BatSpine

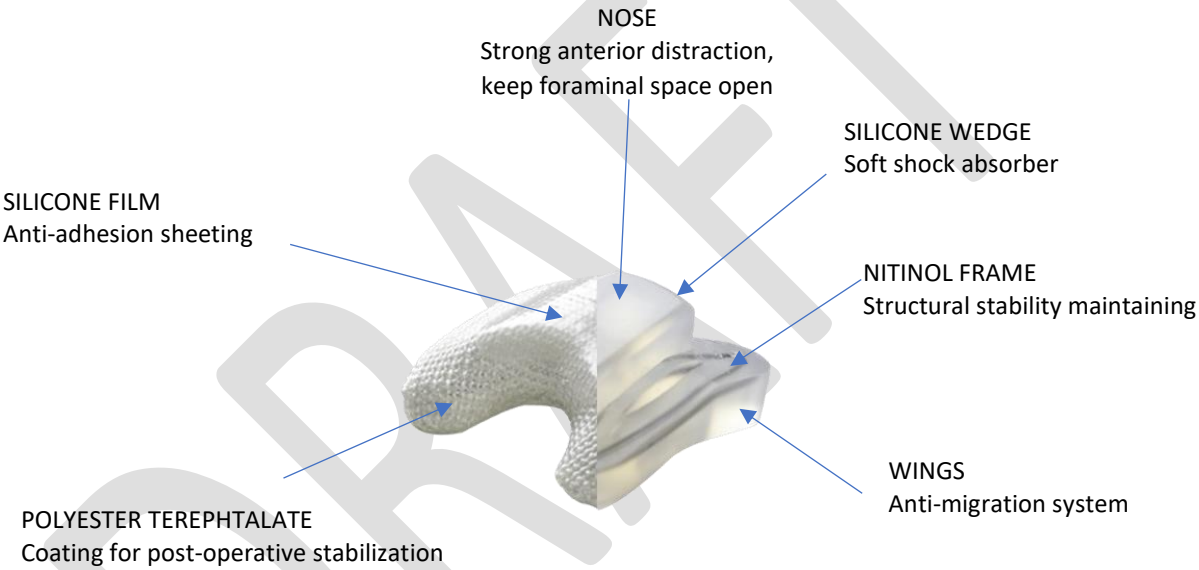
STERILE MINI-INVASIVE DEVICE FOR THE INTER-SPINOUS SPACE WITH LAMINAR SUPPORT

PRODUCT DESCRIPTION

The BatSPINE prosthesis is an interlaminar medical device that comprises a silicone wedge (available in several sizes) with a nitinol frame adapted to the intervertebral space.
The wedge is covered with woven polyethylene terephthalate with an area covered by a dimethyl siloxane (silicone) sheeting on the anterior part in the **medullary zone**.

Its interlaminar implantation enables it to be closer to the center of rotation, thus ensuring tension on the interspinous ligament structure. The cushioning effect is made possible thanks to the elasticity of the silicone-made wedge.

The BatSPINE product is designed to ensure compatibility with minimally invasive surgery through tubular insertion, endoscopy or open surgery.



INDICATIONS / CONTRAINDICATIONS

Indications

BatSPINE is an **intervertebral posterior device** with laminar support prosthesis for discal and/or facet assistance indicated for use from L1-S1 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of nonoperative treatment and indicated for use in:

- Arthropathic facet-syndrome
- Foraminal stenosis
- Degenerative discopathy

Contraindications

1) Do not use the prosthesis in the following cases:
- Allergy to one of the components
- Growing child
- Infected site
- Pregnant woman

2) Factors likely to compromise successful implantation:
- Severe osteoporosis
- Major deformations of the spinal column
- Local bone tumors
- Systemic or metabolic disorders
- Infectious diseases
- Obesity
- Drug addictions
- Surgery at more than 2 levels with BatSPINE prosthesis
- Spondylolisthesis from grade 2 to 4
- Intervertebral disc with Pfirmann classification from grade V
- S1 spinous process length inferior to 18 mm when implanted in L5/S1

