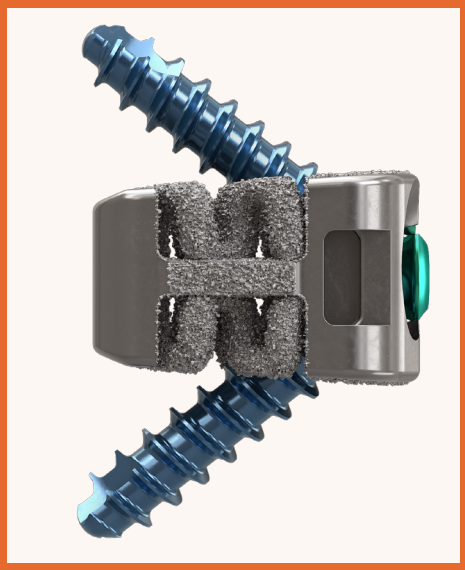
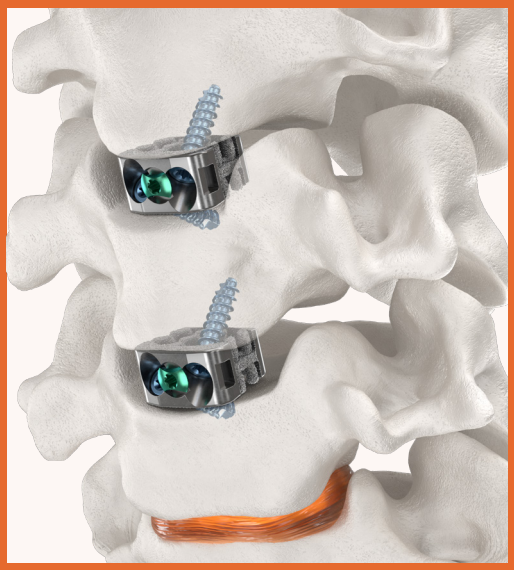
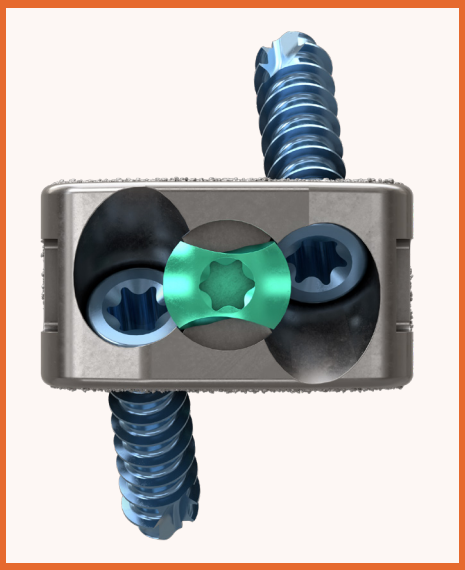
SPIRA®-C INTEGRATED

INTEGRATED FIXATION SYSTEM







SURGICAL TECHNIQUE GUIDE

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LIFE UPRIGHT®

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SPIRA®-C INTEGRATED

INTEGRATED FIXATION SYSTEM

SCZ-800-001 REV B
APRIL 2020

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IMPORTANT INFORMATION

NON-STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The SPIRA®-C Integrated Fixation System consists of a stand-alone interbody fusion device with internal screw fixation. The SPIRA®-C Integrated Fixation System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one or two levels from the C2-C3 disc to the C7-T1 disc. The system is comprised of a Titanium Alloy (Ti-6Al-4V ELI) interbody cage and bone screws.

The SPIRA®-C Integrated Fixation System cages are provided with 7 degrees of lordosis, 6-12mm heights, 14-20mm widths and 13-16mm depths. The titanium alloy interbody cage also comes preassembled with a titanium alloy, built-in rotary locking mechanism. The bone screws used with this device are provided in self-drilling and self-tapping options and are manufactured from medical grade titanium alloy. The bone screws are provided in 3.5mm and 4.0mm diameters and 12-18mm lengths, in variable angle and fixed angle trajectories, along with self-drilling and self-tapping screw tip geometry. This device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The SPIRA®-C Integrated Fixation System has spiral supports to allow for a hollow chamber to permit packing with autogenous bone to facilitate fusion. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place.

MATERIALS

The Camber Spine Technologies SPIRA®-C Integrated Fixation System implants are made from a 3D printed Titanium Alloy TI-6AL-4V (Grade 23) per ASTM F3001-14, in addition with bone screws made of wrought titanium, TI-6AL-4V per ASTM F136.

INDICATIONS FOR USE

The Camber Spine Technologies SPIRA-C Integrated Fixation System consists of a stand-alone interbody device indicated for use at one or two contiguous levels in the cervical spine, from C2-C3 disc to the C7-T1 disc, in skeletally mature patients who have had six weeks of non-operative treatment for the cervical disk disease. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The SPIRA-C Integrated Fixation System must be used with internal screw fixation. The Camber Spine Technologies SPIRA-C Integrated Fixation System must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

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

SURGICAL PROCEDURE

Please contact a customer service representative or company representative for the surgical procedure.

