

AURORA™



ZIP LP



ZIP ULTRA



ZIP 51

zip PRODUCT LINE™

MIS INTERSPINOUS FUSION SYSTEMS

SURGICAL TECHNIQUE GUIDE

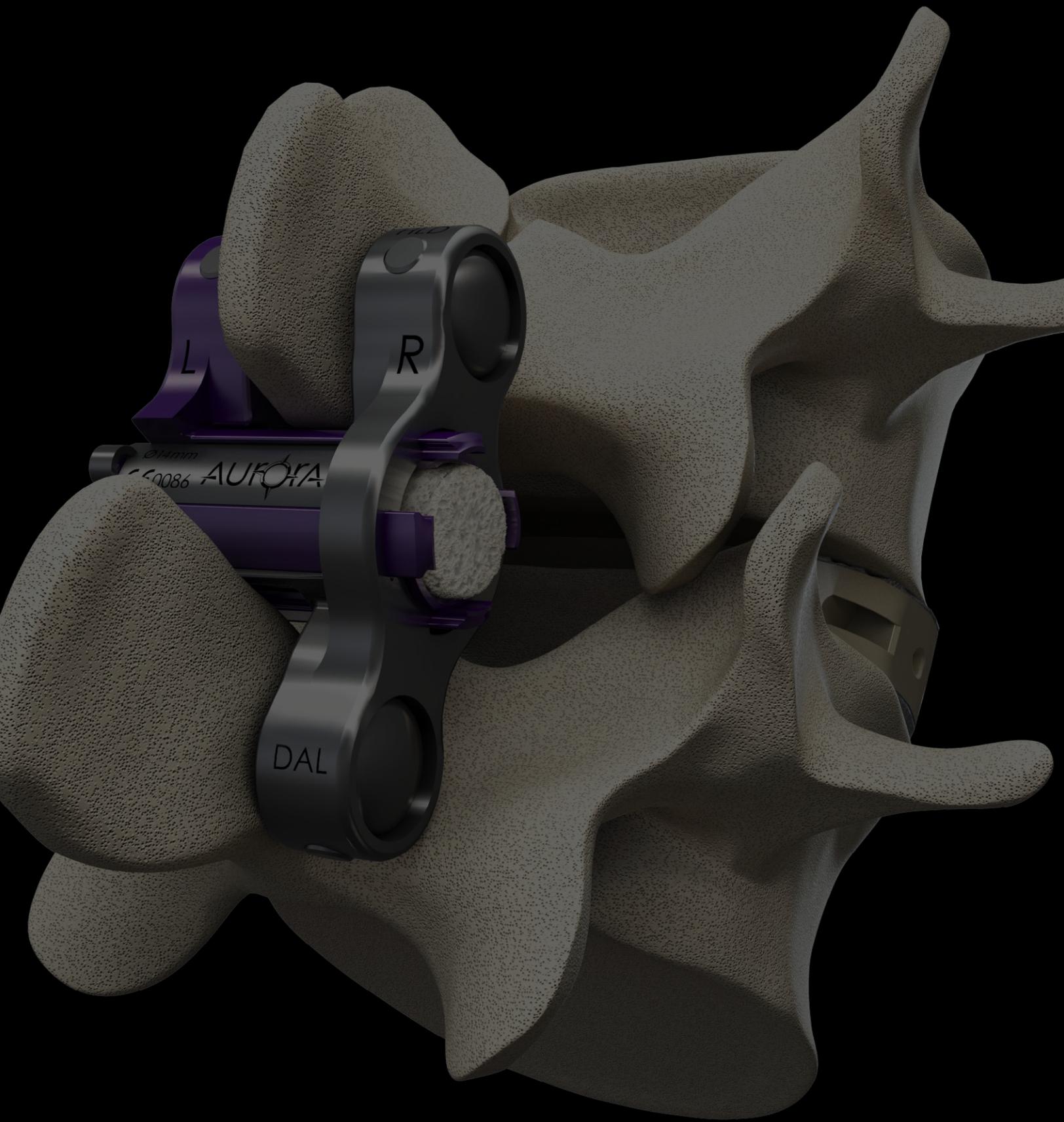


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CAUTION: Federal Law restricts this device to sale by or on the order of a licensed physician.

As with all orthopedic surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those with specialized training and experience in spinal surgery should attempt to use the Aurora ZIP MIS Interspinous Fusion System. Refer to the instructions for use for more information.

Introduction of ZIP Product Line

The ZIP® product line has been designed with patients in mind with minimal need for modifications to the existing spinal structure.

"Aurora implants are designed to fit the patient's anatomy versus the patient's anatomy forced to fit the implant...This produces a more natural healing process."

