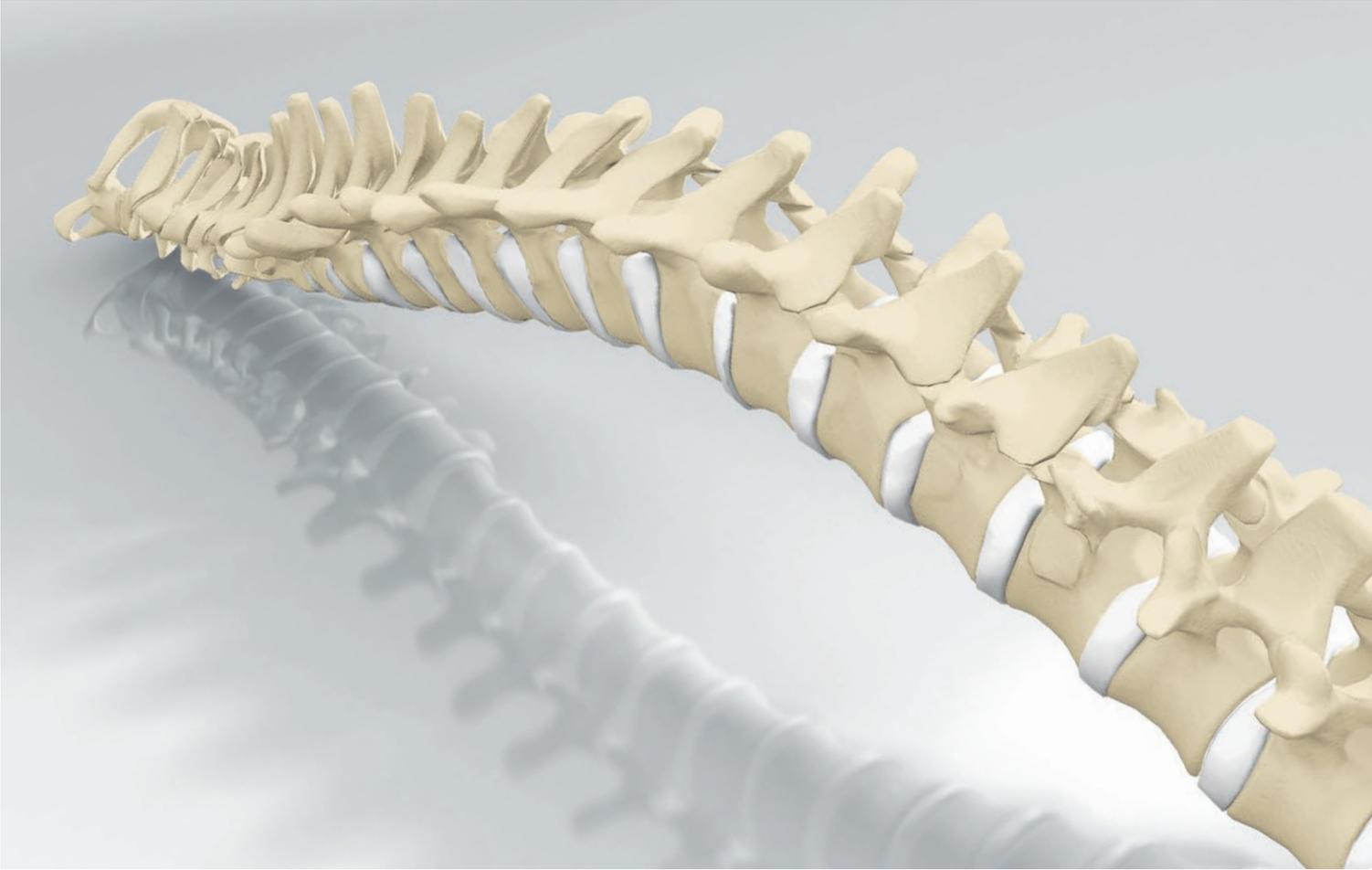




SPINE SURGERY

AESCULAP® TSPACE® 3D
TRANSFORAMINAL INTERBODY FUSION SYSTEM
SURGICAL MANUAL

AESCULAP® LUMBAR SPINE



RELIABLE PARTNER IN SPINE SURGERY

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AESCULAP® TSPACE® 3D

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PROTECTING AND PRESERVING SPINAL STABILITY

Modern lifestyle has resulted in increasing physical inactivity among people all over the world. Of the many medical problems associated with this, spinal disorders are among the most critical. This is even more significant as the spinal column is one of the most important structures in the human body.

It supports and stabilizes the upper body and is the center of our musculoskeletal system, which gives the body movement. Our work in the field of spine surgery is dedicated to protecting the spinal column and preserving its stability. We support spine surgeons with durable, reliable products and partner services for reliable procedures and good clinical outcomes (1-7).

Our philosophy of sharing expertise with healthcare professionals and patients allows us to develop innovative implant and instrument systems that help to preserve stability and stabilize the cervical and thoracolumbar spine.

AESFULAP[®] TSPACE[®] 3D

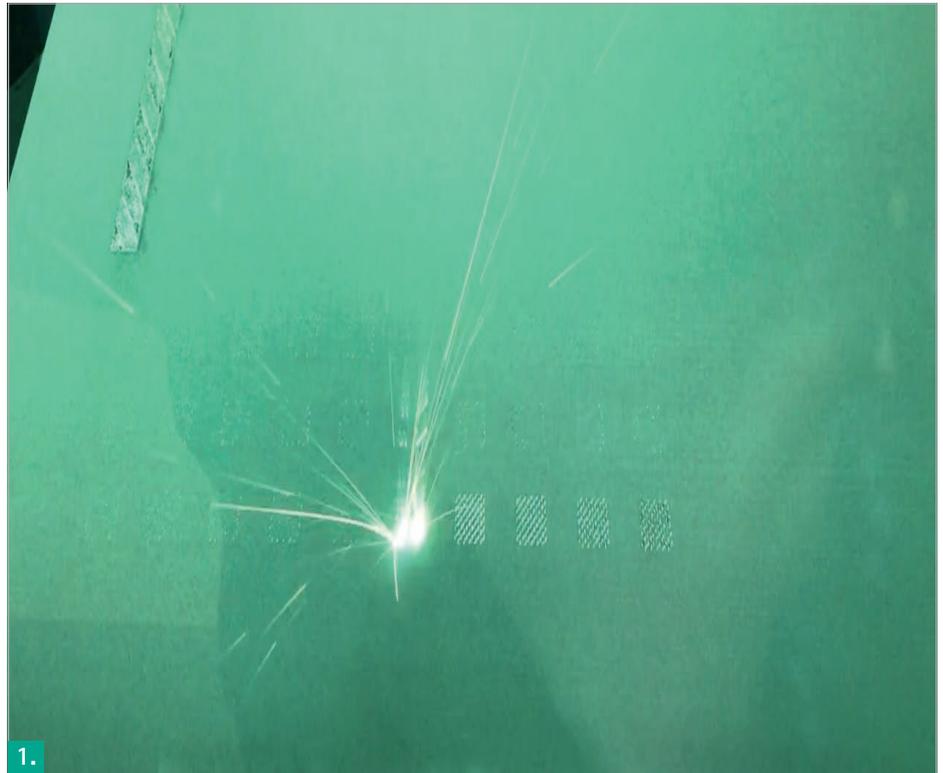
A. IMPLANT MATERIAL

THE TECHNOLOGY OF LASER SINTERING – A WELL-ESTABLISHED ADDITIVE LAYER BY LAYER PROCESS

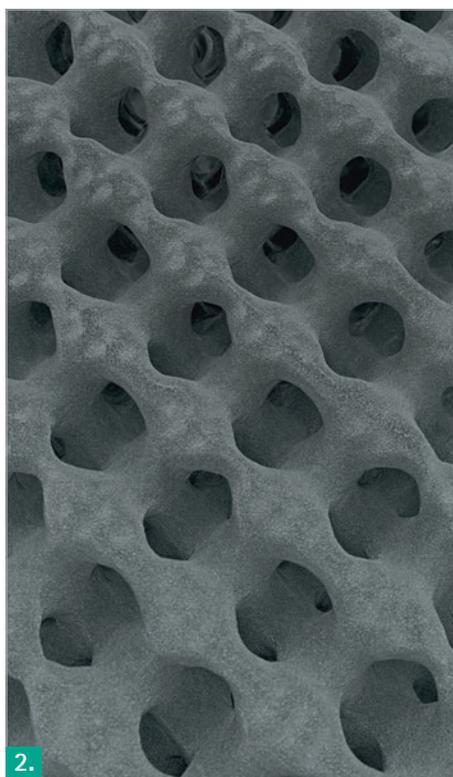
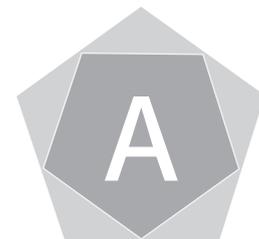
■ Additive manufacturing – 3D printing – means a layer by layer process to design a device using laser beam and metal powder. This innovative laser beam melting technology is of growing importance in the manufacture of implants, as it allows to create various fine and porous surface structures with the aim to support bone-ingrowth. Homogenous or heterogeneous lattice structures or combinations of various kinds of structures and surfaces are generally conceivable.

