

CARSTEN

TRABECULAR STAND
ALONE CAGE

SURGICAL TECHNIQUE

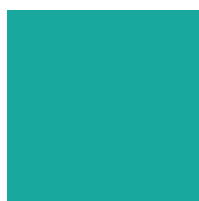
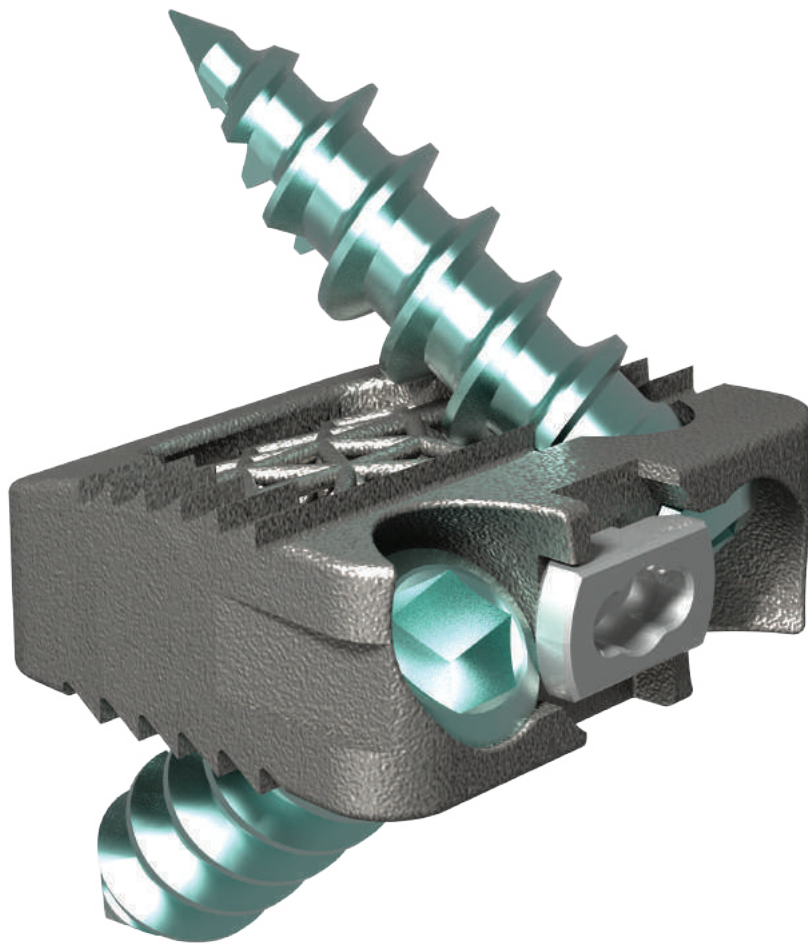




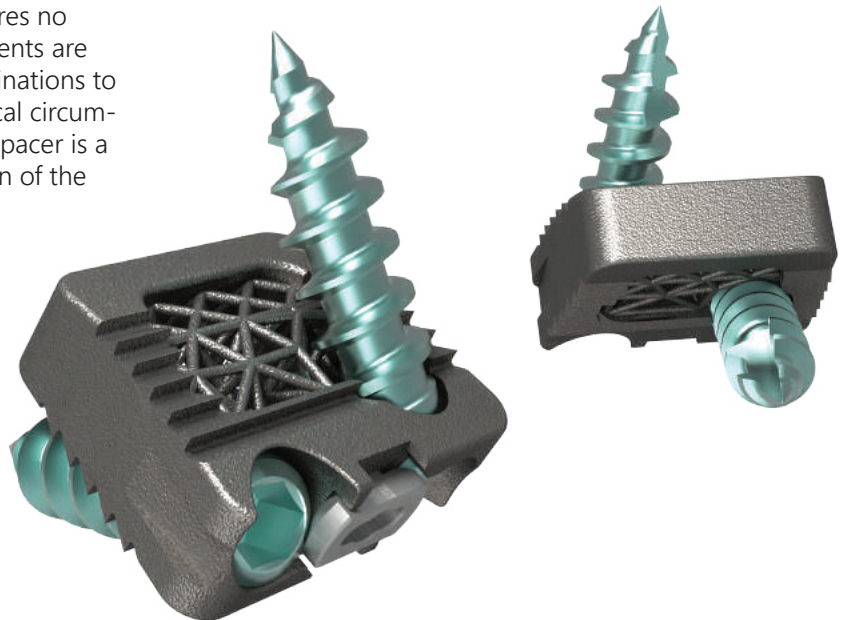
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CARSTEN TRABECULAR STAND ALONE CAGE

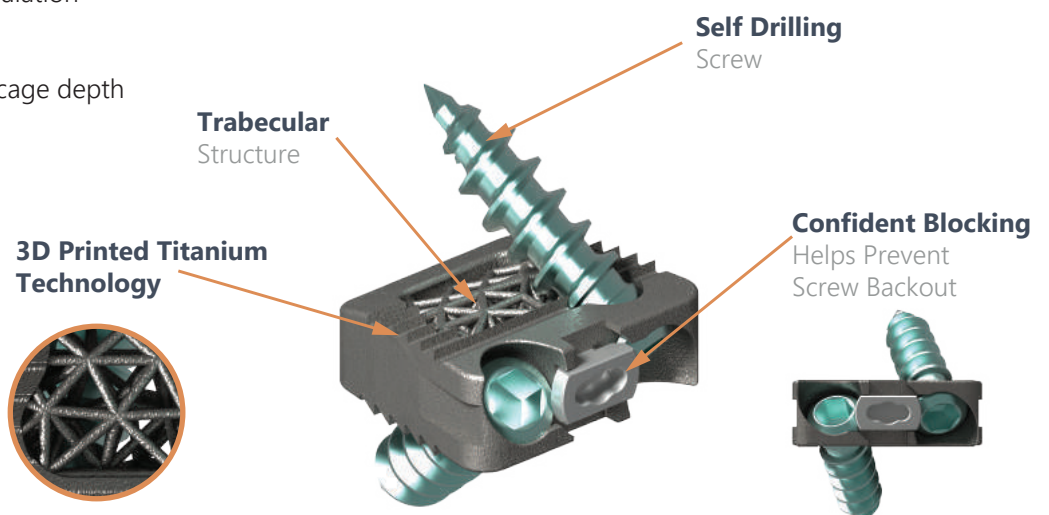
Description

Carsten Trabecular Stand Alone Cage System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). The Carsten Trabecular Stand Alone Cage System is intended to be used with the bone screw fixation provided and requires no additional fixation. The cage and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer is a structural column to provide surgical stabilization of the spine.



System Features

- Anatomical trabecular structure design
- Carsten 3D printed titanium technology Titanium Alloy (Ti-6Al-4V-ELI)
- 40° Cephalad / Caudal screw angulation
- 12.5° Medial screw convergence
- One-Step turn lock
- Screw length designed to match cage depth



INDICATIONS FOR USE

Indications

The Carsten Stand Alone Cage System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease. These patients should have received at least six weeks of non-operative treatment prior to treatment with the cage.

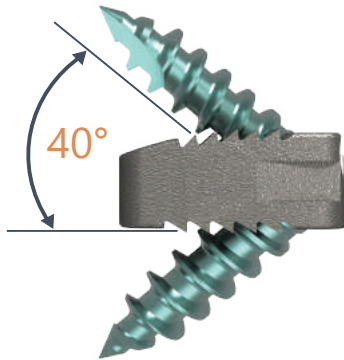
Contraindications

Carsten Stand Alone Cage System contraindications include, but are not limited to:

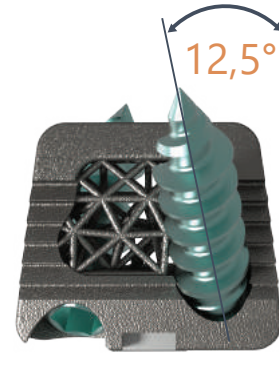
1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, morbid obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Any condition not described in the Indications for Use.
4. Prior fusion at the level(s) to be treated.

