FEHLING Sterile FORMAR Cervical Spine Cages (Single-use Implants)

Sterile FORMAR Cervical Spine Cages
Material: Cage: PEEK
X-ray marker pin: Tantalum

PF-3S..... 14 x 13 x 3 mm	PG-3S.... 16 x 14 x 3 mm	PH-4S.... 18 x 14 x 4 mm
PF-4S..... 14 x 13 x 4 mm	PG-4S.... 16 x 14 x 4 mm	PH-5S.... 18 x 14 x 5 mm
PF-5S..... 14 x 13 x 5 mm	PG-5S.... 16 x 14 x 5 mm	PH-6S.... 18 x 14 x 6 mm
PF-6S..... 14 x 13 x 6 mm	PG-6S.... 16 x 14 x 6 mm	PH-7S.... 18 x 14 x 7 mm
PF-7S..... 14 x 13 x 7 mm	PG-7S.... 16 x 14 x 7 mm	

Accessories

Sizers (trial implants) for reuse
Material: Titanium

SF-3 ..... 14 x 13 x 3 mm	SG-3 ..... 16 x 14 x 3 mm	SH-4 ..... 18 x 14 x 4 mm
SF-4 ..... 14 x 13 x 4 mm	SG-4 ..... 16 x 14 x 4 mm	SH-5 ..... 18 x 14 x 5 mm
SF-5 ..... 14 x 13 x 5 mm	SG-5 ..... 16 x 14 x 5 mm	SH-6 ..... 18 x 14 x 6 mm
SF-6 ..... 14 x 13 x 6 mm	SG-6 ..... 16 x 14 x 6 mm	SH-7 ..... 18 x 14 x 7 mm
SF-7 ..... 14 x 13 x 7 mm	SG-7 ..... 16 x 14 x 7 mm	

Insertion instruments
Material: Titanium

XRE-1 .... Titanium insertion instrument for cervical spine cages
XRE-3 .... Titanium insertion instrument for cervical spine cages with adjustable stop 80 mm
XRE-4 .... Titanium insertion instrument for cervical spine cages with adjustable stop 130 mm

Storage boxes
Material: Plastic Europlex® PPSU

PAZ-1 .... Storage and sterilisation container for FORMAR Cervical Spine Cages and sizers, small
PAZ-2 .... Storage and sterilisation container for FORMAR Cervical Spine Cages and sizers, large

Dissecting curette
Material: Steel

XSE-1 .... Dissecting curette 6 x 220 mm

Patient information

PZ01 ..... Implant card
PZ02 ..... Patient information leaflet
Implanted device label

	FORMAR Cervical Spine Cages (single-use implant) are intended for single use only and must not be reused!
	FORMAR Cervical Spine Cages may only be used and disposed of by qualified medical personnel!
	The sizers, insertion instruments and dissecting curette are supplied non-sterile. They must be reprocessed in accordance with Reprocessing Instructions R14 before use.
	After implantation of the FORMAR Cervical Spine Cage, the patient must be given an implant card with the corresponding implanted device label and the patient information leaflet.

1) Intended purpose

FORMAR Cervical Spine Cages are used to restore disc height after cervical discectomy and to stabilise the cervical spine.

Additional information regarding the intended purpose

Duration of application: FORMAR Cervical Spine Cages are intended for long-term use.

Field of application: FORMAR Cervical Spine Cages are used in all patients requiring restoration of disc height after cervical discectomy and stabilisation of the cervical spine.

User profile: FORMAR Cervical Spine Cages may only be used by medically trained specialist personnel (e.g. specialist surgeon).

Application environment: FORMAR Cervical Spine Cages may only be used under controlled environmental conditions (e.g. in the operating room).

Target patient population: No restrictions

2) Indications

Classic indications include degenerative disc diseases and herniated discs.

3) Contraindications

Contraindications include

- osteoporosis and/or
- osteopathies with reduced bone quality.

