

ACTICOAT[®] FLEX 7

with
SILCRYST[™]
NANOCRYSTALS



Do not use if package is open or damaged.
Single use only.
Do not resterilize.
Store in a dry place (<77°F/25°C).
Protect from light.

Description

The ACTICOAT[®] FLEX 7 dressing consists of a flexible, low adherent polyester layer coated with nanocrystalline silver. ACTICOAT FLEX 7 is a highly conformable dressing that follows the body contours to maintain contact with the wound surface. The dressing is low adherent, which helps to minimise wound trauma at dressing changes. Nanocrystalline silver provides an effective barrier to microbial contamination. When tested *in-vitro*, ACTICOAT FLEX 7 was demonstrated to have effective antimicrobial barrier properties for up to 7 days against a broad spectrum of wound pathogens including: *Staphylococcus aureus*, *pseudomonas aeruginosa*, *Bacteroides fragilis*, *Candida albicans*, *Aspergillus niger*, vancomycin resistant enterococci (VRE) and methicillin resistant *Staphylococcus aureus* (MRSA). The antimicrobial barrier properties and the ability of the dressing to allow fluid to pass through without impairment, (*in-vitro* data) has shown ACTICOAT FLEX 7 to be compatible with negative pressure wound therapy (NPWT) for a period of up to 3 days.

Indications

ACTICOAT FLEX 7 is indicated for use on partial and full thickness wounds. This includes:

- First and second degree burns
- Covering of grafts
- Surgical sites
- Venous ulcers
- Pressure ulcers
- Diabetic ulcers

Contra-indications

- Do not use on patients with a known sensitivity to silver.
- Do not use on patients during MRI (Magnetic Resonance Imaging) examination.
- Prior to administering radiation therapy, remove ACTICOAT FLEX 7. A new dressing can be applied following each treatment.

Precautions

- For external use only; for example, do not apply the dressing to exposed organs.
- ACTICOAT FLEX 7 is not compatible with oil-based products such as petrolatum.
- Avoid contact with electrodes or conductive gels during electronic measurements e.g. EEG and ECG.
- This device is not intended for use on 3rd degree burns.
- ACTICOAT FLEX 7 should only be used on premature infants (less than 37 weeks gestation) when the clinical benefit outweighs potential risks.
- ACTICOAT FLEX 7 is not intended to provide sole treatment for infected wounds. ACTICOAT FLEX 7 may be used on infected wounds which are being managed per local clinical protocol.

Instructions for Use

- Remove the ACTICOAT FLEX 7 dressing from the pack using a clean technique.
- If the wound is dry or there is minimal exudate, moisten the dressing with drinking water (DO NOT use saline). Remove excess water prior to application e.g. leave to drain on a sterile field for approximately 2 minutes. Where there is a moderate to

- high level of exudate, there is no need to pre-moisten.
- Cut the dressing to shape as necessary. When used with compression therapy the dressing must be cut to the size of the wound.
- Without stretching the dressing, apply ACTICOAT FLEX 7, either side down, to the wound surface ensuring there are no creases. The dressing should be applied with the direction of stretch running along the limb to allow movement.
- There may be transient pain experienced on application of ACTICOAT FLEX 7. This can be minimized by carefully following the application instructions. Should continuous pain be experienced after application, remove the dressing and discontinue use.
- When in use with NPWT, the wound filler material should be moistened and changed according to manufacturers' instructions.
- Secure the ACTICOAT FLEX 7 dressing in place with an appropriate secondary dressing that will maintain a moist wound environment. In the case of highly exuding wounds, an absorbent secondary dressing is appropriate. ACTICOAT FLEX 7 allows transport of the exudate directly into the secondary dressing.
- Keep the ACTICOAT FLEX 7 dressing moist but not so wet that tissue maceration occurs.
- Change the dressing depending on the amount of exudate present and the condition of the wound.
- Dressings may be left in place for up to 7 days.
- When using ACTICOAT FLEX 7 under compression, regularly check the entire dressing system and change only if strike-through occurs. An additional non occlusive absorbent dressing may be required if the level of exudate is high.
- Should the dressing dry or adhere to the wound, moisten or soak the dressing to assist removal and avoid disruption of the healing wound.

Chemistry

Ionic silver is the antimicrobial agent.

Pharmacology

Nanocrystalline silver as a source of ionic silver is an effective broad spectrum antimicrobial agent. In contact with wound exudate, silver ions are released in the dressing and kill microbes by disrupting their cell walls and interacting with intracellular components to create an antimicrobial barrier within the dressing.

Toxicology

Ionic silver is non-irritating, non-sensitising, non-mutagenic and biocompatible in a wound environment. Silver is considered to be of low toxicity in humans and has an extensive history of safe use in wound care applications at concentrations found in the wound dressing.

Metabolism and Excretion

Absorption of silver from wound sites is a function of the size of the wound and may also be dependant upon wound depth and vascularisation. Systemically absorbed silver is excreted over time via a biliary route.

Note: ACTICOAT FLEX 7 may cause transient discoloration of the surrounding skin.

Note: The color of the dressing may vary. This does not affect the performance of the dressing.

Product Availability

Code	Size	Dressings per Box
66800403	2in. x 2in.	Carton of 5
66800405	4in. x 5in.	Carton of 5
66800427	6in. x 6in.	Carton of 5
66800407	8in. x 16in.	Carton of 6
66800408	16in. x 16in.	Carton of 6

Patents Nos: US 5681575, 5753251, 5770255, 5837275

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Each dressing contains: 0.84mg/cm² (5.42mg/in²) - 2.01mg/cm² (12.97mg/in²)
Nanocrystalline Silver.

Made in Canada for: Smith & Nephew Medical Limited, Hull HU3 2BN England

Distributed in USA by: Smith & Nephew, Inc., St. Petersburg, FL 33716

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