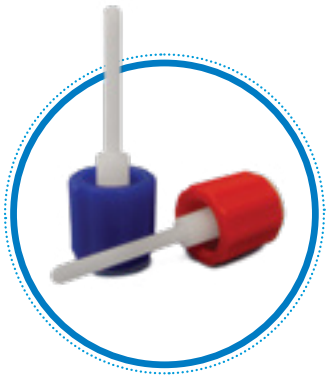
ClearGuard™ HD

Antimicrobial Barrier Caps



Frequently Asked Questions (FAQs)

1. Can ClearGuard HD caps be reused?

The ClearGuard HD cap is intended for single use only and should never be reused. Reuse or reprocessing, including resterilization, may compromise the device integrity and may also create a risk of contamination of the device and/or cause infection.

2. How long can ClearGuard HD caps remain on the hemodialysis catheter hub?

The Instructions for Use state a maximum recommended use time of three days based on the antimicrobial effectiveness bench testing that was conducted at 48 hours and 72 hours to replicate the typical timeframe between dialysis treatments. The cap is designed to maintain a mechanical barrier against contamination until removed.

3. What happens if the chlorhexidine solution enters the patient's bloodstream (is flushed) instead of being aspirated?

After removing the ClearGuard HD cap from the catheter, it is recommended that a minimum of 5mL of fluid be aspirated from the catheter to prevent the lock solution and antimicrobial agent from entering the bloodstream. In the event that the lock solution cannot be aspirated or is inadvertently flushed into the bloodstream, the chlorhexidine in the solution does not pose patient safety risk. As part of the ClearGuard HD Cap review, a risk assessment was performed and demonstrated that the amount of CHA that could be exposed to the patient is both non-therapeutic and non-toxic.

HOME

icumedical
human connections

4. What impact does residual chlorhexidine in the catheter hub have on blood cultures?

During the analysis of the clinical trial results conducted by Fresenius involving 1,245 patients for the treatment group, it was found there was no impact of residual antimicrobial agent effecting the blood culture results.

The ratio of positive blood cultures (PBCs) for treatment vs. control was 0.72 (26/36) when the blood culture was drawn at the catheter hub, and the ratio of PBCs was 0.47 (29/62) when the blood culture was drawn at the bloodline port (see Table 1 below). Thus, there is a greater proportion of PBCs in the treatment group when the blood culture is drawn from catheter hubs where the most residual CHA is expected. Blood draws taken from an arterial bloodline port occur during dialysis when any residual CHA would have been removed from the CVC hub by the flowing blood. Thus, the clinical evidence does not indicate that blood cultures in this study have been inhibited by CHA.

Table 1. Breakdown of Blood Draw Locations for All Blood Cultures

Blood Draw Location	Total PBCs	Treatment PBCs	Control PBCs	Ratio (Tx/Ctrl)
Catheter hub	62	26	36	0.72
Arterial bloodline port	81	29	62	0.47
All specified locations	143	55	98	

5. Which lock solutions are compatible with ClearGuard HD caps?

ClearGuard HD caps can be used with heparin, citrate and saline solutions.

6. Can ClearGuard HD caps be used with Cathflo Activase (alteplase)?

Cathflo Activase (alteplase) was successfully used in the Davita clinical study published in JASN 2018.

7. Have ClearGuard HD caps been used with thrombolytic therapy?

In the study conducted by Brunelli et al, thrombolytic use rate was not significantly different between the two groups (1.84 versus 1.89 per 1000 CVC-days, respectively; P=0.9).[1]

8. Is there any difference between the red and blue lock ring?

No, they are equivalent and can be used on either hub.

9. Can the device be used in a patient with a known chlorhexidine sensitivity?

No. ClearGuard HD caps are contraindicated for use in patients who are allergic to chlorhexidine.

10. Are ClearGuard HD caps latex free?

ClearGuard HD caps and the associated packaging are not made with natural rubber latex.

11. Can ClearGuard HD caps be used in Magnetic Resonance Imaging (MRI)?

The ClearGuard HD Antimicrobial Barrier Cap is comprised of a chlorhexidine disinfectant and plastics commonly found in IV sets and accessories. It is designed using non-metallic, nonmagnetic, and non-conductive materials to prevent additional patient risk in a magnetic resonance environment. While testing has not been performed in a magnetic resonance environment, there are no known incompatibilities associated with the use of ClearGuard HD caps in or around MRI equipment.

HOME

[1] Brunelli, SM et al. Cluster-randomized trial of devices to prevent catheter-related bloodstream infection. J Am Soc Nephrol. 2018 Apr,29(4):1336-1343.

[2] Hymes, JL et al. Dialysis catheter-related bloodstream infections: a cluster-randomized trial of the ClearGuard HD antimicrobial barrier cap. Am J Kidney Dis. 2017 Feb;69(2)220-227.

icumedical
human connections