The following are also considered contraindications:

- posterior pathologies, such as grade 3–4 facet joint osteoarthritis,
- spinal canal stenosis with facet joint hypertrophy,
- spondylolisthesis,
- fractures,
- tumours, and
- active spondylodiscitis

Any use that is incompatible with the physical and/or mechanical properties of the respective implant model is contraindicated. Furthermore, due consideration must be given to any increased risks arising from the patient's anatomical and physiological characteristics and underlying conditions.

4) Possible side effects

The medical literature reports the following adverse effects for ACDF, which may occur despite the intended use of FORMAR Cervical Spine Cages:

- subsidence of the cervical cage
- pseudarthrosis (non-fusion)

The following additional adverse effects may also occur:

- CSF leakage
- ASD (adjacent segment disease)
- (spinal epidural) haematoma

- dysphagia - hoarseness/vocal cord paralysis - nerve/spinal cord injury (worsening of myelopathy/radiculopathy, Horner's syndrome, (incomplete) tetraplegia) - respiratory failure As in adults, the decision to use FORMAR Cervical Spine Cages in children can only be made by the attending physician after weighing up all the advantages and disadvantages.
⚠ FORMAR Cervical Spine Cages are made of PEEK. The x-ray marker pins are made of tantalum. The materials used are biocompatible; however, they may cause allergic reactions or intolerances.

5) Before use	
⚠	Sterile Check packaging for integrity! There is a risk of infection if products from damaged packaging are used! Do not use products from damaged packaging. Return them to the manufacturer! Do not use products from accidentally opened packaging; dispose of them properly.
	Observe the expiry date! Do not use products after the stated expiry date; return them to the manufacturer! Risk of infection!
⚠	Use only intact and sterilised products!
⚠	Perform a safety check before each use of the FORMAR Cervical Spine Cages. Check for scratches, notches, cracks, deformation, and legible labelling.
⚠	Avoid impacts and point loading on the FORMAR Cervical Spine Cages, sizers, insertion instruments, and dissecting curette to prevent any possible secondary damage! Do not overload functional parts!
⚠	The sizers, insertion instruments and dissecting curette are supplied non-sterile and must be cleaned and sterilised by the user before first use and before each subsequent use (see Reprocessing Instructions R14).

6) Configuration and application	
Due to the variety of possible anatomical and physiological conditions, FORMAR Cervical Spine Cages differ in their specific properties such as cage length, width and height.	 Fig. 1: FORMAR Cervical Spine Cage (example)

⚠	Use only intact and sterilised products!
⚠	Before inserting the FORMAR Cervical Spine Cage, ensure that the surgical site has been prepared accordingly.
⚠	The materials used in the medical device do not contain any ferromagnetic substances, so there is no known postoperative risk from exposure to magnetic fields or external electromagnetic influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of the FORMAR Cervical Spine Cage depends on the anatomical and physiological conditions as well as the field of application. Care should be exercised to ensure that the FORMAR Cervical Spine Cages used are of the correct size and have adequate stability.

During application

The vertebral segment to be treated is distracted slightly to allow removal of the intervertebral disc tissue. The disc tissue and the cartilaginous endplates are removed, taking care not to damage the bony endplates.

The cranial inferior endplate and the caudal superior endplate are curetted in the area where bony fusion is to take place.

Any osteophytes in the dorsal areas adjacent to the spinal cord are removed, and the exiting nerve roots are decompressed.

It is important to avoid excessive distraction with the vertebral body distractor so that the cervical cage can be firmly inserted between the endplates without exerting non-physiological pressure or overcorrection of segment height.

Select the appropriate cervical spine cage size based on the patient's anatomy. The anatomically appropriate cervical cage size is determined using sizers (trial implants) whose dimensions match those of the cervical cages (except for the surface profile). The sizer is screwed onto the insertion instrument and inserted into the disc space for trial fitting; the arrow must point cranially.