PATIENT SELECTION

The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

CONTRAINDICATIONS

Contraindications may be relative or absolute. Camber Spine Technologies SPIRA-C™ Integrated Fixation System components are contraindicated in the following patient situations:

1. When there is active systemic infection, local infection at the site of surgery, or when the patient has demonstrated an allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and may lead to the collapse of the vertebral bodies around this or any other orthopedic implant.
3. Conditions that place great stress on the implant or the interface with the endplates of the vertebral bodies such as severe obesity may lead to collapse of the vertebral bodies around the device and are relative contraindications. The treating surgeon must weigh the benefits versus risks of using the device in order to decide what is in the best interest of the patient.
4. Presence of fracture or tumor of the vertebral body.
5. Use of the device is relatively contraindicated in patients who may be at a higher risk for implant or fusion failure due to activity, mental capacity, illicit drug abuse, alcoholism, mental illness, occupation or lifestyle which may interfere with postoperative restrictions and which may place undue stresses on the implant during bone healing.
6. Prior fusion at the level(s) to be treated.
7. Any condition not described in the indications for use.

WARNINGS

1. Inspect implant prior to use. Do not use if implant is damaged.

2. Correct selection of the implant is extremely important. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present a limitation on the size, shape and strength of the implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand the unsupported stress of a full weight bearing indefinitely.

3. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also cause early failure. Patients should be fully informed of the risks of implant failure.

4. Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process which can lead to fatigue fracture and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come in contact with other metal objects, therefore must be made from like or compatible metals.

5. Correct handling of the implant is extremely important. Excessive torque, when applied to long-handled insertion tools can cause splitting or fracture of the implants. When an implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.

6. Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS

Intraoperative:

1. The implantation of the Camber Spine Technologies SPIRA®-C Integrated Fixation System should be performed only by experienced spinal surgeons with specific training in the use of this implant system as this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical procedure. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage.
3. The implants and instruments must be cleaned and sterilized before use.
4. Based on the fatigue testing results, 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.

PRECAUTIONS

Postoperative:

1. The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.
2. The patient should be instructed in the limitation of physical activities which would place excessive stresses on the implant and/or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in/out of bed or other daily activities while minimizing rotational and bending stresses.
3. The removal of supplemental fixation after healing should be determined. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: 1) Corrosion, with localized tissue reaction or pain; 2) Migration of implant position resulting in injury; 3) Risk of additional injury from postoperative 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. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
4. The components of this system are designed to be used with Camber Spine Technologies instruments and should not be used with components of any other system or manufacturer.

POSSIBLE ADVERSE EFFECTS

While the expected life of spinal implant components is difficult to estimate, it is finite.

These components are made of foreign materials that are placed within the body to support potential fusion of the spine. However, due to the many biological, mechanical and physiochemical factors that affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Possible adverse effects include, but are not limited to the following:

- Bending, loosening or fracture of the implants or instruments.
- Implant material sensitivity, or allergic reaction to a foreign body (including possible tumor formation).
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device.
- Vascular damage could result in catastrophic or fatal bleeding.
- Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- Degenerative changes or instability in segments adjacent to fused levels.
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which might result in skin breakdown and/or wound complications.
- Nonunion or delayed union.
- Infection.
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage) gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium).
- Pain or discomfort.
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra).
- Hemorrhage of the blood vessels and/or hematomas.
- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height).
- Bursitis.
- Bone graft donor site pain.
- Inability to resume normal daily living activities.
- Reoperation or revision.
- Paralysis.
- Death.

MAGNETIC RESONANCE

The Camber Spine Technologies SPIRA®-C Integrated Fixation System has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. The Camber Spine Technologies SPIRA®-C Integrated Fixation System has not been tested for heating or migration in the MR environment.

IMPLANT CARE

1. Implants can either be shipped contained within a caddy or individually packaged, non-sterile. Care should be taken when handling the implants to avoid damaging the implant.
2. If an implant was shipped individually packaged, it should be carefully transferred to its appropriate caddy for sterilization and storage. All implants will be provided non-sterile.
3. All implants must be thoroughly inspected for any debris prior to sterilization. This includes prior to initial use. Implant are single-use, and not to be reprocessed. If any biologic material is found on the implant, remove the implant from the set. This implant is not to be used. If any debris or other material is present, contact a Camber Spine Technologies representative using the information listed at the end of this document.
4. Implants should always be contained in their appropriate caddy for sterilization.
5. Implants are identified by both catalog numbers and lot numbers, listed on the implant itself, and additionally on the packaging if received individually packaged. These numbers should be recorded when used in surgery, or when calling for a replacement. Catalog number and lot numbers provide traceability to Camber Spine Technologies, and are crucial in the event of any necessary medical device reporting.

CLEANING

NOTE: IMPLANTS ARE SINGLE-USE ONLY AND NOT TO BE REPROCESSED

MANUAL CLEANING OF INSTRUMENTS:

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instrument(s), in an open position/ disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instrument(s) for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument(s) surfaces.
12. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
13. Brush difficult to reach areas such as lumens/ cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
14. If all debris is not removed, repeat brushing and flushing.
15. Flush device with DI water, or equivalent, by placing the device under the water flow for a minimum of 3x.
16. Actuate parts, if applicable 3x, under running DI water, or equivalent.
17. Rinse lumens, tubes, or cannula under running DI water, or equivalent, 4x.
18. Use heat or lint-free cloth to dry devices following final rinse.

