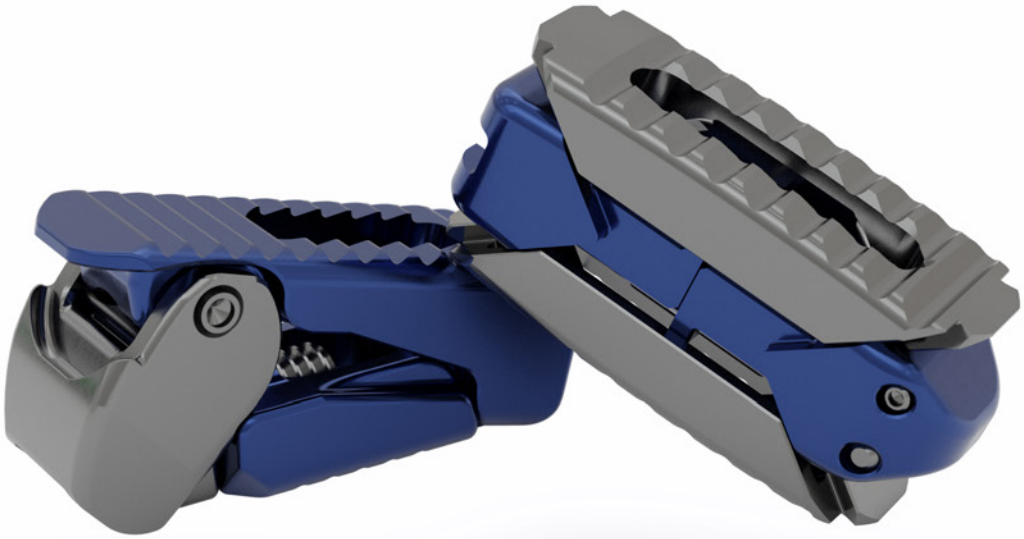
SeaSpine



EXPLORER® TO

EXPANDABLE INTERBODY TECHNOLOGY

SURGICAL TECHNIQUE

CONTENTS

EXPLORER® TO

IMPORTANT

Explorer TO implants are designed and tested for use only with the Explorer TO instruments. This surgical technique sets forth detailed, recommended procedures for this system only. As with any technical guide, each surgeon must consider the needs of each patient and make appropriate adjustments when required.

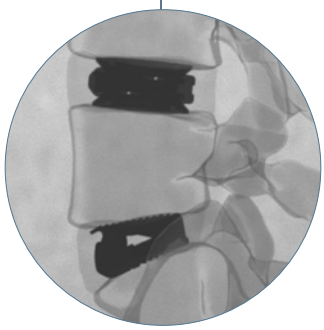
This manual is intended as a guide only. There are multiple techniques for the insertion of interbody implants, and as with any surgical procedure the surgeon should be trained and thoroughly familiar with the components of the implant system before proceeding.

DESIGN RATIONALE

Explorer® TO (TLIF Oblique) Expandable Interbody was designed to minimize impaction forces required with traditional static implants, seamlessly expand within the disc space to restore height and lordosis optimized for each individual patient, and consistently deliver autograft and/or allograft to fill any voids left in the implant from device expansion. With both a height expansion and lordotic expansion implant, surgeons can intraoperatively choose the implant that best fits the needs of the patient.

Expansion indicator for both implant types

Two locations for offset handle attachment



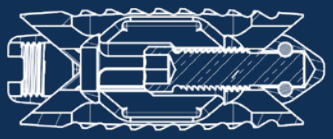
Titanium implants to easily view on fluoroscopy

Inserter allows for open and MIS approach

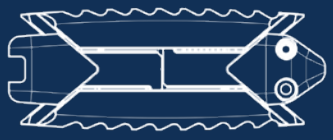
Bone delivery system through proximal end of inserter

EXPANDING POSSIBILITIES WITH MULTIPLE IMPLANT TYPES

Bulleted nose and short starting height for ease of implantation and minimal impaction



Continuous *in situ* expansion



Up to 16mm of height expansion across both implant types

Channel to post pack implants with autograft and allograft

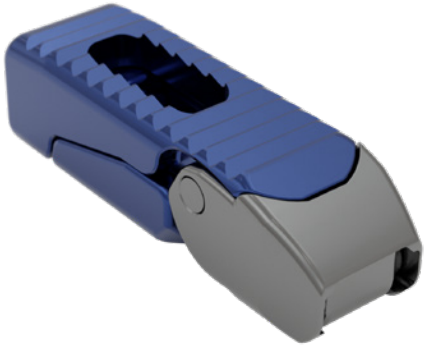
Height Expansion Implants

- Height expansion implants offered at both 0° and 8° of lordosis*

*8° is offered at starting height of 10mm

Lordotic Expansion Implants

- Lordotic expansion implants have up to 20° of lordotic expansion depending on starting height



PREOPERATIVE CONSIDERATIONS

The surgeon should select the appropriate posterior or transforaminal lumbar approach based on patient anatomy, pathology, training, and experience. The same instruments and general technique are used for all selected implant sizes/versions and approaches.

Medial/lateral and anterior/posterior X-rays, CT scans, and MRI images may be helpful in determining damaged inter-vertebral disc space, endplate angulation, and potential instability. These images may also be useful to approximate the correct implant size.

STEP 1. SURGICAL APPROACH

With the patient placed in the prone position, identify the indicated surgical site with the use of fluoroscopy. The appropriate incision is made to effectively access the desired anatomical location.

In order to gain transforaminal access to the disc space, a uni-lateral facetectomy is performed (FIG. 01). The side of approach is often determined by patient pathology or presence of scar tissue. Further boney removal may be performed using a Kerrison or drill.

