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Content, clearances, approvals, specifications, descriptions and illustrative material in this literature are as accurate as known at the time of publication, but are subject to changes without notice. Visit aurora-spine.com for more information. Guides are revised from time to time and placed on the website. Look for updated guides on our website.
The Compass 4D™ MIS Retractor system is designed to aid in exposure, retraction, decompression, and disc preparation of the spine. Compatible with all products used in Aurora’s Screwless Procedure, the Compass 4D provides optimal access while minimizing tissue damage.

Crafted out of titanium, the Compass 4D features three independently moving blades, with an optional fourth blade. Blades are available in various lengths to accommodate patient anatomy and approach. Multiple lights are available to increase the visualization during procedures; one to illuminate the approach, and a disposable, sterile-packed light to illuminate the target area. A disposable, sterile packed optional probe is also available to use with the neuromonitoring system of choice.

The Aurora Spine TiNano™ Lumbar Interbody Fusion Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.
Instruments

- Compass 4D Retractor | 110-318
- Table Clamp Assembly | 110-339
- Retractor Wrench | 110-328
- Adaptor Storz | 110-352-2
- Adaptor Wolf | 110-352-2
- Adaptor Olympus | 110-352-3
- Adaptor ACM | 110-352-4
- Dilator Holder | 110-333
- K Wire and Handle | 110-329 & 110-330
- Light Holder | 110-338

- Blade Set | 110-319-XXX
- Blade Posterior | 110-320-XXX
- Fourth Blade | 110-3211-190
- Dilator Holder | 110-333
- Dilator, 8mm & 14.5mm | 110-332-08 & 110-332-14

- Does not come preassembled.
- 40 mm - 170 mm
- 90 mm - 170 mm
- 50 mm - 80 mm
- 12 mm x 190 mm
- 50 mm - 80 mm
- 8mm
- 14.5mm
Instruments

- Dual Light Cables | 110-351
- Light Cable Extension | 110-350
- Light Cable Disposable | 110-337
- Disposable Probe | 110-340
- Penfield Elevator | 110-345
- Knife Handle | 110-343
- Suction Tube | 110-349
- Shim | 110-323
- Trocar | 110-324
- Inserter | 110-327
Surgical Technique

In this technique guide we will be demonstrating the Compass 4D Retractor’s operational techniques. For illustrative purposes a Lateral approach is shown, though the Compass 4D Retractor System can be used for Lateral or Posterior procedures.

1. Dilators and K-Wire
The Compass 4D Retractor System includes a K-Wire and Dilators to facilitate accurate insertion and to help determine proper blade length. The K-Wire can be used with Anterior/Posterior and Lateral fluoroscopic imaging to locate the affected level and mark the appropriate incisions.

Guide the 8mm Dialator through the determined path, while searching and using appropriate steps for any nerves that are found in the way. Dock the Dialator over the disc space.

A Neuromonitoring System can be used with the Compass 4D Retractor System to verify that no nerves have been affected by the Dilator placement. The neuromonitoring ball-tip Probe can be utilized with the cannulated dilators.
**Instruments**

Slide the K-Wire through the initial Dilator into the targeted disc space.

Further dilate the incision with the 14.5mm Dilator. The 14.5mm Dilator is also cannulated for use with the neuromonitoring Probe.

Note the depth markers on the Dilator.
Surgical Technique

2. Setting up the Compass 4D

Attach the selected blades to the Compass 4D Retractor. Each individual blade is designed to fit a particular slot, marked by L (Left) R (Right) and C (Center). The blade release button will click when the blade has locked into place. If necessary, push the blade release buttons to remove the blades.
**Surgical Technique**

Guide the retractor blades down along the dilators until the blade tips reach the disc space.

The retractor can be secured in place using the Retractor Arm and Table Clamp.

