

Product Information & Commonly Asked Questions



Designed by Two Infusion Nurses, for Nurses

The Dualcap System™ was designed by infusion nurses who understood the unavoidable limitations of “scrubbing the hub” and the difficulty of disinfecting the male luer end of the IV tubing.

- Needle-free valves
 - 42% are scrubbed inadequately¹
 - Up to 67% of needle-free valves could still be contaminated after scrubbing²
 - As many as 31% of catheter hubs are never disinfected³
- Male luer connectors
 - Difficult configuration to effectively scrub
 - Previously overlooked as a source of contamination, the male luer connector is actually colonized at a higher rate than the needle-free valve⁴



Dark Blue DualCap® for the male luer connector at the end of IV tubing



Light Blue DualCap® for needle-free valve

The DualCap System™ Rapid and Ongoing Protection

- Consists of two caps designed to disinfect and protect both needle-free valves and male luer connectors, helping prevent intraluminal contamination and device cross-contamination
- When left in place for 30 seconds, the disinfecting caps disinfect the needle-free valve and the male luer connector and provide a physical barrier to contamination up to 7 days under normal conditions if not removed⁵

All catheter connections can be disinfected and protected with the DUALCAP SYSTEM on the following types of vascular access devices: central venous catheters (CVCs), peripherally-inserted central catheters (PICCs), midline catheters, peripheral venous catheters (PVCs), IV tubing Y-sites, and male luer connectors on the IV tubing end.



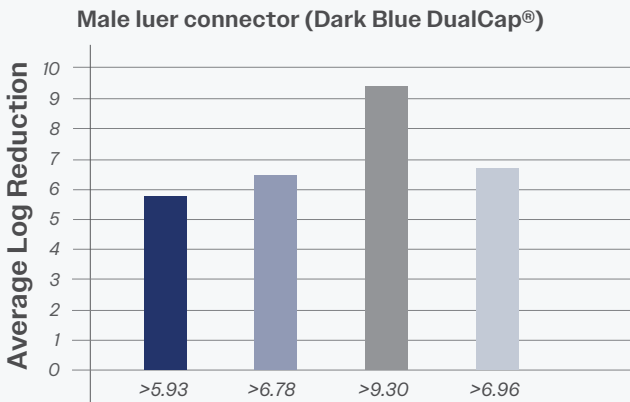
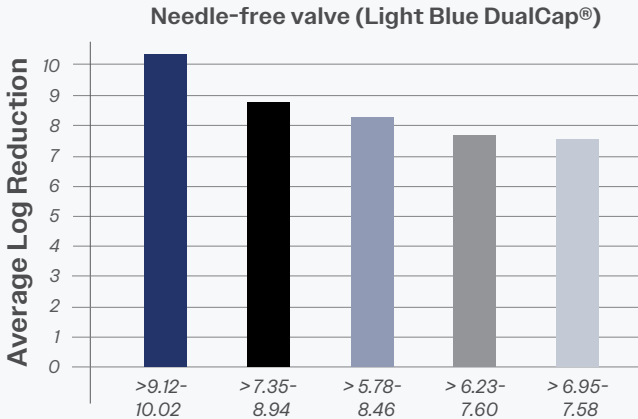
End of central catheter lumen




Y-site on IV line tubing and male luer connector at end of IV tubing

Proven Effectiveness in 30 Seconds for up to 7 Days⁵

Greater than 4-log reduction (99.99%) In each test organism
at 30 seconds⁶



 *P. aeruginosa*  *S. aureus*  *S. epidermis*  *E. coli*  *C. albicans*

The DualCap System™

IV Pole Strips

DualCap® IV Pole Strips™

Use when frequently accessing patient's IV; strip designed so that caps do not break off if strip is twisted



