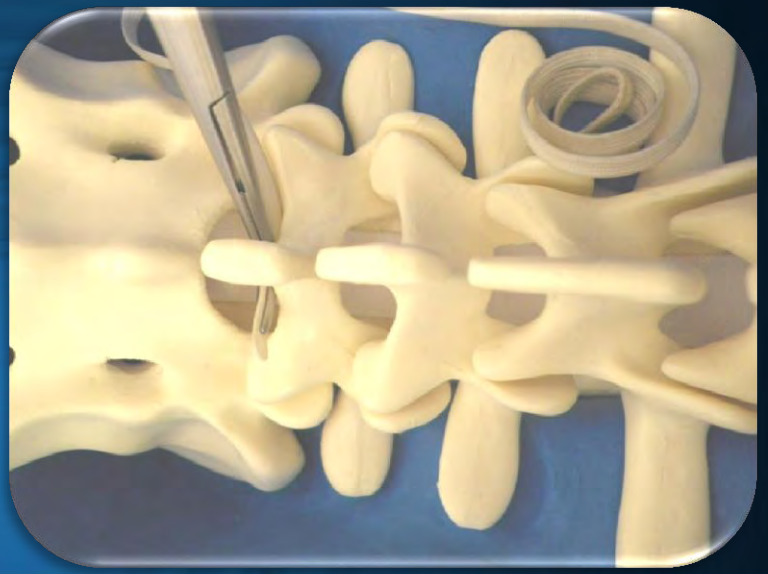
EDEN
SPINE

Wellex™

INTERSPINOUS TECHNOLOGY

Optional Ligament Insertion

INTRODUCTION OF THE WELLEX



The ligament should be inserted initially on the lower inter spinous process.

The ligament holder makes it possible to insert the ligament through the inter spinous ligament.

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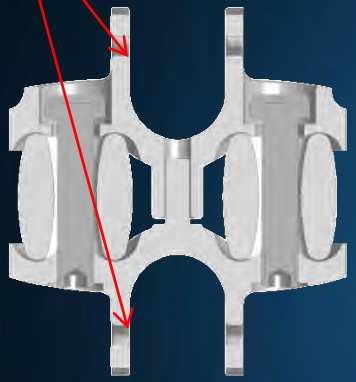
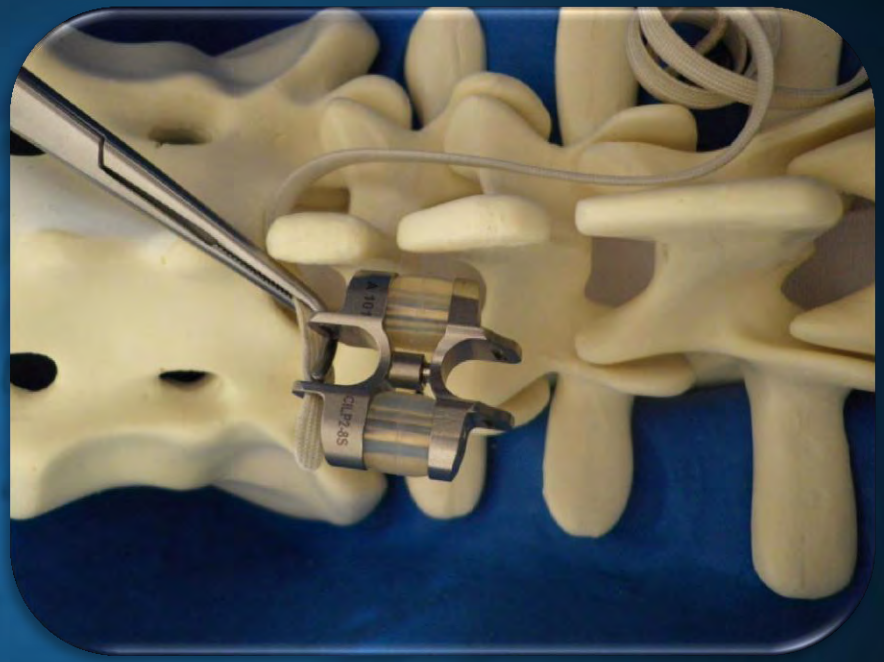
Wellex LOCKING OF THE LIGAMENT STEP 1

Ligament holes





The ligament is inserted in the 2 side holes as described above.