IMPLANT OVERVIEW

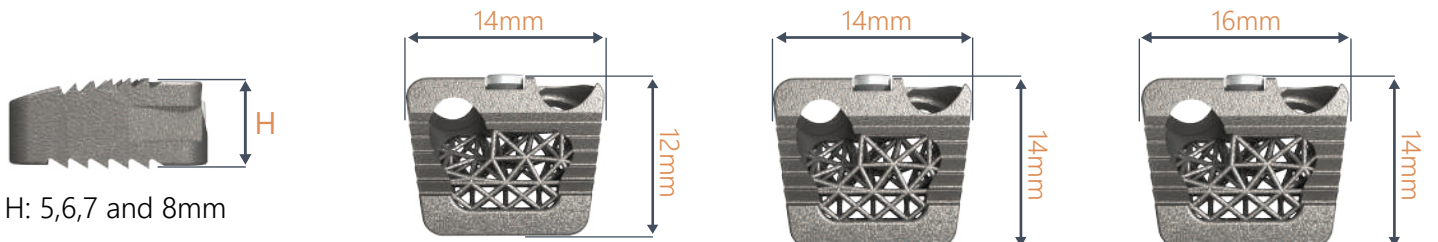
Cephalad / Caudal Angulation



Medial Angulation

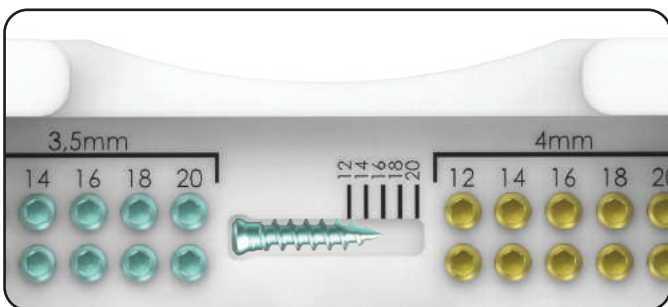
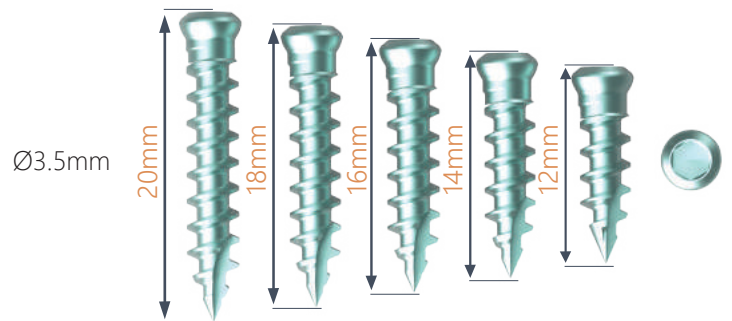


CAGE SPECS

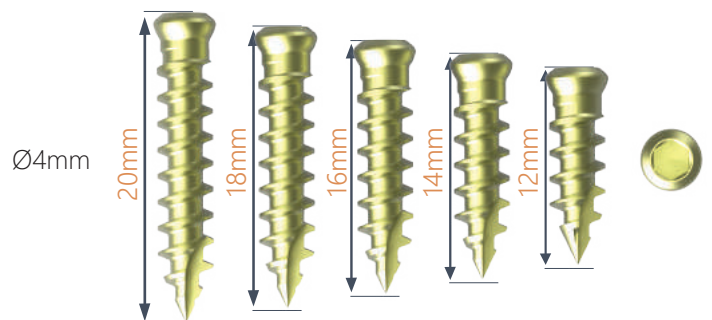


SCREW SPECS

- Screw length designed to match cage depth
- Titanium Alloy (Ti-6Al-4V-ELI) per ASTM F136
- Ø3.5 and Ø4.0mm
- 12mm, 14mm, 16mm, 18mm and 20mm Lengths
- Screw lengths are measured from the anterior to posterior of the footprint.
- Self drilling screw



Screw Length Gauge



PATIENT POSITIONING

STEP 1

- Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension. The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis (Figure 1a).

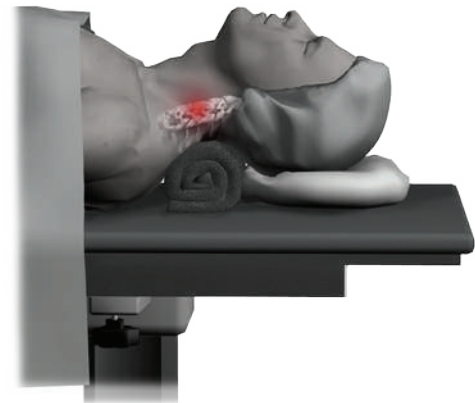


Figure 1a



Figure 1b

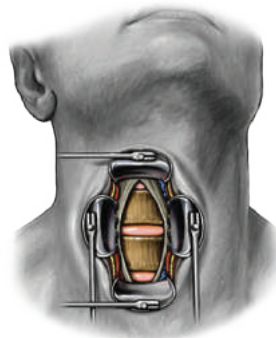


Figure 1c



Figure 1d

Exposure of Operative Levels

- Access the operative site and retract the tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Insert a marker into the disc and confirm the correct operative level using a lateral radiograph (Figure 1b-1c).

Discectomy

- Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression. The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements (Figure 1d).

CASPAR PIN PLACEMENT

STEP 2

Distraction may be accomplished using the **Caspar Retractor (CPC009)** available in this system or other standard methods. To use the **Caspar Retractor (CPC009)**, determine pin placement within the vertebral bodies. Select the appropriate pin length and place the **Caspar Pins (NPC013)** into adjacent vertebral bodies using the **Pin Holder (CPC008)** (Figure 2a). Care should be taken when placing pins to avoid interference with screws, anchors, or any supplemental fixation (Figure 2b).

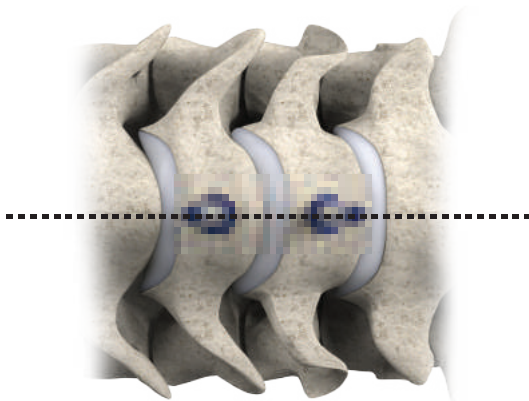


Figure 2b

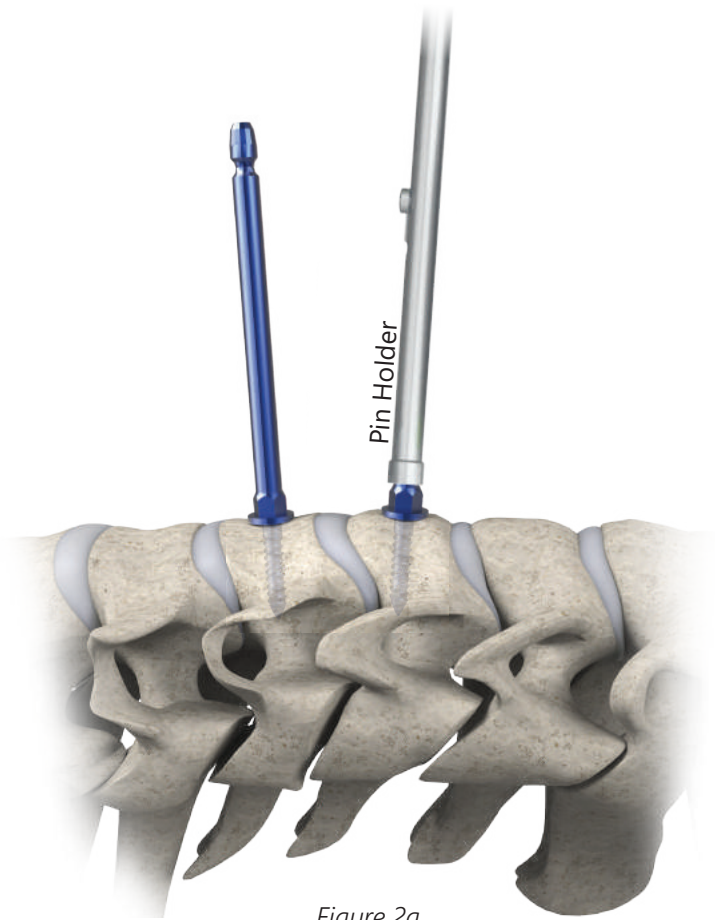


Figure 2a



Pin Holder

CASPAR RETRACTOR PLACEMENT

STEP 3

Place the **Caspar Retractor (CPC009)**, right or left as desired, over pins until seated. Once seated, secure the **Caspar Retractor (CPC009)** in place by attaching the **Caspar Retractor (CPC009)** Locking Nuts and rotating clockwise until secure. Rotate the ratchet handle to distract to the desired amount, being careful not to overdistract the segment.

