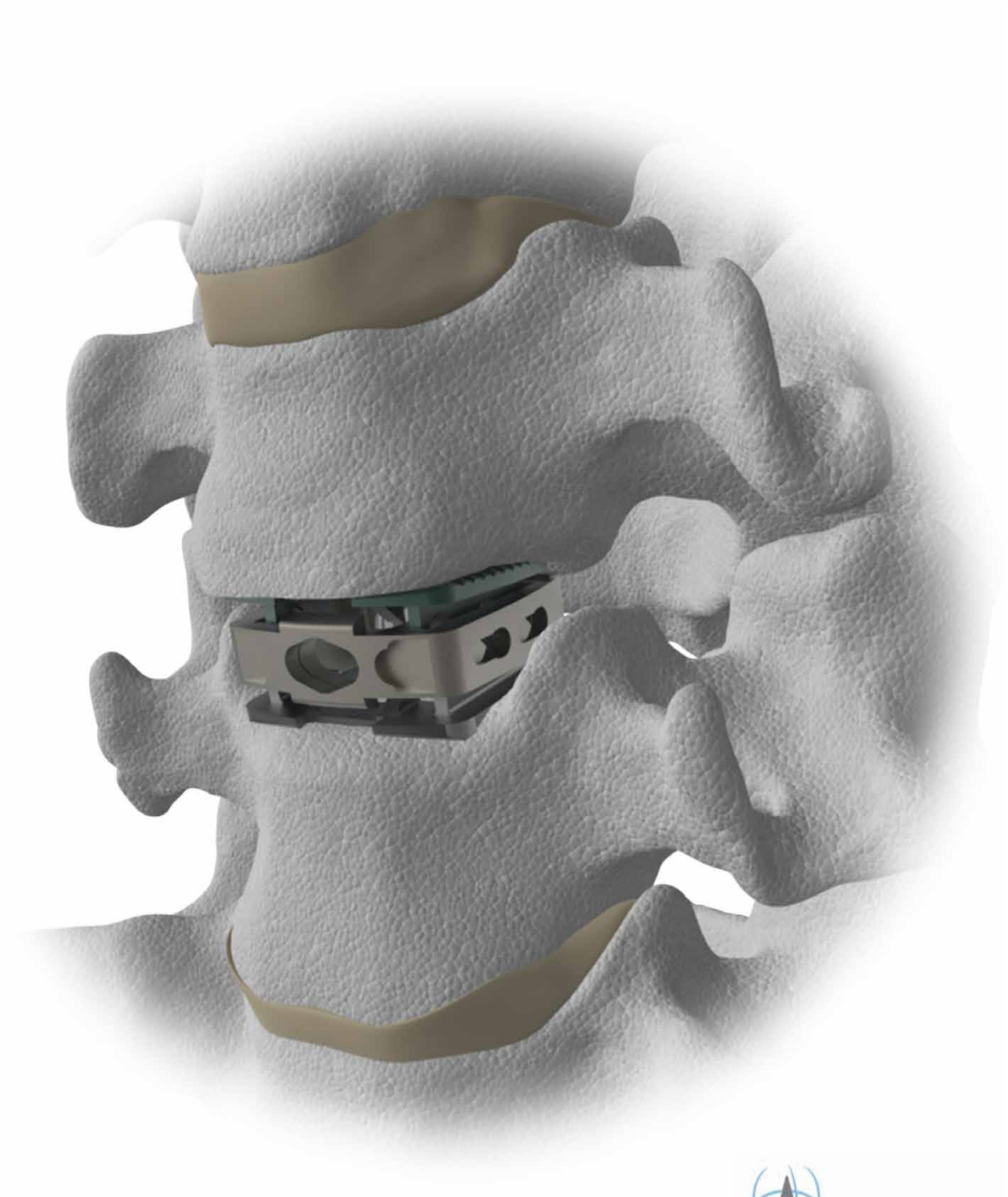
HiJAK ac

SURGICAL TECHNIQUE

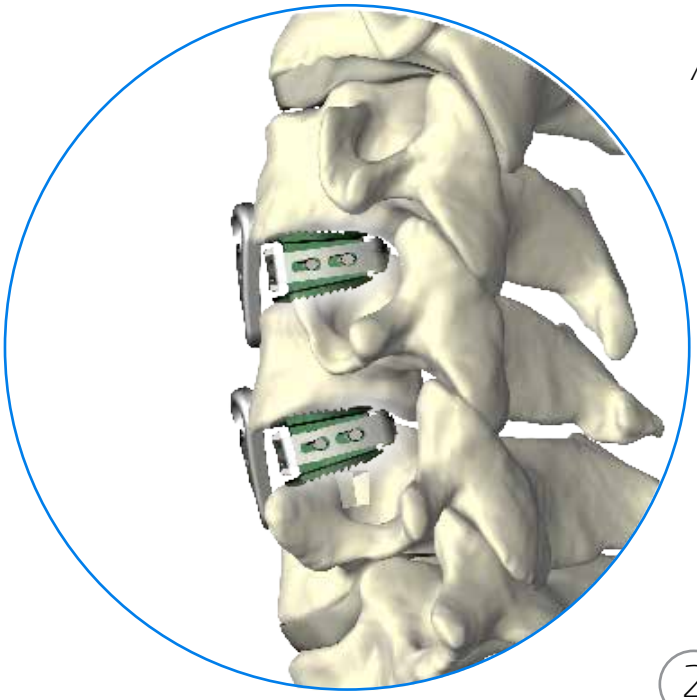


ATLAS spine

Fusing Science With Simplicity

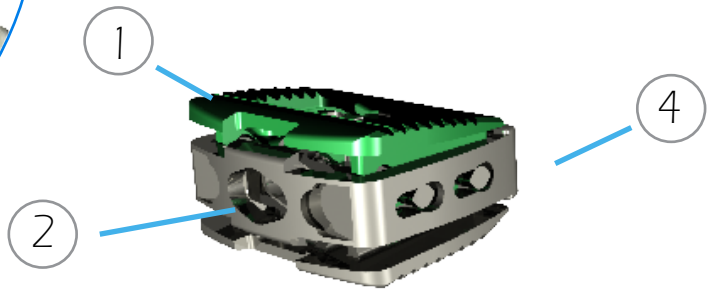
HiJAK AC

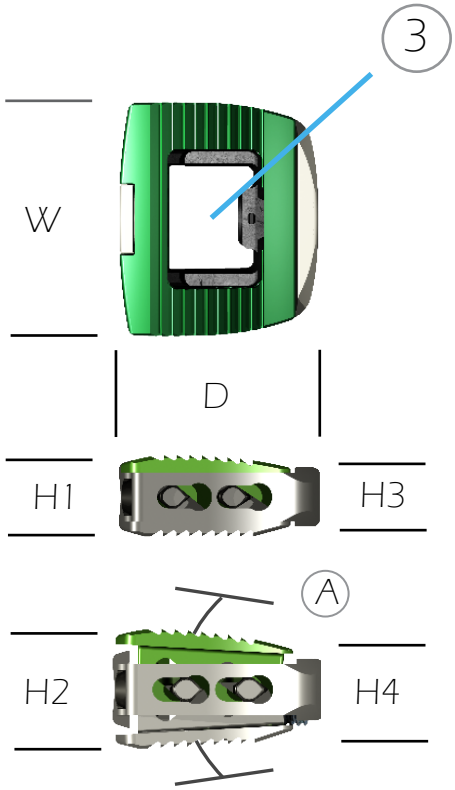
HiJAK AC, the FIRST expandable cervical inter-body with ADJUSTABLE LORDOSIS, was designed for the surgeon who recognizes the importance of lordotic restoration and sagittal balance of the spine.



Additional benifits include:

1. AN OSTEO - PROMOTIVE ENDPLATE SURFACE
2. POST EXPANSION GRAFT- PACKING CAPABILITY
3. AN UNOBSTRUCTED GRAFT CHAMBER
4. *HYPER - LORDOTIC OPTIONS (UP TO 20 deg)





SIZE

	ANTERIOR		POSTERIOR		LORDOSIS
SMALL W 15 mm D 13 mm	H1	H2	H3	H4	A
7mm	4.5	7	4	5.25	7deg
8mm	5.5	8	4	5.25	12deg
9mm	6.5	9	5	6.25	12deg
8mm HL*	5.5	8	4	5	20deg
9mm HL*	6.5	9	5	6	20deg
LARGE W 17 mm D 15 mm					
7mm	4.5	7	4	5.25	7deg
8mm	5.5	8	4	5.25	12deg
9mm	6.5	9	5	6.25	12deg

INSTRUMENTATION APPLICATION

STEP 1: FOOTPRINT TRIAL

A double-ended footprint trial is available to determine the appropriate implant width. The sizes are marked on either end: 13mm x 15mm (small) and 15mm x 17mm (large). The footprint trials are representative of the initial starting height of the smallest available option (4.5 mm).

