

EyeSeal Disposable Instructions for Use

For use with the ArcScan Insight 100 instrument ONLY. Refer to the ArcScan Insight 100 User Manual. Translations for these instructions may be provided upon request.

STERILE

Sterile by Irradiation



CAUTION: See Instructions for Use



Single Use ONLY - Reuse may cause patient infection or cross infection and consequently illness or death.



Do NOT use if package is damaged - Sterility and product performance may be compromised.

Rx ONLY

Federal law restricts this device for sale to or on the order of a physician or licensed practitioner

This product does not contain natural rubber latex



Package Quantity

REF

Catalog Number

LOT

Batch Code



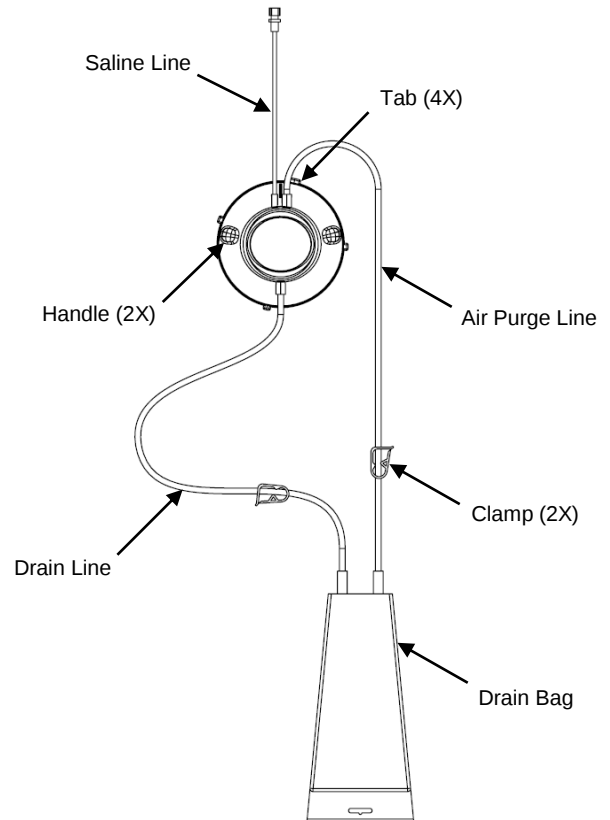
Use By Date



Manufactured for:
ArcScan, Inc.
433 Park Point Drive
Golden, CO 80401 USA
720-287-8800

EC REP

Authorized Representative:
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Preface

This instruction sheet and the accessories it describes are for use only by qualified medical professionals trained in the particular technique and procedure to be performed. These instructions are intended as a guide for the preparation and proper connection of the EyeSeal Disposable. Refer to the ArcScan Insight 100 User Manual for additional technical information.

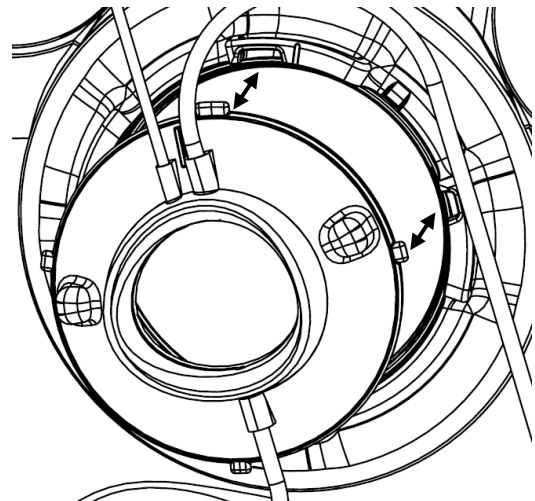
Required Accessories

- 0.9% Sodium Chloride (Baxter Item #2B1322Q), Ringer's Lactate USP (Baxter Item #2B2322Q) or equivalent solution, 100 mL or greater
- Baxter Clearlink System Secondary Medication Set (Baxter Item #2C7461) or equivalent saline administration set