- Direct assembly of the component based on 3D-CAD data
- Design freedom

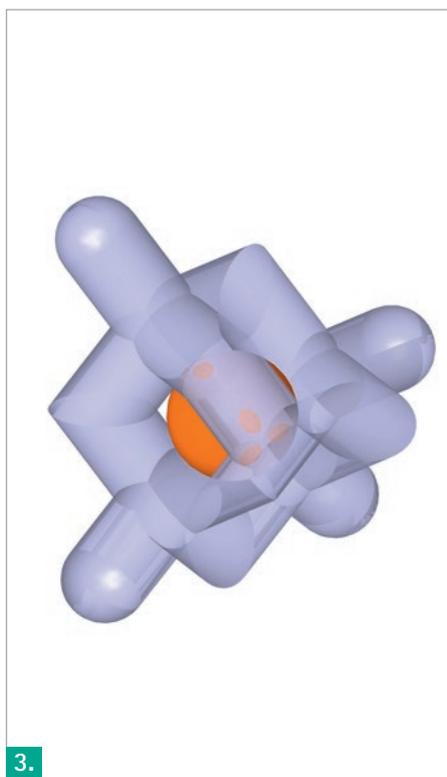
We combined our long-time experience in designing and manufacturing spinal implants with latest technology and produce in-house our AESFULAP[®] 3D Cages (Fig. 1).



Laser beam melting technology



2. Lattice structure Structan®



3. Unit cell with fitted ball of 900 µm

AESCULAP® 3D Cages are engineered from Structan® – a lattice structure with largely isotropic behavior. Ti6Al4V ELI was chosen as a proven and biocompatible material for implants (8).

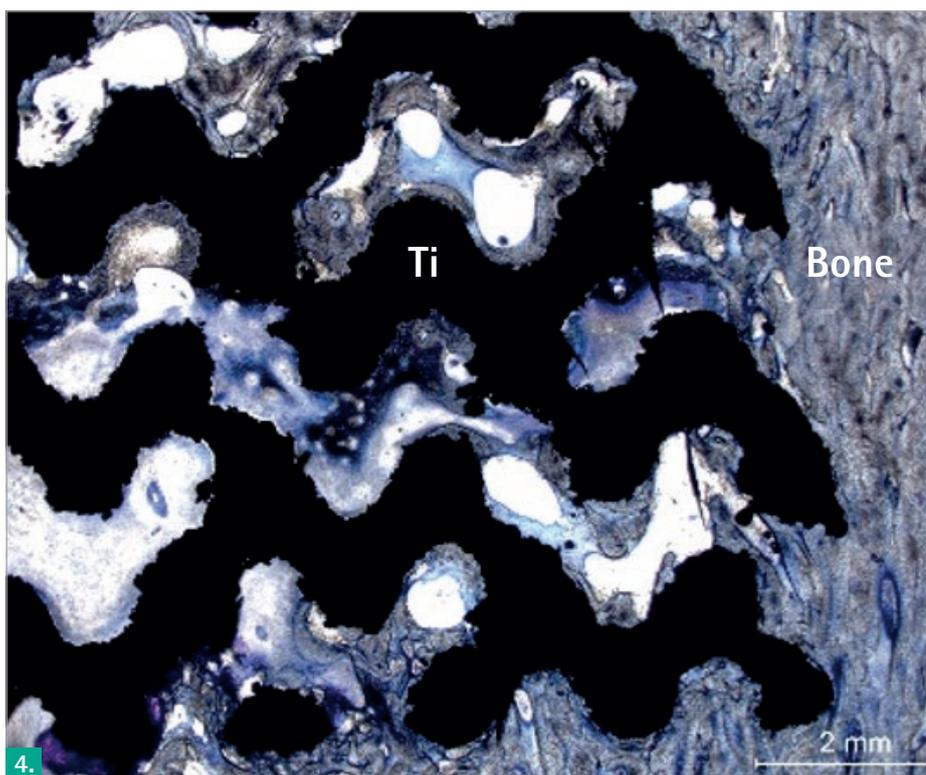
MORE CONNECTION

■ The lattice structure of the AESCULAP® 3D Cages shows an interconnected pore structure (Fig. 2/3). This interconnectivity facilitates migration of bone cells into the structure, thereby providing secondary stability (9, 10).

■ According to the average pore size and porosity of cancellous bone (approximately 1 mm/50-90% (11)) the 3D lattice structure Structan® features an all-over regular pore size of 900 µm as well as a mean interconnected porosity of 50-55%. Pore size and porosity are in a favorable range to stimulate bone in-growth (12, 13).

■ The results of a sheep study with partly loaded implants confirm bone growth on and into the 3D lattice structure without connective tissue layer six months post-operatively. This formation of bone tissue within the 3D lattice structure leads to a high secondary stability (10). The 3D lattice structure serves as a guide rail for bony integration and thus contributes significantly to the secure anchoring of the 3D Cage (Fig. 4).

■ A rough laser sintered surface provides a good interaction between bone cells and implant surface compared to a milled smooth surface and therefore intends to optimize osseointegration (14).



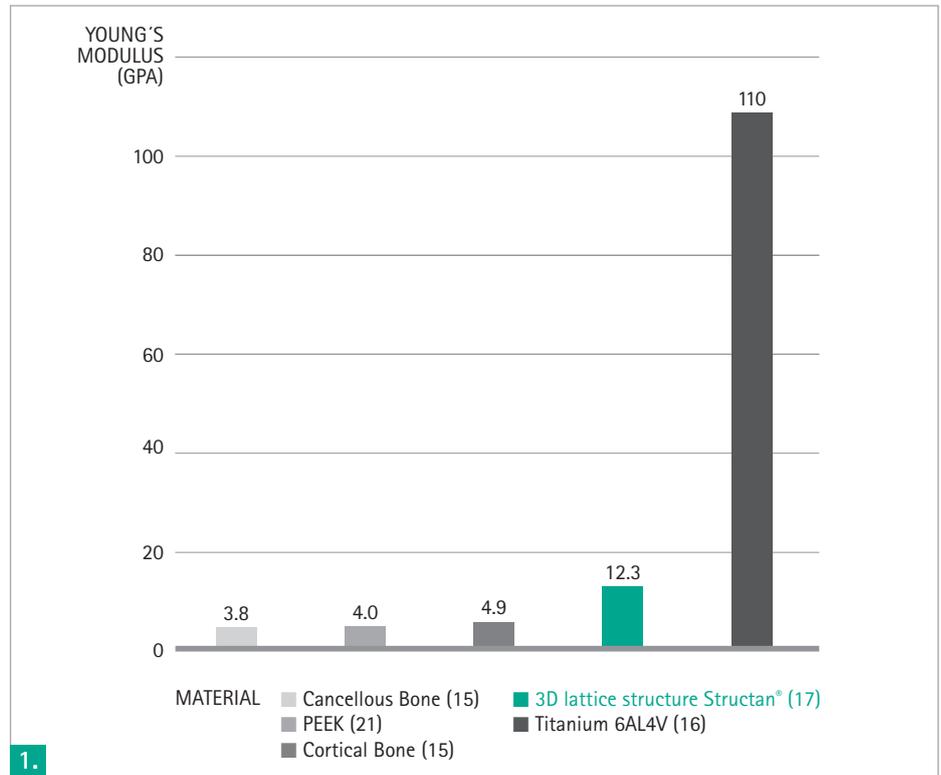
4. Histological section of the 3D Cage lattice structure filled with newly formed bone

AESCULAP® TSPACE® 3D

A. IMPLANT MATERIAL

MORE ELASTICITY

Ti6Al4V ELI as solid material has a Young's modulus of approximately 110 GPa as it is shown in the figure, whereas cortical bone has a Young's modulus of approximately 5 GPa (15, 16). The Young's modulus of Structan® is developed to be close to that of cortical bone (17). This may prevent subsidence into the vertebral body (18). In addition, this may result in improved bone growth (19) (Fig. 1).

