BAGUERA® L

LUMBAR DISC PROSTHESIS

CONTENT

CONCEPT AND DESIGN

Powered in 2007 by a creative and pioneer team, BAGUERA® L has been inspired by the black panther of the “Jungle book”: black and elegant, agile but discret, mature while irresistible.

The goal at this time was to replace the disc function and to drastically simplify the existing technologies in motion preservation. After several years of usage, the BAGUERA® L is still innovative and is now a reference in the lumbar arthroplasty segment.

BAGUERA® L is a cutting-edge device that respects Spineart’s philosophy, Quality, Innovation, Simplicity.

AT A GLANCE

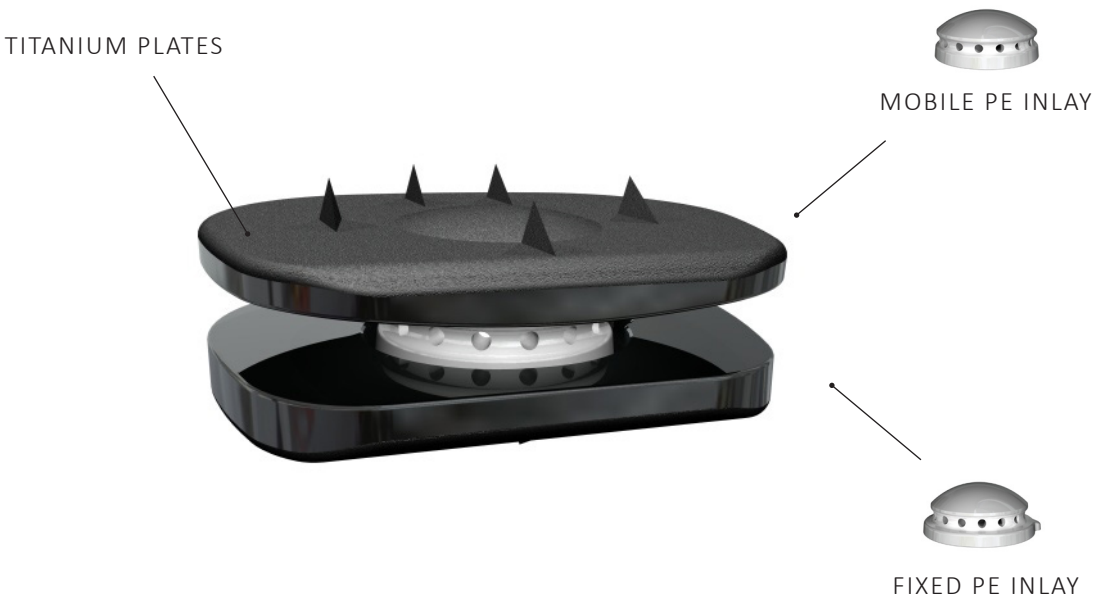
Reduced MRI Artifact
Mobile or Fixed Nucleus
Primary Stability
User Friendly Insertion

INDICATIONS

The BAGUERA® L is a prosthesis intended as a replacement for a lumbar intervertebral disc. Patient suffering from symptomatic lumbar disc disease (SLDD) affecting one vertebral level between L3 and S1, as defined by the following signs:

- Lower back pain or lumbar radicular pain (sciatica);
- Functional and/or neurological deficit accompanied by at least one of the following conditions confirmed by MRI or X-Ray:
  _ Lumbar spondylolisthesis limited to the treated disc segment level, grade 1, no more than 3 mm;
- Age between 18 and 65;
- No response to non-surgical treatment for a period of at least six weeks, or symptoms or signs of progressive root compression despite conservative treatment.