- Retractor Locking Knob
- Arm Height Knob
- Table Clamp Knob
- Lock Articulation Knob
- Retractor Locking Knob
**Surgical Technique**

Tightly secure the Table Clamp onto the OR table rail by turning the Table Clamp Knob. Secure the Retractor Arm to the Table Clamp using the Arm Height Knob, ensuring the arm articulates towards the patient. Insert the end of the arm to the connector on the Retractor and rotate the Retractor Locking Knob clockwise to tighten. The arm can be attached at the silver lock, on the retractor base or at the optional black lock on the central blade holder.

If the arm is attached at the silver lock, then the central blade can slide back and forth while the lateral blades remain stationary. If the arm is attached at the optional black lock, then the lateral blades are mobile, and the central blade is fixed in place.

Remove the dilators and the K-wire. A neuromonitoring ball-tip probe may be inserted to verify that no nerves have been affected by the Retractor Blades.
3. **Retract**

Squeeze the handles, to open the retractor to desired position. Tighten the locking knob on either side of the handles to lock the retracted blades in place.

The Retractor Wrench can be used to make fine adjustments to any of the compatible knobs.

The central blade can be retracted by turning the central retraction knob.
The left and right retractor blades can toe up to 12.5°.

To remove the handle ends of the Retractor, push the Handle Release button and pull the handles out.

The retractor blades can be anchored to the disc material or to the adjoining vertebral bodies, using the Shim and/or Trocar.
Surgical Technique

The Inserter can be used to install the Shim and/or Trocar. Slide either the Shim or Trocar into the end of the Inserter. The laser markings on the Shim and/or Trocar indicate proper orientation.

The square “UP” peg should be pushed into the Inserter claw as shown below. Once the peg is in the claw, push the Locking Button to lock it in place.

Use the Inserter to guide the Shim or Trocar into the dedicated dovetail slot on the inside of the corresponding blade.
Surgical Technique

The Shim is anchored into the disc material and designed to slide down the center blades. Use the Inserter to guide the Shim down the dovetail slot in the center blades until it is anchored into the disc material. Squeeze the trigger on the Inserter to release the Shim and lock it to the center blade. Remove the Inserter from the retracted space.

4. Lighting Options
The Compass 4D Retractor System includes reusable and disposable lights that can be positioned at the end of the Retractor or at the bottom end of the Retractor Blades, inside the retracted space. The disposable Light Cable is a sterile, single use product. The Dual Light Cable is reusable. The disposable Light Cable can be slid down the dedicated slot on the inside of the blade.

The reusable Dual Light Cables can be mounted at the top of the retractor blades with the Light Holders. The Light Holders can be mounted on the Retractor Body. The Dual Light Cable is inserted into the Light Holders.
Surgical Technique

OPTIONAL: 4th Blade Attachment
If additional tissue retraction is desired, the 4th Blade and the 4th Blade Connector can be used. The 4th Blade Connector will insert into the left and right holes on the Retractor Body. The arms of the 4th Blade Connector can be adjusted to align with the left and right holes on the retractor body.

The 4th Blade slides in through the top of the 4th Blade Connector into the retracted space. The 4th Blade’s position can be adjusted vertically and can also be toed.

The vertical position of the 4th Blade can be locked in place by turning the locking knob with the Retractor Wrench.
Surgical Technique

The disposable Light Cable and the Dual Light cable can still be used with the 4th Blade attached.

The Light Holders for the Dual Light Cables can be mounted into the 4th Blade Connector. The Dual Light Cables are inserted into the Light Holders.

5. Removal

Extract the disposable Light Cable up and out of the Retractor Blade. If the Dual Light Cables and Light Holders were used, remove the Dual Light Cables first, then detach the Light Holders. If the 4th Blade and 4th Blade Connector were used, hold the top of the 4th Blade Connector with one hand and use the Retractor Wrench to release the lock on the 4th Blade. With the 4th Blade unlocked, lift it up away from the tissue and out of the 4th Blade Connector. Lift the 4th Blade Connector from the Retractor body.

