

Resolution[®] Clip

When Positioning is Critical, There is a Resolution[™]

RESOLUTION CLIP DEVICE

Order Number	Working Length (cm)	Minimal Working Channel (mm)	Clip Opening (mm)	Box
M00522600.....	155.....	2.8.....	11.....	Each.....
M00522601.....	155.....	2.8.....	11.....	10.....
M00522602.....	155.....	2.8.....	11.....	20.....
M00522610.....	235.....	2.8.....	11.....	Each.....
M00522611.....	235.....	2.8.....	11.....	10.....
M00522612.....	235.....	2.8.....	11.....	20.....

INSTRUCTIONS FOR USE

Refer to the operator's manual for complete instructions for use.

INDICATIONS

The Resolution Clip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:

- Endoscopic marking
- Hemostasis for:
 - Mucosal/sub-mucosal defects < 3cm
 - Bleeding ulcers
 - Arteries < 2mm
 - Polyps < 1.5cm in diameter
 - Diverticula in the colon
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel
- As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively.

CONTRAINDICATIONS

- Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
- Do not perform MRI procedures on patients who have had clips placed within their gastrointestinal tract, as this could be harmful to the patient.
- Arteries greater than 2mm.
- Polyps greater than 1.5cm in diameter.
- Mucosal/sub-mucosal defects greater than 3cm.

WARNINGS

Contents supplied STERILE using an ethylene oxide(EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific Representative.

For single use only. DO NOT REUSE, REPROCESS OR RESTERILIZE. Reuse, reprocess or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance takes place.

Always have pliers and/or wire cutters ready to cut the delivery system at the handle if the clip cannot be detached.

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POTENTIAL ADVERSE EFFECTS

Limited studies indicate that the use of clips in the presence of bacterial contamination may increase or prolong infection.

Re-bleeding may occur if the clips detach within 24 hours.

Although rates of occurrences are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

**Boston
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Ordering Information
1.800.225.3226

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