Instructions For Use
The Bio-Eye® Hydroxyapatite Orbital Implant (Sterile)

I N T E G R A T E D O R B I T A L I M P L A N T S

 Caution  Single Use  Sterile

Catalog Number: 0016, 0017, 0018, 0019, 0020, 0021, 0022, 0023, 0024

Introduction
Integrated Orbital Implants, Inc. developed and sells the Bio-Eye® hydroxyapatite (HA) orbital implant. The Bio-Eye® HA orbital implant is a spherical (ball-shaped) implant composed of naturally derived hydroxyapatite. It is used to replace the volume of the orbit when the eye is surgically removed or as a replacement implant in patients with a poorly functioning, pre-existing implant.

The advantages of using natural porous hydroxyapatite as an orbital implant are as follows: (1) it decreases migration. (2) it decreases extrusion. (3) it can be coupled to the artificial eye to make the artificial eye move in conjunction with the normal eye, (4) it resists infection, and (5) it supports the weight of the artificial eye, thereby relieving lower-lid sag.*

Description
Porous hydroxyapatite is a naturally derived (from marine coral) hydroxyapatite that is very similar in composition to the mineral portion of human bone. The micro-architecture of the Bio-Eye® HA orbital implant is characterized by an interconnected matrix of pores. A patented manufacturing process converts the calcium carbonate exoskeleton of the coral to hydroxyapatite (calcium phosphate), while preserving the unique microstructure of the coral exoskeleton.

A conformer is used to retain the space for the artificial eye and is placed under the lids following placement of the orbital implant.

Indications
The Bio-Eye® HA orbital implant is indicated as a primary implant in cases of enucleation and evisceration, and as a secondary implant in cases of poor performance of a primary implant, such as in cases of poor motility, migration, extrusion, chronic infection, enophthalmos, and lid sag. The Bio-Eye® HA orbital implant is indicated in any situation where silicone, acrylic, polyethylene, glass, or other traditional orbital implants are used.

A conformer is indicated in all cases in which an orbital implant is used.

Contraindications
The Bio-Eye® HA orbital implant is contraindicated in situations where other types of orbital implants are contraindicated, i.e.. in cases of severe orbital infection, severe trauma with possible orbital infection, or a retained foreign body.

Preparations for Use
The Bio-Eye® HA orbital implant is sold STERILE.

Reshaping
The Bio-Eye® HA orbital implant may be reshaped by carving with a scalpel blade, burring, or drilling. Holes may be produced in the implant by mechanical drilling or by twisting a hypodermic needle into the material at the desired locations. Care should be taken to avoid damaging the implant during any shape modifications. Reshaping is most easily done with the implant material being wet. Loose particles of hydroxyapatite should be removed from the implant by irrigation prior to implantation.

General Surgical Procedures
Enucleation
A standard enucleation is done, including tagging of the extraocular muscles with absorbable suture. The Bio-Eye® HA orbital implant should be soaked in antibiotic solution prior to implantation. The orbit is sized, using a set of sizing spheres, to determine the size of the implant to be used. An implant is of the proper size when it is the largest implant that can be placed deep into the orbit without creating tension on the overlying tissues and while allowing adequate room for an artificial eye of sufficient thickness. The implant may be placed into the orbit with or without being wrapped in a homologous or autologous material such as preserved sclera, dura, or fascia lata.The surface of the hydroxyapatite material is very rough, and a wrapping material facilitates insertion and placement of the implant deep into the orbit. Additionally, a wrapped implant may be more resistant to exposure caused by abrasion from the surface of the implant on the overlying tissues. If some material is used to wrap the implant, the four rectus muscles should be sutured to the wrapping material.

Optionally, 3 x 7-mm windows can be cut in the wrapping material at the site of the attachment of the extraocular muscles to increase vascularization of the Bio-Eye® HA orbital implant Other areas of the wrapping material may also be removed to increase vascularization of the implant. For example, a window may be cut in the wrapping material that covers the posterior aspect of the implant. No windows should be cut in the wrapping material over the anterior aspect of the implant. After attaching the extraocular muscles to the wrapping material, Tenon's capsule and the conjunctiva should be closed in separate layers.

