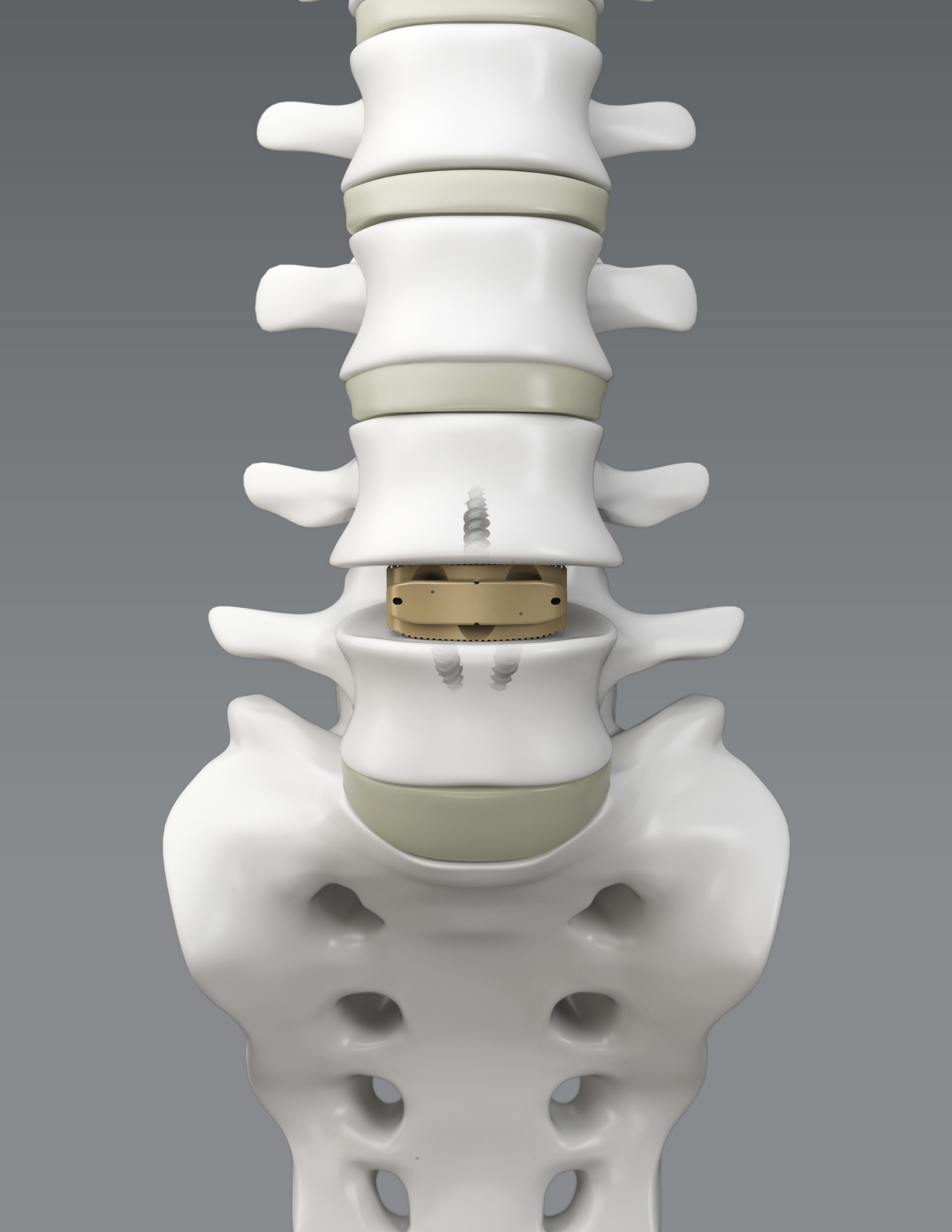
SURGICAL
TECHNIQUE

Sovereign™
Spinal System

Medtronic

MICHELSON TECHNOLOGY AT WORK



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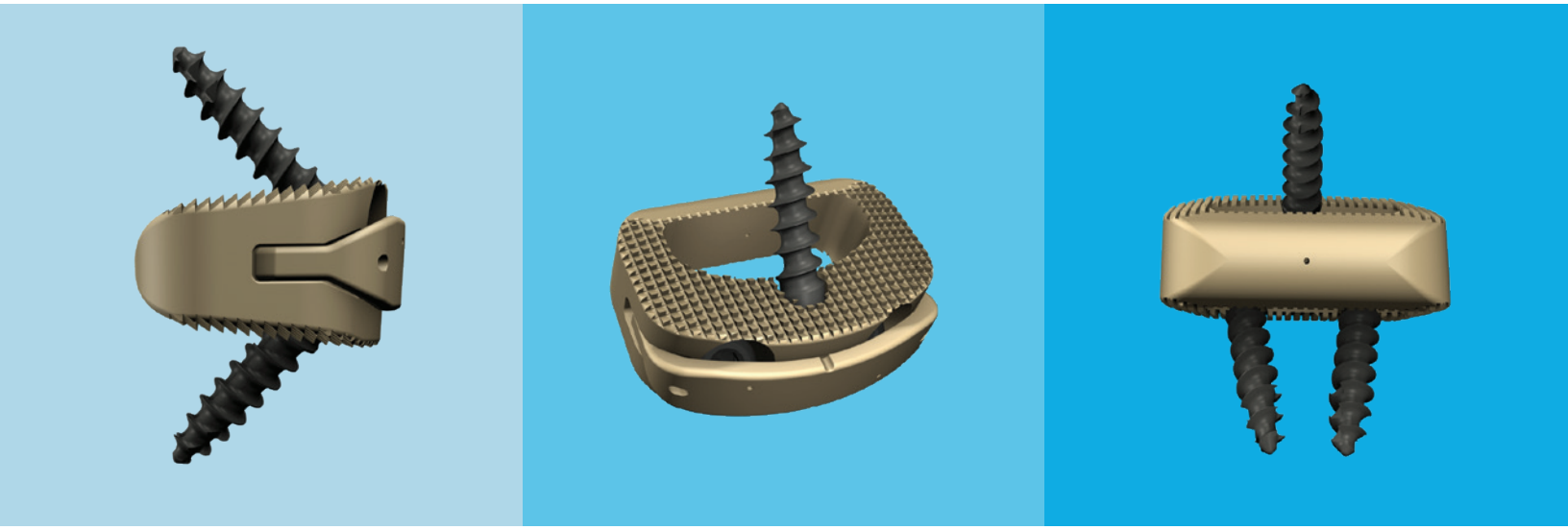
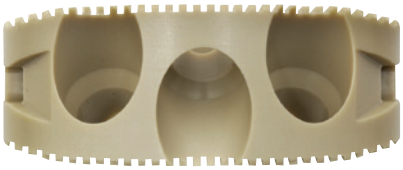
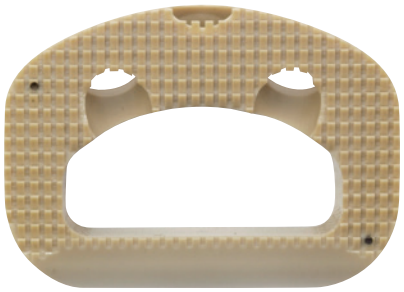


IMPLANT FEATURES

Interbody Spacers

Multiple footprints (small—32mm × 23mm, medium—37mm × 27mm and large—42mm × 30mm)
Multiple lordotic angle options (8°, 12°, 18°, and 24°)





Coverplates

Widths available in small, medium, and large (32mm, 37mm and 42mm)

Screws

20mm, 25mm, 30mm and 35mm standard lengths. Available in Variable Angle and Fixed Angle designs.