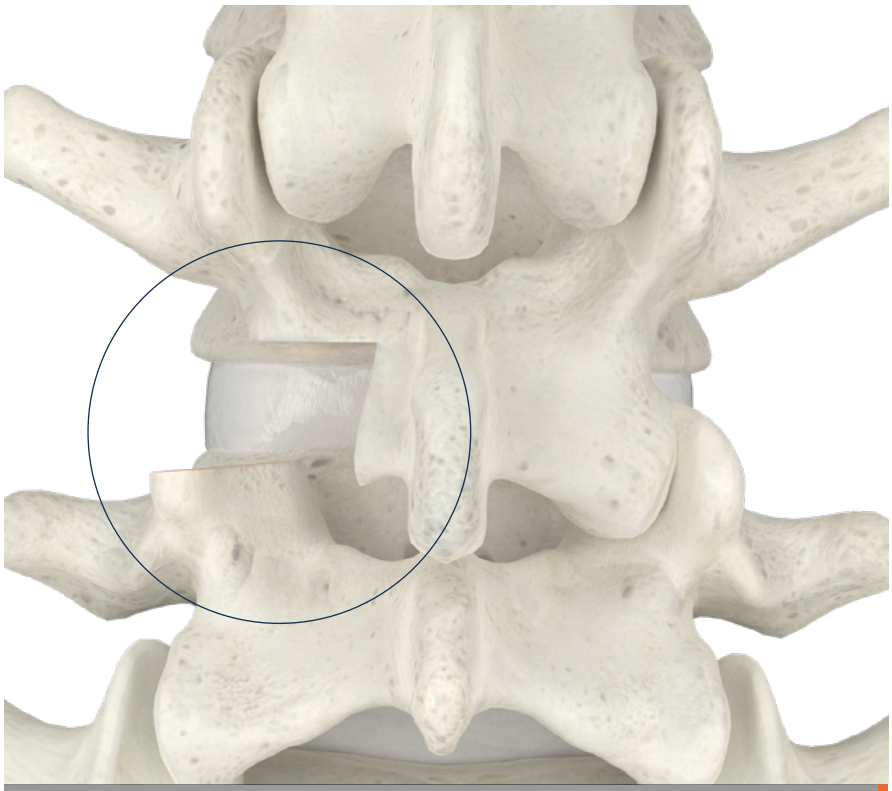


FIG. 01

STEP 2. DISC PREPARATION

The posterior disc prep set provides rotary scrapers, cup curettes, and pituitaries that will assist in the removal of the nucleus material and preparation of the endplates.

Adequate endplate preparation is important to facilitate vascular supply to the bone graft. Therefore, the superficial layers of the cartilaginous endplates are removed for this bleeding.

Placement of either autograft or allograft in the anterior and lateral aspects of the intervertebral space is recommended prior to implant insertion. This bone may be collected during approach and preparation (FIG. 02).

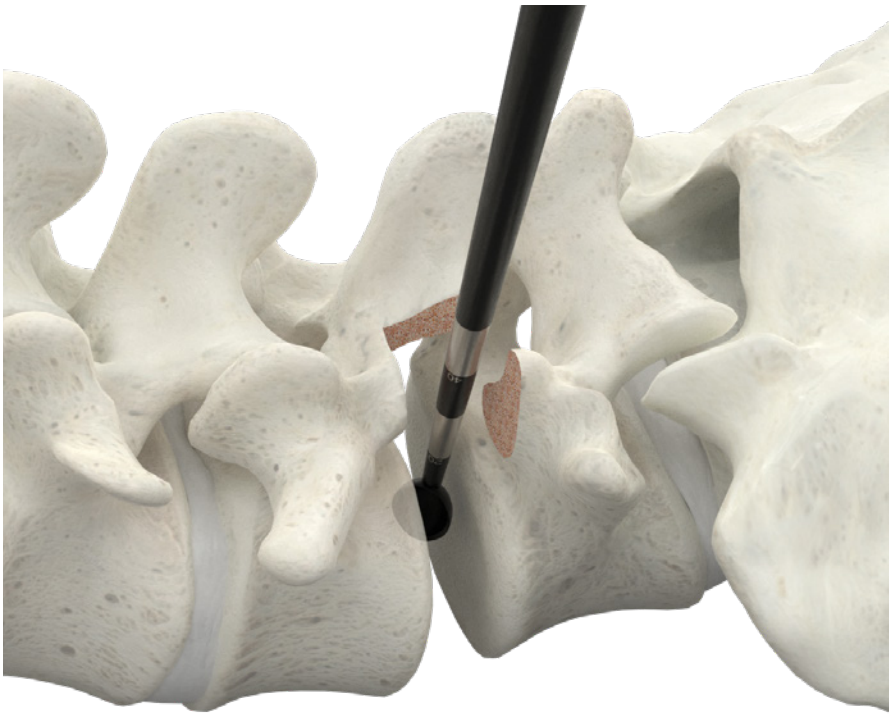


FIG. 02

NOTE
Excessive removal of the endplates may compromise construct strength and increase the potential for subsidence.

STEP 3. IMPLANT TRIALING

Height-specific trials are available to confirm adequate starting implant size. All trials are used with the Inserter T-handle available within the instrument set (FIG. 03).

A starter trial of 6mm is available for severely collapsed disc spaces. This trial can be used for either implant expansion type.

Additional trials are available to indicate the starting height of either the height expansion or the lordotic expansion implant.

Aluminum anodized rings on the trials are the same color as the corresponding implant starting height (FIG. 04).

Trial Height	Trial Color
6mm	Teal
8mm	Navy Blue
10mm	Purple
12mm	Green

NOTE
Ensure you are using the appropriate series of trials dependent on what expansion type of implant will be used. The geometries of these trials vary slightly. The height expanding implants have trials labeled “Height”, while the lordotic expanding implants have trials labeled “Lordotic.”

FIG. 03

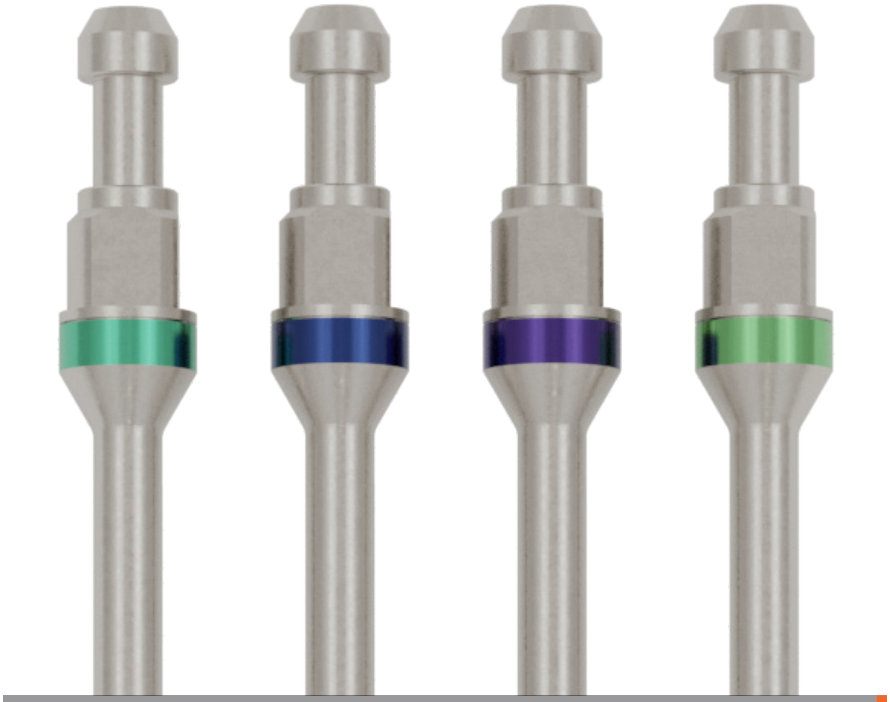


FIG. 04

STEP 3. IMPLANT TRIALING CONTINUED

Under fluoroscopic guidance, impact the selected implant trial into the disc space until the trial is in the desired location. Depending on the fit of the trial, larger trials can be sequentially inserted into the disc space until a satisfactory fit is achieved (FIG. 05).

