ADDITIVE IMPLANTS

SureMAX®-SA
CERVICAL STANDALONE SYSTEM

SURGICAL TECHNIQUE GUIDE

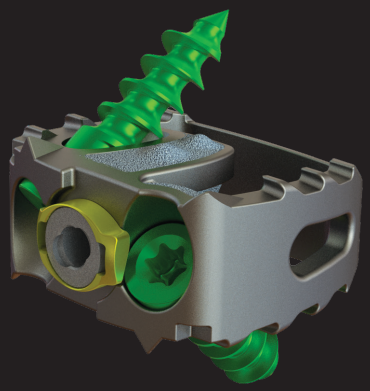
SureMAX®-SA
CERVICAL STANDALONE SYSTEM

The SureMAX®-SA Cervical Standalone System offers:

+ Optimized course open-pore structure.
+ Convex surfaces to match spinal endplates.
+ Large lateral windows to radiologically visualize bone healing.
+ Lordotic 7°, Mid-Lordotic 10°, and Hyperlordotic 14° options.
+ Four footprints: 12 x 14 mm, 14 x 16 mm, 15 x 18 mm, 15 x 20 mm.
+ Multiple fixation options including variable, fixed and helical screws.
+ Narrow low profile inserter to enhance visibility during MIS procedures.
+ Multiple straight and angled instruments for easier screw placement.

These are essential features for the next generation Cervical Interbody Spacer.
They are combined features available in only one system:

SUREMAX®-SA CERVICAL STANDALONE SYSTEM



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INDICATIONS/CONTRAINDICATIONS

Indications For Use

The SureMAX®-SA Cervical Standalone System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients as an adjunct to fusion for the treatment of degenerative disc disease (DDD). DDD is defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with the device. The SureMAX®-SA Cervical Standalone System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. When used with the fixed or variable screws, the SureMAX®-SA Cervical Standalone System is intended to be used at one or two levels from C2-T1 and requires no additional fixation. When used with one or more helical screws, the SureMAX®-SA Cervical Standalone System is intended to be used at one level and with supplemental fixation.

Contraindications

+ Active local infection in or near the operative region.
+ Active systemic infection and/or disease.
+ Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
+ Current metastatic tumors of the vertebrae adjacent to the implant.
+ Known or suspected metal sensitivity.
+ Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).
+ Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions.
+ Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure, or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy, and multiple sclerosis.
+ Pregnancy.
+ Patients unwilling or unable to follow postoperative instructions, especially those in athletic and occupational activities.
+ Morbid obesity.
+ Symptomatic cardiac disease.
+ Skeletal immaturity.
+ Grossly distorted anatomy.
+ Any condition not described in the Indications for Use.

SUREMAX®-SA SYSTEM OVERVIEW

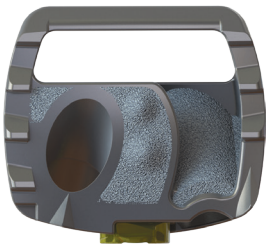
Additive Implant's SureMAX®-SA Cervical Standalone System offers a wide range of implant sizes to accommodate patient anatomy as well as a comprehensive set of instrument options to support surgical technique preferences.

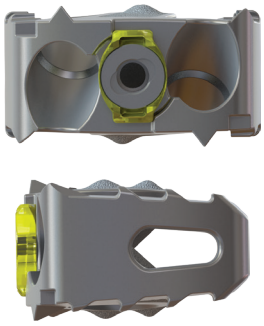
Spacer

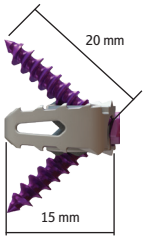
+ Material: Titanium alloy (Ti6Al4V) per ASTM F3001
+ Heights from 5 mm to 12 mm (1 mm increments)
+ 4 footprints
  - Small 12 mm x 14 mm
  - Medium 14 mm x 16 mm
  - Large 15 mm x 18 mm
  - Extra Large 15 mm x 20 mm
+ 3 lordotic angles – 7, 10 and 14 deg* (*14 deg not available in 5 mm and 10 mm heights)

Screw Options

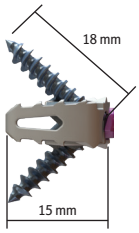
+ Material: Titanium alloy (Ti6Al4V) per ASTM F136
+ Variable and Fixed Angle Screws – 3.5 mm diameter in lengths of 14 mm, 16 mm, 18 mm, and 20 mm (T8 Hexalobe Drive Socket)
+ Variable and Fixed Angle Rescue Screws – 3.7 mm diameter in lengths of 14 mm, 16 mm and 18 mm. (T8 Hexalobe drive socket)
+ Helical Screws – 3.5 mm diameter in lengths of 14 mm, 16 mm, 18 mm and 20 mm (Left-hand Thread Drive Socket)



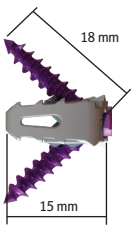




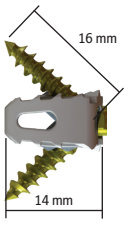
XL with 20 screw



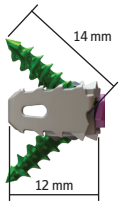
XL with 18 screw



Large with 20 screw



Med with 16 screw



Sm with 14 screw

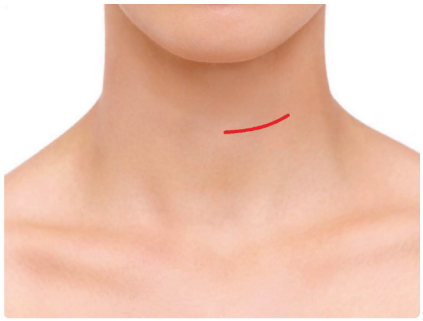
Screw Sizing

Spacer Footprint	15 x 20	15 x 20	15 x 18	14 x 16	12 x 14
Screw Length	20	18	18	16	14

SURGICAL TECHNIQUE

STEP 1:

Pre-Operative Planning and Patient Positioning

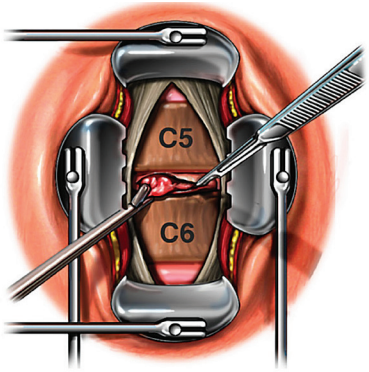


Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, patient history and physical examination.

Place the patient in a supine position. Support the posterior cervical spine to maintain or restore normal lordosis and chose a right or left-sided approach. Identify the symptomatic level and make a skin incision to the corresponding pathology.