Variable Angle Screws

Part Number	(Diameter × Length)
7965520	5.5mm × 20mm
7965525	5.5mm × 25mm
7965530	5.5mm × 30mm
7965535	5.5mm × 35mm
7966020	6.0mm × 20mm
7966025	6.0mm × 25mm
7966030	6.0mm × 30mm
7966035	6.0mm × 35mm

Fixed Angle Screws

	Part Number	(Diameter × Length)
●	7975520	5.5mm × 20mm
●	7975525	5.5mm × 25mm
●	7975530	5.5mm × 30mm
●	7975535	5.5mm × 35mm
●	7976020	6.0mm × 20mm
●	7976025	6.0mm × 25mm
●	7976030	6.0mm × 30mm
●	7976035	6.0mm × 35mm

INSTRUMENT SET

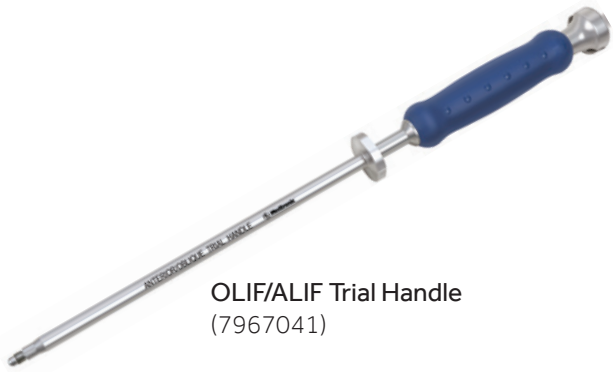
Flexible Screw Driver (7967089)

Flexible Screw Drivers allow insertion of the screws while maintaining a small exposure.

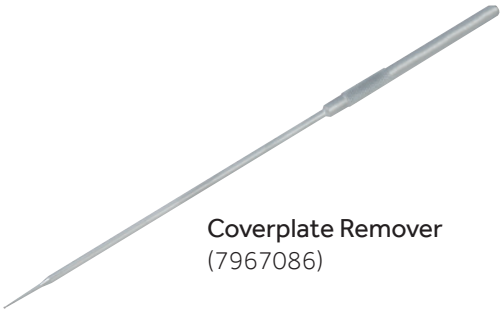
Anterior/Oblique Trial
(Example: 79615212)

Universal Joint Screw Driver (7967088)

Self-retaining.



OLIF/ALIF Trial Handle
(7967041)



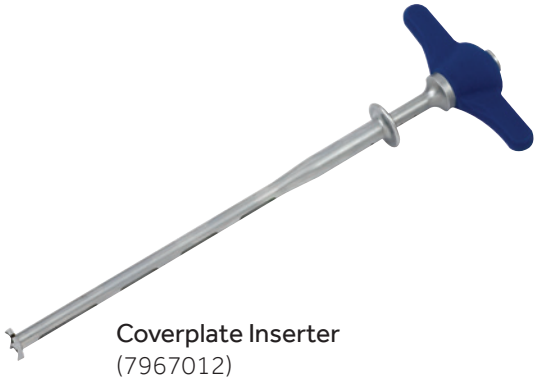
Coverplate Remover
(7967086)

Inserter Shaft, Oblique
(7967095, 7967096, 7967097)

Inserter Shaft, Straight
(7967079, 7967080, 7967081)

Inserter Knob
(7967085)

Inserter Sleeve
(7967028)

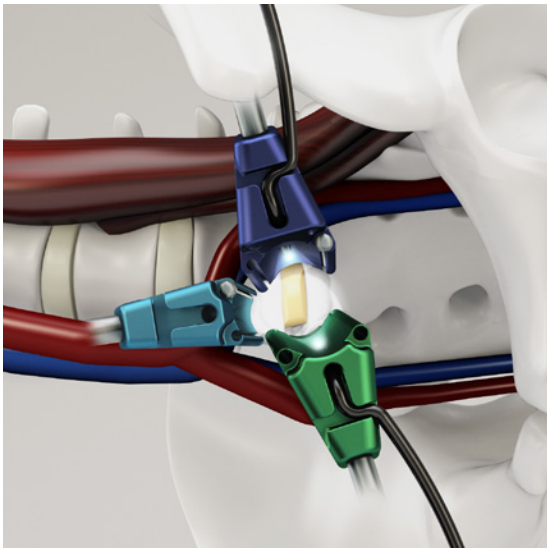


Coverplate Inserter
(7967012)

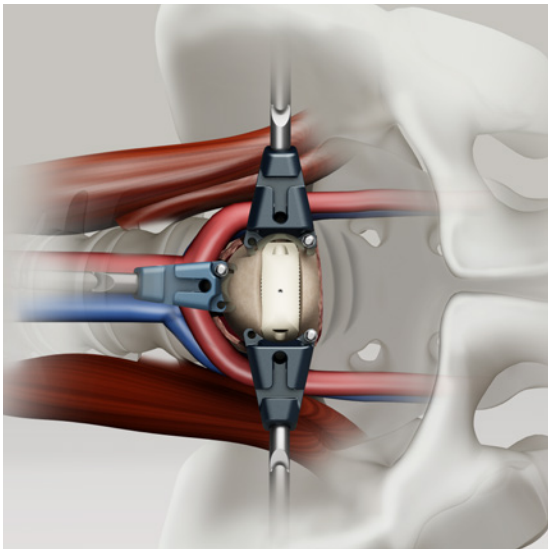
Oblique Coverplate Inserter
(7967098)

ACCESS

The Sovereign Spinal System can be used via an OLIF51™ Procedure or an ALIF Procedure, depending upon the surgeon's preference and anatomical considerations. Refer to the appropriate procedure surgical technique for access instructions.



OLIF51 Procedure



ALIF Procedure

IDENTIFICATION OF MIDLINE

Once the intended level has been exposed and the great vessels have been retracted, the midline should be identified. Thread the Midline Marker onto the Template Inserter and insert into the disc space being treated (**Figure 1**). A bovie can be used to mark the vertebral bodies above and below midline to help maintain a midline reference during the procedure.

Note

The Midline Marker is 26mm long to help determine AP depth intraoperatively.

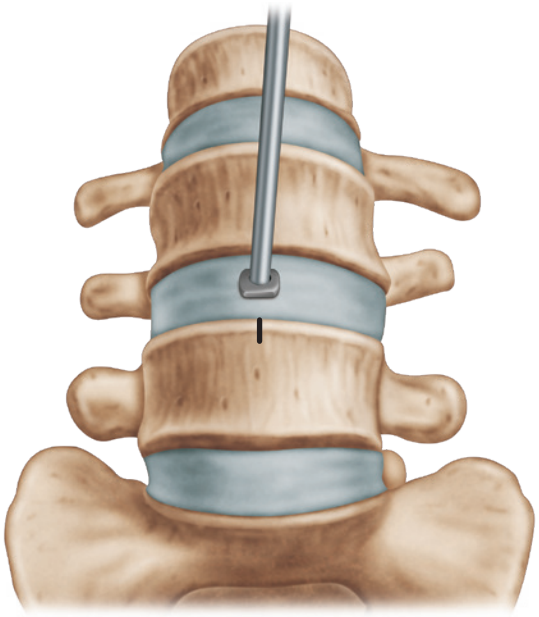


Figure 1

BLOCK DISCECTOMY

Once the midline is established, the lateral width of the discectomy must be determined. Discectomy Templates are provided to help determine this. Thread the Discectomy Template onto the Template Inserter, place it against the disc space (**Figure 2**), and mark the appropriate width of the discectomy site.

Note

Discectomy Templates are 2mm wider per side than their corresponding implants to ensure enough disc material has been removed to allow attachment of the Coverplate.

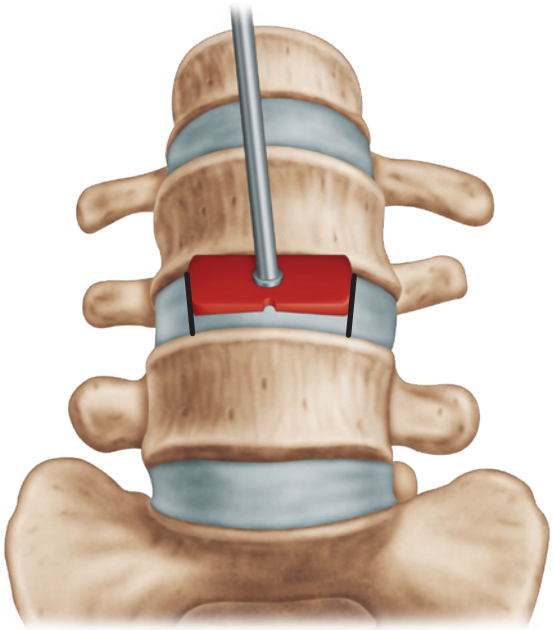


Figure 2

TRIALING

Once the footprint has been determined, Distractor Trials are available to help distract the disc space, determine the correct distraction height, and determine the amount of lordosis needed (**Figures 3 and 4**). Thread the Distractor Trial onto the Trial Handle and impact it within the discectomy. 8-, 12-, 18-, 24- and 30-degree Distractor Trials are available for all footprints.

