Instructions for Use of the Spinal Implants in the System

FAVO® S-TLIF

Important Information—Please Read Before Use!

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These Instructions for Use apply to FAVO S-TLIF Cage spinal implants. Other sets of manufacturer's instructions are available containing information required for application of the system. The additional information, such as Instrumentation Guides, inserts containing useful information, and other product-specific information, may be viewed under the following two links:

- https://elabeling.silony-medical.com
- www.silony-medical.com

Instructions for Use D30003 may be used as reference for reprocessing instruments.

Any manufacturer liability is excluded in the event of non-compliance with the manufacturer's information.

Prior to using a product distributed by Silony Medical, the surgeon is expected to closely study the following recommendations, warnings, and advice as well as the product-specific information. Silony Medical also recommends the attendance of corresponding user training courses.

We kindly request timely notification if complications should occur in connection with the implants and instruments used.

These Instructions for Use do not apply to the USA or its territories.

1 Product Description

The FAVO S-TLIF (straight transforaminal lumbar interbody fusion) Cage is an implant for primary stabilization and improvement of lordosis in the lumbar and thoracic spine. The cage is designed for transforaminal approaches.

The aim is to decrease discogenic back pain, correct deformities, remedy instabilities, restore intervertebral height, may help to restore physiological lordosis, and provide biomechanical support for bone fusion in the disc space.

Silony Medical recommends additional posterior fixation of the spinal segment being treated, for example, with the posterior screw-rod system for the thoracic and lumbar spine from the VERTICALE product family.

The FAVO S-TLIF is manufactured from titanium alloy conforming to ASTM F136 / ISO 5832-3.

The FAVO S-TLIF implant is delivered in a sterile condition and can be used without any further preparations. The cages are packaged in accordance with EN ISO 11607 Part 1+2 and sterilized with gamma irradiation at a minimum dose of 25 kGy.

Implants delivered by the manufacturer in a sterile condition may not be sterilized!

When removing the implant from the packaging, the implant must be verified against the description on the packaging.

The patient labels in the primary packaging must be attached to the patient file or the surgical report.

2 General Information and Warnings

Appropriate patient selection is critical to the surgical outcome. Only patients who satisfy the indications AND who do not have any of the contraindications should be considered for interbody fusion surgery using the FAVO S-TLIF cage to avoid adversely affecting device performance or surgical outcome.

The surgeon should strictly follow the recommendations in the surgical technique. All staff involved should be familiar with the surgical procedures associated with the lumbar interbody fusion technique to avoid adversely affecting device performance or surgical outcome.

Only use instruments and accessories listed in the surgical technique to avoid adversely affecting device performance or surgical outcome. For system compatibility, refer to the Instrumentation Guide (D30166).

The use of implants for other purposes is prohibited.

Complications or other consequences that may be due to an incorrect indication or surgical technique, unsuitable choice of material or treatment, improper use or treatment of the instruments, asepsis, etc., are the responsibility of the surgeon and cannot be attributed to the manufacturer, the importers, or suppliers of products of Silony Medical.

Preoperative planning:

The implantation of the FAVO S-TLIF must be precisely planned using a suitable imaging method. The potential success of surgery depends directly on the correct choice of implant. The X-ray images provide important information about the suitable type of implant, its size and about possible combinations. Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome.

The FAVO S-TLIF cage is available in a wide variety of sizes to ensure appropriate sizing of the implanted components. Correct size selection is critical to the surgical outcome. An under- or oversized implant can lead to premature failure of the cage.

Prior to the surgery it must also be clarified whether the patient has an allergy to the implant material.

For the surgical procedure, all possibly required implant types in the combination recommended by the manufacturer as well as the instruments needed for implantation must be available if a different size becomes necessary.

Notes on Use:
Implantation should only ever be considered if all other conservative treatment options have been carefully assessed and established as not being the better option. The attending physician is responsible for considering the possibility of implant surgery. FAVO S-TLIF is a system that enables the physician to select the implant on a patient-specific basis.

Even a successfully implanted device is inferior to the healthy movement element(s) of the spinal column. Conversely, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic movement element(s) for the patient, as it can help eliminate pain and therefore achieve improved mobility and stability.

