



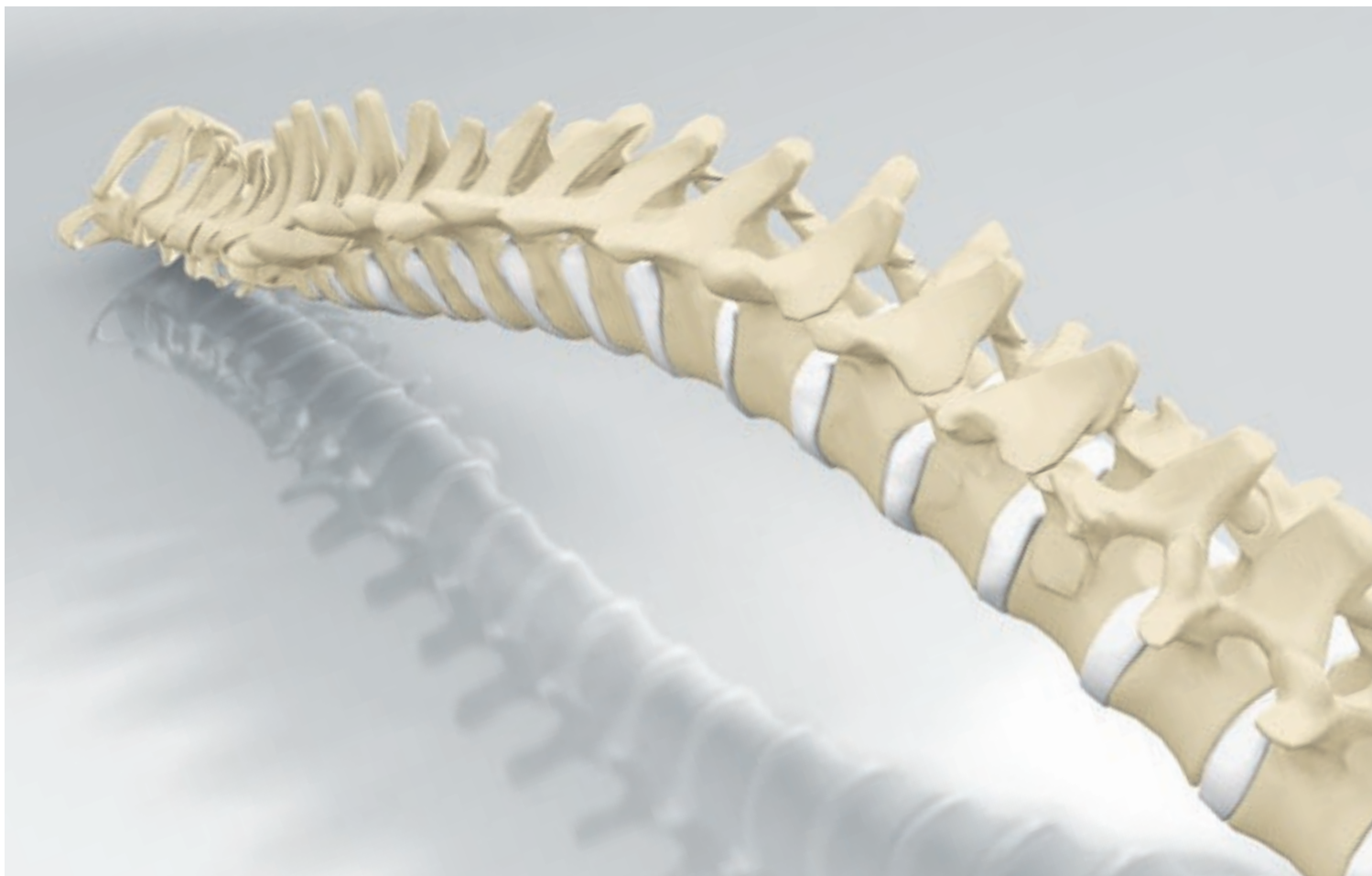
SPINE SURGERY

AESCLAP[®] PROSPACE[®] 3D

POSTERIOR INTERBODY FUSION SYSTEM

SURGICAL MANUAL

AESCULAP® LUMBAR SPINE



Please scan QR code or visit www.aesculap.com
to view full product portfolio

AESCULAP® PROSPACE® 3D

CONTENT



| | | |
|----------|--|-----------|
| A | IMPLANT MATERIAL | 4 |
| B | INTENDED USE & IMPLANT DESIGN | 7 |
| C | SURGICAL TECHNIQUE | 8 |
| C.01. | PATIENT POSITIONING | 8 |
| C.02. | EXPOSURE OF THE INTERVERTEBRAL SPACE | 8 |
| C.03. | RESTORATION OF DISC HEIGHT | 9 |
| C.04. | DISCECTOMY | 9 |
| C.05. | PREPARATION OF ENDPLATES | 10 |
| C.06. | IMPLANT SELECTION | 10 |
| C.07. | IMPLANT REMOVAL FROM PACKAGING | 11 |
| C.08. | FILLING OF CAGE | 11 |
| C.09. | PROSPACE® 3D INSERTION | 11 |
| C.10. | INSERTION OF THE CONTRA-LATERAL SIDE | 12 |
| C.11. | POSTERIOR STABILIZATION | 13 |
| D | IMPLANT OVERVIEW | 14 |
| E | INSTRUMENT OVERVIEW | 18 |

