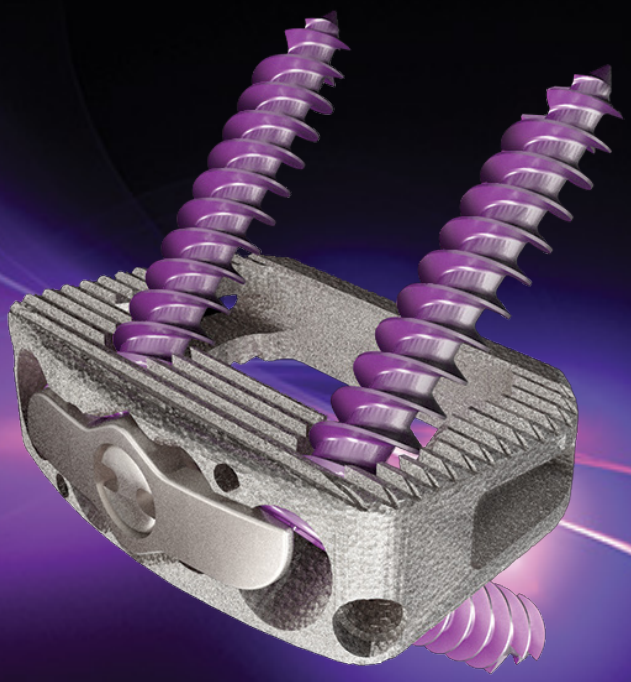
AURORA™ SPINE



SOLA-L™

STAND ALONE ALIF INTERBODY SYSTEM

Surgical Technique Guide

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential. Only those individuals with specialized training and experience in spinal surgery should attempt to use the SOLO-L™. Refer to the Instructions for Use for a more complete description of indications, contraindications, warnings, precautions and other information about the system.

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

Description

SOLO-L™ is a spinal device that is implanted in the intervertebral body space via an anterior approach to improve stability of the spine while supporting fusion.Components are offered in different shapes and sizes to meet the requirements of the individual patient anatomy. SOLO-L™ is made from titanium alloy (Ti-6Al-4V ELI).

Indications

SOLO-L™ is indicated for intervertebral body fusion of the spine in skeletally mature patients who have had at least six months of non-operative treatment. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral body space.

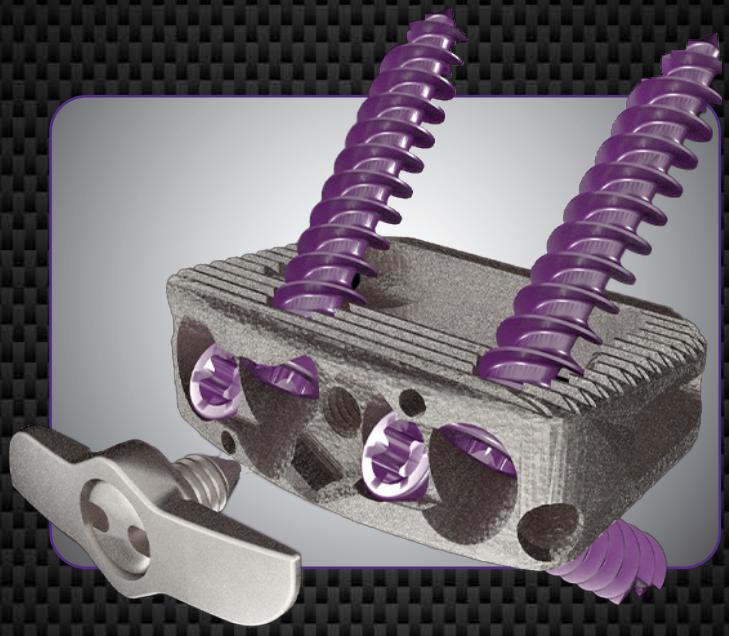
SOLO-L™ is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

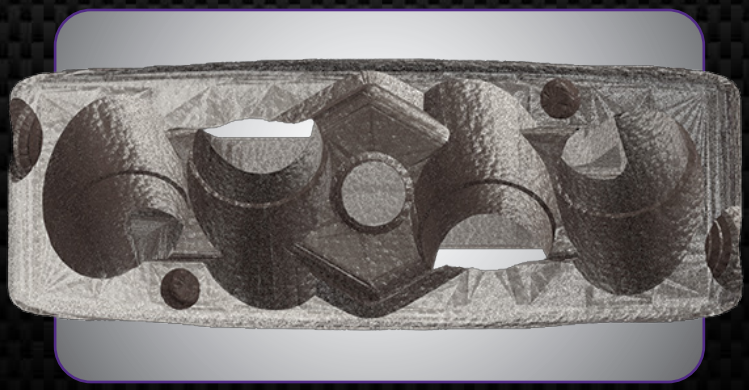
SOLO-L™ may be used as a stand alone device when all four (4) vertebral body bone screws are used. If the physician chooses to use fewer than the four (4) screws, then an additional supplemental spinal fixation system cleared for use in the lumbosacral spine must be used.

