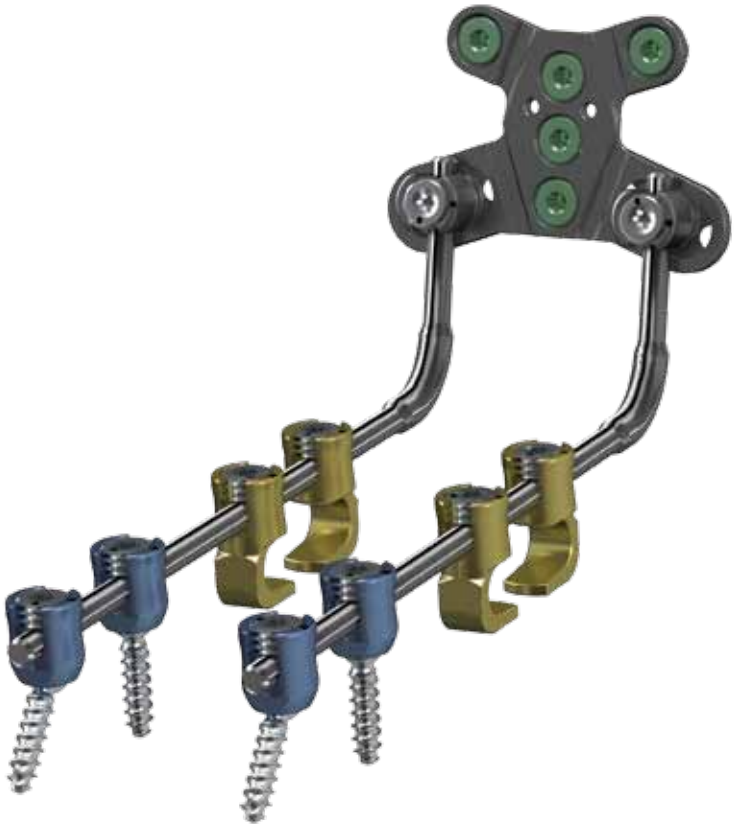
Life Spine

SOLSTICE®

OCCIPITO-CERVICO-THORACIC (OCT) SYSTEM

SURGICAL TECHNIQUE GUIDE



Designs for Life.®

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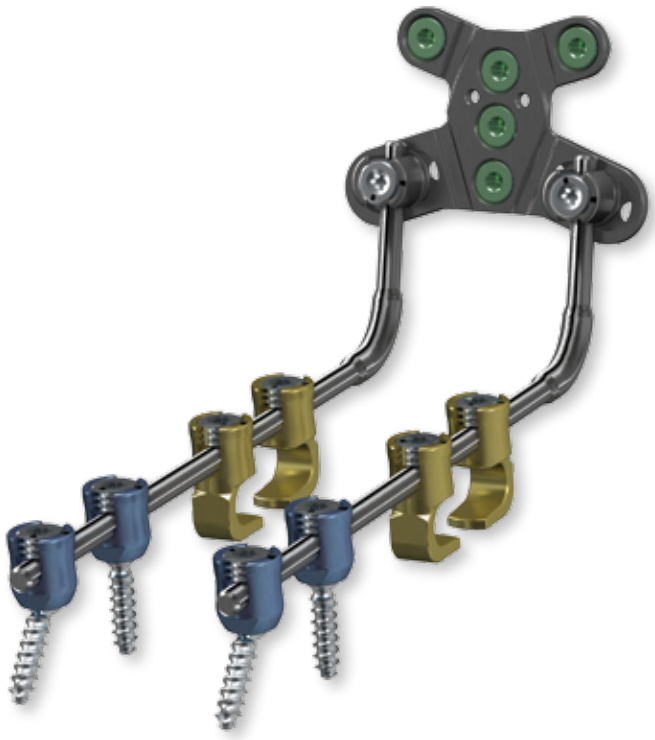


INTRODUCTION

The SOLSTICE® OCT System provides rigid stabilization and promotes fusion of the posterior occipito-cervico-thoracic regions (Occiput -T3) of the spine. The system contains easy to use implants and instruments that address simple and complex cases and unique patient anatomies.

The SOLSTICE OCT System incorporates a number of engineered features that make the system uniquely designed to increase the speed, ease of use, and reliability of posterior occipito-cervico-thoracic fixation of the spine.

FEATURES AND BENEFITS

The SOLSTICE® System offers the following features and benefits.

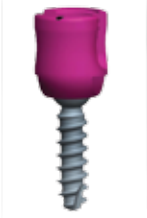
FEATURES	BENEFITS
90° Polyaxial head angulation	Provides for optimal screw placement
Polyaxial "Friction head"	Maintains screw head position within the surgical wound
Pre-timed Locking Cap	Reduces chance of cross threading
Laser marked 3.5mm rods (straight or Pre-Lordosed)	Simplifies contoured rod placement
3.5mm, 4.0mm, & 4.5mm Polyaxial screw diameter	Accommodates various patient anatomies and revision surgeries
10mm - 20mm screws in 2mm increments 25mm - 50mm screws in 5mm increments	Full spectrum of Polyaxial screw lengths
Reduced inner diameter screw tip	Allows for easier insertion into the bone
Low profile system	Reduced construct height reduces soft tissue irritation
2 points of translation/rotation	Facilitates easy rod placement from the occipital plate to the Cervico-Thoracic region.

Important: All referenced implants and instruments are designed and tested for use only with the Solstice OCT System. This surgical technique guide sets forth detailed, recommended procedures for using the Solstice OCT implants and instruments. It offers guidance that you should heed but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when required.

Note: This manual is intended as a guide only. There are multiple techniques for the implantation of spinal fixation systems and, as with any surgical procedure, the surgeon should be trained and thoroughly familiar with the implant system components before proceeding.

