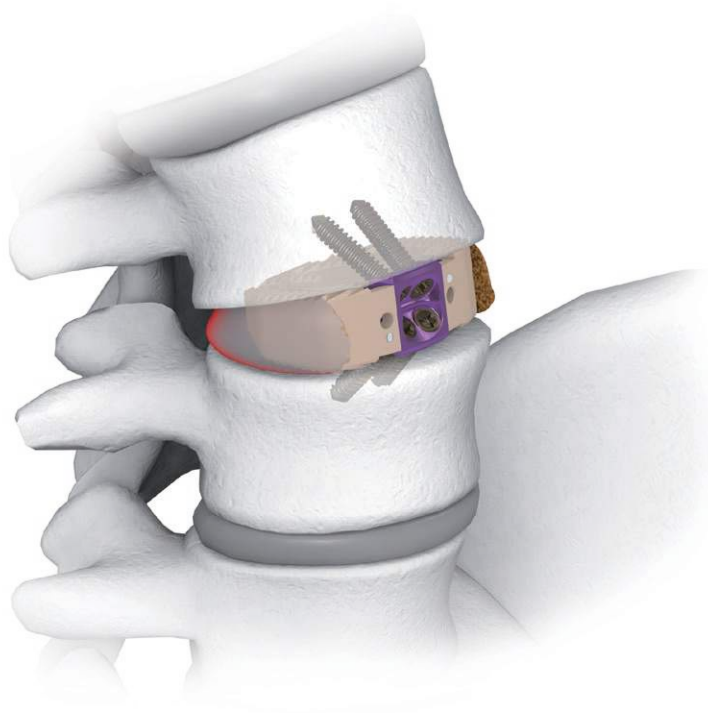




ALIF PEEK INTERVERTEBRAL LOCKING CAGES

- *IMPLANTS*
- *INSTRUMENTS 15.0905.002*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTION

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

www.chm.eu

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*The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu*

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I. INTRODUCTION

I.1. DESCRIPTION AND INDICATIONS

ALIF locking intervertebral cages are indicated for the treatment of degenerative changes and/or mechanical damage to the intervertebral discs of the lumbar spine manifested by severe pain. The pain may result from compression of the surrounding anatomical structures, including the spinal nerves, by the damaged intervertebral disc, and/or from degenerative displacement of adjacent vertebral bodies relative to one another (*spondylolisthesis*).

Implantation of an interbody cage requires complete removal of the affected intervertebral disc (*discectomy*), followed by insertion of the implant into the prepared intervertebral space. This procedure restores the appropriate intervertebral disc height, lumbar lordosis, and anatomical alignment of the adjacent vertebral bodies within the treated spinal segment.

The use of an interbody cage promotes the formation of a spinal fusion (*arthrodesis*) between the vertebral bodies adjacent to the implant. In addition, ALIF locking intervertebral cages are equipped with an integrated stabilization system designed to immobilize the adjacent vertebral bodies until spinal fusion is achieved and to prevent implant migration, without the need for supplemental anterior plate or posterior transpedicular (*screw-and-rod*) fixation.

ChM ALIF locking intervertebral cages are available in two material configurations:

- PEEK (*polymer*) – manufactured from PEEK supplemented with titanium-alloy plate as a part of the stabilization system, and radiopaque tantalum markers for implant positioning.
- 3D-Ti (*titanium alloy*) – manufactured entirely from Ti6Al4V titanium alloy using additive manufacturing (*3D printing*) technology.

Material-Specific Characteristics:

PEEK (*polymer*):

- Elastic modulus comparable to that of bone, providing favorable load transfer conditions.
- Radiolucent material, enabling accurate radiographic visualization and assessment of the developing fusion.
- Implant position is identified after implantation using integrated radiopaque tantalum markers.
- Open cage architecture maximizes the volume available for bone graft material and the formation of the fusion mass; therefore, the implant must be filled with an autologous bone graft or bone substitute.

3D-Ti (*Ti6Al4V titanium alloy*):

- Porous three-dimensional structure designed to facilitate bone ingrowth throughout the implant; the implant does not require filling with a bone graft.
- High potential for osseointegration of the implant surface with the surrounding bone structures.
- Excellent radiographic visibility, facilitating accurate intraoperative positioning of the implant.
- Increased implant contact surface area with the endplates of the adjacent vertebral bodies compared with **ChM** PEEK implants, reducing the risk of implant subsidence.

I.2. CONTRAINDICATIONS

The choice of a particular implant must be carefully considered in terms of patient's overall evaluation.

Circumstances listed below may preclude or reduce the chance of successful outcome:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity (*defined according to the WHO standards*).
- Pregnancy.
- Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
- Any other condition which would preclude the potential benefit of implant application and may disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells (*WBC*) count, or a marked left shift in the *WBC* differential count.
- Suspected or documented allergy or intolerance to implant materials. Doctor shall find out if the patient develops allergic reaction to the material of the implant.
- Any case not needing a surgical intervention.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.
- Any case where the implant components selected for use would be too large or too small to achieve the successful result.
- Any case that requires the simultaneous use of elements from different systems that are made of different metals.
- Any case in which there is inadequate tissue coverage of the operative site.
- Any case in which implant utilization would disturb physiological processes.
- Inadequate bone quality for stable implant fixation (*bone resorption, osteopenia, and/or osteoporosis*). This surgical treatment should not be used in patients with a known hereditary or acquired osteogenesis imperfecta or calcification problems.
- Any case not needing the spine immobilization.
- Significant anatomical deformity caused by congenital abnormalities.
- These implants should not be used in children and patients whose spines are still developing.
- Spondylolisthesis unable to be reduced to Grade 1.
- Prior fusion at the level to be treated.
- Blood supply limitation in the operative site.
- **CAUTION:** Implants intended for use in the lumbar spine (e.g. *PLIF, TLIF and ALIF implants*) are not intended for use in cervical spine.

