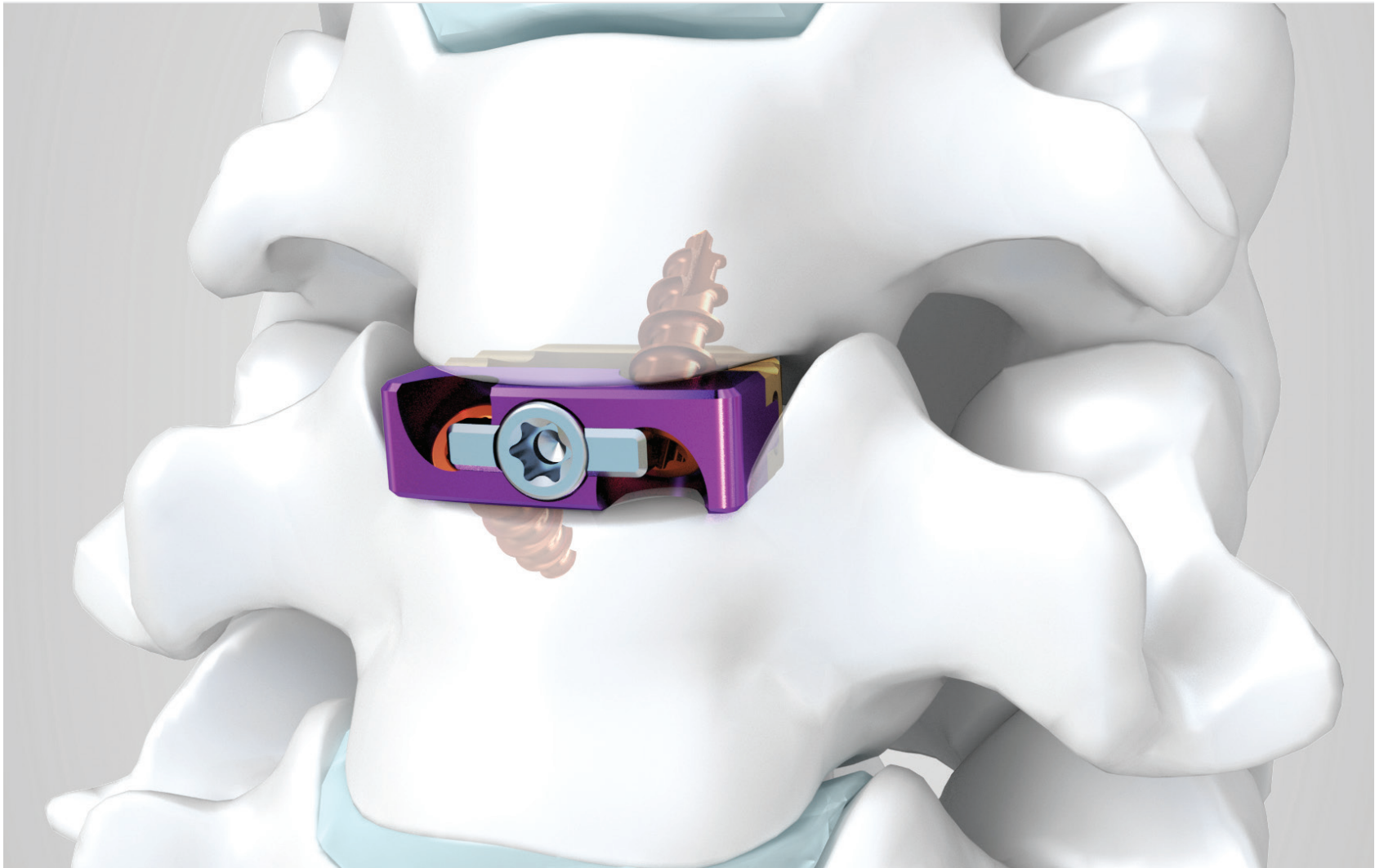


Velofix™ SA Cervical Cage



The Velofix™ SA Cervical Cage is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc



Product Features

Tantalum Markers

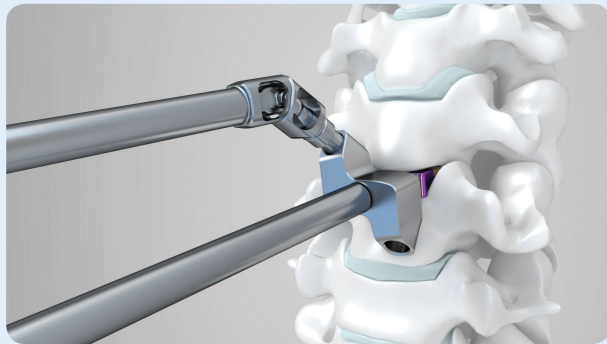
For improved fluoroscopic placement and post-operative examination.

