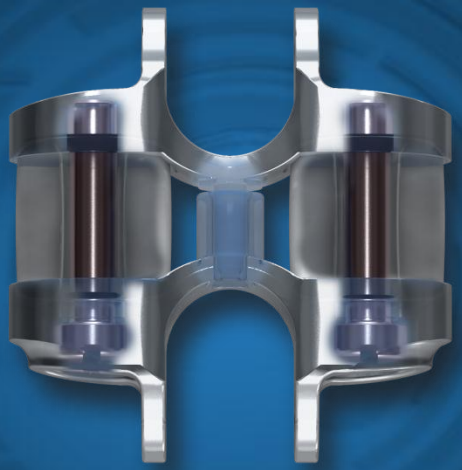
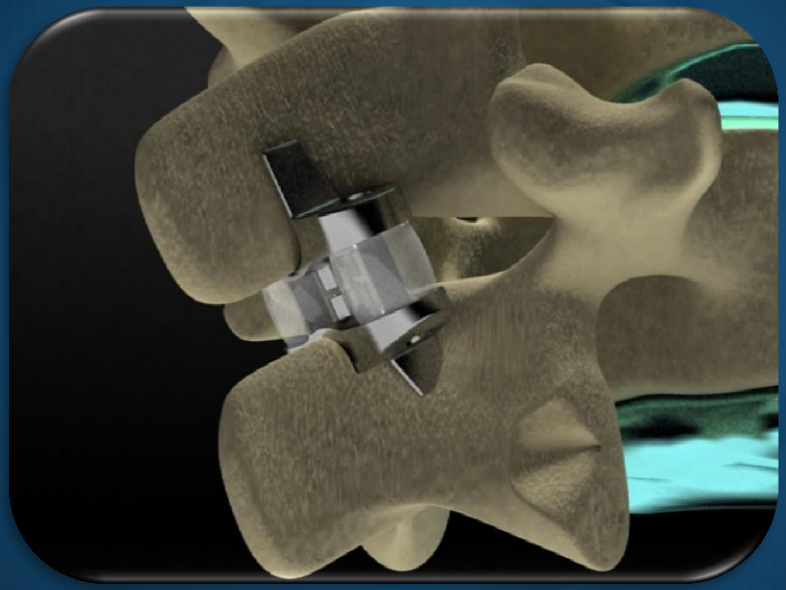
EDEN
SPINE



WELLEX INTERSPINOUS TECHNOLOGY

INTERSPINOUS TECHNOLOGY

Compressible Dynamic Extension Controller



Eden Spine
PROPRIETARY
Technology

Research & Development

* Currently for International use only.

INTERSPINOUS TECHNOLOGY

Clinical problems of the lumbar instability

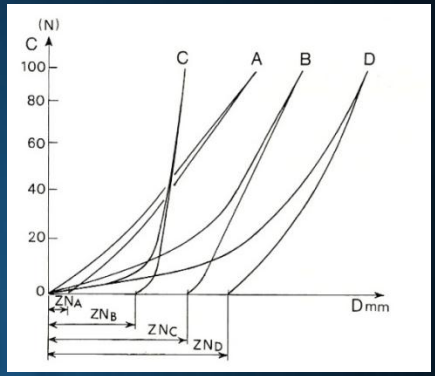
The degenerative process can be described in 3 steps:

- Degeneration
- Instability

  - Reduced disc height
  - Abnormal loading
  - Ligament laxity
  - Facet joint degeneration

  → Abnormal kinematics of the FSU

- Re-stabilization



A: normal disc

B to D: degenerative changes

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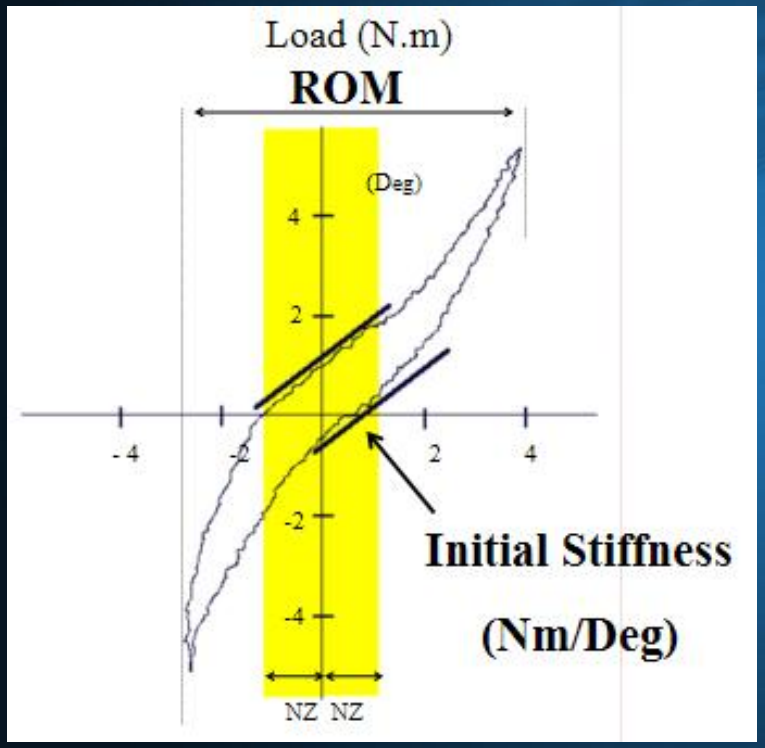
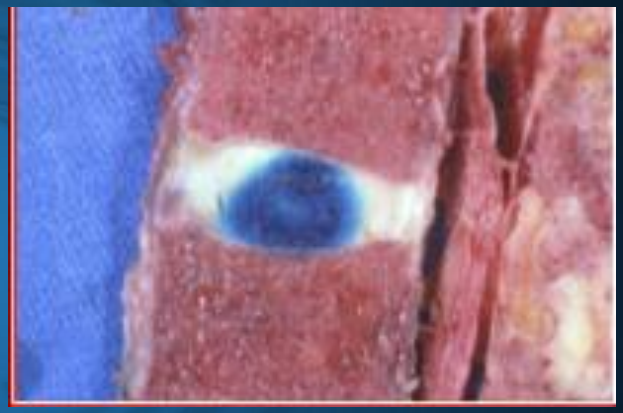
INTERSPINOUS TECHNOLOGY

Kinematic Behavior Of Normal Lumbar Motion Segment





Yamamoto i. 1989
Pope, M i. 1995
Mimura A i, 1994
Kaigle, A i, 1997

The neutral zone (NZ) of a spinal motion segment has been defined as « that part of the range of physiological intervertebral motion, measured from the neutral position, within which the spinal motion is produced with a minimal internal resistance ».
The size of this region of laxity or highd flexibility has been considered an indicator of the stability of a motion segment.

