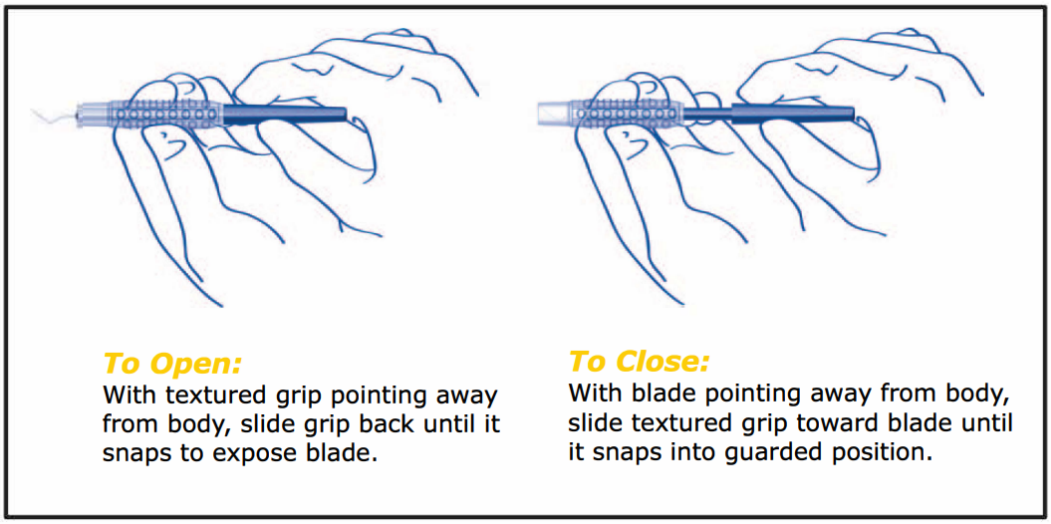
PROTEKT™ Sharps Safety Knives

THE SNAP-SAFE HANDLE DIRECTIONS FOR USE



To Open:
With textured grip pointing away from body, slide grip back until it snaps to expose blade.

To Close:
With blade pointing away from body, slide textured grip toward blade until it snaps into guarded position.

Basic UDI: 081305901ProTekt-IsrNF

The ProTekt™ Sharps Safety Knife with our patented Snap-Safe™ handle features premium quality blades manufactured using ExactEtch™ Technology with the safety of a sliding protective sheath.
They are available in a wide variety of blade styles including trapezoid, paracentesis, slit, precision depth, clear corneal and crescent designs. Six (6) knives per box.

Call 800-867-8081 (US), 281-367-8081 or visit our website at www.diamatrix.com for more information.

US Patent No. 5,254,128

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ProTekt Multi-Use (Reusable) Directions for Use
DMR-001-PL-5-Multi-Use, Version 5
Effective: 2026-09-30

ProTekt Multi-Use Knives - Directions for Use

1. Description and Intended Use

Diamatrix ProTekt Multi-Use Sharps Safety Stainless Steel Knives are for ophthalmic surgery. These knives are equipped with a sliding protection sheath to address and conform to the various regulatory requirements regarding needlestick injury prevention. They are provided sterile via irradiation. These instruments are produced using the most up to date technology available as well as to applicable international standards. The use of them is apparent to qualified personnel.

2. Clinical Benefits

The primary benefit is achieving precise incisions due to their consistency of sharpness. Secondary benefits may include a reduction in incision distortion, minimization of tissue trauma, a reduction in the potential of surgical-induced astigmatism due to no suture needed, and shorter healing time. Although these benefits are not directly related to a diagnosis or public health, they do contribute to the successful outcome of the surgery in which the ophthalmic microsurgical knife is used, and a successful surgery is expected to have a positive outcome with respect to individual patient's health.

3. Device Lifetime

If the device passes the visual inspection as described in these instructions for use, the device can be expected to perform as intended during the surgical period.

