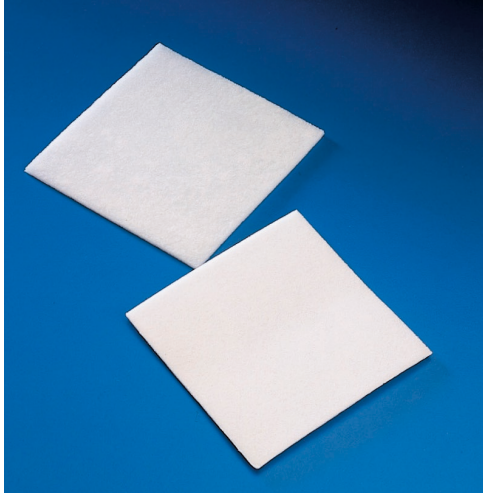


PVA Instrument Wipes Specification Sheet



Product Overview

High quality and performance PVA Instrument wipe, not used in a clinical application on patients:

- Manufactured from ultra-smooth, biocompatible PVA sponge
- Soft, strong, and flexible
- Ultra-absorbent
- Supplied sterile, single use only, declared 5-year shelf life

The PVA Instrument Wipe is also available with the addition of a wick for the efficient management of fluids.

PVA Instrument Wipe Options

Product Description	Pack Size	Product Code
Instrument Wipe	Pack of 1 box of 20	40-900
Wick and Wipe	Pack of 1 box of 20	40-470

PVA Instrument Wipes Specification Sheet

Material Specification

Product Component

Specification

Instrument Wipe	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

PVA instrument wipes are used to help clean medical devices after use.

Intended Purpose

A non-contact, single-use sheet of PVA intended to be used in a sterile condition by healthcare professionals to help clean medical devices prior to full decontamination. The instrument wipe 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 11137-2 (current) and the 25 kGy dose is substantiated by VD₂₅ 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.

Conformity to the European Directives

EYETEC® Instrument Wipes 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.