AUTOMATED CLEANING FOR INSTRUMENTS:

1. Use utility/tap water to rinse instrument(s)/implant(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s)/implant(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s)/implant(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instruments, in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s)/implant(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Open, disassemble and/or flush instrument(s)/implant(s) if applicable, so cleaning solution can reach all instrument surfaces.
12. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
13. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
14. If all debris is not removed, repeat brushing and flushing.
15. Load the instrument(s)/implant(s) into the appropriate washer-disinfector.
16. Select the cycle which reflects the following parameters:

AUTOMATIC WASHER

PHASE	RECIRCULATION TIME (MIN)	TEMPERATURE	DETERGENT TYPE & CONCENTRATION
Pre-wash 1	01:00	Cold Water Tap	N/A
Wash 1	05:00	43°C Tap Water (Set point)	Enzymatic detergent per washer instructions
Rinse 1	01:00	Warm Water Tap	N/A
Pure Water Rinse	01:00	43°C DI Water	N/A
Dry Time	10:00	90°C	N/A

INSPECTION

All devices must be inspected for remaining soil or cleaning solution. The cleaning steps must be repeated until the device is free from soil and cleaning solution.

STERILIZATION FOR IMPLANTS AND INSTRUMENT

Warning: Camber Spine Technologies does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, Camber Spine recommends the following parameters:

METHOD	STEAM	STEAM
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
Preconditioning Pulses	N/A	4
Temperature	132°C (270°F)	132°C (270°F)
Exposure Time	15 minutes	4 minutes
Drying Time	45 minutes	45 minutes
Open Door Drying Time	15 minutes	15 minutes

Note: An FDA Cleared Wrap must be used.

*Camber Spine Technologies has validated the recommended sterilization cycles and has the data on file. The validated sterilization parameters are compliant with the full cycle validation approach per ANSI/AAMI/ISO 17665-1, Annex D. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

SINGLE USE ONLY ②

Note: Implants are single-use only and not to be reprocessed.

FOR FURTHER INFORMATION

If further information on this product, or the Surgical Technique Guide, is needed please contact Camber Spine Technologies at the number listed below:

Manufactured for:
Camber Spine Technologies
501 Allendale Rd, King of Prussia, PA 19406
Phone: (484) 427-7060

IMPLANT SIZES AND PROFLIES

Available in 4 sizes, with heights from 6 – 12mm, with 7° lordosis.

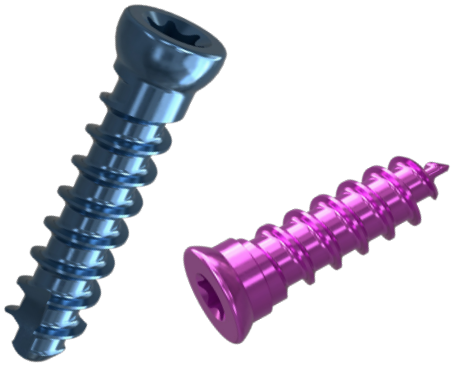
(ADDITIONALLY AVAILABLE)

AVAILABLE SCREWS

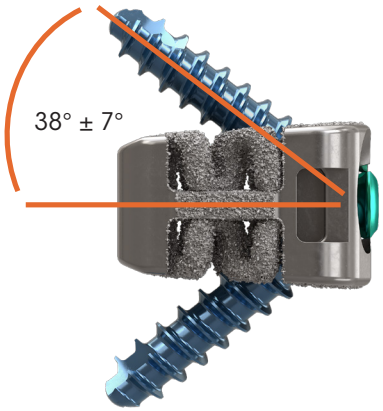
Variable Angle, Self Drilling
Variable Angle, Self Tapping
Fixed Angle, Self Drilling
Fixed Angle, Self Tapping

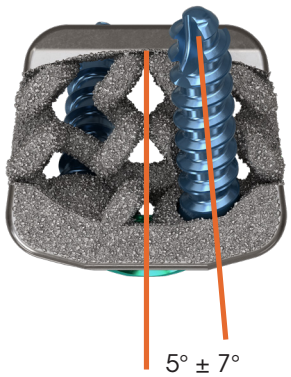
All Screws are ⌀3.5mm with
⌀ 4mm RESCUE available.

Screw Lengths:
12mm, 14mm, 16mm, 18mm



SCREW TAJECTORY

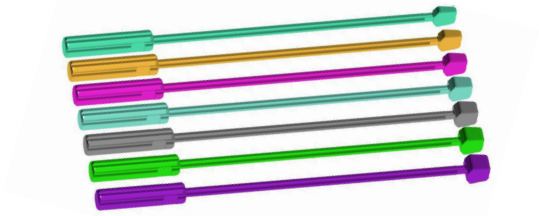




INSTRUMENT OVERVIEW

TRIALS

Cervical Trials (Part Numbers Listed Below)
(Trials are color coated per height)

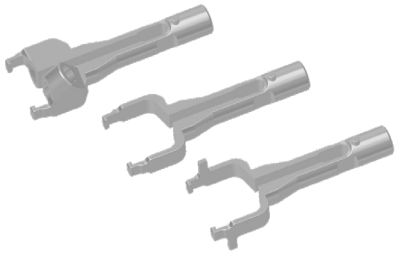


INLINE INSERTER

Implant Inserter (SCZ-103-001)

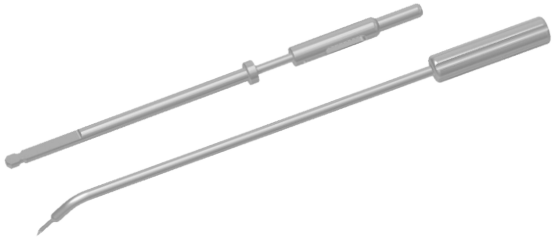
INSERTER TIPS, GUIDED AND DTS

Inserter Tip, Streamline (SCZ-104-001)
Inserter Tip, Streamline w/ Stops (SCZ-104-002)
Inserter Tip, Guided (SCZ-104-006), (SCZ-104-007), (SCZ-104-008),
(SCZ-104-009), (SCZ-104-010), (SCZ-104-011),
(SCZ-104-012)