Both sides of the implant can be used indifferently.

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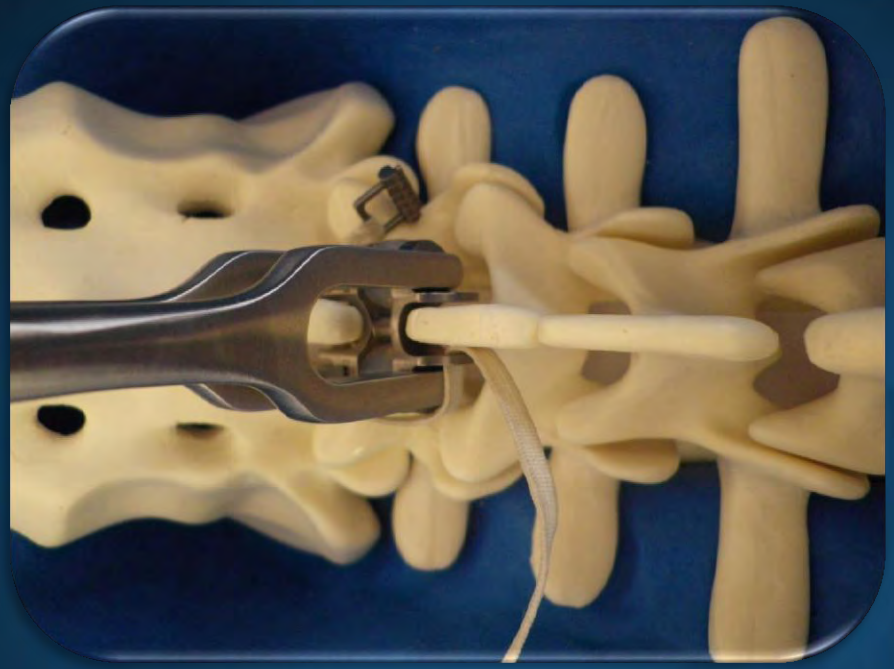
LOCKING OF THE LIGAMENT STEP 1

The free extremity of the ligament is introduced into the buckle, behind the sliding element.

Wellex

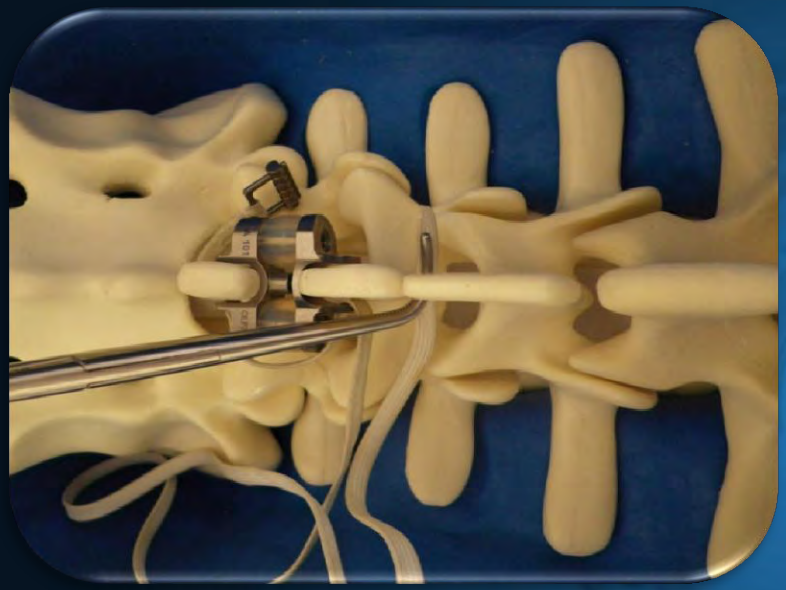
LOCKING OF THE LIGAMENT STEP 1



The Wellex is inserted in the inter spinous space using the holder impactor.

