Reline Fenestrated

Technique guide

NuVasive

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of Reline Fenestrated. It may not be appropriate for all patients and all patients may not benefit.

This surgical technique guide offers guidance but, as with any such technique guide, each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning. Please refer to the corresponding instructions for use (IFU).

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

Please refer to the corresponding IFU for important product information, including, but not limited to, indications, contraindications, warnings, precautions and adverse effects.

Contents

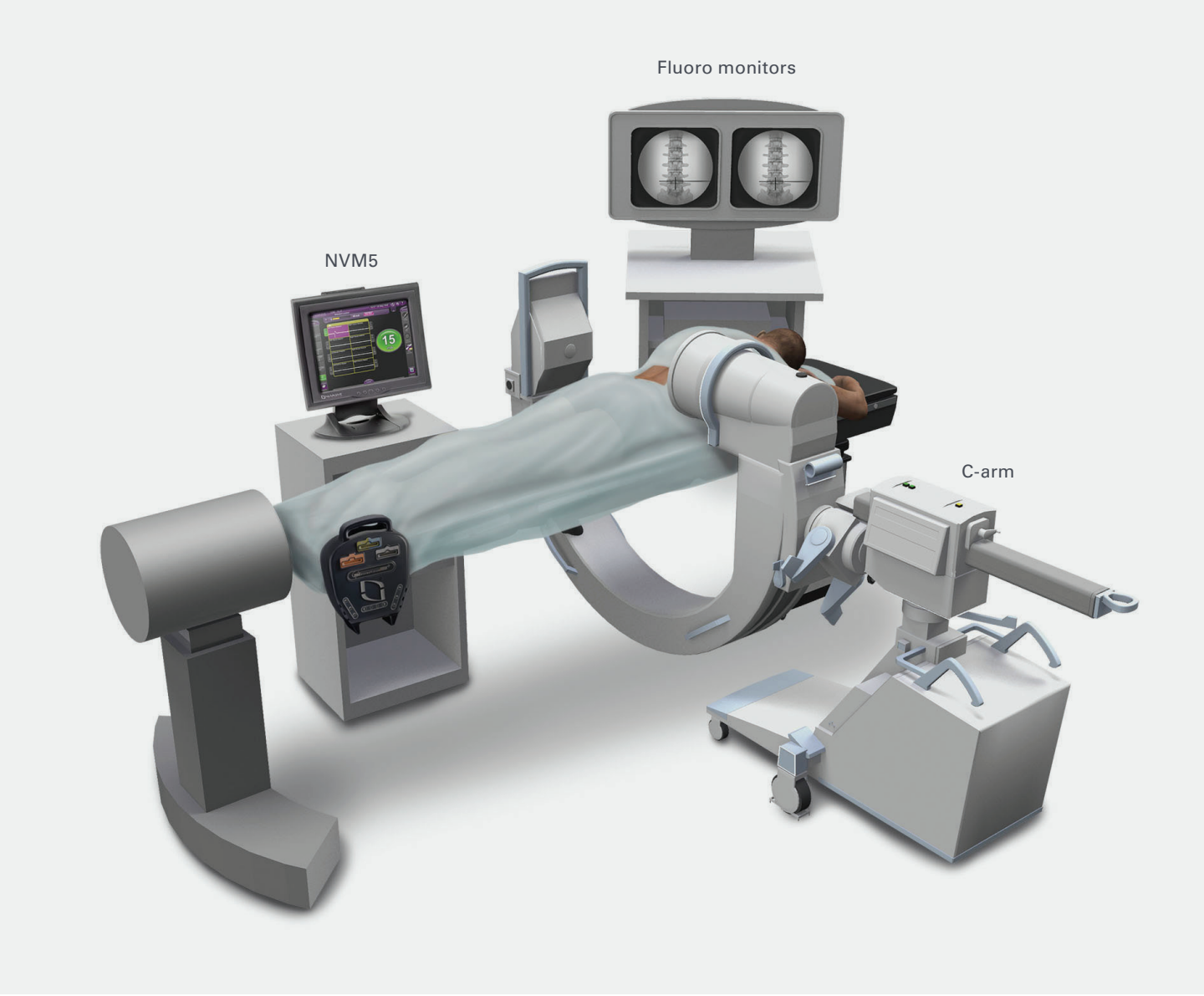
Reline Fenestrated open delivery surgical technique

Equipment requirements

- Reline instrument and implant trays
- Refer to the Reline technique guide (document #9501354) for screw placement.