Bulk Supply, Packed in Dispenser Box

Light Blue DualCap Solo™

Use when needle-free valve needs capping break off if strip is twisted



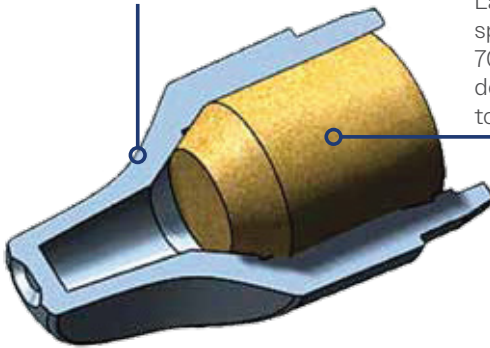
Dark Blue DualCap Solo™

Use when male luer connector at end of IV tubing needs capping

Safe & Secure Lock

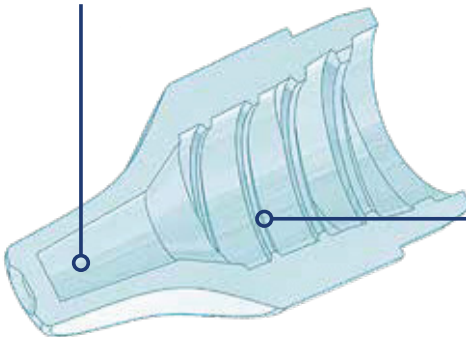
Needle-Free Valves are Completely Covered

Smooth surface prevents cap from snagging and protects skin from irritation



Large, compressible sponge is saturated with 70% IPA, which ensures delivery of disinfectant to all critical surfaces

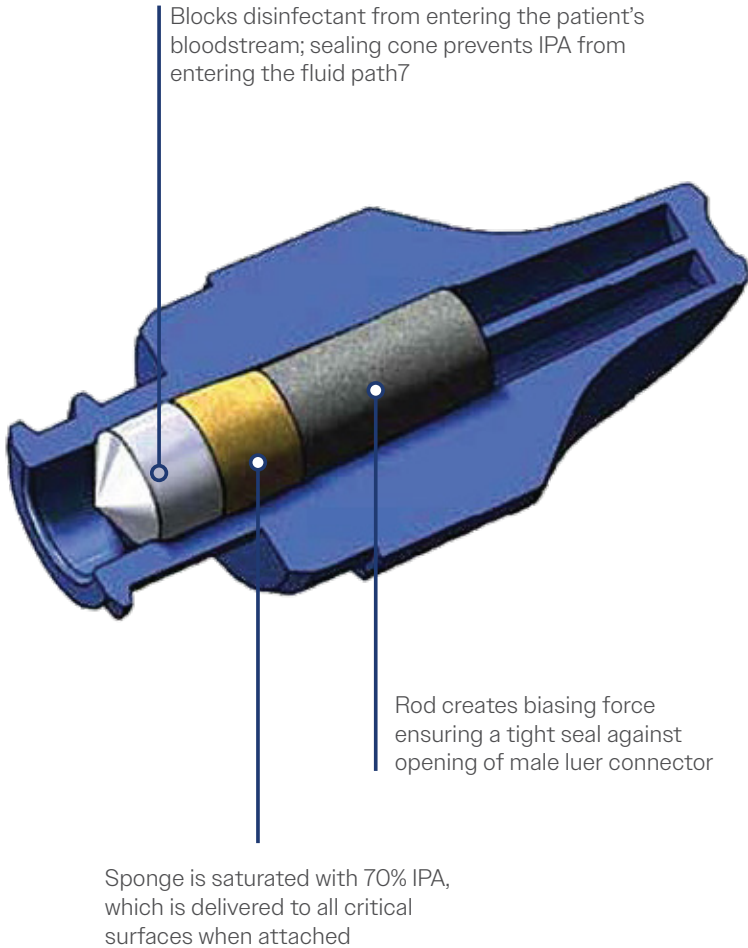
Large grip surface enables easy handling and attachment



Luer-tapered wall and full-threaded design ensures a secure fit on all needle-free valves

Safe & Secure Lock

Exclusive, Safety-Feature Design for Male Luer Connectors



How to Use DualCap®



Light Blue DualCap for Needle-Free Valve

- No scrubbing with alcohol is initially necessary when needle-free valves have been capped with a Light Blue DualCap according to indications for use.
- If the needle-free valve is heavily soiled, it may be cleaned with a 70% Isopropyl Alcohol pad before or after DualCap use.
- A new Light Blue DualCap should be placed on all needle-free valves each time they are not in use.
- Single use only. Change after each use.
- Please also follow your institution's guidelines for use and instructions for disposal.