-Dr. Glenn Keiper, Eugene, OR

ZIP product line implants are minimally invasive interspinous fixation implants for spinal fusion and were developed as an alternative to pedicle screw fixation. The implants are designed for stabilization and load sharing in T1-S1 thoracolumbar fusion procedures as an adjunct to interbody fusion, specifically for the treatment of degenerative disc disease, spondylolisthesis, trauma, and/or tumor. The proprietary ZIP ONE-STEP™ locking mechanism eliminates the use of a set screw. Each fusion implant from the ZIP product line features a large barrel designed for ZIP Graft™ or other bone material. ZIP product line implants are designed in various sizes to accommodate variations in patient anatomy.

The use of ZIP product line implants potentially offer several benefits over pedicle screw fixation that include the potential for less blood loss, shorter operating time, shorter duration hospital stay, and faster post-operation recovery time.

Aurora Spine is dedicated to develop and introduce new MIS technologies to help patients return to their full life activities with peace of mind.

Description

ZIP product line implants are minimally invasive interspinous fixation implants for spinal fusion and were developed as an alternative to pedicle screw fixation. The implants are designed for stabilization and load sharing in T1-S1 thoracolumbar fusion procedures as an adjunct to interbody fusion, specifically for the treatment of degenerative disc disease, spondylolisthesis, trauma, and/or tumor.

Materials ZIP Product Line

All Aurora Spine implants are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ISO 5832-3 or ASTM F 136. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Indications for ZIP Product Lines

The Aurora Spine ZIP® MIS Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process 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 Aurora Spine ZIP® MIS Interspinous Fusion System is intended for use with bone graft material and is not intended for stand-alone use.

Contraindications

The contraindications of this system are similar to other systems of similar design.

Contraindications include, but are not limited to, the following conditions:

- Use in the cervical spine
- Infection or inflammation, local to the operative site
- Allergy or sensitivity to titanium
- Patients who are immune-compromised
- Fever or leukocytosis
- Pregnancy
- Fracture of spinous process
- An anatomical deficit exists in the lamina or posterior arch (*i.e. laminectomy, pars defect, or incompetent spinous processes*)
- Any condition that may affect the process of normal bone remodeling, including, but not limited to, rapid joint disease, poor bone quality, osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis.
- Any medical or surgical condition that would preclude the potential benefit of spinal implant surgery (*i.e. elevation of white blood count (WBC) or marked left shift in the WBC differential count*)
- Grossly distorted anatomy due to congenital abnormalities
- Morbid obesity
- Alcoholism or heavy smoking
- Inadequate tissue coverage over surgical site
- A case not needing bone graft, fusion, or fracture healing
- A case requiring the mixing of metals from different components
- A patient unwilling or unable to comply with postoperative instructions
- Any instance in which the implant would interfere with anatomical structures or expected physiological performances
- Reuse or multiple use
- Any case not described in the indications for use
- Prior fusion at the level(s) to be treated

Possible Complications

Possible complications specific to the device may include:

- Implant breakage, failure, loosening, or migration
- Bone fracture or fracture to the spinous process
- Allergic reaction to the implant material

Other general complications associated with any spinal surgery may include:

- Pseudoarthrosis
- Pain
- Revision surgery
- Bleeding
- Infection, early or late
- Tissue or nerve damage
- Spinal fluid leakage
- Scar formation
- Complications due to the use of bone grafting, including donor site complications.

ZIP ULTRA Sizing Options

A (Barrel Diameter)	B (Plate Length)	Graft Volume	CAT #
Ø 8 mm	35 mm	0.295 cc	001-008-S-ZIP
Ø 10 mm	35 mm	0.664 cc	001-010-S-ZIP
Ø 12 mm	35 mm	1.181 cc	001-012-S-ZIP
Ø 14 mm	35 mm	1.846 cc	001-014-S-ZIP
Ø 8 mm	45 mm	0.295 cc	001-008-ZIP
Ø 10 mm	45 mm	0.664 cc	001-010-ZIP
Ø 12 mm	45 mm	1.181 cc	001-012-ZIP
Ø 14 mm	45 mm	1.846 cc	001-014-ZIP
Ø 16 mm	45mm	2.658 cc	001-016-ZIP



ZIP LP Sizing Options

A (Barrel Diameter)	B (Length)	Graft Volume	CAT #
Ø 8 mm	35 mm	0.295 cc	103-008-035
Ø 10 mm	35 mm	0.664 cc	103-010-035
Ø 12 mm	35 mm	1.181 cc	103-012-035
Ø 14 mm	35 mm	1.846 cc	103-014-035
Ø 8 mm	40 mm	0.295 cc	103-008-040
Ø 10 mm	40 mm	0.664 cc	103-010-040
Ø 12 mm	40 mm	1.181 cc	103-012-040
Ø 14 mm	40 mm	1.846 cc	103-014-040
Ø 16 mm	40 mm	2.658 cc	103-016-040



