



Tesera™ SC - Stand-alone Anterior Cervical Fusion

Surgical Technique

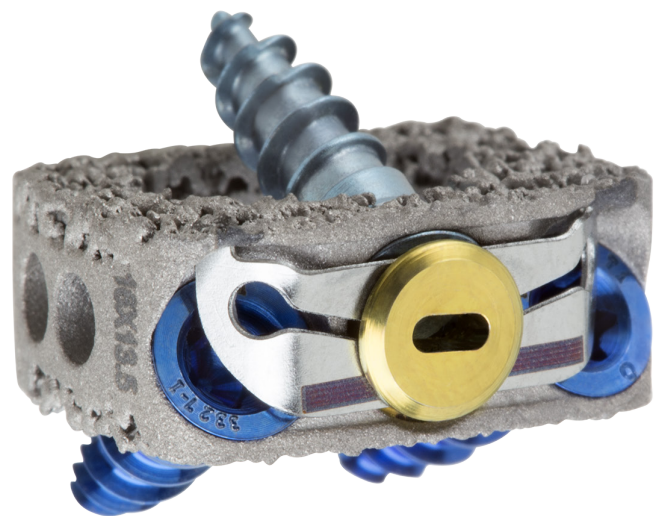


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Surgical Technique

Approach

Using the standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate technique for the given indication.

Determine Appropriate Implant

Footprint

Using the Paddle Sizers (2050-001-004, 005) insert the selected sizer into the disc space to determine the proper footprint. Choose the implant footprint based upon the amount of vertebral body covered by the Paddle Sizer (see figures 1 & 2)

Caution: Anterior osteophytes in the surgical site that prevent desired positioning should be removed.

Height

Once the footprint has been decided, use the Trial/Broach to determine the implant height (refer to page 11 for part numbers). Insert the smooth end of the Trial/Broach into the disc space, stepping up in height until the desired fit is achieved. Once the height has been determined, use the broach end of the Trial/Broach to prep the vertebral endplates by inserting the broach into the disc space and removing. The disc space and vertebral endplates are now ready to receive the implant (Figure 3).

Note: the teeth on the broach are uni-directional, and only cut when pulled backward out of the disc space. When removing the broach, be sure to pull straight back, and not use a side-to-side motion.

If additional force is required to remove the broach, the Cervical Mallet (2050-000-057) can be used to impact the proximal end of the Trial/Broach for removal (Figure 4).

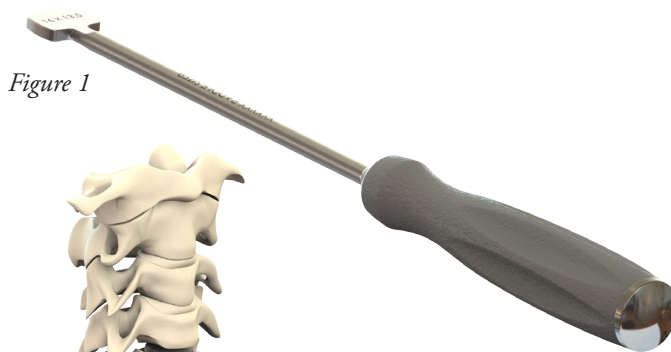


Figure 1

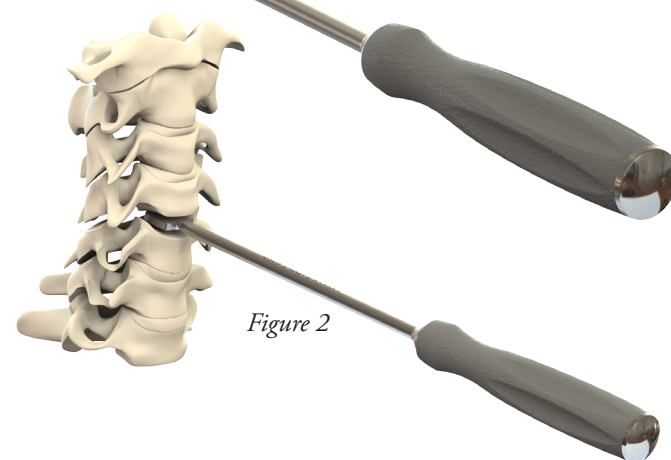


Figure 2

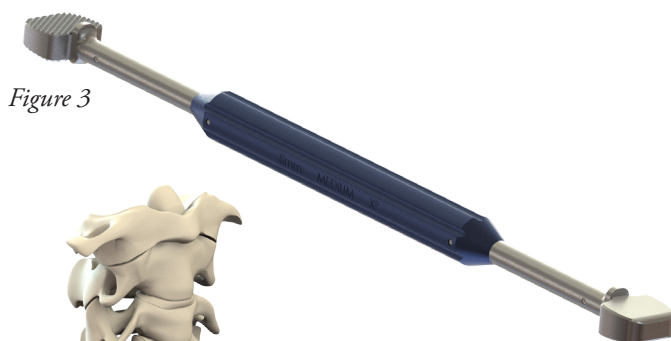


Figure 3

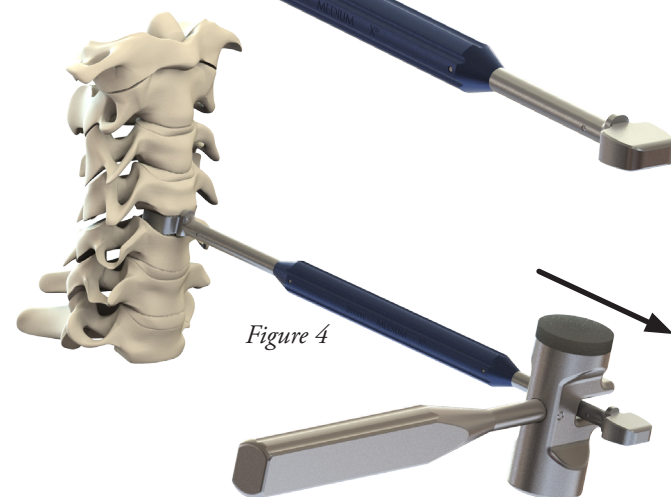


Figure 4

Implant Insertion

Speed Sleeve allows insertion of the outboard screws without removing the inserter from the cage or the use of a separate Drill Guide.

Note the implant height, and load the corresponding Speed Sleeve (2050-001-206-212) onto the Modular Cage Inserter (2050-001-100) by sliding the slotted end of the speed sleeve onto the distal end of the inserter, and guiding it all the way back until the slot is captured by the pin on the proximal end of the Inserter.

Attach the assembled Inserter to the chosen implant by inserting the “hook” at the distal end into the center screw hole on the anterior face of the implant. Push the inserter into the hole with a slight upward pressure to seat the hook (Figure 5). Thread the Speed Sleeve down against the face of the cage to lock the cage on the inserter (Figure 6). The implant can now be inserted into the disc space.

