ST/40C

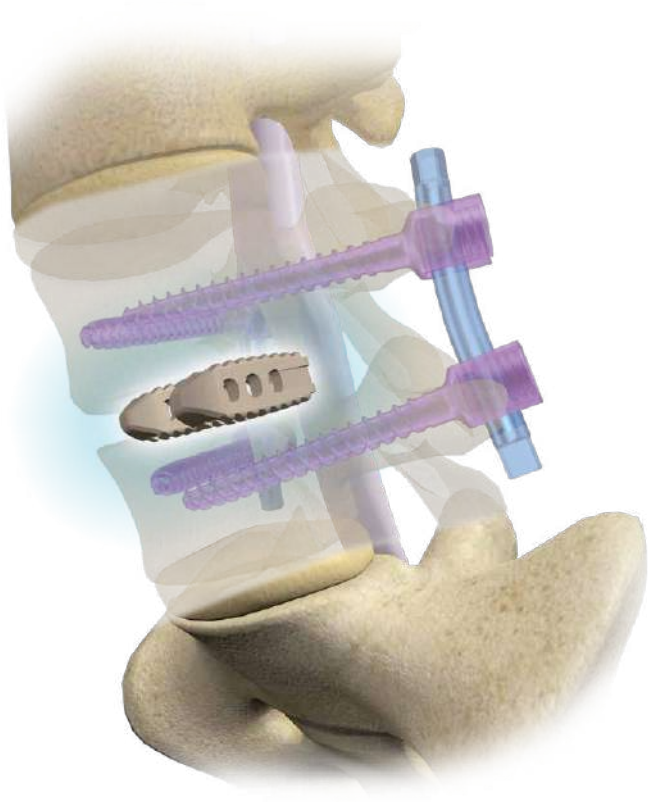
ChM®

CHARSPINE system 3D-Ti
3D Titanium Trabecular Cage System

CHARSPINE system 2

PLIF INTERVERTEBRAL CAGES

- *IMPLANTS*
- *INSTRUMENT SET 15.0901.101*
- *INSTRUMENT SET 15.0901.102*
- *INSTRUMENT SET 15.0908.201*
- *SURGICAL TECHNIQUE*



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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.

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I. INTRODUCTION

I.1. DESCRIPTION AND INDICATIONS

The PLIF Cage system consists of cages of various widths, heights and lordotic angles to adapt to variety of patients' anatomies.

PLIF intervertebral cages are made of biocompatible PEEK (*polyether ether ketone*) polymer, and biocompatible titanium alloy in additive manufacturing technique, by Selective Laser Melting technology (*3D-Ti*).

The implants of PLIF Cage system are designed to be inserted bilaterally (*in pairs*) and are indicated for an open posterior approach for treatment of degenerative disc disease (*DDD*),vertebral instability, Grade 1 spondylolisthesis as well as for spine revision surgery.
The implants should be used at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients qualified for treatment should be skeletally mature and have had six months of non-operative treatment.
The implants of PLIF Cage system are designed to be used with autogenous bone graft and are intended for use with supplemental fixation systems cleared for use in the lumbar spine (*e.g. pedicle screw and rod systems*).

I.2. CONTRAINDICATIONS

Intervertebral PLIF implants are not intended for cervical spine use.

The choice of particular device 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 W.H.O. standards*).
- Pregnancy.
- Neuromuscular disorder which would create unacceptable risk of fixation failure or complications in postoperative care.
- Any other condition which would preclude the potential benefit of spinal implant surgery and disturb the normal process of bone remodeling, e.g. the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases.
- Suspected or documented allergy or intolerance to implant materials. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions; mental illness, senility or substance abuse (*these conditions may cause the patient to ignore certain necessary limitations and precautions in the use of the implant*).
- Patients with a known hereditary or acquired bone fragility or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in whom implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

The above list is not exhaustive.

For further information on:

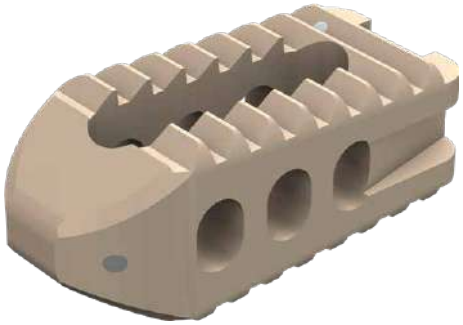
• adverse effects,
• warnings,
• sterilization,
• pre- and post-operative recommendations,

please refer to the Instructions For Use for PLIF Cage system, provided with the implant package unit.

I.3. IMPLANT FEATURES

PLIF PEEK CAGES

- Stiffness of biocompatible PEEK polymer approximates the host bone, which provides ideal load sharing attributes.
- Radiolucentcy of PEEK polymer offers an accurate visualization and assessment of the fusion.
- Radioopaque tantalum markers facilitate intraoperative X-Ray visualization of inserted implant.
- The central hole, intended for bone graft, and the side holes for bone ingrowth.



3D-Ti PLIF Cages

- Intertebral cage, intended for PLIF technique; material - biocompatible titanium alloy.
- Implants having a spatial trabecular structure, manufactured with use of an advanced 3D printing method, providing optimal conditions for bone tissue ingrowth.

ANATOMICAL DESIGN

- Rounded, atraumatic shape of the corners of the cage in cross section for implantation extremely on the sides within the intervertebral space.
- Rounded, wedge-shaped intervertebral cage end for facilitated implantation and implant insertion without preliminary distraction.
- The shape of the cages in the sagittal plane for the reproduction of lumbar lordosis; available in anatomically shaped version (*convex shape of the contact surfaces*) and in four angular versions.

SERRATIONS

Serrated superior and inferior surfaces designed to provide stability by engaging vertebral endplates.

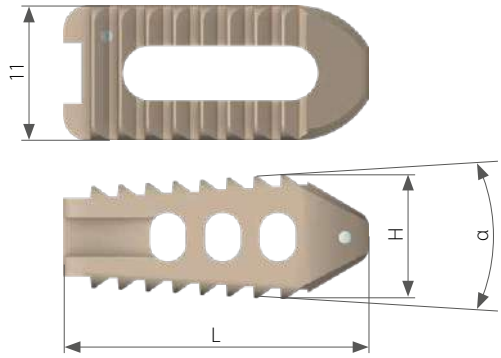
WIDE RANGE OF SIZES

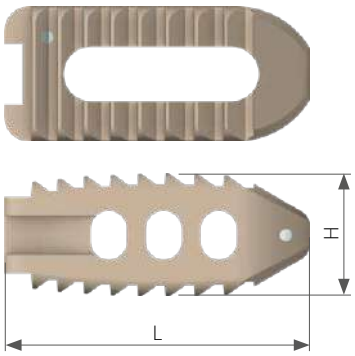
- Four angular versions: 0°, 4°, 7°, 14° and an anatomical type (*convex*),
- Three implants lengths - 20, 25 and 30mm (*two for angular versions: 20 and 25mm*).
- Ten heights in the range from 9 to 18mm