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

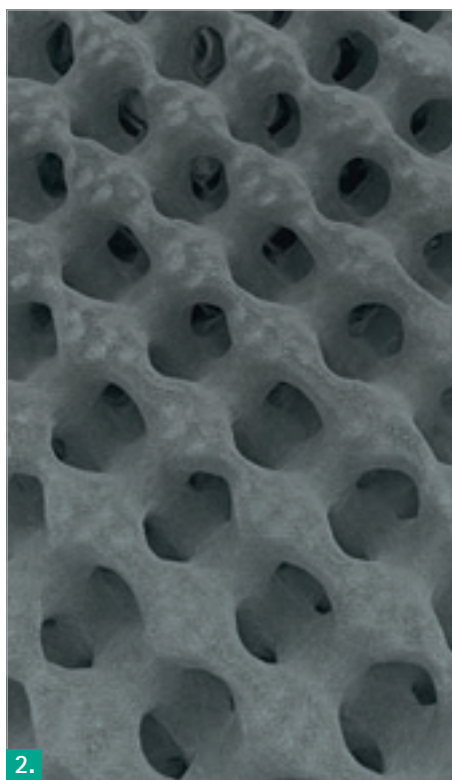
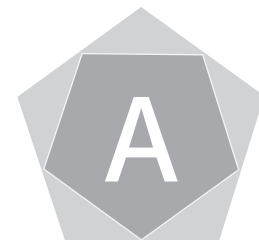
■ Additive manufacturing – 3D printing – means a layer by layer process to design a device using laser beam and metal powder. This innovative laser beam melting technology is of growing importance in the manufacture of implants, as it allows to create various fine and porous surface structures with the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

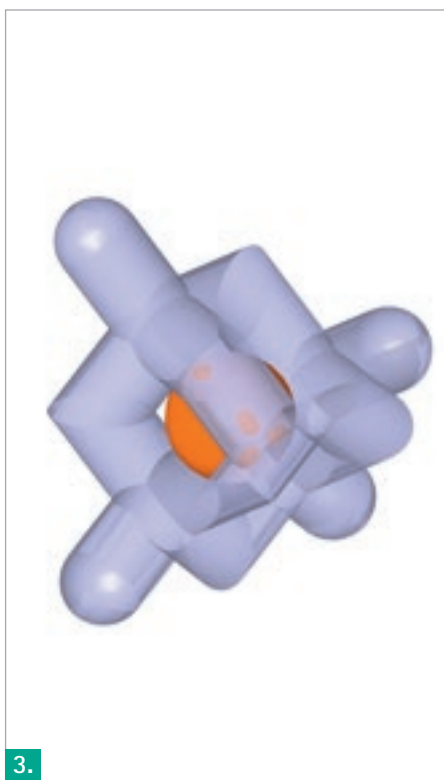


1. Laser beam melting technology



2.

Lattice structure Structan®



3.

Unit cell with fitted ball of 900 µm

AESCU[®] 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).

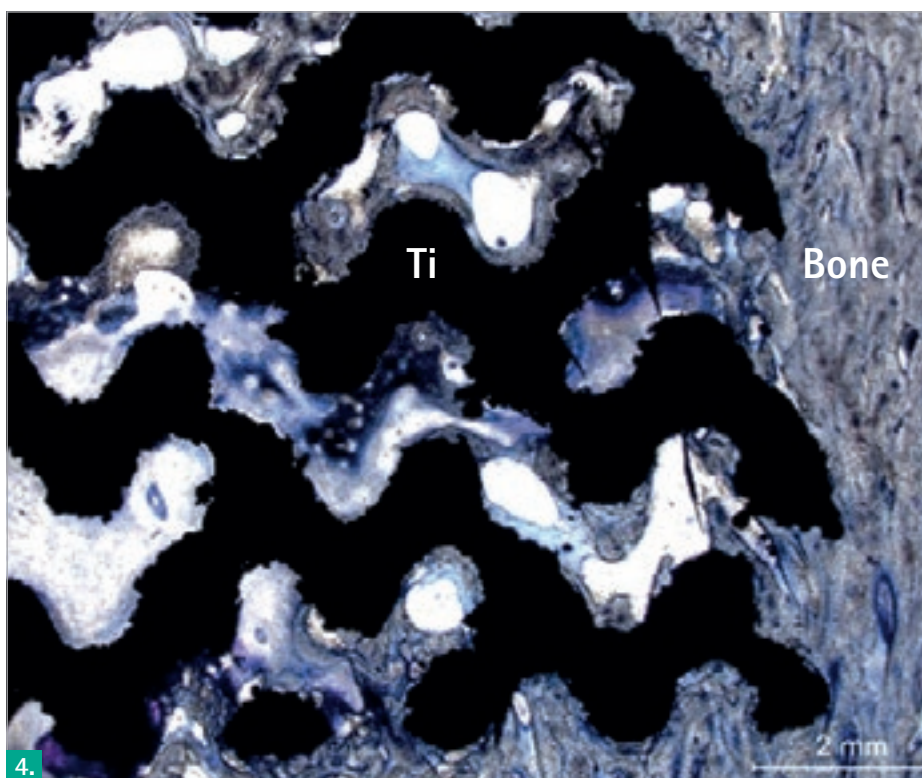
MORE CONNECTION

■ 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.