SYSTEM CONFIGURATION - POLYAXIAL SCREWS

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
9035-10	3.5mm x 10mm	SOLSTICE Poly Screw Assembly	12
9035-12	3.5mm x 12mm	SOLSTICE Poly Screw Assembly	12
9035-14	3.5mm x 14mm	SOLSTICE Poly Screw Assembly	12
9035-16	3.5mm x 16mm	SOLSTICE Poly Screw Assembly	12
9035-18	3.5mm x 18mm	SOLSTICE Poly Screw Assembly	6
9035-20	3.5mm x 20mm	SOLSTICE Poly Screw Assembly	6
9035-25*	3.5mm x 25mm	SOLSTICE Poly Screw Assembly	6
9035-30*	3.5mm x 30mm	SOLSTICE Poly Screw Assembly	6
9035-35*	3.5mm x 35mm	SOLSTICE Poly Screw Assembly	6
9035-40*	3.5mm x 40mm	SOLSTICE Poly Screw Assembly	6
9035-45*	3.5mm x 45mm	SOLSTICE Poly Screw Assembly	6
9035-50*	3.5mm x 50mm	SOLSTICE Poly Screw Assembly	6
9040-10	4.0mm x 10mm	SOLSTICE Poly Screw Assembly	6
9040-12	4.0mm x 12mm	SOLSTICE Poly Screw Assembly	6
9040-14	4.0mm x 14mm	SOLSTICE Poly Screw Assembly	6
9040-16	4.0mm x 16mm	SOLSTICE Poly Screw Assembly	6
9040-18	4.0mm x 18mm	SOLSTICE Poly Screw Assembly	6
9040-20	4.0mm x 20mm	SOLSTICE Poly Screw Assembly	6
9040-25*	4.0mm x 25mm	SOLSTICE Poly Screw Assembly	6
9040-30*	4.0mm x 30mm	SOLSTICE Poly Screw Assembly	6
9040-35*	4.0mm x 35mm	SOLSTICE Poly Screw Assembly	6
9040-40*	4.0mm x 40mm	SOLSTICE Poly Screw Assembly	6
9040-45*	4.0mm x 45mm	SOLSTICE Poly Screw Assembly	6
9040-50*	4.0mm x 50mm	SOLSTICE Poly Screw Assembly	6
9045-10*	4.5mm x 10mm	SOLSTICE Poly Screw Assembly	6
9045-12*	4.5mm x 12mm	SOLSTICE Poly Screw Assembly	6
9045-14*	4.5mm x 14mm	SOLSTICE Poly Screw Assembly	6
9045-16*	4.5mm x 16mm	SOLSTICE Poly Screw Assembly	6
9045-18*	4.5mm x 18mm	SOLSTICE Poly Screw Assembly	6
9045-20*	4.5mm x 20mm	SOLSTICE Poly Screw Assembly	6
9045-25*	4.5mm x 25mm	SOLSTICE Poly Screw Assembly	6
9045-30*	4.5mm x 30mm	SOLSTICE Poly Screw Assembly	6
9045-35*	4.5mm x 35mm	SOLSTICE Poly Screw Assembly	6
9045-40*	4.5mm x 40mm	SOLSTICE Poly Screw Assembly	6
9045-45*	4.5mm x 45mm	SOLSTICE Poly Screw Assembly	6
9045-50*	4.5mm x 50mm	SOLSTICE Poly Screw Assembly	6



SYSTEM CONFIGURATION - LOCKING CAP

CATALOG NUMBER	DESCRIPTION	QTY/SET
900-003	SOLSTICE Locking Cap Assembly	12

* Items are special order. Please contact customer service at 847.884.6117 for availability.

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SYSTEM CONFIGURATION - HOOKS

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
900-045	4.5mm	SOLSTICE Inline Hook	4
900-060	6.0mm	SOLSTICE Inline Hook	4

SYSTEM CONFIGURATION - RODS

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
3350-040*	3.5mm x 40mm	Rod	4
3350-080	3.5mm x 80mm	Rod	4
3350-120	3.5mm x 120mm	Rod	4
3350-240	3.5mm x 240mm	Rod	4
3551-200*	400mm (200/200)	Transitional Rod	4
3551-300*	600mm (300/300)	Transitional Rod	4
4350-080*	3.5mm x 80mm	Pre-Lordosed Rod	4

SYSTEM CONFIGURATION - OCCIPITAL SET - OCCIPITAL BONE SCREWS

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
9250-06	5.0mm x 6mm	SOLSTICE Occipital Bone Screw	4
9250-07	5.0mm x 7mm	SOLSTICE Occipital Bone Screw	4
9250-08	5.0mm x 8mm	SOLSTICE Occipital Bone Screw	4
9250-09	5.0mm x 9mm	SOLSTICE Occipital Bone Screw	4
9250-10	5.0mm x 10mm	SOLSTICE Occipital Bone Screw	4
9250-11	5.0mm x 11mm	SOLSTICE Occipital Bone Screw	4
9250-12	5.0mm x 12mm	SOLSTICE Occipital Bone Screw	4
9250-13	5.0mm x 13mm	SOLSTICE Occipital Bone Screw	4
9250-14	5.0mm x 14mm	SOLSTICE Occipital Bone Screw	4
9250-15	5.0mm x 15mm	SOLSTICE Occipital Bone Screw	2
9250-16	5.0mm x 16mm	SOLSTICE Occipital Bone Screw	2
9250-17*	5.0mm x 17mm	SOLSTICE Occipital Bone Screw	4
9250-18*	5.0mm x 18mm	SOLSTICE Occipital Bone Screw	4
9255-06	5.5mm x 6mm	SOLSTICE Occipital Bone Screw	4
9255-07	5.5mm x 7mm	SOLSTICE Occipital Bone Screw	4
9255-08	5.5mm x 8mm	SOLSTICE Occipital Bone Screw	4
9255-09	5.5mm x 9mm	SOLSTICE Occipital Bone Screw	4
9255-10	5.5mm x 10mm	SOLSTICE Occipital Bone Screw	4
9255-11	5.5mm x 11mm	SOLSTICE Occipital Bone Screw	4
9255-12	5.5mm x 12mm	SOLSTICE Occipital Bone Screw	4
9255-13	5.5mm x 13mm	SOLSTICE Occipital Bone Screw	4
9255-14	5.5mm x 14mm	SOLSTICE Occipital Bone Screw	4
9255-15	5.5mm x 15mm	SOLSTICE Occipital Bone Screw	2
9255-16	5.5mm x 16mm	SOLSTICE Occipital Bone Screw	2
9255-17*	5.5mm x 17mm	SOLSTICE Occipital Bone Screw	4
9255-18*	5.5mm x 18mm	SOLSTICE Occipital Bone Screw	4

* Items are special order. Please contact customer service at 847.884.6117 for availability.

