ENGLISH VERSION

SPINEVISION - Instruments

Intended purpose

SPINEVISION instruments are part of a set dedicated to support the spinal surgical procedure for the implantation of a specific implant in SPINEVISION range. Instruments are re-usable and re-sterilizable from one surgery to another. SPINEVISION instruments are intended to be used by trained physicians and healthcare professionals according to the recommendations described in the instructions for use and surgical techniques related to the spinal implants and instruments of interest.

No clinical benefit is expected.

Description

The surgical instruments are mainly made of stainless steel and designed to support the spinal surgical procedure for the implantation and / or explantation of SPINEVISION implants. The surgical instruments are supplied non-sterile to the users in a reusable instrument tray, according to state of the art for orthopedic procedures and must be cleaned and sterilized before use according to the legislation in force. The exact description of SPINEVISION instruments and the procedure are described in the surgical technique documentations of the implant systems.

Indications

Same indications as the ones listed in SPINEVISION implants associated to the Instruments.

Contraindications

Same contraindications as the ones listed in SPINEVISION's implants associated to the Instruments. For that, refer to the specific instruction for use of the implant systems.

Storage and packaging

Packaging for each of the components should be intact upon receipt. Damaged packaging or products must not be used. If in doubt, please send them back to SPINEVISION.
Keep the products stored in their initial packaging.
For specific storage conditions, refer to labelling.

Patient target group

SPINEVISION instruments are intended to be used in skeletally mature patients, regardless of gender.

Cleaning and sterilization

Instruments are delivered non-sterile. They must be cleaned and decontaminated in conformity with legislation in force prior to sterilization.
For details regarding the following sections, please refer to instruction "I-LG09 - Instructions for cleaning, sterilization, inspection and maintenance of SPINEVISION medical devices".

For cleaning and decontamination of the non-sterile instruments at the Healthcare facility:

SPINEVISION's cleaning validation has been done using the cleaning agent Neodisher Septoclean. It is recommended to use a similar cleaning agent having a neutral pH, enzymatic and alkaline (pH < 11) cleaning agents solution and deionized or distilled room temperature water of soaking, cleaning and rinsing.
Dismantle the necessary instruments. Articulated instruments must be opened.
Inspect each device and repeat the washing in the presence of any residual debris, paying close attention to threads, cannulas, hinges and hard to reach areas.

Note: Certain cleaning solutions, such as those containing bleach or formaldehyde, may damage certain components and must not be used.

Sterilization

Prior to use, instruments should be steam sterilized according to the following applicable parameters.

Method	Steam
Cycle	Prevacuum

Parameters	**134° - 3 minutes**	**134° - 18 minutes**
Hexanium® TLIF	Not applicable	30 minutes of minimum time drying
Hexanium® ACIF	45 minutes of minimum drying time	45 minutes of minimum drying time
Ulis®	Not applicable	30 minutes of minimum drying time
Lumis®	30 minutes of minimum drying time	30 minutes of minimum drying time
Plus®	Not applicable	30 minutes of minimum time drying

Validations were performed with dynamic-air-removal steam sterilization process.

Instruments have been validated up to 200 reprocessing cycles. These operating instructions are valid for the standard surgical instruments of the production of the manufacturer.

Lubrication specifications
SPINEVISION recommends the lubrication instruments with moving or articulating parts. The instruments must be lubricated after each pre-disinfection / decontamination and before each steam sterilization.

Verification
The devices must always be verified before use: any devices presenting signs of weakness or any damages must not be used (Surface damage such as scratches, cracks, nicks, dents, bent parts, tightening torque deviations indicate that the instrument must not be used). Return to the manufacturer or distributor any instruments showing deterioration.

Warnings and precautions
PREOPERATIVE
- Carefully read the instructions for use of the SPINEVISION implants related to the instruments in question, as well as the surgical technique related to the system and which details the operations.
- The use of dedicated adequate instruments has to be done by a trained orthopedic surgeon or neurosurgeon familiar with these recommendations as well as with the operating techniques relating to these implants.
- Instruments are delivered non-sterile and must be cleaned and decontaminated in conformity with legislation in force prior to sterilization.

INTRAOPERATIVE
- Devices have been designed for use specifically to a dedicated SPINEVISION implant system. Do not use instrument with any components not specifically recommended, or with any components from another manufacturer.

POSTOPERATIVE
- Instruments can be reused after appropriate reprocessing, they must be cleaned and decontaminated before transport.
- In case of reuse for another surgery, carefully disassemble / assemble instruments, clean and decontaminate all the parts of the instruments and then, sterilize it according to the legislation in force before putting it back into service (refer to section “Cleaning and sterilization”)
- SPINEVISION instruments are not approved for long term implantation and should not be left in the patient postoperatively.
- Refer to complaints section in case of malfunction of a device. Carefully segregate it to not reuse the device in another surgery.
- Devices have been designed for use specifically to a dedicated SPINEVISION system. Do not use instrumentation with any components not specifically recommended, or with any components from another manufacturer.

Disposal

To discard a product following an error in product range or use, or after the end of life of the devices, the instruments must follow the pathway for removal of hospital waste products in compliance with procedures in force within the institution.

Product complaints

Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identification, durability, reliability, safety, effectiveness and/or performance, should notify SPINEVISION.

If any SPINEVISION product may have caused or contributed to the death or serious injury of a patient or a user, SPINEVISION and the competent authority of the Member State in which the user and/or patient is established should be notified as soon as possible by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from SPINEVISION.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

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IMPORTANT INFORMATION CONCERNING SPINEVISION SYTEM INSTRUMENTATION