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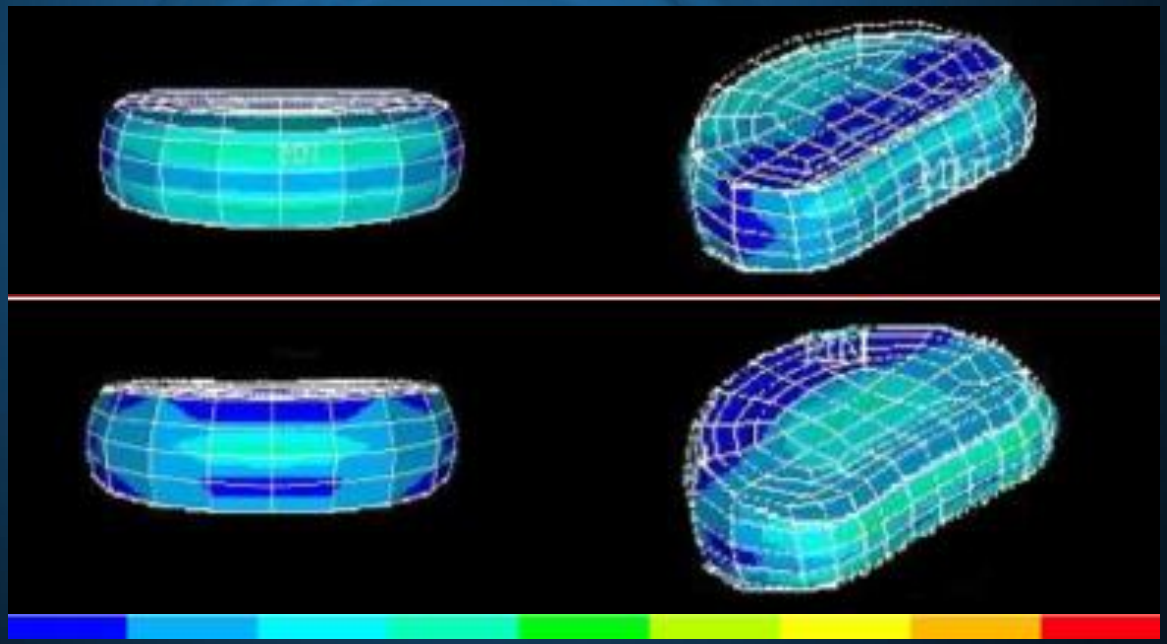
INTERSPINOUS TECHNOLOGY

Normal Intervertebral Segment

Pressure increased on posterior annulus during extension and torsion

Flexion

Extension



For all loading conditions the larger stress occurs in the annulus, not in the nucleus.

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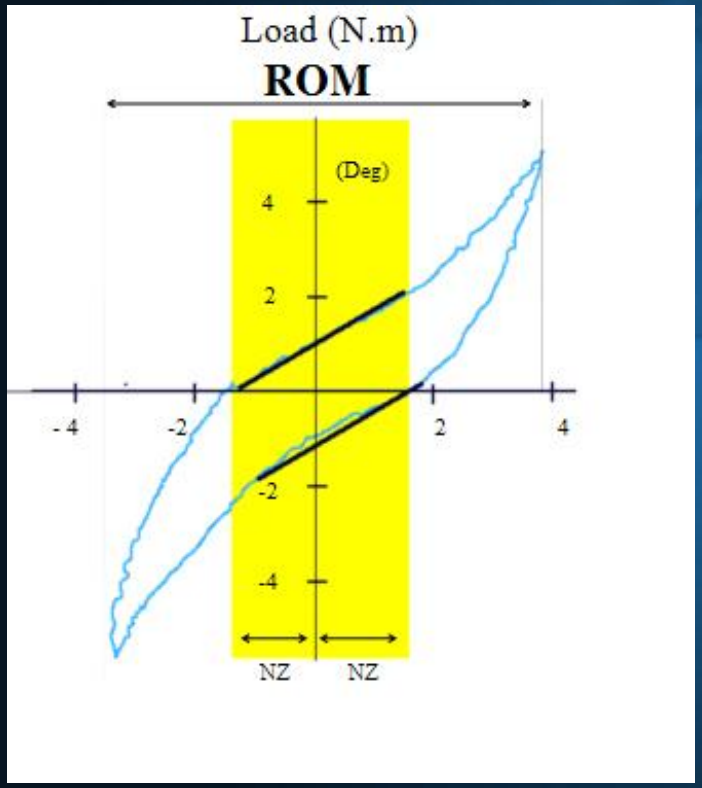
INTERSPINOUS TECHNOLOGY

Kinematic Behavior Of Degenerated Lumbar Motion Segment



- ROM increased
- NZ increased
- Stifness decreased
- Translation increased

Yamamoto i. 1989
Pope, M i. 1995
Mimura A i, 1994
Kaigle, A i, 1997

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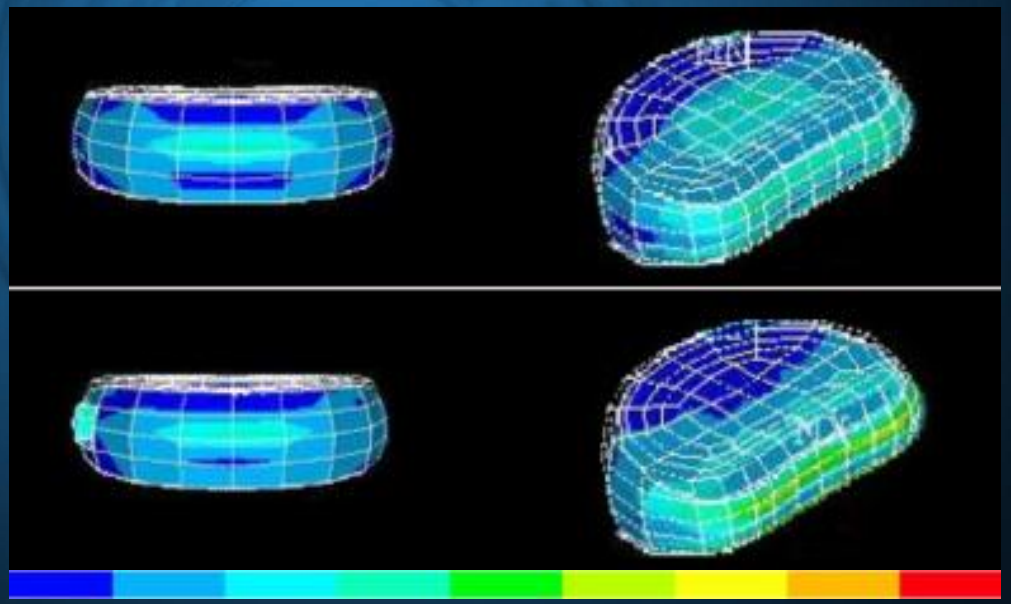
INTERSPINOUS TECHNOLOGY