Wellex

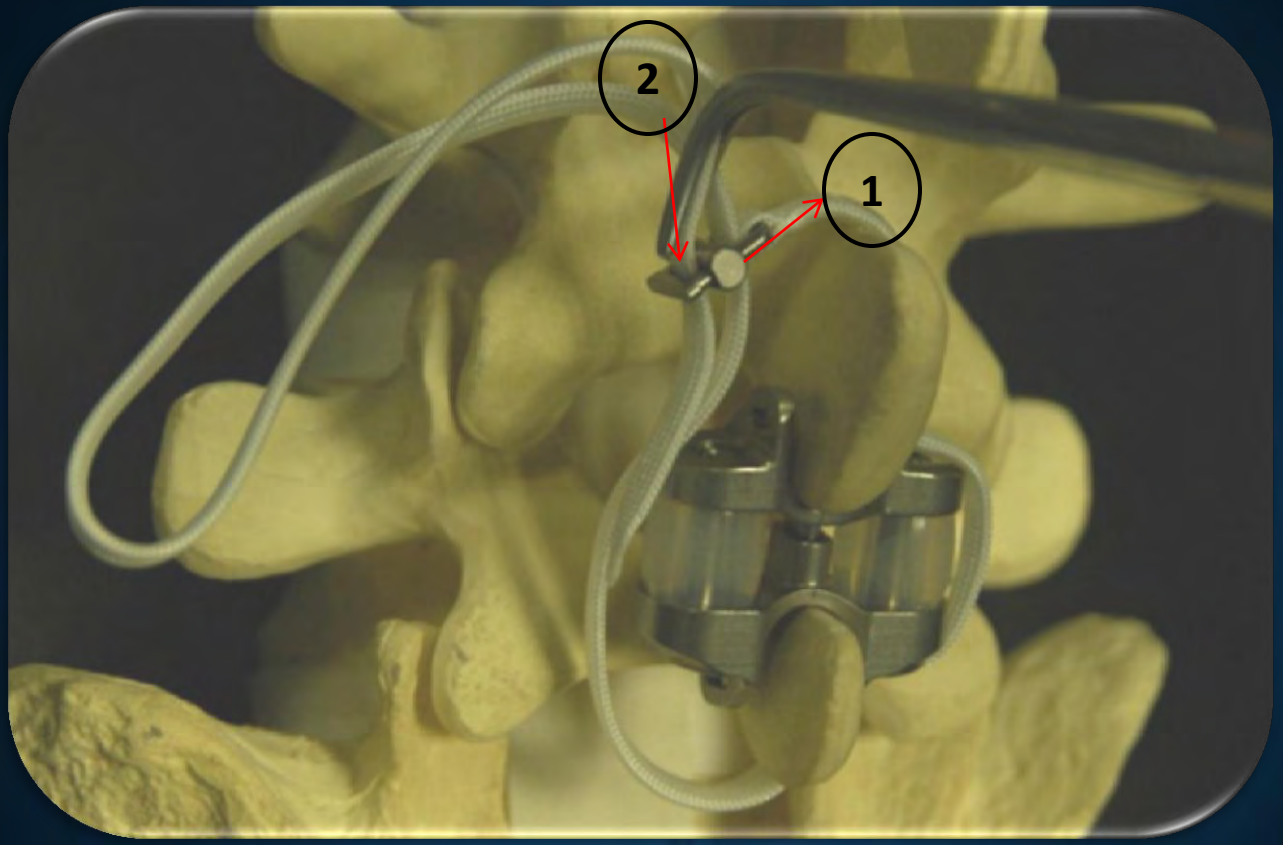
Wellex LOCKING OF THE LIGAMENT STEP 1



The free extremity of the ligament is positioned between the two inter spinous processes.

