

UniVise® Spinous Process Fixation Plate System Surgical Technique

- Simple, One-Piece Design
- Anatomically Shaped Plates
- Optimized Radial Spike Pattern

UniVise Spinous Process Fixation Plate System

Surgical Technique

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Device Description



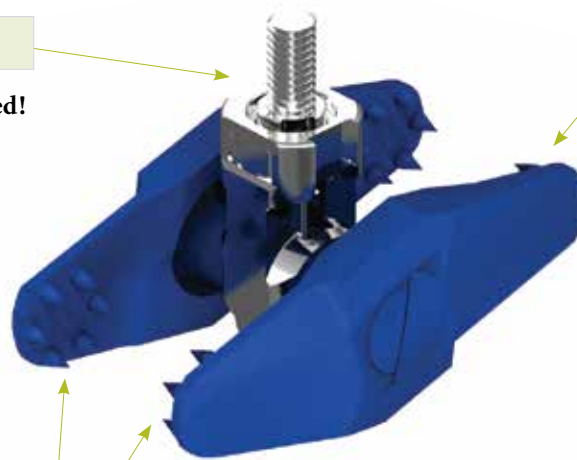
The UniVise Spinous Process Fixation Plate is a one-piece, bilateral locking plate system that attaches to the posterior non-cervical spine at adjacent spinous processes. UniVise is the latest addition to Stryker's LITe (Less Invasive Technologies) Platform, which is segmented into four key areas including:

- **Access Systems:** LITe Decompression Tubes, Phantom and Luxor Retractors
- **Disc Preparation:** Reliance Lite and Reliance Total PLIF
- **Interbody Insertion:** ARIA, AVS Navigator, AVS TL, AVS PL and AVS UniLIF
- **Fixation Solutions:** ES2, Mantis, Mantis Redux and Techtonix

UniVise Key Design Features

One-Piece Design

- One piece – no assembly required!



Anatomically Shaped Plates

- Low-profile, anatomically designed plates
- 35mm and 40mm options

Optimized Radial Spike Pattern

- Radial spike pattern for optimized positioning and grip

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Indications for Use

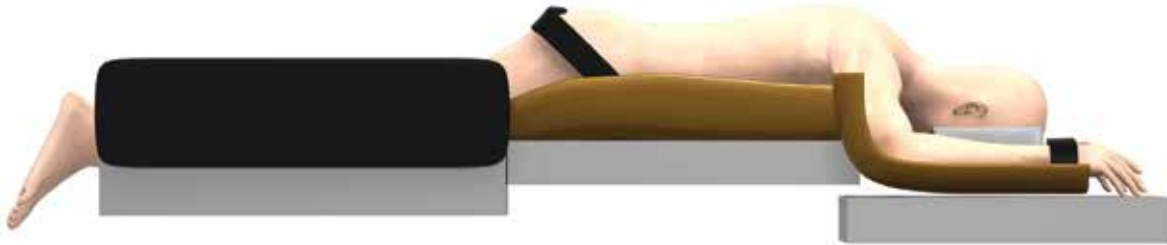
The **UniVise Spinous Process Fixation Plate** is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The UniVise Spinous Process Fixation Plate is intended for use with bone graft and is not intended for stand-alone use.

NOTE: This surgical technique is intended as a guide only. It is recommended that the surgeon be thoroughly trained before proceeding. The surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required.

Please refer to the UniVise Spinous Process Fixation Plate device and instrument package inserts for complete information on indications, contraindications, precautions, warnings, potential adverse events and complications, sterilization, packaging, and storage.

To utilize the UniVise Spinous Process Fixation System in conjunction with AVS ARIA, refer to Surgical Technique **MIUNI-ST-5**.

UniVise Spinous Process Fixation Plate Technique



Step 1: Patient Positioning

Place the patient on a radiolucent table in the prone and optimally-flexed position using a Wilson-like frame. Take care to maintain spine curvature so that the interspinous space is naturally distracted. Avoid any pressure on the abdominal cavity that might result in excessive bleeding.

PRECAUTION: When operating at the L5/S1 level, a preoperative CT reconstruction is recommended to verify the presence and size of the S1 spinous process to ensure the implant will have sufficient support to achieve fixation.

PRECAUTION: If performing a decompression, avoid excessive lamina or other bone removal. Excessive bone removal may compromise the integrity of the spinous processes at the operative level.

