

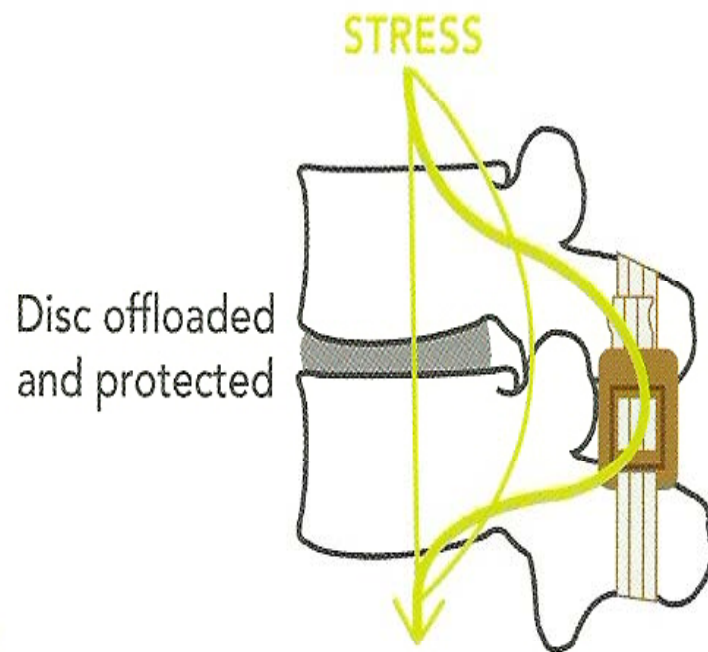
SMS – The History behind the Device

Basic Biomechanics/Lumbar Instability

Disc degeneration leads to

- Loss of water content (black disc)
- Reduction in disc height
- Neural compression (Roots or Dura)
- Increased mobility and INSTABILITY

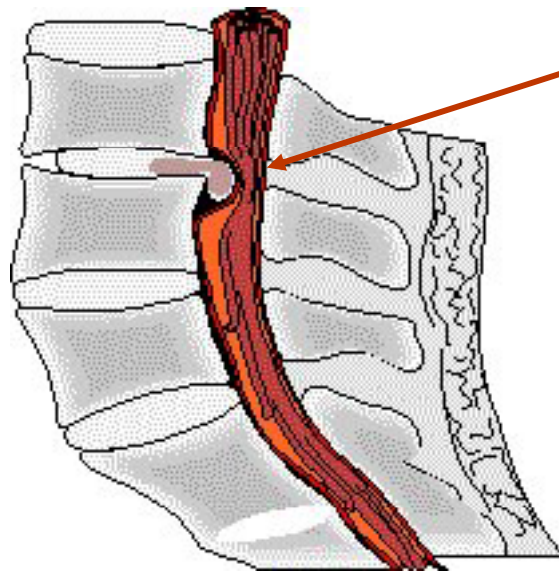
SMS Biomechanical principal



When degenerative disc disease occurs it leads to a loss of water content in the disc which increases the range of motion of the segment and can accelerate the degenerative changes. The SMS device is designed to restore the normal biomechanics by off-loading the pressure on the disc and providing mechanical support in both flexion and extension.

Spine surgery

consequences of discectomy



Discectomy:

- Removes neural compression
- Treats the pain

BUT

- Increases mobility
- Decreases rigidity

- ➔ **Discectomy** only treats the **consequence** of disc degeneration
- ➔ The aim of SMS is to treat the **cause** of disc degeneration: instability

