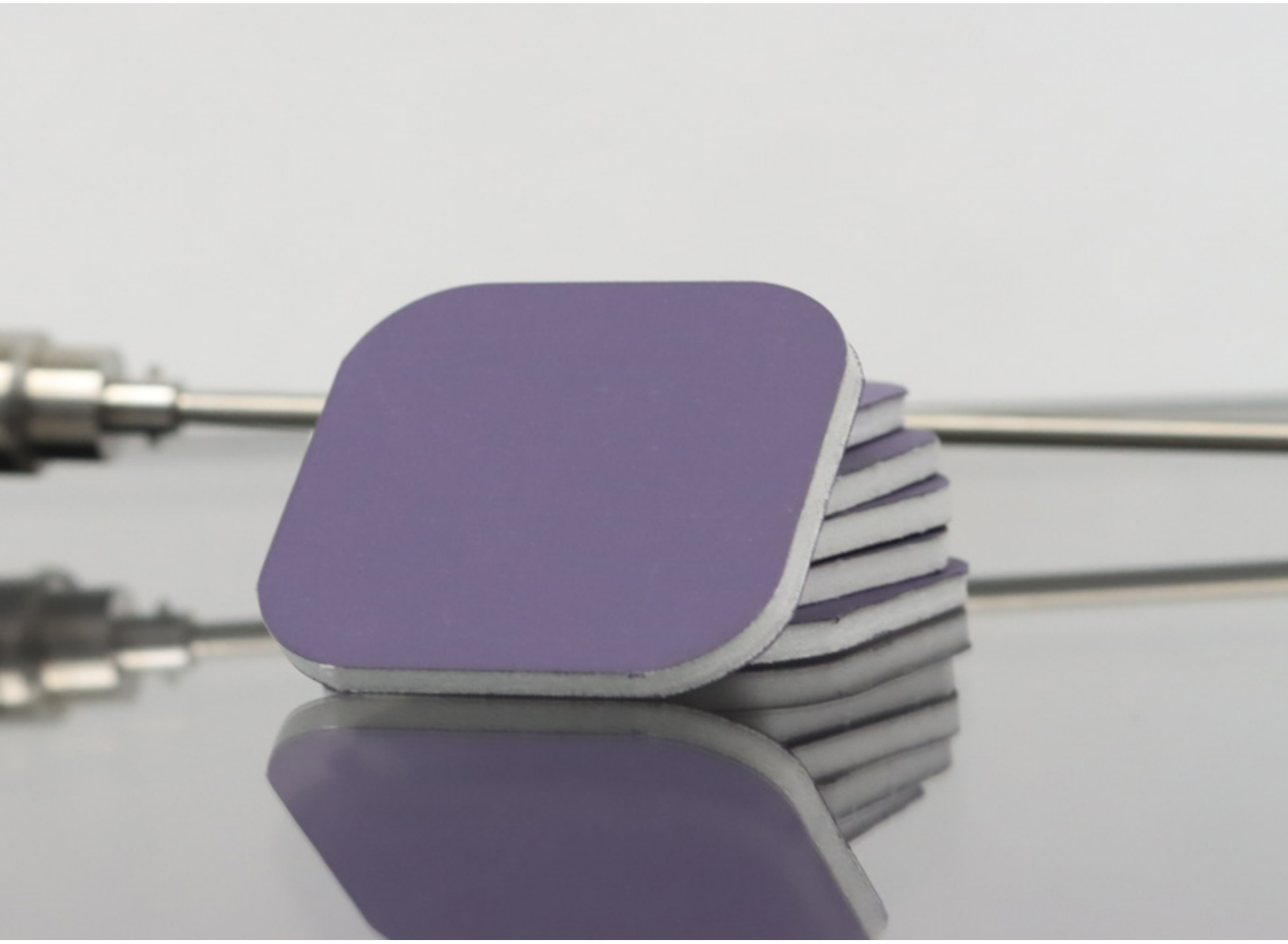
DOMICO™
Med-Device

Non-Sterile Buffing Pad

Instructions for Use



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IMPORTANT INFORMATION

The instructions in this document refer to the product with the following identification:

- **Manufacturer:** Domico Med-Device, LLC
- **Part Number:** 6002
- **Product Name:** Non-sterile Buffing Pad
- **Type Designation:** Non-sterile Disposables
- **Serial Number:** See Identification Tag
- **Manufacture Date:** See Identification Tag

Manufactured By

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Intended Use

The Non-Sterile Buffing Pad, designed for use on rigid endoscopes, features a buffing surface that helps reduce debris from the lens.

Contraindications

- Product is not to be used with any tools, equipment, or machinery other than rigid endoscopes.
- Buffing pads should not be used on surfaces that are extremely hot, as the heat can degrade the pad material, causing it to lose its integrity and effectiveness.
- Avoid using the buffing pad with chemicals or solvents (e.g., acids, cleaners) that could degrade the pad material or react with the surface, leading to damage or poor performance.
- The Non-Sterile Buffing Pad is not intended for use during surgical procedures or in aseptic surgical environments. Use of this device in such settings may compromise sterility and increase the risk of infection. The buffing pad is designed for pre-procedural and post-procedural cleaning only.