SYSTEM CONFIGURATION - OCCIPITAL SET - SMOOTH SHAFT SCREWS

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
9135-20	3.5 x 20mm	SOLSTICE Smooth Shaft Assembly	4
9135-22	3.5 x 22mm	SOLSTICE Smooth Shaft Assembly	4
9135-24	3.5 x 24mm	SOLSTICE Smooth Shaft Assembly	4
9135-26	3.5 x 26mm	SOLSTICE Smooth Shaft Assembly	4
9135-28	3.5 x 28mm	SOLSTICE Smooth Shaft Assembly	4
9135-30	3.5 x 30mm	SOLSTICE Smooth Shaft Assembly	4
9140-20	4.0 x 20mm	SOLSTICE Smooth Shaft Assembly	4
9140-22	4.0 x 22mm	SOLSTICE Smooth Shaft Assembly	4
9140-24	4.0 x 24mm	SOLSTICE Smooth Shaft Assembly	4
9140-26	4.0 x 26mm	SOLSTICE Smooth Shaft Assembly	4
9140-28	4.0 x 28mm	SOLSTICE Smooth Shaft Assembly	4
9140-30	4.0 x 30mm	SOLSTICE Smooth Shaft Assembly	4

SYSTEM CONFIGURATION - OCCIPITAL SET - OCCIPITAL PLATES

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
9200-10*	21mm-32mm	SOLSTICE Occipital Plate	2
9200-11	25mm-36mm	SOLSTICE Occipital Plate Small	2
9200-12	29mm-40mm	SOLSTICE Occipital Plate Medium	2
9200-13	36mm-47mm	SOLSTICE Occipital Plate Large	2

SYSTEM CONFIGURATION - OCCIPITAL SET - OCCIPITAL RODS

CATALOG NUMBER	MEASUREMENT	DESCRIPTION	QTY/SET
9350-170	170mm	Pre-Bent Occipital Rod 110 Degrees	4

* Items are special order. Please contact customer service at 847.884.6117 for availability.

STANDARD INSTRUMENTS - SOLSTICE

Various instruments are available for use with the Solstice Occipito-Cervico-Thoracic System to facilitate implantation.

113-112	Mini Axial Ratcheting Handle w/ A/O Quick Couple

113-161	20 in. lbs. Torque Limiting Driver w/ A/O Quick Couple

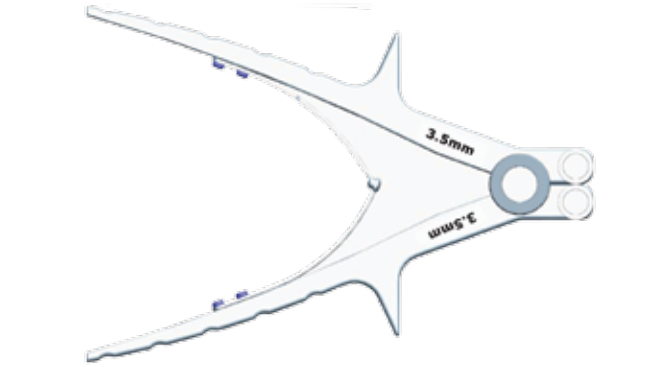
117-894	Solstice Hook Impactor

117-895	Solstice Hook Holder

117-896	Head Positioner/Hook Inserter

117-922	Kerrison Rod Reducer, Solstice

117-892	Rod Pusher/Rod Holder



117-928	3.5mm/4.5mm Rod Bender, Solstice

117-941	Polyaxial Screw Inserter, Solstice

STANDARD INSTRUMENTS - SOLSTICE

117-953 117-953-1	Adjustable Drill Guide with Depth Gauge

117-955	3.5mm Drill (Single Use Only), Solstice

117-956	4.0mm Drill (Single Use Only), Solstice

117-958	Solstice Tap 3.5mm

117-959	Solstice Tap 4.0mm

117-961	Awl

117-962	Counter Torque Tube, Solstice

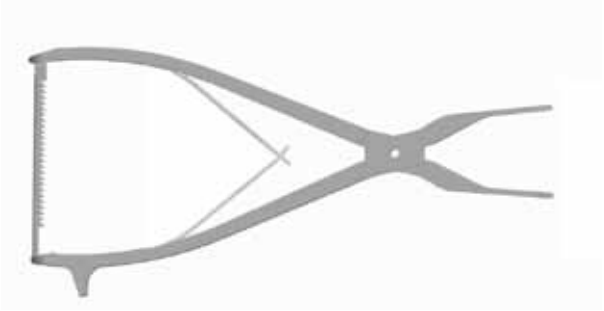
117-963	Lenke Bone Probe Straight, Solstice

117-964	Sounding Probe, Solstice

117-965	Depth Gauge

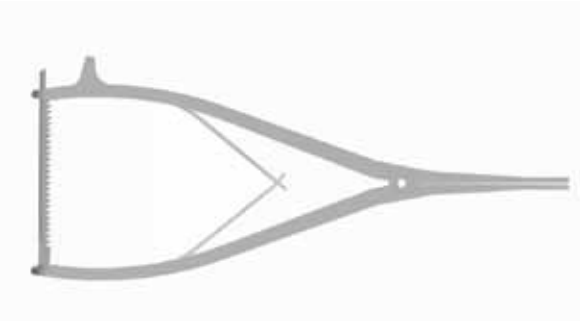
STANDARD INSTRUMENTS - SOLSTICE

117-966	Rod Holder/Inserter, Solstice



117-970	Compressor -Around the Rod, Solstice

117-967	Locking Cap Final Torque Driver Shaft



117-971	Distractor -Around the Rod, Solstice

117-968	Switching Stick/Locking Cap Inserter

117-973	Rod Template, Solstice

117-969	3.5mm insitu Rod Cutter, Solstice

STANDARD INSTRUMENTS - SOLSTICE OCCIPITAL SET

113-106	Fixation Pin Inserter

117-979	5.0mm Occipital Drill (Single Use Only)

117-980	5.0mm Flexible Occipital Drill

117-981	5.0mm Occipital Tap

117-982	5.0mm Flexible Occipital Tap

117-996	3.5mm Cervical Drill (Smooth Shaft)

117-997	4.0mm Cervical Drill (Smooth Shaft)

117-983	Fixation Pin (Large Hole)

113-169	Spin Cap Handle w/ AO Quick Couple

117-986 117-986-1	Occipital Adjustable Drill Guide with Depth Gauge

117-987	Occipital Plate Holder

STANDARD INSTRUMENTS - SOLSTICE OCCIPITAL SET

117-988	Flexible Instrument Holder

117-991	Occipital Plate Bending Pliers

117-989	Occipital Screw Driver

117-992	Occipital Tube Benders

117-990	Flexible Occipital Screw Driver

117-993	Occipital Counter Torque Tube

117-978	Occipital Plate Bender

1. Preoperative Planning and Patient Positioning

Preoperative planning is critical in the preparation for spinal surgery. Due to the anatomic variability of each patient, the surgeon must have the range of necessary images in order to be equipped to plan the operation appropriately. Carefully place the patient in the prone position with head and neck held securely in proper alignment.

