Spineology

Rampart™ One
Lumbar Interbody Fusion Device

DESCRIPTION
Rampart™ One implants are intervertebral body fusion devices for use with bone graft in the intervertebral disc space to stabilize spinal segments as an adjunct to fusion. These devices are manufactured from PEEK-OPTIMA HA Enhanced (spacer), titanium alloy (face plate), and tantalum (radiopaque markers) materials. Rampart One devices incorporate integrated fixation in the form of titanium alloy screws. Rampart One devices are provided in standard and oblique configurations. The standard device accommodates four screws and the oblique device accommodates two screws. In each device the screws are inserted through the anteriorly-located face plate into the adjacent vertebral bodies. Rampart One devices are provided in various heights and lordotic angles and contain a hollow core to receive autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

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INDICATIONS
The standard and oblique Rampart One devices are integrated intervertebral body fusion devices indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment. The standard and oblique Rampart One devices are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The standard Rampart One devices with 8° and 12° lordotic angles may be used with or without supplemental fixation using a fixation system cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One devices with 8° and 12° lordotic angles must be used with four (4) screws. The standard Rampart One devices with 16° and 20° lordotic angles must be used with four (4) screws and a supplemental fixation system cleared by FDA for use in the lumbar spine.

The oblique Rampart One devices must be used with two (2) screws and a supplemental fixation system cleared by FDA for use in the lumbar spine.

CONTRAINDICATIONS
Contraindications include, but are not limited to:
- Infection
- Morbid obesity
- Mental illness
- Fever or leukocytosis
- Pregnancy
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Prior fusion surgery at the involved level(s)
- Cardiovascular complications
- Any patient unwilling to cooperate with the postoperative instructions
- Known or suspected sensitivity to implant materials
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

PRECAUTIONS
- The implantation of this device should be performed only by experienced spinal surgeons with specific training in the use of systems of this type because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The success of any spinal fusion is dependent upon many factors that include, but are not limited to, the health and metabolism of the patient. Medical conditions or disease states that alter a patient's normal metabolism may interfere with bone healing.
- Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.
- Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
- It is important to choose the correct implant size. Surgeons should be fully trained and familiar with use of the instruments and proper placement of the implant.
- The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
- Patients who are taking medications that may interfere with bone or soft tissue healing (e.g. long-term steroid use) may not be suitable candidates as these medications may interfere with bone growth and graft incorporation.
- As with any permanent implant, a perioperative antibiotic protocol is recommended.
- An implant should never be reused.
- Patients receiving the Rampart™ One implants should have had at least six months of non-operative treatment.
- A successful result is not always achieved in every surgical case due to many extenuating circumstances. This device is intended for temporary immobilization of the spine in order to obtain a solid fusion mass using a bone graft. The durability and success of the implant will be compromised in cases where a nonunion develops, or when used without a bone graft.
- Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, nonunion, fracture of the vertebrae, neurological injury, and/or vascular or visceral injury.
- This system should not be used with components of any other system or Manufacturer.

POTENTIAL ADVERSE EFFECTS
All patients considered candidates for fusion using Rampart™ One implants should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects associated with the procedure. Possible adverse effects or risks include, but are not limited to, the following, which may require additional surgery:
- Bending, loosening, fracture, slippage, and/or migration of the component
- Foreign body reaction to the implant
- Skin or muscle sensitivity
- Non-union or delayed union
- Infection of soft tissue and/or bone (osteomyelitis); fever
- Incomplete relief of symptoms
- Loss of proper spinal curvature, correction, height, and/or reduction
- Loss of neurological function, dural tear, pain and/or discomfort
- Epidural bleeding, hemorrhage of blood vessels, and/or hematomas
- Loss of bladder and/or bowel control
- Sterility, impotency, and/or loss of consortium
- Bone loss and/or bone fracture due to stress shielding
- Bursitis
- Bone graft donor site pain or other complications
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and/or myocardial infarction
- Soft tissue injury
- Edema
- Death

MRI WARNING
The Rampart™ One device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Rampart One device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

IMPLANT HANDLING
Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

IMPLANT PACKAGING
Implant packaging should be inspected for package continuity. Packages for each of the sterile implants should be intact upon receipt. Do not use sterile implants if the packaging has been damaged or the shelf life has been exceeded. Devices must be handled properly to maintain sterility. Damaged packages or implants should not be used, and should be returned to Spineology.

- Note that implants are provided sterile for single use only.
- Do not re-sterilize implants.

DEVICE REMOVAL
Please refer to the Rampart One Surgical Technique Guide document L473 for instructions. Please contact your Spineology representative if you need a replacement document.

INSTRUMENT HANDLING
Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned, decontaminated, and re-sterilized immediately after use.

INSTRUMENT CLEANING, DECONTAMINATION, AND STERILIZATION
All instruments must be cleaned, decontaminated, and sterilized by the hospital before use. Please refer to Rampart One Reprocessing Instructions for Spineology Surgical Instruments document L454 for instructions. Please contact your Spineology representative if you need a replacement document.

FURTHER INFORMATION OR PRODUCT COMPLAINTS
Contact Spineology at:

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Federal law (USA) restricts this device to sale by or on the order of a physician.

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