Wellex

LOCKING OF THE LIGAMENT STEP 2



As the two parts of the ligament are on the same side, the first step of the locking can be achieved.

The free extremity of the ligament is now reintroduced into the buckle.

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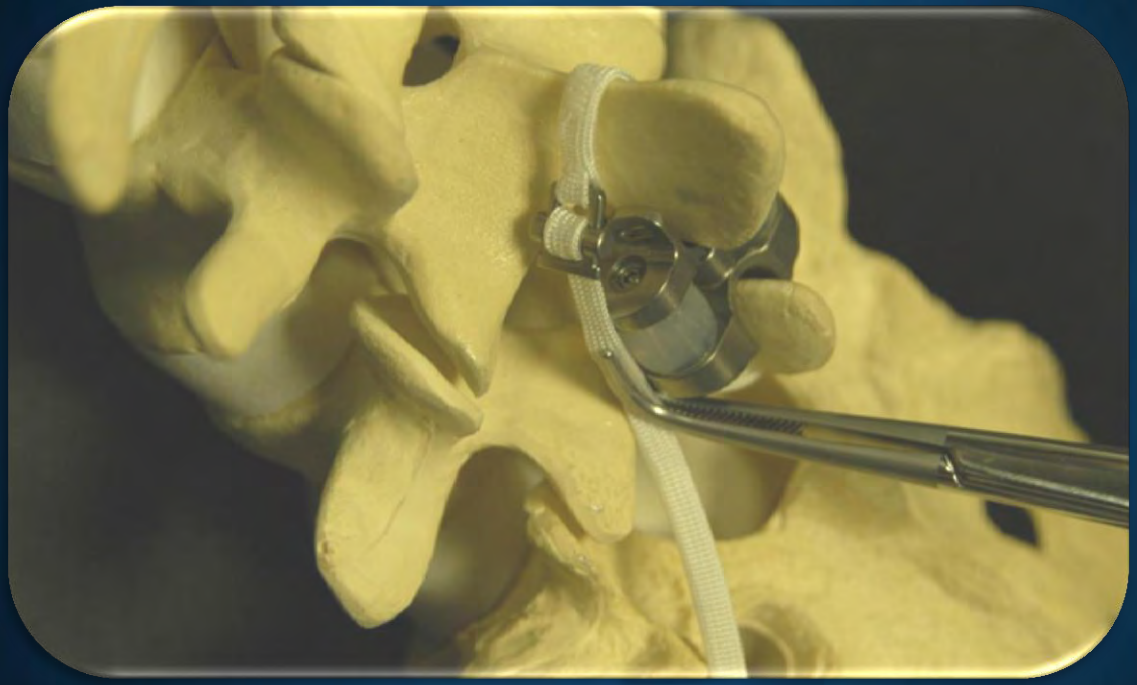
LOCKING OF THE LIGAMENT STEP 3



To finalize the locking of the ligamen, simply pull it with the ligament holder.

The ligament should be at 1.5 cm of the belt.

