ClearGuard® HD

INSTRUCTIONS FOR USE

DESCRIPTION

ClearGuard HD end caps are blood access device accessories. The ClearGuard Hemodialysis (HD) end cap is a male luer lock end cap with the antimicrobial agent chlorhexidine acetate on the rod and lock ring threads.

Each package contains two ClearGuard HD end caps assembled in a shield. Figure 1 shows the product with one ClearGuard HD end cap removed from the shield. The total amount of chlorhexidine acetate on a pair of devices is not more than 2.4 mg, and the maximum amount that is available to be released to the patient is 0.6 mg per device pair. The ClearGuard HD end caps can be used for up to a maximum of 72 hours.

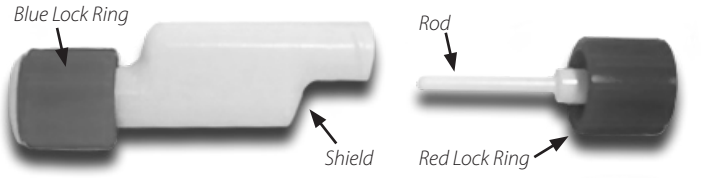

Figure 1 One ClearGuard HD End Cap Removed from the Shield

INDICATIONS FOR USE

ClearGuard HD is indicated for use as an end cap for use with hemodialysis catheter hubs.
The antimicrobial treatment on the ClearGuard HD end cap has been shown to be effective at reducing microbial colonization in hemodialysis catheter hubs against the following microorganisms: *Enterococcus faecium (VRE), Enterococcus faecalis (VRE), Acinetobacter baumannii, Escherichia coli, Staphylococcus aureus (MRSA), Staphylococcus aureus, Staphylococcus epidermidis (MRSE), Pseudomonas aeruginosa, Candida albicans and Candida parapsilosis and has not been shown to be effective against Candida paratropicalis and Klebsiella pneumoniae.*

The antimicrobial effectiveness was evaluated using *in vitro* methods, and correlation between *in vitro* antibacterial activity and any clinical effectiveness has not been tested. The subject device is not intended to be used for the treatment of existing infections. The antimicrobial is only effective within the hub of the catheter, and does not migrate to distal portions of the catheter.

CONTRAINDICATIONS

Do not use the ClearGuard HD end caps for the following:

- Patients who are allergic to chlorhexidine.
- Patients who are allergic to nylon or polypropylene.
- Catheters that are dimensionally incompatible with the ClearGuard HD end caps.
- Catheters with hubs that allow the ClearGuard HD rod to extend beyond the hub within reach of the extension line pinch clamp.
- Catheters that have antimicrobial agents eluting from their inner lumens.

WARNINGS

- Do not use if the package has been opened or is damaged, or if the expiration date has passed.
- Do not reuse any component of the ClearGuard HD end cap. The ClearGuard HD end cap is intended for **single use only** and should never be re-used. Reuse or reprocessing including resterilization may compromise the device integrity and may also create a risk of contamination of the device and/or cause recipient infection.
- Do not close extension line pinch clamp on ClearGuard HD rod.
- The ClearGuard HD end cap has not been evaluated for safety in Magnetic Resonance Imaging (MRI).
- Do not allow the ClearGuard HD rod or luer to contact non-sterile items; touching the rod or luer with non-sterile items may lead to a bloodstream infection.
- Do not touch the rod with gloved hands.
- The ClearGuard HD end cap should be discarded if the rod contacts non-sterile items or gloved hands.

CAUTIONS

- This product contains chlorhexidine acetate.
- Carefully read and follow all instructions prior to use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified dialysis center personnel or healthcare practitioners should place, manipulate or remove the ClearGuard HD end caps.

PRECAUTIONS

- Follow universal precautions when inserting and maintaining the ClearGuard HD end caps.
- Do not allow the ClearGuard HD rod to contact non-sterile items.
- Take care not to damage the ClearGuard HD end cap during placement.

POTENTIAL COMPLICATIONS

- Allergic/anaphylactic/pyrogenic reaction
- Injury/pain/death
- Device failure (device cracking, breaking, leaking, splitting or disconnecting potentially requiring device intervention, removal or replacement)
- Embolism (air or device)
- Incompatibility with administered fluids or sanitizing agent.
- Incompatibility with connecting device/difficulty connecting
- Infection (local, bacteremia, endocarditis, sepsis)
- Sensitization
- Toxicity

PLACING A CLEARGUARD HD END CAP ON A HEMODIALYSIS CATHETER

1. Use the standard facility or industry recommended aseptic technique when accessing the catheter. A mask is to be worn by the caregiver and patient covering the nose and mouth. The caregiver's hands are to be cleaned and gloved.

