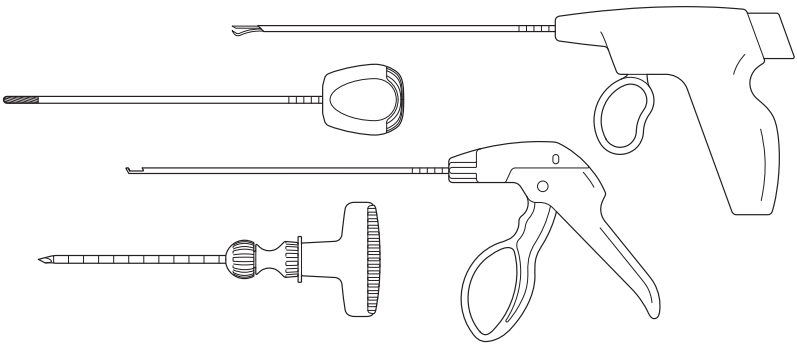
stryker

mild

device kit

Instructions For Use

REF MDK-0002



R_x ONLY

STERILE R

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 Vertos Medical mild® Device Kit. It is not a reference for surgical techniques.

The following signal words may be used throughout this manual:

- **WARNING** - Highlights a safety issue. Always comply with this information to prevent patient and/or healthcare staff injury.
- **CAUTION** - Highlights a product reliability issue. Always comply with this information to prevent product damage.

Device Description

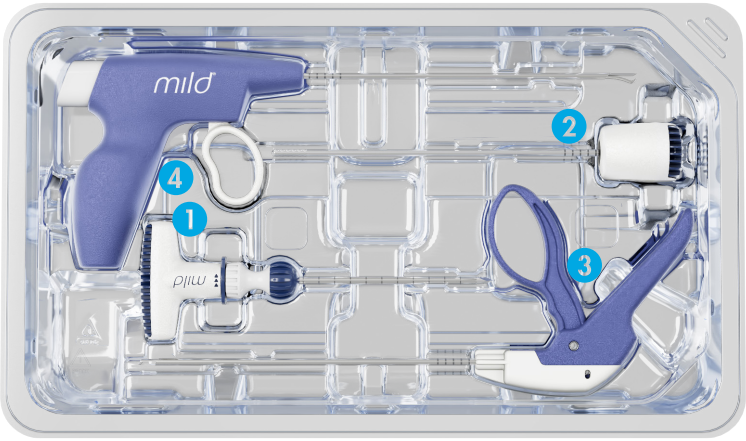
The Vertos Medical mild Device Kit is a sterile, single-use system. The mild Device System is composed of surgical tools consisting of one each of the following components:

1. mild Initiator*

2. mild Access Auger

3. mild Bone Rongeur

4. mild Tissue Sculpter



*The mild Initiator is preassembled for convenience and includes the mild Trocar, mild Portal, mild Portal Grip, and mild Depth Guide. No additional assembly is required to use these specialized surgical instruments to access the treatment area.

mild DEVICE KIT:

mild Initiator

Designed to be used to gain initial access to the interlaminar space. When assembled, the mild Initiator has a working length of 4.9 inches. The mild Portal serves as a cannula through which the mild Trocar, mild Access Auger, mild Bone Rongeur, and mild Tissue Sculpter are inserted into the interlaminar space. The mild Portal has markers every 10 mm to aid the user with depth advancement into tissue. The diameter of the cannula is 6 gauge (5.1 mm), and has a working length of 4.5 inches with the trocar removed. The mild Portal Grip serves to control the angle and depth of the mild Portal against the surface of the skin. The mild Depth Guide serves to adjust the depth of the mild Access Auger, mild Bone Rongeur, and mild Tissue Sculpter within the interlaminar space. The position of the mild Trocar, mild Access Auger, mild Bone Rongeur, and mild Tissue Sculpter must be verified using fluoroscopy.

mild Access Auger

Designed to be used through the mild Portal to access tight or collapsed interlaminar space less than 5 mm in height that could not be previously accessed using the mild Bone Rongeur. With the mild Depth Guide set at the initial 10 mm starting point, the mild Access Auger will start at the same point in-situ as the trocar tip. During manual operation, as the handle is rotated by hand in a clockwise motion, the mild Access Auger will create a pathway through the interlaminar space until it bottoms out at the selected mild Depth Guide setting. The position of the mild Access Auger must be verified using fluoroscopy.

