

INSTRUCTIONS FOR

Supor® Sterile Syringe Filter #12551, 12553, 12554

INDICATIONS

PALL PharmAssure 32 mm Syringe Filters with Supor membrane are designed for rapid filtration, high throughputs, low protein binding and broad drug compatibility to assure quality control in drug preparation and bolus drug administration. STERILE and non-pyrogenic. Sterilized by irradiation.

DESCRIPTION

Re-order No	Pore Size	Housing
HP4642	0.2 µm	Blue/Blue
HP4644	0.45 µm	Red/Clear
HP4648	1.2 µm	Clear/Blue
HP4640	5 µm	Green/Green

SPECIFICATIONS

Materials of Construction

(Fluid Pathway): Acrylic, Supor Polyethersulphone membrane

Effective Filtration Area: 5.3 cm²

Maximum Operating Pressure: 75 psi (5.2 bar)

Maximum Operating Temperature: 55°C

Typical Fluid Retention: <0.1 mL (with air purge*)

<1.0 mL (without air purge**)

Biocompatibility: All materials in the fluid pathway meet USP Biological Reactivity Testing in vivo <88>

* When used for drug preparation.

** When used for bolus drug administration.

NOTE: This product is free of natural rubber latex.

CONTRAINDICATIONS

Blood and other cellular products will not pass through the filter and may cause blockage. This device should not be used to filter solutions that are known to be pyrogenic or contaminated with microorganisms. This filter is not designed to eliminate air. Entrained air upstream of the filter may result in reduced flow. This filter is not designed for intrathecal drug administration.

PRECAUTIONS

Follow instructions carefully. Use aseptic technique. For single use, do not reuse or resterilize. Discard filter after single bolus dose. Do not use if packaging is opened or damaged. When attached to needle dispose of this device in a puncture resistant container.

Caution: As filter removes particles, syringe plunger may become harder to use as resistance from filter increases. Change filters when resistance becomes excessive. Failure to change filter may cause housing or membrane rupture as maximum operating pressure is exceeded. This will result in particulate contamination of filtrate.

Caution: Syringes smaller than 10 mL can generate excessive pressure on filter, which may exceed maximum operating pressure.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or pharmacist.

INSTRUCTIONS FOR USE

(Read and follow carefully)

1. DRUG PREPARATION

Before filling syringe, draw in approximately 1 mL of air. This air will follow sample out of syringe, minimizing fluid retention.

Fill syringe with solution to be filtered. Peel off backing from blister package. Holding blister in one hand, secure syringe to female luer using a twisting motion. Attach a sterile needle or access device to male luer of filter, using a twisting motion.

Cleanse injection site in accordance with local procedures and remove needle cover/access device cap. Using non-coring technique, pierce septum at a 60° angle to rubber closure of bottle or bag. Once closure has been penetrated, straighten the device and push needle/access device completely through septum. Apply gentle pressure to begin filtration, to assure maximum throughput.

2. SYRINGE BOLUS DRUG ADMINISTRATION

Fill syringe with solution to be filtered. Peel off backing from blister package. Holding blister in one hand, secure syringe to female luer using a twisting motion. Prime the filter until fluid exits filter housing outlet, ensuring that all air has been completely removed. Cleanse infusion access site in accordance with local procedures and attach male luer of filter using a twisting motion. Apply gentle pressure to begin filtration and administer bolus dose.

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