Summary of safety and clinical performance intended for patients

LISA – Lumbar Implant for Stiffness Augmentation

BACKBONE

81 Boulevard Pierre 1er

Le Bouscat

33110

France

Contents

List of Acronyms

AFAP: as far as possible

CER: clinical evaluation report

CS: Common specifications

EU: European Union

Eudamed: European database on medical devices

FSCA: Field Safety Corrective Action

FSN: Field Safety Notice

IFU: Instructions for Use

MDCG: Medical Device Coordination Group

MDR: Medical Device Regulation

N/A: not applicable

NB: Notified Body

PEEK: PolyEtherEtherKetone

PMCF: post market follow-up

PMS: post market surveillance

RM: risk management

S&P: safety and performance

SRN: Single Registration Number

SSCP: Summary of Safety and Clinical Performance

UDI-DI: Unique Device Identification – device identifier

Document revision: V05

Date issued: November 21th, 2023

This paper is a "Summary of Safety and Clinical Performance (SSCP)". It is about the **L**umbar **I**mplant for **S**tiffness **A**ugmentation (LISA) device. It aims to give public access to safety and performance data for the device.

The aim is to give general information on the treatment. Please contact your doctor if you have questions about your health or the LISA. This paper is not an implant card nor the Instructions For Use.

1 . Device identification and general information

1.1 Device trade name

The device trade name is LISA (Lumbar Implant for Stiffness Augmentation)

1.2 Manufacturer; name and address

Manufacturer Name	Backbone
Address	81 Boulevard Pierre 1er Le Bouscat 33110
Country	France
Website	https://www.backbone.pro/

1.3 Basic UDI-DI

Product Code	**Device Name**	**Basic UDI-DI**
LISA Implants		
BB-LISA-1-101	Band	376024863LISA101FT
BB-LISA-1-104	Blocker	376024863LISA104FZ
BB-LISA-1-106	Spacer Size 6	376024863LISA106G5

Product Code	Device Name	Basic UDI-DI
BB-LISA-1-108	Spacer Size 8	376024863LISA106G5
BB-LISA-1-110	Spacer Size 10	376024863LISA106G5
BB-LISA-1-112	Spacer Size 12	376024863LISA106G5

1.4 Year when the device was first CE-marked

2018

2. Intended use of the device

2.1 Intended purpose

The LISA implant aims to treat patients with low-back pain. From a scanner image, doctors evaluate if the LISA is right or not for treating the pain.

Between two vertebrae in the spinal column, there is a disc that acts as a schok absorber between the vertebrae. With aging, the disc may decline. The Pfirrmann grading enables to grade the disc decline from I to V. This evaluation is made by doctors from a scanner image. A grade «I » means the disc is intact (no decline). A grade “V” means the disc is collapsed (maximal decline). At that grade, the status of the disc can no longer be improved. The LISA aims to treat patients in grades II, III, IV. At those grades, the disc decline is still reversible.

2.1.1 Intended users

Please refer to section 2.2.

2.1.2 Intended target populations

Please refer to section 2.2.

2.1.3 Indications

Please refer to section 2.2.

2.1.4 Contraindications

Please refer to section 2.3.

2.1.5 Warnings

Please refer to section 4.2.

2.1.6 Precautions

Please refer to section 4.3.

2.1.7 Adverse effects

Please refer to section 4.4.

2.1.8 Residual risks

Please refer to section 4.5.

2.2 Intended users, intended target populations and indications

- Intended users
  LISA devices must be implanted by doctors who have been properly trained in back surgery. The decision to use LISA should be made only after taking into consideration the medical and surgical indications, contraindications, side effects and precautions contained in the Instructions For Use and the limitations of this type of surgery.
- Intended target populations
  The LISA implant aims to treat patients with low-back pain. From a scanner image and as detailed below, doctors evaluate if the LISA is right or not for treating the pain.
- Indications
  The LISA implant aims to treat patients with low-back pain. From a scanner image, doctors evaluate if the LISA is right or not for treating the pain.
  Between two vertebrae in the spinal column, there is a disc that acts as a schok absorber between the vertebrae. With aging, the disc may decline. The Pfirrmann grading enables to grade the disc decline from I to V. This evaluation is made by doctors from a scanner image. A grade «I » means the disc is intact (no decline). A grade “V” means the disc is collapsed (maximal decline). At that grade, the status of the disc can no longer be improved. The LISA aims to treat patients in grades II, III, IV. At those grades, the disc decline is still reversible.

