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JETOX™ SYSTEM WOUND CLEANING AND DEBRIDEMENT SYSTEM

	DO NOT REUSE
	STERILIZED WITH ETHYLENE OXIDE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

IMPORTANT INFORMATION

Please read carefully all instructions, warnings, and cautions before use. Correct setup is essential for proper functioning of product.

INTENDED USE

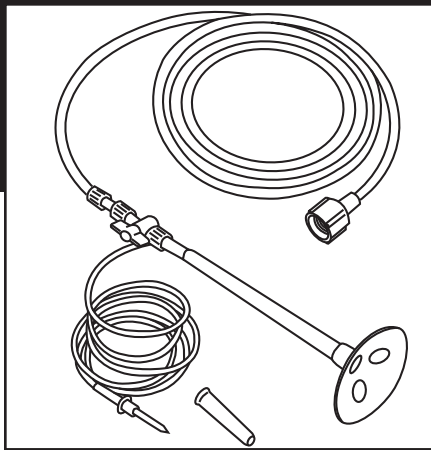
The DeRoyal® Jetox™ System is intended for use in wound management for cleansing and debridement.

INDICATIONS

Use of this device is indicated for pressure ulcers, diabetic ulcers, venous ulcers, infected surgical sites, heavily contaminated or dirty wounds, burns, or when a physician deems lavage treatment appropriate.

WARNINGS

- The use of Jetox™ System should be supervised by a trained wound care professional.
- Use the JETOX™ System unit once only and then discard.
- Using the unit more than once may cause infection and contamination.
- Dispose of used materials safely, according to your local regulations.
- Connect to oxygen source using a standard luer connection.
- The connection must be through a pressure regulator.
- The JETOX™ System must not be used for any use other than wound management for cleansing and debridement.
- DeRoyal intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging or sterilization according to their own validated processes. These products are to be sterilized by ethylene oxide, as other sterilization methods have not been validated by DeRoyal and may damage the product which could cause a device malfunction or injury to the patient.
- This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or re-sterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.



DIRECTIONS FOR USE

NOTE: Jetox™ System creates a jet stream from sterile saline solution and compressed medical oxygen. The microdrops created by Jetox™ System are between 5 -200 microns in size and are accelerated to velocities of up to 200 meters per second.

INSTALLATION

1. Open the Jetox™ System and Tubing packages and remove the components.
2. Connect the oxygen tube to the oxygen source.
3. Assure that the valve on tubing is in the closed position.
4. Screw the other end of the oxygen tube valve to the Jetox™ System's luer.
5. Insert the spike into the solution bag. The bag may be placed near the area to be treated.
6. Affix the shield sleeve onto the Jetox™ System nozzle, up to the grooves. The shield is designed to maintain the optimum treatment distance.

OPERATION

1. Turn on the oxygen source to the appropriate setting for the desired pressure:
9 L/min = 4 psi
11 L/min = 6 psi
13 L/min = 9 psi
15 L/min = 12
2. Gently bring the shield into contact with the wound area to be treated.
3. Open the valve to the Jetox™ System.
4. Begin treatment: cleanse wound until loose debris and exudate are sufficiently removed.

END OF TREATMENT

1. At the end of treatment, close the valve to the Jetox™ System.
2. Turn off the oxygen source.
3. Once again ensure that the oxygen source is closed.

TECHNICAL SPECIFICATIONS

- Recommended liquid solution: Saline 0.9% sodium chloride
- Oxygen tube length: 2.28 meters (7' 5" or 7.4')
- Solution tube length: 1.05 meters (3' 5" or 3.4')



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STORAGE AND TRANSPORT CONDITIONS

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.

WARRANTY

DEROYAL® PRODUCTS ARE WARRANTED FOR NINETY (90) DAYS FROM THE DATE OF SHIPMENT FROM DEROYAL AS TO PRODUCT QUALITY AND WORKMANSHIP. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**



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