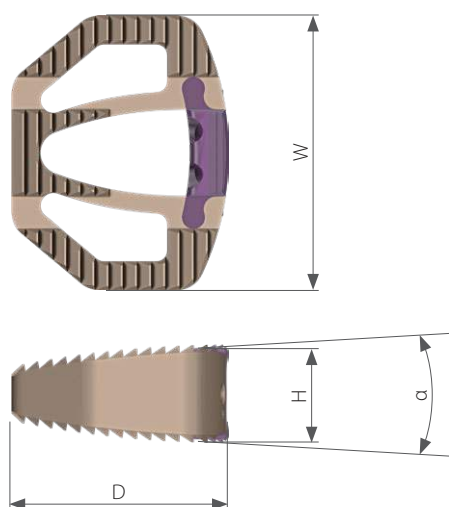
The above-mentioned list of contraindications is not exhaustive



For further information on:

- adverse effects,
 - warnings,
 - sterilization,
 - pre- and post-operative recommendations,
- please refer to the Instructions For Use for the device.

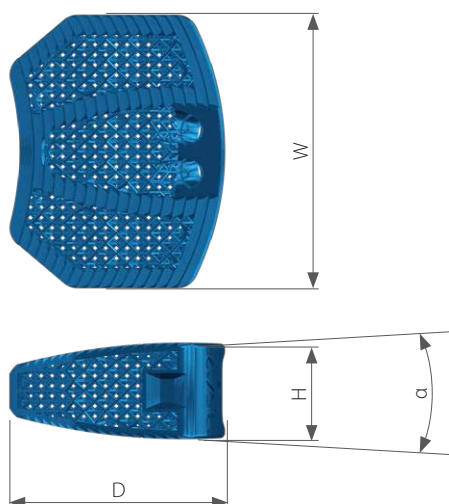
PEEK intervertebral cage (polymer)



					Lordosis angle	
					$\alpha = 8^{\circ}$	$\alpha = 12^{\circ}$
Size	W [mm]	D [mm]	H [mm]	Colors	Catalogue no.	
						
MEDIUM	32	26	12.0		8.3992.082	8.3992.122
			13.5		8.3992.083	8.3992.123
			15.0		8.3992.085	8.3992.125
			17.0		8.3992.087	8.3992.127
			19.0		8.3992.089	8.3992.129
LARGE	38	30	12.0		8.3993.082	8.3993.122
			13.5		8.3993.083	8.3993.123
			15.0		8.3993.085	8.3993.125
			17.0		8.3993.087	8.3993.127
			19.0		8.3993.089	8.3993.129

Material PEEK-

PEEK polymer cages are available in both non-sterile and sterile versions.
When ordering the sterile version, add the suffix "S" to the catalog number (e.g., 8.3992.082S).

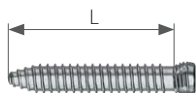


					Lordosis angle	
					$\alpha = 8^{\circ}$	$\alpha = 12^{\circ}$
Size	W [mm]	D [mm]	H [mm]	Colors	Catalogue no.	
						
MEDIUM	32	26	12.0		3.8135.012S	3.8136.012S
			13.5		3.8135.013S	3.8136.013S
			15.0		3.8135.015S	3.8136.015S
			17.0		3.8135.017S	3.8136.017S
			19.0		3.8135.019S	3.8136.019S
LARGE	38	30	12.0		3.8139.012S	3.8140.012S
			13.5		3.8139.013S	3.8140.013S
			15.0		3.8139.015S	3.8140.015S
			17.0		3.8139.017S	3.8140.017S
			19.0		3.8139.019S	3.8140.019S



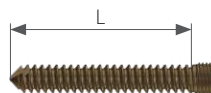
Cages made of titanium alloy are available exclusively in a sterile version.

Locking screw 4.0



L [mm]	Catalogue no.
10	4.3921.015
15	4.3921.020
20	4.3921.025
25	4.3921.030

Locking screw 4.5

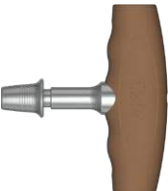
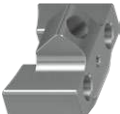


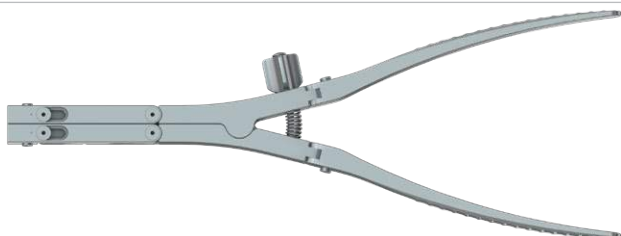
L [mm]	Catalogue no.
10	3.3920.015
15	3.3920.020
20	3.3920.025
25	3.3920.030

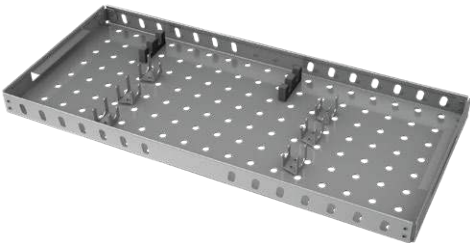


Locking screws are available in both non-sterile and sterile versions. When ordering the sterile version, add the suffix "S" to the catalog number (e.g., 3.3920.015S).

