acton™ TOPICAL DELIVERY SYSTEM

Wound Care Topical Delivery System

Instructions for Use

RX Only

Manufactured for
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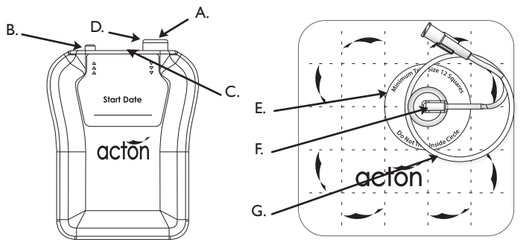
Acton Components

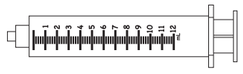


Acton Fluid Delivery Unit
- A. Fill Port
- B. Delivery Port
- C. System Activator Receptacle
- D. Fill Port Cap

Acton Delivery Dressing
- E. No Trim Area
- F. Tube Set Attachment
- G. Delivery Tube Set (Do not Cut)

System Activator

Dressing Application Tape



Syringe

Introduction

The Acton system is designed to provide continuous delivery of prescribed medication or solutions to the wound to facilitate the wound healing process. The Acton system is not to be used beyond seven days per application.

The Acton system is for prescription use as directed by a licensed health care provider and is for topical wound care use only.

Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The Acton Topical Delivery System is an occlusive wound dressing which is intended to provide a moist wound healing environment to facilitate the normal wound healing process. It also permits the introduction of topical wound treatment solutions and suspensions.

Contraindications

The Acton system is not indicated for:
- Heavily exudating wounds
- Actively bleeding wounds
- Ophthalmic wounds

⚠ Warnings

Failure to carefully read and follow all the usage and application instructions and the safety information for each use may lead to improper performance and the potential for serious injury.

1. The Acton System is for prescription use as directed by a licensed medical professional and is for topical wound care use only.
2. The Acton System should be applied and operated by a licensed health care provider.
3. For single use only. Do not reuse or reprocess.
4. Treatment should be appropriately monitored by a clinician while using the Acton System. If any of the following clinical indications are detected, the continued use should be evaluated:
   a. Increasing colonization of bacteria
   b. Increasing wound size
   c. Irritation or sensitivity to the Dressing, Tape, Tubing and/or Fluid Delivery Unit
   d. Excessive maceration
   e. Drying of the wound
5. Replace the current Acton System if leakage occurs in the device, luer fittings and/or from the dressing's Tube Set Attachment.
6. Use only solutions that are approved for topical use. Solutions are to be used in accordance with the manufacturer's directions for use.
7. Use only solutions, do not use gels, creams or pastes in Acton.
8. Remove the Acton System before receiving treatment in a hyperbaric chamber or while undergoing an MRI procedure.
9. Do not place the Acton System in direct contact with a high heat source or open flame.
10. Follow disposal instructions.
11. Do not use the Acton System or its components in any manner other than as stated in the Instructions for Use.

⚠ Precautions

1. Read the Instructions for Use completely before applying the Acton system.
2. Do not use this product if the packaging is compromised or product appears damaged.
3. Each Acton System is intended for a single use with a duration of not more than seven days per application.
4. All fittings are luer type and should be connected by hand to assure a tight, firm fit without over-tightening.
5. Do not use the Acton System beyond its stated expiration date.
6. Protect the Fluid Delivery Unit and the Delivery Dressing from exposure to external moisture such as showers, bathing and swimming. Patient may partially bathe while using the Acton System, however, patient should avoid getting the Fluid Delivery Unit and the Delivery Dressing wet.
7. Care must be taken to protect against crimping of the Delivery Tube Set. Do not cut or damage the Delivery Tube Set.
8. The dressing may be trimmed to accommodate the wound size and shape however, the trimmed dressing should not be trimmed below the equivalent of 12 (48 cm^2) of the printed squares on the dressing.
9. Do not trim the dressing inside the solid line circle printed on top of the dressing.

Instructions

Obtain the following materials (not provided) required for the application of the Acton System before starting the procedure.
- a. Prescribed topical solution
- b. Scissors
- c. Wound and Peri-wound preparation materials (as appropriate)
- d. Off-loading materials (as appropriate)

Delivery Dressing Preparation and Application
It is important to take into consideration, prior to preparing the dressing, the location of the wound with respect to positioning the device on the patient. The location of the device may influence the desired path for the tubing and the resulting orientation of the dressing.

⚠ **Precaution:** Consideration should be given to protect the wound and periwound area from pressure from the Tube Set Attachment. Accommodate bony prominences and utilize protective off-loading, as needed.

1. Clean and prepare the wound as appropriate.
2. Clean and prepare the periwound area. Use a protective moisture barrier if needed.

