

**ProTrap Luma™ In-Line Polyp Trap &
ProTrap Luma™ Polyp Trap Specimen Tray**

INSTRUCTIONS FOR USE



Consult Instructions
For Use



Do Not Reuse



DO NOT USE
IF PACKAGE
IS DAMAGED

Rx Only

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech USA.

INTENDED USE

To collect the polyps through the endoscope channel which are greater than 1mm, for pathological analysis.

WARNINGS AND PRECAUTIONS

- The product is intended for single use only! DO NOT re-use or reprocess. Re-use, or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness, or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, or reprocessed.
- Users must carefully read and follow all instructions in the operating manuals supplied with all related equipment.
- Users should wear personal protective equipment such as gloves, gowns, face masks, goggles, etc., to minimize the risk of cross contamination.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws, and regulations.
- Do not use this product for any purpose other than the stated intended use.
- Do not use the product if the package is damaged.

PRODUCT NAME: ProTrap Luma In-Line Polyp Trap & ProTrap Luma Polyp Trap Specimen Tray

PRODUCTION DATE: See packaging

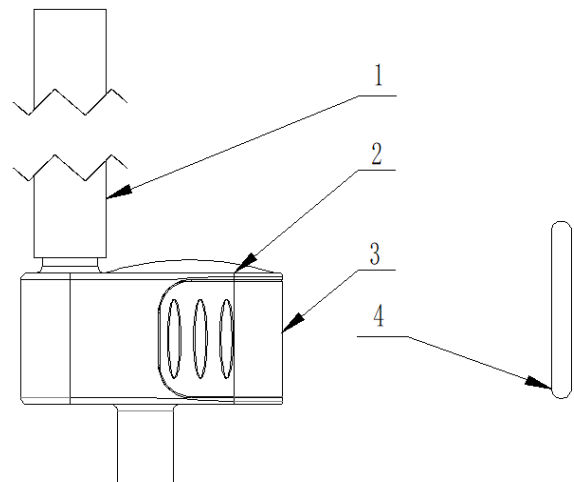
SHELF LIFE: 1 year

Contents supplied non-sterile.

This device is not made with natural rubber latex.

1. ProTrap Luma In-Line Polyp Trap

The device consists of a collection hose, a trap body, a tray, and a glow stick. (see Fig.1).



1. Collection Hose 2. Trap Body 3. Tray 4. Glow Stick

Fig.1

2. ProTrap Luma Polyp Trap Specimen Tray

The device is a single tray. (see Fig.2).

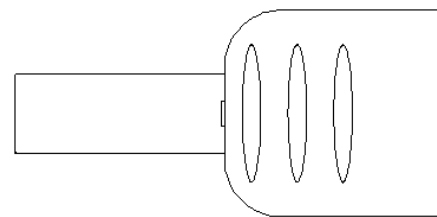


Fig.2

PREPARATION

- Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
- If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Bend the glow stick, shake well to mix chemicals
2. Fix the glow stick in trap body (see Fig. 3) and install the tray
3. Connect the suction hose to the suction unit
4. Connect the collection hose to the endoscope to collect the first tissue sample into the tray
5. After tissue sample is collected remove the tray and install a new tray
6. Repeat step 5 for each additional tissue sample (same patient only)

Note: Collection trays are intended to be placed directly into the specimen jar to reduce handling.

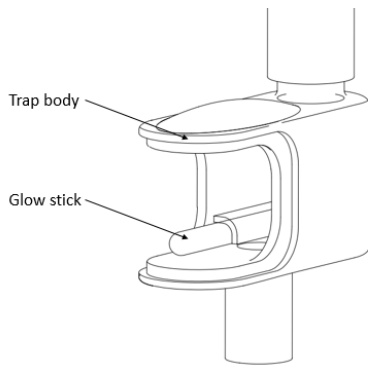


Fig. 3

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation, or ultraviolet radiation.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

Limited Warranty and Disclaimers

1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer. The products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA's part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.
2. Disclaimer and Release. THE WARRANTIES, OBLIGATIONS, AND LIABILITIES OF Micro-Tech USA AS SET FORTH HEREIN ARE EXCLUSIVE. BUYER HEREBY WAIVES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE PRODUCTS AND ANY OTHER GOODS OR SERVICES DELIVERED BY BUYER,

INCLUDING, BUT NOT LIMITED TO: (1) ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND (2) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.

3. Implied Warranties. The purchase of products may be subject to laws in the territories applicable to the sale of the products by Micro-Tech USA to Buyer that impose implied warranties, conditions, or obligations that cannot be excluded, restricted, or modified, or can only be excluded, restricted, or modified to a limited extent. The provisions of Paragraphs 2 and 4 shall apply to the greatest extent allowed by such laws.
4. Limitation of Liability. Except to the extent prohibited by applicable law, Micro-Tech USA's liability under this warranty is limited to: (a) the replacement of the products or the resupply of equivalent products; (b) the repair of the products or payment of the cost of repairing the products; or (c) payment of the cost of replacing the products or acquiring equivalent products. Micro-Tech USA shall have no obligation or liability, whether arising in contract (including warranty), tort (including active, passive, or imputed negligence, strict liability, or product liability) or otherwise, for any special, consequential, punitive, incidental, or indirect damages, or for loss of use, loss of revenue, loss of business, lost profit, or other financial loss arising out of or in connection with any product or other goods or services furnished by Micro-Tech USA, even if Micro-Tech USA was aware of the possibility of such damages or loss.

Manufactured for:



Micro-Tech USA Inc.
 2855 Boardwalk Drive,
 Ann Arbor, MI 48104 USA
 Tel: 734-259-3768
 Toll free: 877-552-4027
info@micro-tech-usa.com
 Made in P.R. China

1-0025275 Rev: 1

2020.11.09