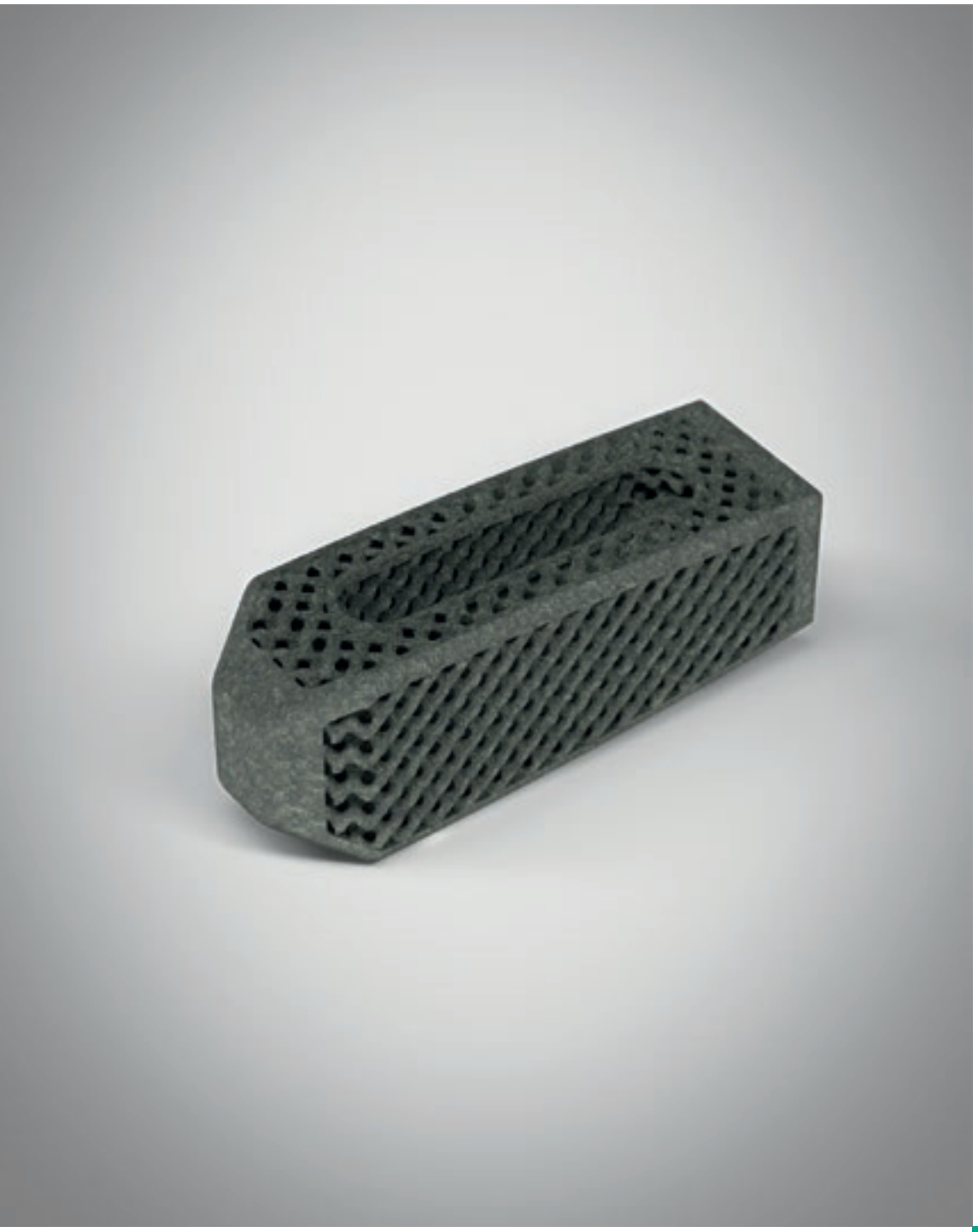
B BRAUN
SHARING EXPERTISE



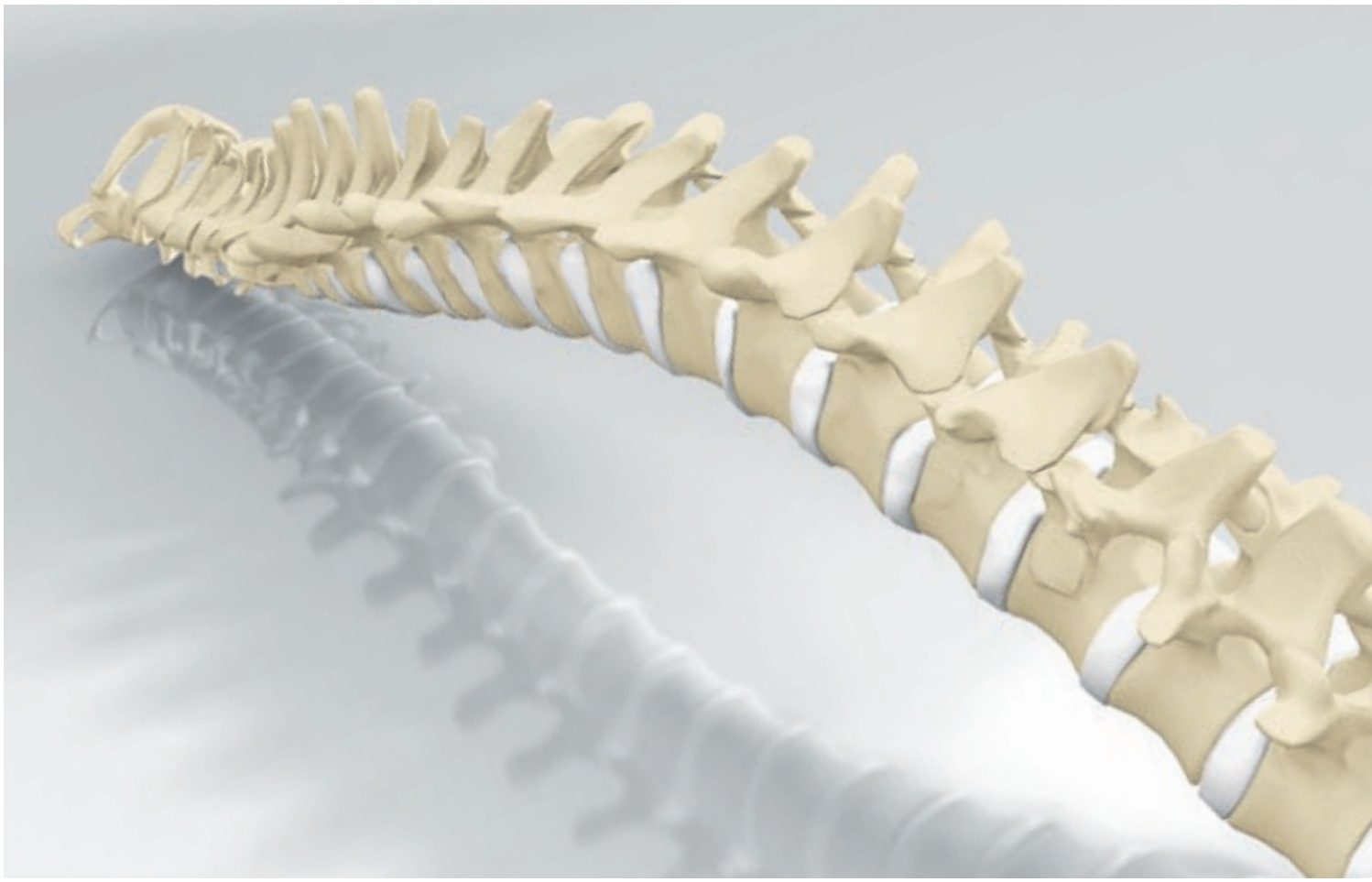
SPINE SURGERY

AESCULAP®
PROSPACE® 3D Oblique

POSTERIOR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

AESCULAP® LUMBAR SPINE



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AESCULAP® PROSPACE® 3D Oblique

CONTENT

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.

