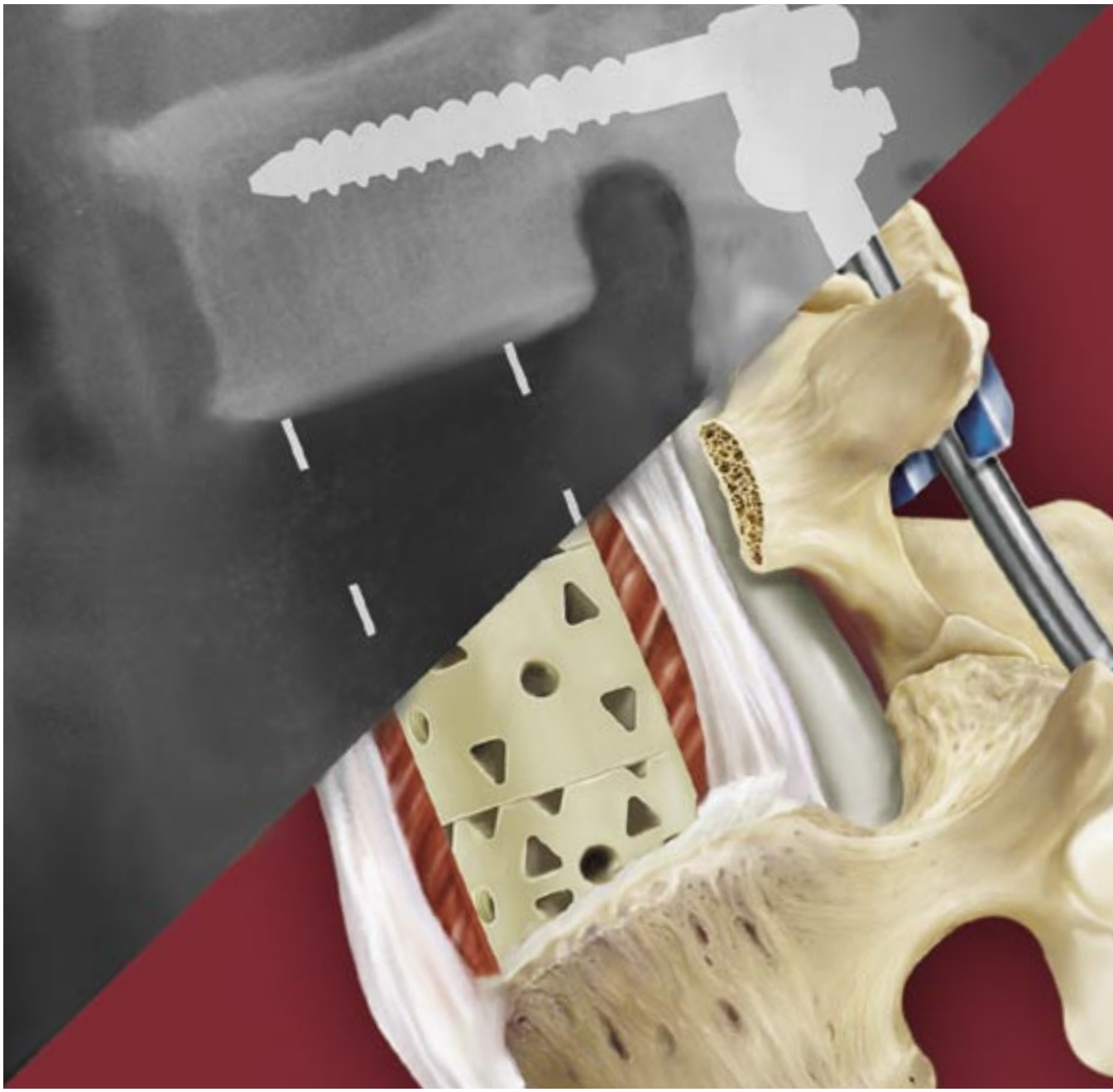
Medtronic
SOFAMOR DANEK

VERTE-STACK™

PEEK Stackable Corpectomy Device
Surgical Technique



MICHELSON TECHNOLOGY AT WORK

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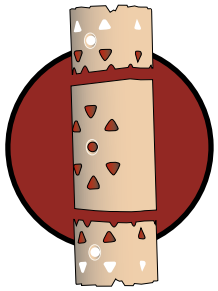
Introduction