SMS implant's effects

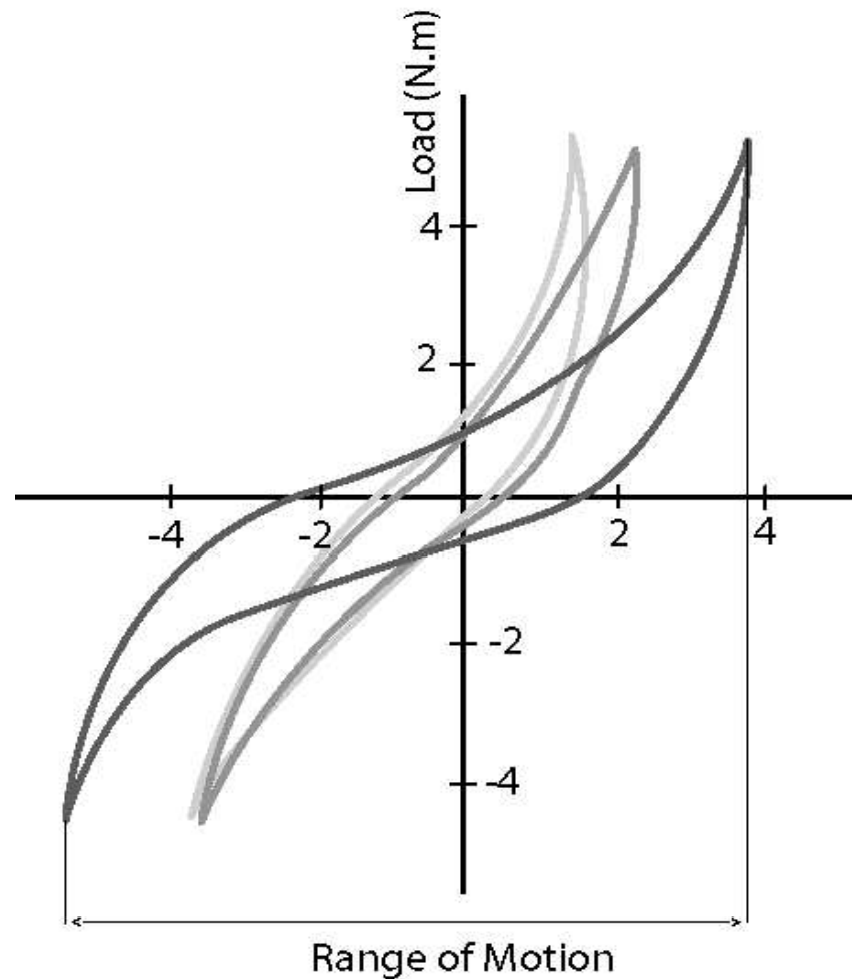
- **Discectomy**

- Treats the ***consequences*** of disc degeneration
- Treats the pain but leaves a void in the disc that leads to further loss of stability, and in turn accelerates the degeneration process.

- **SMS**

- Treats the ***cause*** of the disc degeneration
- When used ***in conjunction with a discectomy***, SMS device stiffens the treated segment in order to avoid further disc degeneration.
 - *Provides pain relief*
 - *Preserves mobility*
 - *Is fully reversible*
 - *Leaves all other options open*