II. IMPLANTS

Material: PEEK-OPTIMA®

Intervertebral cage





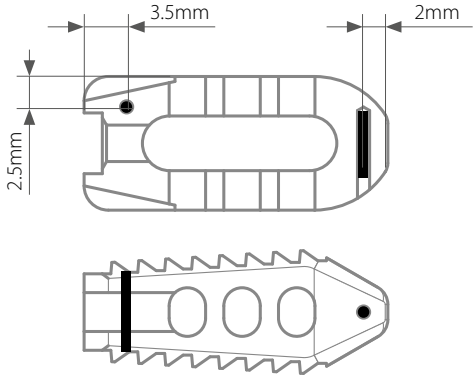
Lordic

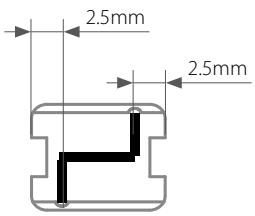
L [mm]	H [mm]	Lordosis angle α = 0°	Lordosis angle α = 4°	Lordosis angle α = 7°
		Catalogue no.		
20	9	8.3988.009	8.3988.409	8.3988.709
	10	8.3988.010	8.3988.410	8.3988.710
	11	8.3988.011	8.3988.411	8.3988.711
	12	8.3988.012	8.3988.412	8.3988.712
	13	8.3988.013	8.3988.413	8.3988.713
	14	8.3988.014	8.3988.414	8.3988.714
	15	8.3988.015	8.3988.415	8.3988.715
	16	8.3988.016	8.3988.416	8.3988.716
	17	8.3988.017	8.3988.417	8.3988.717
	18	8.3988.018	8.3988.418	8.3988.718
25	9	8.3989.009	8.3989.409	8.3989.709
	10	8.3989.010	8.3989.410	8.3989.710
	11	8.3989.011	8.3989.411	8.3989.711
	12	8.3989.012	8.3989.412	8.3989.712
	13	8.3989.013	8.3989.413	8.3989.713
	14	8.3989.014	8.3989.414	8.3989.714
	15	8.3989.015	8.3989.415	8.3989.715
	16	8.3989.016	8.3989.416	8.3989.716
	17	8.3989.017	8.3989.417	8.3989.717
	18	8.3989.018	8.3989.418	8.3989.718

Convex

L [mm]	H [mm]	Catalogue no.
20	9	8.3988.909
	10	8.3988.910
	11	8.3988.911
	12	8.3988.912
	13	8.3988.913
	14	8.3988.914
	15	8.3988.915
	16	8.3988.916
	17	8.3988.917
	18	8.3988.918
25	9	8.3989.909
	10	8.3989.910
	11	8.3989.911
	12	8.3989.912
	13	8.3989.913
	14	8.3989.914
	15	8.3989.915
	16	8.3989.916
	17	8.3989.917
	18	8.3989.918

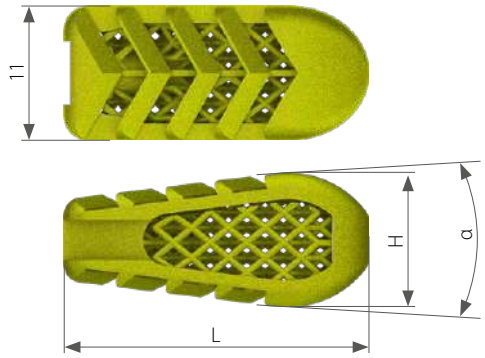
Radiopaque markers location

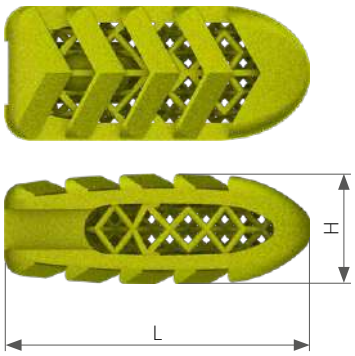




Material: Ti

3D-Ti PLIF Intervertebral cage





Lordic

		Lordosis angle			
		α = 0°	α = 4°	α = 7°	α = 14°
L [mm]	H [mm]	Catalogue no.			
20	9	3.6925.009	3.6925.409	3.6925.709	3.6925.149
	10	3.6925.010	3.6925.410	3.6925.710	3.6925.140
	11	3.6925.011	3.6925.411	3.6925.711	3.6925.141
	12	3.6925.012	3.6925.412	3.6925.712	3.6925.142
	13	3.6925.013	3.6925.413	3.6925.713	3.6925.143
	14	3.6925.014	3.6925.414	3.6925.714	3.6925.144
	15	3.6925.015	3.6925.415	3.6925.715	3.6925.145
	16	3.6925.016	3.6925.416	3.6925.716	3.6925.146
	17	3.6925.017	3.6925.417	3.6925.717	3.6925.147
	18	3.6925.018	3.6925.418	3.6925.718	3.6925.148
25	9	3.6926.009	3.6926.409	3.6926.709	-
	10	3.6926.010	3.6926.410	3.6926.710	3.6926.140
	11	3.6926.011	3.6926.411	3.6926.711	3.6926.141
	12	3.6926.012	3.6926.412	3.6926.712	3.6926.142
	13	3.6926.013	3.6926.413	3.6926.713	3.6926.143
	14	3.6926.014	3.6926.414	3.6926.714	3.6926.144
	15	3.6926.015	3.6926.415	3.6926.715	3.6926.145
	16	3.6926.016	3.6926.416	3.6926.716	3.6926.146
	17	3.6926.017	3.6926.417	3.6926.717	3.6926.147
	18	3.6926.018	3.6926.418	3.6926.718	3.6926.148

Convex

		Convex
L [mm]	H [mm]	Catalogue no.
20	9	3.6925.909
	10	3.6925.910
	11	3.6925.911
	12	3.6925.912
	13	3.6925.913
	14	3.6925.914
	15	3.6925.915
	16	3.6925.916
	17	3.6925.917
	18	3.6925.918
25	9	3.6926.909
	10	3.6926.910
	11	3.6926.911
	12	3.6926.912
	13	3.6926.913
	14	3.6926.914
	15	3.6926.915
	16	3.6926.916
	17	3.6926.917
	18	3.6926.918
30	9	3.6927.909
	10	3.6927.910
	11	3.6927.911
	12	3.6927.912
	13	3.6927.913
	14	3.6927.914
	15	3.6927.915
	16	3.6927.916
	17	3.6927.917
	18	3.6927.918

III. INSTRUMENTS

Instrument set 15.0901.101 is compatible also with 3D-Ti PLIF titanium implants.

Instrument set for PLIF PEEK Intervertebral Cages 15.0901.101 (*basic*)	**Name**	**Catalogue no.**	**Pcs.**
	Reamer 9	40.5805.009	1
	Reamer 10	40.5805.010	1
	Reamer 11	40.5805.011	1
	Reamer 12	40.5805.012	1
	Reamer 13	40.5805.013	1
	Reamer 14	40.5805.014	1
	Reamer 15	40.5805.015	1
	Reamer 16	40.5805.016	1
	Reamer 17	40.5805.017	1
	Reamer 18 Reamer is intended to be used with quick coupling handle T-type 1/4" to distract the disc space. A clockwise rotation gradually increases disc space. A counter-clockwise rotation removes disc material. The reamer should be inserted horizontally and then rotated.	40.5805.018	1
	Quick coupling handle T-type 1/4" The instrument used as quick coupling handle for exchangeable reamers.	40.6673.000	1
	Applicator Applicator is used to implant PLIF Intervertebral cages.	40.5829.000	1
	Impactor for cages Impactor for cages is used to impact the cage to its optimal position.	40.5836.000	1
	Compactor Compactor is used for manual compacting of autologous bone pieces inside the cage.	40.6190.000	1
	Working stand Working stand is used as cage support, where the implant is filled with pieces of autologous bone grafts. .	40.5809.000	1
	Distraction forceps-jaws Exchangeable jaws designed for use with parallel distraction forceps.	40.5812.000	1
	Distraction forceps-jaws Exchangeable jaws designed for use with parallel distraction forceps.	40.5815.000	1
	Elevator 6	40.4467.006	1
	Elevator 10 Elevator is used to retract the dura mater medially to expose the posterior part of the disc.	40.4467.010	1

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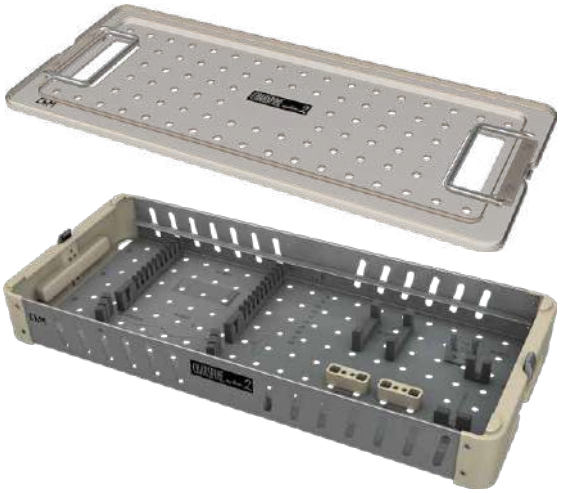
Instrument set for PLIF PEEK Intervertebral Cages 15.0901.101 (*basic*)	**Name**	**Catalogue no.**	**Pcs.**
	Container lid 9x4	14.0901.103	1
	Container 9x4H	14.0901.101	1