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

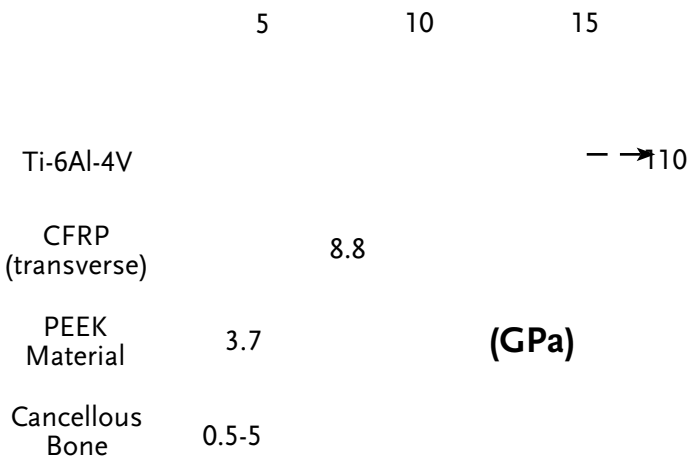
Strength

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

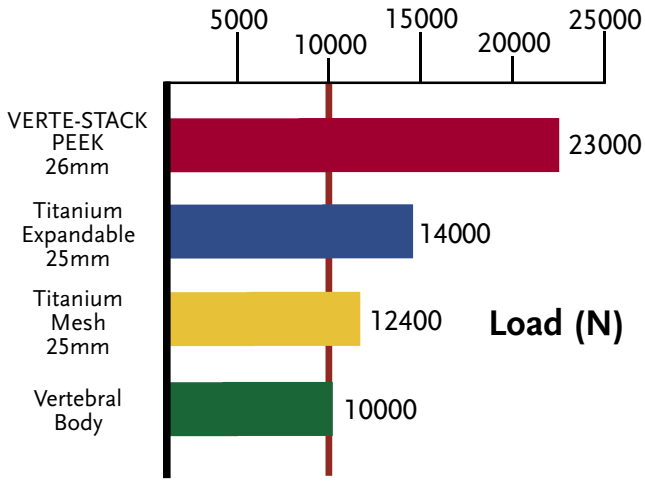
Wear Resistance

ZERO wear debris was generated during fatigue testing

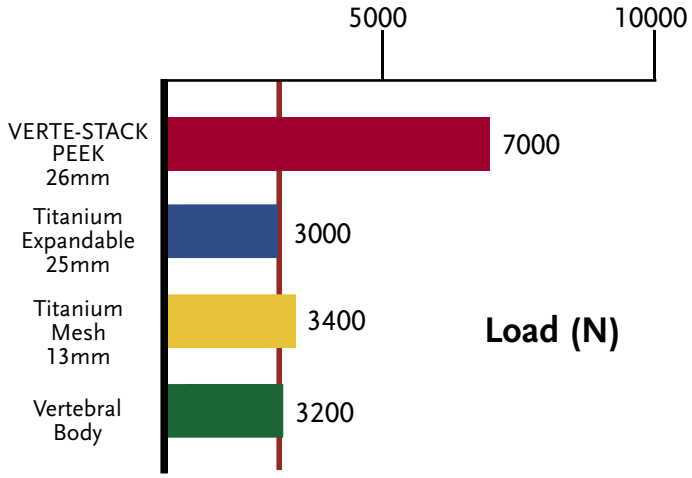
Elastic Modulus



Ultimate Strength



Fatigue Strength



VERTE-STACK™ Design Features

General Device

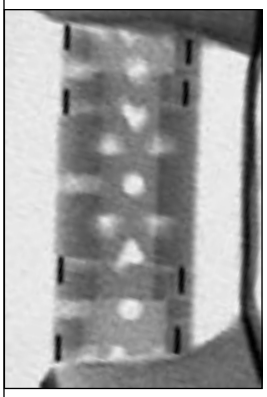
- Versatility
  - 12mm to 80mm heights
  - 0°, 4°, or 8° lordosis
  - Two footprint options
  - Multiple approach possibilities
- Simplicity
  - Integrated snap-connection
  - Easy to read radiographic markers
- Biocompatibility
  - PEEK material
  - Large, continuous graft area
  - Large endplate contact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

