Surgical Technique

Rampart™ One

Interbody Fusion System

Spineology®
anatomyconservingsurgery

Table of Contents

About this Guide:

The Rampart™ One Interbody Fusion System offers both standard and oblique implants, as well as several options for placing standard implants. The “Discectomy” and “Implant Selection with Trials” sections on page 3 apply to all Rampart One procedures. Once implant selection is complete, refer to the appropriate implantation section based on implant type and surgeon instrumentation preference.

A Note for Physicians:

As with any spinal fusion procedure, proper imaging and interpretation of the images are critical to safety. This technique manual describes the parameters for instrument trajectory selection but does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the Rampart One Interbody Fusion System for physicians experienced in the interpretation of biplanar fluoroscopic imaging of the lumbar spine and image-guided instrument placement.

Proper aseptic technique, anesthesia and antibiotic use, patient positioning, and the ability to obtain proper anterior–posterior (AP) and lateral images are assumed. It is always good practice to verify the ability to obtain useable AP and lateral images before preparing the sterile field.

Discectomy

Implant sizing and insertion occur following a discectomy, interim disc space distraction, and endplate preparation. A thorough discectomy is a necessary element of any spinal fusion procedure (Fig. 1).

Figure 1

Implant Selection with Trials

Implant Trials are provided to select an appropriate implant size. Both Standard and Oblique Trials are provided in the Rampart One system. Oblique Trials and implants are recommended when limited vessel mobility prevents a straight anterior approach. When selecting a Trial, take into consideration footprint size, height, and lordosis. Starting with a relatively small Implant Trial to avoid damaging the endplates, thread the Implant Trial onto the Trial Inserter (Figs. 2 and 3).

Figure 2

Figure 3

Implant Selection with Trials (continued)

Use the Mallet to impact the Trial into the disc space (Fig. 4). Sequentially insert increasingly larger Trials into the disc space until the desired annular tension is felt.

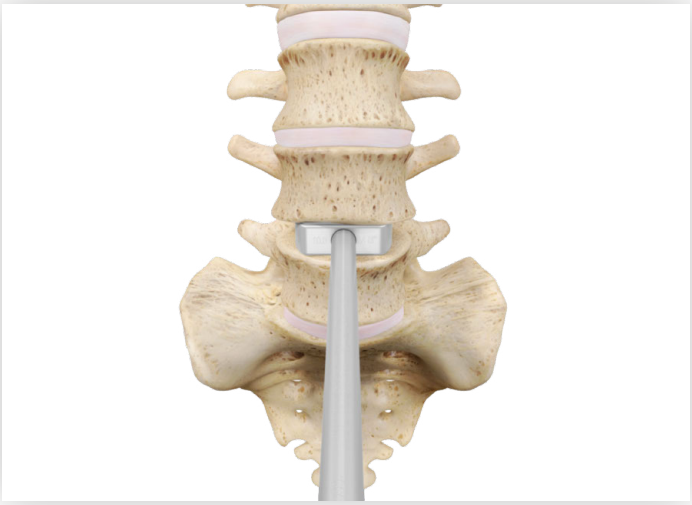

Figure 4

Use AP and lateral fluoroscopy to assess the position and size of the Implant Trial (Figs. 5 and 6).

Note: The Trial Inserter may be removed from the Trial during fluoroscopic imaging.

Remove the Implant Trial.

If the Implant Trial cannot be easily removed, connect the Slap Hammer to the proximal end of the Trial Inserter and remove.

Figure 5

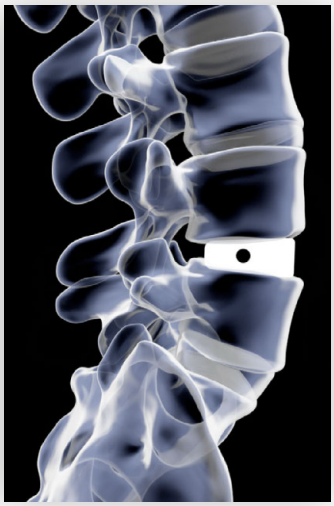

Figure 6

Implantation with the Guide

Loading the Implant onto the Guide

Select a Guide that corresponds to the height of the selected implant.

Ensure the retention mechanism on the implant is open. This is indicated when the laser mark is perpendicular to the superior and inferior Implant surfaces. Align the implant hole with the prong on the Guide (Fig. 7).

Note: The retention mechanism on the 16 mm and 18 mm height implants is at a 45° angle to the superior and inferior implant surfaces when open.

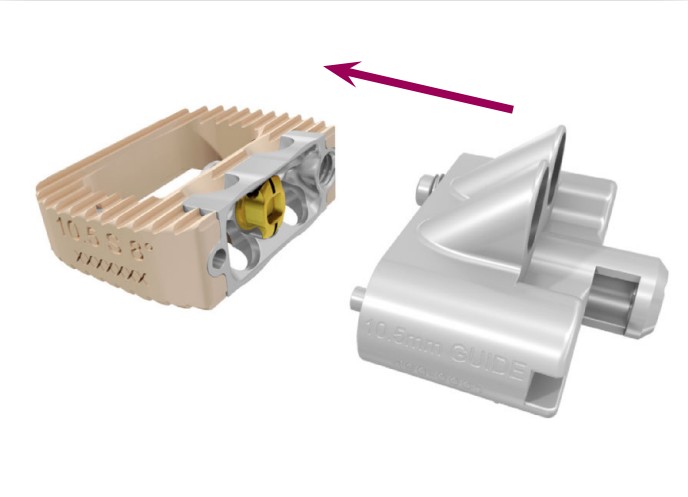

Figure 7

Use the Inserter Driver to turn the set screw inside the Guide clockwise to secure the implant to the Guide (Fig. 8).

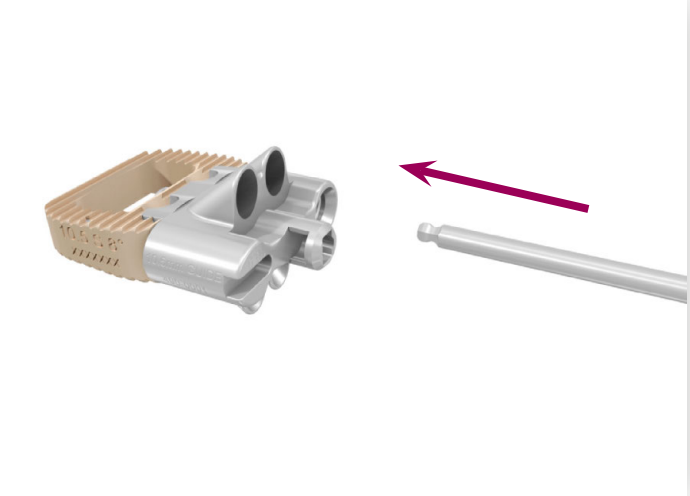

Figure 8

Implantation with the Guide

Assemble Inserter

Place the assembled implant/Guide onto the distal end of the Inserter. Secure by turning the control wing on the proximal end of the Inserter clockwise (Fig. 9).

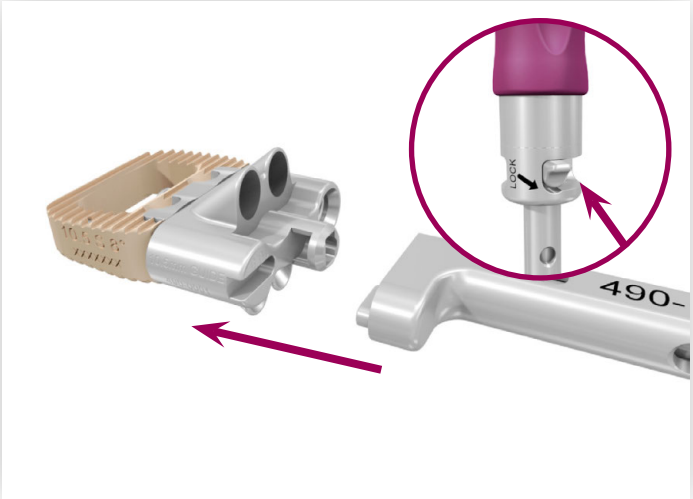

Figure 9

Implant Placement

Fill the implant with bone prior to placement.

Align the implant with the disc space and impact the Inserter with the Mallet until the implant is in the desired final position (Fig. 10).

Figure 10

Implantation with the Guide

Implant Placement (continued)

Use AP and lateral fluoroscopy to assess placement of the implant (Figs. 11 and 12).