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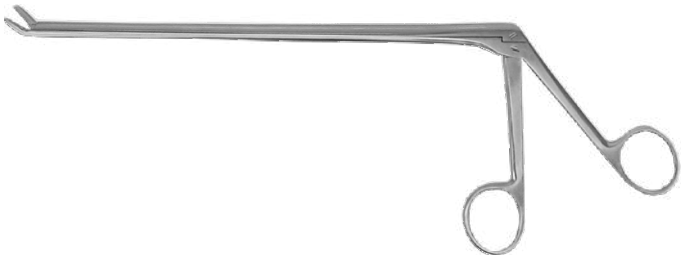
Instrument set [15.0901.102] is additional equipment.
In order to include the instruments to the ordered basic instrument set, please contact your local representative or ChM Sales Department

Instrument set for PLIF PEEK Intervertebral Cages 15.0901.102 (*extended*)	**Name**	**Catalogue no.**	**Pcs.**
	File The file is used to roughen the endplates and generate bleeding prior to implant insertion.	40.6196.000	1
	Bone curette oval Bone curette oval is used to complete the preparation of the endplates.	40.6192.000	1
	Bone curette rectangular Bone curette rectangular is used to complete the preparation of the endplates.	40.6193.000	1
	Bone curette Bone curette can be used to remove the disc material as well as the cartilaginous layer on the endplates.	40.6198.000	1
	Bone curette curved Bone curette curved can be used to remove the disc material as well as the cartilaginous layer on the endplates.	40.6199.000	1
	Osteotome Osteotome is intended for bone. chiseling, cutting or dividing.	40.6191.000	1
	KERRISON bone rongeur, upwards, 130°, 230mm, 2mm	40.7086.002	1
	KERRISON bone rongeur, upwards,130°, 230mm, 4mm The instrument is used for removal of bone tissue.	40.7086.004	1
	CUSHING bone rongeur straight 230mm, 2x10mm	40.7027.042	1
	SPURLING bone rongeur straight 230mm 4x10mm The instrument is used for removal of intervertebral disc tissue.	40.7033.044	1
	CUSHING bone rongeur upwards 230mm, 2x10mm	40.7028.042	1
	SPURLING bone rongeur upwards 230mm, 4x10mm The instrument is used for removal of intervertebral disc tissue.	40.7034.044	1
	Container 9x4H	14.0901.102	1

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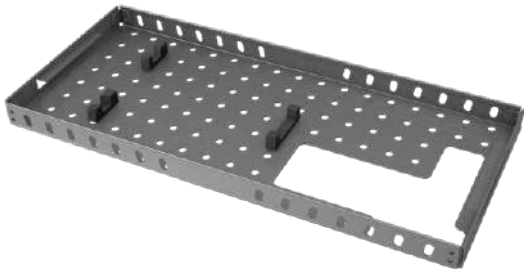
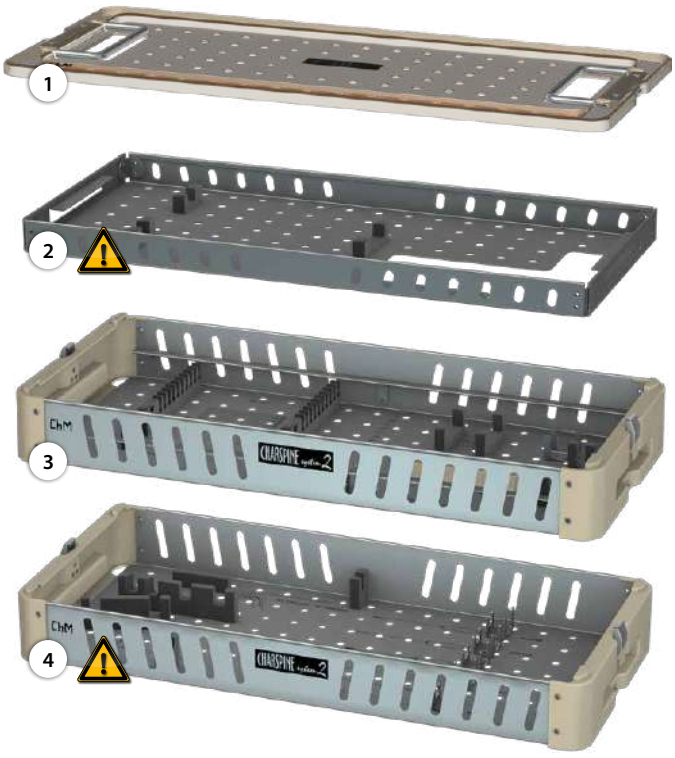
Instrument set for Intervertebral Cages - distraction forceps [15.0908.201] is additional equipment.
In order to include the instrument to the ordered basic instrument set, please contact your local representative or ChM Sales Department.

Instrument set for Intervertebral Cages - distraction forceps [15.0908.201] (*extended*)	**Name**	**Catalogue no.**	**Pcs**
	Tray 9x4 1/2H	14.0908.201	1
	Parallel distraction forceps	40.8093.000	1

III.1. CONTAINERS ARRANGEMENT

No.	Name	Catalogue No.	Pcs
1	Container lid 9x4	14.0901.103	1
2	Tray 9x4 1/2H	14.0908.201	1
3	Container 9x4H	14.0901.101	1
4	Container 9x4H	14.0901.102	1

Tray 9x4 1/2H [14.0908.201] and container 9x4H [14.0901.102] are additional elements and are not included in the basic instrument set.

