mild®

Device Kit

Vertos MEDICAL

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide Instructions for Use of the *mild*® Device Kit. It is not a reference to surgical techniques.

mild is a registered trademark of Vertos Medical Inc.

Instructions for Use

CAUTION: Federal law restricts this device kit to sale by or on the order of a physician. (Rx only)

Device Description

The Vertos *mild* Devices are a sterile, single-use system of surgical tools consisting of one each of the following components **(Figures 1 through 7)**:

1. *mild* Portal*
2. *mild* Trocar and Handle*
3. *mild* Portal Stabilizer
4. *mild* Depth Guide
5. *mild* Bone Rongeur
6. *mild* Tissue Sculpter
7. *mild* Surgical Clamp

*When 1 and 2 are assembled, the result is referred to as the *mild* Tissue Access Device.

Figure 1 - *mild* Portal—serves as a cannula through which the *mild* Trocar, Bone Rongeur and Tissue Sculpter are inserted into the interlaminar space. The *mild* Portal has markers every 1.0 cm for aiding the user in advancement depth into tissue. The cannula is 6 gauge, 6.25 inches (15.9 cm) in working length.

Figure 2 - *mild* Trocar and Handle—when coupled with the *mild* Portal it is used to gain initial access into the interlaminar space. When inserted through the *mild* Portal, the working length of the assembly is 6.6 inches (16.8 cm).

Figure 3 - *mild* Portal Stabilizer—serves to control the angle of the *mild* Portal against the surface of the skin.

Figure 4 - *mild* Depth Guide—serves to adjust the depth of the Bone Rongeur and Tissue Sculpter within the interlaminar space in 5 mm increments.

Figure 5 - *mild* Bone Rongeur—is designed to be used through the *mild* Portal to remove laminar bone. The device consists of a handle and trigger, connected to an 8.5 inch (21.6 cm) long cutting tube and rod. During manual operation, as the trigger is squeezed toward the handle, the device tip is retracted into the cutting tube. With the 120° angled tip positioned against bone, this manual motion enables the bone to be captured within the tip aperture of 0.371 inches (9.4mm) nominal, and then be cut and retained for removal from the body through the *mild* Portal.

Figure 6 - *mild* Tissue Sculpter—is designed to be used through the *mild* Portal to remove tissue from the interlaminar space. The *mild* Tissue Sculpter tip is designed to retract tissue and contours to the shape of the anatomy to specifically fit within the ligamentum flavum for capture and removal of tissue under image guidance. Following tissue capture, the device is manually engaged via a pistol grip handle and a finger trigger. The cutting function is activated by squeezing the trigger. Following device removal from the patient, trigger release opens the cutting component and enables the integrated push rod to advance, allowing for excised tissue removal from the distal tip.

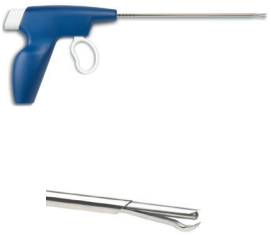


Figure 7 - *mild* Surgical Clamp—is an optional ancillary instrument provided for user convenience. This device is intended to allow the user to handle and maintain the *mild* Portal placement while positioning their hands away from the fluoroscopic imaging field.

Indication for Use

The Vertos *mild* Devices are specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

Warnings

- Use the *mild* Devices prior to the "Use By" date noted on the package.
- Inspect the *mild* Devices and packaging to verify that no damage has occurred as a result of shipping and handling. In the event of damage to the sterile packaging, retain the package with the contents and notify the manufacturer.
- It is the responsibility of the physician to determine if the patient is known to have, or suspected to have, an allergic reaction to contrast, and should assess and evaluate the severity level of the allergy and identify what precautions should be utilized prior to performing the *mild* Procedure.