Note: Orient the hook in the opposite direction of the screw

Caution: If using as a stand-alone system, note the orientation of the cage. This system is designed to use three screws, and can be oriented in a one-up/two-down, or two-up/one-down manner.

Bone Graft

Fill the implant with autograft material. Ensure the implant cavity is densely packed.

Insert the leading edge of the implant into the disc space and push forward to get the implant started. The Mallet (2050-000-057) can be used to tap the proximal end of the inserter to advance the cage into final position. The depth is regulated by the “stop” on the Speed Sleeve, which overhangs the edge of the vertebral body and will limit the insertion depth to 1mm countersink (Figure 7). Once the cage is in place, do not remove the inserter; it is necessary for the next steps – inserting the screws.

Note: Confirm placement using inter-operative fluoroscopy.

Non-Stand-alone Cage

If implanting as a non-stand-alone cage, the implantation is now complete. Supplemental fixation cleared in cervical spine must now be implanted.

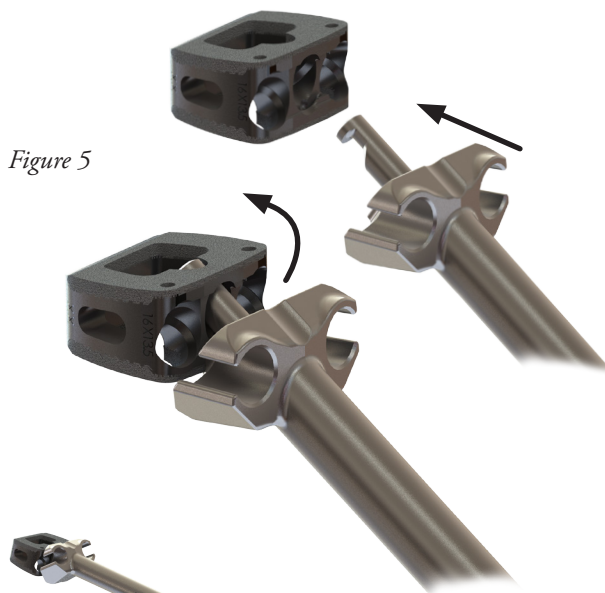


Figure 5

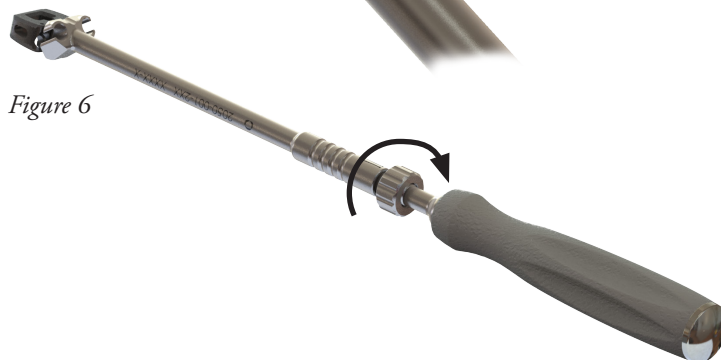


Figure 6

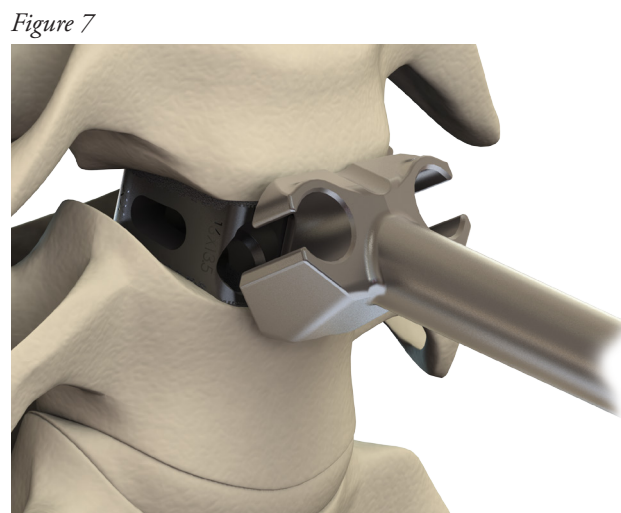


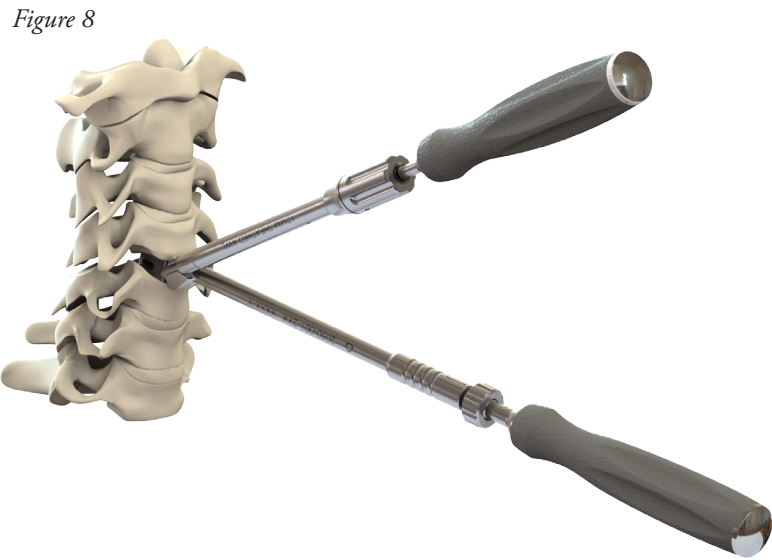
Figure 7

Surgical Technique

Screw Prep and Placement (outboard screws)

Using the Sheathed Awl (2050-002-023), place the distal sheath through either of the two guides on the Speed Sleeve, and push forward until the sheath is docked fully into the screw hole (Figure 8). Using a twisting, forward motion, push the Sheathed Awl forward until it reaches a hard stop. The awl point should perforate the near cortex and make a path for the screw to follow. Once through the bone, the awl point should retract back into the sheath, and the instrument can then be removed from the guide. Repeat this step on the opposite screw hole.

Option: For harder bone, the Sheathed Drill (2050-002-033) can be used by inserting the distal end of the drill into either of the guides on the Speed Sleeve and pushing forward until the sheath is docked fully into the screw hole. Push forward and rotate to engage the drill into the bone. Continue drilling until the hard stop is reached and the drill is fully advanced. Remove the Drill by rotating counter-clockwise until the Drill can be pulled straight back out of the guide on the Speed Sleeve. Repeat the Drill step on the opposite side.



Attach the Tapered Straight Screwdriver (2050-003-041) to the Modular Handle (2701-001-013). Select a screw and attach to the Screwdriver by inserting the distal end of the driver into the hexalobe head of the screw. Push firmly onto the driver to ensure the screw is fully captured. Using the screwdriver, insert the screw through the guide on either side of the Speed Sleeve and push forward until the screw enters the screw hole in the cage and contacts bone. With a gentle forward motion and a clockwise rotation, advance the screw slowly until the screw head contacts the cage and begins to resist rotation (Figure 9).

