



## Diamatrix Diamond Knives Directions for Use

### 1. Description and Intended Use

Diamatrix Diamond knives (DDK) are for ophthalmic surgery. These knives are equipped with a spring-loaded retractable blade on the distal end 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.

### 2. Precautions and Warnings

- The knife may be used only by well-trained physicians and personnel.
- Before use, the knife needs to be cleaned and sterilized.
- Prior to each use, the blade must be thoroughly inspected for sharpness, wear, calibration and damage.
- The end of product life is recognized by decreased sharpness, blade looseness, out-of-tolerance calibration (if applicable), handle malfunctions and appearance of wear and tear (damage). The exact number of reprocessing cycles cannot be determined as it depends on many factors.
- To provide a long life, the knife must be cleaned and dried immediately after surgery.
- The parameters for cleaning, disinfection and sterilization represent the recommended and approved procedure 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 hospital in accordance with local regulations.
- Refer to the safety instructions for the use of cleaning and disinfecting solutions and to the hospital'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. as there are no 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 knife is packaged in a sterilization container with the blade in the retracted position. Immediately prior to use, expose the blade from the handle of the knife by pushing the proximal end of the handle in the direction of the handle barrel. For safety, retract the blade immediately after use.

### 4. Cleaning, Disinfection, Prion Inactivation and Sterilization

#### 4.1 General

The instrument is made from the following materials: natural diamond, titanium, stainless steel, aluminum (in product numbers beginning with "L" only) and epoxy resin. 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.
- 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.
- Ensure the blade is always in the retracted 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

##### • Ultrasonic Cleaner Method

1. Immediately after each use, and prior to the initial use, the blade should be thoroughly rinsed with SWI using a 10cc syringe, taking care not to touch the blade with anything other than the fluid.
2. With the blade extended from the handle, submerge the blade only into an Ultrasonic Cleaner Unit containing ammoniated cleaner. Hold the blade in the solution for one (1) minute.
3. Using SWI in a Steam Generator Cleaner, rinse the blade with flowing steam for ten (10) seconds, taking care not to touch the blade with anything other than flowing steam.
4. Repeat step 3 at least once.
5. Retract the blade into the handle after cleaning
6. Inspect the blade under microscope not less than 40x to insure cleanliness and the condition of the blade. Prior to surgical use, qualified personnel must inspect device under microscope at not less than 40x to insure knife is in proper condition. Pay particular attention to calibration (if applicable), possible blade looseness, and cutting edge condition. IF KNIFE APPEARS TO BE DEFECTIVE, DO NOT USE. CONTACT DIAMATRIX TO OBTAIN AN RGA NUMBER FOR REPAIR.

##### • DiaClean™ Method

1. Immediately after each use, and prior to the initial use, the blade should be thoroughly cleaned with the DiaClean™ Diamond Knife Cleaning System. Fully expose the blade and gently insert it into the blue colored wet cleaning pad located in the larger of the three compartments.
2. Gently pass the blade back and forth and through the cleaning pad several times in a cutting fashion, creating approximately a ½ inch incision in the pad.
3. Repeat Step 2 until all visible residue is removed from the blade.
4. Rinse the DiaClean™ solution from the blade by repeating the cutting motion in both of the smaller compartments located on the tray. Always start with the compartment to the left and above the blue colored pad, and perform a final rinse with the compartment to the right.
5. Retract the blade into the handle after cleaning
6. Inspect the blade under microscope not less than 40x to insure cleanliness and the condition of the blade. Prior to surgical use, qualified personnel must inspect device under microscope at not less than 40x to insure knife is in proper condition. Pay particular attention to calibration (if applicable), possible blade looseness, and cutting edge condition. IF KNIFE APPEARS TO BE DEFECTIVE, DO NOT USE. CONTACT DIAMATRIX TO OBTAIN AN RGA NUMBER FOR REPAIR.

#### 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

1. Submerge the blade end only into a container of fresh 70% isopropyl alcohol. Swish gently to thoroughly wet the blade end with the isopropyl alcohol.
2. Dry DDK thoroughly with filtered compressed air. Hold and rotate the DDK in the stream of air for a period of 15-20 seconds or until there is no visible sign of moisture on the DDK.
3. Package each DDK in a Diamatrix autoclaveable sterilization tray. Include a Biological Indicator in each package/box.

#### 4.5 Sterilization

- The knife must be cleaned, disinfected and dried and properly packaged prior to sterilization.
- Sterilizing the DDK using a flash steam sterilization cycle of 132°C (270°F) for 4 minutes and a 1 minute drying time, a gravity autoclave cycle at 121°C (250°F) @ 15 lbs for 15 minutes, or a standard autoclave cycle of 20 minutes at 134°C (273°F) have been validated. Facilities that sterilize using different parameters must validate the process independently.

