

LISA — Lumbar Implant for Stiffness Augmentation



SURGICAL
TECHNIQUE

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The **L**umbar **I**mplant for **S**tiffness **A**ugmentation (**LISA**) device is a posterior lumbar dynamic stabilization system designed to stabilize the treated level while preserving motion.

The LISA device consists of 3 components: A PEEK interspinous spacer, a polyester band and a titanium blocker. The spacer is positioned between two adjacent spinous processes, the band is belted around the spinous processes and through the spacer, and the blocker is used to lock the band inside the spacer.

INDICATIONS/CONTRAINDICATIONS

Indications

LISA Dynamic Stabilization System treats low-back pain that accompanies degenerative lesions of grade II, III and IV (Pfirmann MRI classification)

Contraindications

- Stage V degenerative lesions in Pfirmann's MRI classification.
- Spondylolisthesis.
- Osteoporosis.
- Non-specific common lower back pain.
- Modic 2 and Modic 3 changes.
- The implant is not indicated for the L5/S1 segment.
- Local or general infections that may compromise the surgical goals.
- Major local inflammations.
- Pregnancy.
- Immuno-depressive diseases.
- Bone immaturity.
- Severe mental illnesses.
- Bone metabolism diseases that may compromise the mechanical support expected from this type of implant.
- Excessive physical activities.

LISA INSTRUMENTATION



Trial Spacers (6, 8, 10 & 12)



Hook wide



Band forceps 1



**Implant holders
(6, 8, 10 & 12)**



Implant locker



Tensioner



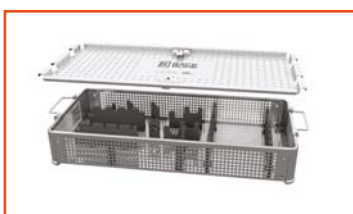
Torque limiting handle



Torque limiting connector



Gripper screwdriver

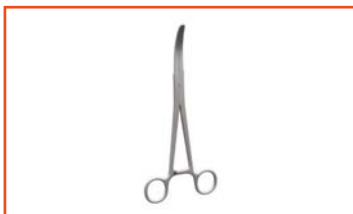


Instruments tray

OPTIONAL INSTRUMENTATION



Hook



Band forceps 2



Interlaminar Distractor

Surgical Technique

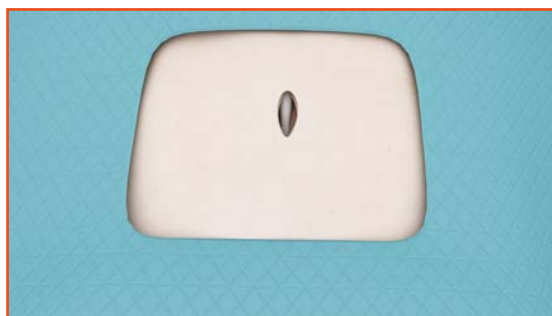
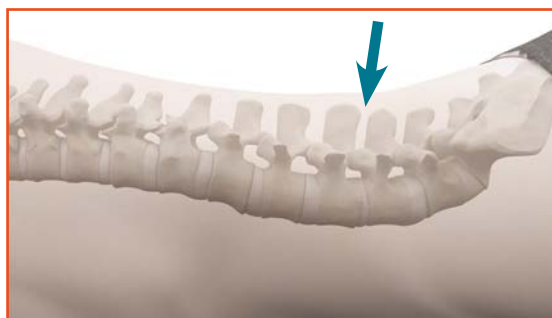
ONE LEVEL SURGERY

STEP 1. Exposure

The patient is placed in the prone position on a frame padding. A neutral position of the physiological lumbar lordosis is best to optimize the effect of the implant.



Carefully locate the segment requiring the implant with an image intensifier.



After making a midline incision, The supra spinous ligament is detached from the two spinous processes at the level involved and retracted laterally allowing direct posterior insertion of the **LISA** Implant.



After the initial incision, it is recommended to temporarily suture a small sterile surgical drape over the wound edge on both sides to prevent contact between the skin and the implant.

The interspinous ligament and any overgrowth of the spinous processes that may interfere with implant insertion is resected without damaging the supraspinous ligament.

The junction between the laminae and the spinous process is trimmed to ensure adequate surface contact between the spacer against the base of the spinous process.

The implant should be positioned as anterior as possible to support patient lordosis. This preparation is key to the final positioning in the interspinous space.

Depending on the indication a microsurgical decompression may be conducted.

Ligamentum Flavum is then resected and microsurgical decompression is performed relieving all points of neural compression.



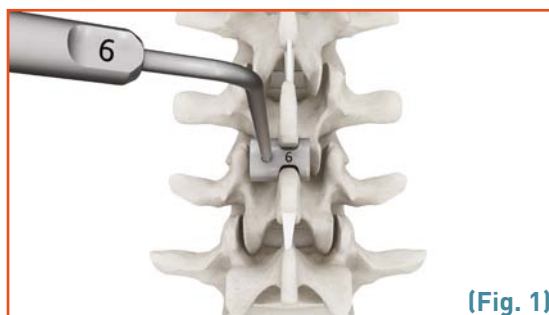
STEP 2. Choice of implant size

The adequate size of the implant is determined by placing different trial spacers between the spinous processes.

