SURGICAL TECHNIQUE MANUAL

Accelus

TORO

Toro-L® Interbody Fusion System

Contents

TORO-L

The Integrity Implants Toro-L Interbody Fusion System incorporates a bi-directional expandable lumbar interbody fusion device intended for use in the thoracolumbar spine and is intended for intervertebral lumbar fusion via a lateral surgical approach. The Toro-L Interbody Fusion System implant is offered in a range of sizes and lordotic options to accommodate variation in patient anatomy. The Toro-L Interbody Fusion System expandable implant has integrated ramps that allow the implant to be inserted in a non-expanded form, and then subsequently expanded to full width and desired height through continuous expansion. When the desired final height is achieved, the locking system is engaged to prevent the implant from collapsing. After the implant is locked it can then be post-packed with bone graft. The implant's configuration has protrusions on the superior and inferior endplates of the implant to grip the adjacent vertebral bodies and resist expulsion.

INDICATIONS FOR USE

The Toro-L Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortical cancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Toro-L Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic Degenerative Disc Disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Toro-L Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

Equipment Requirements

PATIENT POSITIONING

- Radiolucent Bendable Surgical Table
- 3-inch Silk Tape
- Axillary Roll
- Foam Padding

NEUROMONITORING

- Neurophysiologist or Neuromonitoring Technician
- Neuromonitoring Probe for Open Nerve Detection
- Directional Dilators
- Neuromonitoring Clip for Directional Dilation

INSTRUMENTS

- C-Arm
- Light Source
- Toro-L Instrument Tray
- Toro-L Retractor System
- Toro-L Articulating Arm and Bed Rail Mount
- Lateral Disc Prep Tray One
- Lateral Disc Prep Tray Two

IMPLANTS

- Toro-L Implants

POSTERIOR FIXATION OPTIONS

- LineSider MIS Fixation
- LineSider Cortical Fixation
- LineSider Open Fixation

LINESIDER

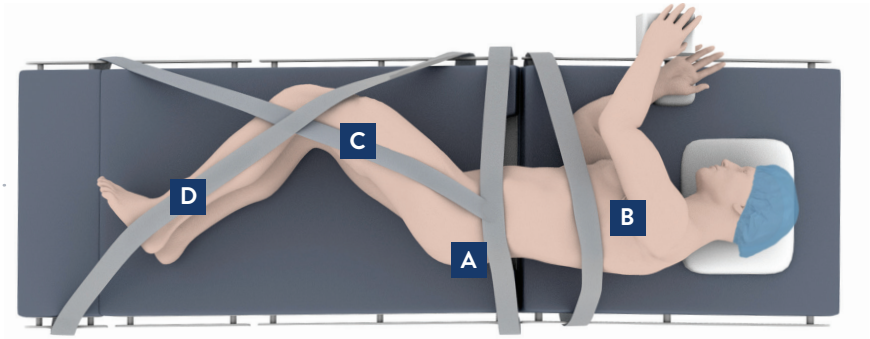
Reference the LineSider Spinal System Surgical Technique (STM-00005) and/or Instructions for Use (IFU-00008) for additional important labeling information

Patient Positioning

1 Position the patient in the lateral decubitus position on a bendable radiolucent table. Make sure the top of the iliac crest is positioned several centimeters superior to the break in the table. This will prohibit the patient from sliding inferiorly should the table need to be bent for better access to the spine.

2 Prior to securing the patient to the table use AP fluoroscopy to ensure the patients spine is a true 90° to the floor. In other words, when the C-Arm is perpendicular to the floor the image taken should show crisp endplates and superimposed pedicles at the operative level.

3 At this time use tape (it is recommended to use three-inch silk tape for the best results) to secure the patient to the table.



▸ Fig. 1

A First tape over the crest and around the bed. Do not break the tape during this process. Go over the patient and around the bed at least three to four times.

B The second piece of tape will go over the patient's upper torso making sure it is completely clear of the surgical site. This tape should also remain unbroken and go around the patient at least two to three times.

C Then start another piece of tape and run it down the patient's ipsilateral leg starting at the tape that was placed over the crest and around the table. Take this tape to the end of the bed and secure it to the foot of the bed but do not break it off.

D Continue the piece of tape across the underside of the bed toward the patient's feet and then back up the patient's lower leg and bring it around the piece of tape that goes over the crest. Repeat this step at least two to three times.

▸ Fig. 1

(B) TIP:

It is important to make sure this tape is tight enough to hold the patient in position but not so tight as to restrict breathing.

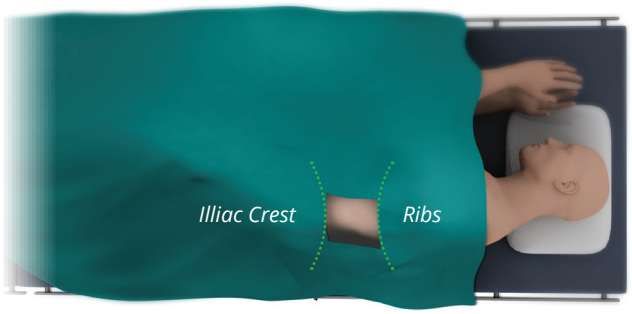
(D) TIP:

Make sure that foam padding is placed between the ipsilateral knee and the tape, between the knees, and between the contralateral knee and the bed.

4 If the surgeon wants to break the bed to tighten the skin or help facilitate access to the L4-L5 Disc space due to high crest, now is the time to do so. It is not recommended to break the bed any more than is necessary. ▸ Fig. 2

▸ Fig. 2

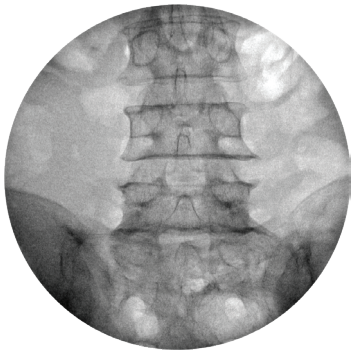
5 The patient can now be draped making sure that opening in the drape allows for sterile prep to done from the top of the crest to the bottom of the rib. ▸ Fig. 3



▸ Fig. 3

6 After the patient is draped and the table is broken it is necessary to recheck the patient's position and make sure the operative level is still perpendicular to the floor. The C-Arm should provide true AP images at 0° (crisp endplates, symmetrical pedicles, and the spinous process midline) and true lateral images at 90° (crisp endplates and superimposed pedicles). If any minor adjustment is necessary, the table should be manipulated to obtain the correct images.

▸ Fig. 4



▸ Fig. 4a

TIP: *If more than one level is being addressed it may be necessary to adjust the bed between levels so true AP and lateral images are obtained.*

7 Once standard surgical site preparation is complete the patient can now be marked to identify incision site and anatomical landmarks.

▸ Fig. 4b

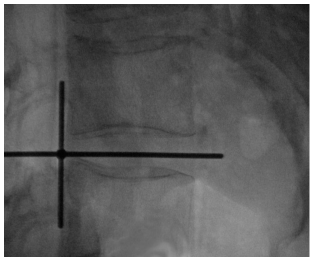
Landmark Identification and Incision Site Marking

1 Make longitudinal lines that mark the anterior and posterior edges of both vertebral bodies at the surgical site.

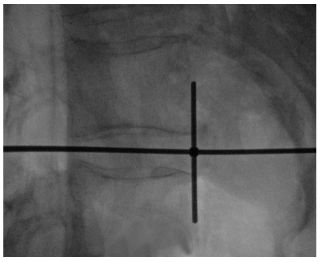
▸ Fig. 5

2 Mark a longitudinal line that goes anterior to posterior all the way through the disc space and continues out to the surgical drape. This line, in between the anterior/ posterior edges of the disc space, will facilitate an incision site for the surgeon. But running it out past the anterior edge of the incision site will also help the C-arm technician by giving them a direction to orient their machine and have it parallel to the endplates. ▸ Fig. 6

3 Lastly mark the middle of the disc space. This will give the surgeon a reference point when they are dilating down through the retroperitoneal space and docking the Retractor on the spine. ▸ Fig. 7

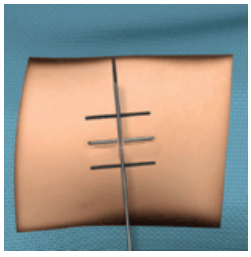


▸ Fig. 5a

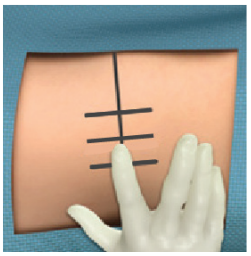


▸ Fig. 5b

Anterior



▸ Fig. 6



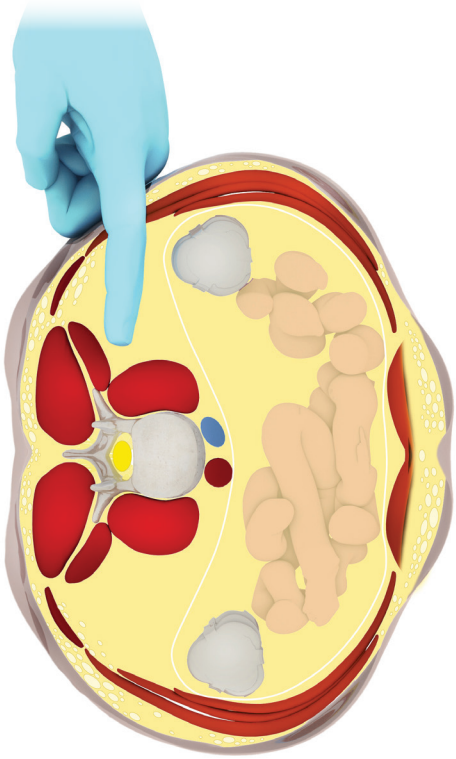
▸ Fig. 7

Posterior

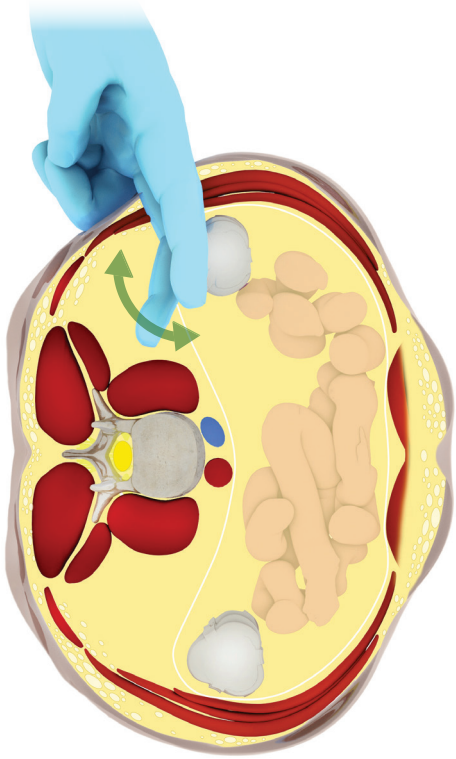
Retroperitoneal Access

The skin and fascia are incised along the predetermined marking using a combination of scalpel and electrocautery. The external obliques, the internal obliques, and the transverse abdominus lye just below the fascia and should be traversed using blunt scissor and finger dissection. Due to the sensory nerves in each of these muscles', electrocautery is not recommended. Once all muscle planes have been dissected through, there should be a distinct "pop". This will be accompanied by a constriction around the top of their dissection finger and a loss of resistance at the end of the finger. This indicates that the retroperitoneal space has been reached. ▸ Fig. 8