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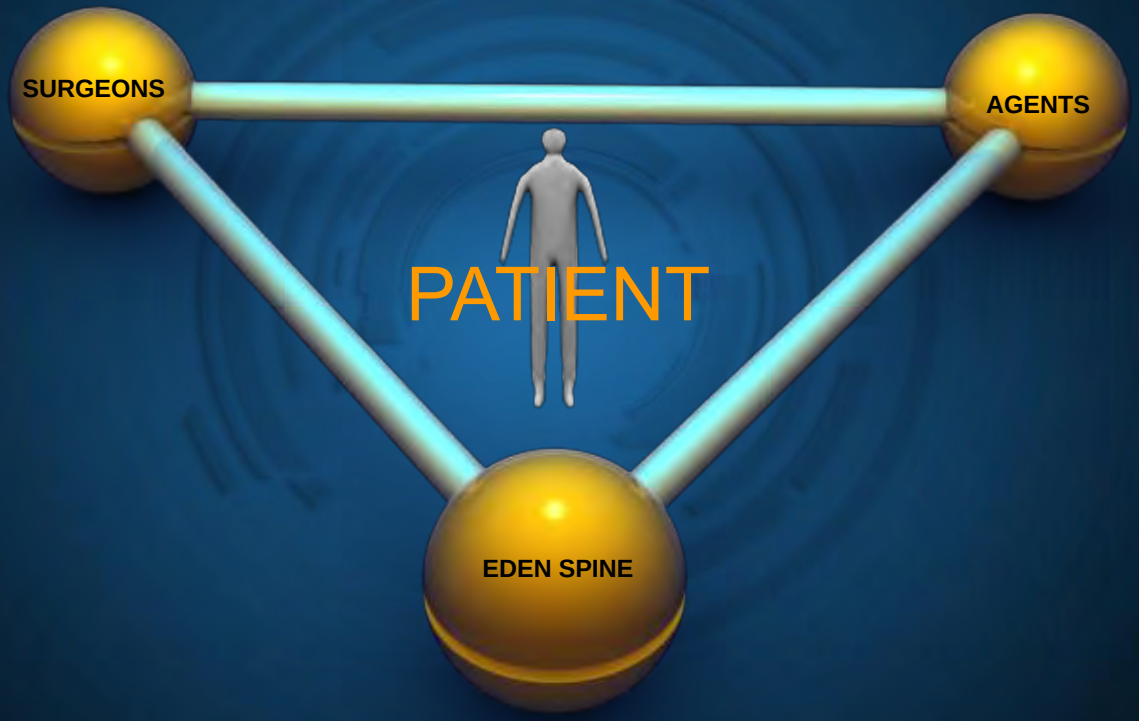
FINAL POSITIONNING

Wellex



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EDEN SPINE EUROPE

Surgical Technique

Wellex™

Dynamic Stabilization Technology

SURGICAL TECHNIQUE

Surgical Technique

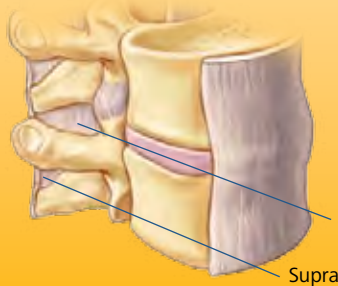
Surgical approach and patient placement

The patient can be placed either in a ventral decubitus or lateral decubitus position. The ventral decubitus position can be achieved either on an ordinary table with pillows under the thorax and under the iliac crests, or it can be achieved on a special type Hall frame which allows abdominal freedom. This avoids all hyper-excess pressure which could generate an increase of venous bleeding. This abdominal freedom is better achieved using a table specially designed for spinal surgery in order to perform external maneuvers during surgery.

With the use of a mobile C-armshaped X-ray machine, a possible radiological control, most often a side view, should be performed if neededis recommended.

The incision is median, posterior and centered. The skin and the subcutaneous cellular tissue being incised, the spinous process and the supra-spinous ligament are exposed. Exposing the treatment area must be done while preserving the surrounding muscular cerclage ture with the utmost care. Only the exposure of the spinous process and of part of the blade is necessary.

Preparation of the interspinous space



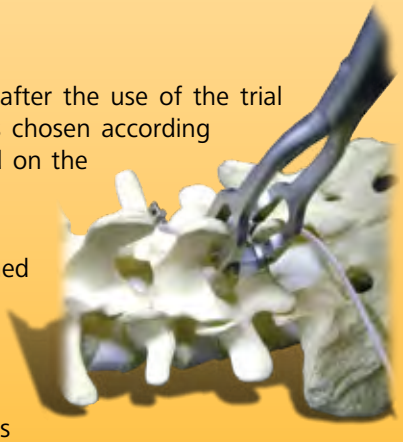
The preparation of the interspinous space must be done with care and only the supraspinous and interspinous ligaments must be resected. The bony parts must be totally preserved.

