



NANO ENGINEERED DIAMOND KNIFE REPROCESSING INSTRUCTIONS

 **Please read before use!**

DESCRIPTION: NANO Engineered Diamond Knives are reusable instruments, consisting of a handle and an engineered diamond blade. These blades are made from engineered Nano diamond by chemical vapor deposition process; the handles are made from anodized aluminum.

APPLICATIONS: NANO Engineered Diamond Knives are designed for various microsurgery incisions.

PRECAUTIONS:  NANO Engineered Diamond Knives are not sterile and **must be sterilized before use.** 

INSTRUCTIONS FOR USE:

- NANO Engineered Diamond Knives **must be thoroughly cleaned and sterilized before use**; knives must also be cleaned and then sterilized and inspected after each subsequent use. For instructions on how to clean and sterilize NANO Engineered Diamond Knives please refer to the sections of this IFU entitled **Cleaning** and **Sterilization**.
- The NANO Engineered Diamond Knives **must never** come into contact with other instruments during surgical operations or during cleaning and sterilization.
- The NANO Engineered Diamond Knives must be cleaned immediately after each use; this prevents drying of cell particles, tissue, blood, viscoelastic material on the blade after use.
- Before use, inspect Nano blades to ensure blades are not damaged. Damaged Nano blades shall not be used for surgery.

After every use of a NANO Engineered Diamond Knife, care must be taken to ensure that the blade is retracted into the protective sleeve.

CLEANING NOTE:

- NANO Engineered Diamond Knives are made from an extremely hard but brittle material. Handle these ultra-sharp blades carefully to prevent damage and personal injury.
- Mechanical contact with other surgical instruments **must** be avoided to prevent damage to the diamond engineered blade.
- The blade must be immediately retracted into the protective sleeve after each use.
- NANO Engineered Diamond Knives must **never** be stored un-cleaned.
- **NANO Engineered Diamond Knives must be cleaned and sterilized before each use.**

The machine cleaning process and the manual cleaning process were performed and validated by SMP GmbH, D-72072 Tübingen, Germany, with the criteria listed in the following table.

No.	Criterion	Acceptance level	References
1	There shall be no soil visible on the sample at the end of the cleaning process	N/A	EN ISO 15883-1:2014 / RKI guideline: 2012 AAMI TIR 30: 2011 /Guideline DGKH, DGSV, AKI: 2014
2	The total amount of protein per sample shall be	<100 µg	RKI guideline: 2012
3	The total amount of protein per sample shall be	< 200 µg	EN ISO 15883-1:2014
4	The amount of protein/cm ² shall be	< 6.4 µg/cm ²	AAMI TIR 30: 2011 Alfa et al AJIC 1999
5	The amount of protein/cm ² shall be	< 3.0 µg/cm ²	Guideline DGKH, DGSV, AKI: 2014
6	The amount of hemoglobin/cm ² shall be	< 2.2 µg/cm ²	AAMI TIR 30: 2011 Alfa et al AJIC 1999
7	The total amount of radioactivity per sample shall be	< 5 cps	SMP Report 11011010605: Validation of the acceptance criteria of the Radionuclide Method as performed by SMP GmbH

MACHINE CLEANING: Use the following process steps for automated cleaning. Prior to cleaning, the recommended washer-disinfector is the Miele Professional G 7836 CD or equivalent.
Do not clean NANO Engineered Diamond Knives in ultrasound cleaning systems.

Note: To prevent damage to the NANO Engineered Diamond Blades, care must be taken to avoid contact with other instruments. Load knives into washing machines with care. During the entire automated cleaning process, **the blade must be retracted** into the protective sleeve.

1. **Ensure that blade is retracted into the protective sleeve**
2. Place NANO Engineered Diamond Knives securely in a Knife sterilization tray (Example: Katena K9-2024).
3. Perform 2 minute pre-cleaning with cold tap water
4. Complete 5 minute cleaning with 55°C tap water and 0.5% cleaning solution Neodisher Mediclean Forte (Dr. Weigert, D-Hamburg) **or equivalent solution.**
5. Drain
6. Complete 3 minute rinsing with cold deionized water
7. Repeat drain
8. Complete 2 minute rinsing with cold deionized water
9. Repeat drain

MANUAL CLEANING:

1. Brush the handle of the knife under running cold tap water with a soft nylon brush until it's visibly clean. The blade has to be retracted into the protective sleeve.
2. Extend the blade and rinse the blade under running cold tap water for 10 seconds or until all visible soil is removed. The blade shall not come into contact with another object.
3. Place the knife (with the blade retracted into the protective sleeve) in a 0.5% cleaning solution of Neodisher Mediclean Forte (Dr. Weigert, D- Hamburg) **or equivalent** at room temperature (20°C ± 2°C) for 10 minutes.
4. Rinse the knife under running deionized water (room temperature 20°C ± 2°C) for 1 minute.

After cleaning, the condition of the instrument must be checked. Visually inspect the blade to ensure that it is not broken or chipped. Following this, the knife must be immediately placed in the sterilization box or in another suitable container.

STERILIZATION:

- NANO Engineered Diamond Knives **must be sterilized before each use.**
- NANO Engineered Diamond Knives must be sterilized with the diamond blade retracted into the protective sleeve. Users shall ensure that the blade is retracted into the protective sleeve during sterilization process. The below sterilization parameters have been validated according to EN ISO 14937

Sterilization method	Type of sterilization	Item loaded	Temperature	Sterilization time
Steam	Gravity Displacement Mode	Double wrapped	132°C (270°F)	15 minutes
Steam	Pre-vacuum Mode	Double wrapped	132°C (270°F)	4 minutes

REGULATORY INFORMATION:

Notice: Any serious incident that occurs in relation to this product should be reported to the manufacturer, and to the healthcare authority of the country in which the incident occurred.

DISPOSAL:

Follow country specific laws and regulations for proper disposal, including procedures for disposal of sharps and/or biohazardous material.

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