

Instructions for Use: P-K™ Titanium Locking Socket Peg, P-K™ Titanium Ball Peg, P-K™ Titanium Threaded Sleeve Ball Tip, P-K™ Titanium Threaded Sleeve and Flat Peg, Large Titanium Threaded Sleeve and Flat Peg, and Fenestrated Flat Peg

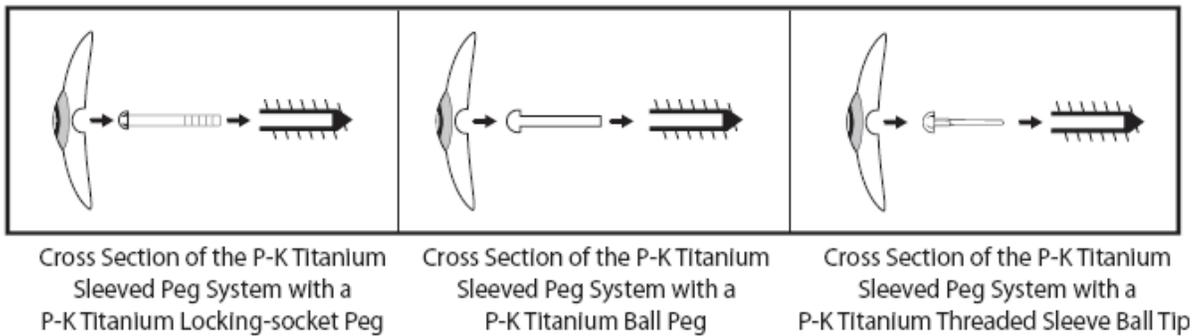
Description: The P-K™ Sleeved Peg System is used to couple the Bio-eye® hydroxyapatite (HA) orbital implant, or other vascularizing orbital implants, to the artificial eye to create a fully integrated motility prosthesis. The P-K Titanium Sleeved Peg System represents the state-of-the-art in motility/support pegs; it is designed to provide the best support for the artificial eye, the fullest range of movement, and the most ease of use for both ocularist and patient.

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™ Titanium Locking-socket Peg, Titanium Ball Peg, and Titanium Threaded Sleeve Ball Tip:

Below is a detailed description of the method for fitting a P-K™ Motility Peg to an artificial eye. **Basic Concept:** The head of the P-K Titanium Locking-socket Peg, Ball Peg and Threaded Sleeve Ball Tip is designed to fit into a socket created on the posterior aspect of the artificial eye. The shaft of the peg is designed to fit into the sleeve of the P-K Titanium Threaded Sleeve (Fig. 1). Refer to the instructions for use for the P-K Titanium Threaded Sleeve and P-K Titanium Flat Peg for instructions on placing the P-K Titanium Threaded Sleeve and P-K Titanium Flat Peg.

Figure 1.



Step 1: Prepare the artificial eye: To prepare the artificial eye for an impression, it may be necessary to remove a small amount of plastic material from the posterior aspect of the eye to create room for the impression and to allow application of a thin layer of wax, which improves adhesion of the alginate. Confirm that the P-K Flat Peg can be easily removed from and re-inserted into the P-K Titanium Threaded Sleeve, and then leave the P-K Titanium Flat Peg in place.

Step 2: Determine the proper location for the pilot hole: Apply a small amount of alginate to the posterior of the artificial eye and place the artificial eye in the socket. Instruct the patient to remain in a seated position and to gaze straight ahead. Using a suction cup, immediately align the artificial eye in its proper location and allow the alginate to set. Remove the artificial eye and trim the excess alginate from its edges. It is normal for the P-K Titanium Flat Peg to remain embedded in the alginate. When trimming is completed, reinsert the artificial eye to confirm proper gaze and then remove it and replace the P-K Titanium Flat Peg in the sleeve. Before making the mold, trim the alginate to expose the disk-shaped impression made by the head of the P-K Titanium Flat Peg. **Note:** Do not leave the sleeve empty. To prevent the conjunctival tissue from closing over the sleeve, immediately replace the P-K Titanium Flat Peg in the sleeve after removing it from the alginate.

Step 3: Make the mold: To avoid dehydrating the alginate, make the mold immediately or store the artificial eye and impression in water until time permits making of the mold without interruption. Using your normal curing process, add plastic to the artificial eye and polish it, taking care to not disturb the disk-shaped impression created by the head of the peg.

