Instructions for Use - Instruments
LISA Dynamic Stabilization System

I. Description

Instruments of LISA dynamic stabilization system are used for the placement of LISA device in the lumbar segments of the spinal column.
The instruments are comprised of:

- Trial spacer (size 6 to 12): It is intended to retract the nose or the superior part of the spinous process to access the interspinous space. The surgeon introduces the trial spacer, starting with the smallest size (6), to appreciate the appropriate size of the spacer (6, 8, 10 or 12).
- Band forceps (I and II): Once the band has been pierced through the interspinous ligament with the hook, the band is clamped and gripped by the band forceps and pulled through the interspinous ligament.
- Hook (Wide and Narrow): It is intended to cut through the interspinous ligaments and accompany the band through the interspinous ligaments.
- Implant Holder (size 6 to 12): It is intended to clamp the spacer with its lateral claws and keep the spacer stable laterally during the procedure.
- Locker: It is intended to be screwed to the spacer through the Implant Holder and keep the spacer stable vertically during the procedure.
- Tensioner: Prior to the LISA band tensioning step, the tensioner is connected to the Implant Holder. It is slipped onto the external diameter of the proximal part of the Implant Holder and is maintained at a height of approximately 8 cm from the patient's skin by resting vertically on the shoulder of the Implant Holder. It should be noted that the tensioner remains mobile in rotation around the vertical axis of the Implant Holder in order to be positioned optimally to maximize the tension. The distal end of the braid is inserted between the flat and the pin of the tensioning wheel. The braid is then tensioned by turning the tensioning wheel clockwise.
- Torque Limiting handle: It is connected to the tensioner via the connector and tension can be provided by the T handle until the torque limit.
- Torque Limiting connector: It connects the Torque limiting handle to the Tensioner
- Gripper screwdriver: It grips the device blocker (its self-retaining extremity holds the blocker and avoids loosening) and introduced through the Implant Holder in order to screw the blocker into the spacer and lock the system.
- Interlaminar distractor: It may be used to retract the laminas before inserting the spacer between the spinous processes.
- Additional Wrench : this instrument can be used to add tension to the braid beyond the limit value given by the Torque Limiting Handle.

All Instruments from LISA dynamic stabilization system are specifically designed to interact together during the surgical procedure for the placement of LISA Implants. In order to avoid the failure of the surgical procedure, the LISA Instruments must exclusively be used together and cannot be replaced by an alternative instrument.

Clinical Benefit: LISA Instruments are intended for the placement of LISA device with minimal invasiveness for the spinal anatomy.

The LISA Instruments must be used by surgeons who have been properly trained in spinal surgery. The decision to use this device should be made only after taking into consideration the medical and surgical indications, contraindications, side effects and precautions contained in these Instructions For Use and the limitations of this type of surgery.

II. Indications

Instruments of LISA dynamic stabilization system are used for the placement of LISA device in the lumbar segments of the spinal column.

The implants of **LISA** Dynamic Stabilization System are intended to treat low-back pain that accompanies degenerative lesions of grade I, III and IV (Pfirrmann MRI classification).

III. Contraindications

a. Stage V degenerative disk lesions in Pfirrmann's MRI classification.
b. Spondylolisthesis.
c. Osteoporosis.
d. Non-specific back pain.
e. Modic 2 and Modic 3 changes.
f. This device is not indicated for the L5/S1 segments.
g. Local or general infections that may compromise the surgical goals.
h. Major local inflammatory phenomena.
i. Pregnancy.
j. Immunosuppressive diseases.
k. Bone immaturity.
l. Severe mental illnesses.
m. Bone metabolism diseases that may compromise the mechanical support expected from this type of implant.
n. Excessive physical activities.

IV. Possible side effects

No undesirable side-effect is known for the instruments of LISA dynamic stabilization system.