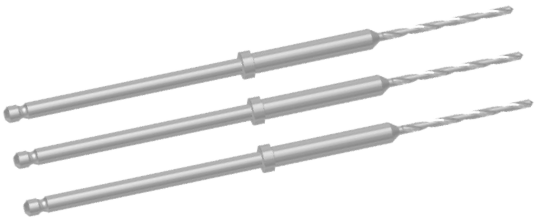
AWLS

Awl, Straight Punch (SCZ-106-001)
Awl, Curved (SCZ-106-002)



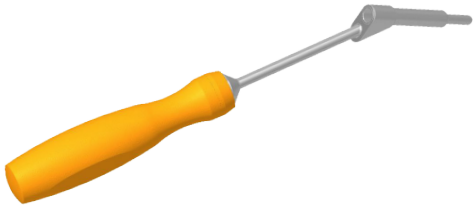
DRILLS

Drill, Straight 12mm (SCZ-108-012)
Drill, Straight 14mm (SCZ-108-014)
Drill, Straight 16mm (SCZ-108-016)
Drill, Straight 18mm (SCZ-108-018)



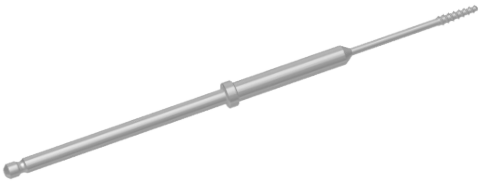
DRILL GUIDE

Drill Guide, Variable (SCZ-120-001)



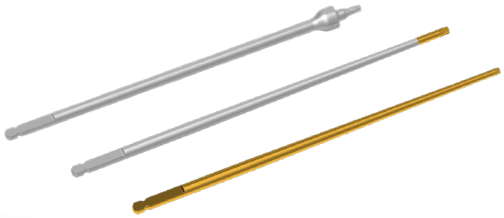
BONE TAP

Tap, Bone (SCZ-110-001)



SCREWDRIVERS

Screwdriver, Straight T10 (SCZ-117-010)
Screwdriver, Straight T8 (FCP-117-008)
Screwdriver, Ball-Joint T10 (SCZ-105-003)



RASP

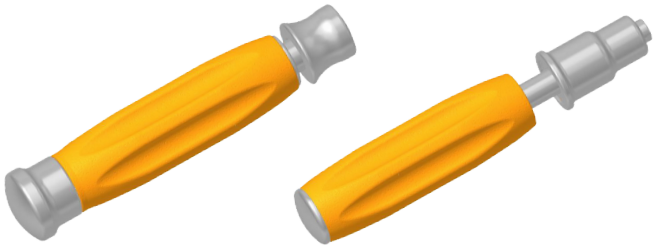
Rasp, 5mm Parallel (CS-106-122)

TAMP

Tamp, Straight (CS-107-001)

QUICK CONNECT HANDLES

Handle, Modular Driver (CY-100-009)
Handle, Torque Limiting (FCP-100-001)



APPROACH AND DISC PREPARTION

PREOPERATIVE PLANNING

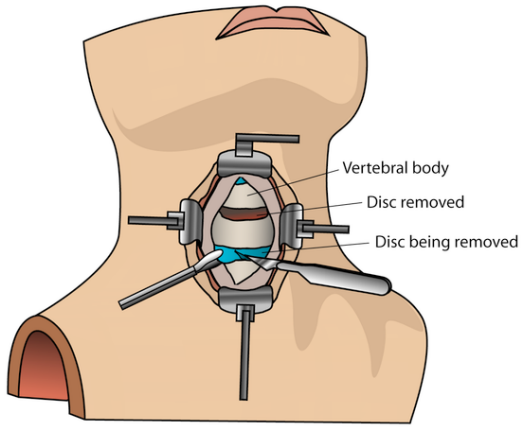
All necessary imaging studies should be available to plan implant placement and visualize patient anatomy.

DISC EXPOSURE AND PREPARATION

Expose the index level(s) through an anterior approach to the cervical spine. Standard cervical retractors should be used. Perform a discectomy, leaving the lateral annulus intact. The entry window through the anterior longitudinal ligament must be large enough to accept the SPIRA®-C Integrated Fixation System Implant. Segmental distraction may be applied by the use of a standard bone distractor as needed to gain access to the disc space.

ENDPLATE PREPARATION

Prior to trialing, the endplates may be prepared by removing disc material to expose bleeding bone. This can be achieved through the use of a Rasp (CS-106-122) in combination with curettes, and scrapers.



Anterior approach using standard cerical retractors.

IMPLANT SIZING AND TRIAL USE

Selection of the Trial depends on the dimensions of the intervertebral space. It is recommended to start with the smallest of the footprints and heights. Select from one of the available trial footprints. All Trials are designed to match the cage geometries, which all have a lordotic profile of 7 degrees. With the segment fully distracted, the Trial should fit tightly into the disc space (Figure 1). Trials are color coated per height (Figure 2).