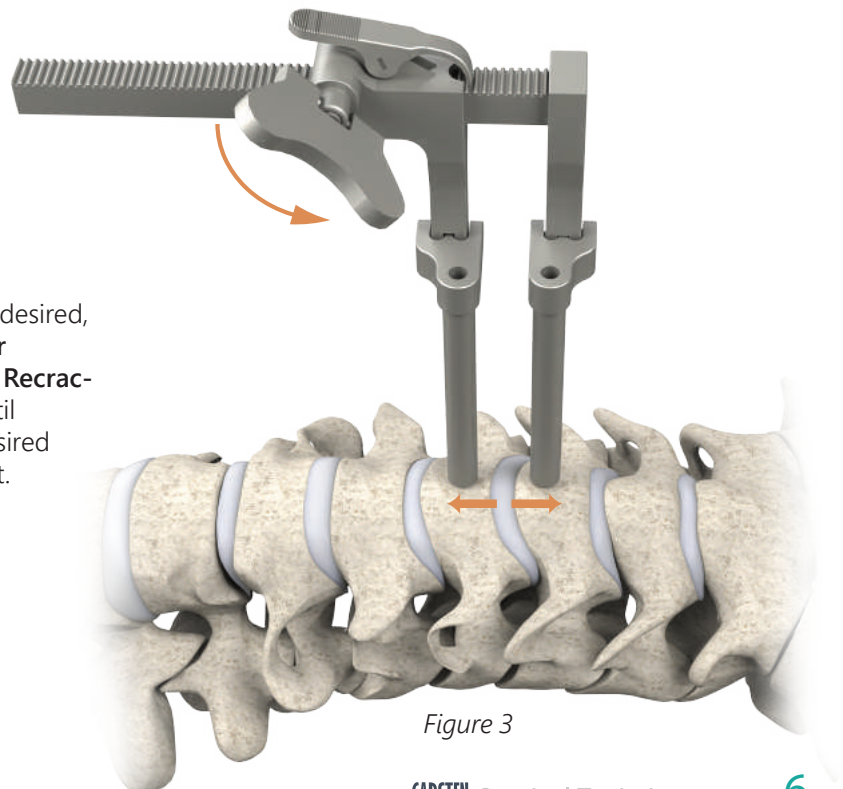
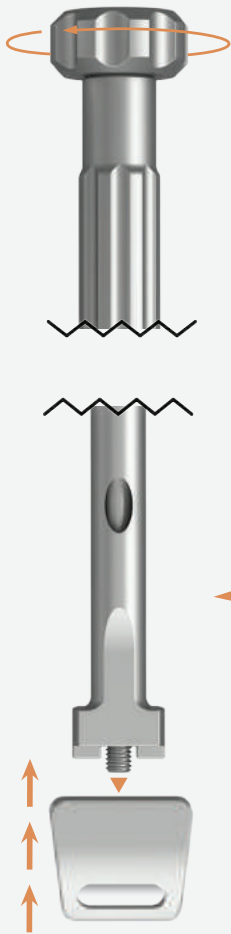
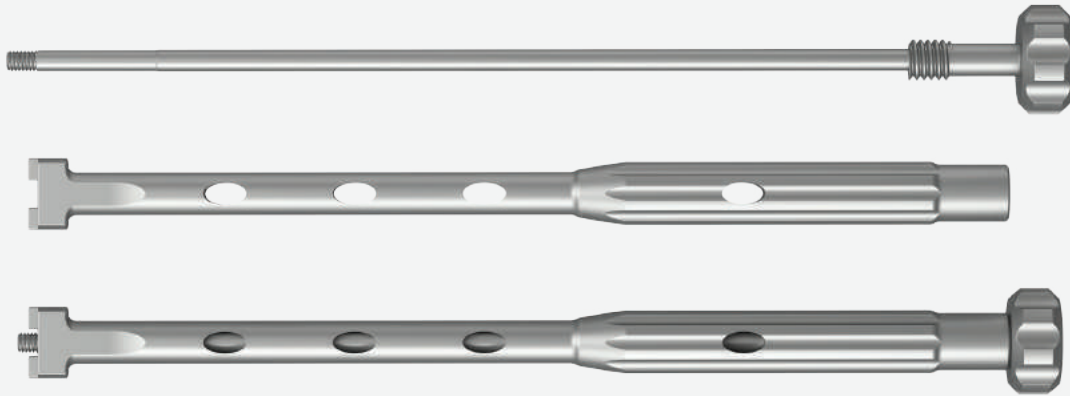
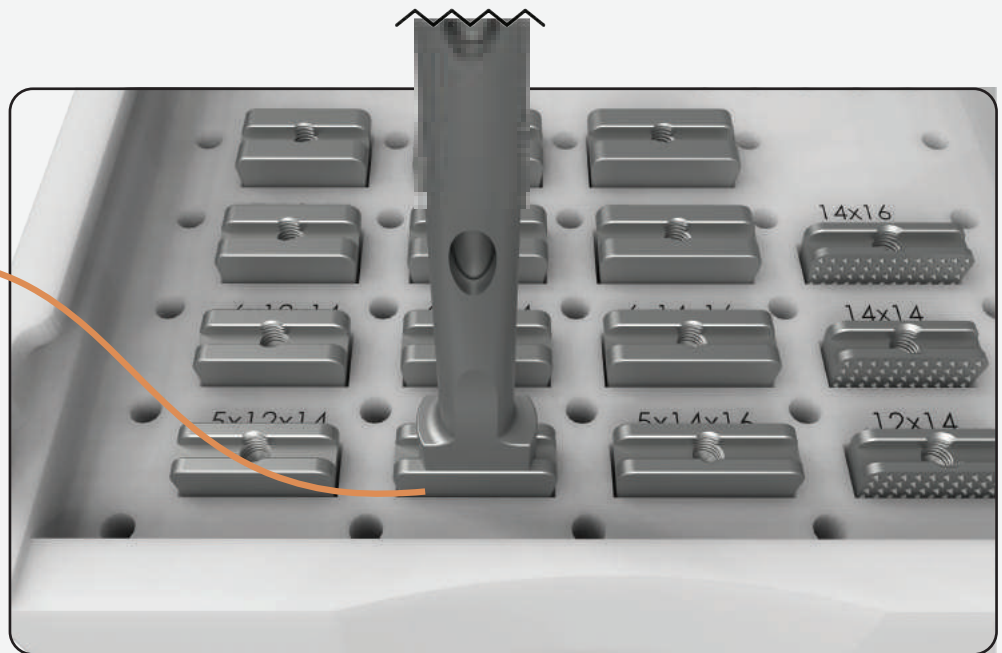


Figure 3

Using the Trial and Reamer Holder System



- The **Reamer & Trial Holder (TSAC019)** is provided in two parts.
- To load **Trial or Reamer** on the **Reamer & Trial Holder (TSAC019)**, insert the tip of the holder into the notch in the appropriate trial or reamer head and rotate clockwise, as shown below.



