AURORA™

SIMPLIFYING THE COMPLEX

zip PRODUCT LINE™

MIS INTERSPINOUS FUSION SYSTEMS

SURGICAL TECHNIQUE GUIDE

Revision: F210119-1 - F

zip™ to Fusion

Check out the zip™ Surgical Technique Guide Animation!
Just scan the QR code:

aurora-spine.com

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Introduction

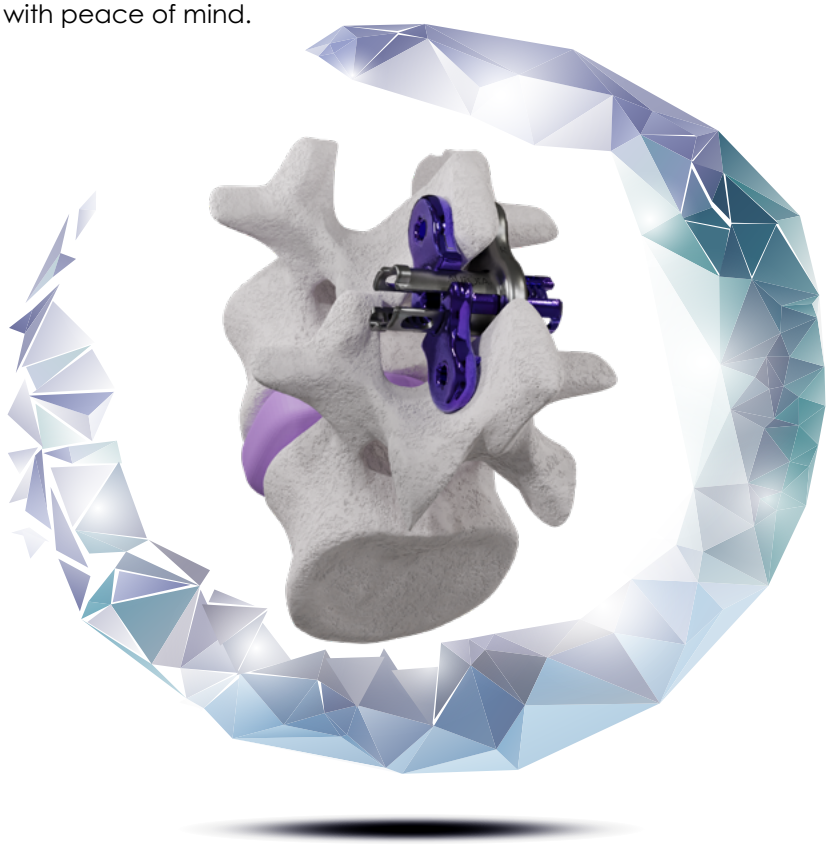
The zip™ product line has been designed with patients in mind with minimal need for modifications to the existing spinal structure.

"Minimally invasive lumbar fusion using an Aurora Spine zip™ interspinous fusion implant is the most advanced procedure available to patients suffering from chronic low back and leg pain. Patients are able to quickly improve their quality of life with an outpatient surgery without having to undergo major back surgery." — Vipul Mangal, MD. National Harbor

The zip™ is Aurora's minimally invasive interspinous fixation implant for spinal fusion to treat back pain. The zip™ implant is designed for stabilization and load sharing during T1-S1 thoracolumbar fusion procedures. The proprietary ZIP ONE-STEP™ locking mechanism eliminates the use of a set screw. Each zip™ implant features a large barrel designed for ZIP Graft™ or other bone material. The zip™ is designed in various sizes to accommodate variations in patient anatomy.

The use of zip™ product line implants 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 life activities with peace of mind.



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

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

Description

The 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 to be used with bone graft, specifically for the treatment of degenerative disc disease, lumbar spinal stenosis, spondylolisthesis, trauma, and/or tumor.