Patient positioning and OR setup

- Refer to the Reline technique guide.



Pedicle preparation and screw insertion

Place Reline Fenestrated open pedicle screws into the operative vertebral level using standard technique. Refer to the Reline technique guide steps 1 and 2. Confirm final screw positioning with A/P and lateral fluoroscopy.

Precautions: *Prior to injection of the cement into the Reline Fenestrated screws, it is important to radiographically confirm the position of each screw using A/P and lateral fluoroscopy. Once the cement has been injected, the position of the Reline Fenestrated screws cannot be modified.*

Confirm that the tips of all Reline Fenestrated screws are within the vertebral body and not beyond the anterior cortex.

Because the Reline Fenestrated screws feature six fenestrations in the distal third of the screw shank, confirm that all fenestrations are within the vertebral body and not located in the pedicle.

Step 1

Attach open quick connect needle guide

Check that the device is clear of any cement prior to use.

Align the distal arms of the quick connect needle guide with the rod slot in the tulip *(Fig. 1)*. Extended arms of the quick connect needle guide should engage the proximal undercut feature of the tulip. In order to seat the needle guide, press down and perform a gentle orbital rotation of the needle guide so that the distal tip finds and engages the cannula of the bone screw *(Fig. 2)*.

When the needle guide and screw are coaxially aligned, the device will lock into place. The quick connect needle guide arms provide tactile and audible feedback when engaged. Confirm needle guide attachment by gently pulling up on the device. Use a quick connect needle guide for each screw intended for screw augmentation.

Fig. 1

Fig. 2

Step 2

Attach additional quick connect needle guides

Repeat step 1 until quick connect needle guides are attached to all levels intended for augmentation. **Do not** mix the cement until correct alignment is confirmed at all levels.

Warning

If a biopsy is completed prior to screw placement, care must be taken not to place the tip of the biopsy needle beyond the desired location of the screw tip in order to reduce the risk for cement leakage or extravasation.

Step 3

High viscosity PMMA bone cement (i.e., cement) preparation

Once the Reline Fenestrated screws are in place and the quick connect needle guides are attached to the levels selected to be augmented, prepare the cement.

Note: *For cement preparation, refer to the cement package inserts and IFU.*

Note: *Reline Fenestrated screws are intended to be used with high viscosity polymethyl methacrylate (PMMA) bone cement (initial viscosity of 1300 Pa-s immediately after mixing).*

Step 4

Assemble the delivery needle

Couple the luer lock of the cement delivery system to the Reline Fenestrated open delivery needle by rotating the connection clockwise. Confirm that the connection is secure to prevent cement leakage.

Step 5

Insert delivery needle

Insert the distal tip of the Reline Fenestrated open delivery needle into the quick connect needle guide. Slightly depress the button on the proximal end of the needle guide to fully seat the needle *(Fig. 3)*.

Note: *Additional orbital rotation may be required to achieve complete coaxial alignment. When aligned, the proximal feature on the delivery needle will be captured in the guide.*

Once the delivery needle is attached correctly to the needle guide, it will sit approximately 6 mm inside the screw shank.

Note: *To confirm that the delivery needle is correctly positioned to deliver cement, the needle must lock into place before proceeding to the next step (you may hear a click). The proximal flat on the black part of the delivery needle will sit flush with the top of the quick connect needle guide when assembled.*

If there is any difficulty inserting the delivery needle into the screw shank, confirm that the screw and needle guide are completely coaxial.

Fig. 3

Step 6

Cement delivery

For cement delivery, refer to the cement package inserts and IFU.

Note: *If cement leakage or extravasation is detected during injection, stop the injection immediately.*

Step 7

Removal of delivery needle

When the appropriate amount of cement has been introduced, stop cement introduction as indicated in the cement package inserts and IFU.

Slightly depress the gold button on the proximal end of the quick connect needle guide to release the delivery needle *(Fig. 4)*. Slide the needle out of the needle guide.

Precaution: *Back off pressure of delivery system to stop flow of cement prior to removal of delivery needle from screw.*

Step 8

Subsequent level augmentation

Place the existing delivery needle and cement delivery system into the next quick connect needle guide and repeat steps 5 through 7.

Repeat for each desired vertebral level, confirming that cement flow has stopped between each level. If an additional cement kit is needed, use a new delivery needle.