Any implant is subject to inevitable wear and tear. An implant that was initially stable upon implantation may become loose or functionally impaired over time. This can lead to, e.g., implant fracture, wear, aging, and loosening, which can result in revision surgery.

Removal of the implant is possible, provided it is performed in accordance with the instrumentation guide. The decision must be made by the attending physician.

Warnings:
Implants must not be mechanically processed or modified in any other way unless this is expressly stipulated in the instrumentation guide. Implants that are contaminated, non-sterile, damaged, or scratched or implants that have been improperly treated or processed in an unauthorized way must not be implanted under any circumstances.

Before use of the FAVO S-TLIF cage check if the sterile double blister system and labelling are intact. The sterile packaging should be free of cracks, holes, tears and any other damage. Use of an Implant from a damaged packaging can lead to an untraceable product or infection.

The FAVO S-TLIF cages are provided as single use implants only, and are not to be reused, resterilized or reimplanted in any situation as this might adversely affect device performance and/or increase risk of infection.

Even if the implant appears to be intact, it may have minor defects and invisible damages due to excessive stress that can lead to premature wear and tear.

In the event of overloading, damage, improper implantation or improper handling, implants may fracture, become loose, wear out excessively, or become functionally impaired. In isolated cases, there may be corrosion of the implant.

Careful preparation of the disc space, especially extensive roughening of the end plates, provides the basis for better vascularization and successful bone fusion. Damage of the bony base and cover plate can lead to sinking of the implant into the vertebral body.

Overdistraction should be avoided. This increases the risk of damaging the base plates and cover plates and subsequent sinking of the implant, and jeopardises the restoration of physiological lordosis.

The cage has teeth to maximize primary stability, however make sure the soft tissue and dura are adequately retracted when inserting the implant to avoid damage from contact with the cage (in particular

the teeth). Adequate implant positioning is critical; an improperly placed implant can adversely affect device performance or surgical outcome.

Any additional warnings (e.g., warning label on the packaging) must be followed.

Magnetic resonance (MR) compatibility:
A patient with this implant/device can be scanned safely after placement under the following conditions:

- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 720-Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence).

Heating
Heating is acceptable with a whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes (per pulse sequence) of scanning in a 3-Tesla MR system.

Migration
It is advisable to perform MR imaging not within the first six weeks post-operatively, to ensure there is sufficient bone ingrowth in the implant.

Artifacts
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant/device. In some cases, the artifact size relative to the size of the implant or device may be indicated.

In all cases, the Healthcare Professional is responsible for the MR conditions, MR imaging quality and patient safety. Any safety issues or major image artefacts should be reported.

Patient information:
Preoperative instructions to the patient are essential. The patient should be made aware of the limitations and potential adverse effects of the surgery. The patient should be instructed to limit the postoperative activity as this will reduce the risk of bent, broken and/or loose implant components. The patient must be made aware that implant components may bend, break and/or loosen, even though restrictions in activity are followed.
The patient must also be issued with an implant pass.

The patient must be informed that implants can have an impact on the outcome of CT scans or MRI examinations as well as about possible negative consequences. The patient must also be instructed to inform the examining physician about the implant and to show his/her implant pass prior to a scheduled CT scan or MRI examination.

Post-operative warnings: During the postoperative phase, it is of particular importance that the physician keeps the patient well informed of all procedures and treatments. Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

3 Indications

The FAVO S-TLIF system can be used to manage the following indications of the lumbar and thoracic spine:

- Degenerative disc diseases
- Deformities
- Spondylolisthesis (up to Grade 1)
- Segmental instability
- Stenosis

4 Contraindications

Absolute contraindications

- Anticipated or documented allergy or intolerance to the materials (e.g. titanium)
- Any case in which the chosen implants would be too large or too small to achieve a successful result
- Any patient for whom the use of the implant would be in conflict with the anatomical structures
- Missing bone structures that render good anchoring of the implants impossible (e.g. in fractures, tumors, osteoporosis or infections).