Materials

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

The Aurora Spine zip™ MIS interspinous fusion system is a posterior, non-pedicle 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 fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radio graphic studies), lumbar spinal stenosis, 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 the 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 LP™ Sizing Options

A *(Barrel Diameter)*	**B** *(Length)*	**Graft Volume**
Ø 10 mm	35 mm	0.664 cc
Ø 12 mm	35 mm	1.181 cc
Ø 14 mm	35 mm	1.846 cc
Ø 16 mm	45 mm	3.299 cc

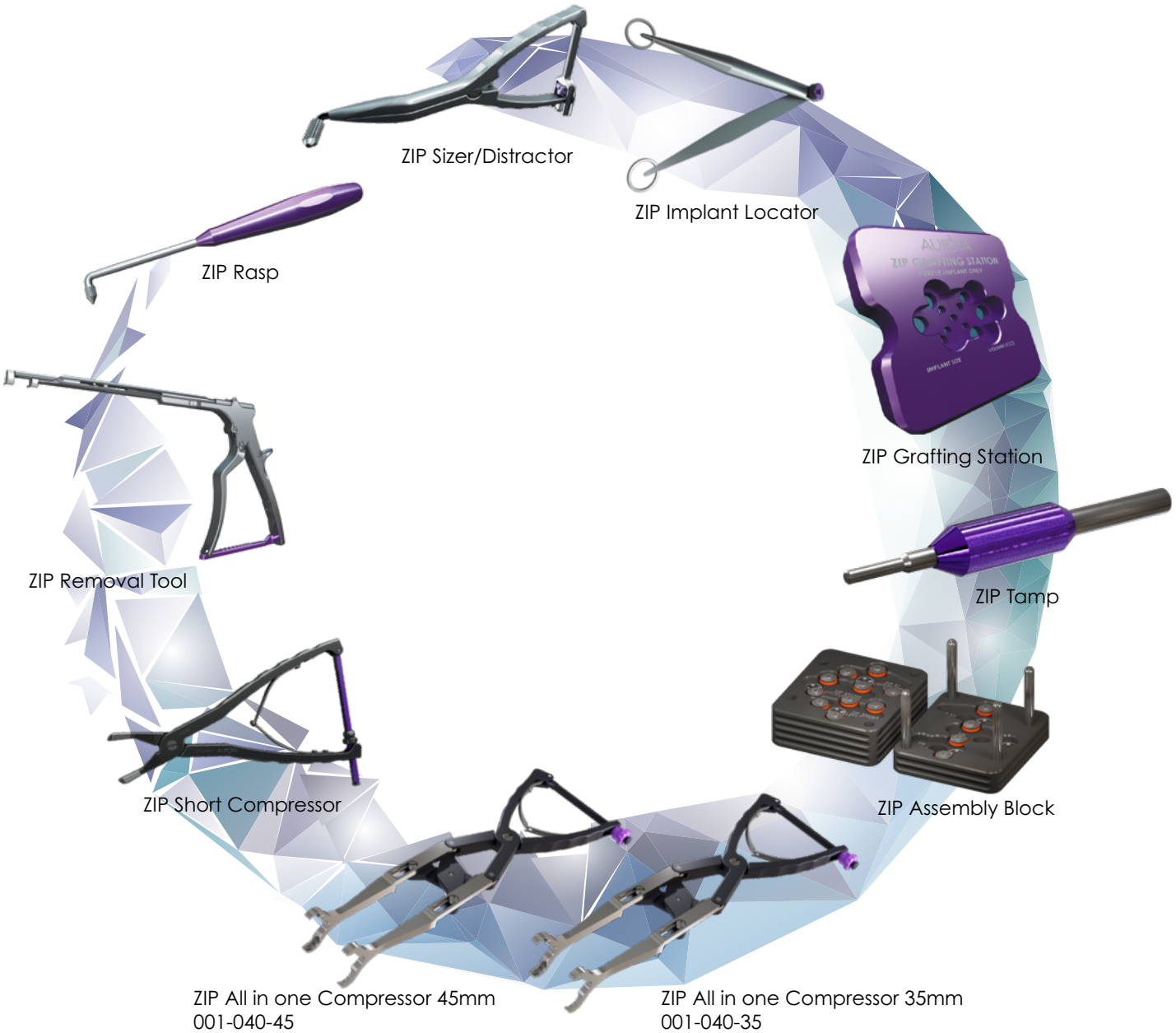
*Sizes and availability may vary. Please contact an Aurora's representative for additional information.

