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DePuy Synthes
SPINE
COMPANIES OF Johnson & Johnson

VBR
Spinal System

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DESCRIPTION

The VBR (Vertebral Body Replacement) System consists of the BENGAL® STACKABLE and OCELOT® Stackable Cage Systems and the Surgical Titanium Mesh and X-MESH™ Expandable Cage Systems. The VBR Spinal Systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period, as well as for treating fractures of the thoracic and lumbar spine.

The structure of the carbon-fiber composite implants has been shown to support anticipated loads with a modulus of elasticity approximating that of cortical bone. The implants have ridges or teeth in both the anterior-posterior and medial-lateral directions, which resist rotation and migration. The polymer/carbon-fiber composite implants have cavities to accept packing of bone graft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery.

STACKABLE CAGE SYSTEM

The Stackable Cage System consists of the BENGAL STACKABLE and OCELOT Stackable Cage Systems. These implants are made of a polymer/carbon-fiber composite. These radiolucent implants are designed with ridges or teeth to resist rotation and migration, and with cavities to accept packing of bone graft materials. The carbon-fiber implants are available in a variety of sizes.

The BENGAL STACKABLE Cage System consists of both one piece (monolithic) and two- to three-piece (stackable) vertebral body replacement components and a supplemental internal fixation system that offer a variety of size options to allow surgeons to achieve a desired height. The two- or three-piece (stackable) construct can be assembled from a variety of different sized components. A titanium alloy screw is then passed through a hole in the cages and with a nut provides a rigid and compressed assembly.

The OCELOT Stackable Cage System consists of one or more stackable vertebral body replacement components and a supplemental internal fixation system. One or more OCELOT Stackable Cage System implants may be stacked to the desired height, as determined by the surgeon. A titanium alloy screw can be passed through a center hole in the cages and with a nut provide a rigid and compressed assembly.

SURGICAL TITANIUM MESH AND X-MESH EXPANDABLE CAGE SYSTEMS

The Surgical Titanium Mesh System is designed to restore biomechanical integrity throughout the thoracic and lumbar spine following vertebrectomy or corpectomy for patients with spine tumors or fractures. The system provides anterior, middle and posterior vertebral column support both immediately after surgery and for prolonged periods in the absence of bone fusion.

The Surgical Titanium Mesh System consists of various shapes and sizes of mesh, standard or angled rings and screws, endplates, and endcaps. The surgeons have the option to place the standard or angled rings and screws, endplates and endcaps within the mesh. These interface devices may be used to provide increased surface area at the Mesh/bone interface, which provides additional support and increased resistance to subsidence.

Surgical Titanium Mesh may be trimmed to the desired height, as determined by the surgeon. The “teeth” at the ends of the mesh, resulting from the diamond shaped perforations, help anchor the device.

The X-MESH Expandable Cage System is available in many heights, and different endplate shapes, sizes and angles. The surgeons have the option to place the standard or angled endplates. The “teeth” on the endplates help anchor the device. The surgeons should use the size and angle that best fits the defect being treated.

INDICATIONS

Caution: USA Law restricts this device to sale by or on the order of a physician.

The VBR Spinal Systems are indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The VBR Spinal Systems are also indicated for treating fractures of the thoracic and lumbar spine.

The VBR Spinal Systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The VBR Spinal Systems are intended for use with DePuy Spine supplemental internal fixation.

CONTRAINDICATIONS

1. Use of these systems is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS

Following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to devices such as the VBR Spinal System. General surgical risks should be explained to the patient prior to surgery.

The VBR Spinal System implants are intended to support the anterior, middle, and posterior vertebral column while fusion is taking place. These implants are intended to be permanent. The following recommendations for removal of hardware apply to the supplemental internal fixation implants used in this procedure.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT**. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size

and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. **MIXING METALS CAN CAUSE CORROSION**. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Avoid coupling of stainless steel with the VBR Spinal System implants.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.**
   A. **Composite Implants:** Polymer/carbon-fiber implants are designed to support physiologic loads. Excessive torque, when applied to long-handle insertion tools, can cause splitting or fracture of the carbon-fiber implants. When a carbon-fiber implant is impacted or hammered into place, the broad surface of the insertion

tool should be carefully seated fully against the carbon-fiber implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.

B. **Metal Implants:** Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid notching, scratching or reverse bending of the implants when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. **REMOVAL OF SUPPLEMENTAL FIXATION AFTER HEALING**. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. **ADEQUATELY INSTRUCT THE PATIENT**. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.

POSSIBLE ADVERSE EFFECTS WITH THE VBR SPINAL SYSTEM IMPLANTS AND/OR METALLIC INTERNAL FIXATION DEVICES

This list may not include all complications caused by the surgical procedure itself.