2.3 Contraindications

According to the instructions for use, LISA implants should not be used in some specific patients. The detail is given below.

- Patients who have low back pain and the disc causing the pain is collapsed (grade V according to the Pfirrmann grading detailed above).
- Patients with “spondylolisthesis”. It corresponds to the slipping of a vertebra in relation to the one above or below. The vertebrae are thus not normally aligned.
- Patients with “osteoporosis”. It corresponds to loss of bone strength (possible broken bones).
- Patients with non-specific back pain (when the origin of pain is not known).
- Patients with vertebrae in decline. There is a grade named “Modic” for doctors to evaluate the status of the vertebrae. They use scanner images for evaluating it. Three types of Modic exist (Modic 1, 2, 3). Modic 2 and 3 are for vertebrae most in decline. Patients with Modic 2 or Modic 3 are not indicated for LISA.
- The low back zone is composed of 5 lumbar vertebrae: L1, L2, L3, L4, L5. Below the lumbar L5 is the sacrum. The implant cannot be placed between L5 and S1.
- The implant cannot be used in patients with local or general infections. It may affect the surgical goals.
- The implant cannot be used in patients with major local inflammatory events.
- The implant cannot be used in pregnant women.
- The implant cannot be used in patients who have diseases which affect the immunologic system
- The implant cannot be used in patients with bone immaturity.
- The implant cannot be used in patients with severe mental illnesses.
- The implant cannot be used in patients with bone metabolism diseases that may compromise the mechanical support expected from this type of implant.
- The implant cannot be used in patients who do excessive physical activities.

3. Device description

3.1 Device description and material/substances in contact with patient tissues

The LISA consists of a spacer, a band and a lock. The surgeon places the spacer between the two vertebrae where the pain comes. The band fastens the spacer to these vertebrae. The surgeon

tightens the band and locks it into the spacer. It ensures that there is enough space between vertebrae. It allows stiffness to protect the disc and keeps natural mobility.

The spacer exists in four sizes: 6, 8, 10 & 12. The surgeon selects the correct LISA size based on your anatomy.

The table below sums up LISA Implants materials in contact with patient tissues.

Implant Component	Material/Substance
Spacer	PolyEtherEtherKetone (PEEK)
Band	Woven polyester (polyethylene terephthalate)
Blocker	Titanium alloy (Ti6Al4V)

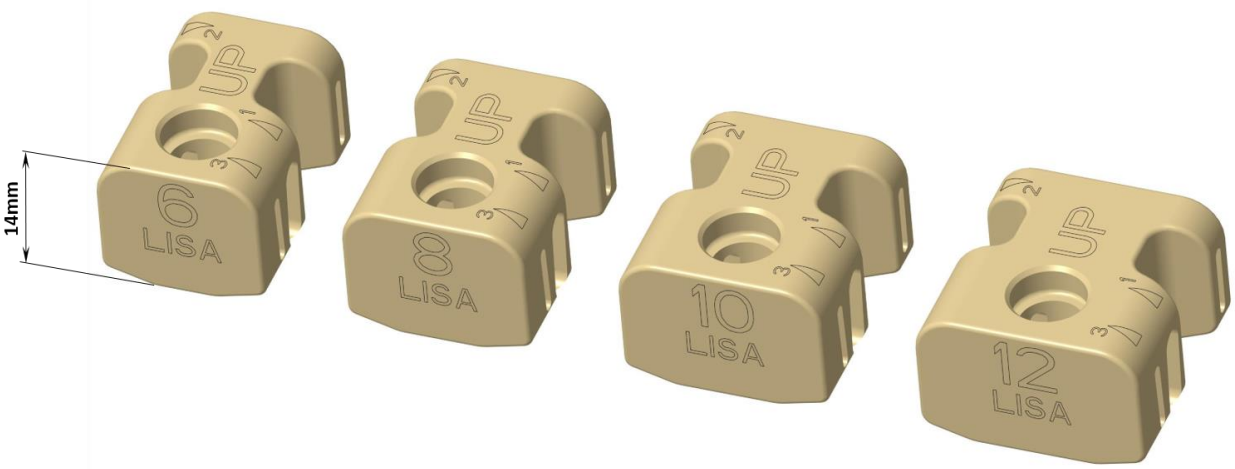

Figure 3.1-1 : Image of LISA spacer which is available in four sizes

3.2 Information about medicinal substances in the device, if any

Not applicable.