END CAGE PREPARATION

STEP 4

Discectomy

Reamer is included standard in the surgical set to remove the superficial layer on the endplates. This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected Cage.

Note: Excessive removal of bone during endplate preparation may weaken the bone, leading to subsidence and/or segmental instability.

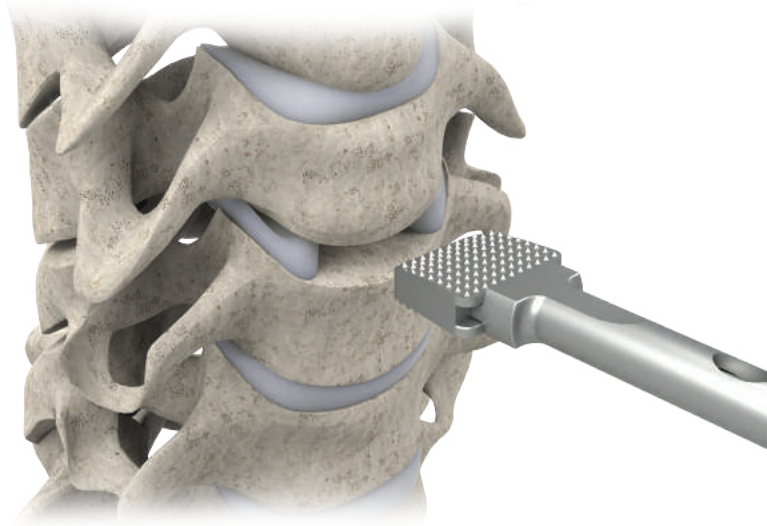


Figure 4a

Trialing

Determine the appropriate spacer profile for the desired segment. Insert the smallest Trial into the disc space first, moving to larger trials as needed. Determine which trial best fits the prepared disc space (Figure 4b). A secure fit is desirable in order to maintain disc height and stabilize the segment. This can be confirmed using fluoroscopy and tactile feedback. Undersized implants lead to increased risk of implant subsidence.

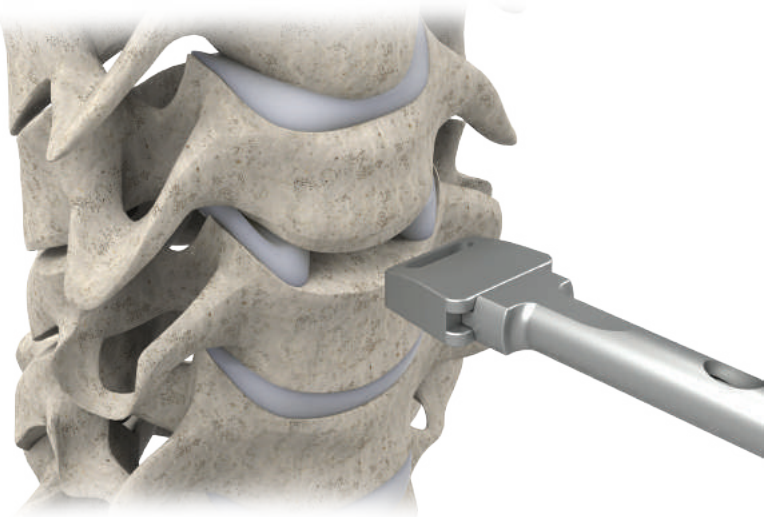


Figure 4c

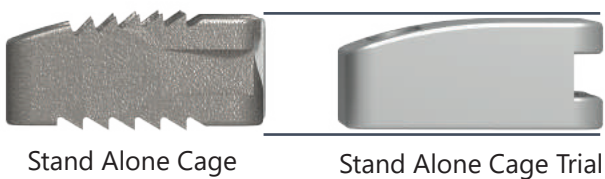
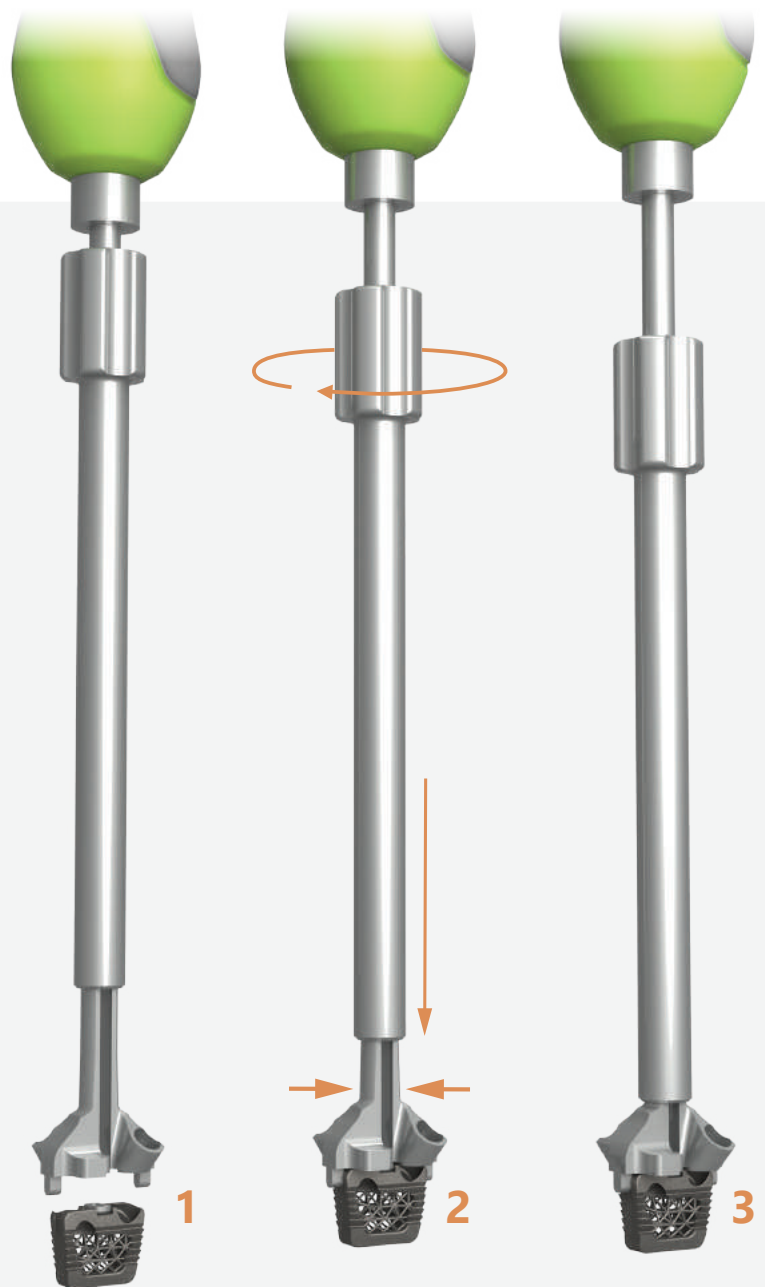
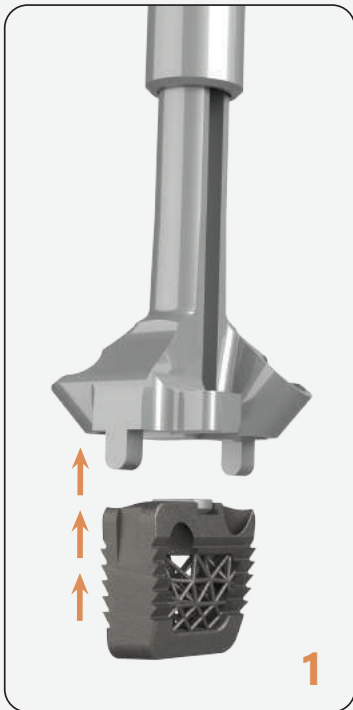


Figure 4b

Using the Combi Guide System

To load cage on the **Combi Guide (TSAC010)**, insert the tip of the holder into the notch in the appropriate cage (1) and rotate clockwise (2), as shown below.



