Cs•DISC

Cervical semi-rigid disc prosthesis

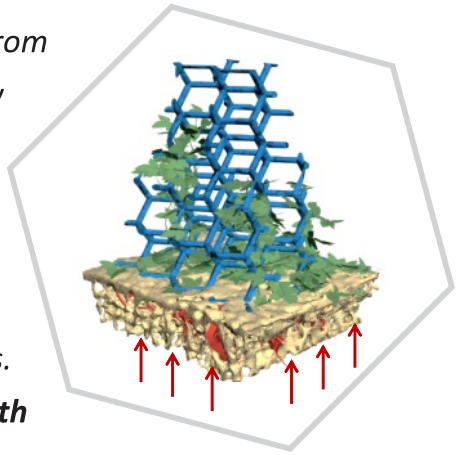
IMPLANTATION PROCEDURE

3D-Truss Titanium cage for cervical intervertebral fusion

DERO Spinal System • Intervertebral Decompression & Fusion • Anterior approach

*The first LfC's 3D-Truss Ti-alloy implant was the **CarЯLIF** (Carving Round Lumbar Interbody Fusion) - it is the first 3D printed, curved spinal cage worldwide. The clinical implantation started in the year 2011. This cage combines the fusion enhancing features of the 3D truss structure together with precision of insertion and placement provided by unique "carving guides". It is still the "flagship" implant of the whole **CarЯLIF-family** – a group of implants based on **3D-Truss-Ti Electron Beam Technology** – which has been for the first time applied for spinal implant by LfC. Those implants constitute a new significant step in spine surgery due to their special function enhancing **new trend** in surgical treatment of the spine:*

"Bridging of the spine" with 3D-Truss-Ti construction.



*At the end of the 20th century, technologies stemming from aero-spacial engineering enabled a whole world of new possibilities in 3D architecture, and were transmitted by LfC to the field of spinal implants. Electron beam melting (EBT-Electron Beam Technology) of Ti-alloy powder with over 2000 deg. C in a vacuum chamber - that is the essence of hi-tech need for creation of new generation 3D-implants. Apart from the structure itself, which favors **bone ingrowth** within special cells, the design also enables a better osteointegration mechanism reducing **fusion time** by approximately 40-50 percent and more. This new phenomenon was studied and called „Ivy-like mechanism, L.C." as a metaphor for mimic way of the natural growth of ivy climbing along the specially made rough surface of truss design.*

„Cs-DISC" is made of Ti-alloy powder by Electron Beam Technology (EBT). Porous implant with special truss structure provides excellent conditions for fusion – bone fills the cage by 65-70%. This is the reason for the bone-like "semi-rigidity", because the fused caged provides flexural modulus consisting of the combination of 3D truss Ti-structure and bone.
Its angled and corrugated endplate contact surfaces prevent dislocation after placement of cage into intervertebral space and restore lordosis. Cage does not require to be filled with bone or bone substitute.

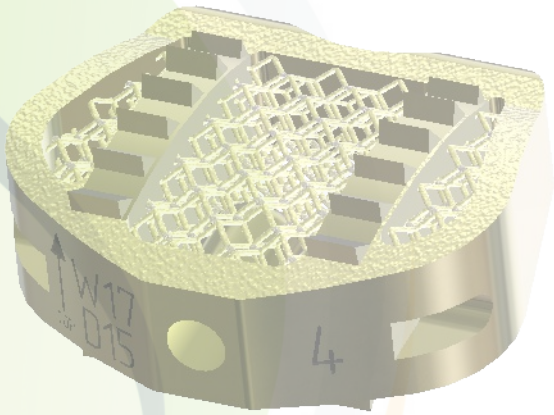
Well-chosen stabilizing implant is designed to achieve a biomechanical function only in those cases, where, after suitably performed surgery, it is followed by bone overgrowth and interception of these functions through the musculosceletal system. The range of sizes enables to deal with every anatomical variation and allows restoration of the natural-balanced height of the interlaminar space as well as the restoration or maintenance of adequate morphometry. Contraindications for use are listed in the „General Instruction for Use of Spinal System DERO". The implantation procedure of interlaminar stabilizer is reserved for spine surgery specialists trained in the use of the specific instrumentation conceived for "Cs-DISC" implants.

This main procedure steps are shown for illustrative purposes only. The technique actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Presented instrumentation should be used solely with "General Instruction for Use of Spinal System DERO". Please see the IFU for the complete list of indications, warnings, precautions and other medical information.

Cs•DISC
Cervical semi-rigid DISC

Cs•DISC

Cervical semi-rigid disc prosthesis



Functions:

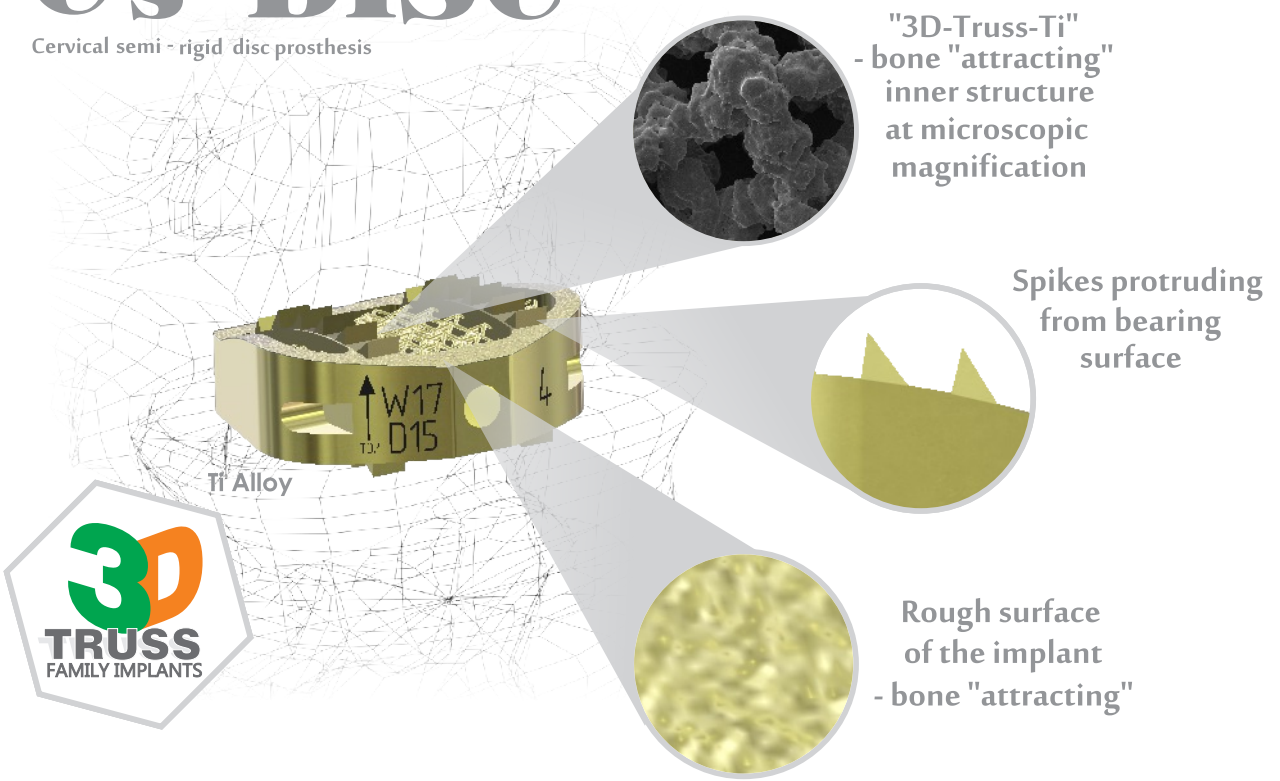
- Accelerated bone fusion
- Biomechanical support for the spine
- Implantation of cervical spine
- Reconstruction of the spinal anatomy
- One or more level stand alone stabilisation
- Possible suport with cervical plate

Features / Benefits:

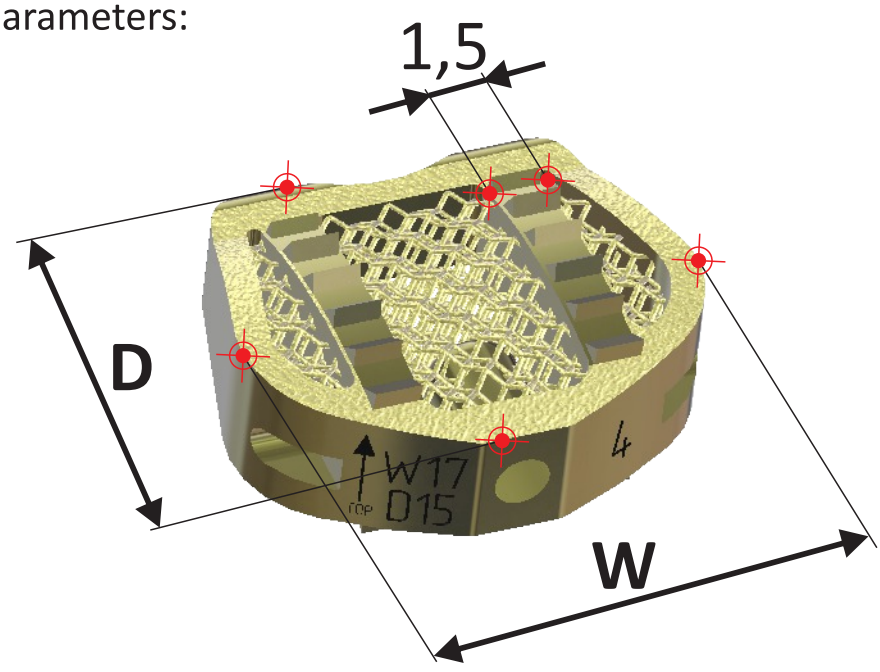
- Specially designed "3D-Truss-Ti" structure
  - minimal volume of titanium
  - over 65% space for fusion
  - light & strong construction
  - high load bearing resistance
  - safe and easy procedure
- Wide range of sizes makes implant choice easier
- Anatomic implant design
- Prosthesis construction gives perfect conditions for a bone fusion
- 3D-Truss elements' surfaces are susceptible for a bone fusion
- Excellent conditions for fusion

Cs·DISC

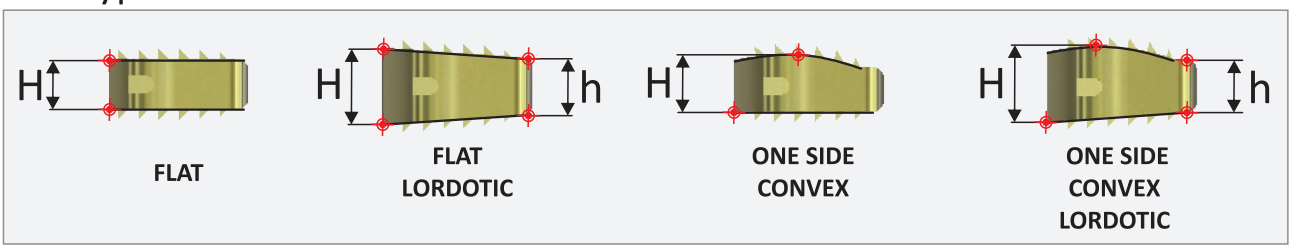
Cervical semi - rigid disc prosthesis



Cs-DISC - parameters:

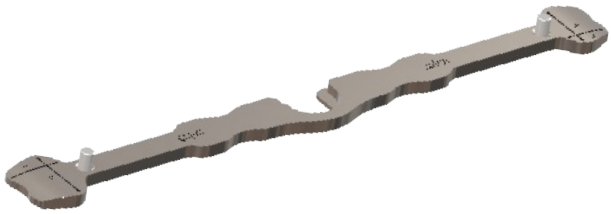


Disc types:



INSTRUMENTS

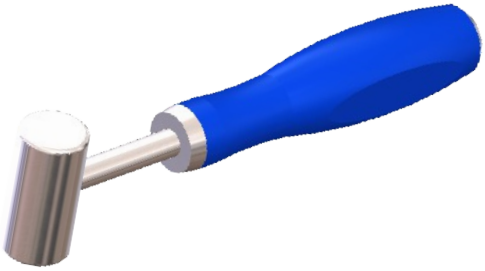
W/D SIZER - *IN868*

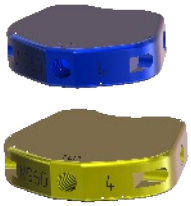


INSERTER Cs-DISC - *IN867*

PUSHER Cs-DISC - *IN878*

MALLET - *IN265*





IN960
TRIAL - flat
4 ÷ 10 set

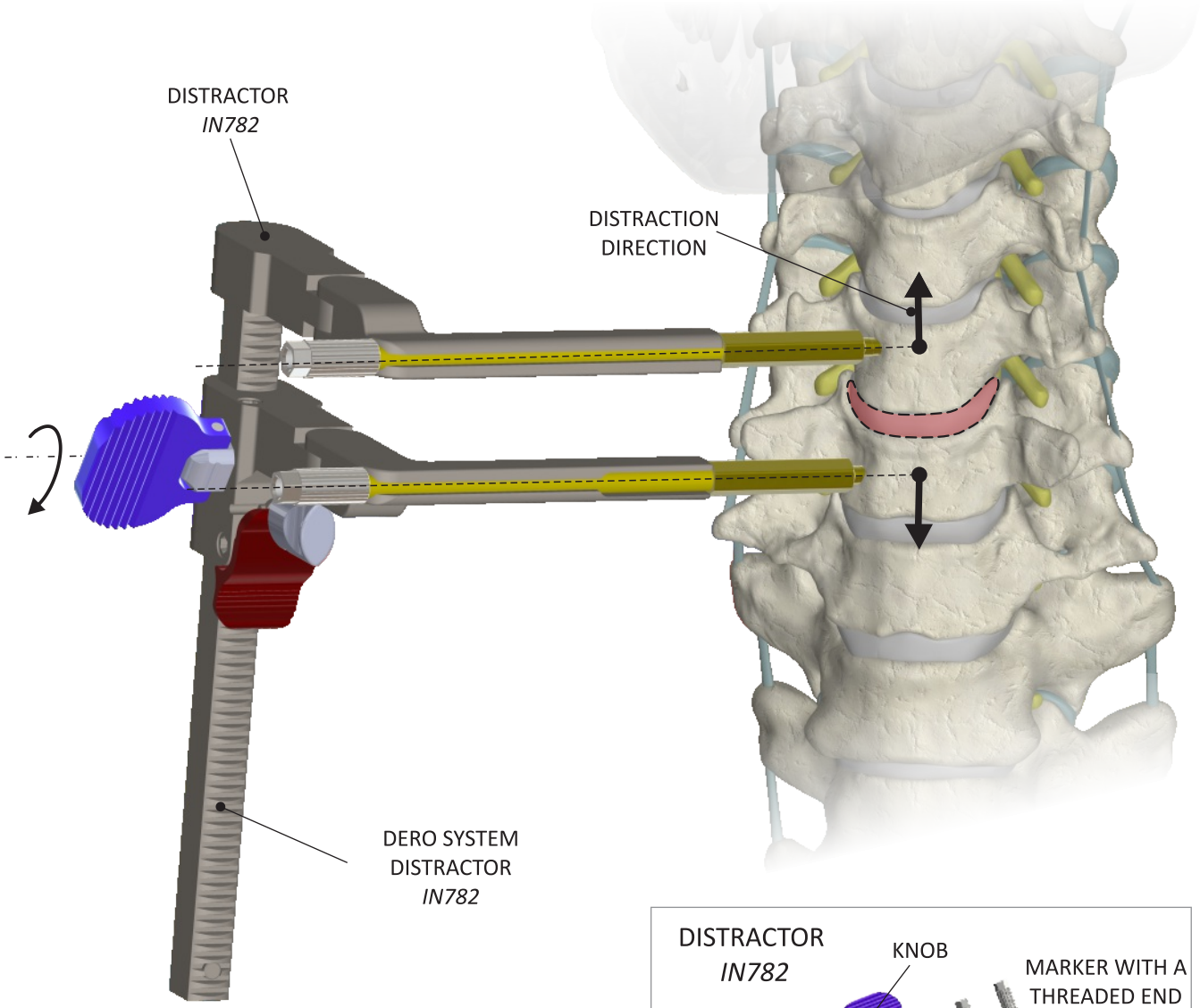
IN961
TRIAL - flat lordotic
4/6 ÷ 10/12 set

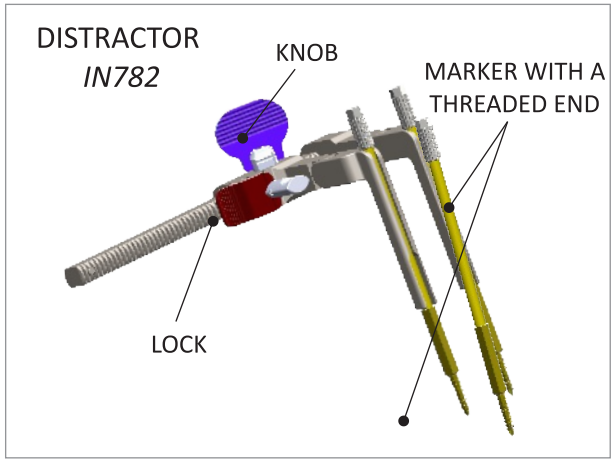
IN962
TRIAL - one side convex
4 ÷ 10 set

IN963
TRIAL - one side convex lordotic
4/6 ÷ 10/12 set

1. Interbody space preparation

Step 1 Surgically prepare an interbody space.
Step 2 Use a standard cervical distractor, when needed.