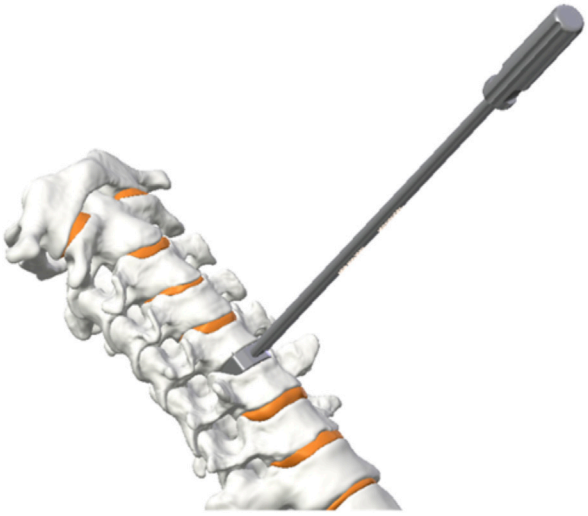


FIGURE 1

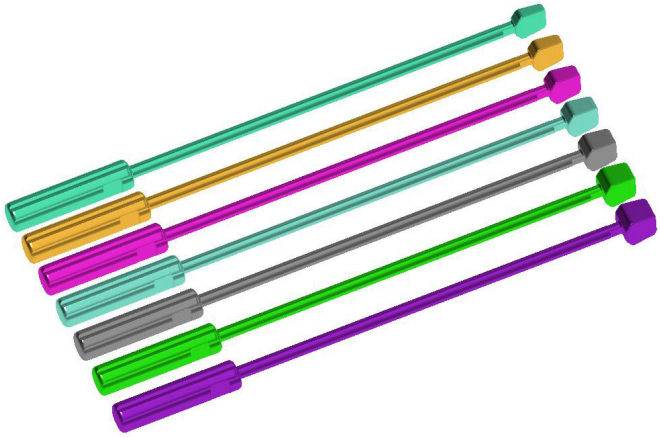


FIGURE 2

IMPLANT PREPARATION

Select the implant that corresponds to the footprint, profile and height determined by the Trial. Insert Free-Hand Jaw or appropriate DTS Jaw, and rotate proximal inserter knob until center pin aligns with black line (Figure 3). Engage the implant to the Implant Inserter Jaws by aligning the female pocket of the implant with the male profile on the Implant Inserter Jaw (Figure 4). Rotate the Proximal Inserter Knob into the implant by turning clockwise. Ensure that the implant is firmly secured to the Implant Inserter (Figure 5).

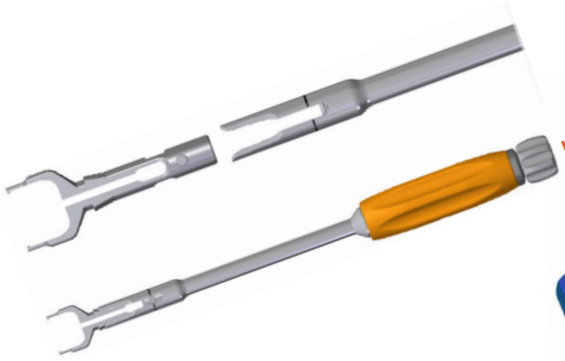


FIGURE 3

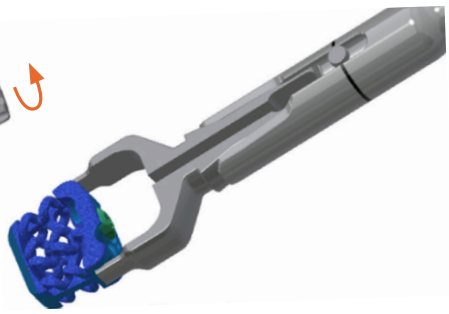


FIGURE 4

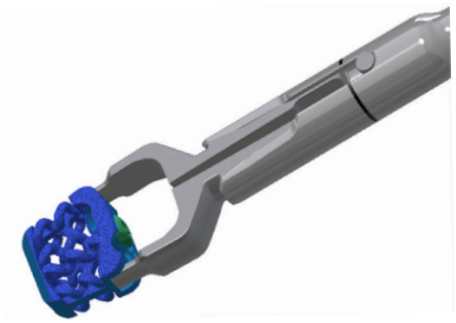


FIGURE 5

Pack the selected implant with an autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

NOTE: Exercise caution while packing the implant; the implant consists of rough titanium surfaces which may catch the handler's gloves. Insert the implant into the distracted disc space. Turn the knob counterclockwise to release the implant from the Implant Inserter. Verify final implant position relative to the vertebral bodies in the AP and lateral direction under fluoroscopy.

SCREW SELECTION AND PREPARATION

Complete the procedure by following one of the four options below for screw selection and insertion.

FREE-HAND WITH AWL TECHNIQUE

1. The Awl (SCZ-106-001 or 002) has a variable angle tip, to punch a hole through the end plate at the desired angulation. The black chevrons on the awl signifies the side with the high, sharp tip to pierce the endplates. The awl pierces through the endplates 10mm (Figures 6 & 7).
2. The implant inserter can either be connected, or disconnected to the implant at this time based on surgeon preference (Figures 5 & 6).