Connecting an EyeSeal

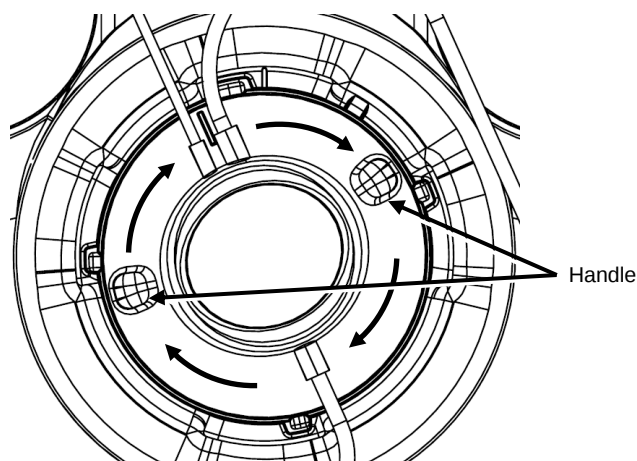
- Remove the EyeSeal Disposable from the packaging.
- Remove the protective cover.
- Locate the four tabs on the perimeter of the EyeSeal. Hold the EyeSeal so the largest tab faces upward.

- Align the tabs with the grooves in the receptacle on the ArcScan Insight100 instrument.

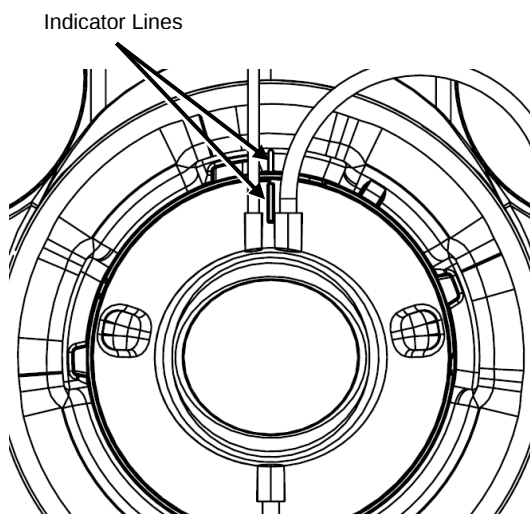


- Lower the EyeSeal into the receptacle. Insert all tabs into the grooves.

6. Grip the handles located on both sides of the EyeSeal Disposable.



7. Rotate the EyeSeal Disposable clockwise until the vertical indicators are aligned.



8. Place the drain bag into the drain bag holder on the side of the ArcScan Insight 100 instrument.

8. Instruct the patient to place their eye against the EyeSeal Disposable. Check the seal for obvious gaps or areas that may leak.
9. Instruct the patient to close their eye to prevent any discomfort when the EyeSeal Disposable fills with saline.
10. Open the clamp on the saline administration set to fill the EyeSeal Disposable with saline. The fill level can be seen on the camera image.
Note: When full, saline will flow through the air purge line.
11. Clamp the air purge line on the EyeSeal Disposable.
12. Close the clamp on the saline administration set to discontinue the flow of saline to the EyeSeal Disposable.

Draining an EyeSeal

1. Open the clamp on the air purge line.
2. Ensure the clamp on the saline administration set is closed.
3. Open the clamp on the drain line to remove saline from the EyeSeal Disposable.

Removing a Used EyeSeal

1. Ensure the scan head has been drained.
2. Disconnect the saline administration set from the saline line on the EyeSeal Disposable.
3. Grip the handles located on both sides of the disposable.
4. Rotate the EyeSeal Disposable counter-clockwise until it cannot rotate further.
5. Gently pull the EyeSeal Disposable out of the receptacle.
6. Discard the used EyeSeal Disposable.
7. Clean all surfaces of the receptacle with a disinfecting wipe.

Filling an EyeSeal

1. Obtain a bag of saline. Remove and discard any packaging. Hang the saline bag from the saline pole.
2. Obtain a saline administration set. Remove and discard any packaging.
3. Close the clamp on the saline administration set. Using aseptic technique, spike the saline bag.
4. Connect the saline administration set to the saline line on the EyeSeal Disposable. Hand-tighten the connection.
5. Clamp the drain line on the EyeSeal Disposable.
6. Ensure the clamp on the air purge line is open.
7. Prepare the patient as described in the ArcScan Insight 100 User Manual.

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