CAGE INSERTION

STEP 5

- Attach the cage to the **Combi Guide (TSAC010)**. Insert the spacer into the intervertebral space. A **Hammer (CPC011)** may be used to gently position the cage within the disc space (Figure 5a-5b).
- The anterior face of the cage should be flush with the anterior portion of the vertebral bodies.

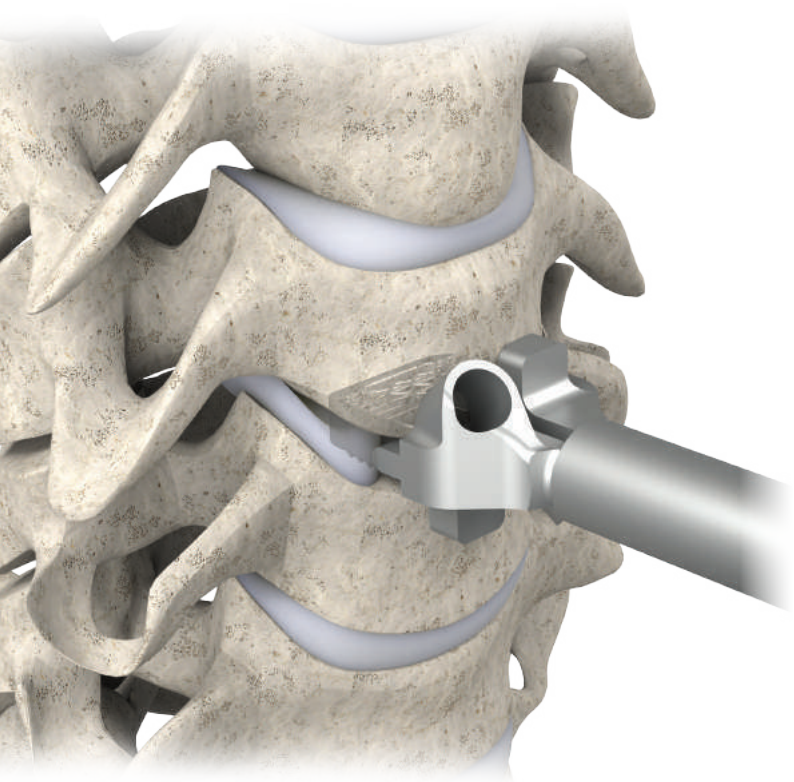


Figure 5a



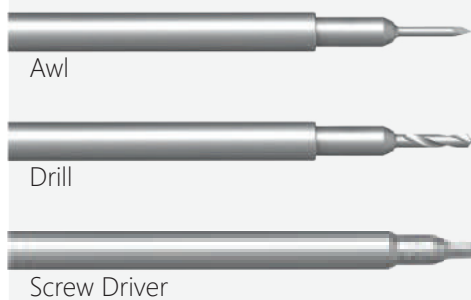
Figure 5b

Hole Prep + Screw Insertion Instruments

There are two styles of Hole Preparation and Screw insertion Instruments: Straight and Jointed to accommodate surgeon preference. These styles can be used interchangeably.

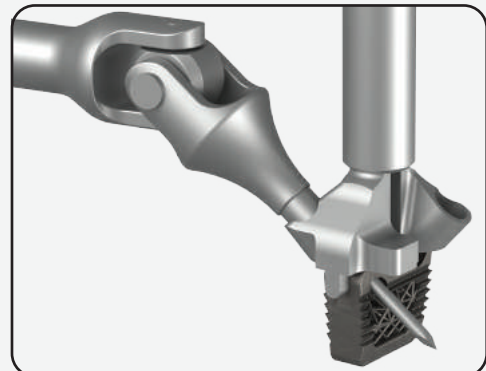
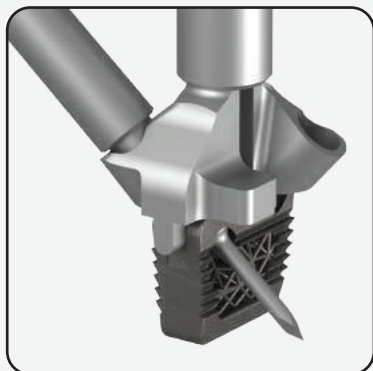
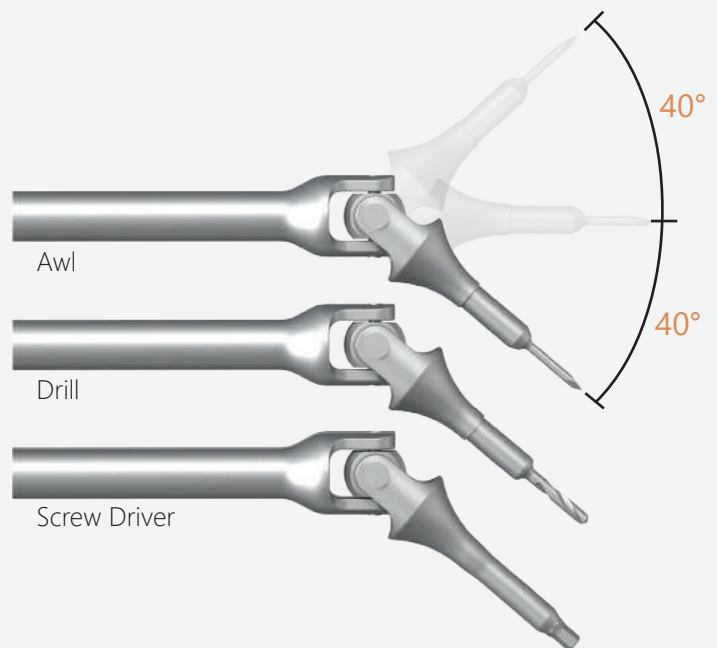
Option 1: STRAIGHT

- Straight instrumentation includes the **Straight Awl (TSAC011)**, **Straight Drill (TSAC012)** and **Straight Screw Driver (TSAC014)** (Figure 6a)



Option 2: JOINTED

- Jointed instrumentation includes the **Jointed Awl (TSAC015)**, **Jointed Drill (TSAC016)** and **Jointed Screw Driver (TSAC018)** (Figure 6b)
- Jointed instruments have a 360° radial range and allow for 40° of angulation (Figure 6c).
- Jointed instruments feature "friction - fit" position retention.



HOLE PREPARATION

STEP 6

Begin the pilot hole with the desired hole preparation instrument(s) based on surgeon preference. Penetrate the cortex with the chosen instrument (Figure 7). Repeat for the second pilot hole.

Note: Jointed Drill (TSAC016) is shown.

Note: All hole preparation instruments are designed such that the pilot hole does not extend past the posterior face of the Cage.

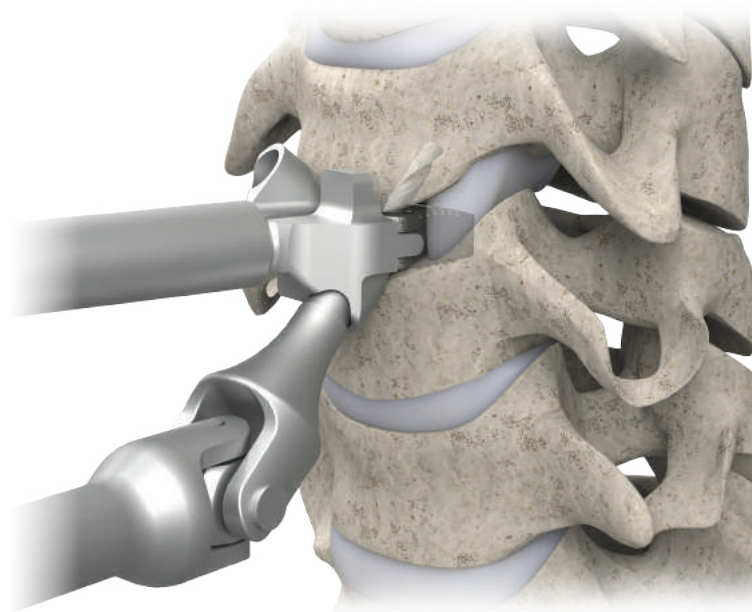


Figure 7

SCREW INSERTION

STEP 7

- Screws are color-coded by diameter.
- Guide the Screw into the pilot hole and thread until fully seated. Ensure Screw is concentrically centered in Screw Pocket and aligned correctly (Figure 8).
- Verify Screw placement and angulation via intraoperative imaging. Repeat the above steps for implanting the second Screw.
- After completing the screw placement, remove the Combi Guide from the cage by turning it counterclockwise.

