The VentroFix System Overview

The VentroFix System is designed to treat instability in the thoracolumbar spine resulting from fractures, tumors and degenerative conditions. The system allows unrestricted compression across the bone graft site. *(See page 2 for indications.)*

The steps of anterior management using the VentroFix System are:

- Corpectomy with complete spinal cord decompression
- Restoration of anatomic alignment
- Reconstruction of the spine using a graft
- Stabilization using the appropriate construct

The VentroFix System allows direct axial compression across the graft site while maintaining rotational and translational stiffness of the bone graft implant construct. This system provides immediate stabilization of the spinal column following spinal cord decompression and bone grafting, facilitating rapid mobilization of patients.*

Use of the Synthes Spinal Instruments for Anterior Surgery facilitates this procedure. For more information, refer to the Synthes Spine brochure on *Spinal Instruments for Anterior Surgery.*

*Note: The surgeon may choose to use external support as well.*
Indications

The VentroFix System is intended for use in stabilizing the anterolateral thoracolumbar spine from T8 to L5 following:

- anterior decompression and subsequent bone grafting of burst fractures.
- vertebrectomy and vertebral body replacement in tumor patients.
- anterior fusion after failed posterior lumbar surgery and/or pseudoarthrosis.
- correction of lumbar scoliosis and lordotic deformities.
- anterior fusion resulting from severe disc degeneration. Degenerative Disc Disease is defined as back pain of a discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

This system is designed for lateral or anterolateral placement on the vertebral bodies.

Contraindications

The VentroFix System is contraindicated for use in cases where there is evidence of:

- severe osteoporosis, which may reduce the holding capacity of the screws.
- active infection of the involved vertebral bodies.
- metastatic tumors in adjacent vertebral bodies.
- conditions that may cause the patient to ignore the precautions and limitations in the use of the device, such as senility, mental illness, drug abuse and obesity.

The VentroFix System should not be used on the posterior spine.

Warnings:

*The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.*
Features

Implants

Three clamp designs facilitate fixation to the left or right anterolateral aspect of the thoracolumbar spine.

- Screws incorporate a machine thread section which locks the screw to the plate to minimize the chance of screw back-out. This design provides a secure construct, eliminating the need for bicortical screw purchase.
- Self-tapping screws with cancellous thread provide secure engagement to the vertebral body.

The 6.0 mm Titanium Hard Rods are available in five lengths and may be cut to achieve optimum construct length.

- Triangular orientation of screws resists construct pull-out.
- Screws are countersunk into the clamps providing a low-profile construct.
- Implants are made of commercially pure (CP) titanium and titanium alloy (Ti-6Al-7Nb).

Instruments

- Precisely crafted instruments permit accurate and easy placement of the implant construct.
- Instruments and implants allow unrestricted compression with minimal effort.
Patient Positioning

Base the surgical approach on the patient’s vascular anatomy and spinal pathology. Ensure the patient is positioned in a lateral decubitus position and is securely held throughout the procedure. Exercise caution to prevent undue pressure points and nerve palsies when positioning and securing the patient.

Surgical Technique

1. **Perform corpectomy and decompress canal**

Expose the spinal segments and excise the discs above and below the area of abnormal anatomy.

Perform a corpectomy and decompress the canal.

2. **Measure screw length**

Measure the coronal width across the vertebral bodies superior and inferior to the corpectomy site using the Depth Gauge for Small Screws [319.09]. The length of the unicortical self-tapping screws to be inserted should be approximately 5.0 mm less than the coronal width of the vertebral body.
3 Implant Graft

Using the Vertebral Body Spreader [389.210] or the Extended Vertebral Body Spreader [389.208], distract against the endplates of the vertebral bodies superior and inferior to the corpectomy site.

Prepare the exposed vertebral end plates for grafting.