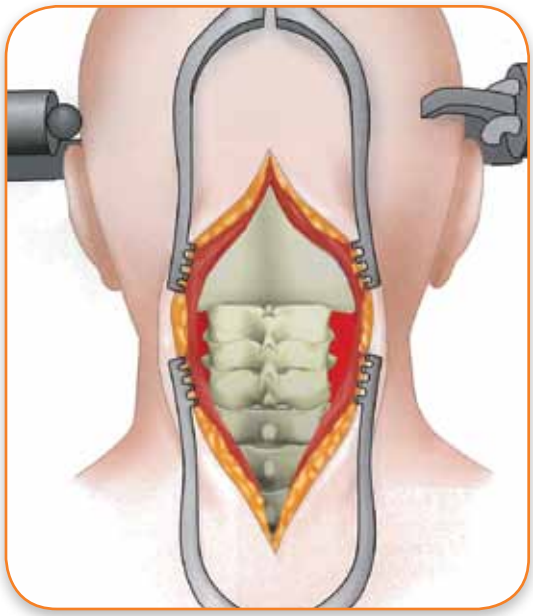


Figure 1

2. Exposure

A midline vertical skin incision can be made (as necessary) extending from the occipital protuberance past the spinous process of the seventh cervical vertebra (prominent vertebra). (Figure 1)

The nuchal ligament is divided in the midline and incised as far as the tips of the spinous processes.

The deep muscle layer is stripped off the spinous processes close to the bone with the aid of electrocautery.

Subperiosteal dissection is carried to the lateral boundary of the articular masses.

3. Placement of Laminar Hooks

There are two hook options: 4.5mm and 6.0mm. Determine the appropriate hook size based on the thickness of the lamina. Prepare attachment point for the hook using a standard preparation technique.

Place the hook in the desired location utilizing the **Hook Holder**. The **Hook Impactor** may be used to facilitate placement of the hook. (Figure 3)

See Steps 7-13 for rod placement and final tightening instructions.

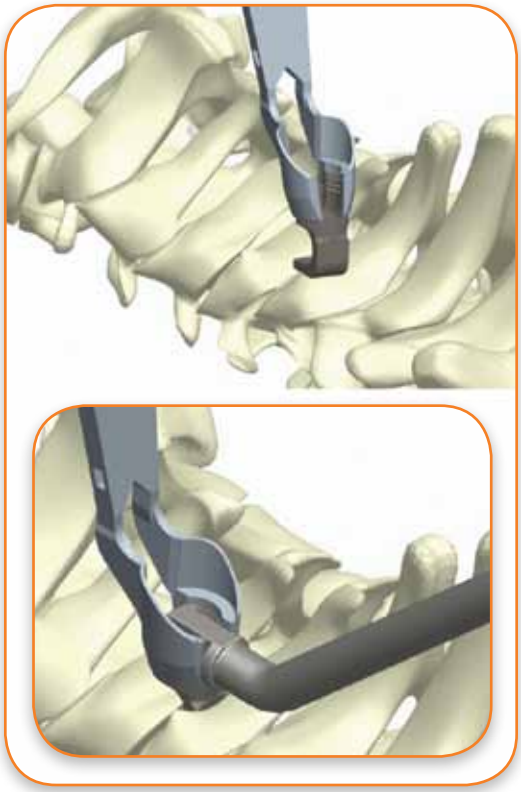
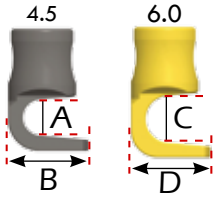


Figure 3



A. Throat Height 4.5mm
B. Blade Length 10.4mm
C. Throat Height 6.0mm
D. Blade Length 10.4mm

Indications for Use of Laminar Hooks

Solstice Laminar Hooks are FDA cleared for use throughout the cervical and upper thoracic (C3-T3) spine.

4. Polyaxial Screw Preparation

Following preparation of the relevant posterior spinal elements by removing all soft tissue and decorticating the facets and laminae, determine and mark the ideal entry point for all **Polyaxial Screws** with a burr or marking pen. (Figure 4)

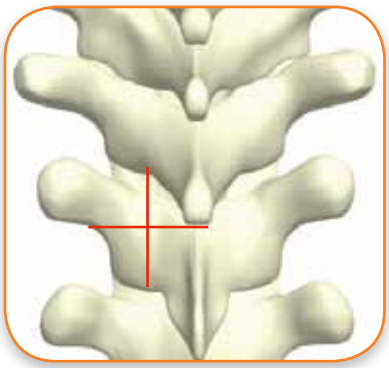


Figure 4

Once the entry point is determined, a pilot hole may be prepared with the **Awl w/ Stop**. This will help to prevent displacement of the **Drill** bit during initial insertion. The **Awl w/ Stop** has a 10mm depth stop distance to prevent over-plunging. (Figure 4a)

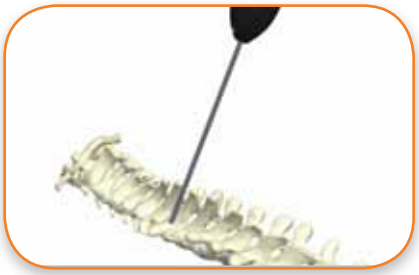


Figure 4a

The **Adjustable Drill Guide** allows for a single drill bit to be used for preparation of variable depths. To set the **Adjustable Drill Guide** depth, depress the adjustment button and slide depth stop to desired depth as indicated on the calibrated depth stop. The depth is defined by the position of the **Drill Guide Stop** relative to the scale of the **Adjustable Drill Guide**. (Figure 4b)

To drill a hole, place the appropriate **Drill** into the barrel of the **Adjustable Drill Guide** and apply downward pressure while turning the **Drill** clockwise until the step of the **Drill** shaft contacts the guide. (Figure 4c) The **Drill** bit depth shown in the inset of Figure 4c will match the depth assigned to The **Adjustable Drill Guide Depth Gauge**.

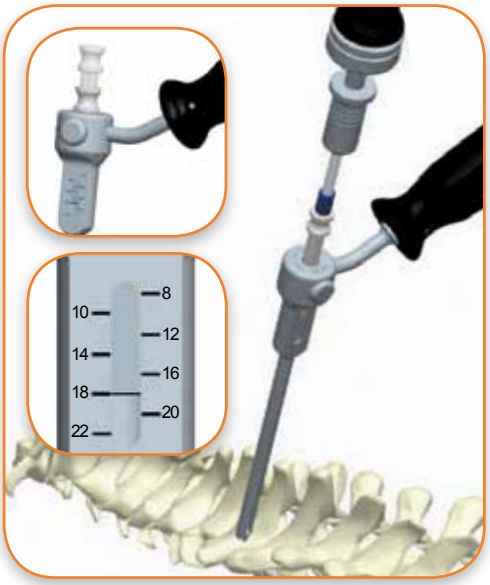


Figure 4b

Each size drill bit has a color ring that corresponds to the color of each Polyaxial Screw head diameter.