Locking Plate

Titanium alloy locking plate prevents screw back-out.

Angled Screw Driver

Angled driver makes it possible to minimize the incisions during the procedure



PEEK Spacer with 7° lordotic angle

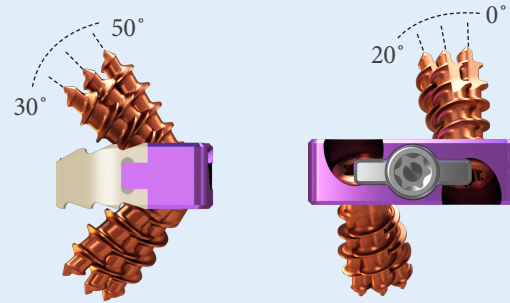
Provides stability and restores spine's natural curvature.

Titanium Alloy Plate

Allows for rigid screw fixation with no added anterior profile.

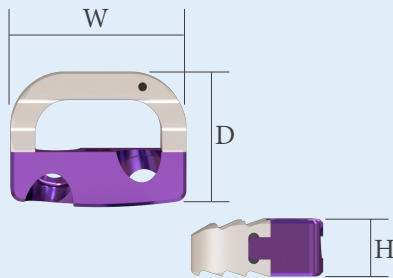
Screw Angulation

Variable angle screws allow for up to 20° angulation in all directions.



Cage Options

PEEK Spacer with Titanium alloy plate



No.	Part No.	W	D	H
1	TSA161205	16	12	5
2	TSA161206	16	12	6
3	TSA161207	16	12	7
4	TSA161208	16	12	8
5	TSA161209	16	12	9
6	TSA161210	16	12	10
7	TSA161405	16	14	5
8	TSA161406	16	14	6
9	TSA161407	16	14	7
10	TSA161408	16	14	8
11	TSA161409	16	14	9
12	TSA161410	16	14	10

Screw Options

Self-Tapping		Self-Drilling		
Part NO.	Length	Part NO.	Length	
D 3.5	TS3510FT	D3.5X10mm	TS3510FD	D3.5X10mm
	TS3511FT	D3.5X11mm	TS3511FD	D3.5X11mm
	TS3512FT	D3.5X12mm	TS3512FD	D3.5X12mm
	TS3513FT	D3.5X13mm	TS3513FD	D3.5X13mm
	TS3514FT	D3.5X14mm	TS3514FD	D3.5X14mm
	TS3515FT	D3.5X15mm	TS3515FD	D3.5X15mm
	TS3516FT	D3.5X16mm	TS3516FD	D3.5X16mm
	TS3517FT	D3.5X17mm	TS3517FD	D3.5X17mm
TS3518FT	D3.5X18mm	TS3518FD	D3.5X18mm	
Part NO.	Length	Part NO.	Length	
D 4.0	TS4010FT	D4.0X10mm	TS4010FD	D4.0X10mm
	TS4011FT	D4.0X11mm	TS4011FD	D4.0X11mm
	TS4012FT	D4.0X12mm	TS4012FD	D4.0X12mm
	TS4013FT	D4.0X13mm	TS4013FD	D4.0X13mm
	TS4014FT	D4.0X14mm	TS4014FD	D4.0X14mm
	TS4015FT	D4.0X15mm	TS4015FD	D4.0X15mm
	TS4016FT	D4.0X16mm	TS4016FD	D4.0X16mm
	TS4017FT	D4.0X17mm	TS4017FD	D4.0X17mm
	TS4018FT	D4.0X18mm	TS4018FD	D4.0X18mm

PATIENT POSITIONING AND SURGICAL EXPOSURE

Place the patient in a supine position and use fluoroscopy for an interoperative check if desired.

Use an anterior approach to expose the anterior aspect of the vertebral bodies cephalad and caudal to the involved segment.

DISTRACTION OF THE DISC SPACE

Instrument	
SC7261	DISTRACTOR FIXATION PIN
SC7262	DISTRACTOR FIXATION NUT
SC7170	TEMPORARY FIXATION PIN DRIVER
SC7230	DISTRACTOR

Screw the DISTRACTOR FIXATION PIN into the vertebrae superior and inferior to the affected disc using the TEMPORARY FIXATION PIN DRIVER (Fig. 1).