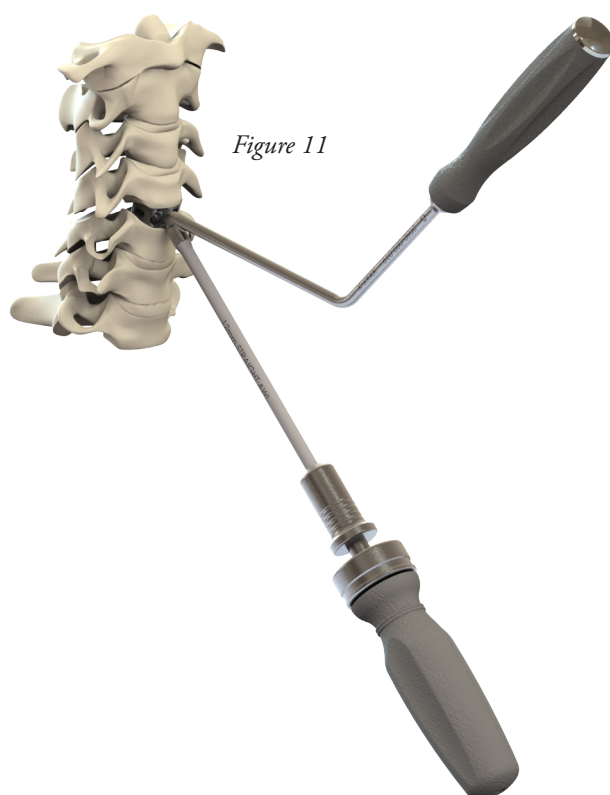
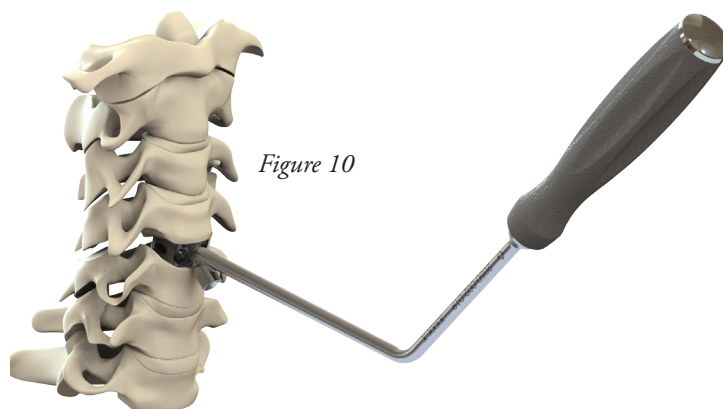
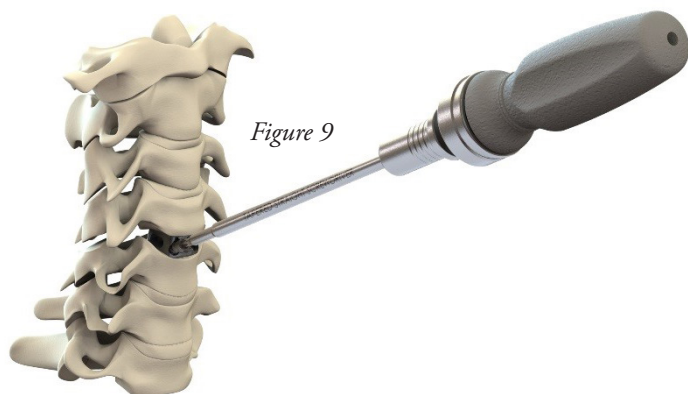
Be careful not to over-tighten the screw, or stripping can occur. Remove the driver from the screw with a gentle tug backwards. Repeat this step with a new screw on the opposite side. Confirm placement and depth with fluoroscopy.

With both outboard screws in place, the Cervical Cage Inserter can now be removed by rotating the knurled ring located proximal to the Speed Sleeve counter-clockwise until the sheath can be retracted proximally away from the cage. Tip the inserter toward the angle of the center screw (opposite the angles of the outboard screws) and pull backwards to remove the inserter from the cage. The center screw hole should now be clear and accessible.

Screw Prep and Placement (center screw)

Insert the distal end of the Angled Drill Guide (2050-002-019) into the center screw hole (Figure 10), taking care to align the slope of the guide to be perpendicular to the cage, so that it can be seated fully into the screw hole. When properly placed, the angle of the guide shaft should be pointed either cephalad or caudal.

Insert the Straight Awl (2050-002-021) into the Drill Guide. Using a twisting, forward motion, push the Awl forward until it reaches a hard stop. The awl point should perforate the near cortex and make a path for the screw to follow. Once through the bone, the awl can then be removed from the guide (Figure 11).



Surgical Technique

Screw Prep and Placement (center screw) (cont)

Option: For harder bone, the Straight Drill (2050-002-031) can be used. Attach the Drill to the Modular Handle (2701-001-013) and insert the distal end of the drill into the Drill Guide and push forward until the tip contacts bone. Push forward and rotate clockwise to engage the drill into the bone. The ratchet can now be moved into the “forward” position. Continue drilling until the hard stop is reached and the drill is fully advanced. Remove the Drill by reversing the ratchet and rotating counter-clockwise until the Drill can be pulled straight back out of the Drill Guide.

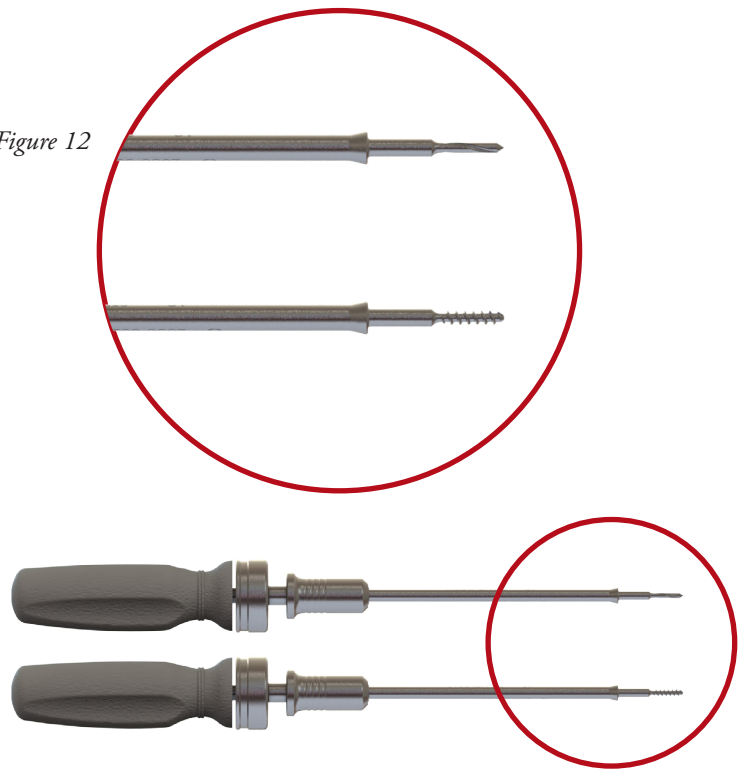
Option: If tapping is desired, the Straight Tap (2050-002-037) (Figure 12) can be attached to the Modular Handle (2701-001-013) and inserted through the Drill Guide, docked against the screw hole on the cage, and actuated using a forward motion with clockwise rotation. Tap until the hard stop is reached. Reverse the ratchet and rotate counter clockwise until the tap is free and clear of the screw hole.