STEP 2:

Exposure and Location

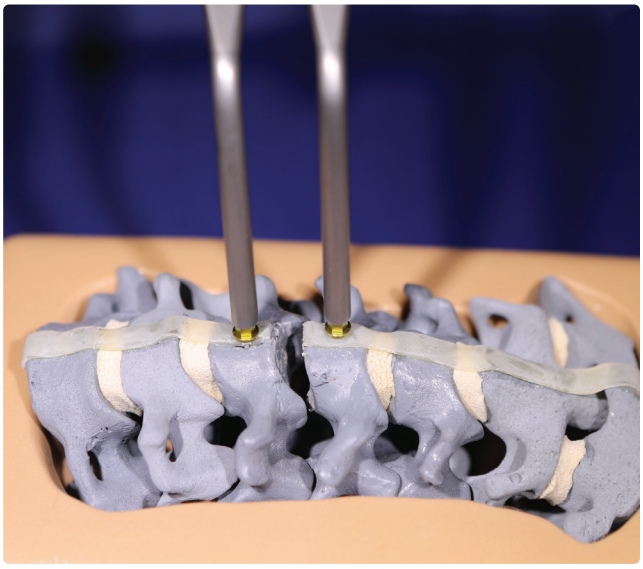


The anterior cervical anatomy is exposed in the standard fashion by identifying a dissection plane. Exposure is then held in place utilizing self-retaining or other retractors.

The proper level is confirmed using a marker and fluoroscopy imaging. A vertebral Caspar Pin Distractor must then be placed through the open incision in the adjacent vertebrae to the discectomy.

STEP 3:

Discectomy

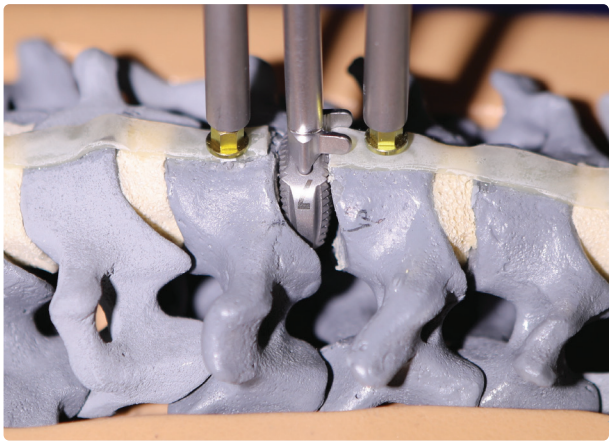


A Caspar Pin Distractor is required for the distraction of the adjacent endplates. Perform a standard cervical discectomy and decompression by resecting the anterior longitudinal ligament over the corresponding vertebrae. Remove the intervertebral disc out to the uncovertebral joints using general instrumentation such as Curettes, Rongeurs or burr.

Caution: *Great care should be taken to ensure that all exposed blood vessels, nerve and other structures are properly retracted prior to the discectomy to avoid injury.*

STEP 4:

Endplate Distraction



Endplates should be distracted by using the Wedge Distractors provided in the set. Distraction should be performed starting with the smallest distractor that fits into the disc space. Distract sequentially in 1 mm increments using tension on the Caspar pins to maintain the achieved space between the vertebral endplates. Caspar pins should only be used to maintain the distraction obtained by the distracting wedges to decrease the likelihood of the Caspar Pins cutting through the vertebral body. Distracting Wedges come in 1 mm increments, and from 2.5 mm to 12.5 mm.

After removing the cartilage, on the endplate using a standard Curette prepare the bone surface using the appropriately sized Rasp. This step is important as it ensures a conforming fit between the implant and the anatomy. As appropriate, a burr may be used to create holes in the endplate in order to enhance blood flow from the subcondral bone to the interface.

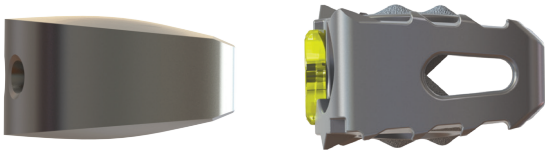
Caution: *Using excessive force with the instrumentation can inadvertently damage the vertebral bodies.*

STEP 5:

Spacer Selection

Determine the implant footprint and degree of lordosis by measuring the disc space using the Trial Spacers and select the size that best fits the disc space. The trials are dimensionally identical to the implant.

Select the appropriate sized spacer to match the prepared disc space.

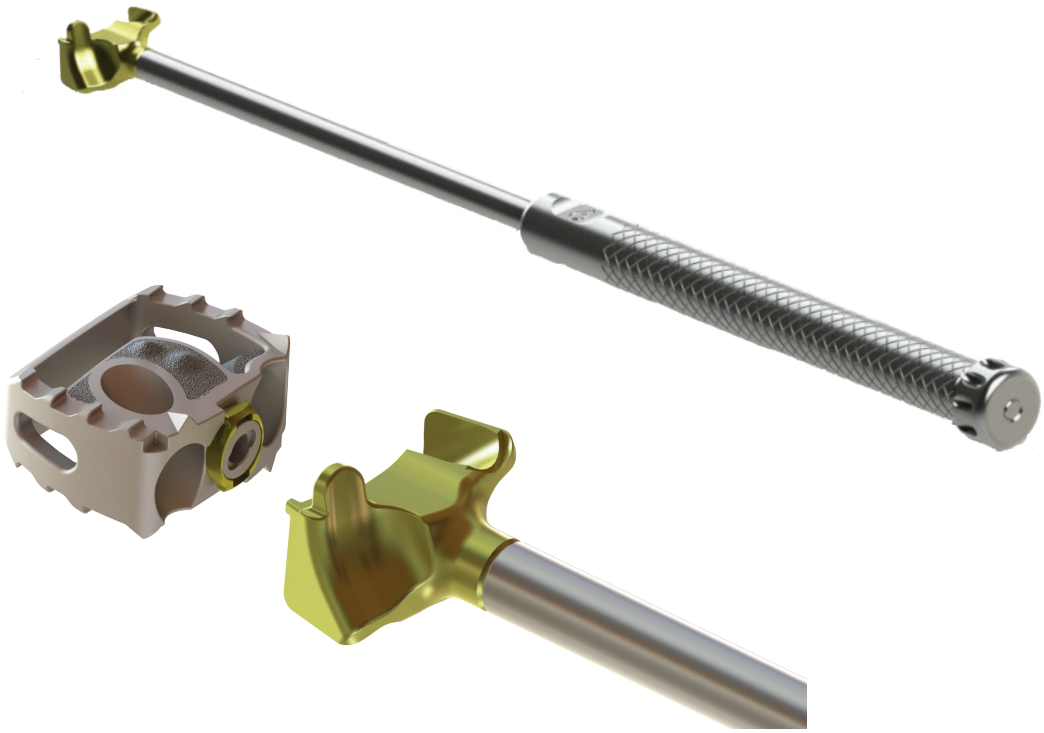


STEP 6:

Spacer Insertion/Positioning

AWL GUIDE INSERTER

Provides implant insertion with defined screw path angles to directly match the spacer.