BatSPINE IMPLANT

Size of BatSPINE	Reference*
8 mm	RCBBATS08U
10 mm	RCBBATS10U
12 mm	RCBBATS12U
14 mm	RCBBATS14U
16 mm	RCBBATS16U

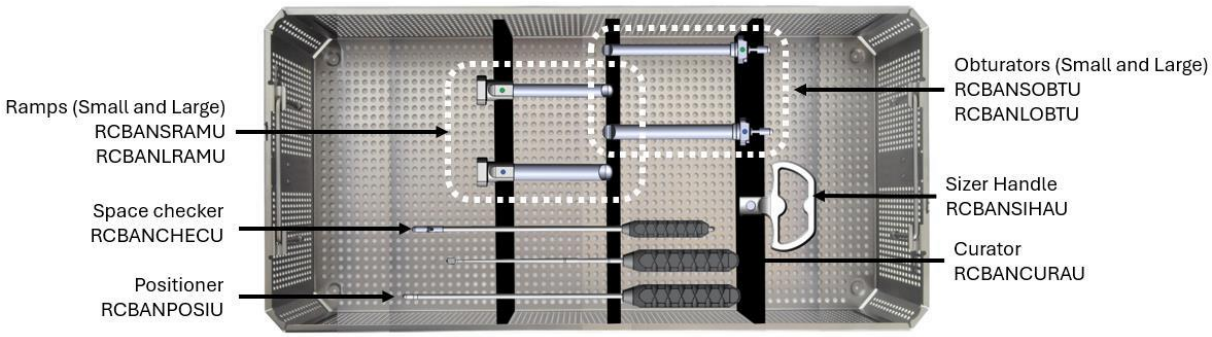
*Implant size is defined by its nose height

BatSPINE INSTRUMENT SYSTEM

The Non-sterile instruments for BatSPINE are divided into 3 instruments systems comprising :

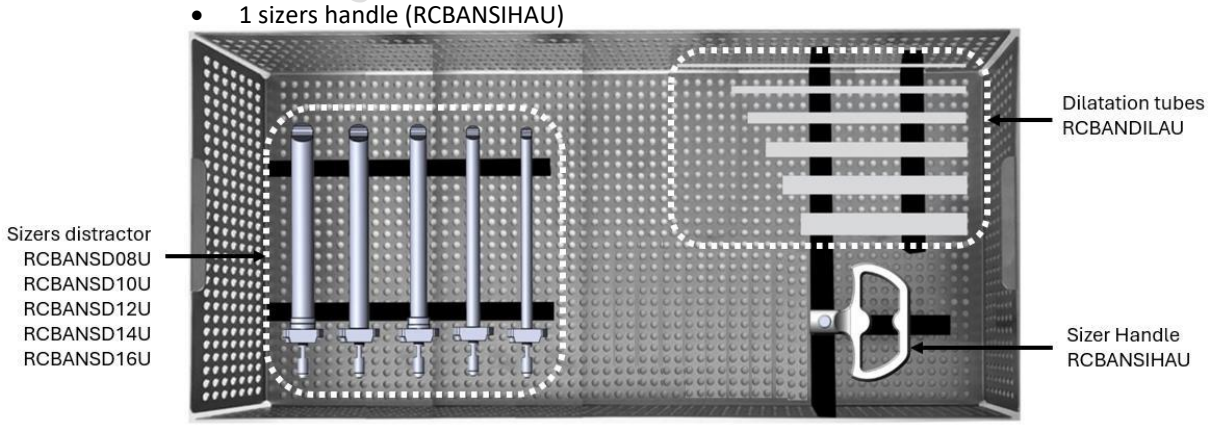
1. Instrument system RCBANBKITU with 2 floors consisting of:
    - 1 Instrument tray with 2 floors (RCBANBCONU)

