

## ClearGuard® HD Frequently Asked Questions (FAQs)

1. [Can ClearGuard HD caps be reused?](#)
2. [How long can ClearGuard HD caps remain on the hemodialysis catheter hub?](#)
3. [What happens if the chlorhexidine solution enters the patient's bloodstream \(is flushed\) instead of being aspirated?](#)
4. [What impact does residual chlorhexidine in the catheter hub have on blood cultures?](#)
5. [Which lock solutions are compatible with ClearGuard HD?](#)
6. [Can ClearGuard HD be used with Cathflo® Activase® \(altaplese\)?](#)
7. [Can ClearGuard HD be used with antimicrobial locks?](#)
8. [Can ClearGuard HD be used or substituted for antibiotic locks?](#)
9. [Is the chlorhexidine acetate in the ClearGuard HD Antimicrobial Barrier Cap compatible with all dialysis catheter types?](#)
10. [Is there any difference between the red and blue lock ring?](#)
11. [Can the device be used in a patient with a known chlorhexidine sensitivity?](#)
12. [Are ClearGuard HD caps latex free?](#)
13. [Do the caps seal properly if there are threads visible on the catheter hub after the cap is applied?](#)

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### 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 suggest a maximum recommended use time of three days because the antimicrobial effectiveness bench testing was conducted at 48 hours and 72 hours to replicate the typical timeframe between dialysis treatments. However, the cap remains 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 is safe. As part of the ClearGuard HD Cap review conducted by FDA, a risk assessment was performed and demonstrated the risk to the patient was acceptable even if all of the chlorhexidine on the device were to be flushed into the bloodstream on a daily basis. Additionally, there have been no reported issues – no device-related adverse events were reported in either large clinical trial (~2,070 patients / 253K treatment-days). Over 3.5 million pairs of caps have been shipped without any reported device-related safety issues.

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Refer to the Instructions for Use for full indications and use.

#### 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)
<b>Catheter hub</b>	<b>62</b>	<b>26</b>	<b>36</b>	<b>0.72</b>
<b>Arterial bloodline port</b>	<b>81</b>	<b>29</b>	<b>62</b>	<b>0.47</b>
<b>All specified locations</b>	<b>143</b>	<b>55</b>	<b>98</b>	

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

ClearGuard HD caps can be used with heparin, citrate and saline solutions. In the study published in the April 2018 *Journal of the American Society of Nephrology* comparing ClearGuard HD caps vs. Tego+Curo, although lock solutions were not required to be reported during the study, the study authors noted, “Within both groups, the vast majority (>95%) of procedures used saline as the lock solution.” The authors also note that “thrombolytic use rate was not significantly different between the two groups (1.84 versus 1.89 per 1000 CVC-days, respectively; P=0.9).”

#### 6. Can ClearGuard HD caps be used with Cathflo® Activase® (altaplese)?

Cathflo Activase was used with ClearGuard HD in both the major clinical studies involving > 2,000 patients without any reported issues.

#### 7. Can ClearGuard HD caps be used with antimicrobial locks?

ClearGuard HD caps can be used with antimicrobial locks. There were over 350 administrations of antimicrobial locks with ClearGuard use during two large post-market clinical studies with no adverse effects reported.

#### 8. Can ClearGuard HD caps be used with or substituted for antibiotic locks?

ClearGuard HD caps can be used with antibiotic locks. The antibiotic lock would be additive to the ClearGuard HD cap since there would be antibiotic throughout the length of the catheter and the ClearGuard HD chlorhexidine does not migrate beyond the clamp. Antibiotics are intended to treat existing infections while the ClearGuard HD cap provides an antimicrobial barrier but is not intended to treat existing infections.

The ClearGuard HD cap would also be additive to the antibiotic lock in that chlorhexidine kills antibiotic resistant organisms in the catheter lumen between the cap and the pinch clamp thus protecting against new infections that may be resistant to the antibiotic lock. The ClearGuard HD cap also contains chlorhexidine on the threads which also provides antimicrobial protection on the outside of the hub when wetted.

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Refer to the Instructions for Use for full indications and use.

**9. Is the chlorhexidine acetate in the ClearGuard HD Antimicrobial Barrier Cap compatible with all dialysis catheter types?**

Yes. The chlorhexidine used in the ClearGuard HD cap (dry form of chlorhexidine acetate) is safe for all types of hemodialysis catheters, including materials such as polyurethane, silicone, polycarbonate, polyvinyl chloride, polyetherimide and others. While other products used with hemodialysis catheters (e.g., antiseptic cleaners) contain both chlorhexidine and alcohol, many catheter manufacturers recommend avoiding prolonged exposure to alcohol and chlorhexidine solutions with alcohol. ClearGuard HD caps do not contain alcohol, polyethylene glycol (PEG) or other solutions that may harm catheters.

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

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

**11. 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.

**12. Are ClearGuard HD caps latex free?**

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

**13. Do the caps seal properly if there are threads visible on the catheter hub after the cap is applied?**

When properly applied as described in the Instructions for Use, ClearGuard HD caps comply with international luer standard requirements (ISO 80369-7). The number of threads on the interior of the ClearGuard HD cap is comparable to that of standard CVC caps and Tego connectors. The length of the cap that extends past the threads varies by manufacturer, but this has no impact on its ability to seal. Testing performed by Pursuit Vascular has confirmed that ClearGuard HD caps properly sealed and did not leak when pressurized up to 45 psi when tested with commonly used hemodialysis catheters.

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