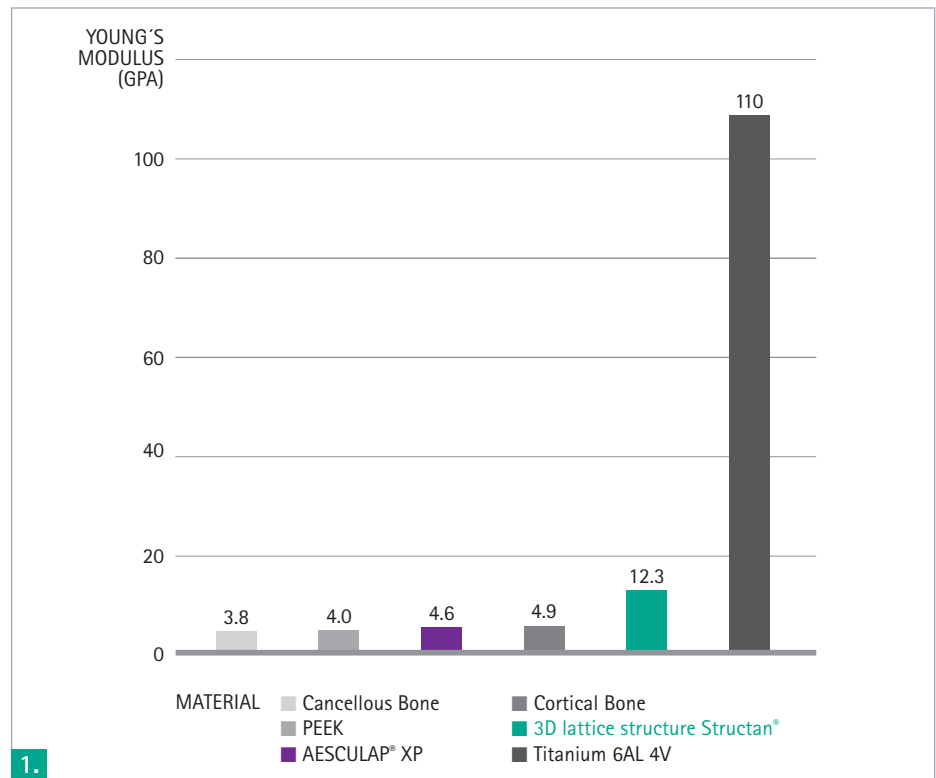
Histological section of the 3D Cage lattice structure filled with newly formed bone

AESCULAP® PROSPACE® 3D

A. IMPLANT MATERIAL

MORE ELASTICITY

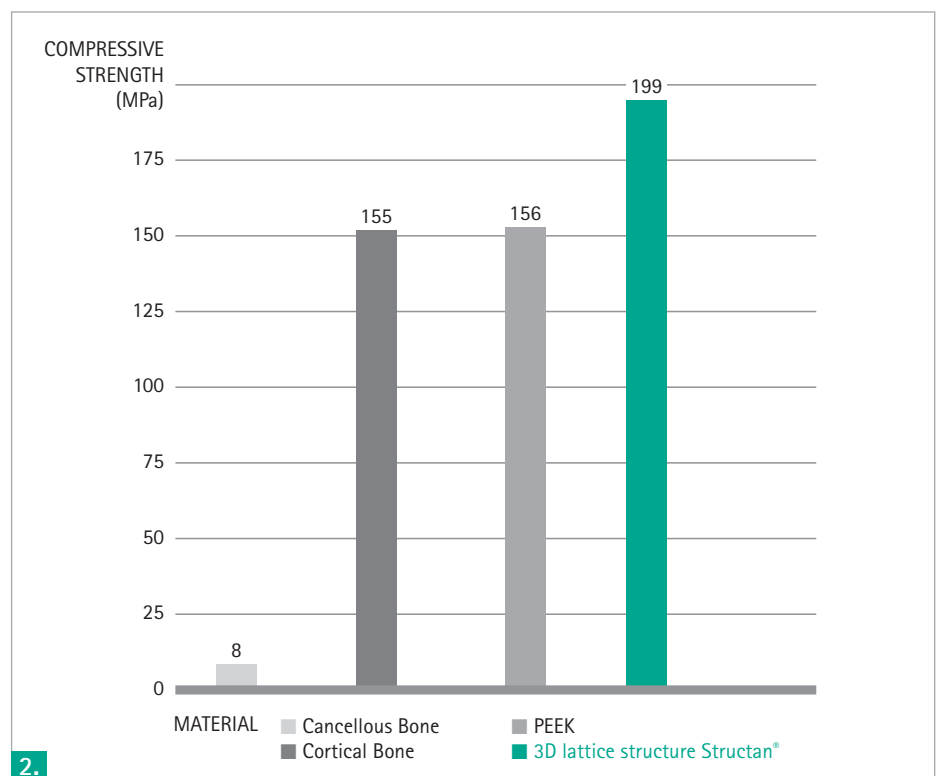
■ Ti6Al4V ELI as solid material has a Young's modulus of approximately 110 GPa as it is shown in the figure, whereas cortical bone has a Young's modulus of approximately 5 GPa (15, 16). The Young's modulus of Structan® is developed to be close to that of cortical bone. This may prevent subsidence into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