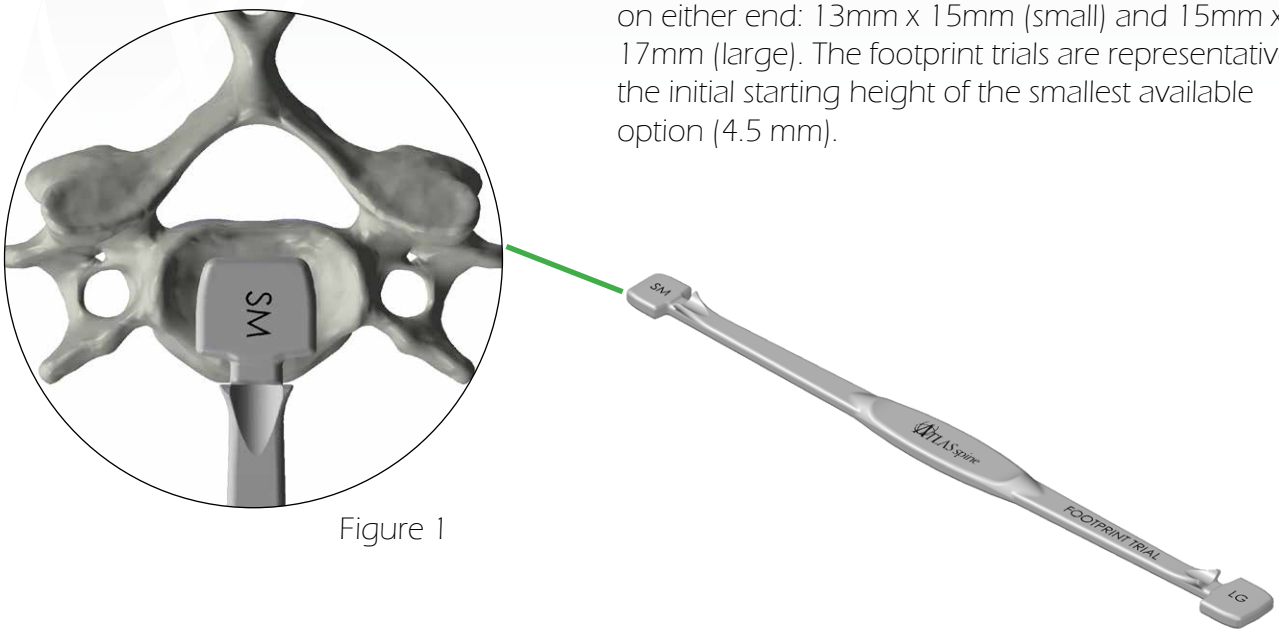


Figure 1

STEP 2: LOADING THE IMPLANT

Once the desired implant is selected, dock the implant onto the implant inserter, as shown in Figure 2. Rotate the locking knob clockwise until snug, see Figure 3.