mild Bone Rongeur

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 long cutting tube and rod. During manual operation, the trigger is squeezed toward the handle and the cutting tube advances toward the footplate to complete the cut. With the angled tip positioned against bone, this manual motion enables the bone to be captured within the tip aperture of 0.4 inches nominal, and to then be cut and retained for removal from the body through the mild Portal. The mild Bone Rongeur must be removed from the mild Portal and cleaned after each pass. The position of the mild Bone Rongeur must be verified using fluoroscopy.

mild Tissue Sculpter

Designed to be used through the mild Portal to remove tissue from the interlaminar space. The device consists of a handle and trigger, connected to an 8.5 inch long cutting tube and rod. 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 live fluoroscopy. 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. The mild Tissue Sculpter has the ability to take 3 passes (bites) before removal for cleaning. The position of the mild Tissue Sculpter must be verified using fluoroscopy.

INDICATIONS FOR USE:

The Vertos Medical mild Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

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

CONTRAINDICATIONS FOR USE:

The Vertos mild Devices are contraindicated for patients with the following:

- Grade 3 or higher spondylolisthesis
- Infection, local to the operative site
- Signs of local inflammation
- Infection

WARNINGS:

- Do not use a device past the expiration date on the label. Use of expired product may result in patient injury.
- Inspect all product components and packaging prior to use. Do not use the device if the device or the packaging has been damaged or if sterility has been compromised. Damaged product may result in patient injury. 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/or device materials, 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 undergone prior laminotomy, laminectomy, or lumbar spine fusion surgery, or have any lumbar spinal hardware and/or devices should be carefully evaluated for access and appropriate visual bony landmarks prior

to performing the mild Procedure. Performing the mild Procedure may result in patient injury if access cannot be obtained and/or appropriate visual bony landmarks cannot be visualized and identified.

- Difficult anatomy and/or scar tissue can result in dural puncture/tear. Proper patient selection could affect outcomes.
- As with all medical procedures and surgeries, the physician should use the appropriate facility standard of care or societal protocols and guidelines for patients on blood thinners (anticoagulants) and other medications before attempting to perform the mild Procedure.
- 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 epidurogram using standard diagnostic techniques, equipment, and non-ionic contrast agents to identify the dural and epidural anatomy prior to commencing the procedure. Alternatively, physicians may choose to use the bony landmarks with the VILL (Ventral Interlaminar Line). Failure to do so may result in inadequate device performance or patient injury.
- Do not reprocess or reuse this product. Reuse or reprocessing may compromise the integrity of the device and/or create a risk of contamination of the device, which may result in patient injury, illness, or death. Reconditioning, refurbishing, repair, or modification of the devices to enable further use is prohibited.
- Do not use components from other systems to perform the mild Procedure. This could result in inadequate performance or patient injury.
- Do not use the device components outside the field of vision or without adequate assurance of device placement via fluoroscopy. Failure to do so may result in patient injury.
- Do not use the mild Access Auger in a counterclockwise rotation while in the patient. Doing so may result in bony fragments within the treatment zone and could lead to diminished outcome or patient injury.
- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.
- 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.
- The components of this system should only be manipulated while under fluoroscopic guidance.
- 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 Access Auger, mild Bone Rongeur, and mild Tissue Sculpter blunt tip profiles are designed to reduce the risk of non-target tissue puncture. It is necessary to advance instruments gently and gradually and use Anterior-Posterior (AP) and contralateral oblique (CLO) fluoroscopic imaging to maintain tip position within the interlaminar space and toward the ventral laminar surface to further minimize inadvertent tissue contact.
- Do not attempt to push or force the mild Access Auger through the lamina as it may advance further than desired which may result in patient injury. The mild Access

Auger should be advanced in a controlled manner using gentle downward pressure combined with clockwise rotation and using the mild Depth Guide, allowing the mild Access Auger flutes to remove laminar material. The mild Depth Guide has visual markings every 5 mm (starting at 10 mm) and a tactile click approximately every 2.5 mm of advancement.