Young's modulus of various materials

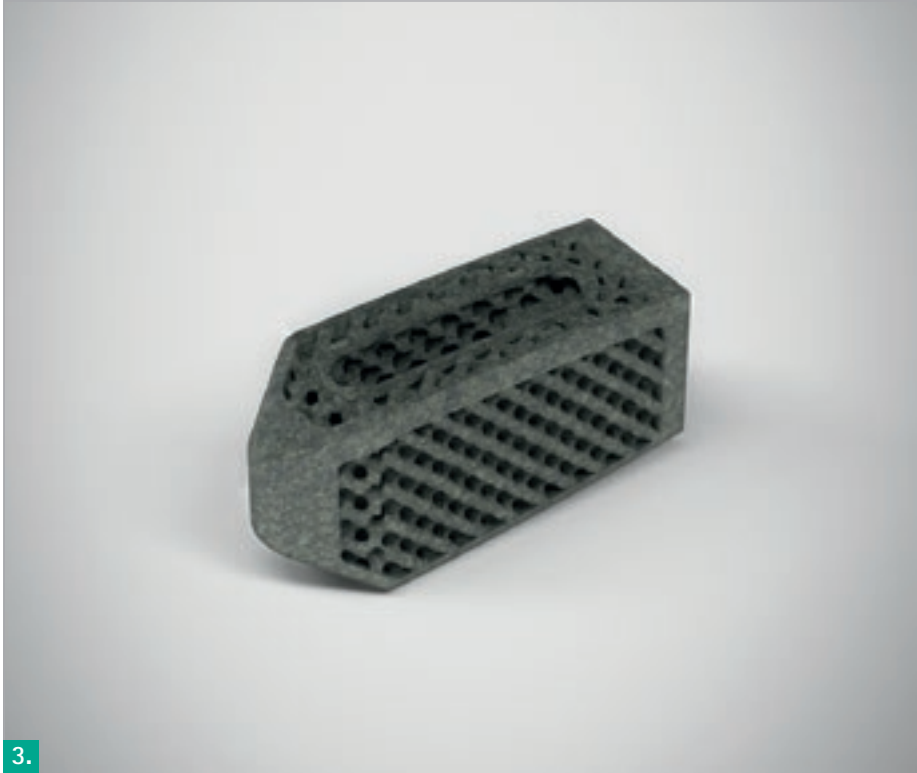
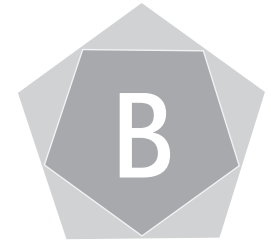
MORE STRENGTH

■ 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).



Compressive strength of 3D lattice structure Structan®

B. INTENDED USE & IMPLANT DESIGN



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

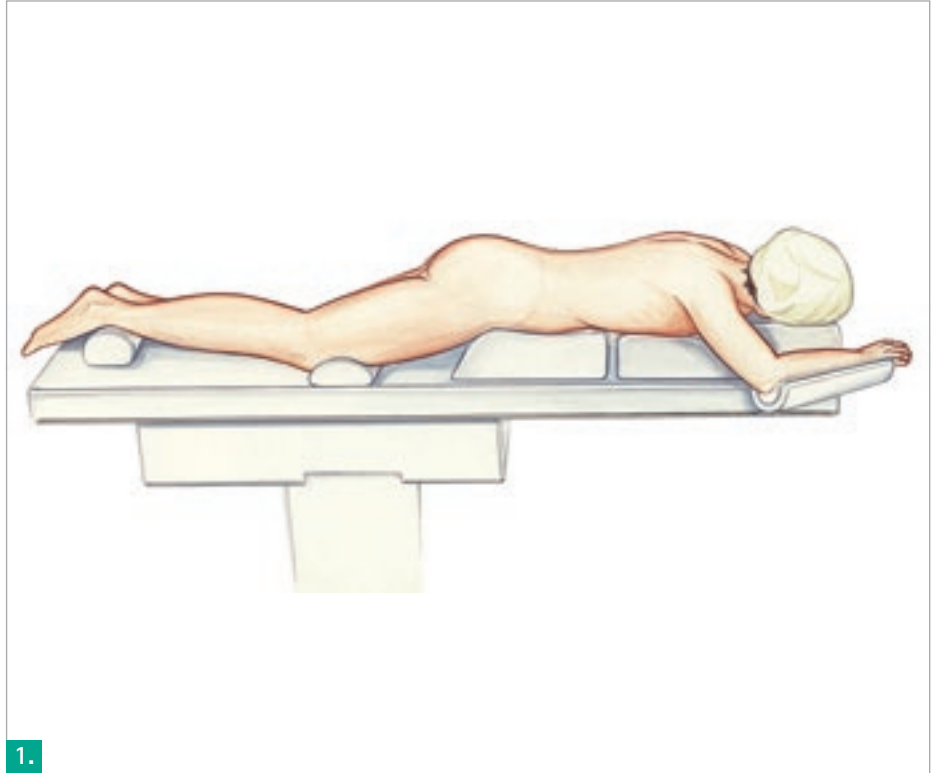
- Solid frame without sharp edges for biomechanical stability and smooth insertion into the disc space minimizing the risk to injure surrounding soft tissue.
- Open porous structure designed to provide primary and secondary stability.
- The implant's anatomical endplate design provides a good contact 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