IMPLANTS



PLATES SMALL 5°

HEIGHT	REFERENCES
H8	LDP-05 SM 08-S
H10	LDP-05 SM 10-S
H12	LDP-05 SM 12-S

PLATES SMALL 10°

HEIGHT	REFERENCES
H8	LDP-10 SM 08-S
H10	LDP-10 SM 10-S
H12	LDP-10 SM 12-S

PLATES MEDIUM 5°

HEIGHT	REFERENCES
H8	LDP-05 ME 08-S
H10	LDP-05 ME 10-S
H12	LDP-05 ME 12-S

PLATES MEDIUM 10°

HEIGHT	REFERENCES
H8	LDP-10 ME 08-S
H10	LDP-10 ME 10-S
H12	LDP-10 ME 12-S

PLATES LARGE 5°

HEIGHT	REFERENCES
H8	LDP-05 LA 08-S
H10	LDP-05 LA 10-S
H12	LDP-05 LA 12-S

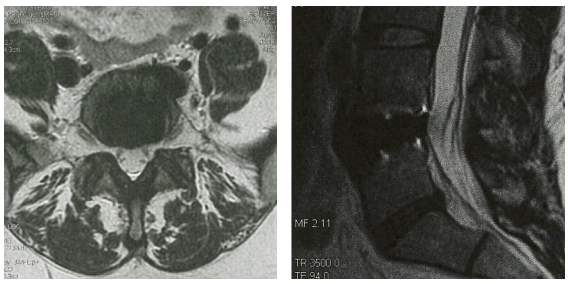
PLATES LARGE 10°

HEIGHT	REFERENCES
H8	LDP-10 LA 08-S
H10	LDP-10 LA 10-S
H12	LDP-10 LA 12-S

NUCLEUS	REFERENCE
FIXED PE INLAY	LDP-PE CO 00-S
MOBILE PE INLAY	LDP-PE SC 00-S

TECHNICAL FEATURES

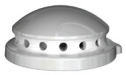
LIMITED MRI ARTIFACT



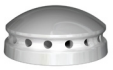
The titanium plates, coated with Diamond-Like-Carbon (DLC) reduce artifacts under MRI for a better postoperative control.

MOBILE OR FIXED PE INLAY

FIXED PE INLAY



MOBILE PE INLAY

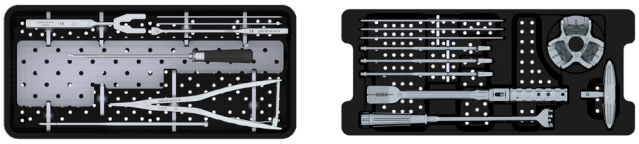


The BAGUERA® L concept allows the surgeon to choose the mobility of the nucleus intraoperatively, without changing the superior or inferior plates. The movement of the nucleus is restricted in respect to rotation movements.

PRIMARY STABILITY

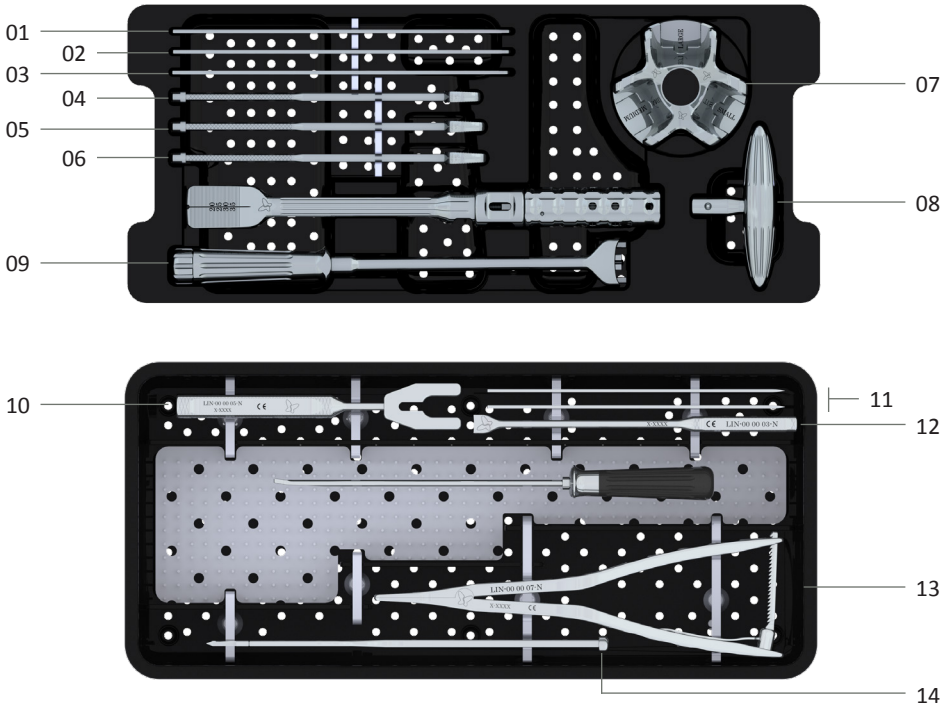
The porous titanium coating as well as the 5 upper and 5 lower fins, are designed for primary and secondary stability.

