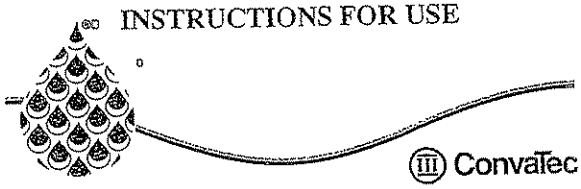
STERILE

AQUACEL® Ag with Hydrofiber®

Silver Impregnated Antimicrobial Dressing

INSTRUCTIONS FOR USE



- For Single Use

STERILE R - Gamma Sterilized

REF - Order Number

 - Keep Dry

 - Store at Room Temperature

 - See Insert for Instructions for Use

LOT - Lot

 - Expiration Date

PRODUCT DESCRIPTION

AQUACEL® Ag with Hydrofiber® (Aquacel Ag), silver impregnated antimicrobial dressing is a soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose and 1.2% ionic silver which allows for a maximum of 12mg of silver for a 4 inch x 4 inch dressing. The silver in the dressing kills wound bacteria held in the dressing, reduces the number of bacteria where the dressing conforms to the wound and aids in creating an antimicrobial environment. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). Moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.[1,2]

INDICATIONS

For over-the-counter use, Aquacel Ag may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

Under the supervision of a health care professional, Aquacel Ag may be used for the management of:

- wounds as an effective barrier to bacterial penetration to help reduce infection;
- partial thickness (second degree) burns;
- diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology) and pressure ulcers/sores (partial & full thickness);
- surgical wounds left to heal by secondary intent;
- traumatic wounds;
- wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided;
- oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma.

Aquacel Ag may be used on minimally exuding, non-exuding and dry wounds, as stated in the DIRECTIONS FOR USE.

CONTRAINDICATIONS

Aquacel Ag should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

PRECAUTIONS AND OBSERVATIONS

- **Caution:** Sterility is guaranteed unless pouch is damaged or opened prior to use. Single use only.
- During the body's normal healing process, non-viable tissue is removed from the wound (autolytic debridement), which could initially make the wound appear larger. If the wound continues to grow larger after the first few dressing changes, consult a health care professional. The wound should be inspected during dressing changes. Consult a healthcare professional if you see a) signs of infection (increased pain, increased redness, wound drainage), b) bleeding, c) a change in wound color and/or odor, d) irritation (increased redness and/or inflammation), e) maceration (skin whitening), f) hypergranulation (excessive tissue formation), g) sensitivity (allergic reaction), h) no signs of healing.
- If you have difficulty removing the dressing, it should be soaked with water or sterile saline until it removes easily. (For partial thickness burns, please refer to the Partial Thickness Burns section of this package insert)
- Because Aquacel Ag provides a moist environment that supports the growth of new blood vessels, the delicate newly formed blood vessels may occasionally produce blood stained wound fluid.
- Aquacel Ag is not compatible with oil-based products, such as petrolatum.
- Secondary dressings should be used as stated in the DIRECTIONS FOR USE.
- When used in second degree burns, adherence of the dressing over joints could interfere with movement. In Aquacel® clinical trials in second degree burns, this was, however, not shown to have any effect on the range of motion after healing was complete.
- Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers, systemic antibiotics and frequent monitoring in the treatment of wound infection, control of blood glucose for diabetic ulcers, etc.)
- This wound dressing should not be used with other wound care products, other than those listed in DIRECTIONS FOR USE section without first consulting a healthcare professional.

In addition, for leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers, pressure ulcers/sores, partial thickness (second degree burns), and surgical, oncology or traumatic wounds left to heal by secondary intention:

- Treatment of wounds listed above should be under the supervision of a healthcare professional.
- Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression bandaging in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers, systemic antibiotics and frequent monitoring in the treatment of wound infection, control of blood glucose for diabetic ulcers, etc.).
- For oncology wounds, a secondary dressing of high absorbency may be required.
- In cavity wounds, the ribbon dressing may be used to pack the wound. For wounds such as fistulae and sinus tracts, employ appropriate techniques during the insertion and removal of the dressing.
- In partial thickness (second degree) burns, consider alternate (surgical) procedures if the wound has not reepithelialized after 14 days.
- Aquacel Ag is not intended for use as a surgical sponge.

DIRECTIONS FOR USE

- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
- Aquacel Ag should overlap 1cm (1/2 inch) onto the skin surrounding the wound.
- When using Aquacel Ag ribbon in cavity wounds, leave at least 2.5cm (1 inch) outside the wound for easy retrieval.
- This primary dressing should be used with a secondary cover dressing. Apply the dressing to the wound and cover with a moisture retentive dressing (e.g. DuoDERM®, CarboFlex®, CombiDERM®), foam dressing, gauze, or other appropriate dressing. See individual cover dressing package inserts for complete instruction for use.
- All wounds should be inspected frequently. Remove the Aquacel Ag when clinically indicated (i.e., leakage, excessive bleeding, increased pain) or after a maximum of seven days.

FOR PARTIAL THICKNESS BURNS (SECOND DEGREE BURNS):

- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
- The Aquacel Ag should overlap 5 cm (2 inches) onto the skin surrounding the burn or other adjacent Aquacel Ag.
- The Aquacel Ag should be covered with sterile gauze and secured with medical tape or a retention bandage.
- Remove the gauze cover dressing periodically and inspect the Aquacel Ag while it remains in place on the burn.
- In this indication adherence to the wound bed of the Aquacel Ag is a desired characteristic.
- Adherence of the dressing over joints could interfere with movement. In Aquacel® clinical trials in second degree burns this was not shown to have any effect on the range of motion after healing was complete.
- Remove the Aquacel Ag dressing when clinically indicated (e.g, excessive bleeding, clinical signs of infection).
- For partial thickness burns (second degree burns), Aquacel Ag dressings may be left in place for up to 14 days or until clinically indicated. If the burn is infected, frequent inspection of the wound may be necessary.
- As the burn wound reepithelizes, the Aquacel Ag will detach or be easily removed.

FOR DRY WOUNDS

Place the Aquacel Ag in the wound and then wet with sterile saline over the wound area only. The vertical absorption properties of Aquacel Ag will help to maintain the moist area over the wound only and reduce the risk of maceration. Cover the dressing with a moisture retentive dressing such as DuoDERM® Extra Thin to avoid drying out of the dressing and subsequent dressing adherence to the wound.

	7-day sustained activity test (simulated wound model)	Zone of inhibition test (Spectrum of activity)
Staphylococcus aureus	✓	✓
Pseudomonas aeruginosa	✓	✓
Candida albicans	✓	✓
MRSA		✓
VRE		
Serratia marscesens (abtc resistant)		✓
P. aeruginosa (abtc resistant)		✓
Enterobacter cloacae		✓
Klebsiella pneumoniae		✓
Escherichia coli		✓
Enterococcus faecalis		✓
Streptococcus pyogenes		✓
Bacteroides fragilis		✓
Peptostreptococcus anaerobius		✓
Clostridium ramosum		✓
Clostridium clostridioforme		✓
Clostridium cadaveris		✓
Clostridium perfringens		✓
Prevotella corporis		

If the immediate product packaging is damaged, do not use.

Store at room temperature (10°C - 25°C/50°F - 77°F). Keep dry.

If further information or guidance is needed, please contact ConvaTec Professional Services.

[1] The biocompatability of Aquacel Ag has been demonstrated through appropriate in vivo and in vitro tests.
[2] Anitmicrobial activity has been demonstrated by relevant in vitro microbiological assays.

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