

LineSHELL

Medical Stopcock Protector



LightSHELL

Protector with Illuminating Apparatus

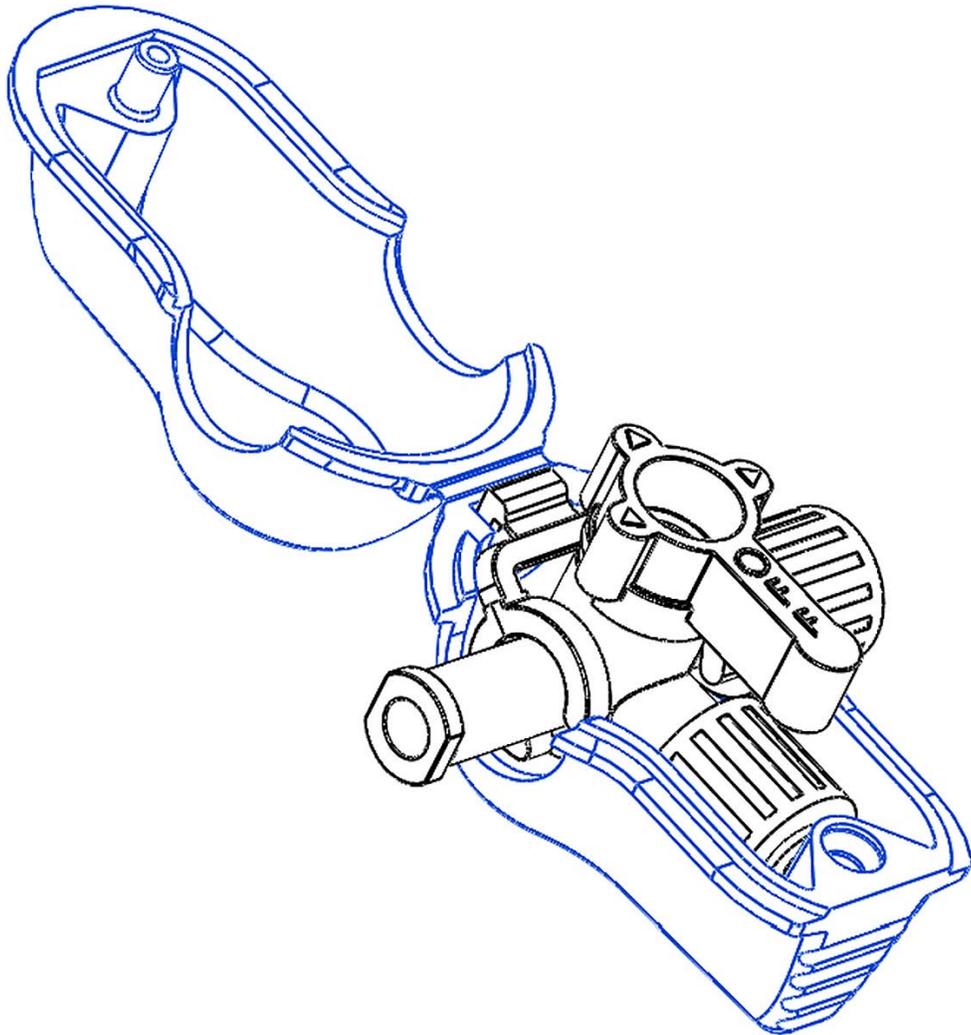


Table of Contents

- 1- LineSHELL product brochure.....2
- 2- Accidental malposition.....3
- 3- Labeling and prevention of medication errors.....4
- 4- Preventing contamination and hospital acquired infections.....5
- 5- LightSHELL product brochure.....6
- 6- Importance of sleep quality in hospital.....7
- 7- Sleep disruption for medication administration.....8
- 8- Patient’s satisfaction and hospital reimbursement8
- 9- LineSHELL & LightSHELL user instructions.....9
- 10- LineSHELL & LightSHELL labels.....10
- 11- Value proposition and Value drivers.....11
- 13- References.....16

The most precious things deserve to be protected



Your Patients are our top priority.