USER FRIENDLY INSERTION



The BAGUERA® L set is composed of one box of specific and intuitive instruments for easy insertion.

INSTRUMENT SET



#	DESCRIPTION	REFERENCE
01	SPACER H12	LIN-00 SP 12-N
02	SPACER H10	LIN-00 SP 10-N
03	SPACER H08	LIN-00 SP 08-N
04	TRIAL IMPLANT SM 35X27	LIN-00 SM TR-N
05	TRIAL IMPLANT ME 39X30	LIN-00 ME TR-N
06	TRIAL IMPLANT LA 42X31	LIN-00 LA TR-N
07	ASSEMBLY BASE	LIN-00 00 04-N
08	INTERSOMATIC DISTRACTOR	LIN-00 00 02-N
09	IMPLANT HOLDER	LIN-00 00 01-N
10	EXTRACTION MALLET	LIN-00 00 05-N
11	CHISEL (X2)	LIN-00 00 06-N
12	PUSHER	LIN-00 00 03-N
13	SPREADER	LIN-00 00 07-N
14	FORK	LIN-00 22 08-N
	INSTRUMENTS CONTAINER	LIN-BX 10 01-N
●	CURETTE	DYN-IP 00 06-N

● : OPTIONAL

INSTRUMENTS

INTERSOMATIC DISTRACTOR	LIN-00 00 02-N

ASSEMBLY BASE	LIN-00 00 04-N

SPACER H12 SPACER H10 SPACER H08	LIN-00 SP 12-N LIN-00 SP 10-N LIN-00 SP 08-N

TRIAL IMPLANTS	LIN-00 SM TR-N LIN-00 ME TR-N LIN-00 LA TR-N

SPREADER	LIN-00 00 07-N

CHISEL	LIN-00 00 06-N

EXTRACTION MALLET	LIN-00 00 05-N

FORK	LIN-00 22 08-N

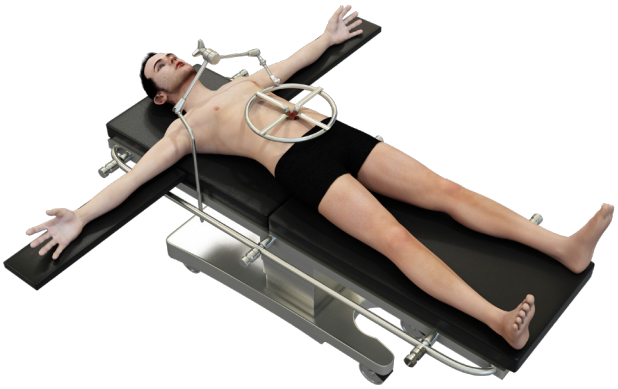
PUSHER	LIN-00 00 03-N

IMPLANT HOLDER	LIN-00 00 01-N

CURETTE (OPTION)	DYN-IP 00 06-N

SURGICAL TECHNIQUE

_STEP 1



PATIENT POSITIONING AND EXPOSURE

For an anterior approach of the lower lumbar levels, place the patient supine in a slight Trendelenburg position, per surgeon preference.

Locate the operative disc level and incision location via lateral fluoroscopy.

Through a standard retroperitoneal approach, dissect and retract the soft tissue to reach the operative disc level.

Cut an appropriately sized window through the anterior longitudinal ligament and the annulus fibrosus, to access the target disc space.

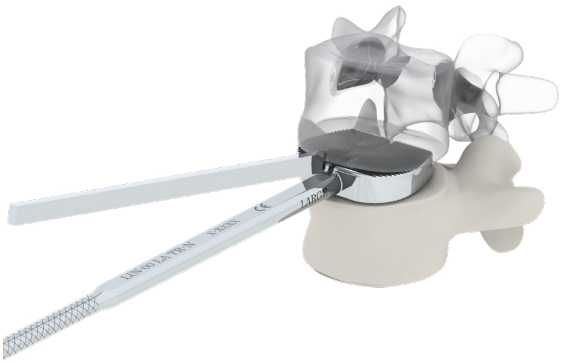
_STEP 2

DISCECTOMY

After having carried out the anterior approach, start discectomy in order to position the distractor. Use the **spreader** to facilitate the discectomy.

