



XSCRUB™ WOUND CLEANSING PAD

GENERAL DESCRIPTION

XSCRUB™ Wound Cleansing Pad is a single use disposable product to help clean and debride wounds with its unique design. The product consists of light green foam welded to a white backing material. XSCRUB™ has a unique weld pattern to help create high and low pressure areas and collect large debris in the crevices of the welds, and smaller debris in its unique pore structure. XSCRUB™ helps remove exudate, devitalized tissue, bacteria, bacterial biofilm, slough, fibrin, and excised or fragmented tissue, in order to manage wounds and speed up the wound healing process.

INTENDED USE / INDICATIONS FOR USE

The XSCRUB™ Wound Cleansing Pad is indicated for use in the cleansing and gentle debridement of chronic open wounds or contaminated acute wounds, such as, but not limited to, burn wounds, diabetic ulcers, venous ulcers, traumatic wounds, pressure ulcers, and surgical site wounds.



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

INTENDED USER(S)

XSCRUB™ is designed to be used by health care professionals or prescribed for individual use who have prior experience and training in advanced wound care principles.

INTENDED PATIENT POPULATION

XSCRUB™ is indicated for use on patients with chronic open wounds or contaminated acute wounds, such as, but not limited to, burn wounds, diabetic ulcers, venous ulcers, traumatic wounds, pressure ulcers, and surgical site wounds.

MATERIALS

Polyurethane foam welded to polyester film.

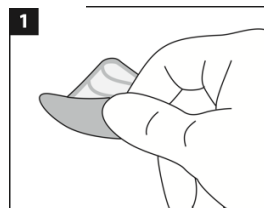
PRINCIPLES OF OPERATION OF THE DEVICE

Use gloves for cleansing wound and changing dressing. Perform hand hygiene by washing hands prior to donning gloves.

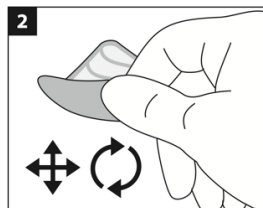
1. To use XSCRUB™, use the green side facing the wound and apply gentle pressure and move it across the wound bed, gripping the edge with your fingers. User can also wrap XSCRUB™ around their index finger to use it.
2. Consult with your health care professional or prescribing physician about how long to use XSCRUB™. Depending on the size of the wound, the XSCRUB™ Wound Cleansing Pad is typically used for 20 seconds to 2 minutes per session. For smaller wounds (<1.5 inches in diameter), approximately 20-30 seconds total use should be sufficient time to clean the wound and periwound. It is not recommended to use XSCRUB™ for more than 30 seconds unless you check with your prescribing physician or have a large wound area to treat.
3. XSCRUB™ is recommended to be used from once weekly, up to every dressing change for maintenance cleansing / wound scrubbing. Consult with your prescribing physician how often you should use XSCRUB™, and ensure the prescribing physician is following the patient's progress on a regular basis.
4. The indicated duration of therapy with XSCRUB™ is from one-time use, up to six months of regular use, depending on prescribing physician's clinical decision making and patient's clinical response.



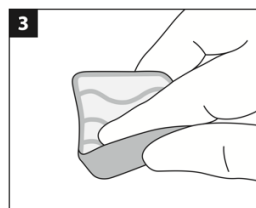
INSTRUCTIONS



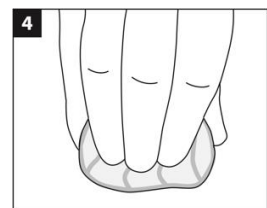
To use, hold green foam face down. Hold on one side



Apply gentle pressure and move gently back and forth or in small circular motion



Optional: Hold XSCRUB™ bent around one finger to use



Optional: Hold XSCRUB™ bent around three fingers to use



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

XSCRUB™ is indicated for hospital inpatient, outpatient clinic, long term care, or home use. Store in a cool, dry place not exceeding 25°C.



CAUTION

- 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 XSCRUB™.
- XSCRUB™ 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.
- XSCRUB™ 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 XSCRUB™ is 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 XSCRUB™.
- Advanced or suspected advanced peripheral arterial disease (PAD) ulcers that have not been revascularized are generally contraindicated for debridement, including XSCRUB™.
- A wound which exhibits pathergy or is high risk for pathergy is generally a contraindication to debridement, including aggressive use of XSCRUB™.
- It is a contraindication to use XSCRUB™ on patients who are intolerable or unpreventable to pain with use.
- XSCRUB™ is indicated on external wounds. It is contraindicated to use XSCRUB™ on internal wounds, wounds with exposed organs, or deep penetrating wounds.
- It is contraindicated to use XSCRUB™ on deep wounds which may involve or be close to large arteries or veins, or any wounds with exposed arteries or veins, as debridement or significant wound cleansing by any method here poses risk of hemorrhage.
- If patient develops pain or bleeding with XSCRUB™, or if the wound enlarges with use of XSCRUB™, use of XSCRUB™ 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

- Make sure XSCRUB™ is not retained in the wound bed after use. XSCRUB™ is not suitable for use with negative pressure devices, nor as a wound dressing.



DO NOT REUSE XSCRUB™

- XSCRUB™ is 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 XSCRUB™.



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