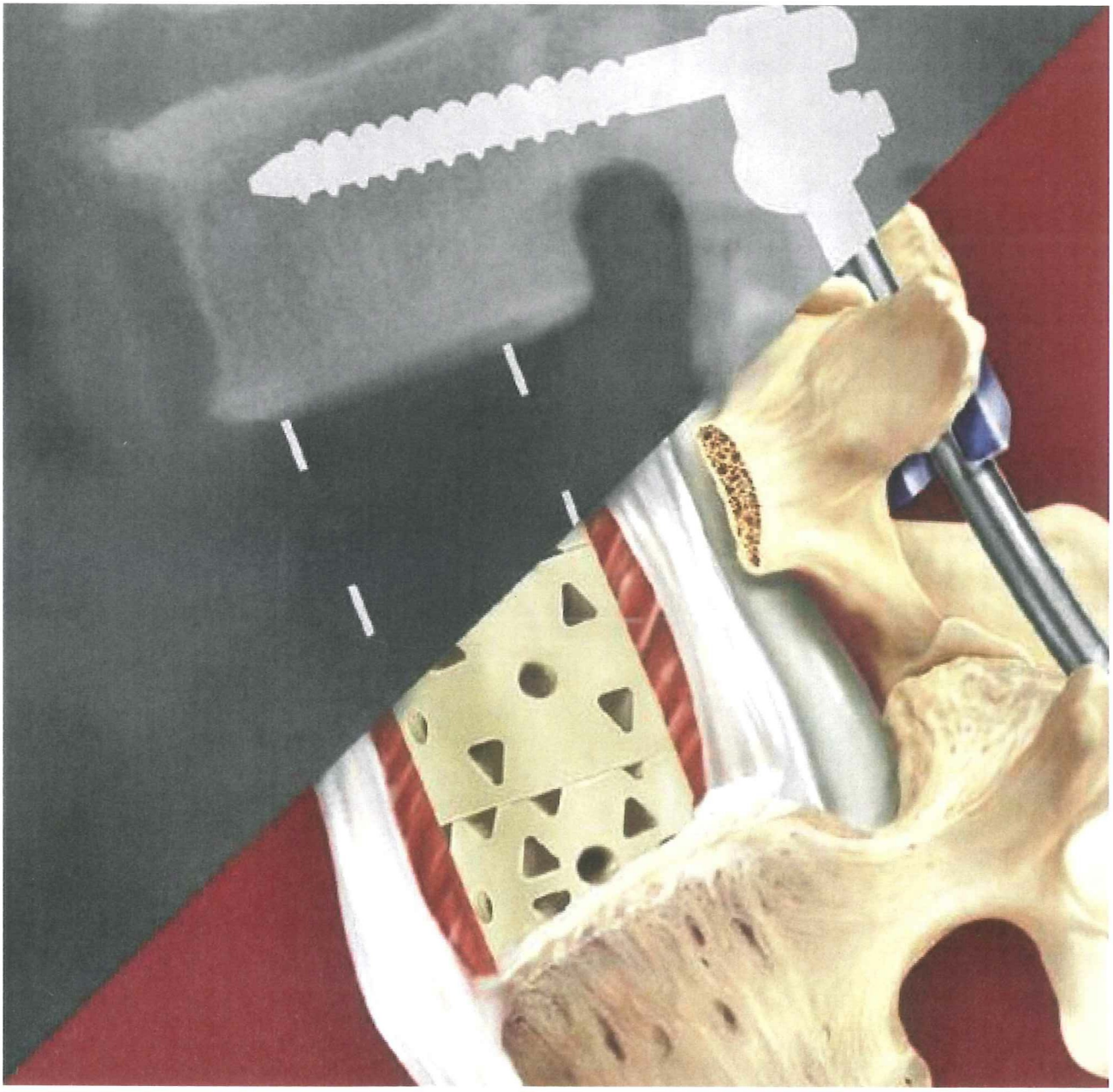
Medtronic
SOFAMOR DANEK

VERTE-STACK™

PEEK Stackable Corpectomy Device
Surgical Technique



EXHIBIT

MICHELSON TECHNOLOGY

MSD 1120
IPR2013-00506
IPR2013-00508

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Introduction

The VERTE-STACK™ device is manufactured from medical grade PEEK (polyetheretherketone) polymer. It has tantalum wires embedded for use as radiographic markers. This device has been cleared for lengths from 12mm to 80mm and can be used as an individual Add-On piece or a construct comprised of two Add-On pieces and one center piece.