NOTE: The use of intraoperative fluoroscopy to confirm instrument and implant placement is strongly recommended.

Step 2: Approach

Identify the spinous processes and accurate midline position at the level to be instrumented through manual palpation and fluoroscopy, using a spinal needle, or scalpel.

Make a standard lumbar midline incision with a scalpel over the adjacent spinous processes at the desired operative level. The incision should be of sufficient length to access the superior and inferior aspects of both spinous processes.

Step 3: Spinous Process Preparation

Prepare the spinous processes for implantation by removing enough bone and/or tissue such that parallel plate compression is possible with both vertebral bodies.

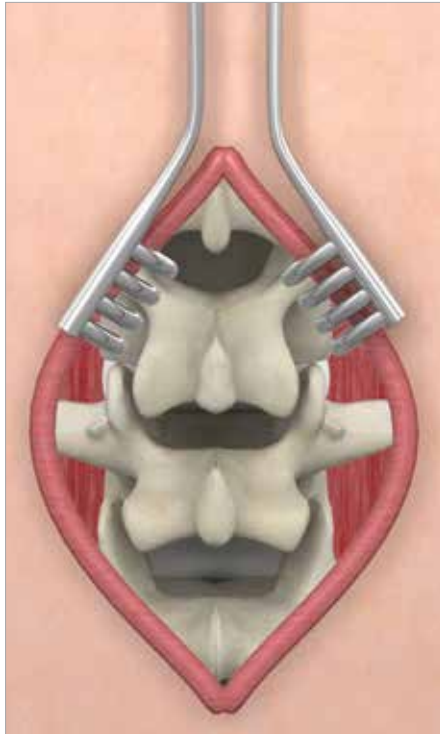
Use the **Cobb Elevator, 16mm Angled Tip** to elevate the paraspinal muscles and remove the soft tissue along both sides of the spinous processes. Dissect and remove the interspinous ligament, any remaining soft tissue and osteophytes from the spinous processes to provide a pathway for trialing and plate insertion. Remove any residual supraspinous ligament and interspinous ligaments, as necessary.

PRECAUTION: Avoid excessive lamina or other bone removal. Excessive bone removal may compromise the integrity of the spinous processes at the operative level.

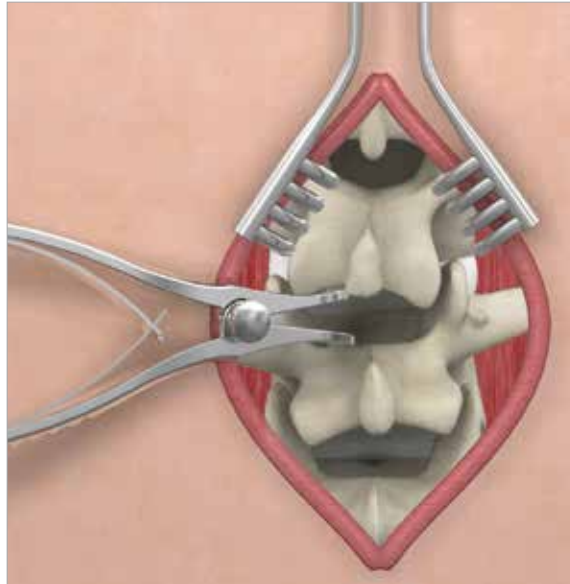
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Step 4: Spinous Process Distraction



Gently distract the spinous processes as required to allow placement of the **Implant Trials** and implant. Ensure that placement of a distractor does not interfere with instrumentation during implant insertion.



Insert the tips of the **Lamina Spreader** into the interlaminar space and distract as necessary. Use a Kerrison Rongeur or similar instrument to perform decompression per standard technique.

PRECAUTION: Use care when distracting spinous processes to avoid damage. Do not over distract.

NOTE: Maintain distraction during implant sizing and insertion.

Step 5: Bone Graft Placement

If fusing through the spinous processes, BIO DBM Shapes or Boats in conjunction with BIO Chips or BIO DBM with Chips may be packed prior to implant placement and/or post-implantation. Additionally, BIO Shafts or BIO Wedges may be cut-to-size if desired to match various patient anatomy and placed prior to implant placement and/or post implantation.

Please refer to the Stryker Biologics Catalog (BIGENBR12011) for a full description of the DBM and allograft product offerings.

NOTE: Use a tamp to position the allograft down onto the lamina, as necessary.