III. INSTRUMENTS

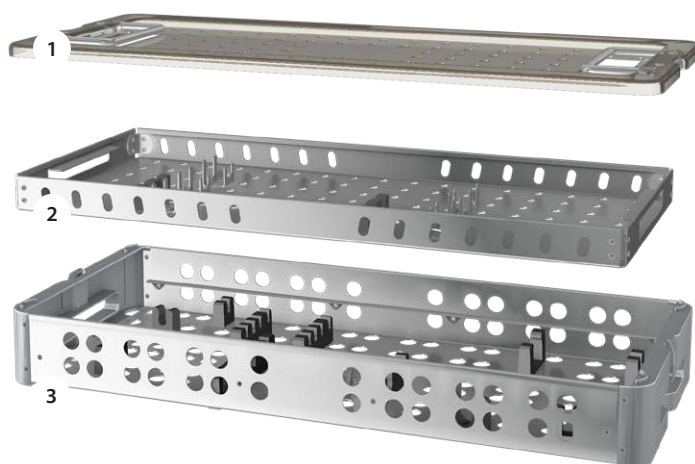
Instruments for ALIF PEEK Intervertebral Locking Cages 15.0905.002		Name	Catalogue no.	Pcs
		Bone rasp medium H-12	40.5816.002	1
		Bone rasp medium H-13.5	40.5816.003	1
		Bone rasp medium H-15	40.5816.005	1
		Bone rasp medium H-17	40.5816.007	1
		Bone rasp medium H-19	40.5816.009	1
		Stand for bone rasps	40.8637.000	1
		Trocar (<i>straight</i>)	40.8719.000	1
		Screwdriver tip T15 (<i>straight</i>)	40.8720.000	1
		Trocar (<i>angularly adjustable</i>)	40.8721.000	1
		Screwdriver tip T15 (<i>angularly adjustable</i>)	40.8722.000	1
		Screwdriver T15	40.5822.100	1
		Handle ratchet device	40.6654.000	1
		Persuader	40.6224.100	1
		Compactor	40.6190.100	1
		T-type torque handle 2.8Nm	40.6666.000	1
		Impactor-extractor	40.8717.000	1
		Aiming block H-12	40.5821.502	1
		Aiming block H-13.5	40.5821.503	1
		Aiming block H-15	40.5821.505	1
		Aiming block H-17	40.5821.507	1
		Aiming block H-19	40.5821.509	1
		Working stand	40.5825.000	1
		Container 9x4H	14.0905.104	1

Instruments for ALIF PEEK Intervertebral Locking Cages 15.0905.002		Name	Catalogue no.	Pcs
	Medium trial 12/8	40.5818.082	1	
	Medium trial 12/12	40.5818.122	1	
	Large trial 12/8	40.5819.082	1	
	Large trial 12/12	40.5819.122	1	
	Medium trial 13.5/8	40.5818.083	1	
	Medium trial 13.5/12	40.5818.123	1	
	Large gauge trial 13.5/8	40.5819.083	1	
	Large trial 13.5/12	40.5819.123	1	
	Medium trial 15/8	40.5818.085	1	
	Medium trial 15/12	40.5818.125	1	
	Large trial 15/8	40.5819.085	1	
	Large trial 15/12	40.5819.125	1	
	Medium trial 17/8	40.5818.087	1	
	Medium trial 17/12	40.5818.127	1	
	Large trial 17/8	40.5819.087	1	
	Large trial 17/12	40.5819.127	1	
	Medium trial 19/8	40.5818.089	1	
	Medium trial 19/12	40.5818.129	1	
	Large trial 19/8	40.5819.089	1	
	Large gauge 19/12	40.5819.129	1	
	Stand for trials (large trials 38x30mm)	40.8638.000	1	
	Stand for trials (medium trials 32x26mm)	40.8639.000	1	
	Parallel distraction forceps	40.8714.000		
	Distraction forceps - Exchangeable jaws 23x18 (set)	40.8724.000		
	Distraction forceps - exchangeable jaws 30/5/8° (set)	40.8716.000		
	Persuader	40.8713.000	1	

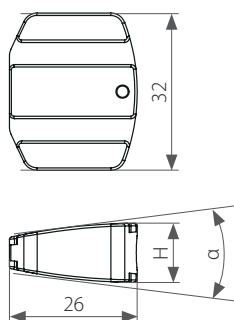
Instruments for ALIF PEEK Intervertebral Locking Cages 15.0905.002		Name	Catalogue no.	Pcs
		Tray 9x4 1/2H	14.0905.201	1
		Container lid 9x4	14.0905.105	1