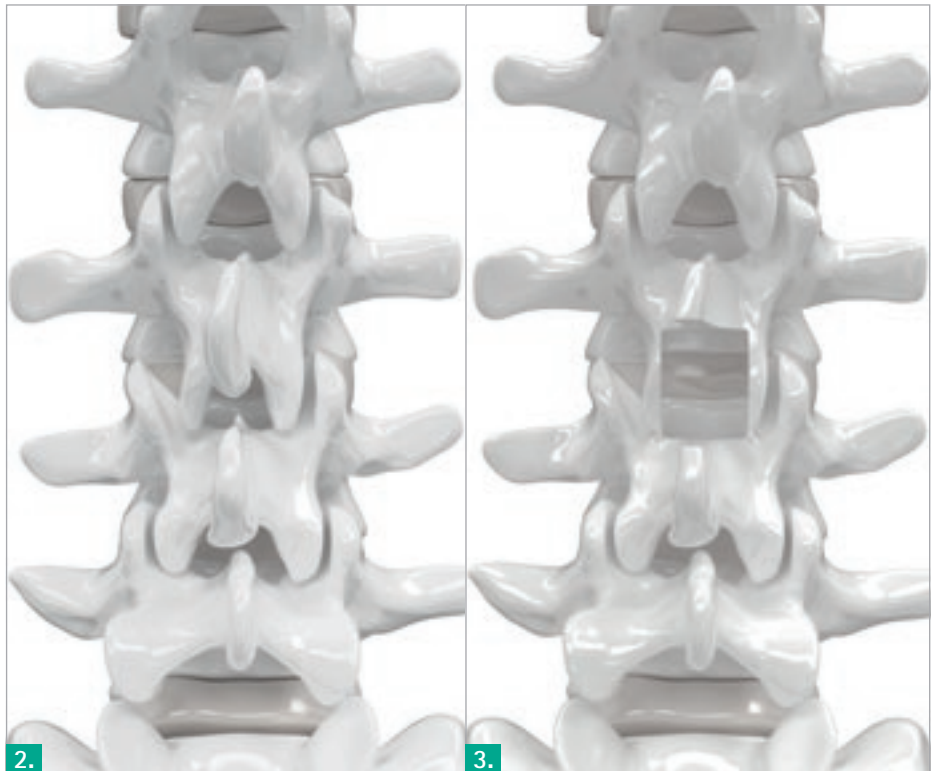
C.01. PATIENT POSITIONING

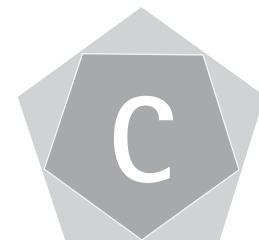
- The patient is positioned in the prone position for posterior fusion with supplemental fixation (Fig. 1).
- A midline incision over the levels to be instrumented is performed.



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.





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.



C.04. DISCECTOMY

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

AESCULAP® PROSPACE® 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.



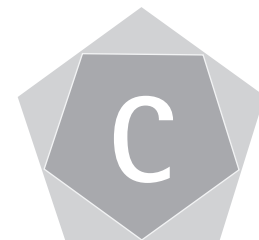
C.06. IMPLANT SELECTION

- 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. Step-wise 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.





3.

C.07. IMPLANT REMOVAL FROM PACKAGING

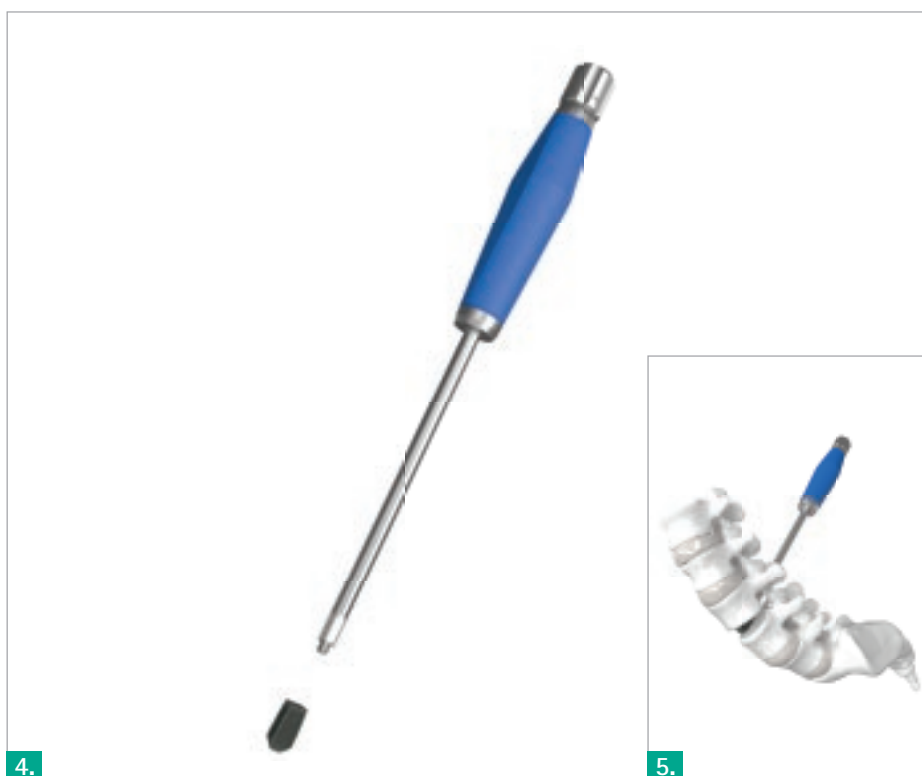
- Open folder blister to remove the PROSPACE® 3D implant.
- The packaging concept allows implant removal with the connected inserter.