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Figure 1

Step 6: Determine Implant Size

The UniVise Spinous Process Fixation Plate is available in 35mm and 40mm lengths to accommodate differences in spinous process height and interspinous distance. To determine the appropriate implant size, always begin with the smaller (35mm) Trial.

Orient the 35mm Trial with the arrow pointing cranially to approximate implant orientation. Insert the Trial into the operative site and gently advance as far anterior as possible into the interspinous space (Fig. 1).

NOTE: If the superior spinous process exhibits an extremely hooked shape, partial resection of the overhang portion may be necessary to avoid excessive force when advancing the Trial and/or implant.

Use lateral fluoroscopy to verify position of the Trial and ensure the Implant Plates will properly engage with the spinous processes. If lateral fluoroscopy indicates sub-optimal sizing, repeat the actions mentioned above using the 40mm Trial. Select the implant size that correlates with the most appropriate Trial size.



Figure 2

Step 7: Inserter Preparation and Implant Loading

Before loading the implant, ensure that the **Inserter** dial is rotated completely to the unlocked position, visually indicated by the alignment of the arrow on the Inserter dial with the arrow on the handle of the Inserter (Fig 2). The UniVise implant is sterile packaged. Remove the implant from the sterile packaging, but keep the implant attached to the **Backer Card** (Fig 3). The Backer Card is designed to hold the plates in an open position and keep the implant locking mechanism perpendicular to the plates for correct alignment with the Inserter. It is also designed to protect the user from the sharp implant plate spikes.

Step 1: While holding the Backer Card by the side, align the arrow on the body of the implant with the arrow on the distal tip of the Inserter (Fig. 3). Slide the distal tips of the Inserter just past the notches on the sides of the implant. There may be a slight gap in between the implant and Inserter sleeve.

NOTE: The Inserter dial **will not** rotate to the locked position if the Inserter is not properly aligned with the implant. If resistance is felt, lift the Inserter and realign it with implant.



Figure 3

NOTE: The distal tip of the Inserter is to rest on the top surface of the Backer Card.

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Figure 4

Step 2: While holding the Backer Card in place, turn the Inserter dial clockwise towards the locked position until the dial cannot be rotated further and the implant is securely attached. The arrow on the dial of the Inserter will align with the locked symbol on the handle of the Inserter to indicate that the implant is locked to the Inserter (Fig. 4).

Step 3: Attach the **Inserter Inner Shaft Handle** to the **Inserter Inner Shaft**.



Figure 5

Step 4: Insert the Inserter Inner Shaft through the proximal entry point of the Inserter and gently rotate until the distal tip engages with the implant. Rotate the Inserter Inner Shaft a half turn (180°) clockwise to **lock** the plates in the rotated position (Fig. 6). The user should confirm that the plates are locked in the orientation shown in Fig. 6. If they are not, the user should perform an additional amount of rotation to the Inserter Inner Shaft until such point that the implant orientation is locked.

Step 5: Remove the implant from the Backer Card by gently pulling through the open side tab of the card (Fig. 6).

NOTE: Implant should be locked in position after removal from Backer Card as demonstrated below.



Figure 6

Correct



Incorrect



CAUTION: The implant plate spikes are sharp. Handle implant carefully at all times.

NOTE: Do not over tighten the Inserter to the implant.

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Step 8: Implant Insertion

Verify proper orientation of the implant and Inserter by checking that the white lettering that reads “SUPERIOR” is oriented cranially.



Figure 7

Step 1: Place the Inserter into the operative site and position the implant plates on either side of the spinous processes (**Fig. 7**). Ensure that there is no soft tissue between the implant plates and lateral aspects of the spinous processes.

NOTE: As the technique states, the implant should be positioned into the operative site and no excessive force should be used.

Step 2: Adjust the implant position as necessary to ensure implant plates align optimally with the spinous processes. Verify positioning using direct visualization as well as A/P and lateral fluoroscopy.

NOTE: Implant plate orientation is designed to accommodate typical spinous process anatomy. However, the surgeon must consider the spinous process anatomy of each patient and make the appropriate adjustments when necessary and as required. This might include reversing the implant orientation to ensure optimum placement and spinous process attachment.

Step 3: Remove the Lamina Spreader after initial entry to fully seat in between the spinous processes.