Key Operational Characteristics

- Efficient buffing surface that easily reduce debris from scope
- Double sided buffing surface for increased buffing capacity
- Ergonomic design that allows for easy handling
- Flexible surface ensures thorough contact with contour of lens window

Intended Users

- The device may be operated only by medical staff who have read this manual and are familiar with proper handling of an rigid endoscopes.

Safety Liability

Domico Med-Device, LLC assumes no liability for the safe and reliable operation of the Non-Sterile Buffing Pad being used other than its intended use as stated above.

WARNING!

To reduce risk of injury to user(s) and patient(s), user(s) must carefully read and understand this document

Patient Target Groups

Age, health, condition - No special limitations

Product Lifetime

The Non-Sterile Buffing Pad is a single use disposable product. The Non-Sterile Buffing pad has a shelf life of 1 year from the manufactured date (ref identification tag).

Environmental Conditions

Environmental conditions for transport and storage:

Ambient Temperature	-10°C to +60°C
Relative Humidity	20% to 75%
Atmospheric Pressure	500 hPa to 1060 hPa

Environmental conditions for use:

Ambient Temperature	-10°C to +60°C
Relative Humidity	20% to 75%
Atmospheric Pressure	500 hPa to 1060 hPa

In The Event Of An Incident

Any serious incident occurring in connection with this device must be reported to the manufacturer and the relevant authority of the member state in which the user and/or patient is based.

Compatibility With Other Medical Devices

The buffing pad is intended to assist in reducing debris and residue from the lenses of rigid endoscopes, enhancing clarity during procedures. It can also be used to clean rigid endoscopes after procedures to maintain optimal lens performance. The buffing pad is compatible with rigid endoscopes.

Instructions

1. Grasp the distal end of the scope, using your index finger to supporting the back side of the scope tip.
2. Hold polishing pad firmly between the thumb and index & middle fingers of your opposite hand.
3. With steady and moderate pressure, place polishing pad against the distal window of the rigid endoscopes.
4. Maintain consistent pressure from the polishing pad onto the distal window of the rigid endoscopes as you "drag" the polishing pad across the window. Repeat 5 to 10 times.
5. Inspect scope and or image for clarity. Repeat if necessary.

CAUTION!

Be careful not to bend the shaft of the scope while buffing

Other Useful Tips

WARNINGS

- DO NOT use with chemicals or solvents (e.g., acids, cleaners) that could degrade the pad material or react with the surface.
- DO NOT make any modifications to pads, as they may compromise the safety of the device and may result in harm to the user or patient.
- DO NOT resuse pads, single patient use.

Warnings: Symbols Used In This Manual

Symbol	Hazard Level	Meaning
	DANGER!	Indicates a direct and immediate risk that may be fatal or cause very serious injuries potentially leading to death.
	WARNING!	Indicates a potential risk that may cause injuries, health hazards or serious material damage leading to injury.
	CAUTION!	Indicates a potential risk that may cause material damage.

Table 1: Hazard levels of safety instructions

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer.
	Non Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.

Additional symbol definitions can be found at https://www.domicomed.com/symbols-glossary

Standards Applied

This device complies with the safety requirements of the following standards and directives:

Reference	Title
IEC 62366-1:2015+AMD1:2020 EN 62366-1:2015/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 20417:2020 EN ISO 20417:2021	Medical devices - Information provided by manufacturer
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be provided by manufacturer Part 1: General requirements

Quality Management

Reference	Year	Title
ISO 13485 EN ISO 13485	2016 2016	ISO 13485:2016 EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971 EN ISO 14971	2019 2019	ISO 14971:2019 EN ISO 14971:2019 Medical devices – Application of risk management to medical devices
21 CFR Part 11	2021	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 11 - Electronic records, electronic signatures
21 CFR Part 820	2021	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices PART 820 - Quality System Regulation

Environmental Standards & Regulations

Reference	Year	Title
Regulation 1907/2006	2006	Registration, evaluation and authorization of chemical substances, as well as the restrictions applicable to these substances
US California Proposition 65 Act	1986	The Safe Drinking Water and Toxic Enforcement Act of 1986
Directive 2018/851	2018	Directive amending Directive 2008/98/CE concerning waste

Warranty and Storage

Limited Warranty

Domico Med-Device, LLC warrants to Customer that this product, manufactured by Domico Med-Device, LLC and sold to customer, will be free from defects in materials and workmanship for a period of one (1) year after delivery to Customer. This warranty shall not apply to any products which have been subjected to misuse, improper installation, alteration, neglect, accident, abnormal conditions of operation, or use under conditions other than those for which the products were designed.

EXCEPT FOR THE FOREGOING LIMITED WARRANTY, SELLER MAKES NO OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING ALL WARRANTIES OF FITNESS OR OF MERCHANTABILITY.

Disposal

Disposed of in an environmentally safe manner, per local governmental guidelines.

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Subject to Technical Changes

The illustrations and technical specifications provided in this manual may, on account of future product developments, differ slightly from the actual product supplied.