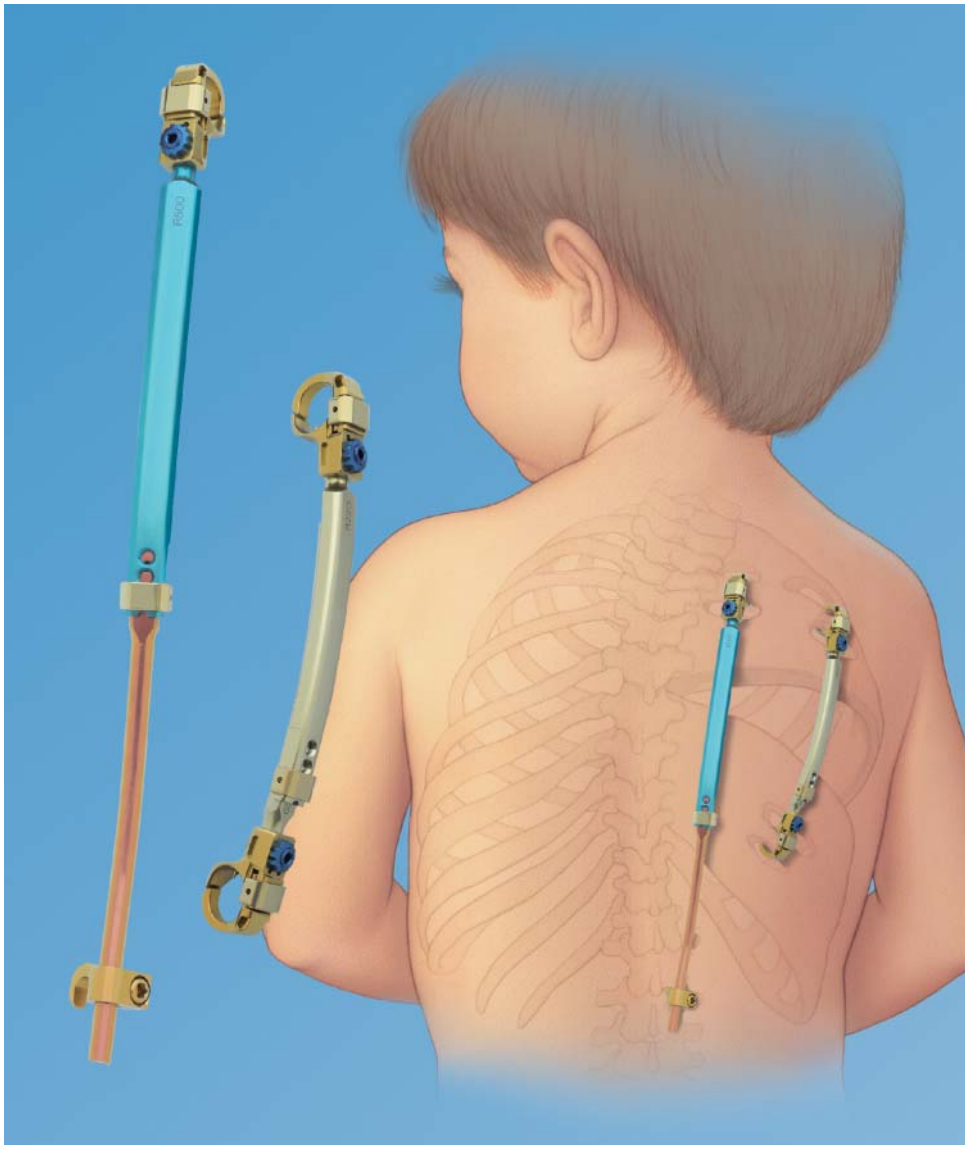
VEPTR/VEPTR II. Vertical Expandable Prosthetic Titanium Rib.

Patient Information



SYNTHES® Spine

Instruments and implants approved by the AO Foundation

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Descriptions, Purpose and Surgical Procedure of the VEPTR/VEPTR II Device

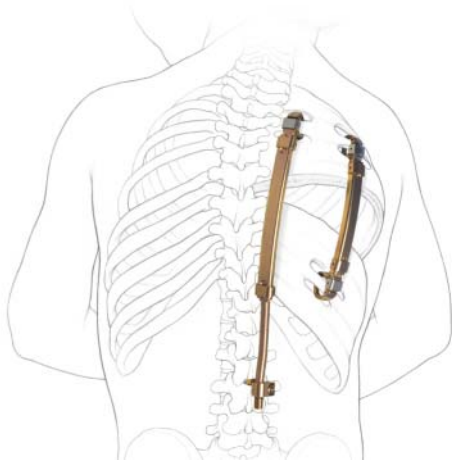
Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II)

Humanitarian Use Device: The Vertical Expandable Prosthetic Titanium Rib (VEPTR/VEPTR II) is authorized by Federal law for use in the treatment of Thoracic Insufficiency Syndrome (TIS), the inability of the thorax to support normal respiration or lung growth in skeletally immature patients. The effectiveness of this device for this use has not been demonstrated.

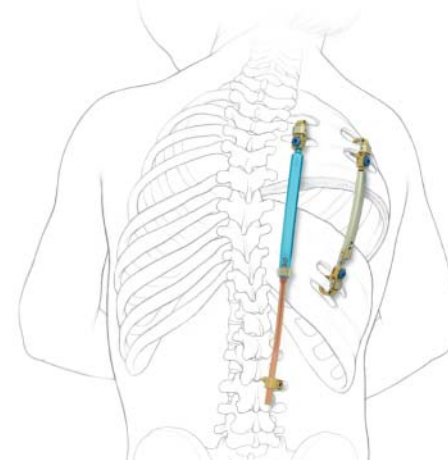
Note: Federal Law restricts this device to sale by or on the order of a physician.

