

GT Metabolic™ Magnetic Retrieval Device (MRD)

INSTRUCTIONS FOR USE

Device Description

The GT Metabolic Magnetic Retrieval Device (MRD) is an endoscopic tool used for the retrieval of a GT Metabolic Magnet within the gastrointestinal (GI) tract. The MRD consists of a long, flexible shaft with a magnetic distal tip that is introduced through the working channel of an endoscope. Once advanced to the target location, the MRD utilizes magnetic attraction to capture the Magnet, facilitating its retrieval from the body.

Intended Use

The GT Metabolic Magnetic Retrieval Device (MRD) is intended for endoscopic use to magnetically attract, capture, and retrieve a GT Metabolic Magnet from the gastrointestinal (GI) tract.

Endoscope Compatibility

The GT Metabolic Magnetic Retrieval Device (MRD) is compatible with endoscopes featuring a working channel diameter of **2.8mm or larger and a working length less than 200cm**. Do not attempt to use the device with endoscopes that have smaller working channel diameters, as this may result in device malfunction or damage.

Important Notice

The GT Metabolic Magnetic Retrieval Device (MRD) is only intended for the retrieval of a GT Metabolic Magnet from the gastrointestinal (GI) tract. The safety and effectiveness of the device have not been established for retrieval of foreign objects other than a GT Metabolic Magnet or for use in other anatomical locations.

Users are encouraged to review all contraindications, warnings, and precautions in this Instructions for Use prior to device operation.

Contraindications

- The GT Metabolic Magnetic Retrieval Device (MRD) is contraindicated for use in the removal of any object other than a GT Metabolic Magnet and has not been evaluated for retrieval of objects other than a GT Metabolic Magnet.
- The GT Metabolic Magnetic Retrieval Device (MRD) is intended solely for use in the gastrointestinal (GI) tract and is contraindicated for use in any other anatomical region.

Warnings and Precautions

- **Caution:** Federal law restricts this device to sale by or on the order of a physician.
- The GT Metabolic Magnetic Retrieval Device (MRD) is intended for use with endoscopes that have a minimum 2.8mm diameter working channel. Do not attempt to use the device with endoscopes that have smaller working channel diameters, as this may result in device malfunction or damage.
- The GT Metabolic Magnetic Retrieval Device (MRD) has been sterilized by gamma irradiation. Before use, confirm the integrity of the packaging. Do not use the device if the packaging is damaged, torn, or in poor condition.
- The GT Metabolic Magnetic Retrieval Device (MRD) is provided in sterile packaging and is intended for single use only. Do not re-sterilize or reuse the device. Re-sterilization or reuse may result in cross-contamination, infection, or device malfunction that may lead to patient injury.
- When using the GT Metabolic Magnetic Retrieval Device (MRD), strict handling and aseptic technique procedures must be followed.
- Do not use the GT Metabolic Magnetic Retrieval Device (MRD) if it is damaged, bent, or shows signs of wear as this may affect performance or lead to breakage during use.

- Do not use the GT Metabolic Magnetic Retrieval Device (MRD) for non-ferromagnetic objects. The device is specifically designed for the retrieval of a GT Metabolic Magnet; it will not be effective for non-ferromagnetic objects.
- The GT Metabolic Magnetic Retrieval Device (MRD) was tested to ensure the endoscope can achieve suction while the MRD was in the working channel. The MRD is not intended and has not been designed for use with electrosurgical devices or accessories.
- The GT Metabolic Magnetic Retrieval Device (MRD) should only be used by healthcare professionals trained in endoscopic procedures.
- GT Metabolic Magnetic Retrieval Device (MRD) must be handled with care. Improper handling or excessive force of the device may cause the device to bend or kink, potentially resulting in compromised functionality, breakage, and tissue or other patient injury.
- During retrieval, continuous visualization of both the GT Metabolic Magnetic Retrieval Device (MRD) and GT Metabolic Magnet is essential to assure the devices remain securely paired throughout the retrieval process.
- Exercise caution when retrieving the GT Metabolic Magnet to minimize the risk of accidental dislodgment and potential patient injury (e.g., aspiration) and require additional retrieval attempts.