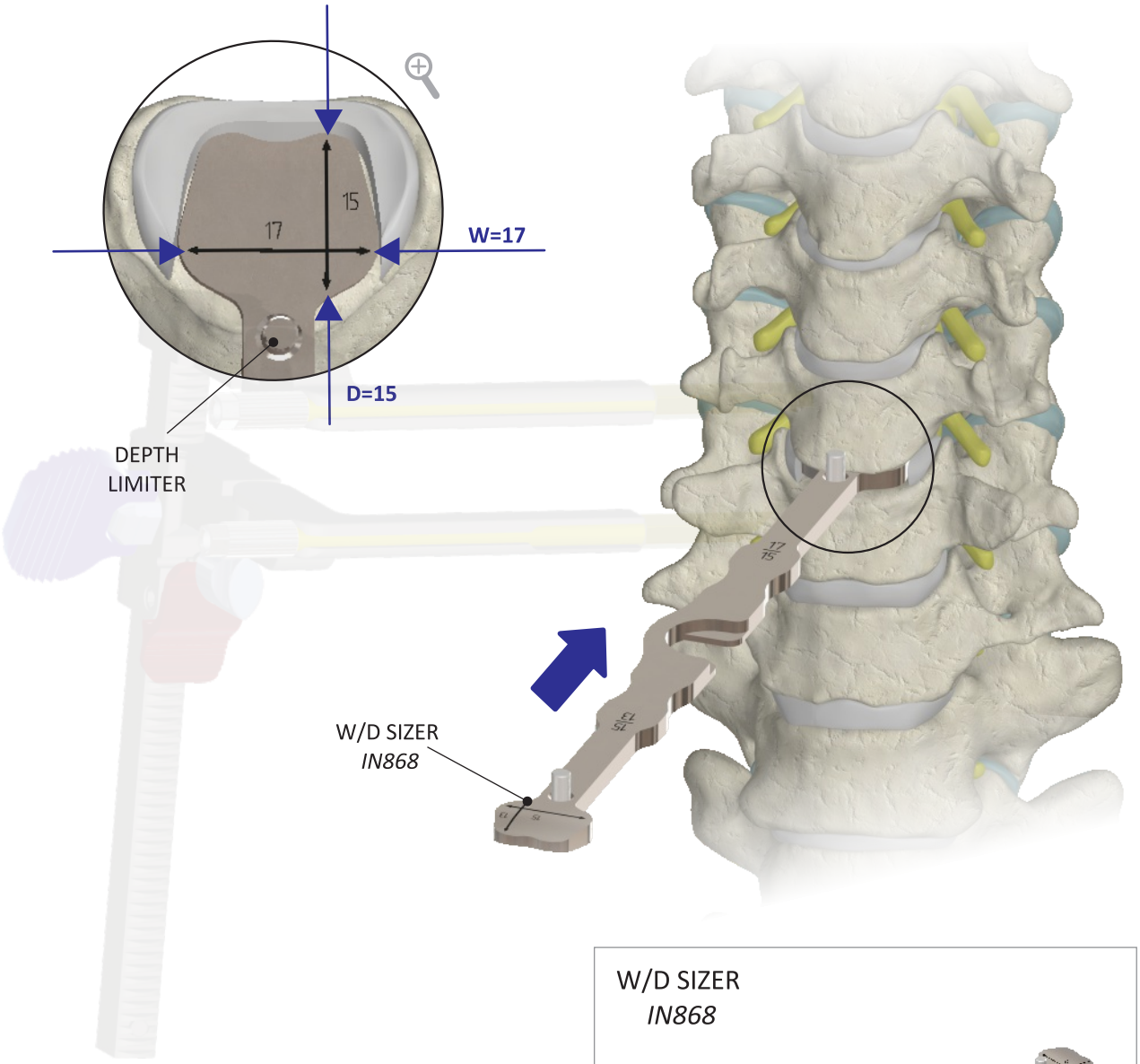


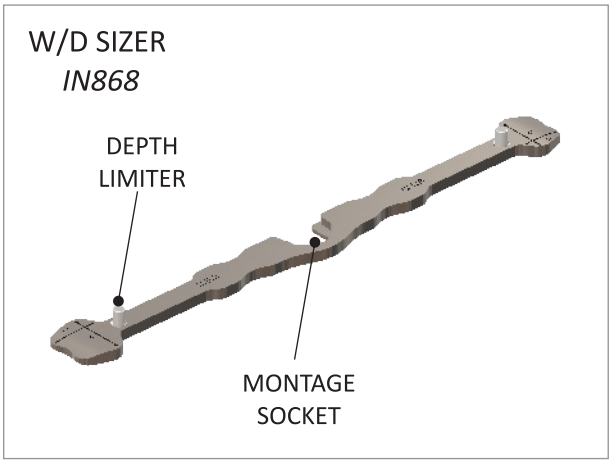
INDICATION

DISTRACTOR *IN782*
of the DERO System – option
available on request

2. Interbody space's width and depth assessment

Step 1 Introduce a W/D SIZER *IN868* into the interbody space.
Step 2 Check mobility of the interbody space using the W/D SIZER *IN868.*
Step 3 Set the width (W) and depth (D) of the interbody space (e.g. W17 and D15).



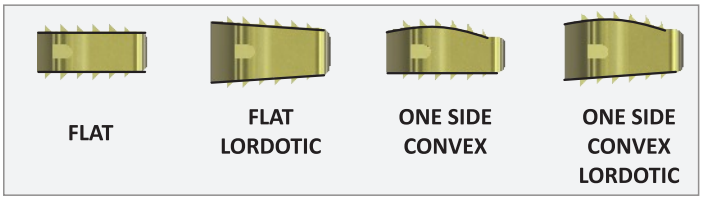


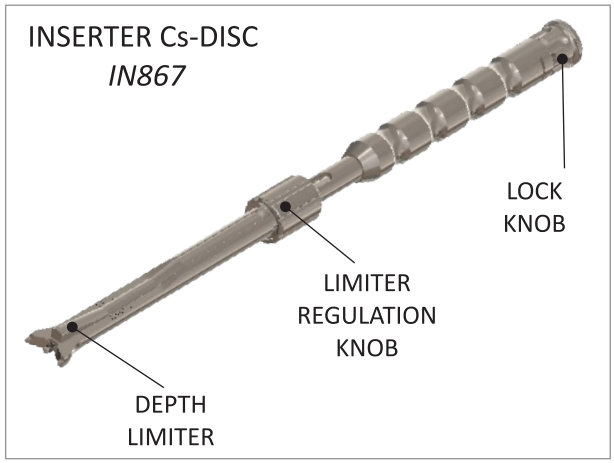
3. Interbody space's shape and height selection

Step 1 Adjust a TRIAL to W/D parameters and the shape of the interbody space taking into account W/D parameters (e.g. 17/15 or 15/13):

- flat
- flat lordotic
- one side convex
- one side convex lordotic.