Starting with the smallest size of trial spacer (size 6), the surgeon places the instrument in the space **(Fig. 1)**.

To facilitate insertion of the trial spacer, an interlaminar distractor may be used. However, it should be removed before testing the stability of the trial spacer in the interspinous space.

Between two implant sizes, the surgeon should choose the smaller one to preserve the physiological lordosis.



WARNING: The interspinous space should NOT be greater after implant insertion.
DO NOT OVERDISTRACT THE INTERSPINOUS SPACE.

STEP 3. Connection of the implant with the implant holder and first passage of the band through the spacer outside the wound

The surgeon takes the chosen spacer in his hand. The implant is then introduced with «UP» marking upwards in the implant holder corresponding to its size (**Fig. 2**).



(Fig. 2)

The assembly is secured thanks to the implant locker that is inserted through the implant holder and screwed into the spacer (**Fig. 3 & 4**).



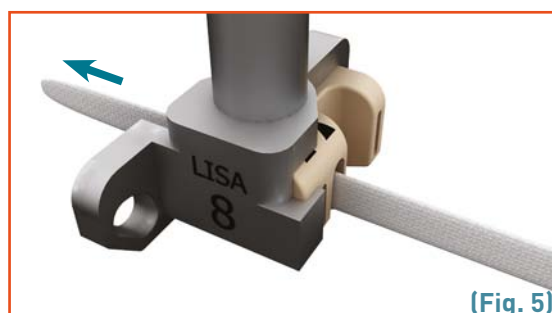
(Fig. 3)

The band is then threaded through the first slot of the **LISA** spacer until the stop (**Fig. 5**).



(Fig. 4)

The first slot is the largest one and is also marked with the number 1 and an arrow indicates the way of insertion.



(Fig. 5)

STEP 4. Passage of the band through the interspinous ligaments above the spacer

It is recommended to initially use the hook alone to make a pilot pathway through the interspinous ligament and behind the spinous process **as close as possible to the periosteal bone**. This instrument is then to be used to pass the band through the same pathway.

The distal part of the band is placed in the notch of the hook (Fig. 6) in order to push clockwise the band through the interspinous ligament and around the spinous process and **as close as possible to the periosteal bone** (Fig. 7).

When the band tip appears in the interspinous space, it may be gripped by the band forceps (Fig. 8). The insertion hook is then withdrawn and the band is pulled through the ligament.

One should make sure that the band lies flat against the spinous process without twists.

Please note that two optional instruments are available on demand and could be used during this step:

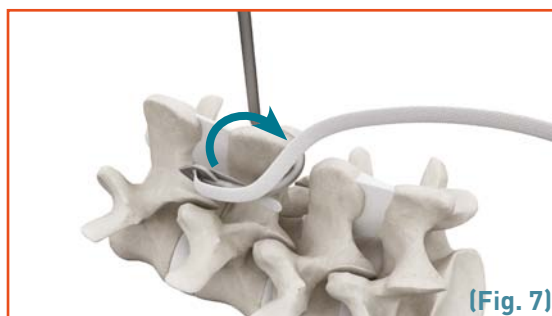
- A Hook with a smaller radius at its distal tip (BB-LISA-2-215)
 - An alternate Band Forceps (BB-LISA-2-214)
- (See picture on page 5)**



TIP: The band should be introduced from 1 to 5 cm onto the hook with the band extremity toward the hook curvature (see Fig. 9).



(Fig. 6)



(Fig. 7)



(Fig. 8)



(Fig. 9)



WARNING: For an optimal implant positioning the passage of the band must be carried out as close as possible to the basis of the spinous processes.

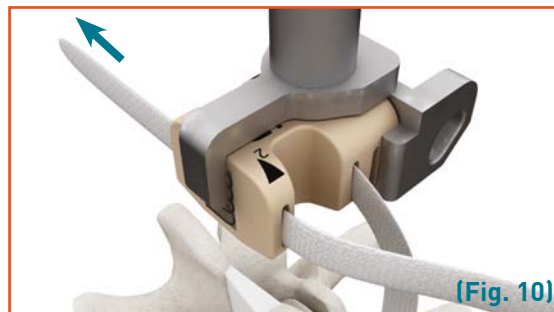
STEP 5. 2nd passage of the band through the spacer and through the interspinous ligament below the spacer

The band is introduced through the second slot of the LISA spacer (Fig. 10).

The second slot is marked with the number 2 and an arrow indicating the way of insertion.

The procedure is repeated as described in the **Step 4**, the surgeon passes the band around the second spinous process below with the hook (Fig. 11).

The surgeon should verify that the band is flat against the spinous processes without being twisted.



(Fig. 10)



(Fig. 11)



WARNING: For an optimal implant positioning the passage of the band must be carried out as close as possible to the basis of the spinous processes.

STEP 6. 3rd passage of the band through the spacer

The band is then introduced into the third slot of the LISA Spacer (Fig. 12 & 13).

The third slot is marked with the number 3 and an arrow indicating the way of insertion.

Finally, before the insertion of the implant into the interspinous space, the distal extremity of the band is introduced through the angle-plate slot of the implant holder (Fig. 14).