Note
Distractor Trials are not line to line with the interbody spacer. They are undersized to provide a 1mm interference fit with the end plates to allow for the teeth to gain purchase into the bone.

Note
Do not impact the Trial assembly unless the Trial Handle is fully threaded into the Trial.

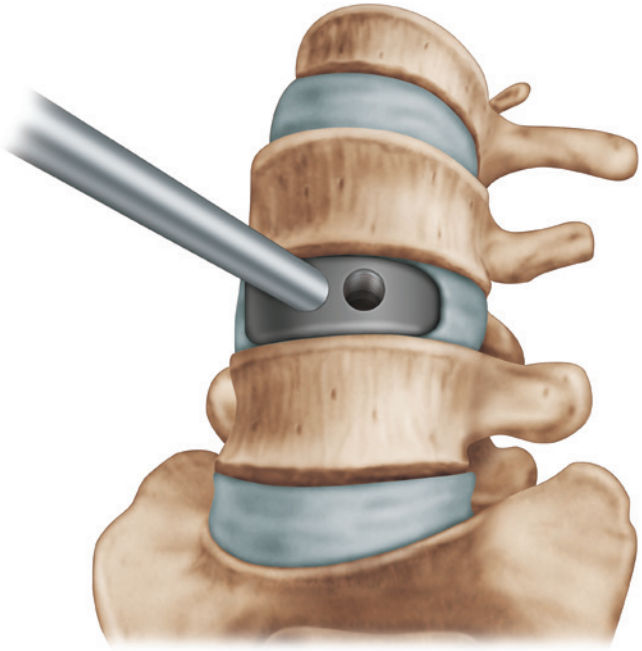


Figure 3

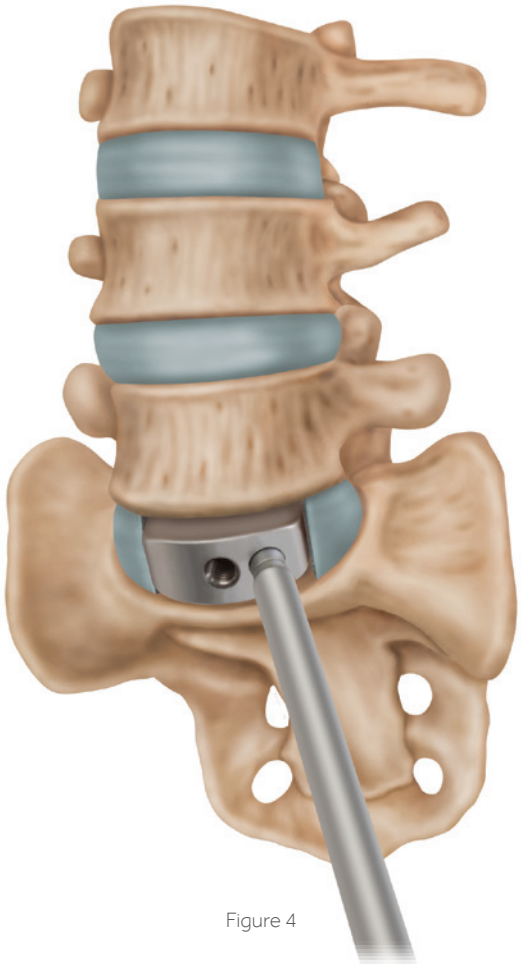


Figure 4

IMPLANT
FILLING

The impant can be filled with either autograft, corticocancellous allograft or a combination of both. Autograft can be collected from the surgical site and morselized using the Midas Rex™ Electric Bone Mill System (Figure 5a) or can be recovered from a secondary site using the Corex™ minimally invasive bone harvester (Figure 5b).

Figure 5a

Figure 5b

INSERTION USING
THE IMPLANT INSERTER

After the appropriate height and lordotic angle have been determined, attach the corresponding Interbody Spacer to the Inserter. Assemble this by inserting the Inserter Shaft into the Inserter Sleeve and advancing the threads a few turns. Attach the Inserter Knob onto the end of the Inserter Shaft. Place the Interbody Spacer between the tips of the Inserter Shaft and rotate the Inserter Sleeve until the Interbody Spacer is secure. Directions to loosen and tighten are noted on the sleeve.

Once the Interbody Spacer is attached, impact the Interbody Spacer into the disc space (**Figures 6 and 7**). The bullet nose of the Interbody Spacer should help distract the disc space.

Once the appropriate Interbody Spacer position is achieved, rotate the Inserter Sleeve counter clockwise to fully loosen. Once the Inserter Sleeve is loosened all the way, remove the Inserter from the Interbody Spacer. For OLIF51 approach, however, to prevent from pulling the Interbody Spacer out, loosen the Inserter Sleeve all the way and then rotate the Inserter Shaft in a lateral direction to initially release the contralateral side of the Inserter from the Interbody Spacer. The Inserter can then be fully removed from the Interbody Spacer.

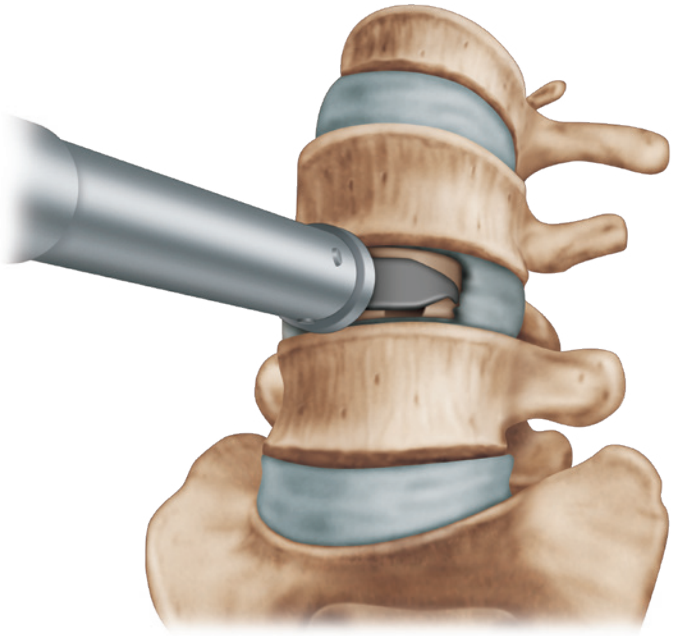


Figure 6

Note

There is an arrow on the side of the Interbody Spacer to help determine screw orientation. The arrow points in the direction of the center screw.

Remember

The Sovereign Spinal System Interbody Spacer has a central opening which is packed tightly with autogenous bone. Surgeon discretion should determine the location and time of the harvesting procedure. Packing the Interbody Spacer prior to attaching it to the Inserter is recommended.

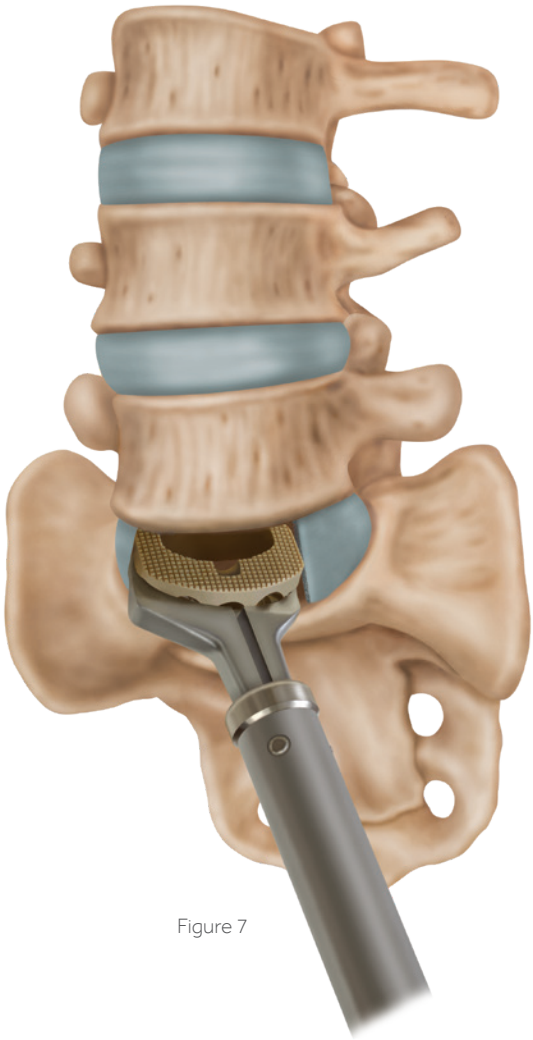


Figure 7

INSERTION OPTION
USING THE CATALYST ANTERIOR INSTRUMENT SET

Sovereign Catalyst Spreaders are found in the Sovereign Spinal System Instrument Set and can be used to insert Sovereign from an anterior approach. For detailed assembly instructions please refer to the Catalyst Anterior Instrument Set Surgical Technique.