Note: If desired, the Implant Inserter can be detached from the Guide for pilot hole creation and screw placement (Fig. 13).

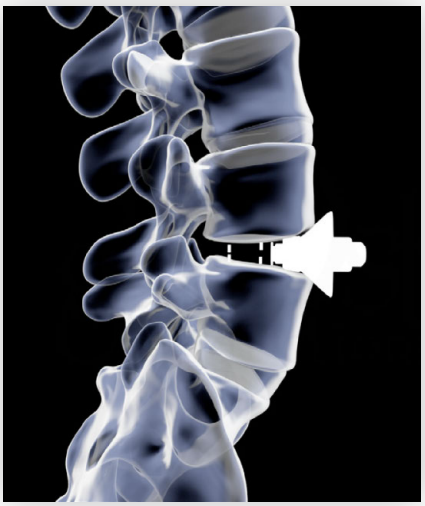

Figure 11

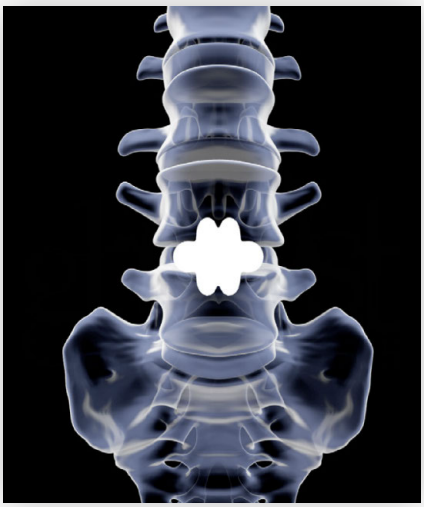

Figure 12

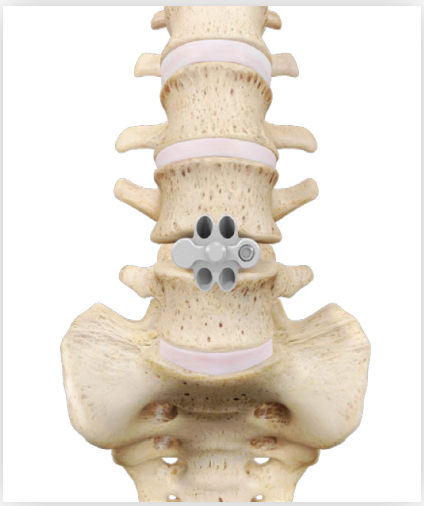

Figure 13

Implantation with the Guide

Awl, Drill, and Driver Options

Straight and Variable Angle Awls, Drills, and Drivers are available for use in creating pilot holes and placing screws through the Rampart One implant.

	Straight	Variable Angle
Awls		
Drills		
Drivers		

Table 1

Implantation with the Guide

Pilot Hole Creation

Select the preferred Awl (see Table 1 on page 8) and pass it through the Guide (Fig. 14). Apply gentle downward pressure while oscillating to advance the Awl and perforate the endplate.

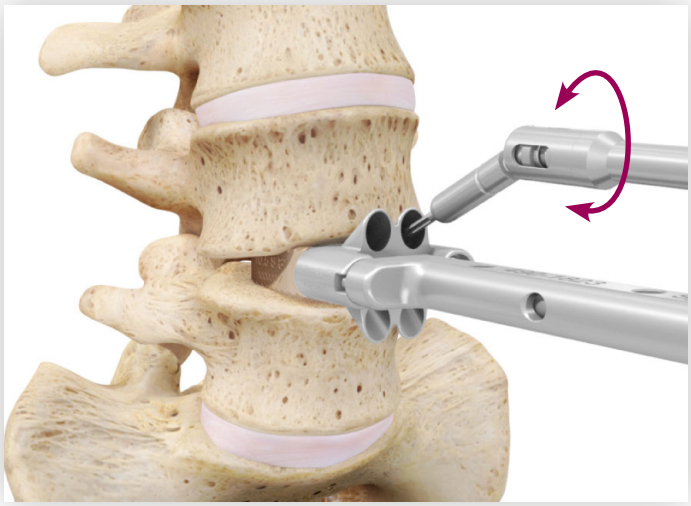

Figure 14

Select the preferred Drill (see Table 1 on page 8) and pass it through the Guide. Apply pressure while turning the handle clockwise to create a pilot hole for the screw (Fig. 15).

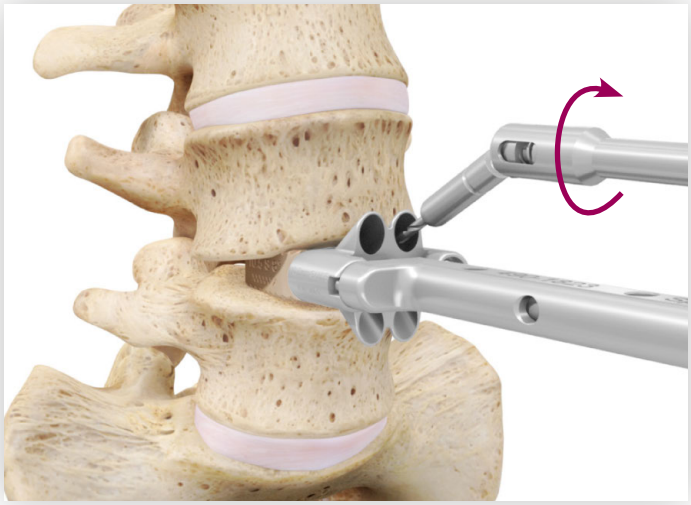

Figure 15

Implantation with the Guide

Screw Placement

Select a screw of the desired length and diameter. Attach the screw (Fig. 16) to the preferred Driver (see Table 1 on page 8).

Note: The Driver utilizes a press fit to secure the screw. Slight pressure is required to press the Driver tip into the screw head.

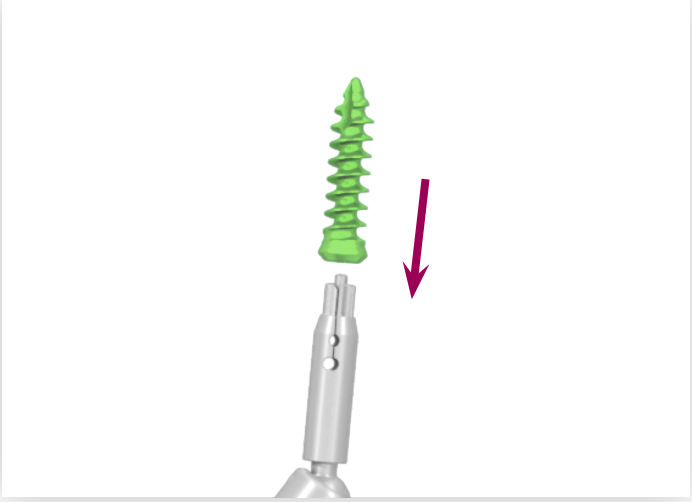

Figure 16

Pass the screw through the Guide and into the pilot hole.

Rotate the Driver clockwise to thread the screw into the vertebra until tight (Fig. 17).

Repeat this process for the remaining three screws.

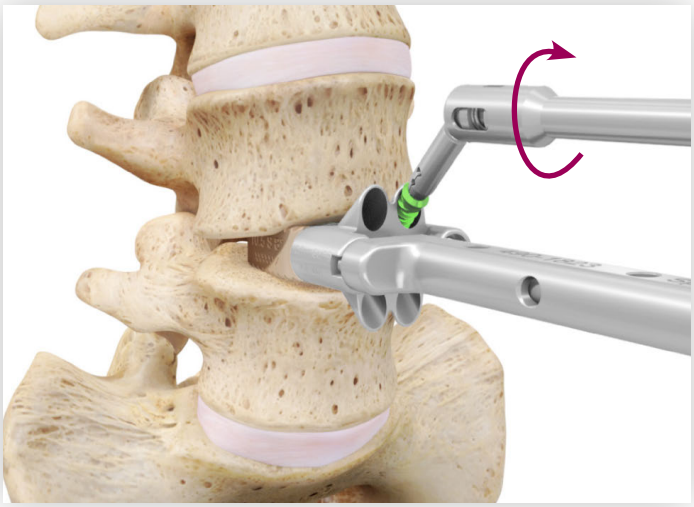

Figure 17

Implantation with the Guide

Screw Placement (continued)

Release the implant from the Inserter by using the Inserter Driver to engage the set screw inside the Guide (Fig. 18). Turn the Inserter Driver counter-clockwise to release the implant.

