SEE END OF DOCUMENT FOR SYMBOLS GLOSSARY

ARMIS VeriCyn® Wound Wash

INSTRUCTIONS FOR USE

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Armis VeriCyn® Wound Wash 500 mL (VWW-2001)
Armis VeriCyn® Wound Wash 1000 mL (VWW-2002)

DESCRIPTION OF DEVICE

The ARMIS VeriCyn® Wound Wash is an aqueous solution for irrigation and debridement of wounds. The solution is a clear, colorless, no-odor aqueous solution that is used to remove debris, including microorganisms from wounds though the use of a lavage system.

ARMIS VeriCyn® Wound Wash contains: Hydrogen Peroxide, Acetic Acid, Disodium EDTA and Purified water.

VeriCyn® Wound Wash has been tested for compliance with ISO 10993 for a surface device with limited contact (≤24 hours) with breached or compromised surfaces.

INDICATIONS FOR USE

The Armis VeriCyn® Wound Wash is to be used with a lavage system to create mechanical movement at the wound surface by delivery of a solution and is indicated for use in cleansing and removal of foreign material including micro-organisms and debris from wounds (such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first degree and partial thickness burns, grafted and donor sites).

CONTRAINDICATIONS

Do not use if there is a history of allergy to any of the ingredients

WARNINGS

NOT FOR IV USE – This product has been tested as a wound wash only. DO NOT inject.

This product should not be used more than once in a 30 day period.

Do not use if packaging has been opened or damaged.

Avoid eye contact.

CAUTION

Dispose of devices in accordance with accepted medical practice and in accordance with local and federal laws and regulations. Improper disposal can result in a biohazardous incident.

DIRECTIONS FOR USE

CIRCULATING STAFF:

1. Remove from packaging
2. Check for leaks by visually inspecting the container. If leaks are found, discard the unit.
3. See appropriate irrigation set instructions for use.

SURGEON:

1. Irrigate the wound bed with approximately 5.4 mL per square centimeter of affected area following the system

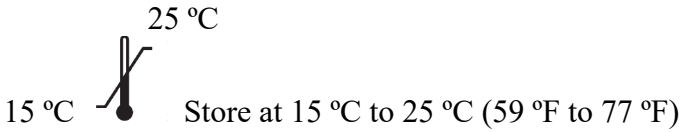
manufacturer's instructions and/or standard practice.

2. Right after irrigating the wound bed, the wound bed may be rinsed with an equal amount of normal saline.
3. Use universal precaution in accordance with hospital protocol for the handling and disposal of contaminated waste.
4. Discard any unused solution.

HOW SUPPLIED:

The ARMIS VeriCyn® Wound Wash is supplied in 500 mL and 1000 mL HDPE bottles.

STORAGE AND HANDLING



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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	DEFINITION
℞	N/A	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1:2016 and ISO 15223-1:2020 Reference no. 5.4.3. (ISO 7000-1641) Reference no. 5.4.3. (ISO 7000-1641)	Consult instructions for use Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use
REF	ISO 15223- 1:2016 Reference no. 5.1.6. (ISO 7000-2493)	Catalogue number Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified
LOT	ISO 15223- 1:2016 Reference no. 5.1.5. (ISO 7000-2492)	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)	Manufacturer	Indicates the medical device manufacturer
YYYY-MM-DD	ISO 15223- 1:2016 Reference no. 5.1.4. (ISO 7000-2607)	Use-by date	Indicates the date after which the medical device is not to be used
	ISO 15223- 1:2016 Reference no. 5.2.8. (ISO 7000-2606)	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	DEFINITION
	ISO 15223-1:2016E Reference no. 5.4.2. (ISO 7000- 1051)	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once.”
	ISO 15223- 1:2016 Reference no. Table 1, Symbol 5.3.7 (ISO 7000- 0632)	Temperature limit	Lower and upper temperature restrictions
	ISO 15223- 1:2016 Reference no. Table 1, Symbol 5.6.3 (ISO 7000- 2724)	Non-pyrogenic	Indicates a medical device that is non-pyrogenic