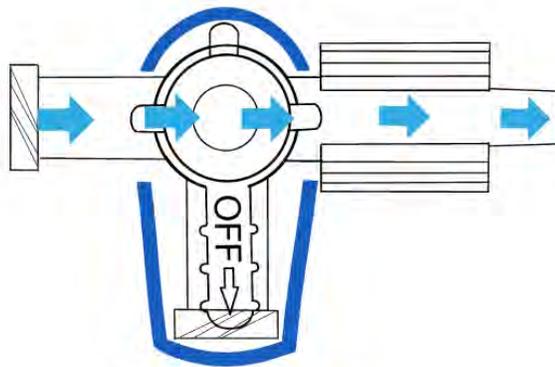
But did you know that **one out of three** stopcocks becomes contaminated on the very first day of admission due manipulation and contact with hospital surfaces?

- ✓ **VIDA LineSHELL Medical Stopcock Protector is designed to provide 360-degree protection** to three-way stopcocks to reduce the potential for bacterial contamination and hospital-acquired infections.
- ✓ **Enhance medication safety** by providing red, blue and clear versions to better label and differentiate three-way stopcocks.
- ✓ **Prevent malpositioning** of the three-way stopcock lever.



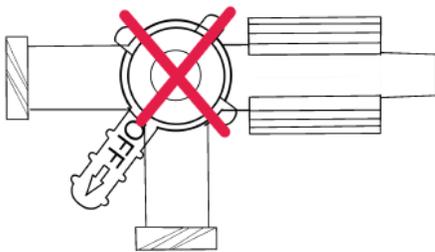
LineSHELL[®]
Medical Stopcock Protector



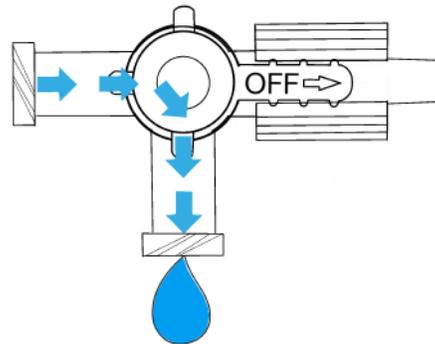


LineSHELL

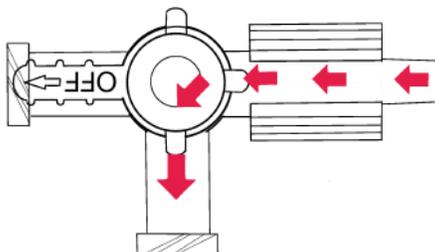
VALVE PROPER POSITION
FLUID FLOW



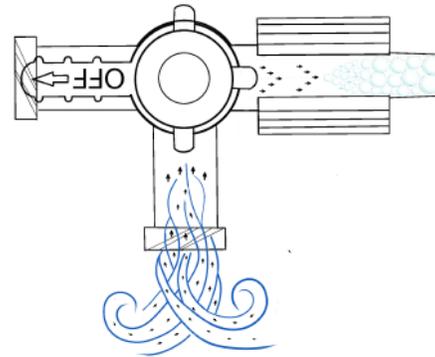
MAL POSITIONING
NO FLOW



FLUID AND
MEDICATION
LEAKAGE



BLOOD
LOSS



AIR EMBOLISM

Malpositioning of the three-way stopcock lever can result in serious complications such as flow blockade, leakage of fluid or medication, blood loss and air embolism. The administration of fluid and medications is an essential therapeutic step for inpatients. LineSHELL will keep the three way selector in correct positioning preventing these problems. Protecting the stopcock is particularly important in situations where the stopcock is not easily accessible, for example, in the operating room the stopcock is often covered under the drapes and in the imaging suite, the patient is on the scanner away from the provider.

