the closure for extension bar through palpation and/or an X-ray to localize the position of the closure for extension bar. Make transverse or longitudinal incision over the cranial and caudal rib support and the closure for extension bar as required. A portion of the previous thoracotomy incision may be used.

Remove locks
– Remove the closure for extension bar using the lock removal pliers or the lock removal device. Remove the closure for extension bar for the cranial and caudal rib supports.

Remove extension bar, rib support and closing half-ring
– Remove the proximal extension bar – unlock the device by loosening the nut on the rib hook using the torque limiting handle and nut driver shaft. Remove the closing half ring and the rib support with the holding forceps for closing half-ring or rib support.
– 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) using the screwdriver, hexagonal, large or loosen the setscrews on the extension or parallel connector (for rib-to-ilium construct). Remove the proximal and distal extension.

Removal of the lamina hook
– Remove the extension connector from the lamina hook using the screwdriver, hexagonal, large. Remove the lamina hook.

Removal of ala hook/s-rod (rib-to-ilium construct)
– Remove the extension/parallel connector from the ala hook/s-rod using the screwdriver, hexagonal, small. Remove the ala hook/s-rod using the rod holder.

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Special Operating Instructions

VEPTR

Primary Procedure

Position patient
– Place the patient in a lateral decubitus position similar to that required for a standard thoracotomy.
– Patient positioning and superior exposure remain the same regardless of the construct being implanted.

Perform superior exposure
– Make a J-shaped thoracotomy incision and 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 and posterior scalene muscle.

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.

Prepare rib for implants
– Make a 1 cm incision into the intercostal muscles above and below the rib where the superior cradle will attach. Insert a periosteal elevator to carefully elevate the periosteum adjacent to the lung.
– Use the rib support feeler to prepare the rib for the cranial rib support and the closing half-ring.

Select proper cranial rib support angulation and radius
– Assess the patient's thoracic anatomy in order to determine the required cranial rib support angulation (neutral, right, or left).
– Choose either a 70 mm or 220 mm radius cranial rib support. A 220 mm rib support is used with either a lumbar extension or a 220 mm radius caudal rib support.
– Only 70 mm rib support is used with the 70 mm radius caudal rib support.
– The corresponding closing half-ring should match the contour of the thorax when the proper angulation is chosen.

Cranial rib support
– Using the holding forceps for rib support, seat the underside of the cranial rib support into the space between the periosteum and the rib. Rotate it into the correct position. For the medial construct, seat as medial as possible to the transverse process.

Select proper closing half-ring size
– Based on the patient's anatomy, select the appropriate closing half-ring (standard or large). The large closing half-ring is used to encircle large areas of fused rib or two ribs.

Insert closing half-ring
Align cranial rib support and closing half-ring
– If the closing half-ring and cranial rib support are not aligned, prepare the pliers for closing half-ring and rib support. Affix the clip for closing half-ring and the clip for rib support to the pliers for closing half-ring and rib support. This assembly is referred to as the pliers for closing half-ring and rib support.
– Align the cranial rib support with the closing half-ring using the pliers for closing half-ring and rib support.

Insert lock for rib support
– Load a blue lock into the inserter for rib support lock. Insert the lock into the aligned holes of the cranial rib support and the closing half-ring. Using a hammer, firmly tap the inserter to seat the lock.
– Alternatively, the lateral lock inserter can be used to seat the lock.
– The implants now encircle the rib.

Distract chest wall
– Assemble two feet to the longitudinal retractor. Distract ribs using the rib retractor assembly as needed. 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.

Select appropriate extension bar
– Using the trial rod, measure the distance between the cranial rib and either the thoracolumbar junction or the chosen caudal rib to determine the appropriate extension bar size.
  – Measure to the thoracolumbar junction when planning a rib-to-ilium or rib-to-lumbar lamina construct.
  – Measure to the caudal rib when using a rib-to-rib construct.
– The measurement in centimeters will correspond to the correct extension bar size. For example, if the distance is determined to be 7 cm, use an extension bar marked with a 7. Implant sizes are identified from 4 to 13 in 1 cm increments.

Lumbar extension assembly (use for rib-to-lumbar lamina, or rib-to-ilium constructs)
Select appropriate lumbar extension
– Lumbar extension sizes correspond with the same size extension bar. For example, if the selected extension bar is a size 9, the correct lumbar extension rod will also be a 9.