- The mild Tissue Sculpter's 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.

CAUTIONS:

- Appropriate fluoroscopic training is required to reduce radiation exposure.
- Familiarity with fluoroscopic imaging techniques and expertise in the epidural space are key qualification requirements for performing the procedure.
- Patients with morbid obesity defined as Body Mass index (BMI) greater than 40 may be difficult to treat due to inadequate length of instruments.
- The mild Procedure should be performed under, at a minimum, local anesthesia.
- Sensitivity to local, monitored anesthesia care (MAC), or general anesthesia should be evaluated prior to starting the mild Procedure.
- Do not use excessive force on any of the mild Device instruments. Excessive force can result in product failure.
- Aggressive cephalad to caudad motion and/or multiple tissue resections may cause overfilling of the mild Tissue Sculpter, which can affect normal action of the trigger mechanism. Please refer to Step 9 of the procedure steps for proper usage of this instrument.
- Proper patient selection, compliance, and postoperative care are important and will greatly affect outcomes. The patient must be informed of this information and the potential of secondary surgical procedures and the associated risks.

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

INSTRUCTIONS FOR USE:

Preparation of the mild Devices

1. mild Initiator

Remove the mild Initiator from the tray **[Figure 1]** and verify the mild Trocar can be detached from the mild Portal by rotating 90° counterclockwise as the blue arrows indicate (using the bilateral blue wings as counter-torque) and pulling straight back proximally **[Figure 2]**. Confirm that the mild Depth Guide is set to 10 **[Figure 3]** as the mild Trocar extends approximately 10 mm distally from the portal (as will corresponding access and treatment instruments). Instrument length exiting the tip can be adjusted in 5 mm increments by utilizing the corresponding markings on the guide with tactile clicks approximately every 2.5 mm. After the mild Initiator is docked in the treatment zone, the mild Depth Guide may be adjusted depending on the in-situ instrument depth desired. Re-attach the mild Trocar to the mild Initiator in reverse order.

Figure 1

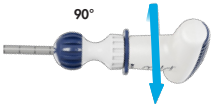


Figure 2

Figure 3

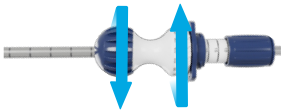


Figure 4

The mild Portal Grip is pre-set to provide resistance to distal and proximal movement along the mild Portal. Loosen or tighten the mild Portal Grip by rotating the white and blue components in opposite directions relative to each other **[Figure 4]**. Set the mild Portal Grip to desired torque and location on the portal. It is recommended to keep the mild Portal Grip in its original position on the mild Initiator during initial treatment zone docking.

2. mild Access Auger

Ensure the mild Access Auger's distal tip is free from any visual defects or deformations **[Figures 5a and 5b]**.

Figure 5a

Figure 5b

3. mild Bone Rongeur

Verify the mild Bone Rongeur's trigger is extended away from the handle **[Figure 6a]** and observe the open distal tip. Squeeze the trigger to close the cutting element. Ensure trigger returns to extended position **[Figure 6b]**.

Figure 6a

Figure 6b

4. mild Tissue Sculpter

Verify the mild Tissue Sculpter's trigger is extended away from handle **[Figure 7a]** and observe the open mild Tissue Sculpter tip **[Figure 7b]**. Depress the Push Rod Activator to advance the push rod **[Figure 7c]**. Observe movement of the Push Rod within the distal tip of the device. 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.

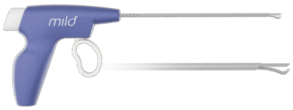


Figure 7a

Figure 7b

Figure 7c

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. **[Figures 8a and 8b]** represents the relevant spinal anatomy for which the mild Devices are intended.