Arterial Access



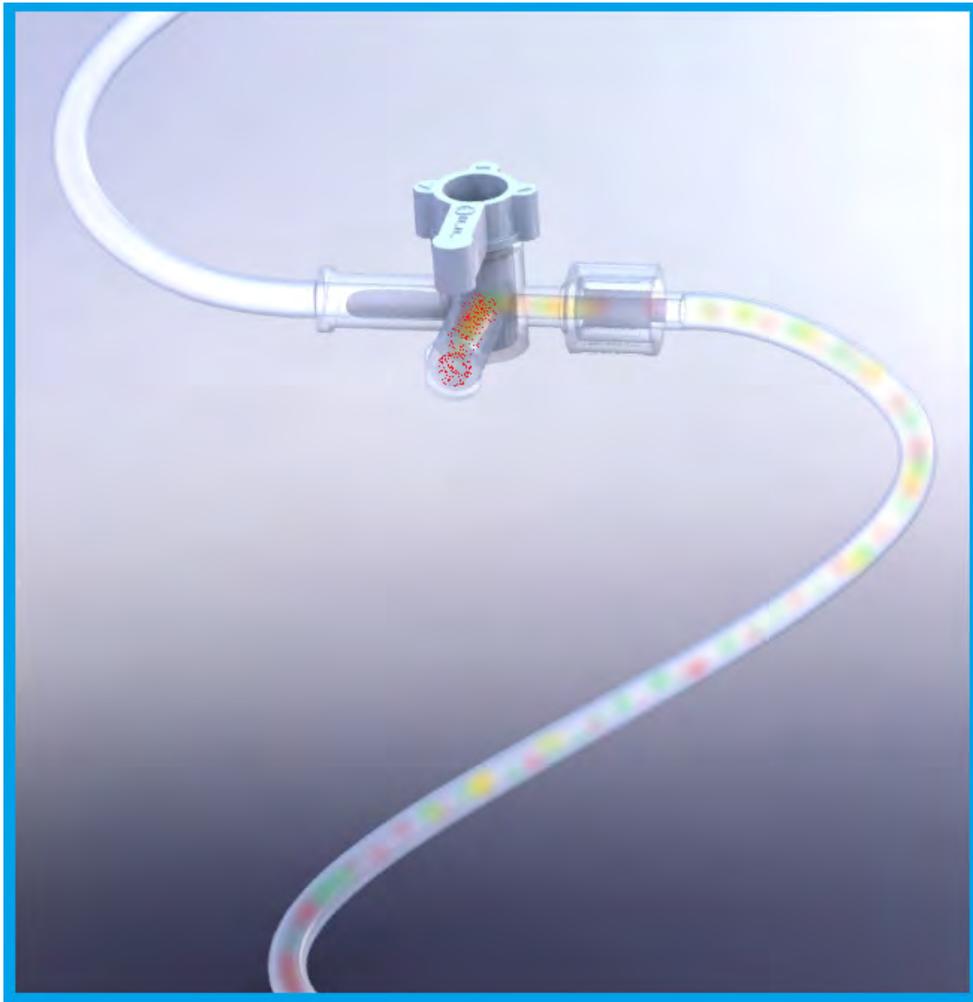
Venous Access



Medication given through an unintended route is a very serious form of medication error. The three-way stopcocks are universally used in different tubing systems across health-care. They are used in several routes of administration for parenteral and enteral fluids as well as invasive pressure monitoring and drainage tubes.

Lack of proper labeling and differentiation is a setup for a system failure and serious adverse events. Accidental intra-arterial injections of medications intended for intravenous use have resulted in severe ischemia, limb loss, and disability.

To prevent accidents a well visible labeling system is necessary. The LineSHELL provides a color-coded based system to label and differentiate what type of route the three-way is placed into. The LineShell was design for small bore stopcock three-way.



Bacterial Contamination and Hospital Acquired Infections.

On average the three-way connectors are manipulated between 10 to 30 times a day. One in every three stopcocks gets contaminated in the first day of a patient's admission due to exposure to hospital environment or manipulation by the health care providers.

Central line associated blood stream infections (CLABSI) occur due to the contamination of catheter tract or the needleless connectors. Extra-luminal catheter contamination germs migrate along the catheter tract. Recent studies have shown germs contaminate the hub of the connectors or intra-luminal contamination. Once the hub is contaminated germs are then flushed downstream into the IV tubing and circulation causing CLABSI.



LightSHELL[®]
Medical Stopcock Protector



Sleep is important but Safety is our top priority

- ✓ Several procedures in operating room, cath lab and endoscopy suite require dimming the room lights. Knowing where the IV push line is can save time and prevent accidents.
- ✓ In low light conditions a micro photo-sensor will automatically activate an LED that will illuminate the LightSHELL. The health care professional can spot and quickly find the tree-way stopcock.