Add-On Pieces

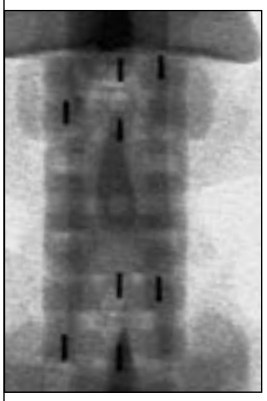
- 12mm to 20mm heights
- 4° or 8° lordosis
- Radiographic markers
- Large surface area to reduce subsidence
- Large area for bone graft
- Multiple Inserter attachment points

Center Pieces

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



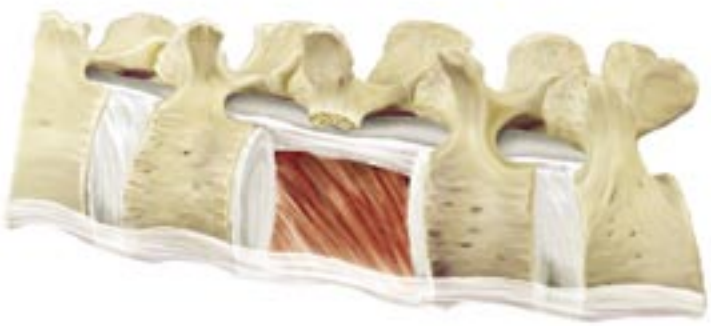
Radiographic markers – Lateral X-ray



Radiographic markers – AP X-ray

Step 1.
Vertebral Body Removal

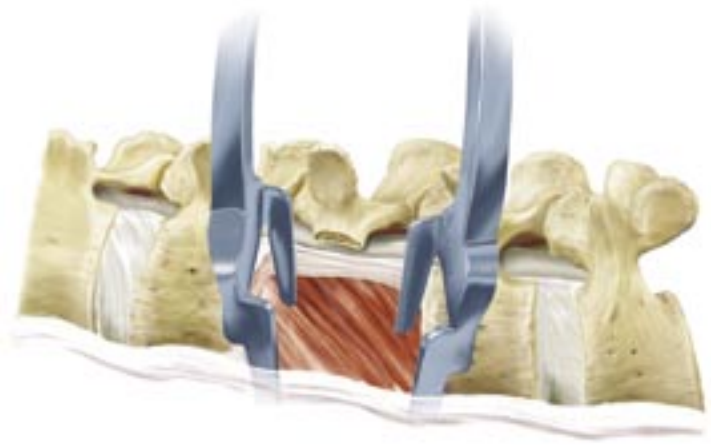
The affected vertebral body is exposed through the appropriate anterior approach. Both discs adjacent to the affected vertebral body are completely excised and the affected vertebral body is removed. Each endplate is then prepared by cartilage removal and light decortication.



Step 2.
Restoration of Anatomy

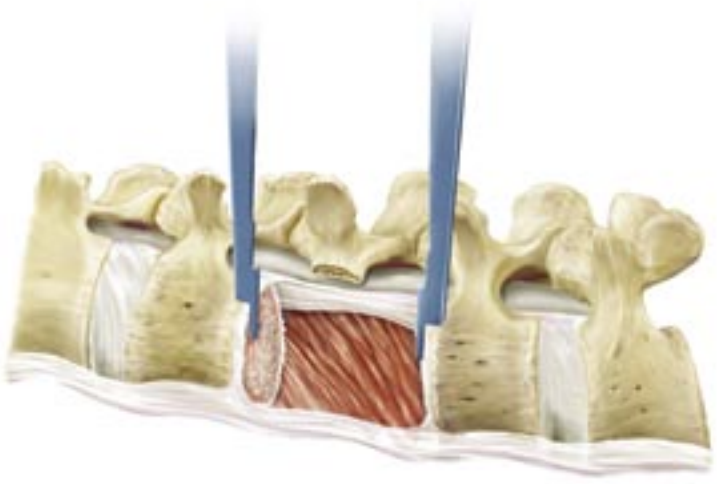
If the VERTE-STACK™ device is being used with one of the anterior supplemental fixation systems, please refer to that particular system's surgical technique for further information.

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.