zip 51™ Sizing Options

A *(Barrel Diameter)*	**B** *(Length)*	**Graft Volume**
Ø 10 mm	35 mm	0.664 cc
Ø 12 mm	35 mm	1.181 cc

*Sizes and availability may vary. Please contact an Aurora's representative for additional information.

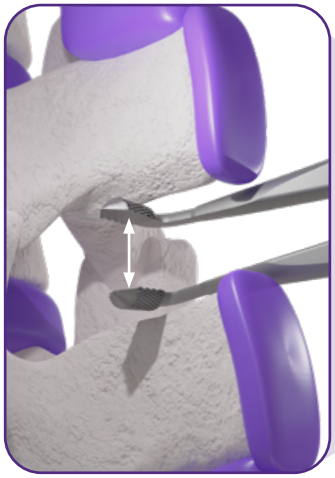
Instruments

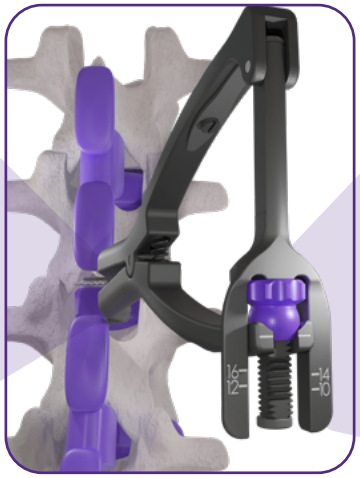


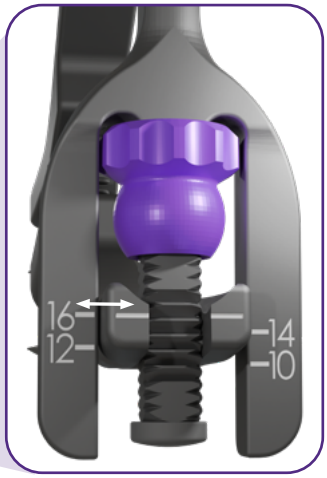
Instructions

1. Place the patient in the physician'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.
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.

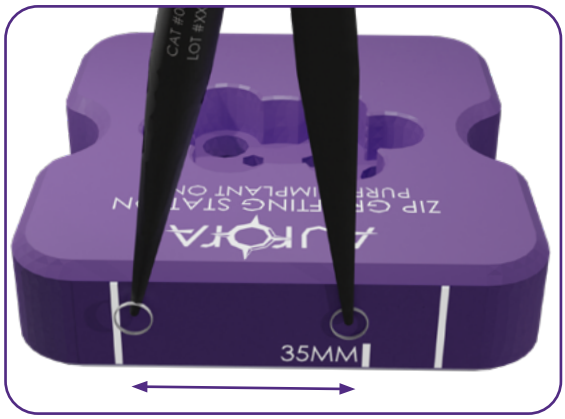
7. To determine barrel diameter, use the ZIP Sizer/Distractor with the ratcheting feature engaged to measure the interspinous space.







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

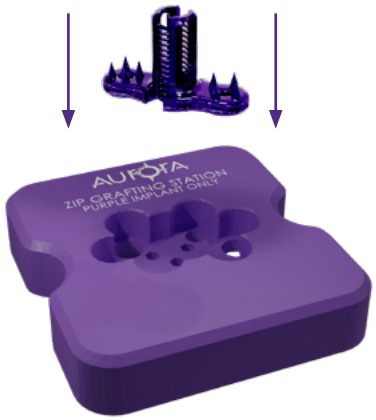


9. Once the appropriate barrel diameter and plate length have been determined, choose the appropriately sized implant.

Note: If using the zip™ Assembly Block (001-033), please proceed to step 10b.