Separate – DualCap Solo™

1



Holding the Light Blue DualCap Solo, grasp the foil and remove.

Separate – DualCap IV Pole Strip™

1



Grasp the Light Blue DualCap and remove from the IV Pole Strip.

Connect

2



Twist the Light Blue DualCap onto the needle-free valve in a clockwise direction. There is no need to overtighten.

Disinfect

3



Disinfection begins in 30 seconds and continues up to 7 days under normal conditions if not removed.

How to Use DualCap®



Dark Blue DualCap for Male Luer Connector

- A new Dark Blue DualCap should be placed on all male luer connectors each time the IV line is disconnected and not in use.
- Single use only. Change after each use.
- Please also follow your institution's guidelines for use and instructions for disposal.

Separate – DualCap Solo™

1



Holding the Dark Blue DualCap Solo, grasp the foil and remove.

Separate – DualCap IV Pole Strip™

1



Grasp the Dark Blue DualCap and remove from the IV Pole Strip.

Connect

2



Twist the Dark Blue DualCap onto the male luer connector in a clockwise direction. There is no need to overtighten.

Disinfect

3



Disinfection begins in 30 seconds and continues up to 7 days under normal conditions if not removed.

The DuaCap System

Bringing Disinfection and Protection Together

- Disinfects rapidly and automatically at both IV catheter access points
- The only male luer connector cap that prevents IPA from entering the fluid path
- Locks in ongoing protection against intravascular infections
- Easy to grasp
- Durable IV Pole Strips™ designed to withstand handling and provide convenient bedside delivery
- Designed by infusion nurses, for nurses



Responses to Commonly Asked Questions

About the DualCap System™

How soon does DualCap® start working and how long can the Light Blue and Dark Blue DualCaps stay on?

DualCap starts working immediately. When left in place for 30 seconds, the Light Blue and Dark Blue DualCaps disinfect needle-free valves and male luer connectors; thereafter the caps provide a physical barrier to contamination up to 7 days under normal conditions if not removed. A new Light Blue DualCap should be placed on all needle-free valves each time they are not in use. A new Dark Blue DualCap should be placed on all male luer connectors each time the IV line is disconnected and not in use.

If I do not use the DualCap immediately, may I save it to use later?

No. Discard the cap and obtain a new one if it is not immediately used.

Is DualCap reusable?

No. DualCap is single use only.

Is DualCap latex free?

DualCap is not made with Natural Rubber Latex or with DEHP.

What if the DualCap System is being used on an outpatient basis and the patient comes in weekly for treatment?

When the IV lines are flushed at home through the needle-free valve, the Light Blue DualCap should be removed and replaced with a new one after flushing is complete. Similarly, if the IV line is disconnected for any reason, a new Dark Blue DualCap should be used.

How far do I need to turn the Light Blue and Dark Blue DualCaps before they are secure?

There is no need to overtighten the Light Blue and Dark Blue DualCap. It is also not necessary for the Light Blue DualCap to completely cover the needle-free valve. Once the Light Blue DualCap is secure, the sponge will release isopropyl alcohol (IPA) to bathe the top of the valve and begin to automatically disinfect it.

About the Light Blue Dualcap®

If the Light Blue DualCap is just sitting on the valve, does it kill the microorganisms?

Yes. Scrubbing is not the method by which alcohol kills microorganisms. Isopropyl alcohol (IPA) kills microorganisms by first attacking the lipids that are part of the outer cell wall. As the cell wall disintegrates, the alcohol enters the cell and denatures the cellular proteins thus disrupting and destroying the structure of the cell.² Scrubbing the valve helps distribute alcohol on all the critical surfaces so that it comes into contact with the microorganisms.