3.5mm = Blue
4.0mm = Green
*4.5mm = Magenta

* Special order, please contact customer service for availability.

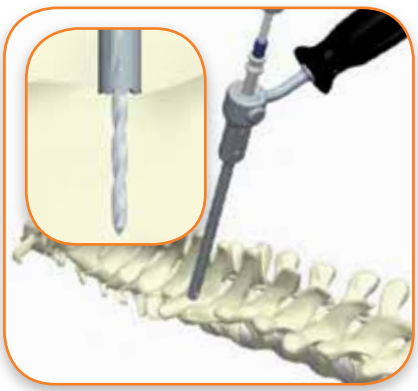


Figure 4c

Indications for Use of Polyaxial Screws

Solstice Polyaxial Screws are FDA cleared for use in the upper thoracic spine (T1-T3).

If the surgeon prefers, a path may be prepared with the **Straight Thoracic Lenke Bone Probe**. The probe should be in contact with the bone at all times. By gently following the path of least resistance, the **Straight Thoracic Lenke Bone Probe** is inserted without violating the walls of the pedicle. Re-evaluate the entry point and trajectory if significant resistance is encountered.

The Straight Thoracic Lenke Bone Probe is calibrated and laser etched in 5mm increments to help indicate the depth to which the probe is inserted as well as to help determine proper screw length. (Figure 4d)

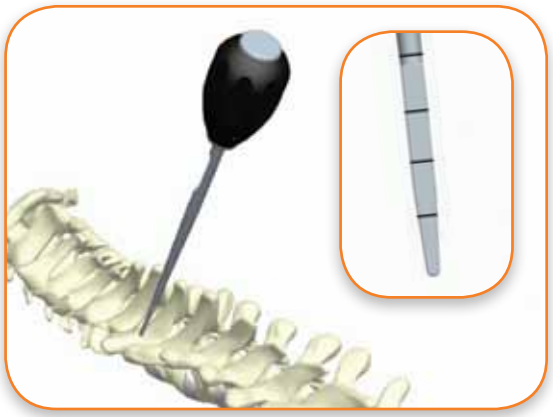


Figure 4d

Verify Pathway

Check the prepared pathway with the **Sounding Probe** to verify that all walls of the pedicle are intact and cancellous bone is felt at the distal end of the path. The **Sounding Probe** is calibrated and laser etched in 5mm increments to help indicate the depth to which the probe is inserted as well as to help determine proper screw length. (Figure 4e)

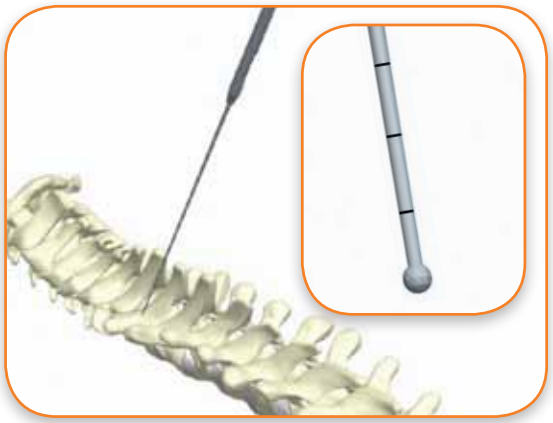


Figure 4e

Measure Pathway

The depth of the pilot hole can be confirmed using the **Depth Gauge**. (Figure 4f)

NOTE: The **Depth Gauge** reflects the actual screw thread length, therefore select the same screw length as indicated by gauge, e.g., 10mm **Depth Gauge** reading, select 10mm **Polyaxial Screw**.

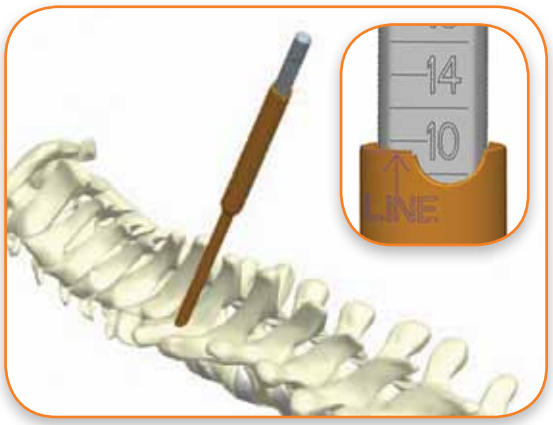


Figure 4f

Tapping Technique (optional)

Tapping is optional since screws have a self-tapping starter tip. **Tap** diameters are a 1:1 ratio with screw outer diameters. The appropriate **Tap** may be used to prepare the pedicle canal when the surgeon is having difficulty starting the self-tapping screw.

To tap, apply downward pressure while turning the **Tap** clockwise until desired number of threads are created within the pedicle pathway. (Figure 4g) The taps are laser etched in 2mm increments to help determine proper screw length.

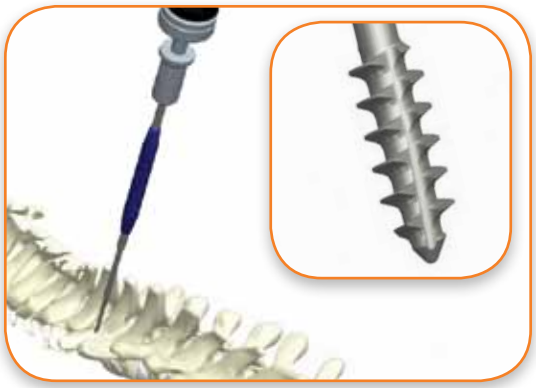


Figure 4g

Each size **Tap** has a color sleeve that corresponds to the color of each **Polyaxial Screw** head diameter.

3.5mm = Blue
4.0mm = Green
***4.5mm = Magenta**

* Special order, please contact customer service for availability.

With the pedicle pathways prepared and the proper screw length and diameter determined, the screw is prepared for insertion.

5. Verify Screw Diameter

Each **Polyaxial Screw** head is color coded by diameter matching the diameters of the **Drills** and **Taps**.

3.5mm = Blue
4.0mm = Green
***4.5mm = Magenta**

* Special order, please contact customer service for availability.