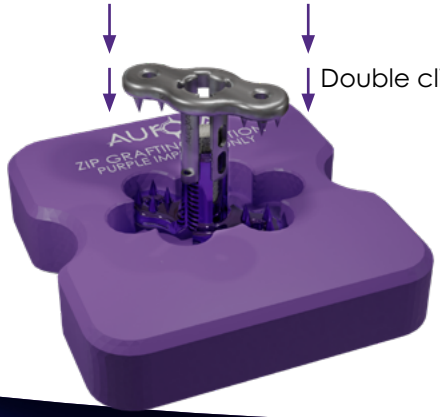
Implant Preparation - Graft Station

10a. 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.



Note:
you can select the bone graft of your preference or add the Aurora zip Graft™.

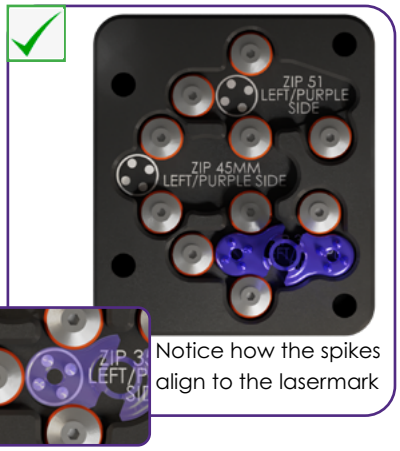
10a-1. Prepare to engage the **RIGHT** implant side onto the **LEFT** implant (purple) side. Before engaging, verify that both sides are oriented correctly, with the Aurora logos and graphic indicators facing the same direction. Engage the two sides only to the first or second click.



Proceed to step 11

Implant Preparation - Assembly Block

10b. Transfer the left implant (Purple) to the Base of the Assembly Block. Choose the appropriate pocket based on the zip™ model and size. Orient the implant so that the spikes on the implant line up with the spikes printed in the pocket of the Assembly base. Press down on the implant until it snaps into place.



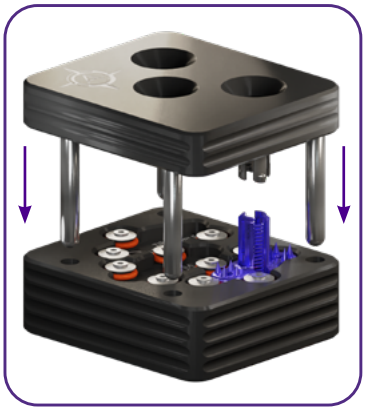
Notice how the spikes align to the lasermark

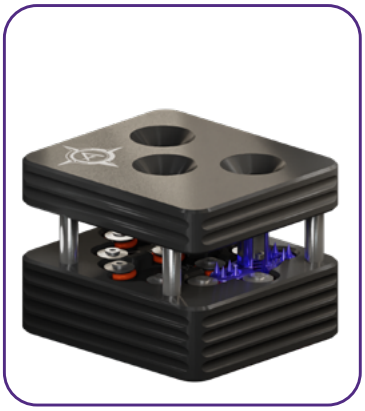
The silver/gold part shouldn't be on the base, but on the Top Assembly block

10b-1. Repeat this process for the right implant in the Top Assembly Block.

The Top Assembly Block is only intended for the silver/gold side of the zip™

10b-2. Flip the Top Assembly Block over, line up the four pins in the Top with the four holes in the base and press down firmly until the two halves of the zip implant are ratcheted together, and the top of the assembly block comes to a stop.





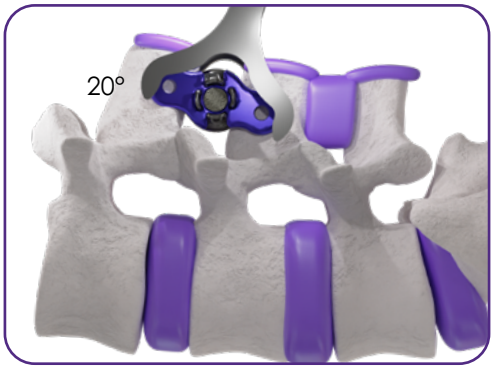
10b-3. Lift the top of the assembly Block off the assembly. Pack the zip™ implant with the appropriate volume of bone graft using the bone tamp when necessary.

