FEHLING sterile FORMAR cervical disc replacements (single-use implants)

Sterile FORMAR cervical disc replacements
Material: Disc replacement: PEEK
X-ray marking 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

Sizer (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	

Setting instruments
Material: Titanium

XRE-1 .... Titanium setting instrument for cervical spine cages
XRE-3 .... Titanium setting instrument for cervical spine cages with stop unit, 80 mm
XRE-4 .... Titanium setting instrument for cervical spine cages with stop unit, 130 mm

Storage boxes
Material: Plastic Europlex® PPSU

PAZ-1 .... Storage and sterilization container for FORMAR c-spine cages and sizer, small
PAZ-2 .... Storage and sterilization container for FORMAR c-spine cages and sizer, large

Dissecting curette
Material: Steel

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

Patient information

PZ01..... Implant passport
PZ02..... Patient add-on
Label of inserted implant

	FORMAR cervical disc replacements (single-use implant) are intended for single implantation only and must not be reused!
	FORMAR cervical disc replacements may only be used and disposed of by qualified medical personnel!
	Sizer, setting instrument and dissecting curette are supplied non-sterile. Prior to use they must be reprocessed according to Reprocessing Instruction R14.
	Following implantation of the FORMAR cervical disc replacement, the patient must be given an implant passport with the corresponding label of the inserted implant as well as the patient add-on.

1) Intended purpose

FORMAR cervical disc replacements are used to compensate for height loss after cervical discectomy and to stabilize the cervical spine.

Additional information regarding the intended purpose

Duration of application: FORMAR cervical disc replacements are intended for long-term use.

Field of application: FORMAR cervical disc replacements are used for all patients in whom height loss after cervical discectomy must be compensated for and where the cervical spine must be stabilized.

User profile: FORMAR cervical disc replacements may only be used by medically trained personnel (e.g. specialist physicians).

Application environment: FORMAR cervical disc replacements are only to be used in controlled environments (e.g. OR).

Intended patient population: No restrictions

2) Indications

The classic indications are degenerative disc disease and disc hernias.

3) Contraindication

Contraindications include

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

Additional contraindications include

- dorsal pathologies such as spondylarthroses Grade 3 - 4,
- spinal canal stenoses with facet joint hypertrophies,
- spondylolistheses,
- fractures,
- tumors and
- florid spondylodiscitides.

All applications that run counter to the physical and/or mechanical properties of the individual implant model are contraindicated. Furthermore, increased risks must be taken into account which could result from the anatomical and physiological conditions as well as the clinical picture of the patient.

4) Possible adverse effects of an ACDF (anterior cervical discectomy and fusion) with cervical disc replacements	
In medical literature, the following adverse effects are described for ACDF that can possibly occur despite the correct intended use of FORMAR cervical disc replacements - Collapse of the cervical disc replacement (subsidence) - Pseudoarthrosis (non-fusion) The following adverse effects may also occur: - CSF leakage - ASD (adjacent segment disease) - Hematomas - Dysphagia - Hoarseness/ paralysis of the vocal cords - Nerve/spinal cord damage (worsening of myelopathy/radiculopathy, Horner's syndrome, (incomplete) quadriplegia) - Respiratory insufficiency As for adults, the decision to use the FORMAR cervical disc replacements in children can only be made by the attending physician after considering all the benefits and risks.	
	FORMAR cervical disc replacements are made of PEEK. The X-ray marking pins are made of tantalum. The materials used are biocompatible, however they may cause allergic reactions or incompatibilities.

5) Prior to use	
	Check sterility and packaging for integrity! Using products from damaged packaging is associated with the risk of infection! Do not use products from damaged packaging and return them to the manufacturer! Do not use products from inadvertently opened packaging and dispose of them properly.
	Observe the use by date! Do not insert products after the use by date and return them to the manufacturer! Risk of infection!
	Use only flawless and sterilized products!
	Perform a safety check prior to each use of the FORMAR cervical disc replacements. Check for scratches, nicks, cracks, deformations and legible marking.
	Avoid striking and applying pressure to FORMAR cervical disc replacements, sizers, setting instruments and the dissecting curette, so as not to cause any consequential damage! Do not overstrain functional parts!
	Sizers, setting instruments and the dissecting curette are non-sterile when delivered so they have to be cleaned and sterilized by the user before initial use and every time before they are used thereafter (see Reprocessing Instruction R14).