III.1. CONTAINERS ARRANGEMENT

No.	Name	Catalogue No.	Pcs
1	Container lid 9x4	14.0905.105	1
2	Tray 9x4 1/2H	14.0905.201	1
3	Container 9x4H	14.0905.104	1

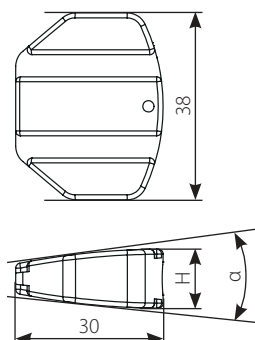


Medium trial



			Lordosis angle	
			$\alpha = 8^\circ$	$\alpha = 12^\circ$
Size	Colors	H [mm]	Catalogue no.	
MEDIUM		12.0	40.5818.082	40.5818.122
		13.5	40.5818.083	40.5818.123
		15.0	40.5818.085	40.5818.125
		17.0	40.5818.087	40.5818.127
		19.0	40.5818.089	40.5818.129

Large trial



			Lordosis angle	
			$\alpha = 8^\circ$	$\alpha = 12^\circ$
Size	Colors	H [mm]	Catalogue no.	
LARGE		12.0	40.5819.082	40.5819.122
		13.5	40.5819.083	40.5819.123
		15.0	40.5819.085	40.5819.125
		17.0	40.5819.087	40.5819.127
		19.0	40.5819.089	40.5819.129

IV. SURGICAL TECHNIQUE

IV.1. SURGICAL APPROACH AND PATIENT POSITION

The operative approach is dependent on the level to be treated; however, direct anterior access to the lumbar spine is required for insertion of the locking screws.

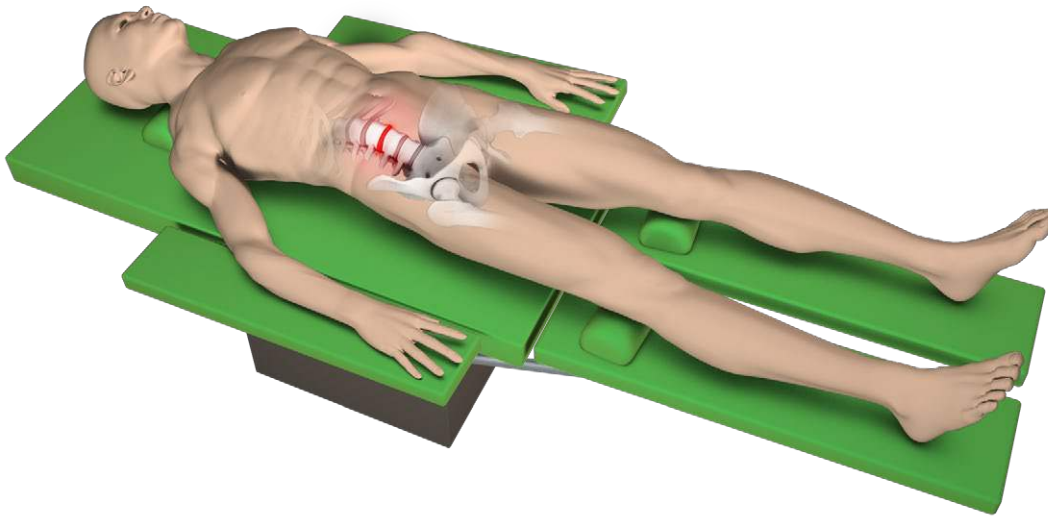
Access to the required spinal level is obtained through a standard transperitoneal or retroperitoneal approach, depending on the surgeon's preference.

The procedure should be preceded by thorough preoperative planning and performed with the involvement of a vascular surgeon or a general surgeon experienced in obtaining operative access to the spine.

The operating table should be radiolucent and allow for intraoperative use of a C-arm fluoroscopy system.

The patient is positioned supine in a manner that provides anterior access to the vertebral bodies of the anterior lumbar spine.

During implant placement, the ability to adjust lumbar lordosis is often beneficial and can be achieved using an operating table with adjustable sections or an inflatable positioning cushion.

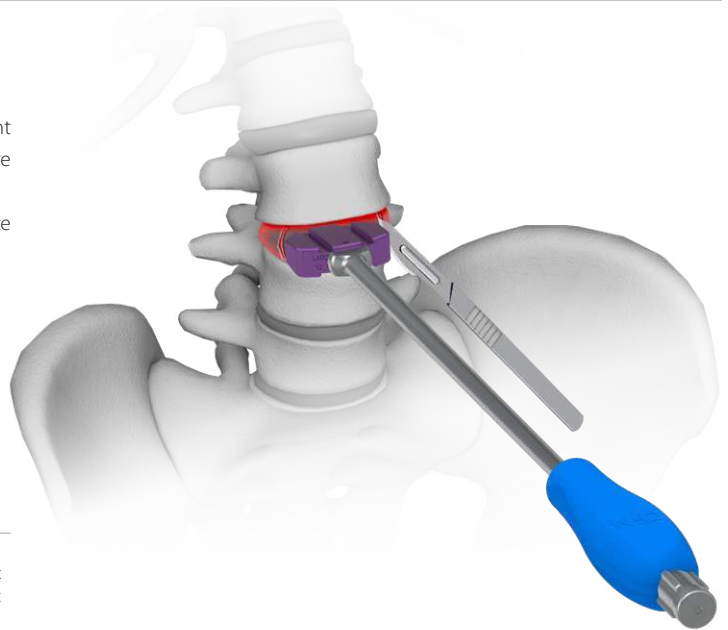


Following the surgical approach, the appropriate disc space to be treated should be identified, and the spinal segment should be exposed symmetrically on both sides of the spinal midline to provide sufficient access corresponding to the width of the implant (*implants are available in two widths: 32 mm and 38 mm*). The midline of the vertebral bodies above and below the level of the discectomy should then be marked.

