FENESTRA CS cages (implants, single-use)

Material: PEEK

	non sterile	sterile
REF	PA-3 … PA-8	PA-3S … PA-8S
	PB-3 … PB-8	PB-3S … PB-8S
	PC-3 … PC-8	PC-3S … PC-8S
	PD-3 … PD-8	PD-3S … PD-8S
	PE-4 … PE-8	PE-4S … PE-8S
	PL-4 … PL-6	PL-4S … PL-6S
	PM-4 … PM-6	PM-4S … PM-6S
	PN-4 … PN-8	PN-4S … PN-8S
	PO-5	PO-5S
	PP-4 … PP-6	PP-4S … PP-6S
	PQ-5 … PQ-6	PQ-5S … PQ-6S
	PR-6	PR-6S
	PS-5 … PS-6	PS-5S … PS-6S

Accessories:

Sizers (trial cage), re-usable

Material: titanium

	non unsterile
REF	SA-3 … SA-8
	SB-3 … SB-8
	SC-3 … SC-8
	SD-3 … SD-8
	SE-4 … SE-8
	SL-4 … SL-6
	SM-4 … SM-6
	SN-4 … SN-8
	SO-5
	SP-4 … SP-6
	SQ-5 … SQ-6
	SR-6
	SS-5 … SS-6

Positioning instruments:

Material: titanium

REF XRE-1
XRE-3
XRE-4

Dissection abrasor

REF XSE-1

Storage boxes:

Material: Europlex ® PPSU plastic

REF: PAZ-0 for cages
SAZ-0 for sizers
PAZ-3 and PAZ-4 for cages and sizers

Sterile cages	**Non sterile cages**	**Sizers, positioning instruments and dissection abrasors**
Single-use implant – do not re-use!		Do not clean devices made of titanium using oxidative processes (processes using hydrogen peroxide H_2O_2, e.g. Orthovario or Oxivario processes by Miele). Using those processes will dissolve the titanium after some time and thus may lead to the destruction of the device.
	Device must be cleaned and sterilized before use!	Reusable – devices must be cleaned and sterilized by the user prior to initial use and prior to all other further uses (see Reprocessing)!

FENESTRA CS cages and accessories may only be used and disposed of by competent medical personnel!

Intended Use:

Compensation of height loss following cervical discectomy and stabilisation of the cervical spine.

Indications and contraindications for the use of FENESTRA CS cages
The classic indications are degenerative disc diseases and disc hernias. Contraindications are - osteoporosis and/or - osteopathies with reduced bone quality Other contraindications include - dorsal pathologies such as spondylarthritis of the 3rd – 4th degree - spinal channel stenosis with facet joint hypertrophies - spondylolisthesis - fractures - tumors and - florid spondylodiscitis
Possible adverse effects of an ACDF (anterior cervical discectomy and fusion) using cages
In the medical literature, the following adverse effects have been reported that may occur during ACDF, despite using FEHLING FENESTRA CS cages according to its intended use: - subsidence of a cage - pseudoarthrosis (non-fusion) In very rare cases, the following adverse effects have been reported: - leakage of cerebral spinal fluid (CSF) - ASD (adjacent segment disease) - subcutaneous hematoma - dysphagia - dysphonia - (incomplete) tetraplegia The decision to use FEHLING FENESTRA CS cages on children – as well as on adults - must be made by the attending physician, with consideration to all dis-/advantages.

<table>
<tr><th colspan="3">Prior to use:</th></tr>
<tr><th><u>sterile cages</u></th><th><u>non-sterile cages</u></th><th><u>sizers, positioning instrument and dissection abrasor</u></th></tr>
<tr><td rowspan="2">⚠
Check integrity of packaging!
Do not use products from damaged packaging!
Use only flawless and sterilized products!</td><td>⚠
Check cages for integrity and cleanliness. Use only flawless and sterilized products!</td><td>⚠
Check sizers and instruments for integrity and cleanliness. Use only flawless and sterilized products!</td></tr>
<tr><td colspan="2">Cages, sizers, positioning instrument and dissection abrasor can be sorted into the storage boxes after cleaning and disinfection and be sterilized together. The boxes provide a better overview of the available sizes.</td></tr>
<tr><td colspan="2">Cages from damaged packages or packages without label may only be used after thorough cleaning, disinfection and sterilization.</td><td></td></tr>
</table>

During use:		
sterile cages	**non-sterile cages**	**sizers, positioning instrument and dissection abrasor**
	To avoid contamination of the cages with blood etc. during surgery, the lid of the box must only be opened when a product is taken from the box.	

The segment to be treated is slightly distracted in order to remove the intervertebral disc tissue. The intervertebral disc tissue and the cartilage structures on the superior vertebral plates are removed; making sure that the bone is not injured.