Disc types:





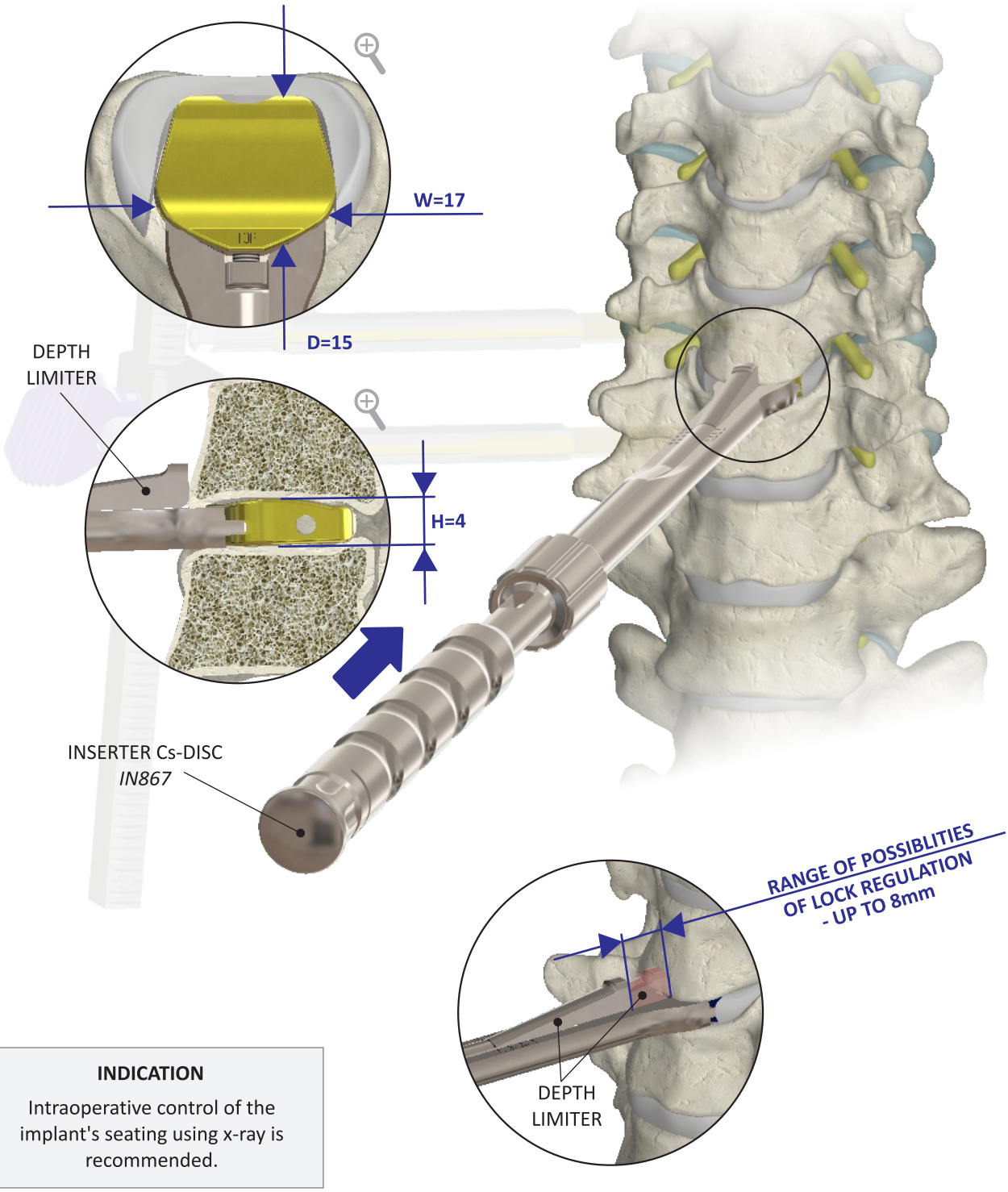
4. Interbody space's height assessment

Step 1 Assess, if the interbody space's height after distraction meets required conditions.

Step 2 Check the interbody space's size using a TRIAL (*IN960, IN961, IN962, IN963*), which highly corresponds with offered cervical prostheses shapes. The TRIAL should be connected with the INSERTER Cs-DISC *IN867*.

NOTE

Implant's height should be selected starting from the smallest; resistance of sliding in and off the TRAIL should be felt (detected).
It is recommended to introduce the TRIAL by careful hit using a hand or the MALLET *IN265* to precise seating (until pre-set depth using DEPTH LIMITER function).



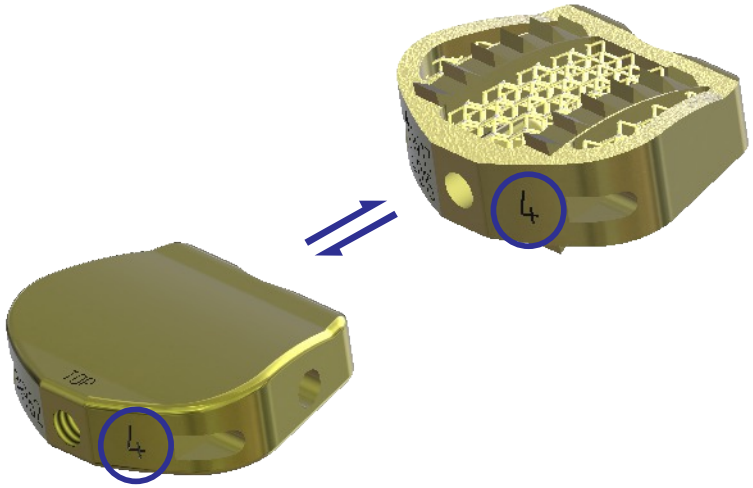
INDICATION

Intraoperative control of the implant's seating using x-ray is recommended.

5. Cs-DISC implant selection

Step 1 Select a Cs-DISC implant based on the selected TRIAL.

NOTE In a case of an implant with spikes, the necessity of diving of spikes within endplates should be taken into account.



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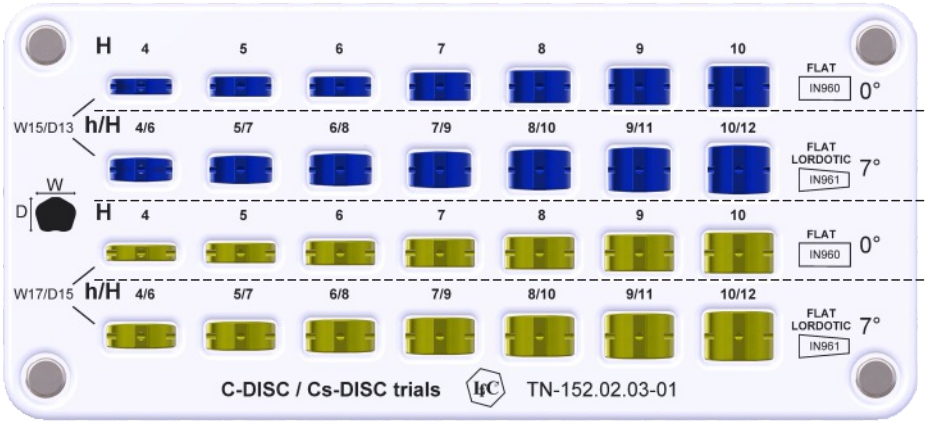
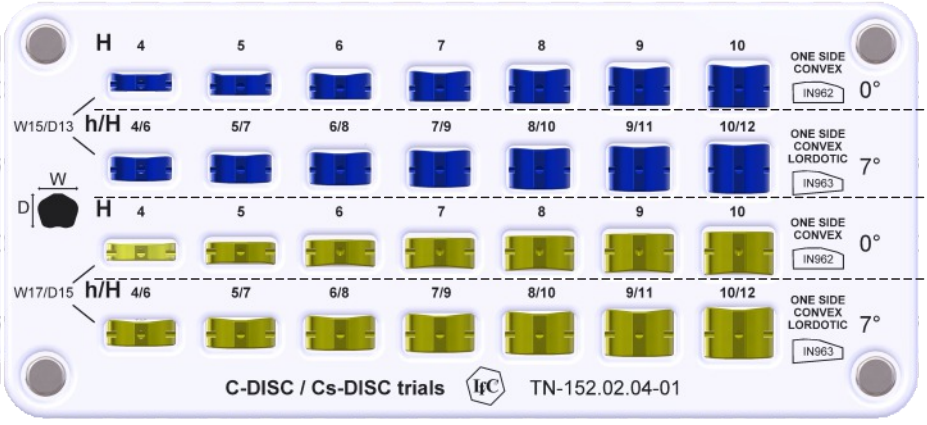