⚠	Do not hammer the sizer into place. → Risk of injury to the endplates!
⚠	The sizer is not intended for implantation! Risk of injury!

There are three different ways to prepare the cervical spine cages:

1. The cervical cage is filled with autologous bone material harvested, for example, from osteophytes removed with a punch or rongeur.
2. The cervical cage is left empty. Bony fusion is achieved through ossification and bone growth from the vertebral bodies.
3. The cervical cage is filled with bone substitute material before implantation.

After removal of the sizer from the disc space, the corresponding cervical cage is screwed onto the insertion instrument and inserted into the disc space, with the arrow pointing cranially (Fig. 2, marking).

Fig. 2: FORMAR Cervical Spine Cage (example)

⚠ The cervical cage must not be impacted with a hammer! Risk of injury!

⚠ Do not use a hammer to reposition an implanted cervical cage! Risk of injury!

⚠ Possible consequences of using a hammer include:

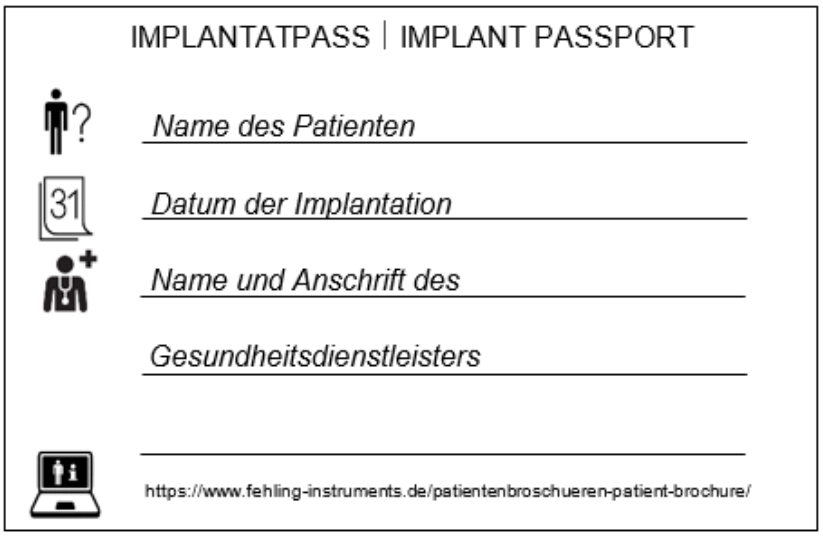
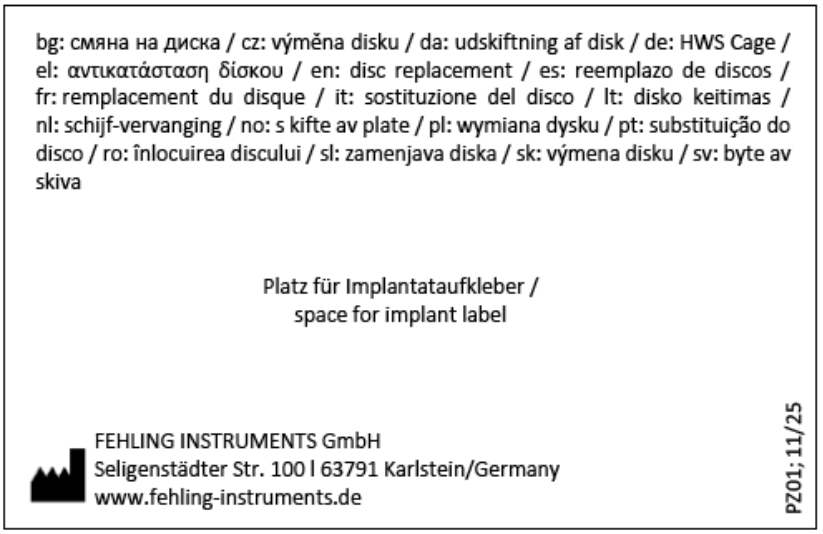
- Injuries to the endplates, possibly resulting in subsidence of the cervical cage into the vertebral bodies.
- Damage to the cervical cage. A cervical cage damaged during insertion (e.g. cracking, fracture) must be removed, as it may not withstand the forces encountered! The cervical cage could subside or become dislodged as a result.

