



Medtronic

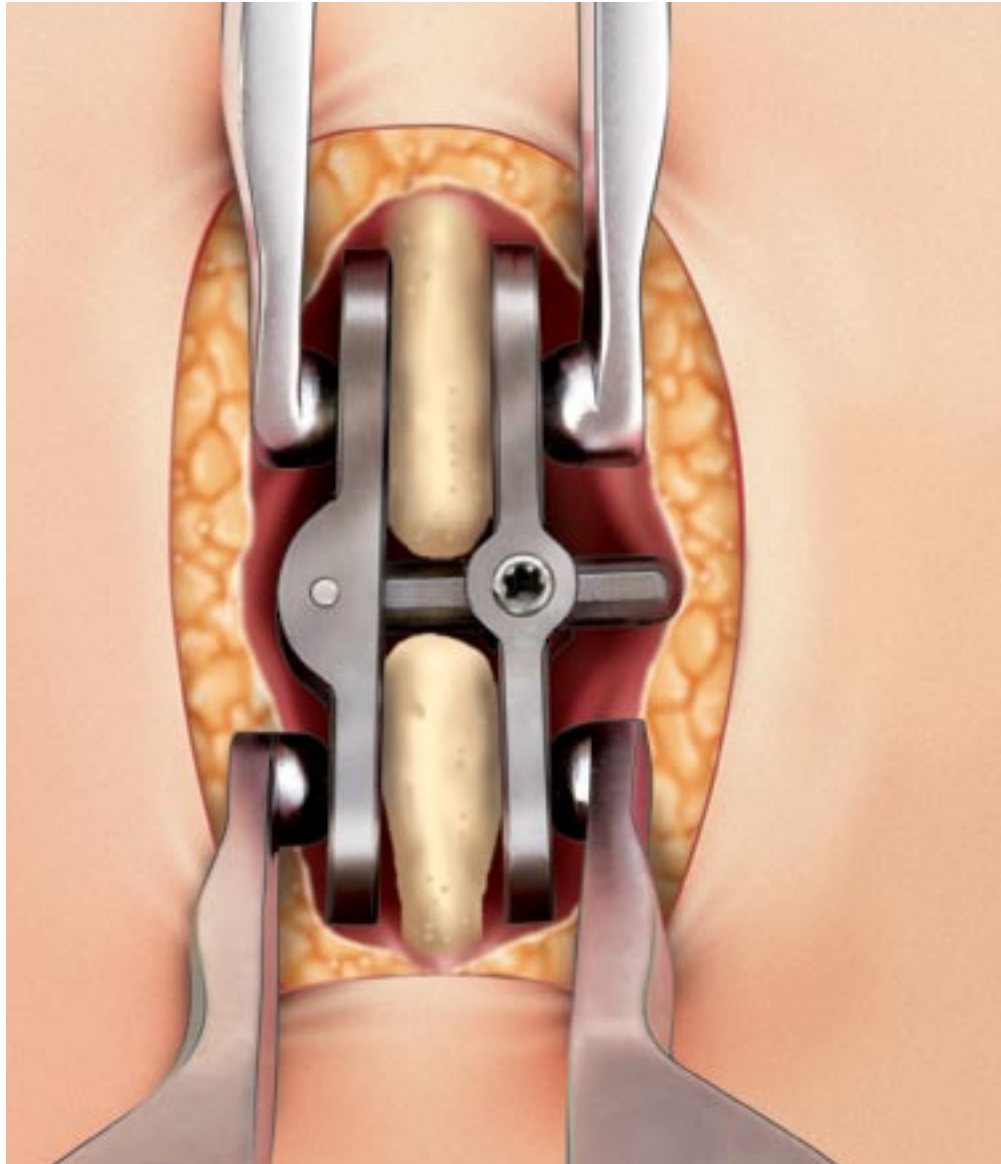
SOFAMOR DANEK

CD HORIZON[®] SPIRE[™]

Stabilization System

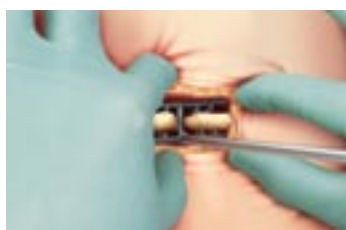
As described by

James Robinson, MD
Atlanta Brain and Spine Care
Atlanta, GA



Surgical Steps

1. The patient is positioned in a prone position on the operating table for surgery.
2. Using a combination of manual palpation and imaging techniques, or image guided technology, the surgeon identifies the appropriate spinous processes for application of the plate.
3. The surgeon makes a midline incision above the spinous processes at the appropriate levels. The incision will be approximately 3 cm in length.
4. All musculature and other soft tissues are elevated from the spinous processes to be fixed. Leave the supraspinous ligament intact. Remove the interspinous ligament.
5. The spinous process construct is fixed to the insertion instrument and inserted through the surgical incision site. One half of the construct is placed on each side of the spinous processes, with the sliding post lying in the space between the spinous processes (A).