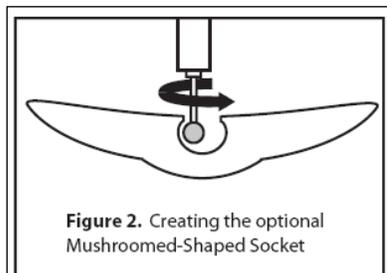
Locking Socket Peg: Use a thickness gauge to confirm there is at least 3.0 mm of thickness in the artificial eye in the area under the disk-shaped impression. **Note:** There must be adequate thickness (≥ 3.0 mm) in the artificial eye in the area under the disk-shaped impression to allow drilling to a depth of at least 2.0 mm, without disturbing the cornea or iris.

Ball Peg: Use a thickness gauge to confirm there is at least 5.0 mm of thickness in the artificial eye in the area under the disk-shaped impression. **Note:** There must be an adequate thickness (≥ 5.0 mm) in the artificial eye in the area under the disk-shaped impression to allow drilling to a depth of 3.0 mm without disturbing the cornea or iris.

Threaded Sleeve Ball Tip: Use a thickness gauge to confirm there is at least 3.0 mm of thickness in the artificial eye in the area under the disk-shaped impression. **Note:** There must be an adequate thickness (≥ 3.0 mm) in the artificial eye in the area under the disk-shaped impression to allow drilling to a depth of 2.0 mm without disturbing the cornea or the iris.

If adequate thickness is not achieved, build up the area with additional plastic. If the addition of plastic is not possible, it may be necessary to directly attach the P-K Titanium Fenestrated Flat Peg to the posterior of the artificial eye. Direct attachment of the peg is effective in providing motility and support for the artificial eye, but it makes patient insertion of the artificial eye much more difficult, and therefore is only recommended in cases of inadequate thickness of the artificial eye.

Step 4: Create a socket in the artificial eye: In the center of the disk-shaped impression created by the head of the peg, drill a 1.0-mm pilot hole.



Locking Socket Peg: Confirm the accuracy of the pilot hole and then enlarge it to create a socket 2.0 mm in diameter and at least 2.0 mm in depth. In cases of an implant with extreme motility, a round burr can be rotated clockwise inside the hole to create a mushroom-shaped socket by undercutting the plastic below the opening of the hole (Fig. 2).

The sides of the 2.0-mm opening will act as a guide for the burr shaft as it continues to cut. Continue rotating the burr until it no longer cuts plastic. Confirm that the head of the P-K Titanium Locking-socket Peg will easily pass through the opening of the socket. If it does not pass easily, enlarge the opening as necessary and make additional passes with the round burr, as above, until it no longer cuts plastic as its shaft is moved along the sides of opening.

Note: Do not enlarge the opening more than is necessary to allow the head of the P-K Titanium Locking-socket Peg to easily pass through it. The opening to the socket must be narrower than the inside of the socket (i.e., the socket must be mushroom shaped) in order for the head of the P-K Titanium Locking-socket Peg to lock in place during extreme gaze. Place the head of the P-K Titanium Locking-socket Peg through the opening of the socket and confirm that the head locks in place when the shaft of the peg is moved to the extreme left or right. Prior to delivery, disinfect the P-K Titanium Locking-socket Peg and artificial eye with hydrogen peroxide or Betadine. Remove the flat peg from the sleeve located in the patient's implant and immediately place the P-K Titanium Locking-socket Peg in the sleeve. Confirm that there is no air pressure beneath the peg and that it is well seated.

Note: Do not leave the sleeve empty. To prevent the conjunctival tissue from closing over the sleeve, immediately replace the P-K Titanium Locking-socket Peg in the sleeve after removing the P-K Titanium Flat Peg.

Ball Peg: Confirm the accuracy of the pilot hole and then enlarge to create a socket 5.0 mm in diameter and 3.0 mm in depth. Insert the head of the P-K Titanium Ball Peg into the socket created in the posterior aspect of the artificial eye and confirm that the flat posterior aspect is flush with the posterior aspect of the artificial eye. The head of the peg should move smoothly within the socket created in the posterior aspect of the artificial eye. It is normally not necessary to polish this socket to make it smooth. If necessary, this socket can be made more smooth by lightly burring its surface.

Threaded Sleeve Ball Tip: Confirm the accuracy of the pilot hole and then enlarge to create a socket 2.7 mm in diameter and 2.0 mm in depth. Insert the head of the P-K Titanium Threaded Sleeve Ball-tip into the socket created in the posterior aspect of the artificial eye and confirm that the flat posterior aspect of the head is flush with the posterior aspect of the artificial eye. The head of the Ball Tip peg should move smoothly within the socket created in the posterior aspect of the artificial eye. It is normally not necessary to polish this socket to make it smooth. If necessary, this socket can be made more smooth by lightly burring its surface.