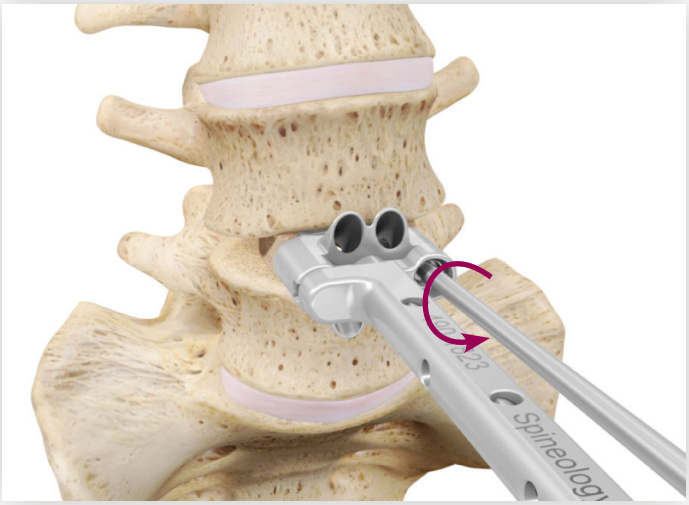

Figure 18

Screw Retention

Visually confirm that the screw heads are fully seated in the implant.

Note: Fully seating screws allows the retention mechanism to properly rotate into final position.

Insert the Retention Mechanism Tool into the retention mechanism (Fig. 19).

Rotate the retention mechanism clockwise until the laser mark is parallel to the vertebral endplates (Fig. 20).

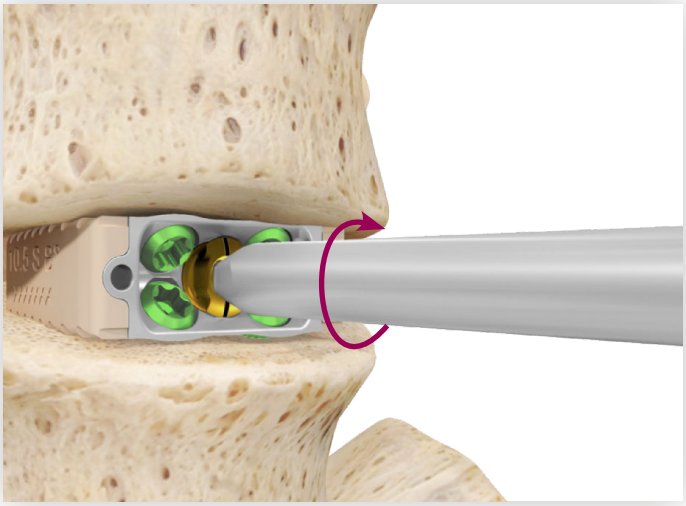

Figure 19

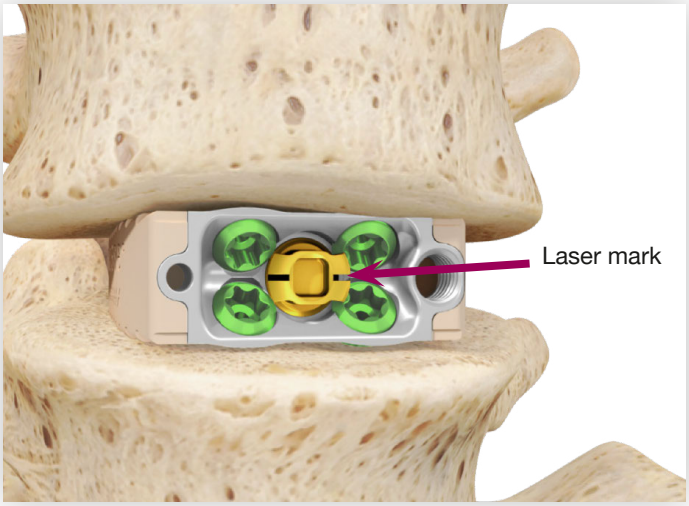

Figure 20

Implantation with the Guide

Final Placement Confirmation

Use AP and lateral fluoroscopy to assess final position of the implant (Figs. 21–24).

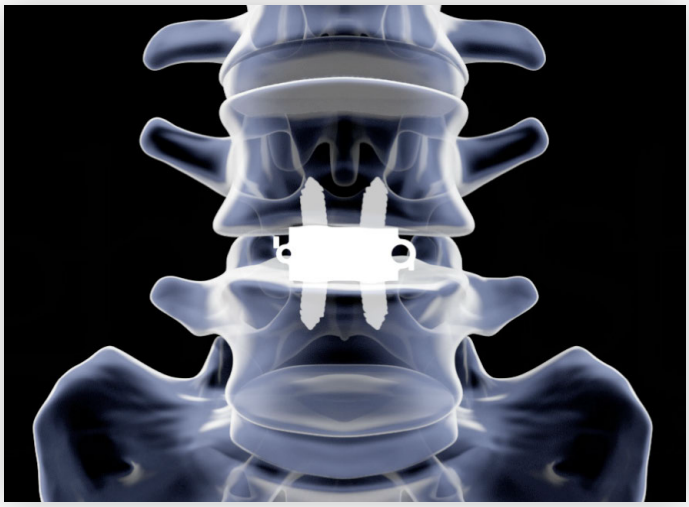

Figure 21

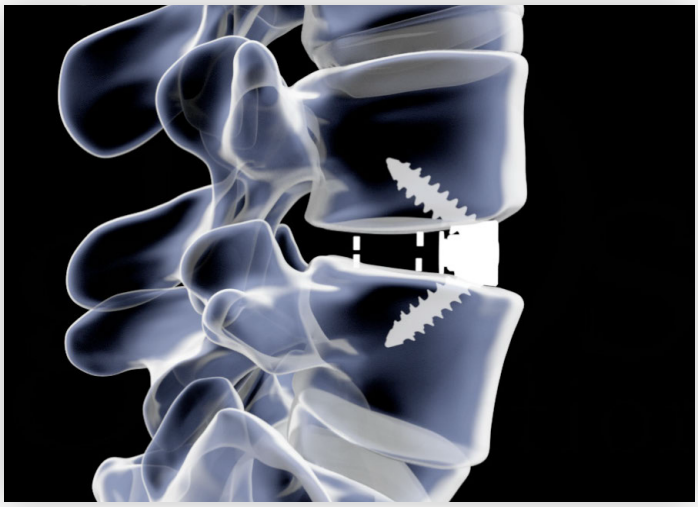

Figure 22

Figure 23

Figure 24

Supplemental Fixation

Following placement of the Rampart One 8° or 12° implant and screws, supplemental fixation can be added at the surgeon's discretion. Following placement of the Rampart One 16° or 20° implant and screws, apply supplemental fixation to complete the construct.

Implantation with the Inserter Block

Loading the Implant onto the Inserter Block

Ensure the retention mechanism on the implant is open. This is indicated when the laser mark is perpendicular to the superior and inferior implant surfaces. Align the implant hole with the prong on the Inserter Block (Fig. 25).

Note: The retention mechanism on the 16 mm and 18 mm height implants is at a 45° angle to the superior and inferior implant surfaces when open.

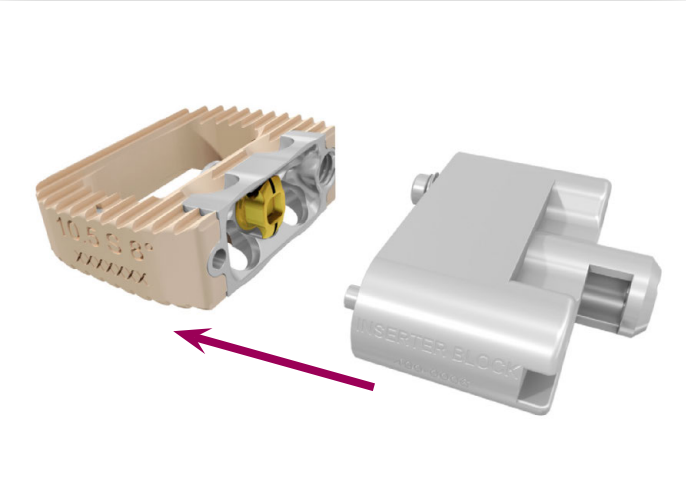

Figure 25

Assemble the Inserter

Use the Inserter Driver to turn the set screw inside the Inserter Block clockwise to secure the implant to the Inserter Block (Fig. 26).