Mechanical behaviour of an unstable segment



- Intact
- Discectomy
- Disc stabilised with SMS

Before significant damage to the mobile segment, the SMS device –

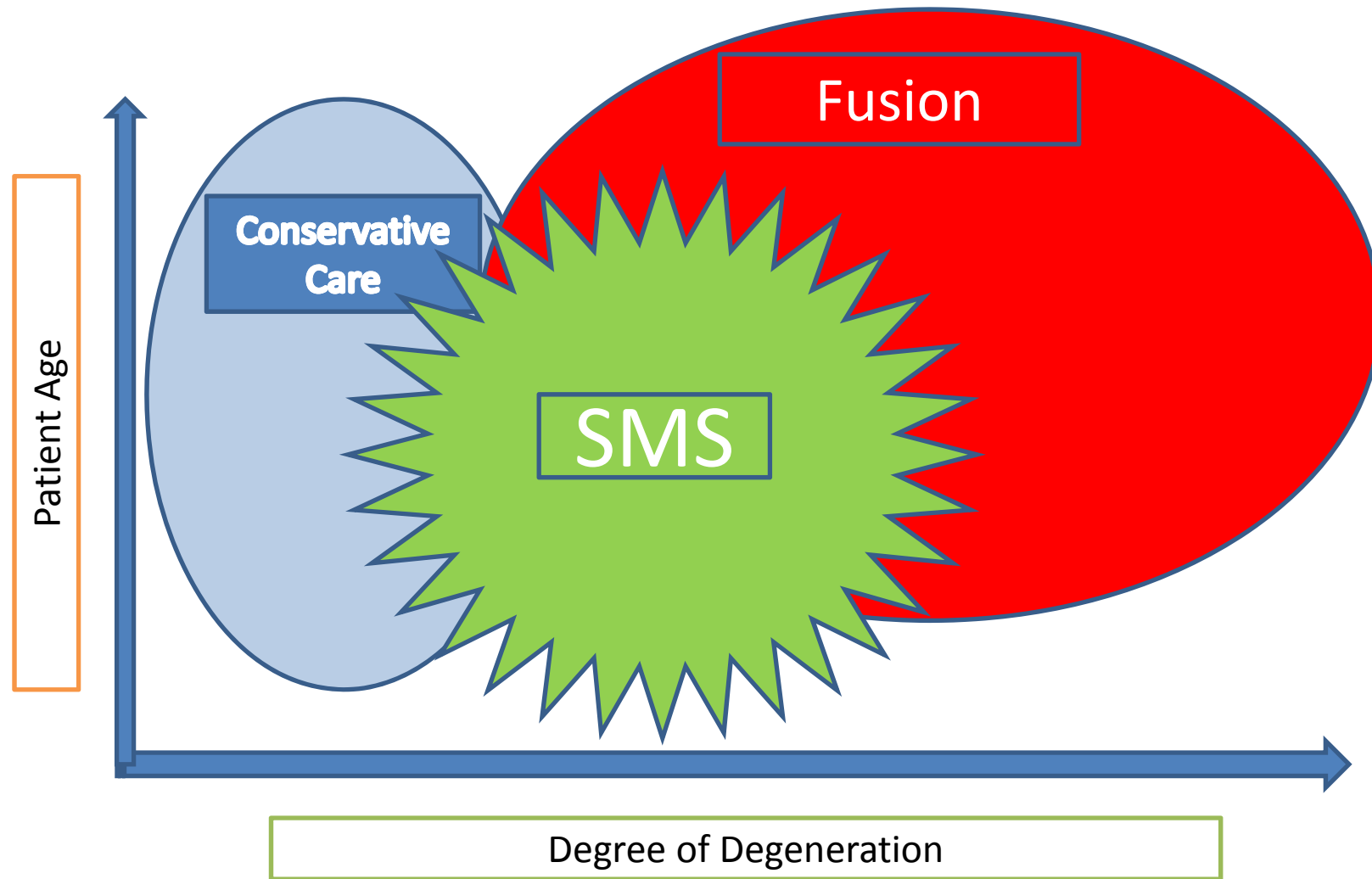
- Increases stiffness at the unstable segment
- Controls the mobility (ROM)

In order to preserve the disc when the muscles are unable to do so.

Summary

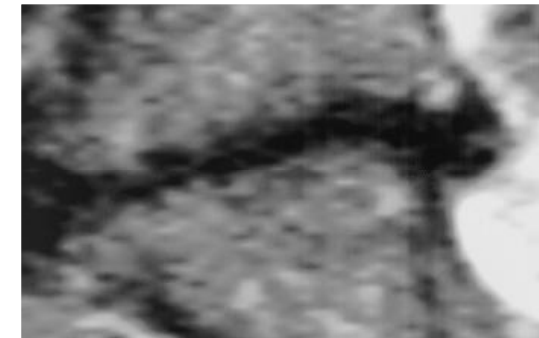
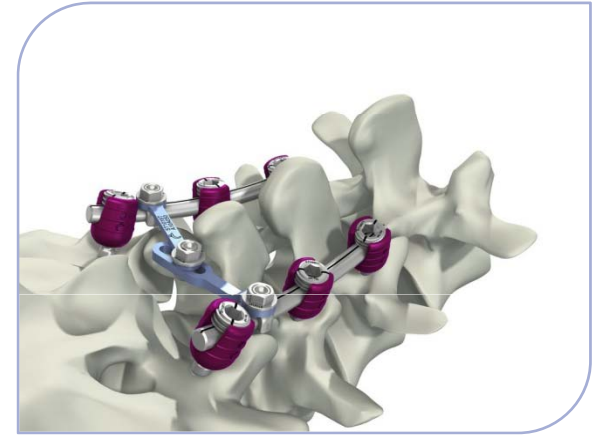
- The SMS device is not just an interspinous spacer – it is a dynamic stabilisation system that works in both flexion and extension.
- The SMS device is an elegant surgical solution that preserves mobility, anatomy and stability while leaving all subsequent options open should the need arise.
- The SMS device fills a therapeutic void that formerly existed between conservative treatment and fusion or disc replacement.