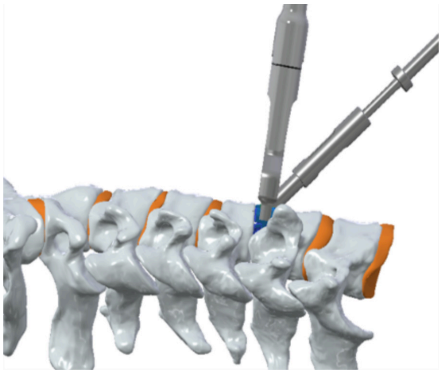


FIGURE 5

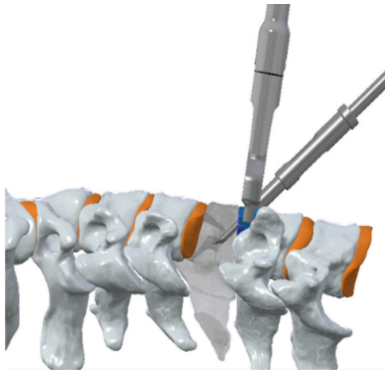


FIGURE 6

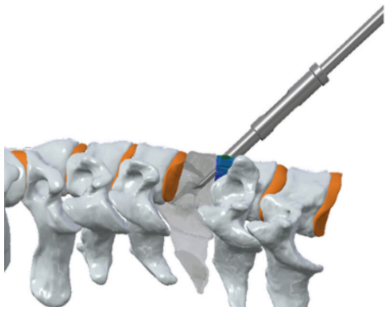


FIGURE 7

DTS WITH AWL TECHNIQUE

1. The awl can be used with the DTS guide as well, for a fixed angle delivery (Figures 8 & 9)

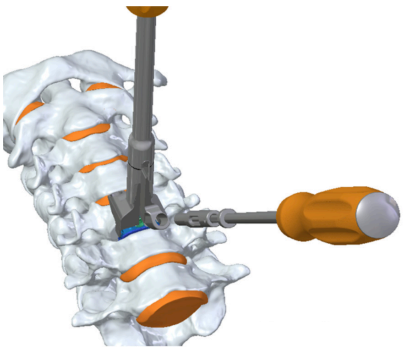


FIGURE 8

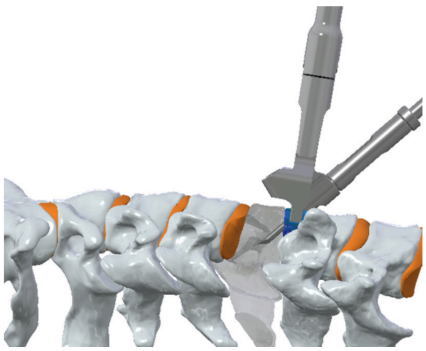


FIGURE 9

FREE-HAND AND DTS DRILL TECHNIQUE

1. The drill guide can be used in variable angle, or with the DTS guide for a fixed angle (Figures 10 & 11).
2. Determine the appropriate screw length based on patient anatomy. The drill bits are labeled to match the available screw lengths and must be used with a drill guide to prevent drilling deeper than intended. Connect the corresponding drill bit to the Mini Quick Connect Swivel Handle. Drill a hole through the previously selected drill guide, and into the vertebral body until the shoulder of the drill bit contacts the drill guide. Repeat as necessary for each hole. Remove the drill and drill guide.

FIGURE 10

FIGURE 11

SCREW INSERTION

DTS SCREW TECHNIQUE

1. The DTS guide will allow you to deliver the screw at a fixed angle (Figure 12)

FREE-HAND SCREW TECHNIQUE

1. The screw can also be delivered free-hand with a straight or ball-socket driver (Figures 13 & 14)

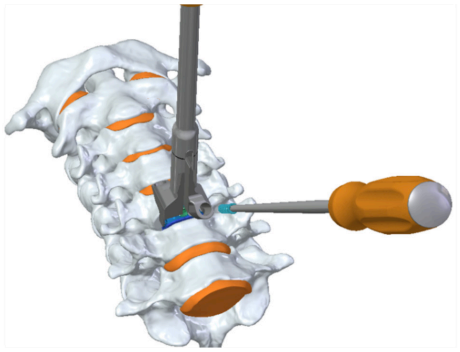


FIGURE 12

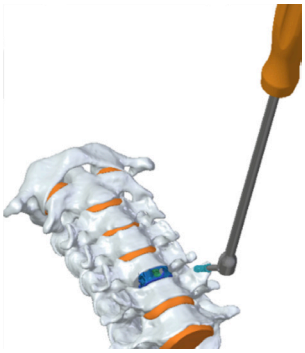


FIGURE 13

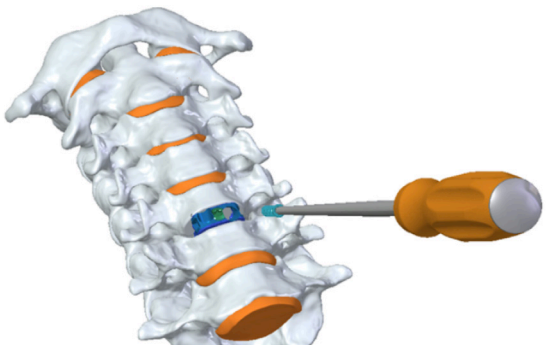


FIGURE 14

FINAL BLOCKING SCREW

1. Connect the straight T8 screwdriver (FCP-117-008) to the torque limiting quick connect handle (FCP-100-001) to rotate the center blocking screw 90° clockwise to block the bone screws (Figure 15).