      1st floor:
    - 1 Positioner (RCBANPOSIU)
    - 1 Spinous curator (RCBANCURAU)
    - 1 Small and 1 large distracting ramp (RCBANSRAMU/ RCBANLRAMU)
    - 1 Small and 1 large obturators (RCBANSOBTU / RCBANLOBTU)
    - 1 Space checker (RCBANCHECU)
    - 1 sizers handle (RCBANSIHAU)



2nd floor:

- 5 dilatation tubes for MIS (RCBANDILAU) – from 2 to 18 mm
- 5 Sizers distractor 8, 10, 12, 14, 16 mm (RCBANSD08U / RCBANSD10U / RCBANSD12U / RCBANSD14U / RCBANSD16U)
- 1 sizers handle (RCBANSIHAU)



2. Compressor system RCBANKCOMU consisting of:
    - 1 Small and 1 large vehicles (RCBANSIMVU / RCBANLIMVU)
    - 1 Gun (RCBANBGUNU)
    - 1 Compression system (RCBANBCOMU)
    - 2 Small (1 up RCBANSUINU and 1 low RCBANSLINU) and 2 large inlays (1 up RCBANLUINU and 1 low RCBANLLINU)
    - 1 Compressor tray (RCBANECOMU)
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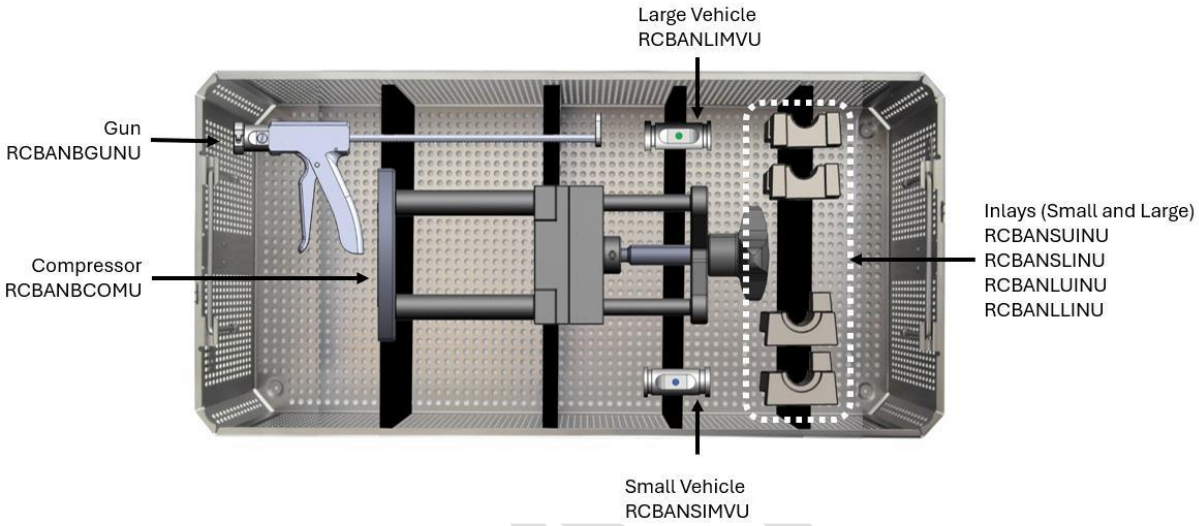
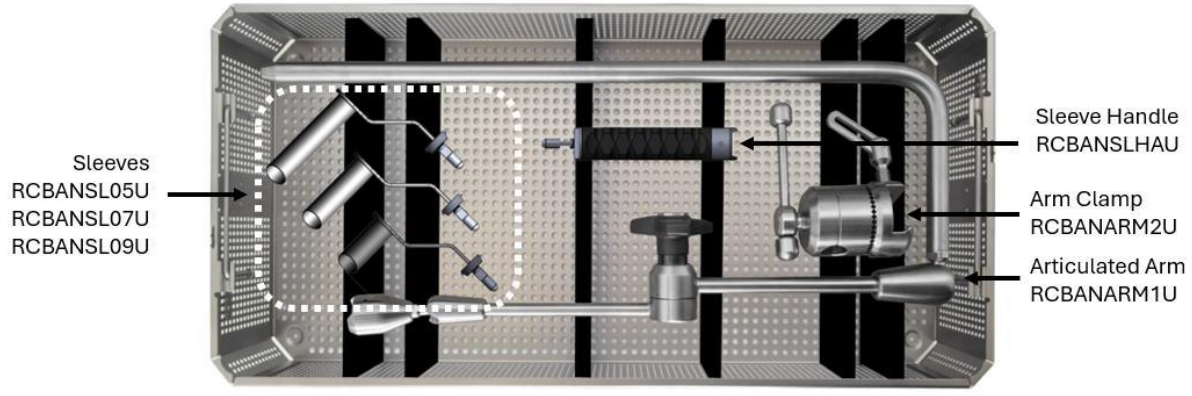