Further confirmation that the retroperitoneal space has been reached can be obtained by identifying anatomical landmarks. If the surgeon takes their finger and advances towards the spine, they should be able to palpate the psoas muscle and feel the edges of the transverse processes. If the incision is close to the pelvis and they move their finger caudal they should be able to palpate the underside of the iliac crest. If their incision is close to the ribs, then they should be able to move their finger cephalad and palpate the twelfth rib. All of this should be done with no resistance to the end of their finger. ▸ Fig. 9



▸ Fig. 8



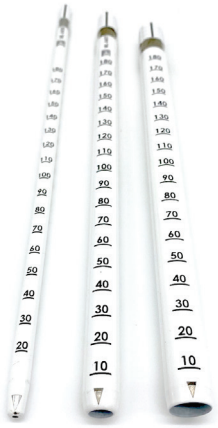
▸ Fig. 9

Dilation

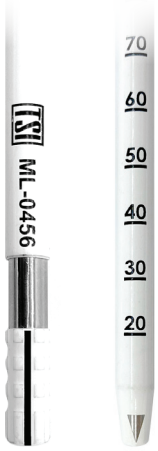
TIP: *If the surgeon elects to utilize neuromonitoring during the dilation, then the dilators should have the neuromonitoring clip attached. The dilators are all capable of directional dilation. The direction of the stimulation is noted distally on the dilator with an arrow and proximally with a line.* ▶ Fig. 10-12

1 Once the surgeon has confirmed their entry into the retroperitoneal space, they can then insert the first dilator. The ideal docking position for the initial Dilator is in the middle off the disc space. ▶ Fig. 13

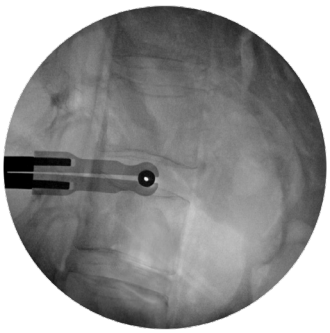
▶ Fig. 10



▶ Fig. 11

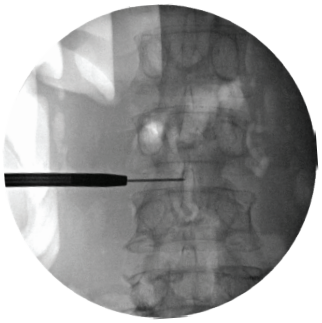


▶ Fig. 12

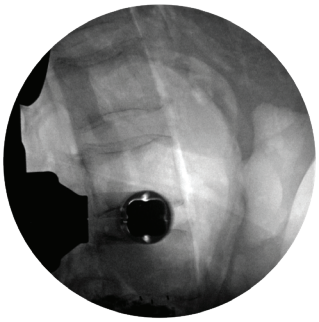


▶ Fig. 13

2 Care should be taken to make sure the surgeon is aiming for this trajectory prior to advancing the Dilator through the psoas muscle. This will ensure that the planes of the psoas muscle are being gently split along the intended pathway which will be followed by the subsequent Dilators and the Inlet Retractor. When the psoas muscle has been traversed and the surgeon has reached the targeted position on the disc space with the Dilator, a cross table AP image should be taken to confirm that the Dilator is fully advanced and sitting directly on the disc space. At this point the Dilator can be docked with the use of the K-wire provided. The K-wire should be advanced to approximately halfway through the disc space to secure its position. The depth of this can be confirmed with a second cross table AP image. ▸ Fig. 14-15

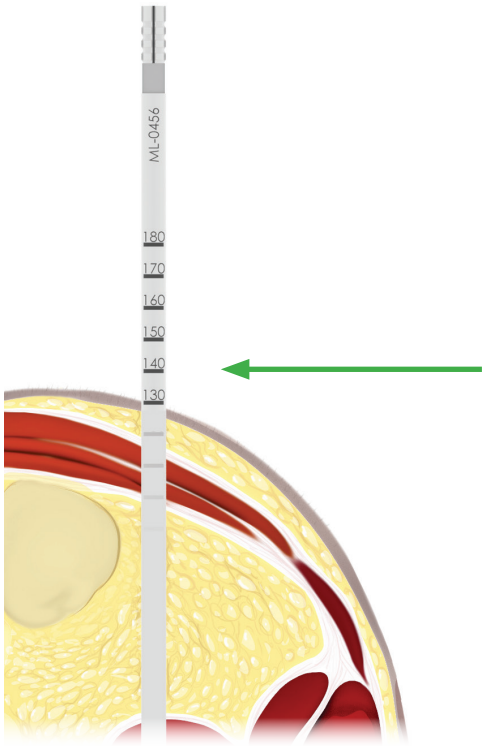


▸ Fig. 14



▸ Fig. 15

3 The surgeon should take note of the depth markings on the initial Dilator so the proper Blade length of the Retractor can be assembled on the back table. ▸ Fig. 16



▸ Fig. 16

Inlet Retractor

The Inlet Rectrator Blades come in depths of 80mm to 160mm in 10mm increments. It is recommended to have the proximal end of the Retractor as close to the skin as possible, but the surgeon should always round up if an intermediary size is observed.

For example: *If the depth reading of the initial Dilator is 135mm then the appropriate size Retractor is 140mm.*

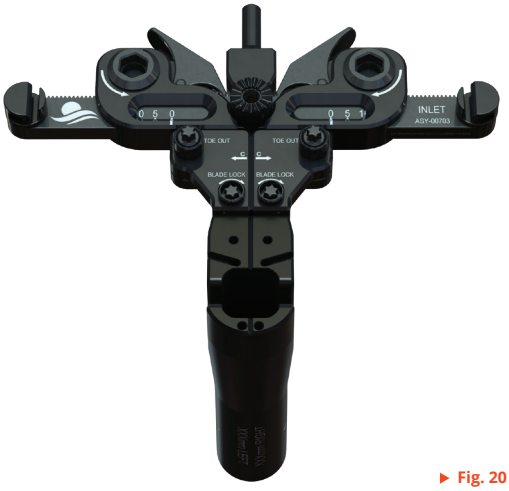
After the Retractor Blade length is established the two subsequent Dilators can be inserted. Once the three Dilators are inserted remove the third Dilator and slide the fourth Dilator over the second Dilator to accommodate for the Inlet Retractor.

When the first, second, and fourth Dilators have been inserted the surgeon can then position the Inlet Retractor. The Retractor has multiple options for Blade material and Blade retention. The three Blade materials available are PEEK, aluminum, and stainless steel. There are two Blade retention options. The Solid Portal Frame creates a fixed tube. The Inlet Rack facilitates a split tube retractor system. Regardless of material, all the Blades are of the same design and can be used with either of the retention options. Which Blade material and blade retention option is utilized is left up to surgeon discretion. For the purposes of this surgical technique, we will discuss the split tube design paired with the PEEK Blades. ▸ Fig. 17-20

▸ Fig. 17

▸ Fig. 18

▸ Fig. 19



▸ Fig. 20

Inlet Retractor

TIP: *The inner diameter (ID) of the Inlet Retractor is square and therefore the orientation to the patient is critical. The Retractor Blades are designed with fixation pin holes on two sides that should be oriented in the cephalad/caudal plane. The fixation pin holes should be equidistant from the endplates and the Retractor should be parallel to the endplates.* ▸ Fig. 21

TIP: *The distal end of the blades have orientation markers for a AP shot in order to make sure the retractor is docked on the vertebral body.* ▸ Fig. 22

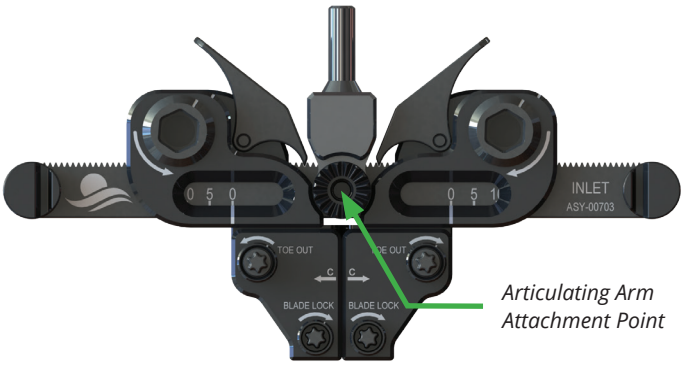
Once the Retractor has been inserted an AP image should be taken for confirmation that the blades are fully seated on the spine. Tantulum Markers on the distal end of the blades can be used as a visual aid during anatomical placement. After confirmation, the surgeon should attach the Articulating Arm to the Retractor. ▸ Fig. 22-23

TIP: *To ensure the Articulating Arm will be out of the surgeon's workspace it is recommended to attach the Arm to the table at the head of the bed, on the anterior side of the patient.*

TIP: *Maintain gentle downward pressure on the Retractor while attaching the Articulating Arm.*

▸ Fig. 21

▸ Fig. 22



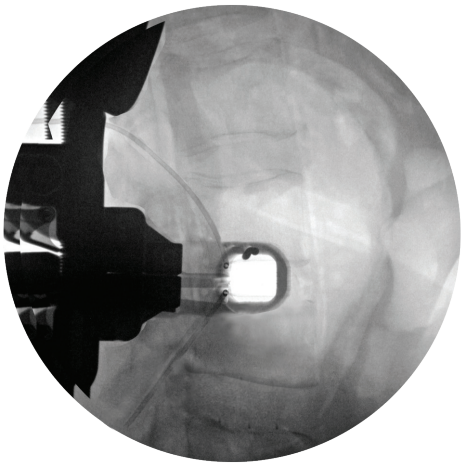
▸ Fig. 23

Inlet Retractor

When the Articulating Arm is fully tightened on both the bed and the Retractor, a lateral image should be taken to confirm the Retractor is oriented correctly to the patient. The Retractor should be straight up and down with relation to the spine. If any anterior or posterior trajectory is noted the Retractor should be adjusted at this time. ▸ Fig. 24

The surgeon can now deliver the Fixation Pin.

TIP: *Prior to inserting the Fixation Pin, it is recommended that the Neuromonitoring Probe be inserted in the Fixation Pin hole on the Retractor to ensure that a nerve is not traversing across the intended path for the Fixation Pin.* ▸ Fig. 25



▸ Fig. 24

The Retractor gives the surgeon the ability to deliver two Fixation Pins. One cephalad and one caudal. It is recommended to utilize only one pin. If two pins are used it will restrict the necessary mobility of the segment during decompression and Implant insertion.

