

P-K™ TITANIUM MOTILITY PEG SYSTEM®



for use with the

BIO-EYE® HYDROXYAPATITE (HA) ORBITAL IMPLANT



Integrated Orbital Implants, Inc.

San Diego, CA 92121, USA

Toll Free: 800-424-6537 • Tel: 858-677-9990 • Fax: 858-677-9993

Email: haimplants@aol.com • Website: <http://www.ioi.com>



TITANIUM PEG PLACEMENT PROCEDURE

FOR USE WITH THE

BIO-EYE[®] HYDROXYAPATITE (HA) ORBITAL IMPLANT

To our valued customer:

Thank you very much for your interest in our P-K Titanium Pegging System. We think you will find this universal titanium pegging system easy to use. We are excited about the results we believe you will see with your patients.

We hope that this information from our Medical Director, Dr. Art Perry, will assist you when you begin to use this system. The following is Dr. Perry's experience with this procedure:

I do this in my office or in an operating room, as a sterile procedure, using 6-8cc's of retrobulbar anesthetic or general anesthesia.

To use the threaded sleeve and the flat peg, a hole will be created using gradually larger hypodermic needles which are also enclosed (20g, 18g, 16g, 14g). First, mark the conjunctiva with a marking pen with the patient sitting up. I use a template made by the ocularist to locate this spot. Use the Implant Ring Stabilizer to stabilize the implant. Make the first hole with the 20g needle slowly and carefully so that you get it very straight (perpendicular to the frontal plane of the patient). Every 3-4mm's check your alignment. I make this hole completely through the implant to allow more vessel ingrowth. As a result of possible new bone growth in the implant, unexpected resistance may be met and a new needle may be needed due to the dulling of the first needle from bone. In difficult cases, a power drill may be needed. The other needles will easily follow the first hole and simply enlarge it. Keep your eye carefully on the entry and exit spot on the conjunctiva so that you can easily find the same hole. After using the 14g needle, I irrigate the hole with injectable gentamycin (40mg/cc). The threaded sleeve easily screws into the hole using the sleeve driver. Place the open end of the sleeve at a depth 2-3mm's below the conjunctival surface so that it will be below the conjunctiva when the edema has resolved. Place the flat peg into the shaft of the threaded sleeve. I put antibiotic ointment into the socket, put the artificial eye in betadine and then rinse it with sterile saline, place it back in the socket and patch the eye overnight. I place the patients on oral antibiotics for 7 days and on topical antibiotics until I see them back in one month.

If there is a need to replace the plastic sleeve, there is a 4mm titanium threaded sleeve with flat peg which can be placed in the same hole. This 4mm sleeve uses the same titanium sleeve driver and pegs as the standard titanium threaded sleeve.

After rechecking the patients at one month, I send them to the ocularist to have the implant coupled to the prosthesis. The ocularist will determine the technique for coupling (ball peg, locking-socket peg, direct attachment, etc.) and he will order the appropriate titanium attachment. I continue the patients on topical antibiotics for 2 weeks post coupling and then have the patients use the medication at bedtime only if they find that it decreases their secretions. About 50% of patients use a drop every night. In these cases, the antibiotic (or antibiotic/steroid) will need to be changed periodically.

We hope this information has been of assistance. Should you have any further questions, please do not hesitate to contact our office at 858-677-9990 or 800-424-6537.

All of us at Integrated Orbital Implants wish you great success.

PHYSICIAN INFORMATION

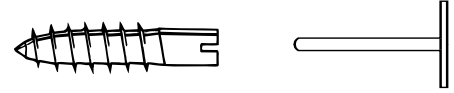
P-K™ TITANIUM PEG SYSTEM

the universal solution for motility and support

FOR USE WITH THE BIO-EYE® HA ORBITAL IMPLANT

P-K TITANIUM THREADED SLEEVE AND FLAT PEG AS A SET

PART NO. I00045



P-K TITANIUM THREADED SLEEVE

(Diameter: 2.8mm / Length: 11.9mm/ Central Bore Diameter: 1.2mm)

To Use: Drive into the hole using the P-K Titanium Sleeve Driver. Hollow shaft holds P-K Titanium Flat Peg after surgery. The shaft accepts various other P-K Titanium Pegs that the ocularist may use to couple to artificial eye.