Caution: Take care not to continue tapping once the stop (or desired depth) is reached, or stripping of the bone threads can occur.

Remove the Angled Drill Guide (2050-002-019) from the center screw hole with a gentle pulling motion until distal end of the guide is free and clear of the hole.

Attach the Tapered Straight Screwdriver (2050-003-041) to the Modular Handle (2701-000-013). Select a screw and attach to the Screwdriver by inserting the distal end of the driver into the hex head of the screw. Push firmly onto the driver to ensure the screw is fully captured. Using the screwdriver, insert the screw into the center screw hole in the cage until it contacts the bone. With a gentle forward motion and a clockwise rotation, advance the screw slowly until the screw head contacts the cage and begins to resist rotation. Be careful not to over-tighten the screw, or stripping can occur. Remove the driver from the screw with a gentle tug backwards. Confirm placement and depth with fluoroscopy.

Figure 12



Lock the Screws with the Locking Cover Plate

Locate the Slotted Straight Cover Plate Driver (2050-003-049) and insert the distal, oblong-end into the open slot on the Locking Cover Plate. Insert the cover plate into the wound and dock against the cage.

Note: the two tabs should be aligned with the two laser marks on the face of the cage near the upper or lower edge, above the two outboard screws (Figure 13).

Tilt the cover plate and push the two tabs up into the small holes above the outboard screws (Figure 14).

Once the tabs are docked in their respective holes, push forward on the inserter to ensure full and flat contact with the face of the cage (Figure 15).

Rotate the center post of the cover plate by gently twisting the Cover Plate Driver clockwise 90 degrees. A tactile “click” should be felt when the Cover Plate has been rotated 90 degrees. This rotation completes the locking step, and the driver can be removed with a slight backward pull until the driver is free and clear of the cover plate.

Note: If the Cover Plate is still attached to the driver upon removal of the driver, then the locking step has not been completed properly. The cover plate should be inspected to be sure the center post is rotated back into the proper starting position (rotated counter-clockwise so the slot in the center of the post is perpendicular to the plate). Once this is completed, the Cover Plate can be re-introduced onto the cage.

Caution: If a tactile “click” is not felt during the locking step, do not continue rotating the driver. It should be turned a maximum of 90 degrees. If no “click” is felt, rotate counter-clockwise back to the perpendicular position, remove the cover plate, inspect to make certain the post is in the proper starting position, and re-introduce to the cage.

Figure 13

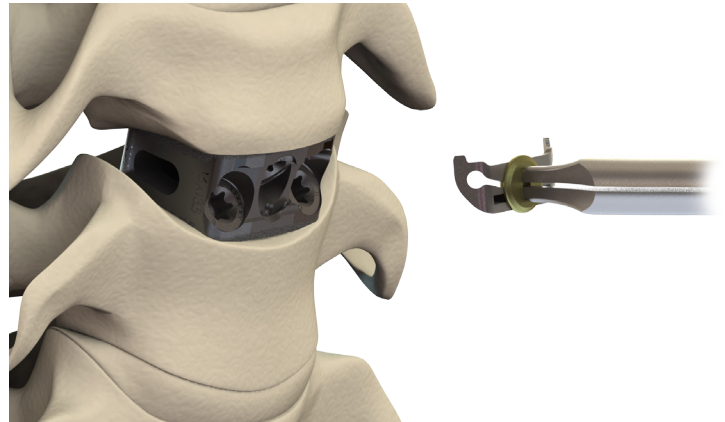


Figure 14

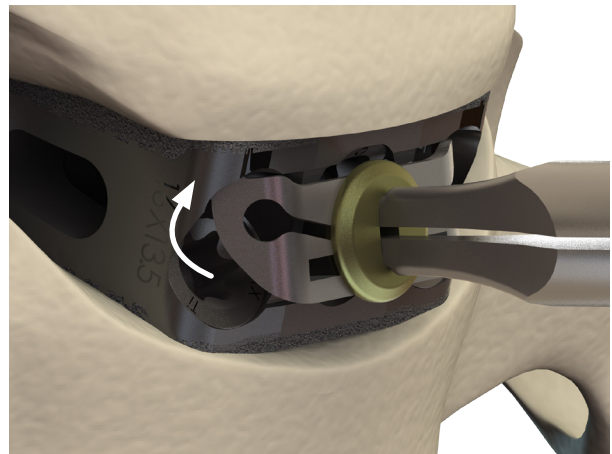
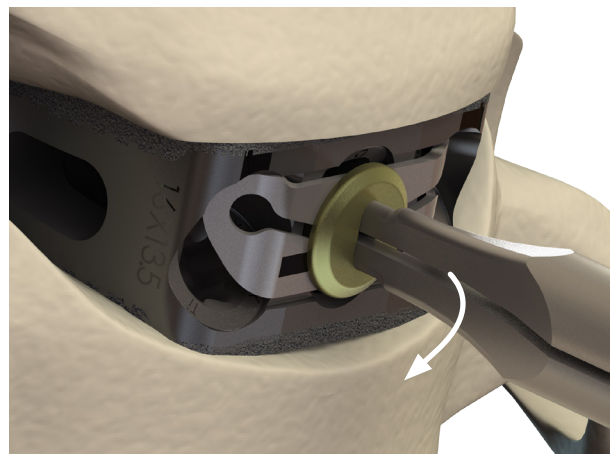


Figure 15



Surgical Technique

Lock the Screws with the Locking Cover Plate (cont)

Confirm locking by visualizing that the slot across the center post of the cover plate; it should be horizontal to the plate (Figure 16). The construct is fully assembled.

If the slot is not horizontal as indicated (for example, if it is vertical) then the cover plate is not locked. Replace the Cover Plate Driver back into the slot in the center post, rotate counter-clockwise until the driver and slot are back in the vertical, starting position, and remove the plate from the surgical suite.

Next, inspect the screws to be sure they are fully seated. Screws can be further seated by using the Solid Straight Screwdriver (2050-003-042). Take care not to over-tighten the screws, or stripping can occur.

Once the screws are fully seated, repeat placement and locking of the cover plate (Figure 17).

