

Resolution™ Clip

NEW INDICATION •
PROPHYLACTIC
CLIPPING TO REDUCE
THE RISK OF DELAYED
BLEEDING POST
LESION RESECTION
• LEAVE NOTHING TO CHANCE™

**Boston
Scientific**
Advancing science for life™

Resolution™ Clip

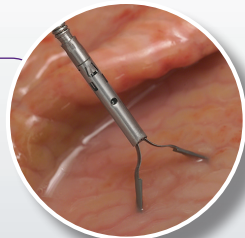
Clips are used today for a large number of indications, most of which are related to bleeding. They are designed for prompt hemostatic effect. Several studies have been published relating to the safety and effectiveness of endoscopic clip placement.*

The Resolution Clip is intended to be used for:

- Hemostasis
 - > Prophylactic clipping
- Endoscopic marking
- Closure
- Anchoring jejunal feeding tubes

(see detailed information in the "Instructions for Use" supplied with the product)

The Resolution Clip is fully exposed and wide open, ready to grasp tissue.



The Resolution Clip is closed, grasping tissue, and is now ready to be deployed.



The Resolution Clip is deployed on tissue.



Pre-loaded

The Resolution Clip is designed to be **ready-to-use**, which is essential for emergency bleeding situations.



Reopening Capability

The radiopaque Resolution™ Clip is **engineered to enable opening and closing up to five times** prior to deployment, aiding in repositioning of the clip.**



11mm-wide Jaw Span

Intended to **grasp a sizeable amount** of tissue.

User-friendly Handle

Designed to deliver a familiar actuation for opening and closing the jaws. Provides tactile feedback upon closing of jaws, indicating that the clip is about to be deployed.



The procedure isn't a success if the clip fails.

June 29, 2004:
First Resolution
Clip sold

2009: More than
1,000,000 Resolution
Clips sold

December 2012:
MR Conditional 510(k)
clearance

December 2014:
Prophylactic clipping
510(k) clearance

2014: More than
5,000,000 Resolution
Clips placed over 10 years

The Resolution Clip
has impacted more
than **2.5 million**
patient lives



MR Conditional
per ASTM F2503

Clinical Evidence: Prophylactic Clipping†

The Resolution Clip is 510(k) cleared for prophylactic clipping to reduce the risk of delayed bleeding post lesion resection.

Post Polypectomy Bleeds

"In a retrospective study, clipping polypectomy sites closed after endoscopic resection of large sessile and flat colorectal lesions was associated with a **reduced incidence of delayed postpolypectomy bleeding.**"¹

"**The delayed hemorrhage rate was 9.7% in the not clipped group versus 1.8% in the fully clipped group.**"¹

"Polyps that were not clipped were **4.4 times more likely to have any complications** (1.8, 10.9; P = .001) compared with polyps that were completely clipped."¹

"[A]voidance of unnecessary surgical resection of endoscopically removable polyps is **another potential cost-savings associated with prophylactic clip closure of large polyp sites**, if the availability of clip closure increases rates of endoscopic resection because of decreased fear of complications."¹

**Re-opening and closing capability may be limited by clinical circumstances and patient anatomy, among other factors.

Clinical Evidence: Prophylactic Clipping[‡]

Post Polypectomy Bleeds

“In univariate analysis, **polyp size was a strong risk factor for post-polypectomy hemorrhage** (OR 1.13 (1.06 – 1.20)), indicating an increase in risk of 13 % per millimeter increase in size.”²

“**Location in the right hemi-colon was also associated with delayed hemorrhage** (OR 4.32, 95 % CI 2.00 – 9.35, $P < 0.001$).”²

“...[P]olypectomies in the right hemi-colon constituted only 31.6 % of all polypectomies (controls), while they were responsible for 66.7 % of all delayed type hemorrhage (cases).”²

Rebleeding in Ulcers

“From recent studies of patients whose ulcer hemorrhage started as an outpatient before hospitalization, approximately 80% of ulcer rebleeds occurred within 72 hours, but **20% rebled between 4 and 30 days.**”³

“For patients with inpatient ulcer hemorrhage (eg, develops after a patient is hospitalized for a nonbleeding medical or surgical diagnosis), the pattern of ulcer rebleeding after hemostasis is quite different. **At least 50% of ulcer rebleeding episodes in such inpatients occur 1 week or more after initial endoscopic hemostasis.**”³

Resolution™ Clip



Upon deployment, clip is designed to lock securely in place for improved retention

Resolution Clip

Order Number	Working Length (cm)	Minimal Working Channel (mm)	Clip Opening (mm)	Box
M00522600	155	2.8	11	1
M00522601	155	2.8	11	10
M00522602	155	2.8	11	20
M00522610	235	2.8	11	1
M00522611	235	2.8	11	10
M00522612	235	2.8	11	20

* Endoclips versus heater probe in preventing early recurrent bleeding from peptic ulcer: a prospective and randomized trial. From Cipolletta, Naples, Italy, in *Gastrointestinal Endoscopy* 2001; 53:147-51.

** Dieulafoy's disease treated by endoscopic hemostatic clipping. Teo EK, Fock KM. *J Gastroenterology Hepatology* 1998; 13:320-1.

† See detailed information in the "Instructions for Use" supplied with the product.

‡ Results from case studies are not predictive of results in other cases. Results in other cases may vary.

1 Liaquat H, Rohn E, Rex DK. Prophylactic clip closure reduced the risk of delayed postpolypectomy hemorrhage: experience in 277 clipped large sessile or flat colorectal lesions and 247 control lesions. *Gastrointestinal Endoscopy*, 2013 Mar;77(3):401-7. doi: 10.1016/j.gie.2012.10.024. Epub 2013 Jan 11.

2 Buddingh KT, Herengreen T, Haringsma J, van der Zwet WC, Vleggaar FP, Breumelhof R, Ter Borg F. Location in the right hemi-colon is an independent risk factor for delayed post-polypectomy hemorrhage: a multi-center case-control study. *American Journal of Gastroenterology*, 2011 Jun;106(6):1119-24. doi: 10.1038/ajg.2010.507. Epub 2011 Jan 25.

3 Jensen DM, Machicado GA. Hemoclipping of chronic canine ulcers: a randomized, prospective study of initial deployment success, clip retention rates, and ulcer healing. *Gastrointestinal Endoscopy*, 2009 Nov;70(5):969-75. doi: 10.1016/j.gie.2009.04.052. Epub 2009 Jul 28.

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Indications, Contraindications, Warnings and Instructions for Use 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.

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