Step 5: Adjust peg length

Locking Socket Peg: Initially, the head of the P-K Titanium Locking-socket Peg may extend 4-5 mm above the conjunctiva. The shaft of the peg may need to be shortened so that the head is about 2.0 mm above the conjunctiva. Break-off points built into the shaft of the peg at 1.0-mm intervals allow easy adjustment of peg length. Modification of the length of the P-K Titanium Locking-socket Peg is best achieved in a stepwise fashion, as follows. **Note** the amount that must be removed to achieve the final head height of 2.0 mm above the conjunctiva. Remove the peg and remove some- but not all-of the excess length. (A pair of small end-cutting pliers works well for this adjustment.) Disinfect the peg, and re-insert it into the sleeve. Repeat this process until the desired size is gradually attained. Insert the artificial eye and gently slide it over the head of the P-K Titanium Locking-socket Peg until the head engages with the opening of the mushroom-shaped socket. If necessary, adjust the peg length, as above, and confirm that the gaze is properly aligned.

Ball Peg: Confirm Placement of the peg, adjust if necessary: Disinfect the artificial eye and peg with hydrogen peroxide or Betadine. Insert the artificial eye and have the patient gaze in all directions. It is normal for there to be some gapping in the medial and lateral corners during the first fitting. The edges of the eye should be kept thin in the corners to help the eye move deeper into the fornices. Since the fornices will deepen with time, more material may need to be added to the eye to prevent additional gapping, if it occurs. If the socket created in the posterior aspect of the artificial eye is located improperly, it can be filled in and re-drilled. To maintain your reference point, use clear plastic when filling in the socket. **Note** the direction in which the gaze is off and plan to relocate the new pilot hole to compensate for the problem. Moving the pilot hole in the direction of the desired correction will usually correct the problem. For example, if the eye points too far laterally, move the hole farther laterally to compensate for the problem. Enlarge the pilot hole into a socket capable of accepting the head of the peg, as described above, and check the gaze again. Repeat the process until the desired gaze has been attained.

Threaded Sleeve Ball Tip: Confirm placement of the peg, adjust if necessary: Disinfect the artificial eye and ball-tip with hydrogen peroxide or Betadine. Insert the P-K Titanium Threaded Sleeve Ball-tip into the Sleeve and apply light pressure to seat the ball tip tapered collar into the sleeve. Next insert the artificial eye and have the patient gaze in all directions. It is normal for there to be some gapping in the medial and lateral corners during the first fitting. The edges of the eye should be kept thin in the corners to help the eye move deeper into the fornices. Since the fornices will deepen with time, more material may need to be added to the eye to prevent additional gapping, if it occurs. If the socket created in the posterior aspect of the artificial eye is located improperly, it can be filled in and re-drilled. To maintain your reference point, use clear plastic when filling in the socket. **Note** the direction in which the gaze is off and plan to relocate the new pilot hole to compensate for the problem. Moving the pilot hole in the direction of the desired correction will usually correct the problem. For example, if the eye points too far laterally, move the hole farther laterally to compensate for the problem. Enlarge the pilot hole into a socket capable of accepting the head of the ball-tip, as described above, and check the gaze again. Repeat the process until the desired gaze has been attained.

Step 6: Confirm placement of the peg, adjust if necessary

Locking Socket Peg: Have the patient gaze in all directions. It is normal for there to be some gapping in the medial and lateral corners during the first fitting. The edges of the eye should be kept thin in the corners to help the eye move deeper into the fornices. Since the fornices will deepen

with time, more material may need to be added to the eye to prevent additional gapping, if it occurs. If the socket created in the posterior aspect of the artificial eye is located improperly, it can be filled in and re-drilled. To maintain your reference point, use clear plastic when filling in the socket. **Note** the direction in which the gaze is off and plan to relocate the new pilot hole to compensate for the problem. Moving the pilot hole in the direction of the desired correction will usually correct the problem. For example, if the eye points too far laterally, move the hole farther laterally to compensate for the problem. Enlarge the pilot hole into a socket that is capable of accepting the head of the peg, as described above, and check the gaze again. Repeat the process until the desired gaze has been attained.

P-K™ Titanium Threaded Sleeve and Flat Peg and Large Threaded Sleeve and Flat Peg:

Below is a detailed description of the procedure for inserting a P-K Titanium Threaded Sleeve into an orbital implant in preparation for a P-K titanium motility/support peg.