LightSHELL[®]
Medical Stopcock Protector



Sleep is essential for recovery from illness and healing from surgery

- ✓ Medical three-way stopcock protector with micro electronic component including photosensor and LED.
- ✓ Nighttime administration of medications without disrupting patient sleep.
- ✓ Provides illumination for easy location of the three-way stopcock in low light conditions.
- ✓ LightSHELL lasts for 7 to 10 days.



No more sleep disruption for medication administration



✓ Quality of sleep is as important as duration of sleep and is key to the feeling of restoration. Scientific studies have proven that sleep is an essential factor for recovery from illness and healing from surgery. Sleep deprivation can have serious consequences. It causes fatigue, irritability, anxiety, stress, agitation, delirium and heart arrhythmias such as tachycardia and atrial fibrillation. Many times, there is a need for medication administration during the night. Turning on the room lights for to find and manipulate the three-way stopcock disrupts the restorative sleep.

✓ Patient satisfaction is increasingly emerging as a top priority for health care providers, institutions and payers. A commonly implemented tool of assessing patient satisfaction is the Consumer Assessment of Healthcare Providers and Systems (HCAHPS), which is utilized by the Centers for Medicare & Medicaid Services (CMS) to determine up to 30% of Medicare reimbursement. Adequacy of the depth and continuity of sleep are essential elements of the patients' satisfaction with their hospital stay. LightShell, allows nighttime administration of intravenous (IV) medication with minimal interference with the dim lighting that is necessary for satisfactory continuation of the patient's deep sleep. By improving the quantity and quality of patient's sleep, LightShell contributes directly to patient's satisfaction and ultimately to improved healthcare reimbursement.

VIDA Medical Devices, Inc.
LineShell™ and LightShell™
Three-Way Stopcock Protective Covers

Single Use Only. Do not reprocess or reuse. For instructions on using a Three-Way Stopcock, refer to the specific stopcock manufacturer's instructions for use (IFU).

Components (Fig. 1):

1. Top Shell
2. Bottom Shell
3. Hinge
4. C-Link Attachment
5. Link Hinge
6. LightShell Activation Tab

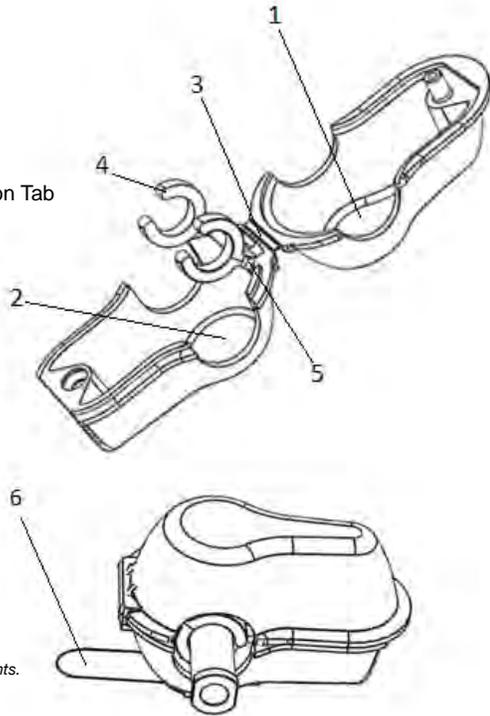


Figure 1. Components.

User Instructions

Note: Unless otherwise indicated, all steps below apply to both the LineShell and LightShell Protective Covers.

1: Attaching the LineShell Protective Cover to a Three-Way Stopcock

After removing from the packaging, open the LineShell and flip the C-Link Attachment upwards as shown (Fig. 2). Align the bottom face of the body of the three-way stopcock with the inner face of the bottom shell and attach the C-Link Attachment to the opposing arms of the body of the three-way stopcock (Fig. 3).

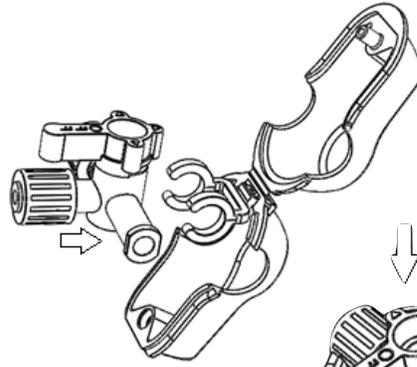


Figure 2. Alignment.

