

INSTRUCTIONS FOR USE

**United States Patent 7,285,096
International Patents Pending**

**Prager Shell® is registered with the
U.S. Patent and Trademark Office**

The Prager Shell® is manufactured by:

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Warranty and Disclaimer

ESI, Inc. warrants that its products are manufactured to the specifications set forth on its product packaging and related literature. If any ESI, Inc. product is defective and fails to meet the company’s published specifications, ESI, Inc. will replace the product at no charge provided the product is returned within six months of purchase date and the following conditions are fulfilled: 1) The product is used in accordance with the “Instructions for Use” included with each Prager Shell®. 2) The Prager Shell® single-use tubing kits are replaced with only those supplied by ESI, Inc. 3) Before product is returned, prior authorization must be obtained from the company. 4) The product is returned to ESI, Inc. at which time it becomes the sole property of ESI, Inc. 5) The product has not been altered, reprocessed, abused or misused. 6) The product was manufactured, packaged, and labeled by ESI, Inc. 7) Customer provides proof of the purchase date. Failure to fulfill the above conditions voids the product replacement warranty.

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Prager Shell® for Immersion Ophthalmic Biometry

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

Caution: USA Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

Indications: The Prager Shell® is indicated when a water path is needed between an ultrasonic transducer and the eye.

Description: The Prager Shell® is a plastic cylinder with a curved rim that conforms to the contour of the eye. The body of the shell is open at the top and bottom. All Prager Shell models have a female Luer fitting located on the side of the instrument for connecting sterile kit tubing to the shell. Prager Shells® vary by series and model.

Prager Shell® Series: Two shell series are available: the “Standard Series” and the autoclavable “Gold Series”. The Standard Series Prager Shell is colorless clear; the Gold Series Prager Shell is gold tinted clear. This instruction manual applies to all Prager Shell series and models.

Prager Shell® Models: There are twelve Prager Shell models designed for the different ultrasound manufacturers probes. The ultrasound manufacturer’s A-scan equipment and probe dimension determine the correct Prager Shell® model. The Prager Shell model number is engraved at the top of the shell and printed on the box label.

See chart below for the Prager Shell® model numbers and corresponding ultrasound manufacturers.

ESI Model Number	Ultrasound Companies
P-100	Accutome / Micro Medical Devices
P-100-OCU	Ocuserv
P-101	DGH 2009 and earlier model
P-101-2	DGH 2010 and later model
P-102	Tomey
P-103	Sonomed / Ellex / OPKO
P-103 SV	Sonomed / Ellex / OPKO 12.5mm diameter
P-104	Quantel Medical
P-104 SV	Quantel Medical 12.5mm diameter
P-107-2	Nidek
P-105	Alcon OcuScan
P-110 RXP	Alcon OcuScan RxP and UltraScan
P-110 RXP SV	Alcon OcuScan RxP and UltraScan 12.5mm diameter

Prager Shell autoclavable Gold Series available by special order.

Contents of Package: This package contains one Prager Shell®. The sterile tubing kits are required for filling the shell and reordered from ESI, Inc. Two types of kits are available: Kit B has a one-way flow check valve, and is used with a squeeze bottle. 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 attaches to the Prager Shell. Kit A does not have a check valve to prevent back flow, and should be used with a syringe.

Special Precautions:

The following precautions should be observed:

- Confirm the correct Prager Shell model for your ultrasound system.
- The Prager Shell is not sold sterile and requires cleaning and disinfection before each use.
- Standard Series Prager Shell (clear colorless) cannot be autoclaved.
- Gold Series Prager Shell® (gold tinted clear) can be autoclaved.
- Connect tubing kit and a BSS source (bottle or syringe) to the Prager Shell before starting patient exam.
- Disconnect and discard tubing kit after each exam.
- The tubing kits are sterile and for single-use only.

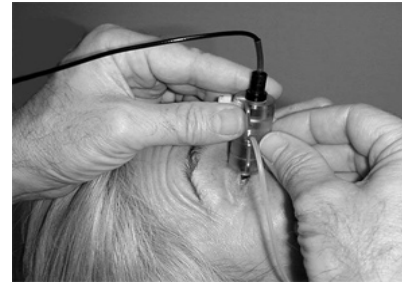
Prepare the Prager Shell® For Use: First clean and disinfect the shell and probe with an approved disinfectant solution, following the instructions on its label. Consult with infection control manager with any questions. Thoroughly rinse the probe and shell before use.

Routine Preparation: Insert the ultrasound probe tip from the top into the Prager Shell and advance the probe to the scored line of the shell lower chamber. The internal auto-stop for Prager Shell Models P-101 thru P-110 will not allow the probe to be inserted past the scored line. Model numbers with P-100 do not include this auto-stop feature and require the probe tip to be placed at the scored line. Once the probe is positioned, tighten the set screw to hold the probe in place. Do not over tighten the set screw. Attach the tubing kit Luer to the connector located on side of the shell and the other connector to the BSS source. Sterile non-preserved BSS is the recommended solution.

To Use the Prager Shell®: The seated patient should either be reclined or have the head tilted back against a headrest. Administer routine topical anesthesia 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 centration of the instrument around the limbus. Avoid contact with the cornea to reduce the chance of abrasion.

Apply minimal pressure to the eye. See pictures:



Note: The BSS filler port is facing temporally. The hand holding the shell rests on the forehead, which reduces shell pressure on the eye.

Hold the bottle upside down to eliminate air bubbles while filling the shell. Dispense approximately 2cc of BSS, enough to cover the lower section of the probe. As the fluid fills the Prager Shell lower chamber, past the tip of the probe, the characteristic waveforms will appear on the screen. Please consult the A-scan ultrasound instruction manual.

Probe Alignment: An indication of correct probe alignment is the presence of the correct waveforms, as indicated in the Ultrasound manufacturer's instructions.

Removing the Prager Shell®: Before removing the Prager Shell® from the eye, place a tissue against the patient's cheek to absorb the BSS and tilt the patient's head toward the tissue. Raise the patient's upper or lower eyelid and direct the patient to continue to look straight ahead. Remove the Prager Shell® from the eye without contacting the cornea.

To remove the Luer: Turn the Luer outer casing counterclockwise and pull back several mm's until it engages with teeth on the Luer stem. Continue turning counterclockwise to separate the Luer from the body of the shell.

Cleaning: AVOID PATIENT CROSS CONTAMINATION. Following each exam, remove the tubing kit from the Prager Shell® and discard. Clean and Disinfect the Prager Shell with FDA and EPA approved cleaning and disinfectant solutions. The solutions must be compatible with polycarbonate and Kynar plastic. Follow the instructions on the cleaning and disinfectant labels. Consult your infection control department or contact ESI, Inc..

To Order Products:

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