Attach the appropriate Spreader to the Catalyst Inserter by sliding the Interbody Spacer between the prongs of the Spreader.

With the Interbody Spacer loaded into the Catalyst Inserter, place the tip of the blades into the disc space until the depth stops contact the vertebral bodies (Figure 8).

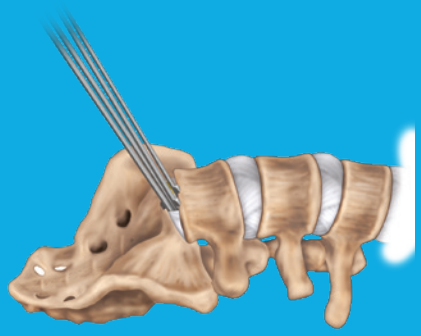
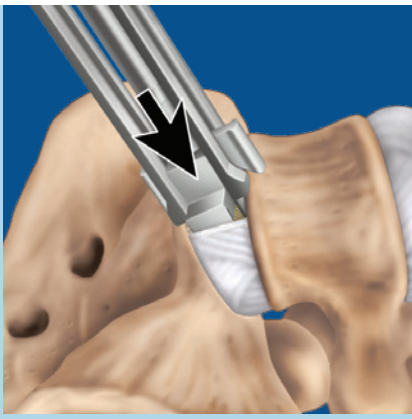


Figure 8

Note
Sovereign Catalyst Spreaders are only to be used from an anterior approach.

Continue to turn the T-Handle until the Spreader contacts the vertebral bodies; the interbody spacer is now in the appropriate position (**Figure 9**).



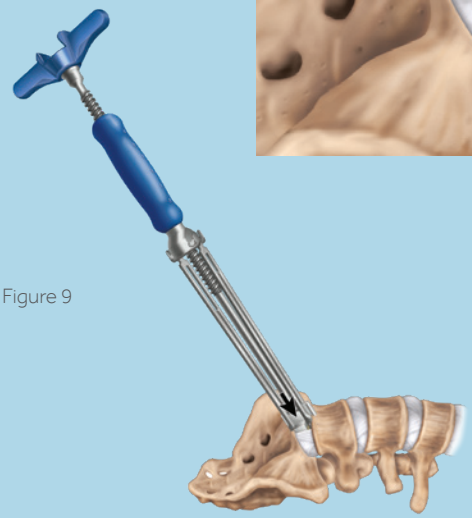


Figure 9

While maintaining downward pressure on the center handle, rotate the T-Handle to advance the interbody spacer down the blades into the disc space (**Figure 10**). As the Interbody Spacer advances, the instrument will provide the distraction required for insertion.

Figure 10

To remove the instrument, turn the T-Handle clockwise until it stops and pull the Spreader from the Interbody Spacer. The Catalyst Inserter can now be removed from the surgical site (**Figure 11**).

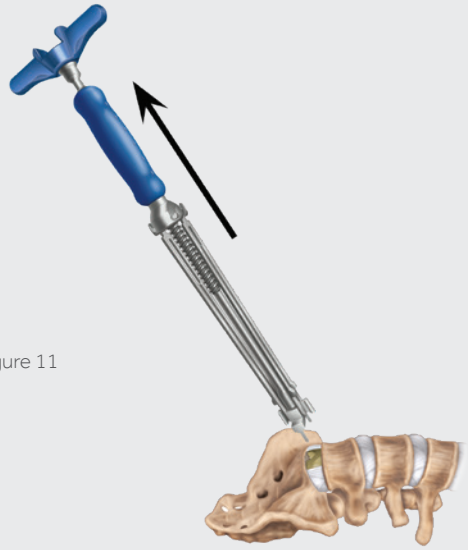


Figure 11

SCREW
INSERTION

Screw holes can be prepared with the Straight Awl Guide and Straight Awl or the Angled Awl Guide and U-Joint Awl. The angle of the screw in relation to the body determines which Awl and Awl Guide to use. The Awl Guide is needed to ensure that the pilot hole is created in the center screw hole of the Interbody Spacer and to help align the screw trajectory with the angle of the screw hole in the Interbody Spacer. The U-Joint Awl is inserted into the hole of the Angled Awl Guide (**Figure 12**). Once the pilot hole is made, there is an option to insert a 5.5mm or 6.0mm diameter Variable Angle or Fixed Angle screw.

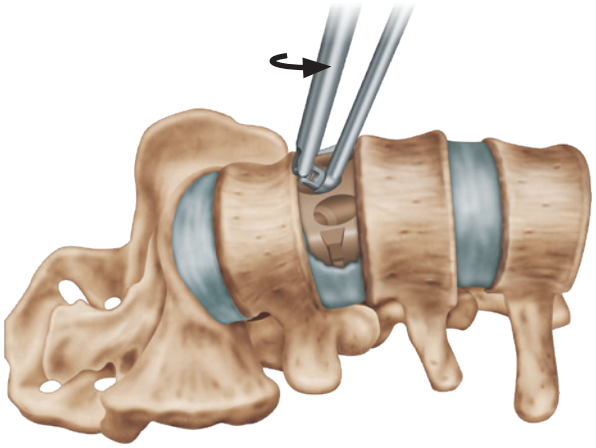


Figure 12

Note
It may be necessary to remove some bone around the Interbody Spacer for accurate screw insertion **(Figure 13).**

Note
When using the Angled Awl, apply downward force and rotate. This will help advance the tip into the bone. Avoid using a mallet if possible.

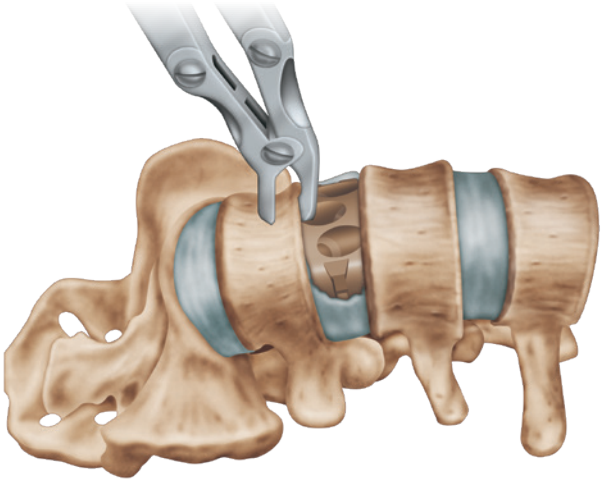


Figure 13

Screw insertion can be accomplished with one of the different screw driver options in the set: U-Joint, Flexible Shaft, or Straight. Repeat the above mentioned steps to insert the remaining screws (**Figure 14**). The screws are fully seated when they are recessed past the front wall of the Interbody Spacer.

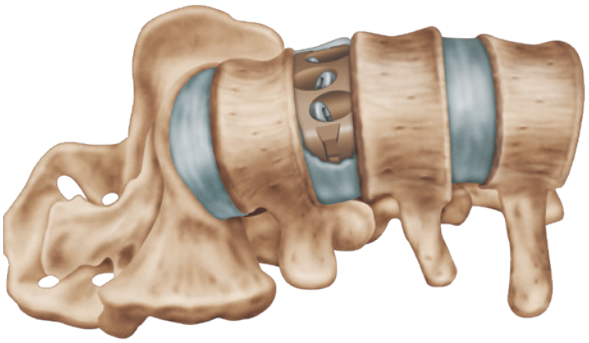


Figure 14

Note
A Variable Angle Screw or Fixed Angle Screw may be used. If using the Fixed Angle Screw, you will notice an increased resistance as the screw engages the PEEK. The resistance increases further when the screw is fully seated in the hole.

Note
Do not over tighten screws.