Step 1: Assess Vascularization: The Bio-eye HA orbital implant must be sufficiently vascularized before being fitted with a P-K Titanium Threaded Sleeve. While most implants are vascularized within 6 months of implantation, an objective measure of vascularization may be useful prior to pegging. Vascularization can be assessed objectively by means of a technetium 99m bone scan or an MRI.

Step 2: Determine the Location of the Sleeve: After the Bio-eye HA orbital implant has become vascularized, a pilot hole must be created in the implant to facilitate placing of the P-K Titanium Threaded Sleeve in the proper position and at the proper angle. Determine the proper location for the P-K Titanium Threaded Sleeve and mark the location on the conjunctiva using a surgical marker. The location should allow maximum movement of the eye in all directions of gaze. The location is best determined via a template (provided by an ocularist) which has a through-and-through hole in the area where the pilot hole is to be created. If no template is available, have the patient sit up, hold the lids apart to approximate the lid opening of the normal eye, and mark the conjunctiva in an area that corresponds to the pupil of the artificial eye. Instruct the patient to gaze laterally and medially and observe the amount of movement in each direction. If necessary, move the mark in the direction of least movement so the peg will not be lost in the fornices on extreme gaze.

Step 3: Create a Pilot Hole: Replace the artificial eye. Give a relatively large-volume (5-7 cc) retrobulbar injection behind the implant and have the patient gently massage the socket for 5-10 minutes to disperse the anesthetic and to reduce conjunctival edema.

Remove the artificial eye and prep and drape the socket for a STERILE procedure. Stabilize the implant with an Implant Ring Stabilizer. The pilot hole will be created by twisting and driving a graduated series of sterile hypodermic needles into the implant. P-K Titanium Needle Handles are available to facilitate handling of the needles. Confirm that STERILE needles are available in the following sizes: 20-, 18-, 16-, and 14 gauges; all should be approximately 1.5 inches in length. Begin by driving a 20-gauge needle into the implant to a depth of about 15 mm or completely through the implant. Check the angle of the needle at each 4-5 mm of depth to ensure it is perpendicular to the frontal plane of the patient. To check the angle, release the needle handle and observe the angle of the needle. If necessary, remove the needle and re-bore with the same needle until the proper angle is achieved. Enlarge the hole by repeating the process using the 18-, 16-, and 14-gauge needles. Always check and adjust the angle of the hole as necessary.

Step 4: Insert the Sleeve: Confirm that the P-K Titanium Threaded Sleeve and P-K Titanium Flat-headed Peg have been sterilized. Use a P-K Titanium Sleeve Driver to drive the P-K Titanium Threaded 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 Titanium 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. **Note:** It may be necessary to remove some plastic material from the posterior aspect of the artificial eye to provide clearance for the head of the P-K Titanium Flat-headed Peg.

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 titanium motility/support peg.

Large P-K Titanium Threaded Sleeve and Flat Peg

A Large P-K Titanium Threaded Sleeve is intended to be used as a replacement peg for the P-K Plastic Sleeve. If the patient has a plastic sleeve that you would like to replace with titanium, take out the plastic sleeve and replace with the Large Titanium Threaded Sleeve. The Large Titanium Threaded Sleeve is the same size as the plastic sleeve, so you will not need to create another hole or make any changes to the original hole.

To use the Large P-K Titanium Threaded Sleeve and Flat Peg: Remove original plastic peg, Remove original plastic sleeve. Insert Large Titanium Sleeve in same hole. Insert peg into large sleeve.

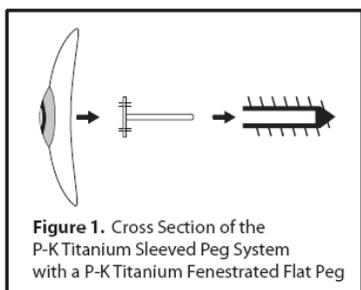


Figure 1. Cross Section of the P-K Titanium Sleeved Peg System with a P-K Titanium Fenestrated Flat Peg

P-K™ Titanium Fenestrated Flat Peg:

Below is a detailed description of the method for fitting a P-K Titanium Fenestrated Flat Peg to an artificial eye.

Basic Concept: The P-K Titanium Fenestrated Flat Peg is designed to be directly attached to the posterior aspect of the artificial eye. This method of peg attachment is useful in eyes where the thickness does not allow for a socket hole, as in the Ball and Socket type fitting. Direct attachment of the peg is effective in providing motility and support of the artificial eye, but it makes patient insertion of the artificial eye much more difficult, and therefore is only recommended in cases of inadequate thickness of the artificial eye. The shaft of the peg is designed to fit into the sleeve of the P-K Titanium Threaded Sleeve. (Fig. 1). Refer to the instructions for use for the P-K Titanium Threaded Sleeve and P-K Titanium Flat Peg for instructions on placing the P-K Titanium Threaded Sleeve and P-K Titanium Flat Peg.