IV.2. DISCECTOMY

Perform a sufficiently wide discectomy to accommodate the selected implant size, ensuring that the posterolateral corners of the intervertebral disc space are adequately cleared of disc material.

At this stage, a cage trial (*medium or large*) may be used to determine the appropriate implant width.



Intervertebral disc space distraction may facilitate the discectomy. This can be performed using parallel distraction forceps [40.8714.000] with exchangeable jaws 30/5/8° [40.8716.000]. Due to their narrow profile, the jaws are inserted into the lateral portion of the intervertebral disc space after the disc material has been removed from that area.



Once the final implant size has been determined, use the appropriately sized rasp to complete preparation of the vertebral endplates. Attach the rasp [40.5816.xxx] to the persuader [40.8713.000], introduce it into the intervertebral disc space, and remove the cartilaginous and osseous material until bleeding bone is exposed.



Excessive removal of subchondral bone may weaken the vertebral bodies and consequently lead to implant subsidence and loss of segmental stability.

IV.3. TRIALING

The implant size to be used during the procedure is determined using trial spacers, which are sequentially inserted into the intervertebral disc space from the smallest to the largest size until the appropriate trial restores the patient's normal anatomical alignment at the treated spinal level.



Each implant has a corresponding trial spacer with an identical shape, height, and lordotic angle. These parameters are indicated on the trial spacers, implants, and implant packaging.

In addition, the height is color-coded, with the same color used for implants and trial spacers of the corresponding height.

The medium trial H-12/12° [40.5818.122], corresponding to the smallest implant size, should be attached to the persuader [40.8713.000]. To do this, insert the gripping end of the persuader into the trial spacer socket and secure it by tightening the locking pin using the knob at the end of the persuader handle. The installed trial spacer should then be inserted into the intervertebral disc space, centered in the sagittal plane, until it contacts the vertebral body margins.

If the selected medium-sized trial spacer is too narrow, it should be replaced with the large trial (38 mm) [40.5819.082].

Once the appropriate implant width has been determined, progressively larger trial spacers should be used until a tight fit is achieved. There should be no gaps between the trial spacer and the vertebral endplates. To ensure maximum stability, the largest possible implant size should be selected.

IV.4. ENDPLATE PREPARATION

An essential step of the discectomy is preparation of the vertebral endplates to improve their vascularization and facilitate achieving solid fusion across the entire endplate surface.

To prepare the endplates, use the rasp [40.5816.00x] mounted on the persuader [40.8713.000], matching the size of the previously selected trial spacer.

Insert the assembled instrument into the intervertebral disc space, press it against the endplate, and scrape the surface by pulling the instrument toward the surgeon. This process helps improve endplate vascularization.



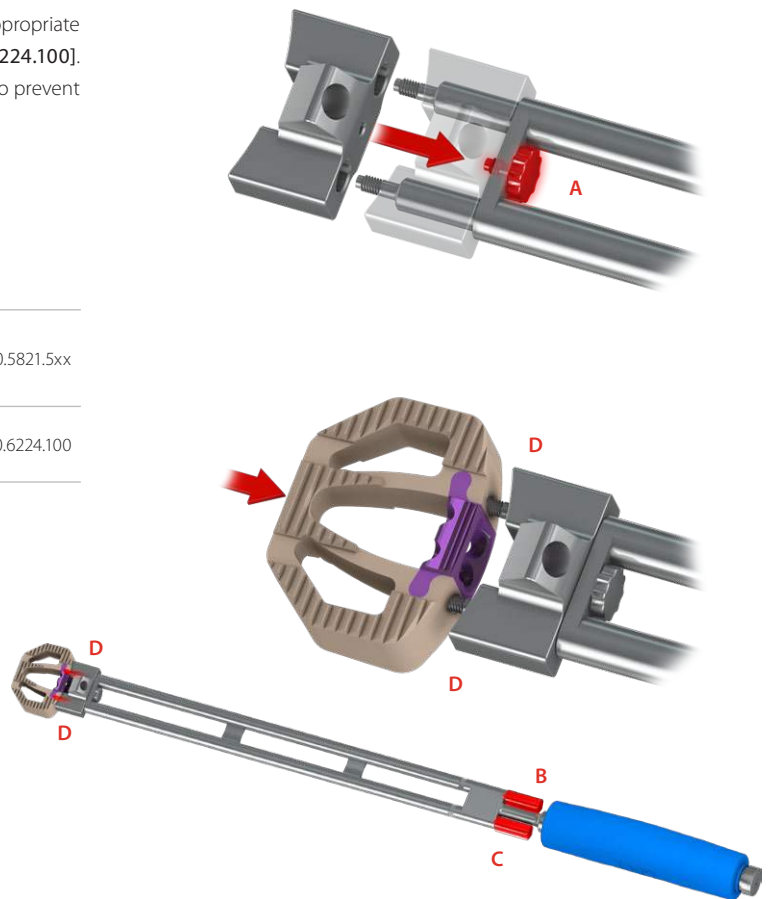
Excessive removal of subchondral bone may weaken the vertebral bodies and consequently lead to implant subsidence and loss of segmental stability.