For reminder, the known undesirable side-effects for the implants of LISA dynamic stabilization system are the following:

- All potential side effects associated with spinal surgery independent of the medical device are possible.
- With the use of implants from LISA dynamic stabilization system, the list of potential side effects includes, among other:
  a. Neurological complications, paralysis, soft tissue injuries, pain, device migration, erosion or device breakage
  b. Superficial or deep infections and inflammatory phenomena.
  c. Allergic reactions to the materials comprising the implant.
  d. Alteration of the bone density due to a change in the distribution of mechanical stresses.
  e. Neurological injuries and/or injuries to the dura mater during the surgical procedure.
  f. Though the risks have been judged to be at a low level, the use of Magnetic Resonance Imaging (MRI) on patients treated with LISA implants may result in possible side effects such as migration or localized heat generation due to the metallic component of the LISA device (Locker).

V. Reception of new surgical instruments

Reception of new surgical instrument is done exclusively be staff members properly trained on adequate procedures to follow to validate the instrument integrity and regulatory conformity. Once conformity with the order has been checked, this instrument is unpackaged and its proper functionality ascertained prior to further processing.

An instrument that appears to be defective must be returned with its original packaging without any attempt at improvised repairs, as this is liable to invalidate the warranty.

If the instrument does not have to be put into service immediately, it should be stored:

- in a clean, dry place,
- without its plastic packaging,
- away from any acid solution, even in a closed container,
- away from any other type of metals, especially ferrous metals,
- free of weight,
- in accordance with classification for easy identification.

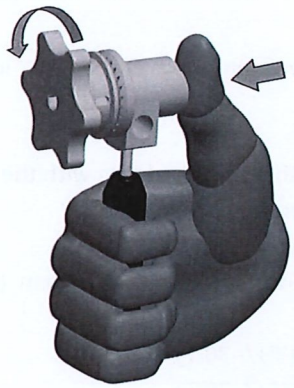
VI. Handling, Storage and shipping

a. The LISA instrumentation has to be considered as sensitive high-precision surgical instruments, which require to be handled with care.
b. If the LISA Instrumentation has to be shipped, special attention must be paid to ensure that handling and shipping do not damage the instrumentation.
c. After each handling and shipping, the instrumentation must be controlled (see section VIII Functionality Inspection and Testing)
d. Damaged or worn instruments must not be used and must be return to the manufacturer.

VII. Cleaning and decontamination

a. The LISA Instrumentation is supplied in a non-sterile condition. A new instrument should be cleaned and sterilized prior to use and as soon as possible after each use. Do not allow blood, body fluids or debris to dry on the instruments. If immediate cleaning is not possible, place soiled instruments in a closed container with enzymatic solution to slow down the drying of soil deposits. The number of cleaning and sterilization procedures is not limited for all LISA instrumentation except for LISA Torque Limiting Handle for which the number of sterilizations is limited to 250.
b. Remove and/or disassemble the moving parts of instruments designed to be disassembled by the user, according to the instructions below:

- **Tensioner - BB-LISA-2-230**



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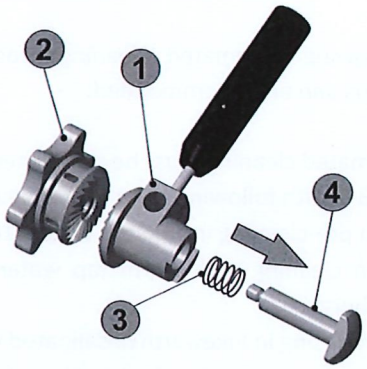
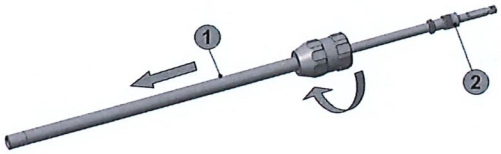


#2

To disassemble the tensioner, the operator must press the Shaft ❹ with his/her thumb as shown in Fig. #1. The Shaft ❹ will be blocked from rotating in the Shank ❶. The Wheel ❷ can then be unscrewed in an anti-clockwise direction to disassemble the instrument as shown in Fig. #2, releasing the spring ❸ and the Shaft ❹. Once the device has been cleaned, and dried, reassemble it by inserting the Shaft ❹ , load it with the Spring ❸, into the Shank ❶. Then, while blocking the Shaft ❹ from rotating, as shown in Fig. #1, the Wheel may be tightened ❷ by screwing it clockwise up to its limit.

