



XSONX DEBRIDEMENT SYSTEM INSTRUCTIONS FOR USE

GENERAL DESCRIPTION

XSONX Debridement System (XDS) is a battery powered wound therapy system to help clean and debride wounds. There are several configurations for cleansing and debridement of the various wounds. Cleansing and debriding wounds helps remove exudates, devitalized tissue, bacteria, bacterial biofilm, slough, fibrin, excised or fragmented tissue, in order to manage wounds and speed the wound healing process.

INTENDED USE / INDICATIONS FOR USE

The XSONX Debridement System is indicated for use in the cleansing and excisional debridement of chronic wounds and acute wounds, such as, but not limited to, burn wounds, diabetic ulcers, venous ulcers, traumatic wounds, pressure ulcers, and surgical site wounds.

R_x only

Caution: Federal law restricts this device to sale (or use) on the order of a licensed practitioner.

INTENDED USER(S)

XSONX is designed to be used by health care professionals on patients who have been prescribed the device by their treating physician. Healthcare professionals should have prior training and experience in both modern wound care principles and wound debridement prior to using XSONX.

LIST OF ACCESSORIES

1. XSONX includes two Energizer Max AAA alkaline batteries. Replace as needed.
2. Irrigation is achieved by use of separate saline bullet(s) such as Teleflex Addipak 0.9% Sodium Chloride bullet 15ml HCS20069. Other approved wound irrigation fluid may be used instead.
3. Single Use Sleeve. These are included with each wound head sold.

INTENDED PATIENT POPULATION

XSONX Wound Hygiene System is intended to be used on patients with chronic open wounds or acute wounds, such as, but not limited to, burn wounds, venous ulcers, diabetic ulcers, traumatic wounds, pressure ulcers, and surgical site wounds.

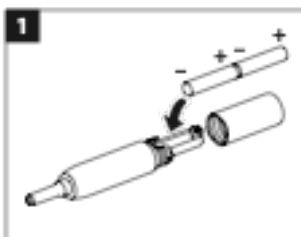
PRINCIPLES OF OPERATION OF THE DEVICE

1. Use gloves for cleansing wound and changing dressing. Wash hands prior to donning gloves.
2. Use the single use sleeve which comes with each wound head sold. First, take the sleeve and slide it over the tip of the handpiece, so that the tip of the sleeve is completely to the tip of handpiece, and the sleeve is on all the way with excess material hanging off the back of the handpiece.
3. Next, take the appropriate Wound Head and slide it over the narrow end of the handpiece. Make sure the handpiece is aligned with the button facing straight up as you slide it on.

4. Separate saline bullet (Addipak 15mL) or other approved irrigation fluid should be used to premoisten wound bed, as well as rinse intermittently during the procedure and afterwards. Irrigation fluid may consist of sterile saline, distilled water, or other FDA approved irrigation fluid.
5. XSONX handpiece has one button to turn the device on and off. A green LED lights up when the unit is on. The LED turns to yellow when the battery is low and will soon run out of power.
6. To use XSONX, turn the device on, and gently use the wound head on the wound. Start in the center of the wound, and gently move in circular direction outward until the entire wound is cleaned. Use irrigation to premoisten the wound bed, during cleansing to help flush out cellular debris and bacteria, and after you are finished.
7. XSONX is typically used for 20 seconds to 3 minutes per session, depending on the size of the wound. Ask the treating physician how long to use XSONX. For smaller wounds (<1.5 inches in diameter), approximately 20-30 seconds total use should be sufficient time to clean them. It is not recommended to use XSONX for more than 30 seconds unless you check with your prescribing physician or have a large wound.
8. XSONX may be used up to 3x a week to cleanse wounds. Ask your practitioner how often you should use XSONX, and make sure the prescribing physician is following the patients progress on a regular basis.
9. The indicated duration of therapy with XSONX is from one-time single use, up to six months regular use, depending on physician's clinical decision making and patient's clinical response.



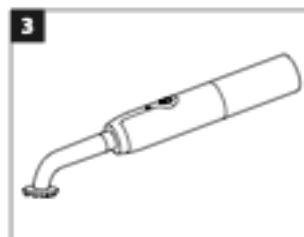
INSTRUCTIONS



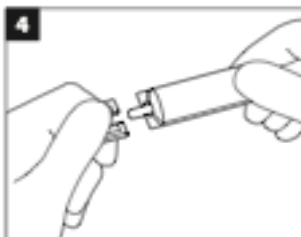
1 Install 2 AAA batteries.