(Fig. 12)



(Fig. 13)



(Fig. 14)

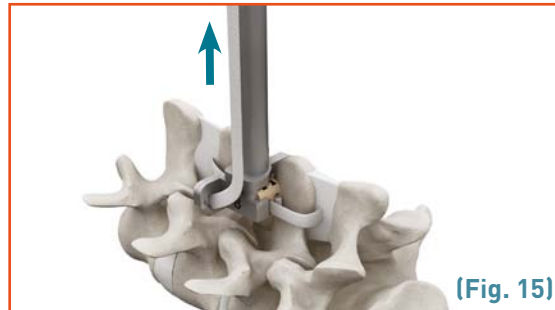
STEP 7. Insertion of the spacer between spinous and pre-tension of the band

The implant holder is introduced between the spinous processes and the implant is placed from the top between the two spinous processes (Fig. 15).

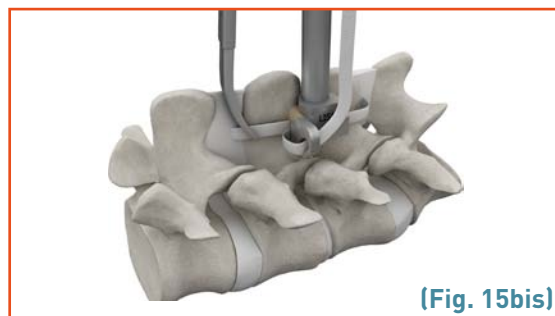
Simultaneously the band is pulled from bottom to top in order to obtain a primary tension. The band forceps should then be used to finalize this primary tension (Fig. 15bis).

This operation is performed by adjusting the tension along the path of the band from the proximal portion to its distal portion, and around the two spinous processes.

The optional instrument Interlaminar Distractor (BB-LISA-2-260) available on demand, may be used to retract the laminae before inserting the spacer between the spinous processes.



(Fig. 15)



(Fig. 15bis)

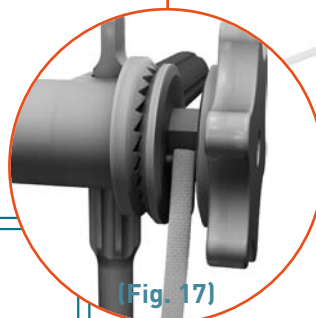


WARNING: Never force the implant into position by impaction. Use an interlaminar distractor, if necessary.

STEP 8. Tensioning the band

The tensioner is slid onto the implant holder (Fig. 16) and the distal end of the band is inserted between the pin and the flat part of the tension wheel (Fig. 17).

Then, by turning the wheel clockwise the band is put on tension (Fig. 18).



(Fig. 17)



(Fig. 16)



(Fig. 18)



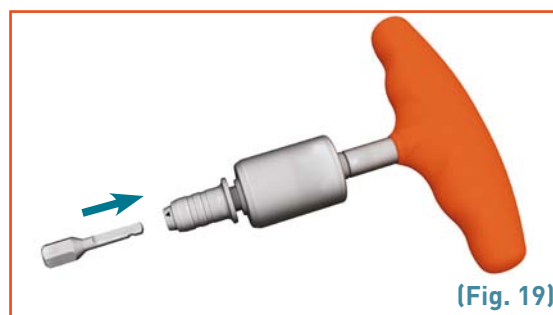
TIP: In order to achieve optimum band tension during this step, the tensioner handle should be held parallel to the axis of the spine with the tension wheel positioned where the band exits the spacer (Fig. 16 and 18).

The strength induced by the traction of the tensioner can be estimated by using the torque limiting handle. To do that the torque limiting connector has to be linked with the torque limiting handle as shown on **Fig. 19 & 20**.

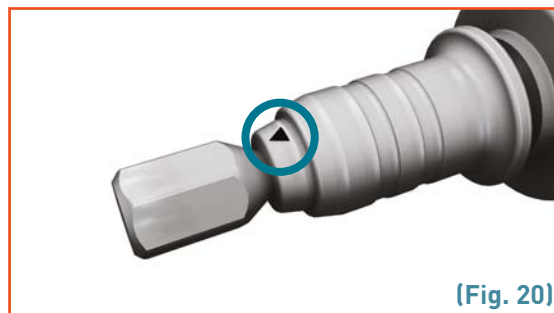
The ring of the handle is pulled up as shown on image 18. The flat area of the connector must be introduced into the torque limiting handle in front of the small triangle (**see Fig. 20**) and then the handle's ring may be released.

The torque limiting handle can be connected with the tensioner and the tension is now provided by the T handle until the torque limit.

The surgeon holds the handle of the tensioner in one hand and turns the handle clockwise with the other hand to tighten the band around the spinous processes until the torque limit (6 N.m). This handle indicates when maximum tension of 300 Newtons on the spinous processes is reached with a specific click sound (**Fig.21**).