A Slap Hammer, is available to assist in removing the trials. To attach the Slap Hammer remove the T-handle from the trial in use. Align the laser marking of the Slap Hammer with the trial and slide until there is an audible click signifying engagement. Remove the trial by impacting the sliding Slap Hammer handle in an upward motion (FIG. 06).

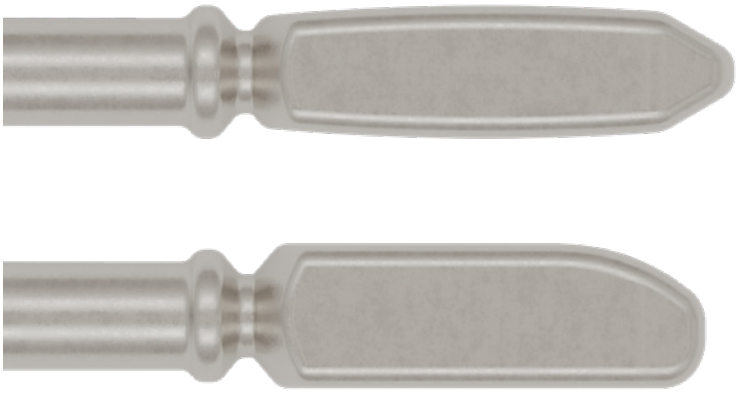


FIG. 05

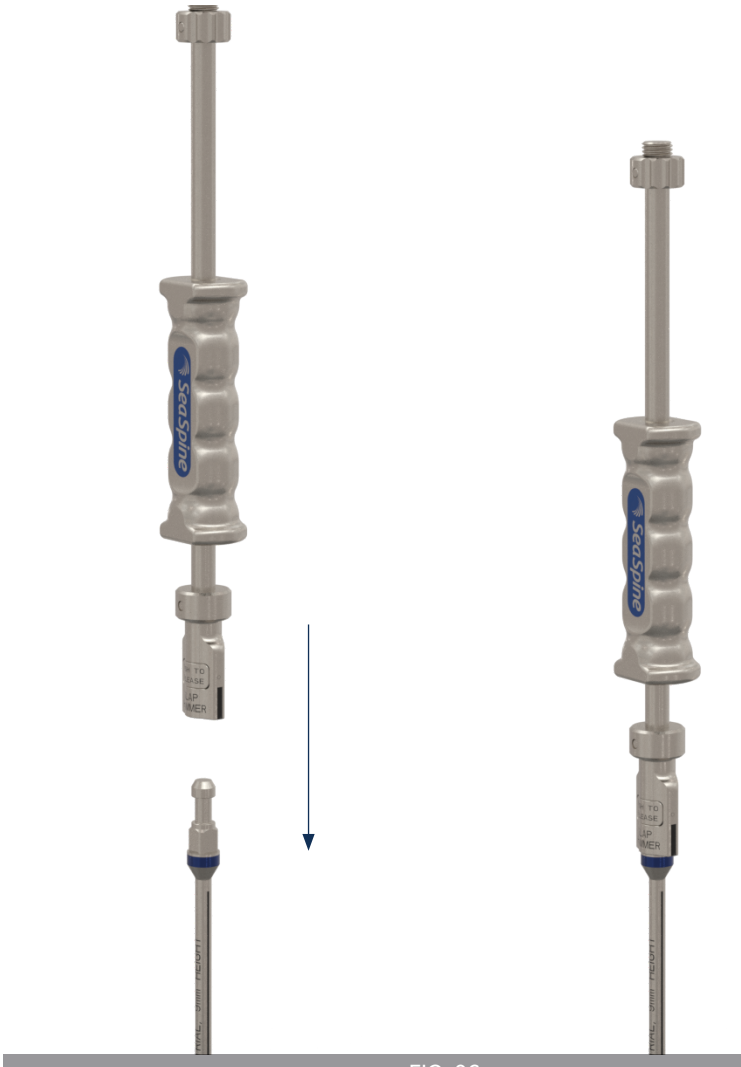


FIG. 06

STEP 4. IMPLANT SELECTION

Based on patient anatomy and initial trialing, select the desired type and size of expandable implant. Explorer® TO is available in either a height or lordotic expansion, and all implant colors correlate to implant starting height.

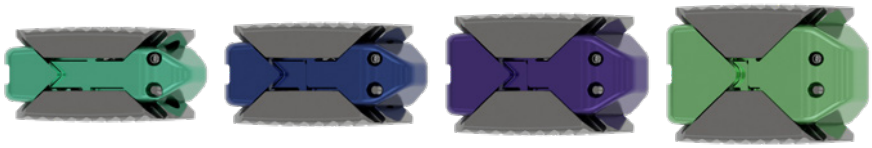
NOTE
The length indicated is overall length of the collapsed implant. All implants will decrease in overall length by 4–5mm once fully expanded.

Height Expansion

Length	Width	Height	Lordosis
28mm, 32mm	9mm, 11mm	7–11mm	0°
28mm, 32mm	9mm, 11mm	8–12mm	0°
28mm, 32mm	9mm, 11mm	10–14mm	0°, 8°
28mm, 32mm	9mm, 11mm	12–16mm	0°, 8°

Lordotic Expansion

Length	Width	Height	Lordosis
26mm, 30mm	9mm, 11mm	8mm	0–14°
26mm, 30mm	9mm, 11mm	10mm	3–17°
26mm, 30mm	9mm, 11mm	12mm	6–20°



STEP 4. IMPLANT SELECTION CONTINUED

Implant Assembly

Attach appropriately-sized implant to the Inserter, by aligning the alignment tabs on the end of the inserter with the slots in the implant. The internal threaded shaft will self-center into the threads of the implant. To tighten the implant to the inserter, rotate the thumbwheel clockwise until the implant is secure (FIG. 07).

An Inserter Wrench is available if additional force is required to tighten or loosen the implant onto the inserter. Place the wrench down the proximal end of the inserter to engage the internal shaft and rotate clockwise to tighten (FIG. 08).