Note: Straight Screw Driver (TSAC014) is shown.

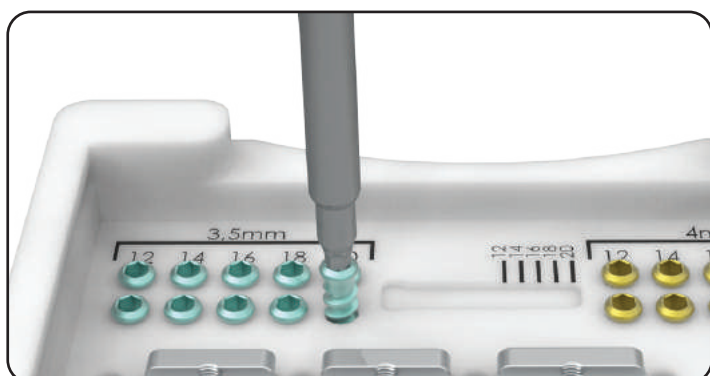
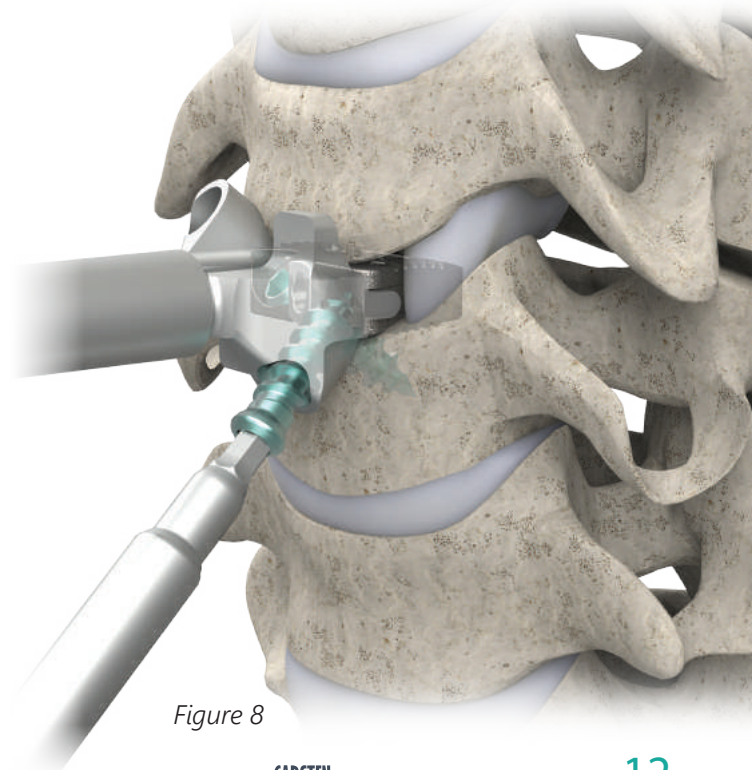


Figure 8



FINAL LOCKING

STEP 8

Ensure that both screws are fully seated and underneath the locking mechanism. 90° Clockwise turn the locking mechanism to the secured position using the **Locker Driver (TSAC021)** (Figure 9a-9b).

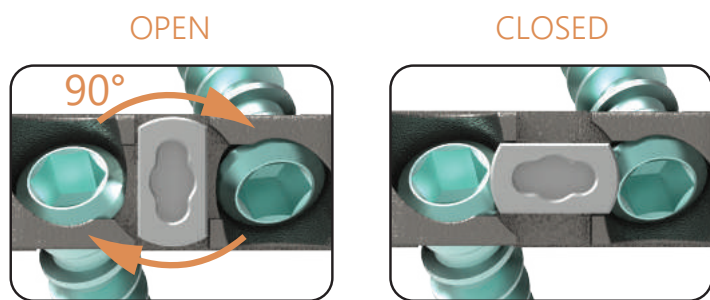


Figure 9a

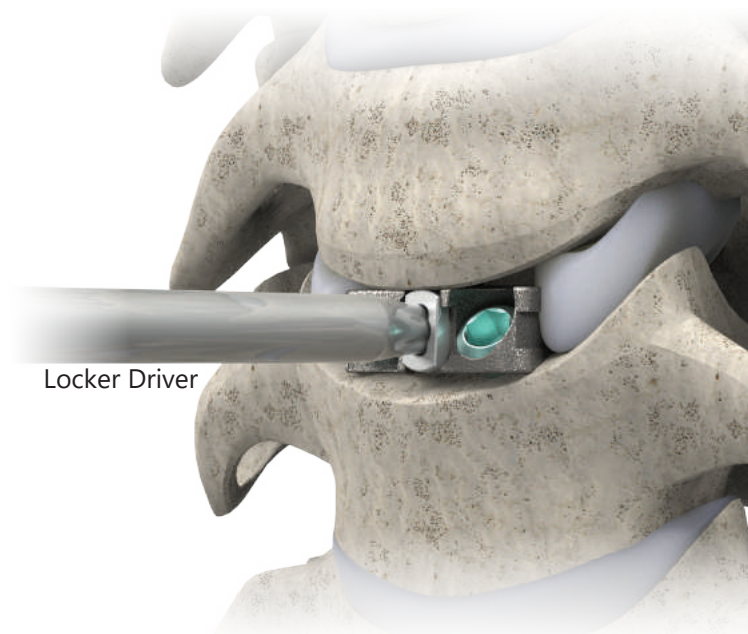


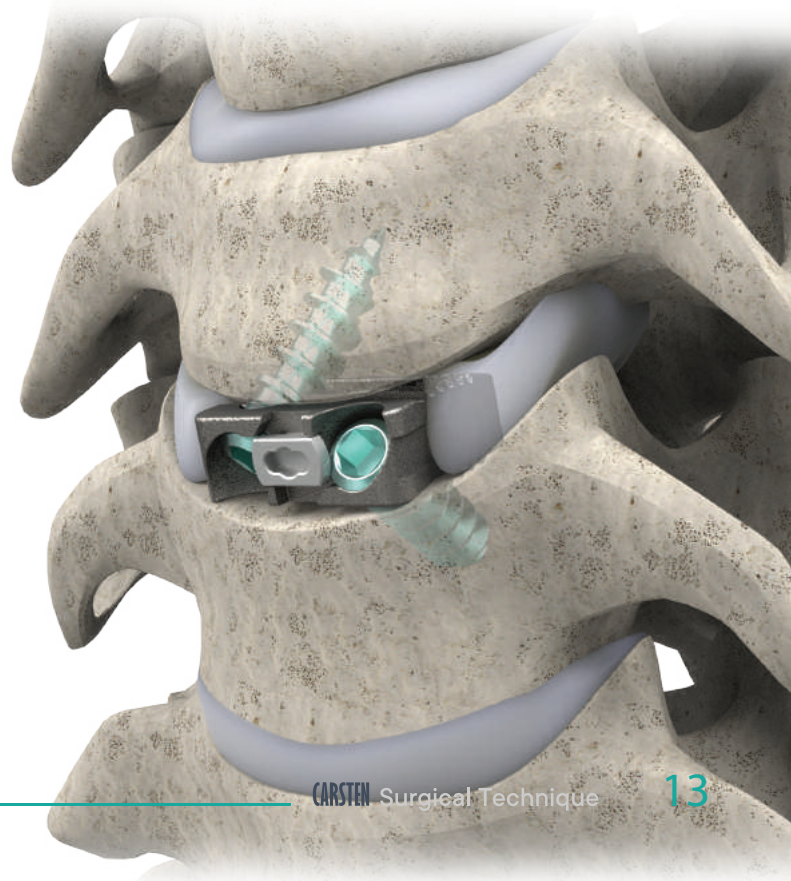
Figure 9b



Locker Driver

FINAL POSITION

Check the final position of the cage and screws both visually and radiographically. Ensure that screws are flush or recessed relative to the anterior surface of the cage, covered by the locking mechanism and that the locking mechanism is in the horizontal position.