The cranial basal plate and the caudal vertebral plate, where the bony fusion is to take place, are to be refreshened. In the dorsal areas near the spinal cord, where osteophytes may occur, the osteophytes should be removed and the out-going nerve roots be decompressed.

It is important to avoid excessible retraction with the Caspar retractor, in order to insert the cage tightly between the vertebral plates without unphysiological pressure or overcorrection of the segment height.

Choose a cage size according to the patient's anatomy. To determine the correct anatomical size, use a sizer (trial plant) beforehand. Sizers are of the same size as the implants, apart from the surface profile. The sizer is screwed onto the positioning instrument and inserted into the intervertebral space for testing purposes. The arrow on the trial implant must point to cranial (upwards).

Do not use a mallet/hammer to insert the sizer → Risk of injury to the vertebral endplates!

Caution! The sizers are not intended to be used as implants! Risk of injury!

Three different procedures are possible for the preparation of the cage:

1. The cage is filled with autologuous bone material before insertion. This can be, for example, material which was recovered from the removal of osteophytes with a bone punch.
2. The cage remains empty. The bone formation within the cage results from ossification and bone growth from the vertebral body.
3. The cage is filled with bone substitute material before insertion.

After removal of the sizer from the intervertebral space, the appropriate implant is screwed onto the positioning instrument and inserted into the intervertebral space; the arrow on the implant must point to cranial (upwards).

Do not use a mallet/hammer to insert the cage! Risk of injury!

Do not use a mallet/hammer to correct the fit of an inserted cage! Risk of injury!

The use of a hammer might result in

- Injury to the vertebral plates, possibly resulting in subsidence of the implant into the vertebral body.
- damage to the implant. Cages that are damaged (e.g. fissure or fracture) while insertion must be removed from the intervertebral space as they possibly cannot withstand the impacting forces in situ as well as a flawless product! As a result, the implant might subside or dislocate.

Check the implant for a correct fit in situ after insertion and removal of the spreading pressure of the Caspar retractor, in order to reduce the risk of dislocation. A postoperative X-ray inspection must be carried out a/p and from lateral.

The cage position should be documented for forensic purposes.

<table>
<tr><th colspan="3">Reprocessing:</th></tr>
<tr><th><u>sterile cages</u></th><th><u>non-sterile cages</u></th><th><u>sizers, positioning instrument and dissection abrasor</u></th></tr>
<tr><td></td><td colspan="2">Restriction for reprocessing:
Frequent reporcessing has only minor effects on these instruments.</td></tr>
<tr><td rowspan="6">Disposal of the cages following explantation:
Dispose of the products professionally into disposal containers for used disposable products in the operating room according to the applicable regulations.</td><td></td><td>Usually, the end of the product service life is determined by wear and damage from use (see “Control and Function Test” for details).</td></tr>
<tr><td colspan="2">Place of application:
Pre-cleaning: Remove surficial contamination with a single-use towel or tissue.</td></tr>
<tr><td colspan="2">Storage:
Store instruments in a dry place to avoid condensation.
It is recommended to reprocess the instruments immediately after use, because it is very difficult to remove dried residues from instrument parts that are difficult to access.</td></tr>
<tr><td colspan="2">Preparation of cleaning:
Automated cleaning according to RKI directives. Automated cleaning should be preferred over manual cleaning.
Ensure that traces of blood, tissue and drug residues are removed from the instruments immediately after completion of the procedure and that they undergo mechanical cleaning immediately. Clean instruments under cold running water with a suitable soft brush until all visible contamination is removed.</td></tr>
<tr><td></td><td>Do not immerse in normal saline (NaCl) solutions (risk of pitting or stress corrosion).</td></tr>
<tr><td colspan="2">Do not immerse in normal saline (NaCl) solutions (risk of pitting or stress corrosion).
Use only an approved solution of a combined detergent and disinfectant that has no protein-fixing effect (be sure to observe the chemicals manufacturer’s recommendation for the mixture).
Avoid overfilling instrument trays and washing trays – use only suitable instrument holders.
When placing and removing the instruments into/from the perforated baskets, take special precautions to ensure that they do not become stuck anywhere..</td></tr>
<tr><td colspan="2">Cleaning/disinfection (according to EN ISO 15883-1)
It is assumed that commercially available products approved for the specific application will be used for cleaning and disinfection. It is also assumed that the recommended concentrations, applications times and temperatures will be complied with.</td></tr>
<tr><td colspan="2">Cleaning/disinfection: mechanically, acc. to standard EN ISO 15883-1:2009
<u>Validated procedure:</u>
Equipment: Washer/disinfector G 7735 CD (Miele)
Process: Vario TD
Cleaning agent: Mediclean Neodisher (Dr. Weigert)
<u>Preparation:</u>
• Make sure that all cavities are completely flushed on the inside as well.
• Make sure that no flushing shadows arise.
<u>Parameter:</u>
• 2 min. pre-cleaning with cold tap water
• Drain
• 5 min. cleaning with tap water with 0,5 % Neodisher at 55 ℃
• Drain
• 3 min. neutralization with deionized water at 40 °C
• Drain
• 2 min. rinsing with deionized water at 40 ℃
• Drain
No disinfection step.</td></tr>
</table>