Read this entire booklet carefully before your child receives the VEPTR/VEPTR II device. Keep this booklet, as you may need to read it again.

If you have more questions, or do not understand the information provided in this booklet, please ask your child's doctor before your child has the first operation.



VEPTR — Rib-to-Rib and Rib-to-Spine Attachment



VEPTR II — Rib-to-Rib and Rib-to-Spine Attachment

What is the VEPTR/VEPTR II device?

The VEPTR/VEPTR II device is a metal rod curved to fit the back of the chest and spine, which is placed in an up and down position. It can be made longer as your child grows. This helps the spine become straighter and allows the lungs to grow and to fill with enough air to breathe. The attachments can be attached to the ribs, spine or pelvis. The device is used to keep the ribs separated after the operation.

The device is made of titanium because of its strength and ability to stay inside your child without causing a bad reaction. Titanium is a metal used to make many implants. Titanium does not keep your child from having Magnetic Resonance Imaging (MRI).

This design is a result of ten years of research.

What is the purpose of the VEPTR/VEPTR II device?

The VEPTR/VEPTR II device is indicated for treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients. TIS has been defined as the lack of ability of the chest to support normal breathing or lung growth, and is considered to be a rare condition. Thoracic Insufficiency Syndrome or TIS describes some of the abnormalities of the thorax, such as:

– flail chest syndrome, which means there are big spaces between the ribs causing poor protection for the lungs and heart

– rib fusion with scoliosis, which means the ribs are stuck together with a crooked spine

– hypoplastic thorax, which means a very small rib cage with little room for the lungs to grow and expand

Your child suffers from Thoracic Insufficiency Syndrome (TIS) because the thorax, which is the area made up of the spine, the ribs and the breastbone fails to support normal breathing and lung growth. If your child's chest cannot grow, his/her lungs cannot grow and life-threatening breathing problems can develop.

Any of the above conditions could cause your child to have trouble breathing. Your child may eventually need a machine that will help his/her breathing (ventilator).

The VEPTR/VEPTR II device has been made to give the rib cage room to grow, in children like yours who suffer from chest wall and/or spine defects. While your child's natural ribs run across his/her chest, the VEPTR/VEPTR II device is placed up and down to give the chest more space. The device is used to rebuild your child's chest by making it larger, longer or more normal in shape and size.

Figure 1 shows what a normal chest wall should look like and Figures 2, 3 and 4 show what a chest wall of a child with Thoracic Insufficiency Syndrome may look like.

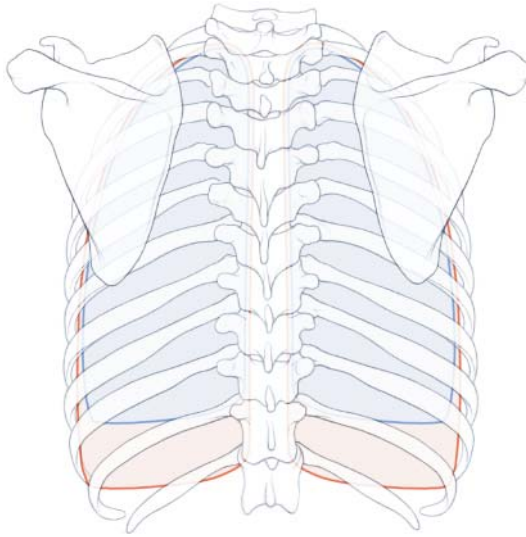


Figure 1: Normal lung space

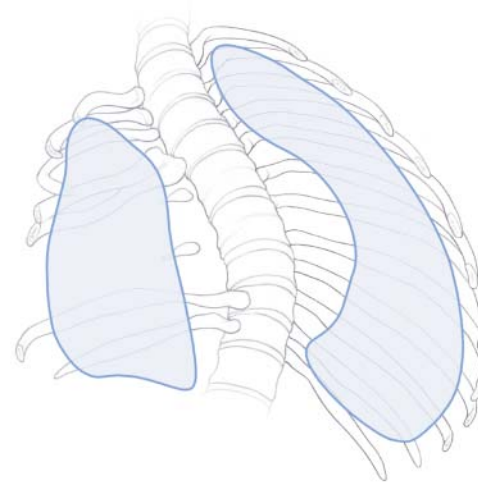


Figure 2: Abnormal lung space

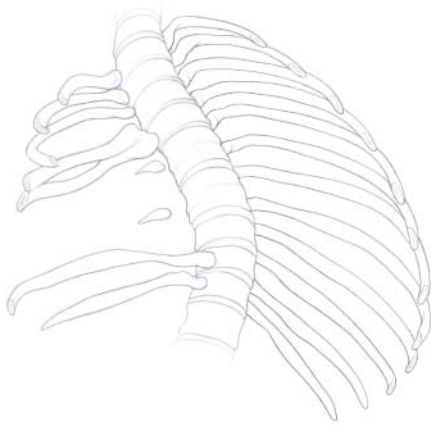


Figure 3: Missing ribs

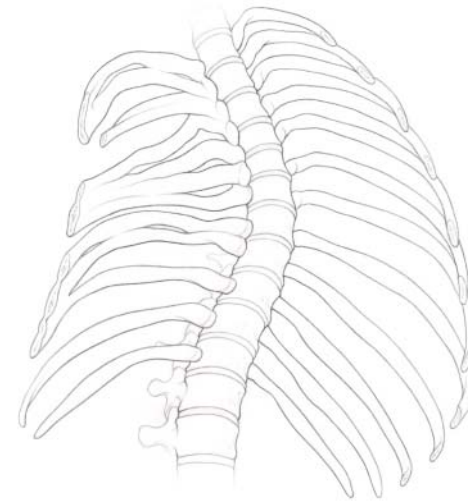


Figure 4: Fused ribs

The VEPTR/VEPTR II implant or device is made of titanium, which is a metal commonly used for implantation. All of the parts are made of titanium or titanium mixed with other metals (titanium alloy). Both of these materials have a long history of safe use when put into the human body.