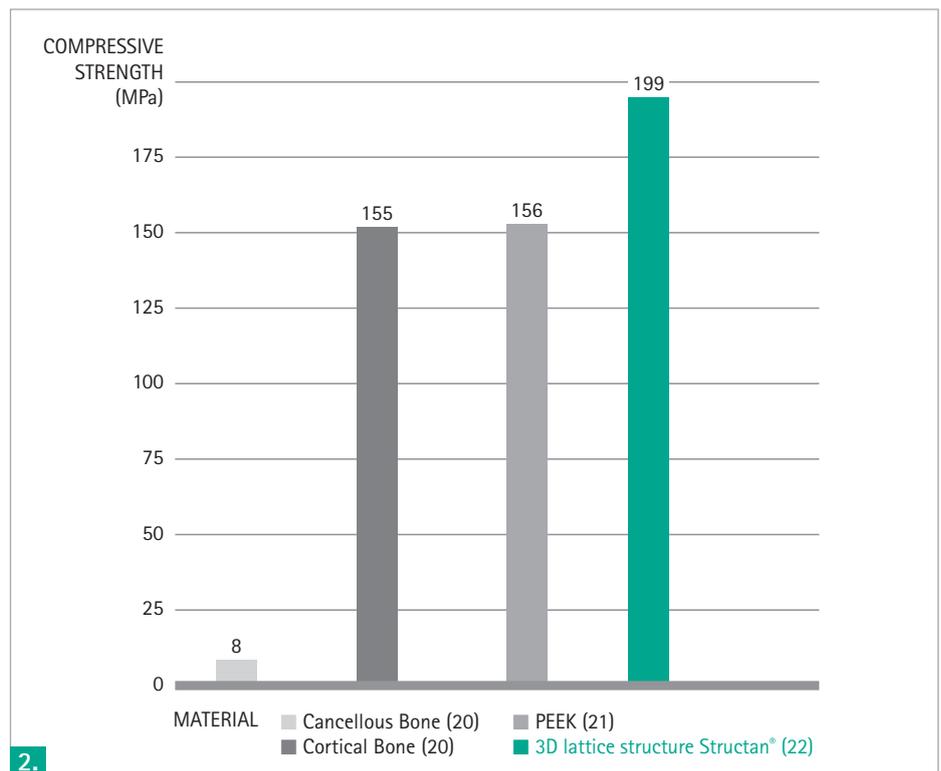


1.

Young's modulus of various materials

MORE STRENGTH

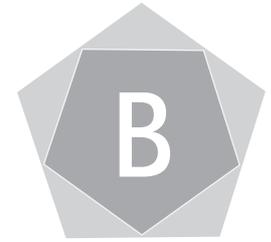
The 3D lattice structure Structan® combines a bone-like Young's modulus with a high compressive strength, which contributes to high safety against failure due to breakage. The compressive strength of the 3D lattice structure Structan® is higher than the mean strength of bone and PEEK (20-22) (Fig. 2).



2.

Compressive strength of 3D lattice structure Structan®

B. INTENDED USE & IMPLANT DESIGN



- Stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.
- Always use TSPACE® 3D in conjunction with an internal fixator.
- TSPACE® 3D can be implanted through an open or minimally invasive transforaminal access.

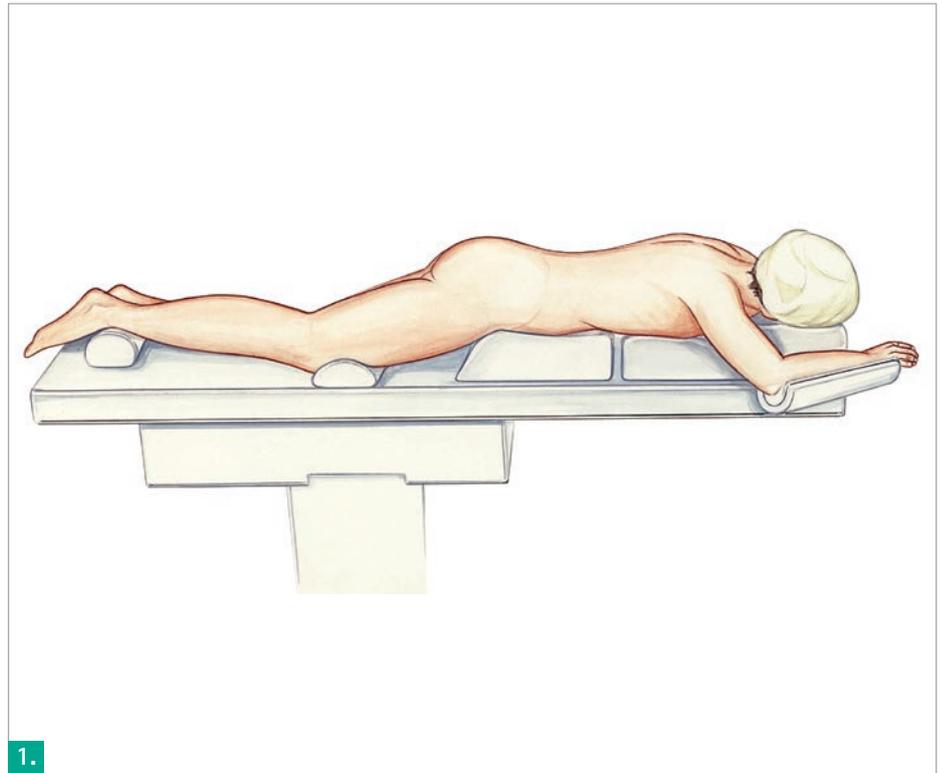
- Solid frame without sharp edges for biomechanical stability and smooth insertion into the disc space minimizing the risk to injure surrounding soft tissue.
- Open porous structure designed to provide primary and secondary stability.
- The implant's anatomical endplate design provides a good contact area between implant and vertebral endplates whilst allowing addition of bone material to enable bone growth through the center of the implant.
- Bulleted nose for smooth insertion into the disc space.
- The articulating interface allows a firm connection to the inserter until the final implant positioning is achieved, thus enabling a controlled insertion.
- Good visibility in X-ray to localize implant positioning (23, 24).

AESCULAP® TSPACE® 3D

C. SURGICAL TECHNIQUE

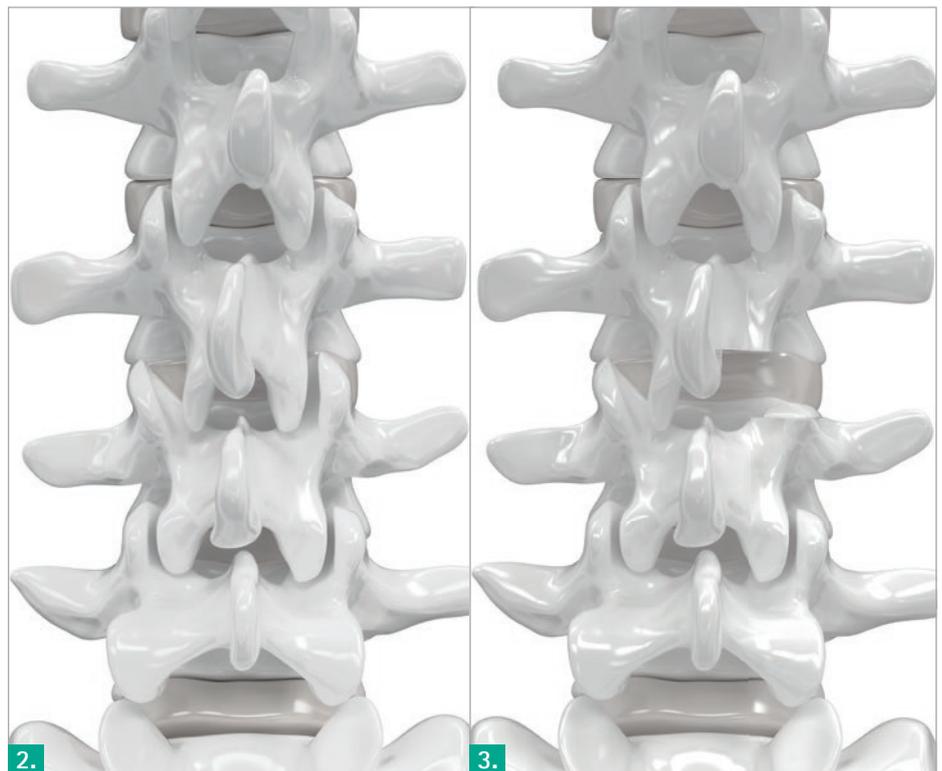
C.01. PATIENT POSITIONING

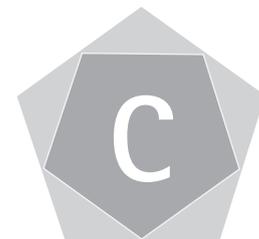
- The patient is positioned in the prone position for transforaminal interbody fusion with supplemental fixation (Fig. 1).
- The TLIF technique describes the unilateral insertion of a single implant through a transforaminal approach.
- TSPACE® 3D can be implanted through an open or minimally invasive access.