Relative contraindications

- Overweight patient
- Malfunctions
- Fever or leukocytosis
- Systemic diseases and metabolic disorders
- Unbalanced diet, abuse of pharmaceutical drugs, consumption of nicotine, alcohol, or Drugs
- Physical activity involving strong vibrations during which the implant is exposed to impact and /or excessive stress (e.g. heavy physical work, competitive sport, marathons, alpine skiing, jumping and team sports)
- Patients who are mentally unable to understand and to follow the physician's instructions
- If possible, surgery on pregnant women should be avoided or require particular care or procedures. They should only be performed at the discretion of the surgeon

Any condition which could exclude the potential benefit of a spinal implantation must be clarified by the responsible physician. This may include tumors, unexplained increase of the erythrocyte sedimentation rate by other diseases, a substantial shift in the complete blood count or other parameters.

5 Possible negative Consequences

As with any major surgical procedures involving implantation of a spinal device, there are possible negative consequences related to the procedure itself and the device used. These include:

<u>Procedure related:</u>

- Wound related complications (e.g. superficial infections, prolonged wound secretion/healing);
- Infection;
- Neurologic complications (e.g. dural tear, CSF leak, (transient) neurologic impairment, nerve root compression/irritation);
- Cardio/vascular complications (hematoma formation, DVT);
- Pulmonary related complications (embolus, pneumonia);
- Adjacent segment disease;
- Post-operative (persistent) pain
- Other procedure related complications (urinary tract infection, persistent post-operative fever, ileus, fracture of adjacent structure, screw malpositioning, pedicle screw breakage, and screw loosening).

Device related:

- Non fusion / pseudoarthrosis;
- Cage breakage (peri- and post-operative);
- Cage subsidence;
- Cage migration;
- Allergic reaction;
- Other Device related complications (adjacent segment disease, post-surgery proximal mild scoliosis, heterotopic ossification in neural foramen, inflammatory cyst in neural foramen, and mild to moderate vertebral osteolysis).

6 Handling and Storage

The cages should be handled appropriately to protect them from unintentional damage. Avoid scratching or damaging the cage at any time (specifically during attachment of the implant to the inserter and implant placement), as this may lead to premature failure of the cage. Do not use damaged implants.

Only the respective Silony Medical instruments and manipulation implants (trial implants) must be used when selecting and adjusting the implants.

Implants must be stored in the unopened original packaging and must not be damaged.

Implants that are supplied sterile must be stored until use in the sealed sterile packaging in accordance with the storage conditions indicated on the product label.

Before using the S-TLIF cage check the use-by date (YYYY/MM/DD) and sterility marker on the packaging. Do not use the implant after its expiration date or if the marker does not indicate it is irradiated, this can lead to infection.

Before use of the S-TLIF cage check if the sterile double blister system and labelling are intact. The sterile packaging should be free of cracks, holes, tears and any other damage. Use of an Implant from a damaged packaging can lead to an untraceable product or infection.

The rules of asepsis must be observed during removal from the sterile packaging.

Implants that can no longer be used can be disposed of in accordance with the regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.

Implants and instruments may only be returned to Silony Medical if the products are still in the undamaged original package or have been cleaned, disinfected, and sterilized. Proof of such treatment is to be attached to the outermost packaging.

When passing on Silony Medical products (in return for payment or free of charge), any party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

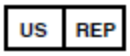
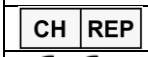
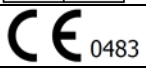
The information and symbols on the packaging must be observed.

7 Reporting of incidents

Users and/or patients are obliged to report all serious incidents involving the device to the manufacturer and the competent authority of the Member State

8 Glossary of symbols

The CE mark with the code number of the Notified Body applies to all class IIb implants in the FAVO S-TLIF system.

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	US representative
	Swiss agent
	The device meets the requirements of EU Regulation MDR 2017/745 / European Directive 93/42/EEC
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Article number
	Lot number
	Number of items
	Medical device
	Unique Device Identification
	Use by *Including the year and month in the following format: YYYY-MM-DD*
	Consult Instructions for Use
	Important – consult the Instructions for Use
	Double sterile barrier system sterilized by irradiation with additional protective packaging
	Sterilized using irradiation
	Non-sterile
	Do not reuse

Symbol	Description according to ISO 15223-1 and Silony specifications
	Do not resterilise
	Do not use if the packaging is damaged
	Store in a dry place
	Keep away from sunlight
	MR* safe
	Caution MR* conditional safe
	Attention MR* unsafe
	Metal detectors can trigger alarm due to the implant
	Contact
	Cage angle

*the term MR is synonymous with MRI and means magnetic resonance imaging

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