What is the difference between VEPTR and VEPTR II?
VEPTR and VEPTR II are both indicated for TIS. VEPTR II is used to treat your child just like VEPTR. The difference between the two systems is the addition of a few more implants in VEPTR II. If needed, these additional implants would provide the doctor more surgical options to address your child's chest wall and/or spine defects.

The VEPTR/VEPTR II device is made up of a combination of the following titanium parts:

VEPTR	**VEPTR II**
– Superior Cradle	– Rib Hooks
– Cradle End Half	– Rib Hook Caps
– Extended Cradle End Half	– Rib Hook Extensions
– Rib Sleeve	– Proximal Extension
– Lumbar Extension	– Distal Extension
– Inferior Cradle	– Long Rib Hook
	– Rib Hook Cap for Long Rib Hook
– Distraction Lock	– Distraction Lock
– Cradle Lock	– VEPTR Adapter (for conversion of VEPTR to VEPTR II)
– S-Hook	– S-Hook
– 2 mm Titanium Rod	– S-Rod
– Lamina Hook	– Lamina Hook
– Connector	– Extension and Parallel Connector
	– Transverse Rib Hook
	– Transverse Bars

THE VEPTR/VEPTR II device can be put together in three combinations:

VEPTR	**VEPTR II**
– Cradle-to-Cradle	– Rib Hook-to-Rib Hook
– Cradle-to-Lumbar Lamina Hook	– Rib Hook-to-Lumbar Lamina Hook
– Cradle-to-S-Hook	– Rib Hook-to-S-Hook

Please see Appendix 1 in the back of this booklet for a more detailed description of these device combinations.

When should the device not be used?

The VEPTR/VEPTR II device should not be used when:

1. There is not enough bone strength of the ribs or the spine where the VEPTR/VEPTR II device would be attached.
2. There are missing ribs nearest and furthest away from where the VEPTR/VEPTR II device needs to be placed and attached.
3. The diaphragm (part of the body located at the bottom of the chest wall) cannot work properly.
4. There is not enough soft tissue for coverage of the VEPTR/VEPTR II device.
5. Your child is skeletally mature (about age 14 for girls and age 16 for boys) with problems other than chest wall instability.
6. Your child is younger than 6 months of age.
7. Your child has a known allergy to any of the device materials.
8. Your child has an infection at the operative site.

What are my child's risks?

Surgery to implant the VEPTR/VEPTR II device into the chest is considered a major operation.

– The risks that are linked with any surgery of the chest include problems from anesthesia, bleeding, infection, heart or lung problems, pneumonia (infection of the lungs), surgical wound problems (like infection or not healing) and sudden death.

– The risks that are linked with the use of the VEPTR/VEPTR II device include but are not limited to the following (Also see Appendix 2):

1. The VEPTR/VEPTR II device could bend or break from an accident, during lengthening, or from becoming worn out because of daily activities. This will be checked by taking x-rays and may result in the device being taken out and replacing it with a new one.
2. Breakage or movement of the device could cause the device to damage areas like the lung, heart, or large blood vessels in or around the chest area that may cause your child to need a surgical repair.
3. As your child grows and expansion surgeries are done, the VEPTR/VEPTR II device(s) could move or loosen from its original placement on the ribs (go through the newly formed bone). This might cause an unscheduled hospitalization and surgery to reposition, take out, and/or put in a new implant.

What are my child's risks?

4. The VEPTR/VEPTR II implant can often be felt or even seen, under the skin. Your child's skin and muscle around and over the VEPTR/VEPTR II device has been stretched. This could cause the skin to break open or become infected. Your child might need treatment or removal of the implant. A protective device or covering should be worn over the VEPTR/VEPTR II implant to avoid injury to the skin.
5. Your child's arm has nerves and blood vessels that lie close to the area where the device will be placed. They could become damaged by the surgery to implant the device, because all of the muscles on the side of the chest are lifted up and moved to allow for the operation on the ribs, or by your child's daily activities. This may call for more surgery.
6. There is the possibility that your child's body will reject the metal which could result in the removal of the implant.
7. There is a possible risk to the spinal cord as the result of straightening the spine by pushing the ribs apart, which could result in temporary or permanent loss of movement in a body part (paralysis).
8. After all surgeries, your child may need to be put on a ventilator to help with his/her breathing. The ventilator may be used for a long time after surgery because of lung complications, and a tracheotomy, which is a temporary opening in your child's windpipe (trachea), may be made to help avoid any long-lasting throat irritation.
9. Your child will most likely have some pain following the surgeries.
10. Your child could experience allergic or unexpected drug reactions, like irritability, vomiting or prolonged drowsiness.

Note: Each child with Thoracic Insufficiency Syndrome comes with a unique combination of medical problems that determine the amount of treatment required. These problems include age, gender (female or male), how long the follow-up needs to be, diagnosis, general health and individual growth pattern.

11. 

