Read Instructions Before Use

Instructions for Use: P-K Sleeve Driver, Implant Ring Stabilizer and Sizing Spheres with Indicator Rings

INDICATIONS: The P-K™ Titanium Motility / Support System is intended to provide a direct mechanical coupling of an ocular prosthesis to an orbital implant (eye sphere implant) in order to enhance motility of the prosthesis over that of a prosthesis used without a direct coupling to the implant. It also reduces the weight of the ocular prosthesis on the lower eyelid. It may be placed in a secondary operation that occurs after the ocular implant has become vascularized, approximately 3-6 months after implant placement. Alternatively, it may be placed during the initial implantation procedure before closing the Tenon's capsule and the conjunctiva.

P-K Sleeve Driver:

DESCRIPTION: This Sleeve Driver is part of the P-K Sleeved Peg System; The P-K Sleeve Driver is used to drive the P-K Threaded Sleeve into an ocular implant in order to couple the implant to the artificial eye to create a fully integrated motility prosthesis. Below is a detailed description of the procedure for using the P-K Sleeve Driver.

PROCEDURE FOR USING A P-K 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 Threaded Sleeve and P-K Flat-headed Peg for instructions on preparing the patient for receiving the P-K Threaded Sleeve.

Step 2: Confirm that the Location of the Sleeve has been Determined: After the orbital implant has become vascularized, a pilot hole must be created in the implant to facilitate driving of the P-K Threaded Sleeve to the proper depth and at the proper angle. Refer to the instructions for use for the P-K Threaded Sleeve and P-K Flat-headed Peg for instructions on proper location of the sleeve.

Step 3: Confirm that the Pilot Hole has been Created: Before driving the P-K 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 Threaded Sleeve and P-K Flat-headed Peg for instructions on proper creation of a pilot hole.

Step 4: Drive the Sleeve: Confirm that the P-K Threaded Sleeve and P-K Flat-headed Peg have been sterilized. Slide the tip of the P-K Sleeve Driver into the P-K Threaded Sleeve and turn it until the blades of the wrench 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 2 to 3 mm below 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 flush with or just below the conjunctiva.

Place the P-K Flat-headed 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-headed peg are well tolerated, refer the patient to an ocularist for replacement of the flat-headed peg with a P-K Motility/Support Peg.

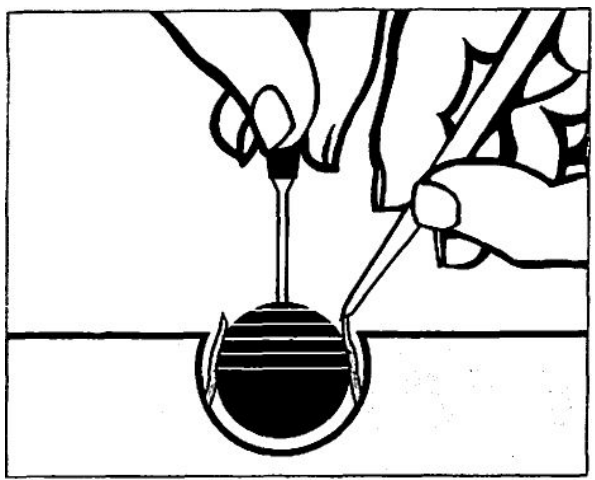
Implant Ring Stabilizer:

THE INSTRUMENT: The Implant Ring Stabilizer is a hand-held ophthalmic surgical instrument composed completely of surgical-grade stainless steel.

USE: The Implant Ring Stabilizer (IRS) is used to stabilize an orbital implant during the creation of a hole for affixation of a motility/support peg. After confirming that the implant is sufficiently vascularized, mark the desired peg location on the implant using a surgical marking pen. Apply a lid speculum and place the toothed ring of the IRS around the mark. With a firm grasp on the handle of the IRS, apply moderate pressure to the implant while boring the hole in the implant through the ring. Remove the IRS as needed to check the depth or accuracy of the hole.

Sizing Spheres with Indicator Rings:

The series of concentric rings on the sizing spheres can be used to indicate the site at which the rectus muscles should be attached to any wrapping material (such as sclera or fascia lata) used to cover the Bio-eve® hydroxyapatite orbital implant. With the proper sizing sphere in place (see Table 1), hold its handle perpendicular to the frontal plane of the patients face and grasp the rectus muscle with forceps. Lay each rectus muscle along the sphere, and note the ring nearest to the anterior end of the muscle. The indicator rings are spaced 3.0 mm apart, starting from the centerline of the handle. i.e. the anterior apex of the sphere. Use this measurement when determining the site of windows to be cut in the wrapping material.