Figure 16

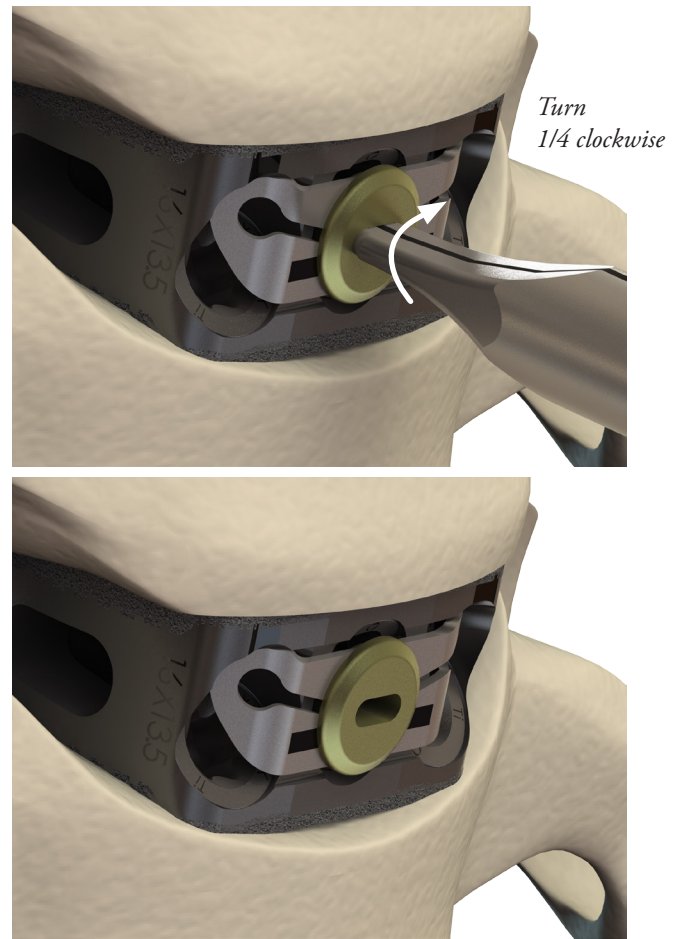
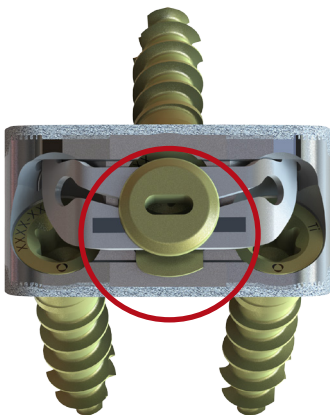


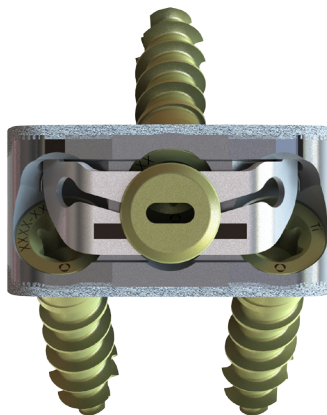
Figure 17

Improperly locked cover plate



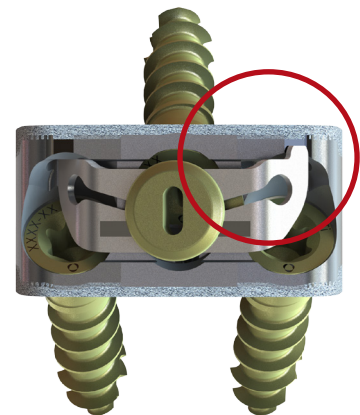
Not Locked

Properly locked cover plate



Locked

Improperly locked cover plate



Not Locked

Removal and Revision

If, during implantation, the surgeon determines the interaction between a screw and bone is loose or has stripped, the loose screw should be removed and replaced with 4.0mm screw.

If removal of the construct is required:

1. Remove the Cover Plate Assembly with the Tapered Straight Cover Plate Driver (2050-003-047) by rotating counter-clockwise until the “click” can be felt and the laser line indicates the cover plate is unlocked. The Cover Plate can now be lifted off the cage and removed.
2. Remove the Screws with the Tapered Straight Screwdriver (2050-003-041) by rotating counter-clockwise until the screws are fully removed from the bone.
3. Ensure the implant is not hindered by any bone or soft tissue. Then, attach the Implant Inserter to the exposed front of the implant and gently remove, following the guidance in figure 5 on page 3 of the surgical technique.

Patient Care Following Surgery

A routine wound closure should be performed after x-ray confirmation of proper implant placement. Following surgery, observe standard patient care protocols and monitoring, including, but not limited to:

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient.
- Pain medication.
- Diet is restricted per surgeon recommendation to small amounts of liquids until return of bowel function is completed.
- The patient is encouraged to ambulate as soon as possible.
- Braces and activity are to be used at each surgeon’s discretion.

Renovis Tesera SC Implants and Instruments

Renovis Tesera SC Implants

Part Number	Description
1050-003-001	SA Cervical Cover Plate, Nitinol
1050-135-012	SA Cervical Screw 3.5mm Self Drilling, 12mm
1050-135-014	SA Cervical Screw 3.5mm Self Drilling, 14mm
1050-135-016	SA Cervical Screw 3.5mm Self Drilling, 16mm
1050-135-018	SA Cervical Screw 3.5mm Self Drilling, 18mm
1050-135-020	SA Cervical Screw 3.5mm Self Drilling, 20mm
1050-140-012	SA Cervical Screw 4.0mm Self Drilling, 12mm
1050-140-014	SA Cervical Screw 4.0mm Self Drilling, 14mm
1050-140-016	SA Cervical Screw 4.0mm Self Drilling, 16mm
1050-140-018	SA Cervical Screw 4.0mm Self Drilling, 18mm
1050-140-020	SA Cervical Screw 4.0mm Self Drilling, 20mm
1050-235-012	SA Cervical Screw 3.5mm Self Tapping, 12mm
1050-235-014	SA Cervical Screw 3.5mm Self Tapping, 14mm
1050-235-016	SA Cervical Screw 3.5mm Self Tapping, 16mm
1050-235-018	SA Cervical Screw 3.5mm Self Tapping, 18mm
1050-235-020	SA Cervical Screw 3.5mm Self Tapping, 20mm
1050-240-012	SA Cervical Screw 4.0mm Self Tapping, 12mm
1050-240-014	SA Cervical Screw 4.0mm Self Tapping, 14mm
1050-240-016	SA Cervical Screw 4.0mm Self Tapping, 16mm
1050-240-018	SA Cervical Screw 4.0mm Self Tapping, 18mm
1050-240-020	SA Cervical Screw 4.0mm Self Tapping, 20mm
1053-161-306	SA Cervical Cage, 16mm x 13.5mm x 6mm, 2° Lordosis, T3
1053-161-307	SA Cervical Cage, 16mm x 13.5mm x 7mm, 2° Lordosis, T3
1053-161-308	SA Cervical Cage, 16mm x 13.5mm x 8mm, 2° Lordosis, T3
1053-161-309	SA Cervical Cage, 16mm x 13.5mm x 9mm, 2° Lordosis, T3
1053-161-310	SA Cervical Cage, 16mm x 13.5mm x 10mm, 2° Lordosis, T3
1053-161-311	SA Cervical Cage, 16mm x 13.5mm x 11mm, 2° Lordosis, T3
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1055-161-311	SA Cervical Cage, 16mm x 13.5mm x 11mm, 7° Lordosis, T3
1055-161-312	SA Cervical Cage, 16mm x 13.5mm x 12mm, 7° Lordosis, T3
1053-171-506	SA Cervical Cage, 17.5mm x 15mm x 6mm, 2° Lordosis, T3
1053-171-507	SA Cervical Cage, 17.5mm x 15mm x 7mm, 2° Lordosis, T3
1053-171-508	SA Cervical Cage, 17.5mm x 15mm x 8mm, 2° Lordosis, T3
1053-171-509	SA Cervical Cage, 17.5mm x 15mm x 9mm, 2° Lordosis, T3
1053-171-510	SA Cervical Cage, 17.5mm x 15mm x 10mm, 2° Lordosis, T3
1053-171-511	SA Cervical Cage, 17.5mm x 15mm x 11mm, 2° Lordosis, T3
1053-171-512	SA Cervical Cage, 17.5mm x 15mm x 12mm, 2° Lordosis, T3

