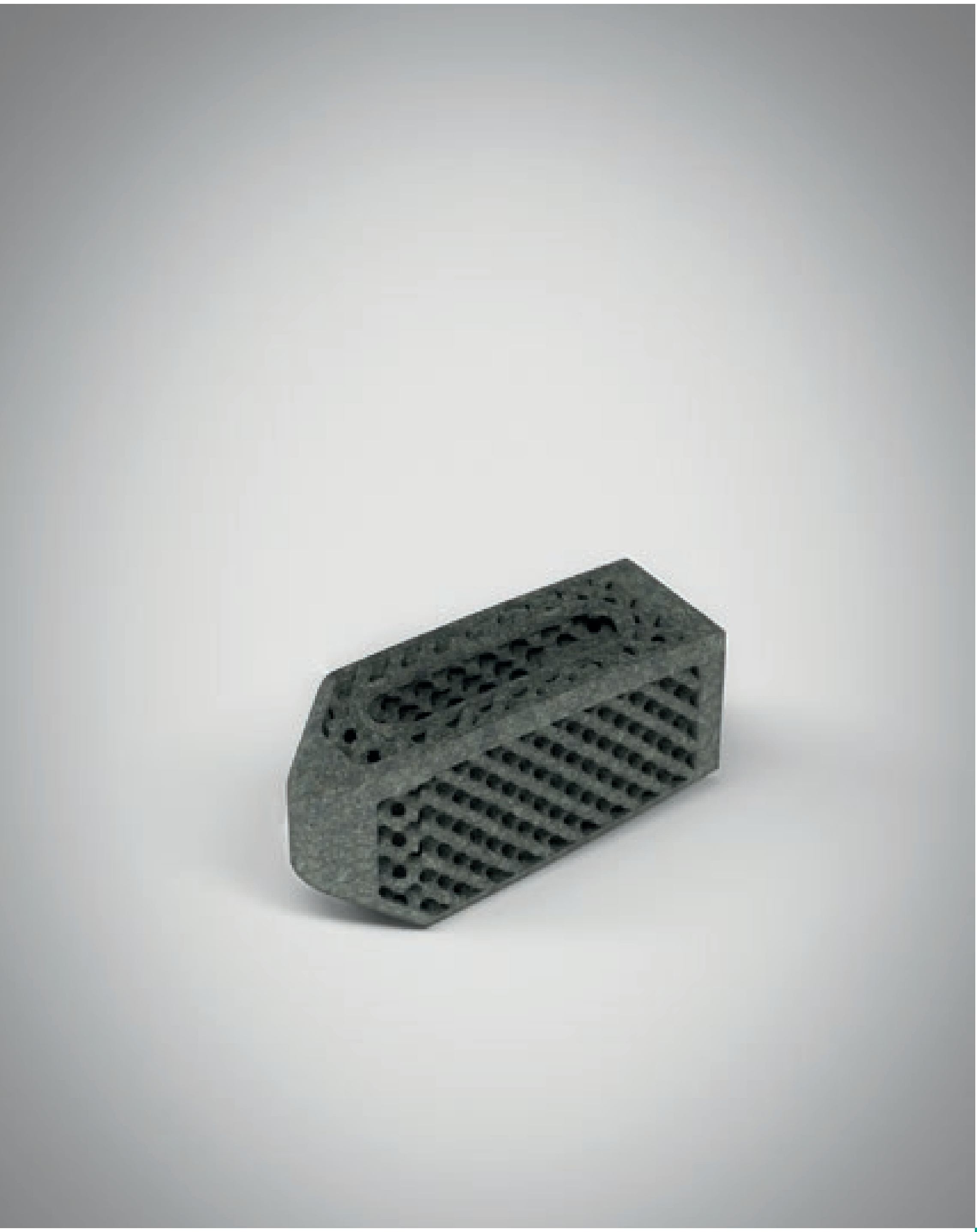


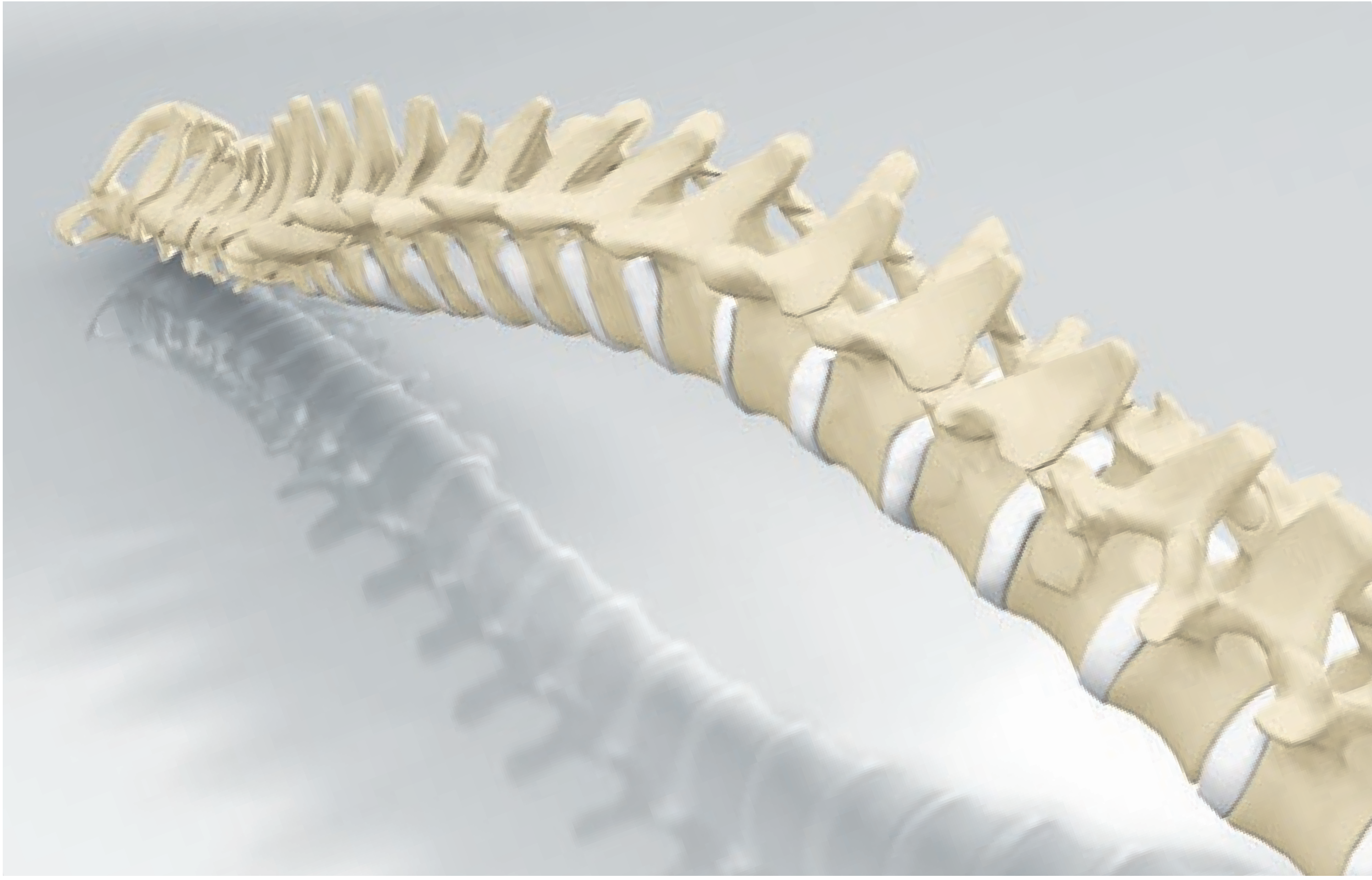
SPINE SURGERY

AESCULAP® PROSPACE® 3D

POSTERIOR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

AESCULAP® LUMBAR SPINE



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to view full product portfolio

AESCULAP® PROSPACE® 3D

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

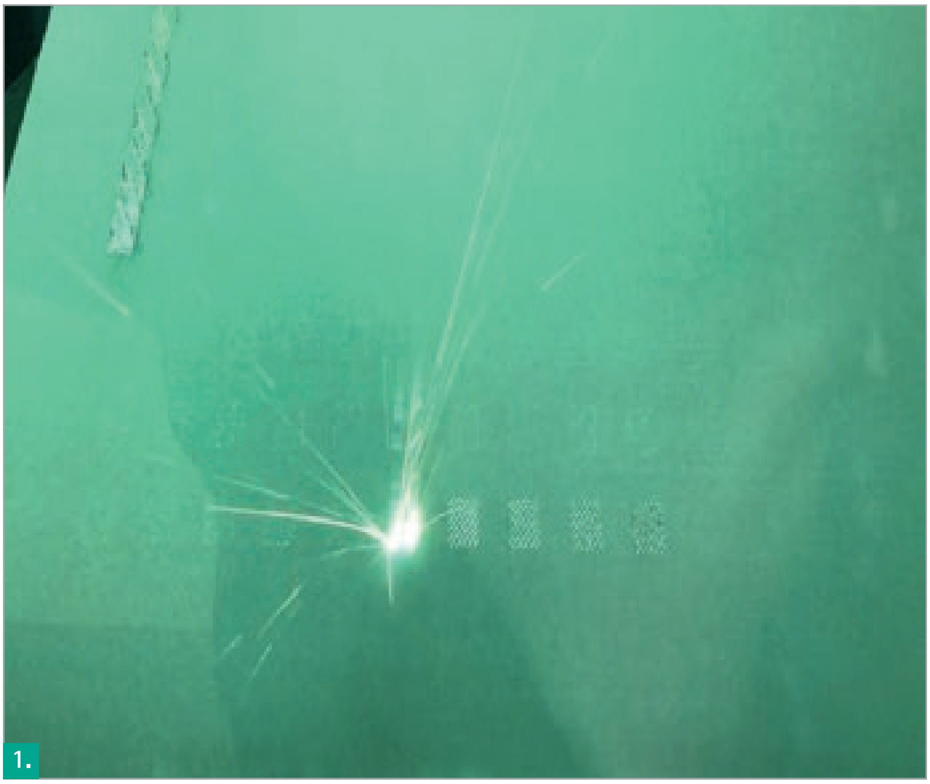
A. IMPLANT MATERIAL

