Endorectal Balloon (ERB)

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Instructions for Use
Caution: Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.

DESCRIPTION

The Endorectal Balloon (ERB) is a single use, disposable, inflatable, non-powered rectal device placed in the rectum to immobilize the prostate in patients undergoing radiation therapy.

Contraindications
- Severe hemorrhoids
- Peri-rectal/per-anal abscess
- Anal fissures in the prior eight weeks
- Prior low anterior resection
**Endorectal Balloon (ERB)**

- Rectal Fistula
- Anal canal stricture
- Surgery of the prostate, rectum or surrounding area within the last eight weeks
- Any standard exclusion criteria recognized for endorectal/intrarectal devices

**Storage**
- Store in a cool dry environment.
- Handle with care. Packages should be stored in a manner that protects the integrity of the package.

**Warnings**
- The placement of the Endorectal Balloon requires a physician or a physician directed healthcare professional.
- The Endorectal Balloon is shipped non-sterile. Do NOT sterilize any portion of the Endorectal Balloon. Attempts to sterilize the device may damage the device and / or result in patient injury.
- The Endorectal Balloon is a SINGLE USE device. Do NOT reuse the device. Attempts to reuse the device may damage the device and / or result in patient injury.
- Do NOT use if the package is open or damaged.
- The Endorectal Balloon must be used prior to the Use By date shown on the product label.
- Do NOT place in rectum if a sharp foreign body may cause the Endorectal Balloon to rupture.
- Do not transport the patient with the Endorectal Balloon inserted. The balloon should be removed prior to transport.
- Failure to perform position verification with the use of an imaging modality may cause the device to not perform as intended.
- Do not apply excessive pressure/force on the shaft or tubing of the Endorectal Balloon.
- Patient fecal matter may occlude the vent valve leading to a build-up of gas and patient discomfort.

**Accessories Provided**
- 100mL Syringe
- Aqueous-Based Lubricant (e.g. K-Y Jelly, Surgilube, etc.)
- Anal Stop

**Technical Information**
The Endorectal Balloon is available in the following catalog codes.

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERB-90-SS</td>
<td>Endorectal Balloon with Standard Shaft</td>
</tr>
<tr>
<td>ERB-90-FS</td>
<td>Endorectal Balloon with Flexible Shaft</td>
</tr>
</tbody>
</table>

The Endorectal Balloon contains 2 radiopaque marker bands located on the catheter shaft. The distance between the markers bands is 90 mm.

The Endorectal Balloon contains two openings in the tip to allow fecal matter and / or gas to accumulate within and / or pass through the device. Control of the fecal matter and / or gas is managed by the RED vent valve.

The Endorectal Balloon contains a BLUE valve which controls the preparation, inflation, and
deflation of the balloon.

The Endorectal balloon has depth markings along its catheter shaft to aid in reproducible positioning over the course of multiple treatments. An Anal Stop is provided with every Endorectal Balloon. The Anal Stop is used as a depth indicator on the catheter shaft and helps prevent movement of the device during treatment. To close the Anal Stop, apply a lateral force on the hinge until you hear a click (Figure 2).

![Figure 2. Endorectal Balloon Anal Stop](image)

**Reference Inflation Volumes**

<table>
<thead>
<tr>
<th>Distal / Proximal Balloon Lobe Diameters</th>
<th>Liquid</th>
<th>Air</th>
</tr>
</thead>
<tbody>
<tr>
<td>45mm</td>
<td>100mL</td>
<td>140mL</td>
</tr>
<tr>
<td>47mm</td>
<td>120mL*</td>
<td>200mL*</td>
</tr>
</tbody>
</table>

* CAUTION: The Balloon is not recommended for volumes greater than 120mL of Liquid or greater than 200mL of air.

**Note:** The inflation volumes above are for reference only. Other inflation volumes may be utilized based on prescribed treatment and / or patient comfort.

**Device Preparation Using Air**

1. Depress the plunger on the 100mL syringe.
2. Connect the syringe to the BLUE inflation valve.
3. Pull back on the syringe plunger to evacuate the balloon.
4. Close the BLUE inflation valve and remove the syringe.

**Device Preparation Using Liquid**

1. Fill the 100mL syringe with approximately 50mL of the desired inflation media.
2. Connect the syringe to the BLUE inflation valve.
3. In an elevated position with respect to the balloon (Figure 3), withdraw the syringe plunger to evacuate the air from the device. It may be necessary to cycle the syringe multiple times by pulling the syringe plunger and allowing the liquid to backfill the balloon until few or no air bubbles can be observed in the syringe when drawing a vacuum.
CAUTION: Allow vacuum to draw fluid into the device. Do not actively depress the syringe plunger to inject fluid into the balloon. Injecting fluid into the balloon may cause patient discomfort or injury when inserting the device into the rectum.

4. Close the BLUE inflation valve and remove the syringe.

**Insertion and Inflation of Device**

1. Position the patient in the desired treatment position.
2. Attach the anal stop to the proximal end of the catheter shaft. (e.g. near the 20cm depth indicator)
3. Fill a syringe with the physician specified inflation media and connect to the BLUE inflation valve.
4. Apply an aqueous-based lubricant to the device tip, balloon, and distal portion of the catheter shaft.
5. Hold the device by the catheter shaft and gently insert the device into the patient’s rectum.
6. Open the BLUE inflation valve and depress the syringe plunger to partially inflate the balloon.