AESCULAP® PROSPACE® 3D Oblique

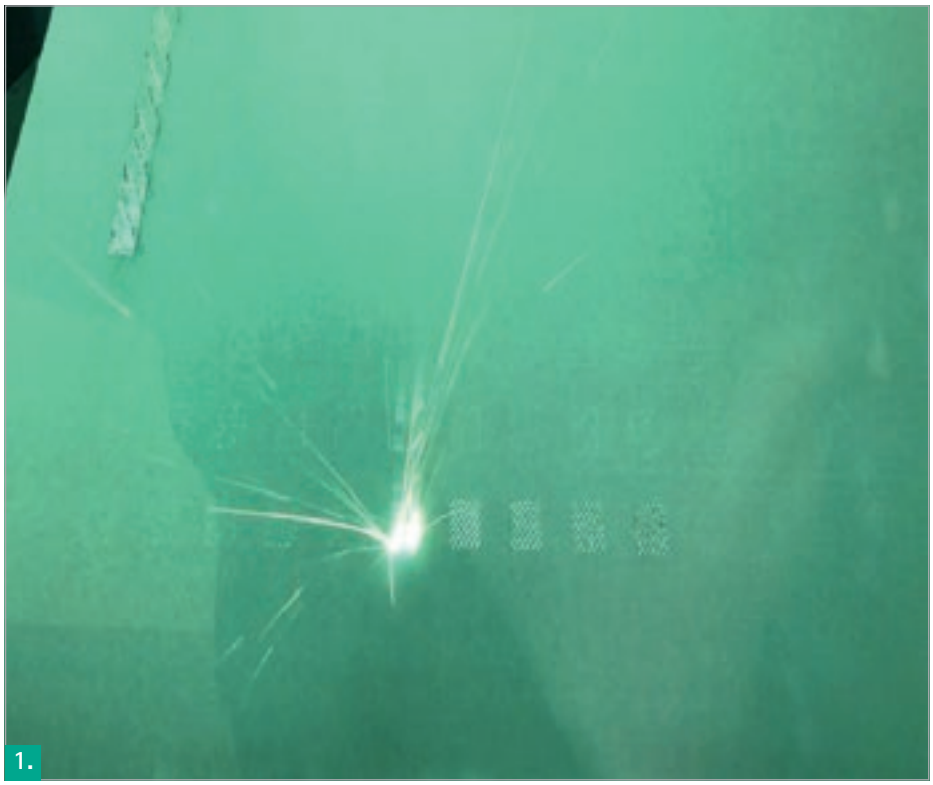
A. IMPLANT MATERIAL

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

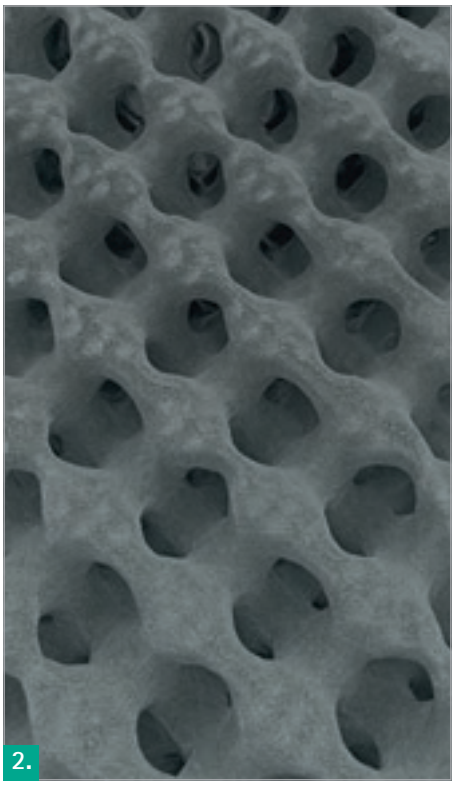
Additive manufacturing – 3D printing – means a layer by layer process to design a device using laser beam and metal powder. This innovative laser beam melting technology is of growing importance in the manufacture of implants, as it allows to create various fine and porous surface structures with the 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 AESCULAP® 3D Cages (Fig. 1).