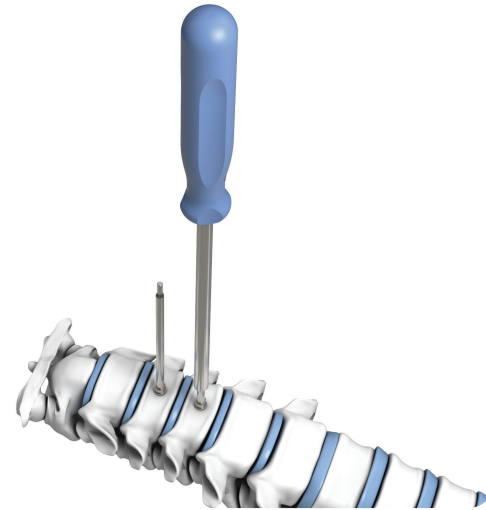
Attach the DISTRACTOR to the DISTRACTOR FIXATION PIN, followed by the DISTRACTOR FIXATION PIN NUTs and compress or distract the DISTRACTOR to desired position (Fig. 2).

Distract until the desired disc height is attained, taking care not to over-distract.

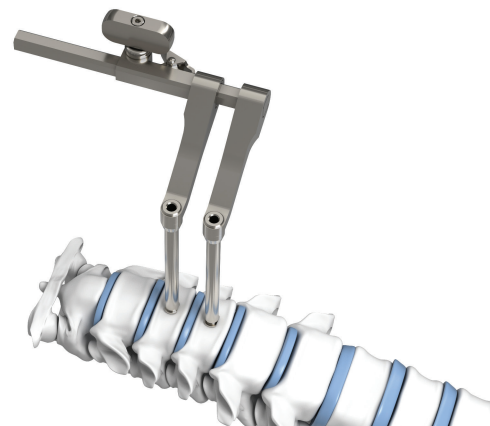
DISCECTOMY

A conventional scalpel discectomy is performed by incising the annulus. Bilaterally, soft fragments from the intradiscal space or extruded fragments are removed with the disc rongeur in a conventional fashion.

A complete discectomy may not be possible at this stage until the disc space distraction is accomplished.



(Fig. 1)



(Fig. 2)

ENDPLATE PREPARATION

Instrument	
PE1040	CERVICAL CAGE CURETTE

Under distraction, complete a neural decompression by trimming large posterior osteophytes (if present).

Remove the cartilaginous endplates to create a flat surface of bleeding bone (Fig. 3).

IMPLANT SELECTION

Instrument	
TS0140 ~ TS0160	DOUBLE SIDED TRIAL

※ Size in H5~H10

Insert the TRIALS until the desired disc space height is established (Fig. 4). Use AP and lateral fluoroscopy to confirm proper placement and size.

Make sure the positive stop is cranial when inserting the TRIAL. This ensures that the TRIAL is aligned with the anterior edge of the vertebral body.

Note :

- It is generally advisable to use the smallest TRIAL cage height for which proper stability is obtained. Distraction can be reduced temporarily to test stability.

FILLING IN THE CAGE

Instrument	
TS0010 ~ TS0030	GUIDE BLOCK
TS0040	CAGE INSERTER
TS0090	BONE PACKING BLOCK
TS0100	BONE PACKING BAR

Use the GUIDE BLOCK that is the same height as the cage.

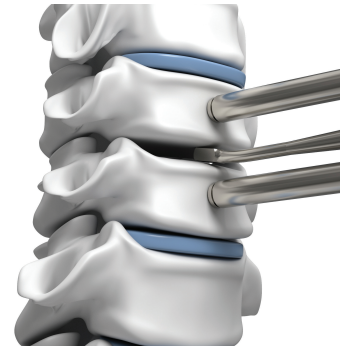
Connect the cage to the appropriate CAGE INSERTER and GUIDE BLOCK (Fig. 5).

※ See Page 6 for full instructions on attaching the cage to INSERTER and GUIDE BLOCK.

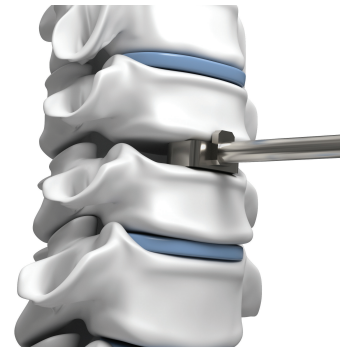
Place on the BONE PACKING BLOCK and fill with graft using the BONE PACKING BAR (Fig. 6).