Step 4: Turn the Inserter Inner Shaft clockwise to close and lock implant plates. Turning the Inserter Inner Shaft clockwise will cause the plates to begin to compress. Apply slight counter torque to Inserter handle when turning Inserter Inner Shaft in order to close and lock the plates. After a few turns, pause and use direct visualization and A/P fluoroscopy to verify implant plates are closing properly.

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Step 9: Compression

To apply supplemental clamping force, the **Compressor** may be used.



Figure 8

Step 1: Advance the Compressor carefully until the open-ended tongs capture the laterally-protruding plate posts (**Fig. 8**). Slowly squeeze handles to actuate the Compressor and continue turning the Inserter Inner Shaft clockwise until implant plates and spikes are fully engaged with the spinous processes.



The Compressor may also be used to apply supplemental clamping force to the lateral plate surfaces if extremely hard cortical bone is encountered or to further compress the plate. Do not apply any compressive loads to the implant with any instrument other than the Compressor.

PRECAUTION: Do not over compress. Doing so may damage the spinous processes.

NOTE: Use direct visualization, lateral, and A/P fluoroscopy, and tactile feedback to verify appropriate implant position and confirm that implant plate spikes have adequately engaged the spinous processes.

NOTE: Visually inspect operative site and gently pull up on the Inserter to confirm secure fixation.

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IMPLANT READJUSTMENT: Implant repositioning may be achieved by turning the Inserter Inner Shaft fully counterclockwise and manually separating the implant plates. Use care to avoid the implant plate spikes and possible spinous process damage.

Alternatively, if implant repositioning is required after tightening the plates, the Compressor may be used to unclamp the plates of the implant. The round cut outs on the feet of the Compressor instrument are designed to provide supplemental force to open the plates if repositioning is desired (**Fig. 9**). First, slowly turn the Inserter Inner Shaft fully counterclockwise until a stop is felt. Do not attempt to overcome the stop during this loosening step. Align the round cut outs of the Compressor with the laterally-protruding plate posts of the implant and squeeze the Compressor handle (**Fig. 10**).



Figure 9

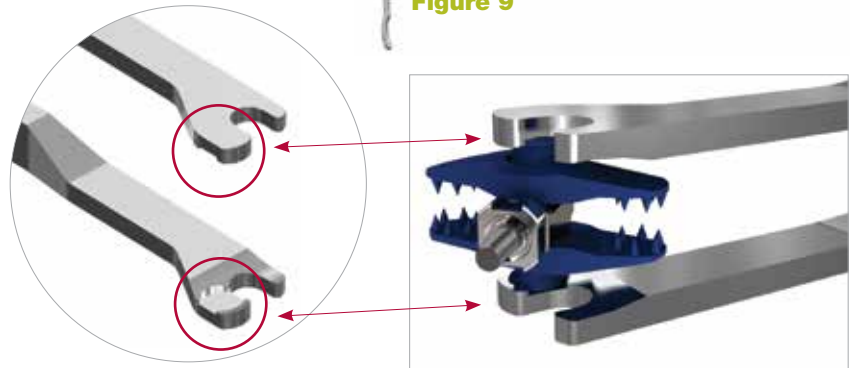


Figure 10

Step 10: Final Implant Locking:

Continue turning the Inserter Inner Shaft clockwise until fully tightened. The final tightened position can be confirmed by tactile feedback and the visual indication that the implant plates and spikes are fully engaged with the spinous processes (**Fig. 11**). The torque-limiting handle, indicated by an audible click, prevents the user from torquing beyond 4.95 Nm. The torque-limiting handle and audible click are safety features designed to prevent the user from damaging or destroying the device due to over-torquing. If torque beyond 4.95 Nm is necessary to achieve final locking of the implant, the Compressor should be used to apply supplemental clamping force to the lateral plate surfaces. Refer to Step 9 on the previous page.

NOTE: Because of the torque-limiting feature, the designated UniVise Inserter Inner Shaft Handle must be used and is not interchangeable with any other AO Connection Handle.

NOTE: Verify desired spine position before final implant locking. Verify position using direct visualization, and A/P and lateral fluoroscopy.

PRECAUTION: Do not over tighten. Doing so may damage the spinous processes.

NOTE: If extremely hard cortical bone is encountered, it may be necessary to use the Compressor provided in the set to apply supplemental clamping force to the lateral plate surfaces while closing the implant plates.