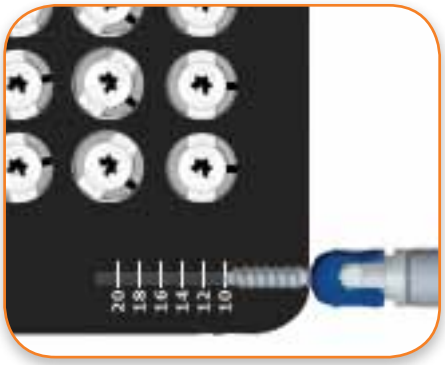


Figure 5

Verify Screw Length

The screw length may be verified by placing the screw in the screw-sizing slot. Place the screw in the slot making sure the screw seat is flush with the top of the screw-sizing slot. Verify the length by using the length indicator located on the side of the screw sizing slot. (Figure 5)

6. Polyaxial Screw Insertion

Lock

Place the tip of the **Polyaxial Screw Inserter** into the screw head. Push the inserter shaft downward and turn knurled knob clockwise to engage the screw head. During this attachment confirm that the screw is aligned with the inserter shaft. (Figure 6)

Unlock

Pull the **Polyaxial Screw Inserter** shaft upward and turn knurled knob counterclockwise to disengage the screw head from the Inserter. (Figure 6a)

Figure 6

Figure 6a

Bone Insertion

To insert the screw into the pedicle, apply gentle downward force to the **Polyaxial Screw Inserter** and rotate the Inserter clockwise. (Figure 6b)

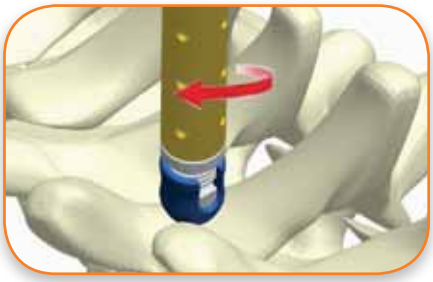


Figure 6b

The **Head Positioner / Hook Inserter** may be used to align the **Polyaxial Screw** heads prior to rod placement. (Figure 6c)

Figure 6c

TIP: If minor screw height adjustment is needed, the **Locking Cap Final Torque Driver Shaft** may be used. (Figure 6d)

Insert all remaining **Polyaxial Screws**. Adjust the height of the screw to allow a contoured rod to seat completely.

Figure 6d

7. Determine Spinal Curve Configuration

Prior to rod insertion, verify the cervical and/or thoracic configuration of the spine. Place the **Rod Template** into the screw/hook seat(s) and mold the template by bending it to fit. Remove the **Rod Template** and choose the appropriate length pre-cut rod. Bend the rod (if necessary) using the **Rod Bender** to match the **Rod Template**.

The **Rod Template** is calibrated and etched in 10mm increments to help determine proper rod length. (Figure 7)

NOTE: Do not implant **Rod Template**.

Figure 7

8. Rod Cutting

The rod length may be altered using the **In Situ Rod Cutter**. Place rod in circular opening and squeeze handles. (Figure 8) For in situ rod cutting, place rod in between distal tips and squeeze handles. Use forceps to prevent loss of cut segment in situ.

Figure 8

9. Rod Contouring

The rod may be contoured using the **Rod Bender**. Place the rod on the appropriate side of the **Rod Bender** and squeeze the handles. (Figures 9 and 9a)

Figure 9

Figure 9a

Insert

Once the rod is bent to the desired contour, the **Rod Holder/Inserter** may be used to place the rod into the screw/hook. (Figure 9b) If the rod is not firmly placed in the screw/hook, follow the Rod Reduction technique, Step 11.

NOTE: Rods are laser marked to simplify rod placement in situ.

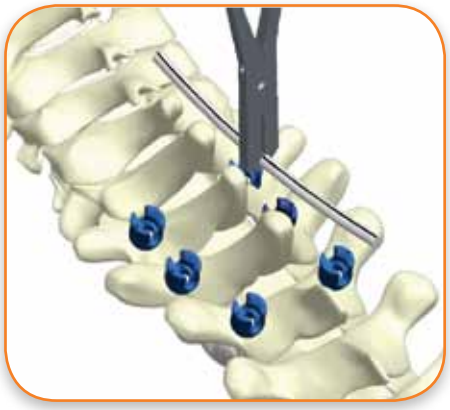


Figure 9b

10. Locking Cap Insertion

Attach

Attach the **Locking Cap** to the tip of the **Switching Stick/ Locking Cap Inserter** and insert the **Locking Cap** into the screw/hook. (Figure 10)

Figure 10

Position

If the laser etch marks are not lined up, turn the **Locking Cap** counterclockwise until the timing marks on the **Locking Cap** and screw/hook line up. In this position, the threads are pre-timed to align automatically and thereby minimize the chance of cross threading. (Figure 10a)

Tighten

Turn the **Locking Cap** clockwise to provisionally tighten the **Locking Cap** down into the screw/hook. Do not over tighten. In the event that physical assistance is required to hold the rod down while tightening the **Locking Cap**, follow the rod reduction technique, Step 11.

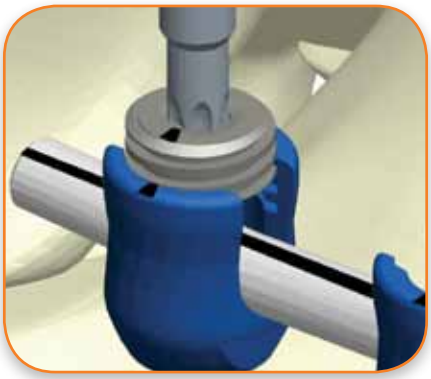


Figure 10a

Extra caution is advised when:

- The rod is not horizontally placed into the screw/hook
- The rod is high in the screw/hook
- An acute convex or concave bend is contoured into the rod near the screw-rod interface

Optional Locking Cap Insertion Technique

Attach

Place **Counter Torque Tube** over the screw/hook head. Attach the Locking Cap on the tip of the **Switching Stick / Locking Cap Inserter** and insert the **Locking Cap** into the **Counter Torque Tube**, using it as your guide for accurate screw placement. (Figure 10b)

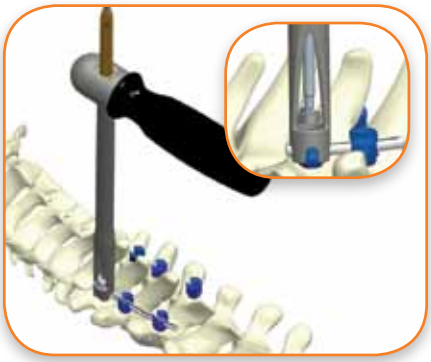


Figure 10b

Position

When using the Counter Torque Tube, the threads are automatically aligned to minimize the chance of cross threading.

