

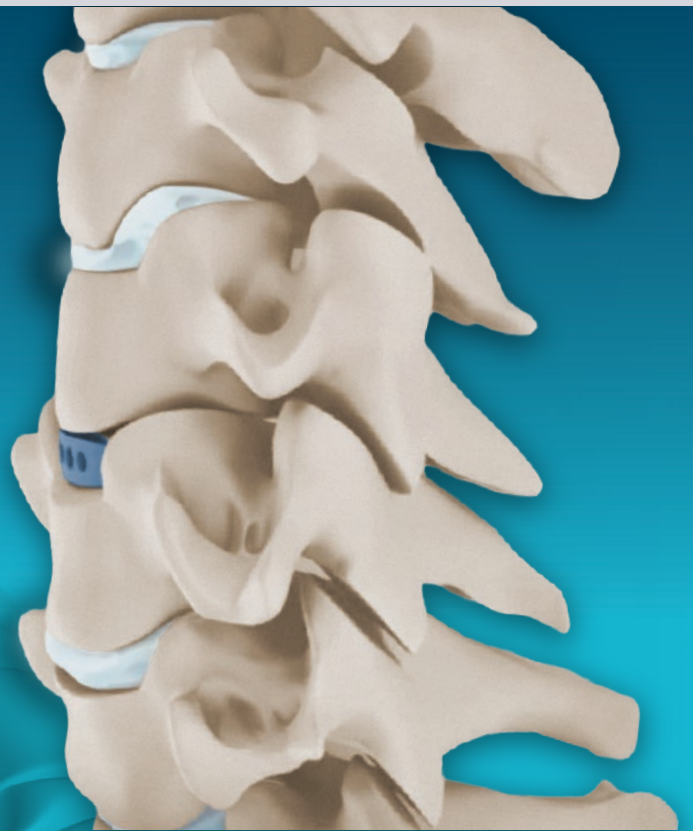
OVERFIX[®]

— SPINE —

SURGICAL TECHNIQUE

Cervical Cage

Coales C
Interbody
Fusion Cage



bioadvance

— DISPOSITIVOS MÉDICOS —



INTRODUCTION

FEATURES

PEEK Interbody Spacer

- Radiopaque marker for posterior visualization during imaging.
- Spacer component is made of pure medical grade PEEK-OPTIMA (polyetheretherketone).
- Teeth on the superior and inferior implant surfaces provide initial stability.

Titanium Alloy Plate

- Provides a secure, rigid screw locking interface.
- Stresses in the plate are decoupled from the spacer through an innovative interface.

Locking Head Screws

- Screws form a bone wedge with a $40^{\circ}\pm 5^{\circ}$ cranial/caudal angle and 2.5° medial/lateral angle.
- One-step locking screws.
- Self-tapping screw improves thread purchase.
- Trilobular thread-cutting flutes are self-centering.

INDICATIONS AND CONTRAINDICATIONS

Indications

In skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2 to T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of nonoperative treatment. The interior of the spacer component of the Zero-Profile Spacer should be packed with autogenous bone graft and implanted via an anterior approach.

Contraindications

- Use of the Zero-Profile Spacer is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
- Severe obesity or degenerative diseases are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow post-operative restrictions. These patients may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Prior fusion at the level to be treated.
- Any condition not described in the Indications for Use.

PREOPERATIVE PLANNING

Determine the surgical approach and estimate the appropriate Zero-Profile Spacer size.

Notes:

- With the segment fully distracted, the Zero-Profile Spacer must fit firmly between the end plates before locking head screws are inserted. When rocking the aiming device backward and forward in a cranial to caudal direction, no toggling of the implant should be evident.
- It is recommended to select the maximum implant size in order to optimize the stability of the segment through tension in the annulus fibrosus and longitudinal ligaments.

SURGICAL TECHNIQUE

1. INTO THE ROAD

Standard surgical approach, exposing the vertebral body to be fused, according to the indications specified. Prepare the fusion area for the operation.