870DT

882DT

870DT

882DT



872DT

883DT

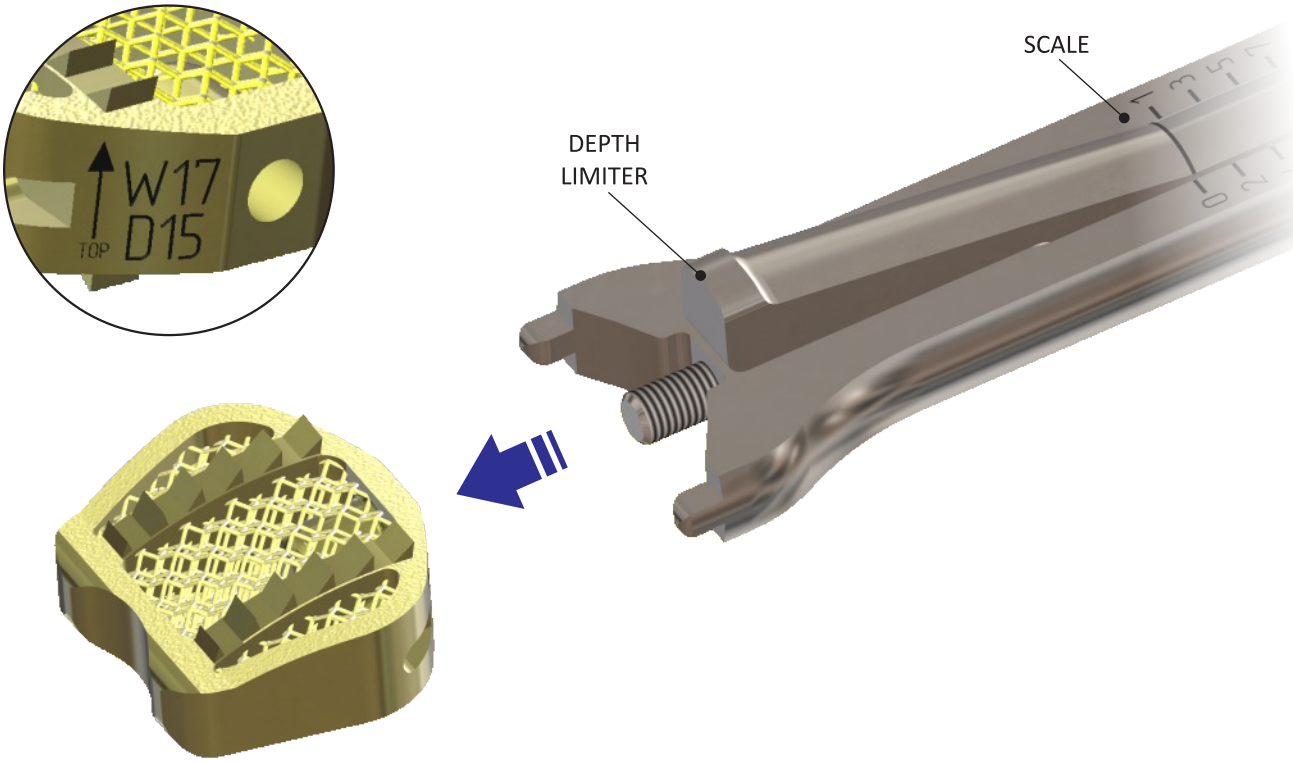
872DT

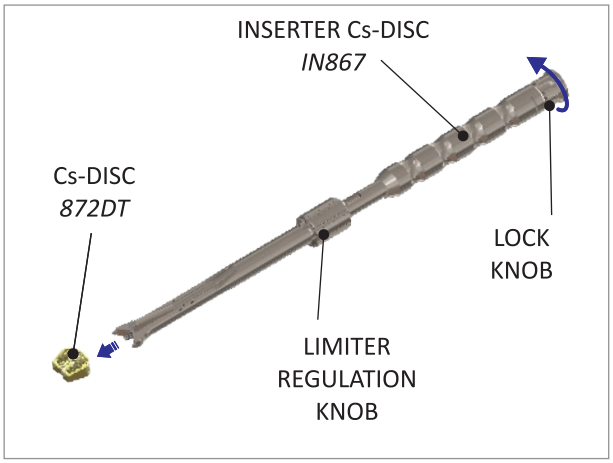
883DT

6. Connection of the prosthesis with an inserter

Step 1 Connect the inserter with the disc prosthesis using a threaded joint ; mount looselessly.

NOTE A scale on the INSERTER Cs-DISC *IN867* applies to the limiter and gives reference information about the depth of seating the Cs-DISC within interbody space. X-ray check is obligatory.
Arrow direction indicates a cranial disc surface.





7. Cs-DISC implantation

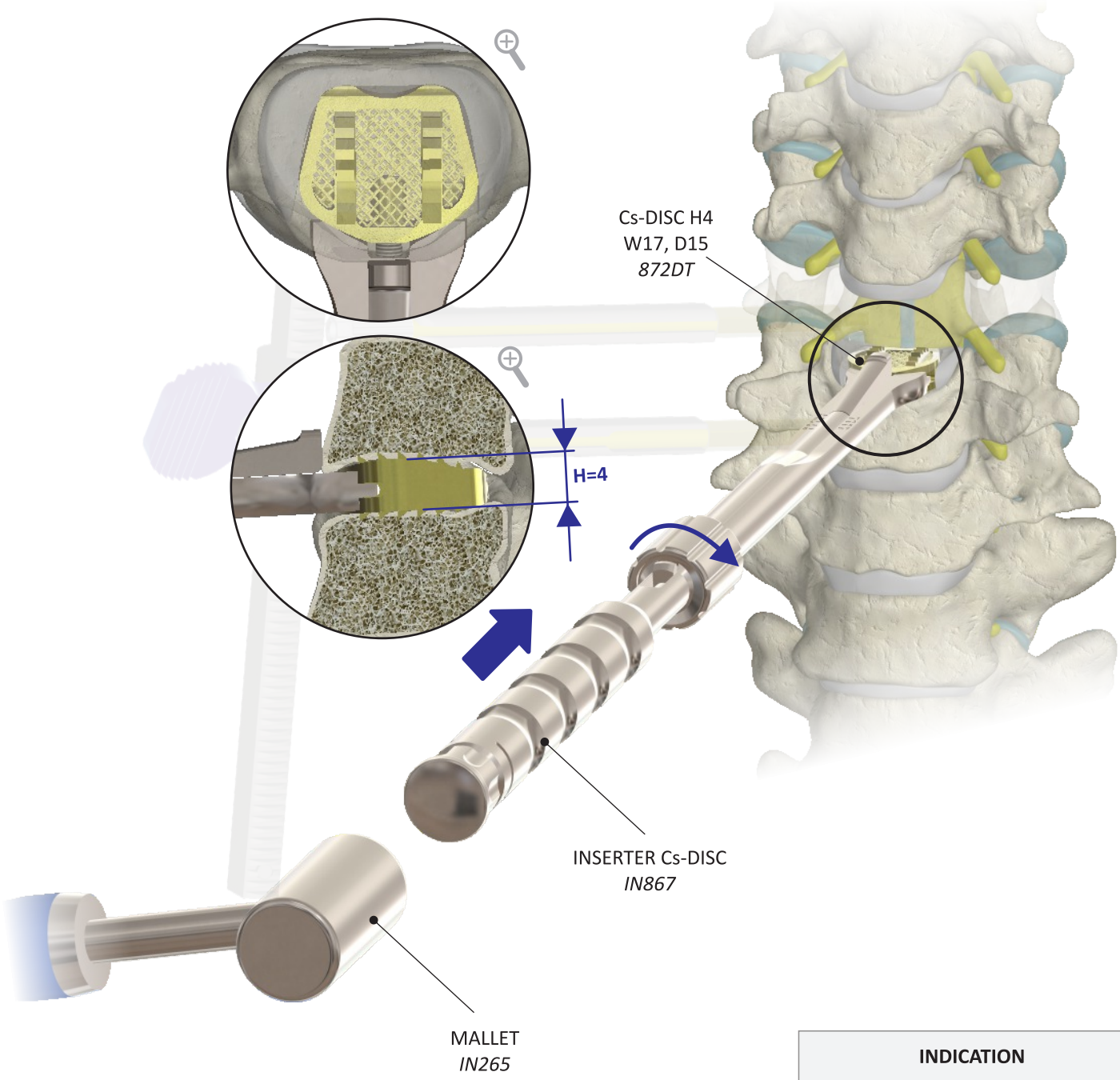
Step 1 Insert the Cs-DISC prosthesis tightly into the interbody space (taking into account geometry of the disc space and bone quality) under the x-ray control.

NOTE

In a proper position, spikes are dived in endplates and the Cs-DISC prosthesis shouldn't project above the vertebral margin.

It is recommended to introduce the implant by careful hitting using a hand or the MALLET *IN265* to final precise seating.

Step 2 In the second option of the procedure, using the DISTRACTOR *IN728*, distraction of the interbody space should be performed before seating or the prosthesis and compression of the space. A proper seating should be assessed manually with a use of x-ray diagnostic.