For Pin delivery, drop the appropriate Fixation Pin into the Retractor Blade cannula. Use the Pin Driver to thread the Pin into the vertebra. ▸ Fig. 26

▸ Fig. 25

Dilators one, two, and four can now be removed from the Retractor and the Light Source can be inserted. It is recommended to leave the K-wire in until after the Light Source has been inserted and illuminated so the surgeon can visually confirm that the K-wire is still in the center of the Retractor. Confirming this placement allows the surgeon to know that the distal end of the Retractor has not drifted in any direction during insertion, and they now have a safe trajectory to begin their discectomy.

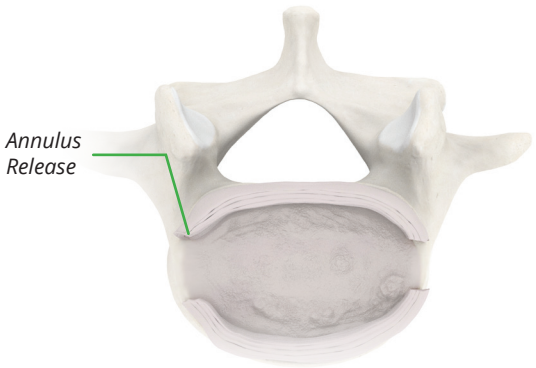
▸ Fig. 26

Annulotomy & Discectomy

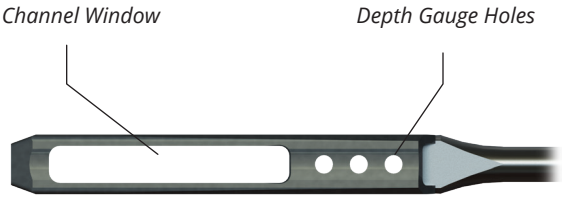
1 After an ipsilateral annulotomy is performed the system is equipped with several instruments that can facilitate the necessary contralateral annulus release. ▸ Fig. 27

The Box Cutter can now be used to remove a working channel of disc material. This channel will be necessary to accommodate the subsequent instruments that will facilitate the removal of disc necessary for full Implant expansion.

▸ Fig. 28

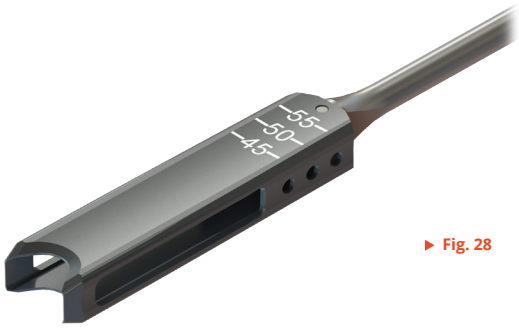


▸ Fig. 27

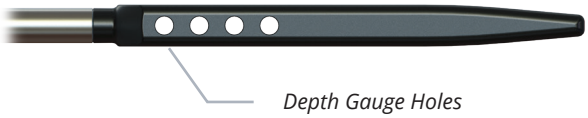


TIP: *When using the Box Cutter, it is important to verify with fluoroscopy that the instrument is being inserted along the intended path to mitigate any chance of endplate damage. The channel window and holes in the instrument are intended to be used to gauge both depth and alignment. The overall length of the Box Cutter is 60mm and the holes are at 45mm, 50mm, and 55mm from the most distal tip of the Box Cutter.*

If there is a severely collapsed disc space the System is equipped with a Disc Wedge to create an initial channel to facilitate subsequent instrument passage. The Wedge can also be used to assess the length of the disc space. The depth holes are at 45mm, 50mm, 55mm, & 60mm. ▸ Fig. 29



▸ Fig. 28



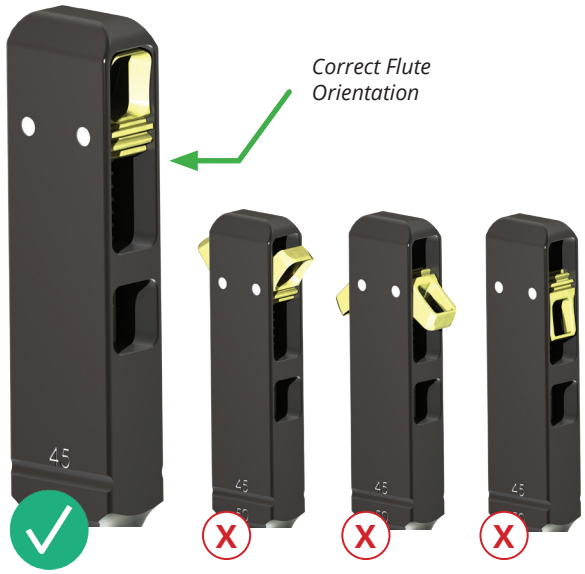
▸ Fig. 29

2 After the working channel is cleared the Bilateral Articulating Thoracolumbar (BATL) Curette should be used to clear out the disc material that is anterior and posterior to the working channel. ▸ Fig. 30a

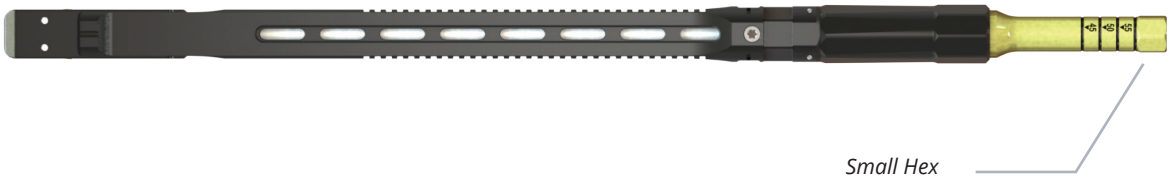
▸ Fig. 30a

3 Prior to insertion, make sure the cutting flutes are fully retracted and inside the channel at the distal end of the instrument. ▸ Fig. 30b

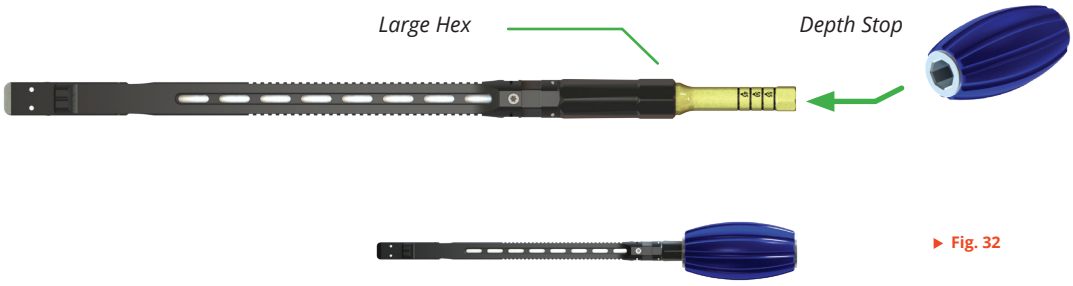
TIP: *If they are exposed or retracted towards the proximal end of the channel, they can be retracted by turning the small hex at the proximal end of the instrument counter clockwise until the cutting flutes are retracted in the distal end of the channel.* ▸ Fig. 31



▸ Fig. 30b



▸ Fig. 31



▸ Fig. 32

4 Next, set the depth stop by turning the large hex at the proximal end of the instrument. Ideally the depth stop will be set to facilitate the working end of the instrument being as long as the vertebral bodies being addressed. ▸ Fig. 32

TIP: *A counterclockwise rotation will lengthen the working segment and a clockwise rotation will shorten the working segment.*

5 Insert the instrument into the working channel until the feet of the BATL Curette are against the vertebra. The surgeon can then place the BATL Retractor Stop in the horizontal groves at the proximal end of the BATL curette. ▸ Fig. 33-34

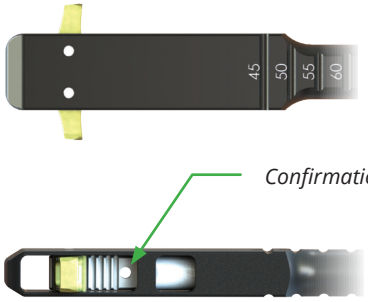
▸ Fig. 33a

▸ Fig. 33b

▸ Fig. 33c

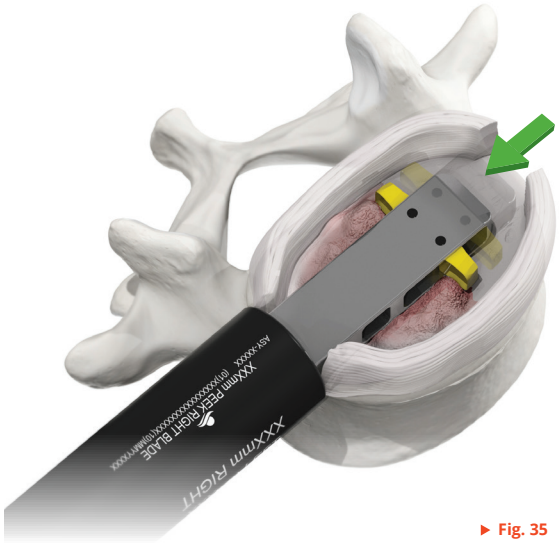
▸ Fig. 33d

6 To begin evacuating the disc material turn the small hex clockwise to bring the cutting flutes out to a 90° angle. When they reach the 90° position a tactile stop will be felt. It can be visually confirmed under fluoroscopy that the flutes are at 90° because a hole will become visible at the distal end of the curette. ▸ Fig. 34



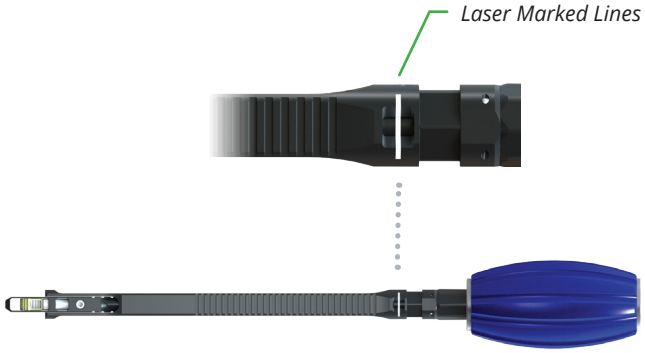
▸ Fig. 34

7 At that point, turn the large hex in a clockwise direction to start to retract the curette head and cut the anterior and posterior disc material. When the flutes are approximately 5mm from the ipsilateral annulus another tactile stop will be felt. It can be visually confirmed that the flutes have fully traversed the disc space and are in position to be retracted by the laser marked lines coming into alignment in the confirmation window at the proximal end of the curette.
▸ Fig. 35-36

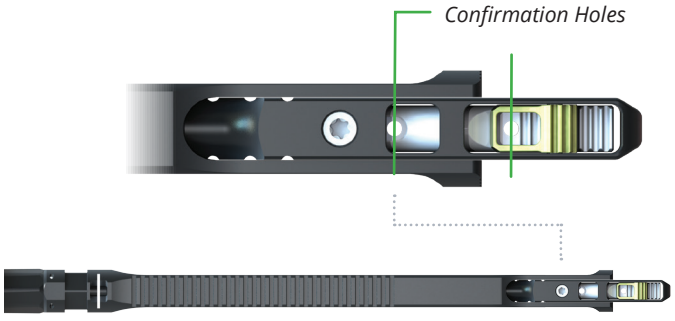


▸ Fig. 35

8 At that point the surgeon can then start to turn the small hex again in a clockwise direction. This will finish the cut and fully retract the flutes into the proximal end of the working channel. It can be confirmed under fluoroscopy that the flutes are fully retracted by visualizing the two holes that now come into view at the distal end of the instrument. ▸ Fig. 37



