sinteaPLUSTEK

VIKING

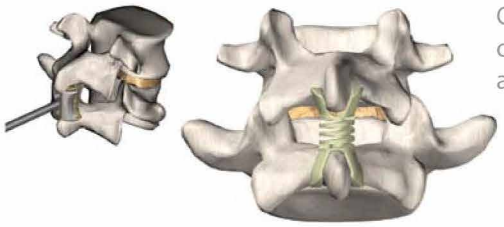
Dynamic Interspinous Stabilization

SURGICAL TECHNIQUE

STEP06

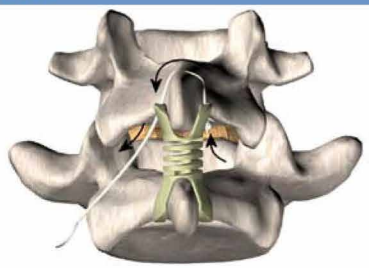
Place the device within the spinous processes. Once placed, remove the central hol - der, VIK.02.00.S, or its alternative, the lateral positioning device, VIK.07.00.S. Continue positioning the implant with the spreader, VIK.01.00.S, to a desired fit.

STEP07



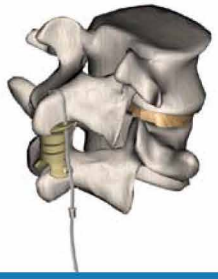
Complete the positioning of the device with the impactor, VIK.05.00.S. The impacter, combined with the use of a hammer, will serve to place the device in front as much as possible.

STEP08



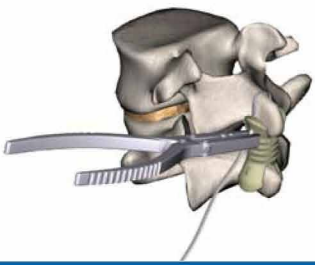
Thread the lace into the hole in the cranial “wing” of the device until it reaches the external area. Pass the lace over the spinous process and further penetrate through the corresponding hole in the cranial seat.

STEP09



Place the clip on the free end of the lace until it reaches the external portion of the “wing” and the lace is taught. This ensures that the device is firmly placed between the spinous processes.

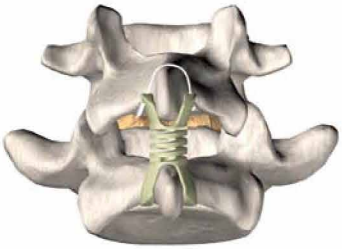
STEP10



Close the clip with the apposite instrument, VIK.03.00.S.

After the clip has been closed, remove the excess lace by cutting.

STEP11



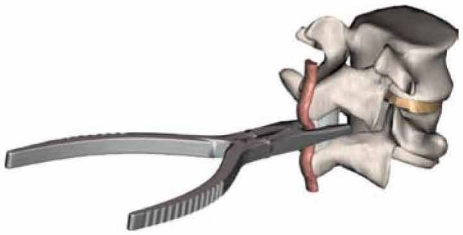
Create another knot on the remaining lace and repeat the procedure for the bottom spinous process. Upon completeion of the bottom of the spinous process, suture the sovraspinous ligament severed at the start of the surgical procedure.

VIKING Dynamic Interspinous Stabilization

INSTRUCTIONS FOR USE Appropriately utilized, Sintea Biotech's spinal dynamic posterior stabilization system, the Viking, is recommended to treat cases of excessive and anomalous mobility between two vertebrae while preserving the normal range. This technique is used in opposition to arthrodesis treatments which stabilize through vertebral fusion. The systems indications are to treat chronic lumbar pain, caused by degenerative pathologies of intervertebral discs, and to represent an alternative to vertebral arthrodesis. The Viking can also be used, in conjunction with the Sintea PLS system, as a dynamic shock absorber between the adjoining segments being stabilized, to allow a gradual load share among the treated and non-treated levels.

SURGICAL TECHNIQUE

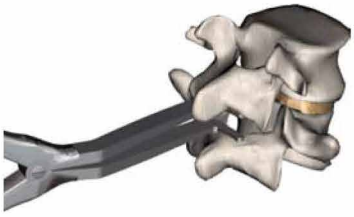
STEP01



With patient lying prone on operating table, engrave the skin longitudinally along the median line, exposing the laminae and the joint masses.

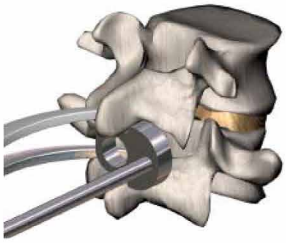
Create space to insert the device between the spinous processes. Remove the interspinous ligament and cut the sovraspinous ligament.

STEP02



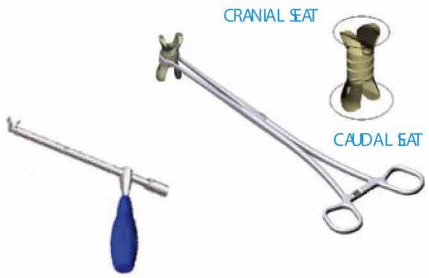
When the area involved in the implant is exposed, use the spreader, VIK.01.00.S, to enlarge the space between the vertebrae. This space is usually reduced due to the disc pathology.

STEP03



Once the correct anatomical postion has been achieved, slide in, sideways, the spreader. The opposite side of the spreader, the trial, composed of the bar, VIK.04.00.S, and a thickness gauge which is available in the instruments set, VIK.04.01.S (10mm) VIK 04.02.S (12 mm) VIK.04.03.S (14 mm) VIK.04.04.S (16 mm) VIK.04.05.S (8 mm).
The gauge will be used to evaluate the space between the spinous processes and aid in choosing the the appropriate size of the implantable device.