Determine contour and cut to length, if necessary
– Use the trial rod to determine the contour of the rod portion of the lumbar extension. Using the bending pliers, contour the rod portion only to match the anatomy. As an alternative, the USS bending irons can be used for contouring.
– If necessary, cut the rod portion of the lumbar extension rod to the correct length using the 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 caudal implant. When using a lamina or ala hook, additional length of 1.5 cm should be left to allow for distraction.

Insert caudal closure for extension bar
– Prior to insertion, connect the extension bar with the lumbar extension by sliding the lumbar extension rod into the extension bar. Align the most caudal hole in the extension bar with the most caudal hole in the lumbar extension rod. The implants should overlap completely to maximize future expansion capacity.
– Place a golden closure for extension bar in this position using the inserter for rib support lock. With a hammer, firmly tap the inserter to seat the lock.

Insert caudal implant: Lamina hook (use for rib-to-lumbar lamina construct)
– 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 unilaterally.
– Use a lamina feeler to separate the ligamentum flavum unilaterally from the underside of the lamina to ensure bony contact with the lamina hook, leaving the interspinous ligament intact. Resect enough ligamentum flavum for the hook to pass.
– Choose the appropriate lamina hook (right or left). The hook will be placed downward-facing and the setscrew will be lateral.
– Use the holding forceps to place the hook in the desired location on the lumbar vertebra.

Insert caudal implant: Ala hook (use for rib-to-ilium construct)
– Make a 4 cm incision just lateral to the posterior superior iliac spine. Identify the posterior third and middle third of the iliac crest. Make a 1 cm transverse incision in the mid substance of the apophysis with equal layers of cartilage above and below the incision. Insert the periosteal elevator through the apophyseal incision to widen it into a tunnel and thread it along the medial cortical surface of the iliac crest. The tip of the periosteal elevator should be just lateral to the sacroiliac joint.
– Choose the appropriate ala hook (45° or 90°, left or right). The correct ala hook should have the upper end lying medial to the downward pointed end.
– Attach an extension connector to the ala hook using the 2.5 mm screwdriver. Confirm that 5.0 mm opening in the extension connector is mated with the ala hook.
– Use the 5.0 mm bending irons to contour the ala hook to fit the ilium. insert the ala hook, pointed end downward, using the holding forceps for USS Paediatric rods 5.0 mm over the top of the iliac crest and medial to the inner table of the iliac wing.

Align lumbar extension to caudal implant
– Create a tunnel through the paraspinal muscles from the proximal incision to just above the caudal attachment point. Place the lumbar extension into the tip of a #20 chest tube and carefully thread proximal-to-distal, to the caudal attachment point.
– If attaching to a lamina hook (for rib-to-lumbar lamina construct), guide the distal extension into the lamina hook.
– If using an ala 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 screwdriver.

Align extension bar to cranial rib support
– Use the holding forceps for extension bar and the holding forceps for rib support to slide the cranial end of the extension bar over the cranial rib support.
– Alternatively, the iron for extension bar and the iron for rib support can be used to align the two implants. The positioner for rib support can also facilitate alignment.

Insert closure for extension bar
– Insert a golden closure for extension bar using the inserter for rib support lock to fix the extension bar to the cranial rib support.
– If necessary, the spreader for rib support can be used to align the holes.
– Using a hammer, firmly tap the inserter to seat the lock.
– Alternatively, the lateral lock inserter can be used to seat the lock.

If using a lamina hook, distract if necessary and tighten
– Using the 2.5 mm small hexagonal screwdriver, place a fixation ring for rods cranial to the lamina hook onto the rod portion of the lumbar extension.
– Using the spreader forceps, gently distract to further seat the hook. Use the 3.5 mm large hexagonal screwdriver to tighten the setscrew in the hook.
– Remove the fixation ring for rods following distraction, using the 2.5 mm small hexagonal screwdriver.

Caudal rib support (use for rib-to-rib constructs)
Choose appropriate caudal rib
– The proper caudal rib for attachment of the rib-to-rib device should be transverse in orientation and of adequate width.

Select appropriate caudal rib support
– Caudal rib support sizes correspond to extension bar sizes. For example, if the selected extension bar is a size 7, the correct caudal rib support will also be a size 7 (see "Select appropriate extension bar").
– If a 70 mm radius rib support is used, a 70 mm radius extension bar must be used. If a 220 mm radius extension bar is used, a 220 mm radius caudal rib support must be used.