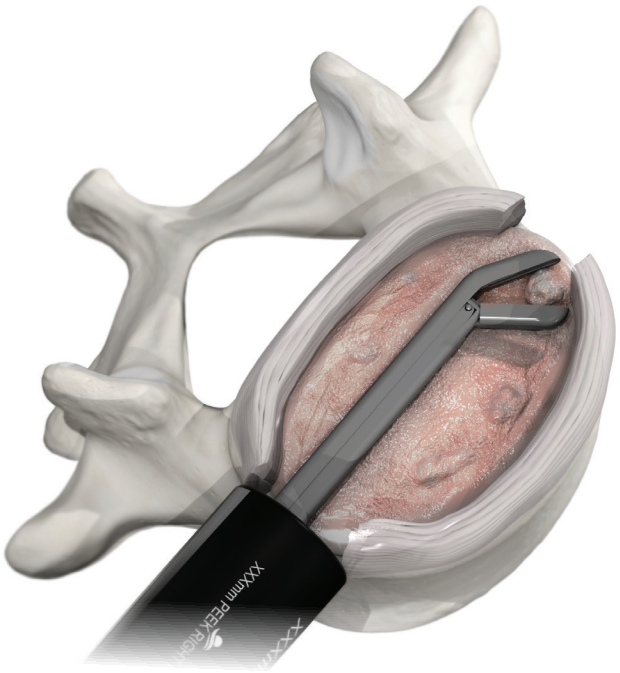
▸ Fig. 36



▸ Fig. 37

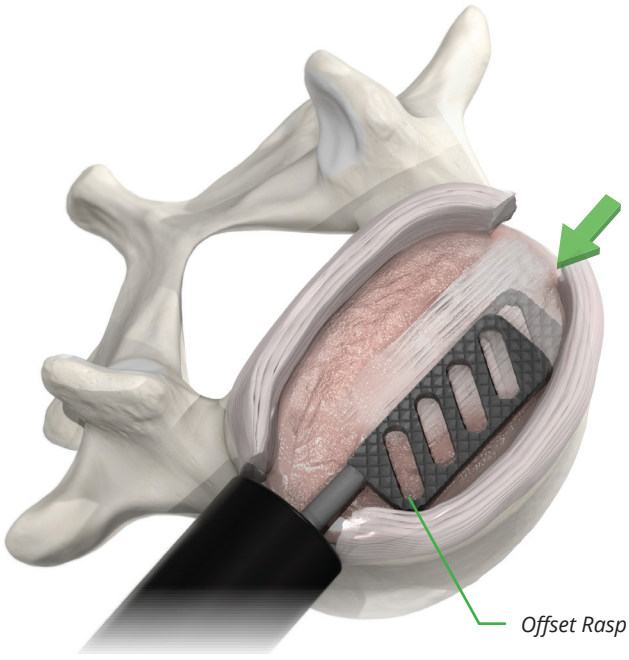
9 After the working channel and the anterior and posterior portions of disc have been removed or dislodged, the system is equipped with Curettes, Stirrup Scrappers, Pituitaries, Kerrisons, and Rasps to remove any residual disc material and prepare the endplates. ▸ Fig. 38-39

Pituitary ▸ Fig. 38a



▸ Fig. 38b

Offset Rasp ▸ Fig. 39a



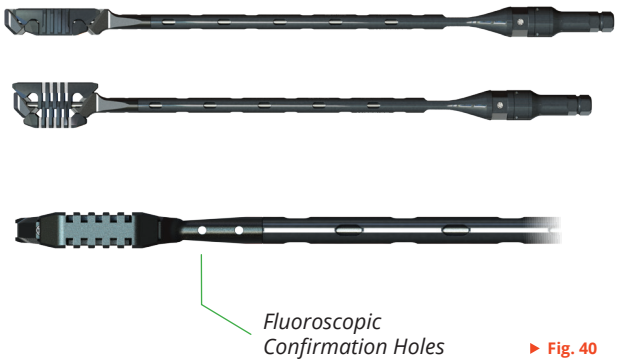
▸ Fig. 39b

Width Trialing

The Toro-L Implant must expand fully in width before it expands in height. For this reason, it is imperative to confirm that enough disc has been removed in both the central channel, as well as anterior and posterior of the channel, to allow the desired Implant to reach its full width. This confirmation is accomplished by selecting the appropriate length Expandable Width Trial and inserting it into the disc space.

The Expandable Width Trial should be gently impacted into the disc space. Confirm under fluoroscopy that it is across the disc space with the middle of the Expandable Width Trial in line with the spinous process and/or equidistant from both pedicles. When the expandable trial is in its fully collapsed state the distal fluoroscopic confirmation hole should reflect open. When the trial is in its fully expanded state both fluoroscopic confirmation holes should reflect open.

▸ Fig. 40

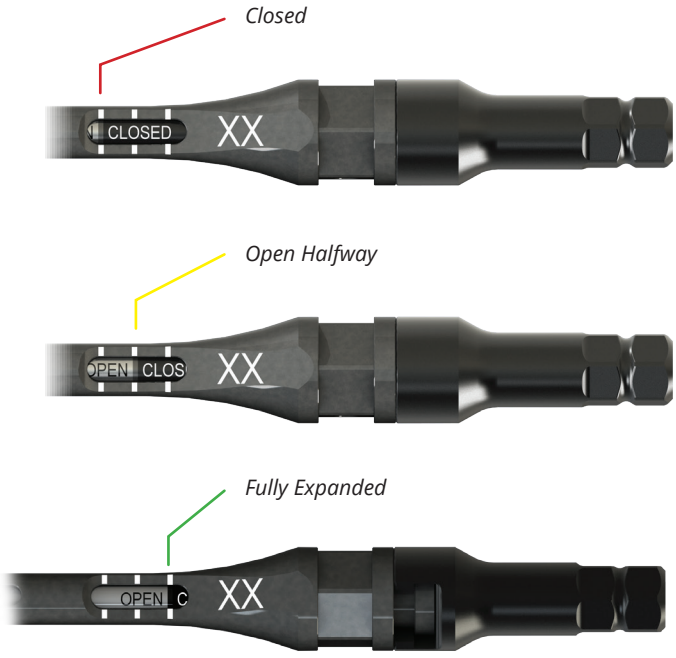


▸ Fig. 40

TIP: *The Expandable Width Trial has a window at the proximal end of the instrument indicating where it is in its expansion cycle. The markings on the Width Trial indicate closed, halfway open, and fully open.* ▸ Fig. 41

After it has been confirmed that the Expandable Width Trial is in the midline position utilize the Double Ended Handle and turn it clockwise until the Width Trial is fully expanded. If the Expandable Width Trial fully expands in the disc space with little or no resistance, then the surgeon will know they have sufficiently cleared the area and it will be able to accommodate the Implant.

TIP: *Like the Implant, the length called out on the Expandable Width Trial notes the instruments length in its expanded form. The Expandable Width Trial and the Implant are 8.5mm longer in their unexpanded form. That additional length is divided evenly between the ipsilateral and contralateral portions of the Instrument and the Implant.*

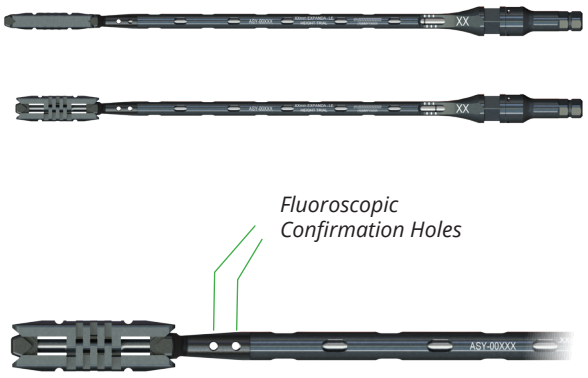


▸ Fig. 41

Height Trialing

The Toro-L Implant is capable of 5mm of height expansion. However, the Implant can be locked at any height during the height expansion cycle. Meaning, it is not necessary to expand the Implant fully in height. It is up to the surgeon's discretion to decide when enough height has been achieved.

To assist the surgeon in knowing when they have achieved enough distraction the system is equipped with an Expandable Height Trial. The Expandable Height Trial should be gently impacted into the disc space without the handle attached. To open the Height Trial, utilize the Double Ended Handle or Torque Limiting Inline Handle (25in-lb) in a clockwise motion. ▸ Fig. 42

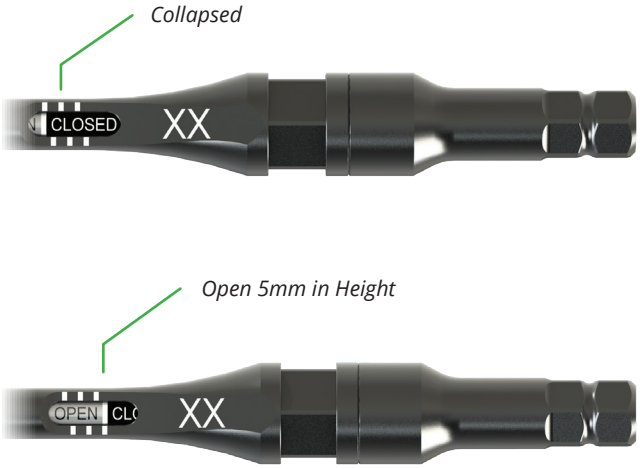


▸ Fig. 42

The Expandable Height Trial has six laser marked lines to inform the surgeon where the instrument is in the expansion cycle.

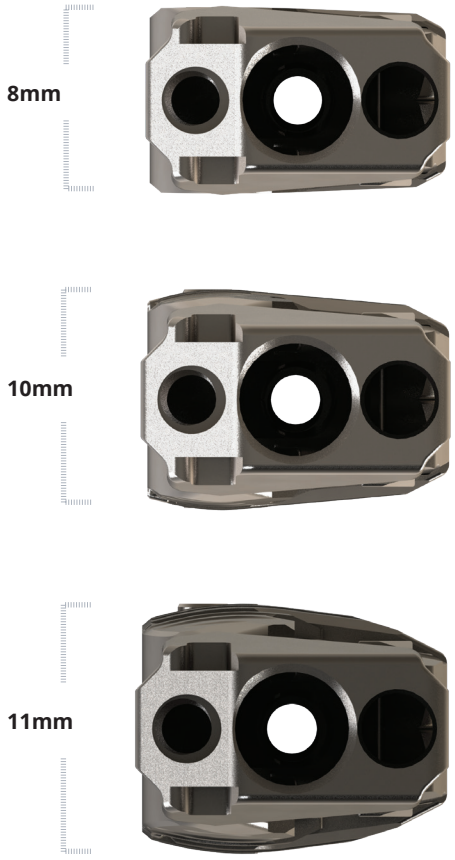
- The first line indicates that the instrument is in the closed position.
- Each subsequent line is an additional 1mm in height. The Height Trial expands up to 5mm.