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.



4.

5.

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.

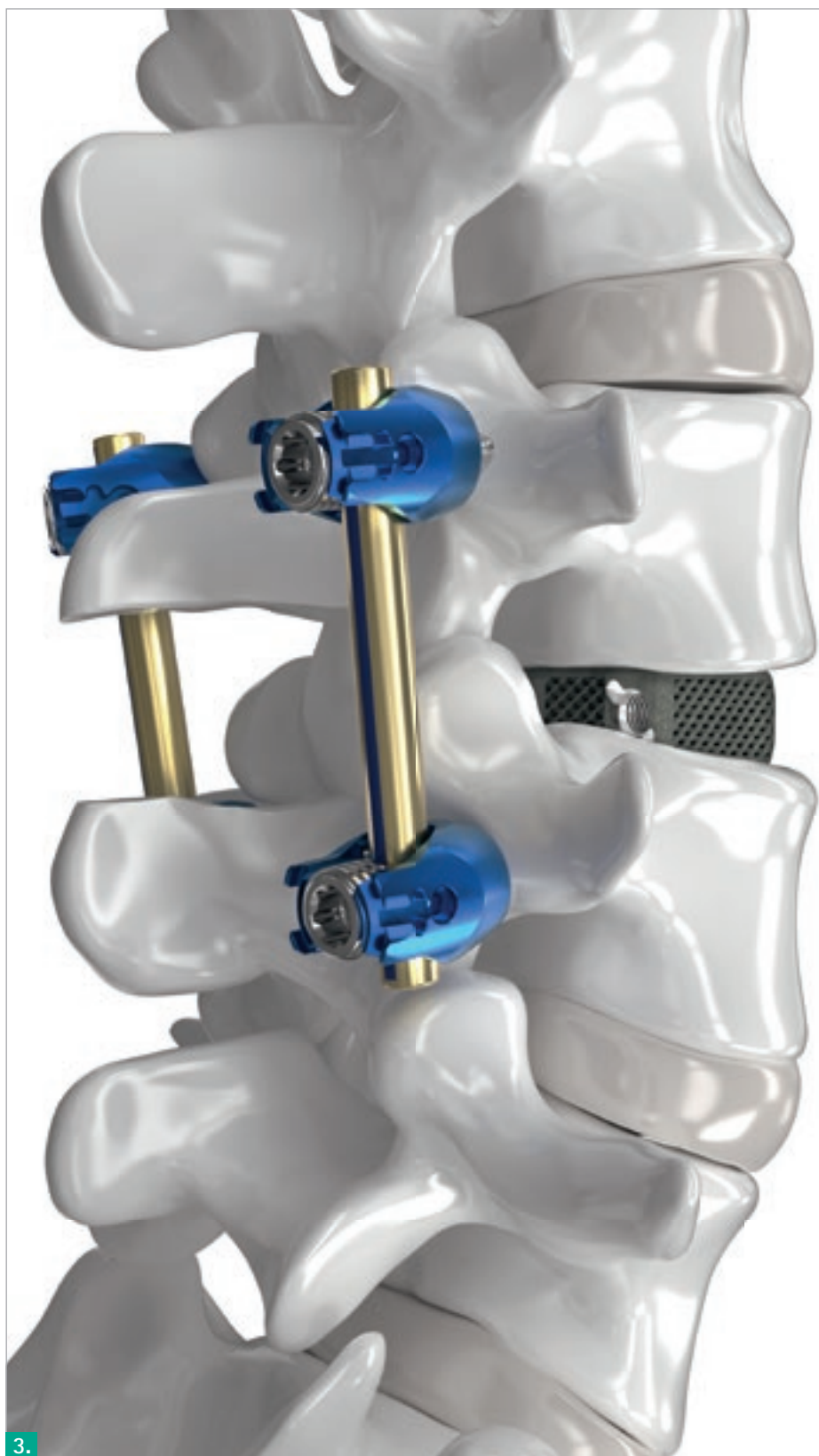
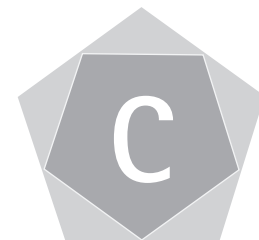
AESCULAP® PROSPACE® 3D

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).





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.