Which vascular access devices are recommended for use with the Light Blue DualCap?

DualCap is recommended for use on all intravenous vascular access devices using needle-free valves including: central venous catheters, peripherally-inserted central catheters (PICCs), midline catheters, peripheral venous catheters (PVCs), and Y-sites on infusion sets. Your institution will provide guidance on the specific situations in which they should be used.

What are the advantages of the Light Blue DualCap compared to an alcohol pad?

A number of studies have shown that it is virtually impossible to ensure that needle-free valves have been scrubbed using the appropriate technique for the required time to be effective^{1-3,8-10}. No scrubbing with alcohol is initially necessary when needle-free valves have been capped with the Light Blue DualCap according to indications for use. If the needle-free valve is heavily soiled, it may be cleaned with a 70% IPA pad before or after DualCap use. When DualCap is used with needle-free valves, the variability in scrubbing time and technique may be eliminated.

When I remove the Light Blue DualCap to access the needle-free valve, do I need to scrub the valve with an alcohol pad?

No. However, if the needle-free valve is heavily soiled, it may be cleaned with a 70% IPA pad before or after DualCap use. A new Light Blue DualCap should be placed on all needle-free valves each time they are not in use.

When I remove the Light Blue DualCap® to access the site for multiple injections or infusions, do I need to put a new cap on and wait 30 seconds in between each valve access?

No. Since it is not practical to wait 30 seconds between multiple injections or infusions, it is recommended that you continue to use an alcohol pad to disinfect the valve between multiple sequential injections or infusions and per your institution's established protocol. A new Light Blue DualCap should then be placed on all needle-free valves each time they are not in use.

Can I use the Light Blue DualCap on a female hub, like a stopcock or open IV catheter hub?

The Light Blue DualCap is not designed for a female hub because there is no valve septum to keep the alcohol out of the line. It may only be used if the female hub has a needle-free valve connected to it; otherwise it would be an open lumen and alcohol could enter the line.

Why do all needle-free valves need to be capped?

Needle-free valves not in regular use may become contaminated or develop biofilms. If a clinician were to access the needle-free valves that were not capped after inadequate scrubbing with alcohol, he or she could run the risk of exposing the patient to an IV CRBSI. Capping all needle-free valves on infusion sets also helps prevent the practice of "looping," which is inserting the male luer connector into a needle-free valve.

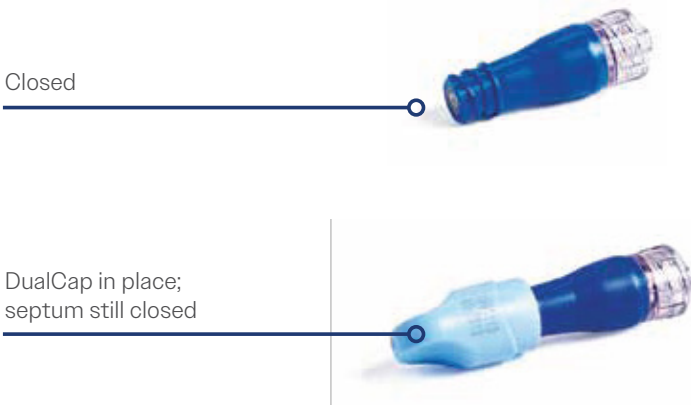
How long should the needle-free valve dry after using the Light Blue DualCap?

The time required for the residual alcohol to evaporate on the needle-free valve after use varies depending on the type of needle-free valve on which it was used, how long it was left in place, temperature and humidity. If the needle-free valve looks wet, wait a few seconds until it looks dry or use the same dry time as defined by your institution's protocol for scrubbing needle-free valves with alcohol.

If the Light Blue DualCap® is used on a needle-free valve, will the cap leave residual alcohol that can get into blood samples drawn from the port?

The residual alcohol left by DualCap is similar to that left by alcohol pads and is very small. The Light Blue DualCap is designed to keep alcohol from entering the needle-free valve. DualCap does not “open” the septum of the valve – the cap stays on top of the needle-free valve and bathes the surface in alcohol, disinfecting the connector.