INSTRUMENT	REFERENCE
SPREADER	LIN-00 00 07-N

_STEP 3



SELECTION OF THE IMPLANT FOOTPRINT

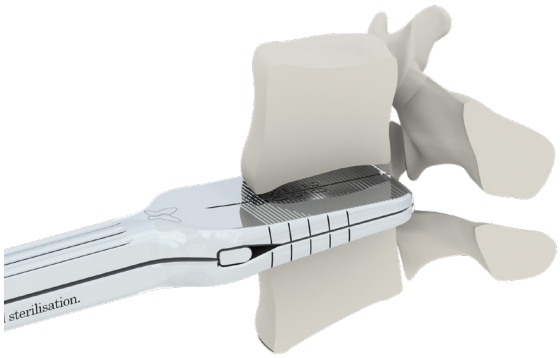
Choose a **trial implant** (small, medium, large), insert it into the disc space.

Carry out an AP and lateral fluoroscopic image control and mark the vertebral body with the **chisel** when the trial implant is positioned in the center.

Take out the trial implant.

INSTRUMENT	REFERENCE
TRIAL IMPLANTS	LIN-00 SM TR-N LIN-00 ME TR-N LIN-00 LA TR-N
CHISEL	LIN-00 00 06-N

_STEP 4



SELECTION OF THE IMPLANT HEIGHT

Position the **intersomatic distractor** until the posterior vertebral body wall has been reached.

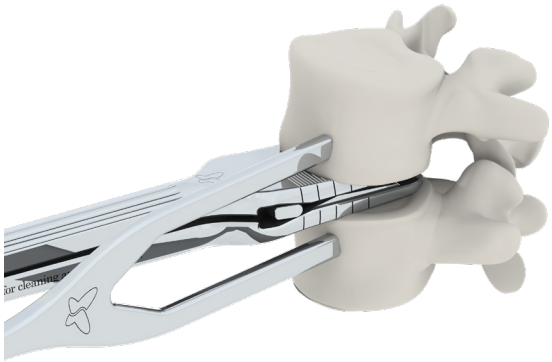
Control the intersomatic distractor position via lateral fluoroscopic images.

Open the intersomatic space progressively and verify the stability until it is sufficient.

Choose the appropriate height of the prosthesis by reading the markings. It is not recommended to overdistract.

INSTRUMENT	REFERENCE
INTERSOMATIC DISTRACTOR	LIN-00 00 02-N

_STEP 5



INTERSOMATIC DISTRACTION

While appropriate distraction is made with intersomatic distractor, impact the fork in the upper and lower vertebral bodies. The fork will maintain distraction while taking out the **intersomatic distractor**.

NOTE: Alternatively the **spacer** can be used. The **spacer** does not serve as a distractor.

INSTRUMENT	REFERENCE
FORK	LIN-00 22 08-N
SPACERS	LIN-00 SP 08-N
	LIN-00 SP 10-N
	LIN-00 SP 12-N

SURGICAL TECHNIQUE

_STEP 6

PROSTHESIS INSERTION

Choose for the fixed or mobile PE (Polyethylene) inlay and the endplate angulation. Attach the prosthesis onto the **implant holder** by using the **assembly base**.

Insert the prosthesis in central position following the mark made by the chisel on vertebral body, while carrying out a lateral control.

Take out the **fork**.

Disconnect the **implant holder**.

Carry out AP and lateral fluoroscopic image control.

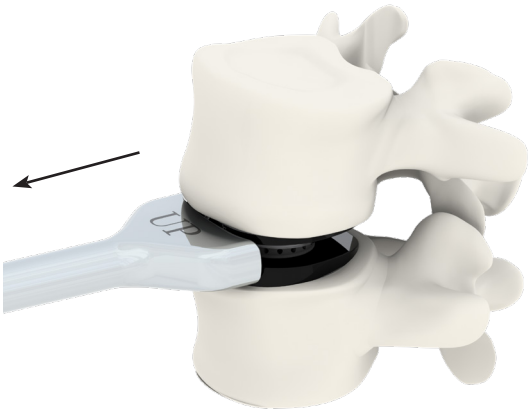
Adjust the position of the prosthesis with the **pusher** if necessary.