VEPTR/VEPTR II implants are labeled MR Conditional, where it has been demonstrated to pose no known hazards in a specified MR environment with specified conditions for use. These implants can be scanned only under certain conditions. For more information about specific scan conditions, please refer to the Synthes website at http://www.synthes.com/sites/NA/Products/Spine/Screw_Hook_Rod_and_Clamp_System/Pages/VEPTR_and_VEPTR_II.aspx, the product packaging insert, or Appendix 3 at the back of this brochure.

Patients and their parents/guardians must provide these scan conditions to an MRI site before their child can safely be scanned with this implant.

What are my child's benefits?

Some of the possible benefits to patients receiving the VEPTR/VEPTR II device are the following:

– More normal growth patterns without spinal growth limitations
– Decreased deformity of the spine
– More room for the lungs to grow
– Increased amount of daily activities because of the increased amount of space for air in the lungs
– Decreased need for using ventilators

For additional benefits regarding quality of life for your child, please consult with your doctor.

What are some warnings and precautions for this device?

Patients implanted with the VEPTR/VEPTR II device should not be braced. It is assumed that a brace would squeeze the chest and stop its natural movement. With the VEPTR/VEPTR II implant, natural breathing movements are encouraged. Additional bandages over the wound will protect it from inadvertent rubbing or bumping. If your child has spina bifida, place an occlusive dressing over the wound site to keep the site dry.

The VEPTR/VEPTR II device should not be used when your child has any of the following:

1. He/She does not have enough bone strength of the ribs or the spine where the VEPTR/VEPTR II device would be attached.
2. He/She does not have ribs nearest and furthest away from where the VEPTR/VEPTR II device needs to be placed and attached.
3. The diaphragm cannot work properly.
4. There is not enough soft tissue to cover the VEPTR/VEPTR II device.
5. He/She is skeletally mature (about age 14 for girls and age 16 for boys) with problems other than chest wall instability.
6. He/She is younger than 6 months of age.
7. He/She has a known allergy to any of the device materials.
8. He/She has an infection at the operative site.

What should I do before VEPTR/VEPTR II surgery to help with the success of the procedure?

– Keep your child away from crowds and anyone who is sick.

– Before surgery, it is important to give your child the proper amounts of foods to encourage good skin healing. Surgery is like a marathon; your child needs to eat very well in the weeks before the surgery.

– Let your doctor or nurse know if your child won't eat or if your child is having trouble eating.

– If your child is not eating, your doctor may prescribe medicine to increase your child's appetite.

– Make sure that your child takes all prescribed medicine and breathing treatments.

– Flu shots are suggested for all children with lung problems.

– Pneumonia shots are suggested if your child is on a ventilator.

– Call your doctor if your child is sick. If you live far away, DO NOT come to the hospital for the surgery unless your doctor tells you to.

– In cases of severe malnutrition or poor eating habits, a tube will be placed into your child's mouth, nose or stomach that will go down the throat and to the stomach (feeding tube). This will help the food reach the stomach and help your child get stronger. Until then, surgery may be delayed.

What happens during the VEPTR/VEPTR II procedure?

During the first surgery the doctor makes a cut (incision) on your child's body and puts in the device that will make the rib cage longer and larger as your child grows. Your child's reconstructed chest can provide more room for your child's lungs to grow and expand. This surgery will take place with your child being completely asleep during the operation (general anesthesia). There may also be other smaller surgical openings to help place the parts of the VEPTR/VEPTR II device and lock them in place.

Your child will stay in the hospital for 10 to 14 days after the initial implant surgery, unless there are complications. The expansion surgery normally only requires an overnight hospital stay. There is a full description of the surgery for an expansion and replacement later in this booklet (See page 13).

After surgery, your child will stay in the Pediatric Intensive Care Unit until the doctor feels that your child is ready to be transferred to a regular hospital room. Your child may be put on a ventilator for a few days to help him/her breathe.

If your child has problems on both sides of the chest and/or spine, another surgery to implant more VEPTR/VEPTR II parts may be needed. If additional implantation surgery is necessary, it will be scheduled about three months after the first operation.

Figures 5a and 5b show the VEPTR and VEPTR II devices, respectively, after they are implanted with rib-to-rib and rib-to-spine attachments.

If your child has fused ribs, his or her x-rays would look something like Figure 6 before implanting the device and Figure 7 after surgery.

During your child's surgery the following will happen:

– Your child will be placed on his/her side.

– Your child's skin will be washed with a liquid that kills germs.

– Then your child will be covered with towels, so that only the place where the incision(s) will be made (surgical site) is left uncovered.

– Then, an incision is made as described in the first paragraph of this section.

After your child's ribs are exposed, the ribs that are fused together will be gently separated into multiple sections, to look like ribs that have not been fused together, with an instrument called a bone spreader.

Examples of what is done are shown on the next page in Figures 6 and 7.

