

PVA Diamond Knife Cleaning Blocks Specification Sheet





Product Overview

PVA diamond knife cleaning blocks - Not used in a clinical application on patients:

- Constructed from ultra-smooth, biocompatible PVA sponge
- Cleans without damage to the instrument
- Soft and snag free material
- Supplied sterile, single use only, declared 5 year shelf life

Diamond Knife Cleaning Block Options

Product	Pack Size	Product Code
Diamond Knife Cleaning Block	Pack of 1 box of 10	40-462





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Material Specification

Product Component	Specification
Diamond Knife Cleaning Block	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Tyvek /Film
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

The PVA Diamond Knife Cleaning Blocks are used to help clean diamond knife blades after use.

Intended Purpose

A non-contact, single-use block of PVA intended to be used in a sterile condition by healthcare professionals to help clean and polish a medical diamond knife blade prior to full decontamination. The diamond knife cleaning block is only to be handled with medical grade gloves and as such is non-contact with a cumulative transient use of less than 60 minutes. There are no known contraindications for this device. These devices are not intended to be used on a patient.

Sterilisation

Products are sterilised by Gamma irradiation from a Cobalt 60 source in accordance with a validated 25 kGy cycle. Sterilisation is carried out in accordance with the requirements of ISO 11137-1 (current) and ISO 1117-2 (current) and the 25 kGy dose is substantiated by VD_{25} Method Max testing.

Instructions for Use

The instructions for use are supplied in the form of a multi-lingual leaflet with instructions given.

The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product and is also available to view and download at https://www.networkmedical.co.uk/ifu-product-group

Conformity to the European Directives

EYETEC® diamond knife cleaning blocks are defined as non-invasive devices which do not touch the patient (Rule 1, Annex IX 93/42/EEC Medical Devices Directive) and are classified as Class I Sterile.