C.02. EXPOSURE OF THE INTERVERTEBRAL SPACE

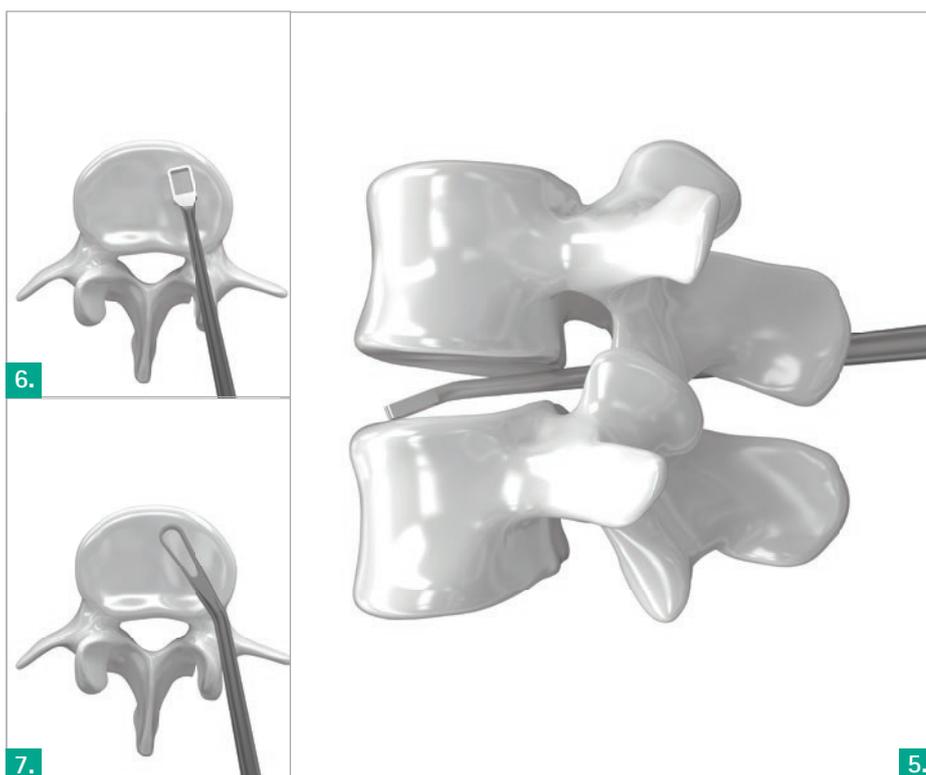
- Using an osteotome and a Kerrison bone punch the bone resection is performed to get access to the disc space. For a transforaminal approach to the disc the facet joint is resected on the side targeted for the implant insertion. The inferior articular process of the facet joint is resected first, then the subjacent superior articular process is resected (Fig. 2/3).
- In order to make room for the insertion of the distractor, resection of disc material is carried out using rongeurs and forceps.





C.03. RESTORATION OF DISC HEIGHT

- The desired distraction can be set using the distractors, available in heights from 7 - 15 mm in 1 mm increments.
- Starting with the smallest height, the distractor must be inserted horizontally and then rotated clockwise (Fig. 4).
- Rotate clockwise for a blunt height restoration maneuver. Rotate counter-clockwise to remove disc material with the built-in sharp rim.
- The distractors are inserted one after the other until the desired distraction is obtained.



C.04. DISCECTOMY

- The disc space is cleared using various rongeurs and curettes. The right- and left-angled curettes facilitate removal of cartilaginous material in the far lateral disc space (Fig. 5/6/7).

AESCULAP® TSPACE® 3D

C. SURGICAL TECHNIQUE

C.05. PREPARATION OF ENDPLATES

- The bone rasps are used to refresh the cartilaginous endplates (Fig. 1).

INFORMATION

Make certain that the endplates of the neighboring vertebral bodies are not weakened, in order to minimize the risk of migration.

Make certain that the implant bed is properly prepared to avoid damage to the implant when it is driven in.



C.06. IMPLANT SELECTION

- Use the inserter to insert the trial implant until the final end position.

INFORMATION

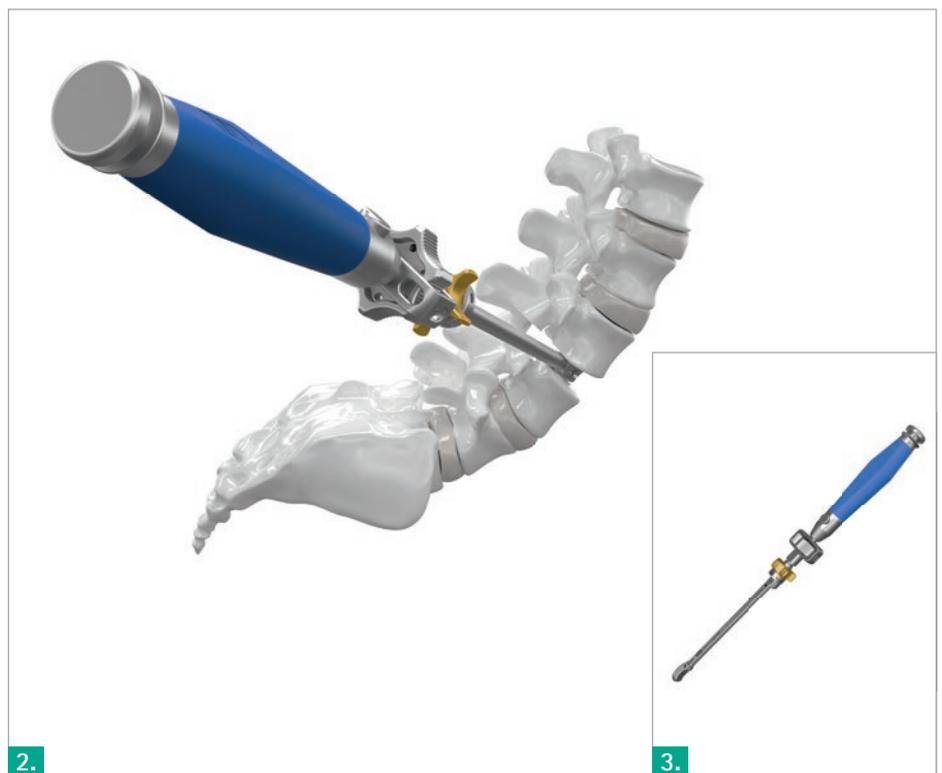
It is essential to use trial implants to establish the correct implant size.

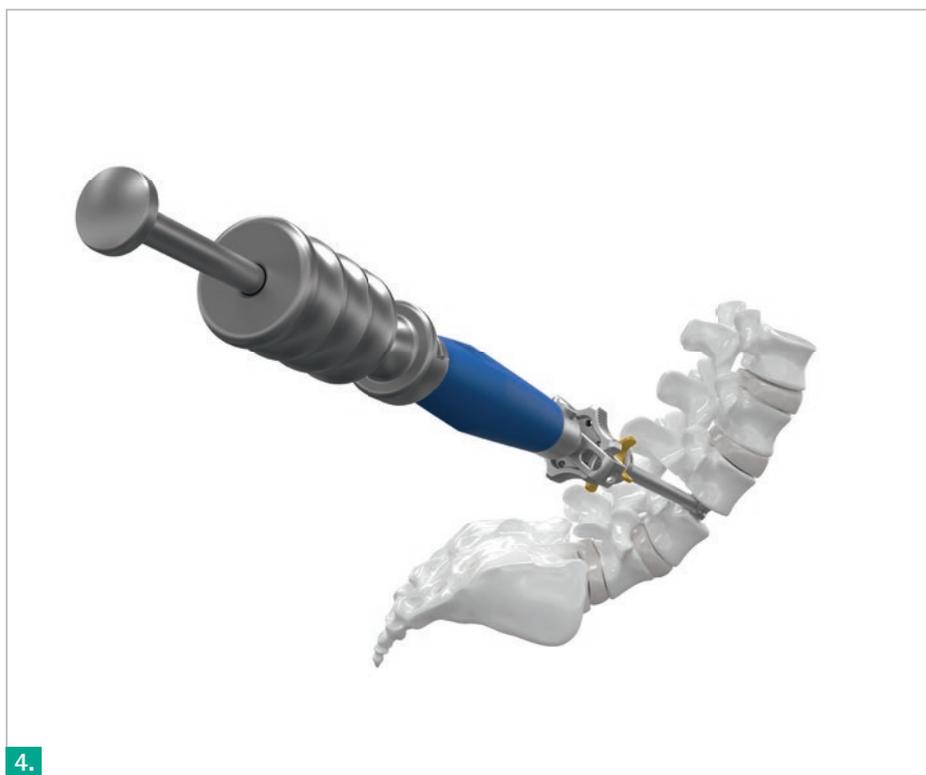
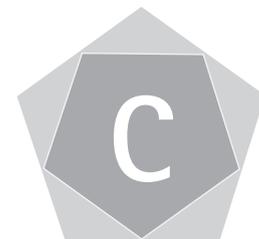
- The trial positioning is done in the same way as the implant positioning, please refer to C.09/C.10. (Fig. 2/3).