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

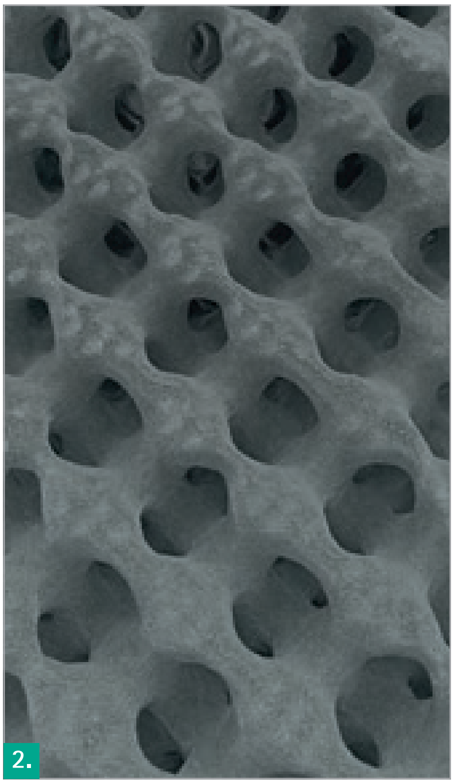
Additive manufacturing – 3D printing – means a layer by layer process to design a device using laser beam and metal powder. This innovative laser beam melting technology is of growing importance in the manufacture of implants, as it allows to create various fine and porous surface structures with the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