Once the cervical cage has been inserted, its secure seating in situ should be checked again after releasing the distraction force of the vertebral body distractor to ensure that dislocation is unlikely. The insertion instrument is then unscrewed from the cervical cage. Postoperatively, follow-up radiographs should be obtained in anteroposterior and lateral views.

A cervical support is recommended to promote successful fusion of the cervical cage.

The position of the cervical cage should be documented for medicolegal purposes.

⚠ After implantation of the FORMAR Cervical Spine Cage, the patient must be given an implant card with the corresponding implanted device label and the patient information leaflet.

After implantation	
After successful implantation, the patient's implant card must be completed and the corresponding implant label affixed to the back of the implant card in the space provided.	
The patient's name, the date of implantation and the name and address of the healthcare provider must be entered on the front of the implant card. Figure 3 provides an example of how to complete the implant card.	 Fig.3: Implant card – front
On the reverse side of the implant card, the corresponding implanted device label must be affixed to the space provided for this purpose: "Space for implant sticker" (see Fig. 4).	 Fig.4: Implant card – reverse side
Once the implant card has been completed, it must be handed over to the patient together with the patient information leaflet.	

7) Storage
In accordance with § 4 MPBetreibV (German Medical Devices Operator Ordinance) and the standards of the DIN EN 868 series, DIN EN ISO 11607 and DIN 58953. Medical devices must be stored dry, at room temperature, clean, protected from damage, direct sunlight and mechanical influences (to prevent condensation and damage).

After cleaning and disinfection, the sizer, insertion instrument and dissecting curette can be arranged in the storage boxes and sterilised together.
The storage boxes provide a better overview of the available sizes.

	Observe the expiry date! Do not use products after the stated expiry date. Instead, return them to the manufacturer!

8) Disposal

FORMAR Cervical Spine Cages do not pose any special or unusual hazards. They are non-toxic, not subject to labelling requirements under the Hazardous Substances Ordinance and are not hazardous to water.

Implantation makes the FORMAR Cervical Spine Cages the patient's property, so they must be made available to the patient after explantation. It should be noted that the explants may be infectious and must therefore be cleaned and disinfected and, if necessary, sterilised.

Damaged, non-implanted FORMAR Cervical Spine Cages may be disposed of in accordance with local authority regulations. The materials used cannot be separated by the user, so the implants must be disposed of as a whole.

Reuse of the explanted implants is not permitted.

9) Required accessories

An insertion instrument is required for the use of the FORMAR Cervical Spine Cages.

The sizer (trial implant) is used to determine the anatomically correct cervical cage size.

The dissecting curette is used to prepare the endplates.

A storage and sterilisation container may be used for sterilisation or safe storage of the sizers.

FORMAR Cervical Spine Cages are stand-alone medical devices. Combination with other products is therefore not intended.

10) Obligation to report serious incidents

The user is obliged to report serious incidents which have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is domiciled.

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	STERILE EO Sterilised using ethylene oxide
Do not re-use	Use-by date	Date of manufacture
Keep dry	Single sterile barrier system	Double sterile barrier system
Keep away from sunlight	Do not use if package is damaged and consult instructions for use	CE 0297 CE marking
CE marking		
Any modification to the device or any deviation from these Instructions for Use will result in exclusion of liability! Subject to change without notice.		

Manufacturer's contact information	
FEHLING INSTRUMENTS GmbH Seligenstädter Str. 100 63791 Karlstein, Germany Tel.: +49 (0) 6188-9574-40 Fax: +49 (0) 6188-9574-45 E-mail: info@fehling-instruments.de www.fehling-instruments.de	CE 0297