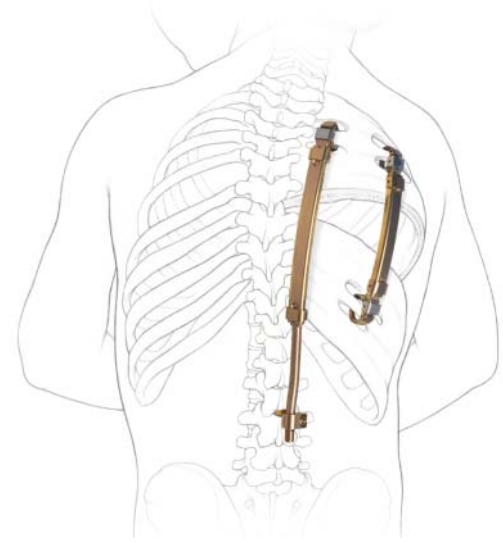


Figure 5a:
VEPTR — Rib-to-Rib and Rib-to-Spine Attachment

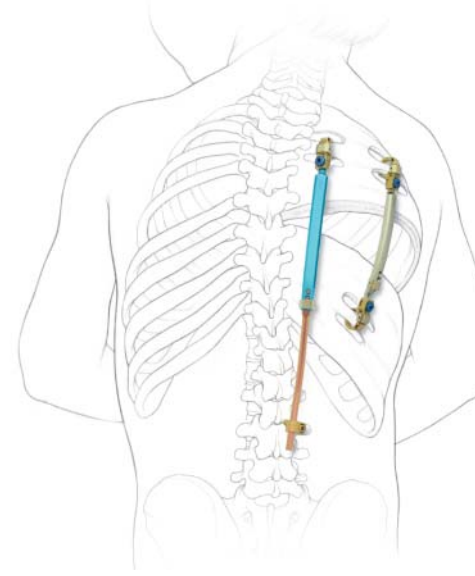


Figure 5b:
VEPTR II — Rib-to-Rib and Rib-to-Spine Attachment

What happens during the VEPTR/VEPTR II procedure?

If separating the fused ribs by the instrument is difficult, there is a possibility that an additional rib(s) will need to be separated.

A VEPTR/VEPTR II device is attached up and down on the back of the chest and spine. At some point, your doctor may suggest that a second titanium rib be placed closer to under the arm on the same side.

After the devices are completely assembled, they are made to fit snugly without much pressure.

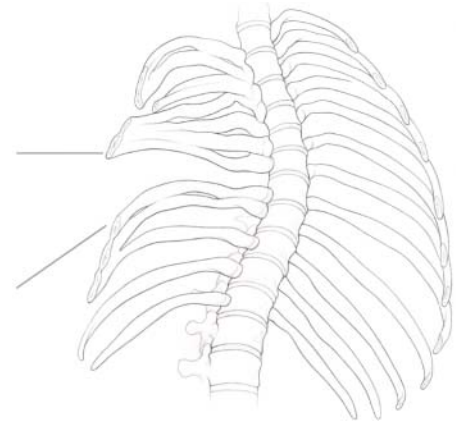


Figure 6: Separating fused ribs

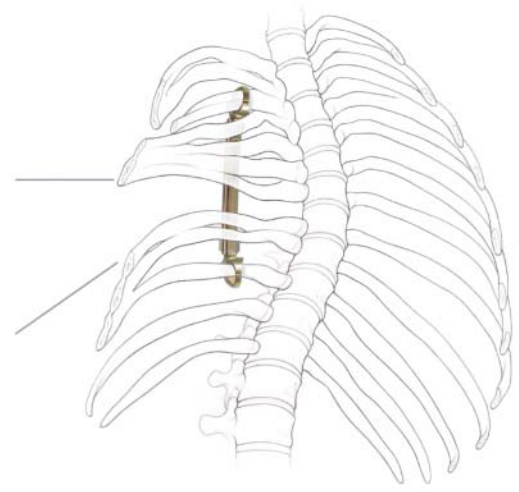


Figure 7: After separation of fused ribs
(Rib-to-Rib Attachment)

Case Example

If your child has a bent spine (scoliosis), he/she may have two VEPTR/VEPTR II devices placed. One will attach from the top of the rib cage to the bottom of the rib cage. The other will be shaped to fit from the top of the rib cage to the lumbar spine.

Once your child stops growing or has reached skeletal maturity (about age 14 for girls and age 16 for boys) the VEPTR/VEPTR II device may no longer be of any benefit, and you and the doctor treating your child will decide if the device should be removed. For a child with a spinal deformity, a spinal fusion may be suggested in the future.

You and your child's physician will continue to work together during your child's treatment.

Your child will need to go back to the hospital for surgery to:

– make the device longer, or

– replace the VEPTR/VEPTR II device at specific times to make room for the growth of your child, and/or

– to further correct spinal or chest wall deformity.

These surgeries will be done while your child is under general anesthesia and may need to be done as often as every four (4) to six (6) months.

A small incision is needed to make the VEPTR/ VEPTR II device longer, to expose the small portion of the device where the expansion takes place. When your child outgrows the device, the central section or middle part of the device will need to be replaced.

Figure 8: Expansion of the VEPTR/VEPTR II device

The following describes the expansion (sometimes called distraction or lengthening) operation:

A small incision is made and an instrument called an expansion pliers is put in place (as seen in Figure 8). Gentle pressure is used to begin the distraction of the device. When there is a large amount of pressure, the pliers are locked and three minutes are allowed to go by to allow the tissue to relax. This process continues until the doctor feels that no further distraction of the device can be done.

Postoperative (after surgery) Wound Care for VEPTR/VEPTR II Surgery

What kind of incision will my child have?

Your child may have two kinds of incisions, as seen in Figure 9.

1. The main incision is long and shaped like the capital letter J.
2. The other incisions are smaller and are used for making the device longer.

Your child will need multiple repeat operations to allow for his/her growth. Over time, the attachments to your child's ribs or spine may loosen and may need to be replaced or repositioned. This can be done as a part of an expansion operation. For the expansion surgeries, a small incision is required at the lower end of each VEPTR/VEPTR II implant. When replacement of your child's VEPTR/VEPTR II implant is required, a larger incision will be needed. The expansion operation is brief, but your child will experience mild to moderate pain following these surgeries. At a minimum, overnight hospitalization will be required.

