Technical IFU

Disinfectant Cap

Date: 07/01/2026	**Date:** 26/09/2025	**Date:** 26/09/2025
Prepared By Executive QA RA	Reviewed By Head RA	Approved By Managing Director

Follow manufacturer's instructions for use and institutional procedures for Disinfectant Cap.

For sterile variant

DESCRIPTION

The Disinfectant Cap is a single-use accessory Medical Device manufactured by **SPM Medicare Pvt. Ltd.** It is intended to disinfect needle-free Luer access connectors prior to line access. The device consists of a cap body containing a medical-grade polyurethane foam impregnated with **70% v/v Isopropyl Alcohol (IPA)** and sealed with aluminium foil. The Disinfectant Cap is designed to fit ISO-compliant needle-free Luer access connectors. The device is available in sterile and non-sterile variants. The sterile variant is sterilized by **gamma irradiation**.

IMAGE OF THE DEVICE

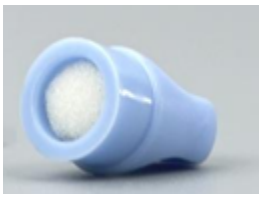


Figure 1: Disinfectant Cap

MODELS

Product Description	**Variant**
Disinfectant Cap – Sterile	Individual blister
Disinfectant Cap – Non-Sterile	Strip pack of 10

INTENDED PURPOSE

The disinfectant cap is a single-use device intended to disinfect needle-free Luer access connectors prior to line access in operation theaters.

INDICATIONS FOR USE

- Intended for use with needle-free Luer access connectors
- Intended for disinfection prior to line access

INTENDED PATIENT POPULATION

The Disinfectant Cap is intended to be used in patients irrespective of age and gender.

INTENDED USER

The Disinfectant Cap is intended to be used by trained healthcare professionals including doctors, registered practitioners, paramedics, or nursing staff.

INTENDED USE ENVIRONMENT

The Disinfectant Cap is intended to be used in hospitals and clinics (Operation Theator).

CLINICAL BENEFITS

- Helps in disinfection of needle-free access connectors prior to line access

PRINCIPLE OF OPERATION

The Disinfectant Cap contains a polyurethane foam impregnated with **70% v/v Isopropyl Alcohol (IPA)**.
When applied to a needle-free Luer access connector, the alcohol disinfects the external surface of the connector prior to access.

PERFORMANCE CHARACTERISTICS

- Disinfection of needle-free Luer access connectors

MATERIALS USED

- Cap Body – Polypropylene (PP) / Polyethylene (PE)
- Internal disinfectant reservoir/foam – Polyurethane (PU)

- Disinfectant agent – Isopropyl Alcohol (IPA) 70% v/v
- Seal – Aluminium foil
- Internal sealing interface – Medical-grade Elastomer (TPE)

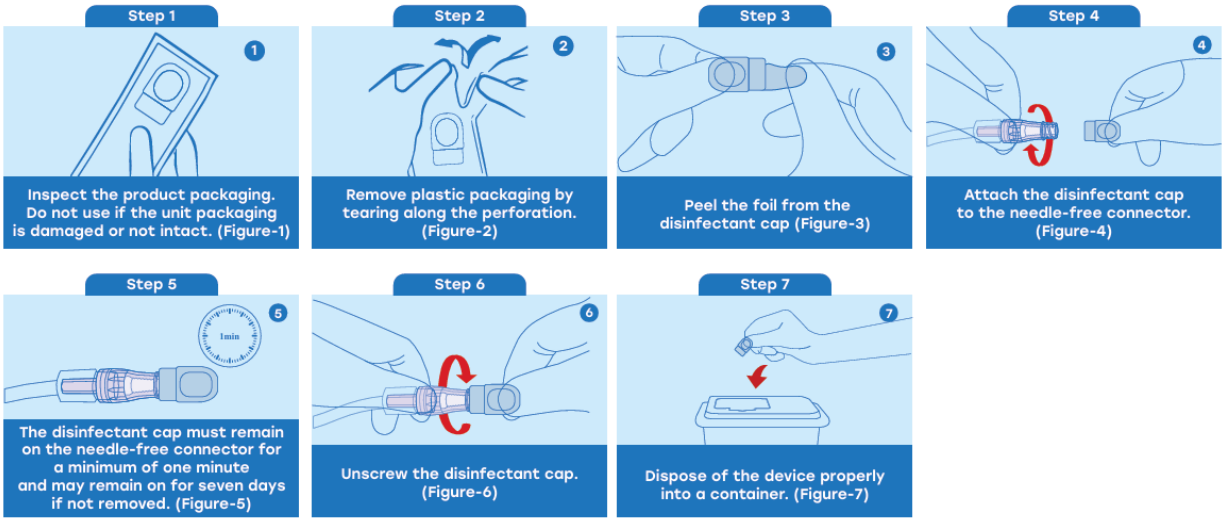
CONTRAINDICATIONS

- Do not use if the patient has known sensitivity to isopropyl alcohol or device materials

POTENTIAL COMPLICATIONS

- Inadequate disinfection if instructions for use are not followed

DIRECTIONS FOR USE



HOW SUPPLIED

- Sterile variant: Individually packed in blister with medical paper
- Non-sterile variant: Strip pack of 10

WARNINGS

- Single use only
- Do not reuse
- Do not re-sterilize

- Do not use if packaging is damaged
- Do not use after expiry date

PRECAUTIONS

- Use only with needle-free Luer access connectors
- Follow institutional procedures for disinfection

CAUTIONS

- Carefully read all instructions prior to use
- Discard after single use

STORAGE

Store at a controlled temperature **(10–40°C)**.
Do not store at freezing temperature.

EXPIRATION PERIOD

Shelf life: **3 years** from the date of manufacturing.
Do not use after the indicated expiration date.

RETURN OF DAMAGED PRODUCT

Return the product in its original packaging with batch number, purchase information, and reason for return.
Contact the manufacturer or local distributor.

DISPOSAL OF THE USED DEVICE

- Dispose of the used product as biomedical waste
- Follow hospital procedures and applicable regulations

REPORTING

In case of any adverse events or product-related incidents, contact the manufacturer or authorized representative.

REGISTERED ADDRESS AND MANUFACTURING FACILITY

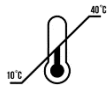
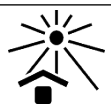
LEGAL MANUFACTURER AND MANUFACTURING FACILITY

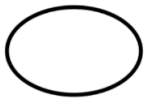
Manufacturer:

SPM Medicare Pvt, Ltd

B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India.
Manufacturing Site 1- B-40, Phase-II, Noida,
Gautam Buddha Nagar, UP-201305, India.
Manufacturing Site 2- Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305.
Customer care: No.: +91-840-7070-718
Email: info@spmmedicare.com
Web Site: www.spmmedicare.com

EXPLANATION OF SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Country & Date of manufacturing		Use-by date
	Do not re-sterilize		Temperature Limit
	Consult instructions for use		Non-Pyrogenic
	Keep away from sunlight		Sterilized using irradiation

Symbol	Explanation	Symbol	Explanation
	Do not re-use		Handle with care
	Fragile, handle with care		Maximum stacking
	This side up		Model number
	Do not use hook		Single Sterile Barrier System
	Medical Device		Gamma Sterile
	Unique Device Identifier		Keep dry
	Authorized representative in the European Community		Recycling
	Biological risks		Model number
	Do not use if package is damaged and consult *instructions for use*		

Revision history

Version No.	Date	Description
00	07/01/2026	Initial Issue