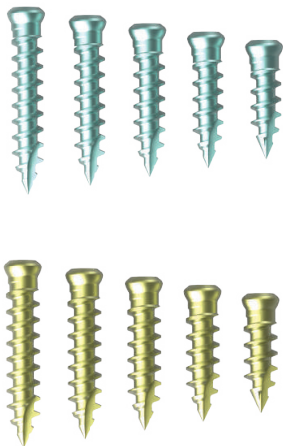
CARSTEN IMPLANT TYPES

Carsten Stand Alone Cage

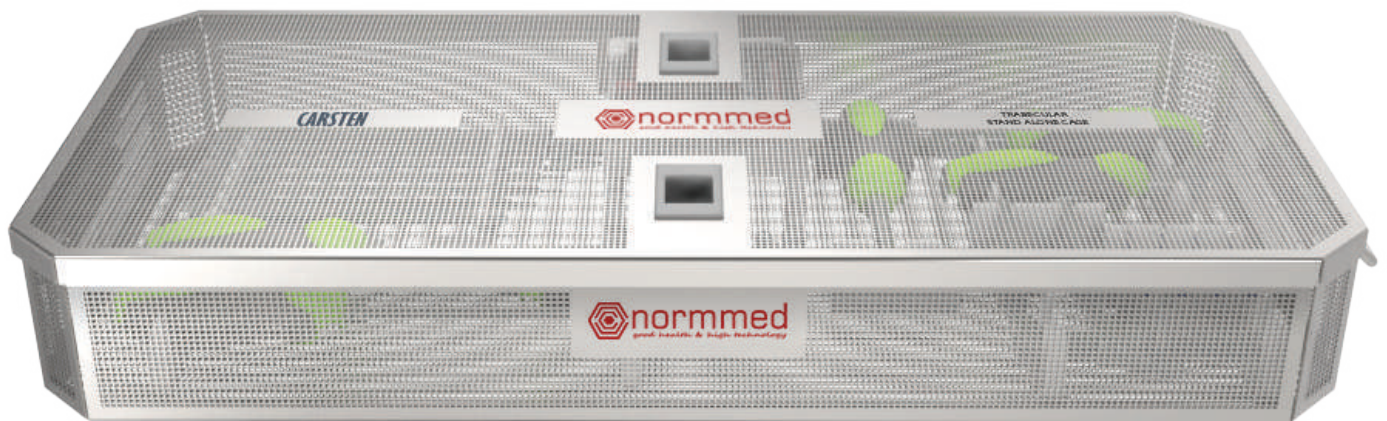


Part Number	Height (mm)	Width (mm)	Depth (mm)
NM-TTC051214	5	12	14
NM-TTC061214	6	12	14
NM-TTC071214	7	12	14
NM-TTC081214	8	12	14
NM-TTC051414	5	14	14
NM-TTC061414	6	14	14
NM-TTC071414	7	14	14
NM-TTC081414	8	14	14
NM-TTC051416	5	14	16
NM-TTC061416	6	14	16
NM-TTC071416	7	14	16
NM-TTC081416	8	14	16

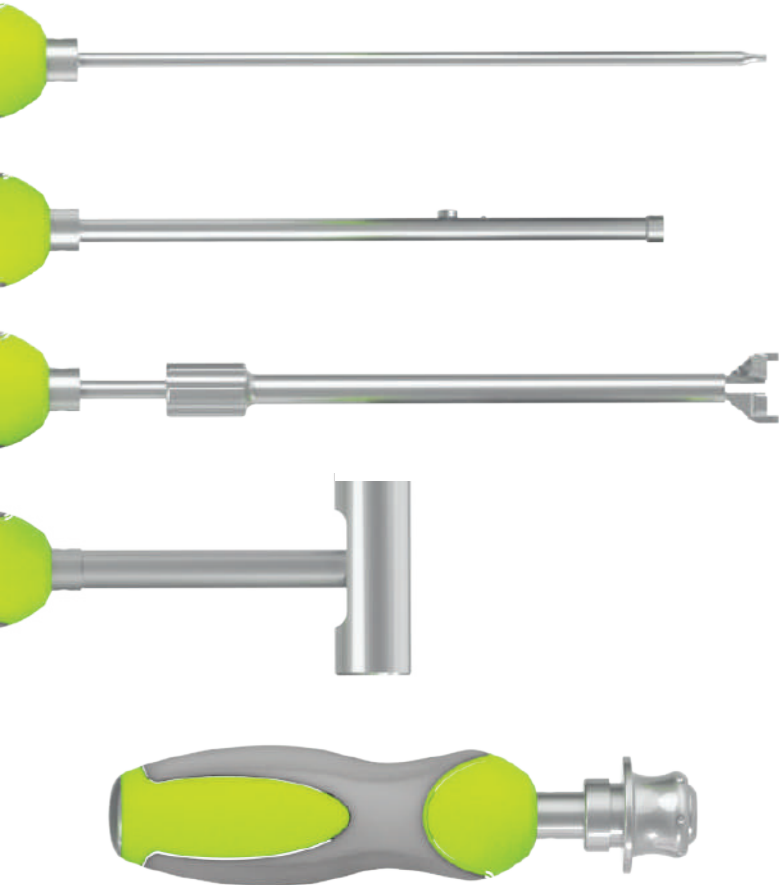
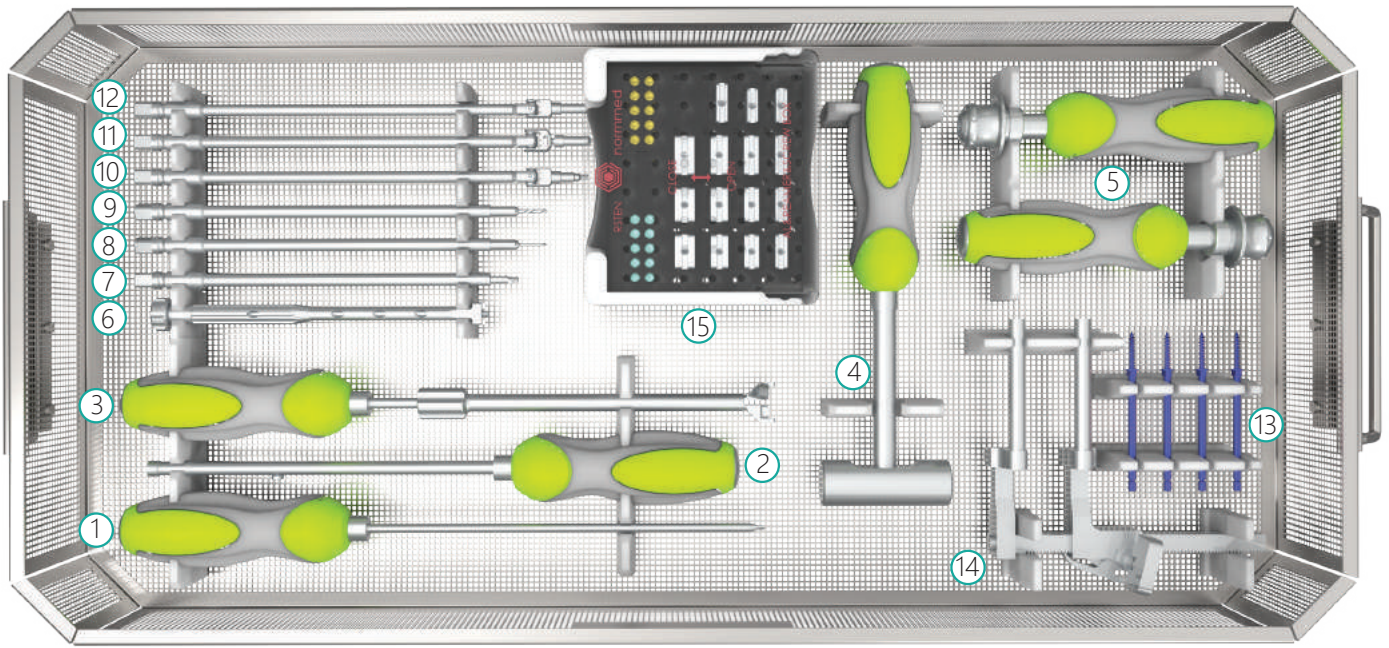
Carsten Stand Alone Cage Screw