   PRECAUTION: Use aseptic technique to avoid contaminating the end cap and catheter.

2. Use the standard facility and industry recommended practices to flush the catheter and to instill locking solution into the catheter prior to placing the ClearGuard HD end cap. Ensure that the catheter extension tubing pinch clamp is closed, that the lock solution completely fills the extension tube and catheter hub, and the syringe remains attached to the catheter.
3. Remove the pair of ClearGuard HD end caps that are contained in a shield from the foil pouch.
4. While holding the shield and a catheter hub in one hand, remove the syringe from the hub and discard syringe. Do not allow the hub to touch non-sterile surfaces.
5. Remove a single ClearGuard HD end cap (red or blue), by rotating the lock ring counterclockwise, taking care to only handle the lock ring; do not touch the rod.

   WARNING: Do not allow the ClearGuard HD rod or luer to contact non-sterile items; touching the rod or luer with non-sterile items may lead to a bloodstream infection. Discard the ClearGuard HD end cap if the rod or luer contacts non-sterile items or gloved hands.
6. Carefully insert the ClearGuard HD rod into the catheter hub and, using a simultaneous push and twist motion, tighten by rotating clockwise.

   NOTE: As the ClearGuard HD rod enters the hub, it will displace some of the lock solution; this is desirable as it can wet the antimicrobial on the ClearGuard HD end cap threads.
7. Repeat with the other ClearGuard HD end cap and dispose of the shield and foil pouch.

REMOVING THE CLEARGUARD HD END CAP FROM A HEMODIALYSIS CATHETER

1. Use the standard facility or industry recommended aseptic technique when accessing the catheter. A mask is to be worn by the caregiver and patient covering the nose and mouth. The caregiver's hands are to be cleaned and gloved.

   PRECAUTION: Use aseptic technique to avoid contaminating the end cap and catheter.
2. Use the facility's standard end cap cleaning procedure, such as wrapping connectors with povidone iodine soaked gauze prior to removing the ClearGuard HD end cap.
3. Ensure that the extension tubing pinch clamp is closed.
4. Carefully support catheter hub with one hand and, using other hand, loosen ClearGuard HD end cap by rotating counter-clockwise.
5. Remove the ClearGuard HD end cap and dispose of the used device in accordance with facility protocol (see DEVICE DISPOSAL, below). The end caps must be discarded after removal.

   PRECAUTION: End caps must never be reused or reconnected to the catheter hub once removed or contamination of the catheter may occur.
6. Attach sterile syringe to catheter and aspirate the lock solution from the catheter using your facility's standard practices.

   WARNING: After removing the ClearGuard HD end cap from the catheter, aspirate a minimum of 5 mL of fluid from the catheter. This will prevent lock solution, along with the dissolved and precipitated antimicrobial agent, from entering the bloodstream.
7. Use the catheter using standard facility and industry recommended practices.

MAXIMUM USE TIME

The recommended maximum use time is three days.

STERILITY & PACKAGING

The ClearGuard HD End Cap is provided sterile in a single sterile barrier foil package and is gamma sterilized. The device should be stored at room temperature and protected from UV exposure and moisture.

DEVICE DISPOSAL

ClearGuard HD end caps that have been in contact with body fluids are a potential biohazard. Handle and dispose of the device and its components with acceptable medical practice and applicable local, state, and federal laws and regulations.

SAFETY AND EFFECTIVENESS DATA

The ClearGuard HD end caps have been found to be safe and effective for their intended use. The ClearGuard HD end caps have been subjected to biocompatibility testing in compliance with EN ISO 10993-1 and found to be non-hemolytic, non-cytotoxic, non-irritating, non-sensitizing, non-mutagenic, non-toxic and non-pyrogenic under intended use conditions. They have also been found to be sterile with a SAL ≤ 10-6. The ClearGuard end caps have also met their requirements for luers, chemical resistance, assembly and disassembly torque and attachment strength.

The ClearGuard HD end cap effectiveness has been assessed using the following *in vitro* test method:

- Heparin lock solution, which was inoculated with microorganism strains that are known to cause catheter related blood stream infections, was injected into the hub region of a catheter.
- Equal numbers of ClearGuard HD end caps and uncoated control devices were then placed on the test catheter systems and allowed to remain in place for two to three days.
- For both the ClearGuard HD end cap and the uncoated control device, the number of surviving microorganisms were determined.
- The ClearGuard HD end cap was deemed to be effective against a microorganism if it produced at least a 4 $\log_{10}$ reduction (99.99% reduction), when compared to uncoated control device.
- Please see indications for use for a summary of results.

TECHNICAL SUPPORT & CUSTOMER SERVICE

To obtain additional information on the ClearGuard HD end cap, contact the customer service department at:

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Doc. #: LM-0002 Rev B
2016-01