The VERTE-STACK™ device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. This device is indicated for use in the thoracolumbar spine (T1-L5) to replace and restore the height of a vertebral body resected or excised for the treatment of trauma or tumor. Two contiguous vertebral bodies are the maximum number of bodies the device is intended to replace. The device is intended to be used with supplemental fixation: Medtronic Sofamor Danek's ZPLATE II™ Anterior Fixation System, LAURAIN DEWALD™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, DYNALOK CLASSIC™ Spinal System or GDLH® Posterior Spinal System.

PEEK Material Advantages

Radiolucency

- Easier visualization of bone growth
- No scatter or artifact with CTs and MRIs

Biocompatibility

Long history of usage:
- Dental Implants
- Heart Valves/Stents
- Artificial Joints
- Finger Implants
- Spinal Implants

Bonelike Stiffness

- Modulus of Elasticity closer to that of cancellous bone
- Helps to mitigate 'stress shielding,' which can lead to bone mass loss

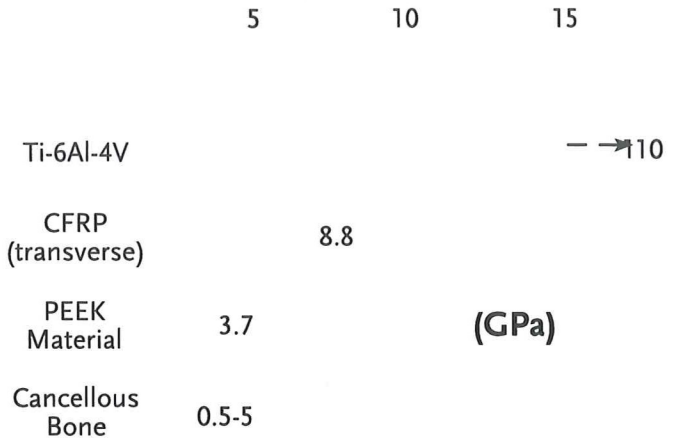
Strength

- Offers greater impact resistance
- High ultimate strength
- High fatigue strength