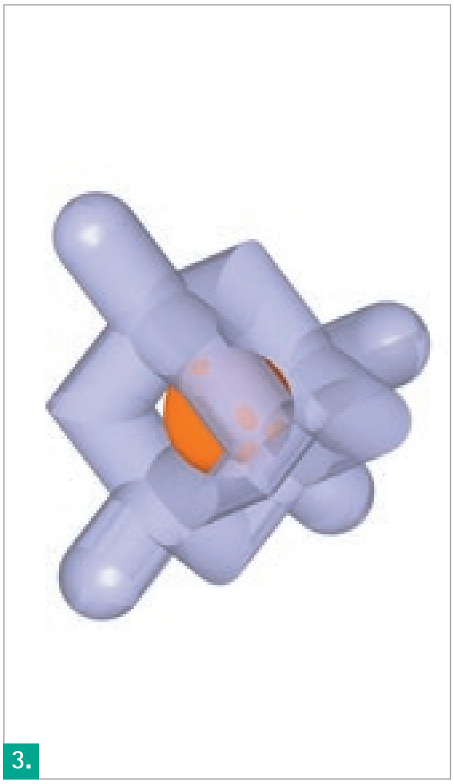


1.
Laser beam melting technology



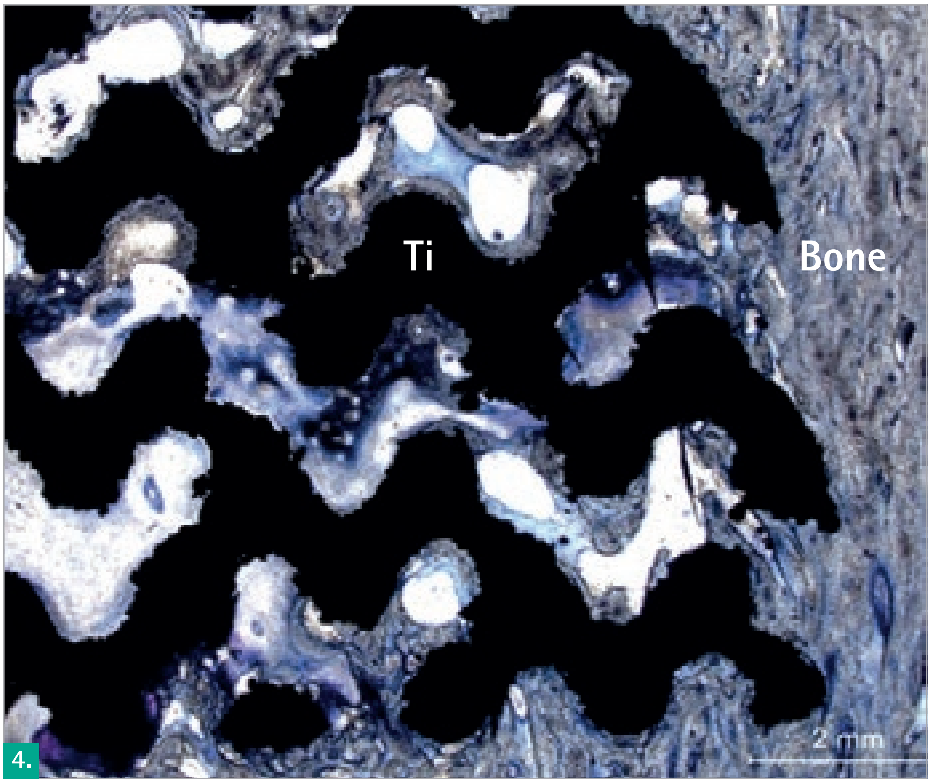
2.

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).

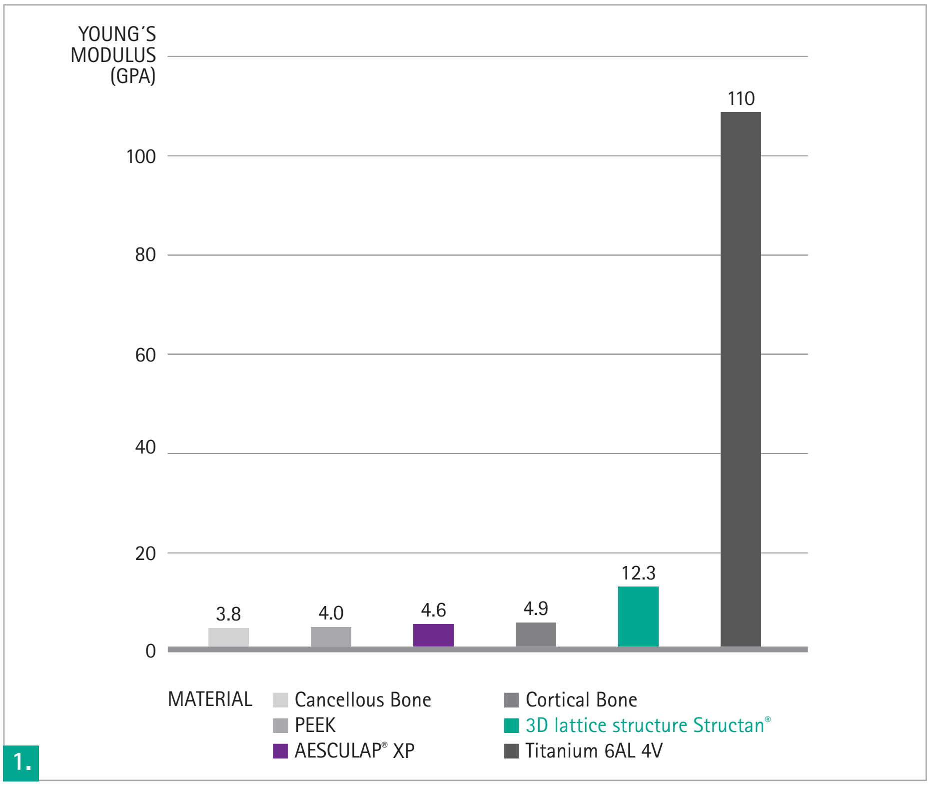
- A rough laser sintered surface provides a good interaction between bone cells and implant surface compared to a milled smooth surface and therefore intends to optimize osseointegration (14).