▸ Fig. 43



▸ Fig. 43

The Toro-L Implant is available in the below sizes:



Lordosis - 5°
Starting Width: 14mm
Final Width: 21mm or 24mm
Starting Height: 8mm
Final Height: 13mm
Final Lengths: 45mm, 50mm, 55mm, 60mm

Lordosis - 10°
Starting Width: 14mm
Final Width: 21mm or 24mm
Starting Height: 10mm
Final Height: 15mm
Final Lengths: 45mm, 50mm, 55mm, 60mm

Lordosis - 15°
Starting Width: 14mm
Final Width: 21mm or 24mm
Starting Height: 11mm
Final Height: 16mm
Final Lengths: 45mm, 50mm, 55mm, 60mm

▶ Fig. 44

TIP: *The length called out on the Implant notes the Implants length in its expanded form. The Implant is 8.5mm longer in its unexpanded form. That additional length is divided evenly (4.25mm per side) between the ipsilateral and contralateral portions of the Implant.*

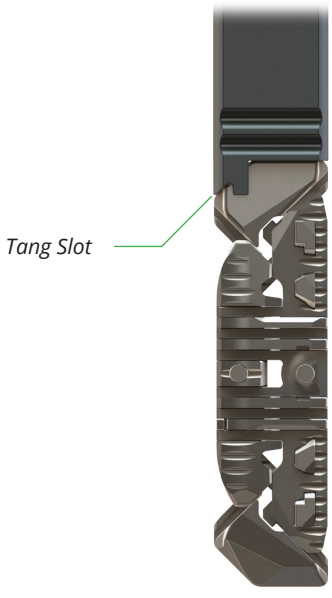
TIP: *The height called out is measured from the tallest portion of the Implant. The Implants anatomical shape dictates that this measurement is taken from the top and bottom of the "dome" of the Implant.*

1 To begin the Implant insertion, place the selected Implant into the Loading Block. Place the Inserter on the proximal end of the Implant aligning the tangs on the Inserter with the tang slots on the Implant.

NOTE: *The tangs on the Inserter ensure the Implant can only be loaded in the correct orientation.* ▸ Fig. 45

To secure the Implant to the Inserter, insert the Attachment Rod into the anterior slot of the Inserter and use the Utility Driver to thread it into the Implant. Do not overtighten.

▸ Fig. 46



▸ Fig. 45

▸ Fig. 46a

▸ Fig. 46b

2 Ensure that the Lock Out Control Knob (LOCK) is rotated counterclockwise on the Inserter to the unlocked position.

▸ Fig. 47

3 Insert the appropriate size Expansion Rod into the central hole of Inserter and tighten clockwise using the Utility Driver until you feel light resistance. ▸ Fig. 48

TIP: *Expansion Rods are Implant length specific. Meaning a 50mm Implant will only work with a 50mm Expansion Rod.*

Unlocked

▸ Fig. 47a

Locked

▸ Fig. 47b

▸ Fig. 48

4 You can now assemble the T-Handle onto the Inserter. Place the T-Handle over the Expansion Rod making sure that the T-Handle seats and the threads on the Expansion Rod are no longer visible.

At this point, rotate the T-Handle clockwise until the handle is fully seated on the Inserter. This can be visually confirmed when there is no gap in between the T-Handle and the Inserter.

▸ Fig. 50

▸ Fig. 50a

▸ Fig. 50b

Implant Insertion

The Implant and Inserter can now be handed off to the surgeon and implanted into the disc space. ▸ Fig. 51

WARNING: *Prior to handing the Implant and Inserter to the surgeon, ensure that the Implant HAS NOT expanded while securing the T-Handle to the Inserter.*

If there is a need for additional support during insertion the Utility Handle can be added to the Inserter. The Utility Handle has a vice-grip mechanism that is utilized to lock it to the Inserter. ▸ Fig. 52

NOTE: *This handle is designed to work with all instruments that have the hex features at their proximal end. This includes Width Trials, Height Trials, Disc Wedge, Box Cutter.*

TIP: *When the Implant is handed off to the surgeon the tech can now start filling the Graft Tubes on the back table. (See Graft filling Instructions on page 30)*

Implant & Inserter

▸ Fig. 51

Utility Handle Unlocked

▸ Fig. 52a

Locked Inserter & Handle Assembled

▸ Fig. 52b

5 When the Implant is in the desired location the Implant can be expanded by rotating the T-Handle clockwise.

▸ Fig. 53

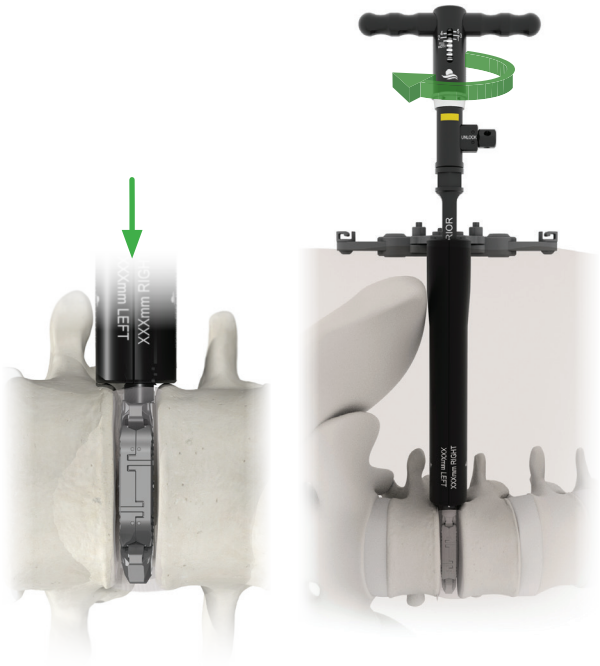
WARNING: *The Implant MUST open fully in width before it can be locked. It can be locked anywhere in its height cycle.*

As the implant moves through its expansion cycle the surgeon will know how much the Implant has expanded by the indictor gauge on the Inserter's T-Handle.

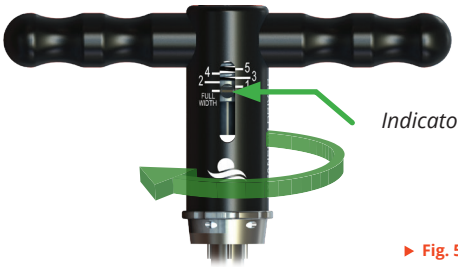
The indicator gauge has six hash marks. The Implant has completed its width cycle when the indicator on the T-Handle is at, or past the first hash mark. Each subsequent hash mark represents 1mm of additional height expansion. ▸ Fig. 54

When the surgeon has expanded the Implant to the desired height the Implant can now be locked in place.

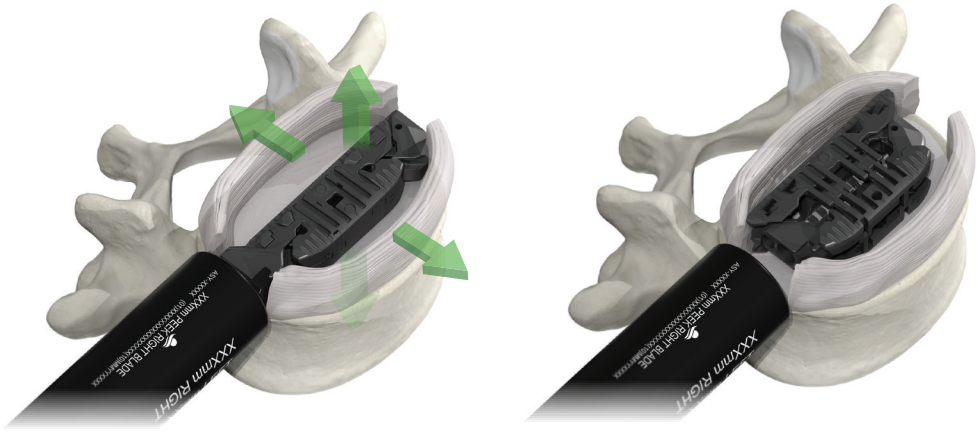
▸ Fig. 55



▸ Fig. 53



▸ Fig. 54



Collapsed *Fully Expanded*

▸ Fig. 55

6 Once the Implant is in the desired location, the LOCK should be rotated clockwise, securing the Expansion Rod in place. This will ensure that the Implant will retain its expansion until the Locking Rod has been introduced.

To tighten the LOCK, utilize the Utility Driver or the double ended handle.

▶ Fig. 58

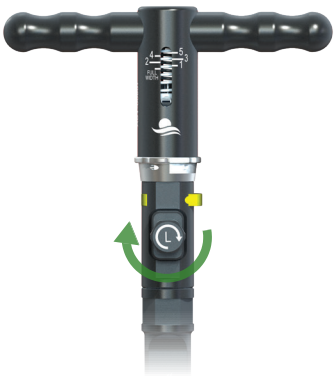
WARNING: *If the surgeon wants to collapse the Implant or remove some of the segmental distraction delivered by the Implant at any time, they MUST rotate the LOCK counterclockwise to "unlock" the inserter. Failure to do so will result in the Implant remaining locked in its current form as well as potential damage to the Inserter.*

7 To begin the locking process the T-Handle must be removed.

To remove the T-Handle press the gold disengage button while rotating the T-Handle counterclockwise until the handle freely lifts off the Inserter and the Expansion Rod.

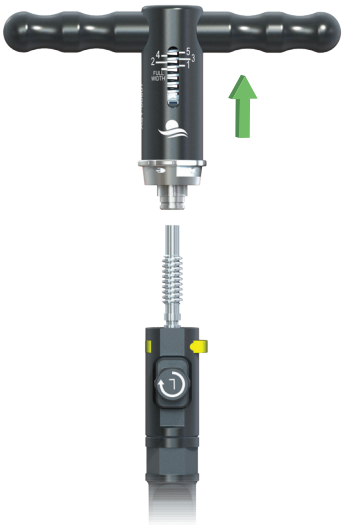
▶ Fig. 59

WARNING: *Do NOT remove the Expansion Rod until the Locking Rod has been inserted into the Implant.*



▶ Fig. 58

▶ Fig. 59a



▶ Fig. 59b

8 Assemble the Locking Rod Driver and the Torque Limiting Inline Handle (4in-lb). Load the Locking Rod onto the Locking Rod Driver. ▸ Fig. 60

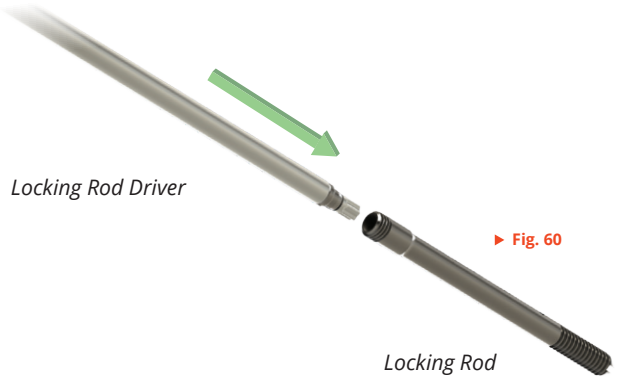
Place the Locking Rod into the posterior most slot on the Inserter.