ZIP 51 Sizing Options

A (Barrel Diameter)	B (Length)	Graft Volume	CAT #
Ø 8 mm	35 mm	0.295 cc	104-008-035
Ø 10 mm	35 mm	0.664 cc	104-010-035
Ø 12 mm	35 mm	1.181 cc	104-012-035



Instruments



ZIP Sizer/Distractor | Cat# 001-020



ZIP Compressor, Large | Cat# 001-023



ZIP Removal Tool | Cat# 001-024



ZIP Compressor, Small | Cat# 001-029



ZIP Implant Locator | Cat# 001-037



ZIP Short Compressor | Cat# 100-303



ZIP Tamp | Cat# 001-026



ZIP Grafting Station | Cat# 001-028



ZIP Implant Holder | Cat#001-032



ZIP Rasp | Cat# 001-025

Instructions

NOTE: *The following steps can be used with the ZIP ULTRA, ZIP LP, and ZIP 51.*

1. Place the patient in the surgeon's preferred position on the operating table.
2. Identify the level to be treated. Fluoroscopic identification is critical (because of transitional anatomy).
3. Make a small midline incision on the level to be treated.
4. Dissect down to the spinolaminar junction, on both sides.
5. Carry dissection out of the facet joints. At this point clear visualization of the supraspinous and interspinous ligaments should be in the surgical field.

NOTE: *For an alternative method of ZIP implant surgery saving the interspinous and supraspinous ligament skip to page 13 and follow the remaining steps.*

6. Use rongeur to resect a segment of the supraspinous ligament and remove the interspinous ligament. It is important to avoid over distracting the inner spinous space.

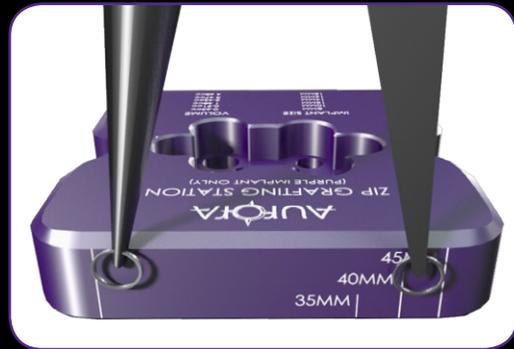
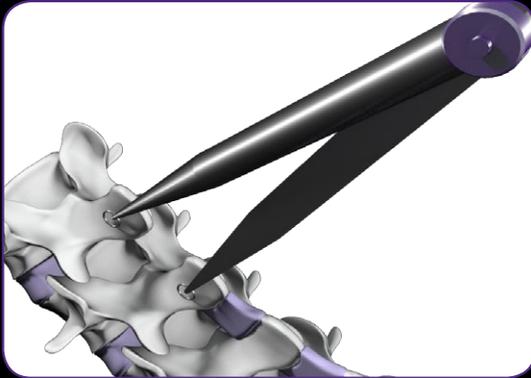


7. To determine barrel diameter, use the ZIP Sizer/Distractor (001-020) with the ratcheting feature engaged to measure the interspinous space.



Instructions Continued

- To determine the proper plate length, use the ZIP Implant Locator (001-037) then compare the outer ring edges with the marked sizes on the side of the ZIP Grafting Station (001-028). Round down if necessary.



- Once the appropriate barrel diameter and plate length have been determined, choose the appropriately sized implant.
- Take the **LEFT** Implant (purple) and place into the ZIP Grafting Station, and pack implant with the appropriate volume of bone graft using the bone tamp when necessary.



- Prepare to engage the **RIGHT** implant (silver) side onto the **LEFT** implant (purple) side. Before engaging, verify that both the purple and silver sides are oriented correctly, with the Aurora Logos and graphic indicators facing the same direction. Engage the two sides only to the first or second tooth.



Instructions Continued

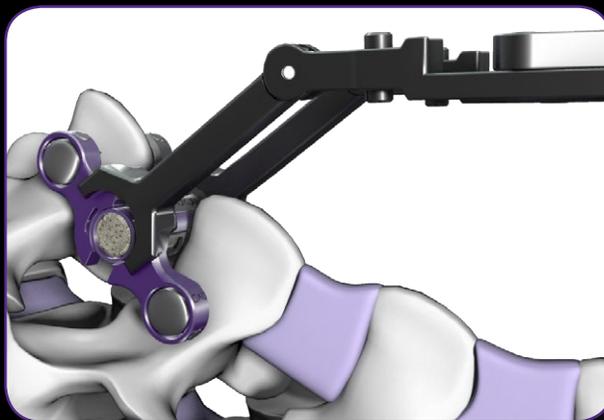
12. Use the ZIP Implant Holder (001-032) to grab along the rim of the implant. You can adjust the grip of the Implant Holder using the adjustment knob at the end of the instrument, prior to clamping. Squeeze the arms shut to clamp.



