

Document TF-30005
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. 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.

Please note an important distinction between item numbers ending in "MU" vs "NS":

- For item numbers ending in "MU" the knife is provided sterile and may be used the first time without the need for any processing. Additional uses will require reprocessing per these directions beginning with 4.2.1.
- For item numbers ending in "NS" the knife is provided non-sterile and must be sterilized per these directions for both the first and any subsequent uses beginning with 4.2.1.

2. Precautions and Warnings

- The knife may be used only by well-trained 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 fifteen. However, sound professional judgment must always be used in determining if a device is fit for use.
- To provide a long lifetime and smooth function, all instruments should be 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.
- If a prion inactivation is required, use sterilization at 134°C or NaOH procedure. Do not expose the instrument to NaClO – as this would cause irreparable damage! No prion inactivation validation has been performed by Diamatrix Ltd. due to missing international standards. It is the user-facility's responsibility to apply an efficient and approved procedure that complies with local regulations.
- If any instrument is received in defective condition, Diamatrix Ltd. should be notified. Never use damaged or defective devices.

3. 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 sharp blade will be exposed at the front end – danger of injury. For safety, slide the protection sheath back to the "guarded" distal position immediately after use. Again, listen for a "click" sound to ensure the sheath is properly engaged.

4. Cleaning, Disinfection, Prion Inactivation and Sterilization

4.1 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 instrument 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.

4.2 Cleaning and Disinfection

- 4.2.1 Immediately after each use, and prior to the initial use for item numbers ending in "NS", the blade should be thoroughly rinsed with SWI using a 10cc syringe, taking care not to touch the blade with anything other than fluid.
- 4.2.2 With blade extended from handle, submerge the blade only into an ultrasonic cleaner unit containing ammoniated solution or other industry-standard instrument cleaning agent. Hold the blade in the solution for one (1) minute.
- 4.2.3 Using SWI in a Steam Generator Cleaner, rinse the blade with flowing steam for 10 seconds, taking care not to touch the blade with anything other than flowing steam (validated method) or submerge blade in ultrasonic unit filled with disinfection solution for one (1) minute.
- 4.2.4 Repeat step 4.2.3 at least once.
- 4.2.5 Retract the blade into the handle after cleaning.
- 4.2.6 To ensure cleanliness and the condition of the blade, prior to surgical use qualified personnel must inspect the device under a microscope at not less than 40x to insure the knife is in proper condition for the procedure.

4.3 Prion Inactivation

This instrument has been designed to withstand temperatures of up to 140°C (284°F) and to withstand NaOH. Any aggressive chemical procedure will compromise the product lifetime. To minimize risk, rinse carefully and, if required, neutralize the instrument. Please follow local regulations carefully.

4.4 Drying and Additional Care

- 4.4.1 Submerge the blade only into a container of fresh 70% isopropyl alcohol. Swish gently to thoroughly wet the blade end with the isopropyl alcohol.
- 4.4.2 Dry knife thoroughly with filtered compressed air. Hold and rotate the knife in the stream of air for a period of 15-20 seconds or until there is no visible sign of moisture on the knife.
- 4.4.3 Package each knife in a Diamatrix autoclaveable sterilization tray, or an industry-standard disposable sterilization pouch. Include a steam sterilization chemical indicator in each package.

4.5 Sterilization

- The knife must be cleaned, disinfected and dried prior to sterilization.
- Sterilizing the knife has been validated using
 - Flash steam sterilization cycle of 132°C (270°F) for 4 minutes and a 1 minute drying time;
 - Gravity autoclave cycle at 121°C (250°F) @ 15 lbs for 15 minutes or 132°C (270°F), 15lbs for 10 minutes
 - Standard autoclave cycle of 20 minutes at 132°C (270°F)
 - PREVAC cycle of 5 minutes @ 132°C (270°F)
- Facilities that sterilize using different parameters must validate the process independently.

5. Repair Service

These instruments are not foreseen for repair.