To remove the Shim and/or Trocar, first verify that the Table Clamp Arm is tightly rigid and firmly securing the retractor in place. The Inserter may be used to remove the Shim and/or Trocar. Slide the inserter down the blade slot until the Shim and or Trocar is fully in the Inserters claw. Press the locking button and carefully pull inserter with the attached Shim or Trocar up and out of the blade slot. With the arm still firmly holding the Retractor, we can steadily detract the central blade by slowly turning the Central Blade Retraction knob counter-clockwise.

If the Retractor handle ends were removed, they should be plugged back onto the Retractor body. If there is any toe on the lateral blades, use the Blade Toe Knobs to reset the Toe angle to 0. Use the Retractor Wrench to very slowly loosen the Locking Nuts for the Retractor handles, thereby steadily detracting the lateral blades. Once all blades have been fully detracted, we can slightly loosen the knob on the Table Clamp Arm. Very slowly lift the Retractor and blades up and out of the patient.
The Aurora Spine interbody devices are constructed of medical grade Polyetheretherketone (PEEK) as described by ASTM F2026 with a Titanium plasma spray as described by ASTM F1580.

- The teeth on the superior and inferior ends resist expulsion in all directions.
- The device is open in the transverse plane to allow insertion of bone graft material into the device prior to placement.
- The tantalum markers used for this product are made to the voluntary standard ASTM F560.
- The radiolucent PEEK material allows visualization of the defect site on radiograph to assess bone growth.
- For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbar spine (e.g., Interspinous fusion devices, posterior pedicle screws and rod systems, anterior plate systems, and anterior screw and rod systems.)

The Aurora Spine interbody devices are supplied sterile.

**INDICATIONS FOR USE**
The Aurora Spine TiNano™ Lumbar Interbody Fusion Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

**MATERIAL**
The Aurora Spine interbody devices are constructed from implant grade Polyetheretherketone (PEEK) per ASTM F2026 and have a titanium plasma spray per ASTM F1580. Each implant contains Tantalum markers per ASTM F560. The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899).

**HOW SUPPLIED**
The Aurora Spine interbody devices are delivered sterile. All sterile implants are gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize.

**CONTRAINDICATIONS**
The operation should not be carried out against the following contraindications:
- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications
WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.

2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

3. All instruments must be cleaned and sterilized prior to surgery.

4. As with all orthopaedic implants, the Aurora Spine interbody devices should never be reused under any circumstances.

5. The Aurora Spine interbody devices should never be used with dissimilar materials.

6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

PRECAUTIONS

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

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.

2. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.

3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

4. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.

2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.

3. Bone graft material may be placed in the area to be fused.

Postoperative:

1. The physician’s postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

2. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during post-operative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.

3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the healing process.

4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed
or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic devices, none of the Aurora Spine interbody device components should ever be reused under any circumstances.

POSSIBLE ADVERSE EFFECTS

1. bending, loosening or fracture of the implants or instruments;
2. loss of fixation;
3. sensitivity to a metallic foreign body, including possible tumor formation;
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. nonunion or delayed union;
6. infection;
7. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. pain or discomfort;
10. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra);
11. hemorrhage of blood vessels and/or hematomas;
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. bursitis;
14. bone graft material donor site pain;
15. inability to resume activities of normal daily living;
16. reoperation;
17. death.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The Aurora Spine interbody devices have not been evaluated for safety and compatibility in the MR environment. The Aurora Spine interbody devices have not been tested for heating or migration in the MR environment.