Remember
The Sovereign Interbody Device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

COVERPLATE ATTACHMENT
(REQUIRED WHEN ANY VARIABLE ANGLE SCREWS ARE USED)

First, load the Coverplate onto the Coverplate Inserter, aligning the notch on the Coverplate with the Inserter, midline. Pull back on the outer sleeve to expand the tip of the instrument so it can accept the Coverplate. Attach the Coverplate by aligning it to the grooves in the side of the Interbody Spacer (**Figure 15**). Push down on the Coverplate until it snaps into place (**Figure 16**). Both sides should snap into place. It may be necessary to rock the Inserter left and right to make sure both sides snap into place. Test the Coverplate using the Inserter or forceps to ensure both sides are locked into place. Inspect the Interbody Spacer visually and obtain final AP and medial/lateral radiographic images to confirm proper placement (**Figures 17 and 18**).

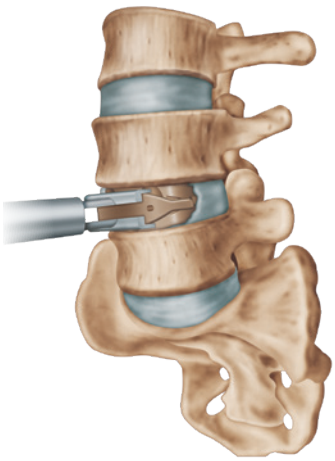


Figure 15

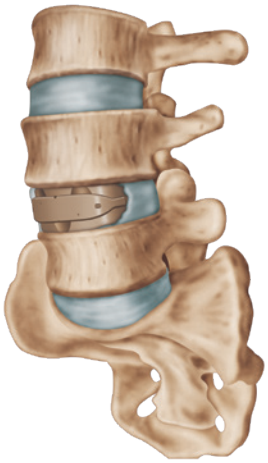


Figure 16

Note

If the Coverplate does not connect properly, mechanically remove soft tissue with a Kerrison or pituitary. Confirm that the head of the screw is recessed into the Interbody Spacer. Reinsert the Coverplate and test it to ensure that it is connected. Do not impact the Coverplate.

Note

The Interbody is able to be used with up to three screws, which allows the surgeon to lag/compress the end plates to the implant. These titanium cancellous screws are provided in both a variable angle and fixed angle option. A Coverplate, which provides a locking mechanism to prevent screw back out, is provided for use with the Variable Angle Screws. The Fixed Angle Screws are self locking and do not require the use of a Coverplate due to an interference fit with the PEEK interbody implant.

Remember

Remove all tissue and fascia at implant Coverplate interface prior to inserting Coverplate.

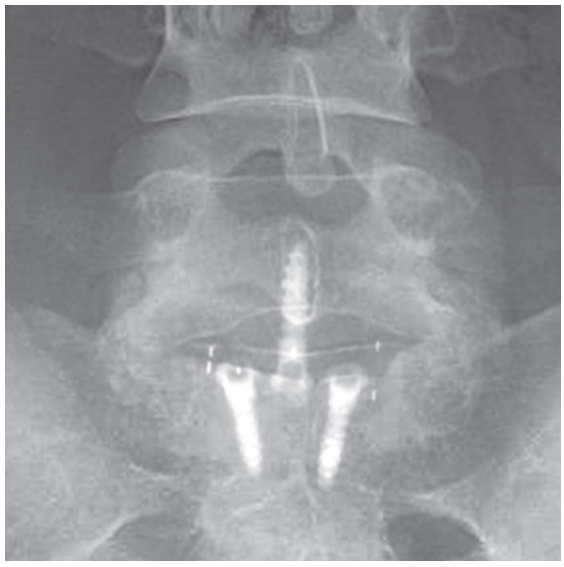


Figure 17
Anterior View

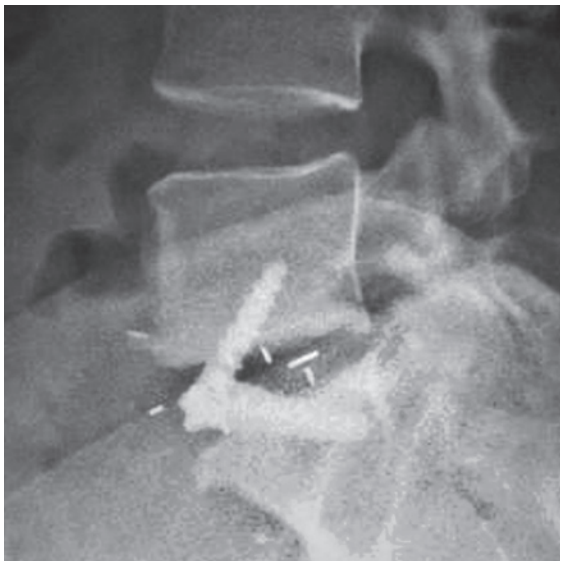
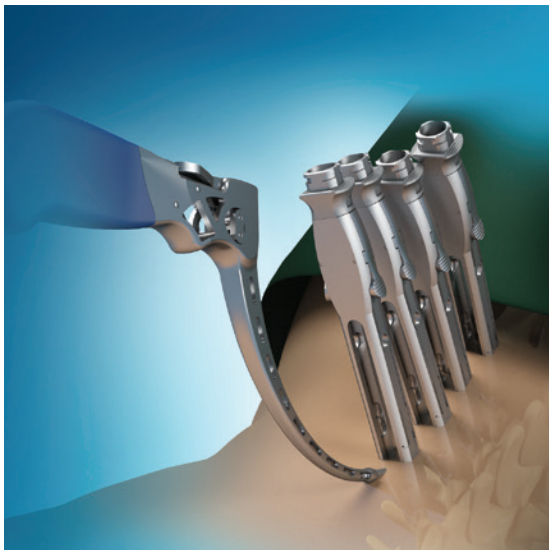


Figure 18
Lateral View

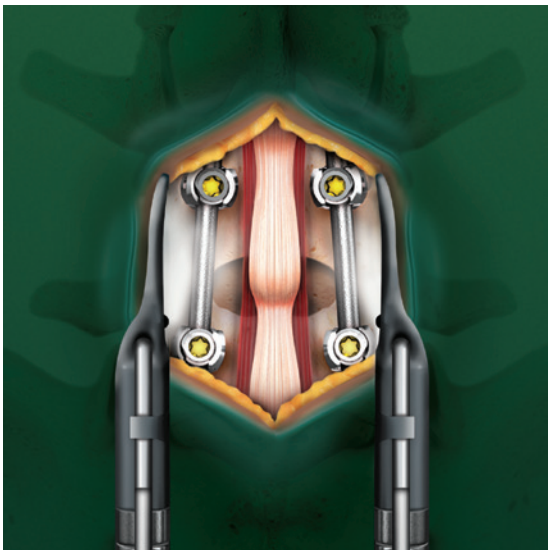
SUPPLEMENTAL FIXATION

Supplemental instrumentation must be placed if physician chooses to use less than three or none of the Sovereign screws. The interbody fusion device can be used with any supplemental fixation systems cleared for use in the lumbar spine. However, all Sovereign interbody devices greater than 18° must include the usage of supplemental fixation. Refer to the appropriate surgical technique for supplemental instrumentation instructions. Some examples of Medtronic supplemental fixation systems include:

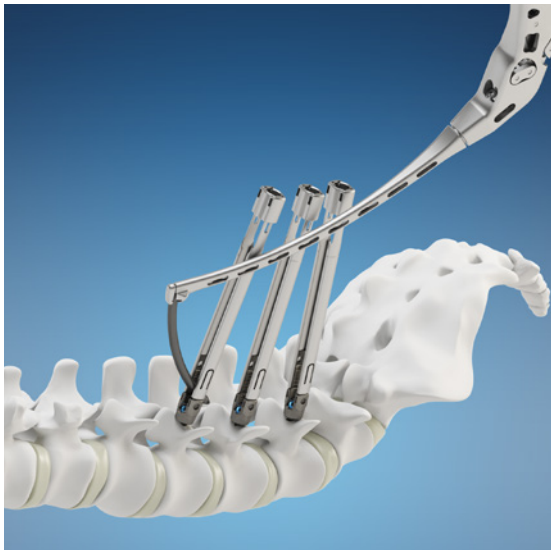
Divergence-L Anterior/Oblique Lumbar Plate and Bone Screws