Table of contents

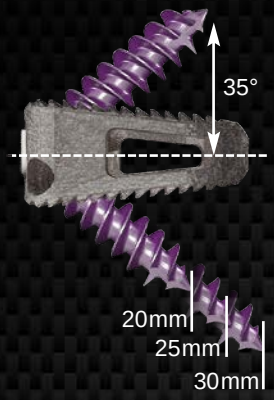
Features/Benefits

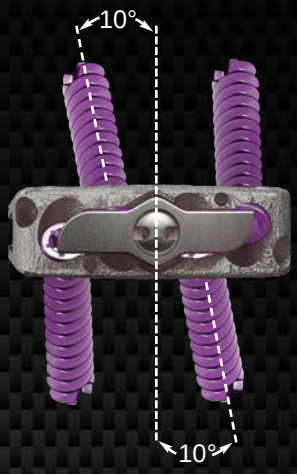
Features	Benefits
Anterior Column Zero Profile.	Reduces or eliminates potential for great vessel interference.
Enhanced porous structure.	Increases bone in-growth to endplate (titanium only).
Lag screws.	Loads the graft compressively to promote fusion.
Locking plate.	Provides visual and audible confirmation of fully seated screw to prevent backout.
Simple instrumentation.	Enhances surgeon efficiency and placement of screws.





Product Overview



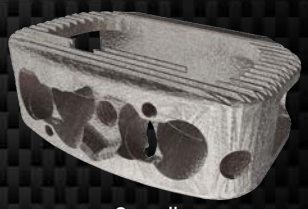


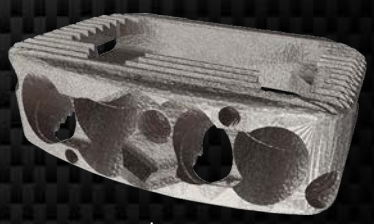
Screw

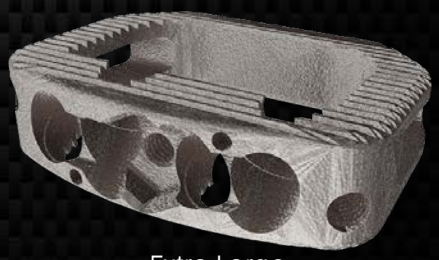
CATALOG #	DESCRIPTION *(ØD X L)*
11-002050	Ø5.0mm x 20mm
11-002550	Ø5.0mm x 25mm
11-003050	Ø5.0mm x 30mm
11-002055	Ø5.5mm x 20mm
11-002555	Ø5.5mm x 25mm
11-003055	Ø5.5mm x 30mm

Cages

CATALOG #	DESCRIPTION *(W X D X H X A°)*
14-32241107	32mm x 24mm x 11mm x 7°
14-32241112	32mm x 24mm x 11mm x 12°
14-32241307	32mm x 24mm x 13mm x 7°
14-32241312	32mm x 24mm x 13mm x 12°
14-32241507	32mm x 24mm x 15mm x 7°
14-32241512	32mm x 24mm x 15mm x 12°
14-36261107	36mm x 26mm x 11mm x 7°
14-36261112	36mm x 26mm x 11mm x 12°
14-36261307	36mm x 26mm x 13mm x 7°
14-36261312	36mm x 26mm x 13mm x 12°
14-36261507	36mm x 26mm x 15mm x 7°
14-36261512	36mm x 26mm x 15mm x 12°
14-36261712	36mm x 26mm x 17mm x 12°
14-38301107	38mm x 30mm x 11mm x 7°
14-38301112	38mm x 30mm x 11mm x 12°
14-38301307	38mm x 30mm x 13mm x 7°
14-38301312	*38mm x 30mm x 13mm x 12°*
14-38301507	*38mm x 30mm x 15mm x 7°*
14-38301512	*38mm x 30mm x 15mm x 12°*
14-38301707	*38mm x 30mm x 17mm x 7°*
14-38301712	*38mm x 30mm x 17mm x 12°*

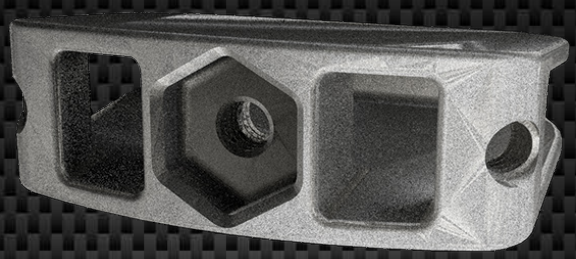

Small


Large

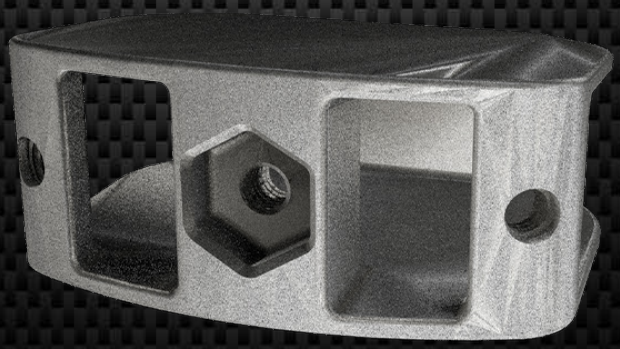

Extra Large

CATALOG #	
11-360003	Cover Plate Assembly

CATALOG #	INSTRUMENTS DESCRIPTION
10-324112	11MM X 24MM X 12° SMALL TRIAL
10-324117	11MM X 24MM X 7° SMALL TRIAL
10-324132	13MM X 24MM X 12° SMALL TRIAL
10-324137	13MM X 24MM X 7° SMALL TRIAL
10-324152	15MM X 24MM X 12° SMALL TRIAL
10-324157	15MM X 24MM X 7° SMALL TRIAL