AESCULAP® PROSPACE® 3D

A. IMPLANT MATERIAL

MORE ELASTICITY

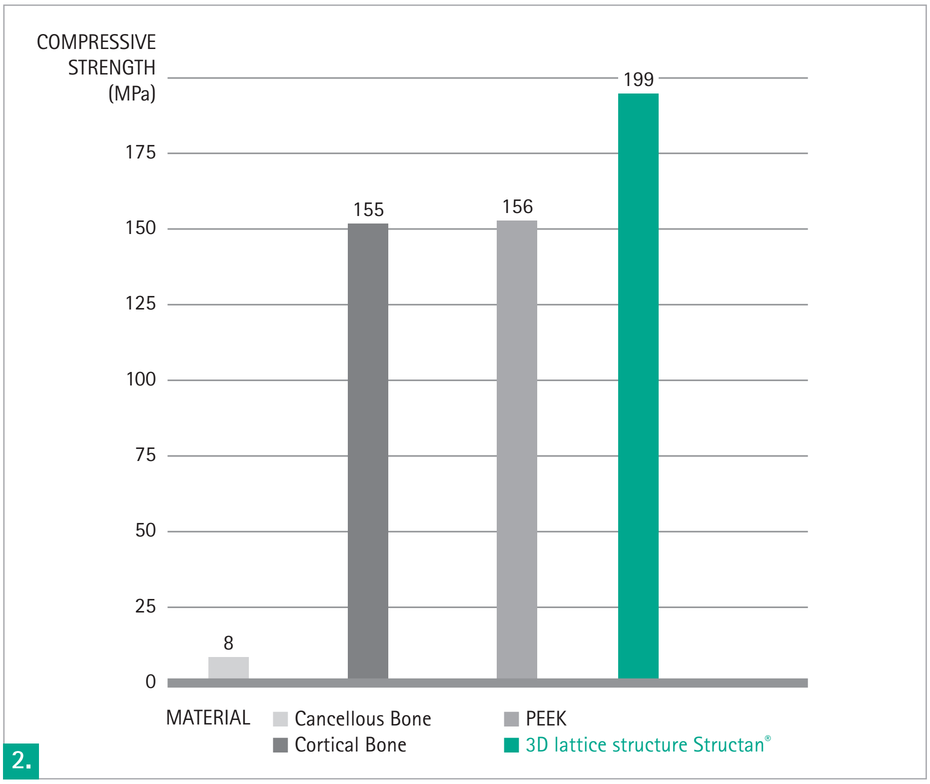
- Ti6Al4V ELI as solid material has a Young's modulus of approximately 110 GPa as it is shown in the figure, whereas cortical bone has a Young's modulus of approximately 5 GPa (15, 16). The Young's modulus of Structan® is developed to be close to that of cortical bone. This may prevent subsidence into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



1. Young´s modulus of various materials

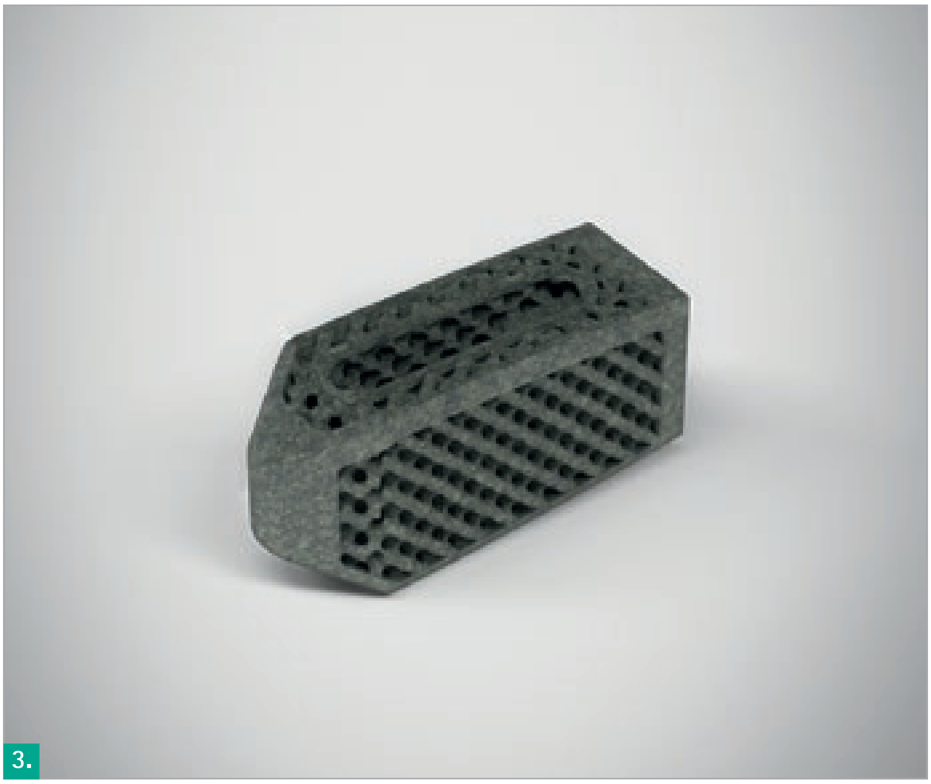
MORE STRENGTH

- 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.

- Stabilization of the lumbar and thoracic spine through posterior approach, mono-segmental and multisegmental.
- Always implant two implants per layer (PLIF technique).
- Always use PROSPACE® 3D in conjunction with an internal fixator.