3. Holding system RCBANKARMU consisting of:
    - 1 Articulated arm for MIS (RCBANARM1U)
    - 1 Clamp for articulated arm MIS (RCBANARM2U)
    - 1 Generic sleeve 50 mm (RCBANSL05U)
    - 1 Generic sleeve 70 mm (RCBANSL07U)
    - 1 Generic sleeve 90 mm (RCBANSL09U)
    - 1 Generic sleeve handle (RCBANSLHAU)
    - 1 Holding tray (RCBANEBAAU)



BatSPINE IMPLANTATION PROCEDURE

MINI-INVASIVE MONOLATERAL SURGICAL TECHNIQUE

STEP 1. POSITIONING OF THE PATIENT

The patient is placed in the prone knee position under general or local anesthesia or in prone position (table allowing to put patient in a lumbar kyphosis).

STEP 2. APPROACH

Alternative percutaneous or endoscopic approaches for decompression are possible.

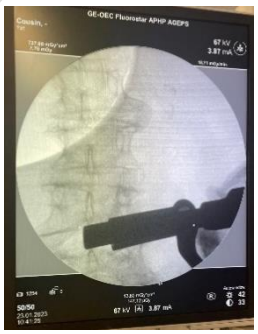
After X-Ray monitoring of the affected level, perform a paravertebral incision of about 2.5 cm length at 2.5 cm away from the midline on the side of the prevalent symptoms.

After performing a small incision of the fascia, insert the dilatation tube (from the smallest) and generic sleeve (around tubes) through the skin and soft tissues down to the spinal column. The dilatation tubes maintain muscles open and preserve it without any muscle dissection throughout the procedure.

3 sizes of generic sleeves are available, use it under surgeon decision (length 50, 70 and 90 mm)

The generic sleeve can be either attached directly to the articulated arm or connected to the handle and the handle to the articulated arm.

On a X-Ray control, the sleeve should be perpendicular to the spine.



STEP 3. PREPARATION

Position the sleeve between 40 to 50° from the midline under surgeon decision.
With the Kerrison rongeur clean the interspinous and interlaminar spaces to create room for BatSPINE device.
Then, with the curator, finalize the cleaning and **make sure the contra-lateral side is sufficiently prepared** to position BatSPINE correctly, insert the space checker straight into the tube.
Once positioned on the contra-lateral side, check the space created is cleaned enough by rotating the tip in the cranial and caudal direction.

Clean the interspinous and interlaminar space with the Kerrison rongeur while preserving as much as possible the interspinous ligament to improve the implant maintaining.

Make sure the contra-lateral side is sufficiently prepared to position BatSPINE correctly, insert the space checker straight into the tube.

The space checker must reach the facet on contra-lateral. The head of the space checker corresponds to the size of half a wing of the BatSPINE biggest size.

STEP 4. DISTRACTION OF THE INTERVERTEBRAL SPACE & CHOICE OF IMPLANT SIZE

The interlaminar space must be distracted gradually by inserting the distractor-sizers size by size (starting with the smallest size). The distraction is performed with a rotation movement of the distractor sizers.