Complications such as infection, device breakage and rib fractures are possible risks associated with these procedures.

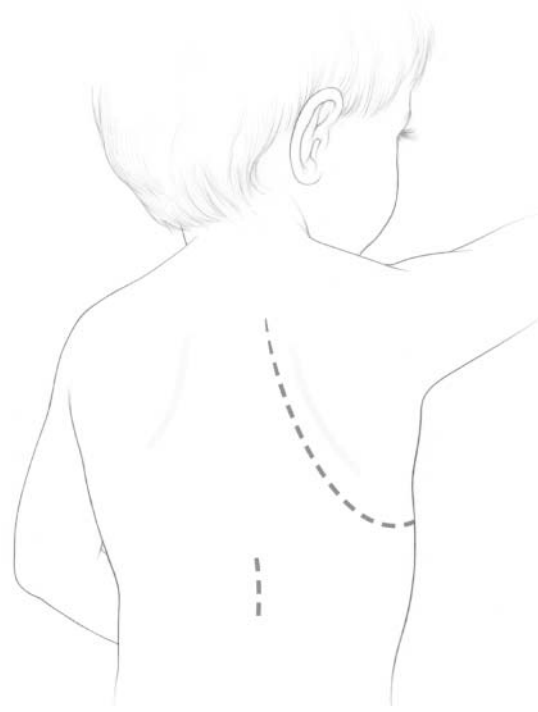


Figure 9: Child with a J-shaped and a smaller incision

What should I know to help my child have a successful surgery?

– It's very important that all caregivers, including yourself, wash their hands before working on the wound or bandages, to avoid infection.

– Your child's skin and muscles over the VEPTR/ VEPTR II device had to stretch a lot to cover the expanded chest. Your child may have been born missing muscles in the area operated on or have had previous surgery in this area. New postoperative wounds may be under strain and may be more easily injured.

– New postoperative sites are more at risk of injury and infection.

– Your child's wound or incision will be covered with a large, thick bandage and then a wrap.

– Some children will have a donut-shaped sponge on the outside of the bandage for protection so that the child doesn't rub or bump the wound area.

– If your child has a diagnosis of spina bifida, your child will then have a sticky plastic wrap-like dressing over the wound site to keep the site dry.

– Your child will stay in the hospital for 10 to 14 days after the initial implant surgery, unless there are complications. Your child's medical condition before surgery will also affect how long your child will be hospitalized.

– The stitches may be left in for about four weeks; you should discuss this with your child's doctor.

– An antibiotic may be given to prevent infection after surgery.

How should I change my child's postoperative bandage?

– All caregivers MUST wash their hands before working on the bandages or the wound area, to avoid infection.

– When your child is allowed to leave the hospital you will be given written discharge instructions from your doctor or nurse about how often to change the wound bandages.

– Your discharge instructions specify what bandages to use.

– Types of bandages:

1. The large, thick bandage (ABD) and a thin gauze-like wrap (Kerlex) will help protect and cover the wound.
2. If your child has a diagnosis of spina bifida, he/she will have a sticky plastic wrap covering the wound directly, to help keep the wound site dry.
3. In some cases, the bandages will have a donut-shaped sponge over the dressing, to protect the wound from bumps and irritations.

What signs or symptoms of wound infection should I look for?

If you observe any of the following signs or symptoms, call your doctor immediately:

– Fever that does not go away

– Fever of 101°F or greater

– Redness and swelling at the wound site

– Pain at the incision site that is getting worse and not better as the days go by

– Tenderness at the wound site that is increasing or does not go away

– Opening of the wound site (the skin coming apart)

– Liquid draining from wound site

How do I protect the postoperative wounds from injury and infection?

– Make sure that all caregivers, including yourself, wash their hands before working on the wound or bandages, to avoid infection.

– Don't let your child pick at the wound, because hands carry many forms of bacteria. Picking at the wound site will increase the risk of an infection.

– Keep the wound covered with protective bandages for the following reasons:

1. New wounds are more likely to get infected.
2. Protect the wound site from irritation and bumps; the VEPTR/VEPTR II device is usually very close to the outer layer of skin.
3. The skin and muscles over the device have been stretched, and are very thin.
4. If rubbed, the thin skin covering the wound can easily break open (for example, when your hands crack in the winter).

– Don't let your child do things that rub directly against the wound because any rubbing may break the thin skin covering the wound.
For example:
  – sitting in a hard chair
  – lying on a hard floor

– If your child returns to school and you see that the chair and/or desk bumps or rubs the wound, ask for padding for the chair or desk or some kind of a protector. If needed, you can ask your doctor for a prescription.

– Either avoid taking your child on long car rides in car seats, or provide extra padding to protect your child's wound. The car seat will rub the wound area and may break the already stretched and thinned-out skin covering the wound.

Common VEPTR/VEPTR II Device Issues with Growth

How often will my child need expansion operations?

Your child will need to go back to the hospital for surgery to:

– make the VEPTR/VEPTR II device longer, or

– replace the VEPTR/VEPTR II device at specific times, to make room for the growth of your child, and/or

– further correct spinal or chest wall deformity.

These operations may need to be performed as often as every four (4) to six (6) months. Your child will be asleep (general anesthesia) during the operation(s). When the rod cannot be made longer, the middle piece will be taken out and a longer rod will be placed. This operation will usually need just an overnight stay in the hospital.

What happens during my child's growth?

The following are signs and symptoms that your child has outgrown the device.

