



M-Catch[®] Retrieval Net

*Instructions for use.
Read carefully prior to use.*

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

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Diversatek Healthcare M-Catch® Retrieval Net
Instructions for Use.
Read carefully prior to use.

INTENDED USE

The M-Catch® Retrieval Net is intended to be used to endoscopically retrieve severed polyps, tissue samples, food bolus, and foreign bodies in the gastrointestinal tract.

| <u>Part Number</u> | <u>Description</u> |
|--------------------|---|
| 1175-00 | M-Catch® Retrieval Net, Standard 3 x 6 cm, 160 cm |
| 1175-01 | M-Catch® Retrieval Net, Standard 3 x 6 cm, 230 cm |
| 1175-02 | M-Catch® Retrieval Net, Standard 3 x 6 cm, 350 cm |
| 1175-10 | M-Catch® Retrieval Net, Polyp 3 x 6 cm, 230 cm |

INTENDED USER

Retrieval nets should only be used by or under the supervision of physicians thoroughly trained in polypectomy and gastrointestinal endoscopy. Consult medical literature relative to techniques, complications and hazards prior to the performance of any endoscopic procedure.

CONTRAINDICATIONS

This device is not intended to be used for severing tissue or polyps and is not intended to be connected to an electrosurgical device to provide cautery.

WARNINGS AND PRECAUTIONS

1. Do not use this device if there is any apparent shipping or handling damage.
2. Avoid blindly passing the M-Catch® Retrieval Net past any foreign object, particularly if the entire lumen is blocked.
3. Care should be exercised when grasping the targeted polyp/object to be retrieved to avoid inadvertently grasping tissue or organs not intended for retrieval.
4. Keep gentle traction on the device during retrieval so that the retrieved object does not become loosened, dislodged or aspirated into the trachea.
5. These devices are not recommended for the retrieval of sharp foreign objects.
6. To prevent inadvertent injury or perforation of internal organs and body structures, retrieval should be performed under direct endoscopic vision.
7. The following conditions may not allow the M-Catch® Retrieval Net to function properly:
 - a. advancing the handle to the open position with too much speed or force
 - b. attempting to pass or open the device in an extremely articulated endoscope
 - c. attempting to actuate the device in an extremely coiled position
 - d. actuating the device when the handle is at an acute angle in relation to the sheath
8. Short strokes, 1"-1.5" (2.5cm – 3.8cm) in length, are recommended throughout device passage to avoid sheath kinking.
9. Insertion forces may be greater for product #1175-02 during enteroscopic use due to scope configuration and scope/device length. The user may experience moderate resistance in device passage as the device exits the distal end of the enteroscope.
10. Devices are intended for single-use only. Do not reuse, reprocess, or resterilize single-use products. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation, which may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also increase the 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.

INSTRUCTIONS FOR USE

1. Prior to usage, check that the accessory channel diameter of the endoscope is compatible with the outer diameter of the M-Catch® Retrieval Net sheath.
2. Inspect the device and/or packaging for damage during shipping and transit. If damage is observed, do not use.
3. To prepare the M-Catch® Retrieval Net for introduction into the endoscope:
 - a. Uncoil the entire device and drape in a "U" shaped configuration, holding the proximal device end in one hand, and the distal sheath end in the opposite hand.

- b. With the device in this position, carefully retract the handle until the M-Catch® Retrieval Net is completely withdrawn into its sheath (see Figure 3).
4. Once the polyp/object has been endoscopically identified, advance the retracted device into the accessory channel of the endoscope using short strokes until the distal end of the sheath is endoscopically visualized.
5. Advance the distal end of the sheath slightly past the polyp/object to be retrieved, however, avoid blindly passing the device past any polyp/foreign object if the entire lumen is blocked. Open the M-Catch® Retrieval Net by advancing the handle forward until it stops (see Figure 1). Confirm the net is fully open via endoscopic observation.

WARNING: The following conditions may cause the device to function improperly: (1) advancing the handle to the open position with too much speed or force, (2) attempting to pass or open the device in an extremely articulated endoscope, (3) attempting to actuate the device in an extremely coiled position and/or (4) actuating the device when the handle is at an acute angle in relation to the sheath.
6. Endoscopically manipulate the M-Catch® Retrieval Net over the polyp/object. For best results, the object should be centered and proximal in the net prior to closure. Once entrapment is accomplished, retract the handle until it stops (see Figure 2). Continuous gentle traction should be applied on the handle to keep the M-Catch® Retrieval Net closed. Excess pressure may cause the net to rupture or tear.
7. Retract the sheath, retrograde, toward the endoscope so the M-Catch® Retrieval Net is endoscopically observed yet not obscuring the endoscopic view. Endoscopic observation is necessary during extubation so as not to lose sight of the polyp/object during removal.

WARNING: Do not attempt to retract the object into the working channel of the endoscope as this will crush the specimen and possibly damage the net sheath and/or endoscope.
8. Once the endoscope and the M-Catch® Retrieval Net have been extubated, the retrieved polyp/object can be removed from the net by advancing the handle forward to open the M-Catch® Retrieval Net (see Figure 1). Specimens should be prepared according to standard technique for histologic evaluation.
9. To repack the M-Catch® Retrieval Net into the sheath for introduction to, or removal from the endoscope, or for additional retrievals:
 - a. Retract the handle until the net of the M-Catch® Retrieval Net is completely retracted into the sheath (see Figure 3).
10. Once the endoscopic retrieval has been completed, remove the device from the endoscope.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

M-Catch® is a registered trademark of Diversatek Healthcare.

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DESCRIPTION OF SYMBOLS USED ON LABELS



Manufacturer



Use-by date
(YYYY-MM-DD)



Lot Number



Part number



Non-sterile



Do not use if package is damaged



Temperature limit
15-25 °C / 59-77 °F



Do not re-use



Consult instructions for use



Caution, consult accompanying documents



Not made with natural rubber latex



Sheath Outer Diameter

Figure 1

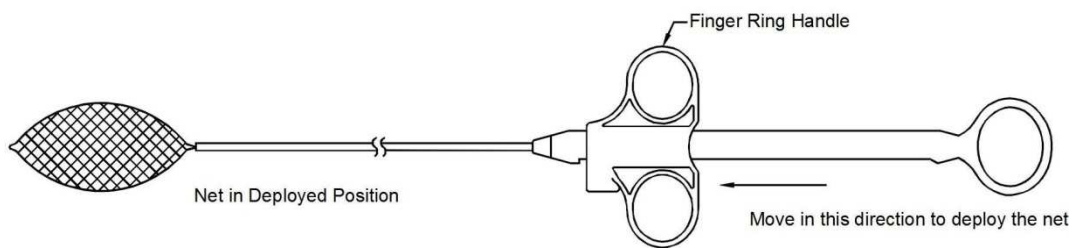


Figure 2

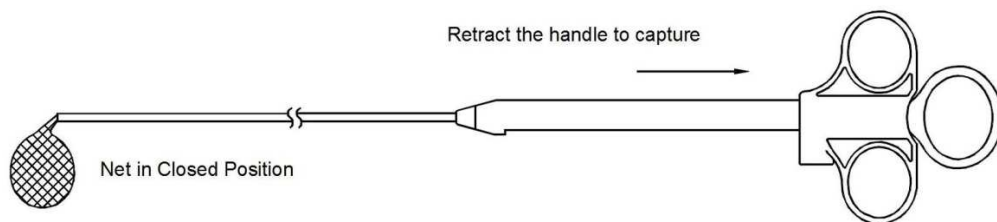


Figure 3