4. Precautions and Warnings

- The knife is provided sterile and may be used the first time without the need for any processing. Additional uses will require reprocessing per the directions beginning section 6.2.
- The knife may be used only by well-trained ophthalmic physicians and personnel.
- The end of product life is recognized by decreased sharpness and appearance of wear on the handle. The maximum number of reprocessing cycles has been validated at ten (10). However, sound professional judgment must always be used in determining if a device is fit for use. Dull or damaged devices should not be reused.
- To provide a long lifetime and smooth function, all instruments should be thoroughly cleaned and dried immediately after surgery. Any remnants, especially saline solution, left on the instruments could trigger irreversible corrosion and other damage.
- The settings for cleaning, disinfection and sterilization represent the recommended and approved configuration by Diamatrix Ltd. It is not possible to provide guaranteed parameters due to the variations found in reprocessing/sterilization devices and the variable bioburden on devices in clinical use. Validation of individual equipment and verification of sterility assurance level (achieved with a given sterilization device) must be performed by each facility in accordance with local regulations.
- Refer to the safety instructions for the use of cleaning and disinfecting solutions and to the facility's hygienic instructions.
- This device is not validated for prion deactivation. In procedures where prion contamination is suspected, single-use alternatives are recommended.
- If any instrument is received in defective condition, Diamatrix Ltd. should be notified. Never use damaged or defective devices. To avoid injury, the product should be carefully examined prior to use.
- There are no contra-indications currently with the device.
- Breakage, slippage, misuse, or mishandling of these devices, such as on sharp edges, may cause injury to the patient or operative personnel.
- Improper handling can render the instrument unsuitable for its intended use or even dangerous to the patient or surgical staff.

5. Directions for Use

The knives are packaged with the protection sheath engaged. Immediately prior to use, slide the protection sheath to the rear of the instrument making sure it is locked – feel for increased resistance and listen for a “click” sound. In doing so be aware that the blade will be exposed at the front end and can produce a danger of injury. For safety, slide the protection sheath back to the “guarded” distal position immediately after use. Again, listen for the “click” sound to ensure the sheath is properly engaged.

NOTE: The knife may be reused on the same patient during the same surgical procedure, provided the device remains within the sterile field, and is not contaminated.

6. Cleaning, Disinfection, and Sterilization

6.1. General

The instrument is made from the following materials: stainless steel and plastic. All applied reprocessing procedures must be compatible to the listed materials.

- The instrument can withstand temperatures up to 140°C (284°F), meaning it can withstand any 132°C (270°F) or 134°C (273°F) autoclave procedure. Do not use original packaging material as a sterilization container.
- Never immerse the hot instrument in cold liquid, allow it to cool by air.
- Prevent blade from touching any hard surface, it could be damaged. Slide the protective sheath to the “guarded” distal position whenever possible.
- If the instrument is not reprocessed immediately after the procedure, minimal care is to rinse it with USP grade sterile water for irrigation (SWI) and to dry it with air from a syringe or with filtered compressed air

6.2. Manual Cleaning and Disinfection

6.2.1. Point-of-use Treatment

- Immediately after use, with the guard closed, place the knife in a clean basin or tray containing sterile water for irrigation (SWI).
- Ensure the knife does not contact other instruments or objects. Do not scrub, flush, or wipe the blade tip at this stage.
- If immediate cleaning is delayed, cover the knife with a moistened lint-free cloth or use a validated holding solution per facility protocol.

6.2.2. Blade Cleaning (Using DUL50 System)

1. Set the blade to the open position by sliding the textured grip back until it snaps open.
2. Insert the blade vertically into the blue scrubbing pad of the DUL50 system. Use a gentle 1–2 inch cutting motion and make several passes.
3. Insert the blade into the first white rinse pad (left) and make several cutting-like passes.
4. Insert the blade into the second white rinse pad (right) and make several cutting-like passes.
5. Optionally, perform a final rinse using a 10 cc syringe filled with SWI.
6. Retract the blade by sliding the grip forward until it snaps closed.

