INTEGRATED ORBITAL IMPLANTS, INC.

Instructions for Use:

P-K™ Titanium Threaded Sleeve Driver
I00057

CAUTION

NON-STERILE

SINGLE-USE

Description

The P-K™ Titanium Threaded Sleeve Driver is used to drive the P-K™ Titanium Threaded Sleeve into the Bio-eye Hydroxyapatite (HA) ocular implant to couple the implant to the artificial eye to create a fully integrated motility prosthesis. This sleeve driver is part of the P-K™ Titanium Motility System, which represents the state-of-the-art motility/support solutions for the artificial eye. The P-K™ Titanium Sleeve Motility System provides the best support for the artificial eye, the fullest range of movement, and the most ease of use for both ocularist and patient. Below is a detailed description of the procedure for using the P-K™ Threaded Sleeve Driver.

Indications

The P-K™ Titanium Threaded Sleeve Driver is used to drive a P-K™ Titanium Threaded Sleeve into a Bio-eye HA ocular implant. The P-K™ Titanium Threaded Sleeve is designed to house a P-K™ Titanium Motility/Support Peg which will provide motility and support for the artificial eye.

Procedure for Using a P-K™ Titanium Threaded Sleeve Driver

Step 1: Prepare the Patient

The patient's socket must be prepped and draped for a STERILE procedure, and proper anesthesia must be established. Refer to the instructions for use for the P-K™ Titanium Threaded Sleeve and P-K™ Titanium Flat Peg for instructions on preparing the patient for receiving the P-K™ Titanium Threaded Sleeve.

Step 2: Confirm that the Location of the Sleeve has been Determined

After the ocular implant has become vascularized, a pilot hole must be created in the implant to facilitate driving of the P-K™ Titanium Threaded Sleeve to the proper depth and at the proper angle. Refer to the instructions for use for the P-K™ Titanium Threaded Sleeve and P-K™ Titanium Flat Peg for instructions on proper location of the sleeve.

Step 3: Confirm that the Pilot Hole has been created.

Before driving the P-K™ Titanium Threaded Sleeve, a pilot hole must be created in the implant using a graduated series of sterile hypodermic needles. Refer to the instructions for use for the P-K™ Titanium Threaded Sleeve and P-K™ Titanium Flat Peg for instructions on proper creation of a pilot hole.

Step 4: Drive the Sleeve

Confirm that the P-K™ Titanium Threaded Sleeve and P-K™ Titanium Flat Peg have been sterilized. Slide the tip of the P-K™ Titanium Threaded Sleeve Driver into the P-K ™ Titanium Threaded Sleeve and turn it until the blades of the sleeve driver engage with the notches in the rim of the sleeve. Stabilize the implant using an Implant Ring Stabilizer and insert the tip of the sleeve into the pilot hole. Firmly drive the sleeve into the implant until its anterior aspect is 1 to 2 mm above the surface of the conjunctiva, to account for edema. When the edema has subsided, several weeks postoperatively, this will help ensure that the sleeve is above the level of the conjunctiva.

Place the P-K™ Titanium Flat Peg in the sleeve to prevent the conjunctiva from obstructing the opening of the sleeve. Place antibiotic ointment in the socket, rinse the artificial eye in Betadine solution and then in saline solution, and place the artificial eye in the socket. Patch the eye for 24 hours and give oral antibiotics for 1 week.

Re-examine the patient 4 weeks postoperatively and, if the sleeve and flat peg are well tolerated, refer the patient to an ocularist for replacement of the flat-headed peg with a P-K™ Motility/Support Peg.

Contraindications

There are no contraindications specific to the P-K™ Titanium Threaded Sleeve Driver itself. However, a P-K™ Titanium Threaded Sleeve should not be placed in an infected socket. Additionally, an unvascularized implant should not be pegged or otherwise exposed due to increased risk of infection. Vascularization is best assessed by means of a technetium 99m bone scan or an MRI.

Precautions
It is important to assess the degree of vascularization of the Bio-eye HA ocular implant prior to drilling. Most Bio-eye HA ocular implants are sufficiently vascularized within 6 months postoperatively, however, vascularization is best assessed by some objective means, such as by a technetium 99m bone scan or an MRI.

To prevent the conjunctival tissue from closing over the P-K™ Titanium Threaded Sleeve, do not allow the sleeve to remain empty.

Complications
There are no complications specific to the P-K™ Titanium Threaded Sleeve driver itself. However, the following complications have been reported following fitting of a P-K™ Titanium Threaded Sleeve: infection, implant exposure, pyogenic granuloma, and an audible clicking sensation of the peg.

How Supplied
The P-K™ Titanium Threaded Sleeve Driver is provided **NONSTERILE** and **SINGLE USE**.

Sterilization
The P-K™ Titanium Threaded Sleeve Driver must be sterilized prior to use. Sterilize using standard hospital protocols for hand-held surgical instruments.

Note
For information on P-K™ Titanium Motility System contact:
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