

NapoleonTM Endoscopic Polyp Measurement Device

Instructions for Use











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.

INTENDED USE

The measurement device is intended to be used as an endoscopic reference when estimating the size or location of a feature under endoscopic examination.

CONTRAINDICATIONS

• Contraindications include, but may not be limited to: Those of the primary endoscopic procedure.

POTENTIAL COMPLICATIONS

• Bleeding, perforation etc

WARNINGS

- 1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization 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, re-sterilization 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, re-sterilized or reprocessed.
- 2. Do not use this instrument for any purpose other than its intended use.
- 3. The product is only intended for adult populations.
- 4. This device is not made with natural rubber latex.
- 5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
- 6. The instrument is intended for use under the direct supervision of a suitably trained physician only. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
- 7. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.

Product Name

Napoleon™ Endoscopic Polyp Measurement Device

Packaging

Packed in Pouch



See packaging

Sterilization

Sterilized by EO (ethylene oxide) gas

Shelf Life

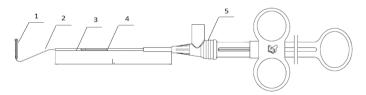
2 years

Compatible Working Channel

>ø2 8mm

STRUCTURE

Endoscopic measurement device includes a distal measurement tip, supporting wire, inhaul cable, outer tube and handle assembly. (Fig.1)



Distal Measurement Tip 2. Supporting wire 3. Inhaul Cable 4. Outer Tube 5. Handle Assembly
 Fig. I Schematic diagram of Endoscopic Polyp Measurement Device

PREPARATION

Reference the product label and choose the appropriate device.

- 1. Contents supplied STERILE.
- Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
- Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
- 4. Before use, please check that no sharp edges or burrs are present.
- 5. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

- Retract the handle in order to make sure the distal tip is inside the outer tube prior to introducing the device into the endoscope instrument channel.
- 2. Under endoscopic visualization, slowly introduce the device into the endoscope working channel, using short movements.
- 3. Advance the distal tip into endoscopic view.
- 4. When ready, slowly advance the finger rings to advance the distal tip and measurement device. Position close to the feature to be measured and document appropriately.
- Caution: Exercise care moving the measurement device endoscopically.
- 6. Pull back the slider to retract the distal tip prior to removing the device from the instrument channel.
- 7. Upon completion of the procedure, remove the instrument from the endoscope.

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.

The product shelf life is 2 years.

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 PARTICU-LAR 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 RE-SUPPLY OF EQUIVA-LENT 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.



Manufacturer Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC

TEL:+ 86 25 58609879, 58646393

FAX:+ 86 25 58744269

Email: info@micro-tech.com.cn www.micro-tech.com.cn;

Distributed By

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