

Patent Pending.

Prager Shell is a registered trademark with the U.S. Patent and Trademark Office

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INSTRUCTIONS FOR USE

PRAGER SHELL® for immersion ultrasonography

Please read the entire instruction pamphlet. Information is also available on our web site www.eyesurgin.com. If you need additional assistance contact ESI, Inc. by telephone or email.

Prager Shell®

There are nine Prager Shell® models with the model number labeled at the top of the instrument. The Manufacturer brand name and type of A-scan unit determines the correct Prager Shell® model needed for immersion biometry.

The Prager Shell® has two internal guide rings that maintain probe perpendicularity. These guide rings are vented to provide proper fluid flow and eliminate air bubble formation in the shell lower chamber. The transducer probe can only be lowered to a fixed depth in the Prager Shell®. This Auto-Stop feature places the probe tip at the correct distance from the corneal surface. (Model numbers with P100 do not include this feature and require the probe tip to be placed at the score line and secured with the setscrew)



All Prager Shell® models have a Luer adapter located on the side of the instrument for connecting the Kit sterile tubing to the shell.

Kit B is custom designed for the Prager Shell®. Each end of the tubing has a different type of Luer connector. The larger diameter Luer connector contains a one-way check valve to stop back flow of contaminated fluid into the BSS source. This larger diameter connector is attached to the sterile BSS vial. The smaller connector is attached to the Prager Shell®.

Kit A does not have the one-way flow check valve for preventing back flow into the BSS source. Kit A should be used only with a syringe and not a squeeze bottle due to the potential of contaminated BSS back flow.



Prager Shell® Kits are for single-use only. **Do not re-use Kit on multiple patients. The Kit components cannot be properly cleaned after patient use.** Exposure of aseptic solution can cause the check valve to malfunction resulting in an accumulation of aseptic fluid in the check valve housing. Kits can only be ordered from ESI, Inc..

Sterile non-preserved BSS is the recommended solution and available in vials with Luer adapter.

Routine Preparation: Insert the biometry probe into the Prager Shell® and advance the probe tip to the scored line of the shell lower chamber. The internal auto-stop will not allow the probe to be inserted past this point. Once the probe is positioned, tighten the set screw to hold the probe in place. **Do not over tighten the set screw.**

Prepare the Prager Shell® for use by attaching the smaller tubing-set Luer to the connector located on side of the Shell. The larger diameter Luer connector with the check-valve is attached to the sterile BSS vial. To prevent bacteria/virus cross contamination, the sterile tubing kit should not be used on multiple patients.

Maintain a sufficient inventory of Prager Shell® Kits and BSS. These items can be ordered from ESI, Inc. at (763) 473-2533 or email sales@eyesurgin.com.

To use the Prager Shell®: Have the patient either reclined with the head firmly against a headrest, or seated with the head tilted back. Routine topical anesthesia is administered to the patient's eyes.

Hold the Probe/Shell and BSS vial in one hand in preparation for eye placement. For patients with large fissures, direct the patient to look straight ahead at a fixation target with both eyes open and gently rest the shell on the limbus. For smaller fissures, direct the patient to look upward and insert the inferior edge of the shell in the lower fornix, keeping the superior edge lifted away from the eye. While holding the upper lid open, request the patient to look straight ahead, and gently place the superior rim of the shell on the superior limbus. The pivotal motion avoids contact with the cornea and insures centeration of the instrument around the limbus. Avoid contact with the cornea to reduce the chance of abrasion.



Apply minimal pressure on the eye. See picture:

Note: the BSS filler port is facing temporally. The hand holding the shell is resting on the forehead, which reduces shell pressure on the eye. Fill the lower chamber of the Prager Shell® by holding the bottle upside down (to eliminate air bubbles within the shell) and dispense approximately 2.0cc of BSS.



As the fluid fills the Prager Shell® lower chamber and past the tip of the probe, the characteristic waveforms of immersion biometry will appear on the screen. Depending on the ultrasound manufacturer, the first spike on the left hand screen will represent the "main bang" from the biometry probe and the second spike represents the anterior cornea. Some manufacturer's A-scans may not demonstrate the probe spike when in immersion mode, and in this case, the first spike visible on the screen will be the corneal echo. Please consult the A-scan equipment manual. Always measure both eyes; there should not be more than 0.3 mm difference. If there is a significant difference in axial length of the eyes, the probe may be misalignment with the scan. Remeasure and check the patient's chart for pathology or previous procedures that may also clarify the difference.

Probe Alignment:

An indication of correct probe alignment is the presence of a strong Scleral Spike posterior to the Retinal Spike. Both spikes should be equal in height and strength.

- If the scleral spike is not present, you are misaligned along the optic nerve
- If the scleral spike is shorter than the retinal spike, perpendicularity to the macula has not been achieved.
- If the orbital fat spikes are not present, you are misaligned and scanning the optic nerve rather than the macula.
- Two Corneal Echoes of equal height should be present indicating the anterior corneal epithelium and the posterior corneal endothelium.

Possible causes for not acquiring a waveform:

- A-scan is set to Contact instead of Immersion
- The Probe is not correctly positioned in the Prager Shell®.
- Misalignment of the Prager Shell and probe on the eye.
- A-scan gain setting needs adjustment.

Before removing the Prager Shell® from the eye, place a tissue against the patient's cheek to absorb the escaping BSS and tilt the patient's head toward the tissue. Raise the patient's upper or lower eyelid, which releases that edge of the Shell, and then pivot the Shell in the opposite direction, directing the patient to continue to look straight ahead. Remove the Prager Shell® from the eye without contacting the cornea.

Cleaning: AVOID PATIENT CROSS CONTAMINATION. Following each biometry procedure, remove the tubing Kit from the Prager Shell® and discard. To insure asepsis, soak both shell and probe in 70% isopropanol or solution of 3% hydrogen peroxide for a minimum of 5 minutes. Follow CDC Guidelines (see below) to avoid viral and bacterial patient cross-contamination. Before using on the next patient, insure that all aseptic solution is completely rinsed from the Shell and probe. Allow to air dry. A custom Prager Shell® Storage/Soak Tray is available from ESI. Always use a new sterile Kit B for each patient.

CDC Guidelines. "Instruments that come into direct contact with external surfaces of the eye should be wiped clean and then disinfected by: (a) a 5- to 10-minute exposure to a fresh solution of 3% hydrogen peroxide; or (b) a fresh solution containing 5,000 parts per million (mg/L) free available chlorine--a 1/10 dilution of common household bleach (sodium hypochlorite); or (c) 70% ethanol; or (d) 70% isopropanol. The device should be thoroughly rinsed and dried before patient use."

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