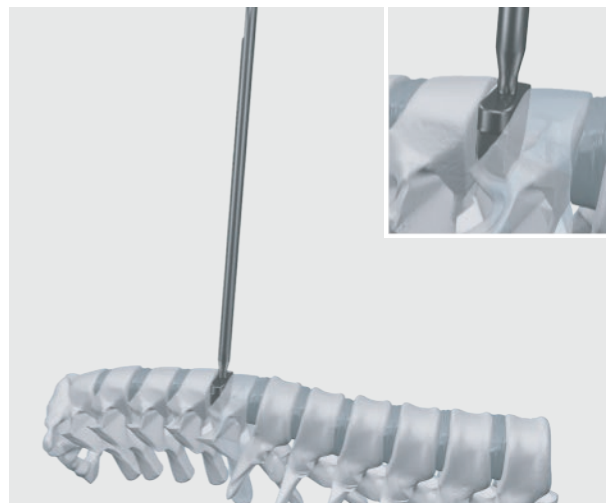


2. DETERMINE APPROPRIATE IMPLANT

551004 Trial, 4mm~551011 Trial, 11mm
551002 Impactor

Choose a parallel, lordotic or convex trial spacer of the appropriate height and depth based on the height of the intervertebral space, the preparation technique and the patient anatomy. Position the trial spacer in the correct cranial/caudal alignment and carefully insert it into the disc space.

NOTE: The trial spacers do not have a depth limiter; an image intensifier should be used to check the position during insertion. With the segment fully distracted, the trial spacer must fit tightly and accurately between the end plates. Choose the appropriate implant footprint and size to accommodate variations in patient anatomy; failure to do so may injure the patient.



3. PACK IMPLANT WITH AUTOGENOUS BONE GRAFT

551003 Bone Plugger
551025 Implant Support

Place the appropriate Zero-Profile Spacer into the packing block. Use the cancellous bone impactor to firmly pack the autogenous graft material into the implant cavity.

NOTE: To ensure optimal contact with the vertebral end plates, it is important to fill the implant until the graft material protrudes from the perforations in the spacer.



4. INSERT IMPLANT

551028 Guide For Cage 551027 Forceps
551012 Impactor, Round 551013 Impactor, Flat

Use the aiming device or implant holder to introduce the implant into the disc space. The recommended orientation is with the medial screws pointing caudally.

Using the Aiming Device

Attach the aiming device to the implant by aligning the screw holes of the implant with the retention features on the aiming device and then expanding the aiming device. Once the implant is securely attached, carefully insert the implant into the distracted segment.

If necessary, the top of the aiming device can be tapped with the mallet to advance the implant into the disc space. If distraction has been applied, release the distraction while leaving the aiming device attached to the implant.

IMPORTANT: Verify final implant position relative to the vertebral bodies in the AP and lateral direction with the help of intraoperative imaging. The PEEK spacer has a single posterior x-ray marker incorporated into the implant to enable accurate intraoperative radiographic assessment of the implant position.



5. TIGHTEN SCREWS

A. Aiming Device

551028 Guide For Cage
 551016/551017/551018
 Drill Bit With Stop, 12mm/14mm/16mm

1. Drill first pilot hole through drill and screw hole of aiming device.

Select a drill bit of appropriate stop depth. Insert the drill bit into the drill and screw hole of the aiming device and drill until the stop on the drill contacts the guide.

NOTE: When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill. Bending forces applied when the tip of the drill is engaged in the aiming device can lead to the drill breaking and potentially increased risk to the patient.



551020 Screwdriver Star, T8
 551023 Handle With Quick Coupling
 551001 Universal Wrench 551019 Locking Device
 551026 Forceps For Screw

2. Insert First Screw

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiting attachment to the screwdriver shaft and handle.

NOTE: The screws should be tightened only after all screws have been inserted.



3. Drill Remaining Pilot Holes

Select a drill bit of appropriate stop depth. Insert the drill bit into a drill hole of the aiming device and drill until the stop on the drill contacts the guide. Repeat for the remaining screw holes.



4. Insert Remaining Screws

Remove the aiming device from the implant. Load the selected screw onto the screwdriver with torque limiting attachment. The screw will self-retain to the screwdriver, however, the holding sleeve may be used for increased screw retention. Advance the screw until the head of the screw contacts the plate.

Repeat for the remaining screws.

NOTE: If the aiming device is difficult to remove, verify that the screw is advanced far enough so that the aiming device is not contacting the screw during removal.



5. Tighten Screws

To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

NOTE: If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.



