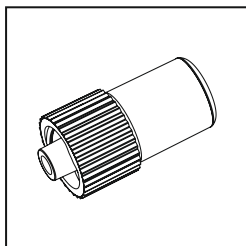




MEDIPLUS
INDIA LIMITED

INJECTION STOPPER



SRN. NO.: IN-MF-000007279

Basic UDI-DI #: 890602530INJSTOPT2

INSTRUCTIONS FOR USE

Material Used: ABS (coloured or transparent) and Isoprene OR Latex.

Device General Description: Injection Stopper is having a Male luer lock and a latex free stopper. It is to be connected to infusion devices.

Intended Purpose/use: The sterile injection stopper is a Male luer lock fitted with latex free stopper which provides a self-sealing injection site for administering medication or draw samples. The duration of use of this product is 72 hours. The injection stopper can also be used as a female luer cap.

Intended Users: Uses is restricted to a qualified Doctor or a Paramedic.

Principle of Operation/Mode of Action: The sterile injection stopper is a Male luer lock fitted with latex free stopper which provides a self-sealing injection site for administering medication or draw samples. Sterile Injection stopper is a device which is having a 6% male luer lock facility and a port at other end.

Residual Risk: There is no residual risk associated with the device, however preventive measures are considered in contraindication.

Instructions for use: • Ascertain the site of use and mating female luer (as per ISO-594-1); site may be wiped with your institute's sterile preparation if not already sterile. • Remove Injection Stopper from sterile packing. • Grip the Injection Stopper from 'top', i.e. side with isoprene or latex plug and connect to the mating female part. • Insert hypodermic needle into the latex or isoprene plug, ensuring that the needle penetrates across the entire length of the plug, and inject fluid, or start infusion.

Indications: • Administration of sterile injectable fluids, including pharmaceutical agents, with use of syringe and hypodermic needle, after connecting injection stopper to IV access device with suitable female mating part (as per ISO-594-1).

Contraindications: • Product should not be used in patients with known hypersensitivity to any of the materials used. • Not to be used for administration of high viscous fluids. • Not to be used for administration of blood or blood products. • Not to be used with NON-STANDARD female luers / mating parts.

Warnings: • The use of this product is restricted to a qualified doctor or a paramedic. • Read instructions before use thoroughly, and use product accordingly. • Do not use needle of size greater than 22G. • The product should not be reprocessed. • Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging. • The product should be used immediately after opening the packaging. • The product is guaranteed to be sterile & non-pyrogenic if the package has not been opened or damaged prior to use. • Do not clean or resterilize. For single use only. Discard after use. • Store in cool & dry place. • Do not expose to heat or direct sunlight. • Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections.

Clinical Risk: None

Patient Population: All age group.

Safer Mode of Use: Up to 72 hrs. for best performance.

Clinical Benefits: Alleviation of disease by providing fluids/medicaments to the patients with channeling other compatible medical device.

Storage: Store in cool & dry place. Do not expose to heat or direct sunlight.

Incidents Report: In case of incidence Immediately inform to Manufacturer (info@mediplusindia.com) and Competent authority of country.

• MEDIPLUS (INDIA) LIMITED DISCLAIM ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

REF	Catalogue number	Mfg. date with country of manufacture	Manufacturer
Use-by date	Do not use if package is damaged	Caution	
LOT	Batch code	Sterilized using ethylene oxide	Do not re-use
Do not re-sterilize	Consult instructions for use	Non-pyrogenic	
Single sterile barrier system	Product is not made with natural rubber latex	Does not contain DEHP	
MD	Medical Device	Unique Device Identifier	Distributor
Importer	Keep away from sunlight	Keep dry	
EU REP	Authorised Representative in the European Union	CE mark European Conformity	AW/PU/00_Rev.11 (Issued date: 23/07/2026)



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*Note: First digit in LOT (1 OR 2) refer to manufacturing unit.
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