(Fig. 19)



(Fig. 20)



(Fig. 21)

STEP 9. Removing the implant locker

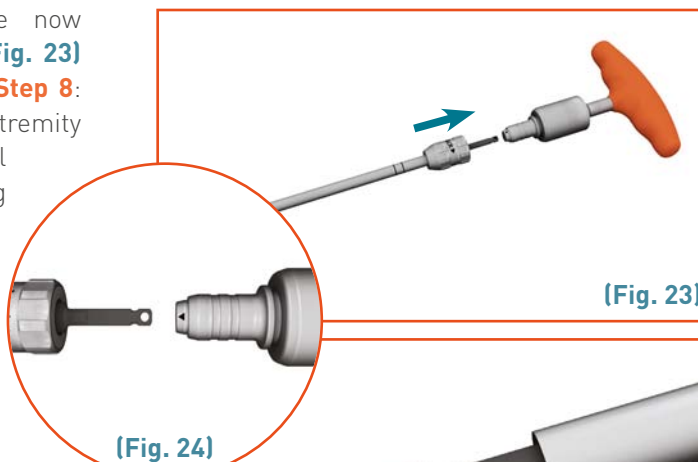
Once the tension step is complete the implant locker can be unscrewed and removed as shown on **Fig. 22**.



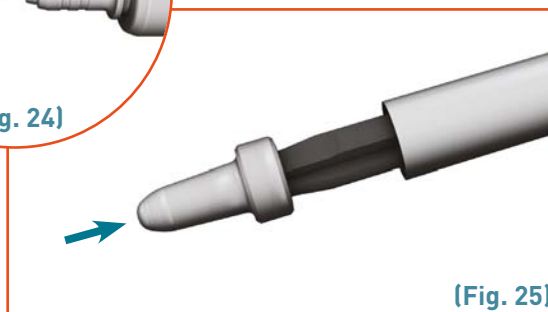
(Fig. 22)

STEP 10. Locking the implant

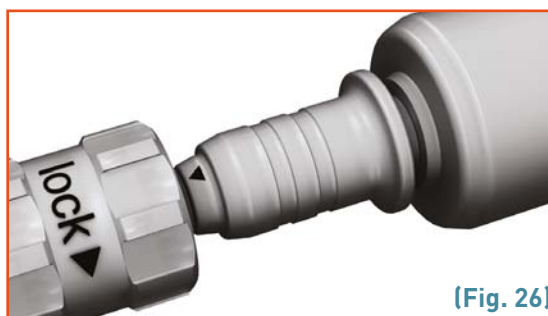
The gripper screwdriver could be now connected to the orange T handle (Fig. 23) following the same principle as the Step 8: The flat area of the screwdriver extremity should be placed in front of the small black triangle and locked by pulling and release the handle ring (Fig. 24).



Then the implant blocker is placed on the tip of the instrument (Fig. 25) and locked by turning the screwdrivers ring to the "lock" position as shown on Fig. 26.

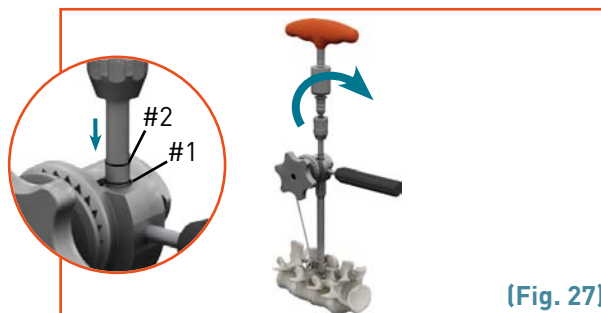


The blocker assembly is then introduced through the implant holder and is automatically positioned to lock the system. The blocker is screwed on the spacer (Fig. 27).



After having engaged the Handle / Screwdriver / Blocker assembly in the implant holder, and as soon as **Mark #1** reaches the top edge of the latter, the operator can begin the insertion of the blocker by turning the screwdriver.

Once **Mark #2** reaches the upper edge of the implant holder, the insertion of the Blocker will be considered complete and confirmed.



WARNING: Once the blocker is introduced into the first threading, the screwing of the blocker must be continued without unduly forcing on the T-handle (holding the handle with two fingers) and must be stopped as soon as a blockage feeling occurs.

NOT TO TRY TO REACH THE TORQUE LIMIT as this will damage the implant by damaging the thread of the spacer.

Once this step is achieved, the blocker is disconnected from the screwdriver by turning the screwdriver ring counter-clockwise **(Fig. 26)**.

The assembly screwdriver and handle can be removed **(Fig. 28)**.



(Fig. 28)

STEP 11. Band release and tensioner removal

At this stage the band tension is released by pushing with the thumb on the opposite side of the wheel as shown on **Fig. 29**.

The band can be now detached from the tensioner, either unrolled or just cut under the wheel **(Fig. 30)** and the whole assembly, tensioner and implant holder, can be removed simultaneously from the implant **(Fig. 31)**.



(Fig. 29)



(Fig. 30)



(Fig. 31)

STEP 12. Final step

The excess band exit the spacer can now be cut at 0,5/1 cm from the spacer **(Fig. 32 & 33)**.



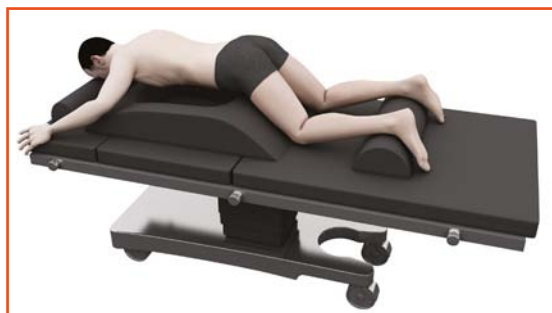
WARNING: During this step, the surgeon should cut the band in an upward direction to eliminate any risk of damaging the band.