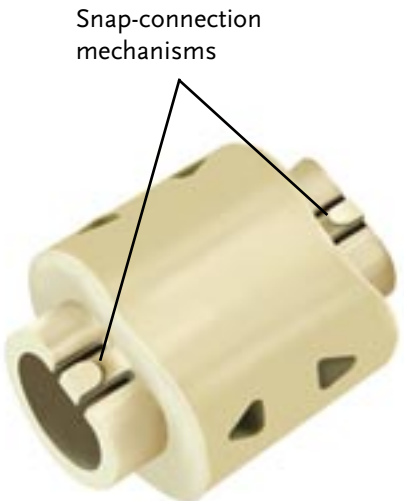
Step 3.
Device Selection

The appropriately sized trial endplates (large or small) are used to verify the full contact between the device and the adjacent vertebral bodies. Additional bone may need to be resected until a proper fit is achieved. Selection of the proper endplate angles is based on the anatomy of the individual patient. Once the proper size and angle have been selected, the proper length of the device is determined by using the calipers and the sizing chart.



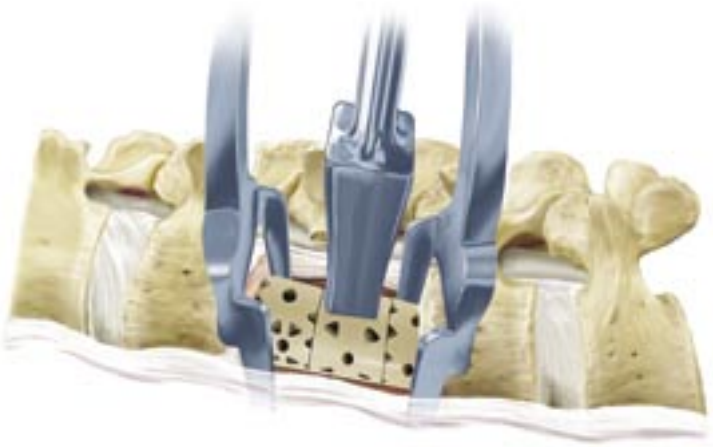
Step 4.
Device Preparation

The device is assembled by pressing the appropriate Add-On sections onto either end of the center cage. **[The flat Add-On cage must be placed with the angled face of the Add-On piece adjacent to the center cage.]** The tab mechanisms on the center device snap into the triangular notches on the Add-On device, holding the device securely together. The central channel of the device is filled with graft.



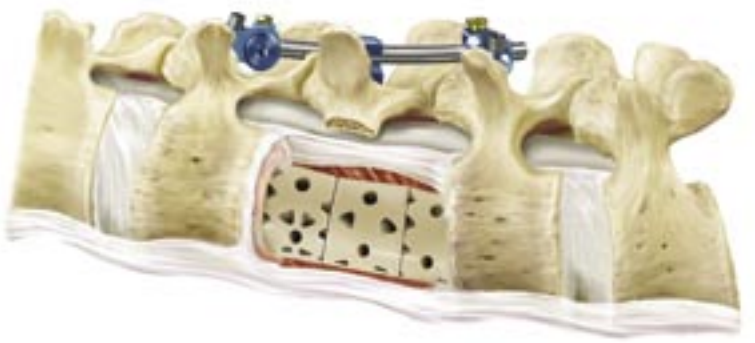
Step 5. Device Insertion and Placement

Prior to insertion of the VERTE-STACK™ device, distraction is applied across the defect. The device is inserted using the appropriately sized Inserter (large or small). Thread the Inserter Rod into the appropriate hole on the center device for the approach used (anterior, oblique, or lateral). Final placement may be refined by attaching the Inserter to either Add-On piece. Compression may be placed across the construct using the appropriate supplemental fixation.



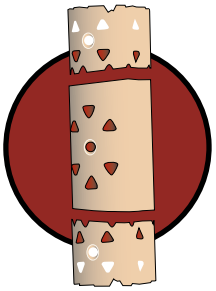
Step 6. Supplemental Fixation

VERTE-STACK™ is intended for use only in conjunction with supplemental fixation. Please refer to the technique manual for the anterior or posterior instrumentation selected. For detailed information on supplemental fixation, the list of systems can be found at the end of this document.



Step 7. Removal of Device (if required)

The vertebral bodies adjacent to the VERTE-STACK™ device are distracted using a spreader instrument. Reattach the Inserter to one of the threaded holes on the VERTE-STACK™ construct. Remove the device from its position.