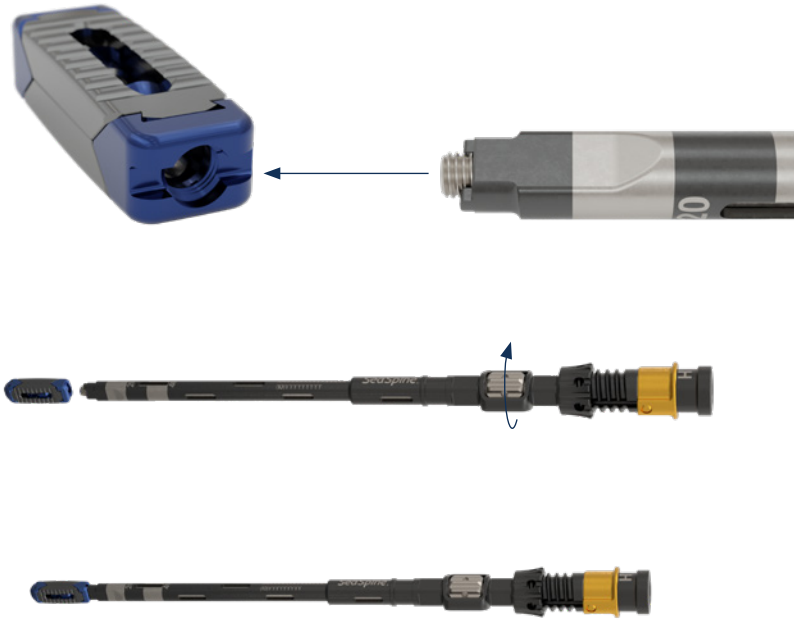


FIG. 07

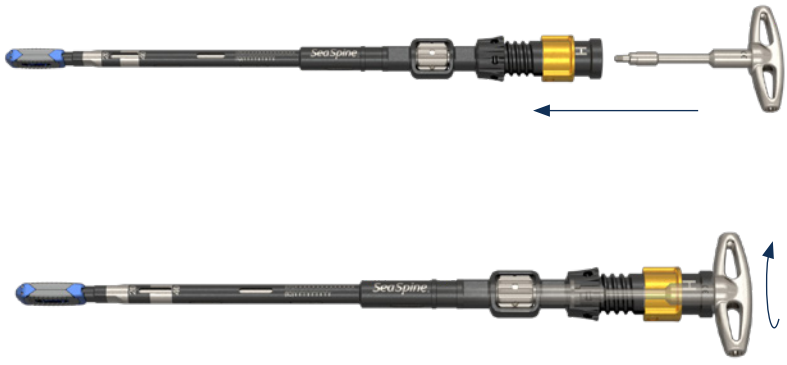


FIG. 08

Attach the Inserter Handle to the inserter to maintain stability during implantation. This handle will also provide counter-torque during expansion of the implant. Based on surgeon preference, the Inserter Handle can attach on the distal or proximal end of the thumbwheel (FIG. 09).

To attach, open the clamp on the Inserter Handle by rotating the thumbwheel counterclockwise. The clamp will slide around the square connect on the inserter. Based on surgeon preference, there are four different orientations in which the handle can be assembled. To tighten, rotate the thumbwheel on the Inserter Handle clockwise until the handle is secure on the inserter (FIG. 10).

FIG. 09

FIG. 10

STEP 4. IMPLANT SELECTION CONTINUED

Pull the gold slider proximal until it clicks into the unlocked position. Ensure the black “back out” thumbwheel has been rotated clockwise until bottomed out distally (FIG. 11). Slide the Expansion Driver through the proximal end of the inserter until the gold slider translates into the implant stating position (FIG. 12).

NOTE
The expansion driver is compatible with both the height and lordotic implants and should be sub-flush prior to impaction.

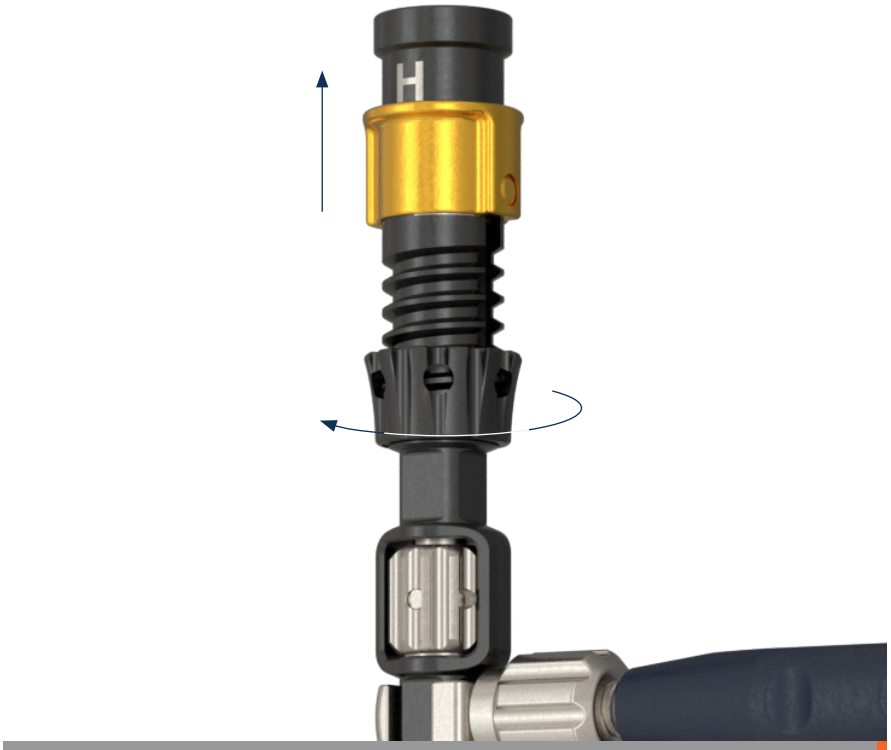


FIG. 11

FIG. 12

Prior to packing with autogenous or allogenic bone graft, confirm the driver has fully engaged the set screw of the implant by expanding the implant (FIG. 13). Connect the Torque Driver Adapter to the Torque-limiting Handle by aligning the flat feature of the AO connect (FIG. 14).

Engage the Torque Driver Adapter to the expansion driver within the inserter and rotate clockwise to confirm expansion (FIG. 15). Collapse implant prior to graft packing and implantation by rotating counterclockwise.

NOTE
Bone graft placement in the anterior and lateral aspects of the intervertebral disc space is recommended prior to interbody implantation.

