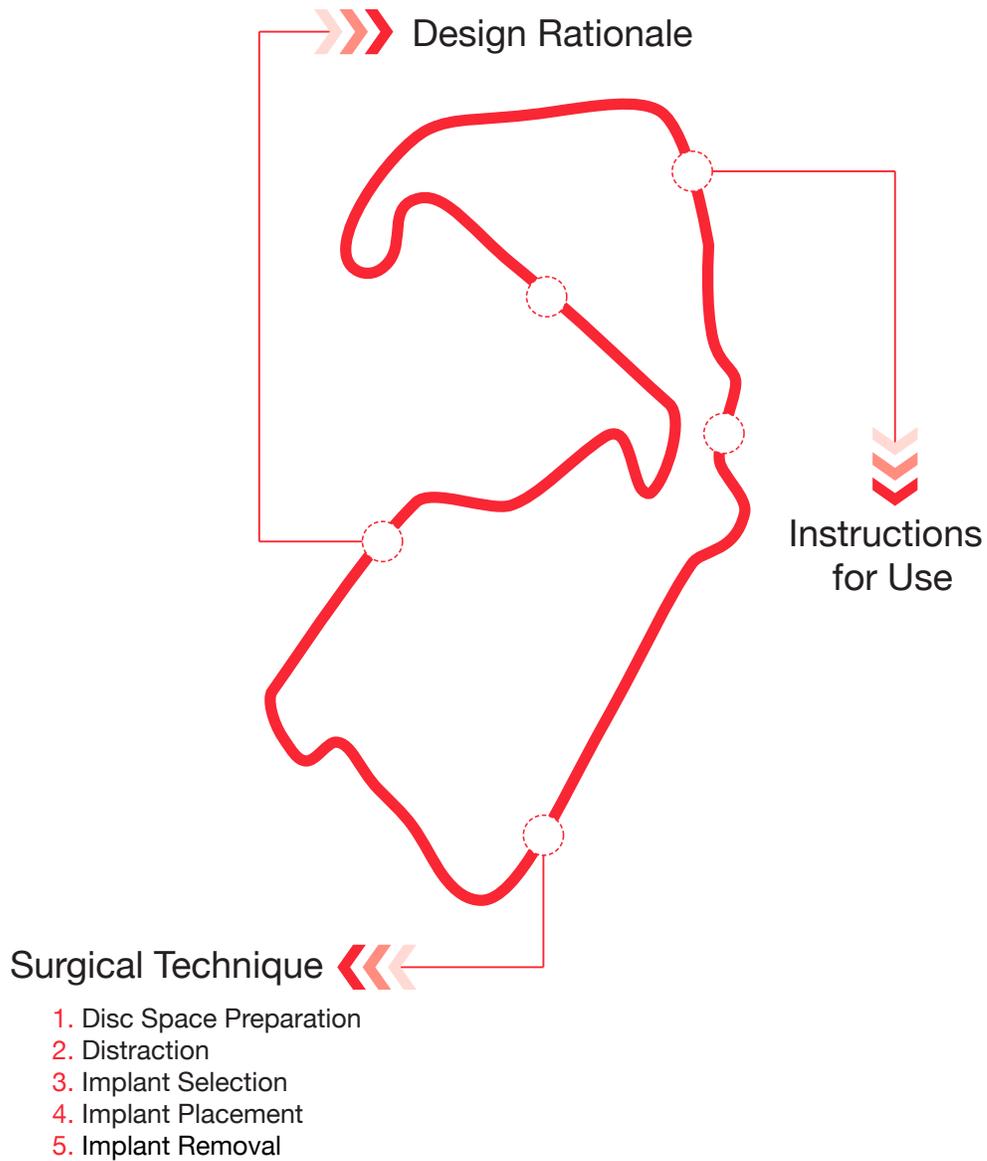


Silverstone Interbody System Surgical Technique



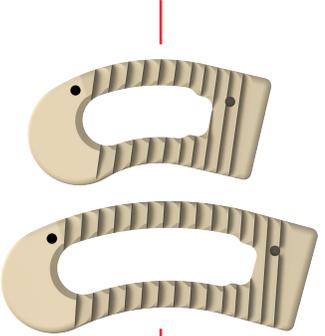
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DESIGN RATIONALE