Note:
you can select the bone graft of your preference or add the Aurora zip Graft™.

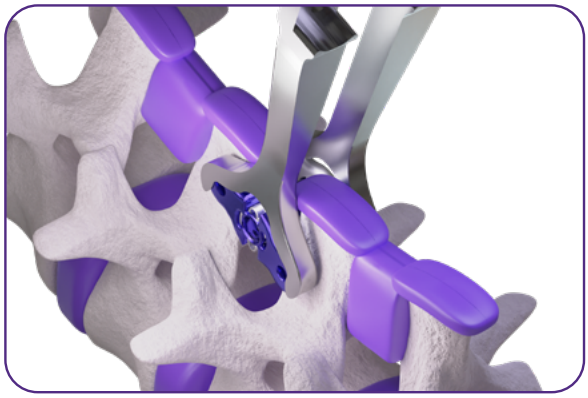
10b-4. Remove the assembled zip™ implant from the base.

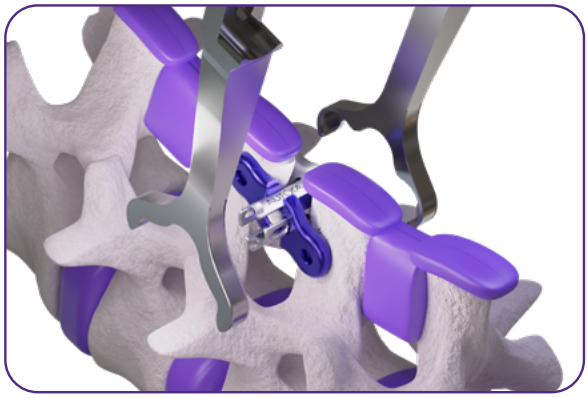
zip™ Insertion

11. Attach the ZIP Compressor instrument to the implant. Use the 35mm Compressor (001-040-35) for barrel sizes Ø10mm, Ø12mm, and Ø14mm. Use the 45mm Compressor (001-040-45) for barrel size Ø16mm. 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 and the cephalad side approximately 20 degrees higher.

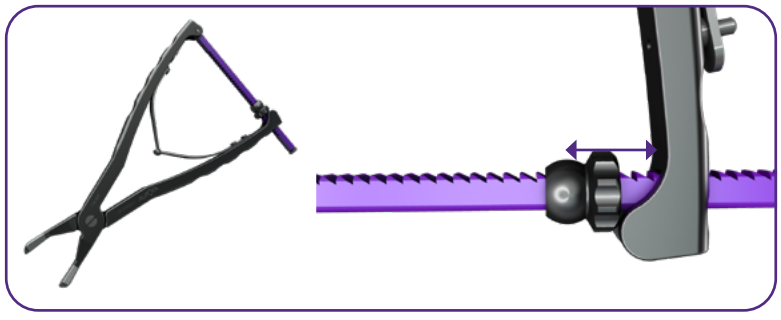


12. Compress the two halves together until the spikes are seated into the bone.

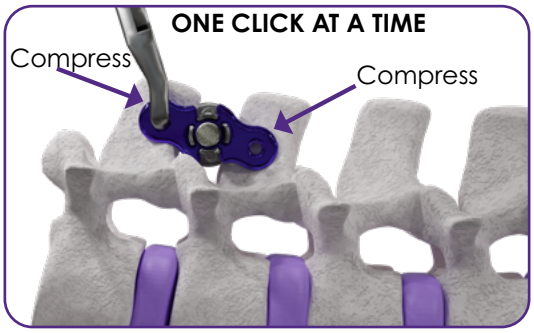




13. Place the ZIP Short Compressor tip over spike area of the implant. At the physician's discretion, determine the maximum compression needed and set the knob on the rack accordingly to allow for additional compression.