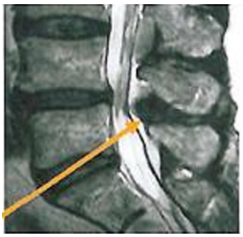


Figure 8a: Lateral view MRI reveals a thickened ligamentum flavum relative to the spinal canal

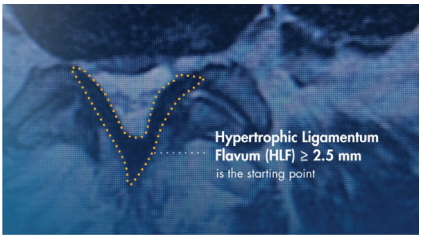
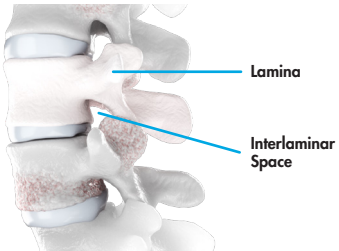


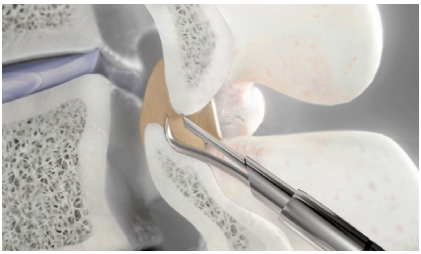
Figure 8b: Axial view MRI also demonstrates a thickened ligamentum flavum relative to the spinal canal

[Figure 9a] identifies a graphical representation of the lumbar spine from a lateral oblique perspective, revealing the interlaminar space for demonstration for the mild Device trajectory.

The lateral oblique graphics in **[Figures 9a and 9b]** demonstrate the landmarks to guide the mild Procedure. These illustrate the position of the mild Devices relative to bony and soft tissue landmarks for excision of the ligamentum flavum.

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





Figures 9a & 9b: Lateral oblique graphics of lumbar spine with demonstration of mild tissue scultper relative to interlaminar space and bone/tissue landmarks

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 AP view and a CLO view, or by using bi-plane fluoroscopy to view both the AP and CLO images at the same time, the mild Tissue Sculpter can be advanced to ligamentum flavum in the target area.

Initially, the AP projection for identifying the target region and guiding mild Device placement for tissue resection is recommended for the mild Procedure **[Figure 10a]**. 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 CLO 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 mild Tissue Sculpter within the ligamentum flavum.

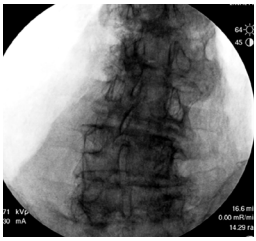


Figure 10a

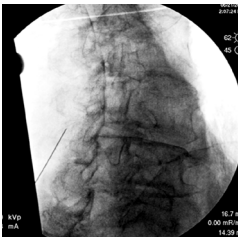


Figure 10b

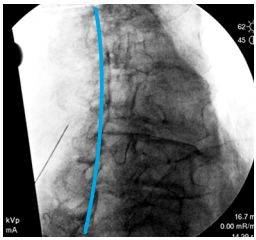


Figure 10c: VILL Example

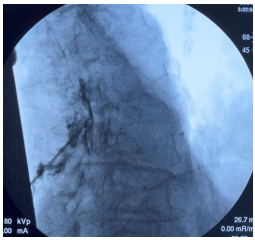


Figure 10d

[Figure 10b] demonstrates a fluoroscopic CLO image of the lumbar spine. In this projection, image guidance for the mild Procedure is not obscured by the bony elements and the VILL **[Figure 10c]** is visible, allowing the target region underlying the lamina and the epidural space to be viewed relative to the mild Tissue Sculpter placement.

As demonstrated in **[Figure 10d]**, the injection of non-ionic contrast media to perform epidurography prior to the mild Initiator insertion is recommended, users can also use bony landmarks with the VILL **[Figure 10c]**. 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.

PROCEDURE:

Positioning of the mild Initiator

Position the patient in a prone manner for spinal access in accordance with standard medical practice. It may be helpful to position a bolster under the patient's mid-section to help reduce lordosis and flatten the back for easier access to the interlaminar space. Administer preferred anesthesia.

1. **Assess fluoroscopy** images to identify path of entry: Perform diagnostic fluoroscopic assessments of the lumbar-sacral spine in the AP and CLO projections.