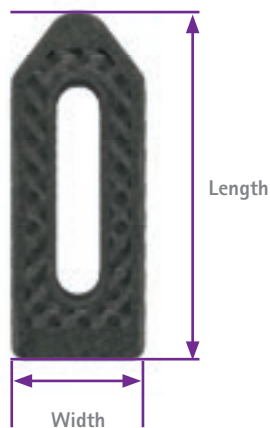
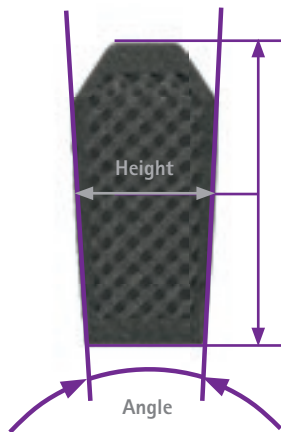
- Subsequent segmental compression with posterior instrumentation allows loading of the anterior column and restoration of sagittal alignment.

- 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 | | 8 x 8.5 x 22 mm | 4 |
| SN414T | 5° | 9 x 8.5 x 22 mm | 4 |
| SN415T | 10° | 10 x 8.5 x 22 mm | 4 |
| SN424T | | 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 |

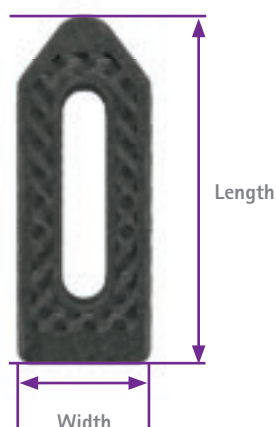
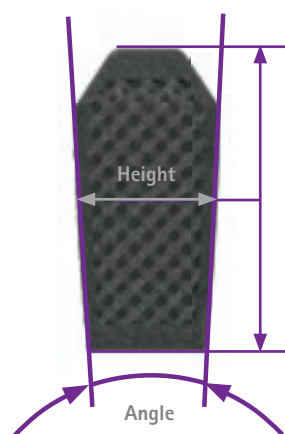


| Article No. | Lordosis | Size (Height x Width x Length) | Quantity |
|-------------|----------|--------------------------------|----------|
| SN429T | 10° | 9 x 8.5 x 26 mm | 4 |
| SN430T | | 10 x 8.5 x 26 mm | 4 |
| SN431T | | 11 x 8.5 x 26 mm | 4 |
| SN438T | 0° | 8 x 10.5 x 22 mm | 2 |
| SN439T | | 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 | 5° | 13 x 10.5 x 22 mm | 2 |
| SN458T | | 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 | 5° | 13 x 10.5 x 26 mm | 2 |
| SN468T | | 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 |








| Article No. | Lordosis | Size (Height x Width x Length) | Quantity |
|-------------|----------|--------------------------------|----------|
| SN489T | 10° | 9 x 10.5 x 26 mm | 4 |
| SN490T | | 10 x 10.5 x 26 mm | 4 |
| SN491T | | 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

■ Currettes (FJ702R - FJ703R),



■ Bone currettes (FJ698R - FJ699R) and

■ Bone rasps (FJ704R - FJ705R) are available.

AESCULAP® PROSPACE® 3D

E. INSTRUMENT OVERVIEW

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



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/extraction 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

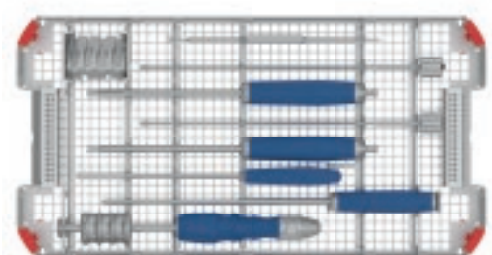
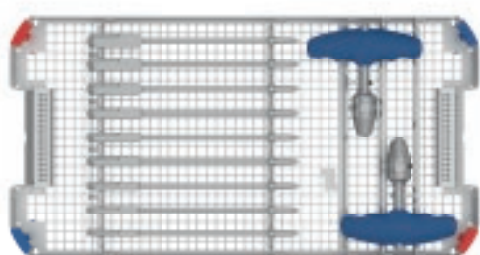
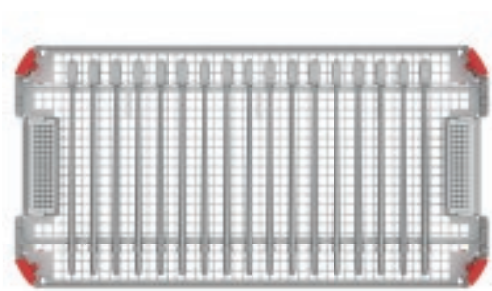
E. INSTRUMENT OVERVIEW