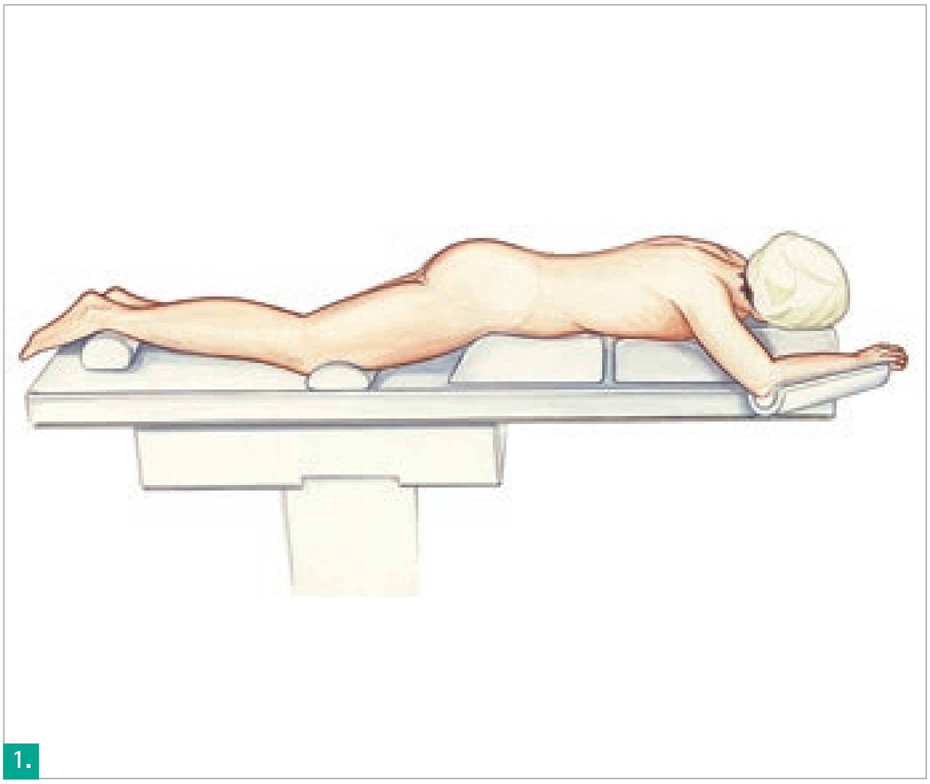
- Solid frame without sharp edges for biomechanical stability and smooth insertion into the disc space minimizing the risk to injure surrounding soft tissue.
- Open porous structure designed to provide primary and secondary stability.
- The implant's anatomical endplate design provides a good contact 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.
- Good visibility in X-ray to localize implant positioning (21, 22).

AESCULAP® PROSPACE® 3D

C. SURGICAL TECHNIQUE

C.01. PATIENT POSITIONING

- The patient is positioned in the prone position for posterior fusion with supplemental fixation (Fig. 1).
- A midline incision over the levels to be instrumented is performed.



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).
- The dura and upper nerve root are carefully retracted in the desired direction using the nerve root retractors.
- In order to make room for the insertion of the distractor, resection of disc material is carried out using rongeurs and forceps.

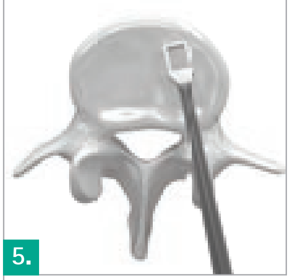
2.

3.

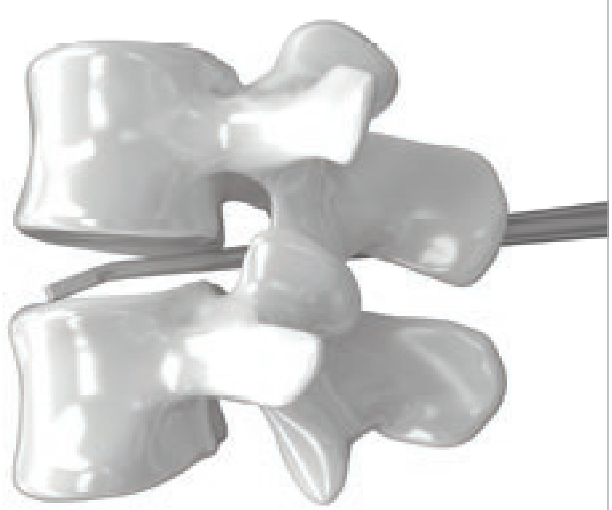
4.

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 counterclockwise to remove disc material with the built-in sharp rim.
- The distractors are inserted one after the other on alternate sides of the disc until the desired distraction is obtained.



5.



6.

C.04. DISCECTOMY

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

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

- Trials corresponding to the implant height, width and lordosis angle are available to determine the implant size. The trials measure 26 mm in length and indicate the length 22 mm by a marking.
- Use trial implants to establish the correct implant size.
- 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.

2.

C.07. IMPLANT REMOVAL FROM PACKAGING

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

INFORMATION

Do not use force during filling to avoid implant damaging.

3.

C.09. PROSPACE® 3D INSERTION

- The PROSPACE® 3D implant is connected with the inserter by means of a screw joint (Fig. 4).
- Once PROSPACE® 3D is attached to the inserter, it can be introduced into the intervertebral space using image converter monitoring. It is recommended to position PROSPACE® 3D 2 - 3 mm in front of the posterior rim (Fig. 5).
- Remove the inserter when final implant positioning is achieved.
- If required, use the impactor to correct the implant position.

4.

5.