Place the assembled implant/Inserter Block onto the distal end of the Inserter. Secure by turning the control wing on the proximal end of the Inserter clockwise (Fig. 26).

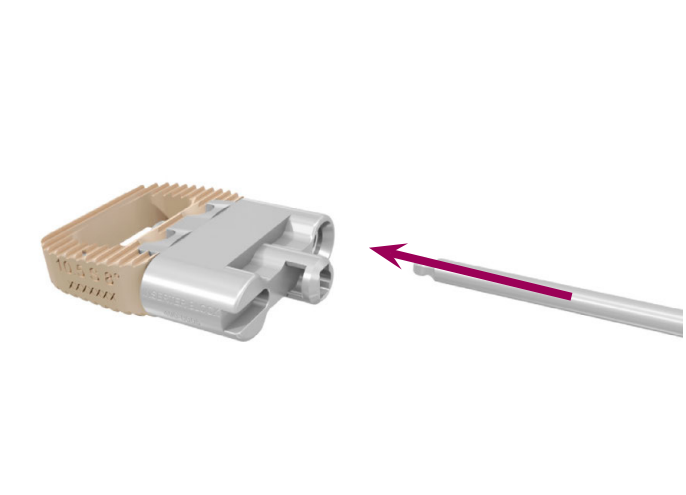

Figure 26

Implantation with the Inserter Block

Implant Placement

Fill the implant with bone prior to insertion.

Align the implant with the disc space and impact the Inserter with the Mallet until the implant is in the desired final position (Fig. 27).

Release the implant from the Inserter by using the Inserter Driver to engage the set screw inside the Inserter Block. Turn the Inserter Driver counter-clockwise to release the implant.

Figure 27

Use AP and lateral fluoroscopy to assess placement of the implant (Figs. 28 and 29).

Note: A Final Position Tamp is available for making small adjustments in the final position of the implant.

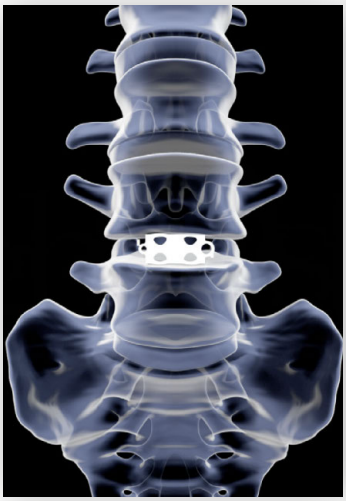

Figure 28

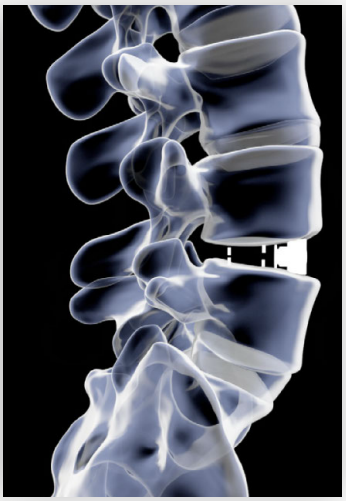

Figure 29

Implantation with the Inserter Block

Pilot Hole Creation

Align the Handheld Guide at the desired trajectory and maintain its position throughout pilot hole creation.

Pass the Handheld Variable Angle Awl through the Handheld Guide. Apply gentle downward pressure while oscillating to advance the Awl and perforate the endplate (Fig. 30).

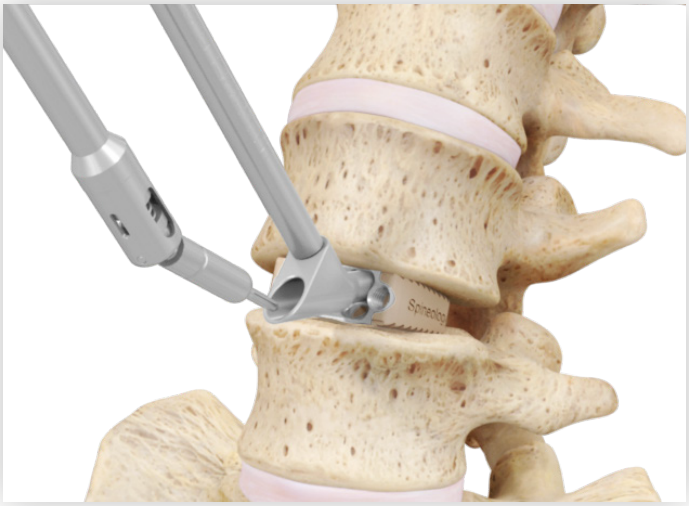

Figure 30

Note: A Sleeved Awl is provided as an alternative to the Handheld Guide and Handheld Variable Angle Awl (Fig. 31).

Seat the Sleeved Awl tip into the screw hole and apply gentle, downward pressure to advance the Awl and perforate the endplate.

Figure 31

Implantation with the Inserter Block

Pilot Hole Creation (continued)

Pass the Handheld Variable Angle Drill through the Handheld Guide. Apply pressure while turning the handle clockwise to create a pilot hole for the screw (Fig. 32).

Remove the Handheld Guide.

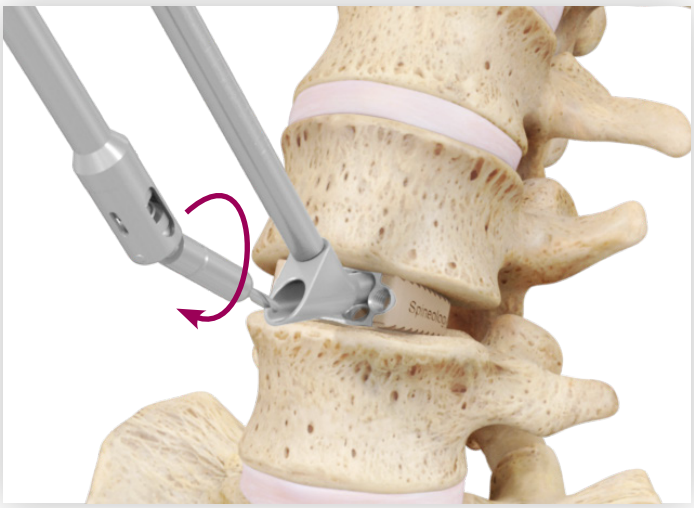

Figure 32

Screw Placement

Select a screw of the desired length and diameter. Attach the screw (Fig. 33) to the preferred Driver (see Table 1 on page 8).

Note: The Driver utilizes a press fit to secure the screw. Slight pressure is required to press the Driver tip into the screw head.

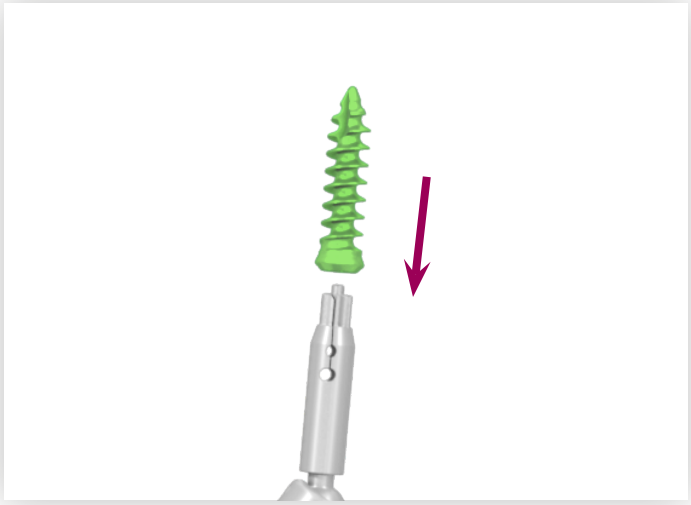

Figure 33

Implantation with the Inserter Block

Screw Placement (continued)

Pass the screw through the implant faceplate and into the pilot hole.

Rotate the Driver clockwise to thread the screw into the vertebra until tight (Fig. 34).

Repeat this process for the remaining three screws.