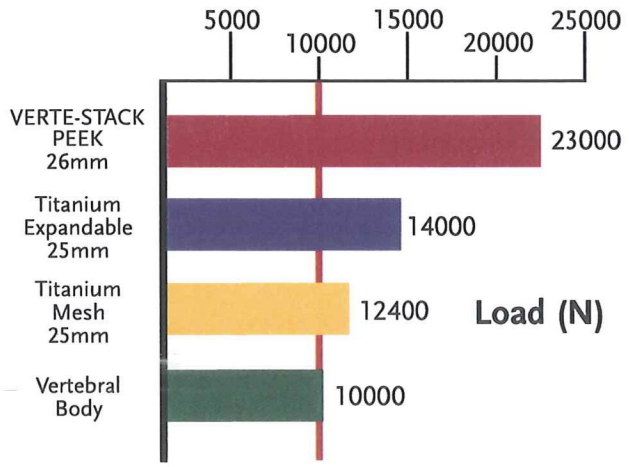
Wear Resistance

ZERO wear debris was generated during fatigue testing

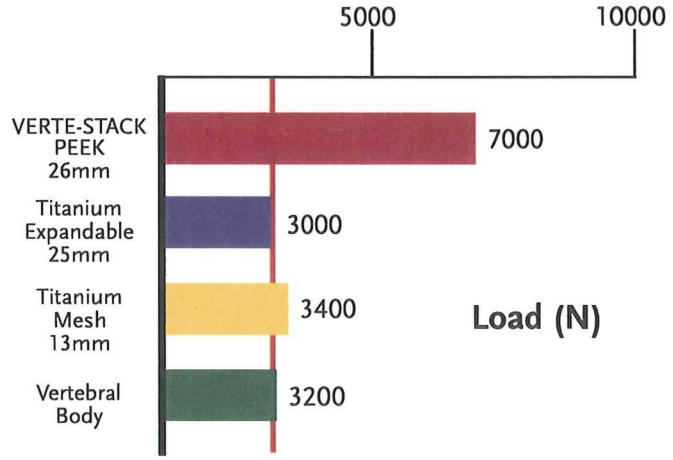
Elastic Modulus



Ultimate Strength



Fatigue Strength



VERTE-STACK™
Design Features

General Device

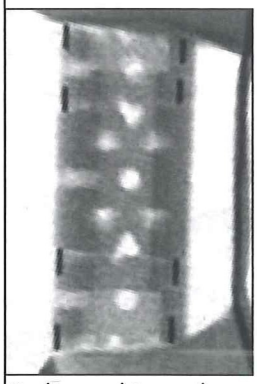
- Versatility
  - 12mm to 80mm heights
  - 0°, 4°, or 8° lordosis
  - Two footprint options
  - Multiple approach possibilities
- Simplicity
  - Integrated snap-connection
  - Easy to read radiographic markers
- Biocompatibility
  - PEEK material
  - Large, continuous graft area
  - Large endplate contact area

Add-On Pieces

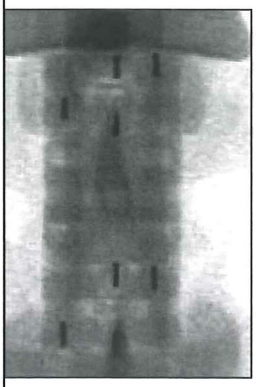
- 12mm to 20mm heights
- 4° or 8° lordosis
- Radiographic markers
- Large surface area to reduce subsidence
- Large area for bone graft
- Multiple Inserter attachment points

Center Pieces

- 5mm to 40mm heights
- Integrated snap-connection mechanism
- Continuous open central column for packing bone graft
- Multiple Inserter attachment points



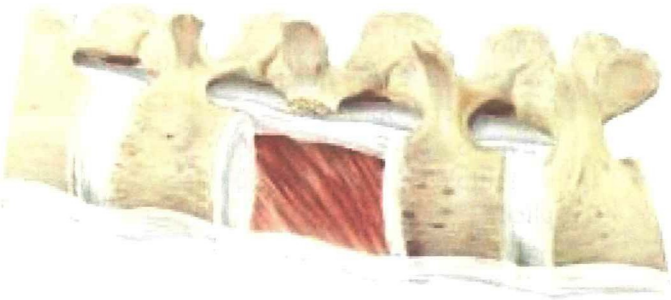
Radiographic markers – Lateral X-ray



Radiographic markers – AP X-ray

Step 1.
Vertebral Body Removal

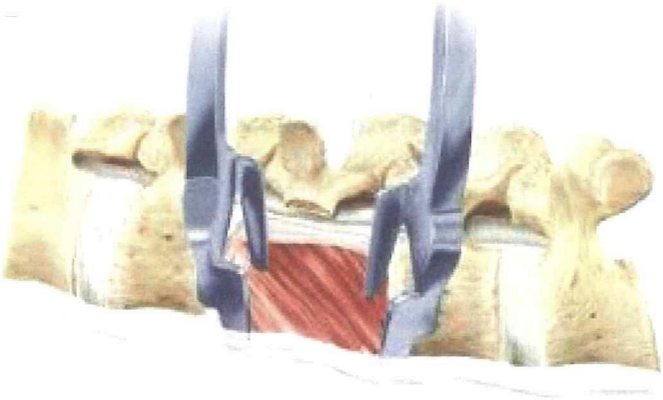
The affected vertebral body is exposed through the appropriate anterior approach. Both discs adjacent to the affected vertebral body are completely excised and the affected vertebral body is removed. Each endplate is then prepared by cartilage removal and light decortication.



Step 2.
Restoration of Anatomy

If the VERTE-STACK™ device is being used with one of the anterior supplemental fixation systems, please refer to that particular system's surgical technique for further information.

The interbody space is distracted using lateral vertebral body screws or the Vertebral Body Spreader. The tangs of the Spreader are placed on the cortical bone of the appropriate endplates and distraction is applied.



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