INSTRUMENT	REFERENCE
ASSEMBLY BASE	LIN-00 00 04-N
IMPLANT HOLDER	LIN-00 00 01-N
FORK	LIN-00 22 08-N
PUSHER	LIN-00 00 03-N

SURGICAL TECHNIQUE

_FINAL CONSTRUCT

_REVISION



IMPLANT REMOVAL

Use a thin osteotome, loosen the inferior and superior bone-to-implant interface.

Connect **implant holder** to the prosthesis. Gently pull the prosthesis out of the intervertebral space.

In addition, the **extraction mallet** can be used with the **implant holder** to help in removing the prosthesis.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	LIN-00 00 01-N
EXTRACTION MALLET	LIN-00 00 05-N

GENERAL INFORMATION

REFERENCE OF THE IFU	BAG-IF BL 01-E	REVISION OF THE FINAL IFU	NOV-2019

_STERILITY

The implants are delivered sterile.

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the implant mustn't be used.

Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The implant must be discarded. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. Such re-use may also result in infection in the patient.

The re-sterilization of the gamma sterilized implant is forbidden.

_DESCRIPTION

The BAGUERA®L implant range was designed to ensure the best possible adaptation to patient's anatomic variations.

The BAGUERA®L disc prosthesis is intended as a replacement for a degenerated lumbar disc.

_INDICATIONS

The BAGUERA®L is a prosthesis intended as a replacement for a lumbar intervertebral disc. Patient suffering from symptomatic lumbar disc disease (SLDD) affecting one vertebral level between L3 and S1, as defined by the following signs:

- Lower back pain or lumbar radicular pain (sciatica);
- Functional and/or neurological deficit accompanied by at least one of the following conditions confirmed by MRI or X-Ray:
  - Lumbar spondylolisthesis limited to the treated disc segment level, grade 1, no more than 3 mm;
- Age between 18 and 65;
- No response to non-surgical treatment for a period of at least six weeks, or symptoms or signs of progressive root compression despite conservative treatment.

_CONTRAINDICATIONS

- Psychologically incompatible patient.
- Facet ankylosis or facet joint degeneration.
- Preoperative remaining disc height < 3mm.
- Active infection, systemic or local.
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year).
- Myelopathy.
- Spinal stenosis.
- Spinal deformity such as scoliosis.
- Isolated radicular compression syndromes, especially due to disc herniation.
- Bone destruction or poor bone quality that could compromise implant stability.
- Osteopenia or osteoporosis defined as DEXA bone density measured T-score < -1.0.
- Severe muscular, neurological, or vascular deficiency in the concerned spine area.
- Heavy and or repetitive stress related to an intense physical activity.
- Tumor in the implantation area.
- Known allergy to implants materials (Pure titanium, titanium alloy, pure carbon or polyethylene).
- Pregnancy.
- Rheumatoid arthritis or other autoimmune disease, bony lumbar spinal stenosis.
- Active malignancy: patient with history of any invasive malignancy.
- Uncontrolled obesity and morbid obesity. (Body Mass Index above 40).
- Complex surgery antecedents, or secondary complications, abdominal and retroperitoneal and particularly any peritonitis antecedent.
- Spondylolisthesis greater than Grade 1
- Pars defect.

_SIDE EFFECTS

Per operative:
Haemostatic problems, injuries to the nervous system resulting in temporary or permanent weakness, pain, or functional handicap, and fractures.

Post operative:
Venous thrombosis and pulmonary embolism, infection, cardiovascular disorders, retrograde ejaculation, hematoma, late cicatrisation, and adjacent degenerative disc disease.

Specific to implant:
Implant migration, subsidence, adhesion and fibrosis, limited range of movement, secondary fractures.

Potential risk identified with the use of this arthroplasty device, which may require additional surgery, include: device component fracture, loss of fixation, fracture of the vertebra, neurological injury, and vascular or visceral injury.

GENERAL INFORMATION

_WARNINGS

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform this procedure.

Every surgeon who uses these implants must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case. Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient. An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of inadequate size, and patient hyperactivity or misuse will increase the risk of complications, including wear and tear or rupture. The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support the implant, thus causing instability and/or malformation. The benefits of this lumbar arthroplasty procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures.

Abnormal use of the device may lead to risks of serious injury and/or health deterioration of the patient.