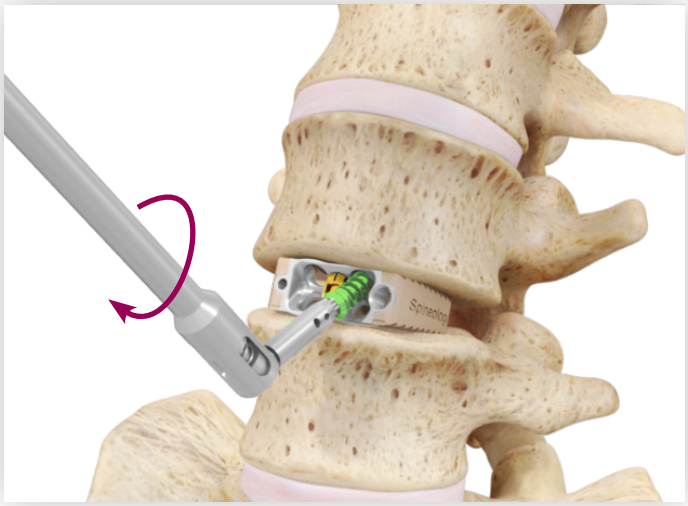

Figure 34

Screw Retention

Visually confirm that the screw heads are fully seated in the implant.

Note: Fully seating screws allows the retention mechanism to properly rotate into final position.

Insert the Retention Mechanism Tool into the retention mechanism (Fig. 35).

Rotate the retention mechanism clockwise until the laser mark is parallel to the vertebral endplates (Fig. 36).

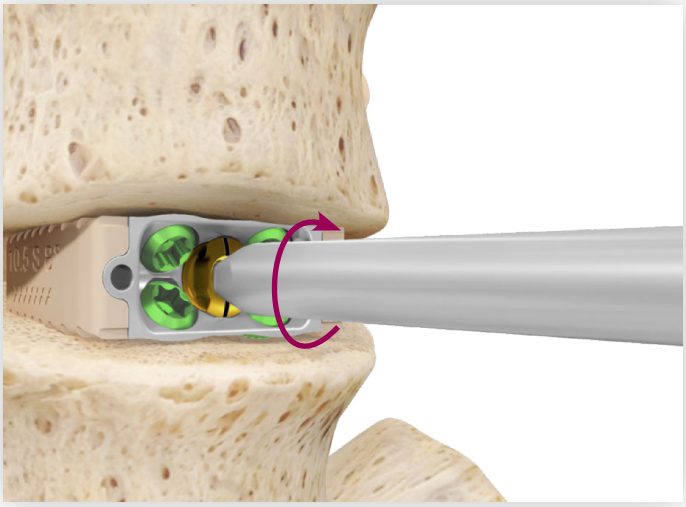

Figure 35

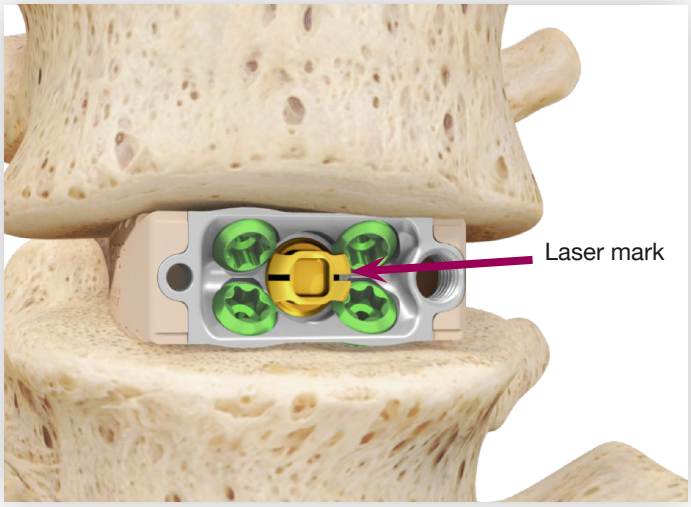

Figure 36

Implantation with the Inserter Block

Final Placement Confirmation

Use AP and lateral fluoroscopy to assess final position of the implant (Figs. 37–40).

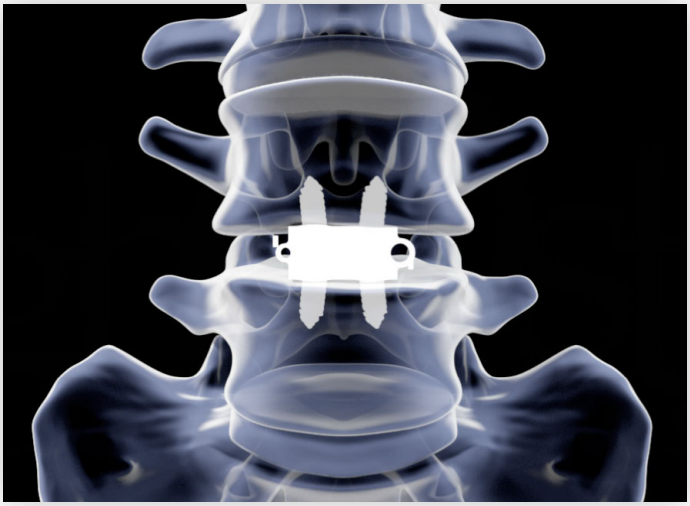

Figure 37

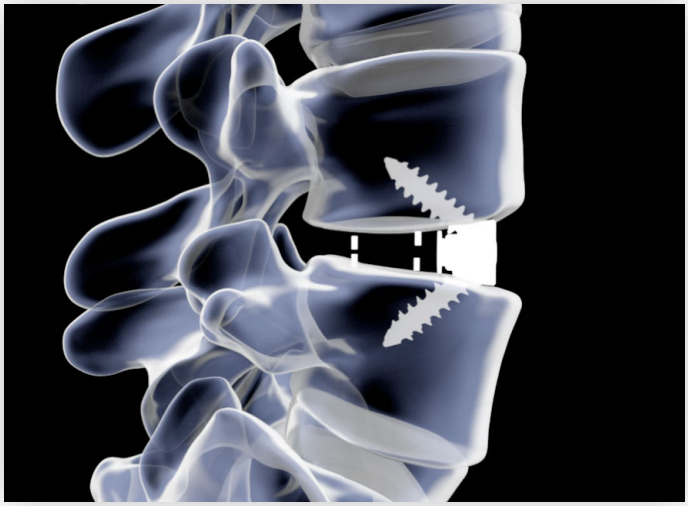

Figure 38

Figure 39

Figure 40

Supplemental Fixation

Following placement of the Rampart One 8° or 12° implant and screws, supplemental fixation can be added at the surgeon's discretion. Following placement of the Rampart One 16° or 20° implant and screws, apply supplemental fixation to complete the construct.

Oblique Implantation

Rampart One Oblique Implant

In the event of limited vessel mobilization, an oblique implant is available (Fig. 41).

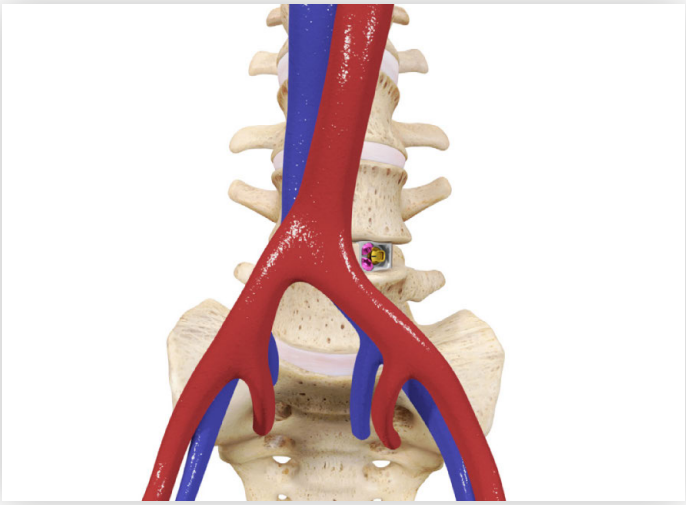

Figure 41

Implant Attachment

Ensure the retention mechanism is open. This is indicated when the laser mark is perpendicular to the superior and inferior implant surfaces (Fig. 42).

Note: The retention mechanism on the 16 mm height implant is at a 45° angle to the superior and inferior implant surfaces when open.

Place the Oblique Inserter, with fingers retracted, into the oblique implant faceplate (Fig. 42).