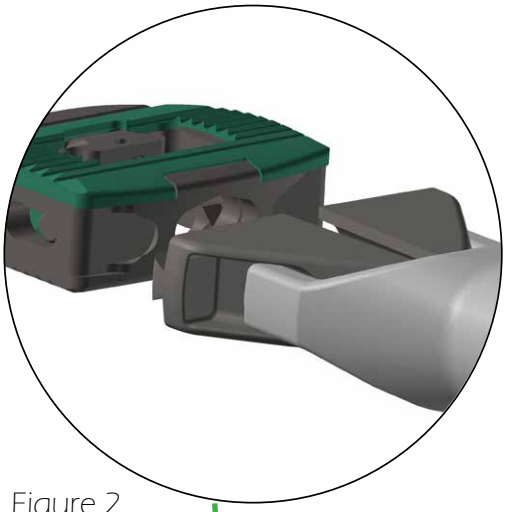


Figure 2

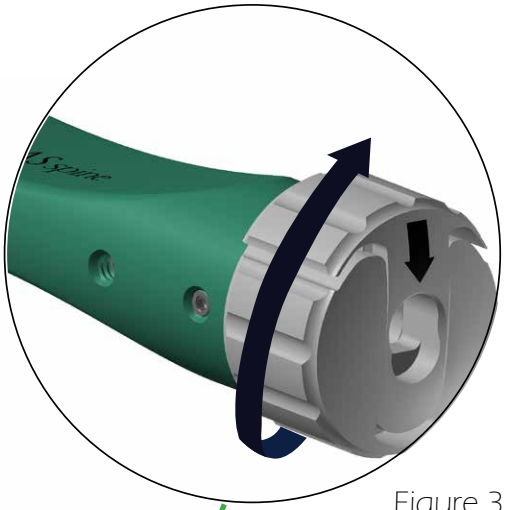
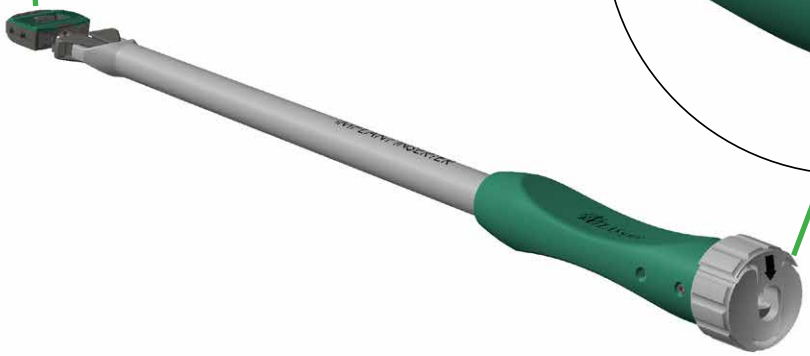


Figure 3



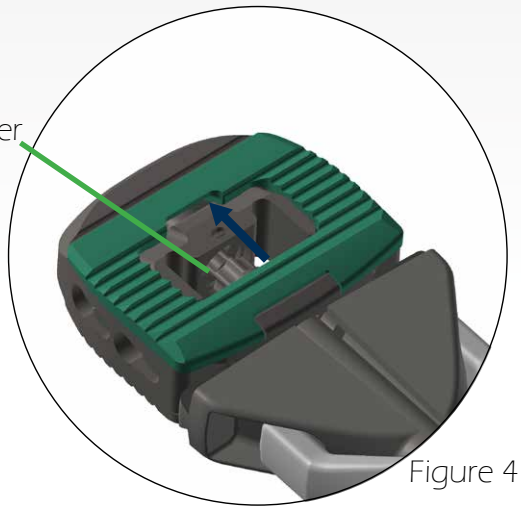


Figure 4

STEP 3: LOADING THE DRIVER/PACKING GRAFT

Select the driver associated with the implant footprint selected and attach to the torque-limiting handle. The drivers are marked small and large as shown in Figure 5 and 6. Insert the driver through the implant inserter and into the implant until the T8 driver engages. Pack biologic material of choice into the cage and around the shaft.

Note: Packing graft material prior to loading the driver can interfere with the operation of the implant.

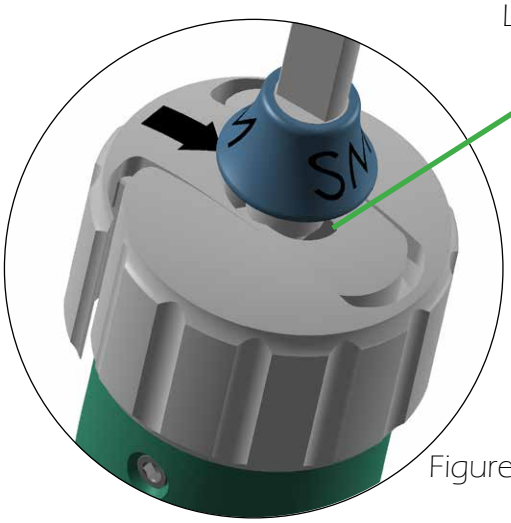


Figure 5

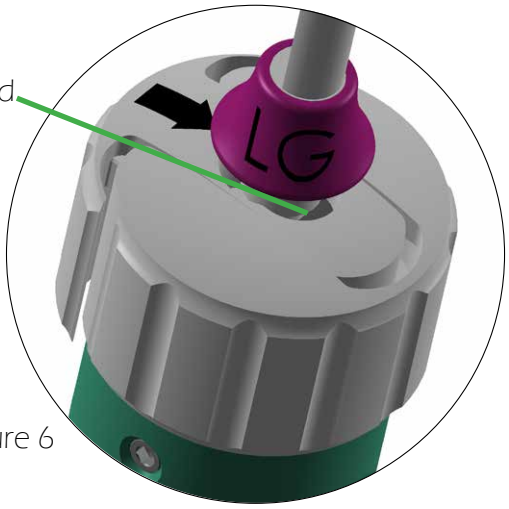


Figure 6

STEP 4: IMPLANT INSERTION AND EXPANSION

The contour on the colored endplate has been designed for an anatomic fit on the superior endplate. Once inserted, expand the implant by rotating the torque-limiting handle clockwise until the desired height is achieved. The implant can be left partially expanded.