First connect the distractor-sizer to its handle, then the distractor-sizer is inserted into the sleeve, following the color spots, with the handle in a horizontal position up to the interlaminar space. Finally rotate the quarter turn the instrument to position the handle vertically and creating distraction.

Perform X-Ray control to check that the distractor-sizer is in the interlaminar space before the rotation of the distractor-sizer.

Pay attention to the orientation of the handle, after the quarter turn, the size of the distractor should be visible on the handle (see picture below).

The appropriate size of the implant is determined by measuring the interlaminar space with the distractor-sizer. The size of the distractor-sizer is indicated on the handle.

5 sizes are available: 08 / 10 / 12 / 14 /16 matching the implant's size.

The distal end width of the distractor-sizer corresponds to the size of the BatSPINE's nose. After the rotation movement the tip of the distractor-sizers is position between the two laminae.

The "nose" of the prosthesis must be compressed between the two laminae: if the distance measured is between two trial devices sizes, it's necessary to choose the biggest size to ensure this compression. If an extensive laminae resection is performed the prothesis can't be implanted.

STEP 5. IMPLANTATION

Once the size of the prosthesis has been chosen, insert the ramp-distractor between the laminae to perform a larger distraction to facilitate the prosthesis positioning.

2 sizes of ramp are available:

Small ramp (yellow color spot) for the BatSPINE 8 / 10 mm

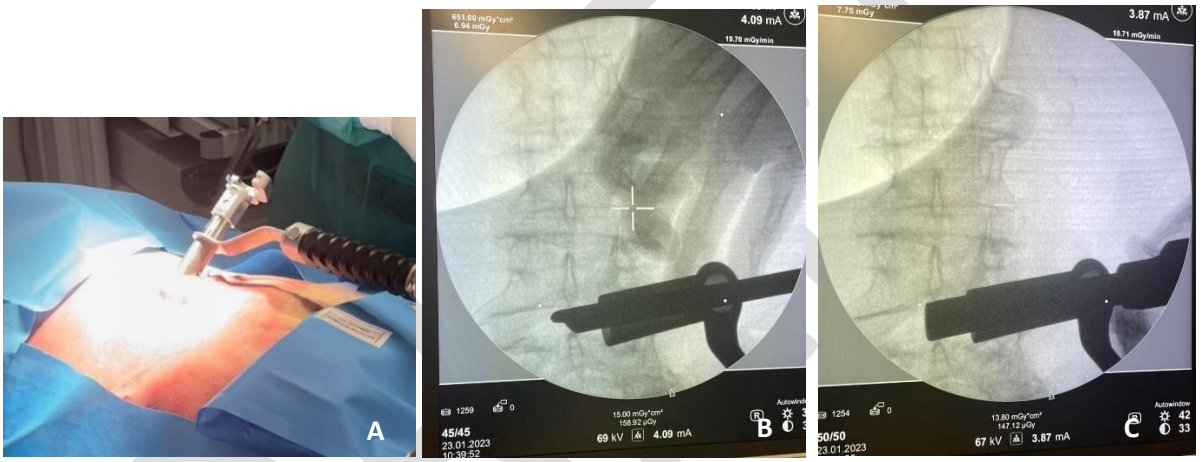
Large ramp (green color spot) for the BatSPINE 12 / 14 / 16 mm

To prevent the penetration of anatomical structures (muscles) into the ramp, the ramp channel is obstructed by the obturator.

While connecting the obturator to the ramp, you must hear an audible click after locking. This click means that the connection is secured in the appropriate position.

The ramp can be positioned through the sleeve or alone, depending on the surgeon's decision. The ramp is inserted with an angulation between 30 and 60° in the interlaminar space. As previously described, a X-ray is performed to check the position of the ramp, then make a quarter turn (the size is then visible on the handle).

The ramp is inserted into the sleeve with the handle in a horizontal position up to the interlaminar space slightly on contra-lateral site (otherwise there is a risk that the device will deploy on the wrong side). Finally rotate the quarter turn the instrument to position the handle vertically and creating distraction.