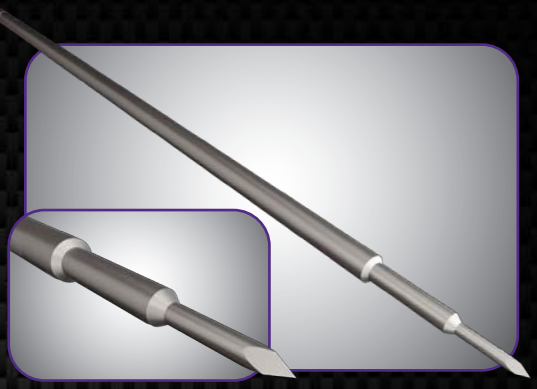


CATALOG #	INSTRUMENTS DESCRIPTION
10-325112	11MM X 26MM X 12°
10-325117	11MM X 26MM X 7°
10-325132	13MM X 26MM X 12°
10-325137	13MM X 26MM X 7°
10-325152	15MM X 26MM X 12°
10-325157	15MM X 26MM X 7°
10-325172	17mm x 26mm x 12°

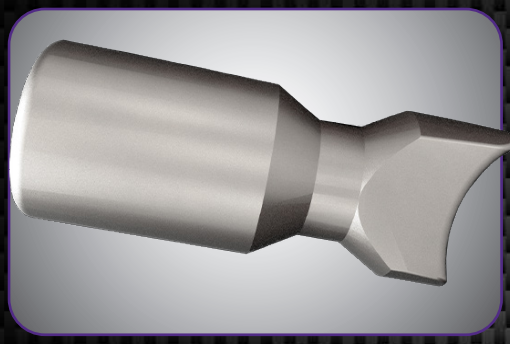


CATALOG #	INSTRUMENTS DESCRIPTION
10-338112	11MM X 38MM X 12° EXTRA LARGE TRIAL
10-338117	11MM X 38MM X 7° EXTRA LARGE TRIAL
10-338132	13MM X 38MM X 12° EXTRA LARGE TRIAL
10-338137	13MM X 38MM X 7° EXTRA LARGE TRIAL
10-338152	15MM X 38MM X 12° EXTRA LARGE TRIAL
10-338157	15MM X 38MM X 7° EXTRA LARGE TRIAL
10-338172	17mm x 38mm x 12° EXTRA LARGE TRIAL
10-338177	17MM X 38MM X 7° EXTRA LARGE TRIAL

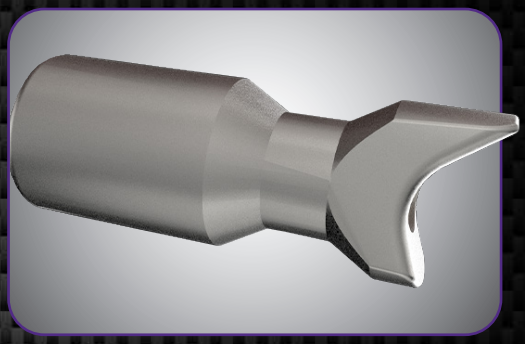
10-000033 | Compact Implant Retainer



10-000037 | Cone Guide Straight Bone AWL



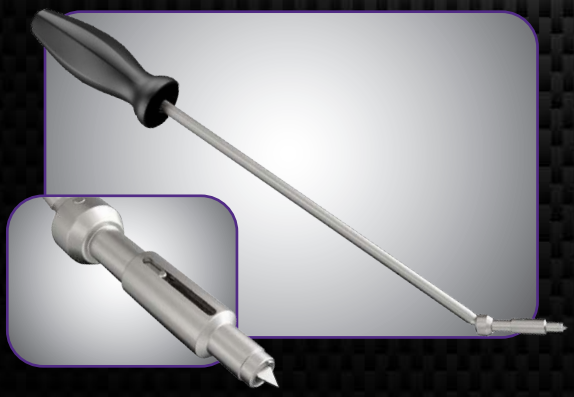
10-000034 | Small Oblique Retainer



10-000035 | Large Oblique Retainer

10-000036 | Cone Guide Inserter

10-000041 | Cone Guide Angled Screwdriver

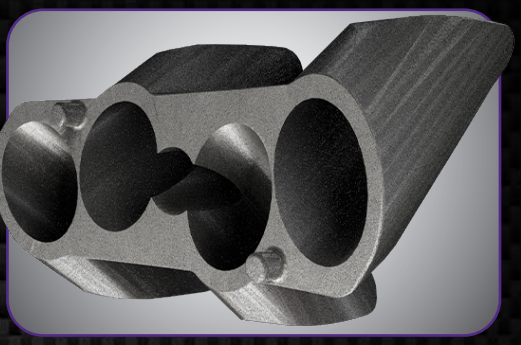


Fixed Handle Angled AWL Spring Tip
10-000057

Fixed Handle Straight AWL Spring Tip
10-000056

Instrument Overview

10-000051 | Small Cone Guide - Short



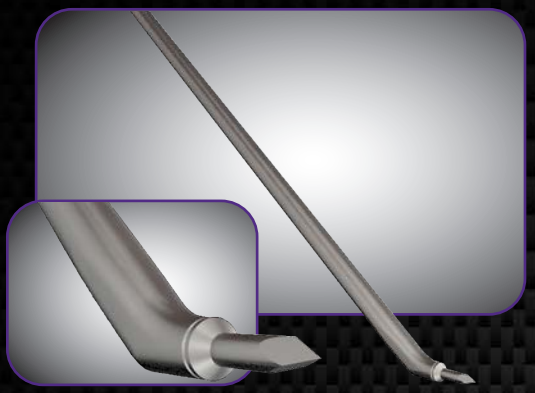
10-000052 | Large Cone Guide - Short

10-000042 | Ratcheting Handle
(Do not mallet on this Ratcheting Handle)

