

ColoShield™ Procedure Drape

Instructions for Use



Consult Instructions for Use



Do Not Reuse



Non-Sterile



Do Not Use If Package Is Damaged

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 Endoscopy USA.

INTENDED USE

The ColoShield Procedure Drape is intended to be used as a barrier during colonoscopy or anorectal diagnostic procedures.

WARNINGS AND PRECAUTIONS

- The product is intended for single use only! DO NOT re-use, and/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.
- Do not use this device for any purpose other than its intended use.
- The product is only intended for adult populations.
- Do not use adhesive strips on the skin of patients with known allergies to medical adhesives.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

【 Product Name 】 ColoShield Procedure Drape

【 Production Date 】 See packaging

【 Shelf Life 】 2 years

This device is not made with natural rubber latex.

PREPARATION

1. Inspect the package before use for any damage. Do not use if package is damaged.
2. Verify the expiration date. Do not use if expired.
3. Open the package and remove the drape.

INSTRUCTIONS FOR USE

1. After the patient is positioned (usually left lateral) for examination / procedure, holding the longer side of the drape with the absorbent side up, place the edge of the drape slightly under the patient's buttocks. Note: Alternatively, ColoShield can be fixed to the bed (after steps #2 and #3) using the adhesive strips instead of tucking the edge under the patient's buttocks, especially for larger size patients.
2. Lift the opposite edge of the drape up and position over the patient, ensuring the access port is aligned with the patient's anus and the absorbent side is facing the patient.
3. Secure the drape using the adhesive strips. The longer adhesive strip is placed on patient's lower back. The horizontal strip is placed on patient's right hip/thigh. The right vertical strip is placed on forward-facing side of patient. Note: Some patients are allergic or sensitive to medical grade adhesives. Exercise caution if applying directly to the patient's skin.
4. Upon completion of the procedure, carefully remove the drape, capturing any fluids or bio-matter within the drape. Start the removal process by carefully peeling the shorter adhesive strip off the patient's hip/thigh. Next, roll ColoShield inward so that the side facing the patient is not exposed to the person handling ColoShield. Fold the rolled up ColoShield in half so that bio-matter is contained in the rolled up ColoShield without spillage. Note: If the adhesive was applied to the patient's skin, support the skin, and remove the drape slowly.

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.

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.

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

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COL-7055-50-A Rev: 1A
2021.11