CD Horizon® Longitude® II Multi-level Percutaneous Fixation System



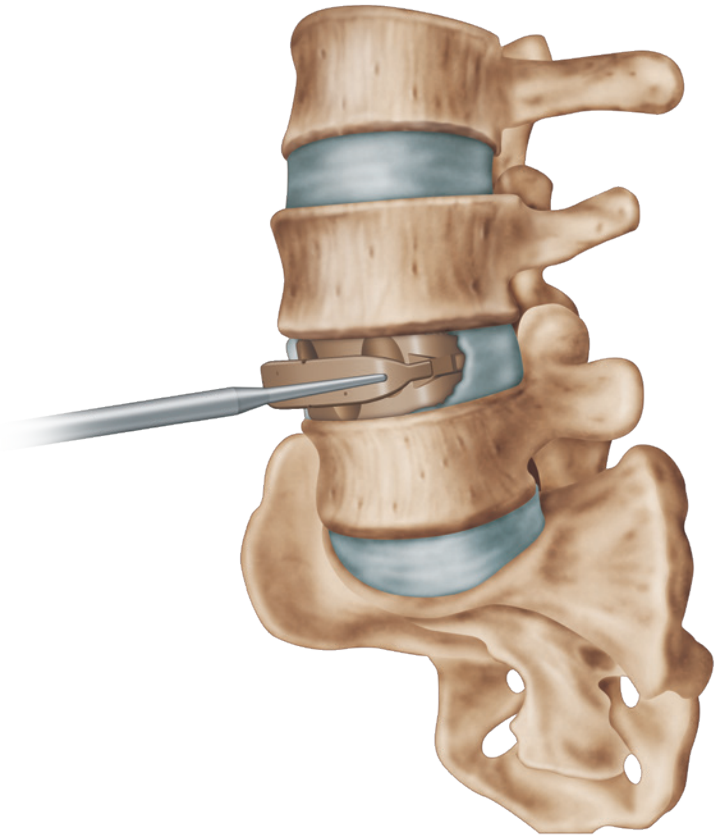
CD Horizon Solera® Screws



CD Horizon Solera Voyager™ Spinal System

EXPLANTATION

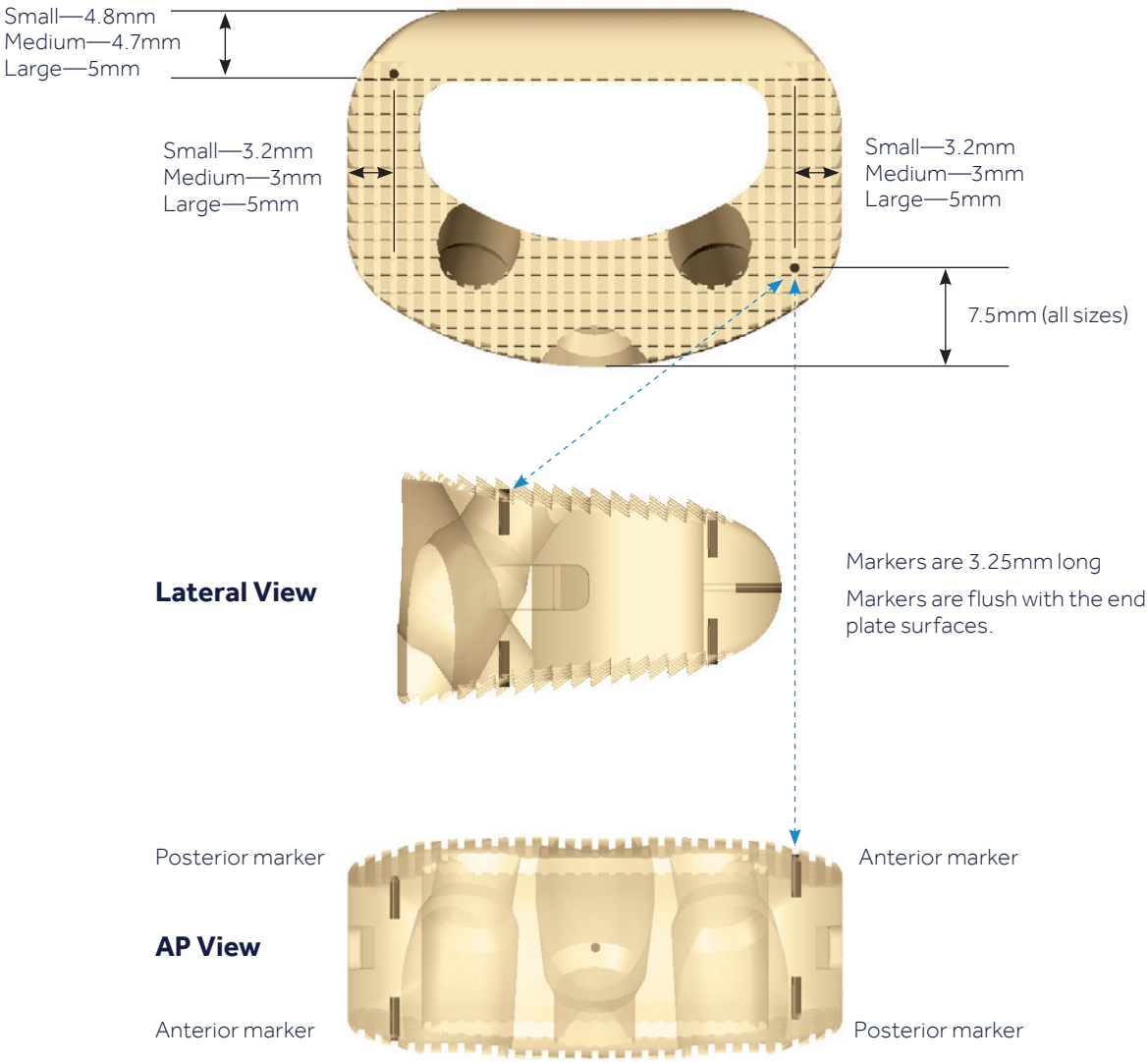
If it becomes necessary to remove the Interbody Spacer, remove the Coverplate using the Coverplate Remover. This is done by inserting the ball tip end of the instrument into the side hole in the Coverplate. Flex the arm out to loosen it from the Interbody Spacer and then pull back the Coverplate from the Interbody Spacer construct. Once the Coverplate is removed, the screws can be removed using the Screwdrivers located in the instrument set, and the Interbody Spacer can be removed by reattaching to the Interbody Spacer Inserter.



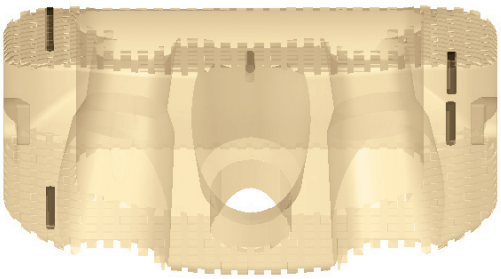
Note

The Oblique Inserter Shaft has a prong on the proximal side to engage the Interbody but is smooth on the distal side for easier removal after implantation. The Straight Inserter Shaft has a prong on each side and may be preferred for Interbody removal. An optional Oblique Interbody Remover with prongs on both sides is available for OLIF51 approaches with part numbers of 7967042 (small), 7967043 (medium), and 7967044 (large).

X-RAY MARKERS



AP view when the shot is not aligned perfectly. This is acceptable.