INFORMATION

Please refer to C.12. for a detailed assembling description of the articulating inserter.

- Start with the smallest trial size. Step-wise the next heights are inserted until the required distraction is achieved.
- Use X-ray control to verify trial implant positioning.





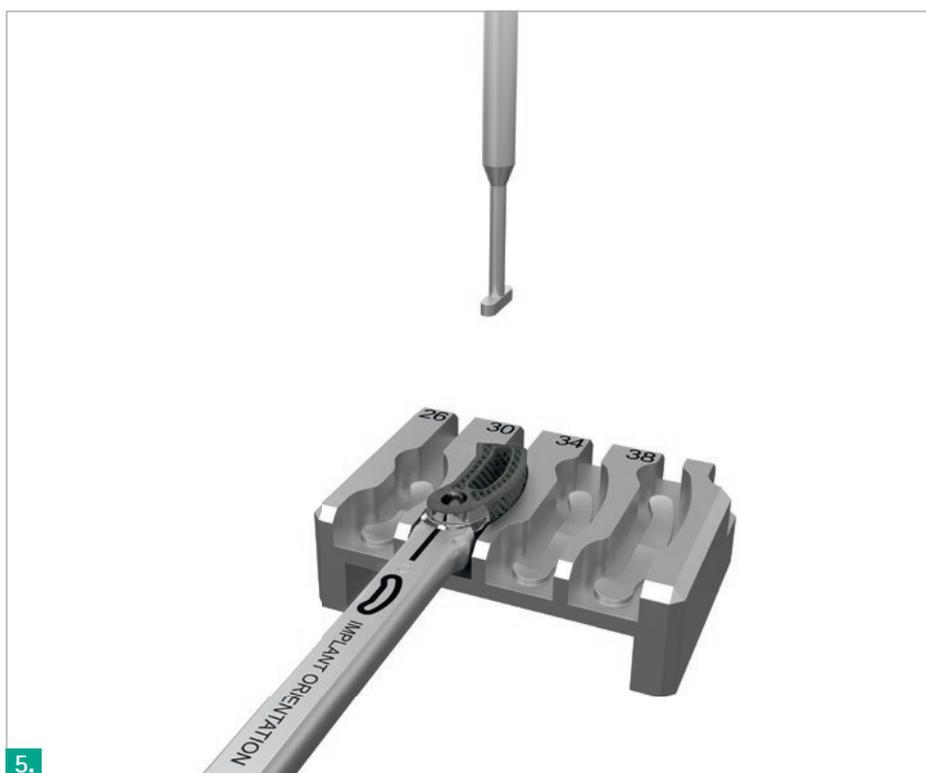
INFORMATION

The trials are essential to ensure the correct implant size to be used.

- Connect the slap hammer to the handle of the inserter (Fig. 4).
- Use the slap hammer to back out the trial carefully.

C.07. IMPLANT REMOVAL FROM PACKAGING

- Open folder blister to remove the TSPACE® 3D implant.
- The packaging concept allows implant removal with the connected inserter.



C.08. FILLING OF CAGE

- Use the packing block and the punch for optional filling of the implant with bone or bone substitute (Fig. 5).

INFORMATION

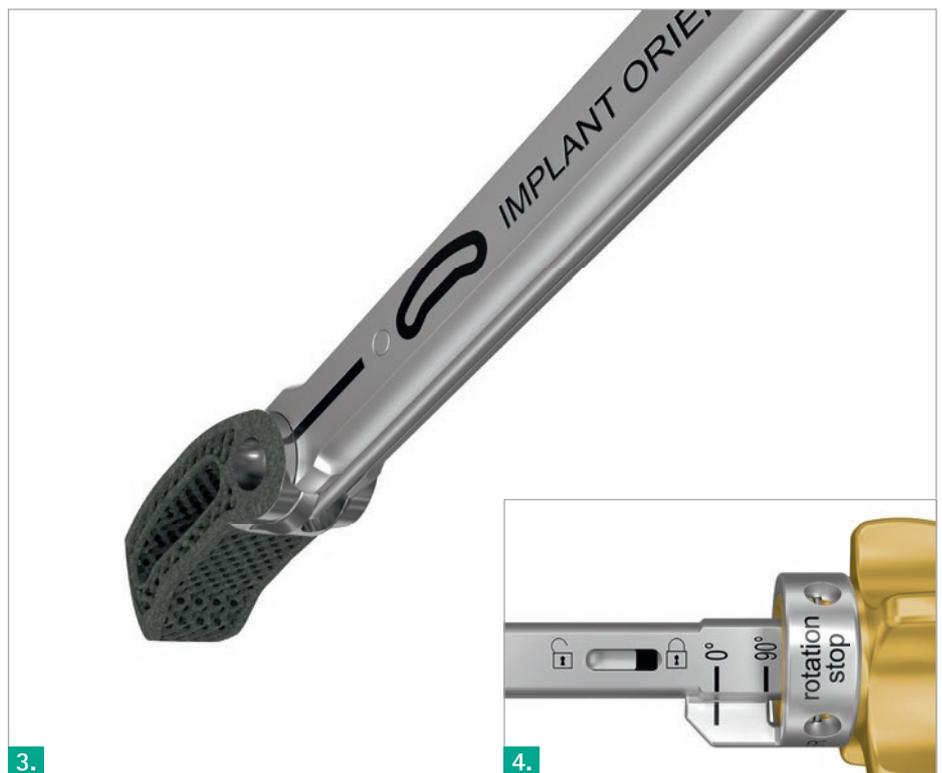
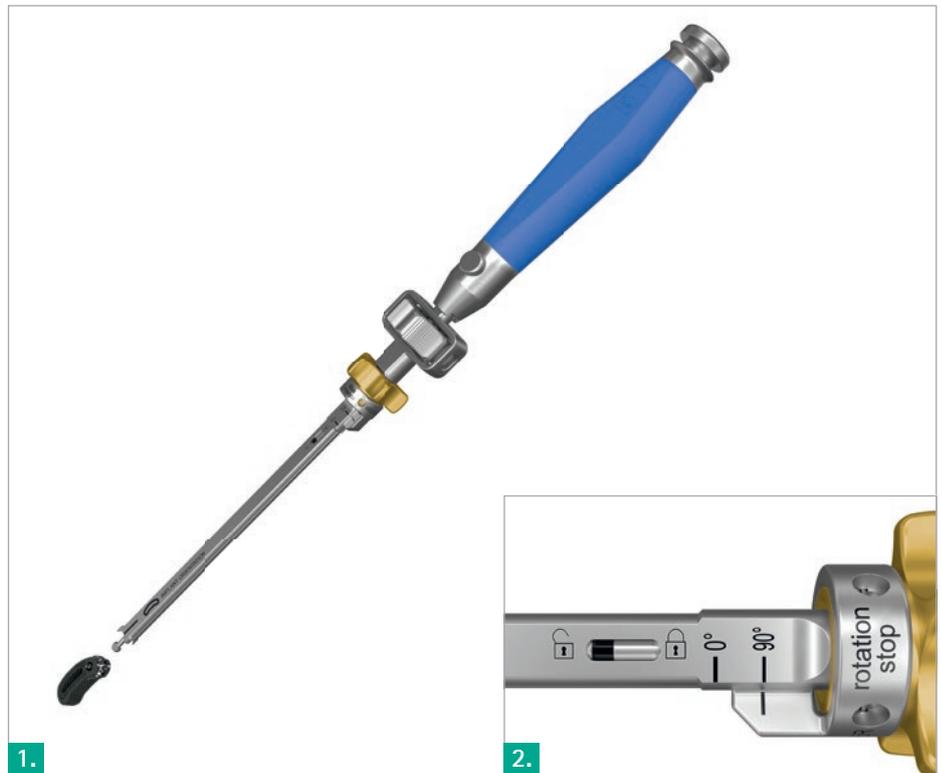
Do not use force during filling to avoid implant damaging.