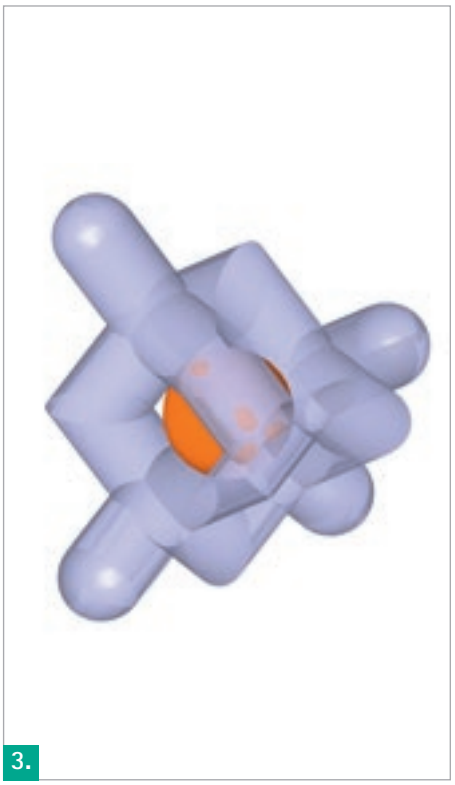


1. Laser beam melting technology



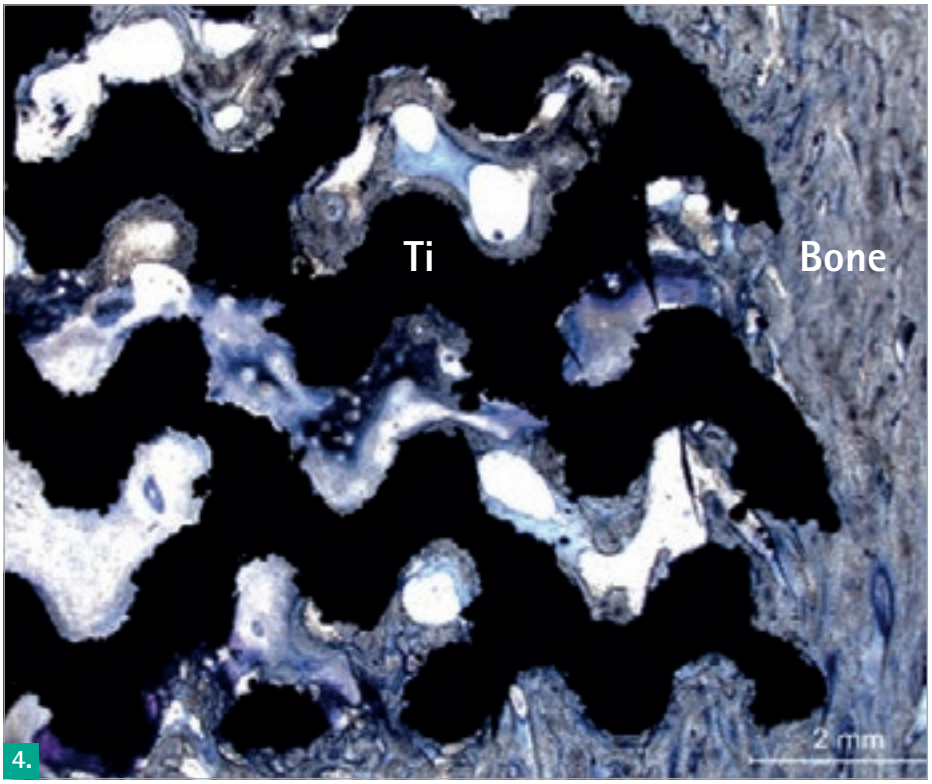
2.

Lattice structure Structan®



3.

Unit cell with fitted ball of 900 µm



4.

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

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).

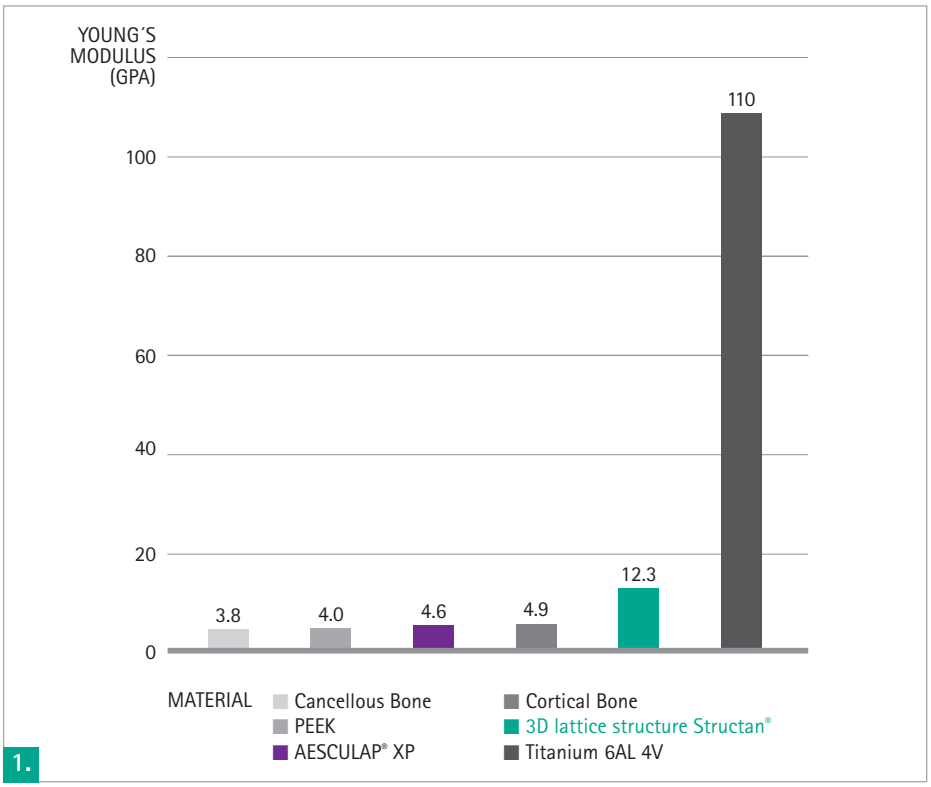
- A rough laser sintered surface provides a good interaction between bone cells and implant surface compared to a milled smooth surface and therefore intends to optimize osseointegration (14).

AESCULAP® PROSPACE® 3D Oblique

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. This may prevent subsidence into the vertebral body (17). In addition, this may result in improved bone growth (18) (Fig. 1).