FIG. 13

FIG. 14

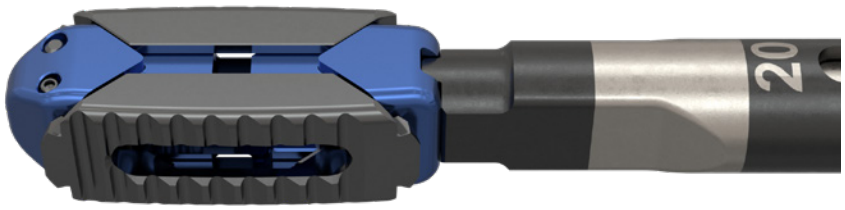


FIG. 15

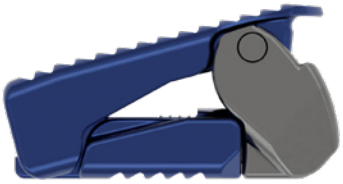
STEP 5. IMPLANT PLACEMENT

Implant Insertion

Under fluoroscopic guidance, introduce the selected implant into the disc space. Gently impact with mallet to insert the implant. Implants should be placed as far anteriorly as possible before expansion. All impaction should be done while the implant is in the collapsed state (FIG. 16).

NOTE
Lordotic expansion implants have a designated top and bottom. The top side of the implant can be identified as the fully color anodized endplate.

FIG. 16



Implant Expansion

Use the assembled Torque-limiting Handle to engage the expansion driver within the inserter and rotate clockwise for implant expansion.

While keeping the inserter stationary, rotate the Torque-limiting Handle clockwise to expand the implant. Continue expansion until desired tactile feedback is attained or maximum torque (22.5 in-lbs.) is achieved (FIG. 17).

FIG. 17

STEP 5. IMPLANT PLACEMENT CONTINUED

As the implant is expanded using the Torque-limiting Handle, the gold slider will move proximally up the shaft of the inserter (FIG. 18).

Height and lordotic indicators will be on the medial/lateral side of the inserter showing how far the implant is expanded.

Additionally, fluoroscopy should be used to visualize implant expansion. Final implant expansion should fit tightly between the vertebral bodies.

After final expansion is confirmed radiographically, remove the expansion driver by pulling the gold slider to the unlocked position. The inserter will remain in the same position for bone graft delivery (FIG. 19).

FIG. 18

FIG. 19

STEP 5. IMPLANT PLACEMENT CONTINUED

Intraoperative Repositioning

If intraoperative repositioning is needed, use the Universal Expansion Driver to collapse the implant completely before repositioning. To collapse, rotate the torque assembly counterclockwise until the handle cannot be rotated any further. Implant is now ready to reposition (FIG. 20).

An Auger is available to remove any bone graft or disc material that may be in the way of the set screw. Place the Auger down the back of the inserter and rotate clockwise. This will make a channel and clear the hex in the set screw for the Expansion Driver. Pull back on the Auger when enough bone graft has been cleared (FIG. 21).

FIG. 20

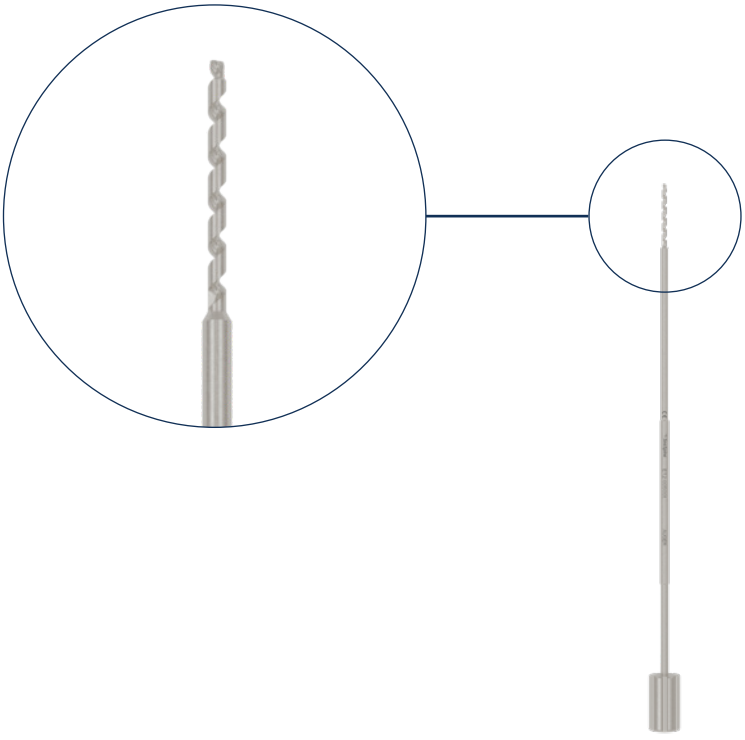


FIG. 21

If implant needs to be pulled back, the Slap Hammer provided can be threaded onto the impaction surface on the inserter (FIG. 22).

FIG. 22

STEP 6. BONE GRAFT DELIVERY

Bone Graft Delivery Assembly

Autograft or allograft can be pre-loaded into 1cc Bone Cartridges. A Syringe Adapter, Bone Cartridge Pusher, and Bone Cartridge Base are available to ease loading the cartridges. The Syringe Adapter can also act as a small funnel (FIG. 23).

Assemble the Bone Delivery Tower, Bone Delivery Rack Plunger, and Bone Cartridge Base. Thread the pre-loaded bone cartridge to the end of the Bone Delivery Tower (FIG. 24).

FIG. 23

FIG. 24

STEP 6. BONE GRAFT DELIVERY

Press the black button to unlock the Bone Delivery Tower to advance the rack plunger until the black laser etch line is at proximal end of Bone Delivery Tower (FIG. 25).