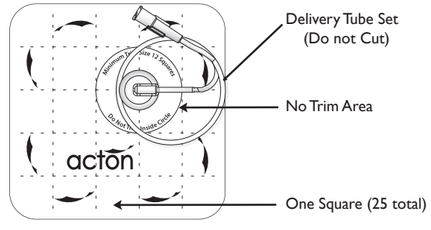
⚠ **Precaution:** The Delivery Dressing should extend beyond the edge of the wound and be secured to intact skin with the provided Dressing Application Tape. Consider use of a skin barrier for periwound protection from moisture and/or adhesive.

3. Determine the Delivery Dressing size, shape, and placement, ensuring that the dressing extends a minimum of 1 cm past the perimeter of the wound.
4. Trim the Delivery Dressing
   a. Minimum Delivery Dressing size is the equivalent of 12 printed squares on top of the dressing (there are 25 squares in total).

⚠ **Precaution:** Trimming the Delivery Dressing smaller than the minimum dressing size may result in excess moisture in the wound dressing.

⚠ **Precaution:** Do not allow the Delivery Tube Set luer to come in contact with contaminants.

⚠ **Precaution:** Do not cut or damage the Delivery Tube Set during trimming of the dressing.



5. Apply the Delivery Dressing to the wound area assuring that it is appropriately positioned and aligned.
6. Secure the Delivery Dressing to the patient using the provided Dressing Application Tape, overlapping the ends of the tape to ensure that the entire perimeter is covered.

⚠ **Precaution:** Using a tape other than the Dressing Application Tape provided may compromise the performance.

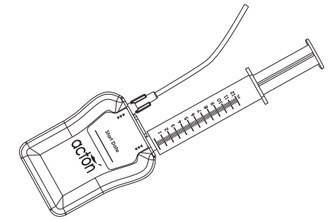
7. As appropriate, off-load the wound and periwound area to accommodate the tube attachment.

Loading the Acton Topical Delivery System
Acton delivers a topical solution to the wound. Following are instructions for selecting and administering the volume of solution required for filling the Fluid Delivery Unit and providing the initial load to the Delivery Dressing.

The topical solution to be used is directed by the clinician based on the prescribed treatment plan. All topical solutions are to be used based on clinical judgement and in accordance with the manufacturer's directions for use.

Instructions (continued)

Loading the Acton Topical Delivery System (continued)
1. Insert the System Activator into the corresponding receptacle of the Fluid Delivery Unit.
2. The System Activator should be inserted until the top ridge of the System Activator sits against the Fluid Delivery Unit.
3. Remove the tube clip from the coiled Delivery Tube Set.
4. Connect the Delivery Tube Set to the Delivery Port of the Fluid Delivery Unit.
5. Fill the syringe with the appropriate volume of selected solution:
   a. A Delivery Dressing less than 16 squares requires the syringe to be filled with 10.4 ml of solution to fill the Fluid Delivery Unit and provide the initial load to the Delivery Dressing.
   b. A Delivery Dressing greater than or equal to 16 squares requires the syringe to be filled with 12.0 ml of solution to fill the Fluid Delivery Unit and provide the initial load to the Delivery Dressing.
6. Remove the Fill Port Cap and place it in a clean location. Connect the Syringe to the Fill Port of the Fluid Delivery Unit.
7. Position the Fluid Delivery Unit so ports are facing upward and tilt so the Fill Port is lower than the Delivery Port. While filling manipulate to ensure that air is purged. It is acceptable to have some small bubbles remain after filling.



8. Expel the entire contents of the Syringe slowly. The Fluid Delivery Unit will fill before the fluid is released to the Delivery Dressing. In the event that a prefilled syringe is used, ensure that only the recommended solution volume is dispensed from the syringe.
9. Disconnect Syringe from Fill Port and apply the provided Fill Port Cap to the port.

Securing the Acton System
1. Coil tubing to desired length ensuring the tubing does not limit the patient's range of motion or present a tripping risk. Also ensure tubing is positioned to prevent kinking. Tape may be used to secure the coiled tubing.
2. If desired obtain an Acton Belt Clip and/or Strap (provided separately) to secure the Acton Topical Delivery System.

Monitoring of Treatment
Clinical judgment should be exercised in determining the duration of time between wound examinations and if adjustments to the treatment plan are indicated. Monitor the patient and wound in accordance with the standard of care, including the following, throughout the course of treatment.
1. Ensure that the Delivery Dressing is properly secured to the wound site.
2. Monitor effectiveness of topical solution with respect to Treatment Plan.

Removal and Disposal
1. Disconnect the Fluid Delivery Unit from the Delivery Dressing by releasing the Delivery Tube Set via the luer from the Delivery Port.
2. Carefully remove the Delivery Dressing and Dressing Application Tape from the patient.
3. Dispose of the Acton Topical Delivery System following standard medical waste procedures and in accordance with all federal, state and local regulations.

aplion® Wound Care Technology