3.3 Description of how the device is achieving its intended mode of action

The LISA stabilizes the treated segment of the spine. It aims to preserve mobility and anatomy. The goal is to reduce low back pain.

3.4 Description of accessories, if any

Not applicable.

4. Risks and warnings

Contact your doctor if you believe that you are facing side-effects related to the device or its use. Also contact your doctor if you are concerned about risks. This report does not intend to replace a consultation with your doctor if needed.

4.1 How potential risks have been controlled or managed

The manufacturer of LISA has thought about all risks of using LISA, and how those risks compare to the benefits of using LISA. The manufacturer has tried to reduce the risks as much as possible. The section below lists the remaining risks. They also are cited in the Instructions for Use.

4.2 Warnings

The Instructions for Use provide the following warnings:

- The LISA is a single-use device. The reuse of LISA may lead to infections or poor care.
- No-one should re-sterilize the LISA. Potential risks related to re-sterilization of the LISA are:
    - The transmission of infectious or viral agents.
    - Change in the properties of the LISA material. It may lead to LISA rupture or damage.

  These risks might affect health and safety of the patients.
- Even if a surgeon removes the LISA and the LISA seems intact, the surgeon must not reuse the LISA. Potential risks related reuse of the LISA are:
    - Spreading of infectious or viral agents. No one should re-clean or re-sterilize the LISA.
    - Loss of properties of the LISA. This may lead to rupture of the LISA.

  These risks might affect health and safety of the patients.
- Medical staff must treat any infected LISA component as biological waste.
- LISA may prevent medical procedures from being carried out.

4.3 Precautions

4.4.1. Before surgery

a. Weight. Overweight causes stress. It may lead to the break of the LISA.
b. Mental illness. There is a higher risk in patients who cannot follow the advice from the doctor.
c. Over reaction to materials of the LISA. If your doctor suspects a high reaction to one of the LISA material, medical staff should check it before inserting the LISA.

4.4.2 During surgery

The surgical technique gives the following precautions:

a. Surgeons must insert the LISA with the instruments designed and supplied for this aim.
b. Bone quality. Before deciding to use LISA, your doctor must consider if you have any disease that may alter the mechanical properties of your spine. This can be loss of bone strength for example.
c. It is crucial the surgeon respects the adequate level of tension. If the surgeon puts tension over the adequate one, there is a risk of harming the back of the spine.

4.4.3. After surgery

The doctor should tell the patient what warnings to take into account after LISA operation. If the outcomes of the LISA change from what the doctor said, the patient must contact the doctor.

a. In general, you will not need a lumbar support after operation. But this decision is up to the doctor and depends on each patient. Quality of bone, diseases, level of activity and weight may influence it.
b. High levels of physical activity increase the risk of mobility, deformity and rupture for the LISA.
c. A physical handicap will need focus for recovery.

4.4 Adverse effects

All potential adverse effects of spinal surgery independent of the medical device are possible. The adverse effects include, among others:

- Neurological complications, paralysis, soft tissue injuries, pain,
- Superficial or deep infections and inflammatory phenomena
- Fractures of the bony projection off the back of each vertebra
- Recurrence of slipped, ruptured or bulging disc at the operated level
- New narrowing of the spinal canal

- Neurological injuries and/or damages to the dura mater (membrane which surrounds the spinal cord) during the surgical procedure
- Alteration of the bone density

With the use of implants from the LISA dynamic stabilization system, the list of potential adverse effect may include:

- Migration of the implant or component, implant move, breakage or release
- Fractures of the bony projection off the back of each vertebra
- Allergic reactions
- Heating or migration of the implant following the use of magnetic resonance imaging (type of scanner image)
- Neurological complications
- Paralysis
- Though the pain is reduced, the pain is not sufficiently contained following LISA use
- Superficial or deep infections
- Inflammatory phenomena
- Alteration of the bone density
- Duramater (membrane which surrounds the spinal cord) injury following the LISA use
- New narrowing of the spinal canal, “stenosis”
- Adjacent level slip
- Modic decline. There is a grade named “Modic” for doctors to evaluate the status of the vertebrae. They use scanner images for evaluating it. Three types of Modic exist (Modic 1, 2, 3). Modic 2 and 3 are for vertebrae most in decline.
- Recurrent slipped, ruptured or bulging disc, “disc herniation”

The Table below reports adverse effects identified for LISA with their frequency. For these adverse effects, the table reports the incidence for alternatives. Acceptability of LISA adverse effects is also discussed.

LISA side-effects	Frequency for LISA	Frequency for alternatives	Acceptability of LISA side-effects
Fractures of the bony projection off the back of each vertebra	0.16%	[0-11%]	Yes: 0.16% in [0-11%]
Slipped, ruptured or bulging disc at the operated level	0.08%	[0.6%-0.9%]	Yes: 0.08% < [0.6-0.9%]

LISA side-effects	Frequency for LISA	Frequency for alternatives	Acceptability of LISA side-effects
Recurrence of slipped, ruptured or bulging disc at the operated level	0.24%	[2-16%]	Yes: 0.24% < [2-16%]
New narrowing of the spinal canal	0.08%	Around 21%	Yes: 0.08% < 21%
LISA removal	0.16%	[3%-18%]	Yes: 0.16% < [3-18%]

All the adverse effects inherent to the use of LISA exist for alternatives.

The adverse effects of LISA are acceptable in comparison to alternatives.

4.5 Residual risks

1. Torque Limiting Handle: The torque limiting handle (one of the instruments used by the doctors during LISA implantation) must be used to limit the tightening of the band around the bony projection off the back of each vertebra. With an excessive tightening, there is a risk of fractures of the bony projection off the back of each vertebra during the surgery or short term after the surgery. The limiting handle and the torque limitation have been defined based on the literature, and the device has been designed and produced to verify that the torque limiting handle achieves its performance. The handle is required to avoid the risk of fractures of the bony projection off the back of each vertebra.

2. Compatibility with MRI (Magnetic Resonance Imaging – one type of scanner image): The implant raw materials have been chosen to be compatible with MRI. The raw materials are non-magnetic: Titanium used for the blocker, PEEK (PolyEtherEtherKetone) used for the spacer, and Polyester used for the band. However, full MRI compatibility has not been verified. Though the risks have been judged to be at a low level, the use of MRI on patients treated with LISA implants may result in possible adverse effects such as migration or localized heat generation due to the metallic component of the LISA device (Blocker).

3. Leachable substance from the band inside the patient: The band raw materials have been selected to be compatible with patient safety. All tests complied with the acceptance criteria and met the expectations of the respective standards though a slight irritation was observed. Possible side effects may include allergic reactions to materials of the implant and inflammatory phenomenon.

4.6 Summary of any field safety corrective action, (FSCA including FSN) if applicable

To date, there is no Field Safety Corrective Action (FSCA) for the LISA.

To date, there is no Field Safety Notice (FSN) for the LISA.

5. Summary of clinical evaluation and post-market clinical follow-up

5.1 Clinical background of the device

The LISA aims to treat patients with low-back pain. From a scanner image, doctors evaluate if the LISA is right or not for treating the pain.

Between two vertebrae in the spinal column, there is a disc that acts as a shock absorber. With aging, the disc may decline. The Pfirrmann grading enables to grade the disc status from I to V. From a scanner image doctors can evaluate this grade. A grade «I » means the disc is intact (no decline). A grade “V” means the disc is collapsed (maximal decline). At that grade, the status of the disc can no longer be improved. The LISA aims to treat patients in grades II, III, IV. At those grades, the disc decline is still reversible.

Spinal surgeons placed the LISA posteriorly, during a surgery. Contrary to fusion (an alternative option to the LISA), LISA keeps motion at the operated level.

The LISA consists of three components: a spacer, a band and a blocker. First, the surgeon places the spacer between the back of two vertebrae. Then the surgeon belts the band around the back of the two vertebrae and through the spacer. Finally, the surgeon uses the blocker to lock the band in the spacer.