Degenerated Intervertebral Lumbar Segment

Pressure increased on the posterior annulus

Normal

Degenerated



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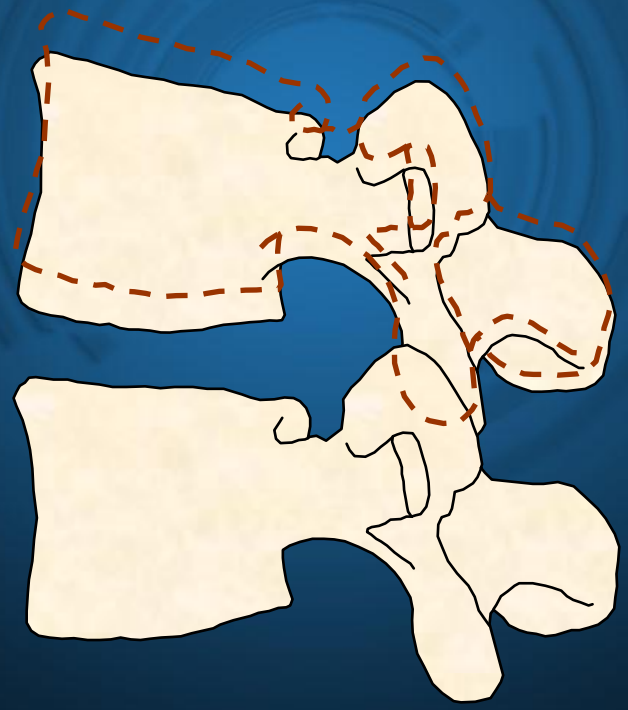
INTERSPINOUS TECHNOLOGY

Surgical Goal

Facets have a load absorption role

- With deterioration they need an artificial adjustment



Segment Intact

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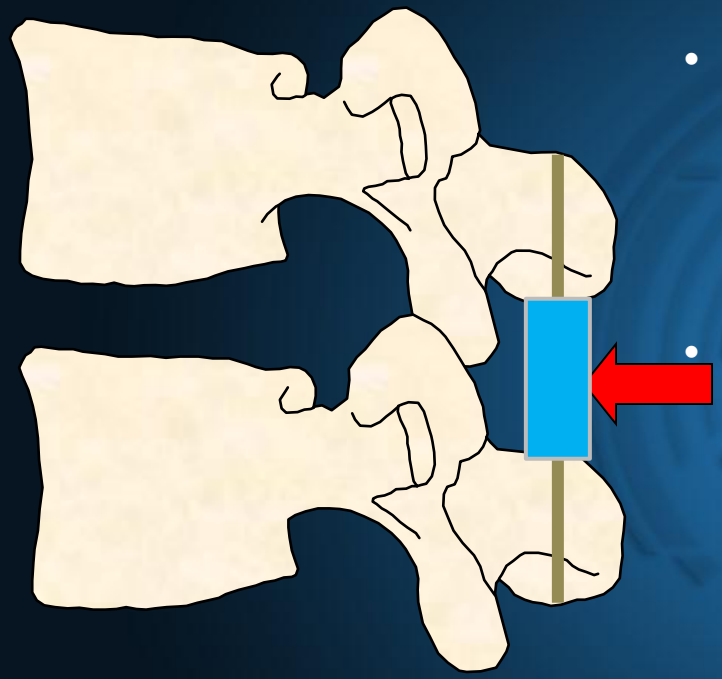
INTERSPINOUS TECHNOLOGY



- The implant needs to be soft to allow the patients to rebalance himself and find his best posture
  - Balance is restored
- The implant material might be bi-phasique to mimic normal segment behavior
  - Dynamic in extension is restored

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INTERSPINOUS TECHNOLOGY

Main Specifications

Use a dynamic technology (Wellex) that will provide controlled segmental mobility while:

- Reducing posterior loading on the disc
- Restoring the posterior tension band
- Reducing abnormal facet loading
- Restoring facets congruence
- Restoring foraminal height

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INTERSPINOUS TECHNOLOGY

Main Specifications

The Wellex has been designed to:

- Restore and maintain intervertebral dimensions
  - Reduces abnormal posterior loading
  - Increases the segmental stiffness
  - Restores the facet congruence

- Maintain physiologic kinematics of the FSU
  - Allows movement in : Flexion
    Extension (Extension Controller)
    Lateral bending
- Maintains the neutral zone