Tighten

Provisionally tighten the **Locking Cap** down into the screw/ hook. Do not over tighten.

11. Rod Reduction

Persuasion

Use the **Rod Pusher** or **Kerrison Rod Reducer** when additional physical assistance is required to ease the rod to the screw/hook. Both instruments push the rod into the screw/hook and allow for simultaneous insertion of the **Locking Cap**.

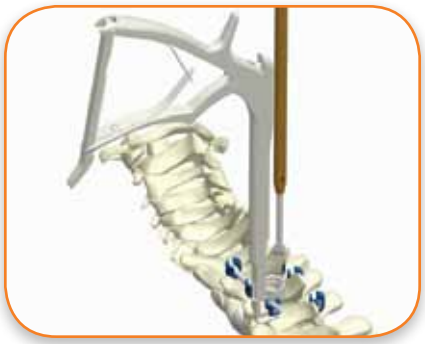


Figure 11

Kerrison Rod Reducer

Engage the **Kerrison Rod Reducer** with the external slots on the screw/hook. Squeeze the handle to introduce the rod into the screw/hook. (Figures 11-11b)

Attach the **Locking Cap** to the **Switching Stick / Locking Cap Inserter**. Insert the **Locking Cap** through the distal tip of the **Kerrison Rod Reducer**, into the screw/hook.

Provisionally tighten the **Locking Cap**.

Disengage the **Kerrison Rod Reducer** from the screw/hook and repeat as necessary.

Figure 11a

Figure 11b

NOTE: The **Kerrison Rod Reducer** generates a great amount of force. Be cautious not to exert too much pressure. This may lead to implant or bone failure.

Rod Pusher

Place the slots of the **Rod Pusher** onto the rod while aligned with the screw/hook. (Figure 11c)

Attach the **Locking Cap** to the **Switching Stick / Locking Cap Inserter**. Insert the **Locking Cap** through the **Rod Pusher**, into the screw/hook.

Provisionally tighten the **Locking Cap**.

Figure 11c

12. Distraction / Compression

Loosen the **Locking Cap** of the level to be adjusted.

Use the **Distractor - Around the Rod** (Figure 12) to achieve distraction or the **Compressor - Around the Rod** (Figure 12a) to achieve compression.

Tighten **Locking Cap** after distraction/compression is achieved.

Repeat for each segment as required.

Figure 12

Figure 12a

13. Final Tightening

Attach the **Locking Cap Final Torque Driver Shaft** to the **20 in-lbs. Torque Limiting Driver w/ AO Quick Couple**.

NOTE: The **20 in-lbs. Torque Limiting Driver w/ AO Quick Couple Handle is orange.** (Figure 13)

Place the **Counter Torque Tube** over the screw/hook seat.

Insert the **Locking Cap Final Torque Driver Shaft** and **Torque Limiting Driver Handle** into the **Counter Torque Tube**.

Firmly hold the **20 in-lbs. Torque Limiting Driver w/ AO Quick Couple Handle** and perform final tightening of the **Locking Cap** until the **20 in-lbs. Torque Limiting Driver w/ AO Quick Couple** "clicks".

Figure 13

14. Closure

Wound closure is performed in the customary manner.

Revision/Implant Removal (If Required)

All implants can be removed by performing the insertion steps in reverse.

Occipital Plate Technique

1. Occipital Plate Selection

Select the plate size to best fit the occiput. The Occipital Plate is available in three sizes, maximizing versatility in the medial-lateral position of the rods.

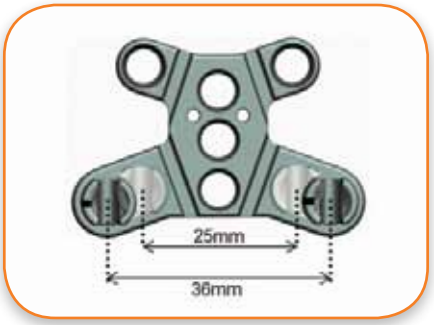
Place the occipital plate with the **Plate Holder** below the exterior occipital protuberance and below the superior nuchal lines. (Figure 1)

Small 25-36mm (width)

Medium 29-40mm (width)

Large 36-47mm (width)

Figure 1



2. Occipital Plate Contouring

Each occipital plate may be contoured to fit the patient's anatomy. The contouring should only be performed in the bend zones. (Figure 2) Use caution to not over bend the plate.

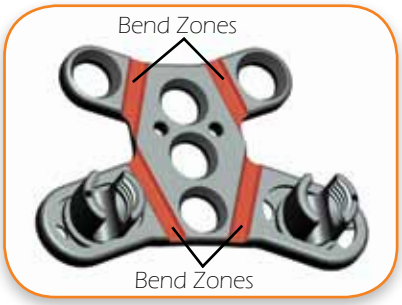


Figure 2

To bend, place the selected occipital plate securely in the **Occipital Plate Bender** and gently bend to achieve desired radius. (Figure 2a)

The **Occipital Plate Bending Pliers** may also be utilized.


Figure 2a

3. Temporary Occipital Plate Holding Pin Insertion

Temporary Fixation Pins can be used to fixate the plate to the occiput.

Utilizing the **Fixation Pin Driver**, drive the **Occipital Plate Holding Pin (Large Hole)** into the occiput by placing the pin through the bone screw holes. (Figure 3)

The Temporary Fixation Pin has a self-drilling tip to allow the pin to be placed without additional hole preparation.


Figure 3

4. Occipital Plate Fixation

Standard or flexible instruments may be utilized for Occipital plate fixation.

Flexible Drill

Attach the **Flexible Instrument Holder** to the **5.0mm Flexible Occipital Drill** to use as a guide. (Figure 4) The **Flexible Occipital Drill** is laser etched in 2mm increments to help determine proper screw length.

Figure 4

Flexible Tap

Attach the **Flexible Instrument Holder** to the **5.0mm Flexible Occipital Tap** to use as a guide. (Figure 4a) The **Flexible Occipital Tap** is laser etched in 2mm increments to help determine proper screw length.

