



Instructions for use

Meyco Nano-diamond scalpels

Legend to Symbols:

Manufacturer	Article Number	Unsterile	Directions for use to consider	Attention	CE Klasse I	CE Klasse Im

Description

Diamond scalpels are reusable instruments, consisting of a handle and a diamond blade. The blades are made from synthetic nano diamond and measure between 100µm and 200µm thick; the handles are made from plastic or aluminium.

Applications

Diamond scalpels are designed for various microsurgery incisions.

Precautions

- Read instructions before use
- Diamond scalpels are not sterile and must be sterilised.

Instructions for use

- Diamond scalpels must be thoroughly cleaned and sterilised before use. Diamond scalpels must also be cleaned and then sterilised after every subsequent use. For instructions on how to clean and sterilise diamond scalpels please refer to the section entitled **Cleaning and Sterilisation**.
- The diamond blades must never come into contact with other instruments. Special care must therefore be taken during surgical operations, to ensure that the blades do not come into contact with instruments such as forceps/tweezers or sharp surgical instruments.
- Ensure that diamond blades are not damaged before use. Damaged diamond scalpels should not be used.
After every use of a diamond scalpel, care must be taken to ensure that the blade is protected by the protection cap.

Cleaning

The machine cleaning process and the manual cleaning process were performed and validated by the company SMP GmbH, D-72072 Tübingen, Germany.

Criteria

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

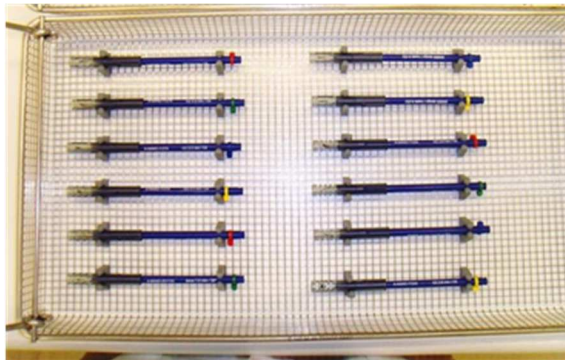


Machine cleaning

Machine Cleaning:

Use the following program for automated cleaning:

- ensure that each blade is retracted into the handle
- place the knives in a metal tray and secure them by silicone brackets. See picture below.
- 2 min pre-cleaning with cold tap water
- 5 min cleaning with 55° tap water and 0.5% cleaning solution neodisher Mediclean forte (Dr. Weigert, D-Hamburg) **or comparable**
- draining
- 3 min rinsing with cold deionized water
- draining
- 2 min rinsing with cold deionized water
- draining



Note:

- During the entire automated cleaning process is **the blade retracted** in the handle.
- Washer-disinfector: Miele Professional G 7836 CD or a similar Washer-disinfector are recommended.

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 handle.
2. Extend the blade and rinse the blade under running cold tap water for 10s or until all visible soil is removed. Do not touch the blade with another object.
3. Place the knife (with the blade retracted in the handle) in a 0.5% cleaning solution of Neodisher Mediclean Forte (Dr. Weigert, D-Hamburg) **or comparable** 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

Note:

The diamond blades must never come into contact with other instruments; otherwise there is a risk that the blades will be damaged. Great care must therefore be taken when loading washing machines.

After cleaning, the condition of the instrument must be checked. Following this, the diamond scalpel must be immediately placed in the sterilisation box or in another suitable container. **Do not clean** Diamond scalpels in ultra-sound cleaning systems.



Sterilization

- Diamond scalpels must be sterilised before each use.
- Diamond scalpels must be sterilised with the diamond blades retracted. Please therefore ensure that the blade is protected.

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

The validation of the sterilization behaviour was examined and validated according to EM ISO 14937.

Note:

- Diamond blades are made from an extremely hard but sensitive material. Handle these ultra-sharp blades carefully to avoid damage.
- Mechanical contact **must** be prevented.
- Diamond scalpels must be cleaned and sterilised before each use.
- After use the blade must be immediately protected by the protection cap.
- Diamond scalpels must never be stored un-cleaned.

Maintenance / Guarantee

The manufacturer does not grant any warranty, neither on the blade nor on the handle.

Proper Disposal

The country specific laws and regulations have to be observed for proper disposal.

Manufacturer:

Anton Meyer & Co. LTD.

Helmstrasse 1

CH-2562 Port