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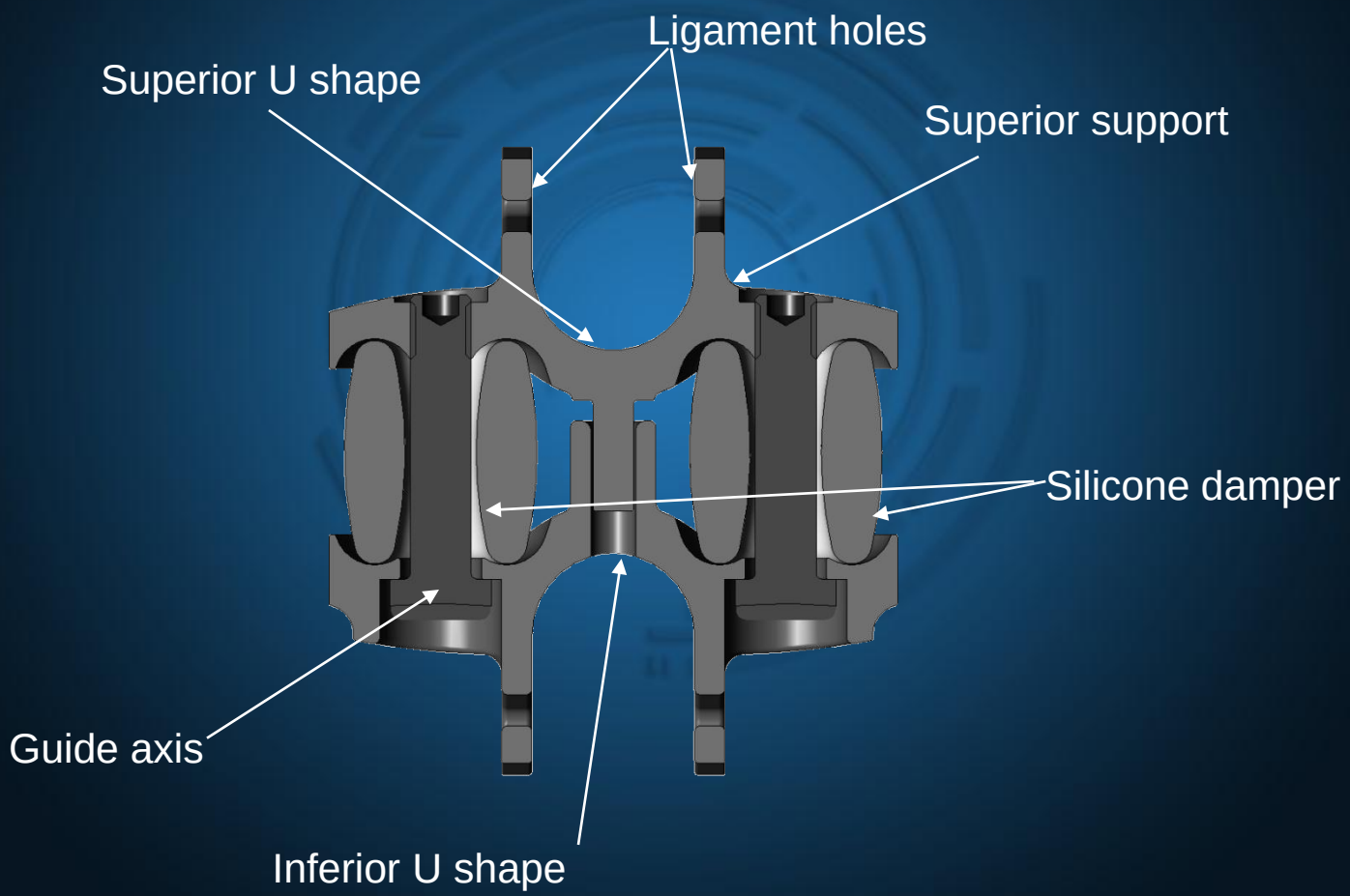
INTERSPINOUS TECHNOLOGY

Wellex Description



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INTERSPINOUS TECHNOLOGY

Wellex description

Internal dynamic mechanisms are used to control the movements described earlier

The surgeon has a choice of stiffnesses intraoperatively

Viscoelastic materials provide physiological nonlinear motion

Position in total extension

Neutral position

Position in total flexion

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INTERSPINOUS TECHNOLOGY

Wellex Material Part 1: Titamium

The Wellex lumbar interspinous wedge is manufactured using:

TA6V ELI Titanium (in compliance with ISO 5832-3 or ASTM-F 136 standards),

MED 4765 Silicon (in compliance with NF S99-401).

The band is made by polyester.

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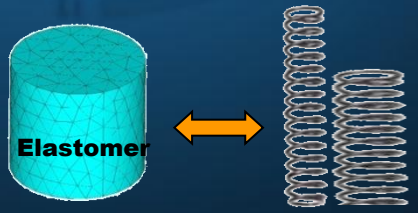
INTERSPINOUS TECHNOLOGY

Wellex Material Part 2: Silicone

General properties of silicone rubber:

- Ability to remain flexible over a board range of temperature for extended periods of time.
- Can withstand extreme temperature ranges and maintain its stress strain properties.
- Radiation resistance so the sterilization dosages have a negligible effects:

  - Biocompatibility
  - Non toxic
  - Physiological inertness
  - Heat stability



Research & Development

INTERSPINOUS TECHNOLOGY

Wellex Material Part 3: Artificial Ligament

Made of polyester

The braid is made of strings. Their amount, angle of braiding and tension depend on the type of braid and its shape.

These strings are made of multi-filaments allowing the best resistance.

They are covered of an ensimage which enable the making of the strings on the braiding machines.

When the product is made, it is cleaned up to get rid of ensimage. Therefore, it is completely clean, and ready for surgery.

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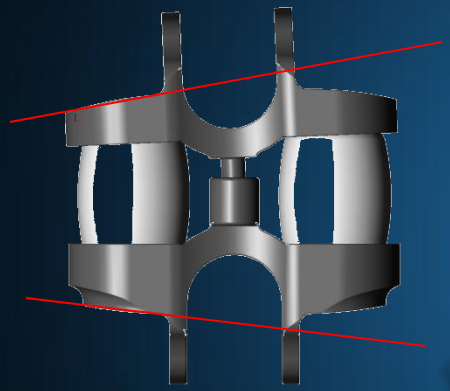
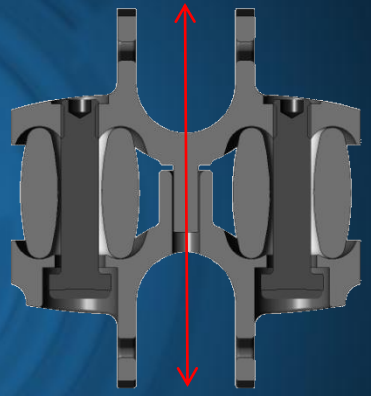
INTERSPINOUS TECHNOLOGY

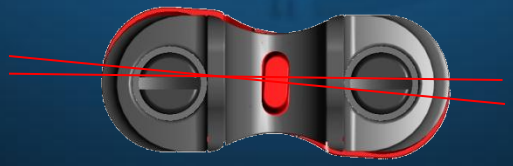
Wellex Range of Motion



Lateral bending ± 4°



Axial translation: 1.5 mm



Axial torsion ± 3°

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INTERSPINOUS TECHNOLOGY

Wellex Pre load Specification

The Wellex has been developed to adapt to the patient. The technology has been specifically designed to work with the anatomy, not against it. To achieve this objective, 2 levels of rigidity are available:

50 N & 100 N.

And, a list of criterias has beed defined:

- Morphology : (BW)
- Professional criteria: (PC)
- Athletic activity :(PA)
- Prior surgery of the rachis (in the pertaining region) (PS)
- Type of leisure activity (HA)