Note :

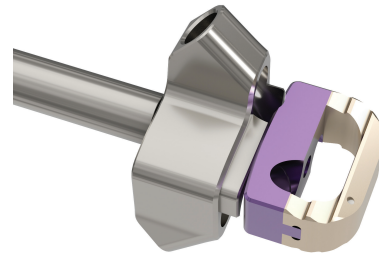
- Autologous bone or biologics are options for filling the cage.



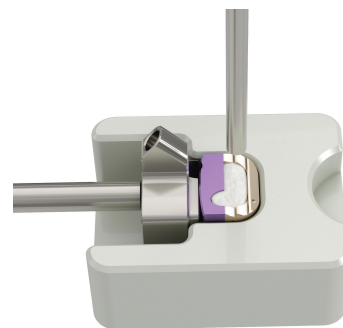
(Fig. 3)



(Fig. 4)



(Fig. 5)



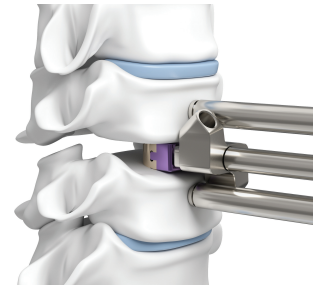
(Fig. 6)

CAGE INSERTION

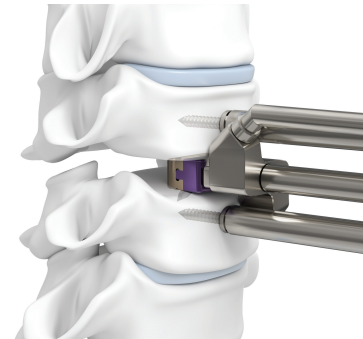
Insert the cage into the disc space, ensuring the implant is in the cranial position (Fig. 7).

Maintain distraction while inserting the cage. Use AP and lateral fluoroscopy to confirm proper placement.

The GUIDE BLOCK should be left in place when preparing the screw hole. The GUIDE BLOCK can accommodate AWL, DRILL-BIT and SCREWDRIVERS.



(Fig. 7)



(Fig. 8)

SCREW INSERTION

Instrument	
TS0050 / TS0070	STRAIGHT / ANGLED SCREW DRIVER
TS0060 / TS0080	STRAIGHT / ANGLED AWL
TS0110, TS0120, TS0130	DRILL BIT D2.0 X 12, 14, 16mm
TS0170	LOCKING SCREW DRIVER & HOLDER
TSA1000	Ti LOCKING PLATE ASSEMBLY

The 3.5mm screw should be used as the primary screw. The 4.0mm screw is provided as a rescue option and should not be used as the primary screw.

OPTION 1 - SELF-DRILLING SCREWS

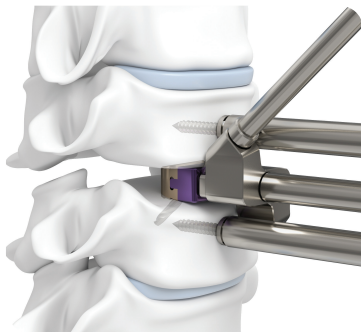
Use the AWL first to prepare the site (Fig. 8), then insert the screw with the SCREW DRIVER (Fig. 10).

OPTION 2 - SELF-TAPPING SCREWS

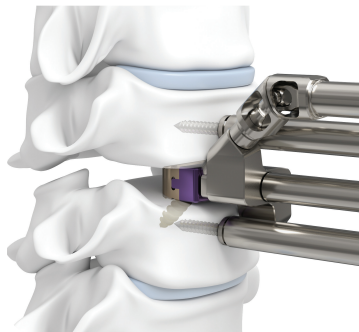
Use the DRILL-BIT to prepare the site (Fig. 9) then insert the screw with the SCREW DRIVER (Fig. 10).

LOCKING PLATE PLACEMENT

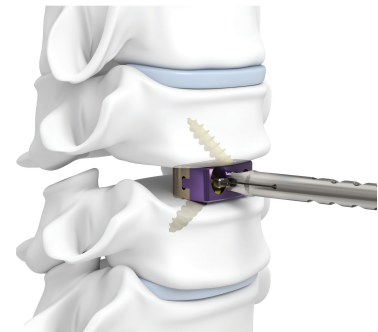
Insert the self-retaining LOCKING SCREW DRIVER & HOLDER into a locking pate. Orient the locking plate with the plate arms in a transverse position.