PRODUCT ORDERING INFORMATION

Implant Set Configuration

Sovereign Instruments for ALIF/OLIF51 – SPS02859

Part Number	Description	Quantity
7969002	Sovereign ALIF/OLIF51 Instrument Set	1
1850095	Generic Metal Lid	1
7967095	Small Oblique Inserter Shaft	1
7967096	Medium Oblique Inserter Shaft	1
7967097	Large Oblique Inserter Shaft	1
7967098	Oblique Coverplate Inserter	1
7967016	Slap Hammer	1
7967010	Middline Marker	1
7967011	Inserter Marker	2
7967041	Anterior/Oblique Trial Handle	2
7967021	Small Discectomy Template	1
7967022	Medium Discectomy Template	1
7967023	Large Discectomy Template	1
7967029	Rongeur	1

Sovereign Implants & Instruments – SPS02860

Part Number	Description	Quantity
7967003	Straight Awl	1
7967005	Straight Awl Guide	1
9339082	Ratchet Handle	1
9098120	Ratchet, Egg Handle	1
7967082	U-Joint Awl	1
7967083	Angled Awl Guide	1
9870011	3.2mm Taper Hex Screwdriver	1
7967088	3.2mm U-Joint Hex Screwdriver	1
7967089	3.2mm Flexible Hex Screwdriver	1
7975520	Sovereign Fixed Angle Screw, 5.5 × 20mm	6
7975525	Sovereign Fixed Angle Screw, 5.5 × 25mm	9
7975530	Sovereign Fixed Angle Screw, 5.5 × 30mm	6
7975535	Sovereign Fixed Angle Screw, 5.5 × 35mm	6
7976020	Sovereign Fixed Angle Screw, 6.0 × 20mm	6
7976025	Sovereign Fixed Angle Screw, 6.0 × 25mm	9
7976030	Sovereign Fixed Angle Screw, 6.0 × 30mm	6
7976035	Sovereign Fixed Angle Screw, 6.0 × 35mm	6

Sovereign Implants & Instruments – SPS02860 continued

Part Number	Description	Quantity
7967028	Inserter Sleeve	1
7967079	Small Inserter Shaft	1
7967080	Medium Inserter Shaft	1
7967081	Large Inserter Shaft	1
7967085	Knob Inserter	1
7967012	Coverplate Inserter	1
7967086	Coverplate Remover	1
7967060	Small Catalyst Sovereign Spreader	1
7967061	Med Catalyst Sovereign Spreader	1
7967062	Large Catalyst Sovereign Spreader	1
7967073	2mm Ctrsk Small Spreader	1
7967074	2mm Ctrsk Medium Spreader	1
7967075	2mm Ctrsk Large Spreader	1
7980067	Sovereign Screw Caddy	1
7980068	Sovereign Screw Caddy Lid	1
7960080	Sovereign Catalyst Adaptor Lid	1
7960081	Sovereign Catalyst Adaptor Caddy	1
1850078	Generic Outer Case	1
1850079	Generic Outer Lid	1
7969006	Bottom Tray	1
7969007	Top Tray	1

Implant Tamp and Handle*

Part Number	Description	Quantity
7967069	Implant Tamp	1
7967018	Trial Handle	1

*Implant Tamp (7967069) is compatible with Trial Handle (7967018). These MUST be ordered together.

Sovereign 8 and 12 Degree Trial Set – SPS02861

Part Number	Description	Quantity
79614210	Trial Small 10mm 12 Deg ALIF/OLIF	1
79614212	Trial Small 12mm 12 Deg ALIF/OLIF	1
79614214	Trial Small 14mm 12 Deg ALIF/OLIF	1
79614216	Trial Small 16mm 12 Deg ALIF/OLIF	1
79614218	Trial Small 18mm 12 Deg ALIF/OLIF	1
79614220	Trial Small 20mm 12 Deg ALIF/OLIF	1
79614810	Trial Small 10mm 8 Deg ALIF/OLIF	1
79614812	Trial Small 12mm 8 Deg ALIF/OLIF	1
79614814	Trial Small 14mm 8 Deg ALIF/OLIF	1
79614816	Trial Small 16mm 8 Deg ALIF/OLIF	1
79614818	Trial Small 18mm 8 Deg ALIF/OLIF	1
79614820	Trial Small 20mm 8 Deg ALIF/OLIF	1
79615210	Trial Med 10mm 12 Deg ALIF/OLIF	1
79615212	Trial Med 12mm 12 Deg ALIF/OLIF	1
79615214	Trial Med 14mm 12 Deg ALIF/OLIF	1
79615216	Trial Med 16mm 12 Deg ALIF/OLIF	1
79615218	Trial Med 18mm 12 Deg ALIF/OLIF	1
79615220	Trial Med 20mm 12 Deg ALIF/OLIF	1
79615810	Trial Med 10mm 8 Deg ALIF/OLIF	1
79615812	Trial Med 12mm 8 Deg ALIF/OLIF	1
79615814	Trial Med 14mm 8 Deg ALIF/OLIF	1
79615816	Trial Med 16mm 8 Deg ALIF/OLIF	1
79615818	Trial Med 18mm 8 Deg ALIF/OLIF	1
79615820	Trial Med 20mm 8 Deg ALIF/OLIF	1
79616210	Trial Large 10mm 12 Deg ALIF/OLIF	1
79616212	Trial Large 12mm 12 Deg ALIF/OLIF	1
79616214	Trial Large 14mm 12 Deg ALIF/OLIF	1
79616216	Trial Large 16mm 12 Deg ALIF/OLIF	1
79616218	Trial Large 18mm 12 Deg ALIF/OLIF	1
79616220	Trial Large 20mm 12 Deg ALIF/OLIF	1
79616810	Trial Large 10mm 8 Deg ALIF/OLIF	1
79616812	Trial Large 12mm 8 Deg ALIF/OLIF	1
79616814	Trial Large 14mm 8 Deg ALIF/OLIF	1
79616816	Trial Large 16mm 8 Deg ALIF/OLIF	1
79616818	Trial Large 18mm 8 Deg ALIF/OLIF	1
79616820	Trial Large 20mm 8 Deg ALIF/OLIF	1
7969001	Sovereign ALIF/OLIF51 Tray 1	1
1850095	Metal Implant Lid	1

Sovereign 18 and 24 Degree Trial Set - SPS02862

Part Number	Description	Quantity
9010002050	Trial S 32 × 23 14mm 18 Deg	1
9010002051	Trial S 32 × 23 16mm 18 Deg	1
9010002052	Trial S 32 × 23 18mm 18 Deg	1
9010002053	Trial S 32 × 23 20mm 18 Deg	1
9010002054	Trial S 32 × 23 22mm 18 Deg	1
9010002055	Trial S 32 × 23 16mm 24 Deg	1
9010002056	Trial S 32 × 23 18mm 24 Deg	1
9010002057	Trial S 32 × 23 20mm 24 Deg	1
9010002058	Trial S 32 × 23 22mm 24 Deg	1
9010002059	Trial S 32 × 23 24mm 24 Deg	1
9010002065	Trial M 37 × 27 14mm 18 Deg	1
9010002066	Trial M 37 × 27 16mm 18 Deg	1
9010002067	Trial M 37 × 27 18mm 18 Deg	1
9010002068	Trial M 37 × 27 20mm 18 Deg	1
9010002069	Trial M 37 × 27 22mm 18 Deg	1
9010002070	Trial M 37 × 27 16mm 24 Deg	1
9010002071	Trial M 37 × 27 18mm 24 Deg	1
9010002072	Trial M 37 × 27 20mm 24 Deg	1
9010002073	Trial M 37 × 27 22mm 24 Deg	1
9010002074	Trial M 37 × 27 24mm 24 Deg	1
9010002080	Trial L 42 × 30 14mm 18 Deg	1
9010002081	Trial L 42 × 30 16mm 18 Deg	1
9010002082	Trial L 42 × 30 18mm 18 Deg	1
9010002083	Trial L 42 × 30 20mm 18 Deg	1
9010002084	Trial L 42 × 30 22mm 18 Deg	1
9010002085	Trial L 42 × 30 16mm 24 Deg	1
9010002086	Trial L 42 × 30 18mm 24 Deg	1
9010002087	Trial L 42 × 30 20mm 24 Deg	1
9010002088	Trial L 42 × 30 22MM 24 Deg	1
9010002089	Trial L 42 × 30 24MM 24 Deg	1
7969000	Tray 7969000 Sovereign 18/24 Deg Trial	1
1850095	Metal Implant Lid	1

Variable Angle Screws – SPS02863

Part Number	(Diameter × Length)	Quantity
7965520	5.5mm × 20mm	6
7965525	5.5mm × 25mm	9
7965530	5.5mm × 30mm	6
7965535	5.5mm × 35mm	6
7966020	6.0mm × 20mm	6
7966025	6.0mm × 25mm	9
7966030	6.0mm × 30mm	6
7966035	6.0mm × 35mm	6
1858711	Screw Gauge	1
7969004	Sovereign Screw Caddy Tray	1
7980067	Sovereign Screw Caddy	1
7980068	Sovereign Screw Caddy Lid	1
1850460	Metal Implant Lid	1