Part Number	Diameter (mm)	Length (mm)
NCAPS12	3,5	12
NCAPS14	3,5	14
NCAPS16	3,5	16
NCAPS18	3,5	18
NCAPS20	3,5	20
NCAPSR12	4	12
NCAPSR14	4	14
NCAPSR16	4	16
NCAPSR18	4	18
NCAPSR20	4	20



- This container is made of wiremesh stainless steel. It has a high stability, low weight and good sterilization feature.

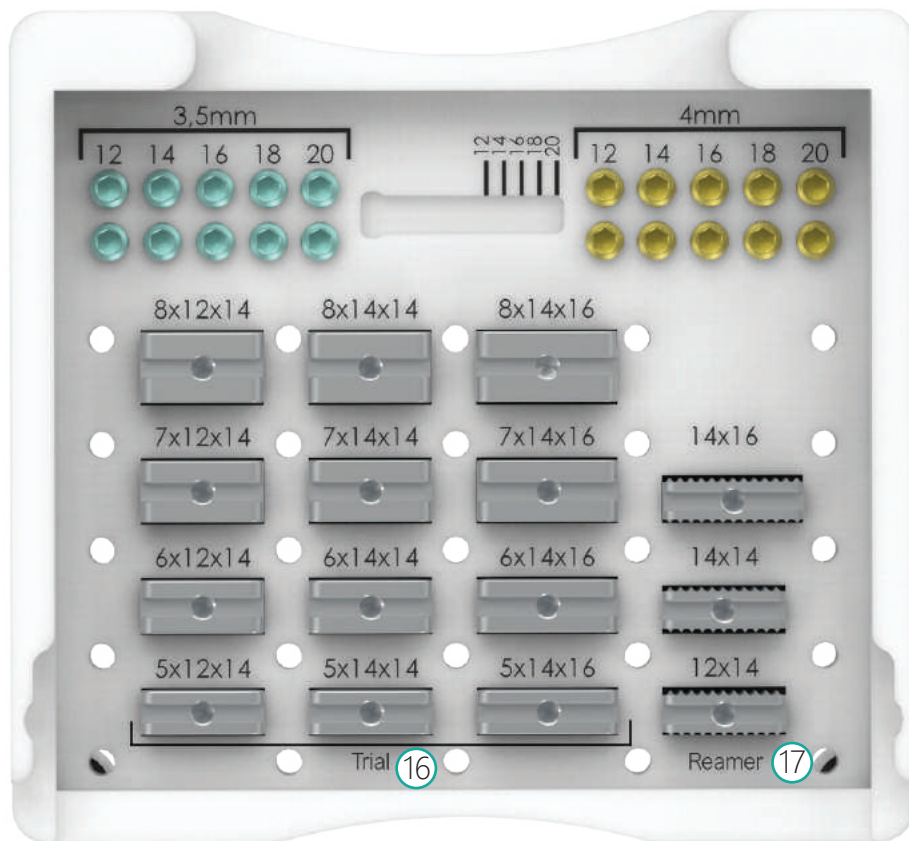


Part Number	Description
① TSAC021	Locker Driver
② CPC008	Pin Holder
③ TSAC010	Combi Guide
④ CPC011	Hammer
⑤ TSAC020	I Handle



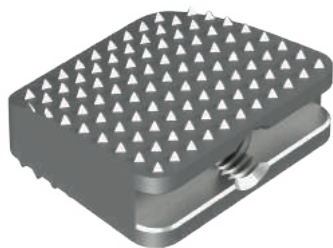
- ⑥ TSAC019 Reamer & Trial Holder
- ⑦ TSAC016 Jointed Drill
- ⑧ TSAC015 Jointed Awl
- ⑨ TSAC018 Jointed Screw Driver
- ⑩ TSAC012 Straight Drill
- ⑪ TSAC011 Straight Awl
- ⑫ TSAC014 Straight Screw Driver
- ⑬ NCP013 Pin 14mm

- ⑭ CPC009 Caspar Retractor



⑮ TSAC023

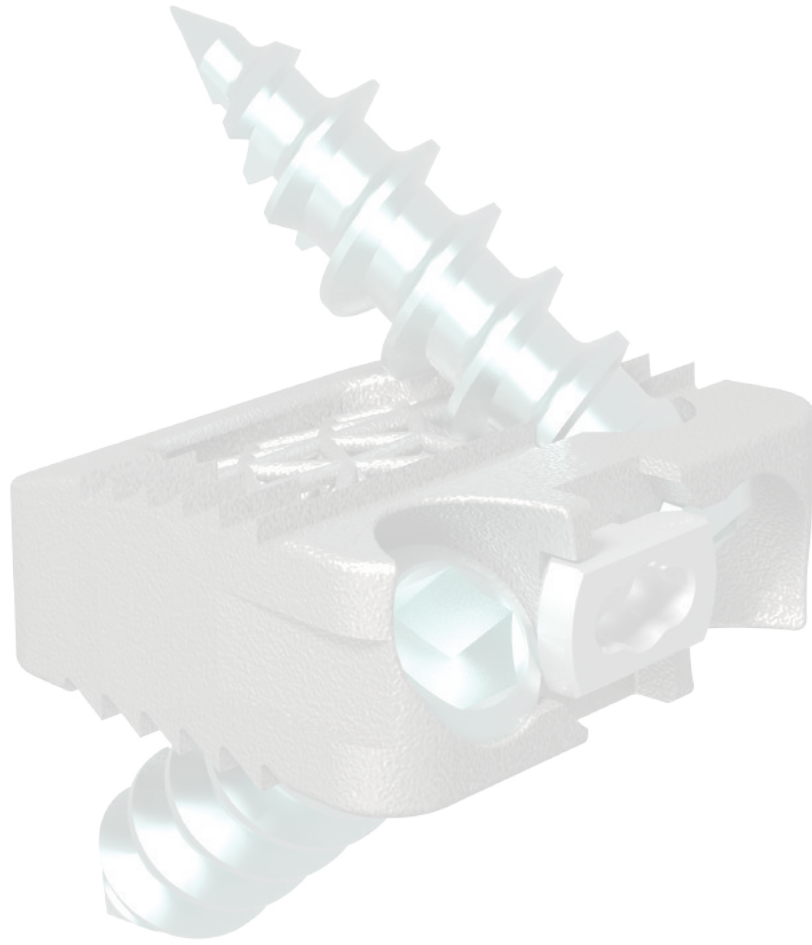
Trial&Reamer&Screw Box



Part Number

Description

⑯	TSAC027	Trial 5x12x14
	TSAC028	Trial 6x12x14
	TSAC029	Trial 7x12x14
	TSAC030	Trial 8x12x14
	TSAC035	Trial 5x14x14
	TSAC036	Trial 6x14x14
	TSAC037	Trial 7x14x14
	TSAC038	Trial 8x14x14
	TSAC039	Trial 5x14x16
	TSAC040	Trial 6x14x16
	TSAC041	Trial 7x14x16
	TSAC042	Trial 8x14x16
⑰	TSAC024	Modular Reamer 12x14
	TSAC025	Modular Reamer 14x14
	TSAC026	Modular Reamer 14x16



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