- All of these specificity are classified in different levels.
  Professional criteria(PC): Sedentary Activity, Medium Activity, and Heavy Labor

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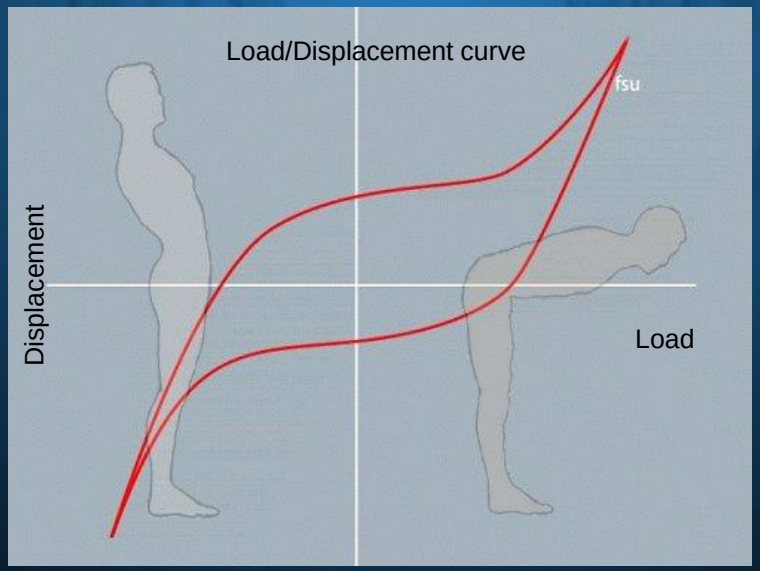
INTERSPINOUS TECHNOLOGY

Wellex Pre load Concept

- The goal is to maintain the implant in the neutral position when the patient is standing up.
- The load on the spinous process is naturally different for one person to the next.
- The range is around 100 N for a body weight of 80 kg in neutral position and decrease with the body weight.



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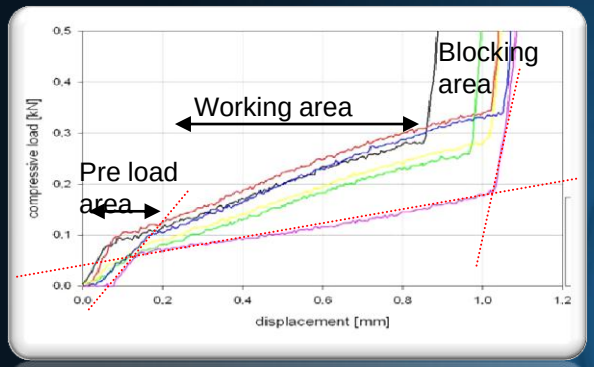
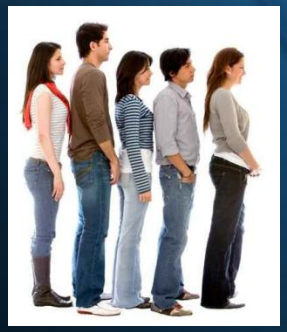
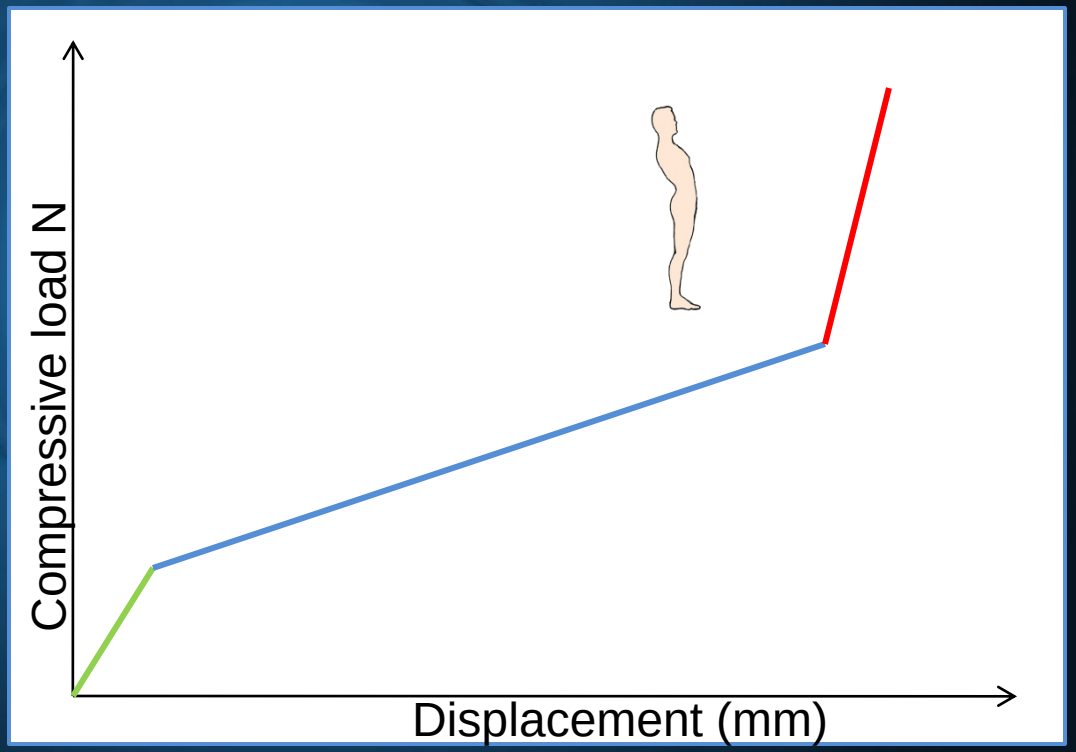
INTERSPINOUS TECHNOLOGY