The torque-limiting handle will click off at 9 in-lbs to protect against damage to the implant. If adequate expansion is not achieved at this torque, the implant should be removed and additional disc prep work conducted.

Note: HiJak AC is designed to be used with the torque handle provided. Use of another handle is not recommended.

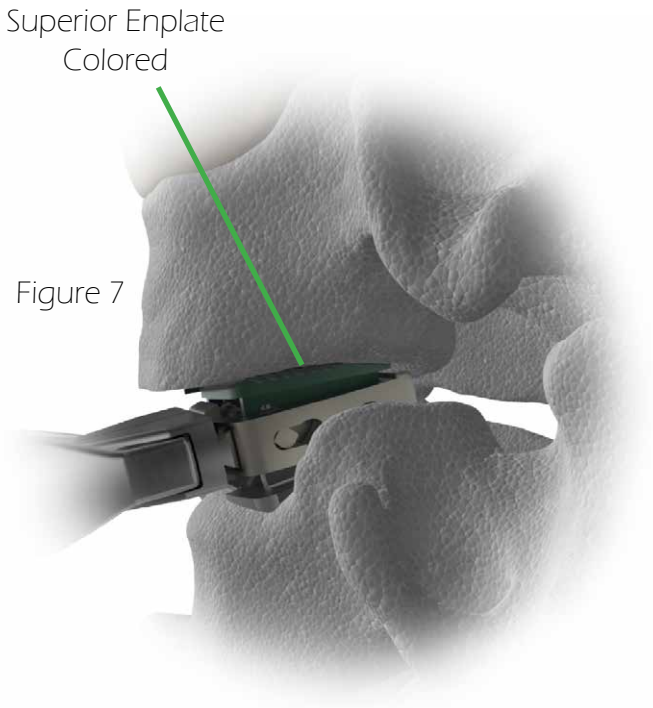


Figure 7

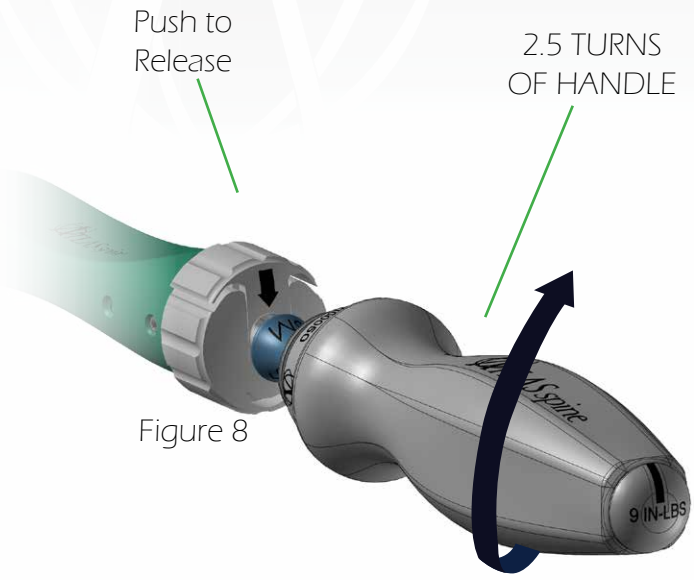


Figure 8

The full 2.5mm of expansion is achieved through approximately 2.5 turns of the handle. A marking on the back of the handle allows monitoring of the number of turns. A marking on the driver will be flush with the top of the implant inserter at full expansion.

Note: Do not begin post packing until final position and height is confirmed. Post packing will make it difficult to engage the T8 drive screw.

STEP 5: POST EXPANSION GRAFTING, FUNNEL CUP

Prior to post packing the cage, imaging should be taken to confirm desired location and size. A funnel cup and plunger are provided to pack an injectable biologic through the implant inserter. Remove the driver by pressing the release button on the inserter while pulling back on the driver. After packing, the inserter may be removed by rotating the knob counterclockwise.