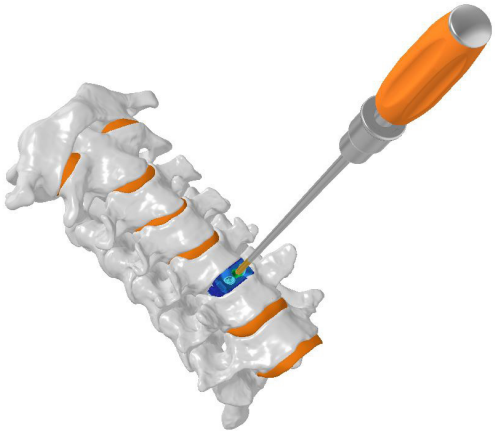


FIGURE 15

SET CONTENTS

IMPLANTS

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SCZ-1314-0706	13mm x 14mm, 7° Lordotic, 6mm	3
SCZ-1314-0707	13mm x 14mm, 7° Lordotic, 7mm	3
SCZ-1314-0708	13mm x 14mm, 7° Lordotic, 8mm	3
SCZ-1314-0709	13mm x 14mm, 7° Lordotic, 9mm	3
SCZ-1314-0710	13mm x 14mm, 7° Lordotic, 10mm	2
SCZ-1314-0711	13mm x 14mm, 7° Lordotic, 11mm	1
SCZ-1314-0712	13mm x 14mm, 7° Lordotic, 12mm	1
SCZ-1416-0706	14mm x 16mm, 7° Lordotic, 6mm	3
SCZ-1416-0707	14mm x 16mm, 7° Lordotic, 7mm	3
SCZ-1416-0708	14mm x 16mm, 7° Lordotic, 8mm	3
SCZ-1416-0709	14mm x 16mm, 7° Lordotic, 9mm	3
SCZ-1416-0710	14mm x 16mm, 7° Lordotic, 10mm	2
SCZ-1416-0711	14mm x 16mm, 7° Lordotic, 11mm	1
SCZ-1416-0712	14mm x 16mm, 7° Lordotic, 12mm	1
SCZ-1518-0706	15mm x 18mm, 7° Lordotic, 6mm	3
SCZ-1518-0707	15mm x 18mm, 7° Lordotic 7mm	3
SCZ-1518-0708	15mm x 18mm, 7° Lordotic, 8mm	3
SCZ-1518-0709	15mm x 18mm, 7° Lordotic, 9mm	3
SCZ-1518-0710	15mm x 18mm, 7° Lordotic 10mm	2
SCZ-1518-0711	15mm x 18mm, 7° Lordotic, 11mm	1
SCZ-1518-0712	15mm x 18mm, 7° Lordotic, 12mm	1
SCZ-3512FD	Ø3.5 mm, 12 mm length, fixed angle, self-drilling	8
SCZ-3514FD	Ø3.5 mm, 14 mm length, fixed angle, self-drilling	8
SCZ-3516FD	Ø3.5 mm, 16 mm length, fixed angle, self-drilling	8
SCZ-3518FD	Ø3.5 mm, 18 mm length, fixed angle, self-drilling	8
SCZ-4012FD	Ø4.0 mm, 12 mm length, fixed angle, self-drilling	4
SCZ-4014FD	Ø4.0 mm, 14 mm length, fixed angle, self-drilling	4
SCZ-4016FD	Ø4.0 mm, 16 mm length, fixed angle, self-drilling	4
SCZ-4018FD	Ø4.0 mm, 18 mm length, fixed angle, self-drilling	4

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SCZ-3512VD	Ø3.5 mm, 12 mm length, variable angle, self-drilling	8
SCZ-3514VD	Ø3.5 mm, 14 mm length, variable angle, self-drilling	8
SCZ-3516VD	Ø3.5 mm, 16 mm length, variable angle, self-drilling	8
SCZ-3518VD	Ø3.5 mm, 18 mm length, variable angle, self-drilling	8
SCZ-4012VD	Ø4.0 mm, 12 mm length, variable angle, self-drilling	4
SCZ-4014VD	Ø4.0 mm, 14 mm length, variable angle, self-drilling	4
SCZ-4016VD	Ø4.0 mm, 16 mm length, variable angle, self-drilling	4
SCZ-4018VD	Ø4.0 mm, 18 mm length, variable angle, self-drilling	4
SCZ-3512FT	Ø3.5 mm, 12 mm length, fixed angle, self-tapping	8
SCZ-3514FT	Ø3.5 mm, 14 mm length, fixed angle, self-tapping	8
SCZ-3516FT	Ø3.5 mm, 16 mm length, fixed angle, self-tapping	8
SCZ-3518FT	Ø3.5 mm, 18 mm length, fixed angle, self-tapping	8
SCZ-4012FT	Ø4.0 mm, 12 mm length, fixed angle, self-tapping	4
SCZ-4014FT	Ø4.0 mm, 14 mm length, fixed angle, self-tapping	4
SCZ-4016FT	Ø4.0 mm, 16 mm length, fixed angle, self-tapping	4
SCZ-4018FT	Ø4.0 mm, 18 mm length, fixed angle, self-tapping	4
SCZ-3512VT	Ø3.5 mm, 12 mm length, variable angle, self-tapping	8
SCZ-3514VT	Ø3.5 mm, 14 mm length, variable angle, self-tapping	8
SCZ-3516VT	Ø3.5 mm, 16 mm length, variable angle, self-tapping	8
SCZ-3518VT	Ø3.5 mm, 18 mm length, variable angle, self-tapping	8
SCZ-4012VT	Ø4.0 mm, 12 mm length, variable angle, self-tapping	4
SCZ-4014VT	Ø4.0 mm, 14 mm length, variable angle, self-tapping	4
SCZ-4016VT	Ø4.0 mm, 16 mm length, variable angle, self-tapping	4
SCZ-4018VT	Ø4.0 mm, 18 mm length, variable angle, self-tapping	4