Directions for Use

1. **Confirm Device Location:** Use appropriate imaging or endoscopic visualization to confirm the presence and location of the GT Metabolic Magnet (Magnet) within the gastrointestinal (GI) tract.
2. **Position the Endoscope:** If not already in place, insert the endoscope into the GI tract and advance it toward the Magnet.
3. **Introduce the Retrieval Device:** Insert the GT Metabolic Magnetic Retrieval Device (MRD) through the working channel of the endoscope.
4. **Advance Toward the Magnet:** Carefully advance the MRD until the magnetic distal tip is positioned near the Magnet.
5. **Engage and Retrieve the Magnet:** Slowly position the magnetic tip of the MRD close to the Magnet, allowing magnetic attraction to engage the devices. Once paired, while maintaining endoscopic visualization of the MRD/Magnet assembly, gently withdraw the MRD/Magnet assembly until it is approximately 1-2 inches (25-50mm) away from the distal end of the endoscope.



Caution: Withdrawing the MRD/Magnet assembly too far back into the working channel of the endoscope may result in dislodgement of the Magnet from the MRD, requiring recapture of the Magnet.

6. **Complete Retrieval:** While maintaining continuous visualization and a secure grip on the MRD, gradually retract both the endoscope and the engaged MRD/Magnet assembly from the GI tract.

How Supplied and Storage Requirements

- **Sterile:** The GT Metabolic Magnetic Retrieval Device (MRD) is sterilized by gamma irradiation. Do not use the device if the packaged is opened or damaged. Use aseptic technique when handling the device.
- **Contents:** One (1) GT Metabolic Magnetic Retrieval Device (MRD) per package.
- **Storage:** No special storage conditions.

Disposal

This GT Metabolic Magnetic Retrieval Device (MRD) does not contain hazardous substances. However, following clinical use, it may be contaminated with biological material. Dispose of the device in accordance with institutional guidelines and local regulations for biohazardous waste. Do not reuse or reprocess the device.

Potential Benefits and Residual Risks

Potential benefits from use of the GT Metabolic Magnetic Retrieval Device includes minimally invasive retrieval with no incision or surgical closure of the intestines. Residual clinical risks may include but not be limited to infection, irritation, inflammation, allergic reaction, aspiration, or tissue injury.

Symbols Glossary

Symbol	Definition
	Model (Catalog) Number
	Lot Number
	Use by Date
	Quantity
	Unique Device Identifier
	Sterilized using irradiation
	Minimum endoscope working channel diameter
	Do Not Reuse
	Do Not Re-sterilize
	Date of Manufacture

Symbol	Definition
	Do Not Use If Package Damaged
	Medical Device
	Caution: Federal law (United States) restricts this device to sale, distribution, and use by or on the order of a physician
	Consult Instructions for Use
	Single sterile barrier system
	Manufacturer
	MRD working length
	Authorized Representative in the European Community
	Caution is necessary when operating/controlling the device



Manufacturer Information

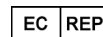
Corporate Address

GT Metabolic Solutions, Inc.
3050 Three Springs Court
San Jose, CA 94140 USA



Manufacturing Location

GT Metabolic Solutions, Inc.
5450 Quam Ave NE, Suite 100
St. Michael, MN 55376 USA



Authorized Representative

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33
Suite 123, 2595 AM, The Hague, The Netherlands
Phone: +31 (0) 70 326 2148

Customer Support: If you have any questions, require additional information, or wish to report a complaint related to this device, please contact:

GT Metabolic Solutions, Inc.

Phone: +1 800-906-4948

Email:

customerservice@gtmetabolic.com

Website:

<https://www.gtmetabolic.com>