



## Frequently asked questions about BD PureHub™ Disinfecting Caps



# BD PureHub™ Disinfecting Cap

Optimally designed to help optimize outcomes



## Efficacy

- 1 Rapid disinfection in just 1 minute
- 2 Disinfects with a sterilized 70% isopropyl alcohol solution
- 3 Provides a >4 log (99.99%) reduction in bacteria\*\*

## Security

- 4 Brightly colored BD PureHub™ Disinfecting Cap provides visual confirmation of compliance with disinfection protocol
- 5 Maintains a physical barrier to contamination for up to 7 days, if not removed\*\*

## Easy to use

- 6 Large width and finger grips for ease of application and removal
- 7 Easy to apply with uniquely designed luer threads
- 8 Designed for compatibility with market leading needle-free connectors

\* Compared to traditional needle-free connector disinfection

† Demonstrated reduction on *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida glabrata*, *Candida albicans* and *Acinetobacter baumannii* as tested in a laboratory.

‡ Bench test results may not necessarily be indicative of clinical performance  
Please read labeling at all times. Active ingredient: 70% IPA.

# Frequently asked questions about BD PureHub™ Disinfecting Caps

## How effective is the BD PureHub™ Disinfecting Cap?

The BD PureHub™ Disinfecting Cap disinfects with a sterilized 70% IPA, providing a >4 log (99.99%) reduction in bacteria\*—including *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida glabrata*, *Candida albicans* and *Acinetobacter baumannii*—within 1 minute after application, and maintains a physical barrier against contamination for up to 7 days.

## What is the use of disinfecting caps with needle-free connectors in relation to the 2021 Infusion Nursing Society (INS) Standards of Practice?

Disinfecting caps containing 70% isopropyl alcohol are supported by the INS 2021 guidelines for passive disinfection of needle-free connectors.

- INS 2021 guidelines state that the use of disinfecting caps containing 70% isopropyl alcohol is associated with a lower rate of CLABSI.
- INS 2021 guidelines recommend the use of a passive disinfecting cap containing 70% isopropyl alcohol to create a physical barrier to contamination between uses.

The BD position on the use of BD PureHub™ Disinfecting Caps is consistent with the 2021 INS Standards of Practice.

## Does the BD PureHub™ Disinfecting Cap replace scrubbing/swabbing the needle-free connector with a disinfectant prior to each access?

BD recommends disinfecting the needle-free connector prior to access. The disinfection method prescribed by hospital protocol should be followed.

Warning: 70% Isopropyl Alcohol is not considered sporicidal and may not prevent Central Line-Associated Blood Stream Infections (CLABSIs) arising from bacterial spores (e.g., *Bacillus* spp., *Clostridia*)

\* Demonstrated reduction on *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida glabrata*, *Candida albicans* and *Acinetobacter baumannii* as tested in a laboratory.



### What types of access points should I use the BD PureHub™ Disinfecting Cap with?

The BD PureHub™ Disinfecting Cap is indicated for use for swabbable needle-free luer connectors prior to I.V. access and to act as a physical barrier between line accesses. The BD PureHub™ Disinfecting Cap should **not** be used with open luer access valves (i.e., stopcocks).

### What needle-free connectors can I use the BD PureHub™ Disinfecting Cap with?

Through internal design validation and verification testing, the BD PureHub™ Disinfecting Cap is shown to be compatible with swabbable needle-free luer connectors prior to I.V. access.

### Is the alcohol in the BD PureHub™ Disinfecting Cap sterile?

Yes. The BD PureHub™ Disinfecting Cap is gamma sterilized. The gamma irradiation process uses Cobalt 60 radiation to kill microorganisms on a variety of different products in a specially designed cell, including medical devices.<sup>1</sup>

### Is the interior surface of the BD PureHub™ Disinfecting Cap sterile?

Yes. The BD PureHub™ Disinfecting Cap is gamma sterilized.

### Can I drop the BD PureHub™ Disinfecting Cap onto a sterile field?

No. The BD PureHub™ Disinfecting Cap has a sterile solution; however, the external surface of each disinfecting cap is not sterile.

### I noticed the alcohol leaks out of the cap upon applying it to the connector. Should I be concerned that the connector is not being adequately disinfected?

The BD PureHub™ Disinfecting Cap does release some alcohol upon application to the connector in order to sufficiently disinfect. Testing on the BD PureHub™ Disinfecting Cap shows that it provides a >4 log (99.99%) reduction of bacteria\* within 1 minute after application to a needle-free luer connector.

\* Demonstrated reduction on *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida glabrata*, *Candida albicans* and *Acinetobacter baumannii* as tested in a laboratory.





## What's the difference if I leave the BD PureHub™ Disinfecting Cap on a needle-free connector for several minutes, 1 hour, 1 day or 7 days?

The BD PureHub™ Disinfecting Cap provides a >4 log (99.99%) reduction of bacteria within 1 minute after application to a needle-free connector.\*† After several hours, the product allows the 70% IPA to evaporate and then provides a physical barrier to bacterial contamination of the needle-free connector for up to 7 days if not removed.

## Is there any dry time required once the BD PureHub™ Disinfecting Cap has been removed from the needle-free connector?

The BD PureHub™ Disinfecting Cap Instructions for Use do not specify a dry time once it has been in contact with the needle-free connector for a minimum of 1 minute. Once the cap has been removed, the clinician can access the needle-free connector immediately.

## Is the BD PureHub™ Disinfecting Cap for single or multiple use?

The BD PureHub™ Disinfecting Cap is for single use only. It should be properly disposed of after removal from the needle-free connector.

## How should I dispose of the BD PureHub™ Disinfecting Cap?

The BD PureHub™ Disinfecting Cap should be safely disposed of in accordance with hospital protocol or local guidelines for medical waste.

\* Demonstrated reduction on *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Candida glabrata*, *Candida albicans* and *Acinetobacter baumannii* as tested in a laboratory.

† Compared to traditional needle-free connector disinfection.



## Does the BD PureHub™ Disinfecting Cap have a 510k?

BD PureHub™ Disinfecting Caps were originally introduced with a 510k. However, per the FDA's Center for Devices and Radiological Health Office of Device Evaluation and their document entitled *Intent to Exempt Certain Unclassified, Class II and Class I Reserved Medical Devices from Premarket Notification Requirements – Guidance for Industry and Food and Drug Administration Staff* issued on August 14, 2015, the Disinfecting Cap code classification was listed as *exempt*, noting that 510k submission and approval were no longer required.

Although a 510k is not required, it is important to note that BD follows all required testing and documentation applicable to a safe and reliable product. In addition, the BD PureHub™ Disinfecting Cap is CE-marked through the European Notified Body NSAI, and has all required documentation for this submission and approval process.

This guide is not intended as a replacement for the detailed information contained in the IFU. Please consult BD product labels and package inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

To learn more about BD PureHub™ Disinfecting Caps contact your local BD sales representative or visit [bd.com](https://www.bd.com)

#### References

1. <https://www.steris-ast.com/solutions/gamma-irradiation>

[bd.com](https://www.bd.com)

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