Note: *If pressure in the cement delivery system is not sufficient to deliver cement (within the cement working time), a new delivery needle may be required.*

Fig. 4

Step 9

Plunge cement (optional)

The plunger can be used to pass the cement remaining in the delivery needle into the screw. Once the cement delivery system has been removed from the delivery needle, proceed with the plunger insertion.

Tip: *This will deliver at most an additional 0.6 cc of cement through the fenestrations.*

Step 10

Removal of quick connect needle guide(s)

Depress the tabs on the sides of the quick connect needle guide and pull up to release from the tulip of the screw *(Fig. 5)*.

Tip: *If there is difficulty removing the quick connect needle guides, rotate the needle guide 90° and depress the tabs to remove. This should free the quick connect arms from any soft tissue and bony anatomy.*

Note: *See Reline technique guide for rod insertion. To determine whether the cement is set in accordance with the guidelines, refer to the cement package inserts and IFU.*

Fig. 5

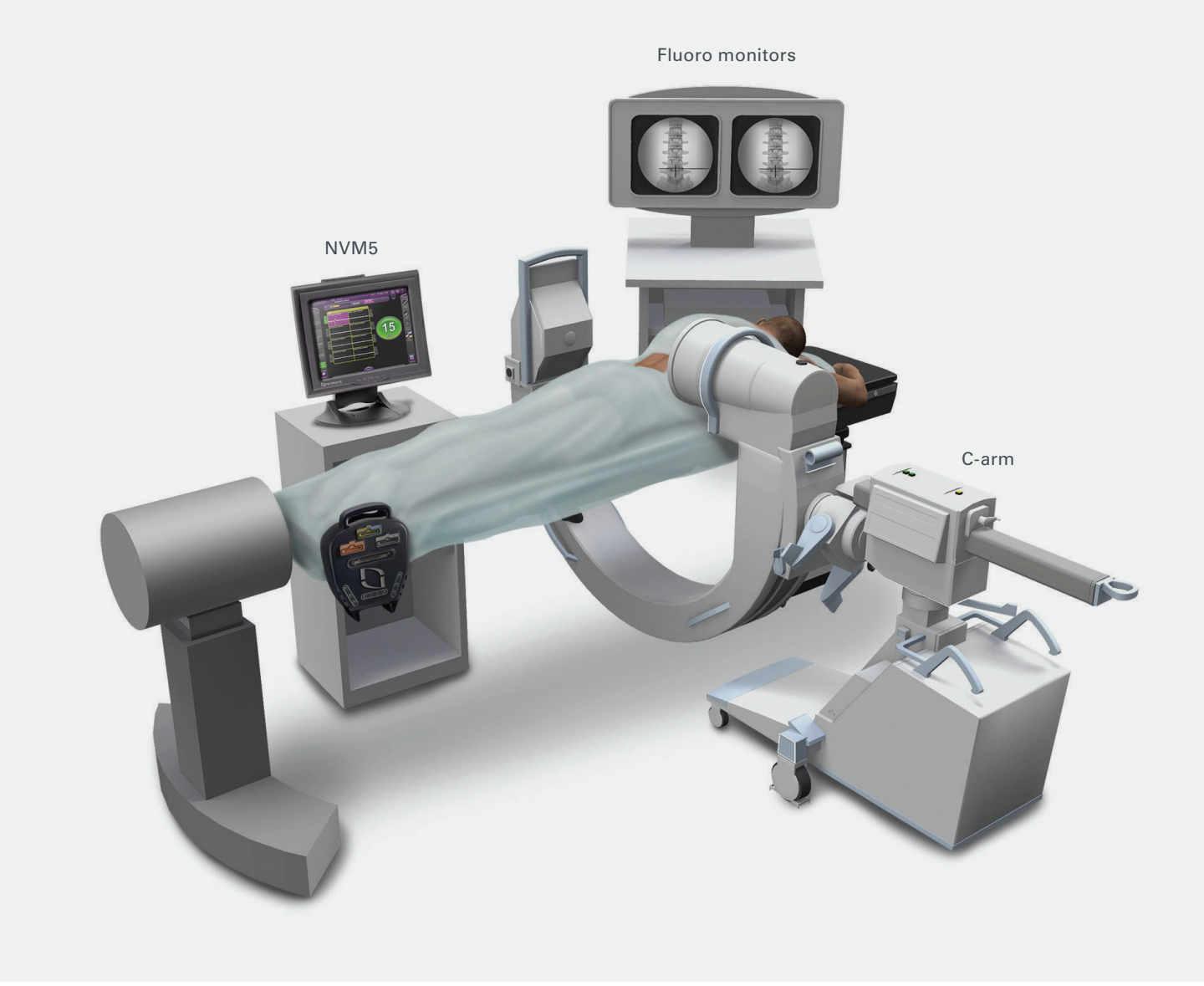
Reline Fenestrated MAS delivery surgical technique

Equipment requirements

- Reline maxiumum access surgery (MAS) instrument and implant trays
- Refer to the Reline technique guide (document #9501354) for screw placement.