13. Place the assembled implant into desired position. The implant should be situated at an angle, with the caudal side positioned near the base of the supraspinous process, and the cephalad side approximately 20 degrees higher.



14. Remove the implant holder and attach either the small or the large ZIP Compressor instrument (001-029/001-023). Using the ZIP Compressor, compress the two halves together until the spikes are seated into the bone.

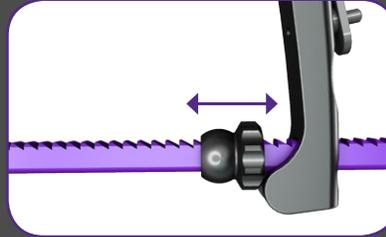


15. Remove ZIP Compressor and assess stability.
Note: After initial implantation, if adjustment of the implant is necessary, the implant is to be removed and replaced with a new implant. The implant should never be disengaged with the ZIP removal tool and re-seated.

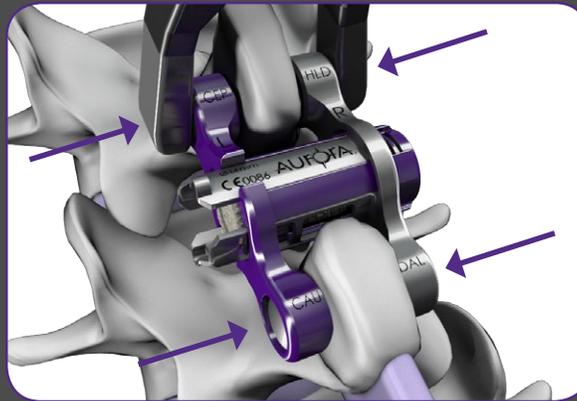
Instructions Continued

OPTIONAL

Place the ZIP ULTRA Short Compressor (100-303) tip over spike area of the implant. At the Surgeon's discretion, determine the maximum compression needed and set the knob on the rack accordingly to allow for additional compression.



Slowly compress the ZIP implant using the ZIP ULTRA Short Compressor over each spike area located at the cephalic and caudal positions to achieve the desired spike penetration.



16. If a ZIP ULTRA implant removal is required, use the ZIP Removal Tool (001-024) to remove the device. Use the gauge on the top of the ZIP Removal Tool to match the barrel diameter and connect the ZIP Removal interface to the silver implant interface.



17. Once the interface is engaged, squeeze the trigger until the locking tabs are disengaged from the purple implant and push the two implant halves apart.
18. Once partially disengaged, use a ZIP Implant holder to lift the ZIP implant assembly off the spine.

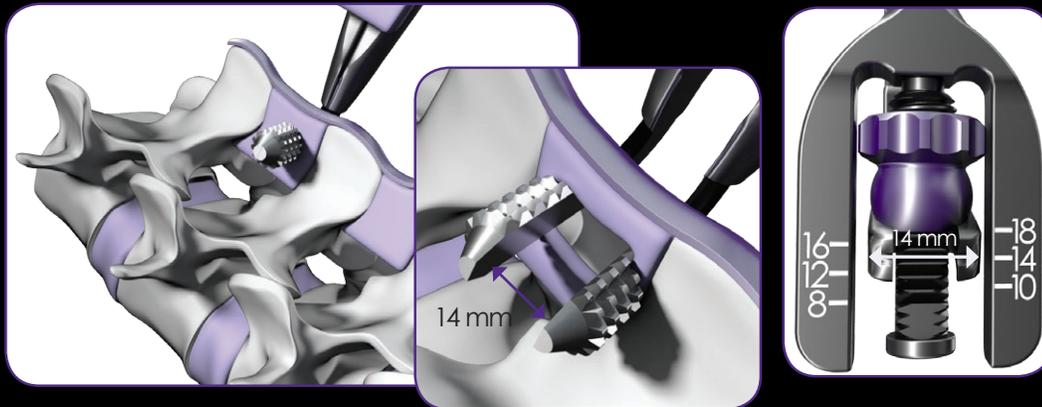
Alternate Steps

Perform Steps 1-5 normally.

IMPORTANT:

Piercing the interspinous ligament too deeply or ventrally can result in neurological injury. Care must be taken to avoid breach of the ligamentum flavum or entry into the epidural space with instruments or implants.