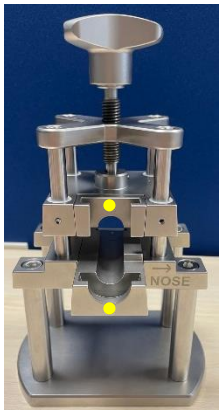
Legend photo : angulation 30- 60°(A) ; insertion slightly on contra-lateral site (B) / after rotation (C)

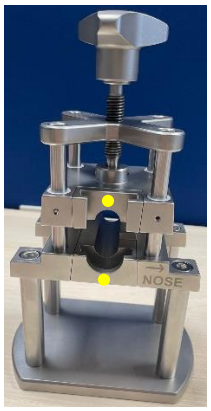
After positioning of the ramp, the distractor-sizer is removed to free up the working channel.

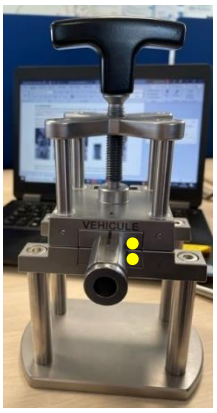
6A. COMPRESSION

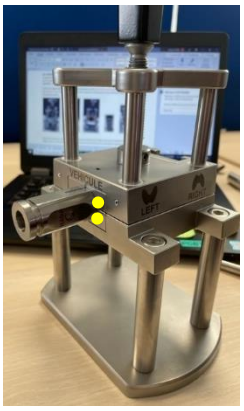
Compression of the prosthesis into the compressor within the inlays. Inlays are available in 2 sizes small (yellow) and large (green). The small inlays are dedicated for the BatSPINE 8 / 10 mm and the large inlays for BatSPINE 12 / 14 / 16 mm.

Insert the upper and lower inlays into the compressor and connect the small (yellow) or large (green) vehicle, depending on the implant size chosen, to the compressor following the laser marking indications and the color spots as describe on the picture below.

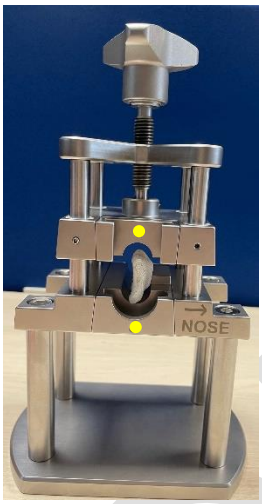


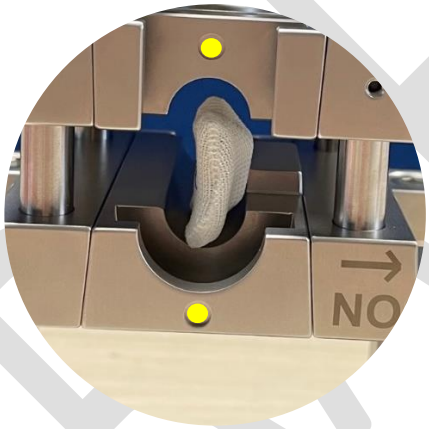






Insert the prosthesis vertically into the compressor between the inlays, the nose is oriented on the side of the NOSE arrow as in the picture below. Then compress the prosthesis by screwing the compressor handle.





Pay attention to the positioning of the prosthesis into the compressor according to the approach side from the left or the right (see picture)

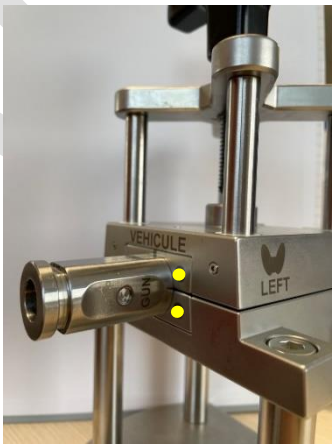
Position the caudal wings up for left approach and the caudal wings down for right approach as indicated on the compressor.

