

vertebration™

**XYCOR™**  
SPINAL IMPLANT FOR MISS

## Essential Product Information

### INDICATIONS

The XYcor™ Spinal Implant is indicated for use as a vertebral body replacement device intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The XYcor™ Spinal Implant is 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 XYcor™ Spinal Implant is intended for use with bone graft and supplemental internal fixation. The supplemental internal fixation systems that may be used with the XYcor™ include Medtronic Sofamor Danek TSRH 3D, DePuy Spine Expedium or Monarch pedicle screw fixation systems, Biomet, Polaris, Array

or Omega-21 pedicle screw fixation systems, and other pedicle screw-rod/plate fixation systems that have similar biomechanical properties to the above-listed systems, including trans-facet fixation systems but excluding semi-rigid or flexible rod-screw systems.

### CONTRAINDICATIONS

Contraindications include, but are not limited to, active systemic infection, localized or spinal infection; morbid obesity; signs of local inflammation; fever or leukocytosis; demonstrated allergy or foreign body sensitivity to any implant materials; any medical or surgical condition which would preclude or impede the potential benefit of spinal implant and/or spinal fusion surgery, which could include, but not be exclusive to, elevated erythrocyte sedimentation rate, unexplained inflammatory/disease processes, elevation of white blood cell count (WBC), marked left shift in the white blood cell count differential; distorted anatomy, due to congenital or remote posttraumatic/postinfectious abnormalities; conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication as this condition may limit the degree of obtainable correction and/or height restoration, the amount of mechanical fixation, and/or the quality of the bone graft); any case in which a bone graft and fusion technique or where fracture fixation is not performed or required; any operative case utilizing the mixing of dissimilar metals from different components; patients having inadequate soft tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any case not described in the indications; patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, smoking, occupation, or lifestyle may interfere with their ability to follow postoperative instructions and/or activity restriction guidelines 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 POTENTIAL ADVERSE EFFECTS/COMPLICATIONS

The 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 XYcor™ Spinal System. General surgical risks should be explained to the patient prior to surgery.

The following warnings, precautions and adverse effects apply to components of XYcor™ Spinal System. XYcor™ implants are intended to support the anterior vertebral column while fusion is taking place.

#### WARNINGS:

Correct selection of the implant is 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 which 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 XYcor™ Spinal 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 which may lead to early breakage.

2. Correct handling of the implant is extremely important. Contouring of this titanium implant should not be done. The operating surgeon should avoid notching, scratching or reverse bending of the implants. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

### 3. 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/COMPLICATIONS:**

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

1. Bending or fracture of implant.
2. Loosening and or collapse of the implant.
3. Implant material sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. 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 paresthesia.
8. 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.

9. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10. Bursitis.
11. Paralysis.
12. Death.
13. Spinal cord impingement or damage.
14. Fracture of bony structures.
15. Reflex sympathetic dystrophy/Complex Regional Pain Syndrome, Types I and II, including dyesthesias/hypesthesias.
16. If a pseudarthrosis occurs with XYcor™ Spinal Implant, 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.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.

#### **IMPORTANT NOTIFICATION TO THE OPERATING SURGEON**

Spinal surgery, and particularly vertebral body replacement/corpectomy, should only be undertaken by a spine fellowship trained surgeon after the surgeon has completed hands-on training in various methods of spinal fixation, and particularly those applicable to the XYcor™ Spinal Implant. The surgeon should have a thorough knowledge about spinal anatomy and biomechanics. A surgical technique manual is available for detailed instructions on the correct use/indications of the XYcor™ Spinal Implant for use in vertebrectomy/corpectomy and should be reviewed by the surgeon and operative team prior to any use of the implant and its techniques. The contents of this manual alone are not adequate for complete instruction in the use of this device. Even experienced spine surgeons may require additional skills best acquired by working with a surgeon experienced with the XYcor™ Spinal Implant. and

technique or through a course of formal instruction with laboratory/bench training. Lack of experience or expertise with these implants and/or techniques may result in complications.

Titanium implants cannot be fabricated/constructed to last and/or function indefinitely, given the constraints/limitations imposed by anatomy and surgical materials. The purpose of the XYcor™ Spinal Implant is to provide immediate spinal stability when used in conjunction with supplemental internal fixation and to allow consolidation of a fusion mass. If any implant breaks/fails, the decision to remove it, and the approach selected, must be made by the surgeon, who must take into consideration the condition of the patient and the risks associated with planned removal and/or the presence of a failed implant.

#### **POSTOPERATIVE IMMOBILIZATION**

Postoperative external immobilization, i.e. bracing and/or casting is recommended, at the surgeon's discretion, as is a comprehensive postoperative core stabilization physical therapy program. Instructions to the patient to reduce stress on the implant(s) are an equally important component of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure and delayed/non-union.

#### **STERILIZATION**

The XYcor™ Spinal Implant is supplied sterile.

MANUFACTURED by Mediscope Manufacturing, Inc. for Vertebroation, Inc.:

Mediscope Manufacturing, Inc.  
2832 NW 22<sup>nd</sup> Terrace  
Pompano Beach, Florida 33069

Vertebroation, Inc.  
3375 Brentwood Court  
Powell, Ohio 43065  
USA