DIRECTIONS FOR USE

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

• Selection of the implant components and their dimensions
• Positioning of the implant components in the bone
• Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

• All requisite implant components are ready at hand
• Operating conditions are highly aseptic
• The implantation instruments are cleaned and sterilized prior to use according to the procedures outlined in this document.
• The implantation instruments, including the special Aurora Spine instruments, are complete and in working condition.
• The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready at hand.
• The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
• The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The intervention has been explained to the patient, whose consent concerning the following information has been documented:
• In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
• The life-span of the implant depends on the patient’s body weight.
• Corrective surgery may become necessary if the implant loosens.
• The patient must undergo regular check-ups of the implant components, performed by a physician.

IMPLANTING THE DEVICES
• Select the appropriate implant size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
• Correctly apply the preparation instruments (rasps, curettes and chisels) for preparing the implant bed, as well as the implantation instrument.
• To implant the Aurora Spine interbody devices, use only the specialized Aurora Spine instrumentation. Do not use implants or instruments from any other system or manufacturer.
• Apply appropriate care when inserting the implant.
• Check implant height and/or angle using the trial implants.

For complete instructions regarding the proper use and application of all Aurora Spine lumbar interbody devices and instruments, please refer to the Aurora Spine TiNano™ Lumbar Interbody Surgical Technique Manual (provided with the system).

CARE AND HANDLING
Aurora Spine instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing
Repeated processing has minimal effect on these implant and instruments. End of life is normally determined by wear and damage due to use.

Point of Use
Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Containment and Transportation
It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning
Where instruments interface with other devices, disassemble prior to cleaning.
Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Cleaning (Automated)
Equipment: Automated washer, soft bristle brush, enzymatic detergent¹, and neutral pH detergent².
• Pre-clean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
• After pre-cleaning, place in the automated washer, making sure the samples do not touch each
Instructions for Use Continued

- Load instruments in such a way that the parts can drain.

- Use a standard instruments cycle with the following parameters (at a minimum):

| Enzyme Wash | Hot (40 - 65°C) (104 - 149°F) for 3 minutes |
| Neutral pH Wash | 60°C (140°F) for 3 minutes |
| Rinse | Ambient temperature for 1.5 minutes |
| Thermal Rinse | 90°C (194°F) for 1 minute |
| Dry | 82°C (180°F) for 6 minutes |

- Determine if the instruments are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning.

Cleaning (Manual)

**Warning:** Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 w of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Pre-clean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft bristle brush while submerged in the detergent.
- Rinse the instruments with a soft bristle brush while submerged in the detergent.
- Rinse the instruments in deionized water.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning.

Maintenance and Repair

**Warning:** The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

**Warning:** Do not attempt to repair any Aurora Spine interbody instrument.

If your Aurora Spine instrument requires repair or maintenance, return the instrument in the Aurora Spine box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008 USA
Attn: Aurora Spine Customer Service

Note: Instruments returned to Aurora Spine must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.
Inspection and Function Testing

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Packaging

Instruments may be loaded into the specified Aurora Spine instrument trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA approved for pre-vacuum steam sterilization.

Sterilization

For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10-6. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Aurora Spine.

If not specifically labeled STERILE, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: Aurora Spine does not recommend that the instruments be sterilized by Flash, ETO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10-6, Aurora Spine recommends the following parameters:

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Pre-Vacuum</th>
<th>Gravity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Temperature</td>
<td>132° C (270° F)</td>
<td>132° C (270° F)</td>
</tr>
<tr>
<td>Exposure*</td>
<td>4 min</td>
<td>15 min</td>
</tr>
<tr>
<td>Dry Time</td>
<td>20 minutes</td>
<td></td>
</tr>
</tbody>
</table>

*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 sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

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.

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.
Instructions for Use Continued

CUSTOMER SERVICE
For further information regarding the Aurora Spine TiNano™ Lumbar Interbody Fusion System or Surgical Technique Manual, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

Aurora Spine, Inc.
1920 Palomar Point Way
Carlsbad, CA 92008, USA
Telephone +1 760 424-2004
Fax +1 760 444-5002
aurora-spine.com

EMERGO Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

These devices are supplied STERILE

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

1 ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation
2 Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.