Surgical Technique

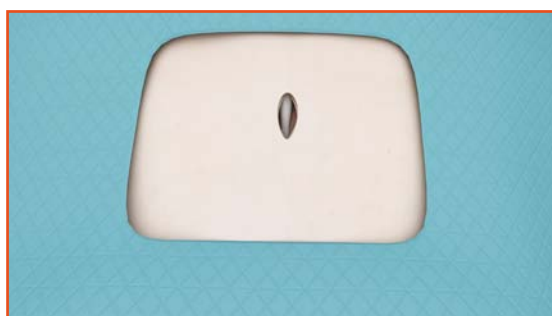
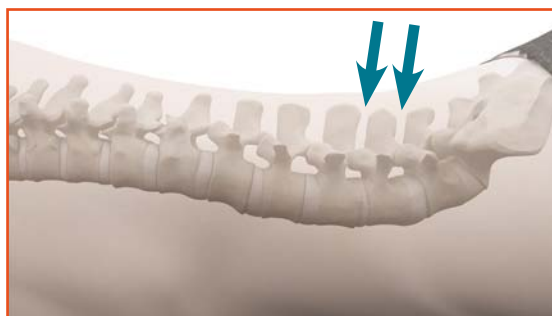
TWO LEVEL SURGERY

STEP 1. Exposure

The patient is placed in the prone position on a frame padding. A neutral position of the physiological lumbar lordosis is best to optimize the effect of the implant.



Carefully locate the two adjacent segments requiring the implant with an image intensifier.



After making a midline incision, the supra spinous ligament is detached from the three spinous processes of the levels involved and retracted laterally permitting direct posterior insertion of the **LISA** Implants.



After the initial incision, it is recommended to temporarily suture a small sterile surgical drape over the wound edge on both sides to prevent contact between the skin and the implant.

The interspinous ligaments and any over growth of the spinous processes that may interfere with implant insertion is resected without damaging the supraspinous ligament. The junction between the laminae and the spinous process is trimmed to ensure adequate surface contact between the spacer against the base of the spinous process.

The implant should be positioned as anterior as possible to support patient lordosis.

Depending on the indication a microsurgical decompression may be conducted. Ligamentum Flavum is then resected and microsurgical decompression is performed relieving all points of neural compression.



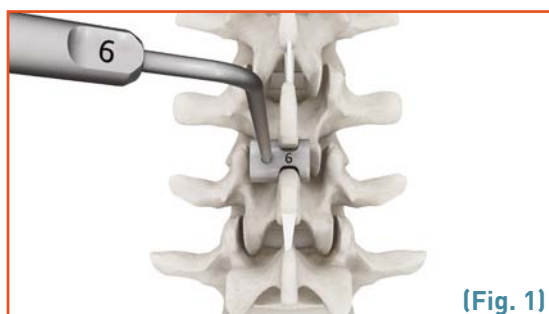
STEP 2. Choice of implant size

The adequate size of the implant is determined by placing different trial spacers between the spinous processes.

Starting with the smallest size of trial spacer (size 6), the surgeon places the instrument in the space **(Fig 1)**.

To facilitate insertion of the trial spacer, an interlaminar distractor may be used. However, it should be removed before testing the stability of the trial spacer in the interspinous space.

Between two implant sizes, the surgeon should choose the smaller one to preserve the physiological lordosis.



WARNING: The interspinous space should NOT be greater after implant insertion.
DO NOT OVERDISTRACT THE INTERSPINOUS SPACE.

STEP 3. Connection of the implant with the implant holder and first passage of the band through the spacer, all of it outside the wound

At this step the goal is to connect the spacer size chosen to fit the lower interspinous space with the dedicated implant holder.

The surgeon takes the chosen spacer in his hand, with the marking « UP » upwards. The implant is then introduced with « UP » marking upwards in the implant holder corresponding to its size **(Fig 2)**.

The assembly is secured by the implant locker that is inserted through the implant holder and screwed into the spacer **(Fig 3 & 4)**.

The band is then threaded through the first slot of the **LISA** spacer until the stop **(Fig 5)**. The first slot is marked with the number 1 and an arrow indicates the way of insertion.



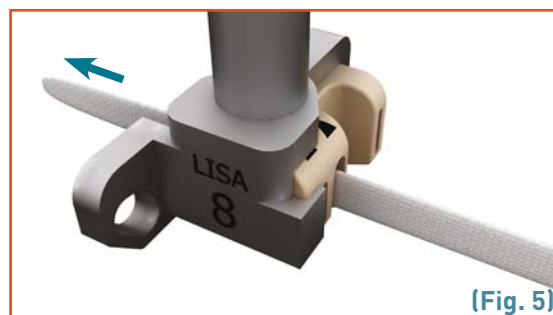
(Fig. 2)



(Fig. 3)



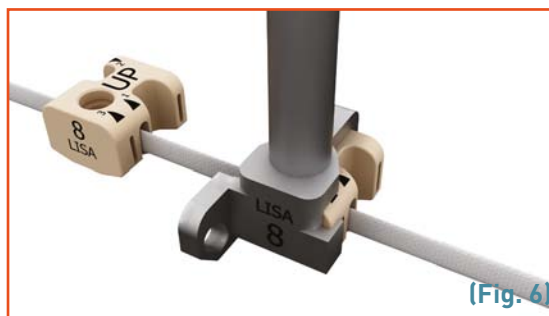
(Fig. 4)



(Fig. 5)

STEP 4. First passage of the band through the second spacer

As shown on **Fig. 6**, the distal tip of the band is then introduced into the entry number 1 of the second spacer.



