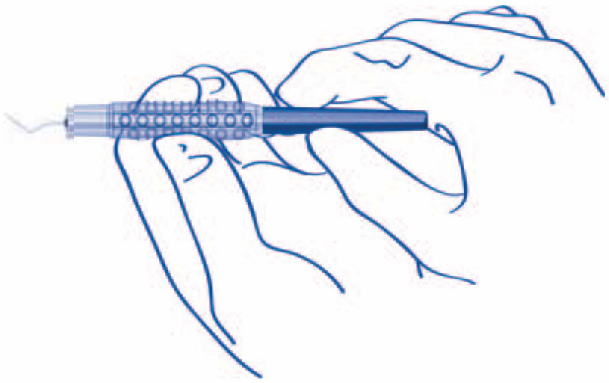
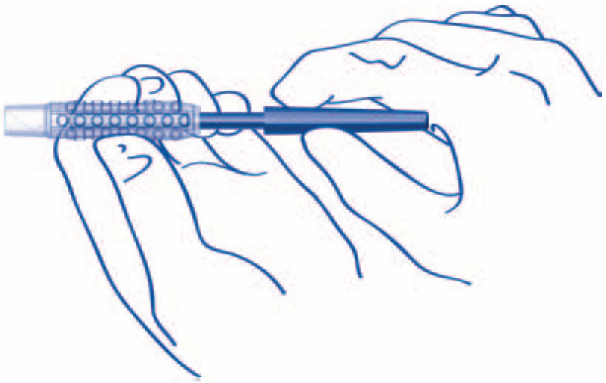
PROTEKT™
Sharps Safety Knives

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.

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 web-site at www.diamatrix.com for more information.

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Quality • Value • Innovation

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ProTekt Single-Use Knives - Directions for Use

1. Description and Intended Use

Diamatrix ProTekt Single 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 needle stick injury prevention. These instruments are produced using the most up to date technology available as well as to applicable international standards. The primary patient benefit is achieving precise incisions. Secondary benefits may include a reduction in wound leakage and / or avoidance of other methods of incisions during surgery (such as radiosurgery). 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. The use of them is apparent to qualified ophthalmic personnel.

- The blade is a rigid component that when pushed into the eye is sharp enough to perform a smooth cut. The size of the cut will be governed by the dimensions of the blade and the portion and dimension of the blade applied to the ophthalmic surgeon.
- Refer to the blade description provided on the label for important specifications prior to use.

2. Precautions and Warnings

- The knife may be used only by well-trained ophthalmic physicians and personnel.
- These products are for SINGLE PATIENT USE ONLY.
- If an instrument is received in defective condition, consult a healthcare professional and inform Diamatrix Ltd. Never used 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.
- There is no preparatory treatment necessary. The device is ready for use.

3. Possible Adverse Events

- 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.
- In case of a serious incident that occurs with the device, report it to Diamatrix Ltd. In the European Union, also inform the Competent Authority of your Member State.

4. 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.

5. Packaging

These products are supplied sterile and are labeled as such on the package label. The sterility can only be assured if the packaging is intact. This STERILE product is intended for SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE THE PRODUCT. DIAMATRIX LTD ASSUMES NO LIABILITY FOR PRODUCTS WHICH HAVE BEEN RESTERILIZED. DO NOT USE IF THE STERILE BARRIER OR PACKAGING HAS BEEN DAMAGED OR UNINTENTIANALLY OPENED BEFORE USE. Products should be carefully checked for signs or damage prior to use. Damaged packages or products should not be used, and Diamatrix Ltd. should be notified. Only sterile product should be used in surgery. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

6. Storage

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

7. Repair Service

These instruments are not foreseen for repair.

8. Disposal

After use, the device is considered potentially contaminated and hazardous. Safe disposal of the device needs to occur in accordance with local regulations.

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.

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