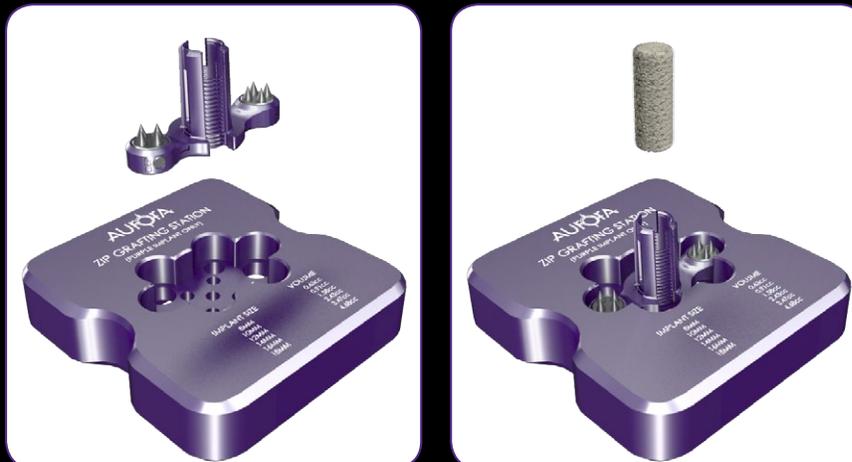
- 6B. Make a cruciate incision in the center of the interspinous ligament.
- 7B. To determine barrel diameter, place the ZIP Sizer/Distractor (001-020) in the punctured cruciate incision and use the ratcheting feature to measure the size of the space.



- 8B. To determine the proper length, use the ZIP Implant Locator (001-037) then compare the outer ring edges with the marked sizes on the side of the ZIP Grafting Station (001-028). Round down if necessary.



- 9B. Once the appropriate barrel diameter and plate length have been determined, choose the appropriately sized implant.
- 10B. Take the **LEFT** Implant (purple) and place into the ZIP Grafting Station, and pack implant with the appropriate volume of bone graft using the bone tamp when necessary.

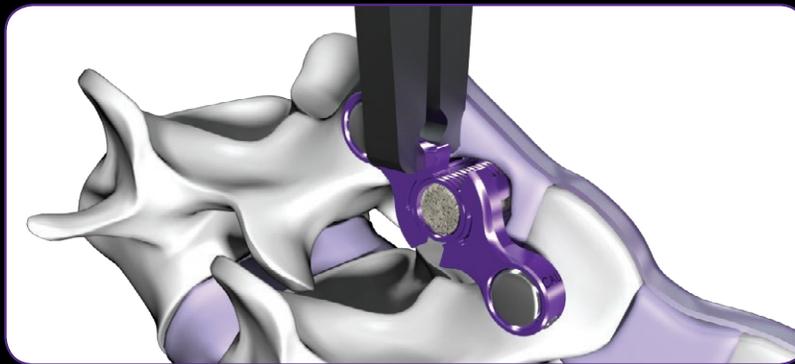


Alternate Steps Continued

- 11B. Use the ZIP Implant Holder (001-032) to grab along the rim of the implant. You can adjust the grip of the Implant Holder using the adjustment knob at the end of the instrument, prior to clamping. Squeeze the arms shut to clamp.



- 12B. Take the ZIP Implant Holder with the **LEFT** implant; pass the cylindrical portion of the **LEFT** implant through the previously prepared opening in the interspinous space. Release the ZIP Implant Holder and remove gently to let the ligament hold the **LEFT** implant in place.



- 13B. Use a ZIP Implant Holder to grab along the rim of the **RIGHT** implant.

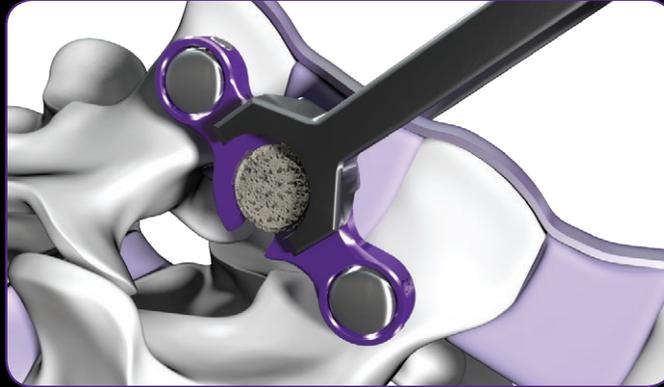


- 14B. Take the ZIP Implant Holder with the **RIGHT** implant, mate the **RIGHT** implant with the **LEFT** implant, and compress to the provisional locking position.



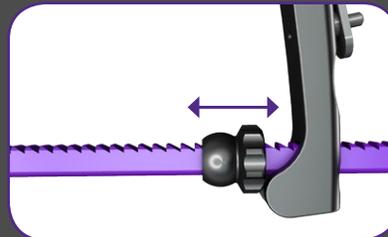
Alternate Steps Continued

- 15B.** Check implant positioning. The implant should be situated at an angle, with the caudal side near the base of the supraspinous process, and the cephalad side approximately 20 degrees higher.
- 16B.** Attach either the small or large ZIP Compressor instrument (001-023/001-029). Using the ZIP Compressor, compress the two halves together until the spikes are seated into the bone.

