



Meyco diamond scalpels (applicable to ME100-ME799)

Legend to Symbols:

Manufacturer Article Number unsterile Directions for use to consider



Attention

CE Class I

CE Class Im



Description

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

Applications

Diamond scalpels are designed for the field of microsurgeries.

Precautions

- Read instructions before use
- Diamond scalpels are not sterile and must be sterilised.
- Diamond scalpels must be handed to surgeons with the blade retracted and handed back by them with the blade in the same position. They must **not** be placed **opened** on the instrument tray.

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. The blades can be re-sharpened.
- **After every use of a diamond scalpel, care must be taken to ensure that the blade is pulled back into the handle, using the pressure or bayonet mechanism.**

Cleaning

Immediately after using a diamond scalpel, the blade must be rinsed with water using a 20ml spray, preventing cell particles or visco-elastic materials from sticking to the blade.

Dirt on the titanium handle can be removed using a small soft brush. Care must be taken to ensure that the blade has been retracted into the handle.

Manual cleaning

The following cleaning process has been approved in accordance with the ASTM standard test method E 2314-03 (with a germ reduction rate of up to 4₁₀). The manufacturer recommends manual cleaning.

- Immediately after use, the blade must be rinsed with water using a 20ml syringe
- The diamond scalpel must be placed in an alkaline cleaning solution (pH ≥ 10) for at least 12 minutes at 55°C. The cleaner "Mediclean Forte" of Dr. Weigert is validated.
- The diamond scalpel must then be neutralised for 2 minutes in citric acid and then washed for at least 2 minutes in running water (3l/min).

Machine cleaning

In accordance with the recommendations of RKI, diamond scalpels must be cleaned in a washing machine designed for micro-surgical instruments. The manufacturer's instructions should be followed. This is not a procedure validated by the diamond scalpel manufacturer.

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.

Diamond scalpels can also be cleaned using ultra-sound cleaning systems.

Sterilisation

- Diamond scalpels must be sterilised before each use.
- Diamond scalpels must be sterilised with the diamond blades retracted. Please therefore ensure that the blade has been pushed back into the titanium handle.
- Sterilisation filters must be fitted with protective materials (cushioned mats).

Sterilisation method	Type of sterilisation	Item loaded	Temperature	Sterilisation time in minutes
Steam	Centrifugal cycle	packaged	134°C (270°F)	18.0
Flash process	Centrifugal cycle	not packaged	134°C (270°F)	4.0
Steam	Flash cycle	packaged	134°C (270°F)	4.0
Flash process	Flash cycle	not packaged	134°C (270°F)	18.0

The above specifications meet the industry standards for steam sterilisation cycles.

Since there are variations in different steam sterilisation systems and the levels of germs on instruments in clinical use vary greatly, ANTON MEYER & CO. AG cannot provide any specific data to guarantee an appropriate level of sterilisation. Every hospital must check the correct procedures for guaranteeing a proper level of sterilisation. Please refer to the current ANSI/AAMI standards on hospital procedures for steam sterilisation and sterilisation guarantees or the hospital's own procedures for the most suitable specifications.

For steam sterilisation, please refer to ANSI/AAMI standards and recommended practice volume 1: Sterilisation, ST46-1993, Section 5.8.

For flash processes, please refer to ANSI/AAMI standards for "Good Hospital Practice": Flash Sterilization – Steam sterilisation for "Patient care items for immediate use". ST37-1996, Section 5.4

We recommend that packaged diamond scalpels should be steam sterilised at 270°F (134°) either in a centrifugal cycle for 4 minutes or in a flash cycle for 18 minutes.

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 retracted into the titanium handle.
- When used correctly, diamond scalpels can withstand several hundred cleaning and sterilisation cycles.
- Diamond scalpels must never be stored un-cleaned.

Diamond scalpels (RK-Blades) with a micrometer (ME400 – ME499)

Setting the micrometer dial;

1. Turn the micrometer dial to the 2nd marker ring
2. Hold the blade upright and activate the pressure mechanism
3. Turn the micrometer dial to zero – the tip of the diamond blade should be level with the slide shoe.
4. Set the required cutting depth – 1 turn = 0.50 mm

We recommend that the cutting depth should be checked. The cutting depth can be measured using an ME409 (for DK-Blades [double edged]) or ME459 (for M-Blades [single edged]) device.

Maintenance / Guarantee

We suggest sending diamond knives for an inspection to our company at least after 500 surgeries.

ANTON MEYER & CO. AG provides a 3-year guarantee for all mechanical components, on condition that the scalpels are used correctly with the titanium handle.

Proper Disposal

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

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