Instructions For Use

The Coated Bio-Eye® Hydroxyapatite Orbital Implant (Sterile) with conformer

Read Instructions Before Use Single Use Product

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

Catalog Number: I0016C, I0018C, I0020C, I0022C, I0024C

Introduction

Integrated Orbital Implants, Inc. developed and sells the Coated Bio-Eye® Hydroxyapatite (HA) Orbital Implant. The 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 will be absorbed in approximately six to eight weeks, and the amber colored polymer 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 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 advantages of using the Coated Bio-Eye® Hydroxyapatite Orbital Implant are that:

a. it requires no wrapping material.
b. Muscles can be sutured directly to the coating.
c. The surface is totally smooth and allows the implant to be easily placed deep in the orbit.
d. 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 Coated Bio-Eye® HA Orbital Implant is characterized by an interconnected matrix of pores. A propriatary 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 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 Coated

Bio-Eye® HA orbital implant is indicated in any situation where materials such as silicon, acrylic, polyethylene, glass, or other traditional orbital implants would be used.

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

Contraindications
The 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 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. 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 desired size of the implant has been determined, a sterile marking pen is used to draw the location of the muscle windows on the amber colored polymer. The muscle windows are 5X4mm rectangles drawn at the location of each rectus muscle attachment. These windows are most easily cut my using a fine tipped, high temperature (>2000°F) battery operated handheld cautery. Use the fine tip to cut the coating material along the previously drawn lines. The small piece of polymer inside the window can then be removed with forceps. Make two small 1mm holes, one near each end of the muscle window, 2-3mm anterior to the anterior edge of each muscle window. The holes are for the exiting of the needle as the suture is passed through the muscle window and out the hole. The sutures are then tied together. An original step to aid the passage of the suture needle is to use a 25 or 27 gauge hypodermic needle to create a tunnel from the suture exit hole to the muscle window. Then small holes (8 to 10) are made with the cautery near the posterior pole of the implant (near the apex of the purple colored hemisphere). This allows for the antibiotic and local anesthetic mixture within the implant to flow into the posterior orbit. These holes also serve as areas for rapid blood vessel in-growth. The Coated Bio-Eye® HA Orbital Implant should then be soaked in an antibiotic and local anesthetic solution after the windows for the muscle attachments and the posterior holes have been made. This is done just prior to implantation.

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
Currently, the Coated Bio-Eye® HA Orbital Implant is supplied STERILE in five diameters: 16, 18, 20, 22 and 24mm. A conformer is also supplied STERILE with each implant. A Motility/ Support Peg System may be ordered with each implant, or may be ordered separately.

Resterilization
DO NOT resterilize the Coated Bio-Eye® HA Orbital Implant or conformer. These devices have NOT been validated for resterilization.

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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