(Fig. 9)



(Fig. 10)



(Fig. 11)

IMPLANT REMOVAL/REVISION

Should removal / revision of the device be determined necessary by the surgeon, after screws and locking plate are removed, an osteotome can be used at the interface between the bone and both superior and inferior faces of the implant. This effectively cuts the fused column of bone at the level of the boundaries of the implant.

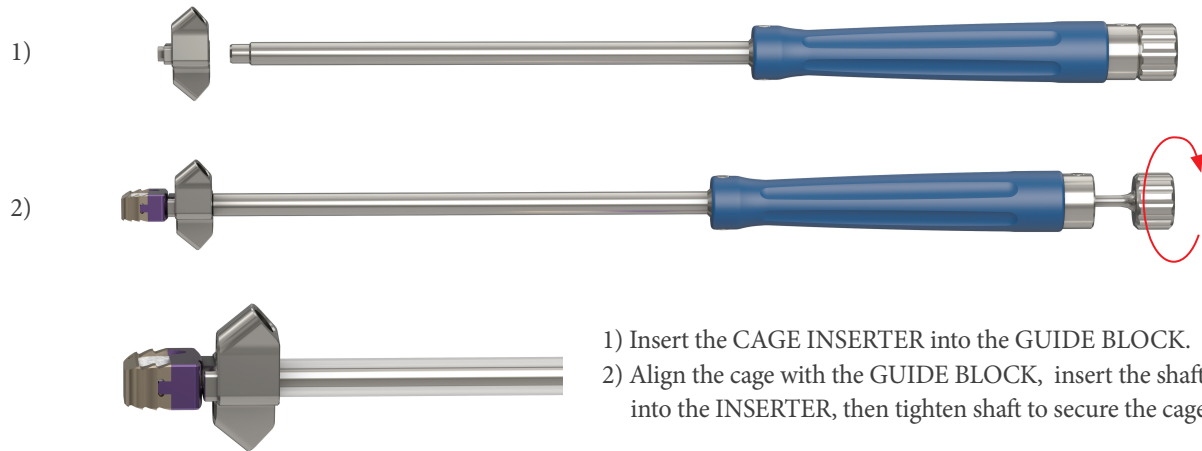
Once the fused column is completely cut, forceps can be used to remove the implant from the space. This may be done under slight distraction.

For a revision, follow the standard surgical technique.

The 3.5mm screw should be used as the primary screw.

The 4.0mm screw is provided as a rescue option and should not be used as the primary screw.

HOW TO HOLD THE CAGE



- 1) Insert the CAGE INSERTER into the GUIDE BLOCK.
- 2) Align the cage with the GUIDE BLOCK, insert the shaft into the INSERTER, then tighten shaft to secure the cage

Instruments

SC7171 _ TEMPORARY FIXATION PIN DRIVER



SC7261 _ DISTRACTOR FIXATION PIN



SC7230 _ DISTRACTOR



OS0030 _ DRIVING HANDLE



SC7262 _ DISTRACTOR FIXATION NUT



TS0010 _ GUIDE BLOCK H5-H6



TS0020 _ GUIDE BLOCK H7-H8



TS0030 _ GUIDE BLOCK H9-H11



TS0040 _ CAGE INSERTER



TS0050 _ STRAIGHT SCREW DRIVER



TS0060 _ STRAIGHT AWL



TS0070 _ ANGLED SCREW DRIVER



TS0080 _ ANGLED AWL



TS0090 _ BONE PACKING BLOCK



TS0100 _ BONE PACKING BAR



TS0110 _ DRILL BIT D2.0X12mm



TS0120 _ DRILL BIT D2.0X14mm



TS0130 _ DRILL BIT D2.0X16mm



TS0140 _ DOUBLE SIDED TRIAL



TS0170 _ LOCKING SCREW DRIVER & HOLDER





Headquarter

20, Sandan-ro, 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea 11781
Tel. +82 (31) 860 6800 / Fax. +82 (31) 852 9025

Seoul Office

U&I Bldg, 1, Sangwon 12-gil, Seongdong-gu, Seoul, Korea 04791
Tel. +82 (02) 2046 6700 / Fax. +82 (02) 420 4955

USA Office

24835 La Palma Ave. Suite G Yorba Linda, CA 92887
Tel. +1 (714) 280 4955