Conservation of Volume

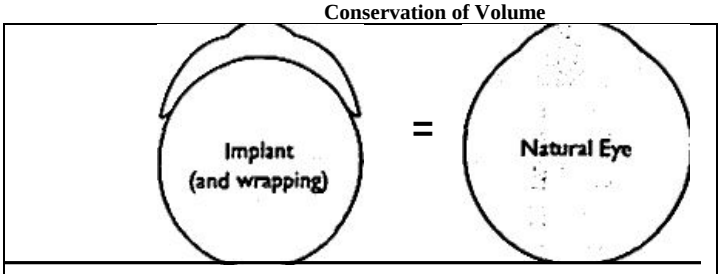


Table 1: Determining Implant Size Based on Natural Eye Size

Diameter of Natural Eye (mm)	Volume of Natural Eye (ml)	Volume of Artificial Eye (ml)	Volume Deficit Remaining (ml)	Diameter of Implant to Use if Unwrapped (mm)	Diameter of Implant to Use if Wrapped (mm)
20.0	4.19	2.5	1.69	15.0	13.5
20.5	4.51	2.5	2.01	15.5	14.0
21.0	4.85	2.5	2.35	16.5	15.0
21.5	5.21	2.5	2.71	17.5	16.0
22.0	5.58	2.5	3.08	18.0	16.5
22.5	5.97	2.5	3.47	19.0	17.5
23.0	6.37	2.5	3.87	19.5	18.0
23.5	6.8	2.5	4.3	20.0	18.5
24.0	7.24	2.5	4.74	21.0	19.5
24.5	7.7	2.5	5.2	21.5	20.0
25.0	8.18	2.5	5.68	22.0	20.5
25.5	8.69	2.5	6.19	23.0	21.5
26.0	9.21	2.5	6.71	23.5	22.0

Determining Proper Implant Size: The actual size of the orbit should be objectively measured prior to implantation using a sizing sphere. Consider the entire prosthetic complex. The implant, wrapping material (if any), and artificial eye should have a volume equal to that of the natural eye. A scleral wrapping adds about 1.5 mm to the diameter of the implant (Table 1). The average eye has a diameter of about 24 mm. and a volume of 7.2 ml (volume=$4\pi r^3/3$).The average artificial eye has a volume of 2.5 ml. Intermediate implant sizes can be made by "shaving down" a larger Implant with a scalpel. In no case should an implant be so large as to cause tension on the closure of Tenon's capsule or the conjunctiva.

CONTRAINDICATIONS: There are no contraindications specific to the P-K Sleeve Driver, Implant Ring Stabilizer or Sizing Sphere Set. However, a P-K Threaded Sleeve should not be placed in an infected socket. Additionally, an unvascularized implant should not be drilled 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 orbital implant prior to drilling. Most Bio-eye HA orbital 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 Threaded Sleeve, do not allow the sleeve to remain empty.

COMPLICATIONS: There are no complications specific to the P-K Sleeve Driver, Implant Ring Stabilizer or Sizing Sphere Set. However, the following complications have been reported following fitting of a P-K Threaded Sleeve: infection, implant exposure, pyogenic granuloma, and an inaudible clicking sensation of the peg.

HOW SUPPLIED: The P-K Sleeve Driver, Implant Ring Stabilizer, Sizing Sphere Set are provided NONSTERILE.

Note: For information on peg systems contact: Integrated Orbital Implants, Inc., San Diego, CA 92121, USA

Tel. 858-677-9990 fax 858-677-9993 In USA only: 800-424-6537, www.ioi.com

STERILIZATION: **Note**: P-K Sleeve Driver and Implant Ring Stabilizer: Remove from plastic package and place in pouch that is able to be steam sterilized. **Note**: Sizing Spheres: Remove from box and place in pouch that is able to be steam sterilized. The P-K Sleeve Driver, Implant Ring Stabilizer and Sizing Spheres should be sterilized using the following parameters:

Validated Steam Sterilization Cycle:

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Sterilizer Type	Prevacuum
Preconditioning Pulses	3
Minimum Temperature	132° C
Full Cycle Time:	4 minutes
Minimum Dry Time	20 minutes
Sample Configuration:	Pouched device