Renovis Tesera SC Implants (cont)

Part Number	Description
1055-171-506	SA Cervical Cage, 17.5mm x 15mm x 6mm, 7° Lordosis, T3
1055-171-507	SA Cervical Cage, 17.5mm x 15mm x 7mm, 7° Lordosis, T3
1055-171-508	SA Cervical Cage, 17.5mm x 15mm x 8mm, 7° Lordosis, T3
1055-171-509	SA Cervical Cage, 17.5mm x 15mm x 9mm, 7° Lordosis, T3
1055-171-510	SA Cervical Cage, 17.5mm x 15mm x 10mm, 7° Lordosis, T3
1055-171-511	SA Cervical Cage, 17.5mm x 15mm x 11mm, 7° Lordosis, T3
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6055-171-512	SA Cervical Cage and Cover Plate, 17.5mm x 15mm x 12mm, 7° Lordosis, T3

Renovis Tesera SC Instruments

Part Number	Description
2050-001-002	Cervical Interbody Cage Holder
2050-001-003	Implant Impactor
2050-001-004	Medium Paddle Sizer
2050-001-005	Large Paddle Sizer
2050-001-013	Packing Block
2050-001-100	Modular Cervical Cage Inserter
2050-001-106	6mm Cage Inserter, Sleeve
2050-001-107	7mm Cage Inserter, Sleeve
2050-001-108	8mm Cage Inserter, Sleeve
2050-001-109	9mm Cage Inserter, Sleeve
2050-001-110	10mm Cage Inserter, Sleeve
2050-001-111	11mm Cage Inserter, Sleeve
2050-001-112	12mm Cage Inserter, Sleeve
2050-001-206	6mm Cage Inserter, Speed Sleeve
2050-001-207	7mm Cage Inserter, Speed Sleeve
2050-001-208	8mm Cage Inserter, Speed Sleeve
2050-001-209	9mm Cage Inserter, Speed Sleeve
2050-001-210	10mm Cage Inserter, Speed Sleeve
2050-001-211	11mm Cage Inserter, Speed Sleeve
2050-001-212	12mm Cage Inserter, Speed Sleeve
2050-002-019	Angled Drill Guide
2050-002-021	12mm Straight Awl
2050-002-023	12mm Sheathed Awl
2050-002-027	12mm 30° Angled Awl
2050-002-029	12mm U-Joint Awl
2050-002-031	12mm Straight Drill
2050-002-033	12mm Sheathed Drill
2050-002-035	12mm U-Joint Drill
2050-002-037	12mm Straight Tap
2050-002-039	12mm U-Joint Tap
2050-003-041	Tapered Straight Screwdriver
2050-003-042	Solid Straight Screwdriver
2050-003-044	Tapered U-Joint Screwdriver

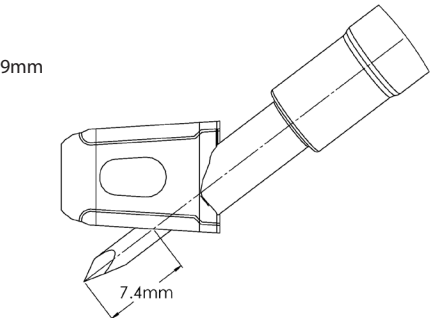
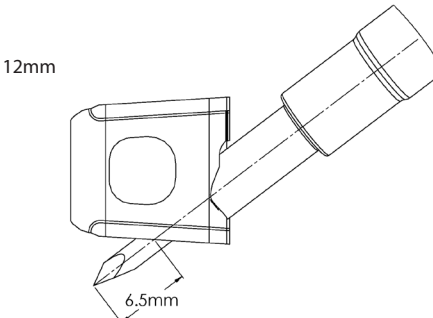
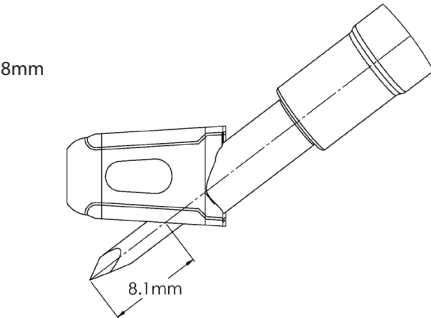
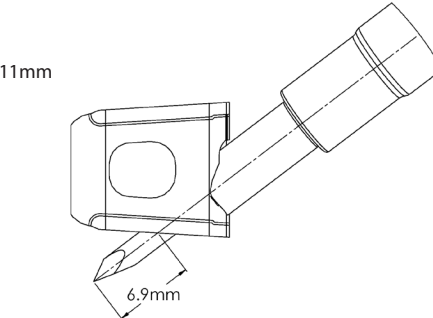
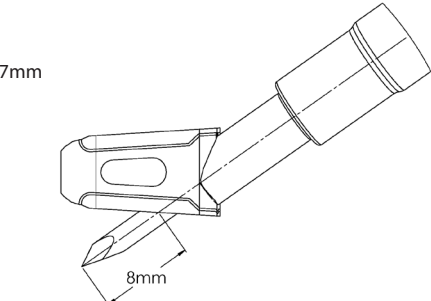
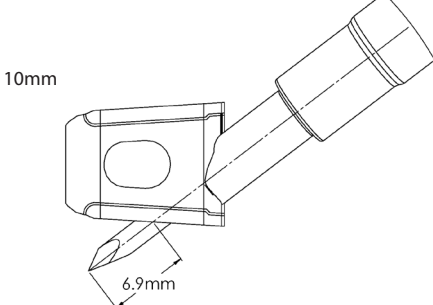
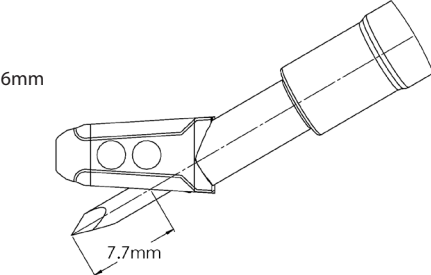
Renovis Tesera SC Instruments (cont)