– Complaints of mild discomfort in the device area

– Worsening of your child's curvature or bent spine

– Your child may actually feel that the device has loosened or drifted

– A bump under the skin in the operative site area

– You can see the device coming through the skin or close to the skin surface

– Your child complains about hearing a pop in the back area (this is usually only with very demanding activity)

Are my child's activities limited?

– After the first month, there are no limitations in your child's daily activities.

– If your child has a device with a lumbar hook or an s-hook, we strongly encourage avoiding violent, demanding sports (such as wrestling, weight-lifting, football, etc.). There have been times when the device has broken or moved from the place where it was attached during surgery as a result of children playing in these rough sports.

What happens at the end of growth?

Once your child stops growing, or has reached skeletal maturity (about age 14 for girls and age 16 for boys), the VEPTR/VEPTR II device may no longer be of any benefit to your child. You and the doctor treating your child will decide if the device should be removed. We strongly suggest that you discuss with the doctor all options and expectations associated with this device at the end of your child's growth.

How long can I expect the device to work?

Once your child stops growing, or has reached skeletal maturity (about age 14 for girls and age 16 for boys) the VEPTR/VEPTR II device may no longer be of any benefit to your child. You and the doctor treating your child will decide if the device should be removed. For children with a spinal deformity, a spinal fusion may be needed.

When and how should I contact my child's doctor?

The doctor and nurse's number is listed below:

_____

_____

You should call your child's doctor if:

– Your child has a fever of 101°F or greater

– You notice redness or swelling at or around the wound site

– Your child has trouble eating

– Your child complains of pain that does not go away

– The pain medication does not appear to be working

– Your child is having difficulty breathing

What alternatives to this procedure are available?

Thoracic Insufficiency Syndrome (TIS) is a life-threatening condition found in children. A mechanical device to help with breathing (ventilator) can be used as a nonsurgical treatment in some patients; however, this is just treating the symptom and not treating the cause of the condition.

Currently available surgical treatments for chest wall defects include:

– A plastic sheet of fixed size that will protect your child's chest wall area

– Artificial (prosthetic) ribs made of plastic that are a fixed size, meaning they cannot be made longer as your child grows

– If your child is old enough, sections of ribs donated from someone who has died (donated tissue/allograft) or autograft (sections split from your child's own ribs on the normal side)

Currently available surgical treatments for fused ribs include:

– Splitting the fused ribs apart, then putting a spacer to stop the ribs from sticking together again or growing back together

– Past treatment for patients with underdeveloped chests has involved splitting the breastbone and inserting a spacer to hold it apart

Currently available surgical treatments for scoliosis include:

– Spinal fusion, but this method does not take care of the malformations of the chest, and fusion will prevent growth

Additional Information

Appendix 1
VEPTR/VEPTR II Combinations
VEPTR combinations are available in 70 mm and 220 mm radii.
VEPTR II combinations are available in 220 mm and 500 mm radii.

Cradle-to-Cradle Assembly, Rib Hook-to-Rib Hook Assembly
These assemblies are normally used when your child has Thoracic Insufficiency Syndrome because of fused/missing ribs, severe scoliosis, and/or hypoplastic thorax. The assemblies attach to the superior rib and to the inferior rib.

Cradle-to-Cradle Assembly, 70 mm radius (VEPTR)

Cradle-to-Cradle Assembly, 220 mm radius (VEPTR)

Rib Hook-to-Rib Hook Assembly, 220 mm radius (VEPTR II)

Cradle-to-Lumbar Lamina Hook Assembly, Rib Hook-to-Lumbar Lamina Hook Assembly
These assemblies are indicated for use where no lower ribs exist or when the scoliotic bend goes into the lower part of the back (lumbar region of the spine). The assemblies attach to the rib and to the lumbar spine.

Cradle-to-Lumbar Lamina Hook Assembly (VEPTR)

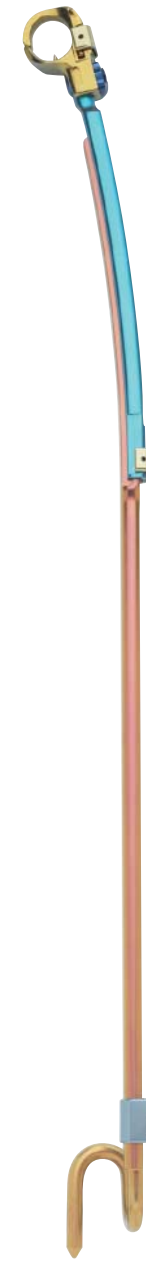
Rib Hook-to-Lumbar Lamina Hook Assembly 500 mm radius (VEPTR II)

Cradle-to-S-Hook Assembly,
Rib Hook-to-S-Hook Assembly

These assemblies are used when attachment of the end section of the device to the hip is necessary because there are no bottom ribs or strong enough lumbar bones to which to attach it. Also, it may be used to help even out your child's hips if one side is higher than the other, or to help him/her sit up while in a wheelchair. The assemblies attach to the rib and to the ilium.

Using instruments that help put the implant in place, the end section can be unlocked and made longer, in a movement similar to flat curtain rods sliding inside each other, and then locked back into place. By making the implant longer, the space in your child's rib cage is increased, and there will be more space within your child's chest to allow the lungs to grow.

Cradle-to-S-Hook Assembly (VEPTR)



Rib Hook-to-S-Hook Assembly, 500 mm radius (VEPTR II)

Appendix 2
Risks associated with the use of the VEPTR/VEPTR II device

What are the results of clinical studies with the VEPTR device?