B. Drill Guide and Freehand Screw

551014 Sleeve With Handle

1. Drill First Pilot Hole

Select a drill bit of appropriate length. Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction.

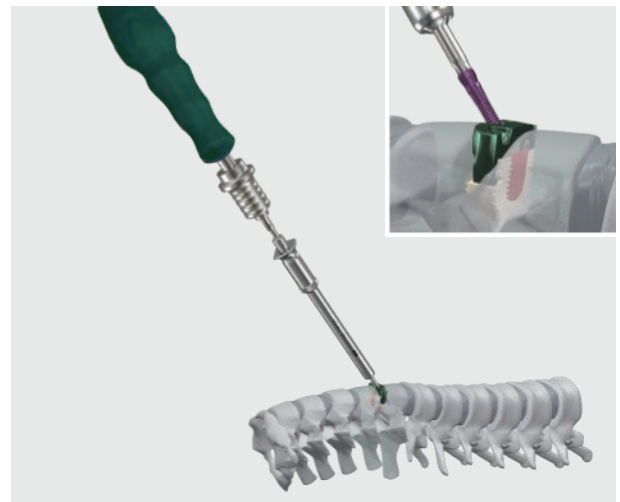
The medial screws point 2.5° laterally and the lateral screws point 2.5° medially. Insert the drill guide into the screw hole at the appropriate angle. The tip of the drill guide is designed to fit inside the screw hole of the plate and guide the correct angle. Insert the drill bit into the guide and drill until the stop on the drill contacts the guide. Remove the drill bit and guide.



2. Insert First Screw

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiting attachment to the screwdriver shaft and handle.

NOTE: The screws should be tightened only after all screws have been inserted.



3. Insert Remaining Screws

Repeat Steps B1 and B2 for the remaining screws.



4. Tighten Screws

To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

NOTE: If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.



C. Drill Guide and Freehand Screw

551015 Sleeve

1. Drill First Pilot Hole

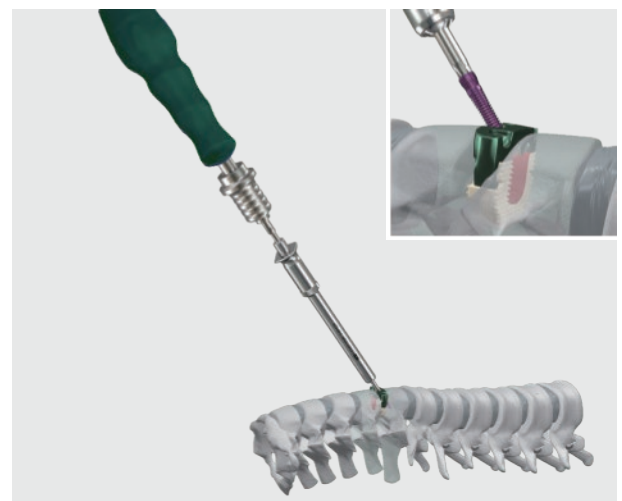
Determine the trajectory for the threaded drill guide. The correct angulations are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially. Insert the threaded drill guide into the screw hole at the appropriate angle. The tip of the drill guide fits into the screw hole of the interbody plate to produce the correct angle. The tip of the drill guide fits into the screw hole of the interbody plate to produce the correct angle. Determine a drill bit of appropriate length. Insert the drill bit into the drill guide and drill until the stop on the drill bit contacts the drill guide. Remove the drill bit and the threaded drill guide.



2. Insert First Screw

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiting attachment to the screwdriver shaft and handle.

NOTE: The screws should be tightened only after all screws have been inserted.



3. Insert Remaining Screws

Repeat Steps B1 and B2 for the remaining screws.



4. Tighten Screws

To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

NOTE: If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.



D. Awl and Freehand Screw

551022 Straight Awl

1. Awl First Pilot Hole

Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially. Insert the awl at the appropriate angle into a screw hole in the plate and push down, while simultaneously twisting the handle. Remove the awl, maintaining alignment of the hole and plate.