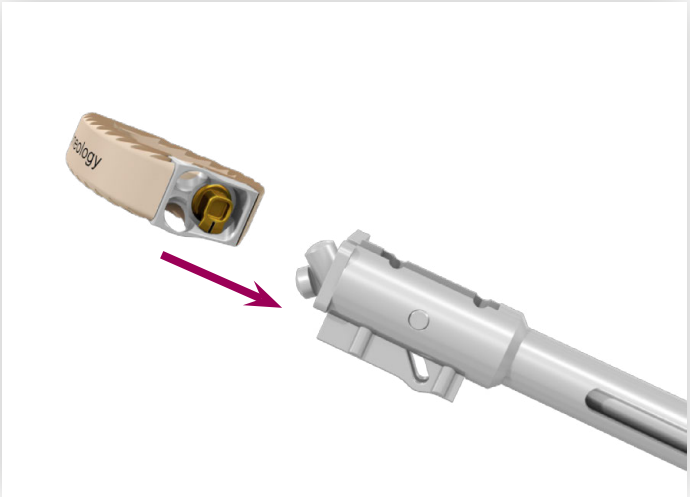

Figure 42

Oblique Implantation

Implant Attachment (continued)

Rotate the knob at the proximal end of the Oblique Inserter clockwise as far as possible to secure (Fig. 43).

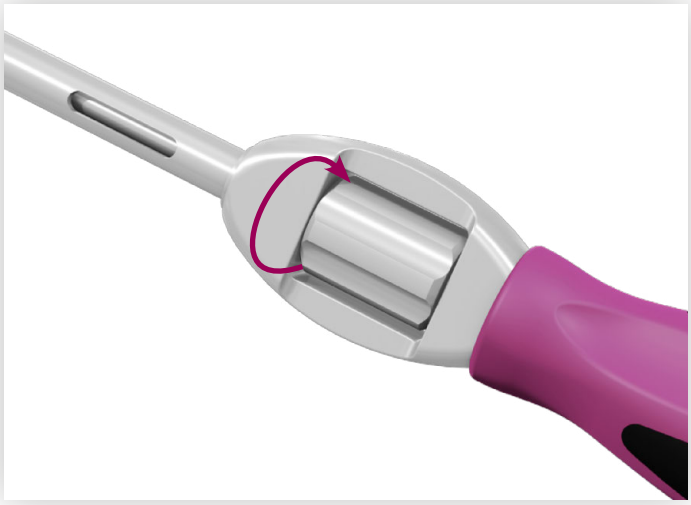

Figure 43

Implant Placement

Fill the oblique implant with bone prior to placement.

Align the oblique implant with the disc space and impact the Oblique Inserter with the Mallet until the oblique implant is in the desired final position (Fig. 44).

Figure 44

Oblique Implantation

Implant Placement (continued)

Release the oblique implant from the Oblique Inserter by turning the knob on the proximal end of the Oblique Inserter counterclockwise.

Use AP and lateral fluoroscopy to assess placement of the oblique implant (Figs. 45 and 46).

Note: A Final Position Tamp is available for making small adjustments in the final position of the oblique implant.

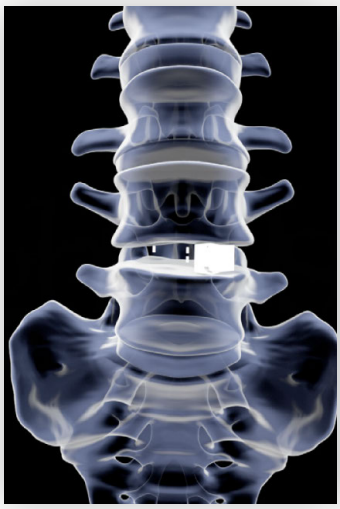

Figure 45

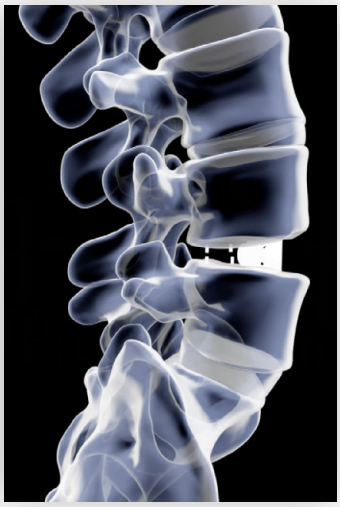

Figure 46

Pilot Hole Creation

Align the Handheld Guide at the desired trajectory and maintain its position throughout pilot hole creation.

Pass the Handheld Variable Angle Awl through the Handheld Guide. Apply gentle, downward pressure while oscillating to advance the Awl and perforate the endplate (Fig. 47).

Figure 47

Oblique Implantation

Pilot Hole Creation (continued)

Note: A Sleeved Awl is provided as an alternative to the Handheld Guide and Handheld Variable Angle Awl (Fig. 48).

Seat the Sleeved Awl tip into the screw hole and apply gentle, downward pressure to advance the Awl and perforate the endplate.

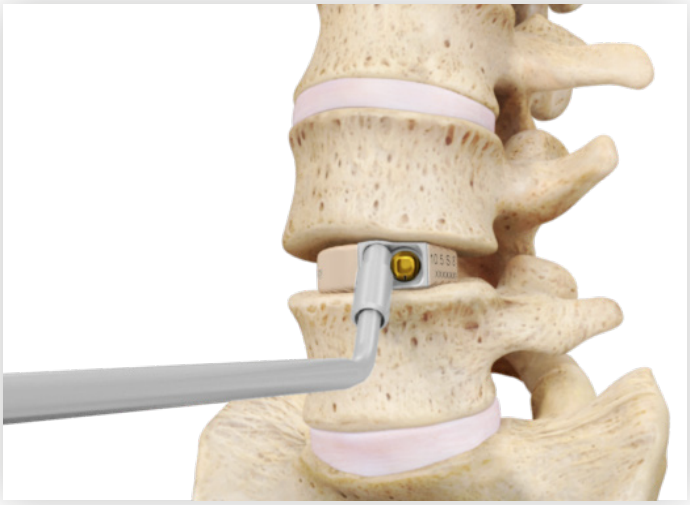

Figure 48

Pass the Handheld Variable Angle Drill through the Handheld Guide. Apply pressure while turning the handle clockwise to create a pilot hole for the screw (Fig. 49).

Remove the Handheld Guide.

Figure 49

Oblique Implantation

Screw Placement

Select a screw of the desired length and diameter. Attach the screw (Fig. 50) to the preferred Driver (See Table 1 on page 8).

Note: The Driver utilizes a press fit to secure the screw. Slight pressure is required to press the Driver tip into the screw head.

Pass the screw through the implant faceplate and into the pilot hole.

Rotate the Driver clockwise to thread the screw into the vertebra until tight.

Repeat this process for the remaining screw.

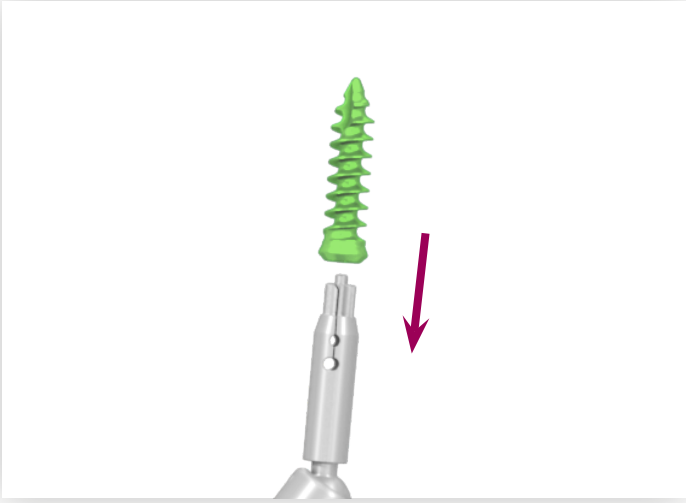

Figure 50

Screw Retention

Visually confirm that the screw heads are fully seated in the oblique implant.

Note: Fully seating screws allows the retention mechanism to properly rotate into final position.

Insert the Retention Mechanism Tool into the retention mechanism (Fig. 51).

Rotate the retention mechanism clockwise until the laser mark is parallel to the vertebral endplates (Fig. 52).