AESCULAP® PROSPACE® 3D

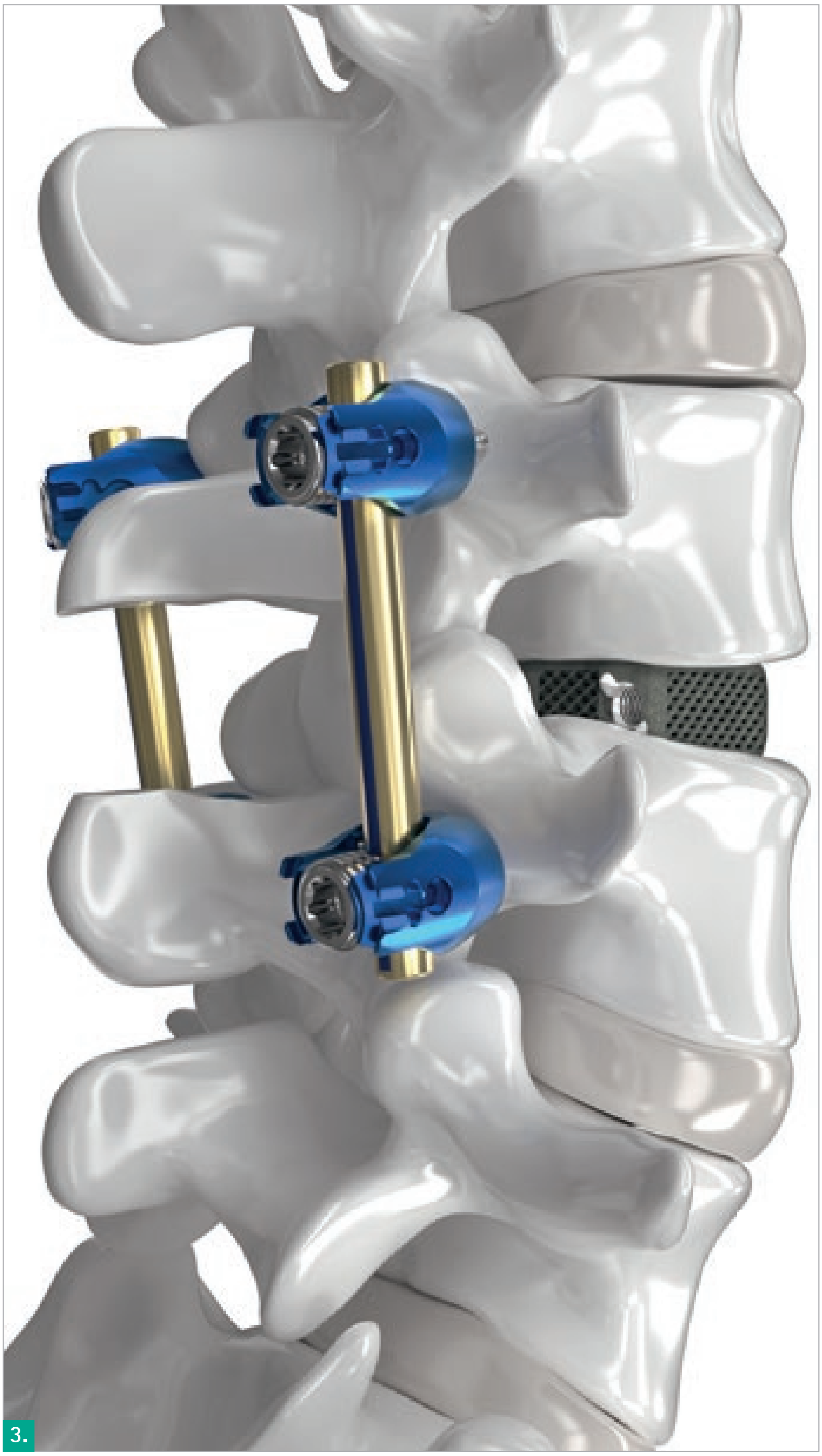
C. SURGICAL TECHNIQUE

C.10. INSERTION ON THE CONTRA-LATERAL SIDE

- The described operative steps are repeated for the contra-lateral side (Fig. 1/2). Bone material can be packed between both implants.
- The implants get jammed by release of distraction as well as by compression with the posterior instrumentation.
- X-ray control to verify the position of the implants (Fig. 2).

1.

2.


3.

C.11. POSTERIOR STABILIZATION

- Additional posterior stabilization of the motion segment using AESCULAP® Ennovate® Open Module (surgical technique 048102) should be performed. (Fig. 3).

INFORMATION

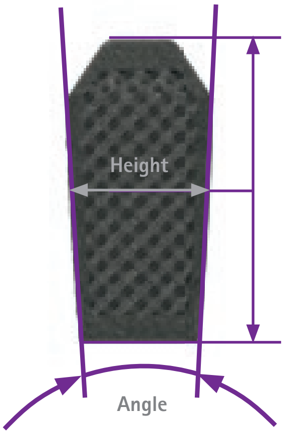
PROSPACE® 3D has to be always used in conjunction with an internal fixator.

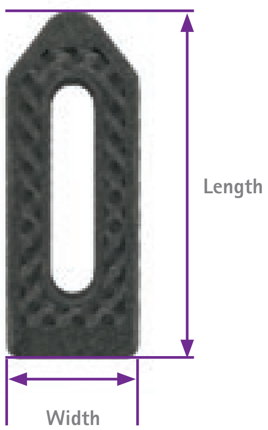
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.
- Final X-ray.

AESCULAP® PROSPACE® 3D

D. IMPLANT OVERVIEW

LORDOSIS 0° | 5° | 10°





Article No.	Lordosis	Size (Height x Width x Length)	Quantity
SN402T	0°	7 x 8.5 x 22 mm	4
SN403T		8 x 8.5 x 22 mm	2
SN404T		9 x 8.5 x 22 mm	2
SN405T		10 x 8.5 x 22 mm	2
SN413T	5°	8 x 8.5 x 22 mm	4
SN414T		9 x 8.5 x 22 mm	4
SN415T		10 x 8.5 x 22 mm	4
SN424T	10°	9 x 8.5 x 22 mm	4
SN425T		10 x 8.5 x 22 mm	4
SN407T	0°	7 x 8.5 x 26 mm	4
SN408T		8 x 8.5 x 26 mm	2
SN409T		9 x 8.5 x 26 mm	2
SN410T		10 x 8.5 x 26 mm	2
SN418T	5°	8 x 8.5 x 26 mm	4
SN419T		9 x 8.5 x 26 mm	4
SN420T		10 x 8.5 x 26 mm	4