<table>
<tr><th>sterile cages</th><th>non-sterile cages</th><th>sizers, positioning instrument and dissection abrasor</th></tr>
<tr><td rowspan="3"></td><td colspan="2">• After mechanical cleaning, check cavities, blind holes, etc. for visible dirt.
Repeat cycle or clean manually if required.</td></tr>
<tr><td colspan="2">Cleaning/disinfection: manually
Manual cleaning should be avoided as it cannot be validated.
<u>Equipment:</u> Cleaning agent (detergent, not protein fixating, with or without antimicrobial effect and/or enzymes), air pressure cleaning gun, soft tissures/sponges, running water.
1. Rinse surficial contamination from the device thoroughly.
2. Apply cleaning agent solution onto all surfaces with a soft tissue/sponge.
3. Rinse all cavities and blind holes with a sufficient amount of cleaning agent (at least 200 ml) using a syringe. Take care to observe the passage of the solution to the distal end.
4. Rinse the device under running water. The water must rinse all cavities, and blind holes must be filled and drained repeatedly.
Use deionized water for the final rinsing step.

Do not warm the cleaning agent to temperatures above room temperature.
<u>Disinfection:</u>
Consult the instructions on the label when selecting a disinfectant (see information on chemical manufacturer’s label). When using automated cleaning, a thermodisinfection step may be performed (at 93 °C, at least 5 min. holding time) (observe manufacturer’s instructions for use referring to the washer/disinfector).
Deionized water must be used for the final rinse. Ensure that no residues remain on the products.</td></tr>
<tr><td colspan="2">Drying:
If drying has been achieved as part of the cleaning/disinfection cycle, do not exceed 120 °C.</td></tr>
<tr><td rowspan="3"></td><td colspan="2">Maintenance:
Use a magnifying lamp to visually inspect the components for damage and wear and tear.</td></tr>
<tr><td>Discoloration (yellowing) may occur but has no impact upon the mechanical properties of the material.</td><td>Especially check critical areas at the distal end of the instruments.
Remove damaged instruments and send to the manufacturer for repair. Clean and disinfect instruments before returning them for repair. A verification form for this process is available from the manufacturer.</td></tr>
<tr><td colspan="2">Packaging:
Single: in accordance with the standard series DIN EN 868, DIN EN ISO 11607 and DIN 58953.
Sets: Sort instruments into designated trays or place them in general-purpose sterilization trays. Pack the trays appropriately.</td></tr>
<tr><td colspan="2">Sterilisation:
Steam sterilization in a fractionated vacuum process at 134 °C (holding time at least 5 minutes) in a device complying with DIN EN 285; validated sterilization processes!
In order to prevent staining and corrosion, the steam must be free of contaminants. The recommended limits for contaminants for feed water and steam condensate are defined by DIN EN 285.
<u>Validated procedure:</u>
Equipment: Selectomat HP666 – 1 HR (MMM)
1. 3 pre-vacuum phases
2. Sterilization temperature 134 °C
3. Holding time: 5 minutes
4. Drying time: at least 10 minutes</td></tr>
</table>

sterile cages	**non-sterile cages**	**sizers, positioning instrument and dissection abrasor**
	Storage: In accordance with § 4 of the Medical Devices Operator Ordinance (MPBetreibV) and standard series DIN EN 868, DIN EN ISO 11607 and DIN 58953.	
	Additional information: When sterilizing more than one instrument in a sterilization cycle, do not exceed the maximum load of the sterilizer (see manufacturer's instructions).	
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Storage / symbols:

Protect from excessive heat!	Follow the instructions for use	Store in a dry place	Single use only! Do not re-use!	Caution!	Do not use if package is damaged
REF Article number	LOT Batch code	Expiration date Do not use after the expiration date!	STERILE EO Sterilized using Ethylene oxide	CE 0297 Notified body	Manufacturer

Any modification to the device or deviation from these instructions for use will result in exclusion of liability.

Subject to change without notice.

The instructions listed above were validated by the medical device manufacturer as suitable for preparing a product delivered in a non-sterile condition (or, in case of cages delivered sterile which were not used but became unsterile) for reprocessing. It is the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routing monitoring of the process. Likewise, any deviation from the instructions provided by the processor should be properly evaluated for effectiveness and potential adverse consequences.