

MEDOVATIONS CAPTURE™ POLYP TRAP

*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.



medovations®

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Made in the U.S.A.

INTENDED USE

The single use Capture™ Polyp Trap is used for suction retrieval and transportation of endoscopically removed polyps for histological examination. The Capture™ Polyp Trap has four chambers to collect the polyps and four open areas for straight suction.

<u>Part Number</u>	<u>Description</u>
1202-01	Polyp trap, non-sterile, individually poly-bagged

The single use Capture™ Polyp Trap consists of:

- One (1) jar with four (4) filtered traps (labeled 1, 2, 3, 4) to collect polyps, and four (4) open areas (labeled ●) for straight suction.
- A lid with one tube for connection to the endoscope.

DESCRIPTION OF SYMBOLS USED ON LABELS



Non-Sterile Device



Caution, Consult Accompanying Documents



Do Not Re-Use



Do Not Use if Package is Damaged



Not Made with Natural Rubber Latex



Date of Manufacture (YYYY-MM-DD)

Medovations® is a registered trademark of Medovations, Inc.

WARNINGS AND PRECAUTIONS

Products marked “single-use” are 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.

Do not disconnect the pre-installed tubing from the polyp trap lid outer port as this may result in damage to the polyp trap lid and may result in exposure to the contents of the trap during removal.

Protective garments (i.e. gloves, protective eyewear, gowns, etc) should be worn during the use of this device to protect against the risk of cross-contamination and injury.

CONTRAINDICATIONS

1. Connect a suction tube (not included) from the center port of polyp trap to suction system (see Figure 1).
2. Connect outer port (endoscope) tubing to the endoscope (see Figure 1).
3. Rotate the lid on the jar to align the arrow on the lid with any open (●) position for normal suctioning (see Figure 2).
4. To entrap the first polyp, rotate the jar and align the arrow with the “1” chamber. Suction through the endoscope using standard endoscopic technique until the excised polyp is entrapped in the chamber retrieval strainer (See Figure 3).n-sterile.
5. After the polyp is trapped, repeat Step 3 for normal suction as needed.
6. Repeat Step 4 for chamber positions 2, 3, and 4 for each additional polyp (same patient only).
7. Disconnect outer port (endoscope) tubing from endoscope. Disconnect suction system tubing from center port.
8. Fill the polyp trap with fixative through the center port or after careful removal of the lid. Replace lid when fixative filling is complete.
9. Bend the outer port (endoscope) tubing toward the center port. Connect the free end of the outer port (endoscope) tubing to the center port, covering both the ports with a single tube (see Figure 4).
10. Unit is ready for transport to the laboratory.

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.

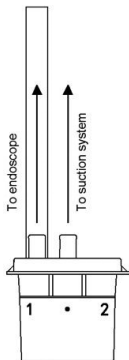


Figure 1

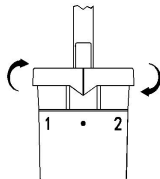


Figure 2

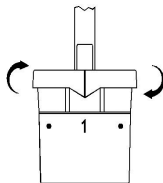


Figure 3

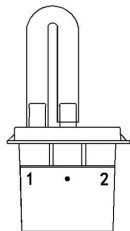


Figure 4