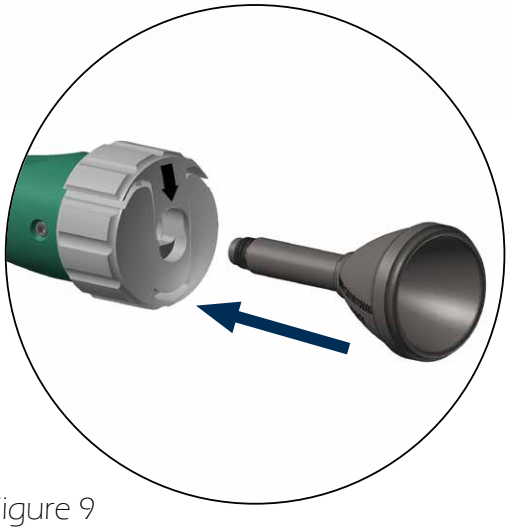


Figure 9

GRAFT VOLUME			
HEIGHT (mm)	PRE PACK (cc)	POST PACK (cc)	TOTAL (cc)
SMALL (13mm x 15mm)			
7	.08	.13	.21
8	.10	.14	.24
9	.12	.15	.27
8 HL	.11	.13	.24
9 HL	.13	.13	.27
LARGE (15mm x 17mm)			
7	.17	.21	.37
8	.21	.21	.43
9	.25	.22	.48

Note: Verify ability of graft choice to flow through funnel prior to usage. Follow volume instructions to ensure cage is not overpacked.

Figure 10

Figure 11

STEP 6: POST EXPANSION GRAFTING, THREADED BONE FUNNEL

Alternatively, the inserter may be removed first, and the implant post packed manually or by using the "Musket Style" threaded bone funnel.

Determination of graft requirement is listed on the "Graft Volume Chart". The desire volume of bone graft can be preset as shown in Figure 10. Rotate the knob to align the marking to the appropiate footprint and pack graft into the distal tip.

Dock the funnel into the implant as shown in Figure 11, and rotate the back knob to advance graft.

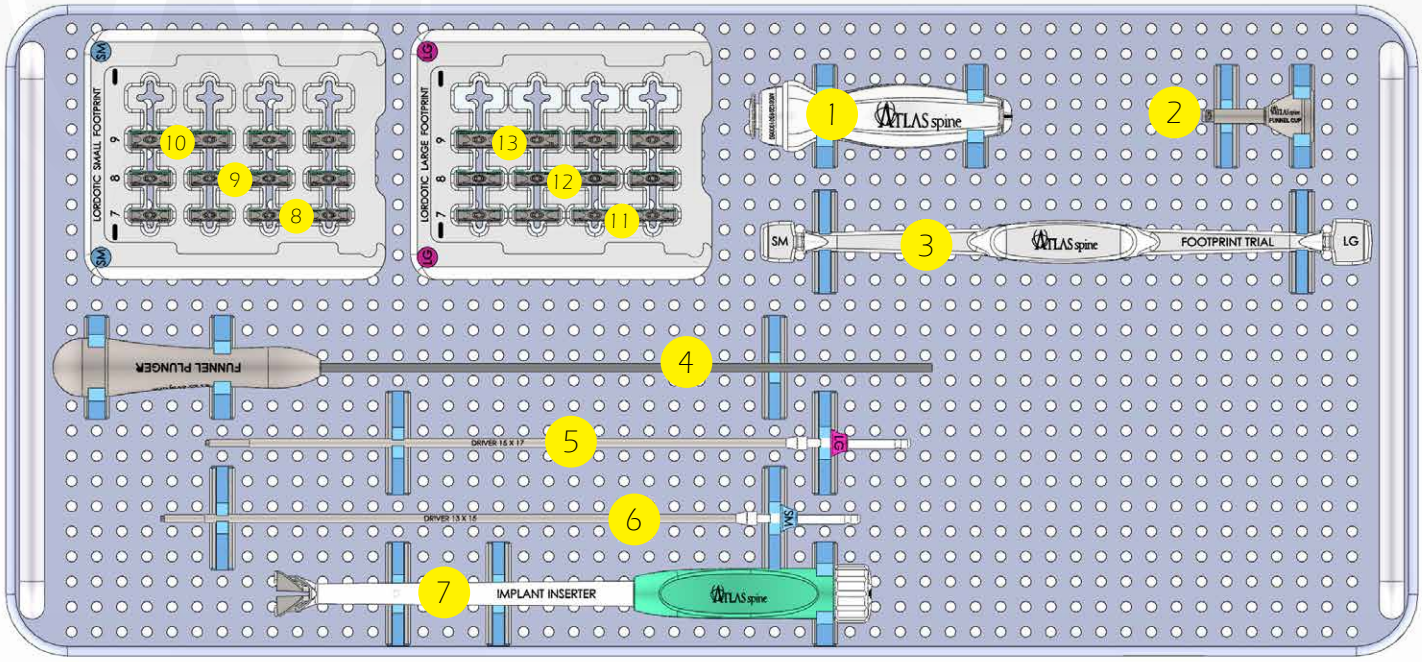
STEP 7: IMPLANT REMOVAL

To remove the implant, collapse to its starting height by rotating the driver shaft counter-clockwise. Re-attach the inserter and remove from disc space.

