Instructions For Use
The Perforated Coated 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

Introduction

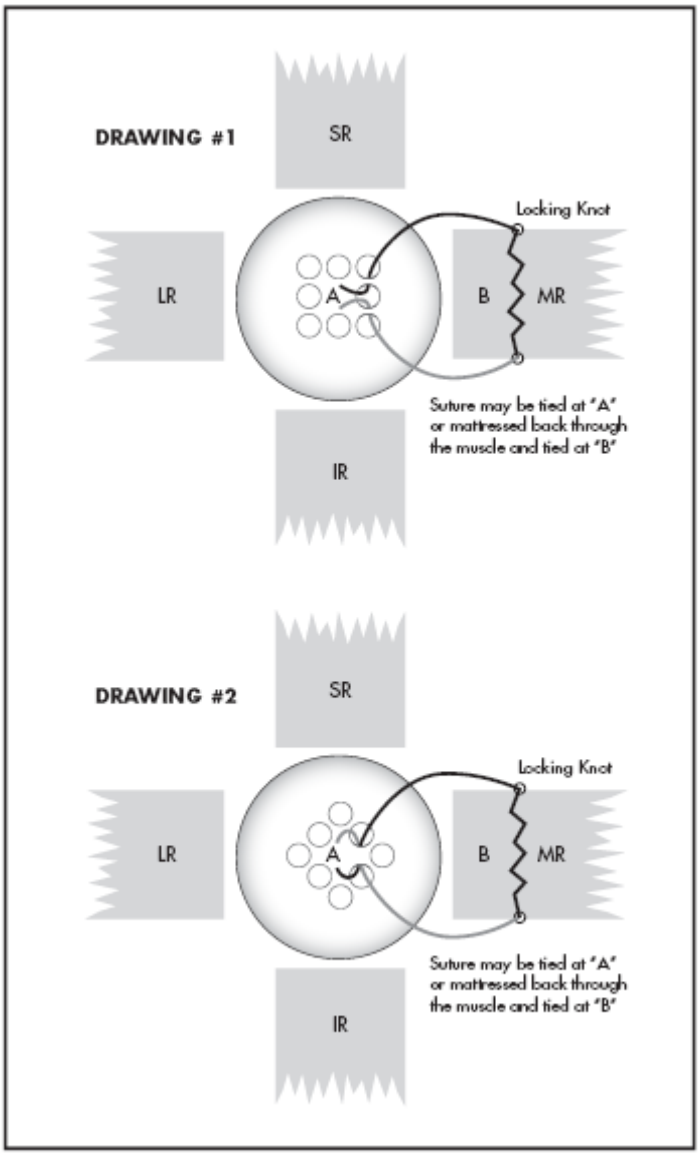
Integrated Orbital Implants, Inc. developed and sells the Perforated Coated Bio-Eye® Hydroxyapatite (HA) Orbital Implant. The Perforated Coated Bio-Eye® HA Orbital Implant is a spherical (ball-shaped) implant composed of naturally derived hydroxyapatite. It is used to replace the volume of the orbit when the eye is surgically removed or as a replacement implant in patients with a poorly functioning, pre-existing implant. The implant is covered on its surface by two different colored absorbable polymers. The purple colored polymer with micro holes will be absorbed in approximately six to eight weeks, and the amber colored polymer with micro holes and eight perforations will be absorbed in approximately eighteen months. The purple colored polymer should be placed posteriorly (deeper) in the orbit (purple = posterior), and the amber colored polymer should be anterior (closer to the conjunctiva) in the socket (amber = anterior). The rectus muscles are attached to the amber colored polymer. 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.

The benefits of using the Perforated Coated Bio-Eye® Hydroxyapatite Orbital Implant are:
a. Requires less operating time.
b. Requires no wrapping material.
c. Muscles can be sutured directly to the coating.
d. The surface is totally smooth and allows the implant to be easily placed deep in the orbit.
e. The polymer coating has differential absorption rates.

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 Perforated Coated 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 place under the lids following placement of the orbital implant.



Indications
The Perforated Coated Bio-Eye® HA Orbital Implant is indicated in orbital implantation following enucleation or as a secondary orbital implant following extrusion, migration or rotation of primary orbital implants. The Perforated Coated Bio-Eye® HA orbital implant is indicated in any situation where materials such as silicon, acrylic, polyethylene or glass orbital implants would be used.

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

Contraindications The Perforated Coated 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
No preparations are needed. The Perforated Coated Bio-eye HA Orbital Implant is sold STERILE.

General Surgical Procedures
Enucleation

A standard enucleation is done, including tagging of the extraocular muscles with absorbable suture 3.5mm from the insertion on the globe. 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.

Once the appropriate size implant has been chosen, the implant is soaked in antibiotic and local anesthetic solution. The implant is then ready to be placed deep in the orbit. The rectus muscles are sutured to the amber colored polymer using the perforations. The drawings #1 and #2 show two possible ways to suture the muscles. Only one muscle is shown being sutured, however, all rectus muscles should be attached. **It is easier to place all the sutures through the perforations prior to tying any of the muscles down tightly to the surface of the implant.**

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 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.

Warnings
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.

Possible Complications
The following complications have been noted in association with surgical procedures using any orbital implant: conjunctival and Tenon's capsule wound dehiscence, implant exposure, and implant infection.

How Supplied
The Perforated Coated Bio-Eye® HA Orbital Implant is supplied STERILE in a range of diameters. A STERILE conformer is also supplied with each implant. A Motility/ Support Peg System may be ordered with each implant, or may be ordered separately either at the time of ordering the implant or at a later date.

Resterilization
DO NOT resterilize the Perforated Coated Bio-Eye® HA Orbital Implant or conformer.

Adverse Reactions
There are no known adverse reactions to the hydroxyapatite material itself or the absorbable polymer material. The material is biocompatible and nonallergenic.

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

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