Insert caudal implants
– Using the holding forceps for rib support, seat the caudal rib support 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 closing half-ring (standard or large).
– Using the holding forceps for closing half-ring, seat the closing half-ring over the opposite side of the rib.
– Align the caudal rib support and closing half-ring using the pliers for closing half-ring and rib support.
– Load a blue lock for rib support into the inserter for rib support lock. Lock the assembly by inserting the lock for rib support into the aligned holes of the caudal rib support and the closing half-ring. Using a hammer, firmly tap the inserter to seat the lock.
– Alternatively, the lateral lock inserter can be used to seat the lock.
– The implants now encircle the rib.

Assemble construct
– Use the holding forceps for extension bar to slide the selected extension bar over the caudal rib support.
– Slide the extension bar onto the cranial rib support. The iron for extension bar and the iron for rib support can be used to align the two implants. The positioner for rib support can also help with alignment.
– Place a golden closure for extension bar in the cranial end of the extension bar, using the inserter for rib support lock. Using a hammer, firmly tap the inserter to seat the lock.
– Use the distractor for extension bar or the spreader for rib support to distract the device until the caudal hole in the extension bar is aligned with a hole in the caudal rib support. Both the cranial and caudal rib supports should be seated against the ribs.

Lock construct
– Using the inserter for rib support lock, place a golden closure for extension bar in the caudal end of the extension bar to lock the assembly in place. Confirm both locks are fully seated, using the lock crimper.
– Alternatively, the lateral lock inserter can be used to seat the lock.
– 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.

Special Procedures

Fused ribs and scoliosis
– After the cranial rib support and caudal point of attachment have been chosen, perform an opening wedge thoracostomy 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.

Hypoplastic thorax
– A hypoplastic, low-volume thorax requires the use of a 70 mm radius rib-to-rib construct (70 mm radius implants include: cranial rib support, caudal rib support, extension bar). These constructs are placed bilaterally in separate procedures.
– After inserting both the cranial and caudal rib supports, 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 two to three 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.

Expansion Procedure

Patient positioning
– Place the patient in a lateral decubitus or prone position.

Exposure
– Identify the approximate location of the caudal closure for extension bar through palpation and/or X-ray. Make a transverse or longitudinal incision over the caudal closure for extension bar.

Remove lock
– Remove the golden closure for extension bar using the lock removal pliers or the lock removal device.

Distraction
– Use the rib distraction pliers or the distractor for extension bar in conjunction with a fixation ring for rods to gently distract the implanted device until the device is adequately lengthened. Use the temporary distraction pins as placeholders to assist distraction.

Final locking
– Insert a new golden closure for extension bar using the inserter for rib support lock to fix the extension bar in its distracted position. With a hammer, tap the inserter to seat the closure. Confirm the closure is fully seated using the lock crimper.
– Alternatively, the lateral lock inserter can be used to seat the lock.

Replacement of components
– For replacement of the extension bar, caudal rib support or lumbar extension rod, 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 thoracostomy incision may be used.
– Unlock the device by removing the golden closure(s) for extension bars using the lock removal pliers.
– Remove the required components and insert the new components through the fibrous canal surrounding the old devices.
– Install new closure(s) for extension bars.
– Refer to detailed instructions above to replace the specific components in need.

VEPTR II

Primary Procedure

Patient positioning
– Place the patient in a lateral decubitus position similar to that required for a standard thoracotomy. Patient positioning and superior exposure remain the same, regardless of the construct being implanted.

Perform superior exposure
– Make a J-shaped thoracotomy incision and 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 and posterior scalene muscle.

Insert superior implants
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.

Prepare rib for implants
– Make a 1 cm incision into the intercostal muscles above and below the rib where the cranial rib support will attach. Insert a periosteal elevator to elevate the periosteum adjacent to the lung.
– Use the trial rib hook 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 trial rib hook to prepare the rib.
– The trial rib hook and trial rib hook small, may also be used to determine the appropriate rib hook size.

Select the suitable rib hook size
– Select the appropriate rib hook size after using the trial rib hook.

Seat the rib hook
– Using the rib hook holder, seat the underside of the rib hook into the space between the periosteum and the rib. Rotate it into the correct position. For the medial construct, seat as medial as possible to the transverse process.
– For ease of grasping the rib hook with the rib hook holder, seat one tip of the rib hook holder first rather than simultaneously.