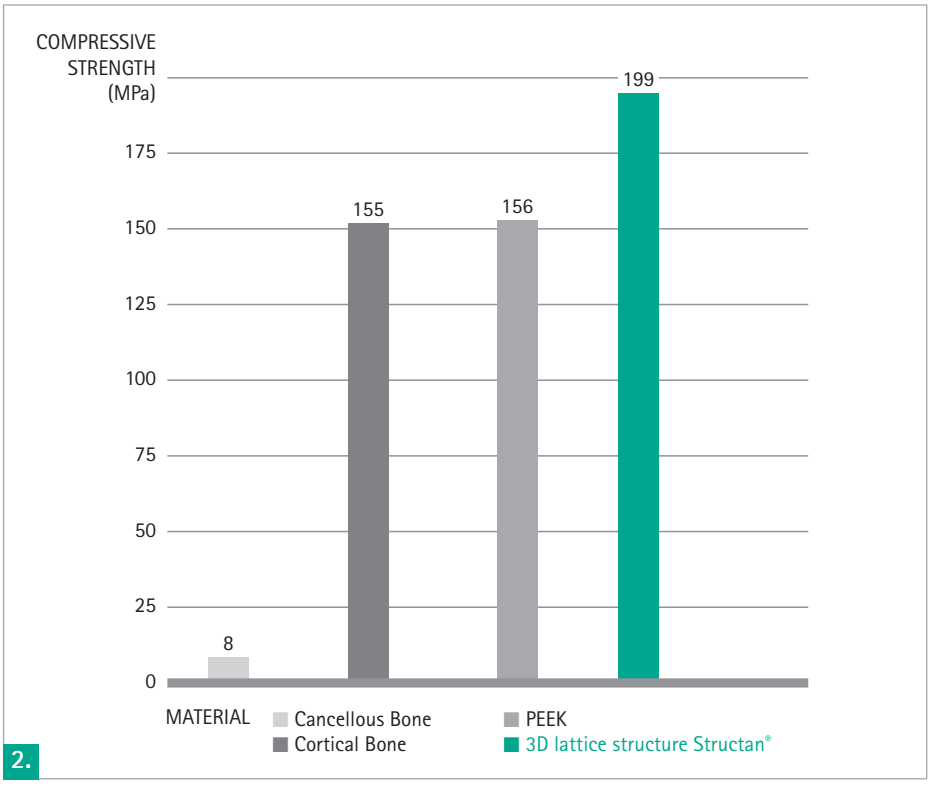


1.

Young´s modulus of various materials

MORE STRENGTH

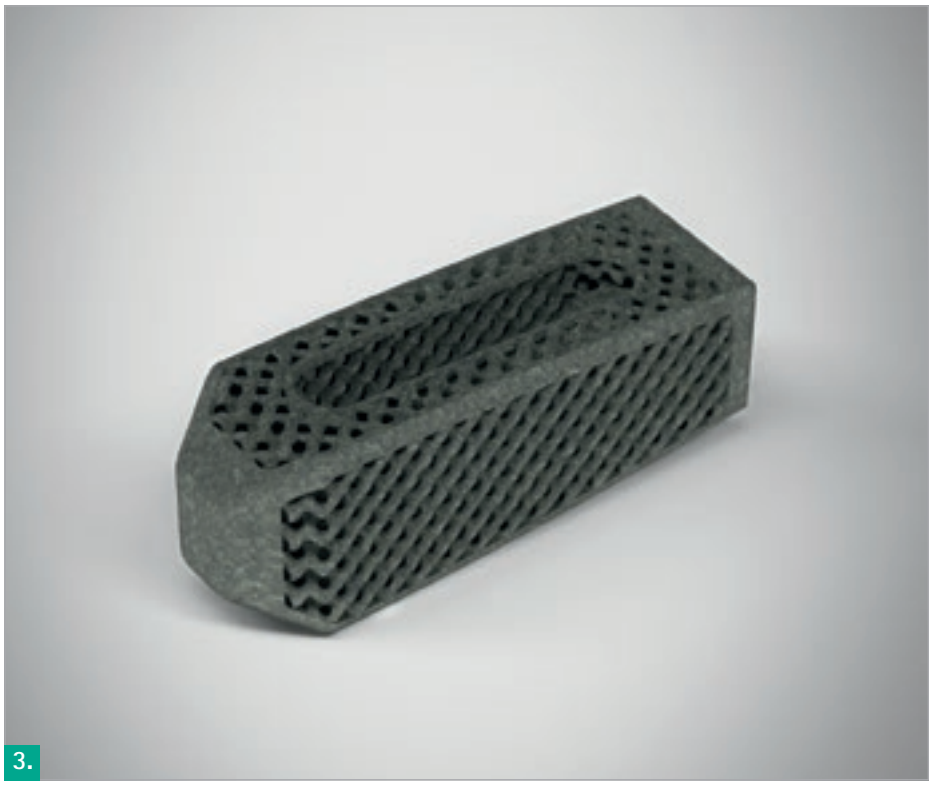
- The 3D lattice structure Structan® combines a bone-like Young's modulus with a high compressive strength, which contributes to high safety against failure due to breakage.
  The compressive strength of the 3D lattice structure Structan® is higher than the mean strength of bone and PEEK (19, 20) (Fig. 2).



2.

Compressive strength of 3D lattice structure Structan®

B. INTENDED USE & IMPLANT DESIGN



3.

- 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.
- Screw thread interface allows a firm connection to inserter.
- Interlaced angle respecting an implant positioning 30° from the sagittal plane.
- Good visibility in X-ray to localize implant positioning (21, 22).