If no wrapping material is used, the rectus muscles should be sutured to each other over the anterior aspect of the implant: lateral to medial and superior to inferior. Tenon's capsule and the conjunctiva should then be closed in separate layers. A temporary wrapping should be made to facilitate placement of the implant deep into the orbit.

In one variation, the following technique can be used to place an unwrapped implant. Cut two 13 x 13-cm squares from the thin, sterile plastic drape used to drape the patient Overlap two of the edges of the squares by about 1.0 cm and place the implant on the center of the overlap. Wrap the plastic around the implant and gather up the plastic to completely surround the implant. The plastic-wrapped implant can then be easily inserted into the orbit. After placing the implant deep into the orbit, unwrap the plastic and, while holding the implant in place with one finger, gently pull the plastic pieces out from under the implant.

Evisceration
A standard evisceration is done, with or without removal of the cornea. The Bio-Eye® HA orbital implant should be soaked in antibiotic solution prior to implantation. Sizing spheres are used to determine the size of the implant to be used. The implant is placed into the sclera and the sclera is sutured closed, with care taken to prevent any tension on the scleral closure. Relaxing incisions and windows may be cut in the sclera to allow deeper placement of the implant in the orbit, to help reduce tension on the closure, and to allow the use of a larger implant than is otherwise possible. Windows also provide additional contact between the implant and the highly vascular tissues of the orbit, thereby accelerating the rate of ingrowth of fibrovascular tissue into the implant. The relaxing incisions should be made in the quadrants between the rectus muscles. The windows should be about 3 x 7 mm and should be placed just posterior to the insertion of the rectus muscles. Additionally, a circular window measuring about 10 mm in diameter may be cut in the posterior aspect of the sclera to facilitate faster ingrowth.

Secondary Orbital Implant
The existing implant is removed in a standard fashion, with care taken to identify the extraocular muscles, if possible. The extraocular muscles may be difficult to identify and isolate in the case of a secondary orbital implantation. If they can be identified, then the above-described enucleation technique is used. If they cannot be identified, then the orbital tissue that corresponds to the approximate location of each rectus muscle should be sutured to the implant.

Postoperative Care Following Enucleation, Evisceration or Secondary Implantation
Place a conformer under the lids and apply a firm pressure dressing for 4 to 6 days. Systemic antibiotics are used for 7 days. Topical antibiotics are used 4 times daily for 4 weeks. Following removal of the pressure dressing fit the artificial eye 6 to 8 weeks postoperatively, provided that all edema has subsided.

Precautions
Exposure of the implant (e.g.. by creating a hole in preparation for the Motility/Support Peg) should be avoided until the implant is completely vascularized (approximately 6 months or longer postoperatively). Vascularization of the implant can be determined by a bone scan or MRI. If inadvertent exposure occurs prior to vascularization of the implant, the patient may require a graft to cover the exposed area. Avoid oversized conformers postoperatively, since they may exert pressure on the closure. Care should be taken to prevent tension on the closure of both Tenon's capsule and the conjunctiva.

Warning
The following complications have been noted in association with surgical procedures using the Bio-Eye® HA orbital implant: conjunctival and Tenon's capsule wound dehiscence, implant exposure, and implant infection.

How Supplied
The Bio-Eye® HA orbital implant is supplied STERILE in 9 diameters: 16, 17, 18, 19, 20, 21, 22, 23 and 24 mm. The method of sterilization is gamma radiation. A Motility/Support Peg system may be ordered with each implant, or may be ordered separately.

Resterilization
DO NOT resterilize the Bio-Eye® HA orbital implant. This device has NOT been validated for resterilization. DO NOT re-use. Risk of Re-use includes, but is not limited to: infection, rejection, extrusion and failure of the implant to properly vascularize.

Adverse Reactions
There are no known adverse reactions to the hydroxyapatite material itself. The material is biocompatible, nonallergenic, and nontoxic.

References
* Hornblass A. et al. Enucleation and evisceration, current techniques: A study of 5439 intraorbital implants and a review of the literature. Presented at the joint meeting of the American Academy of Ophthalmology and the American Society of Ocularists in Dallas, Texas, November 8, 1992.

Caution
Federal law (USA) restricts this device to sale by or on the order of a licensed physician.

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