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 areas of ribs, or multiple ribs.

Insert rib hook cap
– Using the holding forceps, insert the rib hook cap into the intercostal space superior to the rib. Rotate the rib hook cap distally to mate with the rib support until the rib hook and the rib hook cap are aligned.

Insert closure for extension bar
– Load a closure for extension bar into the 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 closure for extension bar. Using a hammer, firmly tap the impactor to seat the closure for extension bar.
– Alternatively, the surelock can be used to place the closure for extension bar and ensure it is fully seated.
– To facilitate loading a closure for extension bar onto the surelock, press the surelock onto the closure while it remains in the graphic case. Pushing on the top of the surelock tip will facilitate grasping the closure.

In case of fused ribs and scoliosis:
– After superior and inferior points of attachment have been chosen, perform an opening wedge thoracostomy through the fused ribs at the apex of the thoracic deformity from the tip of the transverse process to the costochondral junction. Cut a transverse osteotomy from the transverse process to the sternum, in line of the normal rib.
– Separate the fusion mass into multiple longitudinal sections of the approximate width of normal ribs in the patient. Ensure the continuity between the anterior and posterior attachments of the newly separated ribs.

Distract chest wall (if necessary)
– Assemble the two feet for rib distractor 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 thoracostomy.
– Additional resection of medial fused ribs may be required if distraction is difficult.

Select length of proximal extension
Measure expandable portion
– Depending on the patient's anatomy/pathology choose either the extension with radius 220 mm (more curved) or with radius 550 mm (less curved).
– Measure the distance for the expandable portion of the construct to determine the appropriate proximal extension size.
– Measure the distance over the spread thorax, from the cranial rib and either to the thoraco-lumbar junction (rib-to-spine/ilium) or the chosen caudal rib (rib-to-rib).
– 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 to 15 in 1 cm increments for the 500 mm radius implants, and from 3 to 13 in 1 cm increments for the 220 mm radius implants.

Cut and contour proximal extension, if necessary
– Excess rod on the extension needs to be cut before implantation. As a minimum, 11 mm of straight rod must remain on the proximal extension to facilitate the rod to fully seat within the rib hook. The extension measuring device 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.
– Using the rod bender, contour only the rod portion of the proximal extension. As an alternative, the bending irons can be used to contour the rod. The rod portion of the extension can be cut using the handheld rod cutter.

Assemble distal portion of construct
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.
– The green proximal extension matches the pink distal extension.
– The golden proximal extension matches the golden distal extension.

Determine contour and cut to length, if necessary
– Use the trial rod to determine the contour of the rod portion of the lumbar 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.
– 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 device 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.
– When using a lamina hook or ala hook with parallel connector, an additional length of 1.5 cm should be left on the rod portion of the distal extension to facilitate distraction.

Insert closure for extension bar
– Prior to 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 closure for extension bar in this position using the offset lock impactor. Gently tap the impactor with a hammer to seat the lock.
– Alternatively, the surelock can be used to place the closure for extension bar and ensure it is fully seated.

Insert inferior implant: Lamina hook (for rib-to-lumbar lamina construct)
– 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.
– Use the lamina feeler to separate the ligamentum flavum unilaterally from the underside of the lamina to ensure bony contact with the lamina hook and to leave the inter spinous ligament intact. Resect the ligamentum flavum for the hook to pass.
– Choose the appropriate lamina hook (right or left). The hook will be placed downward-facing with the setscrew most lateral.
– Place the hook in the desired location on the lumbar vertebra.

Insert inferior implant: Ala hook or s-rod (for rib-to-ilium construct)
– Make a 4 cm, longitudinal incision just lateral to the posterior superior iliac spine. Identify the posterior third and middle third of the iliac crest. Make a 1 cm transverse incision in the mid substance of the apophysis with equal layers of cartilage above and below the incision. Insert the periosteal elevator through the apophyseal incision to widen it into a tunnel and thread it along the medial cortical surface of the iliac crest. The tip of the periosteal elevator should be just lateral to the sacroiliac joint.
– Choose the appropriate ala 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 ala 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 ala hooks.
– The 6.0 mm/6.0 mm extension connector or 6.0 mm/6.0 mm parallel connector should be used with s-rods. Insert the ala 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.

Insert inferior implant: Rib hook (for rib-to-rib construct)
– Use the same procedure and instrumentation as described earlier for placement of the rib hook and rib hook cap.