IV.5. IMPLANT PREPARATION

Based on the implant height (H) selected in Section IV.3, choose the appropriate aiming block [40.5821.5xx] and attach it to the persuader [40.6224.100]. Secure the block in place by tightening the locking pin using knob A to prevent it from slipping.



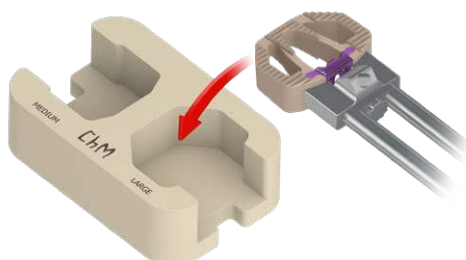
Attach the prepared persuader to the interbody cage by using knobs B and C to tighten the locking pins into the implant's mounting sockets D.



IV.5.1. Filling the PEEK implant with autologous bone graft material

PEEK implants require their internal cavities to be filled with autologous bone graft material. This is essential for the proper progression of bone fusion at the treated spinal level.

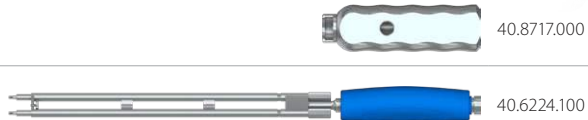
Place the implant on the working stand [40.5825.000] and fill it with the selected autologous bone graft material. The impactor [40.6190.000] may be used to firmly pack the graft material into the implant's cavities.



IV.6. IMPLANT INSERTION

Insert the interbody cage, attached to the persuader [40.6224.100] and filled with autologous bone graft material, into the prepared intervertebral disc space, ensuring that it is centered symmetrically in the sagittal plane.

Attach the impactor/extractor [40.8717.000] to the persuader and use it to gently impact the implant into the intervertebral disc space.



CAUTION: The implant should be impacted carefully and with controlled force. Excessive impact force may damage the implant and the vertebral body structures.

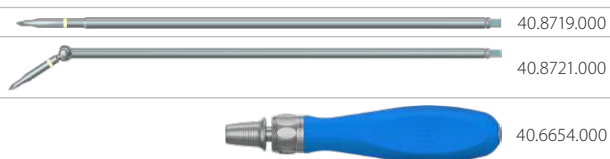
Impaction of the implant should be stopped when its anterior wall is positioned approximately 3 mm below the anterior surfaces of the vertebral bodies.



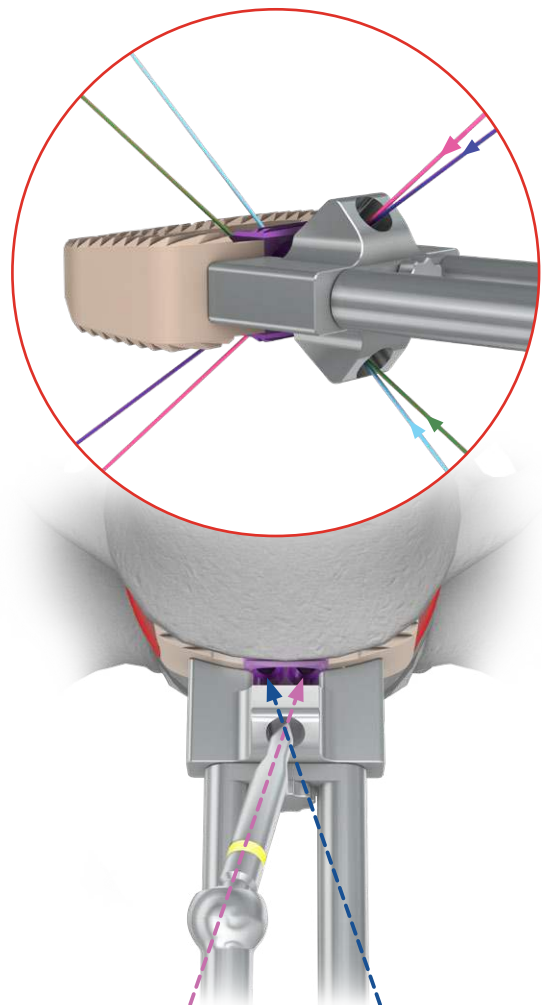
Correct implant positioning should be confirmed with a lateral X-Ray.

Before inserting the locking screws, pilot holes should be prepared in the vertebral endplates. This can be performed using either the straight trocar [40.8719.000] or the angularly adjustable trocar [40.8721.000]. The choice depends on the patient's anatomy and the surgeon's preference.

Attach the selected trocar to the handle ratchet device [40.6654.000].