Wellex pre load concept







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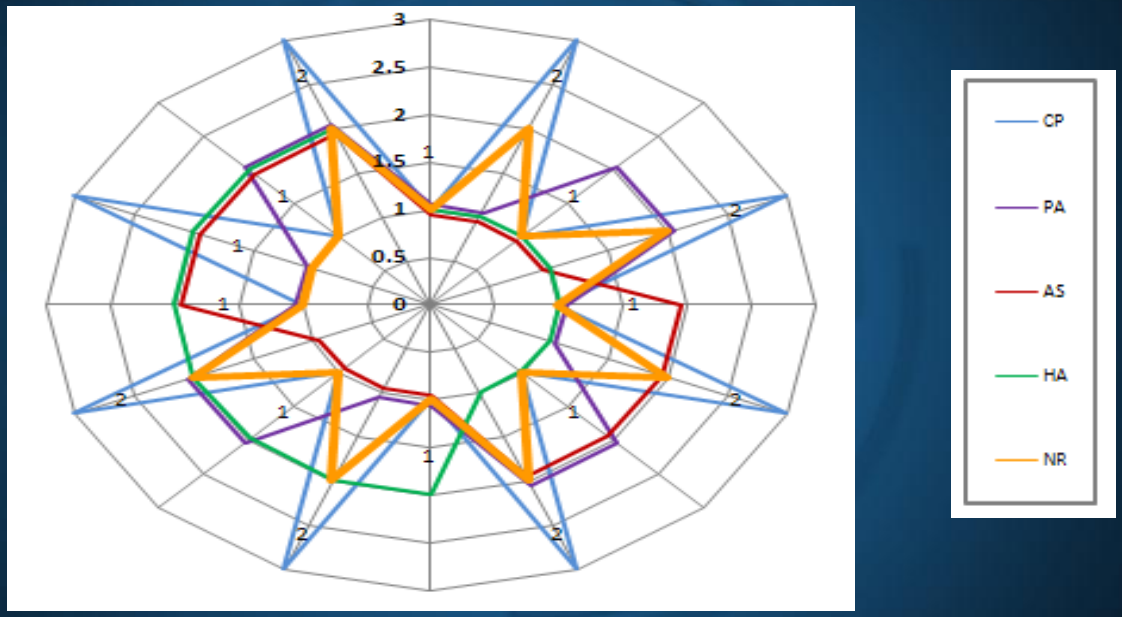
INTERSPINOUS TECHNOLOGY

Stifness Selection



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INTERSPINOUS TECHNOLOGY

Wellex size range

Designation	Reference
Wellex inter spinous implant H:8 mm, pre-loading: 50 N	10001
Wellex inter spinous implant H:8 mm, pre-loading: 100 N	10002
Wellex inter spinous implant H:10 mm, pre-loading: 50 N	10003
Wellex inter spinous implant H:10 mm, pre-loading: 100 N	10004
Wellex inter spinous implant H:12 mm, pre-loading: 50 N	10005
Wellex inter spinous implant H:12 mm, pre-loading: 100 N	10006
Wellex inter spinous implant H:14 mm, pre-loading: 50 N	10007
Wellex inter spinous implant H:14 mm, pre-loading: 100 N	10008
Wellex inter spinous implant H:16 mm, pre-loading: 50 N	10009
Wellex inter spinous implant H:16 mm, pre-loading: 100 N	1000A
Synthetic ligament (with locking mechanism)	FBIOLP0535

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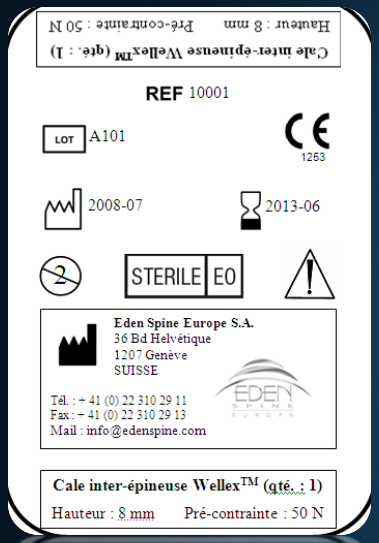
STERILE PACKAGING

Wellex Implant Packaging



The Ethylenoxid (ETO) is a gas used for the sterilization and decontamination of products. It is a very reactive alkylating agent at low-temperature (generally between 40-60°C), it is used particularly for heat-sensible products.
ISO 11135.

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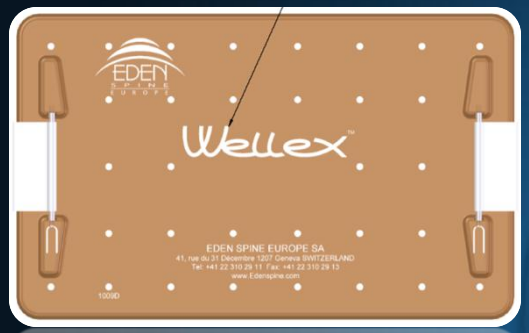
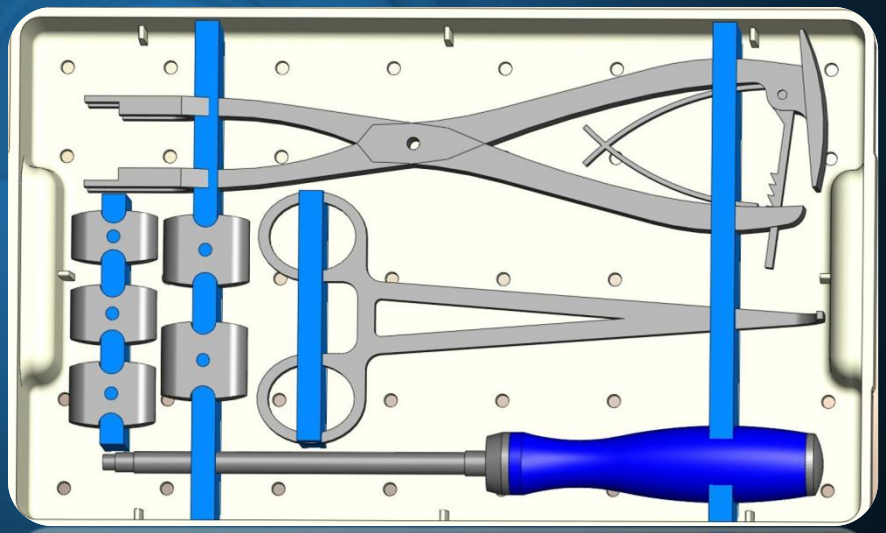
EDEN SPINE

INSTRUMENT SET PACKAGING

Wellex Instruments Packaging





- 5 trial implant:
  H8-10-12-14-16 mm
- 1 Trial implant holder
- 1 Impactor holder
- 1 Ligament holder

Method: **Sterilisation with saturated water vapour**
Minimum length of time: 18 min
Minimum temperature: 134°C
Drying: 20 min return to room temperature