10-000014 | Torque Handle

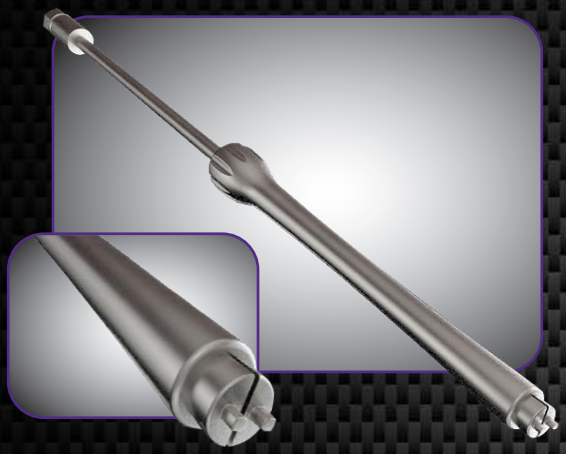
10-000044 | Slap Hammer

10-000043 | Palm Handle

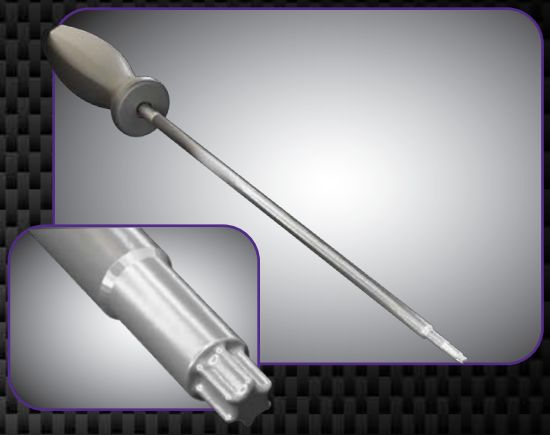


10-000055 | Cone Guide Extra Short Angled AWL

10-000053 | Cone Guide Short Angled AWL



10-000016 | Cover Plate Screwdriver



10-000038 | Cone Guide Straight Screwdriver

Pre-surgery Preparation

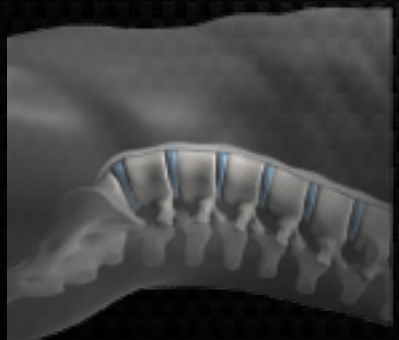
All titanium implants and instruments are provided non-sterile and should be sterilized prior to use. See instructions below.

- Replace or add any needed components for the planned surgery.
- Primary surgeon must be fully experienced with the required spinal fusion techniques.
- Please read the Instructions for Use (IFU) for a list of warnings, cautions, contraindications, risks and product description.

Surgical Exposure & Site Preparation

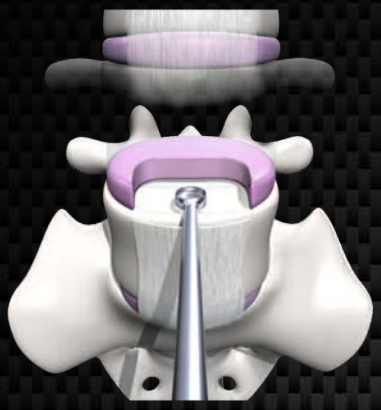
1. Prepare, position and drape the patient in the usual fashion.

2. Expose the affected levels via a standard anterior approach incision and tissue dissection.



3. Perform any necessary bone and tissue removal.

4. Remove disc material and prepare endplates using the appropriate instruments. Use a combination of curettes, rasps, osteotomes, disc shavers or box chisels to remove the disc material and cartilage from the vertebral endplates.



5. After preparing the intervertebral disc space, insert the trials to determine the size of the desired implant, starting with the trial with the smallest footprint and height.

a. Assemble the Palm Handle (10-000043) to the cone guide inserter (10-000036) and insert it into the compact implant retainer (10-000033).

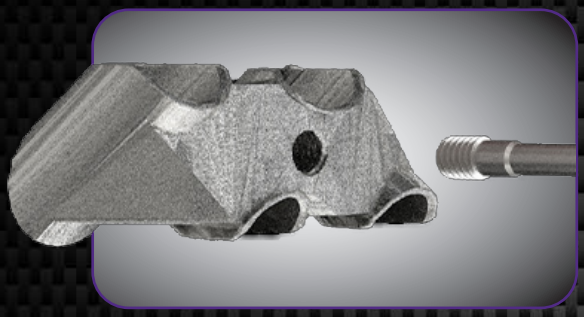
b. Assemble the trial (10-324XXX, 10-325XXX or 10-338XXX)

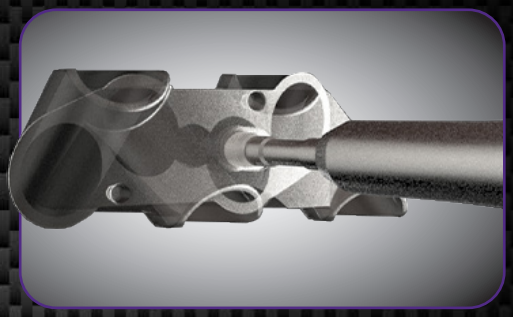
c. Select the trial using radiographic imaging to fit the anatomic conditions, and insert progressively increasing height of the trials until the appropriate height distraction is achieved. **Note:** Use of trials is recommended to ensure usage of an appropriate sized implant.

d. Oblique inserter holes may also be utilized to insert the trials from an antero-lateral approach. Utilize the small oblique retainer (10-000034) or large oblique retainer (10-000035) in place of the compact implant retainer.