   Refer to **[Figure 10b]**. Perform epidurogram if desired 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 **[Figure 10d]**. Alternatively, users can utilize bony landmarks, such as the VILL **[Figure 10c]**.

2. **Make a small horizontal incision** (11 blade is recommended) approximately 1 to 1.5 vertebral segments caudal of the target region **[Figure 11a]**.

3. Following trajectory planning, **initiate access** by selecting one of the following techniques:

   a. **Streamlined:** Ensure the incision is midline under the spinous process of the selected inferior region for bilateral access. With the trocar tip slightly inserted, turgor just enough laterally to obtain a slight medial trajectory toward the treatment area, and lateral to the spinous process **[Figure 11b]**.

   b. **Standard:** Ensure the incision is over the selected inferior lumbar region for ipsilateral access. With the trocar tip slightly inserted, obtain a slight medial trajectory toward the treatment area, and lateral of the spinous process **[Figure 11c]**.

With either approach, when positioning the mild Initiator, a linear trajectory that is parallel to the superior and inferior laminas (typically 30°–70°) is recommended to maximize the amount of tissue that is accessible for the decompression portion of the procedure.

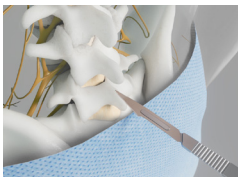


Figure 11a: Horizontal Incision with 11 blade

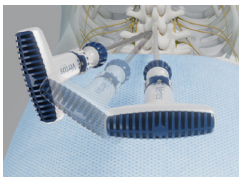


Figure 11b: mild Initiator Placement (Streamlined Technique)

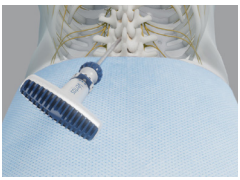


Figure 11c: mild Initiator (Standard Technique)

4. Using manual control and image guidance, **advance the mild Initiator** cephalad at an acute angle to the spine. Direct toward the superior surface of the inferior lamina, inferior to the interlaminar space.

5. **Lock the mild Portal Grip**. First, loosen the mild Portal Grip and then slide onto the skin surface **[Figure 12a]**. Once contact is made, tighten the mild Portal Grip by rotating the white and blue components in opposite directions until secure. Only slight rotation is required to tighten or loosen the mild Portal Grip. To maintain mild Portal control, a general surgical clamp can be attached to one of the blue wings on the mild Initiator. Dock on the superior surface of the inferior lamina of the treatment zone.

Figure 12a

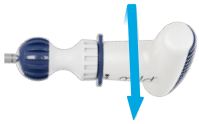


Figure 12b

Figure 12c

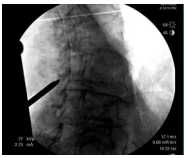


Figure 12d

Caution: Do not over-tighten or over-loosen the mild Portal Grip. Doing so may compromise the structural integrity of the mild Portal Grip. Additionally, if the mild Portal Grip is removed from the mild Portal, do not attempt to reassemble back onto the mild Portal.

6. **Remove the mild Trocar** from the mild Portal by rotating the white t-handle of the mild Trocar 90° counterclockwise from the mild Portal **[Figure 12b]**. Maintain the position of the mild Portal on the laminar surface to remove the mild Trocar. Confirm the mild Depth Guide is at its pre-set value of 10 mm **[Figure 12c]**. Verify mild Portal position with an AP and CLO fluoro image **[Figure 12d]**.

Use of the mild Access Auger

7. **If needed, utilize the mild Access Auger** to help facilitate access to the treatment zone. Insert the mild Access Auger into the mild Portal. Using gentle downward pressure, advance between the lamina by rotating the mild Access Auger clockwise **[Figure 13]**.

Figure 13

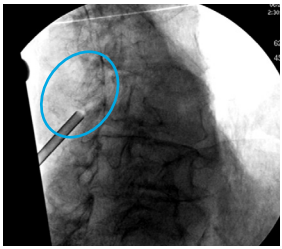


Figure 14: Note the access channel created by the mild Access Auger

The mild Access Auger should be cleaned following approximately 10 rotations. Remove the mild Access Auger by pulling straight back through the mild Portal and clean by rotating counterclockwise on a damp towel.