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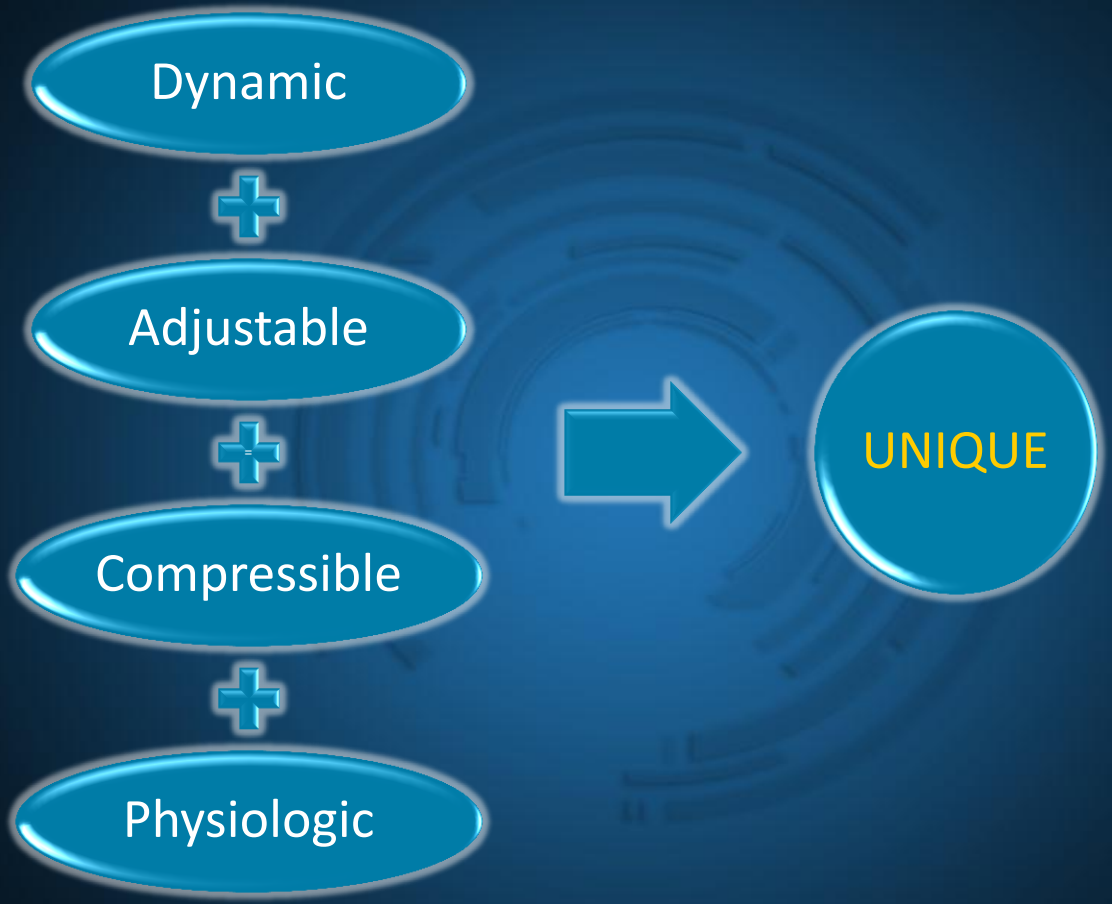
4 KEY DIFFERENTIATING FACTORS



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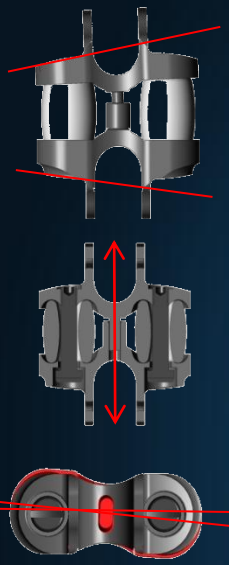
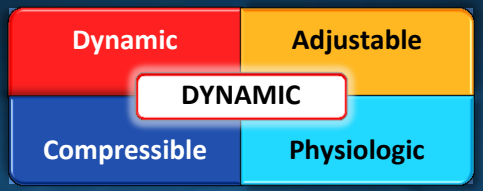
DIFFERENTIATING FACTORS #1





Controls movement dynamically in all planes and all directions

without blocking extension, thus maintaining the Neutral Zone

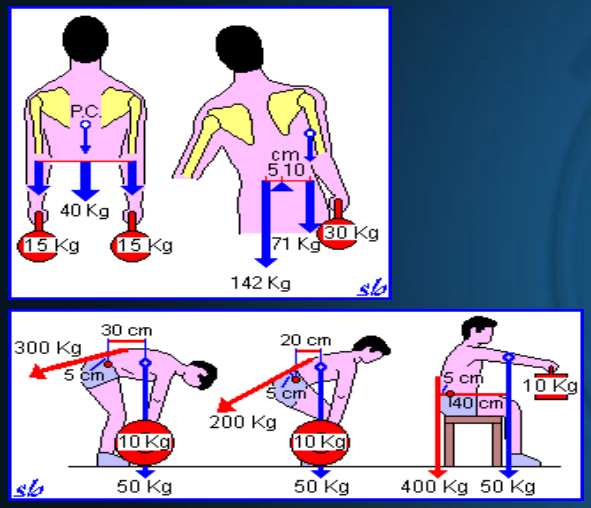
Also reduces loading on the disc and the facet joints

Flexion – Extension - Axial Rotation - Lateral Bending - compression

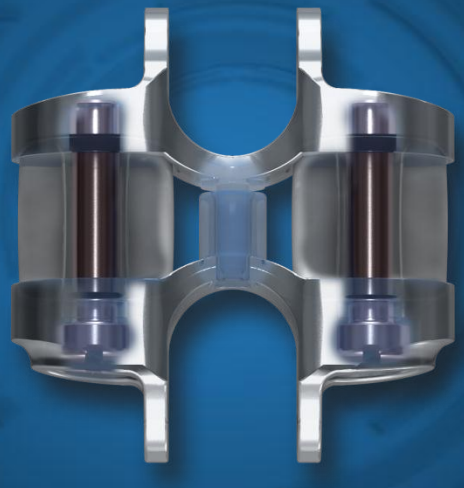
Research & Development

DIFFERENTIATING FACTORS #2

Dynamic	Adjustable
ADJUSTABLE	
Compressible	Physiologic



Anatomie et science du geste sportif"
Virhed R. - Ed. Vigot 1987



"Personalized to patient needs"