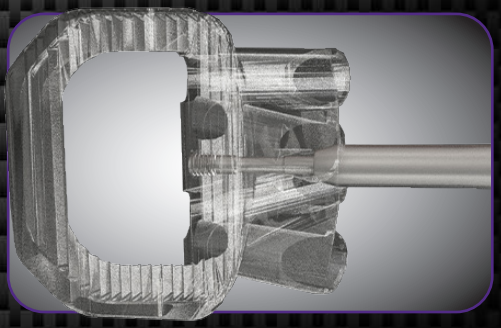
6. Select the appropriate cage.

7. To utilize the cone guide insertion method with the cage, select the appropriate cone guide according to the implant height selected.
    a. If an 11mm or 13mm implant height is selected, use the small cone guide (10-000051)
    b. If a 15mm, 17mm, or 19mm implant height is selected, use the large cone guide(10-000052)
    c. Thread the cone guide inserter (10-000036) through the cone guide to retain it.

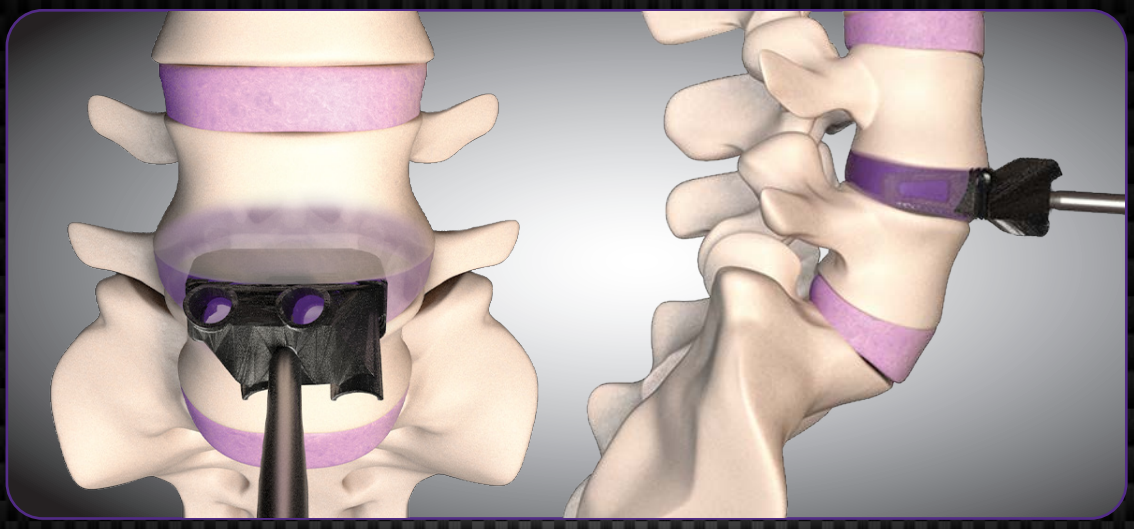




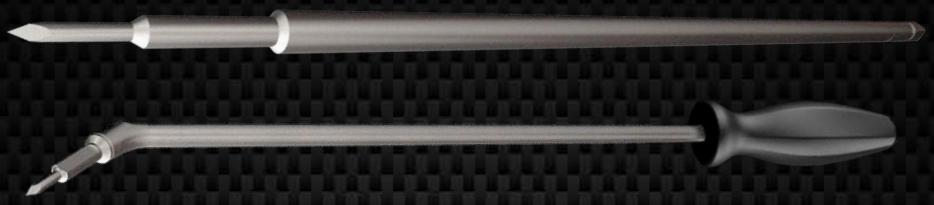
d. Align the mating nubs of the cone guide with the implant and fully thread the cone guide inserter into the cage in a clockwise direction to secure the cone guide.

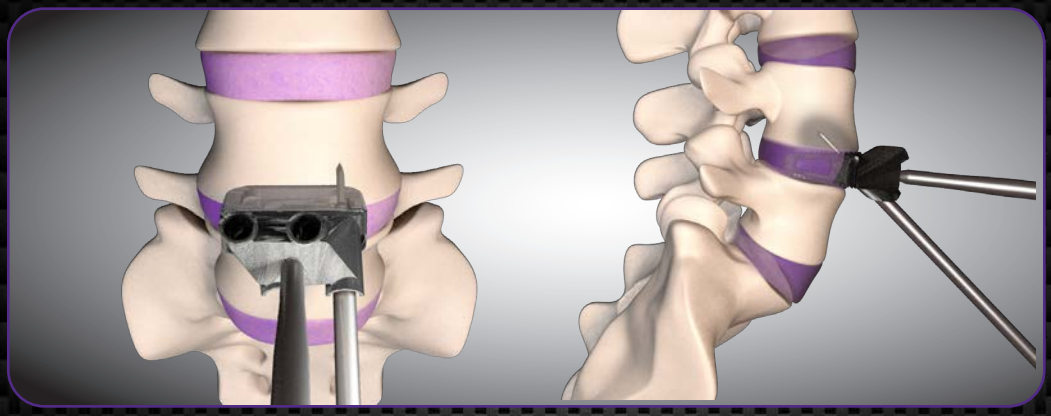


8. Insert the assembled implant into the disc space. Slight impaction may be used to gently advance the implant into the prepared disc space. Radiographically confirm the position and placement of the implant.

