

United States Patent and International Patents Pending

ClearScan® is registered with the
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ClearScan® is manufactured
in the USA by:

ESI, Inc.
2915 Everest Lane
Plymouth, MN 55447
USA
Telephone: 763.473.2533
Fax: 763.208.8105
sales@eyesurgin.com

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ClearScan® Ultrasound Cover CS200

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

Sterile only if package is unopened or undamaged.

For Single-Use Only. Do Not Re-Sterilize.

Indications for Use

The ClearScan® ultrasound probe cover is indicated when it is necessary to have a sterile, single-use protective sheath with fluid coupling between the examined surface and an ultrasonic transducer.

I. Description

The ClearScan® ultrasound probe cover is a sterile, single-use, and latex free protective cover intended for immersion ultrasound examination preventing patient cross contamination. ClearScan® device covers the end of an ultrasonic probe with a sterile barrier and a liquid path for ultrasound waves to pass through to the examination area.

II. Construction

ClearScan® accommodates ultrasonic probes with a probe case outer diameter of 25 mm (1 inch) to 30 mm (1.2 inches). A probe adaptor may be required for smaller diameter probes. The adaptor can be ordered from ESI, Inc. The ClearScan® ultrasound probe cover consists of a green flexible collar with a sealing ring, and a clear membrane that contacts the exam area. The green collar has a single raised post on the top surface. The ClearScan® bag needs to be filled with a liquid medium and the ultrasound probe inserted into the top of the ClearScan®. When the probe is inserted, positive internal pressure inflates the ClearScan® cover into an optimized conical shape for accurate placement on the examination area. ClearScan® does not contain latex.

III. Precautions

- ClearScan® is supplied sterile and for single-use only. Do not reuse.
- Position the ClearScan® flexible sealing ring with the post facing up.
- If fluid is leaking from the membrane area after probe insertion, the membrane is punctured and the device will not function. Discard and replace with a new ClearScan®.
- If fluid is leaking from the collar area after probe insertion, the probe may have been inserted into the wrong side of the ClearScan® or the green collar seal is placed on a probe case gap.
- Do not exert excessive downward probe pressure..
- Avoid contacting the eye with the collar or ultrasound probe tip.

IV. Instructions for Use UBM

Note: Position the ClearScan® cover with the green collar raised post side pointing up revealing the flexible ring seal.

Prepare ClearScan® Cover

- Ultrasound probe with exposed/open transducer: Fill ClearScan® to the top of the green collar with sterile or distilled water. Minimize the formation of air bubbles.
- Ultrasound probe with enclosed/sealed transducer: Fill approximately ¾ full. Minimize the formation of air bubbles.

Insert Ultrasound Probe

- With the green collar post and flexible seal facing up, insert the ultrasound probe tip.
- For exposed transducer probes, position the probe case tip even with the bottom of the green collar or no more than 3 mm (1/8 inch) below the collar rim.
- For enclosed probes, insert the probe end approximately 12 mm (1/2 inch) below the green colored collar.

Note: Inserting the probe deeper into the ClearScan® cover more than recommended will cause excessive internal bag pressure and deform the optimum conical shape. A small air bubble at the top will not affect the ultrasound exam.

Internal Pressure Change: The internal bag pressure must be lower than the pressure of the eye or corneal denting will occur. Internal bag pressure may be altered in four ways. 1) Vary ClearScan® fill level, 2) Change probe insertion depth: Inserting the probe deeper into the bag increases pressure, withdrawing slightly lowers pressure, 3) To quickly reduce internal bag pressure or to expel internal air bubbles, point the probe downward, hold the flexible green collar at opposite sides, firmly squeeze and release 4) or grasp the green collar and move the probe laterally.

Administer Anesthetic and BSS Interface

Administer a topical anesthetic to the eye and prior to the ultrasound exam, immediately before placing ClearScan® add one or two drops of Balanced Saline Solution (BSS) on the area to be examined. UBM exam with ClearScan® does not require ultrasonic gel.

Apply ClearScan®

The patient should be seated with head slightly tilted. Use your thumb to push the upper eye lid upward to the brow. While holding the probe in the other hand, curl the fingers and pull downward on the cheek to maximally retract the lower lid.

Scan Image

Gently place the ClearScan® cover on the examination area. An image will appear at the bottom of the ultrasound screen. Slowly apply slight downward pressure until the structures under examination are at the middle of the screen. The positive pressure within the ClearScan® cover provides resistance, minimizing the probability of the probe's transducer contacting the eye or examination surface. Low internal bag pressure may produce wrinkles resulting in image artifacts above the exam surface. This does not affect the image of structures below. To eliminate wrinkles, insert the probe slightly further into the bag or apply less pressure on the eye. If corneal denting or incomplete coverage occurs, squeeze and release at opposite sides of the flexible green ring to immediately lower internal bag pressure. If the image is located at the very top of the screen, the probe may be too close to the eye. If the cornea deforms due to low IOP, reduce internal ClearScan® pressure by expelling air, varying probe insertion depth or reducing the water level. See note above, describing the four methods for changing internal pressure.

V. B-scan Examinations of the Retina

ClearScan® can be used with typical 10 MHz B-scan probes for both retinal and anterior segment ultrasounds. A probe case adaptor may be required for a proper ClearScan® seal. Probe adaptors for ClearScan® are available for the various B-scan probes.

Retinal B-scan ultrasound exams:

Add a few drops of a viscous gel, such as Genteal or Goniosol, to the inside bag surface, fully insert the probe to the bottom of the bag until the probe tip is covered by the gel. Place gel, such as Genteal or Goniosol on the outer surface of the bag and begin your ultrasound examination.

Remove the ClearScan® from the probe and discard.

ClearScan® is single-patient use only and cannot be properly cleaned, re-sterilized or reused.

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Web Site: www.eyesurgin.com