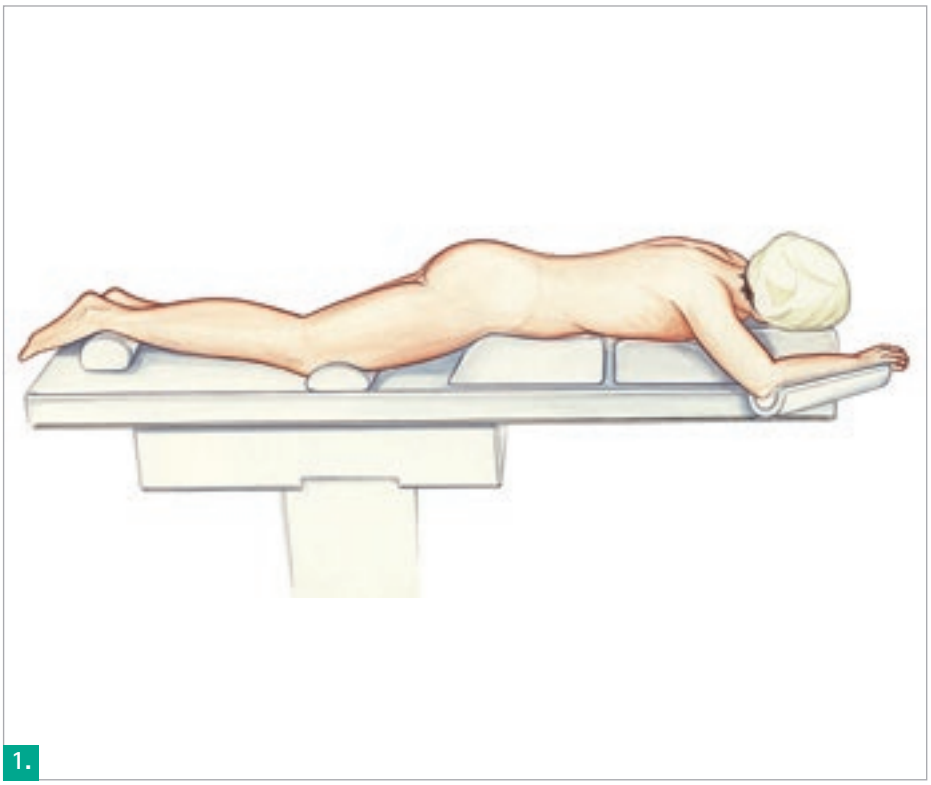
- Stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.
- Always use PROSPACE® 3D Oblique in conjunction with an internal fixator.
- PROSPACE® 3D Oblique can be implanted through an open or minimally invasive transforaminal access (Oblique TLIF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

AESCULAP® PROSPACE® 3D Oblique

C. SURGICAL TECHNIQUE

C.01. PATIENT POSITIONING

- The patient is positioned in the prone position for posterolateral interbody fusion with supplemental fixation (Fig. 1).
- The Oblique technique describes the unilateral insertion of a single implant. Using an Oblique TLIF procedure the PROSPACE® 3D Oblique Cage is placed diagonally (about 30° from the sagittal plane) across the disc space.



1.

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. (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.

2.

3.

4.

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.

6.

7.

5.

C.04. DISCECTOMY

- The disc space is cleared using rongeurs and curettes (Fig. 5/6/7).

AESCULAP® PROSPACE® 3D Oblique

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.

1.

C.06. IMPLANT SELECTION

- Use trial implants to establish the correct implant size.
- The marking on the trial designates medial.
- Start with the smallest trial size. Stepwise the next heights are inserted until the required distraction is achieved (Fig. 2).

INFORMATION

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

When inserting the PROSPACE® 3D Oblique trial implants, make sure the marking points medially to correctly align the trial implant.

2.

3.

C.07. IMPLANT REMOVAL FROM PACKAGING

- Open folder blister to remove the PROSPACE® 3D Oblique 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. 3).

INFORMATION

Do not use force during filling to avoid implant damaging.

4.

C.09. PROSPACE® 3D Oblique INSERTION

- The PROSPACE® 3D Oblique implant is connected with the inserter by means of a screw joint (Fig. 4).
- When mounting the implant on the inserter ensure that the line marks on the implant and inserter meet each other.
- The PROSPACE® 3D Oblique implant features an interlaced lordosis angle respecting an implant positioning 30° from the sagittal plane.

AESCULAP® PROSPACE® 3D Oblique

C. SURGICAL TECHNIQUE

- Once PROSPACE® 3D Oblique is attached to the inserter, it can be introduced into the intervertebral space (Fig. 1).
- Make sure that the markings on the implant and inserter point medially during insertion.
- Use image converter monitoring during the insertion process.
- It is recommended to position PROSPACE® 3D Oblique 2 - 3 mm in front of the posterior rim.
- Remove the inserter when final implant positioning is achieved.
- If required, use the impactor to correct the implant position.
- The implant gets jammed by release of distraction as well as by compression with the posterior instrumentation.
- X-ray control to verify the position of the implant (Fig. 2 / 3).