2 Cover handle with disposable sheath.



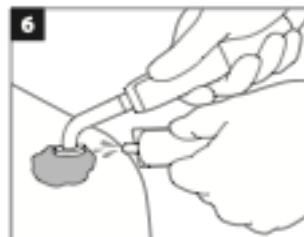
3 Select appropriate head and push onto tip of handle.



4 *Optional:* If using saline bullet, twist off tip.



5 Press power button.



6 Gently apply head to wound and begin cleaning. Rinse with saline bullet.



CONDITIONS OF USE (i.e., ENVIRONMENT OF USE)

XSONX is indicated for hospital inpatient, outpatient clinic, long term care, or home use.



CAUTIONS

- A full clinical wound assessment by a qualified medical professional should be made prior to making a decision to do any debridement, including use of XSONX.
- XSONX should be used with precaution with wounds that have underlying known or suspected autoimmune component, diagnosis, or suspected Pyoderma Gangrenosum or other wounds with pathergy.
- XSONX should be used with precaution with patients that are anticoagulated or have a known or suspected coagulopathy.
- It is recommended if the patient has multiple wounds and one is infected, that different wound heads are used for each wound.
- For patients who are known or suspected to have sensitivity to pain during debridement or cleaning, topical anesthesia can be considered (i.e. Rx lidocaine jelly 2-4%, EMLA cream) as indicated and prescribed by the treating physician as needed for pain control.

CONTRAINDICATIONS

- A malignant wound or suspected malignant wound is generally contraindicated for debridement, including XSONX.
- Advanced or suspected advanced peripheral arterial disease (PAD) ulcers that have not been revascularized are generally contraindicated for debridement, including XSONX.
- Heel pressure ulcers which are not infected and have closed eschar are generally contraindicated for debridement by NPUAP guidelines, including XSONX.
- A wound which exhibits pathergy or is high risk for pathergy is generally a contraindication to debridement, including XSONX.
- It is a contraindication to use XSONX on patients who are intolerable or unpreventable to pain with use.
- XSONX is indicated on external wounds. It is contraindicated to use XSONX on internal wounds, wounds with exposed organs, or deep penetrating wounds.
- It is contraindicated to use XSONX on deep wounds which may involve or be close to large arteries or veins, or any wounds with exposed arteries or veins, as debridement by any method here poses risk of hemorrhage.
- If patient develops pain or bleeding with XSONX, or if the wound enlarges with use of XSONX, use of XSONX should be stopped, and the treating physician promptly notified. There are many causes of wounds enlarging, including vascular status, whether there is an underlying condition such as chronic venous disease or diabetes, wound infection, as well as underlying wound pathology.



PRECAUTIONS

- Do not submerge handpiece.
- Handle / Handpiece should be properly cleaned and disinfected immediately after every use following the Cleaning & Disinfection Instructions.



DO NOT REUSE WOUND HEADS. DO NOT REUSE THE SLEEVE

- Wound Heads are sold sterile single use and intended for use on a single patient and not to be reused on the same patient, or other patients. Do not reuse wound heads.
- The single use sleeve should not be re-used.


CLEANING & DISINFECTION INSTRUCTIONS FOR THE HANDPIECE

Caviwipe Manual Cleaning Procedure for Handpiece

- 1.1 Throw away Wound Head. Remove sleeve and throw away.
- 1.2 Next, wipe handpiece with a Caviwipe to remove visible soil. Use well ventilated area.
 - 1.2.1 At least partly unscrew the back of the handpiece and wipe there to remove visible soil.
 - 1.2.2 Use additional wipes as necessary to aid in the removal of soil.
- 1.3 Allow the handpiece to air dry.
- 1.4 Next perform Disinfection Procedure before re-use.

Caviwipe Disinfection Procedure for Handpiece

- 2.1 Using a Caviwipe, wipe the handpiece.
- 2.2 Using a Caviwipe, wipe the handpiece and ensure that the handpiece remains wet for 10 minutes. Do not submerge the handpiece.
 - 2.2.1. At least partly unscrew the back of the handpiece to wipe there and that it remains wet for 10 minutes.
 - 2.2.2. Use additional wipes as necessary to ensure that the handpiece remains wet for the 10 minutes.
- 2.3 Allow the handpiece to air dry before re-use.

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