Align the distal extension to the inferior implant
Placement using the lamina hook (for rib-to-spine) or ala hook or s-rod (for rib-to-ilium)
– 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 number 20 chest tube and thread 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 ala hook or s-rod (for rib-to-ilium construct), guide the distal extension into the opposing side of the extension or parallel connector. Tighten the setscrews in the connector using the screwdriver, hexagonal, small.

Align the distal extension to the inferior implant:
Placement using the rib hook (for rib-to-rib construct)
– 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 VEPTR nut driver shaft for hexagonal coupling, 6mm, into the handle with torque limiter 5 Nm, for hexagonal coupling, 6mm. Use the handle with torque limiter and VEPTR nut driver shaft to tighten the nut onto the rib hook, connecting the distal extension.

Final assembly
Assemble the proximal extension to the rib hook
– 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.

Tighten the nut on the rib hook
– Insert the nut driver shaft into the handle with torque limiter. Use the handle with torque limiter and VEPTR nut driver shaft to tighten the nut onto the rib hook, connecting the proximal extension.
– 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.

If using a lamina hook, distract if necessary and tighten
– Using the screwdriver, hexagonal, small, place a fixation ring superior to the lamina hook onto the rod portion of the distal extension.
– Using the distractor against the fixation ring, gently distract to further seat the hook. Use the screwdriver, hexagonal, large to tighten the setscrew in the hook.
– Remove the fixation ring following distraction, using the screwdriver, hexagonal, small.
– If the patient is older than 6 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.

Alternative implant usage
Using the rib hook extensions (series attachment)
– 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 closure for extension bar.

Using the transverse rib hooks and rod connectors (parallel attachment)
– The transverse rib hooks and the rod connectors 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 rod connector (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 rod connector into the transverse rib hook. Attach the rod connector to the rod portion of the proximal extension using the screwdriver, hexagonal, small.
– Refer to detailed instructions above to install specific components.

Expansion Procedure

Patient positioning
– Place the patient in a lateral decubitus or prone position.

Exposure
– Identify the approximate location of the closure for extension bar, locating the proximal and distal extension through palpation and/or X-ray to localize the position of the closure for extension bar. Make a transverse or longitudinal incision over the closure for extension bar.

Remove the closure for extension bar
– Remove the closure for extension bar using the lock removal pliers or the lock removal device.

Distraction
– Use the rib distraction pliers, or the distractor in conjunction with a fixation ring, to gently distract the implanted device until the device is adequately lengthened. Use the temporary distraction pins as placeholders to assist distraction.
– For the initial expansion (when the rib distraction pliers cannot be used), the temporary distraction pins can be used to assist distraction. Use the distractor with the fixation ring to distract the proximal extension. When the desired hole location is reached, place the round tip of the first temporary distraction pin in the desired hole of the proximal extension. Remove the distractor and place the rectangular end of the second temporary distraction pin in the distal extension to prevent the proximal extension from slipping (the "foot" on the pin may need to be rotated 90° depending on the desired hole location). Remove the first temporary distraction pin to allow final locking.
– The hole spacing in the VEPTR II device will allow for incremental lengthening of 2.5 mm (minimum).

Final locking
– Insert a new closure for extension bar using the offset lock impactor to fix the proximal extension in its distracted position. Using a hammer, firmly tap the impactor to seat the closure.
– Alternatively, the surelock can be used to both place the closure for extension bar and ensure it is fully seated.

Replacement of components
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 handle with torque limiter and VEPTR 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-ilium construct).
– Remove the proximal and distal extension and insert the new components through the fibrous canal surrounding the old devices.

VEPTR component replacement (conversion of existing VEPTR to VEPTR II)
– For replacement of a VEPTR construct (extension bar/lumbar extension rod or extension bar/caudal rib support) without removing the implanted VEPTR cranial rib support, use the VEPTR adapter. Detach and remove the VEPTR extension bar/lumbar extension rod or extension bar/caudal rib support from the cranial rib support(s). Attach the VEPTR adapter to the VEPTR cranial rib support using a closure for extension bar. Now a VEPTR II proximal or distal extension can be used to replace the VEPTR extension bar construct.
– Refer to detailed instructions above to replace the specific components in need.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Implant Card & Patient Information Leaflet
If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com

Instructions for Use:
www.e-ifu.com