The vascular anatomy in the vicinity of the treatment level shall be evaluated pre-operatively, in particular for the treatment of the L3-L4 level as anomalies may be encountered and exposing the patient to serious risks of injury.

It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.

The BAGUERA®L Implant must only be used with the BAGUERA®L instruments.

_MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that Baguera total disc replacement devices (Baguera C and Baguera L) are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 4,000 G/cm (40.0 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of:
  - 2.0 W/kg (Normal Level Controlled Operating Mode)at 1.5 T and 3 T.

RF Heating

Under the scan conditions defined above, Baguera total disc replacement devices (Baguera C and Baguera L) are expected to produce a maximum temperature rise of less than 4.0 ºC after 15 minutes of continuous scanning.

Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 3.8 cm from Baguera total disc replacement devices (Baguera C and Baguera L) when imaged with a gradient-echo pulse sequence in a 3 T MRI system.

_SURGERY METHODS

The surgeon is responsible for familiarizing him/herself with the surgical technique used for implanting these devices, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful procedure. The metal templates provided can be used to assess disc space and help in making this selection.

We strongly recommend that excessive force should not be applied when installing any of the BAGUERA®L implants.

The surgical procedure is standard for experienced surgeons. Your local representative should have communicated the handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly Spineart®.

_HANDLING PRECAUTIONS

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing each implant.

Implants are mechanical devices that can be worn, damaged or broken.

When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device. Sharp-edged, serrated or toothed instruments should not be used.

Surgeons are advised not to remove the device from its sterile packaging until after the implant site has been properly prepared and precise measurements have been taken.

GENERAL INFORMATION

_STORAGE CONDITIONS

It is mandatory that the implants are stored in their original packaging, in a clean, dry location where atmospheric pressure is moderate.

_INSTRUMENTATION

The instruments were specifically designed for use when installing the BAGUERA®L implant.

They are delivered non-sterile.

Specific markings are engraved on each instrument to facilitate identification of the corresponding implant size.

_ DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below.

Prior to starting the surgical procedure, all non sterile reusable instruments must be properly cleaned, decontaminated and sterilized.

The BAGUERA®L instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments..

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled will be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 2 minutes using soft-bristled brush at room temperature (+15/+25°C).
- Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts will be activated during rinsing.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

Automatic disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 30 seconds, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled will be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 30 seconds. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts will be activated during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Water	<45°	2 minutes
Cleaning	Water + Neutral enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Water	<45°	2 minutes
Rinsing	Tap water	<45°	2 minutes
Thermal disinfection	Reversed osmosis water	90°C	5 minutes

GENERAL INFORMATION

_STERILIZATION TRAYS CLEANING AND DISINFECTION

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

• Subsequent sterilization in containers is recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10-6.The validation for sterilization have been done according to overkill/half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report.

_STERILIZATION PARAMETERS

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave)

Cycle 1 (EU):

- Exposure time: 18 minutes
- Temperature: 134°C
- Drying time: 30 minutes

Cycle 2 (USA):

- Exposure time: 4 minutes
- Temperature: 132°C
- Drying time: 30 minutes
- “Do not stack trays during sterilization”

_MAINTENANCE AND REPAIR

Spineart® instruments are guaranteed for at least 150 steam sterilization runs.

Spineart® instruments that need to be repaired must be decontaminated and cleaned, then sent to the address mentioned in this document.

_FURTHER INFORMATION

If further directions for use of this system are needed, please check with the Spineart® Customer Service. If further information is needed or required, please see the addresses on this document.

GENERAL INFORMATION

PRODUCT TYPE	NOTIFIED BODY CE N°	MANUFACTURER
Implants	CE 1984	SPINEART SA CHEMIN DU PRÉ-FLEURI 3 1228 PLAN-LES-OUATES SWITZERLAND
Surgical Reusable Instruments	CE 0123	
Instruments box/trays/containers	CE	
Surgical Instruments intended to select correct implant size	CE 1984	
FOR ADDITIONAL INFORMATION REGARDING REGULATORY STRATEGY OF SPINEART PRODUCTS, PLEASE CONTACT SPINEART AT REGULATORY@SPINEART.COM		

S P I N E A R T

SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

SEP-2021-REF-BAG-LU-ST-EN