SMS in the care pathway



To fuse or not to fuse

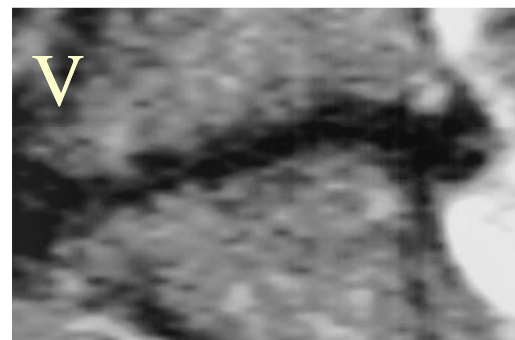
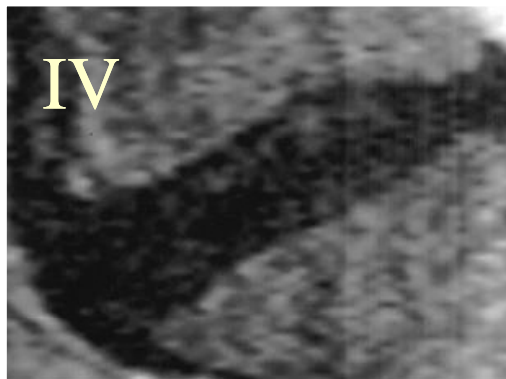
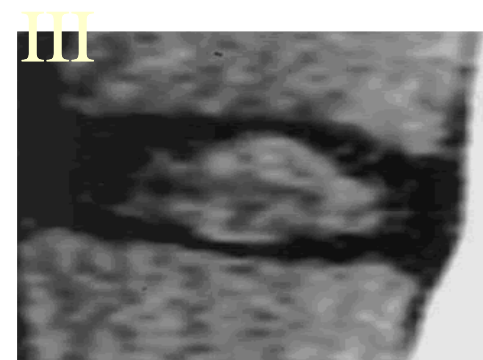
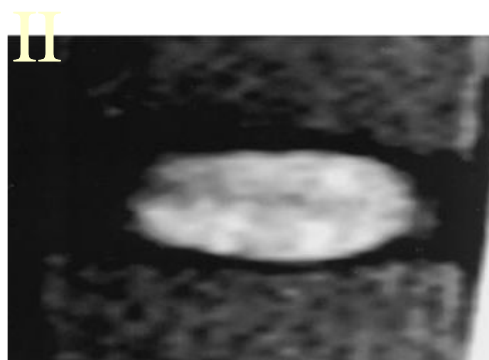
- Why fuse?
 - Immobilise because of instability
- End of the road
- Necessary for some
- Problems with pedicle screws
 - exposure, missed pedicles, op time, nerve root damage, blood loss, recovery time, success??
 - ADJACENT LEVEL DEGENERATION : Published



Stabilisation not fusion

Pfirmann classification

- MRI classification of Lumbar Intervertebral Disc Degeneration
- SMS appropriate for II, III and IV



All Interspinous devices are the same!!

