

“...a thorough assessment...”

Does the evidence support the recommendation?

SUPPLEMENT ARTICLE: SHEA/IDSA PRACTICE RECOMMENDATION

Strategies to Prevent Central Line-Associated Bloodstream Infections in Acute Care Hospitals

III. Approaches that should not be considered a routine part of CLABSI prevention

3. Do not routinely use positive-pressure needleless connectors with mechanical valves before a thorough assessment of risks, benefits, and education regarding proper use (B-II).⁸⁸⁻⁹¹

a. Routine use of the currently marketed devices that are associated with an increased risk of CLABSI is not recommended

Evidence Rating of BII:



Moderate evidence to support a recommendation for use

An overview of product deficits that increase the risk and product features that reduce the risk.

The references and their assessment of risk...



88. **Maragakis LL, Bradley KL, Song X, et al.** *Increased Catheter-Related Bloodstream Infection Rates after the Introduction of a New Mechanical Valve Intravenous Access Port.* Infection Control and Hospital Epidemiology 2006; 27: 67-70.

- “the fluid path in the mechanical valve devices has moving parts, and at least one of the mechanical valve devices have internal corrugations that may serve as reservoirs and foster the growth of microbial contaminants.”
- “the mechanical valve devices have intricate access surfaces that are more difficult to disinfect...”
- “some of the devices have been noted by healthcare personnel to have incomplete flushing of blood from the fluid channel, and some are opaque, so that this would not be readily apparent to the user”

Before	After
	
PICU BSI Rate 5.3	PICU BSI Rate 17.3



89. **Field K, McFarlane C, Cheng AC, et al.** *Incidence of Catheter-Related Bloodstream Infection Among Patients with a Needleless, Mechanical Valve-Based Intravenous Connector in an Australian Hematology-Oncology Unit.* Infection Control and Hospital Epidemiology 2007; 28:610-613.

- “risk of colonization of the connector device may be higher for mechanical valve devices because of the potential difficulty in sterilizing the gap between the valve and the hub”

Before	After
	
BSI Rate 2.6	BSI Rate 5.8



90. **Salgado CD, Chinnes L, Paczesny TH, Cantey JR.** *Increased Rate of Catheter-Related Bloodstream Infection Associated with Use of a Needleless Mechanical Valve Device at a Long-Term Acute Care Hospital.* Infection Control and Hospital Epidemiology 2007; 28:684-688.

- “the mechanical valve system could be more difficult to disinfect because of the complicated nature of the multipart device.”

Before	After
	
BSI Rate 1.79	BSI Rate 5.95

91. **Rupp ME, Sholtz LA, Jourdan DR, et al.** *Outbreak of Bloodstream Infection Temporally Associated with the Use of an Intravascular Needleless Valve.* Clinical Infectious Disease 2007; 44:1408-1414

- “a shallow depression and rim between the diaphragm and plastic housing...It is possible that microbes and debris could collect in this area, which would be relatively resistant to cleansing or disinfection”
- “internal mechanism of the valve contains moving parts, which introduces irregularities in the fluid flow and may promote areas of stagnation and create potential reservoirs for microbial growth. Also the plastic housing is opaque, which prohibits visual inspection of the connector valve.”

Before	After
	
CCU BSI Rate 3.87	CCU BSI Rate 10.64

What are the specific product deficits identified by these references?

- Intricate access surfaces are more difficult to disinfect
- Internal corrugations and moving parts may serve as reservoirs and foster growth of microbial contamination
- Housing is opaque which prohibits visual confirmation of flushing
- Potential difficulty in disinfecting the gap between the housing and internal components (also known as interstitial space)

Dr. Jarvis identifies potential risk factors...²

<i>Best Practices</i>	Difficulty cleaning access surface	HCW's may not adequately clean the intricate surface details, leading to fluid path contamination.
<i>Swabability</i>	Gap around plunger harbors bacteria	Gap cannot be accessed for disinfection and can lead to fluid path contamination especially with repeated access such as SAS or SASH method.
<i>Flush Clearance</i>	Opaque housing hides incomplete flushing of media based fluids	During the course of normal manipulation of the catheter small amounts of media like fluid contaminate the valve. If these organisms proliferate, then they can be infused with subsequent manipulations.
	Internal mechanisms obscure fluid path	Impossible to visually confirm complete flushing.



