



PACKAGE INSERT FOR IMPLANT DEVICES VBS™ SPINAL FUSION CAGES AND END PLATES

DEVICE DESCRIPTION

Implants International Ltd's Titanium Fusion Cages comprise a mesh design, which is ovaloid in pattern. These devices are manufactured from commercially pure (CP) titanium conforming to ISO 5832-2. Because of its design range, taper angle and cage size, a wide range of anatomical conditions can be catered for. OUR CAGES ARE DESIGNED TO BE USED WITH TWO DEDICATED END-PLATES which facilitate the containment and compression of bone or other graft material, whilst minimising the risk of device migration under load. In the case of good quality bone, the cage may be used without end plates, but with the support of our inter-vertebral bridge plates.

INDICATIONS

Surgical Titanium Mesh is indicated for use in reinforcing, weak bony tissue and cement restriction in orthopaedic surgery and oral-maxillofacial reconstruction procedures.

STERILE PRODUCT

For products supplied sterile, check seals are intact. If seals are broken, DO NOT USE as sterility may be compromised.

UNSTERILE PRODUCTS

For products supplied unsterile, follow cleaning regime and sterilisation procedures detailed below.

CLEANING

Use deionised or warm (room temperature) distilled water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minutes. Immerse and hand wash with neutral pH or mild detergent. Scrub with a soft bristle brush, paying close attention to threads and hard-to-reach areas. If product is cannulated, insert soft nylon brush into the cannula. Rinse immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilisation or storage.

STERILISATION

For Surgical Titanium Mesh components supplied UN-STERILE: Prior to use, all components should be steam sterilised using the following guidelines:

Method	Cycle	Temperature	Exposure Time
Steam	Vacuum	270°F (130°C)	10 minutes

CONTRADICTIONS

Surgical Titanium Mesh, as with other metallic orthopaedic appliances, are contraindicated for use in situations involving active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection. The device is also contraindicated for use in patients with known allergies to any of the materials used in the implant.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

Potential adverse effects include: failures of the device to provide adequate mechanical stability; loss of fixation of the implant device; device component failure; migration or bending of the device; loss of bony alignment; non-union; fracture of bony structures; resorption without incorporation of any bone graft utilised and immunogenic response to the implant materials.

As with any major surgical procedure, there are risks involved in orthopaedic surgery. Infrequent operative and post-operative complications known to occur are: early or late infection which may result in the need for additional surgeries; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNINGS AND PRECAUTIONS

In using metallic surgical implants, the surgeon should be aware of the following:

1. THE CHOSEN CAGE SHOULD BE USED WITH A PAIR OF END PLATES OR WITH THE INTER-VERTEBRAL BRIDGE PLATES.
2. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
3. The correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided where possible. If contouring is necessary, they should not be bent sharply, reverse bent, notched or scratched. All these operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.
4. No metallic surgical implant should be re-used. Any metal implant once used should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure. We advise you to use only new appliances of current design.
5. Post-operative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weight bearing and body stresses on the appliance prior to secure bone healing.

STERILITY

THESE DEVICES ARE SUPPLIED STERILE. DO NOT RE-STERILISE. IF DEVICE STERILITY IS COMPROMISED, CONTACT THE MANUFACTURER.

CAUTION: United States Federal Law restricts this device to sale by or on the order of a licensed physician.

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