1.

2. 3.

4.

C.10. POSTERIOR STABILIZATION

- Additional posterior stabilization of the motion segment using AESCULAP® Ennovate® Open Module (surgical technique 048102) or Ennovate® MIS Module (surgical technique 000702) should be performed (Fig. 4).

INFORMATION

PROSPACE® 3D Oblique has to be always used in conjunction with an internal fixator.

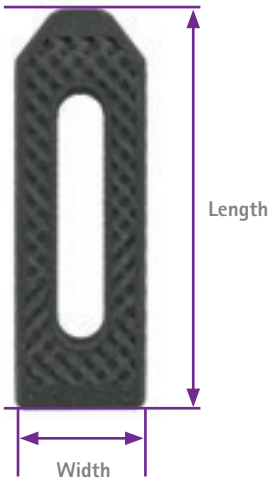
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.

- Final X-ray.

AESCULAP® PROSPACE® 3D Oblique

D. IMPLANT OVERVIEW

LORDOSIS 5° | 10°



Article No.	Lordosis	Size (Height x Width x Length)	Quantity
SN509T		9 x 10.5 x 32 mm	2
SN510T		10 x 10.5 x 32 mm	2
SN511T	5°	11 x 10.5 x 32 mm	2
SN512T		12 x 10.5 x 32 mm	2
SN513T		13 x 10.5 x 32 mm	2
SN530T		10 x 10.5 x 32 mm	2
SN531T		11 x 10.5 x 32 mm	2
SN532T	10°	12 x 10.5 x 32 mm	2
SN533T		13 x 10.5 x 32 mm	2
SN519T		9 x 10.5 x 36 mm	2
SN520T		10 x 10.5 x 36 mm	2
SN521T	5°	11 x 10.5 x 36 mm	2
SN522T		12 x 10.5 x 36 mm	2
SN523T		13 x 10.5 x 36 mm	2

SN505 PREPARATION INSTRUMENTS - LUMBAR PREPARATION CLEANING DISC SPACE

	Article No.	Description	Quantity
	SN506R	Tray lumbar prep. 3D Cages discectomy	1
	TF366	Graphic template F/SN506R (SN505)	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

AESCULAP® PROSPACE® 3D Oblique

E. INSTRUMENT OVERVIEW

SN505 PREPARATION INSTRUMENTS - LUMBAR PREPARATION CLEANING DISC SPACE

	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
- Curettes (FJ702R-FJ703R),
- Bone curettes (FJ698R-FJ699R) and
- Bone rasps (FJ704R-FJ705R) are available.

SN505 PREPARATION INSTRUMENTS - LUMBAR PREPARATION DISTRACTION

	Article No.	Description	Quantity
	SN507R	Tray lumbar prep. 3D Cages distraction	1
	TF367	Graphic template F/SN507R (SN505)	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: JK485
Recommended identification label: JG785B

AESCULAP® PROSPACE® 3D Oblique

E. INSTRUMENT OVERVIEW

SN500 IMPLANTATION INSTRUMENTS - PROSPACE® 3D Oblique IMPLANTATION

Article No.	Description	Size (Height x Width x Length)	Quantity
SN501R	PROSPACE® 3D Oblique tray F/instrumentation		1
TF362	Graphic template F/SN501R (SN500)		1
TF352	Packing stencil F/SN501R (SN500)		1
JA455R	Lid for OrthoTray DIN w/o handle		1
SN549R	PROSPACE® 3D Oblique trial 5°	9 x 10.5 x 32 mm	1
SN550R	PROSPACE® 3D Oblique trial 5°	10 x 10.5 x 32 mm	1
SN551R	PROSPACE® 3D Oblique trial 5°	11 x 10.5 x 32 mm	1
SN552R	PROSPACE® 3D Oblique trial 5°	12 x 10.5 x 32 mm	1
SN553R	PROSPACE® 3D Oblique trial 5°	13 x 10.5 x 32 mm	1
SN555R	PROSPACE® 3D Oblique trial 10°	10 x 10.5 x 32 mm	1
SN556R	PROSPACE® 3D Oblique trial 10°	11 x 10.5 x 32 mm	1
SN557R	PROSPACE® 3D Oblique trial 10°	12 x 10.5 x 32 mm	1
SN558R	PROSPACE® 3D Oblique trial 10°	13 x 10.5 x 32 mm	1
SN559R	PROSPACE® 3D Oblique trial 5°	9 x 10.5 x 36 mm	1
SN560R	PROSPACE® 3D Oblique trial 5°	10 x 10.5 x 36 mm	1
SN561R	PROSPACE® 3D Oblique trial 5°	11 x 10.5 x 36 mm	1
SN562R	PROSPACE® 3D Oblique trial 5°	12 x 10.5 x 36 mm	1
SN563R	PROSPACE® 3D Oblique trial 5°	13 x 10.5 x 36 mm	1