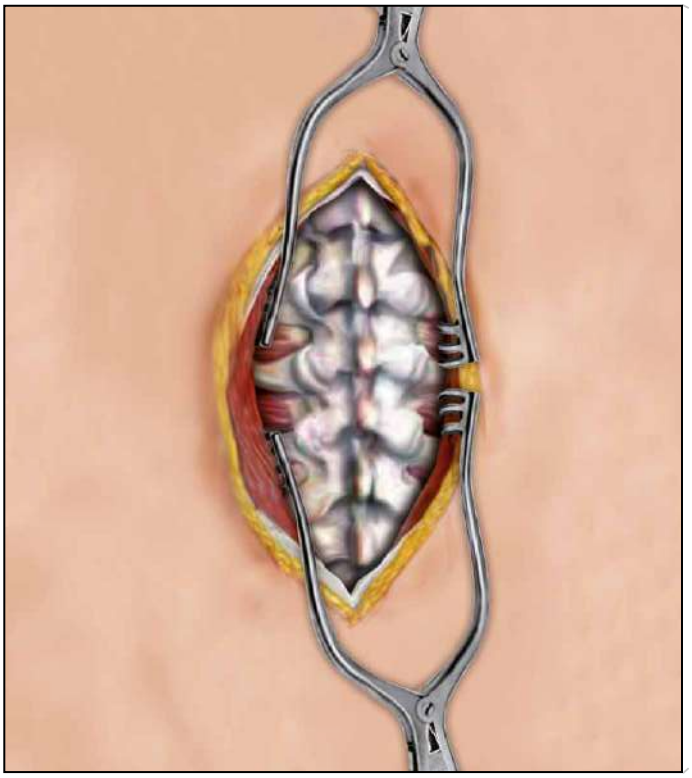


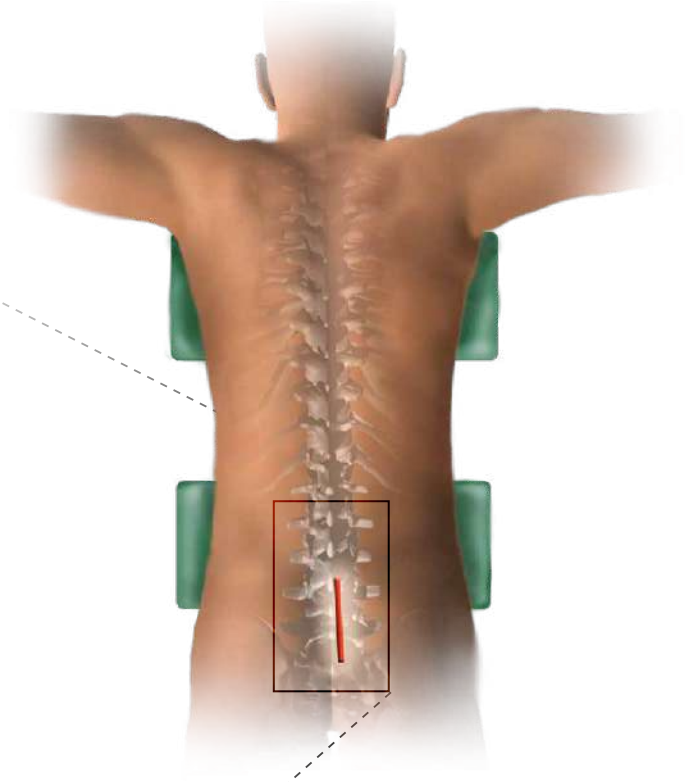
IV. SURGICAL TECHNIQUE

IV.1. PATIENT POSITIONING AND SURGICAL APPROACH

The patient is positioned on an operating table with adequate clearance for intraoperative radiographic control. Special care should be taken to protect patient pressure points.

A posterior medial skin incision is performed and then the tissues are laterally dissected. The laminae and articular processes are exposed laterally to the base of the transverse processes.





The soft tissue retractors can be used to maintain proper exposure. The X-Ray control can be used to help to determine the precise intraoperative position of the relevant spine segment.

IV.2. LAMINECTOMY

The spinal canal is opened by incision of the laminae and articular processes. The laminectomy is extended laterally until reaching the level of the medial edge of the pedicle, which is located by palpation with a spatula.

Using osteotome **[40.6191]** 1 and Kerrison rongeurs **[40.7086.002]** or **[40.7086.004]** 2, the inferior articular process of the superior vertebra is progressively resected until the nerve root is visible 3.

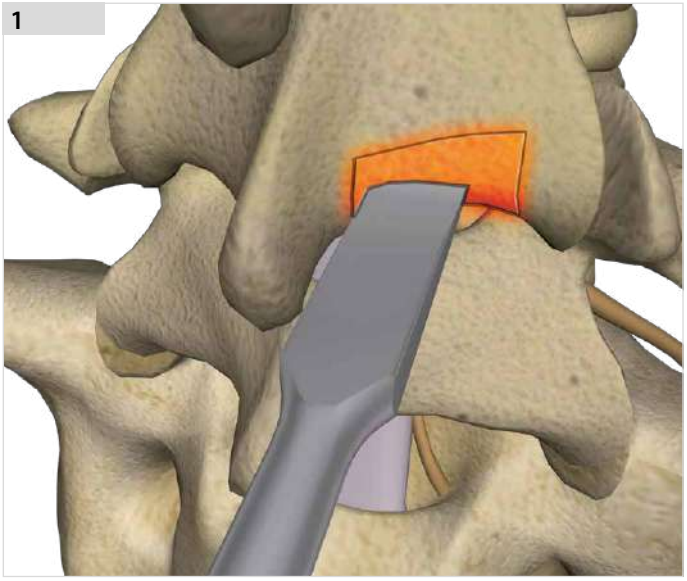
Great care is taken to verify the mobility of the right and left nerve roots prior to applying distraction to the disc space.

40.6191.000

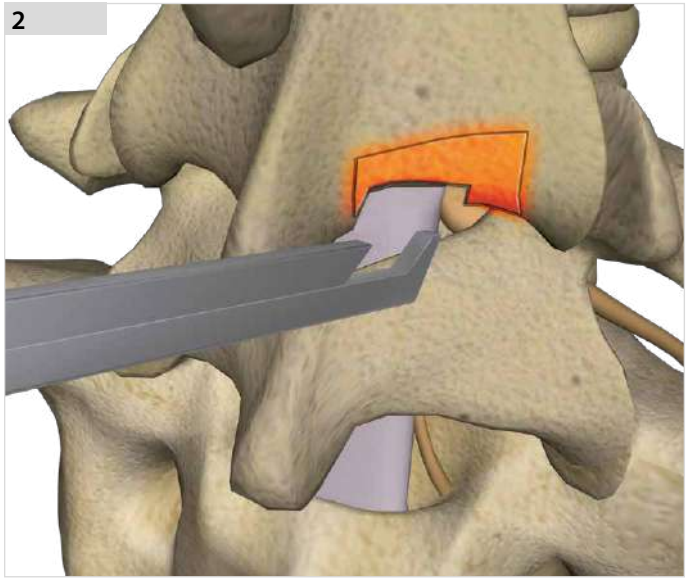
40.7086.002
40.7086.004

Files, bone curette, osteotomes and rongeurs are additional equipment provided in instrument set [15.0901.102].

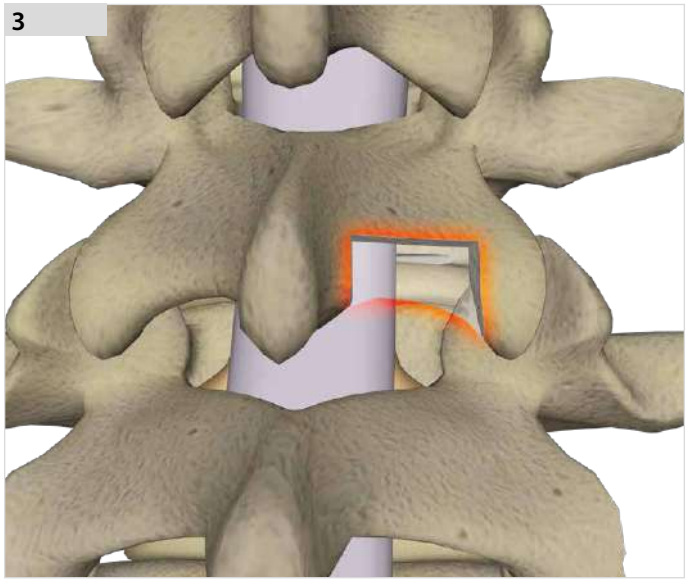
1



2



3



IV.3. DISCECTOMY AND PREPARATION OF INSERTION SITE

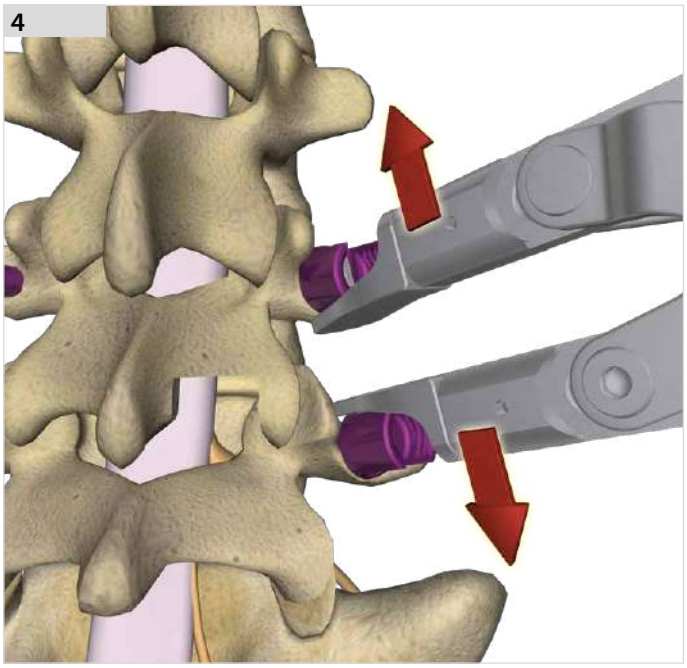
Effective distraction aids removal of the superior articular process, decompression of the spinal canal, preparation of the disc space and insertion of the PLIF Cage. Distraction may be achieved using pedicle screws or reamers.