### 5. Repair Service

- The knife should be inspected by the Diamatrix Repair Department annually to ensure the knife is within specifications.
- If damage occurs to the knife or if it not performing properly, contact Diamatrix at 800-867-8081 or 281-367-8081 to receive an RGA number.
- See the reverse side of this document for proper shipping and packaging instructions.

## IMPORTANT REMINDERS REGARDING CLEANING OF DIAMATRIX DIAMOND KNIVES

- DO NOT USE PEROXIDE ON THE KNIFE.
- DIAMATRIX DIAMOND KNIVES ARE INTENDED FOR STEAM AUTOCLAVE STERILIZATION ONLY. DO NOT USE GAMMA, ETO, CHEMICAL OR DRY HEAT STERILIZATION METHODS AS SIGNIFICANT DAMAGE TO THE KNIFE COULD OCCUR.
- THE BLADE SHOULD ONLY BE EXPOSED WHEN IT IS IN THE SURGEON'S HANDS, WHEN IT IS BEING RINSED WITH SWI, WHEN IT IS BEING SUBMERGED IN THE ULTRASONIC CLEANER OR *DIACLEAN*<sup>™</sup> CLEANING TRAY, WHEN IT IS BEING CLEANED WITH THE STEAM CLEANER OR WHEN IT IS BEING INSPECTED UNDER THE MICROSCOPE.
- DO NOT SUBMERGE THE ENTIRE KNIFE IN THE ULTRASONIC SOLUTION, ONLY SUBMERGE THE BLADE.
- SEND THE KNIFE TO DIAMATRIX ANNUALLY FOR A COMPLETE INSPECTION.

### CLEANING PRODUCTS:

DUL 50 *DIACLEAN*<sup>™</sup> CLEANING SYSTEM

## RETURN PACKAGING / SHIPPING INSTRUCTIONS

1. To comply with OSHA Bloodborne Pathogens Standards, the device must be sterilized prior to shipment. If it is not, the shipment must be labeled as a biohazard.
2. Secure the instrument in the sterilization container it was originally supplied with using a cable tie or similar device.
  - a. If the blade is loose, please indicate so by putting a note on the sterilization tray.
  - b. If the blade will not retract into the handle, cover the exposed blade by placing a Styrofoam packing peanut or a plastic instrument guard over the blade.
  - c. If the blade has fallen out of the handle, locate the blade and secure it to a thick piece of paper, such as a business card or post-it-note, using scotch tape. Indicate the paper has a blade attached to it and place it in the sterilization container.
3. Place the cover on the sterilization container and wrap the sterilization container in bubble wrap or other suitable material.
4. Box and ship to our facility, making sure to include a contact name and telephone number. Diamatrix recommends using a time-definite service and insuring the knife for its original cost. Diamatrix does not assume responsibility for shipping loss or damage.

## WARRANTY INFORMATION

### New Knives:

#### New Diamond Knife Warranty:

All Diamatrix Diamond Knives are guaranteed against defects in materials and workmanship. All items must be inspected immediately upon receipt and any damage reported to Diamatrix within 24 hours. Sterilization of the product indicates acceptance.

Handle - Lifetime Warranty (Item Numbers Beginning with "N") or Two Year Warranty (Item Numbers Beginning with "L")

Epoxy - One Year\*

Blade - Defect Free at 300x Upon Delivery

#### Returns:

Product returned for any reason must have a valid authorization number. Call 281-367-8081 to obtain an RGA number. Items must be returned within 10 days in the original packaging. Upon inspection by Diamatrix, a credit will be issued to your account, minus a 15% restocking fee. Custom orders cannot be returned.

\*Accounts that return their knives for the complimentary cleaning and inspection service on the one-year anniversary of the purchase of the knife will have their epoxy warranty extended for an additional year.

### Repaired Knives:

All Diamatrix Diamond Knife Repairs are guaranteed against defects in materials and workmanship. All items must be inspected immediately upon arrival and any damage reported to Diamatrix within 24 hours. Sterilization of product indicates acceptance.

#### Handle Repair:

Diamatrix - Lifetime Warranty (Item Numbers Beginning with "N") or Two Year Warranty (Item Numbers Beginning with "L")

Others - None

Calibration - One Year

Epoxy - One Year\*

Blade - Defect Free at 300x Upon Delivery

\*Accounts that return their knives for the complimentary cleaning and inspection service on the one-year anniversary of the purchase or repair of the knife will have their epoxy warranty extended for an additional year.

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