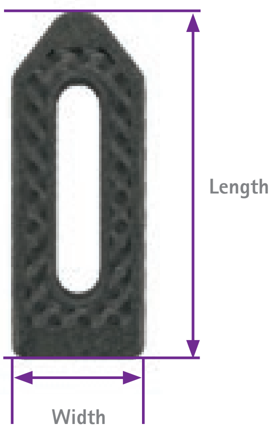
D

Article No.	Lordosis	Size (Height x Width x Length)	Quantity
SN429T	10°	9 x 8.5 x 26 mm	4
SN430T		10 x 8.5 x 26 mm	4
SN431T		11 x 8.5 x 26 mm	4
SN438T	0°	8 x 10.5 x 22 mm	2
SN439T		9 x 10.5 x 22 mm	2
SN440T		10 x 10.5 x 22 mm	2
SN441T		11 x 10.5 x 22 mm	2
SN442T		12 x 10.5 x 22 mm	2
SN443T		13 x 10.5 x 22 mm	2
SN458T	5°	8 x 10.5 x 22 mm	4
SN459T		9 x 10.5 x 22 mm	4
SN460T		10 x 10.5 x 22 mm	4
SN461T		11 x 10.5 x 22 mm	4
SN462T		12 x 10.5 x 22 mm	4
SN463T		13 x 10.5 x 22 mm	4

AESCULAP® PROSPACE® 3D

D. IMPLANT OVERVIEW

LORDOSIS 0° | 5° | 10°



Article No.	Lordosis	Size (Height x Width x Length)	Quantity
SN479T	10°	9 x 10.5 x 22 mm	4
SN480T		10 x 10.5 x 22 mm	4
SN481T		11 x 10.5 x 22 mm	4
SN482T		12 x 10.5 x 22 mm	4
SN483T		13 x 10.5 x 22 mm	2
SN448T	0°	8 x 10.5 x 26 mm	2
SN449T		9 x 10.5 x 26 mm	2
SN450T		10 x 10.5 x 26 mm	2
SN451T		11 x 10.5 x 26 mm	2
SN452T		12 x 10.5 x 26 mm	2
SN453T		13 x 10.5 x 26 mm	2
SN468T	5°	8 x 10.5 x 26 mm	4
SN469T		9 x 10.5 x 26 mm	4
SN470T		10 x 10.5 x 26 mm	4
SN471T		11 x 10.5 x 26 mm	4
SN472T		12 x 10.5 x 26 mm	2
SN473T		13 x 10.5 x 26 mm	2

D

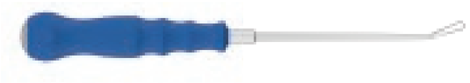
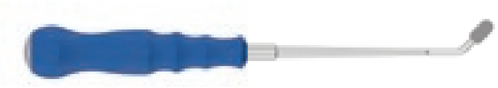
Article No.	Lordosis	Size (Height x Width x Length)	Quantity
SN489T		9 x 10.5 x 26 mm	4
SN490T		10 x 10.5 x 26 mm	4
SN491T	10°	11 x 10.5 x 26 mm	4
SN492T		12 x 10.5 x 26 mm	2
SN493T		13 x 10.5 x 26 mm	2

AESCULAP® PROSPACE® 3D

E. INSTRUMENT OVERVIEW

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

	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.

E. INSTRUMENT OVERVIEW

SN505 PREPARATION INSTRUMENTS – LUMBAR PREPARATION DISTRACTION

Image	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
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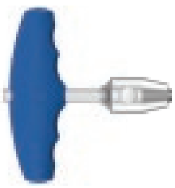
	FJ654R	Distractor 14 mm	1
	FJ655R	Distractor 15 mm	1
	**SJ033R**	T-handle W/ANVIL	2

INFORMATION

Recommended container: JK446
Recommended container lid: JK485
Recommended identification label: JG785B

SN400 IMPLANTATION INSTRUMENTS – PROSPACE® 3D TRIALS

Article No.	Description	Size (Height x Width x Length)	Quantity
SN499R	PROSPACE® 3D tray F/trial implants		1
TF369	Graphic template F/SN499R (SN400)		1
TF359	Packing stencil F/SN499R (SN400)		1
JA455R	Lid for OrthoTray DIN W/O handle		1
SN564R	PROSPACE® 3D trial implant 0°	7 x 8.5 x 26 mm	1
SN565R	PROSPACE® 3D trial implant 0°	8 x 8.5 x 26 mm	1
SN566R	PROSPACE® 3D trial implant 0°	9 x 8.5 x 26 mm	1
SN567R	PROSPACE® 3D trial implant 0°	10 x 8.5 x 26 mm	1
SN575R	PROSPACE® 3D trial implant 5°	8 x 8.5 x 26 mm	1
SN576R	PROSPACE® 3D trial implant 5°	9 x 8.5 x 26 mm	1
SN577R	PROSPACE® 3D trial implant 5°	10 x 8.5 x 26 mm	1
SN586R	PROSPACE® 3D trial implant 10°	9 x 8.5 x 26 mm	1
SN587R	PROSPACE® 3D trial implant 10°	10 x 8.5 x 26 mm	1
SN568R	PROSPACE® 3D trial implant 0°	8 x 10.5 x 26 mm	1
SN569R	PROSPACE® 3D trial implant 0°	9 x 10.5 x 26 mm	1
SN570R	PROSPACE® 3D trial implant 0°	10 x 10.5 x 26 mm	1
SN571R	PROSPACE® 3D trial implant 0°	11 x 10.5 x 26 mm	1