- Patients who have had a laminotomy or laminectomy surgery, lumbar spine fusion, or have any lumbar spinal hardware should be carefully evaluated for access and appropriate visual bony landmarks prior to performing the *mild* Procedure.
- As with all medical procedures and surgeries, the physician should use the appropriate protocol for patients on blood thinners (anticoagulants) and other medications before attempting to perform the *mild* Procedure.
- Difficult anatomy and/or scar tissue can result in dural puncture/tear. Proper patient selection could affect outcomes.
- Ensure the device components DO NOT come into contact with the dura, cauda equina/nerve roots or major blood vessels. Doing so may result in patient injury.
- Perform epidurography using standard diagnostic techniques, equipment, and non-ionic contrast agents to identify the dural and epidural anatomy prior to commencing the procedure.
- *mild* Devices are supplied sterile (by gamma radiation) and are intended for Single Use Only. DO NOT re-sterilize and/or reuse *mild* Devices. Reuse can compromise the *mild* Devices' performance characteristics and may also result in infection.
- Reconditioning, refurbishing, repair, or modification of the devices to enable further use is prohibited.
- Inadvertent movement of the device components outside the field of vision or without adequate assurance of device placement via fluoroscopy may result in patient injury.

Precautions

- *mild* Devices should only be used by physicians who have received appropriate training through a formal Vertos-sponsored *mild* training event.
- It is important to read the Instructions for Use prior to device operation.
- The *mild* Procedure should be performed under, at a minimum, local anesthesia.
- Familiarity with fluoroscopic imaging techniques and expertise in the epidural space are key qualification requirements for performing the procedure.
- Only use the manually-powered devices provided in the *mild* Device Kit when performing the *mild* Procedure. Never use electric power (or any other alternative power sources) in conjunction with the *mild* Devices.
- Do not use excessive force on any of the *mild* Device instruments. Excessive force can result in product failure.

- *mild* Devices should only be manipulated while under fluoroscopic visualization with radiographic equipment which provides high quality images. *mild* Devices enable bilateral approaches to the interlaminar space and should not be used in a contralateral approach to cross the medial plane of the posterior spine.
- The *mild* Tissue Sculpter and Bone Rongeur blunt tip profiles are designed to reduce risk of non-target tissue puncture. It is necessary to use Anterior-Posterior (AP) and contralateral oblique fluoroscopic imaging to maintain tip position within the interlaminar space and toward the ventral laminar surface to further minimize inadvertent tissue contact.
- Tissue Sculpter rotation clockwise or counterclockwise should remain in the 5 to 7 o'clock range in either direction to ensure positioning of the rounded spoonbill tip as the leading edge during the scooping and cutting movement, thus maximizing the safety aspect of the design.
- Aggressive cephalad to caudad motion and/or multiple tissue resections may cause overfilling of the Tissue Sculpter, which can affect normal action of the trigger mechanism.
- Sensitivity to local, monitored anesthesia care (MAC), or general anesthesia should be evaluated prior to starting the *mild* Procedure.
- *mild* Devices enable bilateral approaches to the interlaminar space and should not be used in a contralateral approach to cross the medial plane of the posterior spine.

Potential Adverse Events and Complications

As with most surgical procedures, serious adverse events can occur. This procedure is not for everyone. Physicians should discuss potential risks with patients. Potential adverse events could be:

- Damage to the nerve roots resulting in numbness, motor weakness, or cauda equina syndrome
- Damage to the dural sac causing cerebrospinal fluid leak (CSF)
- Damage to epidural vessels causing hematoma
- Epidural hematoma
- Cerebral spinal fluid leak
- Dural tear
- Sub-acute bleed
- Fever of unknown origin/ new pain
- Chemical meningitis
- Contact and/or damage to pre-existing patient implant device

Preparation of the *mild* Devices

1. ***mild* Trocar and Handle with the *mild* Portal**

   Insert the *mild* Trocar through the central lumen of the *mild* Portal **(Figure 8A)**. Rotate the thumb screw on the Trocar handle until the Portal is securely tightened to the Trocar Handle **(Figure 8B)**. The assembled unit is referred to as the *mild* Tissue Access Device.

2. ***mild* Tissue Sculpter**

Figure 8A

Figure 8B

The Tissue Sculpter is packaged ready for use. Inspect prior to use. Verify trigger is extended away from handle **(Figure 9A)** and observe open Tissue Sculpter tip **(Figure 9B)**. Depress the Push Rod Activator to advance the push rod **(Figure 9A)**. Observe movement of the push rod within the distal tip of the device **(Figure 9C)**. Release the Push Rod Activator. Squeeze the trigger to close the cutting element. Observe advancement of the outer shaft toward the distal tip of the Device, closing the cutting element. Ensure trigger returns to extended position.