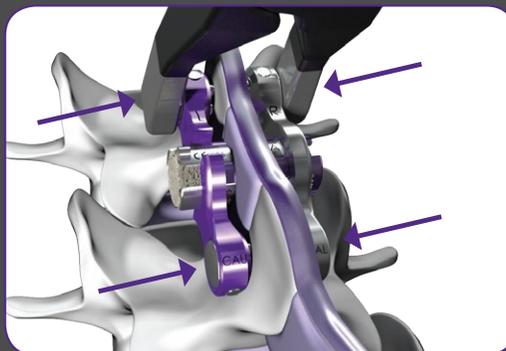


Optional

Place the ZIP Ultra Short Compressor (100-303) tip over spike area of the implant. At the surgeon's discretion, determine the maximum compression needed and set the knob on the rack accordingly to allow for additional compression.



Slowly compress the ZIP implant using the ZIP Ultra Short Compressor over each spike area located at the cephalic and caudal positions to achieve the desired spike penetration.



- 17B.** If removal is required, remove ligament of the subject level.
- 18B.** Once the interface is engaged, squeeze the trigger until the locking tabs are disengaged from the purple implant and push the two implant halves apart.
- 19B.** Once partially disengaged, use a ZIP Implant holder to lift the ZIP implant assembly off the spine.

Instructions for Use

The surgeon implanting the Aurora Spine ZIP® is expected to be fully educated in the techniques and methods of placement of the system. A successful result may not occur in every event in which the Aurora Spine ZIP® is implanted. Failure rates in spinal fusion procedures are published and spinal fusion failure is an accepted risk of the procedure. This is particularly true for the patient who chooses to smoke tobacco products, patients in malnourished or obese states, or who abuse alcohol products.

Proper selection of patients and good compliance of patients with pre-surgical instructions are an integral part of realization of a successful surgical procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations regarding activities that the patient will face following surgery.

Use of the Aurora Spine ZIP® should only be considered when the following preoperative, intraoperative, and postoperative conditions exist.

Preoperative

Patients should be in the previously described diagnostic categories described under 'Indications for Use'.

Patients should not be in the contraindication groups listed under 'Contraindications'.

Sterilization and handling procedures conforming to accepted standards are mandatory.

The techniques for implanting this system should be reviewed by the surgeon prior to use of the system.

The surgeon should inspect the available components of Aurora Spine ZIP® prior to surgery to assure that all necessary components are present.

The surgeon is expected to follow the instructions made available in surgical technique guides and literature relative to implantation of the Aurora Spine ZIP®.

The surgeon is expected to exercise extreme care in the placement of implants, particularly in regard to neural elements.

Radiographs should be made if there is any question as to the location of the intended or the actual placement of the implants.

The Aurora Spine ZIP® components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage and corrosion and where applicable, a loss of sterility.

Intraoperative

The surgeon is expected to follow the instructions made available in training manuals and literature relative to implantation of the Aurora Spine ZIP®.

The surgeon is expected to exercise extreme care in the placement of implants, particularly in regard to neural elements.

Radiographs should be made if there is any question as to the location of the intended or the actual placement of the implants.

Bone graft material must be used in conjunction with the Aurora Spine ZIP® to augment stability. The bone graft material should be packed inside the device prior to insertion and around the device after insertion. The bone graft material should extend from the upper vertebra being fused to the lower vertebra being fused.

Postoperative

The patient is expected to follow the detailed instructions, limitations, and warnings from the operating surgeon. The patient and the surgeon must understand that the implant is not expected to support the spine if fusion does not occur. The risk of bending, loosening or breakage of the implants during postoperative rehabilitation may be increased if the patient is active, if the patient is debilitated, or otherwise unable to use crutches or other such weight supporting devices.

Instructions for Use Cont.

The patient should not be exposed to mechanical vibrations that may loosen the device. They should also avoid falls or other sudden jolts in the spinal position.

The patient should avoid the consumption of alcohol or the use of tobacco products during the postoperative phase.

There is a risk of failure of the implant if the fusion of the spine does not occur. It should be recognized that this may occur and is a function of biology. More surgery may be required in such an event. If a non-union develops or the components loosen, bend, and/or break, the device should be removed immediately.

The surgeon is expected to supply detailed instructions to the patient regarding postoperative activities. The patient should be advised at their inability to bend at the point of spinal fusion and receive training on how to compensate for this loss of motion.

The potential for multiple complications exist. These are not necessarily due to deficiencies of the implants, and may include fracture of the implants due to fatigue, late infection or sensitivity due to fretting-corrosion, prominence of the implants, and displacement of the implants due to failure of the supporting spinal structure.

Retrieved implants should be properly disposed of, or where applicable, returned to Aurora Spine for complaint investigation and are not to be reused under any circumstance.