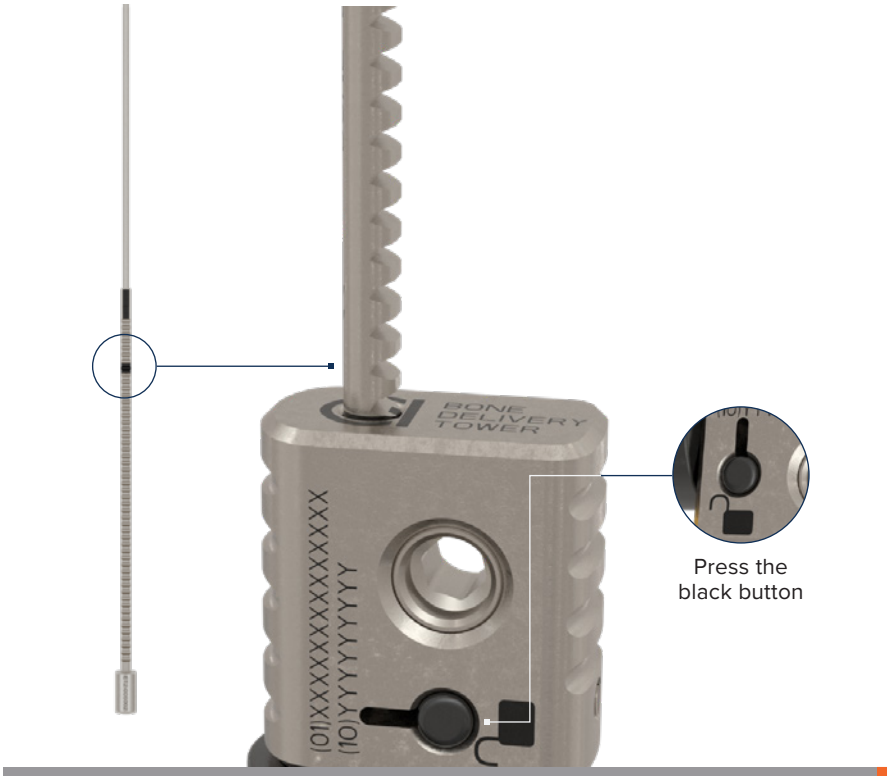


FIG. 25

Lock the rack plunger by pressing the gold button on the Bone Delivery Tower. This lock will prevent bone graft from unnecessarily extruding out the cartridge.

Multiple towers and cartridges are available to increase speed and efficiency during surgery (FIG. 26).

FIG. 26

STEP 6. BONE GRAFT DELIVERY CONTINUED

Bone Graft Delivery

Insert the bone graft delivery assembly through the back of the inserter. The Bone Delivery Tower will be locked to the inserter once the gold slider transitions to the lock position; this can be confirmed by an audible click (FIG. 27).

NOTE
Failure to lock bone graft delivery instrument to the inserter may result in allograft/autograft clogging the inserter.

To advance bone graft into implant, push the black button on the Bone Delivery Tower to unlock the Bone Delivery Rack Plunger (FIG. 28).

FIG. 27

Press the black button

FIG. 28

Advance the plunger by pushing on the proximal end. If challenging, use the torque-limiting assembly and rotate clockwise to advance (FIG. 29).

FIG. 29

STEP 6. BONE GRAFT DELIVERY CONTINUED

To remove the Bone Delivery Tower, pull the gold slider proximally to the unlocked position (FIG. 30).

If another 1cc of bone graft is required, repeat previous bone graft delivery step until desired amount of bone graft has filled the implant. Resistance will be felt in the instrumentation as the cage becomes full.

FIG. 30

STEP 7. FINAL STEPS

Inserter Release

Radiographically, verify final position and expansion of the implant prior to inserter release. To release the inserter from the implant, rotate the thumbwheel counterclockwise and pull back on the inserter (FIG. 31). The Inserter Wrench is available to ease loosening the inserter if it is difficult to get sufficient grip on the thumbwheel (FIG. 32).

If bilateral insertion is desired for PLIF approach, a second implant of the same type and size may be inserted into the contralateral side of the disc space. Follow steps 2–7.

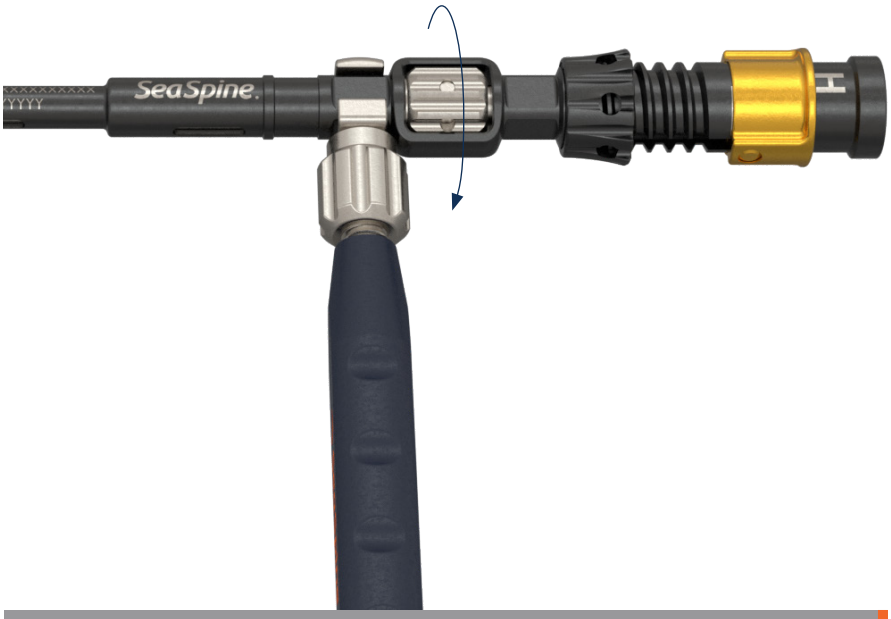


FIG. 31

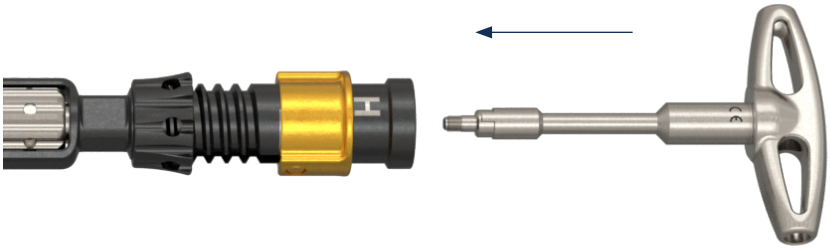


FIG. 32

STEP 7. FINAL STEPS CONTINUED

Closure

Supplemental internal fixation is implanted using methods and techniques as described in the surgical technique specific to the system chosen. Close the wound using an appropriate procedure depending on the approach utilized (FIG. 33).