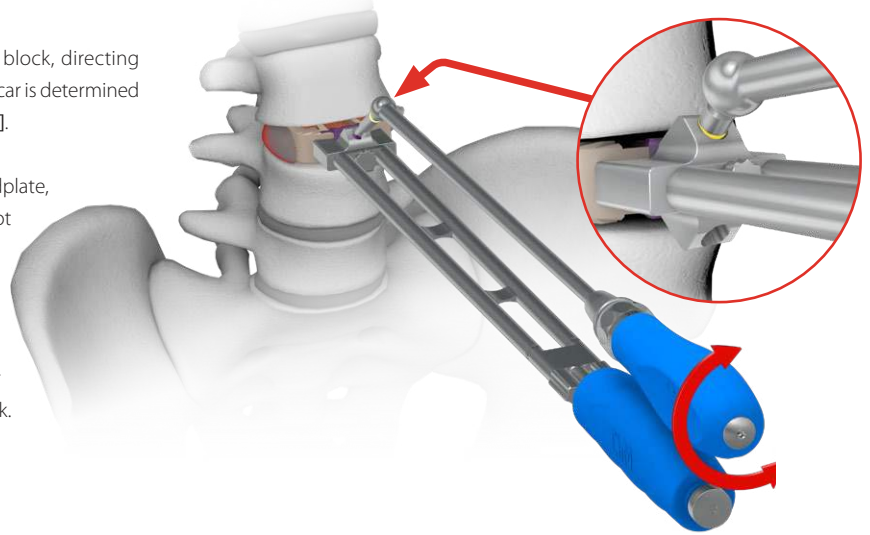
On the persuader side of the aiming blocks, there are two openings: one cranial and one caudal. Each opening branches into two pilot holes, whose positions correspond to the holes in the implant.



Insert the trocar tip into the selected opening of the aiming block, directing it toward either the left or right pilot hole. The trajectory of the trocar is determined by angling it horizontally relative to the persuader [40.6224.100].

When resistance is felt as the trocar tip contacts the vertebral endplate, increase the pressure applied to the handle and create the pilot hole using controlled oscillating movements.

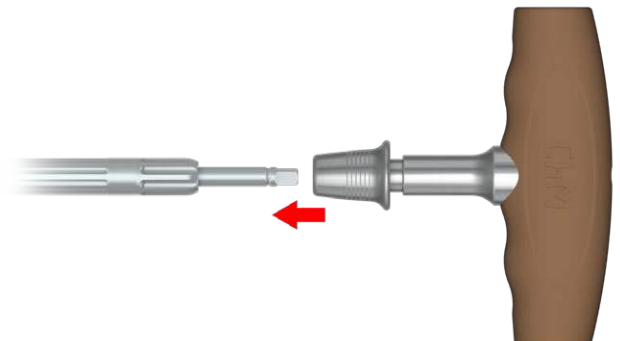
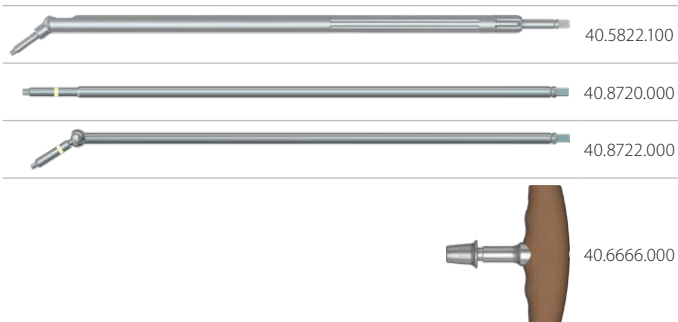
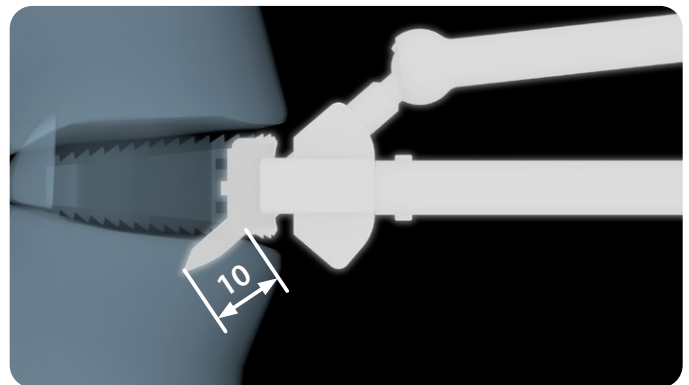
Advance the trocar until firm resistance is felt and further insertion is no longer possible, indicating that the pilot hole has reached the required depth. At this point, the yellow marker on the trocar will be recessed into the opening of the aiming block.



At this stage, a lateral X-Ray should be taken to determine the appropriate screw length. The tip of the trocar indicates the depth to which the shortest screw, L-10 [3.3920.015], will extend.



The selected screw length should ensure that the screws penetrate through the entire thickness of the cortical bone. In two-level fixation, the screw length should be selected to prevent potential screw-to-screw interference.



Following preparation of the pilot hole, insert the locking screw. Screwdriver tip T15 [40.8720.000], [40.8722.000], or the Screwdriver T15 [40.5822.100], are available for screw insertion. The appropriate instrument should be selected according to the patient's anatomy and the surgeon's preference.