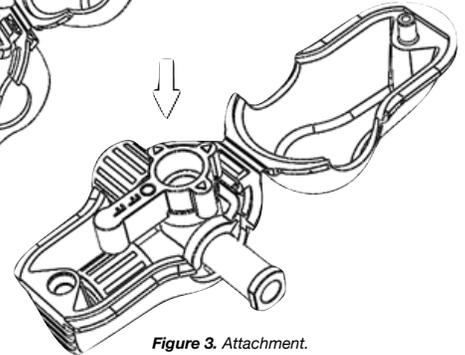


Figure 3. Attachment.

2: Closing the LineShell Protective Cover

To close the LineShell Protective Cover, bring the top and bottom shells together until they achieve full contact (Fig. 4).

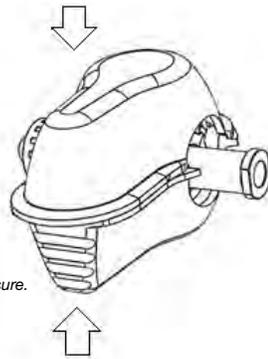


Figure 4. Closure.

3: Activating the Photosensitive LED (LightShell Protective Cover Only)

To activate the photosensitive LED component of the LightShell Protective Cover, remove and discard the Activation Tab. The photosensitive LED will automatically light in low ambient light (Fig. 5).

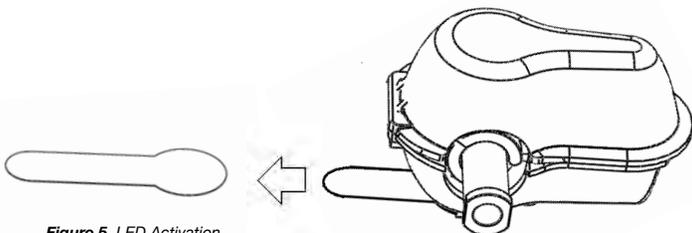


Figure 5. LED Activation.

4: Opening the LineShell Protective Cover

To open the LineShell, place your right and left index fingers on the back of the shell and use your thumbs to separate the front part of the shell (Fig. 6).

NOTE: If necessary to facilitate opening, squeeze the front sides of the LineShell Protective Cover along the contact line between top and bottom halves.

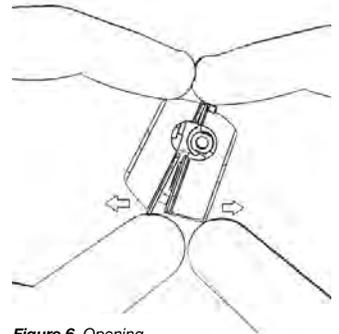


Figure 6. Opening.

5: Accessing the Three-Way Stopcock

To access the Three-Way Stopcock, open the LineShell Protective Cover and angle the Three-Way Stopcock upwards without detaching from the C-Link (Fig. 7). The Luer Cap may be attached to the bottom shell while medication is being dispensed.

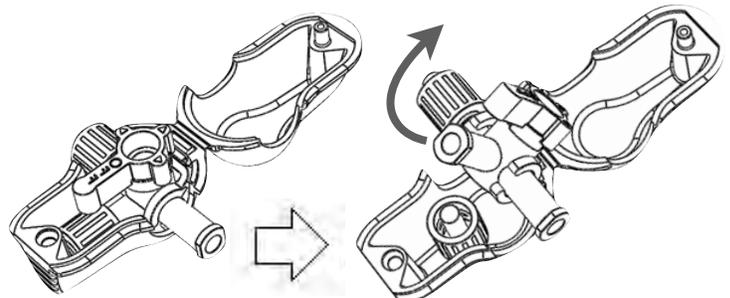


Figure 7. Accessing the Three-Way Stopcock.