22 and 28mm Lengths



Large axial graft window

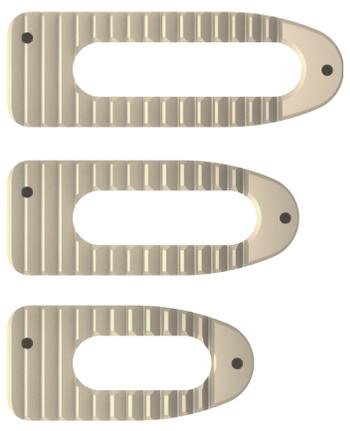
Inserter supports less invasive procedures



Tapered, self-distracting leading edge

6mm through 16mm Heights

22, 26, and 30mm Lengths



INDICATIONS FOR USE

The Altus Spine Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Altus Spine Interbody Fusion System is to be combined with cleared supplemental fixation systems, such as the Altus Spine Pedicle Screw System.

Reference product insert (**PI-009**) for complete system indications for use, description, warnings and precautions

1. DISC SPACE PREPARATION

PREPARE DISC SPACE AND ENDPLATES

Assemble the appropriate Shaver-Distractor to the T-Handle

Pull back the plunger and insert the shaft until the 'load line' is flush with the plunger, then release

Insert the Shaver-Distractor into the disc space with its flat surface parallel to the endplates

Rotate the Shaver-Distractor in a clockwise direction to shave the endplates

Note: Clockwise rotation will shave the endplates; counterclockwise rotation provide blunt distraction



2. DISTRACTION

DISTRACT

A starter size of 6mm is available for initial distraction, sizes increase sequentially by 1mm

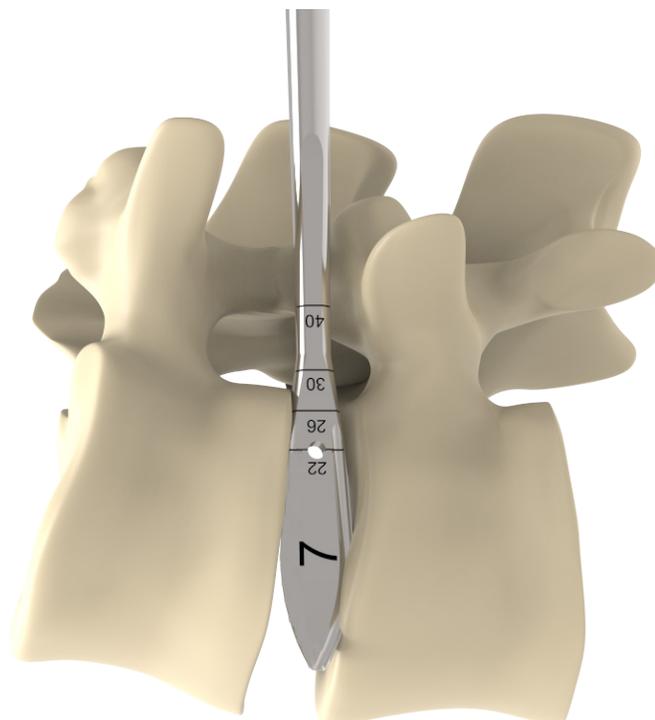
Assemble the appropriate size Shaver-Distractor to the T-Handle

Pull back the plunger and insert the shaft until the 'load line' is flush with the plunger, then release

Insert the Shaver-Distractor into the disc space with its flat surface parallel to the endplates

Rotate the Shaver-Distractor assembly in a counterclockwise direction to distract the disc space

Incrementally introduce increasing heights Shaver-Distractors until the desired height is achieved



3. IMPLANT SELECTION

TRIAL USAGE

Select an appropriately sized Implant Trial in the desired footprint; starting size is 6mm and height increases sequentially by 1mm

Assemble the appropriate size Trial to the T-Handle

Pull back the plunger and insert the shaft until the 'load line' is flush with the plunger, then release

Insert the trial assembly into the disc space, impact the trial assembly if necessary