Implant the bone graft into the corpectomy space while distracting against the endplates. Once the bone graft is in place, the vertebral body spreader may be removed.
Prepare vertebral bodies

Remove the prominent osteophytes on each vertebral body to be instrumented to permit flat placement of the VentroFix construct.

Measure VentroFix construct length

Determine the length of the construct using the 6.0 mm Coated Rod Template, 150 mm [388.87]. Select the appropriate length 6.0 mm Titanium Hard Rods [498.10x]. If necessary, cut the rods to the desired length using the Rod Cutter [388.72]*.

Note: Bending or contouring of rods is not recommended

Assemble VentroFix construct

Choose the appropriate clamp for each end of the construct: Titanium Lower Clamp [498.261], Titanium Upper Clamp [498.262] or Titanium Fracture Clamp [498.263].

*Note: In most cases the VentroFix construct is applied to the left, lateral side of the vertebral bodies, in which case the Upper Clamp is placed superiorly and the Lower Clamp is placed inferiorly. All descriptions and techniques presented in this brochure are based on this frame of reference.

In cases where an alternate construct is preferred, the Upper Clamp can be placed inferiorly and the Lower Clamp placed superiorly to the bone graft.

In cases where only part of the vertebral body is intact, the Fracture Clamp may be used in place of the Lower Clamp.

*Available in the Synthes Universal Spinal System Rod Instrument Set [107.721].
6 Assemble VentroFix construct (cont’d)

Insert a 6.0 mm Titanium Hard Rod of desired length into the closed hole of each clamp. Securely tighten the corresponding set screw to lock the rod in place using the Long Small Hexagonal Screwdriver [388.31].

Assemble the construct by inserting the free end of each rod into the open hole of the opposing clamp. Adjust the clamps so that the construct is the desired length. Tighten the set screw of one open hole to maintain construct length during placement. If the rods protrude more than 5.0 mm from the clamps, remove the rods and cut to the appropriate length using the Rod Cutter.

7 Prepare and implant the VentroFix construct

Insert a 5.0 mm Threaded Drill Guide [389.227] into the posterior screw-hole of each clamp.

Attach the Construct Holder [388.428] mounted on the Straight Threaded Drill Guide Applicator [389.209] securely to either rod of the construct, ensuring the base of the Construct Holder is fully seated on both rods.
Surgical Technique (cont’d)

7 Prepare and implant the VentroFix construct (cont’d)

Position the construct on the anterolateral aspect of the vertebral bodies and hold it firmly in the desired position using the Construct Holder and Straight Threaded Drill Guide Applicator.

8 Insert posterior screws

Drill a hole in one of the vertebral bodies through the posterior drill guide using the 5.0 mm Flexible Drill Bit with stop [389.215].

Remove the drill guide and insert the appropriate length 7.5 mm Titanium Anterior Spinal Locking Screw [489.0xx] using the Flexible Screwdriver with 3.5 mm Hex Captive Twist [389.226] or the Long Large Hexagonal Screwdriver with Holding Sleeve [389.217 and 389.218]. Be sure to hold the construct firmly in place using the Construct Holder to ensure the clamp remains fully seated during screw insertion.

Repeat this sequence for the posterior hole of the remaining clamp.

Note: Screws must be inserted perpendicularly to the clamp to ensure proper engagement of the self-locking threads.
9 **Insert anterior screws**

The Straight Threaded Drill Guide Applicator can now be removed from the Construct Holder, leaving the Construct Holder in place for use in compression. Insert a 5.0 mm Threaded Drill Guide into the anterior hole of each clamp using the Straight Threaded Drill Guide Applicator. Repeat the process outlined in Step 8 for placement of anterior screws.

10 **Compress the construct**

If compression is needed, loosen the set screws on the open hole of each clamp so that the rods can slide through the clamps. Do not remove the set screws from the clamps.

Be sure that compression is applied along the rod opposite the one to which the construct holder is secured. Compress the construct by applying the jaws of the Compression Forceps [388.423] against the Construct Holder and the countersink of the clamp.

