

BlueBoost™ Submucosal Injectable Solution

Instructions for Use



Rx only

Prescription only



Consult instructions for use



Sterilized using steam



Do not re-sterilize



Do not use if package is damaged



Fragile, handle with care



Do not re-use



Use by date



Not made with natural rubber latex



Keep away from sunlight



Store between 1°C and 30°C

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.

DEVICE DESCRIPTION

BlueBoost™ Submucosal Injectable Solution consists of a sky-blue viscous solution in a 5ml or 10ml prefilled syringe. The contents of the syringe are sterile and nonpyrogenic. Under the surveillance of endoscope, the material is injected into the submucosal layer by means of an endoscopic injection needle (Needles with a diameter equal to or greater than 23G are recommended).

The solution, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure (EMR, ESD or polypectomy).

INTENDED USE

BlueBoost™ Submucosal Injectable Solution is indicated for submucosal lift of polyps, adenomas, early state cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

CONTRAINDICATIONS

Allergy to device or any of the ingredients in the product.

POTENTIAL COMPLICATIONS

Potential complications that are not known or observed.

ADVERSE REACTIONS

Rarely, local bleeding and/or inflammatory reaction could occur which may or may not be associated with the product.

WARNINGS

- For use in the GI tract only– NOT FOR INTRAVACULAR OR INTRAMUSCULAR INJECTION.
- Only the fluid is sterile. Do not use in a sterile or aseptic area without proper precautions.
- **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.

- Do not use this instrument for any purpose other than its intended use.
- The product is only intended for adult populations.
- This device is not made with natural rubber latex.
- **The instrument is intended for use under the direct supervision of a trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
- Do not use if packaging is damaged.
- The product is to be used in conjunction with endoscopic injection needles with a diameter equal to or greater than 23G are recommended.
- This product is used directly without dilution.
- The safety of the material has not been established in pregnant or lactating women.
- Do not use if the emulsion is not clear, shows any signs of opalescence, or contains floating or precipitated visible particles.
- Product compatibility with other substances has not been tested.

【Product Name】 BlueBoost™ Submucosal Injectable Solution

【Packaging】 Packaged in 5ml or 10ml syringe inside a sealed pouch

【Production Date】 See packaging

【Sterilization】 Fluid sterilized by steam

【Shelf Life】 2 years

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Fluid is supplied STERILE.
3. Open the package carefully after verifying the expiration date. CAUTION: For use in the GI tract only–NOT FOR INTRAVACULAR OR INTRAMUSCULAR INJECTION.
4. Sterile unless damaged. Leakage of product may be evidence of damage. Do not use if damaged.

INSTRUCTIONS FOR USE

1. Select a suitable endoscopic injection needle(not provided with the device).
Caution: Narrow gauge needles should be avoided. Needles with a diameter equal to or greater than 23G are recommended.
2. Screw the syringe to the selected injection needle with a luer lock connection, prime the endoscopic injection needle with the solution to expel any air.
3. With the needle retracted, carefully insert the catheter through the biopsy channel of the endoscope under direct visualization until the needle emerges into the endoscopic view.
4. When the needle is properly positioned, advance the needle

and inject the product beneath the lesion. The dose should be determined based on the dimensions of the lesion to be removed by the physician. Not exceed a total dose of 50ml per patient in a single procedure.

CAUTION: Do not insert the needle perpendicular to the colon, as this may lead to perforation of the serosa and injection of the product directly into the peritoneal cavity.

STORAGE

Store between 1°C and 30°C. Protect from light. Do not freeze.

PRODUCT DISPOSAL

1. Discard any unused product after the syringe/vial has been opened.
2. 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 RE-SUPPLY 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.**



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

1-0027979 REV.A/3

2020-10-15