SPACER INSERTION

Insert the Inserter Inner Shaft into the cannulation of the appropriate sized Awl Guide Inserter and rotate clockwise until past the retaining threads in the guide. (Fig. 1)

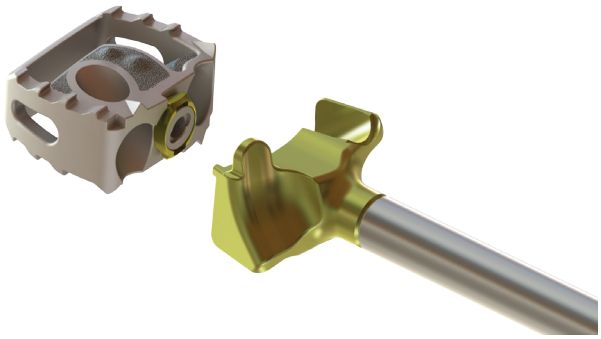


Fig. 1 ▲

Attach the matching sized spacer by aligning the pockets at the edges of the spacer with the keys on the Awl Guide Inserter. Thread the Inserter Inner Shaft into the spacer by rotating clockwise until the spacer is firmly fixed to the guide.

> ***Caution:*** *Do not overtighten this connection to avoid damage to the threads.*

Ensure that the spacer is attached flush with guide and that the holes in the guide align with the holes in the spacer. (Fig. 2)

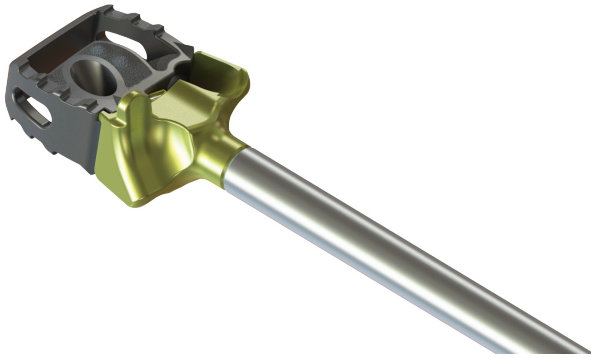


Fig. 2 ▲

Pack the central opening of the spacer with the desired graft material. Using imaging, introduce the spacer into the disc space to the desired position. (Fig. 3)

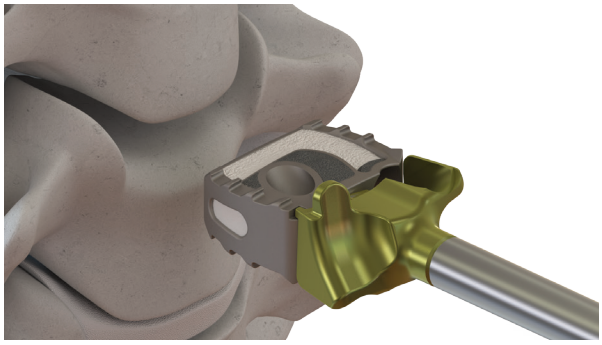


Fig. 3 ▲

Advance the spacer until the guide is fully abutted against the anterior surface of the vertebrae. Gentle malleting on the end of the guide handle may be required. The guide is designed to recess the spacer 1 mm into the disc space. (Fig. 4)

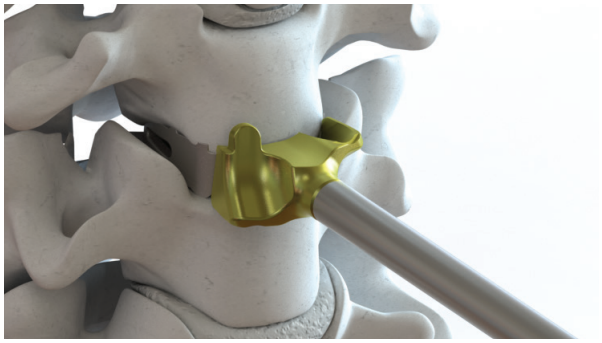


Fig. 4 ▲

STEP 7:

Screw Path Preparation

STANDARD INSTRUMENTS

Introduce the Straight Awl into the hole in the Awl Guide Inserter and tap firmly until fully seated in the spacer. Care should be taken not to reposition the spacer during impaction. (Fig. 5)

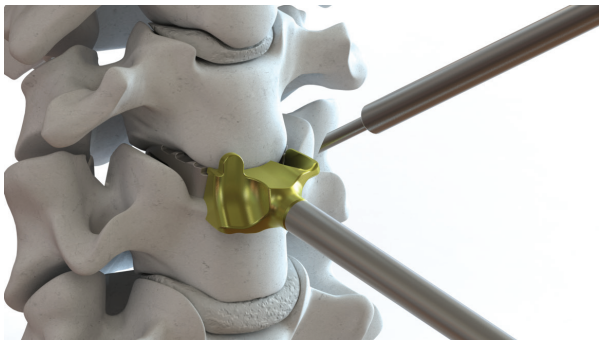


Fig. 5 ▲

Alternatively the hole may be prepared by using the Hand Drill. Insert the drill into the guide hole and advance until fully seated in the guide. (Fig. 6)

Quick-Couple Drills are also available if a power option is preferred.

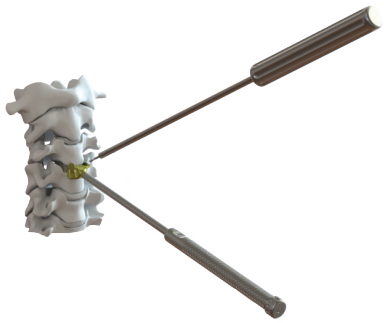


Fig. 6 ▲

ANGLED INSTRUMENTS

At certain levels or with some patients, it may be advantageous to use the angled instruments provided for better access.