Turn the handle until the breakaway torque is reached.

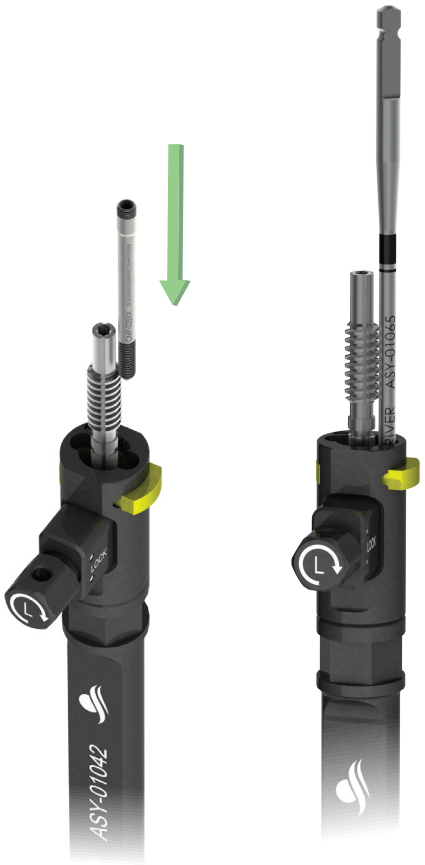
The Implant is now locked. ▸ Fig. 61

NOTE: *Each Locking Rod is specific to the Implant length. For example: A 50mm Implant will need a 50mm Locking Rod.*

NOTE: *The Locking Rod Driver is a stab & grab self-retaining Driver.*



▸ Fig. 60



▸ Fig. 61a ▸ Fig. 61b

9 To remove the Expansion Rod, rotate the LOCK counterclockwise to the unlocked position. ▸ Fig. 62a

Utilizing the Utility Driver unthread the Expansion Rod from the Implant. ▸ Fig. 62b

The Expansion Rod may now be removed.

▸ Fig. 62a ▸ Fig. 62b

10 The Implant can now be post-packed with Graft.

For instructions on filling the Graft Tubes see Graft Filling Instructions on page 30. The surgeon can insert the prefilled Graft Tubes into the center slot of the Inserter and utilize the Graft Tamp to deploy the graft.

TIP: *If the Graft Tube* **DOES NOT** *fully seat on the Inserter, then the attachment rod needs to be loosened (quarter turn counterclockwise) to allow for proper Graft Tube/Implant alignment.*

TIP: *Each Graft Tube holds approximately 4cc of graft material. Depending on size, each Implant holds between 2 to 3 Graft Tubes worth of graft.*

After the desired amount of Graft has been delivered the surgeon can now remove the Inserter from the Implant. ▸ Fig. 63

While putting gentle upward pressure on the Inserter, utilize the Utility Driver to unthread the Attachment Rod from the Implant. When the Attachment Rod is fully unthreaded the Inserter should easily lift off the Implant and may now be removed from the wound.

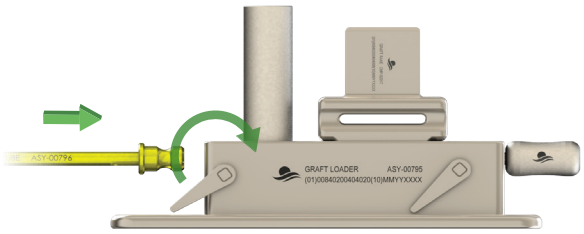
▸ Fig. 63

Graft Filling Instructions

The Graft Tray offers the surgeon multiple ways to load the provided Toro-L Graft Tubes.

The primary and recommended loading option works best when loading the Graft Tubes with allograft.

1 Begin by attaching the proximal end of the Graft Tube to the circular loading area located on the side of the block. Once the Tube has been inserted into the loading hole turn the Graft Tube Locking Lever to the locked position. ▸ Fig. 64



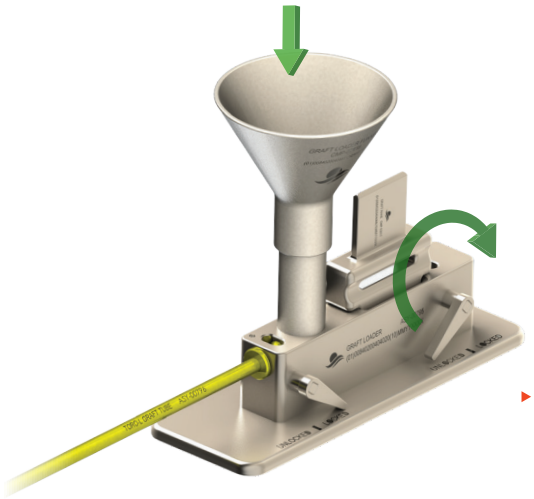
▸ Fig. 64

2 Next lock the Horizontal Push Rod in place by lining up the slit in the rod with the locking lever window on the Loading Block. Once it is lined up, turn the Push Rod Locking Lever to the locked position. Ensure that the Horizontal Push Rod cannot be moved. ▸ Fig. 65

▸ Fig. 65a

▸ Fig. 65b

3 Load the graft into the top of the cylinder. To ease the process there is a Graft Loader Funnel that attaches to the top of the cylinder. ▸ Fig. 66

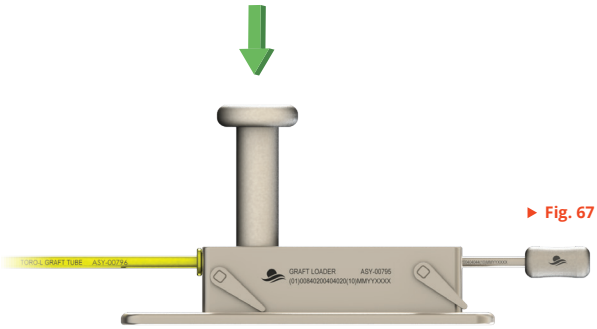


▸ Fig. 66

4 Once the graft is loaded into the cylinder remove the Funnel and use the Vertical Push Rod to push the graft down into the loading device and out into the Tube. ▸ Fig. 67

TIP: *To help know how much graft is being loaded as well as when the Graft Tube is full, insert the Graft Loading Indicator in the distal end of the Graft Tube until you hit the stop line. While loading graft it will show how many CC's have been loaded into the Graft Tube and give you an indication when to stop pushing graft out of the Loading Block. Depending on size, each Implant holds between 2 to 3 Graft Tubes worth of graft.*

5 To remove the Graft Tube, turn the Graft Tube Locking Lever to the unlocked position and pull the Graft Tube out of the Graft Loading Block.



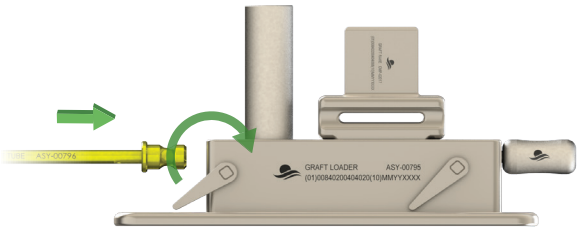
▸ Fig. 67

6 To load additional tubes, repeat steps 1-4.

SUBSEQUENT GRAFT LOADING METHODS

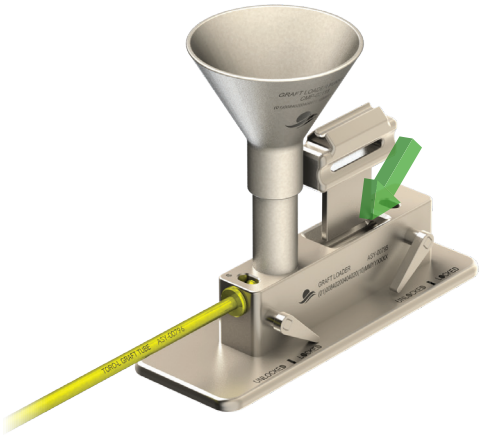
Loading Autograft:

1 Begin by attaching the proximal end of the Tube into the circular loading area located on the side of the block. Once the Tube has been inserted into the loading hole, turn the locking lever to the locked position. ▸ Fig. 68



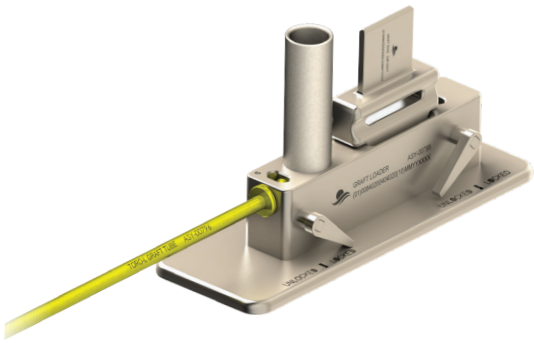
▸ Fig. 68

2 Place the double-milled autograph in the "trough." Utilizing the "rake" portion of the Graft Rake sweep the autograft back and forth, forcing it down into the track. ▸ Fig. 69



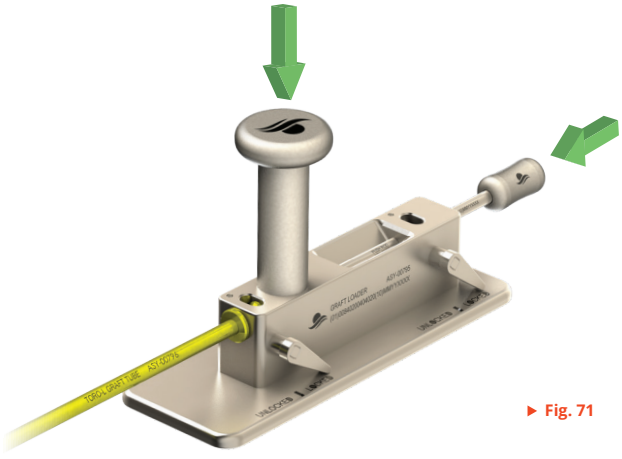
▸ Fig. 69

3 Once the bone graft has been pushed down into the track flip the Graft Rake over so that it is seated in the trough completing the top portion of the track and keeping it closed. ▸ Fig. 70



▸ Fig. 70

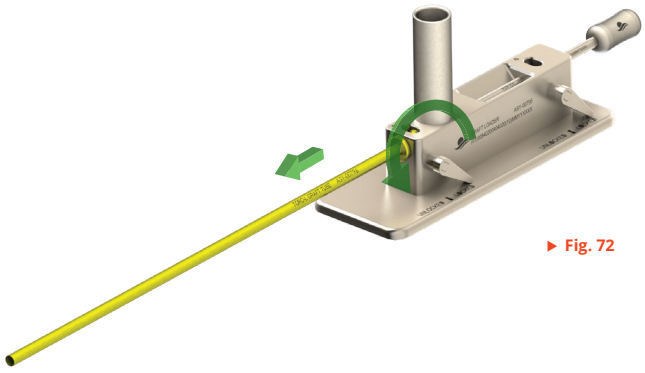
4 Advance the Horizontal Tamp using a mallet to drive the autograph into the Tube while simultaneously maintaining downward pressure on the Vertical Tamp. ▸ Fig. 71



▸ Fig. 71

5 Repeat steps 2-4 until the desired amount of autograft is in the Tube.

6 To remove the Tube, turn the Graft Tube Locking Lever to the unlocked position and pull the Tube out of the Graft Loading Block. ▸ Fig. 72



▸ Fig. 72

IN SITU LOADING:

1 Place the Graft Funnel over the proximal end of the Graft Tube and drop the Tube in the center slot of the Inserter.

2 Load the funnel with the surgeon's choice of graft.

▸ Fig. 73

▸ Fig. 73

Retractor Removal and Closure

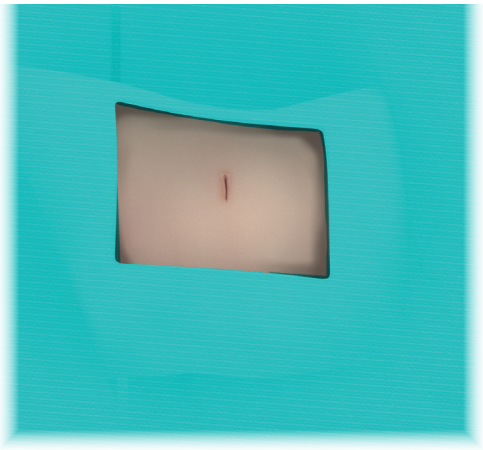
Once the procedure is completed, the Inlet Retractor is removed while using direct visualization to verify the absence of significant bleeding in the disc space or psoas muscle.