The patient must be told that the device can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans. Possible risks associated with these types of imaging scanners include, but are not limited to, heating and/or migration.

The Aurora Spine ZIP® has not been evaluated for safety and compatibility in the MR environment. The Aurora Spine ZIP® has not been tested for heating or migration in the MR environment.

Complications and Adverse Reactions:

The complications and adverse effects of this system are similar to other System of similar design. Complications and adverse reactions include, but are not limited to, the following:

- Loosening, bending, dislocation, and/or breakage of the components, possibly requiring further surgery
- Cessation of growth of the fused portion of the spine
- Nonunion or pseudoarthrosis, possibly requiring further surgery
- Infection and/or wound complications
- Physiological reaction to implant devices due to foreign body intolerance including inflammation local tissue reaction, and possible tumor formation
- Loss of neurological function by several mechanisms, including direct compression by component parts, stretching of the spinal cord by component parts, vascular spinal cord compromise, or other mechanisms
- Malalignment of anatomical structures (*i.e. loss of normal spinal contours or change in height*)
- Pain or discomfort
- Scar tissue formation possibly causing neurological and/or vascular compromise
- Bone loss and/or decrease in density due to stress shielding
- Subsidence of the device into the vertebral body
- Revision surgery
- Death

NOTE: Loss of normal spinal motion is an expected result, and does not constitute an adverse effect.

Warnings

The selection of the proper size, shape, and design of the implant for each patient is extremely important and crucial to the success of the procedure. Implants are subject to repeated stresses in use, and their strength is limited by the size and shape of the human spine.

Instructions for Use Cont.

The Aurora Spine ZIP® is an implant device used only to provide internal fixation during the bone fusion process with the assistance of a bone graft or other materials. A successful result may not be achieved in every instance of use with this device. This fact is especially true in spinal surgery where other patient conditions may compromise the result.

Surgical outcomes with this device are significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants, and complete compliance of the patient.

All implants are provided sterile and instruments are provided non-sterile and must be cleaned and sterilized prior to use.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc. which may impact on the performance of the system.

This device must not be reused. Reuse may result in patient injury or other complications including, but not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

A successful result will not be achieved in every instance of use of this device. Strict adherence by the patient to the instructions of the surgeon is necessary to insure the optimal result. Known conditions associated with poor or less than optimal results include malnutrition, cigarette smoking, obesity, and alcohol abuse.

Precaution:

Implantation of the Aurora Spine ZIP® should be performed only by experienced spinal surgeons with specific training in the use of this system as this is a technically demanding procedure presenting a risk of serious injury to the patient.

Cleaning

The following recommendations are for the manual cleaning and decontamination of Aurora Spine surgical instruments. These recommendations are considered guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user.

Automated cleaning systems may differ between hospitals and therefore must be qualified by the hospital.

Remove all labels and packaging materials before cleaning and sterilization. Submerge products in a standard hospital grade surgical instrument enzymatic detergent (e.g. Miltex®) for a minimum of one hour prior to cleaning with a soft bristle brush, lint free cloth or sponge for a minimum of 8 minutes to remove any visible soil.

Follow the manufacturer's instructions for solution concentration. During cleaning, special attention should be applied to hard to reach areas and tight lumens. Lumens should be flushed several times. Rinse each product in a brisk stream of clean, room temperature tap water for a minimum of 2 minutes then soak again for a minimum of 30 minutes in a freshly prepared solution of the cleaning detergent followed by sonication for a minimum of 30 minutes.

Once all visible soil has been removed, rinse immediately and thoroughly with running tap water for a minimum of 3 minutes to remove detergent residues. Use de-ionized water as a final rinse. Immediately dry product with a lint-free towel and allow to air dry. Sterile compressed air may be used to dry product. Inspect all products prior to sterilization or storage for evidence of wear or damage.

Instructions for Use Cont.

NOTE: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

Sterility:

Implants are supplied "STERILE" and do not require autoclaving prior to use. All implants are single use only.

STERILE	R
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 Sterilized using irradiation  Do not Re-use.

Instruments, cases and carrier trays are supplied "**NON-STERILE**" and must be cleaned and sterilized before use.

The recommended sterilization process for the instruments, cases & carrier trays is a high temperature steam autoclave sterilization. It is recommended that the loaded cases be double wrapped using two standard FDA cleared sterilization wraps. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10⁻⁶.

Reuse of this 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 and transmission of infectious agents.

Recommended Sterilization Cycle:

Method 1: Steam (Dynamic-Air-Removal)

Cycle: Pre-vacuum
 Minimum Temperature and Exposure Time: 270°F (132°C) for 4 minutes
 Drying Time: 20 minutes

Method 2: Steam

Cycle: Gravity
 Minimum Temperature and Exposure Time: 270°F (132°C) for 15 minutes
 Drying Time: 15 minutes

All packages containing implants should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned. The product must be handled, stored, and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following the cleaning, sterilization, and accepted surgical technique.