If pedicle screw distraction is chosen, the screws should be inserted at this stage using standard technique and e.g. **CHARSPINE2** pedicle screw system.
Required distraction is applied between inserted pedicle screws with the use of parallel distraction forceps **[40.8093]** 4 .

Parallel distraction forceps [40.8093] are additional equipment provided in instrument set [15.0908.201].
When CHARSPINE2 system has been used for the pedicure stabilization, the forceps are standard equipment of the stabilizer.

40.8093

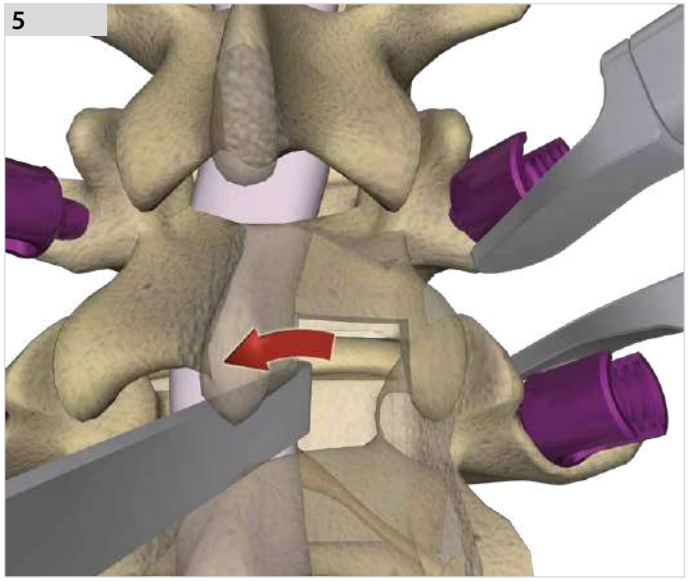
4



The elevator **[40.4467]** 5 is used to retract the dura mater to expose the posterior part of the disc. In most cases, the elevator is placed at the beginning of the inferior nerve root.

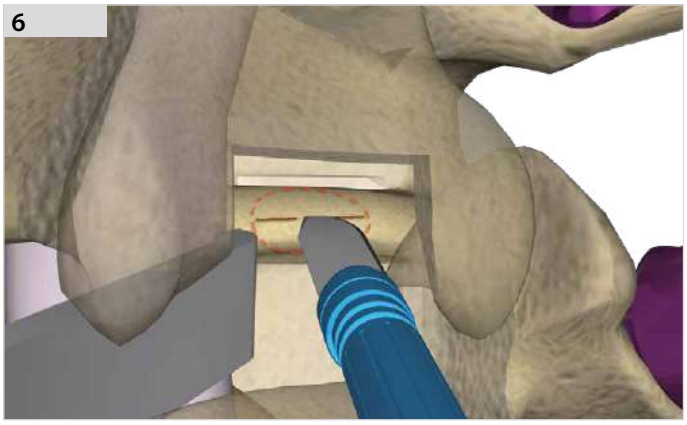
40.4467

5



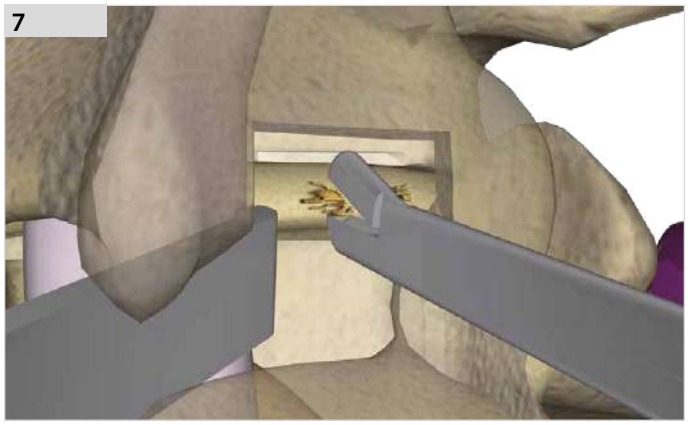
Using a thin-bladed scalpel 6, an incision of approximately 1 centimeter in diameter is performed in the annulus fibrosus.

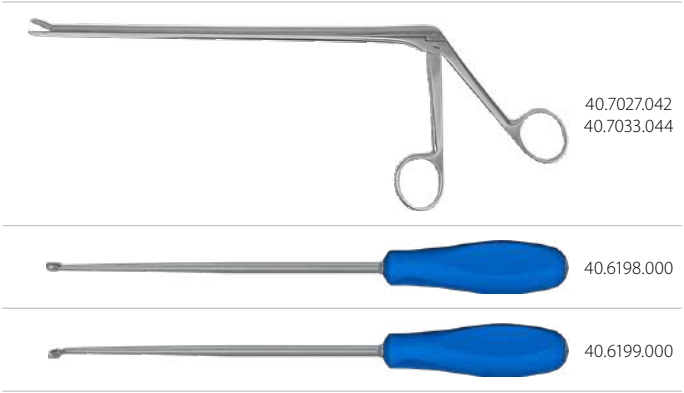
6



Disc fragments are removed through the incision performed with the use of the bone rongeurs **[40.7027.042]** or **[40.7033.044]** 7 and curettes **[40.6198]** or **[40.6199]** 8.

7



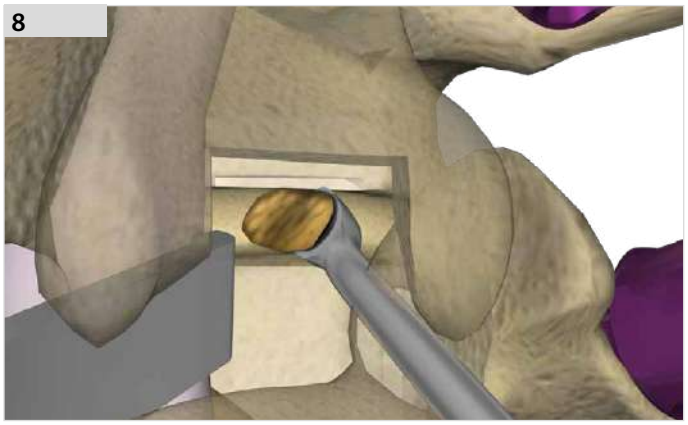


40.7027.042
40.7033.044

40.6198.000

40.6199.000

8

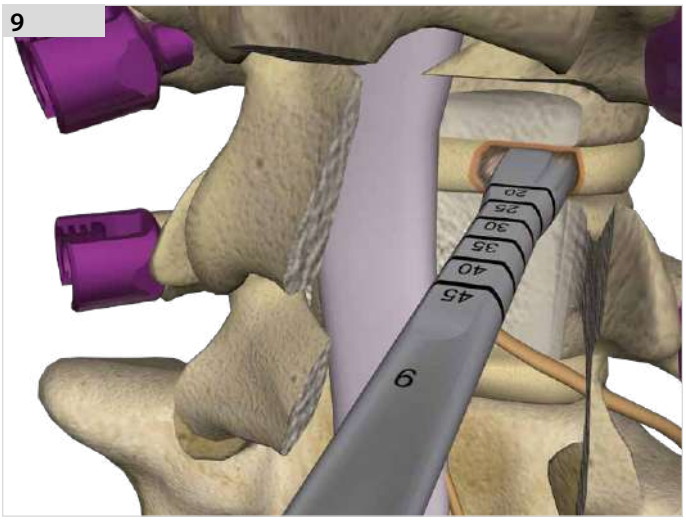


Files, bone curette, osteotomes and rongeurs are additional equipment provided in instrument set [15.0901.102].