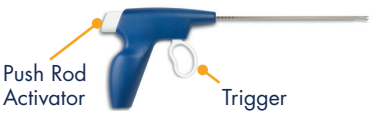


Figure 9A

Figure 9B

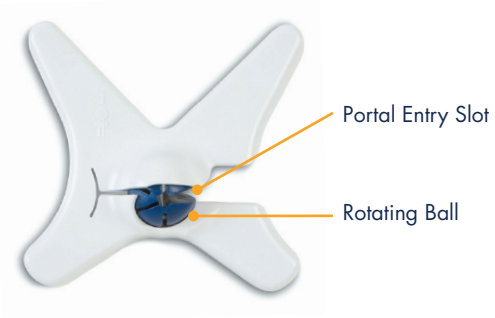
Figure 9C

3. ***mild* Depth Guide**

   Rotate the Depth Guide **(Figure 4)** to zero for initial procedure setting. Attach the Depth Guide to the Portal. Insert the Tissue Sculpter into the Depth Guide and Portal and observe the distance of tip extension from the Portal over the adjustable length of the Depth Guide. Instrument length exiting the tip can be adjusted utilizing the corresponding markings on the guide. After Portal placement into the patient, the Depth Guide may be adjusted, attached to, or removed from the Portal when desired. Disassemble Depth Guide from the Portal prior to procedure initiation.

4. ***mild* Portal Stabilizer**

Ensure the large opening in the rotating ball of the *mild* Portal Stabilizer is aligned with the Portal Entry Slot **(Figure 10)**.

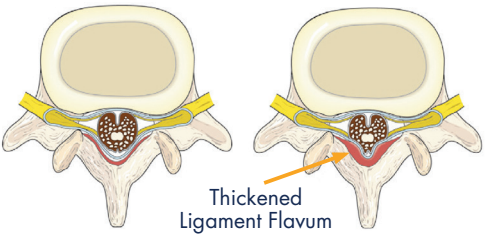


Use of the *mild* Devices

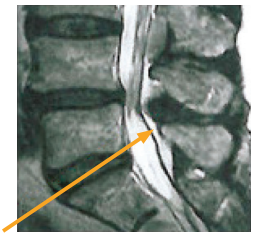
Overview of Lumbar Spinal Anatomy and Approach for *mild* Procedure

The *mild* Devices are designed to access the interlaminar space from the posterior lumbar spine, enabling the user to remove small portions of the lamina and preferentially resect and debulk the thickened ligamentum flavum, accomplishing a lumbar decompression. **Figure 11** represents the relevant spinal anatomy for which the *mild* Devices are intended.

Figure 11 – Graphical Representation and MRI of Thickened Ligamentous Tissue in Lumbar Spine



Axial view illustrations reveal a normal (left) and thickened ligamentum flavum (right) relative to the spinal canal.



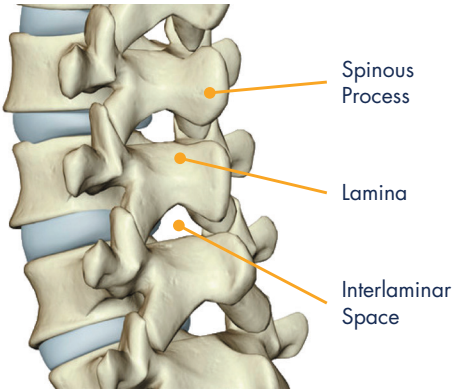
Lateral view MRI reveals a thickened ligamentum flavum relative to the spinal canal.

Figure 12 identifies a graphical representation of the lumbar spine from a lateral oblique perspective, revealing the interlaminar space for demonstration of the *mild* Device trajectory.

The lateral oblique graphics in **Figure 12** demonstrate the landmarks to guide the *mild* Procedure. These illustrate the position of the *mild* Devices relative to bony and soft tissue landmarks for selection of the ligamentum flavum.