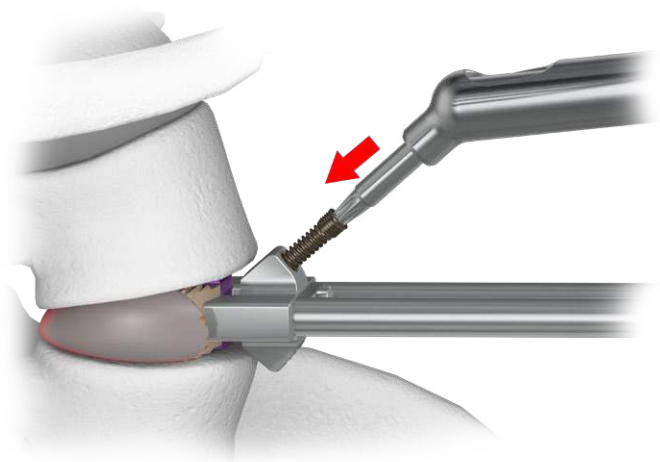
Connect the selected instrument to the T-type torque handle 2.8Nm [40.6666.000].

Place the screw onto the driver bit by engaging the screw head with the bit and apply slight pressure. The tapered design of the driver bit prevents the screw from inadvertently disengaging from the bit.

Insert the screw through the hole in the aiming block and orient it toward the opening previously created with the trocar in the endplate of the vertebral body. Advance the screw until resistance is felt.

When using titanium screws 3.3920.0xx, further insertion begins by engaging the screw thread with the thread of the locking holes of the interbody cage locking system. While applying slight axial pressure to the screw, rotate the T-handle [40.6666.000] clockwise.

If resistance is felt during the initial phase of screw insertion, when engaging the screw thread in the titanium implant insert, rotate the handle counterclockwise and then resume screw insertion.



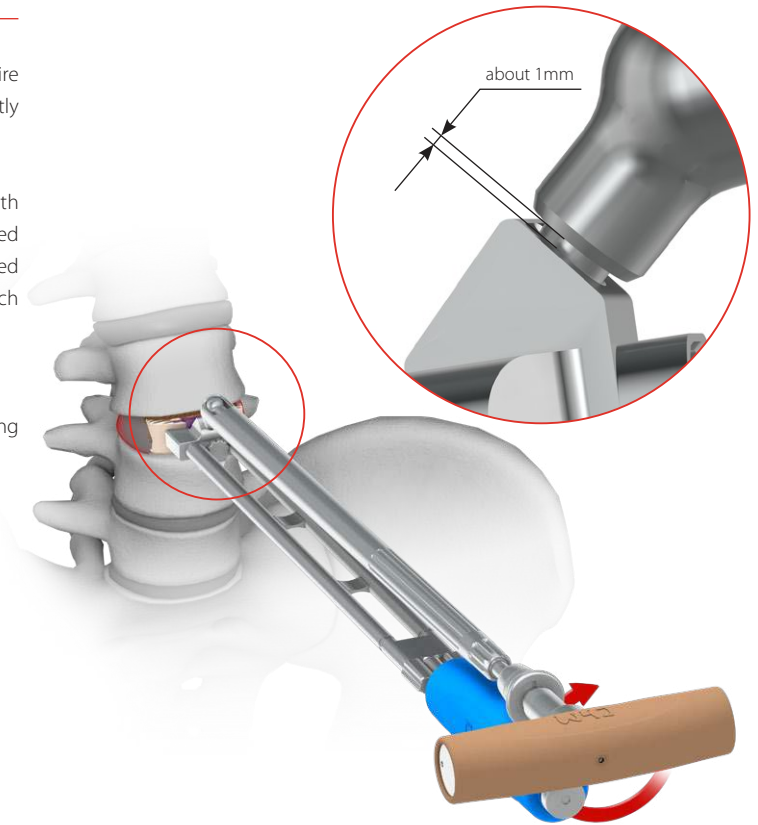


NOTE: Excessive force applied at this stage may damage the threads of both the screw and the threaded hole in the interbody cage, potentially preventing successful insertion of the screw.

In the case of cobalt screws 4.3921.0xx, their smaller diameter does not require engagement with the locking holes in the cage. The screw is inserted directly into the vertebral body.

When the screwdriver tip goes inside the opening of the aiming block, with approximately 1 mm of the tip remaining visible, the screw has been fully inserted into the locking hole of the interbody cage. Final locking of the screw is achieved once the rotational resistance is overcome, as indicated by the torque wrench clicking and an audible "snap."

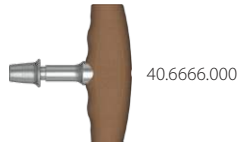
Repeat the pilot-hole preparation and screw insertion procedure for the remaining three cage holes.



V. IMPLANT REMOVAL

Should the implant removal be required, the following steps shall be performed:

- Remove the soft tissue from the anterior surface of the implant.
- Remove the screws using the screwdriver T15 [40.5822.100] (assembled with the T-type torque handle 2.8Nm [40.6666.000]).



- Attach the persuader [40.6224.100] to the implant.
- Connect the impactor/extractor [40.8717.000] to the persuader and use it to extract the implant from the intervertebral space.



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