Step 1: Prepare the artificial eye: To prepare the artificial eye for an impression for direct attachment, it may be necessary to remove a small amount of plastic material from the posterior aspect of the eye. This is necessary to create room for the impression and to allow application of a thin layer of wax, which improves adhesion of the alginate. Confirm that the P-K Titanium Flat Peg can be easily removed from and re-inserted into the P-K Titanium Threaded Sleeve, and then leave the P-K Titanium Flat Peg in place. The P-K Titanium Fenestrated Flat Peg and the Flat Headed Peg are the same dimensions except for the fenestration holes. The impression left by the Flat Headed Peg will provide the proper disc size for the direct attachment gluing procedure.

Step 2: Take impression: Apply a small amount of alginate to the posterior of the artificial eye and place the artificial eye in the socket. Instruct the patient to remain in a seated position and to gaze straight ahead. Using a suction cup, immediately align the artificial eye with the companion eye for gaze and allow the alginate to set. Remove the artificial eye and trim the excess alginate from around its edges. It is normal for the P-K Titanium Flat Peg to remain embedded in the alginate. If so, leave the peg embedded for now. When trimming is completed, reinsert the artificial eye to confirm proper gaze and then remove it and replace the P-K Titanium Flat Peg in the sleeve. Before making the mold, trim the alginate that may have covered over the flat peg to expose the disk-shaped impression made by the head of the P-K Titanium Flat Peg. It is important to have a perfect impression for the direct attachment peg. If not, redo the impression until satisfied with the result.

Note: Do not leave the sleeve empty. To prevent the conjunctival tissue from closing over the sleeve opening, immediately replace the P-K Titanium Flat Peg in the sleeve after removing it from the alginate.

Step 3: Make the mold: To avoid dehydrating the alginate, make the mold immediately or store the artificial eye and impression in water until time permits making of the mold without interruption. Using your normal curing process, add plastic to the artificial eye and polish it, taking care to not disturb the disk-shaped impression created by the flat peg.

Step 4: Glue the P-K Titanium Fenestrated Flat Peg to the eye: After the polishing has been completed, remove any residual stone/plaster from the flat disc impression in the posterior of the eye. Confirm that the P-K Titanium Fenestrated Flat Peg will fit into the depression completely and seats against the disc depression. If necessary burr away plastic around the periphery of the disc depression until good contact is assured. The P-K Titanium Fenestrated Flat Peg may be glued using Krazy® Glue (cyanoacrylate) or cold cure plastic. Krazy® Glue works well and is easy to use. Once a good peg to eye fit has been confirmed, apply a small drop of glue to the middle of the disc depression. Using tweezers hold the peg by the shaft and push the P-K Titanium Fenestrated Flat Peg into the depression, allowing the glue to flow up and through the holes in the peg. Hold firmly for several minutes until well attached and allow for drying, at least one hour.

Step 5: Insert the eye: Disinfect the artificial eye and peg with hydrogen peroxide or Betadine. Insert the peg with the attached eye into the sleeve carefully while viewing the shaft from the side as it slides into the sleeve hole. Next have the patient gaze in all directions. It is normal for there to be some gapping in the medial and lateral corners during the first fitting. The edges of the eye should be kept thin in the corners to help the eye move deeper into the fornices. Since the fornices will deepen with time, more material may need to be added to the eye to prevent additional gapping, if it occurs. The gaze of the eye should be correct, if you were careful in your original impression. Corrections to the gaze are very difficult without taking another impression. It therefore behooves you to check and recheck the impression before adding the plastic to the posterior of the eye.

Note: For information on other peg systems contact: Integrated Orbital Implants, Inc.
Phone: 800-424-6537 · www.ioi.com

Contraindications: Do not place 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 orbital implant prior to pegging. 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. If peg is placed at the time of placement of the orbital implant and covered by Tenon's capsule and conjunctiva, see indications for use. The peg should not be exposed for 3-6 months after surgery when the implant should be vascularized. To prevent the conjunctival tissue from closing over the P-K Titanium Threaded Sleeve, do not allow the sleeve to remain empty.

Complications: The following complications have been reported: infection, implant exposure, pyogenic granuloma and an inaudible clicking sensation of the peg.

How Supplied: Provided NON STERILE.

Sterilization: All Pegs should be sterilized using the following parameters:

Note: Remove peg from plastic vial and place in pouch that is able to be steam sterilized.

Validated Steam Sterilization Cycle:

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