LineShell

Medical stopcock protector

REF **V100.100B** LOT **001-A**

USE BY: 2022-02-22 QTY: 100EA


 non-sterile


 do not reuse


 consult electronic instructions for use


 Keep dry


www.vmdevices.com

RedStar Contract Manufacturing
 1560 N. State Road 5
 Larwill IN 46764
 ISO 13485-2016
 FDA Registered
 300631939
 Manufactured for VIDA





LineShell

Medical stopcock protector

REF **V100.100C** LOT **001-A**

USE BY: 2022-02-22 QTY: 100EA


 non-sterile


 do not reuse


 consult electronic instructions for use


 Keep dry


www.vmdevices.com

RedStar Contract Manufacturing
 1560 N. State Road 5
 Larwill IN 46764
 ISO 13485-2016
 FDA Registered
 300631939
 Manufactured for VIDA





LineShell

Medical stopcock protector

REF **V100.100R** LOT **001-A**

USE BY: 2022-02-22 QTY: 100EA


 non-sterile


 do not reuse


 consult electronic instructions for use


 Keep dry


www.vmdevices.com

RedStar Contract Manufacturing
 1560 N. State Road 5
 Larwill IN 46764
 ISO 13485-2016
 FDA Registered
 300631939
 Manufactured for VIDA





Light Shell

Medical stopcock protector with illuminating apparatus

REF **V100.200B** LOT **001-A**

USE BY: 2022-02-22 QTY: 100EA


 non-sterile


 do not reuse


 consult electronic instructions for use


 Keep dry


www.vmdevices.com

RedStar Contract Manufacturing
 1560 N. State Road 5
 Larwill IN 46764
 ISO 13485-2016
 FDA Registered
 300631939
 Manufactured for VIDA





Light Shell

Medical stopcock protector with illuminating apparatus

REF **V100.200C** LOT **001-A**

USE BY: 2022-02-22 QTY: 100EA


 non-sterile


 do not reuse


 consult electronic instructions for use


 Keep dry


www.vmdevices.com

RedStar Contract Manufacturing
 1560 N. State Road 5
 Larwill IN 46764
 ISO 13485-2016
 FDA Registered
 300631939
 Manufactured for VIDA



VIDA LineShell and LightShell

Value Proposition & Value Drivers

Value Proposition

- Medical facilities want to reduce costs and complications associated with three-way stopcock valves. Stopcocks are part of the tubing assembly of intravenous drug delivery systems and intra-arterial access. The new VIDA Medical Devices LineSHELL and LightSHELL securement devices are the first protective covers for three-way stopcocks that are designed to enable them to perform their intended use more safely and effectively. They prevent complications such as bacterial contaminations, accidental changes in the stopcock valve position and introduction of medication through an unintended route. The LightShell prevents sleep disruption for medication administration during the night and it also allows better identification of the IV site in an environment with poor lighting.



VIDA LineShell and LightShell Value Proposition & Value Drivers

- **Designed to prevent bacterial contaminations.**
- On average three-way connectors are manipulated between 10 to 30 times a day. One out of three stopcocks become contaminated on the very first day of admission due to direct exposure to hospital surfaces or manipulation by health care providers. Once germs contaminate the hub, they are flushed into the IV tubing and circulation, potentially causing central line associated blood stream infections (CLABSI).
- LineShell cover reduces time of exposure to the environment as well as provides a receptacle to hold the luer lock cover while medications are being administered.



VIDA LineShell and LightShell

Value Proposition & Value Drivers

Value Drivers

- **Prevents accidental malpositioning.**
 - The stopcock on the top of the valve can get accidentally misaligned. Malpositioning of the three-way stopcock lever can result in flow blockade, blood loss (exsanguination) or leakage of fluid and medication outside of the IV tubing.

The blockade can result in loss of intravenous access or a-line measurements.

Malpositioning is particularly pertinent in situations when direct access to the three-way valve is not available, such as in the operating room where IV sites and connectors can be covered under the drapes or in the imaging suite where the provider is away from the patient. In either case, the ongoing procedure must be interrupted to address malpositioning.
 - The LineShell provides a physical barrier to protect the three-way stopcock from misalignment during procedures where contact with the stopcock is common.