STEP 5. First passage of the band through the interspinous ligaments above the second spacer

It is recommended to initially use the hook (**Fig. 7**) alone to make a pilot pathway through the interspinous ligament and behind the spinous process as close **as possible to the periosteal bone**. This instrument is then to be used to pass the band through the same pathway.

The distal part of the band is placed in the notch of the hook (**Fig. 9**) in order to push it clockwise through the interspinous ligament and around the spinous and **as close as possible to the periosteal bone** (**Fig. 7**).

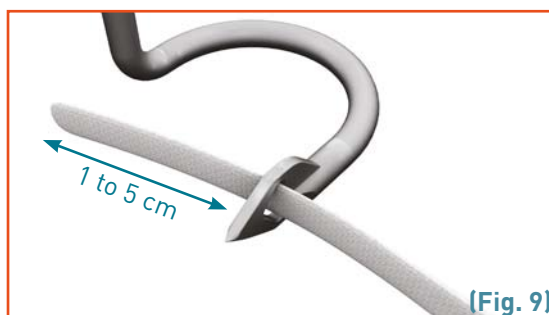
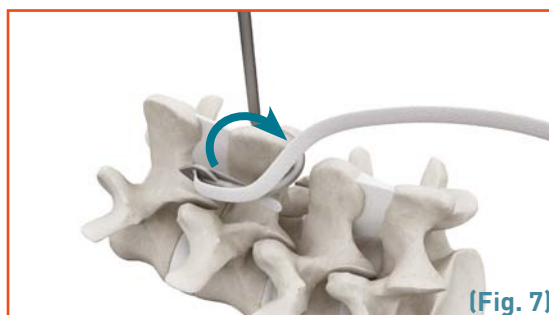
When the band tip appears through the ligament, it may be gripped by the band forceps (**Fig. 8**). The insertion hook is then withdrawn and the band is pulled through the ligament.

One should make sure that the band lies flat against the spinous processes without twists.

Please note than two optional instruments are available on demand and could be used during this step:

- A Hook with a smaller radius at its distal tip (BB-LISA-2-215)
- An alternate Band Forceps (BB-LISA-2-214)

(See picture on page 5)



TIP: The band should be introduced from 1 to 5 cm onto the hook with the band extremity toward the hook curvature (see Fig. 9).



WARNING: For an optimal implant positioning the passage of the band must be carried out as close as possible to the basis of the spinous processes.

STEP 6. 2nd passage of the band through the two spacers

The band is introduced through the second slot of the upper spacer first (**Fig. 10**) and then threaded into the second slot of the lower spacer (**Fig. 11**).

The second slots are marked with the number 2 and an arrow indicating the way of insertion.



(Fig. 10)



(Fig. 11)

STEP 7. Passage of the band through the interspinous ligament below the first spacer

The procedure is repeated as described in the **Step 5**, the surgeon passes the band around the lower spinous process with the hook.

The surgeon should verify that the band is flat against the spinous processes without being twisted. The band forceps may be used to adjust the band.



WARNING: For an optimal implant positioning the passage of the band must be carried out as close as possible to the basis of the spinous processes.

STEP 8. Third passage of the band through both spacers

The band is first introduced into the third slot of the lower spacer (**Fig. 12**) and into the same entry of the upper spacer (**Fig. 13**).

The third slots are marked with the number 3 and an arrow indicating the way of insertion.



STEP 9. Insertion of both spacers in the interspinous spaces

The lower spacer is first introduced in the lower interspinous space with the help of the implant holder (**Fig. 14**) and when the spacer is in place the implant holder is removed by unscrewing the implant locker (**Fig. 15**).

The optional instrument Interlaminar Distractor (BB-LISA-2-260) available on demand, may be used to retract the laminae before inserting the spacer between the spinous processes.



Then an appropriate size of implant holder is connected with the upper spacer with the implant locker. One must thread the distal tip of the band through the slot of the implant holder (**Fig. 16 & 17**).

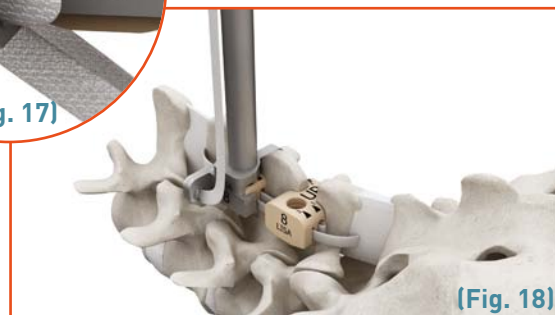


(Fig. 17)

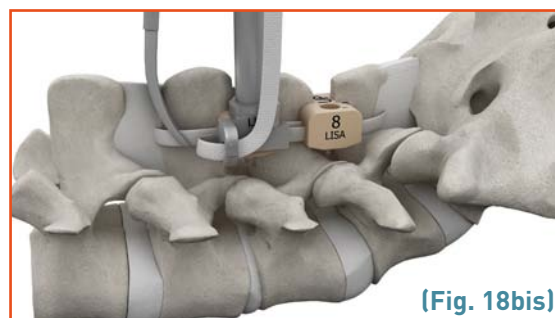


(Fig. 16)

The other spacer is placed into the upper interspinous space. (**Fig. 18**) The band forceps should then be used to finalize this primary tension (**Fig. 18bis**). This operation is performed by adjusting the tension along the path of the band from the proximal portion to its distal portion, and around the two spinous processes.