Sovereign Spinal System Small Implants – SPS02163

Part Number	Description	Quantity
7967820	Small 32 × 23 20mm 8 Deg Spacer with Coverplate	1
7967818	Small 32 × 23 18mm 8 Deg Spacer with Coverplate	1
7967816	Small 32 × 23 16mm 8 Deg Spacer with Coverplate	2
7967814	Small 32 × 23 14mm 8 Deg Spacer with Coverplate	2
7967812	Small 32 × 23 12mm 8 Deg Spacer with Coverplate	2
7967810	Small 32 × 23 10mm 8 Deg Spacer with Coverplate	2
7967220	Small 32 × 23 20mm 12 Deg Spacer with Coverplate	1
7967218	Small 32 × 23 18mm 12 Deg Spacer with Coverplate	1
7967216	Small 32 × 23 16mm 12 Deg Spacer with Coverplate	2
7967214	Small 32 × 23 14mm 12 Deg Spacer with Coverplate	2
7967212	Small 32 × 23 12mm 12 Deg Spacer with Coverplate	2
7967210	Small 32 × 23 10mm 12 Deg Spacer with Coverplate	2

Sovereign Spinal System Medium Implants – SPS02164

Part Number	Description	Quantity
7968820	Med 37 × 27 20mm 8 Deg Spacer with Coverplate	1
7968818	Med 37 × 27 18mm 8 Deg Spacer with Coverplate	1
7968816	Med 37 × 27 16mm 8 Deg Spacer with Coverplate	2
7968814	Med 37 × 27 14mm 8 Deg Spacer with Coverplate	2
7968812	Med 37 × 27 12mm 8 Deg Spacer with Coverplate	2
7968810	Med 37 × 27 10mm 8 Deg Spacer with Coverplate	2
7968220	Med 37 × 27 20mm 12 Deg Spacer with Coverplate	1
7968218	Med 37 × 27 18mm 12 Deg Spacer with Coverplate	1
7968216	Med 37 × 27 16mm 12 Deg Spacer with Coverplate	2
7968214	Med 37 × 27 14mm 12 Deg Spacer with Coverplate	2
7968212	Med 37 × 27 12mm 12 Deg Spacer with Coverplate	2
7968210	Med 37 × 27 10mm 12 Deg Spacer with Coverplate	2

Sovereign Spinal System Large Implants – SPS02165

Part Number	Description	Quantity
7969820	Large 42 × 30 20mm 8 Deg Spacer with Coverplate	1
7969818	Large 42 × 30 18mm 8 Deg Spacer with Coverplate	1
7969816	Large 42 × 30 16mm 8 Deg Spacer with Coverplate	2
7969814	Large 42 × 30 14mm 8 Deg Spacer with Coverplate	2
7969812	Large 42 × 30 12mm 8 Deg Spacer with Coverplate	2
7969810	Large 42 × 30 10mm 8 Deg Spacer with Coverplate	2
7969220	Large 42 × 30 20mm 12 Deg Spacer with Coverplate	1
7969218	Large 42 × 30 18mm 12 Deg Spacer with Coverplate	1
7969216	Large 42 × 30 16mm 12 Deg Spacer with Coverplate	2
7969214	Large 42 × 30 14mm 12 Deg Spacer with Coverplate	2
7969212	Large 42 × 30 12mm 12 Deg Spacer with Coverplate	2
7969210	Large 42 × 30 10mm 12 Deg Spacer with Coverplate	2

Sovereign Spinal System Hyperlordotic Implants - SPS 02938

Part Number	Description	Quantity
9010002000	Spacer S 32 × 23 × 14mm 18 Deg	2
9010002001	Spacer S 32 × 23 × 16mm 18 Deg	2
9010002002	Spacer S 32 × 23 × 18mm 18 Deg	1
9010002003	Spacer S 32 × 23 × 20mm 18 Deg	1
9010002004	Spacer S 32 × 23 × 22mm 18 Deg	1
9010002005	Spacer S 32 × 23 × 16mm 24 Deg	2
9010002006	Spacer S 32 × 23 × 18mm 24 Deg	2
9010002007	Spacer S 32 × 23 × 20mm 24 Deg	1
9010002008	Spacer S 32 × 23 × 22mm 24 Deg	1
9010002009	Spacer S 32 × 23 × 24mm 24 Deg	1
9010002015	Spacer M 37 × 27 × 14mm 18 Deg	2
9010002016	Spacer M 37 × 27 × 16mm 18 Deg	2
9010002017	Spacer M 37 × 27 × 18mm 18 Deg	1
9010002018	Spacer M 37 × 27 × 20mm 18 Deg	1
9010002019	Spacer M 37 × 27 × 22mm 18 Deg	1
9010002020	Spacer M 37 × 27 × 16mm 24 Deg	1
9010002021	Spacer M 37 × 27 × 18mm 24 Deg	1
9010002022	Spacer M 37 × 27 × 20mm 24 Deg	1
9010002023	Spacer M 37 × 27 × 22mm 24 Deg	1
9010002024	Spacer M 37 × 27 × 24mm 24 Deg	1
9010002030	Spacer L 42 × 30 × 14mm 18 Deg	1
9010002031	Spacer L 42 × 30 × 16mm 18 Deg	1
9010002032	Spacer L 42 × 30 × 18mm 18 Deg	1
9010002033	Spacer L 42 × 30 × 20mm 18 Deg	1
9010002034	Spacer L 42 × 30 × 22mm 18 Deg	1
9010002035	Spacer L 42 × 30 × 16mm 24 Deg	1
9010002036	Spacer L 42 × 30 × 18mm 24 Deg	1
9010002037	Spacer L 42 × 30 × 20mm 24 Deg	1
9010002038	Spacer L 42 × 30 × 22mm 24 Deg	1
9010002039	Spacer L 42 × 30 × 24mm 24 Deg	1

IMPORTANT INFORMATION
ON THE SOVEREIGN™ SPINAL SYSTEM

PURPOSE

The SOVEREIGN™ Spinal System is a fusion system intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and instructed as to its mechanical and material applications and limitations. This system may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

DESCRIPTION

The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with 3 holes for placement of titanium screws using an anterior or oblique approach. The SOVEREIGN™ Spinal System contains both a fixed and a variable angle screw option. The fixed angle screw option provides an interference fit with the PEEK interbody implant. The variable angle screw option provides a slight clearance between the PEEK interbody implant and the screw which allows for a small amount of variable screw angulation. This system is intended to be radiolucent and the interior space of the product is to be used with autogenous bone graft. The accompanying cover plate is designed to resist screw backout and must be used when the variable angle screws are implanted.

The SOVEREIGN™ Spinal System interbody device is manufactured from PEEK (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

INDICATIONS

The Sovereign™ Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the Sovereign™ Spinal System is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. The Sovereign™ Spinal System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The Sovereign™ interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign™ interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include:

- Any case where there is translational instability (spondylolisthesis of any grade or retrolisthesis) at the level treated unless posterior supplemental fixation is used to augment stability.
- Any case where posterior elements were removed such that it introduces instability at the level(s) treated unless posterior supplemental fixation is used to augment stability.
- Severe osteoporosis.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Any case where the implants would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from 2 different components or systems.
- Any patient in which implant use would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- **Osteoporosis unless posterior supplemental fixation is used to augment stability.**
- **Severe bone resorption.**
- **Osteomalacia.**

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation. The risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include, but are not limited to:

- Implant migration.
- Breakage of the device.
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Autogenous bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device.
- Urinary retention, loss of bladder control, or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or autogenous bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

WARNINGS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Supplemental fixation systems which may be used with this device include: the CD

HORIZON™ Spinal System, the TSRH™ Spinal System, the DYNALOK™ Classic Spinal System, the Z-PLATE II™ Anterior Fixation System, the PYRAMID™ Anterior Plate Fixation System, and/or their successors. When additional support instrumentation is used, refer to the package insert for requirements and limitations related to those devices.

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

Use of this product without autogenous bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.

Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

Do not re-use or re-process devices labeled as single use devices. Re-use or re-processing of a single use devices may compromise the structural integrity and the intended function of the device which could result in patient injury.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

PRECAUTIONS

Physician note: although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA For US audiences only

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

SUMMARY OF INDICATIONS FOR COREX™ BONE HARVESTER

Corex™ Bone Harvester is a supplied sterile single patient use, manually operated trephine intended for harvesting cancellous bone from various skeletal sites. Device is a single patient use item. Reuse may result in failure of proper actuation and or biologic contamination. These consequences could result in adverse patient effects. Extreme caution should be utilized when placing the sharp tip of the device near vulnerable, "at risk" structures.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.