The principle of the LISA is identical to other devices, particularly the Wallis.

Professor Sénégas designed the first generation of the Wallis, in the 1980’s. His students and him believed the device must evolve. The aim was the device to become easier to use for surgeons and less traumatic for the patients. BACKBONE accompanied Professor Sénégas and Professor

Pointillart with a team of most experienced engineers to develop LISA. LISA is a multi-patent device. LISA respects the anatomy. Surgeons place LISA with no bone graft.

BACKBONE markets the LISA in Europe (CE marking) since 2018. BACKBONE did not apply significant design changes to LISA since 2018.

5.2 The clinical evidence for the CE-marking

The design of the LISA was validated. Tests on the LISA were also done. The tests are:

- mechanical
- biocompatibility
- sterilization
- usability

LISA is marketed since 2018. In total, there was a maximum of **1,602 surgeries with LISA**.

Backbone did not identify:

- Any unknown clinical risks
- unacceptable trends in non-serious incidents and expected side-effects

Backbone is still collecting data on LISA with clinical studies. There are one ongoing and two planned studies.

Table 5.2-1- Ongoing and planned studies

Study	Aim	Location	Status
NCT04631133 (ClinicalTrials.gov)	Collect safety and performance data until 6 years after operation	Denmark France Germany	Ongoing 129 of 136 (95%) patients enrolled
Pending	Collect additional safety and performance data	Germany	Not started yet
Pending	Evaluate radiographies after LISA operation	France	Not started yet

A LISA study is ongoing. To date, 129/136 patients (95%) were included.

The doctors reported three LISA adverse effects in the study so far:

- Fractures of the back of a vertebra in two patients. The patients are well. And the surgical results are good at three months follow-up.
- Recurrent bulged disc in three patients. In one patient, the surgeon removed the LISA.
- New narrowing of the spinal canal, “stenosis”, in one patient. The surgeon removed the LISA.

Preliminary results from the study are:

- One year after operation, patients have less pain in the back and the legs than before operation. They find it easier to carry out activities from days to days. They still have mobility at the operated level.
- Surgeons report mean time for LISA surgery to be 58 minutes. It is less than the time used for a fusion. Shorter time may lead to less blood loss and post operative days at hospital.
- 85% of patients go home after surgery.

5.3 Safety

LISA is a device for which the benefits outweigh the risks, when compared to alternatives.

Since 2018, there was a maximum of **1,452 surgeries with LISA**.

The LISA design, manufacturing, packaging and labelling:

- are in accordance with the current state of the art

- meet relevant requirements

- meet all acceptance criteria of European and other international standards

Results of the ongoing study confirm the LISA performs as intended. To date, 129 patients have been included in the study.

The doctors reported three LISA adverse effects in the study so far:

- Fractures of the back of a vertebra in two patients. The patients are well. And the surgical results are good at three months follow-up.
- Recurrent bulged disc in three patients. In one patient, LISA was removed.
- Narrowing of the lumbar canal in one patient. LISA was removed.

Backbone is still collecting data on LISA. There are one ongoing and two planned studies. *Please see Table 5.2-1 in section 5.2.*

Also, Backbone is still collecting data on LISA safety, such as:

- user complaints
- adverse event reports
- scientific articles

6. Possible diagnostic or therapeutic alternatives

As regards to alternatives to LISA, please enter in contact with your doctor. And take the time to discuss your situation with him/her. Your doctor will take into account your individual situation.

6.1 General description of therapeutic alternatives

Spinal surgery is usually only considered when all other non-surgical options have failed.

"LISA surgery" is one the existing surgical options to treat your back pain. However, there are other surgical options than the LISA implant. Some may be more suitable for some patients. This depends on the progress of your back pain and its origin. The following alternatives to LISA surgery exist:

- decompression alone: decompression surgery releases pressure on irritated nerve fibers but may destabilize the segments

- fusion surgery: two vertebrae are fused and the motion is lost at that level

- similar devices to the LISA

Some of these alternatives may not be appropriate for you. Only you and your doctor can decide on which alternative is the best for you.

7. Suggested training for users

LISA users are spinal surgeons. Backbone ensures they are trained before using LISA for the first time.

Only spinal surgeons should implant the LISA. Before using it, the surgeon must consider the pros and cons.