WARNING: *The Fixation Pins should be removed from the Retractor prior to removal.*

The skin is closed using standard surgical techniques.

Supplemental fixation instrumentation is required

▶ Fig. 74



▶ Fig. 74

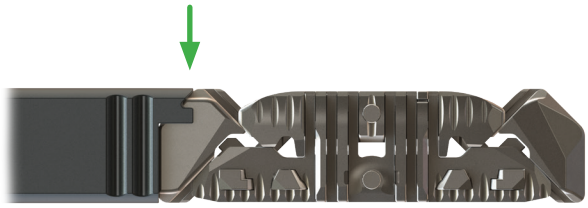
LINESIDER

Reference the LineSider Spinal System Surgical Technique (STM-00005) and/or Instructions for Use (IFU-00008) for additional important labeling information

Implant Removal

Should the Toro-L Interbody need to be removed the Implant can be exposed in a similar fashion to the original access.

1 Place the Inserter down over the Implant aligning the male tangs on the Inserter with the female slots on the Implant. ▸ Fig. 75



▸ Fig. 75

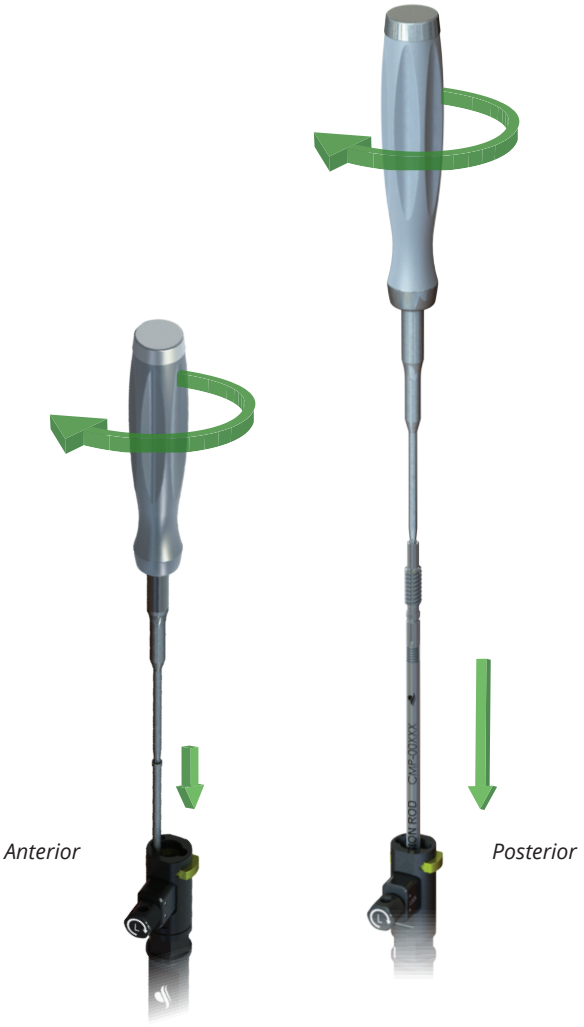
2 Place the Attachment Rod through the anterior most hole in the Inserter. Utilize the Utility Driver to thread it into place, locking the Inserter and the Implant together. ▸ Fig. 76

3 If the Implant has not been expanded, it can be slap hammered out to remove it from the disc space.

If the Implant needs to be collapsed, start by ensuring that the LOCK is in the unlocked position and place the Expansion Rod down the center slot of the Inserter. When the Expansion Rod reaches the distal end of the Implant thread it into place using the Utility Driver. ▸ Fig. 77

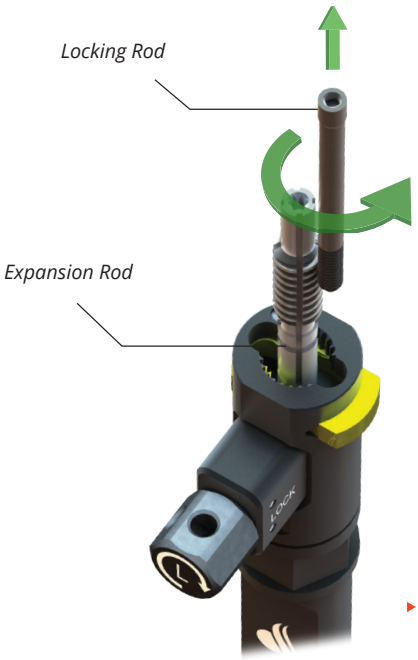
NOTE: *The Expansion Rods are Implant length specific. Meaning a 50mm Implant will need a corresponding 50mm Expansion Rod.*

TIP: *If bone graft has been delivered, use suction to clear out the center hole throughout the Implant. This ensures that the Expansion Rod can be threaded into the Implant so that the Implant can be collapsed.*



▸ Fig. 76 ▸ Fig. 77

4 Next insert the Locking Rod Driver with the Handle attached into the posterior hole of the Inserter. Engage it with the Locking Rod and turn the Driver counterclockwise until the Locking Rod is no longer engaged with the Implant. At this point, the Locking Rod should be removable utilizing the stab-and-grab feature of the Locking Rod Driver. ▸ Fig. 78



▸ Fig. 78

5 With the Expansion Rod in place the T-Handle needs to be assembled onto the Inserter.

Place the T-Handle over the Expansion Rod making sure that the T-Handle seats and that the threads on the Expansion Rod are no longer visible.

At this point, rotate the T-Handle clockwise until the handle is fully seated on the Inserter. This can be visually confirmed when there is no gap between the T-Handle and the Inserter.

▸ Fig. 79

6 Prior to collapsing the implant, ensure that the LOCK is rotated counterclockwise and set to the unlocked position. The handle can now be turned counterclockwise, collapsing the Implant. ▸ Fig. 80

When the Implant is in its collapsed state it can be removed from the disc space. Utilization of the slap hammer is recommended to maintain control of Implant removal.

▸ Fig. 81

▸ Fig. 79 ▸ Fig. 80 ▸ Fig. 81

TORO-L Articulating Arm Tray

Part Numbers	Description	Quantity
ASY-00650	Articulating Arm Tray	1
ASY-00711	Articulating Arm	1
ASY-00712	Bed Rail Clamp	1
ASY-00722	Targeting Instrument	1
IFU-00008	Toro-L Interbody Fusion System Instructions for Use	1

TORO-L Lateral Access Tray

Part Numbers	Description	Quantity
ASY-00649	Lateral Access Tray	1
ASY-00577	Dilator Holder	1
ASY-00703	Inlet	1
ASY-00767	Pin Driver	1
ASY-00784	80 - 100mm Slide	2
ASY-00785	110 - 130mm Slide	2
ASY-00786	140 - 160mm Slide	2
ASY-00848	Quick Connect Handle	2
ASY-00850	Contrast Paddle	1
ASY-00851	Solid Portal Frame	1
ASY-00856	Manual Retractor Stop Bar, Inlet	2
ASY-00884	140 - 160mm Wide Manual Retractor	2
ASY-00885	110 - 130mm Wide Manual Retractor	2
ASY-00886	80 - 100mm Wide Manual Retractor	2
ASY-00887	140 - 160mm Narrow Manual Retractor	2
ASY-00888	110 - 130mm Narrow Manual Retractor	2
ASY-00889	80 - 100mm Narrow Manual Retractor	2
CMP-01784	Inlet Driver	2
CMP-01925	80mm Inlet Fixation Pin	4
CMP-02149	90mm Inlet Fixation Pin	4
CMP-01926	100mm Inlet Fixation Pin	4
CMP-02150	110mm Inlet Fixation Pin	4
CMP-01927	120mm Inlet Fixation Pin	4
CMP-02151	130mm Inlet Fixation Pin	4
CMP-01928	140mm Inlet Fixation Pin	4
CMP-02152	150mm Inlet Fixation Pin	4
CMP-01929	160mm Inlet Fixation Pin	4
CMP-01935	80mm Aluminum Right Blade, Inlet	1
CMP-01936	90mm Aluminum Right Blade, Inlet	1
CMP-01937	100mm Aluminum Right Blade, Inlet	1

TORO-L Lateral Access Tray (Continued)

Part Numbers	Description	Quantity
CMP-01938	110mm Aluminum Right Blade, Inlet	1
CMP-01939	120mm Aluminum Right Blade, Inlet	1
CMP-01940	130mm Aluminum Right Blade, Inlet	1
CMP-01941	140mm Aluminum Right Blade, Inlet	1
CMP-01942	150mm Aluminum Right Blade, Inlet	1
CMP-01943	160mm Aluminum Right Blade, Inlet	1
CMP-01944	80mm Aluminum Left Blade, Inlet	1
CMP-01945	90mm Aluminum Left Blade, Inlet	1
CMP-01946	100mm Aluminum Left Blade, Inlet	1
CMP-01947	110mm Aluminum Left Blade, Inlet	1
CMP-01948	120mm Aluminum Left Blade, Inlet	1
CMP-01949	130mm Aluminum Left Blade, Inlet	1
CMP-01950	140mm Aluminum Left Blade, Inlet	1
CMP-01951	150mm Aluminum Left Blade, Inlet	1
CMP-01952	160mm Aluminum Left Blade, Inlet	1
CMP-02124	Dilator 4	1
ASY-00866	80mm PEEK Right Blade, Inlet	1
ASY-00867	90mm PEEK Right Blade, Inlet	1
ASY-00868	100mm PEEK Right Blade, Inlet	1
ASY-00869	110mm PEEK Right Blade, Inlet	1
ASY-00870	120mm PEEK Right Blade, Inlet	1
ASY-00871	130mm PEEK Right Blade, Inlet	1
ASY-00872	140mm PEEK Right Blade, Inlet	1
ASY-00873	150mm PEEK Right Blade, Inlet	1
ASY-00874	160mm PEEK Right Blade, Inlet	1
ASY-00875	80mm PEEK Left Blade, Inlet	1
ASY-00876	90mm PEEK Left Blade, Inlet	1
ASY-00877	100mm PEEK Left Blade, Inlet	1
ASY-00878	110mm PEEK Left Blade, Inlet	1
ASY-00879	120mm PEEK Left Blade, Inlet	1
ASY-00880	130mm PEEK Left Blade, Inlet	1
ASY-00881	140mm PEEK Left Blade, Inlet	1
ASY-00882	150mm PEEK Left Blade, Inlet	1
ASY-00883	160mm PEEK Left Blade, Inlet	1
CMP-02312	160mm Stainless Left Blade, Inlet	1
CMP-02321	160mm Stainless Right Blade, Inlet	1
ML-0301	K-WIRE, BLUNT, 1.5 X 350 MM	3
ML-0303	K-WIRE, SHARP, 1.5 X 350 MM	3
IFU-00008	Toro-L Interbody Fusion System Instructions for Use	1
TSI-0102080	TeDan K-WIRE IFU	1