Access begins at the inferior lumbar segment and is lateral to the spinous process margin. The Trocar and Portal are advanced through the back muscles and tissue to the inferior vertebral segment lamina, toward the border of the interlaminar space. The Portal accepts the cutting instrument (either the Bone Rongeur or Tissue Sculpter), which is advanced into the interlaminar space, toward the inferior border of the adjacent lamina for bone or tissue resection.

Figure 12 – Lateral Oblique Graphics of Lumbar Spine with Demonstration of *mild* Tissue Sculpter Relative to Interlaminar Space and Bone/Tissue Landmarks



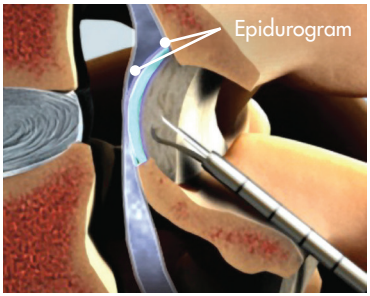


Illustration demonstrates the position of *mild* Devices relative to bony and soft tissue landmarks for selection of the ligamentum flavum.

Description of the Recommended Fluoroscopic Imaging for *mild* Device Placement

An image-guided posterior lumbar spinal access, lateral to the spinous process and with the cephalad approach is required for use of the *mild* Devices. By switching between an Anterior-Posterior (AP) view and a contralateral oblique view, or by using bi-plane fluoroscopy to view both the Anterior-Posterior (AP) and contralateral oblique images at the same time, the Tissue Sculpter can be advanced to ligamentum flavum in the target area.

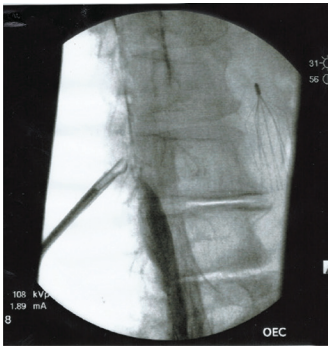
Initially, the Anterior-Posterior (AP) projection for identifying the target region and guiding *mild* Device placement for tissue resection is recommended for the *mild* Procedure. This projection positions the fluoroscopic imaging head substantially parallel to the surface of the lamina to enable an unobstructed imaging trajectory into the interlaminar space and ligamentum flavum.

Additionally, the contralateral oblique imaging plane is required to assess the posterior-anterior depth, viewed from the lamina to the epidural space. This aids to determine the relative position of the Tissue Sculpter within the ligamentum flavum.

Figure 13 demonstrates a fluoroscopic image of the human lumbar spine. In this projection, image guidance for the *mild* Procedure is not obscured by the bony elements, allowing the target region underlying the lamina and the epidural space to be viewed relative to the Tissue Sculpter placement.

As demonstrated in **Figure 13**, the injection of non-ionic contrast media to perform epidurography prior to *mild* Device insertion is recommended. The contralateral oblique orientation reveals a partial lateral view of the interlaminar space occupied by ligamentum flavum on the anterior side of the lamina and its position relative to the underlying contrast media-marked epidural space.

Figure 13 – Contralateral Oblique Projection of the Lumbar Spine with Epidurography and *mild* Tissue Sculpter Placement



Note:
Contralateral oblique photo shows posterior to anterior plane.

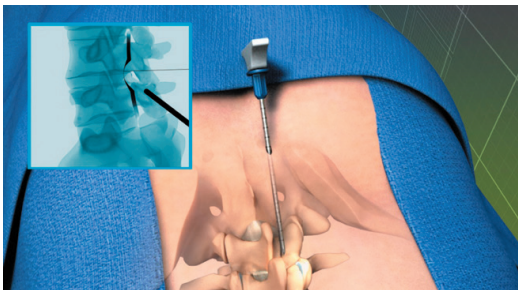
Contrast media marks epidural space, and position of *mild* Tissue Sculpter tip (left side of photo) is shown relative to bony and soft tissue landmarks.