Part Number	Description
2050-003-045	Solid U-Joint Screwdriver
2050-003-047	Tapered Straight Cover Plate Driver
2050-003-049	Slotted Straight Cover Plate Driver
2050-000-055	Axial Handle
2701-001-013	Modular Driver Handle, Small
2050-000-057	Cervical Mallet
2052-161-306	16mm X 13.5mm X 6mm 2° Lordotic Trial/Broach w/ Stop
2052-161-307	16mm X 13.5mm X 7mm 2° Lordotic Trial/Broach w/ Stop
2052-161-308	16mm X 13.5mm X 8mm 2° Lordotic Trial/Broach w/ Stop
2052-161-309	16mm X 13.5mm X 9mm 2° Lordotic Trial/Broach w/ Stop
2052-161-310	16mm X 13.5mm X 10mm 2° Lordotic Trial/Broach w/ Stop
2052-161-311	16mm X 13.5mm X 11mm 2° Lordotic Trial/Broach w/ Stop
2052-161-312	16mm X 13.5mm X 12mm 2° Lordotic Trial/Broach w/ Stop
2053-161-306	16mm X 13.5mm X 6mm 7° Lordotic Trial/Broach w/ Stop
2053-161-307	16mm X 13.5mm X 7mm 7° Lordotic Trial/Broach w/ Stop
2053-161-308	16mm X 13.5mm X 8mm 7° Lordotic Trial/Broach w/ Stop
2053-161-309	16mm X 13.5mm X 9mm 7° Lordotic Trial/Broach w/ Stop
2053-161-310	16mm X 13.5mm X 10mm 7° Lordotic Trial/Broach w/ Stop
2053-161-311	16mm X 13.5mm X 11mm 7° Lordotic Trial/Broach w/ Stop
2053-161-312	16mm X 13.5mm X 12mm 7° Lordotic Trial/Broach w/ Stop
2052-171-506	17.5mm X 15mm X 6mm 2° Lordotic Trial/Broach w/ Stop
2052-171-507	17.5mm X 15mm X 7mm 2° Lordotic Trial/Broach w/ Stop
2052-171-508	17.5mm X 15mm X 8mm 2° Lordotic Trial/Broach w/ Stop
2052-171-509	17.5mm X 15mm X 9mm 2° Lordotic Trial/Broach w/ Stop
2052-171-510	17.5mm X 15mm X 10mm 2° Lordotic Trial/Broach w/ Stop
2052-171-511	17.5mm X 15mm X 11mm 2° Lordotic Trial/Broach w/ Stop
2052-171-512	17.5mm X 15mm X 12mm 2° Lordotic Trial/Broach w/ Stop
2053-171-506	17.5mm X 15mm X 6mm 7° Lordotic Trial/Broach w/ Stop
2053-171-507	17.5mm X 15mm X 7mm 7° Lordotic Trial/Broach w/ Stop
2053-171-508	17.5mm X 15mm X 8mm 7° Lordotic Trial/Broach w/ Stop
2053-171-509	17.5mm X 15mm X 9mm 7° Lordotic Trial/Broach w/ Stop
2053-171-510	17.5mm X 15mm X 10mm 7° Lordotic Trial/Broach w/ Stop
2053-171-511	17.5mm X 15mm X 11mm 7° Lordotic Trial/Broach w/ Stop
2053-171-512	17.5mm X 15mm X 12mm 7° Lordotic Trial/Broach w/ Stop

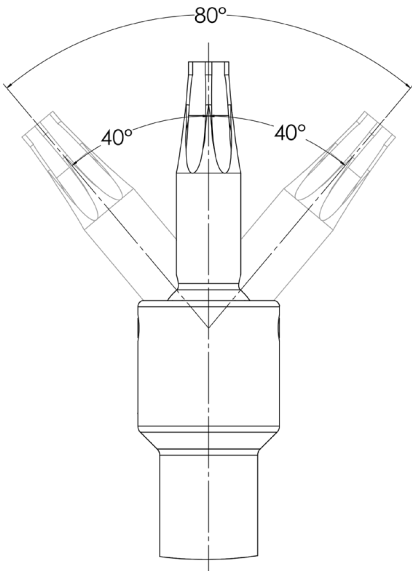
Renovis Tesera SC Implants and Instruments

Critical Dimensions

AWL - Depth of Penetration (per cage height)

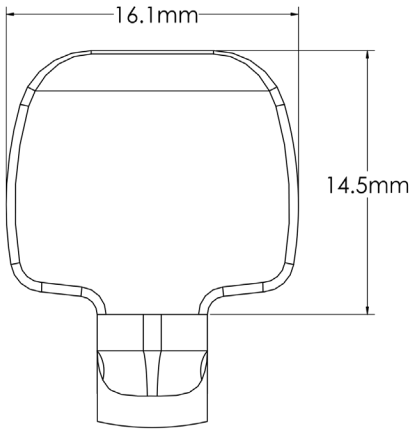


Screwdriver ROM

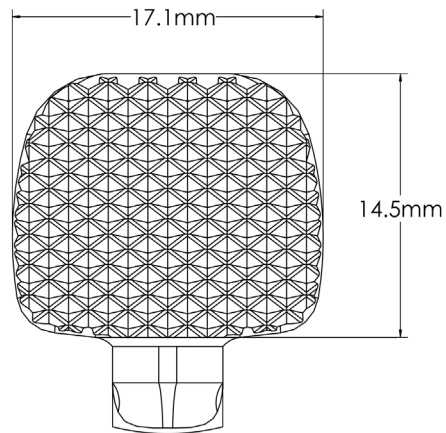


Trials and Broaches

Trial, top



Broach, top

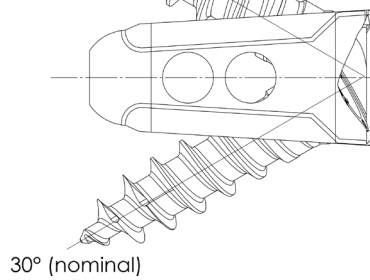


Screw Angles

6mm

2° Range

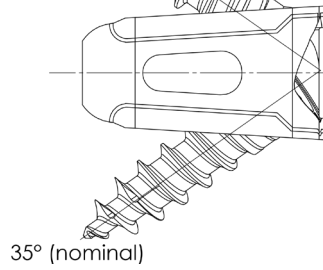
31°
29°



7mm

2° Range

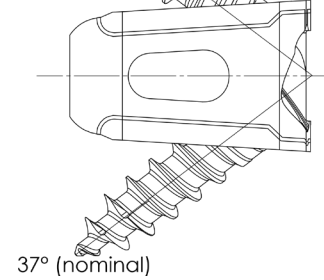
36°
34°



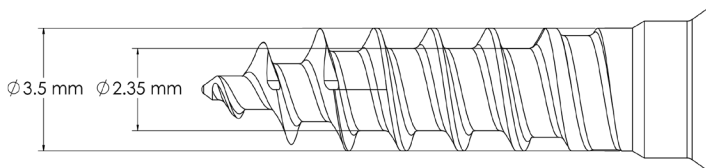
8 - 12mm

2° Range

38°
36°



Screw Dimensions



Renovis Safety Statement / Instructions for Use

Renovis Tesera™ SC –
Stand-alone Anterior Cervical Fusion (ACF) System, Sterile Packaging