**Note:** Recommended initial inflation volume is 30mL.

7. Close the BLUE inflation valve and note the initial inflation volume in the patient’s chart.
8. Firmly, but gently, pull back on the device to seat the balloon against the anal verge.
9. Open the BLUE inflation valve and fill the balloon with additional inflation media based on the prescribed volume and / or patient comfort.
10. Close the BLUE inflation valve.
11. While gently holding the catheter shaft, slide the anal stop into position against the anal verge. Squeeze the hinge on the anal stop to lock it into position. Note the depth position in the patient’s chart for subsequent treatments.
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12. Verify the position and placement of the Endorectal Balloon through standard imaging practices prior to administering the radiation treatment.

   **Note:** If the Endorectal Balloon is not in the correct position, open the BLUE inflation valve, partially deflate the balloon, adjust the position of the device, adjust the position of the anal stop (if necessary), re-inflate the balloon, and re-verify the position of the device prior to administering the treatment.

**Removal**

After the prescribed radiation treatment has been completed:

1. Open the BLUE valve and pull back on the syringe plunger to evacuate the balloon. Ensure all the inflation media is removed from the balloon and then close the BLUE valve.

   **CAUTION:** Failure to fully evacuate the balloon prior to removal may cause patient injury.

2. Gently remove the Endorectal Balloon from the patient and discard.

**Disposal Procedure**

The device and components that require disposal should be considered a biohazard and disposed of in accordance with local regulations and hospital guidelines.

**Imaging Methods**

The Endorectal Balloon has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Endorectal Balloon in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The Endorectal Balloon is safe for use with CT and X-ray Imaging.
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Label Symbol Glossary
(NOTE: Not all Symbols may be applicable to this product)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title of Symbol</th>
<th>Description of Symbol</th>
<th>Symbol Designation Number</th>
<th>Title of Symbol Standard Development Org. Standard</th>
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</thead>
<tbody>
<tr>
<td>![Manufacturer]</td>
<td>Manufacturer</td>
<td>Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</td>
<td>5.1.1</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Authorized representative in the European Community]</td>
<td>Authorized representative in the European Community</td>
<td>Indicates the authorized representative in the European Community.</td>
<td>5.1.2</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Date of manufacture]</td>
<td>Date of manufacture</td>
<td>Indicates the date when the medical device was manufactured.</td>
<td>5.1.3</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Use-By Date]</td>
<td>Use-By Date</td>
<td>Indicates the date after which the medical device is not to be used.</td>
<td>5.1.4</td>
<td>ISO 15223-2012</td>
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<tr>
<td>![Batch Code]</td>
<td>Batch Code</td>
<td>Indicates the manufacturer’s batch code so that the batch or lot can be identified.</td>
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<td>ISO 15223-2012</td>
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<td>![Catalog Number]</td>
<td>Catalog Number</td>
<td>Indicates the manufacturer’s catalog number so that the medical device can be identified.</td>
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<td>ISO 15223-2012</td>
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<tr>
<td>![Serial number]</td>
<td>Serial number</td>
<td>Indicates the manufacturer’s serial number so that a specific medical device can be identified.</td>
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<td>ISO 15223-2012</td>
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<tr>
<td>![Sterilized using ethylene oxide]</td>
<td>Sterilized using ethylene oxide</td>
<td>Indicates a medical device that has been sterilized using ethylene oxide.</td>
<td>5.2.3</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Sterilized using irradiation]</td>
<td>Sterilized using irradiation</td>
<td>Indicates a medical device that has been sterilized using irradiation.</td>
<td>5.2.4</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Do Not Resterilize]</td>
<td>Do Not Resterilize</td>
<td>Indicates a medical device that is not to be resterilized.</td>
<td>5.2.6</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Non-sterile]</td>
<td>Non-sterile</td>
<td>Indicates a medical device that has not been subjected to a sterilization process.</td>
<td>5.2.7</td>
<td>ISO 15223-2012</td>
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<tr>
<td>![Do Not Use if Package is Damaged]</td>
<td>Do Not Use if Package is Damaged</td>
<td>Indicates a medical device that should not be used if the package has been damaged or opened.</td>
<td>5.2.8</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Biological Risks]</td>
<td>Biological Risks</td>
<td>Indicates that there are potential biological risks associated with the medical device.</td>
<td>5.4.1</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Do Not Reuse]</td>
<td>Do Not Reuse</td>
<td>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</td>
<td>5.4.2</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Consult Instructions For Use]</td>
<td>Consult Instructions For Use</td>
<td>Indicates the need for the user to consult the instructions for use.</td>
<td>5.4.3</td>
<td>ISO 15223-2012</td>
</tr>
<tr>
<td>![Caution]</td>
<td>Caution</td>
<td>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.</td>
<td>5.4.4</td>
<td>ISO 15223-2012</td>
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<tr>
<td>![Only]</td>
<td>By Prescription Only</td>
<td>Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.</td>
<td>N/A</td>
<td>FDA 81 Federal Register pg. 38911-38931</td>
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</tbody>
</table>

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