Compress as required. Maintain compression with the Compression Forceps while tightening set screws in the open holes, locking the construct in place.

*In this illustration, the Construct Holder is applied to the anterior rod, thus compression must be applied against the clamp countersink adjacent to the posterior rod.*
Surgical Technique (cont’d)

11 Tighten screws and remove instrumentation
Tighten all set screws and 7.5 mm Locking Screws. Remove the Compression Forceps and Construct Holder.

Alternate constructs
In cases where only part of the vertebral body is intact, the Titanium Fracture Clamp may be used on the vertebral body adjacent to the bone graft site.

For longer constructs a Titanium VentroFix Parallel Connector [498.164] may be used to maintain rod alignment.

Notes: In cases where the Titanium VentroFix Parallel Connector is being used, it must be preloaded onto the rods before inserting the rods into the clamps. The Titanium VentroFix Parallel Connector is not intended for end-to-end rod connections.
VentroFix System Instruments

- Depth Gauge for Small Screws [319.09]
- Vertebral Body Spreader [389.210]
- Extended Vertebral Body Spreader [389.208]
- 6.0 mm Coated Rod Template, 150 mm [388.87]
- Long Small Hexagonal Screwdriver [388.31]
- Straight Threaded Drill Guide Applicator [389.209]
- 5.0 mm Flexible Drill Bit with Stop [389.215]
- Flexible Screwdriver with 3.5 mm Hex Captive Twist [389.226]
- Holding Sleeve [389.218] and Long Large Hexagonal Screwdriver [389.217]
- Compression Forceps [388.423]
VentroFix System [105.760]

Instruments

304.832 VentroFix System Graphic Case

319.09 Depth Gauge for Small Screws
388.31 Long Small Hexagonal Screwdriver
388.423 Compression Forceps
388.428 Construct Holder
388.902 Coated Rod Template for 6.0 mm Rod, 150 mm
389.208 Extended Vertebral Body Spreader
389.210 Vertebral Body Spreader
389.215 5.0 mm Flexible Drill Bit with stop, 2 ea.
389.217 Long Large Hexagonal Screwdriver
389.218 Holding Sleeve for Long Large Hexagonal Screwdriver
389.226 Flexible Screwdriver with 3.5 mm Hex Captive Twist
389.227 5.0 mm Threaded Drill Guide, 4 ea.

Additionally Available

105.81 Spinal Instruments for Anterior Surgery
388.72 Rod Cutter
Implants

498.260  Titanium Single Rod Clamp, 6 ea.
498.261  Titanium Lower Clamp, 2 ea.
498.262  Titanium Upper Clamp, 2 ea.
498.263  Titanium Fracture Clamp, 2 ea.
498.164  Titanium VentroFix Parallel Connector, 2 ea.
498.102  6.0 mm Titanium Hard Rod, 50 mm, 4 ea.
498.103  6.0 mm Titanium Hard Rod, 75 mm, 4 ea.
498.104  6.0 mm Titanium Hard Rod, 100 mm, 4 ea.
498.105  6.0 mm Titanium Hard Rod, 125 mm, 4 ea.
498.106  6.0 mm Titanium Hard Rod, 150 mm, 4 ea.
489.025  3.2 mm Titanium Temporary Fixation Screws, 25 mm, 6 ea.
489.030  7.5 mm Titanium Anterior Spinal Locking Screw, 30 mm, 6 ea.
489.035  7.5 mm Titanium Anterior Spinal Locking Screw, 35 mm, 8 ea.
489.040  7.5 mm Titanium Anterior Spinal Locking Screw, 40 mm, 8 ea.
489.045  7.5 mm Titanium Anterior Spinal Locking Screw, 45 mm, 8 ea.
489.050  7.5 mm Titanium Anterior Spinal Locking Screw, 50 mm, 6 ea.
489.055  7.5 mm Titanium Anterior Spinal Locking Screw, 55 mm, 6 ea.