It may take multiple sets of rotations to reach the treatment zone. Once clean, reinsert the mild Access Auger into the mild Portal under fluoro and continue accessing the treatment zone.

To further advance the mild Access Auger, rotate the mild Depth Guide clockwise in 1-click increments, as needed, until the mild Access Auger reaches the treatment zone. Each click of the mild Depth Guide allows the mild Access Auger to advance approximately 2.5 mm. The position of the mild Access Auger must be verified using fluoroscopy.

Note the access channel created by the mild Access Auger **[Figure 14]**. Before advancing to the treatment phase, ensure the mild Depth Guide is set to 15.

Caution: When inserting or removing the mild Access Auger, do not apply lateral pressure on the mild Depth Guide as it may result in difficulty passing the instrument through the portal. As with all mild working instruments, use the appropriate angle for insertion.

Use of the mild Bone Rongeur

8. 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 **[Figure 15a]**. Squeeze the trigger and maintain in closed position until removed from the mild Portal **[Figure 15b]**. Remove any bone and/or tissue from the device tip. Repeat as needed on the inferior and superior laminar surfaces to create a pathway for the mild Tissue Sculpter **[Figure 15c]**.

TIP: Typically, this can be accomplished by taking 3-5 passes of the inferior lamina and 3-5 passes of the superior lamina.

Figure 15: Positioning and Use of the mild Bone Rongeur

Figure 15a

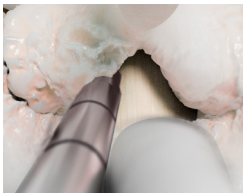


Figure 15b

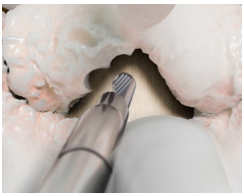


Figure 15c

Use of the mild Tissue Sculpter

9. **Perform tissue sculpting** by squeezing the trigger and advancing the mild Tissue Sculpter tip through the mild Portal, releasing the trigger prior to exiting into the interlaminar space. Direct the tip toward the ventral aspect of the adjacent superior lamina to capture ligamentous and fatty tissue with each trigger activation. The mild Tissue Sculpter is designed to work in a scooping motion from inferior to superior and is always performed under live fluoro. Handle rotation is restricted to a 5 to 7 o'clock range in either direction which keeps the "scoop" portion of the mild Tissue Sculpter within the appropriate position **[Figure 16a]**. Three passes may be taken before removing the mild Tissue Sculpter from the mild Portal **[Figure 16b]**. To remove the mild Tissue Sculpter, maintain closed trigger and withdraw from the mild Portal. Release the trigger to open the cutting element and advance the white push rod to eject the tissue. Sterile saline can assist in cleaning the instrument **[Figure 16c]**. Repeat as necessary to complete the ipsilateral portion of the mild Procedure.

TIP: Positioning the mild Portal and mild Tissue Sculpter parallel to the inferior lamina (30°–70° depending on patient positioning and lumbar level being treated) is recommended for ease of entry to the interlaminar space and space available to excise portions of the ligamentum flavum.

Figure 16a

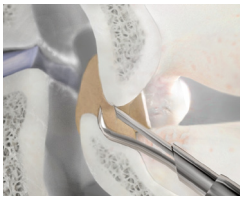


Figure 16b

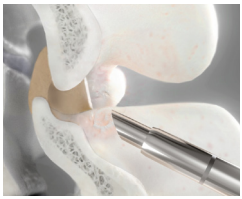
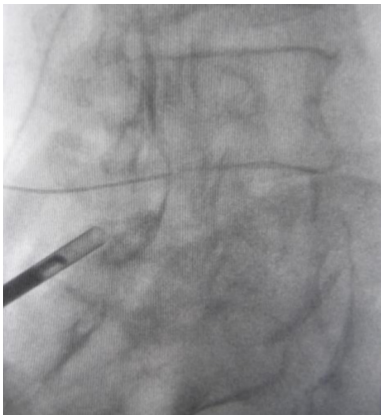