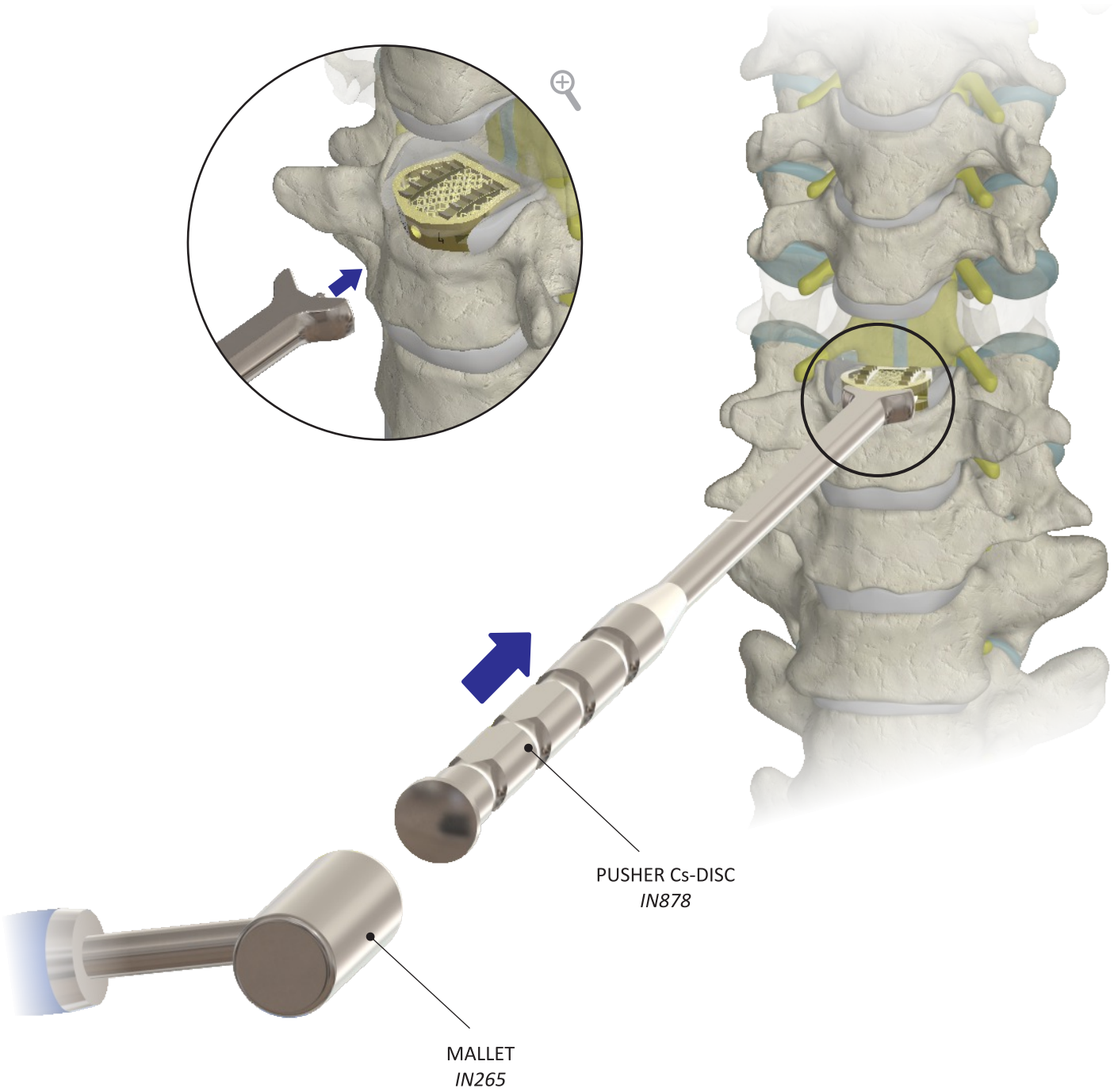
INDICATION

Intraoperative control of the implant's seating using x-ray is recommended.

8. Correction of Cs-DISC position

Step 1 If needed, correct the position of the prosthesis after seating within the interbody space using the PUSHER Cs-DISC *IN878.*

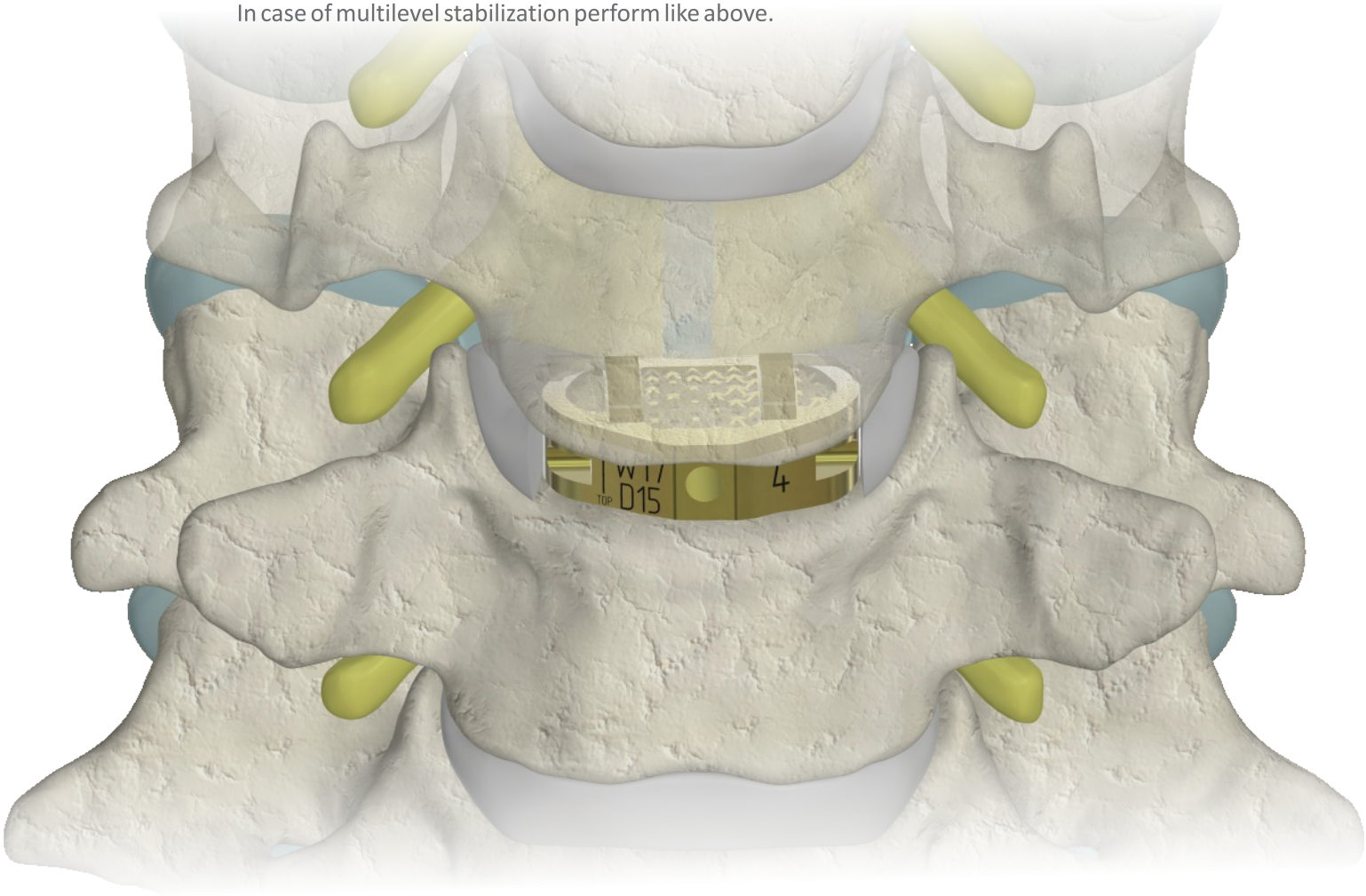
NOTE Properly seated disc should be situated in the central part of the space.



Additional notes

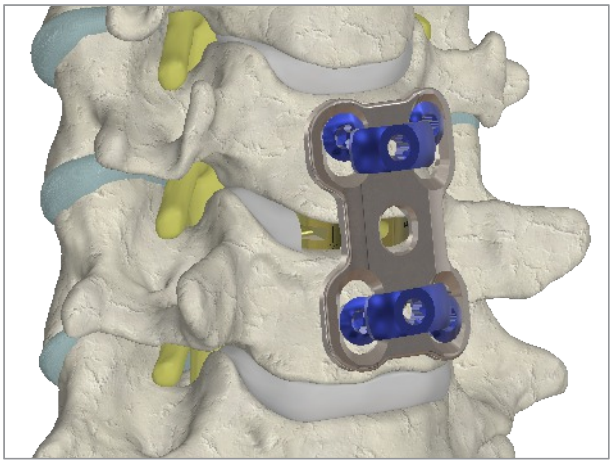
Step 1 After removal of instruments out of the operating field perform final surgical activities.