P-K TITANIUM FLAT PEG

(Shaft Diameter: 1.1 mm / Shaft Length: 10 mm)

To Use: Insert into shaft of P-K Titanium Threaded Sleeve immediately after sleeve is placed to prevent closure. Ocularist will replace with P-K Titanium Ball Peg or various other coupling pegs when fitting to artificial eye.

LARGE REPLACEMENT P-K THREADED SLEEVE AND FLAT PEG AS SET

(Diameter: 4.0mm/ Length: 12.2mm/ Central Bore Diameter: 1.2mm)

PART NO. I00100

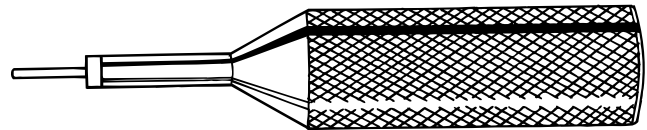


To Use: This 4mm sleeve with flat peg is used to replace the plastic sleeve and can be placed in the same hole. This large titanium threaded sleeve uses the same titanium sleeve driver and pegs as the standard titanium threaded sleeve.

P-K TITANIUM SLEEVE DRIVER

PART NO. I00057

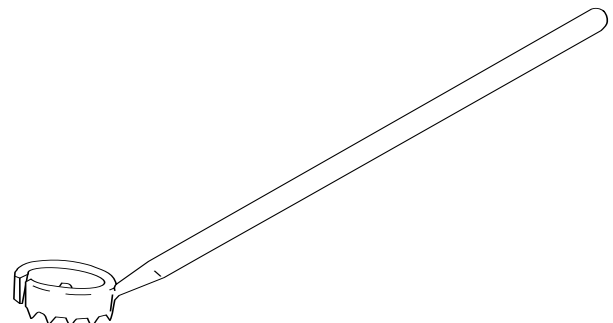
Use: Drive the P-K Titanium Threaded Sleeve into a vascularized porous Bio-eye implant.



IMPLANT RING STABILIZER

PART NO. I00012

- Stabilizes Bio-eye implant in the orbit during peg placement procedure
- Stainless steel construction allows use of firm pressure



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OCULARIST INFORMATION

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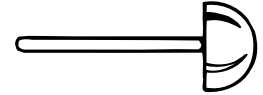
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P-K TITANIUM BALL PEG

(Shaft Diameter: 1.1mm / Shaft Length: 10mm/ Ball Thickness: 3mm)

PART NO. I00049

To Use: Fit into the P-K Titanium Threaded Sleeve after the P-K Titanium Flat Peg has been removed (approx. 4 weeks postoperatively). This motility peg allows a ball-and-socket coupling to the posterior of the artificial eye.

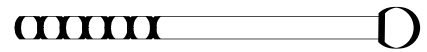


P-K TITANIUM LOCKING-SOCKET PEG

(Shaft Diameter: 1.1mm / Shaft Length: 19mm/ Ball Thickness: 1.8mm)

PART NO. I00051

To Use: Fit into the P-K Titanium Threaded Sleeve after the P-K Titanium Flat Peg has been removed (approx. 4 weeks postoperatively). This motility peg allows ball-and-socket coupling to the posterior part of artificial eye and an “lock” in place to support entire weight of the artificial eye. Notched break-off points facilitate length adjustment.

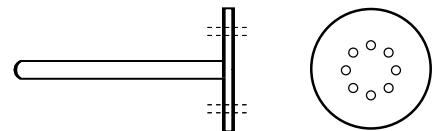


P-K TITANIUM FENESTRATED FLAT PEG

(Shaft Diameter: 1 mm / Shaft Length: 10 mm)

PART NO. I00087

To Use: Fit into the P-K Titanium Threaded Sleeve after the P-K Titanium Flat Peg has been removed (approx. 4 weeks postoperatively). Holes in head improve glue bond between peg and prosthesis. Used where direct attachment is required, such as in the case of an artificial eye that is very thin.



P-K TITANIUM THREADED SLEEVE BALL-TIP

(Shaft Diameter: 1 mm / Shaft Length: 10 mm)

PART NO. I00089

To Use: Fit into the P-K Titanium Threaded Sleeve at the time the threaded sleeve is inserted. The threaded sleeve is left extended above the conjunctiva to become the coupling post. The head diameter of the ball-tip matches the diameter of the sleeve to round off the end of the sleeve. This motility design allows a post-and-hole coupling to the posterior of the artificial eye.