PEEK Stackable Corpectomy Device

VERTE-STACK™

Height & Volume Chart

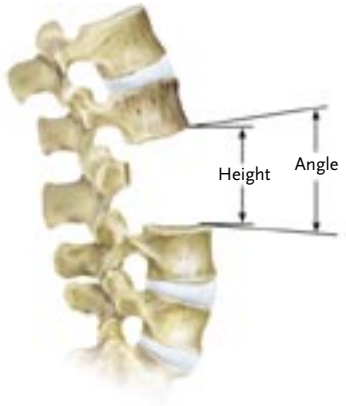
Device Height (mm)	Add-On Piece (mm)	Center Piece (mm)	Add-On Piece (mm)	Small Volume (cc)	Large Volume (cc)
12	12			3	5
14	14			3	6
16	16			4	7
18	18			4	7
20	20			4	8
29	12	5	12	4	9
31	12	5	14	5	9
33	14	5	14	5	10
34	12	10	12	5	10
35	14	5	16	5	11
36	12	10	14	5	11
37	16	5	16	6	12
38	14	10	14	6	11
39	16	5	18	6	12
40	14	10	16	6	12
41	18	5	18	7	13
42	16	10	16	6	13
43	18	5	20	7	14
44	12	20	12	6	12
45	20	5	20	7	15
46	12	20	14	6	13
48	14	20	14	7	14
50	14	20	16	7	14
52	16	20	16	7	15
54	12	30	12	7	15
56	12	30	14	7	15
58	14	30	14	8	16
60	14	30	16	8	17
62	16	30	16	8	17
64	12	40	12	8	17
66	12	40	14	8	18
68	14	40	14	9	18
70	14	40	16	9	19
72	16	40	16	9	20
74	16	40	18	10	20
76	18	40	18	10	21
78	18	40	20	11	22
80	20	40	20	11	23

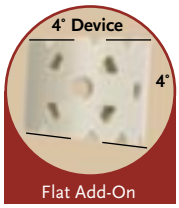
Small Size 26mm x 24mm
Wall Thickness: 5mm

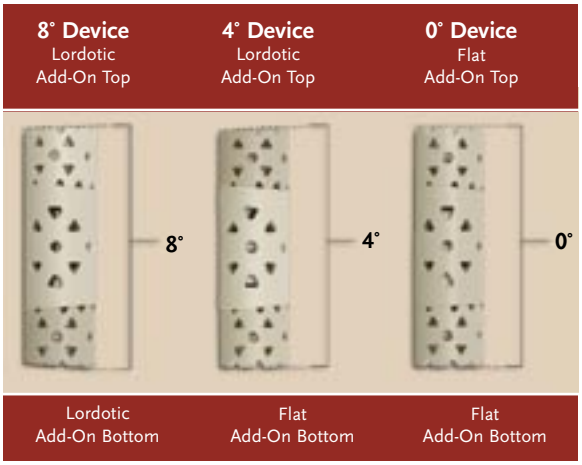
Large Size 36mm x 28mm
Wall Thickness: 5mm

Height Calculation

$$\frac{\text{Device Height}}{} = \frac{\text{Add-On}}{} + \frac{\text{Center Piece}}{} + \frac{\text{Add-On}}{}$$







Important Information on the VERTE-STACK™ Spinal System

The VERTE-STACK™ Spinal System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. This system is indicated for single and two-level use only in the thoracic and lumbar anterior spine.

DESCRIPTION: The VERTE-STACK™ DEVICE CONSISTS OF PEEK (POLYETHERETHERKETONE) hemi-cylindrical center cages of various lengths and diameters, as well as hemi-cylindrical add on cages of various lengths, diameters and angulation. The assembled VERTE-STACK™ DEVICE CONSISTS OF THREE COMPONENTS (ONE HOLLOW PEEK CENTER CAGE, AND TWO HOLLOW ADD-ON CAGES). THE VERTE-STACK™ COMPONENTS CAN BE RIGIDLY LOCKED INTO A VARIETY OF CONFIGURATIONS, WITH EACH CONSTRUCT BEING TAILOR-MADE FOR THE INDIVIDUAL CASE. THE VERTE-STACK™ SPINAL SYSTEM IMPLANT COMPONENTS ARE MADE OF MEDICAL GRADE PEEK LT1 DESCRIBED BY ASTM STANDARD F-1579. THE TANTALUM MARKER USED FOR THIS PRODUCT IS MADE TO THE VOLUNTARY STANDARD OF ASTM F-560. MEDTRONIC SOFAMOR DANEK EXPRESSLY WARRANTS THAT THESE DEVICES ARE FABRICATED FROM THE FOREGOING MATERIAL SPECIFICATIONS. NO OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE MADE. IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE ARE SPECIFICALLY EXCLUDED.