NOTE In case of weak or osteoporotic bone it is recommended to perform reinforcing stabilization using properly selected cervical plate.
In case of multilevel stabilization perform like above.

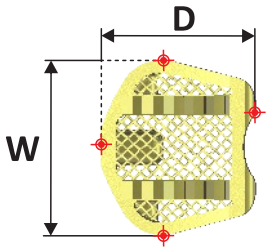


Examples of optional use of the on-vertebral stabilizer:

Th-L Plate



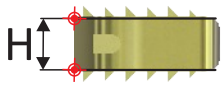
SIZE CHART - Cs-DISC



Cat. No. 870DT

Intervertebral Cs•DISC, flat

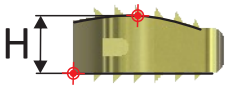
W/D \ H	4	5	6	7	8	9	10
15/13	✓	✓	✓	✓	✓	✓	✓
17/15	✓	✓	✓	✓	✓	✓	✓



Cat. No. 872DT

Intervertebral Cs•DISC, one-side convex

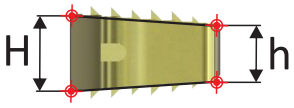
W/D \ H	4	5	6	7	8	9	10
15/13	✓	✓	✓	✓	✓	✓	✓
17/15	✓	✓	✓	✓	✓	✓	✓



Cat. No. 882DT

Intervertebral Cs•DISC, flat, (*without Ti- spikes), lordotic* α=7°

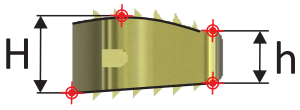
W/D \ h/H	4/6	5/7	6/8	7/9	8/10	9/11	10/12
15/13	✓	✓	✓	✓	✓	✓	✓
17/15	✓	✓	✓	✓	✓	✓	✓



Cat. No. 883DT

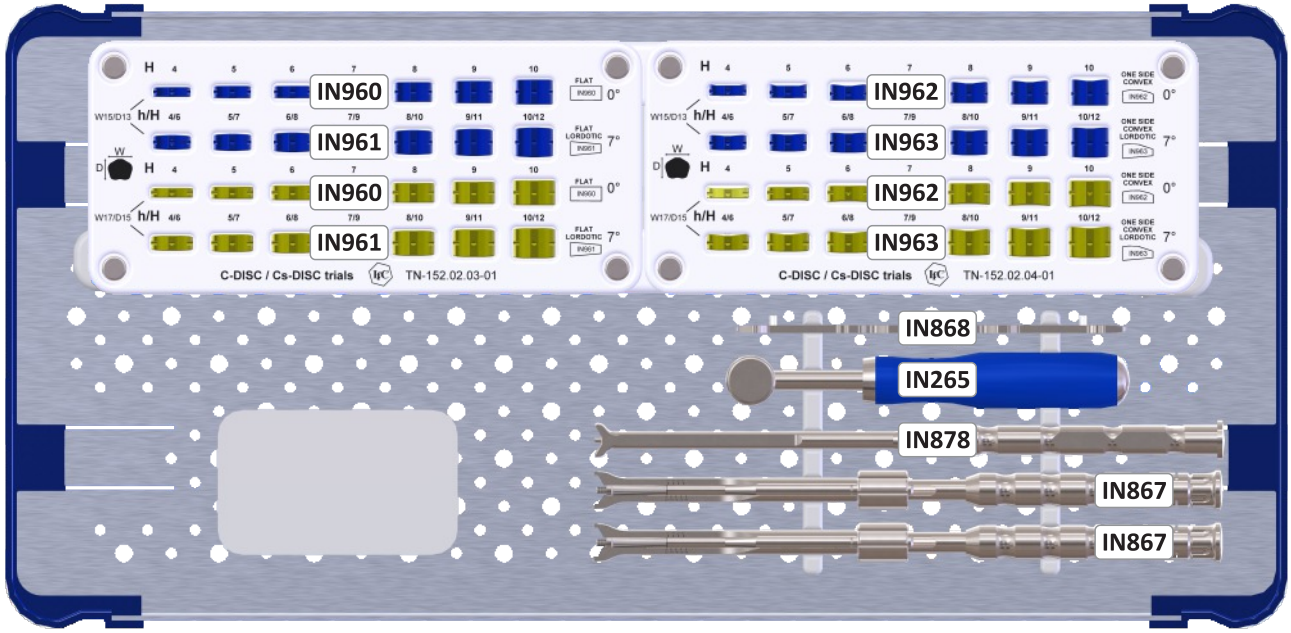
Intervertebral Cs•DISC, one side convex, *lordotic* α=7°

W/D \ h/H	4/6	5/7	6/8	7/9	8/10	9/11	10/12
15/13	✓	✓	✓	✓	✓	✓	✓
17/15	✓	✓	✓	✓	✓	✓	✓



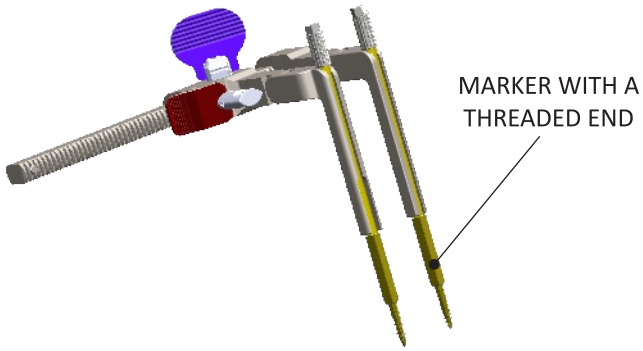
INSTRUMENTS

Tray 1 - *TN-152*



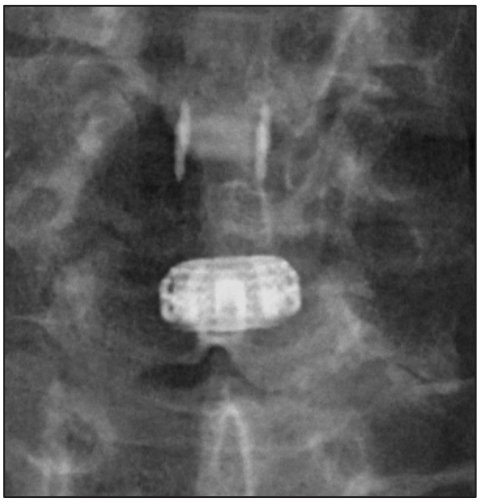
IN265 - MALLET
IN867 - INSERTER Cs-DISC
IN868 - W/D SIZER
IN878 - PUSHER Cs-DISC
IN960 - TRIAL - flat 4 ÷ 10 set
IN961 - TRIAL - flat lordotic 4/6 ÷ 10/12 set
IN962 - TRIAL - one side convex 4 ÷ 10 set
IN963 - TRIAL - one side convex lordotic 4/6 ÷ 10/12 set

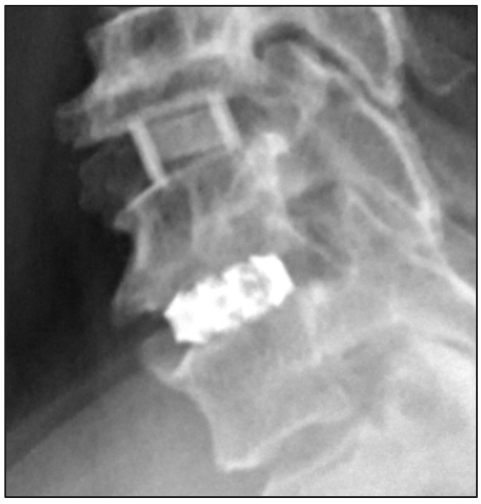
Instruments available on demand:
IN782 - DISTRACTOR
- ***IN782-12*** - MARKER L=12, grey
- ***IN782-14*** - MARKER L=14, blue
- ***IN782-16*** - MARKER L=16, gold