- **Gripper screwdriver LISA - BB-LISA-2-250**



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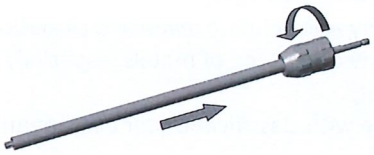

#4

To disassemble the gripper Screwdriver, the operator must hold the central Shaft ❷ in place and completely unscrew the outer Shank ❶ by turning the ring on the outer Shank anti-clockwise until these two components are completely disassembled (Fig. #3). Once the device has been cleaned, and dried, reassemble it by inserting the central Shaft ❷ into the outer Shank ❶, and then screw the unit together by turning the ring on the outer Shank clockwise, without tightening it to the limit (Fig. #4).

c. The following Manual Cleaning process parameters are validated by BACKBONE in laboratory conditions and are recommended:

i. Metal brushes or scouring pads should not be used for manual cleaning as there is risk of damage to the surface and the coating of the instruments. Brushes and swabs with soft nylon fibers should be used primarily.

ii. Completely immerse the instruments in an ultrasound bath with enzymatic solution diluted according to the manufacturer's recommendations, and allow to soak for 10 minutes at 45-50 KHz (optimal temperature between 27°C and 44°C, not exceeding 55°C). Next, gently brush each device for between 30 seconds and 1 minute until all visible soil deposits have been removed. Pay particular attention to areas that are difficult to clean (cavities, uneven surfaces, grooves). Deep apertures should be cleaned with a swab. Manipulate jointed parts, if applicable.

iii. Next, remove the instruments from the cleaning solution and rinse them in purified water for a minimum of 1 minute. Flush thoroughly until visible blood and soil deposits have been removed, paying particular attention to inaccessible areas (blind slots, notches), or use a recommended water nozzle.

d. The following Automated Cleaning process parameters are validated by BACKBONE in laboratory conditions and are recommended:

The automated cleaning must be performed in a validated dishwasher in accordance with the standard EN ISO 15883-1 with following steps (before every step the dishwasher has to be drained):

- 2 min pre-cleaning in cold tap water (16°C +/- 2°C) (61°F+/- 30°F)
- 5 min cleaning with warm tap water (55°C, 131°F) and 0.5% Neodisher MediClean (Dr. Weigert, Hamburg)
- 3 min rinsing in lukewarm desalinated water (20°C +/- 2°C) (68°F+/- 30°F)
- 2 min rinsing in lukewarm desalinated water (20°C +/- 2°C) (68°F+/- 30°F)
- Thermal disinfection taking into account the national requirements A0 > 3000 at 90°C and at least 5 min holding time.

e. Dry all inner and outer surfaces using filtered compressed air.

f. Next, visually inspect for cleanliness by closely examining each device under normal lighting, paying particular attention to all inaccessible areas. If there are still soil deposits to be seen, repeat the cleaning procedure.

VIII. Functionality inspection and testing

a. Examine each instrument, inspecting it for damage or any signs of wear.
b. Sharp edges should be free of notches, with no interruptions along the edge.
c. Jaws and teeth should be correctly aligned.
d. Movable parts should move fluidly, without excessive play.
e. Locking mechanisms should function correctly.
f. Long, thin instruments should not be warped.

The lifetime of the LISA instruments is 5 years. After this time, the instrumentation must be replaced by a new ancillary kit to guarantee its safety and performance.

The LISA Torque Limiting Handle (BB-LISA-2-240) can be reused up to 250 times.

IX. Maintaining

a. Damaged or worn instruments must be discarded and returned in order to be reworked or replaced by BACKBONE
b. For LISA Gripper Screwdriver (BB-LISA-2-250), prior to sterilization, all hinges or mobile connections shall be lubricated with medical grade instrument oil that is explicitly suitable for steam sterilization.