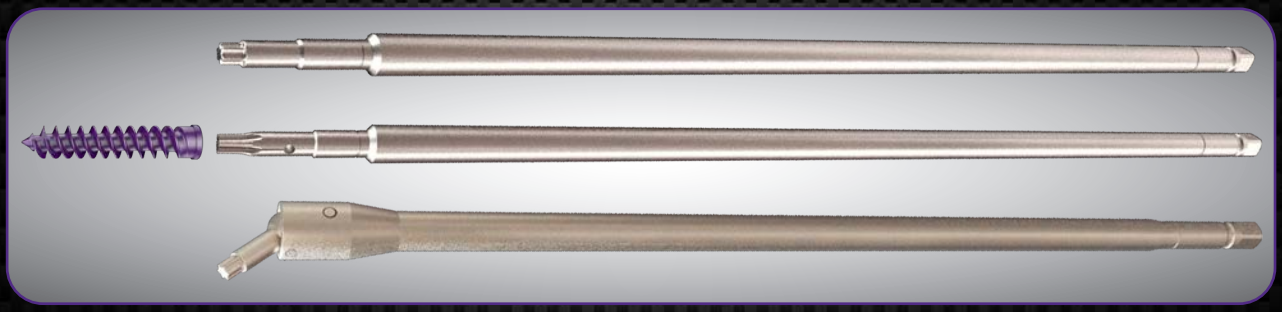


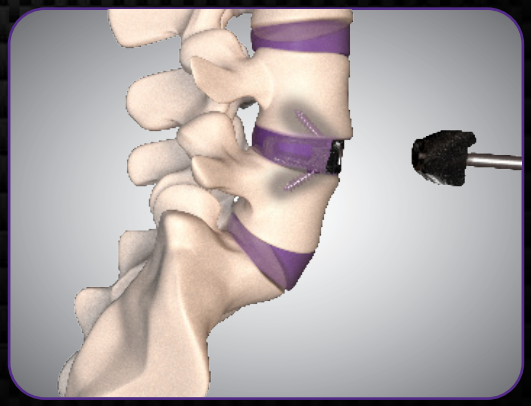
9. Prepare the bone for the screws using either Fixed Handle Angled AWL Spring Tip (10-000057), Fixed Handle Straight AWL Spring Tip (10-000056) or Cone Guide Straight Bone AWL (10-000037), Cone Guide Short Angle AWL (10-000055), Cone Guide Short Angled AWL (10-000053) attached to a Palm Handle (10-000043) through each tube of the cone guide.





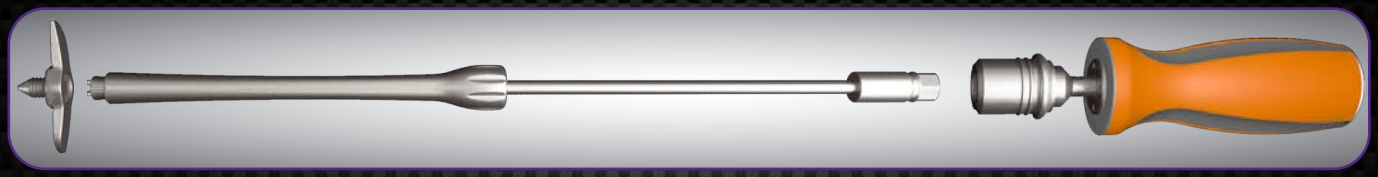
10. Insert the screws (11-00XXXX) using either the cone guide straight screwdriver (10-000038), cone guide straight screwdriver, slotted tip (10-000039), or cone guide angled screwdriver (10-000041) attached to a ratcheting handle through each tube of the cone guide. Once all screws are inserted, unthread and remove the cone guide.