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

REFERENCES

- (1) Tropiano P, Bronsard JJ, Louis C, Tallet JM, Sauget Y. Three column stabilisation through a posterior approach with a titanium PLASMAPORE® intervertebral block (PROSPACE®). Radiological and clinical study after 4 years. *Rivista di Neuroradiologia*. 1999;12(Suppl 1):89-94.
- (2) Kroppenstedt S, Gulde M, Schönmayr R. Radiological comparison of instrumented posterior lumbar interbody fusion with one or two closed-box PLASMAPORE® coated titanium cages. Follow-up study over more than seven years. *Spine*. 2008;33(19):2083-8.
- (3) Kreinest M, Schmahl D, Grützner PA, Matschke S. Radiological Results and Clinical Patient Outcome After Implantation of a Hydraulic Expandable Vertebral Body Replacement following Traumatic Vertebral Fractures in the Thoracic and Lumbar Spine: A 3-Year Follow-Up. *Spine (Phila Pa 1976)*. 2017 Apr 15;42(8):E482-E489.
- (4) Takeuchi M, Yasuda M, Niwa A, Wakao N, Nakura T, Osuka K et al. PLASMAPORE®-coated titanium cervical cages induce more rapid and complete bone fusion after anterior cervical discectomy and fusion as compared to noncoated titanium cage. *World Neurosurgery*. 2014;82(3/4):519-22.
- (5) Vanek P, Bradac O, Konopkova R, de Lacy P, Lacman J, Benes V. Treatment of thoracolumbar trauma by short-segment percutaneous transpedicular screw instrumentation: prospective comparative study with a minimum 2-year follow-up. *J Neurosurg Spine*. 2014;20:150-6.
- (6) Beisse R. Endoscopic surgery on the thoracolumbar junction of the spine. *Eur Spine J*. 2006;15:687-704.
- (7) Finger T, Bayerl S, Onken J, Czabanka M, Woitzik J, Vajkoczy P. Sacropelvic fixation versus fusion to the sacrum for spondylodesis in multilevel degenerative spine disease. *Eur Spine J*. 2014;23:1013-20.
- (8) Ngoc Bich VU et al. In vitro and in vivo biocompatibility of Ti-6Al-4V titanium alloy and UHMWPE polymer for total hip replacement. *Biomedical Research and Therapy*. 2016;3(3):567-77.
- (9) Van der Stok J, Van der Jagt O, Yavari S, De Haas M, Waarsing J, Jahr H et al. Selective laser melting-produced porous titanium scaffolds regenerate bone in critical size cortical bone defects. *Journal of Orthopaedic Research*. 2013;31(5):792-9.
- (10) In vivo study of porous metallic lattice structures, Ulm, 2019. The biocompatibility, osseointegration and biomechanical properties of porous Ti6Al4V implants manufactured by SLM were tested under mechanical loading conditions in an ovine model study sponsored by Aesculap AG. The samples were evaluated histologically and biomechanically after implantation. Porous Ti6Al4V implants exhibited very good biocompatibility, bone-implant interface strength and osseointegration. Six months after implantation, bone ingrowth on and into the porous Ti6Al4V implants was reported. Inflammatory reactions that may influence bone formation were not observed.
- (11) Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. *Biomaterials*. 2005;26(27):5474-91.
- (12) Taniguchi N et al. Effect of pore size on bone ingrowth into porous titanium implants fabricated by additive manufacturing: an in vivo experiment. *Materials Science and Engineering: C*. 2016;59:690-701.
- (13) Van Bael S et al. The effect of pore geometry on the in vitro biological behavior of human periosteum-derived cells seeded on selective laser-melted Ti6Al4V bone scaffolds. *Acta biomaterialia*. 2012;8(7):2824-34.

- (14) Elias CN et al. Mechanical and clinical properties of titanium and titanium-based alloys (Ti G2, Ti G4 cold worked nano structured and Ti G5) for biomedical applications. *Journal of Materials Research and Technology*. 2019;8(1):1060–9.
- (15) Kuhn JL, Goldstein SA, Choi K, London M, Feldkamp LA, Matthews LS. Comparison of the trabecular and cortical tissue moduli from human iliac crests. *J Orthop Res*. 1989;7(6):876–84.
- (16) Ratner BD, Hoffmann AS, Schoen FJ, Lemons JE. *An Introduction to Materials in Medicine*. Academic Press. 1996.
- (17) Chen Y, Wang X, Lu X, Yang L, Yang H, Yuan W et al. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: a prospective, randomized, control study with over 7-year follow-up. *Eur Spine J*. 2013;22(7):1539–46.
- (18) Brizuela A et al. Influence of the elastic modulus on the Osseointegration of Dental Implants. *Materials*. 2019;12(6):980.
- (19) Azami M, Moztarzadeh F, Tahriri M. Preparation, characterization and mechanical properties of controlled porous gelatin/hydroxyapatite nanocomposite through layer solvent casting combined with freeze-drying and lamination techniques. *Journal of Porous Materials*. 2010;17(3):313–20.
- (20) Rae PJ, Brown EN, Orler EB. The mechanical properties of poly (ether-ether-ketone) (PEEK) with emphasis on the large compressive strain response. *Polymer*. 2007;48(2):598–615.
- (21) Usability-Test, Usability Validation of AESCULAP® PROSPA-CE® 3D Cages, Tübingen, 2019.
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.
- (22) Rehnitz, Christoph, PD Dr. med. Radiological image evaluation of AESCULAP® interbody fusion devices, Heidelberg, 2019.
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

The main product trademark "AESCULAP" and the product trademarks "Ennovate", "PLASMAPORE", "PROSPACE" and "Structan" are registered trademarks of Aesculap AG.

Subject to technical changes. All rights reserved. This brochure may only be used for the exclusive purpose of obtaining information about our products. Reproduction in any form partial or otherwise is not permitted.