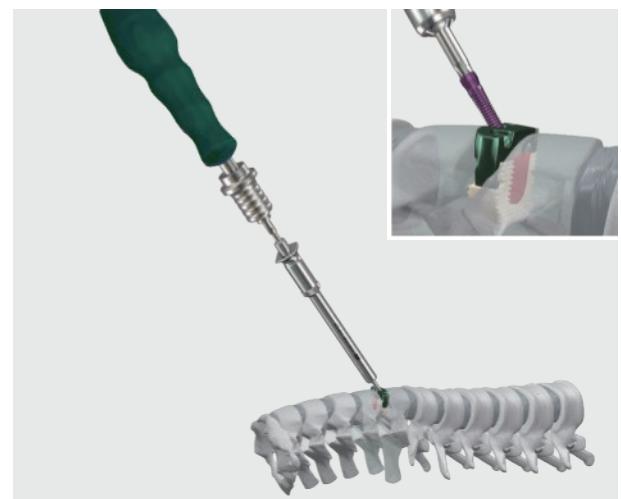
NOTE: Take care that the awl does not move the implant relative to the vertebral body. For particularly hard bone, drilling is recommended to minimize implant movement.



2. Insert First Screw

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiting attachment to the screwdriver shaft and handle.

NOTE: The screws should be tightened only after all screws have been inserted.



3. Insert Remaining Screws

Repeat Steps B1 and B2 for the remaining screws.



4. Tighten Screws

To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

NOTE: If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.



E. Angled Instruments

551021 Curved Awl

1. Awl First Pilot Hole

Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially. Insert the awl at the appropriate angle into a screw hole in the plate and tap with the slotted mallet until the awl is seated. Remove the awl, maintaining alignment of the hole and plate.

NOTE: Intraoperative imaging should be used to verify awl position.



551001 Universal Wrench

551019 Locking Device

2. Insert First Screw

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiting attachment to the screwdriver shaft and handle.



3. Insert Remaining Screws

Repeat Steps B1 and B2 for the remaining screws.




4. Tighten Screws

To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

NOTE: If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.

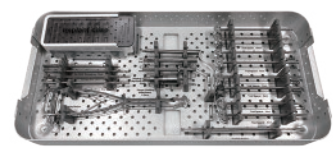
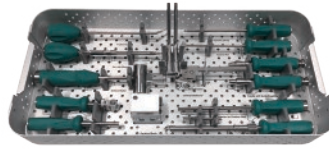


CERVICAL CAGE COALES C (4T)	CODE	SIZE	MATERIAL
	507079290	4x17.5x13.5mm	PEEK
	71500005	5x17.5x13.5mm	PEEK
	71500006	6x17.5x13.5mm	PEEK
	71500007	7x17.5x13.5mm	PEEK
	71500008	8x17.5x13.5mm	PEEK
	71500009	9x17.5x13.5mm	PEEK
	71500010	10x17.5x13.5mm	PEEK
	71500011	11x17.5x13.5mm	PEEK

LOCKING SCREW COALES (4T)	CODE	SIZE
	51563012	12mm
	51563014	14mm
	51563016	16mm
	51563018	18mm

INSTRUMENTS

550000 Zero-Profile Cervical Cage Instrument Set



551001 Universal Wrench

551002 Impactor

551003 Bone Plugger



551004 Trial,4mm

551005 Trial,5mm

551006 Trial,6mm



551007 Trial,7mm

551008 Trial,8mm

551009 Trial,9mm



CERVICAL CAGE Instruments



551010 Trial,10mm



551011 Trial,11mm



551012 Impactor, Round



551013 Impactor, Flat



551014 Sleeve With Handle



551015 Sleeve



551016 Drill Bit With Stop, 12mm



551017 Drill Bit With Stop, 14mm



551018 Drill Bit With Stop, 16mm



551019 Locking Device



551020 Screwdriver Star, T8



551021 Curved Awl



CERVICAL CAGE Instruments



551022 Straight Awl



551023 Handle With Quick Coupling



551024 Insert For Distractor Pin



551025 Implant Support



551026 Forceps For Screw



551027 Forceps



551028 Guide For Cage



551030 Cervical Distractor



551029 Position Rod



551031 Torque Limited Handle, 1.2N.m

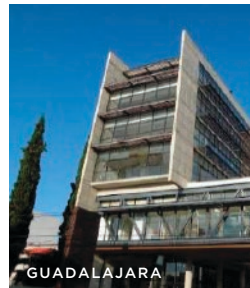


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