- No they're not
- Do they work in flexion?
- IPDs – Interspinous Process DISTRACTION systems

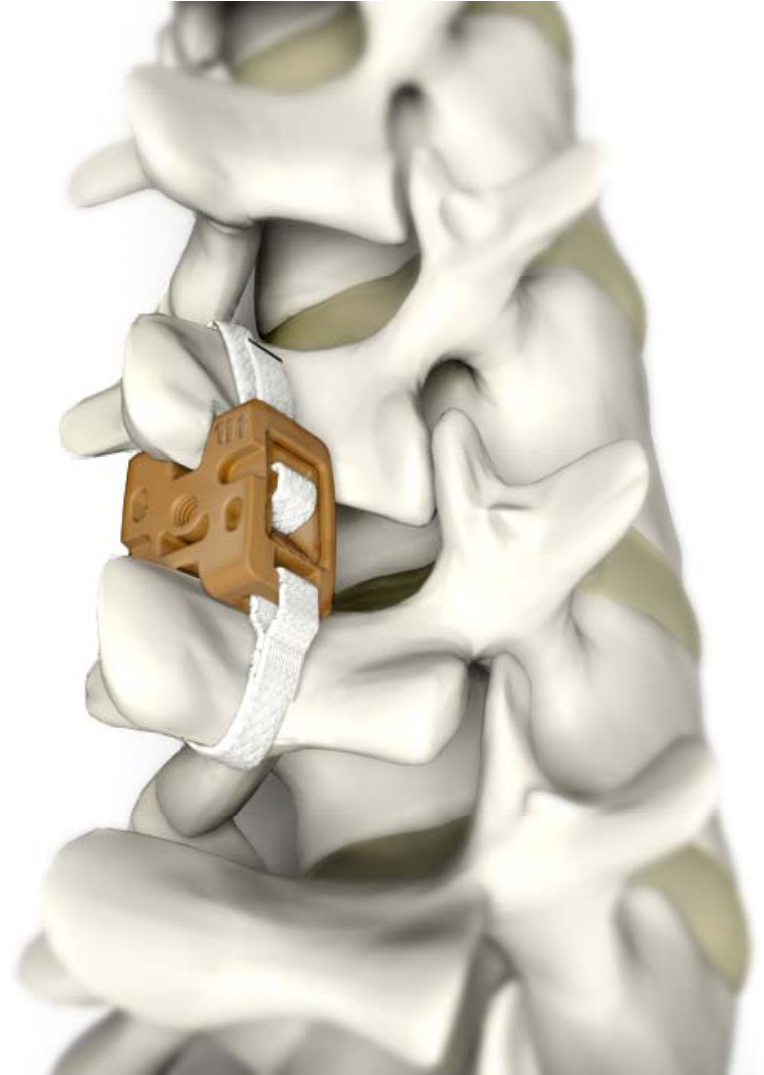


Most Definitely
Not all Interspinous Devices are the
same

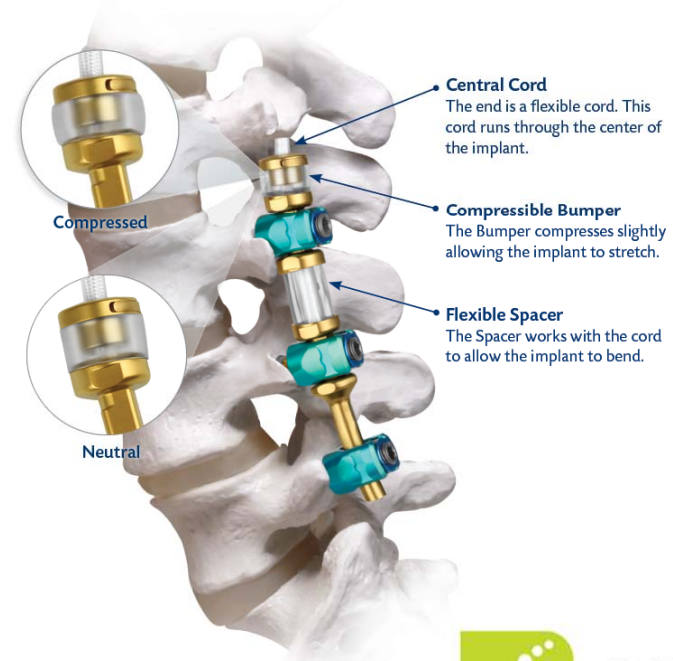
In Fact
SMS is NOT JUST a Spacer

It is

A Lumbar Stabilisation System



SMS is more akin to Dynesys BUT Without the problems of pedicle screws



Key Indications

- Patient selection is the key to good clinical outcomes
 1. Lumbar stabilisation following decompression/discectomy
 2. Recurrent disc herniation or revision decompression
 3. Large discs in young patients
 4. Topping off above a fusion
 5. Low back pain with isolated disc disease
 - Not non-specific low back pain

