

Product Information for Patients

Resolution™ Resolution 360™ Resolution 360™ ULTRA Clip

REF M00522600, M00522601, M00522602, M00522610, M00522611, M00522612, M00521240, M00521241, M00521242, M00521243, M00521230, M00521231, M00521232, M00521233, M00521400, M00521401, M00521402, M00521403

Device Information


The Resolution, Resolution 360 and Resolution 360 ULTRA Clip are single-use clips. They are intended to stop and prevent bleeding, hold tissue together, close a hole in the GI tract, hold a feeding tube in place, and/or mark for a procedure.

Your doctor should provide you with an implant card that identifies your clip. Always carry this card with you and present it to all health professionals (doctors, nurses, and technicians).

Information on Safe Use

Follow your doctor's instructions on dietary restrictions and physical activity. Take medication as instructed by your doctor. Contact your doctor immediately if any of the following occur:

- You have bloody or discolored (black tarry) stool.
- You have a fever of 101 °F (38.3 °C) or higher.
- You have a change in bowel habits.
- You are vomiting.
- You are vomiting blood.

	
MRI Safety Information	
A person with the Resolution, Resolution 360 and Resolution 360 ULTRA Clip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Resolution, Resolution 360 and Resolution 360 ULTRA Clip
Static Magnetic Field Strength (B₀)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration / Temperature Rise	Under scan conditions defined above, Resolution, Resolution 360 and Resolution 360 ULTRA Clips are expected to have a temperature rise of less than 4°C and can be used for 60 minutes of continuous RF



MR Safety Information

A person with the Resolution, Resolution 360 and Resolution 360 ULTRA Clip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

MR Image Artifact

Image artifact caused by device may extend approximately 90mm from the implant

Warning: Failing to follow the MR Conditional labeling can cause the clip to detach from the tissue where it is placed. If the clip detaches, a serious injury, rebleeding, or death can occur. Rebleeding may require further treatment or surgery. Not following the labeling can also result in heating of the clip and the tissue near the clip. If the tissue heats, a burn and/or tissue damage can occur.

Warning: This clip contains ferromagnetic material. Ask your doctor if you need an X-Ray before you have an MRI exam. When you are in or near an MRI scanner, magnetic forces can act on the clip. There may be a small potential risk that the clip can move from where it was originally placed in your body. If the clip was used in weak and/or easily torn tissue or healing tissue, rebleeding may occur.

Expected Lifetime and Follow-up

The Resolution, Resolution 360 and Resolution 360 ULTRA Clip have been tested for up to 60 days after implantation. The clip may stay inside the body for up to 60 days.

Carry your implant card for as long as your physician instructs.

Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (<https://www.tga.gov.au>).

Patient Contacting Materials

The following materials in this device are in contact with the patient:

Resolution Clip

Implantable Material	% (wt) (Total assembly weight = 0.116g)
Stainless steel	73%
Cobalt-Chrome	24%
Styrene acrylonitrile copolymers	3%

Resolution 360 Clip

Implantable Material	% (wt) (Total assembly weight = 0.116g)
Stainless steel	73%
Cobalt-Chrome	24%
Styrene acrylonitrile copolymers	3%

Resolution 360 ULTRA Clip

Implantable Material	% (wt) (Total assembly weight = 0.139g)
Stainless steel	77%
Cobalt-Chrome	20%
Styrene acrylonitrile copolymers	3%

This material contains cobalt. Based on animal studies, the European Commission has classified cobalt as a substance that may:

- cause cancer, or
- interfere with normal reproduction.

However, research shows that metal alloys containing cobalt used in medical devices do not cause an increased risk of these effects in humans. Talk with your doctor if you have questions about your device.










Warning: This device contains nickel which may cause an allergic reaction in individuals with nickel sensitivity.

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Symbol Definitions

The symbols used for patient information are as follows:

 Date	 Health care center or doctor	 Patient identification
 Catalog Number	 Lot Number	 Contains hazardous substances
 Indicates the date the device must be implanted by.	 MR Conditional	 Unique Device Identifier

EC REP

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