Note: Implants are single use only and should not be used again after any expansion within the disc space.

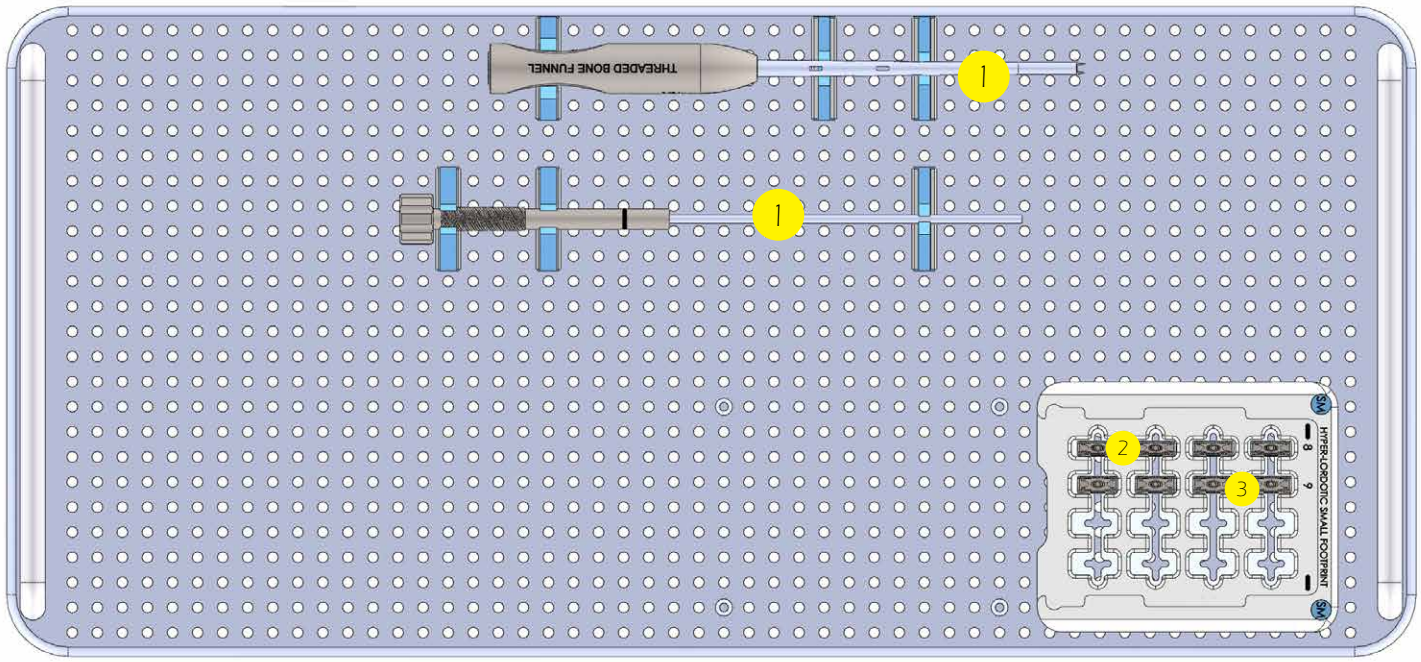
TRAY LAYOUT
INSTRUMENTS AND IMPLANTS

Top



1	2019-01-0005	Torque Limiting Handle, 9 in-lbs	8	1119-01-0007	Small Lordotic 7mm
2	2019-01-0000	Funnel Cup	9	1119-01-0008	Small Lordotic 8mm
3	2019-01-0006	Footprint Trial	10	1119-01-0009	Small Lordotic 9mm
4	2019-01-0001	Funnel Plunger	11	1119-02-0007	Large Lordotic 7mm
5	2019-01-0003	Large Driver, 15 x 17	12	1119-02-0008	Large Lordotic 8mm
6	2019-01-0004	Small Driver, 13 x 15	13	1119-02-0009	Large Lordotic 9mm
7	2019-01-0002	Implant Inserter			

Bottom



1	2019-01-0008	Threaded Bone Funnel	2	1119-03-0008	Small Hyper-Lordotic 8mm
			3	1119-03-0009	Small Hyper-Lordotic 9mm

INSTRUCTIONS FOR USE

Device System Name:
Atlas Spine Expandable Cervical Interbody System

Description:
The Atlas Spine Expandable Cervical Interbody System is comprised of an assortment of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) spacers with height expansion capability. The expandable interbody spacer is inserted into the cervical disc space and expanded to fit the patient anatomy.