Figure 11

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Step 11: Inserter Instrument Removal

Remove the Inserter Inner Shaft from the Inserter (Fig. 12).



Figure 12

To detach the implant from the Inserter, turn the Inserter dial counterclockwise towards the unlocked position until the dial will not rotate further.

Carefully withdraw the Inserter.

NOTE: If implant resists detachment you may apply minimal twisting motion to the Inserter while withdrawing. Do not apply excessive force when withdrawing the Inserter.

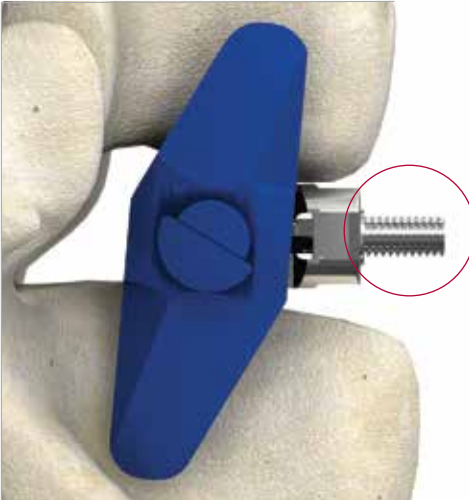
NOTE: If the proximal end of the actuator shaft protrudes excessively after placement, e.g., beyond the dorsal tip of the spinous processes, the clinician may elect to cut the excess shaft away with a rod cutter. In the event that after cutting the actuator shaft of the implant needs be removed, refer to the **Implant Removal** section of this technique.

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Step 12: Removing Excess Actuator Shaft

To cut and remove excess actuator shaft, first select an appropriately sized *in-situ* rod cutter. Carefully place the rod cutter distal end over the actuator shaft and squeeze the handles until the desired portion of the actuator shaft is removed. Use care to ensure that you are not applying torque to the spinous processes. Maintain direct visualization of the cut section at all times and secure for removal from the surgical site.



WARNING: Do not attempt to reuse a device after cutting the actuator shaft, as failure of the locking mechanism may result. Select a new device.

Complete final visual and fluoroscopic inspection of the implant in its fully closed and locked position (**Fig. 13**).

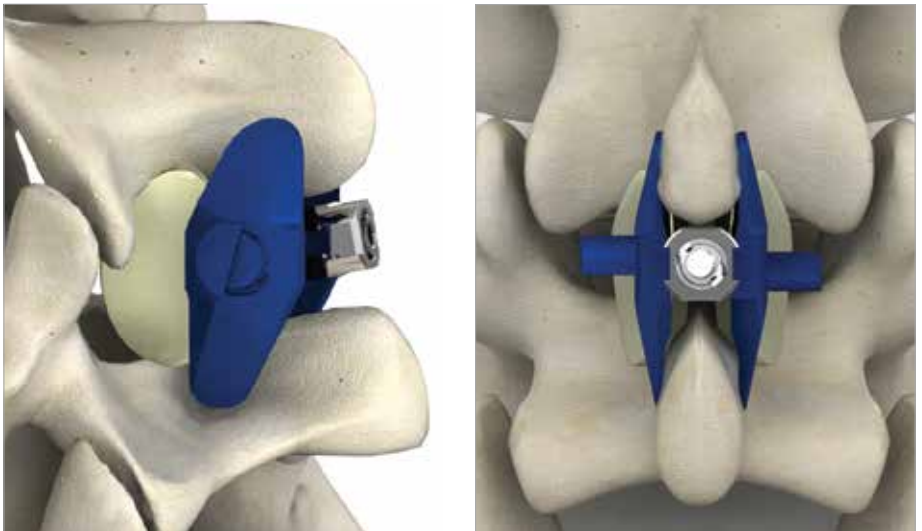


Figure 13

Implant Removal

A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in device positioning, etc. If necessary, the UniVise implant can be removed. The surgeon must use his/her professional judgment to determine the appropriate revision strategy taking into consideration the patient's health, the reason for revision, the patient's bone quality, and the surgeon's expertise with other spinal treatments and instrumentation.

If implant removal is required:

Access the implant site with the preferred posterior surgical approach and retract the paraspinal muscles to allow full direct visualization of the implant body and plates. Remove any soft tissue or bone from around the implant to allow the Inserter to be reattached to the implant and to permit the implant plates to be reopened.

Before reattaching the implant, ensure the Inserter dial is rotated to the unlocked position.