The introduction of trial implants must not require any bone resection.

Determination of the implant size

The choice of interspinous height to be restored is determined by the use of the trial implants. Trial implants are available in several heights going ranging from 8 mm to 16mm with in increments of 2 mm. The introduction of these trial implants will start byshould start with the smallest size in order to obtain a progressive distraction. In certain cases, the use of distraction pliers could may be useful. The trial implants will have tomust be positioned in the most anterior way possible. The trial partas far anteriorly as possible and must be stable in position and must offer a sufficient distraction.

Placement of the implant



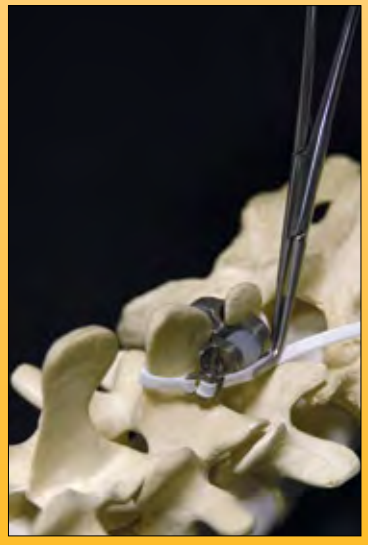
The choice of the implant to be used is made according to the height selected after the use of the trial implantsfinal height selected for the trial implants. The implant rigidity must beis chosen according to the morphologic parameters of the patient. The synthetic ligament is mounted on the implant beforehand.

The fixation of the ligament to the Wellex implant is unilateral and can be performed from either side, left or right. The implant is mounted on the holder impactor. A unique ancillary, of prehension and impaction, is used for the placement of the implant. The implant is introduced in a compressed position in order to avoid all excessive distraction of the interspinous space. The implant must be positioned in the most anterior wayas far anteriorly as possible. The compression is released once the implant is stable in its final position.

The respect of the bony structures allows the Wellex implant to maintain itself in the chosen position.Because no bone is resected during the procedure, the implant will remain stable in its final position.

Fixation to the spinous processes

An implant fixation to the spinous processes is finalized with the help of a the synthetic ligaments. The ends two extremities of the ligamentss are passed through the subjacent and supra-jacent interspinous spaces. This operation is performed with the help of ligament holder. The blocking of the ligament is performed thanks to the integrated blocking system. The ligament is once the ligaments are in position, they are introduced into the integrated locking system loop and placed under tension. in order to obtain the final blocking.



The procedure ends by Rinsing and closing after hemostasis verification.

Implants List

Reference	IMPLANTS
10001	Wellex Interspinous Implant - H: 8mm, Pre-loading: 50N
10002	Wellex Interspinous Implant - H: 8mm, Pre-loading: 100N
10003	Wellex Interspinous Implant - H: 10mm, Pre-loading: 50N
10004	Wellex Interspinous Implant - H: 10mm, Pre-loading: 100N
10005	Wellex Interspinous Implant - H: 12mm, Pre-loading: 50N
10006	Wellex Interspinous Implant - H: 12mm, Pre-loading: 100N
10007	Wellex Interspinous Implant - H: 14mm, Pre-loading: 50N
10008	Wellex Interspinous Implant - H: 14mm, Pre-loading: 100N
10009	Wellex Interspinous Implant - H: 16mm, Pre-loading: 50N
1000A	Wellex Interspinous Implant - H: 16mm, Pre-loading: 100N
FBIOLP0535	Synthetic Ligament (Locking Mechanism)

Instruments List

Reference	INSTRUMENTS
1000B	Wellex Trial Implant - H : 8 mm
1000C	Wellex Trial Implant - H : 10 mm
1000D	Wellex Trial Implant - H : 12 mm
1000E	Wellex Trial Implant - H : 14 mm
1000F	Wellex Trial Implant - H : 16 mm
1000G	Trial Implant Holder
1000H	Holder Impactor
1000I	Ligament Holder

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