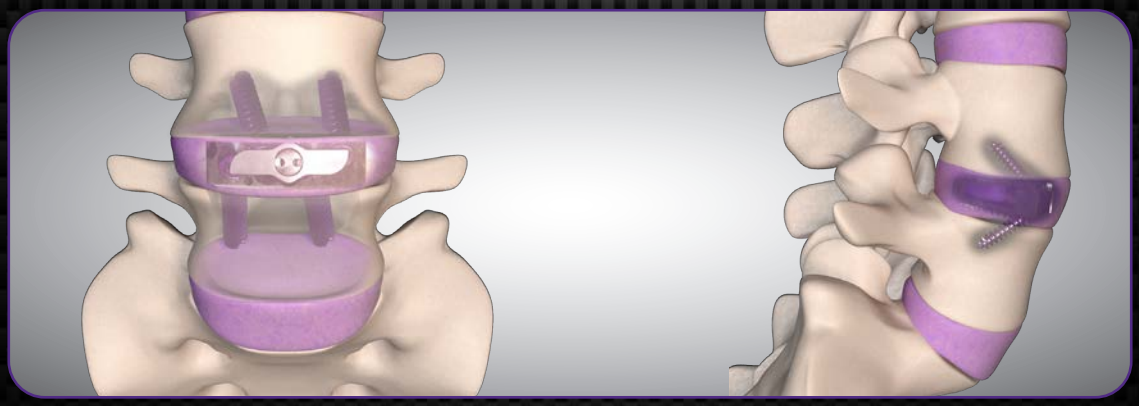


11. For all implants, use the cover plate assembly (11-360003) to secure all screws, preventing them from backing out.

a. Assemble the Cover Plate Screwdriver (10-000016)and attach it to the Torque Handle (10-000014).
b. Connect the two prong tip of the compact cover plate screwdriver to the screw of the cover plate assembly. Secure the screw to the screwdriver by threading the outer sleeve down to clamp the two prong tip.
c. Insert the cover plate into the interbody assembly and ensure the cover plate aligns properly with the mating features on the front of the implant. Note: to aid in alignment of the cover plate assembly, unthread the cover plate screw from the cover plate 1 to 2 turns before inserting into the implant.
d. Tighten the cover plate assembly to the implant to the limit of the torque handle (~12 in-lbs).



12. Inspect final implant for correct position and assembly.



Removing the SOLO-L™ implant

1. Unscrew the Cover Plate using the Cover Plate Screwdriver (10-000016) and attach it to the Torque Handle (10-000014).
2. Remove all screws using the screwdriver (10-000038) or angled screwdriver (10-000041) attached to a ratcheting handle.
3. Assemble the Ratcheting Handle (10-000042) to the cone guide inserter (10-000036) and compact Implant Retainer (10-000033). Insert the tip of the cone guide inserter into the implant.
4. Attach the Slap Hammer (10-000044) to the cone guide inserter and tap until the implant is removed from the disc space.

Maintaining device effectiveness

Prior to using the SOLO-L™ device, check all sets and confirm that all instruments and implants are present. Inspect all set components for functionality to ensure that there is no damage prior to use. Immediately return any damaged components to Acuity Surgical without using them.

Instrument cleaning & decontamination

Aurora Spine instruments are not supplied sterile. Before sterilization, instruments must be cleaned using the following procedures.

Caution: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or alkaline cleaners may damage some devices, particularly instruments. Such cleaning solutions should not be used.

Note: Some instruments may require disassembly prior to cleaning.

Machine Cleaning Instructions (Recommended)

1. Prepare cleaning detergent

a. Prepare an enzymatic detergent, following the manufacturer's instructions for preparation and use.
b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. Prepare devices for soaking

a. To prevent injury, separate out sharp and pointed devices and handle with care.
b. Disassemble devices with removable parts.
c. Open hinged, toothed or threaded joints.
d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. Clean and soak in bath

a. Immerse devices in prepared bath.
b. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in water, ensuring that all visible soil is removed.
c. Whenever applicable:
    i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
    ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
    iii. Repeatedly operate/bend/articulate movable joints while cleaning.
    iv. Brush the inside of hollow spaces along their entire length.
d. Allow devices to soak in detergent bath for the manufacturer's recommended soaking time.

4. Load devices into washer

a. Place devices so they do not collide during operation.
b. Place heavy items at the bottom and hollow objects in the washing machine baskets.
c. Ensure that no part is obstructed by large objects.
d. Place articulating instruments in the fully open position and cannulated instruments horizontally.
e. Place disassembled instruments in the washing machine baskets.

5. Washing and drying cycles

a. 2 minutes: Prewash with cold water; drain.
b. 5 minutes: Detergent wash with hot water; drain.
c. 2 minutes: Neutralize with neutral pH detergent; drain.
d. 2 minutes: Rinse with hot water; drain.
e. Dry with hot air at a maximum of 115°C.

6. Inspect

a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
b. If visible soil remains, repeat the cleaning procedure.

Manual Cleaning Instructions

1. Prepare cleaning detergent

a. Prepare an enzymatic detergent, following the manufacturer's instructions for preparation and use.
b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.

2. Prepare devices for soaking

a. To prevent injury, separate out sharp and pointed devices and handle with care.
b. Disassemble devices with removable parts.
c. Open hinged, toothed or threaded joints.
d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.

3. Clean and soak in bath

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    iii. Repeatedly operate/bend/articulate movable joints while cleaning.
    iv. Brush the inside of hollow spaces along their entire length.
d. Allow devices to soak in detergent bath for the manufacturer's recommended soaking time.

4. Rinse

a. Remove the devices from the soak bath.
b. Thoroughly rinse the devices under running water for a minimum of 1 minute.
c. Thoroughly flush cannulae, lumens and holes.

5. Ultrasonic bath

a. Prepare an ultrasonic bath containing a blood-dissolving detergent, following the manufacturer's instructions for preparation and use.
b. Cover/seal the devices during transport from the rinse to the ultrasonic bath to prevent contamination.
c. Place devices in the ultrasonic bath.
d. Ensure that the devices are completely submerged and do not overlap
e. Sonicate for 15 minutes. To avoid corrosion, do not exceed 15 minutes.

6. Rinse in sterile water

a. Thoroughly rinse the devices with purified water (i.e., RO or DI) for a minimum of 3 minutes.

7. Dry

a. Dry the devices with single-use, non-shedding absorbent wipes and/or medical quality compressed air (e.g., interiors of cannulae).
b. Be sure to completely dry the devices immediately after rinse to inhibit corrosion.