E

	Article No.	Description	Quantity
	**FJ666R**	Insertion / extration instrument (slap hammer)	1
	**SN504R**	PROSPACE® 3D / Oblique packing block	1
	**SN503R**	Tamper F / lumbar 3D Cage systems	1
	**SJ805R**	PROSPACE® 3D / 3D Oblique insertion instrument	2
	**FJ039R**	PROSPACE® 3D / 3D Oblique impactor	1

AESCULAP® PROSPACE® 3D Oblique

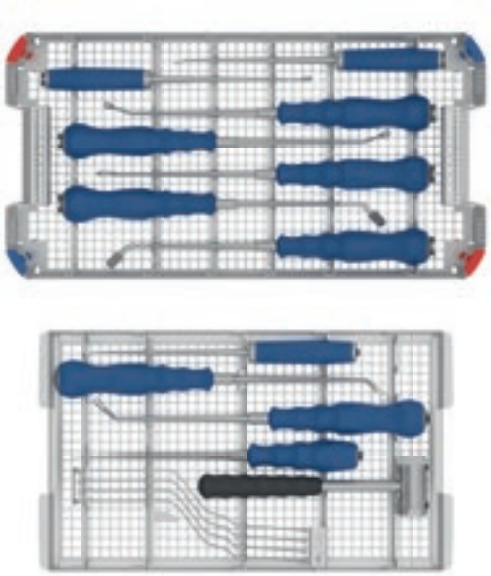
E. INSTRUMENT OVERVIEW

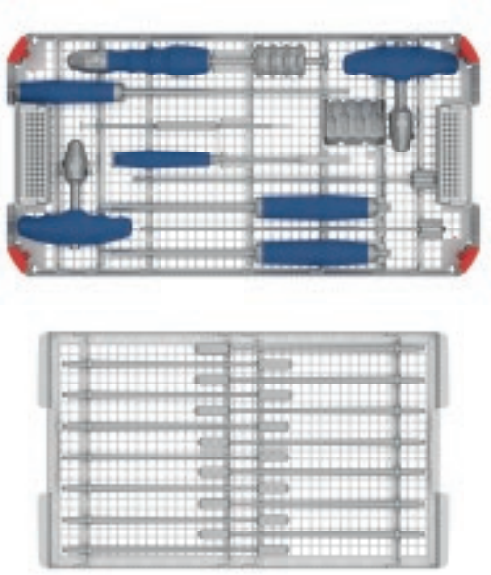
SN500 IMPLANTATION INSTRUMENTS - PROSPACE® 3D Oblique IMPLANTATION

	Article No.	Description	Quantity
	**SJ806R**	PROSPACE® 3D / 3D Oblique revision instrument	1
	**SJ033R**	T-Handle W / ANVIL	2

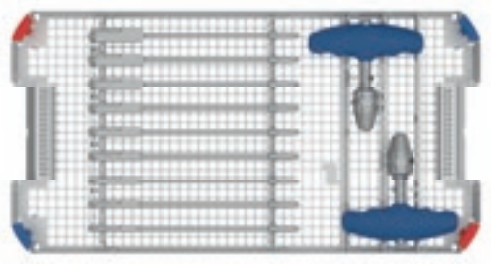
INFORMATION

Recommended container: JK441
Recommended container lid: JK485
Recommended identification label: JA785B





SN500



SN505

AESCULAP® PROSPACE® 3D Oblique

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The usability of the AESCULAP® 3D Cage System PROSPACE® 3D Oblique was tested in April 2019, in a cadaver workshop with six independent test persons as intended users (surgeons specialized in spinal surgery or comparable fields). Parameters such as implant visibility under x-ray control, mechanical stability of the implant/instrument interface and implant surface evaluation in terms of tissue injury risk were tested among others. Acceptance criteria were fulfilled for all the above-mentioned parameters. All test users confirmed the absence of critical features that must be improved prior to clinical use.

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CT and X-ray visualization of different AESCULAP® interbody fusion cages (full titanium, porous Ti6Al4V and PLASMAPORE® XP cages) was tested in a cadaver setup. A radiologist evaluated the implant visibility and the presence of artefacts that may limit the visualization of adjacent structures. Visualization and assessment of implant position was achieved in X-ray and CT for all tested cages. Minor artefacts were visible in CT reconstructions in the surrounding of porous Ti6Al4V and full titanium implants. Porous Ti6Al4V implants showed slightly fewer artefacts in CT in comparison to full titanium implants. The minor artefacts observed did not limit the assessment of the surrounding anatomical structures.

AESCULAP® – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-2600 | www.aesculap.com

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