1. Bending or fracture of implant. Loosening of the implant.
2. Implant material sensitivity, or allergic reaction to a foreign body.
3. Infection, early or late.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensations due to the presence of the device.
6. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
7. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
8. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
9. Bursitis.
10. Paralysis.
11. Death.
12. Spinal cord impingement or damage.
13. Fracture of bony structures.
14. Reflex sympathetic dystrophy.
15. There is an additional risk if there were to be long term in vivo degradation of the polymer/carbon-fiber composite resulting in possible local or systemic adverse reactions from any potential degradation products.
16. If a pseudarthrodesis occurs coupled with the VBR Spinal Systems, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.

IMPORTANT NOTE TO OPERATING SURGEON

Vertebral body replacement should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the VBR Spinal Systems for use in corporectomies and vertebrectomies. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and vertebral body replacement procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. The purpose of the VBR Spinal System is to provide immediate spinal stability and to allow for consolidation of the fusion mass. If any implant of the VBR Spinal System does break, the decision to remove it must be made by the physician, who must consider the condition of the patient and the risks associated with the presence of the broken implant.

Detailed instructions for placement and removal of a specific implant can be found in the Surgical Technique, which can be obtained from DePuy Spine sales representatives or by contacting the DePuy Spine Customer Service at +1-800-365-6633.

POSTOPERATIVE MOBILIZATION

Postoperative external immobilization (such as bracing or casting) is recommended, at the surgeon's discretion. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

The VBR System(s) implants may be provided either sterile or non-sterile and this will be clearly identified on the product labels.

Sterile Implants

For the implants supplied sterile, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging, using aseptic technique, only after the correct size has been determined.

PRECAUTION: Do not use implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile.

Implants must **not** be resterilized.

Non-sterile Implants

For the implants supplied non-sterile, they will be supplied clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

RECOMMENDATIONS FOR STEAM STERILIZATION:

In a properly functioning calibrated steam sterilizer, independent testing has shown that effective sterilization may be achieved using the following parameters:

Cycle:	Pre-Vacuum
Temperature:	270° F (132° C)
Exposure time:	6 minutes

Post-sterilization drying of the sterilization load within the sterilization vessel is standard practice in hospitals. ANSI/AAMI ST79:2006, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” provides guidance to hospitals for selecting appropriate drying parameters based on the sterilization cycle that is being conducted. Sterilizer manufacturers also typically provide recommendations for drying parameters for their specific equipment.

Inspect visually for damage or the presence of blood or tissue. If blood or tissue is observed on the implant, it must be thoroughly cleaned manually using a soft brush and neutral pH detergent or discarded.

Cleaning instructions

- Enzyme soak
- Rinse
- Ultrasonic cleaning (10-20 minutes)
- Rinse
- Automated cleaning in a washer disinfector with lid on to contain implant components
- Dry

Avoid impact, scratching, bending or surface contact with any materials that might affect the implant surface or configuration.

Special attention shall be paid to recesses since both chemicals and rinse water may be entrapped in them.

Implants previously implanted must **not** be re-used.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The VBR System(s) implants have not been evaluated for safety and compatibility in the MR environment. The VBR System(s) implants have not been tested for heating or migration in the MR environment.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of surgical implants, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants.

VBR Spinal System components should not be used with components of spinal systems from other manufacturers.

LIMITED WARRANTY AND DISCLAIMER

PRODUCTS FROM DEPUY SYNTHES PRODUCTS, LLC ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/ REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT DEPUY SYNTHES SPINE FOR CURRENT INFORMATION AT 800-365-6633 OR AT +1-508-880-8100.

SYMBOL TRANSLATION

LOT LOT NUMBER	2 STERILIZE DO NOT RESTERILIZE	SINGLE USE	STERILE STERILE	MANUFACTURER
REF CATALOG NUMBER	T2 T1 Lower Limit of temperature = T1 Upper Limit of temperature = T2	ATTENTION. SEE INSTRUCTIONS FOR USE	STERILE A Sterile medical device processed using aseptic technique	DATE OF MANUFACTURE
QTY QUANTITY			STERILE R STERILIZATION BY IRRADIATION	US REP US REPRESENTATIVE
SZ SIZE	25°C STORE AT ROOM TEMPERATURE	PACKAGE CONTAINS FLAMMABLE LIQUID	STERILE EO STERILIZATION BY ETHYLENE OXIDE	EC REP AUTHORIZED EUROPEAN REPRESENTATIVE
MADE IN MADE IN			LATEX FREE LATEX FREE	DIST DISTRIBUTED BY
NTI NEURAL TISSUE INSTRUMENT		DO NOT USE IF PACKAGE IS DAMAGED		
IOM NEUROMONITORING INSTRUMENTS	KEEP AWAY FROM SUNLIGHT	MSR MEASURING DEVICE	NON STERILE NONSTERILE	XXXX-XX USE BY
Rx Only Federal (USA) law restricts this device to sale by or on the order of a physician				

PEEK/C PEEK/CARBON FIBER COMPOSITE Polyether Ether Ketone/ Carbon Fiber Composite	T Ti Titanium and its alloys

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