Package Insert

Normandy VBR System

Device Description: The Normandy VBR System is an adjustable height vertebral body replacement device that is implanted into the vertebral body space to provide structural stability in skeletally mature patients following corpectomy or vertebrectomy. The system is comprised of spacers of various sizes and options to fit the anatomical needs of a wide variety of patients. The device can be adjusted to the required height after implantation. The device is mechanically locked at the required height by means of a locking screw. Each spacer has an axial hole to allow autograft or allograft to be packed inside each spacer. Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Components are manufactured from titanium alloy (Ti-6AL-4V) per ASTM F-136.

Intended Use: The Normandy VBR System is indicated for use in the cervical spine (C2-C7) and thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Normandy VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Normandy VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Normandy VBR System is intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, and anterior plate systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Materials: The Normandy VBR System components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.

Contraindications:
-The Normandy VBR System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice
-Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation
-This device is not intended for use except as indicated

Potential Adverse Events:
Potential adverse events include, but are not limited to:
-Pseudoarthrosis
-Early or late loosening of the components
-Bending, and/or breakage of the components
-Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, straining, tumor formation, and/or auto-immune disease
-Post-operative change in spinal curvature, loss of correction, height, and/or reduction
-Infection

-Vertebral body fracture at, above, or below the level of surgery
-Loss of neurological function, including paralysis (complete or incomplete)
-Non-union, delayed union
-Pain, discomfort, or abnormal sensations due to the presence of the device
-Hemorrhage
-Cessation of any potential growth of the operated portion of the spine
-Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings 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. Use of this product without autograft or in cases that do not develop a union will not be successful
-Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion
-Non-sterile, the Normandy VBR System implants are sold non-sterile, and therefore, must be sterilized before each use
-Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
-Do not reuse implants; discard used, damaged, or otherwise suspect implants
-Single use only
-The Normandy VBR System components should not be used with components of any other system or manufacturer.
-The Normandy VBR System has not been evaluated for safety and compatibility in the MR environment. The Normandy VBR System has not been tested for heating or migration in the MR environment.
-Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Other preoperative, intraoperative and postoperative warnings are as followed:

Implant Selection:
The selection of the implant for each patient is crucial to the success of the procedure. Metallic surgical 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:
-Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
-Carefully screen the patient, choosing only those that fit the indications described above
-Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments
-An adequate inventory should be available at surgery than those expected to be used
-All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need

Intraoperative:
-Instructions should be carefully followed
-Extreme caution should be used around the spinal cord and nerve roots

-The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct
-To assure proper fusion below and around the location of the fusion, autogenous bone graft should be used.
-Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and 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:
-Detailed instructions should be given to the patient regarding care and limitations, if any
-To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process
-The patient should be advised or their limitations and taught to compensate for this permanent physical restriction in body motion
-If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred
-Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):
For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays as long as the inspection criteria provide below are acceptable for the tray.

<table>
<tr><td colspan="2">Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.</td></tr>
<tr><td colspan="2">Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.</td></tr>
<tr><td colspan="2">1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.</td></tr>
<tr><td colspan="2">2-Containment and transportation: Avoid damage and minimize time before cleaning</td></tr>
<tr><td colspan="2">3-Preparation for cleaning: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap and screw drivers and remove drills, taps and awl that are left in the drill guides. Remove the lock screw inserter from the cage inserter instrument. (note that these items are normally stored in their dedicated tray already disassembled).</td></tr>
<tr><td colspan="2">4 Thoroughly clean instruments per one of the following (Manual or Automated)</td></tr>
<tr><th>Manual</th><th>Automated</th></tr>
<tr><td>4.1 Pre-Cleaning-Manual:
Alcohol wipe
Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35- 40°C) per the instructions of the enzymatic solution manufacturer.
Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
Change the soak solution if the solution becomes visibly soiled.
While still in the soak solution, use a soft brush the remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen
Rinse instruments thoroughly with clean warm (35-40°C) deionized water, taking care to flush all lumens or</td><td>4.1 Pre-Cleaning-Automated:
Soak in ultrasonic bath
15 minutes
Use nonmetallic brush
Rinse thoroughly with cold (>40°C) running tap water, 2 minutes</td></tr>
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crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear	
4.2 Cleaning-Manual: • Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under clean warm (35-40°C) running deionized water for a least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear. • Dry the exterior of the instruments with a clean soft cloth. Use clean compressed air or 70% isopropyl to dry any lumens or crevices where water may become trapped.	**4.2 Washer Disinfector:** • Wash, 45°C, 4 minutes • Wash, 60°C, 3 minutes • Rinse, >40°C tap water, 1 minute • Rinse, 60°C tap water, 1 minute • Thermal rinse, ≥93°C tap water, $A_0$3000 • Rinse, 35-40°C deionized water, 1 minute • When unloading check cannulations, holes, etc. for complete removal of visible soil. If necessary, repeat cycle or use manual cleaning. • Dry, 123°C, air, 14 minutes
Inspection: • Visually inspect each device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean. • Check instruments with long slender features for distortion • Inspect the devices for any cracking, pitting, or other signs of deterioration	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization: The Normandy VBR System should be sterilized by the hospital using the recommended cycle:
Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

Product Complaints: Any Healthcare 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 Zavation Medical Products LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119.

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