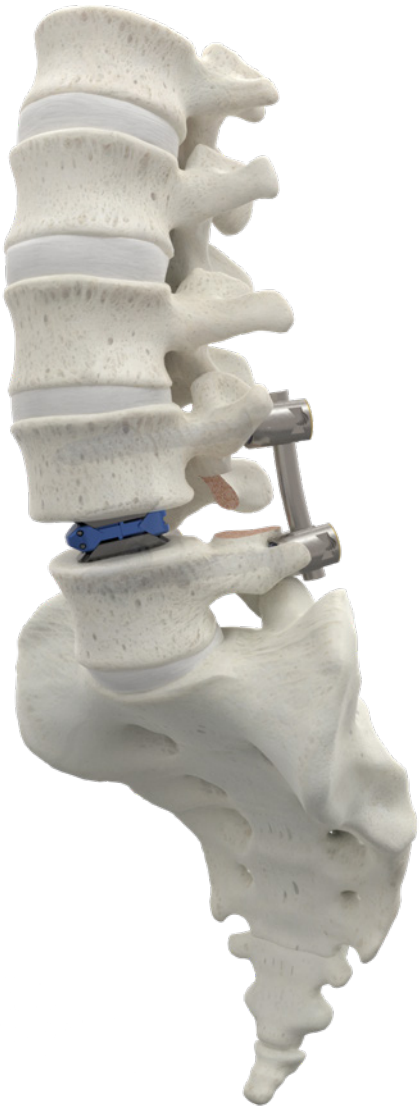


FIG. 33

Removal or Revision Procedure

Using radiographic guidance if necessary, locate the implanted device with the inserter. The lead-in on the inserter internal shaft will assist in self-centering onto the implant. Thread the inserter back onto the implant by rotating the thumbwheel clockwise.

An Auger is available to remove any bone graft that may be in the way of the set screw. Place the Auger down the back of the inserter and rotate clockwise. This will make a channel and clear the hex in the set screw for the expansion driver. Pull back on the Auger when enough bone graft has been cleared.

Place the expansion driver in the inserter until in the locked position. Engage the expansion driver with the torque assembly and turn counterclockwise to collapse the implant. Resistance will be felt when the implant is fully collapsed. Radiographic confirmation is advised.

With the implant collapsed and connected to inserter, the implant can be removed by pulling back on the inserter. If additional force is needed, remove the expansion driver and thread the Slap Hammer into the back of the inserter.

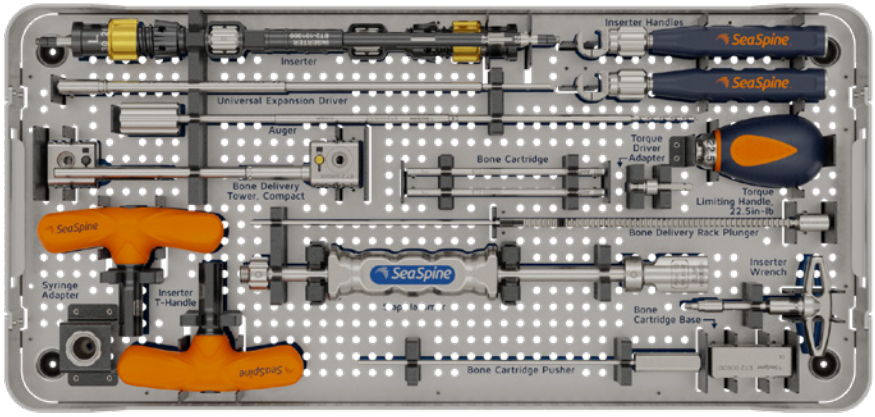
ORDERING INFORMATION

TRAY CONFIGURATION EXPLORERTO: EXPLORER® TO INSTRUMENT & IMPLANT SET

TOP LEVEL

Instrument & Implant Set

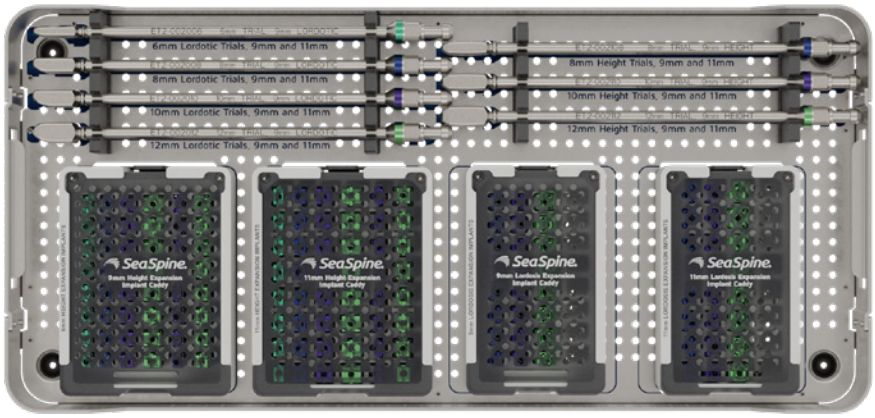
PN ET3-109001



BOTTOM LEVEL

Implant & Trials

PN ET3-109002

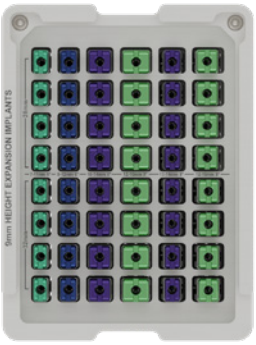


TRAY CONFIGURATION EXPLORERTO: EXPLORER® TO IMPLANT SET

CADDY

Height Expansion,
9mm Width (Standard)

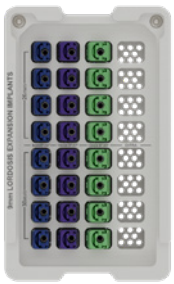
ET3-009301



CADDY

Lordosis Expansion,
9mm Width (Standard)

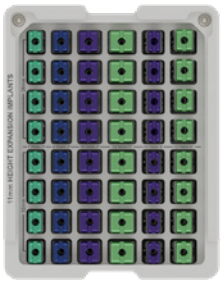
ET3-009101



CADDY

Height Expansion,
11mm Width (Optional)

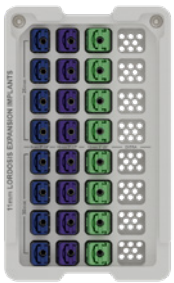
ET3-009400



CADDY

Lordosis Expansion,
11mm Width (Optional)

ET3-009200



For additional information or set configurations, please contact SeaSpine® customer service.