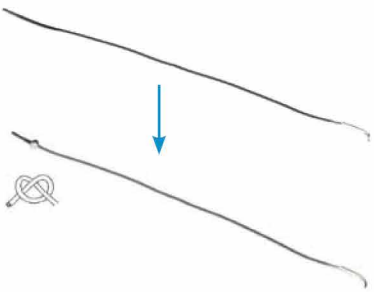
STEP04



Grab the device with the appropriate holder, VIK.02.00.S, by closing the clamps around its central cylindrical section.

Two different types of device holders are supplied: one which holds the device centrally, and the other for a lateral grab

STEP05

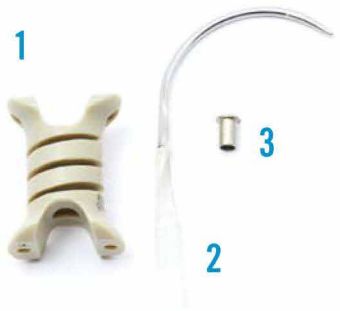


Remove the lace from its sterile envelope. At one end of the lace there is a non-traumatic needle, size 3/8', with a rounded tip to ease the handling of the ligament. Create a flat knot at the opposite end of the lace.

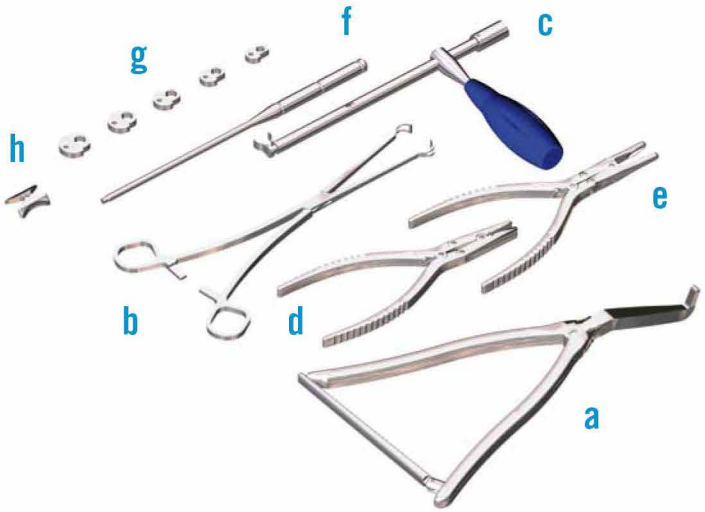
Dynamic Interspinous Stabilization

The products are supplied sterile

To order: Fax +39 02 45 79 02 09		
Viking Paek - height 8	VIK.08.PK.5	1
Viking Paek - height 10	VIK.10.PK.5	1
Viking Paek - height 12	VIK.12.PK.5	1
Viking Paek - height 14	VIK.14.PK.5	1
Viking Paek - height 16	VIK.16.PK.5	1
Lace	VIK.20.Pt.1	2
Clip	VIK.30.T3.1	3



Instruments set		
Spreader	VIK.01.00.S	a
Holder	VIK.02.00.S	b
Lateral Holder	VIK.07.00.S	c
Forceps	VIK.03.00.S	d
Ligaments removal pincer	VIK.06.00.S	e
Trial beam	VIK.04.00.S	f
Trial size 8	VIK.04.05.S	g
Trial size 10	VIK.04.01.S	g
Trial size 12	VIK.04.02.S	g
Trial size 14	VIK.04.03.S	g
Trial size 16	VIK.04.04.S	g
Impactor	VIK.05.00.S	h



INDICATIONS

Appropriately utilized, Sintea Biotech spinal dynamic posterior stabilization system Viking is recommended to treat cases of an excessive and anomalous mobility between two vertebras, maintaining the normal range between the same vertebras, in opposition to the treatments that stabilize through vertebral fusion which fix the adjoining vertebras irreversibly. The system is indicated to treat chronic pain in back and legs caused by degenerative pathologies of intervertebral disc and it is indicated in alternative to vertebral arthrodesis for spinal stenosis and spondylolisthesis.

CONTRAINDICATIONS

The contraindications of spinal dynamic posterior stabilization system are analogous to those of similar products currently available, and include, but are not limited to:

ABSOLUTE:
- Infections in the active state.
- Allergy to the metal components.
- Patients who are either unwilling or unable to follow instructions.

RELATIVE:
- Metastasis.
- Traumas.
- Serious muscular, neurological, or vascular disease.
- Fever or leucocytosis.
- Signs of flogosys at the planned site of the implant.
- Inadequate soft tissue coverage at the implant site.
- High level osteoporosis.
- Spondylolisthesis / reduced height of the disc.

If the implant of Sintea Biotech Viking spinal stabilization system is considered the best solution for the patient, and if the patient presents one or more of the above contraindications, it is essential that the patient is informed of the possible negative consequences that might hinder the success of the procedure.

Sintea Biotech S.p.A.

Commercial and administrative office:
Via E.Fermi 44 20090 Assago (MI)
Ph. +39 02 45 79 03 80
Fax +39 02 45 79 02 09
e-mail: info@sinteabiotech.com

Production and registered office:
Via Aquileia 33/H 20021 Baranzate (MI)
Ph. +39 02 38 20 42 22
Fax +39 02 38 20 42 30