NOTE: It is the responsibility of the user to ensure the sterilization process used is validated.

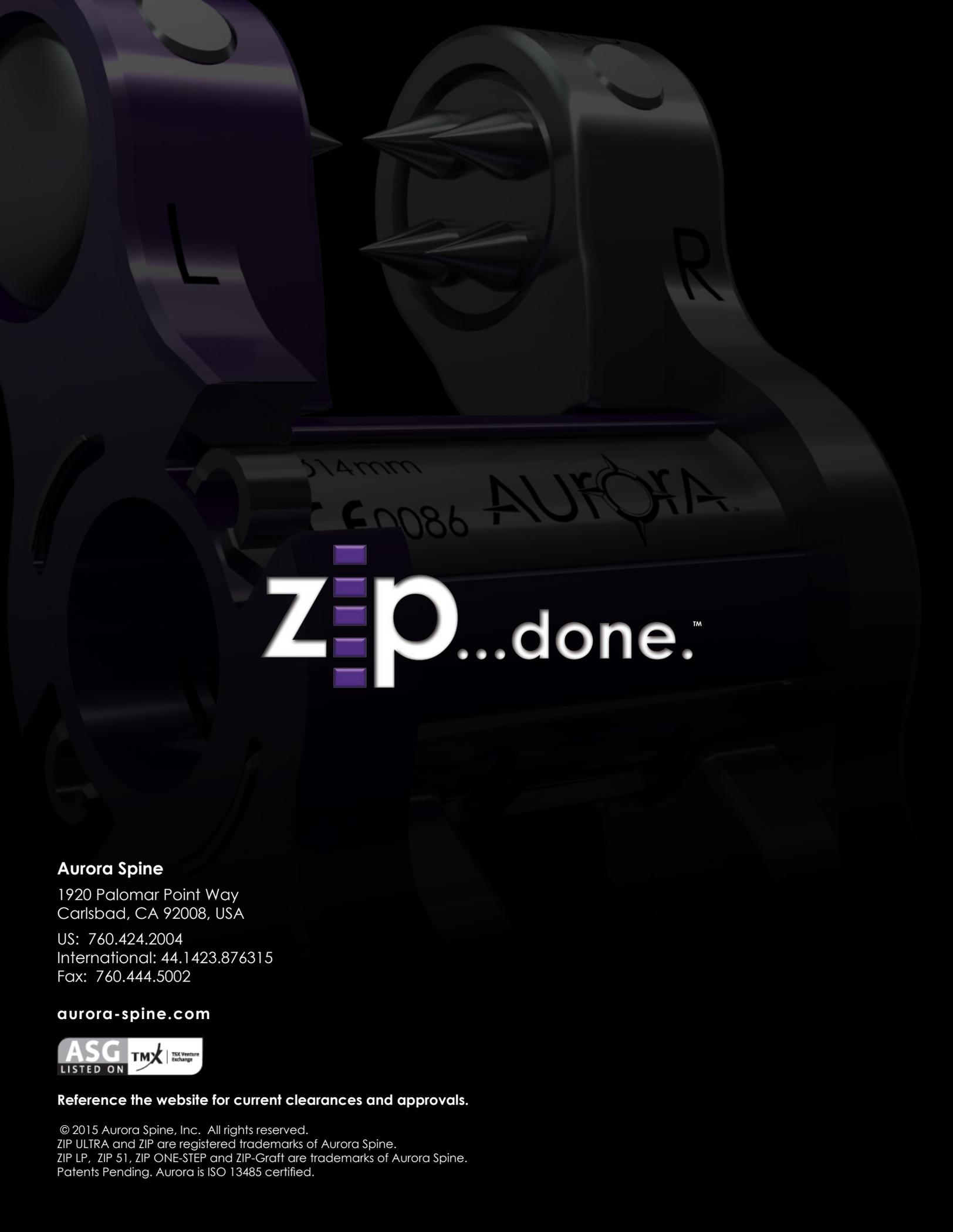
Manufacturer

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Authorized Representative

EC	REP
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 The Netherlands

The background of the advertisement features a close-up, high-contrast photograph of two Aurora Spine ZIP Ultra vertebrae. The vertebrae are dark, possibly black or dark purple, and are positioned to show their interlocking structure. The left vertebra is marked with a large 'L' and the right with a large 'R'. A central cylindrical component, likely a pedicle screw, is visible between them. This component has '514mm', '60086', and 'AURORA' engraved on it. The overall lighting is dramatic, highlighting the metallic textures and sharp edges of the hardware.

zip...done.™

Aurora Spine

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Reference the website for current clearances and approvals.

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Patents Pending. Aurora is ISO 13485 certified.