Confirm the position and fit of the trial

Implant length can be estimated using the etched lines of the trial

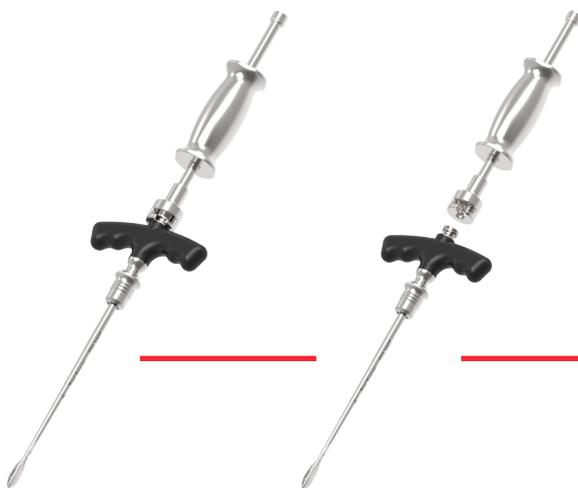
Note: Straight and curved trials are available based on the implant being used

REMOVE TRIAL

A Slap Hammer is available to aid in removing the trial assembly from the disc space

Attach the Slap Hammer to the distal end of the trial assembly

Remove trial assembly from disc space



4. IMPLANT PLACEMENT

ASSEMBLE IMPLANT TO INSERTER

Select the appropriately sized implant with the desired footprint

Utilize the Graft Block and Tamp to pack the Implant with autograft

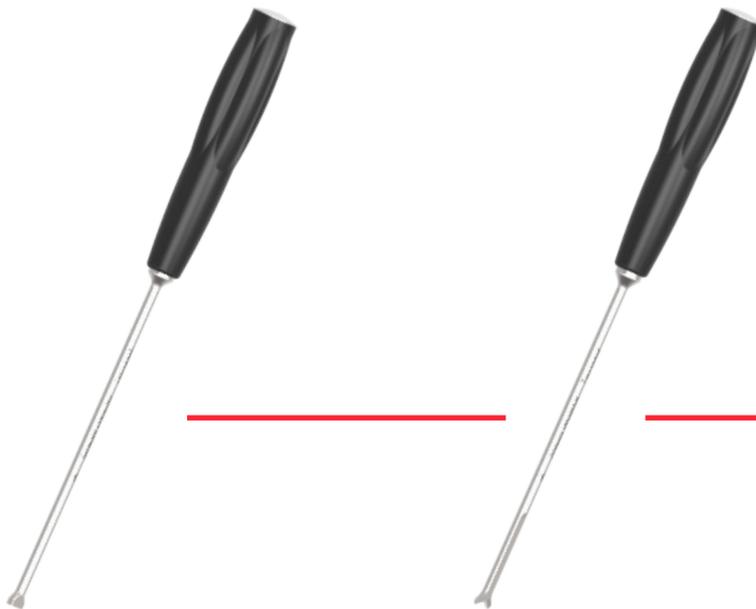
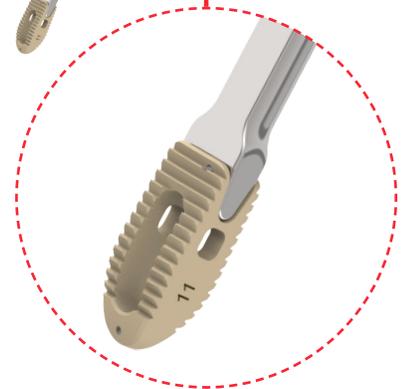
Engage the forks of the Inserter into the female treaded portion of the implant

Insert the Implant into the disc space by manual manipulation or instrument impaction using the inserter handle

REMOVE THE INSERTER

Rotate the thumbwheel on the Inserter in a counterclockwise motion to release the implant from the Inserter

Utilize the Tamp or Angled Impactor for additional implant manipulation



5. IMPLANT REMOVAL

USING IMPLANT INSERTER

Thread the Implant Inserter to the implant

Attach the Slap Hammer to the end of the Implant Inserter

Remove assembly from disc space

USING IMPLANT REMOVER

Using the hook of the Remover, engage a window on the side of the implant

Thread the inner rod of the Remover into the female threaded portion of the implant

Use the etch window of the Remover to help ensure the implant is fully engaged

Attach the Slap Hammer to the end of the Remover

Remove assembly from disc space