In patients with poor bone quality, it might be useful to use reamers 9 instead of distaction forceps.
One side of the reamer **[40.5805.009÷018]** has smooth surfaces that when applied to the endplates distract the intervertebral body space. The other side has a cutting edge that removes the endplates, exposing the subchondral bone.

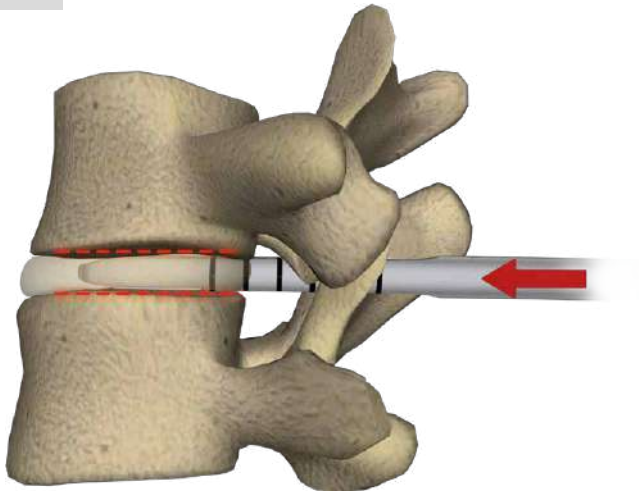
40.5805.009
40.5805.010
40.5805.011
40.5805.012
40.5805.013
40.5805.014
40.5805.015
40.5805.016
40.5805.017
40.5805.018

9



The reamer should be inserted horizontally 10 and then rotated.

10



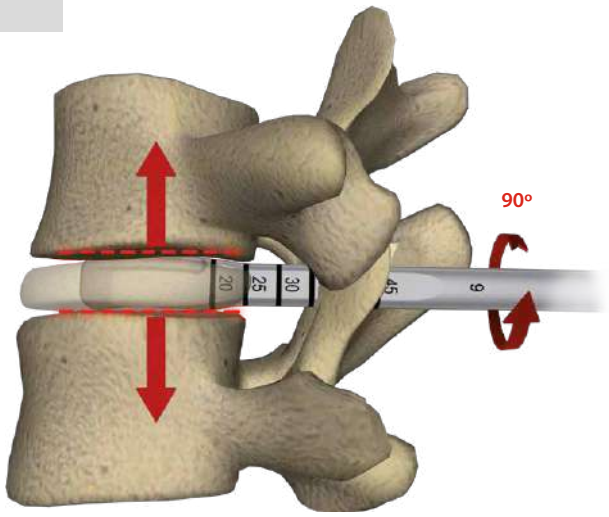
A clockwise rotation of the reamer 11 gradually increases the disc space.

A counter-clockwise rotation of the reamer removes disc material.

Distraction should be repeated sequentially on both sides using larger sizes of reamer, until adequate intervertebral height is obtained.

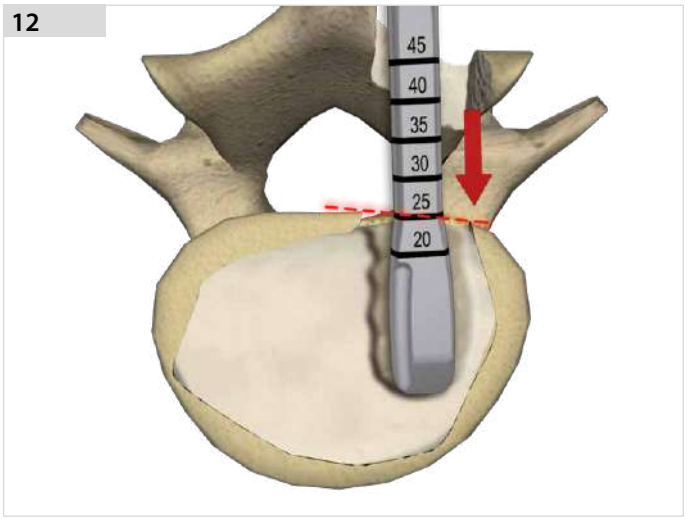
For fully distracted segment, the reamer must fit tightly and accurately inside the disc space.

11

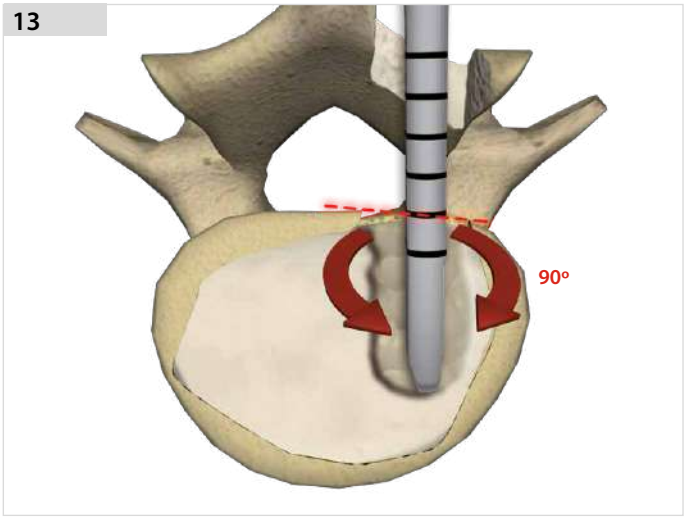


When 25-mm cages are to be used, the posterior wall of the vertebral body should be flush with the 30-mm mark on the reamer.
For 20-mm cages, the posterior wall of the vertebral body should be flush with the 25-mm mark on the reamer 12.

12



13



The bone curette oval **[40.6192]** or bone curette rectangular **[40.6193]** 14 may be used to complete the preparation of the endplates that are not accessible for the reamers.

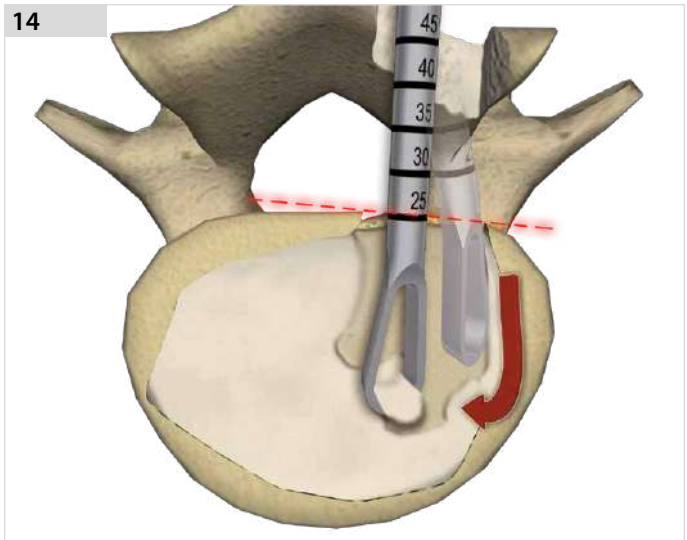
The scale on the instrument allows for exact measurement of the instrument depth.

40.6192

40.6193

Files, bone curette, osteotomes and rongeurs are additional equipment provided in instrument set [15.0901.102].