Procedure:

Step A – positioning of the *mild* tissue access device (assembled trocar and portal)

1. Position the patient in a prone manner for spinal access in accordance with standard medical practice. Perform diagnostic fluoroscopic assessments of the lumbar-sacral spine in the Anterior-Posterior (AP) and contralateral oblique projections as described previously. Assess the images to identify the path of entry.
2. **Refer to Figure 13**. Perform epidurography using standard diagnostic techniques and non-ionic contrast agents to identify the border of the dural and epidural space relative to the ligamentum flavum and interlaminar space.
3. Following trajectory planning and administration of preferred anesthesia, make a small skin incision over the selected inferior lumbar region for ipsilateral access, approximately 1 to 1.5 vertebral segments caudad of the target region. Position the Trocar tip of the Tissue Access Device within the incision.
4. Using manual control and imaging guidance, advance the Tissue Access Device cephalad at an acute angle to the spine with gentle but firm pressure. Direct toward the dorsal surface of the spinal lamina of the adjacent vertebral segment, inferior to the interlaminar space and lateral to the spinous process.

Figure 14 – *mild* Tissue Access Device Placement



5. Remove the Trocar from the Portal by unscrewing the connecting collar from the Portal. Position the Portal tip atop the laminar surface and toward the superior margin of the laminar surface.
6. Secure the Portal by either Option A or Option B **(Figure 15)**.

Option A – *mild* Portal Stabilizer – Re-verify the large opening in the rotating ball of the Portal Stabilizer is aligned with the Portal Entry Slot **(Figure 10)**. Attach the Portal to the Portal Stabilizer by sliding the Portal into the Portal Entry Slot until they snap into place. The Portal is now in position to accept the Bone Rongeur.

Option B – *mild* Surgical Clamp – Secure Portal by attaching Surgical Clamp to the Portal through the positioning hole on the Surgical Clamp **(Figure 7)**.

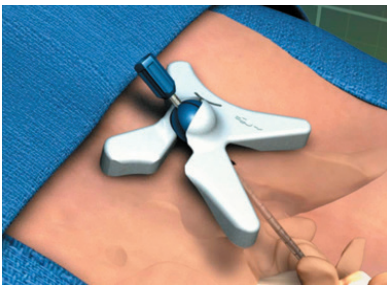


Figure 15A
Positioning with *mild* Portal Stabilizer

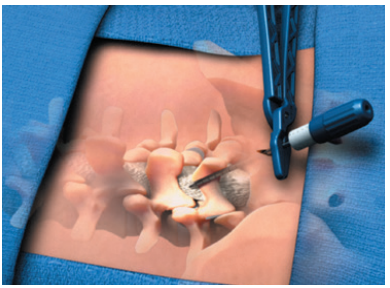


Figure 15B
Positioning with *mild* Surgical Clamp

7. At this time, the Depth Guide may be attached over the Portal limiting the forward motion of the working devices **(Figure 16)**.

Figure 16

Step B – Use of the *mild* Bone Rongeur

1. Using manual control and the appropriate imaging guidance, utilize the *mild* Bone Rongeur. First, ensure *mild* Depth Guide is set to 15 and insert the *mild* Bone Rongeur through the *mild* Portal to reach the selected laminar bone surface.
2. The *mild* Bone Rongeur is packaged ready for use. Inspect prior to use. Squeeze the trigger mechanism and observe retraction of tip toward cutting tube. Release the trigger and observe extension of the tip aperture to starting position of the tip aperture as the cutting tube returns.
3. Using manual control and the appropriate imaging guidance, advance the Bone Rongeur through the Portal to the selected laminar bone surface, traversing the interlaminar space if desired, in accordance with the *mild* Procedures **(Figure 17A)**.

4. Place the tip of the Bone Rongeur against the target bone and squeeze the trigger to enable the cutting action at the tip. Maintain the trigger in this position until removed from the Portal **(Figure 17B)**.
5. Completely withdraw the Bone Rongeur through the Portal and remove any bone and/or tissue from the device tip. Repeat the procedure as needed **(Figure 17C)**.
6. Typically, this can be accomplished by taking 3 bites of the inferior lamina and 3 bites of the superior lamina.