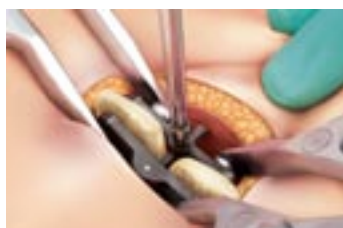


A

6. Using the compression instrument(s), the spinous process construct is clamped to the spinous processes, driving the spikes into the bone. Once securely seated, the compression instrument(s) are used to maintain compression and stabilize the implant (B) while the locking plug is tightened. At a pre-determined torque (C), the top of the locking plug will break away, indicating the plug is sufficiently tightened (D).



B



C



D

7. After implantation of the device, the surgical site will be closed using standard techniques. The fascia can be closed back to the supraspinous ligament.
8. The CD HORIZON® SPIRE™ Stabilization System is not intended as a stand alone device and is used with the CD HORIZON® Spinal System.

Construct Removal

The set screw removal tool* can be used to disengage the screw. Once the set screw has been removed, the device can be separated and removed from the spinous processes.



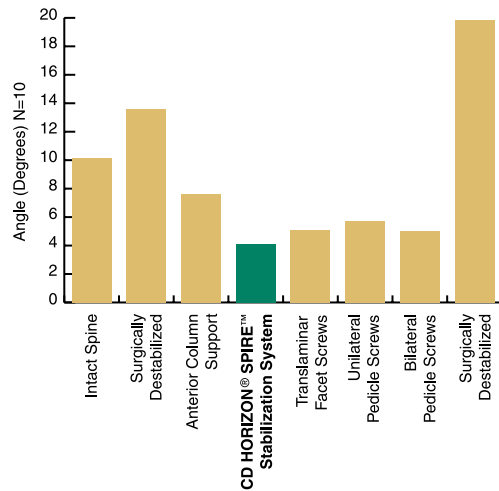
E

* Standard in the set, part# 8910641

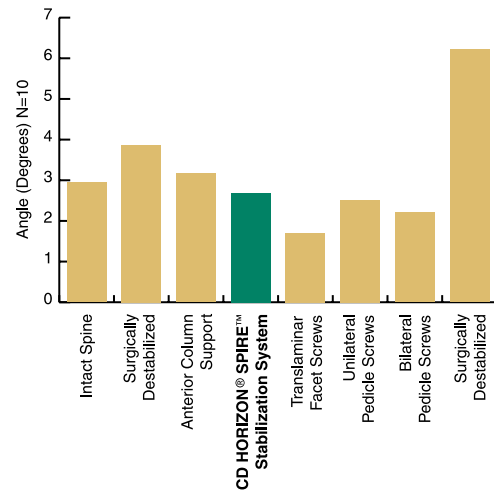
● Biomechanical Data

WITH ANTERIOR COLUMN SUPPORT

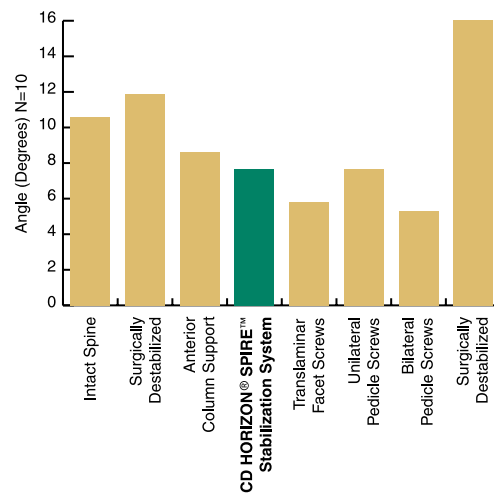
Flexion Extension Range of Motion



Axial Rotation Range of Motion



Lateral Bending Range of Motion



CD HORIZON® SPIRE™ Stabilization System Biomechanical Study Criteria:

- L4–5 cadaveric spines (n=10)
- Ages 40–79 (mean=66)
- Bone mineral density ranged from 0.7 g/cm²–1.25 g/cm²
- 10 test conditions loaded in consecutive order and then retested the destabilized condition
- Each condition subjected to a ±6.0 Nm non-destructive quasi-static loading in axial rotation, flexion/extension, and lateral bending with a constant displacement/rotation rate
- Axes of rotation:
 - ~ Axial rotation—junction of the mid-sagittal plane and posterior two-thirds of the L4–5 disc from the anterior margin of the column
 - ~ Flexion/Extension—junction of the mid-coronal plane of the L4–5 disc and posterior two-thirds of the disc from its anterior margin
 - ~ Lateral bending—junction between mid-sagittal plane and the mid-coronal axis of L4–5

CD HORIZON® SPIRE™ Set Configuration

Item Number	Description	Qty	Item Number	Description	Qty
185-064	General Base Lid	1	9240150	M4 Breakoff Set Screw	2
9240099	General Base	1	9240210	SPIRE Single Compressor	2
9240100	CD HORIZON SPIRE Device	2	8910640	SPIRE Set Screwdriver	1
1000117	SPIRE Set Screw Module	1	8910641	SPIRE Set Screw Removal Tool	1

For product availability, labeling limitations, and/or more information on any MEDTRONIC SOFAMOR DANEK product, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.



Medtronic
SOFAMOR DANEK

listen. respond. deliver.

MEDTRONIC SOFAMOR DANEK USA, INC.

1800 Pyramid Place Memphis, TN 38132

(901) 396-3133 (800) 876-3133

Customer Service: (800) 933-2635

www.sofamordanek.com

For more information go to www.myspinetools.com

See package insert for labeling limitations.