

# EndoRings™ device E102 /E103

## Instructions for Use

**Disposable:** This device is intended for single-use only. Do not clean or reuse. Store at room temperature.

**Shelf life:** The recommended shelf life is printed on each package. Storage beyond the expiration date may result in product deterioration.

**CAUTION:** Federal (USA) Law restricts this device to sale by or on the order of a physician with appropriate training. Read all instructions prior to use.

### Indications for Use:

The EndoRings™ device is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following:

- Keeping the suitable depth of endoscope field of view

### Contraindications:

- Do not use the device in patients with known strictures or other conditions that may present with narrowed colonic segments.

### Warning:

- The device is intended for one-time use only. Do not reuse. Reuse of the device may result in cross-patient contamination.
- The EndoRings™ device should only be used with compatible colonoscopes. See attached chart for compatibility.

### Precautions:

- The EndoRings™ device is not intended for deep ileal intubation.
- The EndoRings™ device should not be used in cases with acute, severe colitis or where there is a known colonic stricture.
- DO NOT reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.
- Do not use if packaging is damaged. Damaged packaging could compromise sterility possibly leading to patient infection.

### Potential Complications or Adverse Events:

- Potential complications related to colonoscopy include, but are not limited to perforation, bleeding, infection, discomfort and allergic reaction to sedation agents. All of these events could cause prolonged illness, permanent impairment of daily function or in rare cases death.

### How Supplied:

- The device is supplied in a sealed, peel-open package and is intended for single use. Do not use the product if there is doubt as to whether packaging has been compromised.
- Thoroughly inspect the product before opening the package to ensure no damage occurred during shipment.
- Do not use the EndoRings™ device if its “Use By” date, found on the package labeling, has expired.
- The device is Latex free

### Compatibility:

- Measure the outer diameter of the endoscope at the distal end to make sure the E102 EndoRings is compatible according to the EndoRings device Sizing Chart.
- The EndoRings™ device should only be used with compatible colonoscope distal end diameter.

### Directions for Use:

- Thoroughly inspect the product before opening the package and after installation.
- Wet the tip of the colonoscope with sterile water.
- WARNING:** DO NOT apply a water soluble lubricant to the colonoscope prior to fitting the Endorings™ device on the colonoscope. Doing so could cause the Endorings™ device to slip off the colonoscope during use.
- When mounting the EndoRings™ device on the colonoscope, hold the colonoscope as close to the distal end as possible, to minimize the force applied to the bending section of the colonoscope.
- Ensure that the EndoRings™ device is fully assembled in the correct arrow direction (according to Fig.1) over the colonoscope distal end prior to use. Gently pull the EndoRings to ensure that it is secure.
- Apply water soluble lubricant on the EndoRings™ device rings /wings before insertion into colon.
- After use, and prior to re-processing the colonoscope, the EndoRings™ device should be removed from the colonoscope. There is potential risk for biological hazard and therefore the EndoRings™ device should be disposed of as clinical waste.
- To remove the EndoRings™ device from the colonoscope, hold the colonoscope as close to the distal end as possible, use second hand to hold the EndoRings™ device with a lint-free cloth and gently pull while slowly rotating the EndoRings™ device from the colonoscope.
- If strong resistance is encountered when removing the EndoRings™ device from the colonoscope, apply a water soluble lubricant to the colonoscope distal end and to the interior of the colonoscope attachment area. You may need to pull the EndoRings™ device rings/wings to insert the water soluble lubricant to the interior of the colonoscope attachment area. Forcible removal could damage the distal end of the colonoscope.

# EndoRings™ device E102 /E103

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### Warning, Warranty, and Limitations:











- The EndoRings™ device may fail to function for a variety of reasons, including medical complications and/or the EndoRings™ device failure due to tearing.
- The EndoRings™ device may be damaged before, during, or after insertion despite all efforts in design, manufacturing, and testing.
- No representation or warranty is made that the EndoRings™ device will not fail or malfunction.
- The EndoRings™ device is sold in an "as is" condition. All steps in the Instructions for Use are to aid the user in assessing the quality and performance of the EndoRings™ device. The entire risk as to the quality and performance of the EndoRings™ device is borne by the buyer.
- EndoAid Ltd. disclaims all warranties, expressed or implied, with respect to the EndoRings™ device, including but not limited to any implied warranty of merchantability or fitness for a particular purpose. EndoAid shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of the EndoRings™ device or caused by any defect, failure, or malfunction of the EndoRings™ device, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind EndoAid to any representation or warranty with respect to endoscopy accessories.

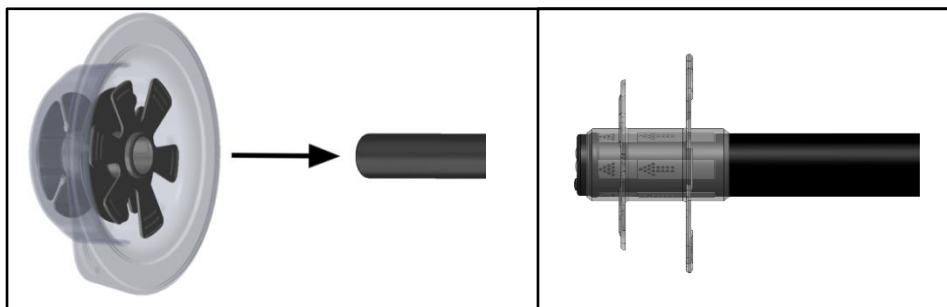
### EndoRings™ device\_Sizing Chart

Category of Colonoscopes		Compatible Colonoscopes Distal End Diameter [mm]
<b>E102</b>	<b>Adult Colonoscope</b>	<b>12.8 - 14.5</b>
<b>E103</b>	<b>Slim Adult Colonoscope</b>	<b>11.5 – 13.0</b>

*The above information should be used as a reference guide. Endoscope specifications may vary, and designs are subject to change. Please consult with your local Product Specialist for questions regarding endoscope compatibility and sizing*

### Description of Graphical Symbols

									
Manufacturer: EndoAid Ltd. P.O. Box 3067 Caesarea business park, Israel 38900 Tel: +972-4-623-9014 <a href="mailto:info@endo-aid.com">info@endo-aid.com</a>	Authorized European Representative: Mednet GmbH Borkstrasse 10 48163 Munster, Germany Tel: +49-251- 322660	Consult instructions for use	Single use. Do not reuse or resterilize	Use by	Batch code	Provided sterile by ethylene oxide	sale or use on physician order	Catalog number	



A

B

**Fig. 1 – EndoRings™ E102/E103 device assembly over the colonoscope distal end before (A) and after (B)**