Pay attention the device is positioned straight between the 2 inlays and not falls to ensure correct compression inside the cylindrical hole.

6B. PREPARATION OF IMPLANTATION SYSTEM

To insert the folded prosthesis into the vehicle, connect the gun to the compressor following “GUN” laser marking indication.

Then engage the gun several times until you reach the first black mark (loading indication) on the ratchet mechanism, this means that the folded prosthesis is inserted into the vehicle.



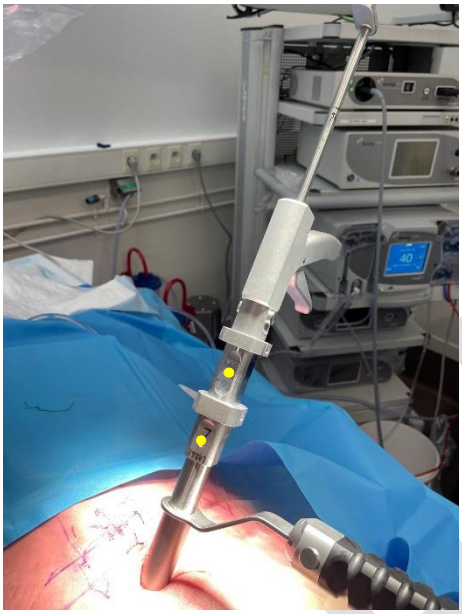
Disconnect the vehicle and the gun from the compressor then connect the vehicle, containing the folded prosthesis, to the gun with the locking system. The vehicle color spot, green or yellow depending on the size chosen, needs to be positioned upward.

Before clicking it, unlock the ratchet system by pulling it back and making half a turn with its tip

The vehicle needs to be connected to the gun with respect to the laser marking indications.

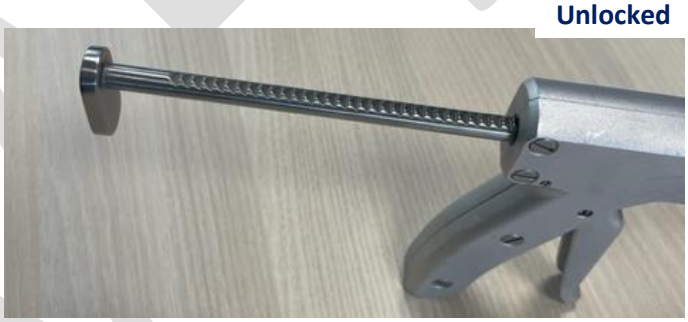
6C. IMPLANTATION

Then connect the system vehicle/gun to the ramp, previously positioned in the interlaminar space, by the same locking system and click it. The colored spots on the vehicle/gun and the ramp ensure correct sizing and positioning.



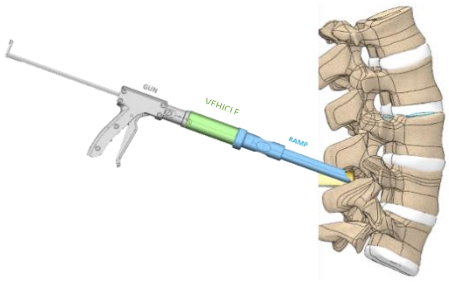
Locked

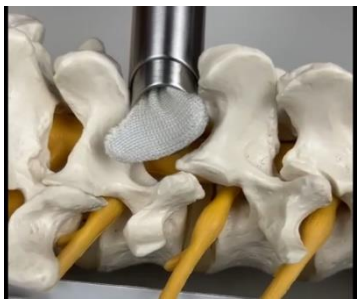
Unlocked



Before clicking it, lock the ratchet system by making half a turn with its tip.