The Angled Awl may be used in the same manner as the standard awl technique. Care should be taken not to dislodge the cage from its desired position when impacting the awl. Note that the divot in the handle aligns with the bend direction of the awl tip. (Fig. 7)

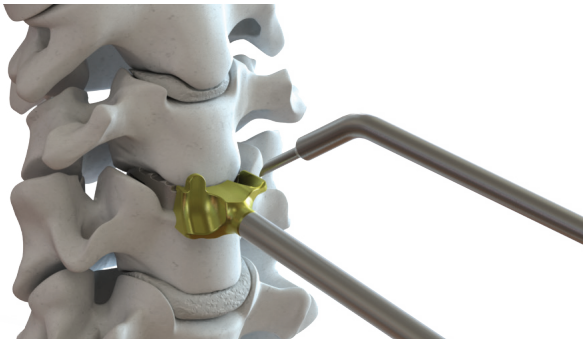
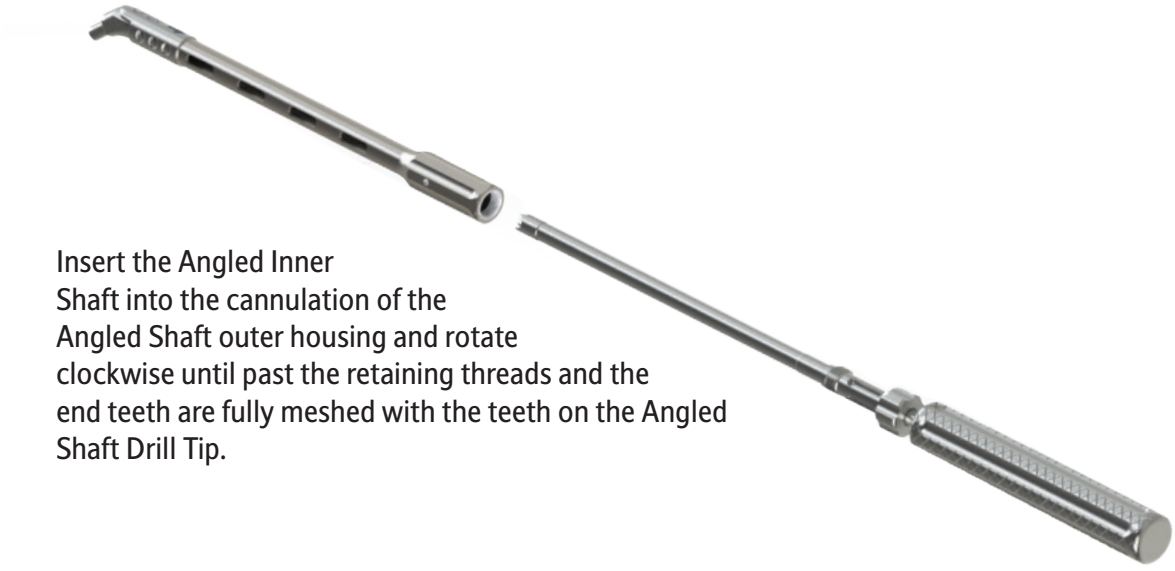


Fig. 7 ▲

The Angled Shaft Instrumentation may also be used to prepare the screw hole.

To assemble this instrument, select the Angled Shaft Drill Tip and insert it into the Angled Shaft outer housing after retracting the sliding sleeve. Advance the drill tip until it is fully seated into the tip of the shaft. Return the sliding sleeve to its closed position. (Fig. 8)

Fig. 8 ▲



Insert the Angled Inner Shaft into the cannulation of the Angled Shaft outer housing and rotate clockwise until past the retaining threads and the end teeth are fully meshed with the teeth on the Angled Shaft Drill Tip.

Rotate the handle and ensure that the drill tip is rotating freely. Insert the Angled Shaft Drill Tip into the Awl Guide Inserter and advance until fully seated in the guide. The Counter Torque may be attached to the Angled Shaft for added control. To assemble, slide the Counter Torque over the Angled Shaft outer housing and slide toward the handle to engage the splines. (Fig. 9)

Fig. 9 ▲

STEP 8:

Screw Insertion

SCREW FIXATION

Select the desired length Fixed or Variable screw. Refer to the chart on page 3 for screw sizing. Attach the screw to the Screw driver using firm pressure to seat the screw socket onto the driver's tapered tip. Ensure that the screw is firmly retained by the driver and is aligned with the driver shaft. (Fig. 10)

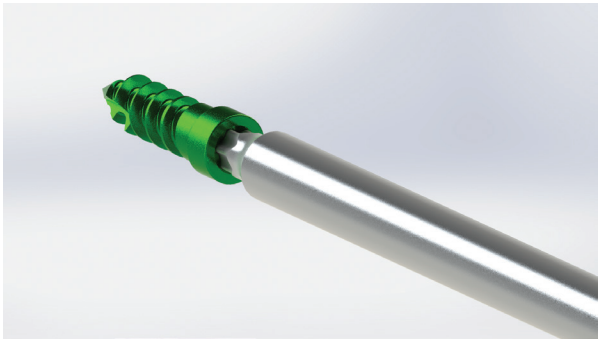


Fig. 10 ▲

Insert the screw into the hole in the Awl Guide Inserter and advance until fully seated in the spacer. (Fig. 11)

The Short Handled Screwdriver may be used to fully tighten the screws if desired. Note that this driver does not have a self-retaining feature.

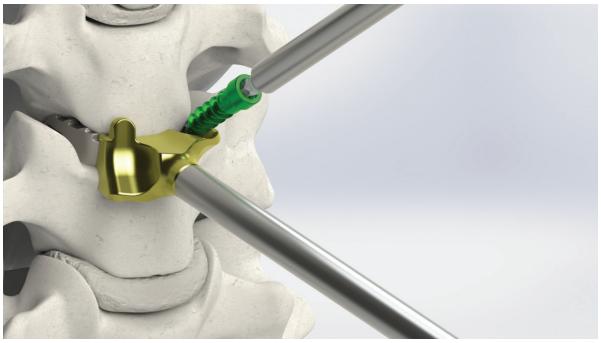


Fig. 11 ▲

Alternatively the Angled Shaft Instrumentation may be used to implant the screws. Assemble the Angled Shaft, Inner Shaft, and Angled Shaft Driver Tip in the same manner previously described for the Angled Shaft Drill Tip making sure that the driver tip rotates freely. Attach the desired screw to the Angled Shaft Driver Tip as previously described. Introduce the screw into the hole in the Awl Guide Inserter and advance until the screw is fully seated in the spacer. (Fig. 12)

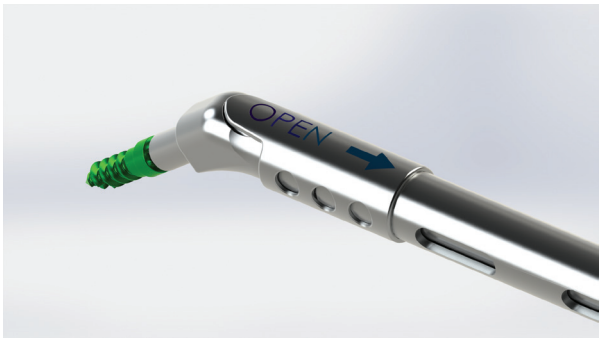


Fig. 12 ▲

HELICAL SCREW IMPLANTATION

To implant the Helical Screws, first attach the Helical Screw Straight Inserter onto the SureMAX® Cervical Inserter with or without Guard (Part No. 9100-0010 or 9100-0011) using the Central Shaft. Alternatively, the Helical Straight Inserter may be threaded onto the Slap Hammer (Part No. 9100-0025 or 9100-0026). Fully hand tighten this connection. (Fig. 13)