14

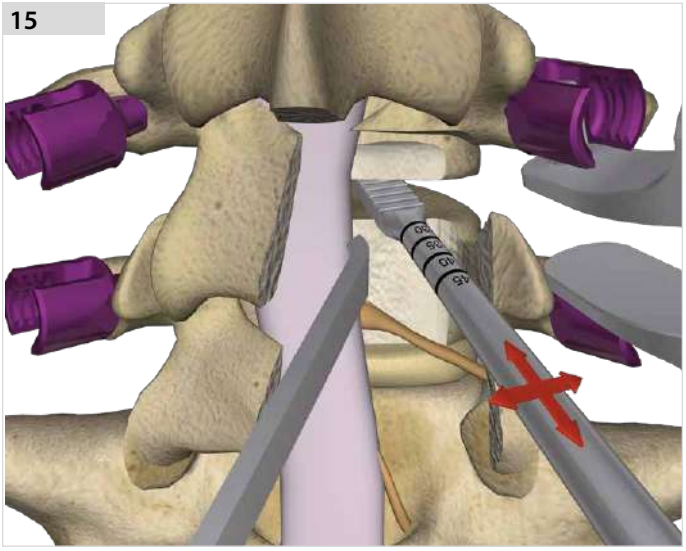


In addition, the file **[40.6196]** can be used to remove the disc material and to prepare the endplate (*to roughen the endplates and generate bleeding*) 15 .

40.6196

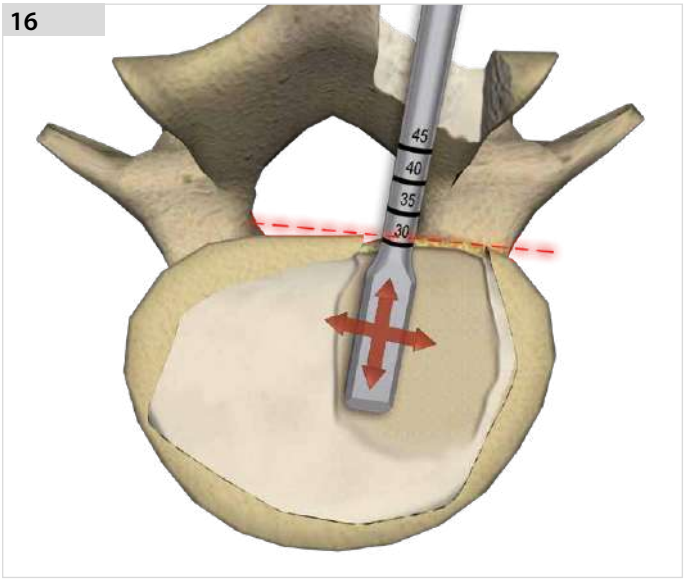
Files, bone curette, osteotomes and rongeurs are additional equipment provided in instrument set [15.0901.102].

15



The scale on the instrument 16 allows for exact measurement of the instrument depth.

16



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sales@novutechusa.com

IV.4. IMPLANT PREPARATION

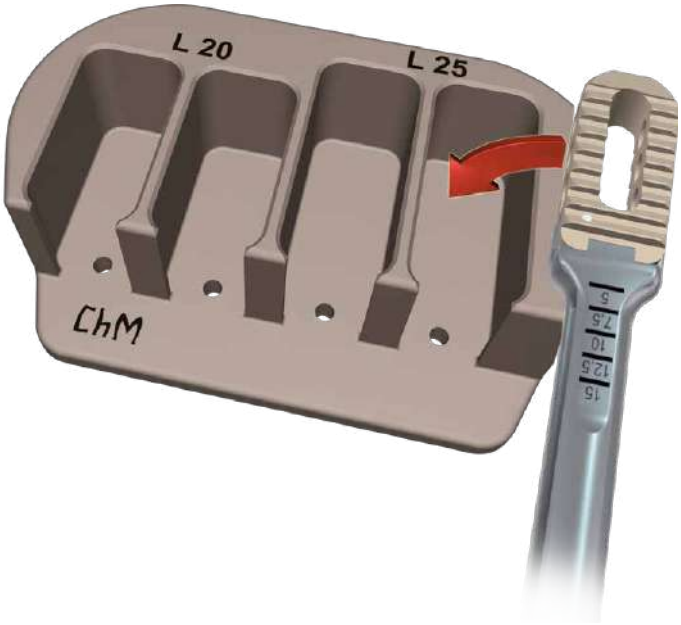
The cage is mounted on the applicator **[40.5829]** 17 and placed in the working stand **[40.5809]** 18, where is filled with pieces of autologous bone.

40.5829

40.5809

17

18

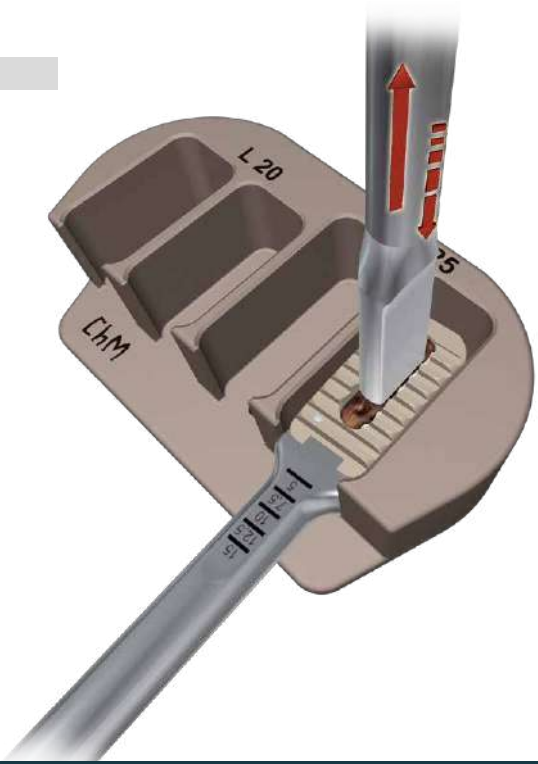


The pieces of bone are compacted manually in the cage with the use of compactor **[40.6190]** 19.

The compacted graft should be flush with the upper and lower surfaces of the cage in order to be in contact with the endplates.

40.6190

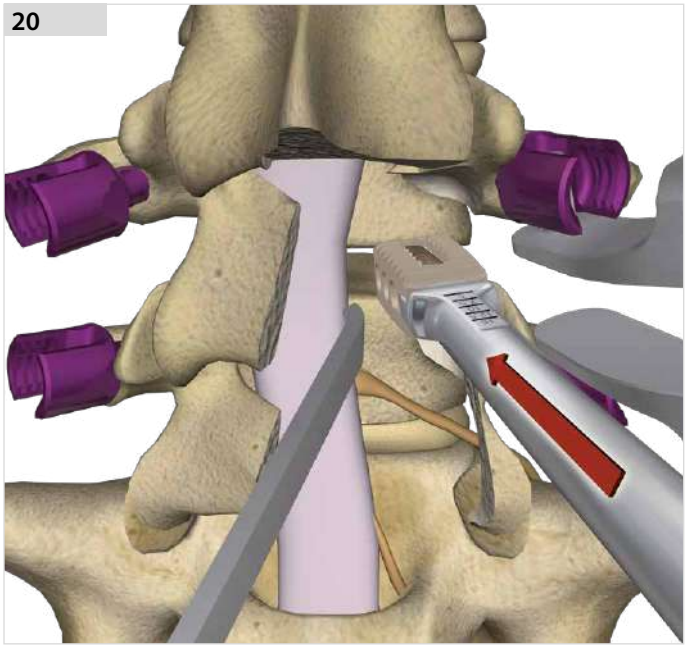
19



IV.5. INSERTION OF THE INTERVERTEBRAL CAGE

The cage should be inserted gently and progressively in a wide open disc space 20. Its serrated sides should face the endplates.
To ensure that the intervertebral space is freely accessible to the cage, the reamer should be left in place on the contralateral side or prior achieved distraction should be maintained with the use of parallel distraction forceps.
Thanks to its blunt "*bullet-shaped*" part, the cage can be inserted without the risk of penetrating the endplates.