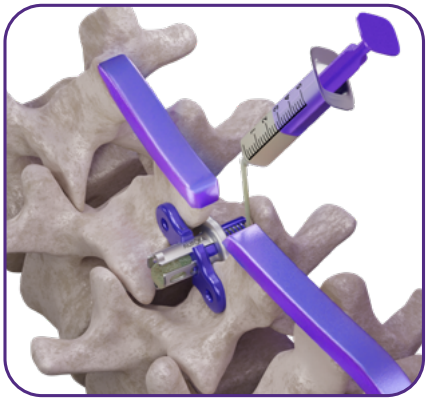
14. **Slowly** compress the zip™ implant using the ZIP Short Compressor over each spike area located at the cephalic and caudal positions to achieve the desired spike penetration.



Note: When using the ZIP Short Compressor, the zip™ implant should only be advanced **one click at a time, alternating between the two sides (inferior and superior),** until full compression is achieved.

15. Remove ZIP Compressor and assess stability.

16. Place additional bone graft across the barrel in the interspinous space as well as along the lamina, including the facets bilaterally.



Removal

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.*

1. If a zip™ implant removal is required, use the ZIP Removal Tool to detach 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/gold implant interface.

2. 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.

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Instructions for Use

The physician implanting the 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 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 and good compliance of patients with pre-surgical instructions are an integral part of performing 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 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 physician prior to use of the system.

The physician should inspect the available components of zip™ prior to surgery to assure that all necessary components are present.

The physician is expected to follow the instructions made available in surgical technique guides and literature relative to implantation of the zip™.

The physician 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 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 physician is expected to follow the instructions made available in training manuals and literature relative to implantation of the zip™.

Failure to use the surgical instruments provided by Aurora in the order described in the ZIP Surgical Technique Guide may lead to the non-desired assembly of implant components.

The physician 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 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 physician. The patient and the physician 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.

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 physician 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 zip™ has not been evaluated for safety and compatibility in the MR environment. The 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. The 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 physician'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 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 physician 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 zip™ should be performed only by experienced physicians 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.
NOTE: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

Sterility (STERILE IMPLANTS):
Implants are supplied "STERILE" and do not require autoclaving prior to use. All implants are single use only.

STERILE	R

Sterilized using irradiation ⊘ Do not Re-use.

NON-STERILE IMPLANTS:
If implants are supplied "**NON-STERILE**" they do require autoclaving/steam sterilization prior to use. All implants are single use only.

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.

Sterilizer Type	Pre-Vacuum	Gravity
Minimum Temperature	132º (270º F)	132º (270º F)
Exposure*	4 minutes	15 minutes
Dry Time	20 minutes	15 minutes
*Aurora Spine has verified the above sterilization cycles and has the validation data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665_1. Other sterilizations cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validateany alternative method using appropiate laboratory techniques.		

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.

Aurora Spine recommends following ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.
NOTE: It is the responsibility of the user to ensure the sterilization process used is validated.

Storage
Aurora Spine instruments must be completely dry before storing and must be handled with care to prevent damage.
Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

Retrieval and Analysis of Removed Devices
The most important part of surgical retrieval of devices is preventing damage that would render scientific examination useless.
Special care should be given to protect the device during handling and shipping.
Follow internal hospital procedures for the retrieval and analysis of devices removed during surgery.
When handling removed devices, use precautions to prevent the spread of bloodborne pathogens.
Please contact Aurora Spine Customer Service for return of removed devices.