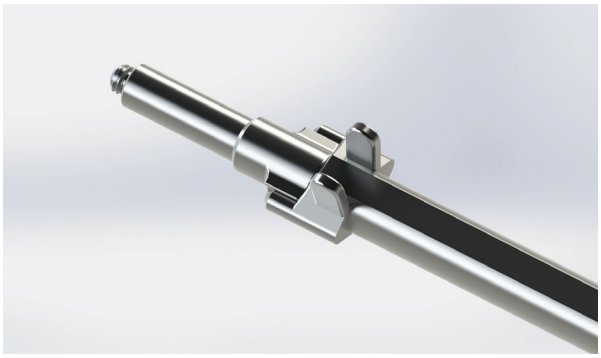


Fig. 13 ▲

Select the desired length Helical Screw and thread it onto the tip of the Helical Screw Straight Inserter. See the chart on page 3 for screw sizing information. (Fig. 14)

Note: *This connection utilizes a left hand thread.*

Fig. 14 ▲

Align the Helical Screw with the hole in the Awl Guide Inserter and impact the screw until fully seated in the spacer. The surgeon should maintain a grip on the inserter during impaction which will allow the instrument and Helical Screw to rotate as the screw imbeds into the bone. (Fig. 15)

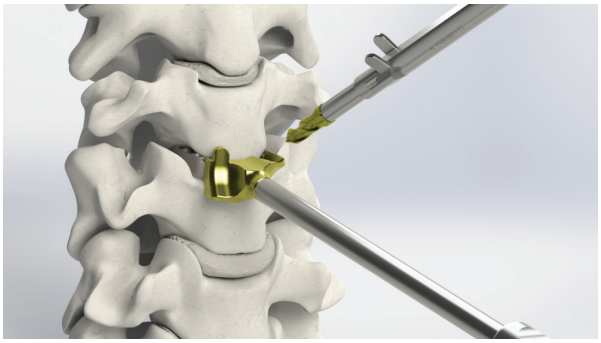


Fig. 15 ▲

For difficult insertion angles, the Helical Screw U-Joint Inserter may be used to implant the Helical Screws. Attach the U-Joint Inserter to the Inserter or Slap Hammer and attach the Helical Screw to the U-Joint Inserter as described above for the Straight Helical Screw Straight Inserter.
(Fig. 16)

Fig. 16 ▲

Impact the Helical Screws into the prepared holes until fully seated in the spacer. (Fig.17)

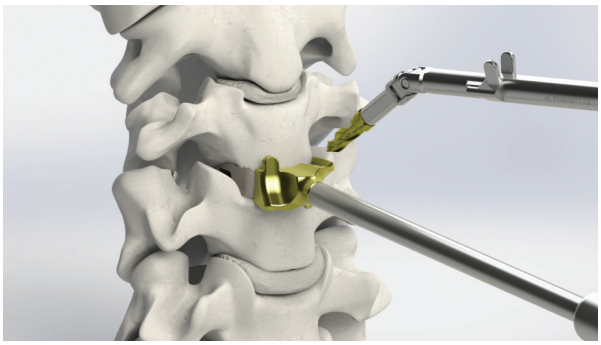


Fig. 17 ▲

Alternatively, after partially inserting the Helical Screw with the Slap Hammer, the Tamp may be used to fully seat the Helical Screw. After removing the inserter/slap hammer assembly, engage the ball nose of the tamp with the drive socket of the Helical Screw and gently mallet into place. Great care should be taken to ensure that the tip of tamp remains engaged with the Helical Screw during insertion to avoid injury to surrounding structures. (Fig. 18)

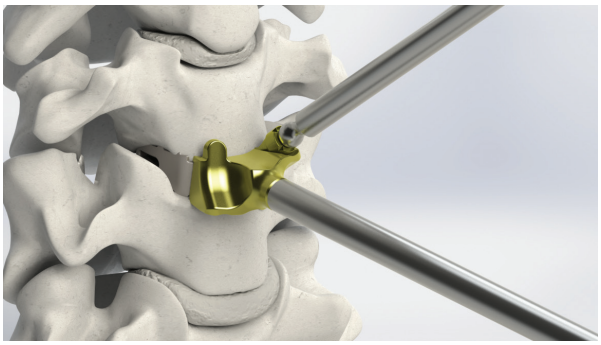


Fig. 18 ▲

For difficult insertion angles, the Helical Screw Angled Driver Tip may be used with the Angled Shaft Assembly to insert the Helical Screws. Install the tip into the Angled Shaft Assembly as previously described for Angled Driver Tip. Introduce the Helical Screw into the Awl Guide Inserter and gently mallet the end of the Angled Shaft Assembly until the Helical Screw is fully seated in the spacer.
(Fig. 19)

Fig. 19 ▲

Repeat these steps for the second screw and detach the Awl Guide Inserter from the spacer. Supplemental fixation is to be used when the device is used with one or more Helical Screws. Apply supplemental fixation to complete the construct.

RESCUE SCREWS

In the event a standard screw becomes stripped or is providing poor purchase, 3.7 mm diameter Rescue Screws are available in fixed and variable options in lengths of 14, 16, and 18 mm. They are implanted in the same manner as described above for the standard screws.

ALTERNATE METHOD STEPS 6-8:

Low Profile Inserter

Provides increased visibility to the surgical site.

The Low Profile (LP) Inserter may also be used to implant the spacer. Attach the spacer to the appropriate sized Low Profile Inserter using the Inserter Inner Rod Shaft in the same manner as described for the Awl Guide Inserter (see Step 6, Fig. 1). Pack the spacer with the desired graft material. (Fig. 20)

Fig. 20 ▲

Unlike the Awl Guide Inserter, there is no safety stop on the Low Profile Inserter to prevent implanting the spacer too deeply into the disc space. The surgeon must make every effort to prevent over insertion of the spacer which may result in catastrophic irreversible neurological injury. Image guidance should always be used with the LP Inserter to correctly position the spacer within the disc space. Gentle malleting may be required. It is recommended to recess the spacer 1 mm into the disc space as is achieved with the Awl Guide Inserter. After confirming the desired spacer position, the same instruments (awls, drills, drivers, and Helical Screws inserters) described above with the Awl Guide Inserter technique may be used to prepare the screw holes and to insert the screws. Imaging should be used to confirm the desired screw depths. Care should be taken to ensure that screws are positioned within the angulation limits of the spacer to allow for full seating of the screw heads into the spacer. Improper screw seating may result in the inability to properly engage the locking mechanism or in loss of fixation. The locking mechanism must be properly deployed to prevent screw backout which could result in injury to the esophagus and/or surrounding structures.

After placing the screw, detach the LP Inserter from the spacer.