Patient positioning and OR setup

- Refer to the Reline technique guide.



Pedicle preparation and screw insertion

Place Reline Fenestrated MAS pedicle screws into the operative vertebral level using standard technique. Refer to the Reline technique guide steps 1 and 2. Confirm final screw positioning with A/P and lateral fluoroscopy.

Precautions: *Prior to injection of the cement into the Reline Fenestrated screws, it is important to radiographically confirm the positioning of each screw using A/P and lateral fluoroscopy. Once the cement has been injected, the position of the Reline Fenestrated screws cannot be modified.*

Verify that the tips of all Reline Fenestrated screws are within the vertebral body and not beyond the anterior cortex.

Because the Reline Fenestrated screws feature six fenestrations in the distal third of the screw shank, verify that all fenestrations are within the vertebral body and not located in the pedicle.

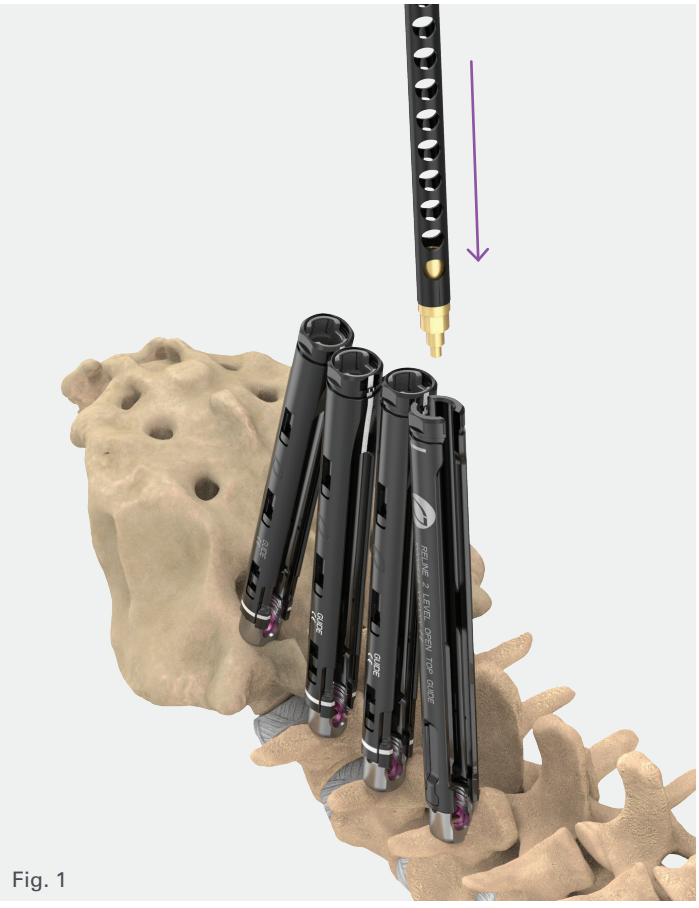


Fig. 1

Step 1

Attach MAS quick connect needle guide

Check that the device is clear of any cement prior to use.

Insert the quick connect needle guide through the Reline MAS guide and slide down to the tulip *(Fig. 1)*. In order to seat the distal tip, rotate the quick connect needle guide to become coaxial with the screw shank. Once aligned, apply downward pressure until the needle guide locks on to the outer Reline MAS guide. Confirm needle guide attachment by gently pulling up on the device *(Fig. 2)*. Use a quick connect needle guide for each screw intended for screw augmentation.

Fig. 2

Step 2

Attach additional quick connect needle guides

Repeat step 1 until quick connect needle guides are attached to all levels intended for augmentation. **Do not** mix the cement until correct alignment is confirmed at all levels.