INSTRUMENTS

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SCZ-103-001	Implant Inserter	2
SCZ-104-001	Inserter Tip, Streamline	1
SCZ-104-002	Inserter Tip, Streamline w/ Stops	1
SCZ-104-006	Inserter Tip, Guided 6mm	1
SCZ-104-007	Inserter Tip, Guided 7mm	1
SCZ-104-008	Inserter Tip, Guided 8mm	1
SCZ-104-009	Inserter Tip, Guided 9mm	1
SCZ-104-010	Inserter Tip, Guided 10mm	1
SCZ-104-011	Inserter Tip, Guided 11mm	1
SCZ-104-012	Inserter Tip, Guided 12mm	1
SCZ-117-010	Screwdriver, Straight T10	2
FCP-117-008	Screwdriver, Straight T8	2
SCZ-105-003	Screwdriver, Ball-Joint T10	1
SCZ-106-001	Awl, Straight Punch	1
SCZ-106-002	Awl, Curved	1
CS-107-001	Tamp, Straight	1
CS-106-122	Rasp, 5mm Parallel	1
SCZ-108-012	Drill, Straight 12mm	1
SCZ-108-014	Drill, Straight 14mm	1
SCZ-108-016	Drill, Straight 16mm	1
SCZ-108-018	Drill, Straight 18mm	1
SCZ-110-001	Tap, Bone 12mm	1
SCZ-120-001	Drill Guide, Variable	1
CY-100-009	Handle, Modular Driver	2
FCP-100-001	Handle, Torque Limiting	1
SPC-102-002	Trial, 13mm x 14mm, 7° Lordotic, 6mm	1
SPC-102-003	Trial, 13mm x 14mm, 7° Lordotic, 7mm	1
SPC-102-004	Trial, 13mm x 14mm, 7° Lordotic, 8mm	1
SPC-102-005	Trial, 13mm x 14mm, 7° Lordotic, 9mm	1
SPC-102-006	Trial, 13mm x 14mm, 7° Lordotic, 10mm	1
SPC-102-007	Trial, 13mm x 14mm, 7° Lordotic, 11mm	1
SPC-102-008	Trial, 13mm x 14mm, 7° Lordotic, 12mm	1
SPC-102-010	Trial, 14mm x 16mm, 7° Lordotic, 6mm	1

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SPC-102-013	Trial, 14mm x 16mm, 7° Lordotic, 9mm	1
SPC-102-014	Trial, 14mm x 16mm, 7° Lordotic, 10mm	1
SPC-102-015	Trial, 14mm x 16mm, 7° Lordotic, 11mm	1
SPC-102-016	Trial, 14mm x 16mm, 7° Lordotic, 12mm	1
SPC-102-018	Trial, 15mm x 18mm, 7° Lordotic, 6mm	1
SPC-102-019	Trial, 15mm x 18mm, 7° Lordotic 7mm	1
SPC-102-020	Trial, 15mm x 18mm, 7° Lordotic, 8mm	1
SPC-102-021	Trial, 15mm x 18mm, 7° Lordotic, 9mm	1
SPC-102-022	Trial, 15mm x 18mm, 7° Lordotic 10mm	1
SPC-102-023	Trial, 15mm x 18mm, 7° Lordotic, 11mm	1
SPC-102-024	Trial, 15mm x 18mm, 7° Lordotic, 12mm	1

CADDIES

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SCZ-504-002	Screw Caddy Base	1
SCZ-504-001	Inserter Jaw Caddy Base	1
SPC-502-007	Implant Caddy	1

TRAYS

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SCZ-500-002-01	Trial Tray	1
SCZ-500-002-01	Instrument Tray	1
FCP-500-003	Implant Tray	1

ADDITIONALLY AVAILABLE IMPLANTS

ITEM NUMBER	DESCRIPTION
SCZ-1620-0706	16mm x 20mm, 7° Lordotic, 6mm
SCZ-1620-0707	16mm x 20mm, 7° Lordotic, 7mm
SCZ-1620-0708	16mm x 20mm, 7° Lordotic, 8mm
SCZ-1620-0709	16mm x 20mm, 7° Lordotic, 9mm
SCZ-1620-0710	16mm x 20mm, 7° Lordotic, 10mm
SCZ-1620-0711	16mm x 20mm, 7° Lordotic, 11mm
SCZ-1620-0712	16mm x 20mm, 7° Lordotic, 12mm

ADDITIONALLY AVAILABLE TRIALS

ITEM NUMBER	DESCRIPTION	QUANTITY PER SET
SPC-102-026	Trial, 16mm x 20mm, 7° Lordotic, 6mm	1
SPC-102-027	Trial, 16mm x 20mm, 7° Lordotic 7mm	1
SPC-102-028	Trial, 16mm x 20mm, 7° Lordotic, 8mm	1
SPC-102-029	Trial, 16mm x 20mm, 7° Lordotic, 9mm	1
SPC-102-030	Trial, 16mm x 20mm, 7° Lordotic 10mm	1
SPC-102-031	Trial, 16mm x 20mm, 7° Lordotic, 11mm	1
SPC-102-032	Trial, 16mm x 20mm, 7° Lordotic, 12mm	1

NOTES

SEE INSTRUCTIONS FOR USE (IFU) FOR INDICATIONS, CONTRAINDICATIONS AND WARNINGS.

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