VIDA LineShell and LightShell Value Proposition & Value Drivers

- **Prevents accidental injection of medication into an unintended route.**
- Medication given through an unintended route is a very serious form of medication error. The three-way stopcocks are universally used in different tubing systems across health care. They are used in several routes of administration for parenteral and enteral fluids as well as invasive pressure monitoring and drainage tubes. Lack of proper labeling and differentiation is the perfect setup for a system failure and serious adverse events. Accidental intra-arterial injections of medications intended for intravenous use, have resulted in severe ischemia, limb loss, disability and death of many patients. Fasciotomy or ultimately amputation may result from a medication error. To prevent accidents, a visible labeling system is valuable. The LineShell is available in clear, red and blue options for improved labeling and identification of the appropriate line.



VIDA LineShell and LightShell Value Proposition & Value Drivers

- **Prevents accidents associated with nighttime or dim-light administration.**
- When medicine administration is required during the night, the healthcare professional often must turn the room lights on to find and manipulate the three-way stopcock, thus disrupting the patient's sleep. Scientific studies have shown that sleep is an essential factor for recovery from illness and healing from surgery, and quality of sleep is just as important as duration of sleep. Additionally, some procedures in cardiac catheterization labs, operating rooms, and endoscopy suites require dimming the room lights. In those cases, knowing the location of the IV push line may help save time and prevent accidents.
- LightSHELL[®] is a variant of LineSHELL[®] containing a micro photosensor that will automatically activate a LED to make the device glow when ambient light is low. LightSHELL[®] is designed to last 7 to 10 days.



References

Sen S, Chini EN, Brown MJ. **Complications after unintentional intra-arterial injection of drugs: risks, outcomes, and management strategies.** Mayo Clin Proc. 2005 Jun;80(6):783-95.

Bertil J, Murray A, **Fatal mix-up of three-way stopcocks.** Medical Devices: Use and Safety. Page 205. Elsevier, PA 2007.

Timpa JG, O'Meara C, McIlwain RB, Dabal RJ, Alten JA. **Massive systemic air embolism during extracorporeal membrane oxygenation support of a neonate with acute respiratory distress syndrome after cardiac surgery.** J Extra Corpor Technol. 2011;43(2):86–88.

Collyer TC, Yates DR, Bellamy MC. **Severe air embolism resulting from a perforated cap on a high-flow three-way stopcock connected to a central venous catheter.** Eur J Anaesthesiol. 2007 May;24(5):474-5.

Mermel, L., Bert, A., Chapin, K., & LeBlanc, L. (2014). **Intraoperative Stopcock and Manifold Colonization of Newly Inserted Peripheral Intravenous Catheters.** Infection Control & Hospital Epidemiology, 35(9), 1187-1189.

Loftus RW, Brown JR, et al. **Multiple reservoirs contribute to intraoperative bacterial transmission.** Anesth Analg. 2012 Jun;114(6):1236-48

Berkowitz DM, Lee WS, Pazin GJ. **Adhesive tape: potential source of nosocomial bacteria.** Appl Microbiol. 1974 Oct;28(4):651-4.

Redelmeier DA, Livesley NJ. **Adhesive tape and intravascular-catheter-associated infections.** J Gen Intern Med. 1999;14(6):373–375.

References

Curran E. ***Needleless connectors: the vascular access catheter's microbial gatekeeper.*** J Infect Prev. 2016;17(5):234–240.

Marples RR, Kligman AM. ***Growth of bacteria under adhesive tapes.*** Arch Dermatol. 1969 Jan;99(1):107-10.

Sandora, Thomas J. et al. ***Impact of needleless connector change frequency on central line-associated bloodstream infection rate.*** American Journal of Infection Control, Volume 42, Issue 5, 485 – 489.

Hutchens MP, Drennan SL, Cambronne ED. ***Calibration of optimal use parameters for an ultraviolet light-emitting diode in eliminating bacterial contamination on needleless connectors.*** J Appl Microbiol. 2015;118(6):1298–1305.

Kamdar BB, Needham DM, Collop NA. ***Sleep deprivation in critical illness: its role in physical and psychological recovery.*** J Intensive Care Med. 2012;27(2):97–111.

Randy W. Loftus, Matthew D. Koff, et al; ***Transmission of Pathogenic Bacterial Organisms in the Anesthesia Work Area.*** Anesthesiology 2008;109(3):399-407.