6) Configuration and application	
Due to the variety of possible anatomical and physiological conditions, the FORMAR cervical disc replacements differ in their specific characteristics, such as length, width and height of the cervical disc replacements.	 Fig. 1: FORMAR cervical disc replacement (exemplary)

⚠	Use only flawless and sterilized products!
⚠	Prior to inserting the FORMAR cervical disc replacement, ensure that the surgical field has been prepared accordingly beforehand.
⚠	The materials used in the medical device do not contain any ferromagnetic substances, so that there is no known postoperative risk associated with exposure to a magnetic field or to electromagnetic external influences.
⚠	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
⚠	The choice of FORMAR cervical disc replacements depends on the anatomical and physiological conditions as well as the field of application. Here care should be exercised to ensure that the FORMAR cervical disc replacements used are of the correct size and have adequate stability.

During use

The segment to be treated is slightly distracted to remove the disc tissue. The disc tissue and the cartilage structures on the cover plates are removed, and the bony part should not be damaged.

In the area where bony fusion is to take place, the cranial base plate and caudal cover plate must be cleaned.

In the dorsal areas towards the spinal cord, where osteophytes may be present, these should be removed and the area of the efferent nerve roots decompressed.

It is important to avoid any significant excess spreading with the vertebra spreader so that the cervical disc replacement can be firmly inserted between the cover plates without any unphysiological pressure or overcorrection of the segment height.

Select the suitable cervical disc replacement to match the anatomical conditions. The anatomically correct size of the cervical disc replacement is determined by using sizers (trial implants), which correspond to the cervical disc replacements in terms of dimensions (apart from the profile). The sizer is screwed onto the setting instrument and inserted into the disc space on a trial basis whereby the arrow must point in a cranial direction.

⚠	The sizer must not be driven in with a mallet → Risk of damage to the end plates!
⚠	The sizer is not intended for implantation! Risk of injury!

Three different procedures are possible for preparing the cervical disc replacements:

1. The cervical disc replacement is filled with autologous bone material - this can, for example, be obtained from the ablated osteophytes which are removed with the punch.
2. The cervical disc replacement remains empty. In this case, osseous development is achieved via ossification and bone growth from the vertebra.
3. The cervical disc replacement is filled with bone substitute materials prior to implantation.

After removing the sizer from the disc space, the corresponding cervical disc replacement is screwed onto the setting instrument and inserted into the disc space with the arrow pointing in cranial direction (Fig. 2, marking).

Fig. 2: FORMAR cervical disc replacement (exemplary)

⚠ The cervical disc replacement must not be driven in with a mallet! Risk of injury!

⚠ The fit of an already inserted cervical disc replacement must not be corrected with a mallet! Risk of injury!

⚠ The consequences of using a mallet may include:

- Damage to the end plates, possibly resulting in a sinking of the cervical disc replacements into the vertebrae,
- Damage to the cervical disc replacement. Cervical disc replacements damaged during insertion (e.g. cracks, fracture) must be removed, as they may not be able to withstand occurring forces! As a consequence, the cervical disc replacement could sink in or dislocate.

Once the cervical disc replacement is in place, the cervical disc replacement should be rechecked for a stable fit in situ after relieving the spreading pressure on the vertebra to ensure that dislocation becomes unlikely. The setting instrument is then unscrewed from the cervical disc replacement. An X-ray check, a.p. and lateral, must be performed postoperatively.

A cervical support is recommended for better healing of the cervical disc replacement.

The position of the disc replacement should be documented for forensic reasons.

⚠ Following implantation of the FORMAR cervical disc replacement, the patient must be given an implant passport with the corresponding label of the inserted implant as well as the patient add-on.

After use
Following successful implantation, the implant passport is to be completed for the patient and the corresponding label on the back of the implant passport must be affixed on the space provided.

The patient's name, the date of implantation, and the name and address of the health care provider are to be entered on the front of the implant passport.
In Figure 3 depicts an example of how to fill out the implant passport.