STEP 9:

Screw Retention

After seating the screws into the spacer, the locking cam should be deployed to prevent screw backout. Introduce the Cam Locker Tool to the front surface of the spacer and engage the tines of the tool into the recesses of the cam lock. (Fig. 21)

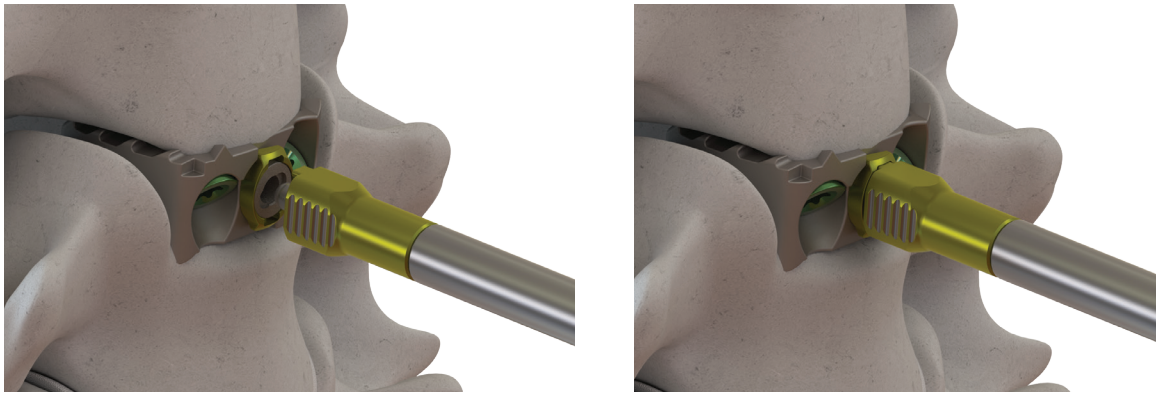


Fig. 21 ▲

Rotate the cam clockwise until it rests against the positive stop, approximately 90 degrees. (Fig. 22)

When properly deployed, the edges of the cam should cover the outer edges of the screw heads. Confirm that the cam is correctly positioned. If the cam lock cannot be fully deployed ensure that the screws are fully seated and not blocking the cam. Retighten or reposition the screws as needed to allow full deployment of the cam lock.

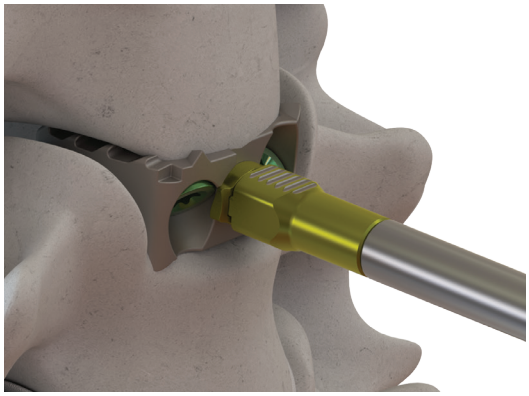


Fig. 22 ▲

Tactile feedback from the cam's locking mechanism will be felt when the cam is advanced towards the positive stop. (Fig. 23)

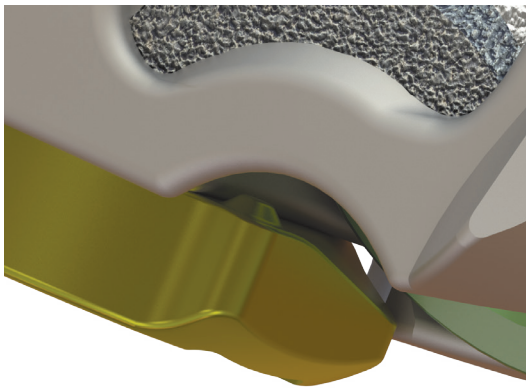


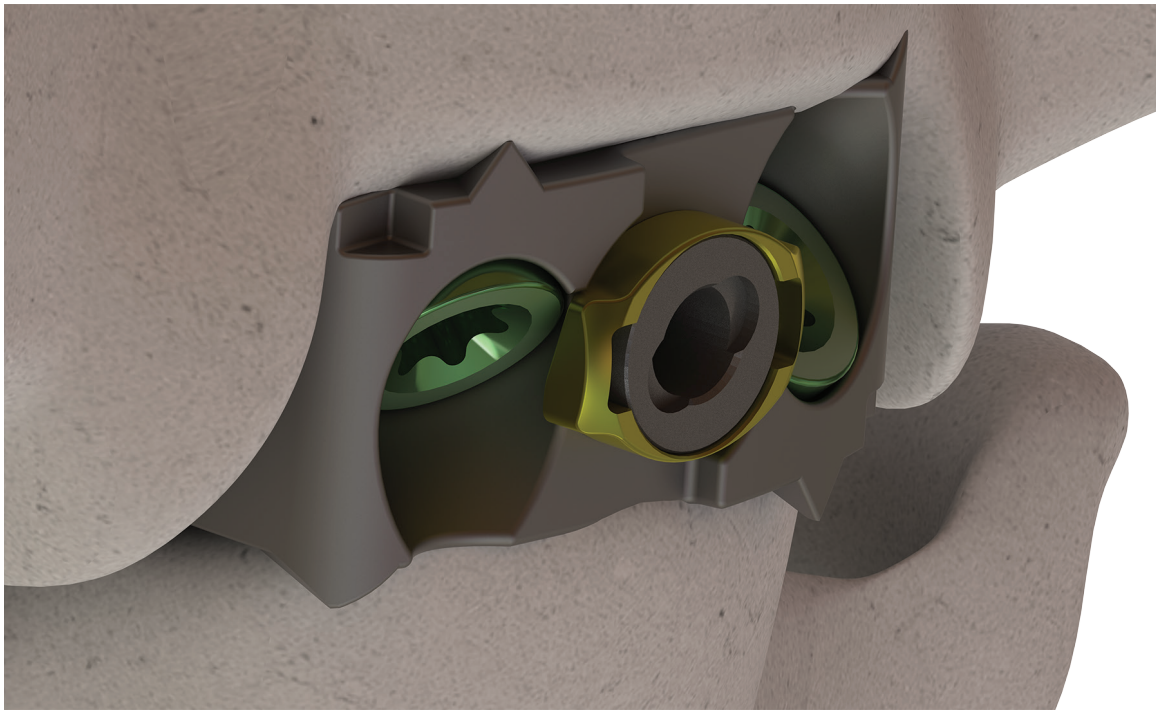
Fig. 23 ▲

STEP 10:

Inspect Cam in Fully Locked Position

FINAL CONSTRUCT

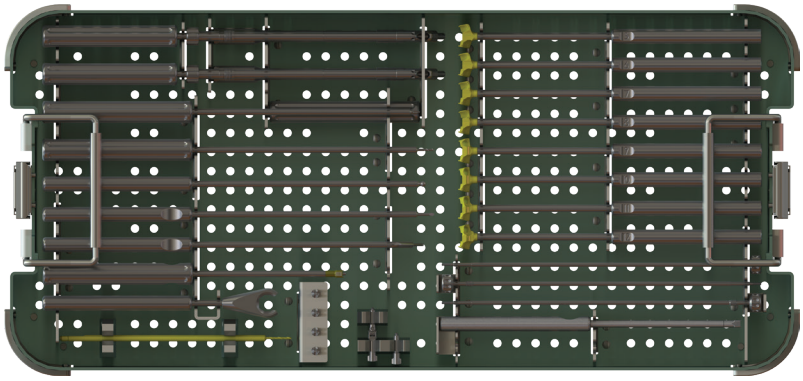
When used with the fixed or variable screws, the final construct is illustrated below. When used with one or more helical screws, the final construct will also include supplemental fixation.