TORO-L Lateral Disc Prep 1 Tray

Part Numbers	Description	Quantity
ASY-00651	Lateral Disc Prep 1 Tray	1
ASY-00472	Stirrup Straight	1
ASY-00507	Rasp	1
ASY-00508	Offset Rasp	1
ASY-00509	Strirrup Right	1
ASY-00510	Stirrup Left	1
ASY-00536	Ring Curette	1
ASY-00542	Small Curette	1
ASY-00544	Large Curette	1
ASY-00545	Small Up Curette	1
ASY-00547	Large Up Curette	1
ASY-00549	Medium Down Curette	1
ASY-00940	14mm 10° Cobb	1
ASY-00554	14mm Straight Cobb	1
ASY-00555	14mm Angled Cobb	1
IFU-00008	Toro-L Interbody Fusion System Instructions for Use	1

TORO-L Lateral Disc Prep 2 Tray

Part Numbers	Description	Quantity
ASY-00652	Lateral Disc Prep 2 Tray	1
780-1010-3	Bayoneted Bipolar Forceps Straight	1
780-1011-3	Bayoneted Bipolar Forceps Angled	1
ASY-00463	Slap Hammer	1
ASY-00466	Bilateral Articulating TL Curette	1
ASY-00467	Disc Wedge	1
ASY-00532	Penfield Push	1
ASY-00533	Penfield Pull	1
ASY-00534	3mm Kerrison	1
ASY-00535	5mm Kerrison	1
ASY-00537	3mm Pituitary	1
ASY-00538	5mm Pituitary	1
ASY-00540	4mm Up Pituitary	1
ASY-00834	Osteophyte Removal Tool	1
ASY-00559	Small Suction	1
ASY-00560	Large Suction	1
ASY-00561	Knife Handle	1
ASY-00593	6.5mm Box Cutter	1
ASY-00594	8.5mm Box Cutter	1
ASY-00716	Double Ended Handle	2
ASY-00726	Hudson T-Handle	2
CMP-01731	Slap Hammer Attachment	2
CMP-01924	BATL Stop	1
IFU-00008	Toro-L Interbody Fusion System Instructions For Use	1
IFU-LIRF-5	Life Instruments Reusable Biopolar Forceps IFU	1

TORO-L Instruments Tray

Part Numbers	Description	Quantity
ASY-00587	Toro-L Instrument Tray	1
ASY-00464	Offset Handle	2
ASY-00468	45mm Expandable Width Trial	1
ASY-00504	50mm Expandable Width Trial	1
ASY-00505	55mm Expandable Width Trial	1
ASY-00506	60mm Expandable Width Trial	1
ASY-00591	60mm Expandable Height Trial	1
ASY-00512	Implant Tamp	1
ASY-00645	Utility Driver	2
ASY-01065	Locking Rod Driver	2
ASY-01042	Toro-L Inserter	2
ASY-00807	Expansion Driver	2
ASY-00999	Torque Limiting Inline Handle - 4 in-lb	1
ASY-00998	Torque Limiting Inline Handle - 25 in-lb	1
CMP-01859	AO Handle	1
CMP-01985	Attachment Rod	3
CMP-02073	45mm Expansion Drive Rod	3
CMP-02074	50mm Expansion Drive Rod	3
CMP-02075	55mm Expansion Drive Rod	3
CMP-02076	60mm Expansion Drive Rod	3
CMP-02384	Height Trial Adapter	1
IFU-00008	Toro-L Interbody Fusion System Instructions For Use	1

TORO-L Implants Tray

Part Numbers	Description	Quantity
ASY-00843	Toro-L Implant Tray	1
ASY-00893	Toro-L Implant Caddy	1
CMP-02578	45mm Locking Rod	4
CMP-02579	50mm Locking Rod	4
CMP-02580	55mm Locking Rod	4
CMP-02581	60mm Locking Rod	4
TL10-002445	TORO-L 10° x 14mm-24mm x 45mm	3
TL10-002450	TORO-L 10° x 14mm-24mm x 50mm	3
TL10-002455	TORO-L 10° x 14mm-24mm x 55mm	3
TL10-002460	TORO-L 10° x 14mm-24mm x 60mm	2

TORO-L Graft Delivery Tray

Part Numbers	Description	Quantity
ASY-00836	Graft Delivery Tray	1
ASY-00795	Graft Loader	1
ASY-00796	Toro-L Graft Tube	6
ASY-00797	Push Rod	2
ASY-00824	Graft Tamp	2
ASY-00894	Tube Fill Indicator	1
CMP-02017	Graft Rake	1
CMP-02020	Palm Press	1
CMP-02118	Graft Loader Funnel	1
CMP-02273	Graft Spoon	2
CMP-02274	Graft Tube Funnel	1
IFU-00008	Toro-L Interbody Fusion System Instructions For Use	1

Instructions For Use

Please carefully read and understand this document in its entirety before using the Toro-L® Interbody Fusion System. The components of the device are designed to be used in combination and function as a single unit. Failure to properly follow instructions may lead to patient injury and may result in improper functioning of the device.

Device Description

Integrity Implants' Toro-L Interbody Fusion System incorporates a bi-directional expandable interbody fusion device and a monolithic interbody fusion device intended for use in the thoracolumbar spine. The Toro-L Interbody Fusion System implants are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136 and Ti-6Al-4V per ASTM F2924) and polyetheretherketone (PEEK per ASTM F2026) are offered in a range of sizes and lordotic options to accommodate variations in patient anatomy.

The Toro-L Interbody Fusion System expandable implant has integrated ramps and a threaded actuator that allow the implant to be inserted in a non-expanded form, and then subsequently expanded to full width and desired height through continuous expansion. When the desired height is achieved, the locking system is engaged to secure the construct in its final expanded configuration. The implant is then post-packed with bone graft.

The biplanar expandable implant has protrusions on the superior and inferior surfaces of the endplates to grip the adjacent vertebral endplates to resist expulsion.

Indications for Use/Intended Use

The Toro-L Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortical cancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Toro-L Interbody Fusion System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Toro-L Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

Contraindications

Contraindications include but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Patients with known sensitivity to the materials implanted.
- Patients who are unwilling to restrict activities or follow medical advice.
- Patients with inadequate bone stock or quality.
- Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
- Prior fusion at the level(s) to be treated.

Compatibility

Do not use Toro-L devices with components of other systems. Unless stated otherwise, Integrity Implants devices are not to be combined with the components of another system.

Methods of Use

Please refer to the Surgical Technique Manual (STM-00007) for this device.

Potential Adverse Events

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

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

Warnings/Precautions

The subject device is intended for use only as indicated.

The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not

occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion.

Care should be taken to insure that all components are ideally fixated prior to closure.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Additional care should be taken to ensure a thorough discectomy is completed in order to correctly size, place, and expand the device. An incomplete discectomy may result in difficulty to fully deploy and place the device in its intended position

Pre-Operative Warnings

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the Toro-L implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments. Do not use Toro-L implants if there is any evidence of damage.
- Toro-L devices are provided non-sterile and are intended to be cleaned and sterilized prior to use. Refer to Cleaning and Sterilization Instructions below.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

Patient Education

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Post-Operative Warnings

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

Single Use/Do Not Re-Use

Implants are intended for single use. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

Magnetic Resonance (MR) Safety

The Toro-L System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Toro-L System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Packaging

Packaging for each of the devices should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packaging or devices should not be used and should be returned to Integrity Implants. The instruments and implants of the Toro-L system are provided non-sterile. All implants are single use and should be sterilized per instructions provided below. Instruments provided non-sterile can be single-use or reusable. Reusable instruments should be reprocessed using instructions provided below. Discard single-use instruments after use.

Cleaning and Decontamination

All instruments must first be thoroughly cleaned using the validated methods prescribed below before sterilization and introduction into a sterile surgical field.

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- After surgical procedure remove debris from each instrument using a water moistened pad, exchanging pad if it becomes soiled
- Neutral pH enzymatic and cleaning agents with low foaming surfactants are recommended.
- Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing.
- Only agents with proven efficacy (FDA cleared, VAH listed, or CE mark) should be used.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Manual Cleaning Instructions

1. Completely submerge instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
2. Remove the devices from the cleaning solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes, slots and other difficult-to-reach areas.
3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
4. Rinse devices in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible, contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used and should be returned to Integrity Implants. Contact your local representative or Integrity Implants directly for any additional information related to cleaning of Accelus surgical instruments.

Sterilization

Trays are provided for storing and sterilizing the implants and instruments. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in **Table 1** for recommended minimum sterilization parameters that have been validated by Integrity Implants to provide a 10^{-6} sterility assurance level (SAL).

- The hospital is responsible for in-house procedures for inspection and placing devices in the correct location in the sterilization trays.
- Steam sterilization is the prescribed method for Integrity Implants device sets.
- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Implant and instrument trays do not provide a sterile barrier. Double-wrap the trays for sterilization and handling with an FDA-cleared wrap using the envelope technique per ANSI/AAMI ST79.

Table 1: Recommended Pre-Vacuum Steam Sterilization Parameters[1]

Temperature	Exposure Time	Minimum Dry Time[2]
132°C/270°F	4 minutes	20 minutes

[1] This cycle is not to be used for the inactivation of prions.

[2] Drying times vary according to load size and should be increased for larger loads.

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

Information

To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local representative or Accelus directly at +1-561-529-3861 or 800-201-9300. You may also email: customerservice@accelusinc.com.

Symbols Glossary

Symbol	Definition
REF	Reference number (Catalogue number)
LOT	Batch Code
NON STERILE	Non-Sterile
	Do not re-use (Single Use Only)
	Consult instructions for use
	Manufacturer
	Date of Manufacture

Symbol	Definition
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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SURGICAL TECHNIQUE MANUAL

Accelus

TORO 3

Toro-L Interbody Fusion System

Multi-Directional Expansion | Minimal Insertion Profile | Maximum Graft Delivery

Accelus

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STM-00007 RevB