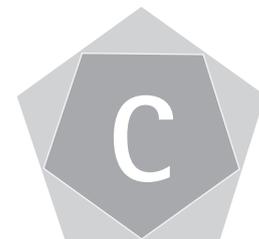
AESCULAP® TSPACE® 3D

C. SURGICAL TECHNIQUE

C.09. TSPACE® 3D INSERTION

- It is recommended to place bone graft in the anterior part.
- Mount the TSPACE® 3D implant along the axis of the instrument (Fig. 1).
- Ensure that the tip of the insertion rod is in horizontal position to connect the implant with the inserter. At this point, the marking shows plug lock open and rotation stop at 90° (Fig. 2).
- Turn the big rotary wheel next to the handle until the marking shows plug lock is closed. Now the implant is firmly hold (Fig. 3/4).
- Bring rotation stop to 0° position to block the rotation during initial insertion (Fig. 4).
- Recheck the connection between the implant (and respectively trial implant C.06.) and the inserter.



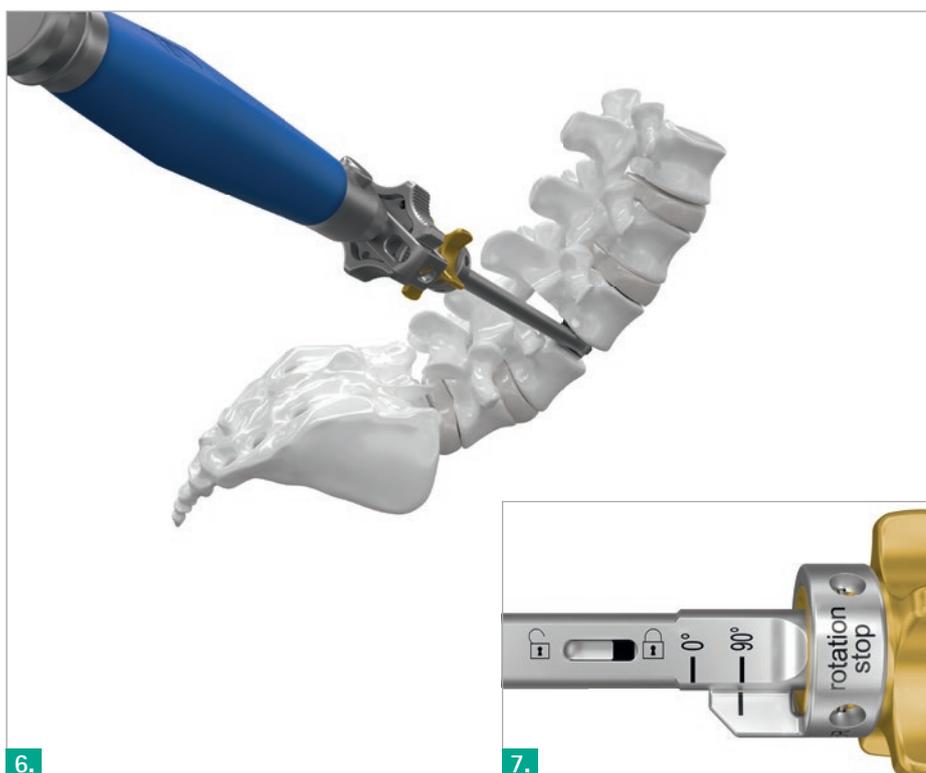


■ The TSPACE® 3D implant is introduced straight into the intervertebral space by gentle hammering on the intended surface of the handle (Fig. 5).

■ Use the nerve root retractors to protect the dura during insertion.

5.

C.10. TSPACE® 3D FINAL IMPLANT POSITIONING



■ Slightly turn the big rotary wheel counterclockwise to release the preload. Therefore turn the big rotary knob just one thumb movement in counterclockwise direction, i.e. approx. up to the frame.

■ Pulling back the stop rod to 90° by turning the union nut allows a rotation maneuver of the implant.

■ Carefully hammer in the implant until it reaches the final position required. When hammering in to further advance the cage into the disc space ensure that the big rotary knob is still sufficiently tightened.

■ Alternatively, stepwise pull out the stop rod by turning the union nut (rotation range is between 0° and 90°) and further hit the implant with the mallet until it reaches the stop. Repeat until the final position is reached. If rotation maneuver is done stepwise, recheck the tension of the big rotary wheel. (Fig. 6/7).

6.

7.

AESCULAP® TSPACE® 3D

C. SURGICAL TECHNIQUE

■ Intra-operative X-ray control to verify the implant positioning (Fig. 1).

■ After the final positioning release the implant and remove the inserter by turning the big rotary wheel until the marking shows plug lock is open (Fig. 2).

INFORMATION

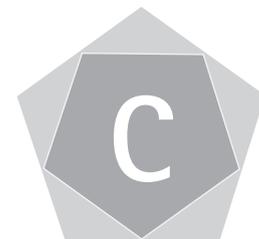
Ensure not to turn further than "plug lock open" and that the black bar marking is still visible in the shaft window.

■ It is recommended to put bone material harvested from the facet joint around the TSPACE® 3D implant.

INFORMATION

Carefully pull the inserter out of the implant. Avoid tilting of the instrument.





C.11. POSTERIOR STABILIZATION

- Additional posterior stabilization of the motion segment using AEscULAP® Ennovate® Open Module (surgical technique 048102) or AEscULAP® Ennovate® MIS Module (surgical technique 000702) should be performed (Fig. 3).
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.
- Final X-ray.

AESCULAP® TSPACE® 3D

C. SURGICAL TECHNIQUE

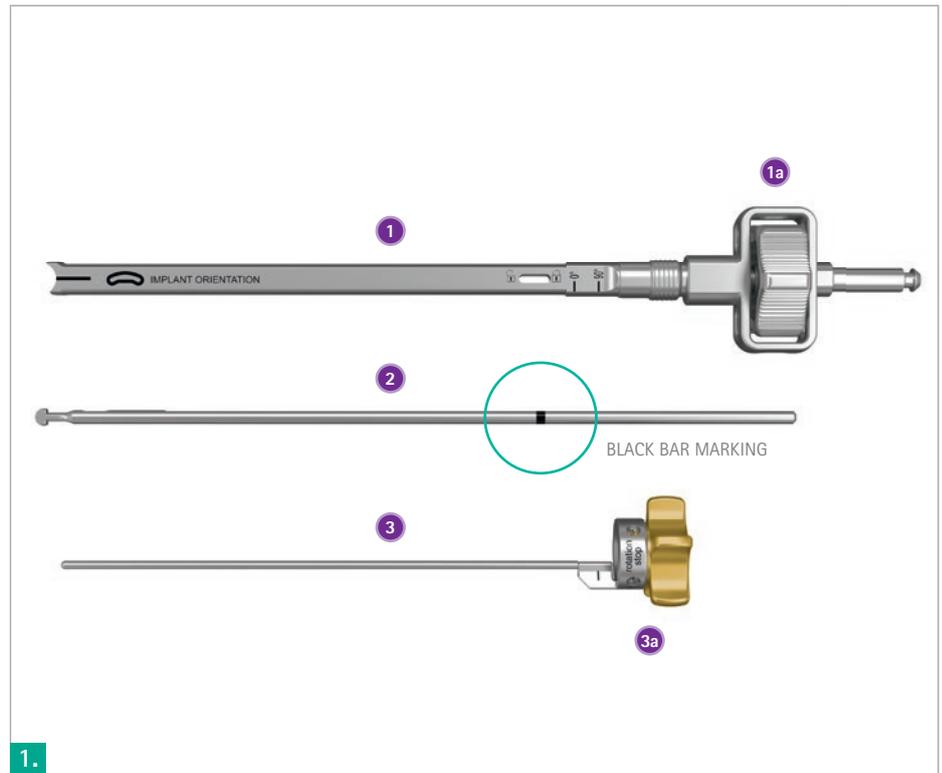
C.12. ASSEMBLING OF THE TSPACE® INSERTER SN705R

The inserter consists of three parts and the handle (Fig. 1).