The goals of VEPTR surgery in the clinical trials are the following:

1. To even out the height of each half side of the chest and maintain this change with each expansion (lengthening) of the devices.
2. A decrease in Cobb angle (a measurement used to help figure out the degree of a scoliotic curve) represents an improvement. If possible, a lessening in the Cobb angle is the goal of both scoliosis surgery and expansion using the VEPTR device.

The VEPTR device was evaluated in a single-site feasibility study with 33 patients and a multi-center, prospective study done at 7 sites with 224 patients. A total of 257 patients were studied, but 10 patients were excluded from the analysis due to the absence of baseline data. Enrolled patients at each site received the VEPTR device assembly according to their specific disease and body dimension requirements. Patients experienced no life-threatening or fatal adverse effects that were considered to be device related.

There were 4 intraoperative complications reported for the feasibility and multi-center studies (1.9% of all patients), including a technical error in device placement; a dural laceration, and pressure on the brachial nerve. Sixteen feasibility patients, or 48%, experienced 37 device-specific adverse events, and 34 multi-center patients, or 16%, experienced 52 device-specific adverse events. These device-specific adverse events included device fractures, device migrations, and other device-related adverse events. Device migrations occurred frequently—25 migrations in the feasibility study and 49 migrations in the multi-center study. They were more common with the cradle-to-lumbar lamina hook and cradle-to-S-hook assemblies (these two configurations undergo greater flexion, extension, rotation and lateral bending forces than the cradle-to-cradle assemblies, which are primarily subjected only to the forces of respiration because they function rib-to-rib). Device migration describes the shift of the superior rib cradle proximally into the rib of attachment, or the distal hook migration through the lamina causing dislodgement, or "disattachment." Some of these reported device migrations "through" bone were actually bone growing around the superior cradle giving the appearance of device migration. Some cradles actually eroded through the bone and emerged superior to the rib into the surrounding muscle.

There were 13 device fractures in 7 of 33 patients in the feasibility study, and 6 device fractures in 5 of 214 patients in the multi-center study. When the total number of actual surgical procedures (initial surgeries, expansions and replacements) are considered, the rate of device fractures were 3.3% in the feasibility study (13 events in 398 procedures) and 0.5% in the multi-center study (6 events in 1,140 procedures). There were 50 procedure-related infections in the 1,538 surgical procedures for the feasibility and multi-center studies (3.3%).

During the course of this 14-year study, there were 12 deaths among the 257 patients enrolled in the study, 4 in the feasibility study and 8 in the multi-center study. None of the deaths were determined by the investigators to be related to the study device.

Appendix 3

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

Glossary

ABD
A type of large, thick bandage sold under this particular brand name that will help protect the wound.

Autograft
Tissue or organ that is taken from one part of a body and placed in another part of the same body.

Centimeter (cm)
A unit of length. (2.54 cm is equal to one [1] inch.)

Chest wall
Structure that contains the hollow space surrounding the lungs.

Diaphragm
Part of the body located at the bottom of the chest wall.

Distraction and Expansion
These two words are used for describing how the device is made longer.

Donated Tissue/Allograft
Bone, muscle, or skin from someone who has died and donated their body because they wanted to help save other people's lives.

Feeding Tube
A tube that is placed into a patient's throat and goes down to the stomach to help food reach the stomach.

Feasibility Study
A clinical study to find out if a new medical device does or does not work. It usually happens before a bigger clinical study is started.

Fusion
To be joined or stuck together.

Flail Chest Syndrome
A condition of big spaces between the ribs causing poor protection for the lungs and heart.

General Anesthesia
Being put completely to sleep for an operation.

Hypoplastic Thorax
A condition that leaves children with a very small rib cage with little room for the lungs to grow and expand.

Incision
Cutting into body tissue.

Kerlex
A type of thick white gauze-like wrap sold under this particular brand name that will help cover the wound.

Magnetic Resonance Imaging (MRI)
A test that uses a large magnet to take pictures of the inside of the body.

Malnutrition
A condition that is caused by poor eating habits or the body's inability to take food in and use it. Good nutrition encourages good skin healing.

Millimeter (mm)
A unit of length. (25.4 mm is equal to one [1] inch.)

OpSite Post-Op
A sticky, plastic wrap-like covering sold under this particular brand name that lies directly over the wound to help keep the wound site dry.

Paralysis
A complete or partial loss of movement in body parts.

Pneumonia
Infection of the lungs.

Postoperative
After surgery.

Progressive Scoliosis
A medical condition of a crooked or bent spine that is getting more crooked (bent) as time goes by.

Rib fusion
A medical condition of the ribs being stuck together.

Scoliosis
A medical condition of the spine being very crooked (bent).

Spina Bifida
A defect of the spinal cord that a child is born with, that does not allow the arches on individual vertebrae to close together.

Thoracic Insufficiency Syndrome (TIS)
TIS has been explained as the chest not being able to support normal breathing or lung growth, and is considered to be a rare condition.

Thorax
The area of the chest that is made up of the spine, ribs and breastbone.

Trachea
The main tube or windpipe by which air passes to and from the lungs. This is a very important tube for breathing.

Tracheotomy
Temporary opening in the windpipe, made by an incision in the throat.

Ventilator
A mechanical device that helps a patient to breathe.

VEPTR/VEPTR II (Vertical Expandable Prosthetic Titanium Rib)
Titanium device that is curved to fit the back of the chest and is placed in an up and down position. It can be made longer as your child grows. This helps the spine become straighter and allows the lungs to grow and to fill with enough air to breathe. The attachments can be attached to the ribs, spine, or pelvis. The device is used to keep the ribs separated after the operation.

Vertebra
One of the many bony parts that make up the spine.

X-ray
Image that is taken to see the bones inside the body.

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