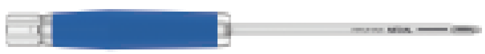
AESCULAP® PROSPACE® 3D

E. INSTRUMENT OVERVIEW

SN400 IMPLANTATION INSTRUMENTS – PROSPACE® 3D TRIALS

	Article No.	Description	Size (Height x Width x Length)	Quantity
	SN572R	PROSPACE® 3D trial implant 0°	12 x 10.5 x 26 mm	1
	SN573R	PROSPACE® 3D trial implant 0°	13 x 10.5 x 26 mm	1
	SN578R	PROSPACE® 3D trial implant 5°	8 x 10.5 x 26 mm	1
	SN579R	PROSPACE® 3D trial implant 5°	9 x 10.5 x 26 mm	1
	SN580R	PROSPACE® 3D trial implant 5°	10 x 10.5 x 26mm	1
	SN581R	PROSPACE® 3D trial implant 5°	11 x 10.5 x 26 mm	1
	SN582R	PROSPACE® 3D trial implant 5°	12 x 10.5 x 26 mm	1
	SN583R	PROSPACE® 3D trial implant 5°	13 x 10.5 x 26 mm	1
	SN589R	PROSPACE® 3D trial implant 10°	9 x 10.5 x 26 mm	1
	SN590R	PROSPACE® 3D trial implant 10°	10 x 10.5 x 26 mm	1
	SN591R	PROSPACE® 3D trial implant 10°	11 x 10.5 x 26 mm	1
	SN592R	PROSPACE® 3D trial implant 10°	12 x 10.5 x 26 mm	1
	SN593R	PROSPACE® 3D trial implant 10°	13 x 10.5 x 26 mm	1
	SN588R	PROSPACE® 3D trial implant 10°	11 x 8.5 x 26 mm	1
	**SJ033R**	T-handle W/ANVIL		2

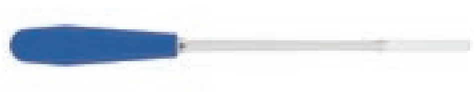
SN400 IMPLANTATION INSTRUMENTS – PROSPACE® 3D IMPLANTATION

	Article No.	Description	Quantity
	SN498R	PROSPACE® 3D Tray F/implantation instrument	1
	TF368	Graphic template F/SN498R (SN400)	1
	TF358	Packing stencil F/SN498R (SN400)	1
	JA455R	Lid for OrthoTray DIN W/O handle	1
	**FJ666R**	Insertion/extration instrument (slap hammer)	1
	**SN504R**	PROSPACE® 3D/3D Oblique packing block	1
	**SN503R**	Tamper F/lumbar 3D cage systems	1
	**SJ805R**	PROSPACE® 3D/3D Oblique insertion instrument	2

AESCULAP® PROSPACE® 3D

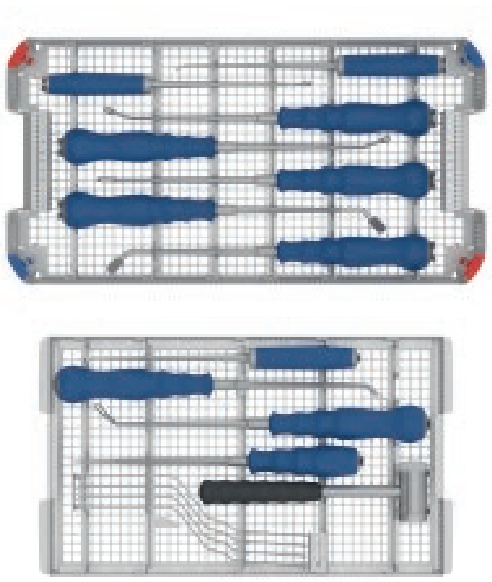
E. INSTRUMENT OVERVIEW

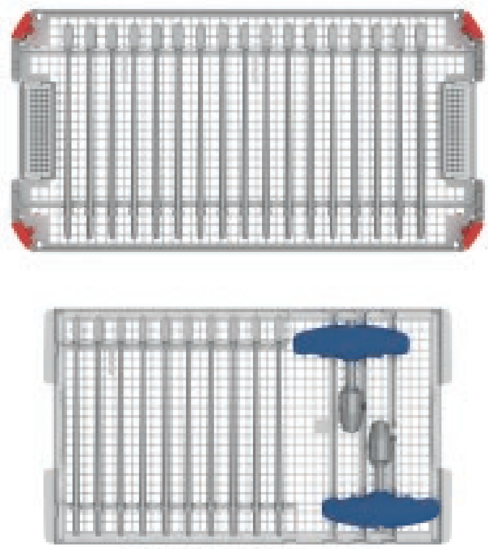
SN400 IMPLANTATION INSTRUMENTS – PROSPACE® 3D IMPLANTATION

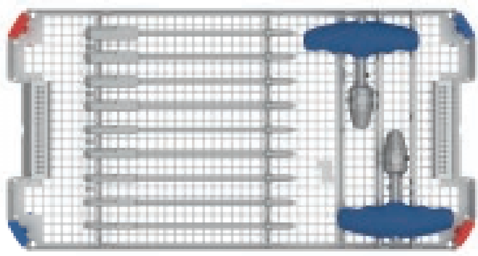
	Article No.	Description	Quantity
	**FJ039R**	PROSPACE® 3D / 3D Oblique impactor	1
	**SJ806R**	PROSPACE® 3D / 3D Oblique revision instrument	1

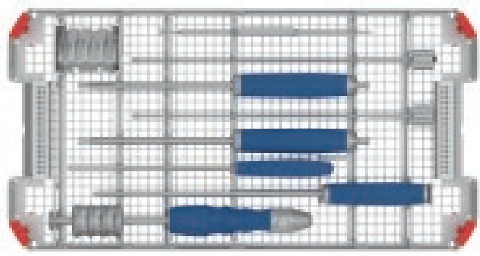
INFORMATION

Recommended container: JK444
Recommended container lid: JK485
Recommended identification label: JG785B









SN505

SN400

AESCULAP® PROSPACE® 3D

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The usability of the AESCULAP® 3D Cage System PROSPACE® 3D 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.

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