Figure 17 – Positioning and Use of the *mild* Bone Rongeur

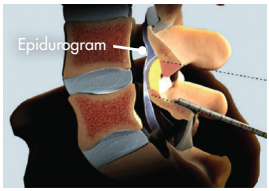


Figure 17A –
Pre-Bone Sculpting

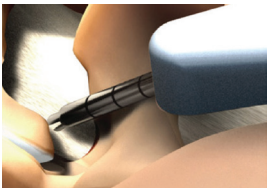


Figure 17B –
Bone Sculpting

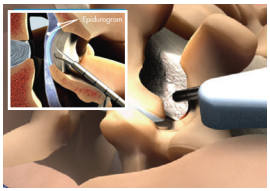


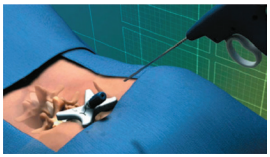
Figure 17C –
Post-Bone Sculpting

Step C – Use of the *mild* Tissue Sculpter

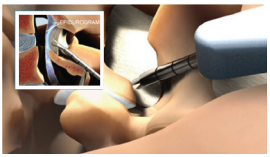
1. The *mild* Tissue Sculpter is packaged ready for use. **Reference preparation instructions**.
2. **Refer to Figure 12**. Using the appropriate image guidance techniques as described previously, squeeze the trigger, and insert Tissue Sculpter into the Portal tube. Slowly advance the Tissue Sculpter towards the Portal tip. Release the trigger just prior to exiting near the margin of the interlaminar space. Adjust the Depth Guide as needed.
3. With the trigger in the released position, slowly advance the Tissue Sculpter tip out of the Portal. The *mild* Tissue Sculpter is in position to advance and excise portions of ligamentum flavum.
4. Manually adjust by turning in a clockwise or counterclockwise direction to allow extension of the Tissue Sculpter from the Portal tip and into the tissue and interlaminar space as needed.

   Precaution: Tissue Sculpter rotation clockwise or counterclockwise should remain restricted to a 5 to 7 o'clock range in either direction to ensure positioning of the rounded spoonbill tip as the leading edge during the scooping and cutting movement, thus maximizing the safety aspect of the design.
5. The Portal may be positioned at various angles relative to the lamina and interlaminar space to enable the Tissue Sculpter to capture the tissue for resection.

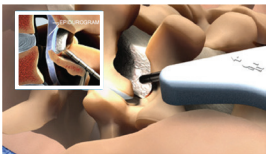
Figure 18 – Introduction, Positioning and Use of the *mild* Tissue Sculpter



Pre-Tissue Sculpting



Tissue Sculpting



Post-Tissue Sculpting

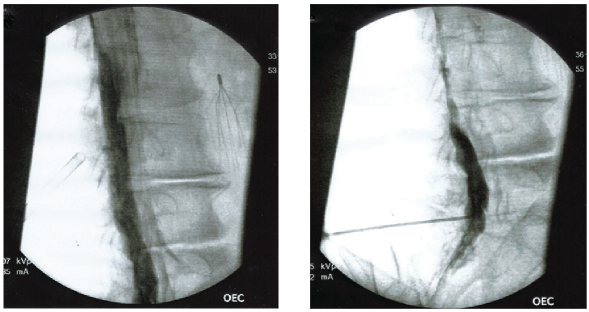
6. Fully release the trigger to completely open the Tissue Sculpter tip. Advance the Tissue Sculpter tip into the interlaminar space and direct the tip toward the ventral aspect of the adjacent superior lamina to capture ligamentous and fatty tissue **(Figure 18)**.
7. A single tissue cut can be completed by squeezing the trigger. This enables the outer cutting tube to close over the device tip for tissue resection. Maintain the trigger in this position for removal from the patient.

   Precaution: Aggressive cephalad to caudad motion and/or multiple tissue resections may cause overfilling of the Tissue Sculpter, which can affect normal action of the trigger mechanism.
8. Completely withdraw the Tissue Sculpter through the Portal, release the trigger to open the cutting element, and advance the push rod by depressing the push rod activator to remove the tissue specimen. Additional removal of tissue specimen may be employed as needed to ensure captured tissue is sufficiently discharged.
9. Steps 2 through 8 are repeated as necessary to complete the ipsilateral *mild* Procedure. The depth and lateral placement of the Tissue Sculpter is controlled by the Portal position and use of the Depth Guide.