The VERTE-STACK™ Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. One of the following titanium Medtronic Sofamor Danek spinal systems or their successors must be used with the VERTE-STACK™ Spinal System.

	Anterior	Posterior
ZPLATE II™ Anterior Fixation System	✓	
DYNALOK CLASSIC™ Spinal System	✓	✓
Laurain De Wald Anterior Fixation System	✓	
TSRH® Spinal System	✓	✓
CD HORIZON® Spinal System	✓	✓

Do not use implant components from any other manufacturer with VERTE-STACK™ Spinal System components. Stainless steel and PEEK implants are not compatible with each other. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used.

INDICATIONS: The VERTE-STACK™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK™ Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK™ device is to be used with the Medtronic Sofamor Danek ZPLATE II™ Anterior Fixation System, Titanium DYNALOK CLASSIC™ Spinal System, Laurain DeWald Anterior Fixation System, Titanium TSRH® Spinal System, Titanium CD HORIZON® Spinal System or the Titanium GDLH® Spinal System. Additionally, the VERTE-STACK™ device is intended to be used with bone graft.

CONTRAINDICATIONS:

The VERTE-STACK™ device is not intended for cervical nor posterior surgical implantation.

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
9. Suspected or documented metal allergy or intolerance.
10. Any case needing to mix metals from different components.
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. Any case not described in the indications.
13. Any patient unwilling to cooperate with postoperative instructions.
14. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

POSSIBLE ADVERSE EVENTS:
All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

1. Early or late loosening of the components. Implant migration.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
4. Infection.
5. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
6. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
7. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
8. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
9. Scar formation possibly causing neurological compromise around nerves and/or pain.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Bone loss or decrease in bone density, possibly caused by stress shielding.
12. Subsidence of the device into vertebral body(ies).
13. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
14. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
15. Non-union (or pseudarthrosis). Delayed union. Mal-union.
16. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
17. Graft donor site complications including pain, fracture, infection, or wound healing problems.
18. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
19. Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNING AND PRECAUTIONS:
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This device system is not intended to be the sole means of spinal support. **The VERTE-STACK™ device must be used with additional anterior or posterior instrumentation to augment stability.** Use of this product without a bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Medtronic Sofamor Danek because the combination with other instrumentation may be incompatible, and may not be guaranteed.

The assembled parts have in situ length adjustment. Self-breaking plugs are provided for plate fixation to the cylinders. The final torque setting is determined by the rupture of the bolt. The screws should be tightened and broken off in situ after the final placement of the device. The broken part should not remain in the patient. Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.

PATIENT INFORMATION: The internal fixation device used in your recent spinal surgery is a plastic polymer implant that attaches to the bone and aids in the healing of bone grafts. The VERTE-STACK™ Spinal System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. This system is indicated for single level and two-level anterior use from T1 to L5 only.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician .

CAUTION: For use on or by the order of a physician only.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Implant Selection:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. Further information on the use of this system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. All parts should be cleaned and sterilized before use. Additional components should be available in case of an unexpected need.

INTRAOPERATIVE:
1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, a bone graft should be used. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused. When using the VERTE-STACK™ device, grafts containing autogenous bone should be used.
5. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

POSTOPERATIVE:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone graft healing process.
3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic Sofamor Danek. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately resterilize all implants and instruments which have been previously in the operation area. This process must be performed before handling or returning products to Medtronic Sofamor Danek.

CLEANING AND DECONTAMINATION:
Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled, if applicable, and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should <u>not</u> be used.

Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION:
Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery <u>must</u> be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. For a 10^{-6} Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270˚F (132˚C)	4 Minutes
Steam	Gravity	250˚F (121˚C)	30 Minutes
Steam*	Gravity*	273˚F (134˚C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and validate the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic Sofamor Danek. Further, if any of the implanted spinal system component(s) ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic Sofamor Danek product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

IN THE USA
Director, Customer Service Division
MEDTRONIC SOFAMOR DANEK USA
1800 Pyramid Place
Memphis, Tennessee 38132
USA
Telephone: 800-876-3133 or 901-396-3133
Telefax: 901-396-0356 or 901-332-3920

IN EUROPE
SOFAMOR SNC**
13, rue de la Perdrix
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Medtronic Sofamor SNC-RCS Bobigny
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For product availability, labeling limitations, and/or more information on any MEDTRONIC SOFAMOR DANEK USA, INC. products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.

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