- Step 1:** Align the arrow on the body of the implant with the arrow on the distal tip of the Inserter.
- Step 2:** Turn the Inserter dial towards the locked position until the dial cannot be rotated further and the implant is securely reattached, similar to the depth used during implant loading in Figure 3 on page 7, and the arrow on the dial of the Inserter aligns with the locked symbol on the handle of the Inserter. Do not over tighten.
- Step 3:** Insert the Inserter Inner Shaft through the proximal entry point of the Inserter and gently rotate clockwise until the distal end of the Inserter Inner Shaft is properly seated on the implant.
- Step 4:** Press the Inserter Inner Shaft gently and turn fully counterclockwise to unlock the implant plates.
- Step 5:** The Compressor may be used to unclamp the implant plates from the spinous process after the implant plates are unlocked using the Inserter Inner Shaft. To do so, align the round cut outs on the feet of the Compressor instrument with the laterally-protruding plate posts of the implant and squeeze the handle of the Compressor. Alternatively, the implant plates may be manually separated. Use care to avoid the implant plate spikes and possible spinous process damage.
- Step 6:** Remove the Inserter Inner Shaft from the Inserter.
- Step 7:** Carefully remove the attached implant and Inserter from the surgical site.
- Step 8:** To detach the implant from the Inserter, turn the Inserter dial towards the unlocked position until the dial comes to a stop.

CAUTION: The implant spikes are sharp. Handle implant carefully at all times.

CAUTION: Do not reuse an implant which has been implanted and final locked.



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Set Definition - Instruments

	P/N	Description	Quantity in Set
	48590135	35mm Trial	1
	48590140	40mm Trial	1
	48590100	Inserter	1
	48590101	Inserter Inner Shaft	1
	48590102	Inserter Inner Shaft Handle	1
	48590103	Compressor	1
	48758401	Rasp/Scraper	1
	48758000	Cobb Elevator 16mm Angled Tip	1
	48252506	Kerrison Rongeur, Bayonet, 40° x 2mm	1
	48252507	Kerrison Rongeur, Bayonet, 40° x 3mm	1
	48252508	Kerrison Rongeur, Bayonet, 40° x 4mm	1
	48360134	Reliance Pituitary Rongeur 2mm	1
	48590104	Lamina Spreader	1
	48590105	Lamina Spreader with Teeth	1
	48590000	Container	1

Set Definition - Implants

	P/N	Description	Quantity in Set
	48590035	35mm UniVise Spinous Process Fixation Plate	3
	48590040	40mm UniVise Spinous Process Fixation Plate	3

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STRYKER SPINE UniVise Spinous Process Fixation Plate

STERILE PRODUCT

INDICATIONS

The UniVise Spinous Process Fixation Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The UniVise Spinous Process Fixation Plate is intended for use with bone graft and is not intended for stand-alone use.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Allergy or sensitivity to titanium or titanium alloy;
- Active or suspected systemic infection, or infection or inflammation localized to the site of implantation;
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable *in situ*;
- Any condition that may affect the process of normal bone remodeling, including, but not limited to osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis;
- Patients who are immune-compromised;
- Morbid obesity;
- Alcoholism or heavy smoking;
- Pregnancy;
- The UniVise Spinous Process Fixation Plate is also contraindicated where:
 - An anatomical deficit exists in the lamina or posterior arch (i.e. laminectomy, or incompetent spinous processes), or;
 - There is a significant instability of the lumbar spine, e.g., isthmus spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4), or;
 - There is an acute fracture of the spinous process, Pars interarticularis or laminae fracture (unilateral or bilateral).
- Any case requiring the mixing of metals from two different systems.
- Any patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation implants.

As in any surgical condition, these contraindications may be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

INSTRUMENTS

Surgical instruments are provided by Stryker Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments, which have experienced extensive use or extensive force, are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery. Instruments must be properly cleaned, maintained and lubricated as usually recommended for all surgical instruments.

REUSE

Re-sterilization of the implants is strictly forbidden, regardless of the method that might be employed. Never reuse or reimplant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

HANDLING

Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

IMPLANT SELECTION AND USE

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient. Patients who are overweight may experience additional stresses and strains on the device, which may cause metal fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates only is recommended if necessary according to the surgical technique of each system. Rods or plates must only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Stryker Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

GENERAL CONDITIONS OF USE

The implantation of a spinal fixation system must be performed by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in this Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion must be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up. The surgeon must warn the patient of the surgical risks and make the patient aware of possible adverse effects. The

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surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warned them of the potential consequences. For patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

INFECTION

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES

When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

METAL COMPONENTS

Some of the alloys used to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as

rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system must not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of STRYKER Spine for the performance of the resulting mixed component implant.

