Spineology®

Rampart™-O and Rampart™-T

DESCRIPTION:

Rampart™-O and Rampart™-T implants are intervertebral body fusion devices for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments as an adjunct to fusion. The device is made of PEEK-OPTIMA LT1 with Tantalum markers and is provided in various configurations and heights, containing a hollow core to receive bone autograft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

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INDICATIONS:

Rampart™-O and Rampart™-T implants are 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 1spondylolisthesis 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 non-operative treatment.

Rampart™-O and Rampart™-T implants are designed for use with autograft as an adjunct to fusion and are intended for use with supplemental fixation systems cleared by the 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™-O and Rampart™-T 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 non-union 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, non-union, fracture of the vertebrae, neurological injury, and/or vascular or visceral injury.

POTENTIAL ADVERSE EFFECTS:

All patients considered candidates for fusion using Rampart™-O and Rampart™-T 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:

Rampart™-O and Rampart™-T implants have not been evaluated for safety, heating, migration, or and compatibility in the MR environment.

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.

INSTRUMENTS:

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 and resterilized immediately after use.

CLEANING AND DECONTAMINATION:

- Cleaning and decontamination of surgical instruments are required before introduction into the sterile field.
- Following use, disassemble devices as instructed for cleaning. Preventing drying will facilitate later cleaning.
- Soak in enzymatic detergent (mixed per manufacturer's recommendations) for five (5) minute or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes. Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is acceptable.
- Rinse each part thoroughly under running water for one (1) minute or longer.

STERILIZATION:

- Note that these implants and instruments are non-sterile
- Spineology recommends using an FDA-cleared wrap for sterilizing

All implants and instruments must be cleaned and sterilized by the hospital before use as described below.

Instrument trays are provided for storing and sterilizing the instruments. Instrument trays do not provide a sterile barrier. Trays must be used with a sterilization wrap. Sterilization can be performed on wrapped trays with the following cycle parameters:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270° F Minimum
	(132° C) Minimum
Exposure time:	4 Minutes Minimum
Drying time:	30 Minutes Minimum

Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

DEVICE RETRIEVAL:

Contact Spineology to discuss Revision / Retrieval.

FURTHER INFORMATION OR PRODUCT COMPLAINTS:

Contact Spineology at:
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Please contact your local Spineology representative for a complete surgical technique manual or further cleaning instructions

Manufactured by:

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Do Not Reuse

Product is Packaged Non-Sterile