Example of a Needle-Free Valve



About the Dark Blue Dualcap

What are the advantages of the Dark Blue DualCap compared to sterile end caps?

A sterile “dead-end” cap does not disinfect the male luer connector. After the tubing has been in use and it is disconnected, it is no longer sterile. Research has shown that both ends of the IV tubing are at risk for infection and should be disinfected and protected. In one study, male luer connectors were found to be contaminated more frequently than needle-free valves (37% vs. 24%). It also revealed that cross-contamination does occur between the IV line male luer connector and the needle-free valve.⁴ The Dark Blue DualCap is the only FDA-cleared solution to disinfect and protect male luer connectors on IV lines.

Under what circumstances would I use a Dark Blue DualCap® for male luer connectors?

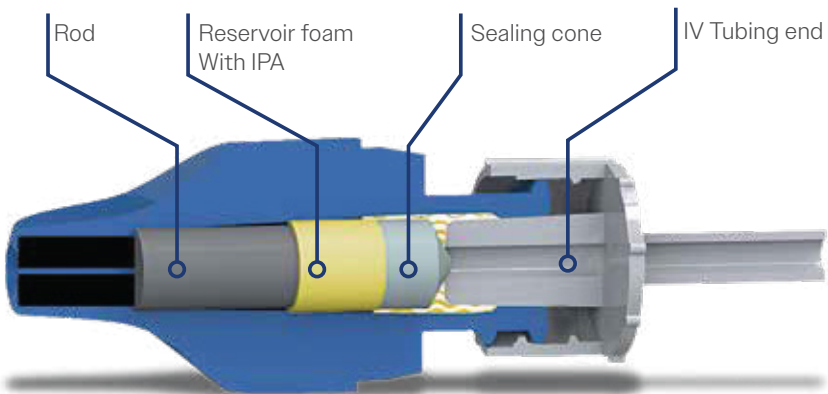
Anytime the IV tubing administration set is disconnected. Most often this would involve intermittent delivery of medication through a secondary set that may be disconnected and reconnected, such as a piggybacked IV antibiotic.

How can I be assured that no alcohol enters the infusion line when the Dark Blue DualCap is attached?

DualCap has a proprietary patented sealing cone that engages and seals the opening of the male luer connector to prevent alcohol from entering the infusion line.

Do I need to let the male luer connector dry after removing the Dark Blue DualCap? Will alcohol get in the line when disinfecting the male luer connector with DualCap?

The sealing cone in the Dark Blue DualCap blocks IPA from entering the fluid pathway of the IV tubing line. Therefore, any alcohol that may be on the surfaces of the male luer connector immediately after the DualCap is disconnected will not be in the fluid pathway of the IV tubing line. However, the male luer connector does connect into the fluid pathway of the needle-free valve; if it looks wet, wait a few seconds until it looks dry before connecting it to the needle-free valve.





Disinfection & Protection System

Bringing Disinfection and Protection Together

Before using refer to Instructions for Use for indications, contraindications, warning, precautions, and directions for use.

References

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2. Menyhay S, Maki D. Disinfection of Needleless Catheter Connectors and Access Ports with Alcohol May Not Prevent Microbial Entry: The Promise of a Novel Antiseptic-Barrier Cap. *Inf. Control and Hosp Epidemiol.* 2006; 27 (1); 23-27
3. Karchmer TB, Cook EM, Palavecino E, Ohl CA, Sherertz RJ. Needleless valve ports may be associated with a high rate of catheter-related bloodstream infections. SHEA 2005. Los Angeles, CA: April 9-12. Abstract #307.
4. Lopansri et al. SHEA 2011, poster presentation #228 "Microbial Colonization of Needleless Intravenous Connectors and the Male Luer End of IV Administration Sets: Does the Partner Matter?"
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10. Sherertz RJ, Ely EW, Westbrook DM, et al. Education of physicians-in-training can decrease the risk for vascular catheter infection. *Ann Intern Med.* 2000; 132(8):641-648.