(Fig. 18)



(Fig. 18bis)

STEP 10. Tensioning the band

The tensioner is slid onto the implant holder (**Fig.19**) and the distal end of the band is inserted between the pin and the flat part of the tension wheel (**Fig. 20**).



TIP: In order to achieve optimum band tension during this step, the tensioner handle should be held parallel to the axis of the spine with the tension wheel positioned where the band exits the spacer (**Fig. 19 and 20**).



(Fig. 19)



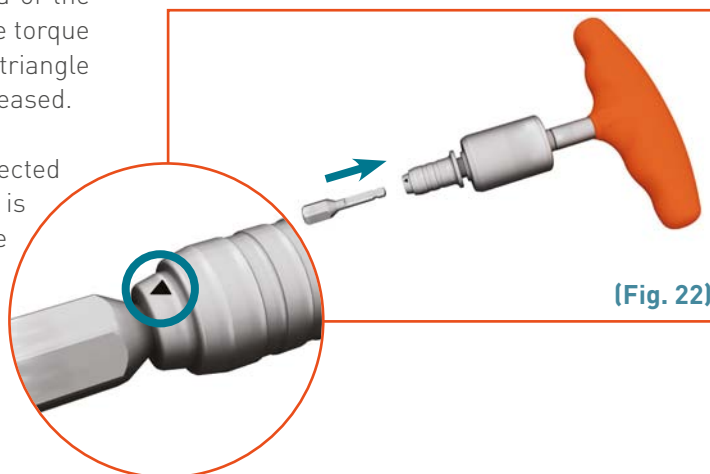
(Fig. 20)

Then the tension of the band can start manually by turning the wheel clockwise (Fig. 21).

The strength induced by the traction of the tensioner can be estimated by using the torque limiting handle.

To do that the ring of the handle is pulled up as shown on Fig 22. The flat area of the connector must be introduced into the torque limiting handle in front of the small triangle and then the handle's ring may be released.

The torque limiting handle can be connected with the tensioner and the tension is now provided by the T handle until the torque limit.



Then the torque limiting handle is connected with the tensioner (Fig. 23) and the tension is given by the handle until the torque limit.

The surgeon holds the handle of the tensioner in one hand and turns the handle clockwise with the other hand to tighten the band around the spinous processes until the torque limit (6 N.m). This handle indicates when maximum tension of 300 Newtons on the spinous processes is reached with a specific click sound.



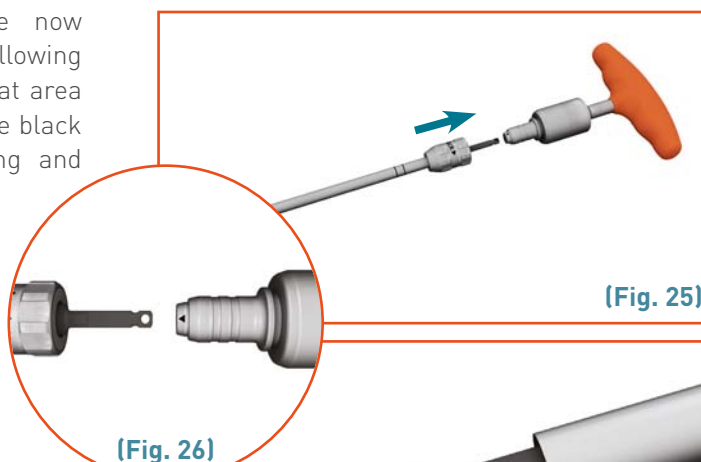
STEP 11. Removing the implant locker

Once the tension step is complete the implant locker can be unscrewed and removed as shown on Fig. 24.



STEP 12. Locking the upper spacer

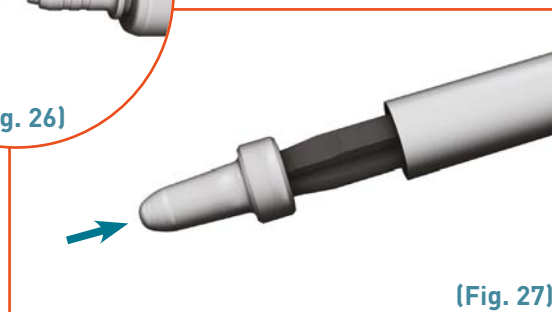
The gripper screwdriver could be now connected with the handle (Fig. 25) following the same principle as the Step 10: flat area threaded into the handle in front of the black small triangle and locked by pulling and releasing the handle ring (Fig. 26).