Figure 16c

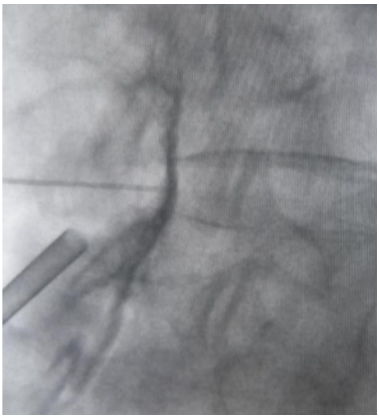
Caution: Aggressive cephalad to caudal motion and/or multiple tissue resections may cause overfilling of the mild Tissue Sculpter, which can affect normal action of the trigger mechanism.

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 mild Tissue Sculpter along the posterior-anterior plane is adjusted with fluoroscopic guidance from the CLO view along with appropriate positioning of the mild Portal between approximately 30°–70° relative to the patient's posterior back surface. This can typically be accomplished by utilizing the mild Tissue Sculpter in 3 scooping passes, performed 3 times.

If desired, decompression can be visually observed through changes in the epidurogram's contrast flow (thicker, straighter, easier flow) **[Figures 17a and 17b]**, or through diminished returns when using the mild Bone Rongeur or mild Tissue Sculpter, and/or a feeling of those instruments "dropping" into the space that has been created.



17a: Example of pre-epidurogram



17b: Example of post-epidurogram

Figure 18

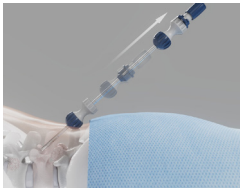


Figure 19

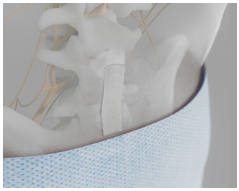


Figure 20

10. **To treat multiple zones**, set the mild Depth Guide to the initial position of 10. Reinsert the mild Trocar into the mild Portal. Release the mild Portal Grip from the skin and secure in its initial position. Redirect the mild Initiator to address additional vertebral levels or contralateral sides and repeat the same procedural steps **[Figure 18]**.
11. **When treatment is complete, remove the mild Portal** as a single unit **[Figure 19]**.
12. **Complete the mild Procedure** by wicking the portal tracks by rolling a towel from superior to inferior stopping just below the incision site. This will help remove any fluid before closure. Follow standard medical practice for postoperative cleaning and closure of the surgical site **[Figure 20]**.

PACKAGING & INSPECTION:

- STERILE: FOR SINGLE USE ONLY
- Do not re-sterilize and/or reuse the Vertos mild Device. The mild Device is supplied sterile (by gamma radiation) and non-pyrogenic (patient contact surfaces) in a thermoformed tray.
- Only patient-contacting surfaces of the mild Device are tested for bacterial endotoxins (pyrogens) and are non-pyrogenic. This includes the stainless steel portions of the mild Initiator, mild Access Auger, mild Bone Rongeur, and mild Tissue Sculptor.
- Inspect the mild Devices and packaging to verify that all contents are intact, and no damage has occurred as a result of shipping and handling.
- In the event of damage to the product, damage to the sterile packaging, or if the integrity has been compromised, do not use the product. Retain the package with the product contents and notify the manufacturer.

STORAGE:

- The mild Devices should be stored in the original device packaging.
- Proper care should be taken to ensure that the device will not be damaged.

DISPOSAL OF DEVICE:

Dispose of device per healthcare facility biohazardous waste protocols.

RETURN OF DEVICES:

If any portion of the Vertos mild Device fails prior to or during a procedure, discontinue use and contact your local representative and/or email quality@vertosmed.com.

PATENTS:

The mild Procedure and products are protected by United States Patents assigned to Vertos Medical, Inc. and user 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:

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

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

Keep Dry

Consult instructions for use or consult electronic instructions for use

Keep Away from Sunlight

Quantity

Catalog Number

Use-by date

Do not re-use

Manufacturer

Non-Pyrogenic (Patient Contact Surfaces)

Sterilized Using Irradiation

Caution

Batch code

Medical Device

Single sterile barrier system with protective packaging inside

Do not resterilize

Date of manufacture

General warning sign

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