Indications

1. Stabilisation following decompression/discectomy

IPD area : They open the foramen

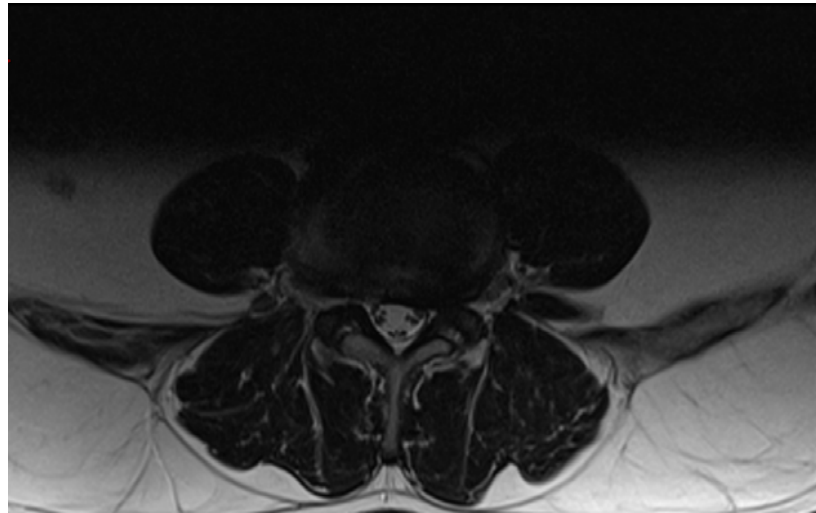
- surgeon doesn't generally decompress

SMS - do the normal operation then if you feel it is moving/unstable then stabilise with SMS.

- Treat the instability : Towel clip test**

Indications

2. Recurrent disc herniation or decompression



Why is this a good indication??

- Been in before : reoccurred : check stability
- Stabilise if unstable

Indications

3. Large disc in younger patients

Why is this a good indication??

Big Prolapse

<100% disc left

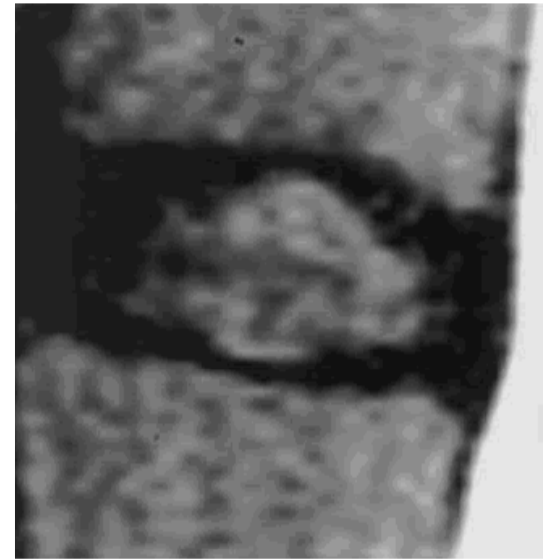
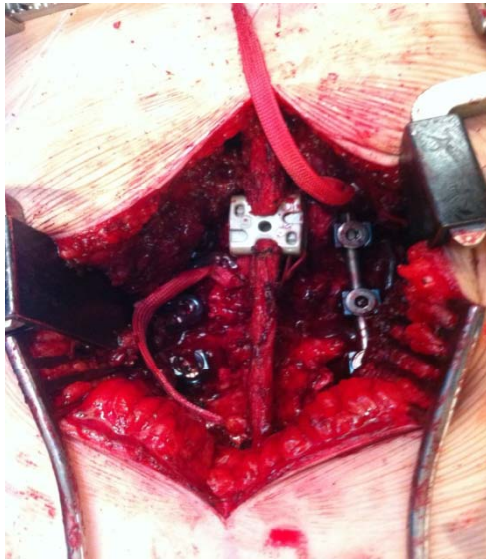
Greater instability