Figure 4a

Drill

To set the **Occipital Adjustable Drill Guide** depth, depress the adjustment button and slide depth stop to desired depth as indicated on the calibrated depth stop. The depth is defined by the position of the **Drill Guide Stop** relative to the scale of the **Occipital Adjustable Drill Guide**. (Figure 4b)

Insert the **Occipital Adjustable Drill Guide** into the desired hole in the plate. (Figure 4b)

Figure 4b

Attach the **5.0mm Occipital Drill** securely into the **Spin Cap Handle w/ AO Quick Couple**. Insert the **5.0mm Occipital Drill** through the **Occipital Adjustable Drill Guide** and drill to the appropriate depth. (Figure 4c)

A positive stop on the drill will prevent over-drilling. Intraoperative imaging should be used to confirm appropriate drill depth.

Figure 4c

Tap

Attach the **5.0mm Occipital Tap** securely into the **Spin Cap Handle w/ AO Quick Couple** and tap to the appropriate depth. (Figure 4d) The **5.0mm Occipital Tap** is laser etched in 2mm increments to help determine proper screw length.

Figure 4d

5. Occipital Bone Screw Insertion

Use the ***Occipital Screw Driver*** or the ***Flexible Occipital Screw Driver*** in conjunction with the ***Flexible Instrument Holder*** and insert the appropriate length occipital bone screw into the prepared hole. (Figure 5)

Repeat drill and tap occipital bone screw placement for remaining occipital bone screws. (Figure 5a)

Confirm screw placement with intraoperative imaging.

Figure 5

Figure 5a

6. Occipital Rod Placement

Determine the appropriate contour and length of the occipital rod with the ***Rod Template***. Once the length is determined, cut the occipital rod to the desired length.

Place the rod into the saddle of the occipital plate. (Figure 6)

For rod cutting, contouring and insertion, refer to Steps 8 and 9.

Figure 6

7. Locking Cap Placement

Use the ***Switching Stick/Locking Cap Inserter*** to position and tighten the Locking Cap on the occipital plate. (Figure 7)

Prior to initial insertion, ensure the laser etch marks on both the locking cap and screw assembly line up. This will minimize the chance of cross threading. (Figure 7a)

All Locking Caps should be inserted prior to final tightening.

Figure 7

Figure 7a

8. Final Tightening

Attach the **Locking Cap Final Torque Driver Shaft** to the **20in-lbs. Axial Torque Limiting Driver w/ AO Quick Couple.**

NOTE: The 20in-lbs. Axial Torque Limiting Driver w/ AO Quick Couple Handle is orange.

Place the **Occipital Counter Torque Tube** over the screw head.

Insert the **Locking Cap Final Torque Driver Shaft** and **20in-lbs. Axial Torque Limiting Driver w/ AO Quick Couple** into the **Occipital Counter Torque Tube.** (Figure 8)

Firmly hold the **20in-lbs. Axial Torque Limiting Driver w/ AO Quick Couple** and perform final tightening of the Locking Cap until the **20in-lbs. Axial Torque Limiting Driver w/ AO Quick Couple** "clicks".

Repeat on remaining occipital screw head. (Figure 8a)

Figure 8

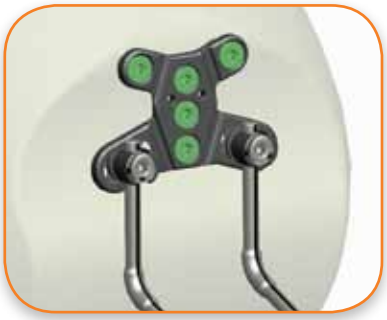


Figure 8a

9. Closure

Wound Closure is performed in the customary manner.

Removal (If Required)

All implants can be removed by performing the insertion steps in reverse.

Important Information on the SOLSTICE OCT System

Description:

The SOLSTICE OCT System is a temporary, titanium alloy (6AL-4V-ELI per ASTM F 136), multiple component system comprised of a variety of non-sterile, single use implantable components. The system consists of an assortment of occipital plates, occipital bone screws, polyaxial screws, hooks, rods, and locking breakaways.

Indications, Contraindications, and Possible Adverse Effects.

Indications:
When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T_3), the SOLSTICE OCT System, when properly used, is intended for: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; fracture/dislocation; Atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery;
and tumors.

When used with occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of polyaxial screws is limited to placement in T_1-T_3 in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C_1-T_3) spine.

Contraindications:
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness, alcoholism, drug abuse.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis
14. Any case not described in the Indications.
15. Any patient unwilling to cooperate with the post-operative instructions.
16. Any time implant utilization would interfere with anatomical structures or expected physiological performance

Potential Adverse Events:
A listing of possible adverse events includes, but is not limited to:
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery
14. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
15. Graft donor site complications including pain, fracture, or wound healing problems.
16. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
17. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
18. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
19. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
20. Change in mental status
21. Non-union (or pseudarthrosis). Delayed union. Mal-union.
22. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
23. Inability to perform the activities of daily living.
24. Paralysis
25. Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The SOLSTICE OCT System is only a temporary implant used for the correction and stabilization of the spine. This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the SOLSTICE OCT System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the SOLSTICE OCT System by the surgeon. 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 and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: FEDERAL (USA) LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Implant Selection:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The SOLSTICE OCT System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.

6. All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

7. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

1. Any instruction manuals should be carefully followed.

2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.

3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.

4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.

6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.

7. Before closing the soft tissues, recheck the tightness of all screws, ensuring that none have loosened during the tightening of the other screws. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

8. Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

9. Do not overtap or use a screw that is either too long or too large. Over-tapping or using an incorrectly sized implant may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

2. To allow the maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.

5. The SOLSTICE OCT System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position possibly resulting in injury, (3) Risk of additional injury from post-operative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved SOLSTICE OCT System components should ever be reused under any circumstances.

Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Life Spine.

Cleaning and Decontamination:

Precleaning:

Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Cleaning:

All instruments must be cleanded before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled (demineralized) water if possible. Instruments should be fully submerged for at least 10 minutes.

Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Immerse instruments fully opened and flush all cannulas until rinse water runs clear. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running water for at least 1 minute to remove solutions.

If contamination is unable to be removed, return the instrument to Life Spine in a sealed container clearly marked "contaminated."

Instruments should never be exposed to cleaning agents containing any peroxides.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices; these solutions should not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
Unless noted otherwise on the package labeling, the SOLSTICE OCT System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Gravity Displacement	270°F(132°C)	30 minutes	60 minutes
Method	**Cycle**	**Temperature**	**Exposure Time**	**Dry Time**
Steam	Prevacuum	270°F(132°C)	4 minutes	60 minutes

The Sterility Assurance Level (SAL) is 1 x 10-6, via the indicated methods.

No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or (if applicable) returning to Life Spine.

Product Complaints:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Life Spine. Further, if any of the implanted SOLSTICE OCT System component(s) ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Life Spine product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence.

When filing a complaint, please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

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