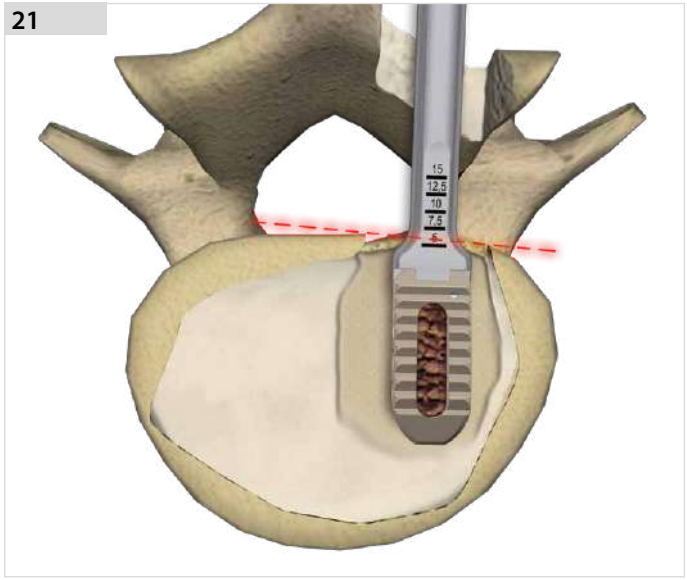
20



Advance the cage to the correct depth (*approx. 4 mm from the posterior edge of the vertebral body*).
Verify the cage insertion depth on the scale on the implant applicator 21.

After proper insertion, the cage should be released.

21

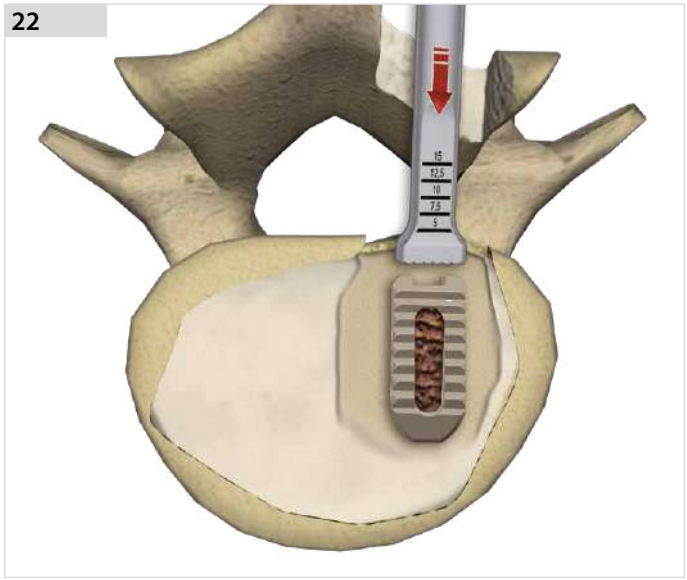


If needed, the impactor for cages **[40.5836]** 22 can be used to impact the cage to the desired position.

The roughened end of the instrument prevents implant slippage during the impaction process.

The scale on the instrument allows for exact measurement of the distance between the implant and the posterior edge of the vertebral body.

22



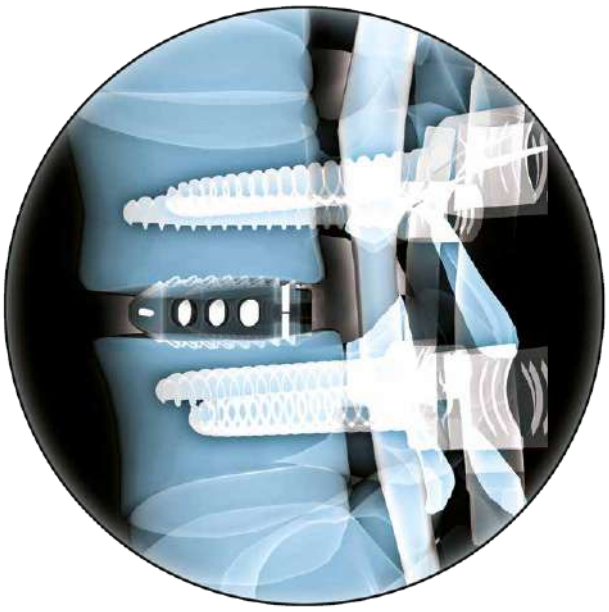
40.5836

Implantation is then carried out on the contralateral side of the intervertebral space and afterwards, all the instruments are removed.

Use image intensifier control to verify the position of the cages.

Since the both of intervertebral cages are inserted, distraction can be released.

If pedicle screws have not been inserted earlier in the procedure, they may now be inserted using standard technique and e.g. **CHARSPINE2** pedicle screw system.

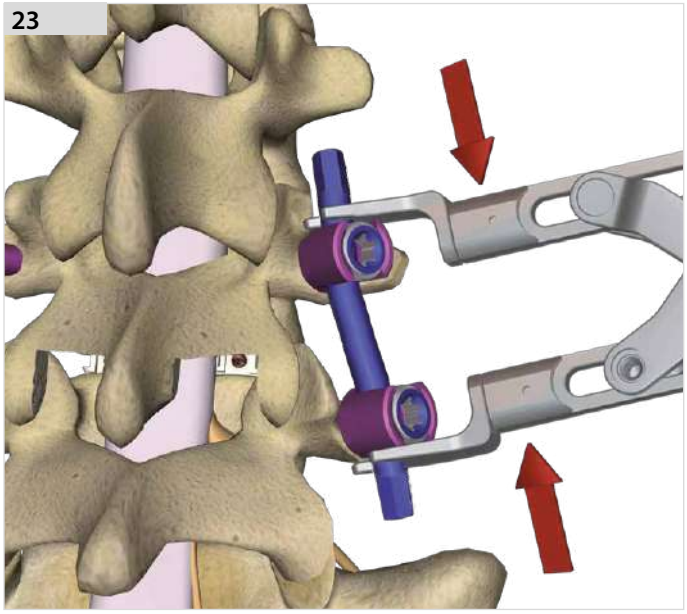


On this stage, final, gentle compression of the vertebrae can be applied. Anterior portions of vertebrae bodies are loosened. This will naturally cause restoration of lumbar segment lordosis and compression of the intervertebral cage.

When **CHARSPINE2** system has been used for the pedicure screw stabilization, the parallel compression forceps **[40.8094.000]** that are standard equipment of the stabilizer may be used 23.

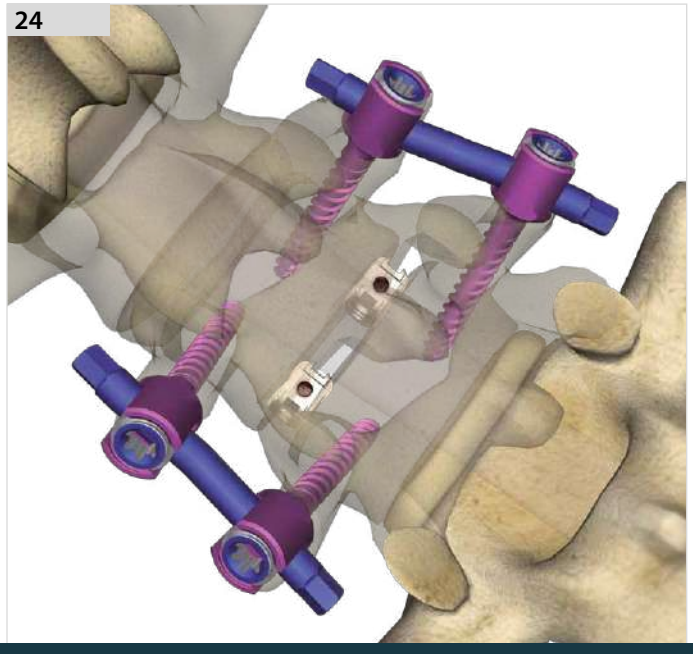
Instrument set for intervertebral PLIF Cage does not include parallel compression forceps [40.8094.000].

23



Once compression of the pedicle screws is done, the construct should be locked 24.

24



IV.6. IMPLANT REMOVAL

Should cage removal be required, vertebra distraction using reamer **[40.5805.009÷018]** or parallel distraction forceps **[40.8093.000]** is needed.

Attach the applicator **[40.5829.000]** to the cage and remove the implant from the intervertebral space.

40.5829

25