DESCRIPTION

The Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System is an internal spinal fixation system comprised of Titanium Interbody cages, Titanium screws and a Titanium and Nitinol cover plate assembly. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, Cage Inserters, and Cover Plate Inserters.

Tesera SC ACF Implant – Summary Description

Dimensions(mm)	
M/L	16, 17.5
A/P	13.5, 15
H	6-12
Lordosis	2°, 7°
Number of screws	3
Screw Diameter (mm)	3.5, 4.0
Screw Length (mm)	12, 14, 16, 18, 20
Cover plate (mm)	5.25 H; 12.5 W

For implant and instrument parts numbers, as well as implant dimensions, refer to the Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System Surgical Technique.

IMPORTANT NOTE

This product is marketed for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL

All implant components of the Tesera SC Anterior Cervical Fusion (ACF) System are made of the following materials:

1. Cages and Screws: Titanium Alloy: Ti6Al4V according to ASTM F-136
2. Cover Plate: Titanium Alloy: Ti6Al4V according to ASTM F-136 and Nitinol Alloy according to ASTM F-2063

INDICATIONS FOR USE

The Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The Tesera SC ACF System is a stand-alone system when used with the cover plate and screws provided, and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of three (3) screws and the cover plate assembly.

When used without the cover plate and three screws the Tesera SC ACF System is a non-stand-alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

GENERAL CONDITIONS OF USE

The safe implantation of Tesera SC Anterior Cervical Fusion (ACF) System requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Tesera SC ACF System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Tesera SC ACF System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Under no circumstances should any component of the Tesera SC ACF System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. The Tesera SC ACF System has been tested as a standalone construct. If used without the integrated screws and cover plate, it requires additional supplemental fixation cleared in the cervical spine.

CONTRAINDICATIONS

Contraindications to using the Tesera SC Anterior Cervical Fusion System are similar to those of other Anterior Cervical Discectomy and Fusion (ACDF) Systems and consist of the following:

1. Prior fusion at the level(s) to be treated.
2. Any condition not describe in the Indications for Use.
3. Patients with conditions that may place excessive stresses on bone and implant, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
6. Patients with a suspected or documented metal allergy or intolerance.
7. Inadequate tissue coverage over the operative site.
8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and pregnancy.

POTENTIAL RISKS

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The devices must be handled and stored carefully to protect from damage. They should be carefully unpacked and inspected for damage prior to use.
3. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
4. Correct implant handling is vital. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.
5. The Tesera SC Anterior Cervical Fusion System implants are provided sterile. Do not re-sterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after expiration date.
6. The Tesera SC Anterior Cervical Fusion System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.
7. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients may be particularly at risk during postoperative rehabilitation.

PATIENT SELECTION

The following factors can be extremely important to the eventual success of the procedure:

1. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
2. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
3. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
4. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

WARNINGS AND CAUTIONS

Only experienced spinal surgeons with specific training in the use of interbody fusion system should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.

MAGNETIC RESONANCE (MR) ENVIRONMENT

1. Implants: The Renovis Stand-alone Anterior Cervical Fusion (ACF) implants are manufactured from non-ferromagnetic materials. The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifacts in the MR environment. The safety of the Renovis Stand-alone Anterior Cervical Fusion (ACF) implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
2. Instruments: Renovis instruments used with the stand-alone Anterior Cervical Fusion (ACF) implants may be manufactured from ferromagnetic materials and may be MR unsafe. Potential risks of placing instruments in or near the magnetic field include:
 - a. Movement of ferromagnetic components through magnetically induced force and torque.
 - b. Localized heating of components caused by radio frequency induction heating.
 - c. Image artifacts created by interaction between metallic components and the magnetic field.

ADVERSE AFFECTS

In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants

Renovis Safety Statement (cont)

and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.

2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While formation wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

HANDLING OF IMPLANTS

1. Receipt – Carefully unwrap and handle non-sterilized instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration. Implants are provided sterile. Wrappings should not be removed by receiving personnel.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants and instruments prior to use in such a manner as to maintain the devices' surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and to provide traceability to the manufacturer.

IMPLANT - STERILITY

All implants are sterilized by exposure to a minimum dose of 25kGy of gamma radiation.

Do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date.

INSTRUMENTS – DECONTAMINATION AND CLEANING

All instruments must be thoroughly cleaned before each sterilization (including first use) and introduction into a sterile field. All devices should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the devices. More information is provided in Renovis Surgical Instruments IFU (p/n 4001-001).

Instruments that are specifically designed for use with the Tesera SC ACF System include trials, sizers, implant/cage inserters and the cover plate inserter. Other instruments are also provided for use with the Tesera SC ACF System. For a list of all instruments, refer to the Tesera SC ACF System Surgical Technique manual.

All instruments must be thoroughly cleaned, decontaminated and sterilized as follows (and as per Renovis Surgical Instrument IFU, p/n 4001-001):

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL® Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all hard to reach areas are accessed.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap.
4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
5. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection for moisture and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
6. **Inspection:** After cleaning/disinfection, instruments should be visually inspected for contamination. If contamination is still visible, repeat steps 3, 4 and 5. If instruments continue to have visual contamination, they should not be used and should be disposed of.
7. **Preparation and Assembly:** Visually inspect all instruments for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Renovis has qualified the above cleaning method with the provided solution examples. Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

INSTRUMENTS STERILIZATION

Sterility: Renovis Instruments are provided non-sterile. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	30 Minute Minimum 40 Minute Maximum

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

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

Comments regarding this device can be directed to:

Renovis Surgical Inc.
Attn: Regulatory Department
1901 W. Lugonia Ave., Suite 340
Redlands, CA 92374 USA
1-800-RENOVIS
Fax: (909)-307-8585
Email: info@renovis-surgical.com
www.renovis-surgical.com



Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

Renovis Surgical Technologies, Inc.

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Redlands, CA 92374

(800) RENOVIS

www.renovis-surgical.com

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Part #4150-002 Rev A



The CE mark is valid only if it is also printed on the product label.