8. Inspect

a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
b. If visible soil remains, repeat the cleaning procedure.

Instrument sterilization

The SOLO-L™ system is provided non-sterile and should be cleaned and sterilized by the user. The following standard steam sterilization cycle should be used for the SOLO-L™ sterilization case:

Sterilizer Type:	Prevacuum
Preconditioning pulses:	4
Minimum Temperature:	132° C
Full Cycle Time:	4 minutes
Dry Time:	60 minutes
Open Door Time:	15 minutes
Cool Down Time:	30 minutes
Configuration:	Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or equivalent) using sequential envelope folding techniques.

COMPLAINTS

Any healthcare professional (e.g. a surgeon using a product) who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the system should notify Aurora Spine. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, telephone, fax or otherwise notify Aurora Spine as soon as possible.

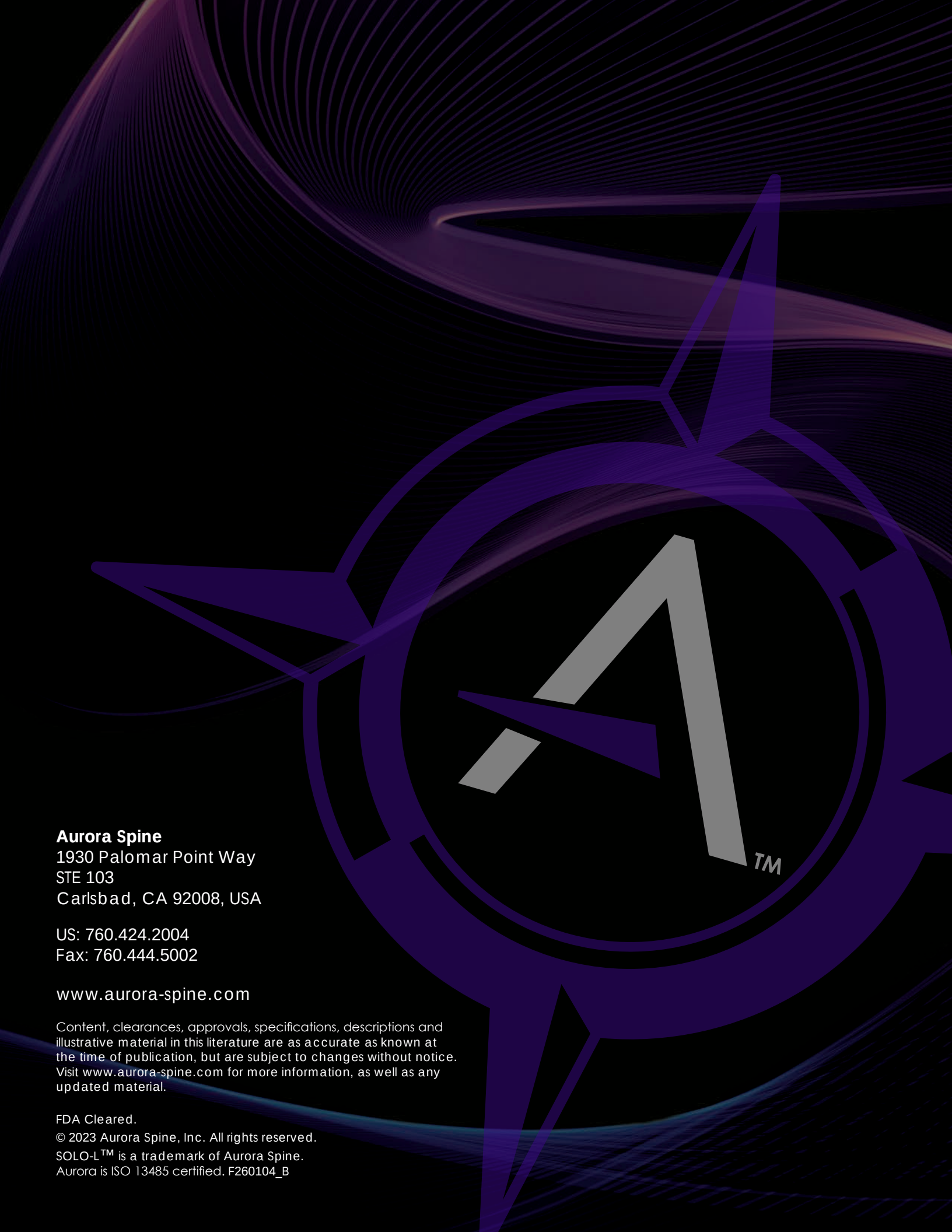
All complaints should be accompanied by the name(s), reference(s), and batch number(s) of the component(s). The person formulating the complaint should give as many details as possible and state the response required. For further information, kindly contact Aurora Spine.

CUSTOMER SERVICE

For further information regarding the Aurora Spine SOLO-L™ implant or this surgical technique guide, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

Aurora Spine, Inc.
1930 Palomar Point Way
STE 103
Carlsbad, CA 92008, USA
Telephone +1 760.424.2004
Fax +1 760.444.5002
aurora-spine.com

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



Aurora Spine
1930 Palomar Point Way
STE 103
Carlsbad, CA 92008, USA

US: 760.424.2004
Fax: 760.444.5002

www.aurora-spine.com

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FDA Cleared.

Aurora is ISO 13485 certified. F260104_B