Warning

If a biopsy is completed prior to screw placement, care must be taken not to place the tip of the biopsy needle beyond the desired location of the screw tip in order to reduce the risk for cement leakage or extravasation.

Step 3

High viscosity PMMA bone cement (i.e., cement) preparation

Once the Reline Fenestrated MAS screws are in place and the quick connect needle guides are attached to the levels selected to be augmented, prepare the cement.

Note: *For cement preparation, refer to cement package inserts and IFU.*

Note: *Reline Fenestrated screws are intended for use with high viscosity PMMA bone cement (initial viscosity of 1300 Pa-s immediately after mixing).*

Step 4

Assemble the delivery needle

Couple the luer lock of the cement delivery system to the Reline Fenestrated MAS delivery needle by rotating the connection clockwise. Confirm that the connection is secure to prevent cement leakage.

Step 5

Insert delivery needle

Insert the distal tip of Reline Fenestrated MAS delivery needle into the quick connect needle guide. Slightly depress the gold button on the proximal end of the needle guide to fully seat the needle *(Fig. 3)*.

Note: *Additional orbital rotation may be required to achieve complete coaxial alignment. When aligned, the proximal feature on the delivery needle will be captured in the guide.*

Once the delivery needle is attached correctly to the needle guide, it will be approximately 6 mm inside the screw shank.

Note: *To confirm that the delivery needle is correctly positioned to deliver cement, the needle must lock into place before proceeding to the next step (you may hear a click). The proximal flat on the black part of the delivery needle will sit flush with the top of the quick connect needle guide when assembled.*

If there is any difficulty inserting the delivery needle into the screw shank, confirm that the screw and needle guide are completely coaxial.

Fig. 3

Step 6

Cement delivery

Precaution: *For cement delivery, refer to cement package inserts and IFU.*

Note: *If cement leakage or extravasation is detected during injection, stop the injection immediately.*

Step 7

Removal of delivery needle

When the intended amount of cement has been introduced, stop cement introduction as indicated in the cement package inserts and IFU.

Slightly depress the gold button on the proximal end of the quick connect needle guide to release the delivery needle. Slide needle out of the needle guide.

Precaution: *Back off pressure of delivery system to stop flow of cement prior to removal of delivery needle from screw.*

Step 8

Subsequent level augmentation

Place the existing delivery needle and cement delivery system into the next quick connect needle guide and repeat steps 5 through 7.

Repeat for each desired vertebral level, confirming that cement flow has stopped between each level. If an additional cement kit is needed, use a new delivery needle.

Note: *If pressure in the cement delivery system is preventing cement delivery (within the cement working time), a new delivery needle may be required.*

Step 9

Plunge cement (optional)

The plunger can be used to pass the cement remaining in the delivery needle into the screw. Once the cement delivery system has been removed from the delivery needle, proceed with the plunger insertion.

Tip: *This will deliver at most an additional 0.75 cc of cement through the fenestrations.*

Step 10

Removal of quick connect needle guide(s)

Depress the proximal silver tabs on the sides of the quick connect needle guide and pull up to release from the tulip of the screw *(Fig. 4)*.

Note: *See the Reline technique guide for rod insertion. To determine whether the cement is set in accordance with the guidelines, refer to the cement package inserts and IFU.*

Fig. 4

Instructions for use

Fenestrated screws with PMMA bone cement pedicle screw system **IFU**

Rx only

GRAPHICAL SYMBOLS	
	Consult instructions before use
	Single use only
REF	Catalog number
LOT	Lot number
QTY	Quantity
MATL Ti6Al-4V PMMA	Material: titanium alloy, polymethylmethacrylate
	Non-sterile, sterilize by steam before use

Description

The Reline Fenestrated screws are part of the Reline system and are manufactured from Ti-6Al-4V ELI per ASTM F136 and ISO 5832- 3.

Indications for use OUS

When used in conjunction with PMMA bone cement, the Reline Fenestrated screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Reline Fenestrated screws augmented with PMMA bone cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Refer to selected PMMA bone cement IFU for information related to PMMA bone cement.

Reline Fenestrated screws are recommended for use with high viscosity PMMA bone cement with initial viscosity of 1300 Pa-s immediately after mixing.

Indications for use US

When used in conjunction with high V+ bone cement, Reline Fenestrated screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. Reline Fenestrated screws augmented with high V+ bone cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

When used in conjunction with the Reline Fenestrated screws, high V+ bone cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. High V+ bone cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

Refer to high V+ bone cement IFU for information related to high V+ bone cement.