Customer Service
For further information regarding the Aurora Spine zip™ MIS Interspinous Fusion System or Surgical Technique Manual, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

Manufacturer

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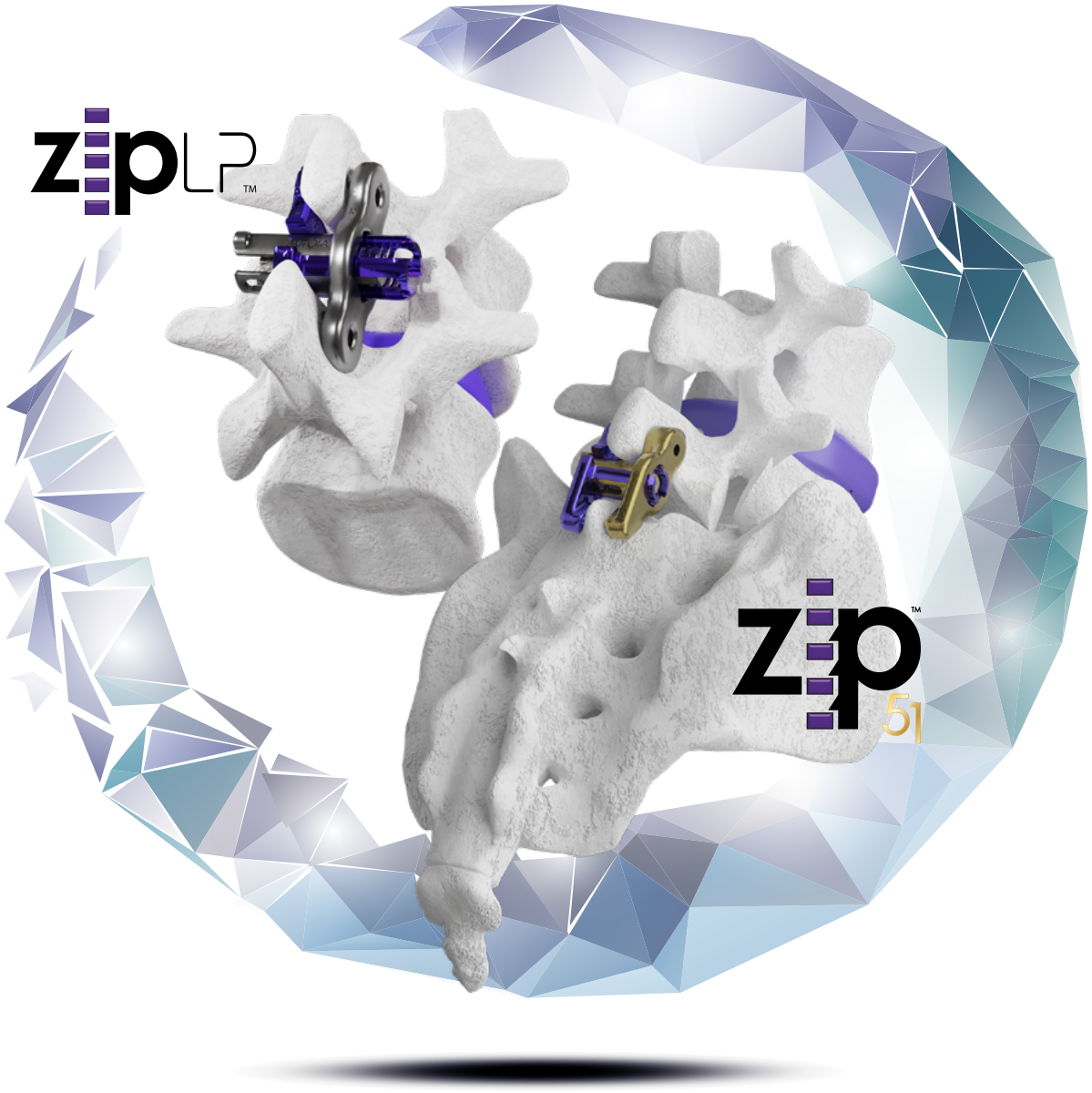
aurora-spine.com

zip™ to Fusion



AURORA™

SIMPLIFYING THE COMPLEX

STAY UP TO DATE! FOLLOW US!

LISTED ON
OTCQB ASAPF | TMX ASG.V

Reference the website for current clearances and approvals.

Aurora is ISO 13485 certified.
The zip™ product family is patented under US 9,364,267 and other international patents.

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