IMPLANT REMOVAL

Disengage the cam lock and remove the screws by reversing the implantation procedure described above. Reattach the appropriate sized Awl Guide Inserter or the Low Profile Inserter and remove the spacer.

SUREMAX®-SA INSTRUMENTATION PLATFORM



SureMAX®-SA Instrument Sterilization Tray
1022-02

Angled Shaft
Tube Assembly
1022-1301

Angled Shaft Inner Shaft
1022-1401

Low Profile
Inserter
1022-10157

Angled Shaft Drill Tip
1022-1501

Inserter
Inner Shaft
1022-301

Angled Shaft Driver Tip
1022-1601

Awl Guide
Inserters
1022-502
thru 1022-1202

Angled Helical Screw Tip
1022-2801

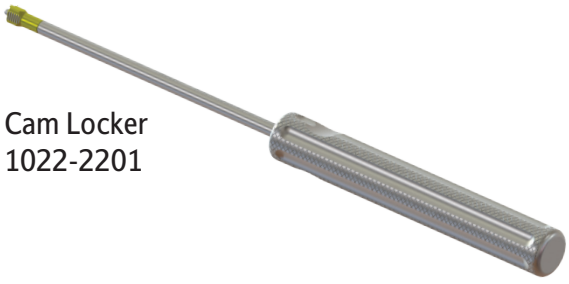
Straight Awl
1022-1701

Angled Awl
1022-1801

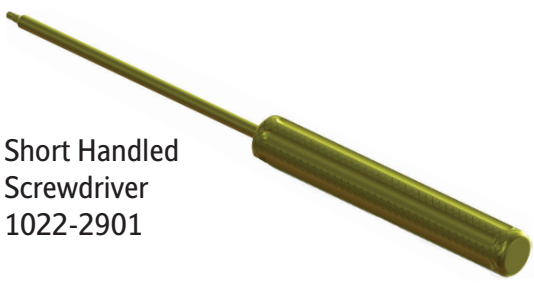
Hand Drill
1022-1901

Screwdriver
1022-2101

Cam Locker
1022-2201



Short Handled
Screwdriver
1022-2901



Helical Screw
Straight Inserter
1022-2301

Helical Screw
U–Joint Inserter
1022-2401

Helical Screw Tamp
1022-2501

Counter Torque
1022-2601

Quick-Connect Drills

1022-2701 (Size 14)

1022-3001 (Size 16)

1022-3101 (Size 18)

1022-3201 (Size 20)

SUREMAX®-SA SYSTEM CONTENTS

SureMAX®-SA Spacers

Depth x Width (mm)	Height (mm)	Part Numbers		
		Lordotic 7˚	Mid-Lordotic 10˚	Hyperlordotic 14˚
Small 12 x 14	5	1022-07121405		
	6	1022-07121406	1022-10121406	1022-14121406
	7	1022-07121407	1022-10121407	1022-14121407
	8	1022-07121408	1022-10121408	1022-14121408
	9	1022-07121409	1022-10121409	1022-14121409
	10	1022-07121410	1022-10121410	1022-14121410
	11	1022-07121411	1022-10121411	1022-14121411
	12	1022-07121412	1022-10121412	1022-14121412
Medium 14 x 16	5	1022-07141605		
	6	1022-07141606	1022-10141606	1022-14141606
	7	1022-07141607	1022-10141607	1022-14141607
	8	1022-07141608	1022-10141608	1022-14141608
	9	1022-07141609	1022-10141609	1022-14141609
	10	1022-07141610	1022-10141610	1022-14141610
	11	1022-07141611	1022-10141611	1022-14141611
	12	1022-07141612	1022-10141612	1022-14141612
Large 15 x 18	5	1022-07151805		
	6	1022-07151806	1022-10151806	1022-14151806
	7	1022-07151807	1022-10151807	1022-14151807
	8	1022-07151808	1022-10151808	1022-14151808
	9	1022-07151809	1022-10151809	1022-14151809
	10	1022-07151810	1022-10151810	1022-14151810
	11	1022-07151811	1022-10151811	1022-14151811
	12	1022-07151812	1022-10151812	1022-14151812
Extra Large 15 x 20	5	1022-07152005		
	6	1022-07152006	1022-10152006	1022-14152006
	7	1022-07152007	1022-10152007	1022-14152007
	8	1022-07152008	1022-10152008	1022-14152008
	9	1022-07152009	1022-10152009	1022-14152009
	10	1022-07152010	1022-10152010	1022-14152010
	11	1022-07152011	1022-10152011	1022-14152011
	12	1022-07152012	1022-10152012	1022-14152012

SureMAX®-SA Screws

Length (mm)	Part Numbers				
	Variable Angle Bone Screw	Fixed Angle Bone Screw	Variable Angle Rescue Screw	Fixed Angle Rescue Screw	Helical Screw
14	1322-VS14	1322-FS14	1322-RVS14	1322-RFS14	1322-HB14
16	1322-VS16	1322-FS16	1322-RVS16	1322-RFS16	1322-HB16
18	1322-VS18	1322-FS18	1322-RVS18	1322-RFS18	1322-HB18
20	1322-VS20	1322-FS20			1322-HB20

SureMAX®-SA Instruments

Part Number	Description
1022-01	SureMAX-SA Sterilization Tray — Lid
1022-02	SureMAX-SA Sterilization Tray — Base
1022-10157	Low Profile Inserter
1022-301	Inserter Inner Shaft
1022-502	Awl Guide Inserter 5
1022-602	Awl Guide Inserter 6
1022-702	Awl Guide Inserter 7
1022-802	Awl Guide Inserter 8
1022-902	Awl Guide Inserter 9
1022-1002	Awl Guide Inserter 10
1022-1102	Awl Guide Inserter 11
1022-1202	Awl Guide Inserter 12
1022-1301	Angled Shaft
1022-1401	Angled Inner Shaft
1022-1501	Angled Shaft Drill Tip
1022-1601	Angled Shaft Driver Tip
1022-1701	Awl – Straight
1022-1801	Awl – Angled
1022-1901	Hand Drill
1022-2101	Screwdriver
1022-2201	Cam Locker
1022-2301	Helical Screw Straight Inserter
1022-2401	Helical Screw U-Joint Inserter
1022-2501	Tamp
1022-2601	Counter Torque
1022-2701	Quick-Connect Drill
1022-3001	Drill
1022-3101	Drill
1022-3201	Drill
1022-2901	Short Handled Driver
1022-2801	Helical Screw Angled Tip