The implants are offered in adjustable lordotic, fixed lordotic and adjustable hyper-lordotic configurations to help restore the natural curvature of the spine. The implants can be used in Anterior Cervical Discectomy and Fusion (ACDF).

The implants feature a bulleted nose for ease of insertion and anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

The Atlas Spine Expandable Cervical Interbody System is not intended to be used as a stand-alone device. The system must be used with a supplemental fixation system and is provided non-sterile and requires sterilization prior to use.

Indications for Use:
The Atlas Spine Expandable Cervical Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Atlas Spine Expandable Cervical Interbody System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Contraindications:
The Atlas Spine Expandable Cervical Interbody System, as with other orthopedic implants, is contraindicated for use in patients with:
1. Active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection.
2. Rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Prior fusion at the level to be treated.
5. Any circumstances not listed under the heading indications.

Potential Adverse Events:
Potential adverse events include, but are not limited to:
1. Failure of the device to provide adequate mechanical stability.
2. Loss of fixation of the implant.
3. Device component failure.
4. Migration or bending of the device.
5. Loss of bony alignment.
6. Non-union.
7. Fracture of bony structures.
8. Resorption without incorporation of any bone graft utilized.
9. Immunogenic response to the implant materials.

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings and Precautions:

The surgeon should be aware of the following when using implants:
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. No implant can be expected to withstand the unsupported stresses of full weight bearing. The size, shape and condition of human bones are also contributing factors to the success of the surgery.
2. Do not use damaged implants. The correct handling of the implant is extremely important. Implants should not be bent, notched or scratched. These operations can produce defects in surface finish and may cause internal stress concentrations which may become the focal point for eventual failure of the device.
3. Non-sterile; the Atlas Spine Expandable Cervical Interbody System implants and instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized prior to each use.
4. Single use only. Atlas Spine Expandable Cervical Interbody System implants are intended for SINGLE USE ONLY. No surgical implants should be reused. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure.
5. Do not re-sterilize single-use implants that come in contact with body fluids.
6. Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
7. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.
8. The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
9. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

MRI Compatibility Information:
The Atlas Spine Expandable Cervical Interbody System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. This system has not been tested for heating or migration in the MR environment.

Cleaning and Decontamination:

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Atlas Spine rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. Cavicide) and allow to remain in contact with devices for 5 minutes.
2. **Pre-Cleaning:** Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and disassemble instruments per instructions provided in the following page The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. Scru with the appropriate soft bristle brush until visibly clean.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and sonicat for 10 minutes. For ultrasonic cleaning follow the manufacturer's specifitions for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures.

4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes three (3) times.

5. **Drying:** Allow devices to air dry a minimum of 30 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.

Preparation and Assembly: After cleaning/disinfection, the disassembled instruments should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to Atlas any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective instruments.

Sterilization:

The Atlas Spine Expandable Cervical Interbody System instruments and implants are supplied NON-STERILE. Prior to use, all instruments and implants should be placed in the appropriate Atlas Spine case which will be wrapped in a FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using the following recommended cycle:

Method: Steam
Cycle: Pre-vac
Temperature: 270°F (132°C)
Preconditioning: Per manufacturer's settings
Exposure time: 4 minutes
Drying time: 30 minutes
Double wrapped (FDA cleared wrap)

Packaging:

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Atlas Spine.

The Atlas Spine Expandable Cervical Interbody System instruments and implants are provided in a modular case specifically intended to contain and organize the system's components. The system's instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments and implants are provided in sealed poly bags with individual product labels.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Atlas Spine Inc., 1555 Jupiter Park Dr., Suite 1, Jupiter, FL 33458, USA, by telephone at 1-561-741-1108.

Further Information:

A recommended operative technique for the use of this system is available upon request from Atlas Spine at the phone numbers provided above.

Latex Information:

The implants, instruments and/or packaging material for the Atlas Spine Expandable Cervical Interbody System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Atlas Spine Inc., 1555 Jupiter Park Drive, Suite 4 Jupiter, FL 33458 www.atlasspine.com Ph. 561-741-1108 Fx. 561-741-1870