POSTOPERATIVE CARE

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants, which may lead to fixation or implant failure and accompanying clinical problems. The surgeon must also instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

Include but are not limited to:

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated *in vivo*, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices

which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.

- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.
- Failure of the device/procedure to improve symptoms and/or function.
- Complications due to the use of bone grafting, including donor site complications.

Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary.

UniVise Spinous Process Fixation Plate System

Surgical Technique

REMOVAL OF IMPLANTS

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Bone growth restraint due to the presence of the implants
- Failure or mobilization of the implant

Instruments are provided by Stryker Spine to be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal must be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

PRE-OPERATIVE PRECAUTIONS

Surgical Technique brochures may be requested from a distributor or from Stryker Spine directly. Those using brochures published more than two years before the surgical intervention are advised to obtain an updated version.

Stryker Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Stryker Spine. For example, the forces exerted when repositioning an instrument *in-situ* must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Stryker Spine Surgical technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments may be reused after decontamination, cleaning and sterilization.

CAUTIONS

Federal (USA) law restricts these devices to sale by, or on the order of, a licensed physician.

The UniVise Spinous Process Fixation Plate is manufactured from titanium alloy, which is known to produce MRI artifacts. Patients should be warned to disclose the presence of the UniVise Spinous Process Fixation Plate prior to an MRI exam. Failure to do so may affect the quality of diagnostic information obtained from the scans.

The implant spikes are sharp! Handle implant with care at all times to avoid injury.

Do not reuse an implant that has been implanted, deployed, and locked.

WARNINGS

- Use of an undersized device in an area of high functional stresses may lead to inadequate fixation or possible SP fracture.
- A single plate should never be used across more than one level.
- Plates, rods and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the spine.
- The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
- Over-distraction with a laminar spreader, distractor screws, or other instrumentation may cause damage to the spinous process or lamina.
- If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure because incorrect placement may result in device dislodgement. Alternative fixation methods should be available intraoperatively.

- In the event the user elects to cut the protruding proximal end of the actuator shaft after placement of the implant and subsequently re-engages and removes the implant, do not attempt to re-use that implant or locking mechanism failure may occur. Select a new device to complete the procedure.
- The UniVise Spinous Process Fusion Plate has not been evaluated for safety and compatibility in the MR environment. The UniVise Spinous Process Fusion Plate has not been tested for heating or migration in the MR environment.

PRECAUTIONS

- The implantation of the UniVise Spinous Process Fixation Plate should be performed only by experienced spinal surgeons with specific training in the implantation of the device because this is a technically demanding procedure presenting risk of serious injury to the patient. The techniques for implanting the UniVise Spinous Process Fixation Plate should be thoroughly reviewed and understood by the surgeon prior to use of the system.
- Surgeons should not implant the UniVise Spinous Process Fixation Plate until receiving adequate training in surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events.
- When operating at the L5/S1 level, a preoperative CT reconstruction is recommended to verify the presence and size of the S1 spinous process, and to ensure the implant will have sufficient support to achieve fixation.
- Exercise caution when considering use of the UniVise Spinous Process Fixation Plate in patients having abnormal curvature of the spine, or misaligned spinous processes, as failure to achieve adequate fixation of the device to the spinous processes may result.
- If performing a decompression, or when preparing the site for device placement, do not remove excessive lamina or other bone, as excessive bone removal may compromise the bony structure supporting the spinous processes at the operative level.
- Use care when distracting the spinous processes to avoid damage. Do not over-distract.
- Do not over-tighten the implant after placement, or spinous process damage may result.

UniVise Spinous Process Fixation Plate System

Surgical Technique

Reconstructive

Hips
Knees
Trauma & Extremities
Foot & Ankle
Joint Preservation
Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories
Computer Assisted Surgery
Endoscopic Surgical Solutions
Integrated Communications
Beds, Stretchers & EMS
Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants



Stryker Spine
2 Pearl Court
Allendale, NJ 07401-1677 USA
t: 201-760-8000
www.stryker.com

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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