X. Packaging

a. The instruments should next be placed in their specific containers in assembled condition, in accordance with their positioning. If necessary, have a layout plan on the container cover as an aid.
b. Biological or chemical indicators (BI or CI) used to test sterilisation performance should be placed on the median values in the packaged trays. They should be tested according to the manufacturer's instructions for BI or CI.
c. Place the container with instruments in double packaging in accordance with local procedures, using standardized packaging techniques, such as those set out by the ANSI/AAMI ST79 standard in effect.
d. Label the contents of the packaged tray with an indelible marker or other labelling system compatible with sterilisation.

XI. Sterilization

a. Use a validated steam sterilizer, correctly maintained and set.
b. Individual users should validate the cleaning and autoclaving procedures used on-site, particularly on-site validation of the minimum parameters recommended below.
c. Effective vapour sterilisation may be performed with the following minimum cycles which have been validated by BackBone in laboratory conditions and according to EN ISO 17655-1:

Type of steriliser	**Pre-vacuum**		
Pre-conditioning pulses	5 (maximum = 2.8 bar – minimum = 339 mbar)		
Minimum temperature	134°C (273.2°F)	134°C (273.2°F)	132°C (271,2°F)
Duration of full cycle	3 minutes	18 minutes	4 minutes
Minimum drying time	16 minutes	20 minutes	20 minutes
Configuration	Kits packaged in double WRAP		

XII. Storage after sterilization

a. The boxes of instruments that have been reprocessed and packaged to maintain their sterile state should be stored in such a way as to avoid extremes of temperature and humidity.

b. When handling the packaged boxes, care should be taken to avoid damaging the sterile barrier. The healthcare establishment should set a storage life for the packaged instruments, based on the type of sterile packaging and on the manufacturer's recommendations for this sterile packaging.

c. The user must be cognizant of the fact that maintenance of a sterile state is contingent upon the circumstances and that the probability of a contaminating event occurring increases over time with handling, depending on whether woven or non-woven fabric, or bags or containers are used for packaging.

XIII. Additional information

a. The LISA – Surgical Technique is available upon request from your BACKBONE representative or directly from BACKBONE. If the Surgical Technique in the user's possession is older than two years prior to the date of surgery, it is recommended that you request an updated version.

b. It is imperative that the level of tension given to the band by the tensioner used simultaneously with the torque limiting handle be followed according to the surgical technique. If the user overtightens beyond the recommended tension, the resulting tension on the band may damage the spinous processes, depending on the patient's bone density and quality.

XIV. Manufacturer's contact information

Any healthcare professional (customer or user) who has a complaint concerning the services and/or quality, identification, robustness, reliability, safety, efficacy and/or performance of BACKBONE products should report it to their representative or distributor of these products. The distributor will inform BACKBONE of this complaint as soon as possible, using an incident report form. The company should be immediately alerted by phone or by any written means in the case of a malfunction or deterioration of the device, or of any inappropriate part of the Instructions For use that has caused, or might have caused, death or serious deterioration in the health of a patient or user.
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Medical device vigilance: Incident report forms must contain as many details as possible, such as identification of the product (description, batch number, reference number), the type of complaint and a detailed description of the incident, as well as its consequences. Incident report forms must be submitted along with any technical aspects that might facilitate an expert appraisal, such as the device itself, X-rays, etc...

For further information or to submit a complaint, please contact:

BACKBONE
81 Boulevard Pierre 1er
Le Bouscat
33110
France
Phone Number : +33 (0) 556 424 430
Email : customerservice@backbone.pro

CE 2797 CE NON STERILE MD

e-IFU

https://backbone.pro/patients-information/

AND SIGNATURE FOR APPROVAL		
R&D Manager: C. BACCELLI *Date: 6th March 2023* *Signature:*	*RA Manager*: E. FACHE *Date: 6th March 2023* *Signature*:	*CTO*: N. SAHAMI *Date: 6th March 2023* *Signature*: N SAHAMI