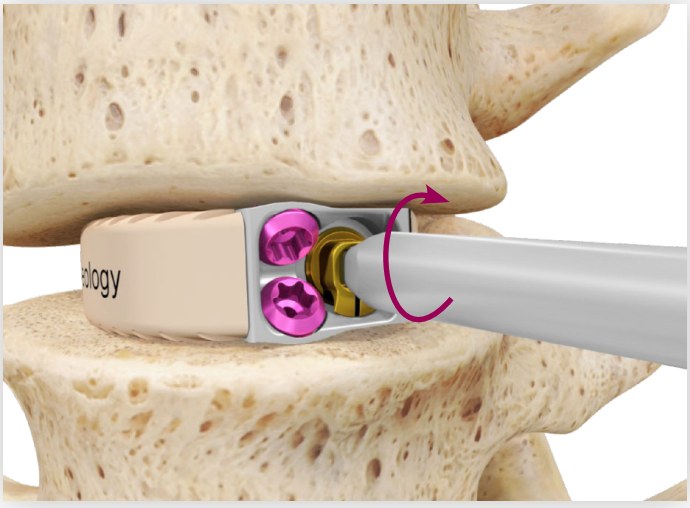

Figure 51

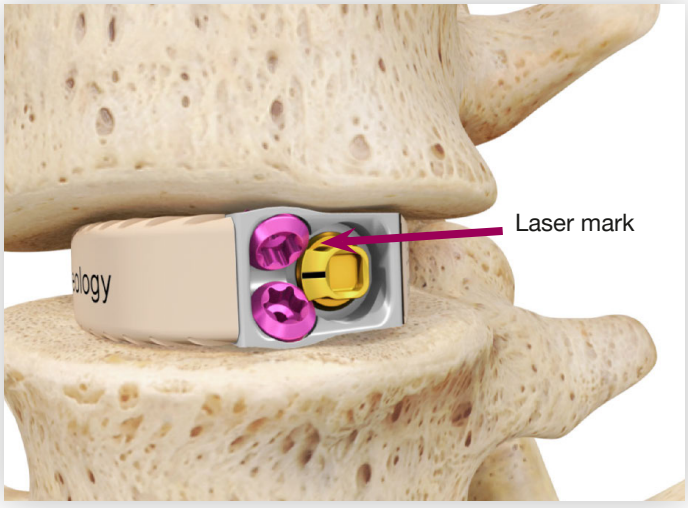

Figure 52

Oblique Implantation

Final Placement Confirmation

Use AP and lateral fluoroscopy to assess final position of the oblique implant (Figs. 53–56).

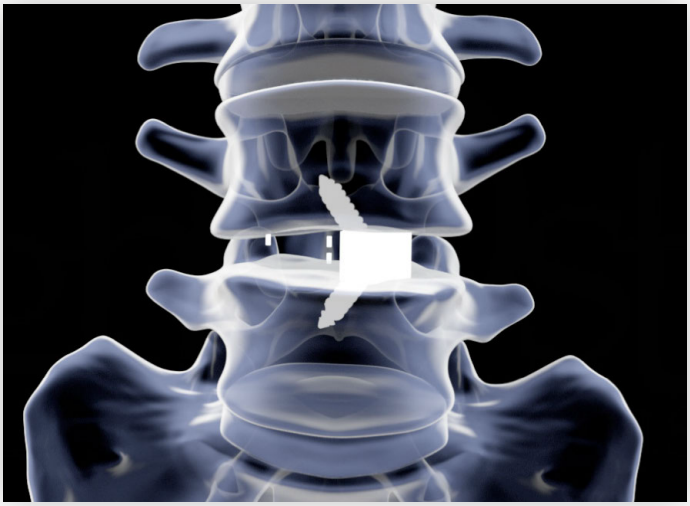

Figure 53

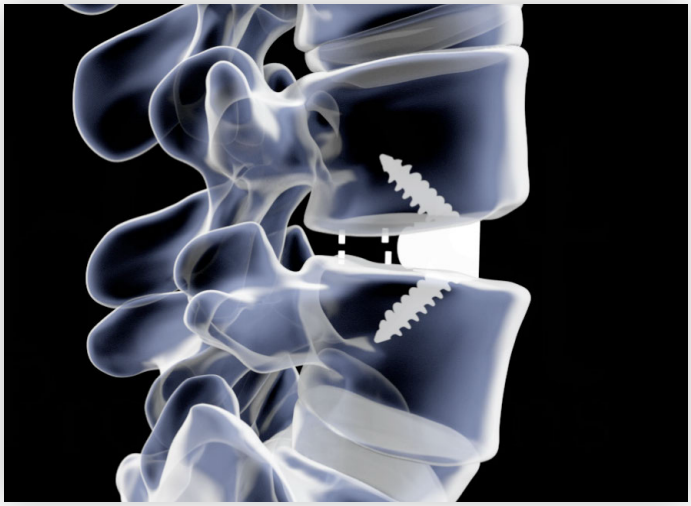

Figure 54

Figure 55

Figure 56

Supplemental Fixation

Following placement of the Rampart One oblique implant and screws, apply supplemental fixation to complete the construct.

Appendix A: Rampart One Interbody Fusion System

ALIF Discectomy Set

CATALOG #	DESCRIPTION
303-2804	3.5 x 5.5 mm Straight Curette
303-2805	5.5 x 8 mm Straight Curette
303-2806	7.5 x 11.5 mm Straight Curette
303-2807	3.5 x 5.5 mm Angled Curette
303-2808	5.5 x 8 mm Angled Curette
303-2809	7.5 x 11.5 mm Angled Curette
303-2810	10 mm Teardrop Ring Curette
303-2811	20 mm Cobb Elevator
303-2812	25 mm Cobb Elevator
303-2801	Anterior Double Action Rongeur
860-0638	T-Handle
490-1301	8 mm Paddle Distractor
490-1302	10.5 mm Paddle Distractor
490-1303	12 mm Paddle Distractor
490-1304	14 mm Paddle Distractor
490-1305	16 mm Paddle Distractor
860-6024	Long-Handled Scalpel
303-2814	Rasp
303-2815	3 mm 40° up-biting Kerrison
303-2816	6 mm 40° up-biting Kerrison
303-2817	3 mm Pituitary Rongeur
303-2818	6 mm Pituitary Rongeur

Instrument Case 1

CATALOG #	DESCRIPTION
490-2028	Trial Inserter
490-2001	Trial 10.5 mm (S) 8°
490-2002	Trial 12 mm (S) 8°
490-2003	Trial 14 mm (S) 8°
490-2006	Trial 12 mm (S) 12°
490-2007	Trial 14 mm (S) 12°
490-2010	Trial 10.5 mm (M) 8°
490-2011	Trial 12 mm (M) 8°
490-2012	Trial 14 mm (M) 8°
490-2013	Trial 16 mm (M) 8°
490-2015	Trial 12 mm (M) 12°
490-2016	Trial 14 mm (M) 12°
490-2017	Trial 16 mm (M) 12°
490-2029	Trial 14 mm (M) 16°
490-2030	Trial 16 mm (M) 16°
490-2031	Trial 16 mm (M) 20°
490-2032	Trial 18 mm (M) 16°
490-2033	Trial 18 mm (M) 20°
490-2020	Trial 12 mm (L) 8°
490-2021	Trial 14 mm (L) 8°
490-2024	Trial 12 mm (L) 12°
490-2025	Trial 14 mm (L) 12°
490-2026	Trial 16 mm (L) 12°
490-2029	Trial 14 mm (M) 16°
490-2030	Trial 16 mm (M) 16°
490-2031	Trial 16 mm (M) 20°
490-2032	Trial 18 mm (M) 16°
490-2033	Trial 18 mm (M) 20°

Appendix A:
Rampart One Interbody Fusion System

Instrument Case 1 (continued)

CATALOG #	DESCRIPTION
490-2201	Oblique Trial 10.5 mm (S) 8°
490-2202	Oblique Trial 12 mm (S) 8°
490-2203	Oblique Trial 14 mm (S) 8°
490-2205	Oblique Trial 10.5 mm (M) 8°
490-2206	Oblique Trial 12 mm (M) 8°
490-2207	Oblique Trial 14 mm (M) 8°
490-2208	Oblique Trial 16 mm (M) 8°
301-0013	Mallet
280-0051	Slap Hammer
490-0017	Implant Trial Caddy Assembly

Instrument Case 2

CATALOG #	DESCRIPTION
490-1807	Straight Awl
490-1808	Straight Drill
490-1809	Straight Driver
490-1810	Variable Angle Drill
490-1811	Variable Angle Awl
490-1812	Variable Angle Driver
490-1814	Retention Mechanism Tool
490-1816	Axial Handle
490-0008	Handheld Variable Angle Drill
490-0009	Handheld Variable Angle Awl
490-1823	Inserter
490-0001	10.5 mm Guide
490-0002	12 mm Guide
490-0003	14 mm Guide
490-0004	16 mm Guide
490-0005	18 mm Guide
490-0006	Inserter Block
460-0001	Oblique Inserter
490-0007	Sleeved Punch Awl
490-1813	Final Position Tamp
490-0010	Handheld Guide
490-1824	Inserter Driver
490-0012	T20 Hexalobe Ball Driver