6.2.3. Handle Cleaning

1. Inspect the handle for visible soil, damage, or corrosion.
2. Rinse the handle under running tap water for at least 30 seconds.
3. Immerse the handle in a neutral pH cleaning solution compatible with surgical instruments and soak for at least 5 minutes.
4. While submerged, gently wipe or brush all exterior surfaces with a soft cloth or soft brush.
5. Rinse the handle thoroughly under running tap water for at least 30 seconds.
6. Perform a final rinse under deionized or distilled water for at least 30 seconds.
7. Dry the handle using a lint-free cloth or low-pressure filtered air.

6.2.4. Final Inspection

Check that the blade is intact and undamaged and that the handle is clean before use. Do not use if the blade appears damaged or dull.

Note(s):

- Do not disassemble the handle.
- Do not use ultrasonic cleaners unless validated for this product.
- Use only neutral pH cleaning solutions compatible with surgical instruments and follow the solution manufacturer's instructions.
- Follow local facility protocols and national reprocessing guidelines.
- Inspect the knife for visible soil, damage, and function. If soil remains, reprocess or perform manual cleaning.

6.3. Automated Cleaning and Thermal Disinfection

1. Follow the washer/disinfector manufacturer's instructions, using the delicate cycle.
2. Use only neutral pH cleaning solutions compatible with ophthalmic surgical instruments.
3. If visible soil is present, perform manual cleaning and disinfection steps listed in 6.2. If protein deposits are suspected, enzymatic cleaners may be used per the cleaner manufacturer's instructions. Rinse thoroughly.
4. Ensure the knife is positioned to allow effective drainage and prevent damage. Use suitable carriers or trays to prevent movement or contact with other instruments.
5. Process the knife using the following conditions:

Phase	Time	Temperature
Pre-Wash	3 min	30°C (86°F)
Wash (1)	10 min	40°C (104°F)
Wash (2)	10 min	30°C (86°F)
Rinse	3 min	30°C (86°F)
Heated Rinse	50 min at 80°C (176°F) or 10 min at 90°C (194°F)	
Drying	By observation, do not exceed 110°C (230°F)	

6. After processing, inspect the knife for visible soil, damage, and function. If soil remains, reprocess or perform manual cleaning.

6.4. Sterilization

1. Diamatrix's Multi-Use ProTekt knives are delivered to the end user as gamma sterilized. Sterilization is not required for initial use. For subsequent uses these knives shall be sterilized before each use.
2. The ProTekt Knives must be sterilized with the safety guard extended.
3. Sterilization trays must be lined with protective materials (knobbed mats).

Sterilization Method	Sterilization Type	Sample Load	Temperature	Sterilization Duration in Minutes
Steam	Gravitation procedure	Sterile barrier system- Double package: STERKING – R43 type inside. STERKING – R43 type outside.	134ºC (273ºF)	15 minutes
Steam	Pre-vacuum procedure		134ºC (273ºF)	5 minutes

Note: The sterilization methods described above were tested and validated according to EN ISO 14937.

To maintain effectiveness of the blade during its useful life, avoid touching the blade tip with any material other than the ones described in this document.

7. Storage

Sterile instruments should be stored in an area that provides protection from the loss of sterility.

8. Repair Service

These instruments are not foreseen for repair.

9. Further Information

In the case of a complaint, malfunction, or for supplementary information, please contact Diamatrix Ltd. Any Health Care Professionals (i.e. customer users of Diamatrix Ltd. products) who have any complaint or who have experienced dissatisfaction in the product quality, durability, reliability, safety, effectiveness, performance and/or if injuries were sustained related to the use of these products, should notify Diamatrix Ltd. as soon as possible.

Patients in the European Union experiencing a serious incident in relation to the device should contact Diamatrix and the competent authority of the Member State in which they are established.

DMR-001-PL-5-Multi-Use (Reusable) (DOC-1374) Ver. 3

Approved By:

(CO-330) ProTekt IFU Update

Description

For ProTekt Reusable IFU * Update to change validation from 15 to 10. * Incorporation of feedback from users * Update of EC rep symbol to EU rep symbol For ProTekt Single Use IFU * Update of EC rep symbol to EU rep symbol

Justification

Continuous improvement

Assigned To:	Initiated By:	Priority:	Impact:
RookQS - Jakemia Barnette	RookQS - Jakemia Barnette	Medium	Minor

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