Accelerated degeneration

Needs support

Indications

4. Topping off above a fusion



Don't fuse more levels than you have to.
Black disc above fusion level.
Put in SMS to give it support

Indications

5. Low back pain with isolated disc disease

- Definitely not non-specific back pain

Great indication : Just put SMS in to stabilise

Not a first indication for the first time user

Build up to it when they have seen the results

L5/S1

- Not first few surgeries
- L5/S1 – usually achievable
- Need 10 mm at least S1 spinous process
- If in doubt look at lateral X-ray or do CT scan
- Need to consent patients for this.
- May need to fuse if not possible

Disc Rehydration?

- Lumbar stabilisation off loads the pressure on the disc which has been shown to contribute to disc rehydration.

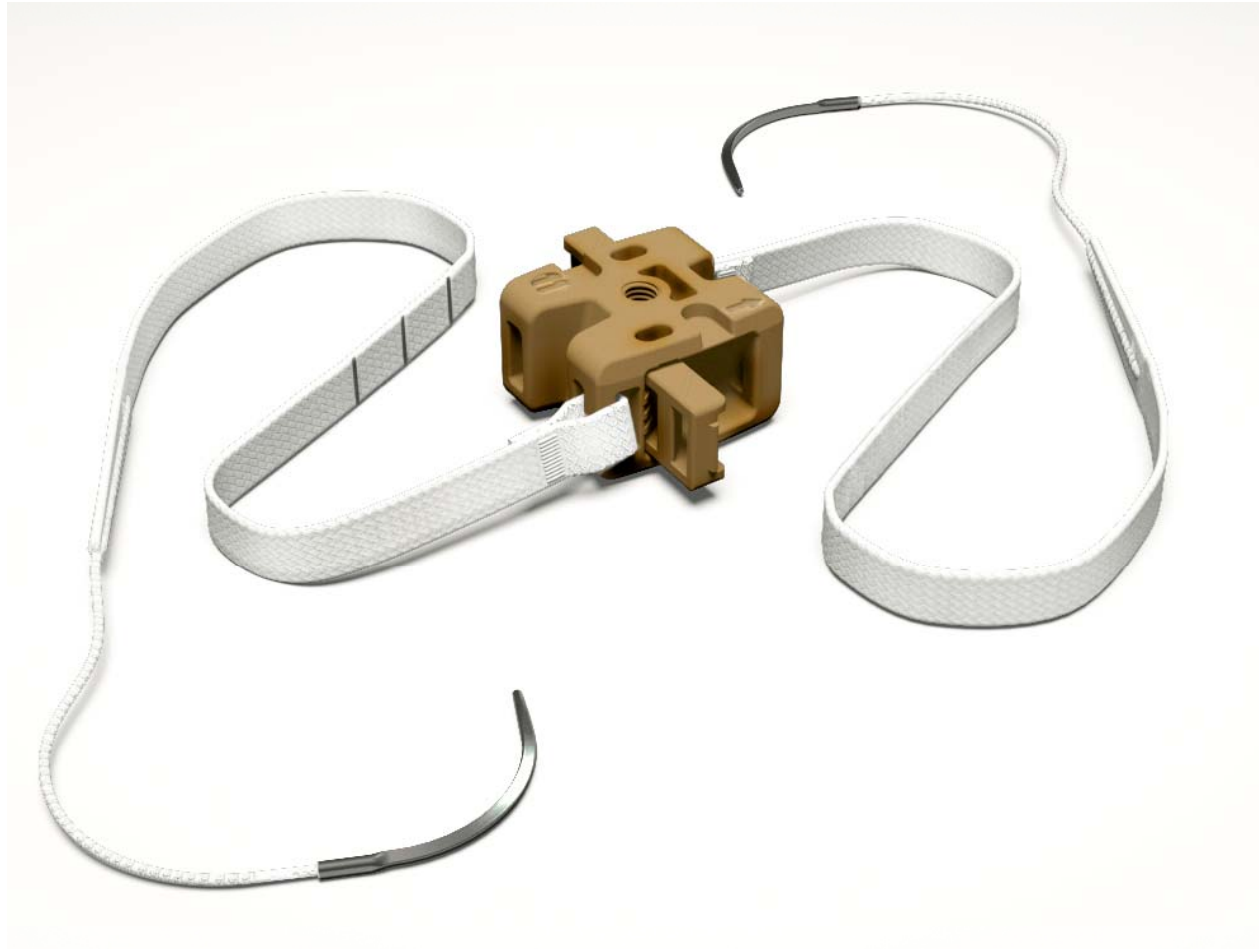
Pre-op



5 months



SMS : Stabilise with Motion Support



SMS - Ease of Use – An Elegant Solution!

SMS features and benefits

Threaded hole allows positive attachment of installation tools.

Black dyed bands indicate cutting positions on the braid. Welded bands on braid prevent fraying after cutting. No extra parts or procedures are required.

The end of the braid is stiffened and features have been added to the main body. This ensures the braid feeds easily through the implant gates.

Braid lock gates permanently attached to the main body so there is no need to fit during surgery. Supplied in the open position to allow easy routing of the braids.

Needle attached to braid to allow for piercing of the interspinous ligaments. This is cut off prior to threading through the implant.

Gates slide closed, and when braids are tightened they pull the gates into the locked position.

Main body made from radiopaque BaSO₄ filled PEEK so that whole implant can be seen clearly under X-Ray. Implant size and correct orientation moulded into the main body.

SMS Implant Features and Benefits

SMS	Feature	Benefit
Peek Body with 6% BaSulphate	See implant outline on x-ray	Safety for the surgeon : Clearly see the implant at the correct level Easier production process