- 1 Shaft
- 1a Rotary wheel
- 2 Bayonet rod
- 3 Rotation stop with stop rod
- 3a Union nut

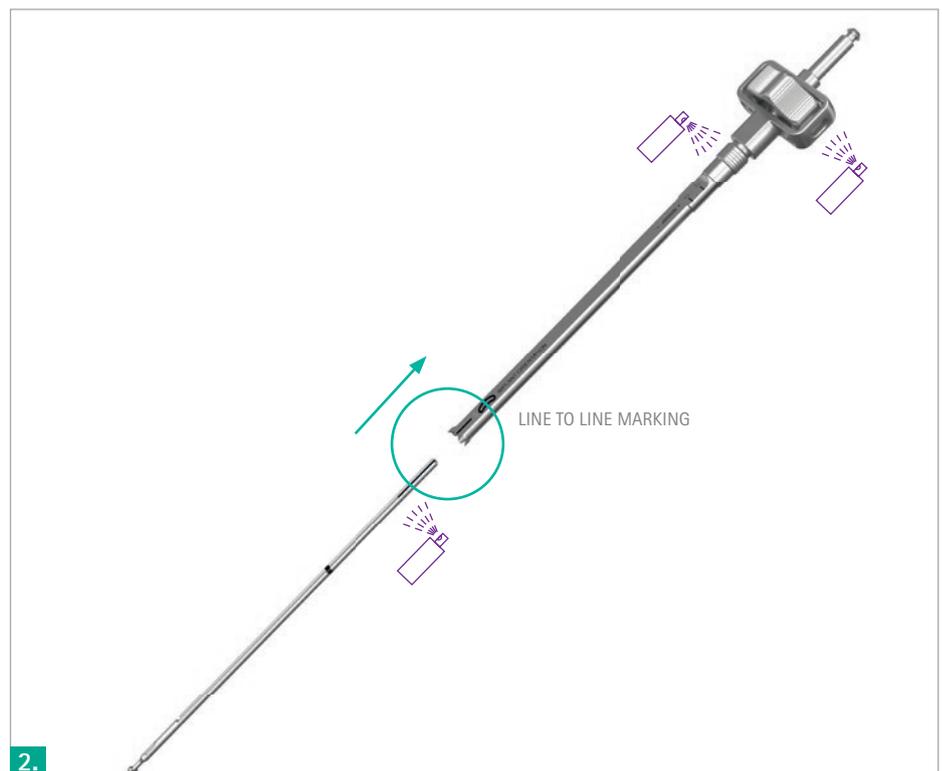
INFORMATION

Please consider regular oiling.

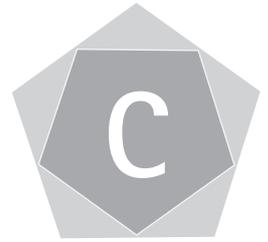


1.

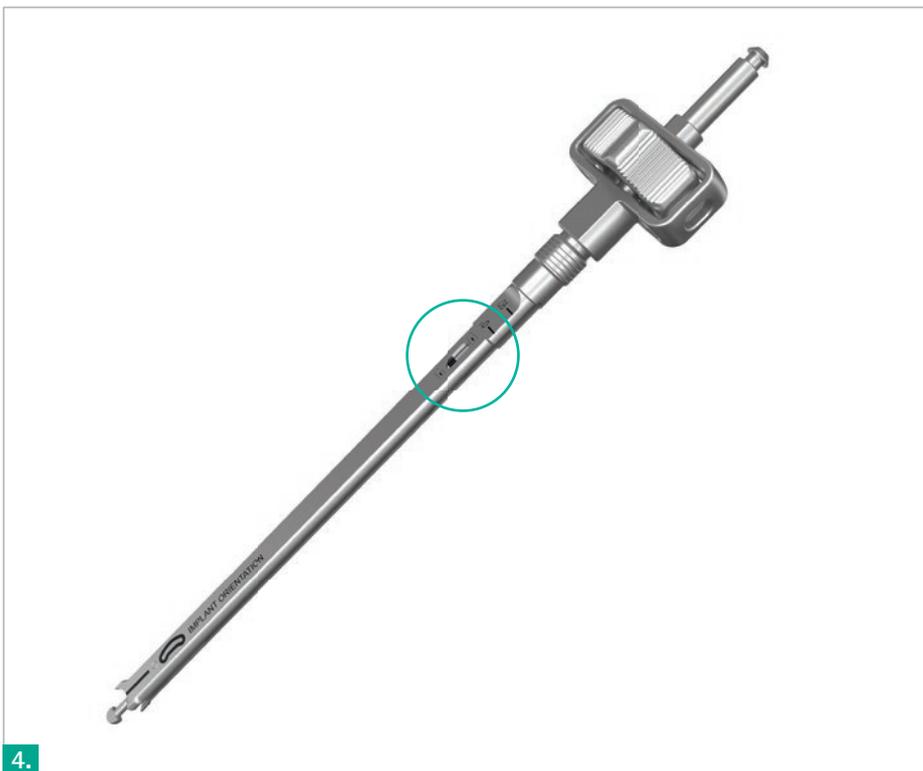
To assemble the inserter first put the bayonet rod 2 in the shaft 1 up to the stop. Markings on the shaft and the bayonet rod (line to line) have to be observed (Fig. 2).



2.



After the stop is achieved (Fig. 3) turn bayonet rod 90° and push it further in shaft 1.



Turn rotary wheel 1a in clockwise direction until the black bar marking of the bayonet rod 2 is visible in the window (Fig. 4).

AESCULAP® TSPACE® 3D

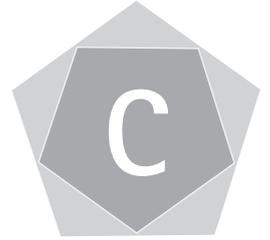
C. SURGICAL TECHNIQUE

- Put the rotation stop 3 in the lateral slot of shaft 1 and push it until the threads (Fig. 1).



- Turn the union nut 3a in counterclockwise direction up to the stop (Fig. 2).





■ Attach handle S0505R to the inserter (Fig. 3 / 4).

■ The handle offers the possibility to attach the slap hammer extension SN320R for trial removal.



4.

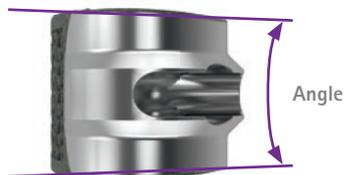
AESCALAP[®] TSPACE[®] 3D

D. IMPLANT OVERVIEW

LORDOSIS 5°



Nominal height



Article No.	Size (Height x Width x Length)	Quantity
SN707T	7 x 11.5 x 26 mm	2
SN708T	8 x 11.5 x 26 mm	2
SN709T	9 x 11.5 x 26 mm	2
SN710T	10 x 11.5 x 26 mm	2
SN711T	11 x 11.5 x 26 mm	2
SN712T	12 x 11.5 x 26 mm	2
SN713T	13 x 11.5 x 26 mm	2
SN715T	15 x 11.5 x 26 mm	2
SN727T	7 x 11.5 x 30 mm	2
SN728T	8 x 11.5 x 30 mm	2
SN729T	9 x 11.5 x 30 mm	2
SN730T	10 x 11.5 x 30 mm	2
SN731T	11 x 11.5 x 30 mm	2
SN732T	12 x 11.5 x 30 mm	2
SN733T	13 x 11.5 x 30 mm	2
SN735T	15 x 11.5 x 30 mm	2



Article No.	Size (Height x Width x Length)	Quantity
SN748T	8 x 11.5 x 34 mm	2
SN749T	9 x 11.5 x 34 mm	2
SN750T	10 x 11.5 x 34 mm	2
SN751T	11 x 11.5 x 34 mm	2
SN752T	12 x 11.5 x 34 mm	2
SN753T	13 x 11.5 x 34 mm	2
SN755T	15 x 11.5 x 34 mm	2
SN768T	8 x 11.5 x 38 mm	2
SN769T	9 x 11.5 x 38 mm	2
SN770T	10 x 11.5 x 38 mm	2
SN771T	11 x 11.5 x 38 mm	2
SN772T	12 x 11.5 x 38 mm	2
SN773T	13 x 11.5 x 38 mm	2
SN775T	15 x 11.5 x 38 mm	2

AESCALAP[®] TSPACE[®] 3D

E. INSTRUMENT OVERVIEW

SN505 PREPARATION INSTRUMENTS – LUMBAR PREPARATION CLEANING DISC SPACE

	Article No.	Description	Quantity
	SN506R	Tray lumbar prep. 3D Cages discectomy	1
	TF356	Packing stencil f/SN506R (SN505)	1
	JA455R	Lid for OrthoTray DIN w/o handle	1
	FJ658R	Osteotome	1
	FL045R	Mallet	1
	FJ051R	Retractor S	1
	FJ052R	Retractor M	1
	FJ053R	Retractor L	1
	FJ054R	Retractor XL	1
	SJ883R	Box curette straight	1
	SJ885R	Teardrop curette large	1



	Article No.	Description	Quantity
	FJ682R*	Curette 45° Lt. ang	1
	FJ683R*	Curette 45° rt. ang	1
	SJ882R	Bone curette straight	1
	FJ679R*	Bone curette 45° Lt. ang	1
	FJ680R*	Bone curette 45° rt. ang	1
	FJ684R	Bone rasp straight	1
	FJ685R*	Bone rasp 45° Lt. ang	1
	FJ686R*	Bone rasp 45° rt. ang	1

INFORMATION

* Alternatively 20° angled

■ Currettes (FJ702R - FJ703R),

■ Bone currettes (FJ698R - FJ699R) and

■ Bone rasps (FJ704R - FJ705R) are available.