Assembled in this manner, the system ramp/ vehicle / gun is now ready for the BatSPINE implantation. pull the gun trigger up to the second laser marking indication on the ratchet mechanism "implantation", to push the device up to the extremity of the ramp. At this moment, the device is still inside the ramp. Check the correct positioning of the ramp distal end along the midline to be sure the implant will be deployed on the contralateral side. Then, while slowly continuing to push the device out of the ramp with the ratchet mechanism of the gun, perform X-Ray monitoring to check that the first wing comes out on the contra-lateral side. Once the first wing is completely deployed, continue to push the device while slowly releasing the gun to deploy the second wing on the ipsilateral side. Perform X-Ray monitoring to check the device is correctly positioned between vertebrae.



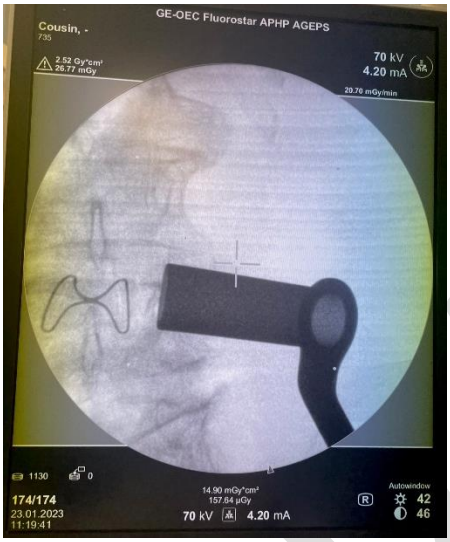


Check the correct positioning of the ramp distal end along the midline to be sure the implant will be deployed on the contralateral side.

When you release the prosthesis, the first wing comes out on the contra-lateral side, then you feel a backward movement. Let yourself be guided by this movement to release the second wing.

Remove the distracting ramp with a quarter turn movement, check the position of the prosthesis by X-Ray.

And use the positioner to finalize positioning of the prosthesis in the interlaminar space.



After X-Ray monitoring, finalization of the BatSPINE positioning using the positioner.

If the surgical table is tiltable, place the patient in lordosis to finally check the position of the prosthesis, if required you can re-use the positioner and do an X-ray.

After X-Ray monitoring, if the implant does not deploy correctly on contralateral side, then remove the ramp/vehicle/gun system and remove the implant through the sleeve using forceps. Restart the compression of the implant from step 6A.

STEP7. CLOSING

Remove the sleeve and suturing of the soft parts in layers.

STEP 8. POST-OPERATIVE CARE

According to the pathology, and to the surgeon's habit, the patient can stand-up 3 to 4 hours after surgery.

Brace according to the practice of the surgeon.

Advice to the patient:

- no flexion for 3 weeks

- in sitting position, it is necessary to maintain a good lumbar lordosis

Post-operative control of the prosthesis positioning one month after surgery.

In case of implant misplacement, proceed with the explantation procedure by removing the ramp-vehicle-gun system from the sleeve. Remove the BatSPINE using forceps.

EXPLANTATION PROCEDURE

1. Perform a midline incision on the implantation level.
2. Locate the implant and clean the fibrotic tissue to access the polyester cover.
3. Cut the polyester cover to expose the silicon part of the implant.
4. Using forceps, pull out the silicon part out of the patient.
5. Then grab the polyester cover and twist it while pulling it out. It will slowly be detached from the fibrotic tissue from the implantation site and the silicon sheeting on the anterior part avoid adherence with the spinal cord.

BatSPINE is a class III medical device manufactured by COUSIN BIOTECH S.A.S. The CE conformity has been carried out by the notified body KIWA (CE0476). The management system of COUSIN BIOTECH S.A.S is certified for compliance with ISO 13485 standard. Please read carefully the instructions for use before using the device. The IFU is available electronically at: https://www.cousin-biotech.com/en/implant-notices

Reference: FPRBAEGB01 - Version: 23/02/24

Cousin Biotech S.A.S capital : 340 656 € - 398 460 261 RCS Lille - N°TVA FR 34 398 460 261
Cousin Biotech is the legal manufacturer of the medical devices proposed by Cousin Surgery.