Integral gates assembled into body	Less implant parts	No fiddly introduction of clips Cannot drop clips on floor Safety : Know gates are attached securely Easier surgical technique
Braid has suture attached	Suture attached to braid	Easy to pass through the interspinous ligament : Improved surgical technique Less instruments
No hole in band	Band stiffened at suture connection	Stronger, no band distortion Easy to pass through gates
Implant has 4mm screw thread for implant holder	Screw thread for holder to attach into	Much firmer connection between implant and holder : Safer and stronger

SMS Implant Features and Benefits

SMS	Feature	Benefit
Gate already inserted	Integral gate : Ensures gate stays in	Much easier surgical technique Safer and stronger
Ramp on side of body		Assists in passing the band through the gate
Body has 2 recesses for tightening holder	Very good hold on implant during tightening	More tactile feedback for surgeon. Safer and stronger connection
Gate has lip	Ensure gate doesn't come out of implant during tightening	No danger of gate not being properly inserted Additional safety
No Ti Clip	Band has heat treated points that are marked for safe cutting	No Ti in body Less Cost Less Instruments Easier to use No danger of long-term damage to tissue.

SMS Instruments Features and Benefits

SMS	Feature	Benefit
9 instruments		Easy of Use Cost of Manufacturing Easier surgical technique Cost for distributors
Implant holder screws into implant	Secure fixation to implant	Assists in tightening procedure.
Implant tightener fits securely over implant holder and is secured onto implant into recesses		Safety Ease of use Secure fixation to implant
Gate held in place by lip Guide will not go over implant if gate is not closed	Good instrument design	Safety Ease of use Easier Tightening
Tightener held at bottom of tightening guide	Extended c-ring at bottom of tightening guide	Ensures tightener cannot move laterally Safety, easier to tighten the implant