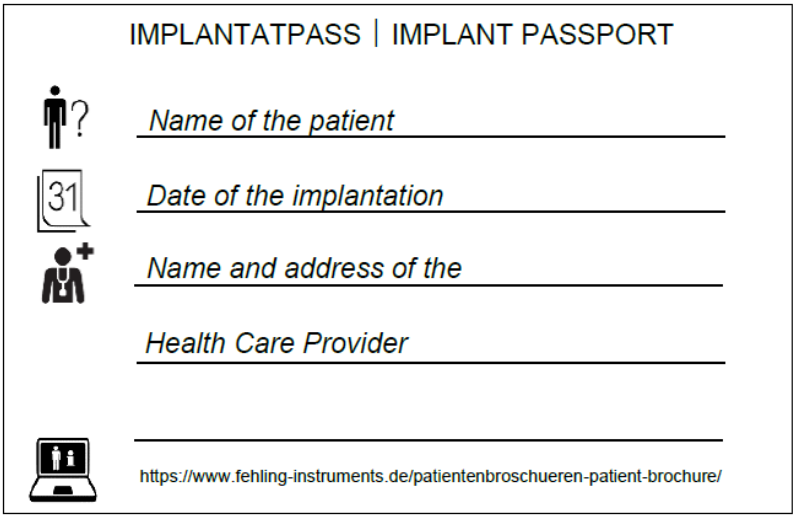

Fig. 3: Implant passport – front side

The corresponding label of the inserted implant must be affixed to the back of the implant passport on the space provided "space for implant label" (see Fig. 4).

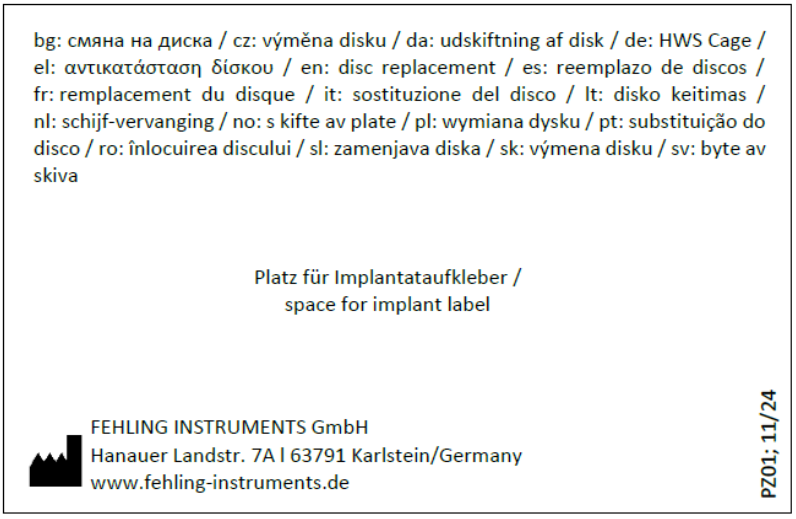

Fig. 4: Implant passport – back side

Once the implant passport has been completed, it must be handed over to the patient together with the patient add-on.

7) Storage

In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standard series DIN EN 868, DIN EN ISO 11607, and DIN 58953.
Medical devices must be stored dry, at room temperature, clean, protected from damage, sunlight and mechanical influences (avoid condensation, damage).

The sizer, setting instrument and dissecting curette can be sorted into the storage boxes after cleaning and disinfection and sterilized together.
The storage boxes provide for a better overview of the available sizes.

	Observe the use by date! Do not use products after the use by date and return them to the manufacturer!

8) Disposal

Fehling FORMAR cervical disc replacements do not pose any special or unusual hazards. They are non-toxic, do not require labeling according to the Ordinance on Hazardous Substances, and are not water-polluting.

As a result of implantation, the FORMAR cervical disc replacements become the property of the patient, which is why they must be made available to the patient following explantation. It should be noted here that the explants may be infectious and must therefore be cleaned and disinfected and, if necessary, sterilized.

Damaged, non-implanted FORMAR cervical disc replacements can be disposed of in accordance with local authority regulations. The materials used cannot be separated from each other by the user, therefore the implants are disposed of as a whole.

Reuse of the explanted implants is not permitted.

9) Required accessories

A setting instrument is required for the application of the FORMAR cervical disc replacements.

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

The dissecting curette is used to clean the cover plates.

A storage and sterilization container can be used for sterilization or storage to keep the sizers safe.

FORMAR cervical disc replacements are stand-alone medical devices. Therefore, a combination with other products is 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

In as far as the medical device or medical device label or instructions for use are labeled, the symbols according to DIN EN ISO 15223-1 represent the following meaning:

 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 Sterilized with ethylene oxide
Do not re-use	Use-by date	Date of manufacture
Single sterile barrier system	Double sterile barrier system	Keep dry
Keep away from sunlight	Patient identification	31 Date
Patient information website	Health care centre or doctor	CE 0297 CE marking
Do not use if package is damaged and consult instructions for use	CE 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.

To contact the manufacturer:	
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CE 0297