SureMAX® Instruments : Rasps

Depth x Width (mm)	Height (mm)	Part Numbers
		Lordotic 7°
Small 12 x 14	5	9101-07121405
	6	9101-07121406
	7	9101-07121407
	8	9101-07121408
	9	9101-07121409
	10	9101-07121410
	11	9101-07121411
	12	9101-07121412
Medium 14 x 16	5	9101-07141605
	6	9101-07141606
	7	9101-07141607
	8	9101-07141608
	9	9101-07141609
	10	9101-07141610
	11	9101-07141611
	12	9101-07141612
Large 15 x 18	5	9101-07151805
	6	9101-07151806
	7	9101-07151807
	8	9101-07151808
	9	9101-07151809
	10	9101-07151810
	11	9101-07151811
	12	9101-07151812

SureMAX® Instruments : Trials

Depth x Width (mm)	Height (mm)	Part Numbers	
		Lordotic 7˚	Hyperlordotic 14˚
Small 12 x 14	5	9102-07121405	9102-14121405
	6	9102-07121406	9102-14121406
	7	9102-07121407	9102-14121407
	8	9102-07121408	9102-14121408
	9	9102-07121409	9102-14121409
	10	9102-07121410	9102-14121410
	11	9102-07121411	9102-14121411
	12	9102-07121412	9102-14121412
Medium 14 x 16	5	9102-07141605	9102-14141605
	6	9102-07141606	9102-14141606
	7	9102-07141607	9102-14141607
	8	9102-07141608	9102-14141608
	9	9102-07141609	9102-14141609
	10	9102-07141610	9102-14141610
	11	9102-07141611	9102-14141611
	12	9102-07141612	9102-14141612
Large 15 x 18	5	9102-07151805	9102-14151805
	6	9102-07151806	9102-14151806
	7	9102-07151807	9102-14151807
	8	9102-07151808	9102-14151808
	9	9102-07151809	9102-14151809
	10	9102-07151810	9102-14151810
	11	9102-07151811	9102-14151811
	12	9102-07151812	9102-14151812

SureMAX® Instruments : Distraction Wedges

Size	Height (mm)	Part Numbers
Small	2.5	9100-07121402
	3.5	9100-07121403
	4.5	9100-07121404
	5.5	9100-07121405
	6.5	9100-07121406
	7.5	9100-07121407
	8.5	9100-07121408
	9.5	9100-07121409
	10.5	9100-07121410
	11.5	9100-07121411
	12.5	9100-07121412
Medium	2.5	9100-07141602
	3.5	9100-07141603
	4.5	9100-07141604
	5.5	9100-07141605
	6.5	9100-07141606
	7.5	9100-07141607
	8.5	9100-07141608
	9.5	9100-07141609
	10.5	9100-07141610
	11.5	9100-07141611
	12.5	9100-07141612
Large	2.5	9100-07151802
	3.5	9100-07151803
	4.5	9100-07151804
	5.5	9100-07151805
	6.5	9100-07151806
	7.5	9100-07151807
	8.5	9100-07151808
	9.5	9100-07151809
	10.5	9100-07151810
	11.5	9100-07151815
	12.5	9100-07151812

SureMAX® Instruments

Part Numbers	Descriptions
9100-0001	Cervical Interbody Sterilization Tray
9100-0004	Cervical Tamp
9100-0005	Mallet: one poly, one metal surface, 11.5 ounces
9100-0010	Cervical Inserter without Guard
9100-0011	Cervical Inserter with Guard
9100-0020	Cervical Slap Hammer
9100-0025	Slap Hammer Handle — Ergonomic
9100-0026	Slap Hammer Handle — Egg Shape

WARNINGS AND PRECAUTIONS

Warnings

- Surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and or alcohol abuse may lead to unsuccessful results.
- Implants are single use only and should not be reused. Once a device has been implanted, it must never be reused. 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 and transmission of infectious agents.
- Appropriate endplate preparation and device selection is needed to obtain proper fit.
- Delayed healing can lead to fracture of the implants due to increased stress and material fatigue. Patients must be fully informed of all the risks associated with the implant and the importance of following postoperative instructions regarding weight bearing and activity levels to facilitate proper bone healing.
- The implant must be handled carefully, following the manufacturer's instructions, to prevent damage to the implant.
- Implants must not be modified or otherwise processed in any way.
- Care must be taken to avoid using dissimilar metals, in contact with one another, as corrosion may occur. Additional fixation instrumentation that is used to stabilize the affected level must be made of compatible materials, such as Titanium or Titanium alloy. Corrosion may accelerate metal fatigue and lead to failure of the implant.
- This surgical procedure requires the use of the screw fixation provided to stabilize the fusion site.

Precautions

- The implantation of an intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The surgeon must have a thorough knowledge of the mechanical and material limitations of surgical implants made of Titanium Alloy and be thoroughly familiar with the surgical technique for implanting the SureMAX®-SA Cervical Standalone System for the given Indications for Use.
- The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning the surgery. Additionally, the packaging and implant should be inspected for damage prior to implantation.
- In the event that removal of the implant is considered (e.g. due to loosening, fracture, migration of the implant; infection; increased pain, etc.), the risks versus benefits must be carefully weighed. Such events can occur even after healing, especially in more active patients. Appropriate postoperative care must be given following implant removal to avoid further complication.
- Implants must be fully seated within the inserter prior to use. Care must be taken not to over-tighten the implant-inserter assembly. Additionally, care must be taken not to manipulate the inserter implant interface in a way not recommended by the surgical technique.
- The surgeon must ensure that the implant is properly seated prior to closing of the soft tissue.
- Extreme caution must be used around the spinal cord, nerve roots and blood vessels.

MRI Safety Information

The SureMAX®-SA Standalone 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 these implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

ADDED NOTES

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SOLUTIONS BY THE PEOPLE OF ADDITIVE IMPLANTS

We are devoted to helping your patients obtain excellent surgical outcomes. We are dedicated to supporting you with novel tools, instruments and implants. We are driven by the opportunity to share our developments with the world. We are committed partners who will do everything in our power to assist you in your quest to provide the absolute best in spinal care. You can count on us to always to act as ethical partners with integrity who are worthy of your trust.

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L0304 Revision 2

U.S. Patent No. 11,123,201