Surgeon has a choice of stiffness intra-operatively

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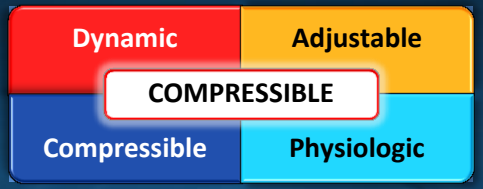
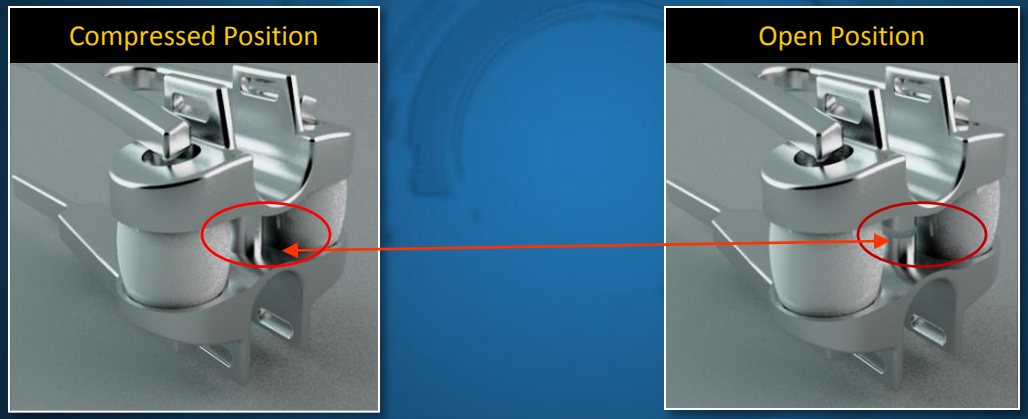
DIFFERENTIATING FACTORS #3





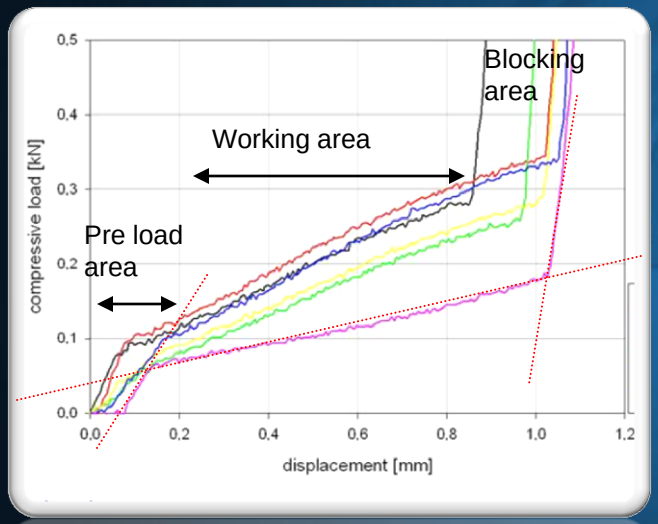
"Inserted compressed in a minimally invasive fashion."

No need to remove bony elements of the spinous process, avoiding the risk of implant migration.

Research & Development

DIFFERENTIATING FACTORS #4

Dynamic	Adjustable
PHYSIOLOGIC	
Compressible	Physiologic



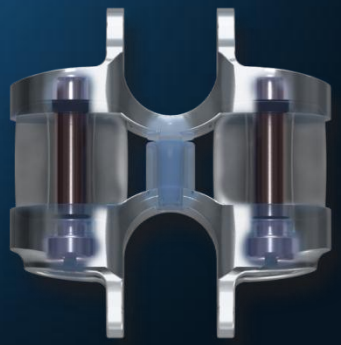
"Viscoelastic material allows for physiological motion"

Research & Development

* Currently for International use only.

KEY BENEFITS

- Dynamic implant allows and controls mobility of the FSU in Flexion/extension, axial rotation and lateral bending
- Respect the bony structure (no need to cut the spinous process)
- Adapted to the patient morphologia (different stiffness)
- Physiological way of working



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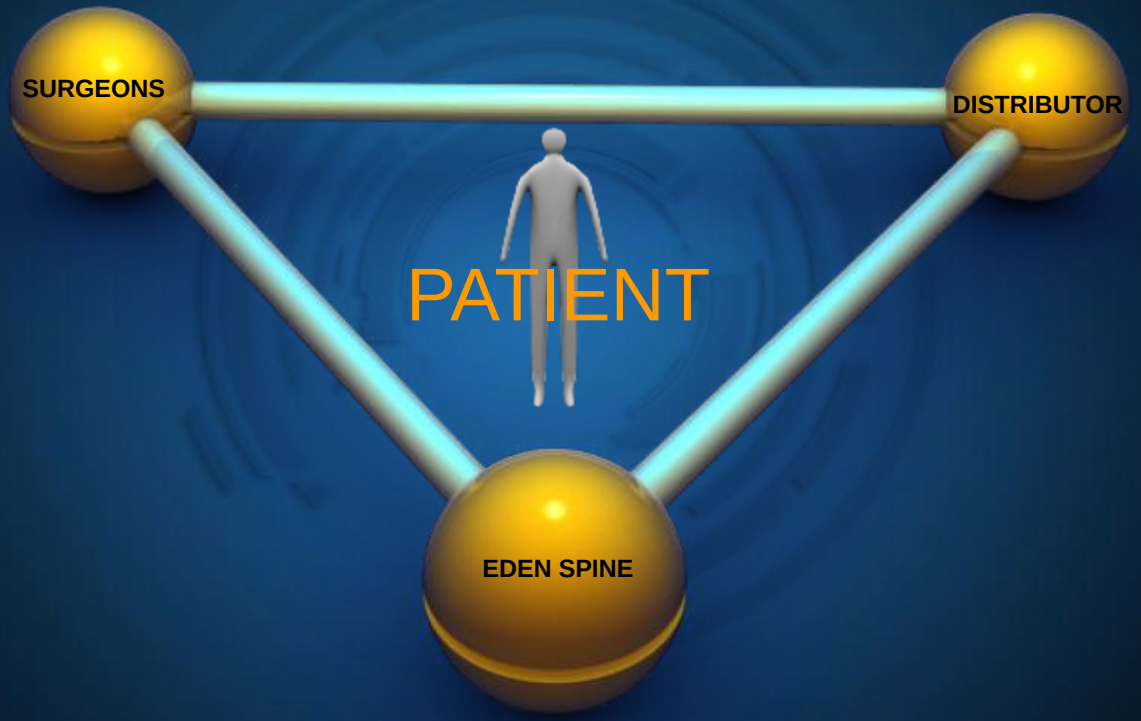

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