Contraindications

Contraindications include but are not limited to:

1. infection, local to the operative site,
2. signs of local inflammation,
3. patients with known sensitivity to the materials implanted,
4. patients who are unwilling to restrict activities or follow medical advice,
5. patients with inadequate bone stock or quality,
6. patients with physical or medical conditions that would prohibit beneficial surgical outcome, and
7. reuse or multiple use.

Potential adverse events and complications

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur include: cement leakage (intervertebral foramina, spinal canal, adjacent discs, epidural vessels, paravertebral segmental veins, renal vein, inferior vena cava, pulmonary vein), cement embolism, cement-related cardiopulmonary complications, tissue necrosis from cement heat, vertebral body fractures, inadequate screw fixation, difficulty with screw or cement removal, early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings, cautions and precautions

The subject device is intended for use only as indicated.

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Reline Fenestrated screws are intended to be used only in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

If a biopsy is completed prior to screw placement, care must be taken not to place the tip of the biopsy needle beyond the desired location of the screw tip in order to reduce the risk for cement leakage or extravasation.

For cement-augmented pedicle screws, it is critically important to avoid breaches of the pedicle walls and the vertebral body cortex with instruments, such as drill tips, taps, probes and Kirschner wires. If the pedicle wall or vertebral body cortex has been breached, do not inject bone cement into either pedicle screw at this level.

For cement-augmented pedicle screws, it is critically important to avoid breaches of the pedicle walls and the vertebral body cortex. If the pedicle wall or vertebral body cortex has been breached, do not inject bone cement into either pedicle screw at this level.

Prior to injection of bone cement into the Reline Fenestrated screws, it is important to radiographically confirm the proper positioning of each screw using AP and lateral fluoroscopy. Once the bone cement has been injected, the position of the Reline Fenestrated screws cannot be modified.

Verify that the tips of all Reline Fenestrated screws are within the vertebral body and not beyond the anterior cortex.

Because the Reline Fenestrated screws feature fenestrations in the distal third of the screw shank, verify that all fenestrations are within the vertebral body and not located in the pedicle.

If cement leakage is detected during injection, stop the injection.

Manipulation of the cement-augmented Reline Fenestrated screws, such as rod reduction, compression, distraction and final tightening, should be delayed until after the setting time of the bone cement.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone. Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or non-union. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Care should be taken to confirm that all components are ideally fixated prior to closure.

All implants should be used only with the appropriately designated instrument (reference surgical technique).

Do not reuse

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables and transmission of infectious agents.

Patient education

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Magnetic resonance (MR) safety

Refer to Reline system IFU for MR safety information for each system.

Compatibility

Refer to Reline system IFU for compatibility information for each system.

Preoperative warnings

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, and from corrosive environments.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.
6. Refer to selected PMMA bone cement IFU for information related to PMMA bone cement and delivery.

Intraoperative warnings

1. Do not inject the PMMA bone cement into the Reline Fenestrated screw until it has reached the proper viscosity.
2. Before delivery, dispense a small sample of the PMMA bone cement from the delivery device to confirm proper viscosity.
3. When the proper viscosity has been reached, the PMMA bone cement can be injected following the screw surgical technique.
4. Back off pressure of delivery system to stop flow of PMMA bone cement prior to removal of delivery needle from screw.
5. While the PMMA bone cement hardens, it is important to maintain patient positioning until the end of the polymerization or hardening process.
6. PMMA bone cement injection should only be performed under fluoroscopic control.
7. It is recommended that a maximum of 0.8 cc of PMMA bone cement be injected in the vertebral body for each screw in the thoracic spine (except T11 and T12) and that a maximum of 1.8 cc of PMMA bone cement be used in the lumbar spine along with T11 and T12. However, the volume of PMMA bone cement used in the Reline Fenestrated screws should ultimately be determined by the surgeon based on individual patient anatomy.

Postoperative warnings

During the postoperative phase, it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as other complications. To confirm the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

NuVasive, Inc.
7475 Lusk Blvd., San Diego, CA 92121 USA
+1 800.475.9131

EC REP **NuVasive Netherlands B.V.**
Jachthavenweg 109A, 1081 KM Amsterdam, The Netherlands
+31 20 72 33 000

©2020. NuVasive, Inc. All rights reserved. 9511358 C

CE 2797

nuvasive.com

NUVASIVE