Appendix A: Rampart One Interbody Fusion System

Standard Implants

CATALOG #	DESCRIPTION
490-1001	Small 10.5 x 32 x 26, 8°
490-1002	Medium 10.5 x 36 x 28, 8°
490-1201	Small 12 x 32 x 26, 8°
490-1202	Small 12 x 32 x 26, 12°
490-1203	Medium 12 x 36 x 28, 8°
490-1204	Medium 12 x 36 x 28, 12°
490-1205	Large 12 x 39 x 30, 8°
490-1206	Large 12 x 39 x 30, 12°
490-1401	Small 14 x 32 x 26, 8°
490-1402	Small 14 x 32 x 26, 12°
490-1403	Medium 14 x 36 x 28, 8°
490-1404	Medium 14 x 36 x 28, 12°
490-1405	Large 14 x 39 x 30, 8°
490-1406	Large 14 x 39 x 30, 12°
490-1407	Medium 14 x 36 x 28, 16°
490-1603	Medium 16 x 36 x 28, 8°
490-1604	Medium 16 x 36 x 28, 12°
490-1605	Large 16 x 39 x 30, 8°
490-1606	Large 16 x 39 x 30, 12°
490-1607	Medium 16 x 36 x 28, 16°
490-1608	Medium 16 x 36 x 28, 20°
490-1817	Medium 18 x 36 x 28, 16°
490-1818	Medium 18 x 36 x 28, 20°

Oblique Implants

CATALOG #	DESCRIPTION
490-2101	Small 10.5 x 32 x 26, 8°
490-2102	Medium 10.5 x 36 x 28, 8°
490-2103	Small 12 x 32 x 26, 8°
490-2104	Medium 12 x 36 x 28, 8°
490-2105	Small 14 x 32 x 26, 8°
490-2106	Medium 14 x 36 x 28, 8°
490-2108	Medium 16 x 36 x 28 8°

Screws

CATALOG #	DESCRIPTION
490-4515	4.5 mm x 15 mm
490-4520	4.5 mm x 20 mm
490-4525	4.5 mm x 25 mm
490-4530	4.5 mm x 30 mm
490-5015	5.0 mm x 15 mm
490-5020	5.0 mm x 20 mm
490-5025	5.0 mm x 25 mm
490-5030	5.0 mm x 30 mm

Unique Device Identification (UDI)

All Spineology devices are labeled with UDI in human readable and/or Automatic Identification and Data Capture (AIDC) format. The human readable UDI is formatted starting with M740 and followed by device identifying characters.

The UDI of single use devices is found on the package label in both formats.

The UDI of reusable devices is directly marked on the device in human readable format or can be derived from the catalog number directly marked on the device. For example, a device with catalog number 123-4567 would have a UDI of M74012345670.

Appendix B: Implant Removal

- Place the Retention Mechanism Tool into the retention mechanism and turn counterclockwise to uncover screws.

- Use the preferred Driver to remove all screws with counterclockwise turns.

- When removing the standard Rampart One implant, attach the Inserter Block to the Inserter. Follow the steps on page 13 of the surgical technique. With the Inserter Block attached to the Inserter, align the Inserter Block/Inserter with the implant and use the Inserter Driver to engage the set screw in the Inserter Block. Turn the Inserter Driver clockwise until tight. This will secure the implant to the Inserter.

- When removing the Rampart One oblique implant, place the Oblique Inserter, with fingers retracted, into the implant faceplate. Rotate the knob until it stops to affix the implant to the Inserter.

- Attach the Slap Hammer to the Inserter to aid in removal of the implant.

DESCRIPTION
Rampart™ One implants are intervertebral body fusion devices for use with bone graft in the intervertebral disc space to stabilize spinal segments as an adjunct to fusion. These devices are manufactured from PEEK-OPTIMA HA Enhanced (spacer), titanium alloy (face plate), and tantalum (radiopaque markers) materials. Rampart One devices incorporate integrated fixation in the form of titanium alloy screws. Rampart One devices are provided in standard and oblique configurations. The standard device accommodates four screws and the oblique device accommodates two screws. In each device the screws are inserted through the anteriorly-located face plate into the adjacent vertebral bodies. Rampart One devices are provided in various heights and lordotic angles and contain a hollow core to receive autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

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INDICATIONS
The standard and oblique Rampart One devices are integrated intervertebral body fusion devices indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment. The standard and oblique Rampart One devices are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The standard Rampart One devices with 8° and 12° lordotic angles may be used with or without supplemental fixation using a fixation system cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One devices with 8° and 12° lordotic angles must be used with four (4) screws. The standard Rampart One devices with 16° and 20° lordotic angles must be used with four (4) screws and a supplemental fixation system cleared by FDA for use in the lumbar spine.

The oblique Rampart One devices must be used with two (2) screws and a supplemental fixation system cleared by FDA for use in the lumbar spine.

CONTRAINDICATIONS
Contraindications include, but are not limited to:
- Infection
- Morbid obesity
- Mental illness
- Fever or leukocytosis
- Pregnancy
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Prior fusion surgery at the involved level(s)
- Cardiovascular complications
- Any patient unwilling to cooperate with the postoperative instructions
- Known or suspected sensitivity to implant materials
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

PRECAUTIONS
- The implantation of this device should be performed only by experienced spinal surgeons with specific training in the use of systems of this type because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The success of any spinal fusion is dependent upon many factors that include, but are not limited to, the health and metabolism of the patient. Medical conditions or disease states that alter a patient's normal metabolism may interfere with bone healing.
- Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.
- Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
- It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the implant.
- The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
- Patients who are taking medications that may interfere with bone or soft tissue healing (e.g. long-term steroid use) may not be suitable candidates as these medications may interfere with bone growth and graft incorporation.
- As with any permanent implant, a perioperative antibiotic protocol is recommended.
- An implant should never be reused.
- Patients receiving the Rampart™ One implants should have had at least six months of non-operative treatment.
- A successful result is not always achieved in every surgical case due to many extenuating circumstances. This device is intended for temporary immobilization of the spine in order to obtain a solid fusion mass using a bone graft. The durability and success of the implant will be compromised in cases where a nonunion develops, or when used without a bone graft.
- Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, nonunion, fracture of the vertebrae, neurological injury, and/or vascular or visceral injury.
- This system should not be used with components of any other system or Manufacturer.

POTENTIAL ADVERSE EFFECTS
All patients considered candidates for fusion using Rampart™ One implants should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects associated with the procedure. Possible adverse effects or risks include, but are not limited to, the following, which may require additional surgery:
- Bending, loosening, fracture, slippage, and/or migration of the component
- Foreign body reaction to the implant
- Skin or muscle sensitivity
- Non-union or delayed union
- Infection of soft tissue and/or bone (osteomyelitis); fever
- Incomplete relief of symptoms
- Loss of proper spinal curvature, correction, height, and/or reduction
- Loss of neurological function, dural tear, pain and/or discomfort
- Epidural bleeding, hemorrhage of blood vessels, and/or hematomas
- Loss of bladder and/or bowel control
- Sterility, impotency, and/or loss of consortium
- Bone loss and/or bone fracture due to stress shielding
- Bursitis
- Bone graft donor site pain or other complications
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction
- Soft tissue injury
- Edema
- Death

MRI WARNING
The Rampart™ One device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Rampart One device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

IMPLANT HANDLING
Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

IMPLANT PACKAGING
Implant packaging should be inspected for package continuity. Packages for each of the sterile implants should be intact upon receipt. Do not use sterile implants if the packaging has been damaged or the shelf life has been exceeded. Devices must be handled properly to maintain sterility. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or implants should not be used, and should be returned to Spineology.
- Note that implants are provided sterile for single use only.
- Do not re-sterilize implants.

DEVICE REMOVAL
Please refer to the Rampart One Surgical Technique Guide document L473 for instructions. Please contact your Spineology representative if you need a replacement document.

INSTRUMENT HANDLING
Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned, decontaminated, and re-sterilized immediately after use.

INSTRUMENT CLEANING, DECONTAMINATION, AND STERILIZATION
All instruments must be cleaned, decontaminated, and sterilized by the hospital before use. Please refer to Rampart One Reprocessing Instructions for Spineology Surgical Instruments document L454 for instructions. Please contact your Spineology representative if you need a replacement document.

FURTHER INFORMATION OR PRODUCT COMPLAINTS

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