

See end of document for symbols glossary

INTENDED USE: Wound Lavage

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 through the use of a lavage system.

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

When used as intended, the VeriCyn® Wound Wash is categorized according to ISO 10993-1 as a surface medical device having prolonged (> 24 hours to 30 days) exposure to 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 microorganisms 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.
- Do not use if packaging has been opened or damaged.
- Avoid eye contact.

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

HOW SUPPLIED


The Armis VeriCyn® Wound Wash is supplied in:


1. 500 mL Wound Wash Bottle (VWW-2001) hanging bottle with serum stopper
2. 1000 mL Wound Wash Bottle (VWW-2002) hanging bottle with serum stopper
3. 236 mL bottle with a trigger sprayer (VWW-2005)
4. 59 mL bottle with a fine mist sprayer (VWW-2006)











DIRECTIONS FOR USE:

1. Remove from packaging
2. Check for leaks by visually inspecting the container. If leaks are found, discard the unit.
3. See appropriate bottle configuration instructions for use in Appendices A - C
4. Appendix A: Instructions for Use – 500 mL and 1000 mL hanging bottles
5. Appendix B: Instructions for Use – 236 mL bottle with trigger sprayer
6. Appendix C: Instructions for Use – 59 mL bottle with fine mist sprayer
7. Appendix D: Regulatory and Standards Compliance

STORAGE AND HANDLING

15 °C  25 °C
Store at 15 °C to 25 °C (59 °F to 77 °F)

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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	DEFINITION
	21 CFR Part 801	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1:2021 Reference no. 5.4.3	Consult instructions for use Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use
	ISO 15223-1:2021 Reference no. 5.1.6	Catalogue number Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified
	ISO 15223-1:2021 Reference no. 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1:2021 Reference no. 5.1.1	Manufacturer	Indicates the medical device manufacturer
 YYYY-MM-DD	ISO 15223-1:2021 Reference no. 5.1.4	Use-by date	Indicates the date after which the medical device is not to be used
	ISO 15223-1:2021 Reference no. 5.2.8	Do not use if package is damaged Do not use if the product sterile barrier system or its packaging is compromised	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
	ISO 15223-1:2021 Reference no. 5.4.2	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 15223-1:2021 Reference no. 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223-1:2021 Reference no. 5.6.3	Non-pyrogenic	Indicates a medical device that is non-pyrogenic

APPENDIX A: 500 mL and 1000 mL Hanging Bottles

CLINICIAN:

1. See appropriate irrigation system set instructions for use.
2. 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.
3. Use universal precautions in accordance with hospital protocol for the handling and disposal of contaminated waste.
4. Discard any unused solution.

APPENDIX B: 236 mL Bottle with Trigger Sprayer

CLINICIAN:

1. **Do not use** if the outer protective barrier or seal is compromised.
2. Remove the bottle from the outer protective overwrap.
3. Hold the bottle upright on a clean surface. Unscrew and discard the factory-installed shipping cap.
4. Visually confirm the foil induction seal is intact. **Do not use** if the induction seal is missing or damaged prior to opening.
5. Grasp the pull tab and peel back the induction seal completely from the opening of the bottle.
6. **Do not puncture** the seal or push it into the solution.
7. **Do not touch** or contaminate the bottle opening.
8. Discard the removed induction seal.
9. Remove the trigger sprayer from the protective overwrap.
10. Ensure the nozzle is set to "LOCK" position before use.
11. Ensure the dip tube is straight and free of damage.
12. Insert the dip tube into the bottle opening.
13. Screw the sprayer nozzle clockwise until tight, but do not overtighten.
14. Turn the nozzle to the "UNLOCK" position.
15. If needed, prime the sprayer by pressing the trigger several times until an even stream appears.
16. Gently squeeze the trigger and irrigate the wound bed with approximately 5.4 mL per square centimeter of affected area until the desired irrigation result is achieved.
17. **Do not allow the sprayer tip to touch the wound or any other surface.**
18. Allow excess fluid to drain freely or gently blot dry with sterile gauze.
19. Use universal precautions in accordance with hospital protocol for the handling and disposal of contaminated waste.
20. Discard any unused solution.
21. **Do not recap** or reuse the bottle.

APPENDIX C: 59 mL Bottle with Fine Mist Sprayer

CLINICIAN:

1. **Do not use** if the outer protective barrier or seal is compromised.
2. Remove the bottle from the outer protective overwrap.
3. Hold the bottle upright and lift the cap off the fine-mist sprayer.
4. Verify the nozzle is clean and unobstructed. Do not touch or contaminate the nozzle tip.
5. If needed, prime the sprayer by pressing the trigger several times until a fine mist appears.
6. Hold the bottle over the wound area and gently squeeze the trigger and irrigate the wound bed with approximately 5.4 mL per square centimeter of affected area until the desired irrigation result is achieved.
7. **Do not allow the sprayer tip to touch the wound or any other surface**
8. Allow excess fluid to drain freely or gently blot dry with sterile gauze.
9. Use universal precautions in accordance with hospital protocol for the handling and disposal of contaminated waste.
10. Discard any unused solution.
11. **Do not recap** or reuse the bottle.

APPENDIX D: Regulatory and Standards Compliance

STANDARD NUMBER AND REVISION	SYMBOL TITLE
ISO 13485:2016	Quality Management Systems for Medical Device Manufacturing
ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 10993-1:2018	Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological Evaluation of medical Devices, Tests for in vitro cytotoxicity
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer, Part 1: General Requirements
ISO 20417:2021	Medical Devices - Information to be supplied by the manufacturer