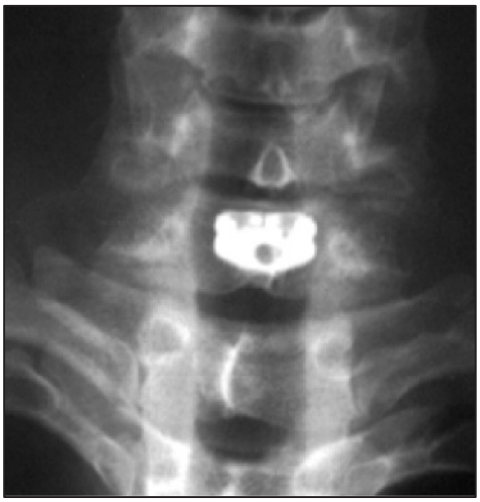
APPENDIX

Clinical cases Cs•DISC (X-ray)

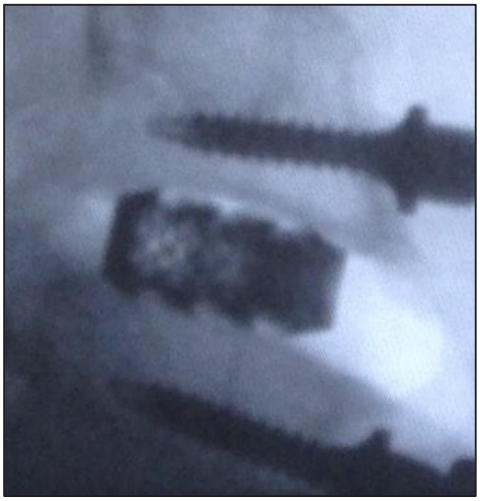




Patient, age 58, female with advanced multilevel degenerative disc disease.
Treatment: **C-DISC PEEK + Cs-DISC "3D-Truss-Ti"**



Patient, age 53, female with cervical discopathy.
Treatment: **Cs-DISC "3D-Truss-Ti"**



Patient, age 62, male with spondylosis.
Treatment: **Cs-DISC "3D-Truss-Ti"**

Important information about the product

GENERAL DESCRIPTION

The geometry and dimensions of the prosthesis are adapted to the physiology of the cervical spine. The product is intended for use in the stabilization of the cervical spine from the anterior approach. The implant reflects the outline of the vertebra. It has directional, notched planes with diversified dimensions, which are in contact with vertebrae, preventing against displacement in the interbody space. The design of the prosthesis includes spatial "3D-Truss-Ti" structures which promotes bone growth and provides stimulation of bone fusion.

INDICATIONS

Cervical disc prosthesis Cs-DISC is designed for intervertebral stabilization of C2–C7 of cervical spine. Its function is to replace resected disc, restore natural size of intervertebral disc space and restore/maintain cervical lordosis.

Indications for use:

- Degenerative disc disease
- Spondylosis
- Stenosis
- Pseudoarthrosis
- Spinal instability
- Tumors
- Injuries

Note: When the use of implants is necessary - the decision must always be made by a trained and qualified surgeon. The Cs-DISC implant is intended for single use only. Repeated use is forbidden and threatens to malfunction of the product (the possibility of deformation, bending, loosening, cracks, fracture of the implant, the possibility of early or late infections, delayed adhesion, lack of bone union). Re-operation may be necessary.

CONTRAINDICATIONS

- bone changes preventing from secure fixation of the implant;
- situations in which there may be an excessive loading on bones and implants, including the patient's work or lifestyle indicating such a threat;
- allergy or foreign body type hypersensitivity to any of the implant materials;
- pregnancy;
- overweight;
- malnutrition;
- advanced age, dementia;
- alcoholism,
- mental illness;
- addiction to medicaments, drugs, and/or other intoxicating substances;
- limited ability to perceive medical indications and post-operative restrictions;
- infection.

A list may not include all of the contraindications. Other contraindications are also given in “General Instruction of Spinal System DERO”.

PRECAUTIONS

- implants of the DERO system are intended for single use only;
- before use, check the expiry date of the product and the condition of the packaging and the product. Damage to the packaging and/or product eliminates it from further use;
- for products delivered in a sterile condition, the date of validity of sterilization should be additionally checked;
- both implantation and removal of DERO system implants can only take place using specialized DERO instruments;
- each operation should be properly planned: the type and number of implants should be selected by a specialist physician based on relevant diagnostic data and other patient's individual circumstances;
- it is unacceptable to make any changes to the geometry of the implant before and during the operation, unless the manufacturer recommends otherwise for the specific product;
- it is unacceptable to use the DERO implant with other manufacturer's implants and to mix the supplied sets;
- mechanical and other damage to the implant surface is unacceptable;
- every effort should be made to ensure that loads transmitted by implants are as small as possible and that points of application are consistent with the purpose and principles of biomechanics;
- the manufacturer is not liable for damage in case of improper use of products;
- each implant sent by the manufacturer is placed in a separate package with a label having data regarding to the implant and its manufacturer. In addition, self-adhesive identification labels are attached. The label should be removed from the packaging, pasted onto the attached implant use card and secured in the hospital documentation. In the case of complications, implants should be removed in accordance with disposal regulations.

WARNINGS

- lack of bone fusion due to the implant rejection;
- patient's allergy to chemical elements contained in the material of which the implant is made;
- skin irritation, e.g. allergic or mechanical;
- feeling of discomfort, abnormality, pain caused by the presence of a foreign body in the organism;
- mechanical wear of the implant, destructive physical and chemical processes, especially in places of implant's joints;
- loosening, rupture, displacement, fracture or migration of the implant; destabilization of the system caused by improper biomechanical selection, improper installation, wear and tear, non-compliance with postoperative recommendations;
- temporary or permanent paralysis resulting from improper attachment, loosening of the implant or its displacement due to extreme life activities;
- bleeding, scarring, infection, damage to vessels or other organs;
- other, general surgical and hospital risks

CONTACT INFORMATION

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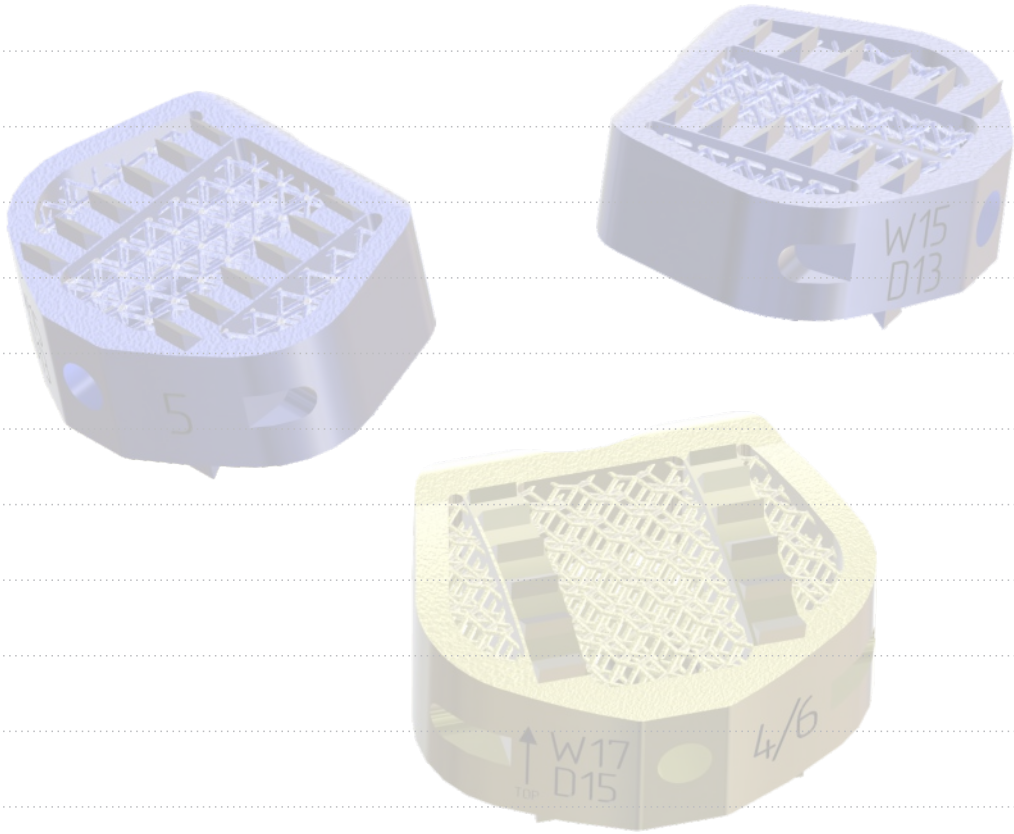
NOTES



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