The ability to disinfect the access port is of utmost importance

Robert Garcia clarifies risk reduction factors...³

Smooth, flat surface with minimal crevices	Reduces risk of contamination
No Interstitial Space	Eliminates space within the valve where blood or fluid can accumulate reducing risk of bacterial growth medium.
Advance Seal Design	Multiple seals reduce risk of bacterial entry.
Positive Fluid Pulse	Reduces risk of occlusions. No need for clamping during flush procedures

Two compelling studies not included in the references...

Costello, et al. *Systematic intervention to reduce central line-associated blood-stream infections rates in a pediatric cardiac intensive care unit.* Pediatrics 2008; 121:915-923

Before	After
	
BSI Rate 4.7	BSI Rate 2.3

“The positive displacement valve has a fully cleanable surface and eliminates retrograde flow into the catheter when an infusion device is disconnected from an infusion port.”

This study reports of a systematic intervention to reduce central line associated bloodstream infections in a pediatric cardiac intensive care unit. The addition of the MaxPlus Positive Displacement Connector lead to a break in the plateau resulting in a BSI rate of 2.3 per 1000 catheter days, a 51% decrease.

- “For access to CVLs. We converted our needleless connector system from a luer lock activated valve system to a device that has a flat access surface and contains a positive displacement valve (MaxPlus needleless connector).”
- “We estimated an annual attributable cost savings of \$236,000 to \$782,000.”

What specific connector features reduce infection risk?

- Smooth, flat and tightly sealed access port ➔ complete disinfection
- No intricate surface details, nooks, or crannies ➔ no areas to harbor bacteria
- Visible fluid path ➔ allows for complete flushing
- Simple design ➔ minimal parts to obscure fluid path

What additional features does the Advanced Luer Activated Device offer that simpler connectors do not?



- Positive displacement pulse ➔ helps prevent reflux occlusion
- Saline only flush ➔ reduces the use of heparin and associated heparin risks

References:

1. **Marschall, Jonas MD et al.** *Strategies to Prevent Central Line-Associated Bloodstream Infections in Acute Care Hospitals* Infection Control and Hospital Epidemiology, October 2008, Volume 29, Supplement 1
2. **Jarvis, W. MD, et al.** *Increased central venous catheter-associated bloodstream infection rates temporarily associated with changing from a split-septum to a luer access mechanical valve needleless device: A nationwide outbreak?* American Journal of Infection Control June 2005, Volume 33, Number 5 and Presentation at AVA 19th Annual Conference
3. **Garcia, et al.** *A Study if the Effects on Bacteremia and Sharps Injury Rates after Introduction of an Advanced Luer Activated Device (LAD) for Intravascular Access in a Large Hospital Setting* Abstract/Poster presented at APIC Conference 2007
4. **Costello, et al.** *Systematic intervention to reduce central line-associated blood-stream infections rates in a pediatric cardiac intensive care unit.* Pediatrics 2008; 121:915-923

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MaxPlus® is a trademark of Medegen, Inc.

Garcia, et al. *A Study of the Effects on Bacteremia and Sharps Injury Rates after Introduction of an Advanced Luer Activated Device (LAD) for Intravascular Access in a Large Hospital Setting.* AJIC: June 2007; 35(5); E75

Before	After
	
BSI Rate 1.16	BSI Rate 1.15

“No increase in bloodstream infections”

This study compares an Advanced Luer Activated Device (Flo-Link®, aka MaxPlus® Positive Displacement Connector) to the same Split Septum device associated with low BSI rates in three of the four studies referenced by the SHEA/IDSA recommendation. The results of this study state:

- “At 95% confidence intervals, p values did not indicate a significant difference in the BSI rates in the SSD or LAD groups in patients with peripheral and central lines. Sharp injuries related to IV port access were reduced from four during the Group 1 (SS period) to zero during the Group 2 period.”
- “The complexity of the design appears to be associated with an increase in bacterial transfer in many of the currently manufactured mechanical valves...The results of this study suggest that the use of an advanced LAD in coordination with adherence to proper infection control practice does not contribute to increases in either BSI rates or sharp injuries.”³



ML-3091 Rev C