INSTRUMENTATION EXPLORERTO: EXPLORER® TO INSTRUMENTS

Inserter, Explorer TO

PN ET2-101000

Inserter Handle

PN ET2-001001

Universal Expansion Driver

PN ET2-101101

Torque-limiting Handle, 22.5 in–lbs

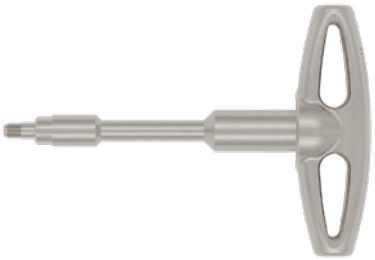
PN ET2-001102

Torque Driver Adapter

PN ET2-001112

Inserter Wrench

PN ET2-101003



PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION EXPLORERTO: EXPLORER® TO INSTRUMENTS

Slap Hammer, Explorer TO

PN ET2-105000

Bone Delivery Tower, Compact

PN ET2-106001

Bone Delivery Rack Plunger

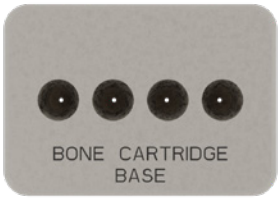
PN ET2-106002

Bone Cartridge

PN ET2-006000

Bone Cartridge Base

PN ET2-006010



Bone Cartridge Pusher

PN ET2-006012

Syringe Adapter

PN ET2-006020

Inserter T-handle

PN TO2-001001

PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION EXPLORERTO: EXPLORER® TO INSTRUMENTS

Auger

PN ET2-005001

6mm Trial, 9mm Lordotic

PN ET2-002006

8mm Trial, 9mm Lordotic

PN ET2-002008

10mm Trial, 9mm Lordotic

PN ET2-002010

12mm Trial, 9mm Lordotic

PN ET2-002012

8mm Trial, 9mm Height

PN ET2-002108

10mm Trial, 9mm Height

PN ET2-002110

12mm Trial, 9mm Height

PN ET2-002112

PRODUCTS SHOWN NOT TO SCALE

INSTRUMENTATION EXPLORERTO: EXPLORER® TO INSTRUMENTS

6mm Trial, 11mm Lordotic

PN ET2-102006

8mm Trial, 11mm Lordotic

ET2-102008

10mm Trial, 11mm Lordotic

PN ET2-102010

12mm Trial, 11mm Lordotic

PN ET2-102012

8mm Trial, 11mm Height

PN ET2-102108

10mm Trial, 11mm Height

PN ET2-102110

12mm Trial, 11mm Height

PN ET2-102112

PRODUCTS SHOWN NOT TO SCALE

IMPLANTS EXPLORERTO: EXPLORER® TO

EXPLORERTO: 9mm Height Implants (Standard)

Part Number	Part Description
ET1-302807	Height Expansion, 9 x 28 x 7–11mm, 0°
ET1-302808	Height Expansion, 9 x 28 x 8–12mm, 0°
ET1-302810	Height Expansion, 9 x 28 x 10–14mm, 0°
ET1-302812	Height Expansion, 9 x 28 x 12–16mm, 0°
ET1-303207	Height Expansion, 9 x 32 x 7–11mm, 0°
ET1-303208	Height Expansion, 9 x 32 x 8–12mm, 0°
ET1-303210	Height Expansion, 9 x 32 x 10–14mm, 0°
ET1-303212	Height Expansion, 9 x 32 x 12–16mm, 0°
ET1-382810	Height Expansion, 9 x 28 x 10–14mm, 8°
ET1-382812	Height Expansion, 9 x 28 x 12–16mm, 8°
ET1-383210	Height Expansion, 9 x 32 x 10–14mm, 8°
ET1-383212	Height Expansion, 9 x 32 x 12–16mm, 8°

EXPLORERTO11H: 11mm Height Implants (Optional)

Part Number	Part Description
ET1-402807	Height Expansion, 11 x 28 x 7–11mm, 0°
ET1-402808	Height Expansion, 11 x 28 x 8–12mm, 0°
ET1-402810	Height Expansion, 11 x 28 x 10–14mm, 0°
ET1-402812	Height Expansion, 11 x 28 x 12–16mm, 0°
ET1-403207	Height Expansion, 11 x 32 x 7–11mm, 0°
ET1-403208	Height Expansion, 11 x 32 x 8–12mm, 0°
ET1-403210	Height Expansion, 11 x 32 x 10–14mm, 0°
ET1-403212	Height Expansion, 11 x 32 x 12–16mm, 0°
ET1-482810	Height Expansion, 11 x 28 x 10–14mm, 8°
ET1-482812	Height Expansion, 11 x 28 x 12–16mm, 8°
ET1-483210	Height Expansion, 11 x 32 x 10–14mm, 8°
ET1-483212	Height Expansion, 11 x 32 x 12–16mm, 8°

EXPLORERTO: 9mm Lordotic Implants (Standard)

Part Number	Part Description
ET1-142608	Lordosis Expansion, 9 x 26 x 8mm, 0–14°
ET1-172610	Lordosis Expansion, 9 x 26 x 10mm, 3–17°
ET1-102612	Lordosis Expansion, 9 x 26 x 12mm, 6–20°
ET1-143008	Lordosis Expansion, 9 x 30 x 8mm, 0–14°
ET1-173010	Lordosis Expansion, 9 x 30 x 10mm, 3–17°
ET1-103012	Lordosis Expansion, 9 x 30 x 12mm, 6–20°

EXPLORERTO11L: 11mm Lordotic Implants (Optional)

Part Number	Part Description
ET1-242608	Lordosis Expansion, 11 x 26 x 8mm, 0–14°
ET1-272610	Lordosis Expansion, 11 x 26 x 10mm, 3–17°
ET1-202612	Lordosis Expansion, 11 x 26 x 12mm, 6–20°
ET1-243008	Lordosis Expansion, 11 x 30 x 8mm, 0–14°
ET1-273010	Lordosis Expansion, 11 x 30 x 10mm, 3–17°
ET1-203012	Lordosis Expansion, 11 x 30 x 12mm, 6–20°

INSTRUCTIONS FOR USE

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Indications for Use

When used as an intervertebral body fusion device, the system is intended for spinal fusion procedures at one or two contiguous levels (L2–S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation.

SeaSpine® Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

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

Contraindications

Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

Absolute contraindications:

- Infection in or around the operative site
- Allergy or sensitivity to implant materials
- Any case not described in the indication

Relative contraindications:

- Local inflammation
- Morbid obesity
- Pregnancy
- Fever or leukocytosis
- Prior fusion at the level(s) to be treated
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Paraparesis or progressive neurologic conditions
- Spondylolisthesis or retrolisthesis > Grade 1
- Known endocrine or metabolic disorder that may affect bone healing or resistance to subsidence
- Any case not requiring bone graft and fusion or where fracture healing is not required
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality or anatomical definition
- Unsuitable or insufficient bone support
- Bone immaturity
- The patient's activity level, mental condition, occupation and/or a patient unwilling to cooperate with the postoperative instructions
- Any case where implant utilization would interfere with anatomical structures or expected physiological performance
- Use of incompatible materials from other systems

INSTRUCTIONS FOR USE

Cleaning & Sterilization for Instruments & Implants

Instruments and Implants are supplied “NON-STERILE” and must be decontaminated and sterilized before use. Please refer to the IFU for details.

RxOnly

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www.seaspine.com/eIFU
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EXPLORER® TO

EXPANDABLE INTERBODY TECHNOLOGY

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