AESCALAP[®] TSPACE[®] 3D

E. INSTRUMENT OVERVIEW

SN505 PREPARATION INSTRUMENTS – LUMBAR PREPARATION DISTRACTION

	Article No.	Description	Quantity
	SN507R	Tray lumbar prep. 3D Cages distraction	1
	TF357	Packing stencil f/SN507R (SN505)	1
	JA455R	Lid for OrthoTray DIN w/o handle	1
	FJ647R	Distractor 7 mm	1
	FJ648R	Distractor 8 mm	1
	FJ649R	Distractor 9 mm	1
	FJ650R	Distractor 10 mm	1
	FJ651R	Distractor 11 mm	1
	FJ652R	Distractor 12 mm	1
	FJ653R	Distractor 13 mm	1
	FJ654R	Distractor 14 mm	1
	FJ655R	Distractor 15 mm	1
	SJ033R	T-handle w/anvil	2

INFORMATION

Recommended container: JK446

Recommended container lid: JK486

Recommended identification label: JG786B



SN700 IMPLANTATION INSTRUMENTS – TSPACE® 3D IMPLANTATION

Article No.	Description	Size (Height x Width x Length)	Quantity
SN701R	TSPACE® 3D tray f/instrumentation		1
TF354	Packing stencil f/SN701R (SN700)		1
JA455R	Lid for OrthoTray DIN w/o handle		1
SN322R	TSPACE® PEEK/XP/3D trial implant 5°	7 x 11.5 x 26 mm	1
SN323R	TSPACE® PEEK/XP/3D trial implant 5°	8 x 11.5 x 26 mm	1
SN324R	TSPACE® PEEK/XP/3D trial implant 5°	9 x 11.5 x 26 mm	1
SN325R	TSPACE® PEEK/XP/3D trial implant 5°	10 x 11.5 x 26 mm	1
SN326R	TSPACE® PEEK/XP/3D trial implant 5°	11 x 11.5 x 26 mm	1
SN327R	TSPACE® PEEK/XP/3D trial implant 5°	12 x 11.5 x 26 mm	1
SN328R	TSPACE® PEEK/XP/3D trial implant 5°	13 x 11.5 x 26 mm	1
SN330R	TSPACE® PEEK/XP/3D trial implant 5°	15 x 11.5 x 26 mm	1
SN352R	TSPACE® PEEK/XP/3D trial implant 5°	7 x 11.5 x 30 mm	1
SN353R	TSPACE® PEEK/XP/3D trial implant 5°	8 x 11.5 x 30 mm	1
SN354R	TSPACE® PEEK/XP/3D trial implant 5°	9 x 11.5 x 30 mm	1
SN355R	TSPACE® PEEK/XP/3D trial implant 5°	10 x 11.5 x 30 mm	1



AESCULAP® TSPACE® 3D

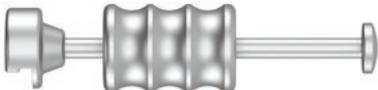
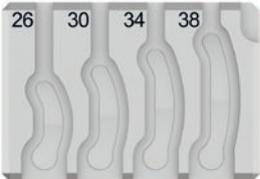
E. INSTRUMENT OVERVIEW

SN700 IMPLANTATION INSTRUMENTS – TSPACE® 3D IMPLANTATION

	Article No.	Description	Size (Height x Width x Length)	Quantity
	SN356R	TSPACE® PEEK/XP/3D trial implant 5°	11 x 11.5 x 30 mm	1
	SN357R	TSPACE® PEEK/XP/3D trial implant 5°	12 x 11.5 x 30 mm	1
	SN358R	TSPACE® PEEK/XP/3D trial implant 5°	13 x 11.5 x 30 mm	1
	SN360R	TSPACE® PEEK/XP/3D trial implant 5°	15 x 11.5 x 30 mm	1
	SN383R	TSPACE® PEEK/XP/3D trial implant 5°	8 x 11.5 x 34 mm	1
	SN384R	TSPACE® PEEK/XP/3D trial implant 5°	9 x 11.5 x 34 mm	1
	SN385R	TSPACE® PEEK/XP/3D trial implant 5°	10 x 11.5 x 34 mm	1
	SN386R	TSPACE® PEEK/XP/3D trial implant 5°	11 x 11.5 x 34 mm	1
	SN387R	TSPACE® PEEK/XP/3D trial implant 5°	12 x 11.5 x 34 mm	1
	SN388R	TSPACE® PEEK/XP/3D trial implant 5°	13 x 11.5 x 34 mm	1
	SN390R	TSPACE® PEEK/XP/3D trial implant 5°	15 x 11.5 x 34 mm	1
	SN783R	TSPACE® 3D trial implant 5°	8 x 11.5 x 38 mm	1
	SN784R	TSPACE® 3D trial implant 5°	9 x 11.5 x 38 mm	1
	SN785R	TSPACE® 3D trial implant 5°	10 x 11.5 x 38 mm	1
	SN786R	TSPACE® 3D trial implant 5°	11 x 11.5 x 38 mm	1
	SN787R	TSPACE® 3D trial implant 5°	12 x 11.5 x 38 mm	1
	SN788R	TSPACE® 3D trial implant 5°	13 x 11.5 x 38 mm	1
	SN790R	TSPACE® 3D trial implant 5°	15 x 11.5 x 38 mm	1



SN700 IMPLANTATION INSTRUMENTS – TSPACE® 3D IMPLANTATION

	Article No.	Description	Quantity
	SN320R	TSPACE® PEEK/XP/3D slap hammer	1
	SN704R	TSPACE® 3D packing block	1
	SN503R	Tamper f/lumbar 3D cage systems	1

AESCULAP® TSPACE® 3D

E. INSTRUMENT OVERVIEW

SN700 IMPLANTATION INSTRUMENTS – TSPACE® 3D IMPLANTATION

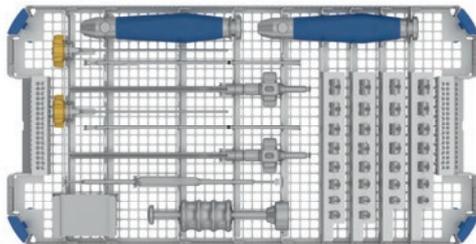
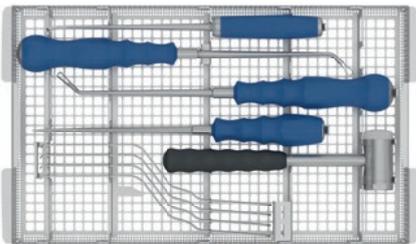
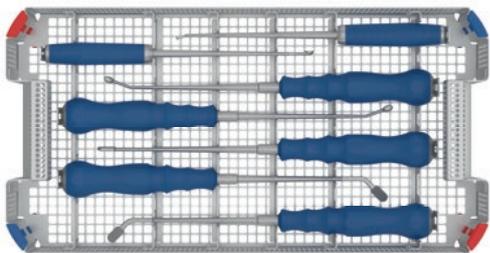
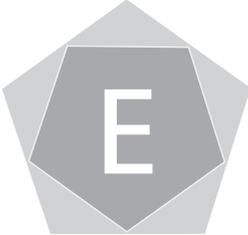
	Article No.	Description	Quantity
	SN705R	TSPACE® PEEK/XP/3D insertion instrument	2
	S0505R	Handle	2

INFORMATION

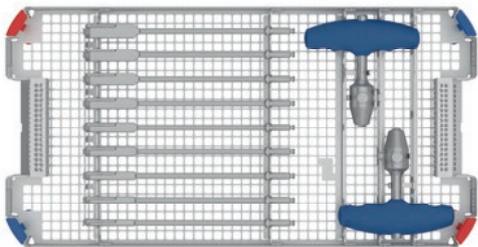
Recommended container: JK440

Recommended container lid: JK486

Recommended identification label: JG786B



SN700



SN505

AESCULAP® TSPACE® 3D

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