Note: Tissue excision is generally performed across the interlaminar space and laterally along the width of the ligamentum flavum, from the posterior toward the anterior border of the epidural space. The actual depth of the distal end of the Tissue Sculpter along the posterior-anterior plane is adjusted with fluoroscopic guidance from the contralateral oblique view along with appropriate positioning of the Portal between 30° and 70° relative to the posterior back surface. This can typically be accomplished by utilizing the Tissue Sculpter in 3 scooping passes, performed 3 times.

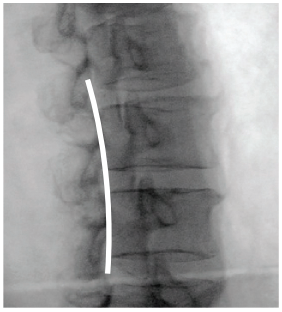
10. Decompression can be visually observed through changes in the epidurogram's contrast flow (thicker, straighter, easier flow) **(Figure 19)**, or through diminished returns when using the Bone Rongeur or Tissue Sculpter, and/or a feeling of those instruments dropping into the space that has been created.

Figure 19 – Changes in Epidurogram



11. Upon procedure completion at targeted site, remove the Portal/Portal Stabilizer assembly out of the patient as a unit. Remove the Portal from the Portal Stabilizer by pulling the Portal axially through the rotating ball of the Portal Stabilizer. Do not remove the Portal laterally from the Portal Stabilizer as this could damage the rotating ball.
12. For tissue excision at another vertebral level, or, on the contralateral side of the medial plane, repeat preparation of the *mild* Devices followed by steps A through C. Alternatively, experienced users may utilize bony landmarks to identify a Ventral Inter Laminal Line (VILL) (**Figure 20**) instead of an epidurogram and a horizontal midline incision for access to multiple levels or sides.

Figure 20 – Bony Landmarks and VILL



13. Upon completion, follow standard medical practice for postoperative cleaning and closure of the surgical site.

How Supplied

- **STERILE: FOR SINGLE USE ONLY**. Do not re-sterilize and/or reuse the Vertos *mild* Devices. The *mild* Devices are supplied sterile (by gamma radiation) and non-pyrogenic (patient contact surfaces) in a thermoformed tray.
- Only the patient-contacting surfaces of the Devices are tested for bacterial endotoxins (pyrogens) and are non-pyrogenic. This includes the stainless steel portions of the Portal, Trocar, Bone Rongeur and Tissue Sculpter, as well as the Portal Stabilizer.
- Do not use if the package is opened or damaged. In the event of damage to the sterile packaging, retain the contents and notify the manufacturer.

Storage

- The devices should be stored in their original shipping materials.
- Proper care should be taken to ensure that the devices will not be damaged.

Patents

- The *mild* Procedure and products are protected by United States Patents assigned to Vertos Medical, Inc and use virtual patent marking. This website page is provided to satisfy the virtual patent marking provisions of various jurisdictions including the virtual patent marking provisions of the America Invents Act, 35 U.S.C. § 287(a). Foreign patents not listed here, may also apply.
- See www.vertosmed.com/patents/ for further details.

Symbols Legend

Catalog Number

Lot Number


Use By

Sterilized Using Radiation


Do Not Reuse


Manufacturer:
Vertos Medical Inc.
Aliso Viejo, CA 92656 USA
Tel: +1 877.958.6227
Fax: +1 877.285.7811
www.Vertosmed.com
customerservice@Vertosmed.com


Non-Pyrogenic (Patient contact surfaces)


Caution: Consult Accompanying Documents

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner


Consult instructions for use

Country of manufacture

Medical Device

Do not resterilize

Do not use if package is damaged and consult instructions for use

Date of manufacture

This page intentionally left blank

This page intentionally left blank

Vertos Medical Inc.
Aliso Viejo, CA 92656
www.Vertosmed.com | 877.958.6227

PRT-00566 REV. I
10/2024