(Fig. 25)

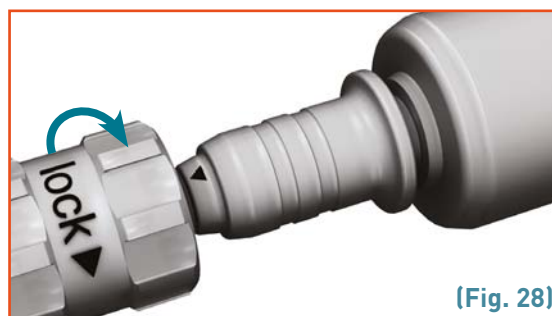
(Fig. 26)

Then the implant blocker is placed on the tip of the instrument (Fig. 25) and locked by turning the screwdrivers ring to the "lock" position as shown on Fig. 26.



(Fig. 27)

The blocker assembly is then introduced through the implant holder and is automatically positioned to lock the system. The blocker is screwed on the spacer (Fig. 27).



(Fig. 28)

After having engaged the Handle / Screwdriver / Blocker assembly in the implant holder, and as soon as **Mark #1** reaches the top edge of the latter, the operator can begin the insertion of the blocker by turning the screwdriver.

Once **Mark #2** reaches the upper edge of the implant holder, the insertion of the Blocker will be considered complete and confirmed.



(Fig. 29)



WARNING: Once the blocker is introduced into the first threading, the screwing of the blocker must be continued without unduly forcing on the T-handle (holding the handle with two fingers) and must be stopped as soon as a blockage feeling occurs. NOT TO TRY TO REACH THE TORQUE LIMIT as this will damage the implant by damaging the thread of the spacer

Once this step is achieved, the blocker is disconnected from the screwdriver by turning the screwdriver ring counter-clockwise.

The assembly screwdriver and handle can then be removed. **(Fig. 30)**.



STEP 13. Band release and tensioner removal

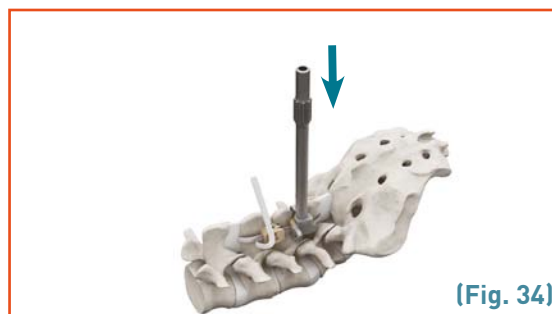
At this stage the band tension is released by pushing with the thumb on the opposite side of the wheel as shown on **Fig. 31**.

The band can be now detached from the tensioner, either unrolled or just cut under the wheel **(Fig. 32)** and the whole assembly, tensioner and implant holder, can be removed from the lower spacer **(Fig. 33)**.



STEP 14. Locking the lower spacer

To lock the lower spacer you place the appropriate size of implant holder without implant locker (see Fig. 34) and you proceed to the insertion of the blocker with the gripper screwdriver as described on Step 12 (Fig. 35).

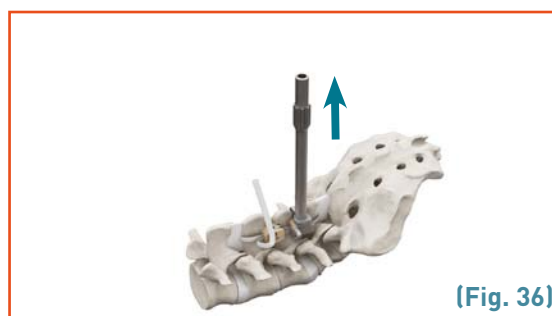


(Fig. 34)



(Fig. 35)

When this operation is done the implant holder can be removed as shown on Fig. 36.



(Fig. 36)

STEP 15. Final step

The excess band exiting the upper spacer can now be cut at 0,5/1 cm from the spacer as indicated by the arrow on Fig. 37.



(Fig. 37)



WARNING: During this step, the surgeon should cut the band in an upward direction to eliminate any risk of damaging the band.

LISA CATALOG NUMBERS

IMPLANTS

Designation	Reference
Band	BB-LISA-1-101
Blocker	BB-LISA-1-104
Spacer Size 6	BB-LISA-1-106
Spacer Size 8	BB-LISA-1-108
Spacer Size 10	BB-LISA-1-110
Spacer Size 12	BB-LISA-1-112

INSTRUMENTS

Designation	Reference
Trial spacer - Size 6	BB-LISA-2-206
Trial spacer - Size 8	BB-LISA-2-208
Trial spacer - Size 10	BB-LISA-2-210
Trial spacer - Size 12	BB-LISA-2-212
Band Forceps 1	BB-LISA-2-213
Hook wide	BB-LISA-2-220
Implant Holder - Size 6	BB-LISA-2-224
Implant Holder - Size 8	BB-LISA-2-225
Implant Holder - Size 10	BB-LISA-2-226
Implant Holder - Size 12	BB-LISA-2-227
Implant Locker	BB-LISA-2-228
Tensioner	BB-LISA-2-230
Torque Limiting Handle	BB-LISA-2-240
Torque Limiting Connector	BB-LISA-2-242
Gripper Screwdriver	BB-LISA-2-250
Instruments Tray	BB-LISA-2-300
<i>Band Forceps 2*</i>	<i>BB-LISA-2-214</i>
<i>Hook*</i>	<i>BB-LISA-2-215</i>
<i>Interlaminar Distractor*</i>	<i>BB-LISA-2-260</i>

* optional

Manufacturer:
BACKBONE
81, Boulevard Pierre 1^{er}
33110 LE BOUSCAT - France

