Turning Technology-Related Evidence into Optimal Protocols for Line Maintenance

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2017

Discloser

Michele Biscossi is a paid consultant for BD.

Objectives

1. Discuss the impact of needleless connector design on documented risk of contamination, complications and cost.

2. Describe optimal design features identified in both in-vitro and in-vivo studies

3. Discuss integration of recently reported, evidence-based data into design-specific needleless connector protocols


Sometimes we just need to
change our perspective...

Needleless Connector Evolution

- All provide an access point
- Designs evolved to improve:
  - Safety
  - Effectiveness
  - Efficiencies

- All have varying degrees of risk and benefits associated with **protocols for use** in various clinical settings

Evolution of Needleless Technology

1980's	1991	2000	2001	2005	2008
Bloodborne pathogen exposure risks gain greater attention	Occupational Safety & Health Administration (OSHA) recommends healthcare facilities use "engineering controls" to help protect Health Care Workers from these pathogens	Needlestick Safety and Prevention Act (Pub. L 106-430) signed into law	Engineered controls, including Needleless Connector (NC) systems mandatory under Needlestick Safety and Prevention Act	**FDA recognizes microbial risk** with NC's Testing should demonstrate disinfection procedures used are effective for removing microorganisms from the device	**FDA revises Guidance Testing** should demonstrate disinfection procedures are effective
Healthcare Worker Protection				Patient Protection	

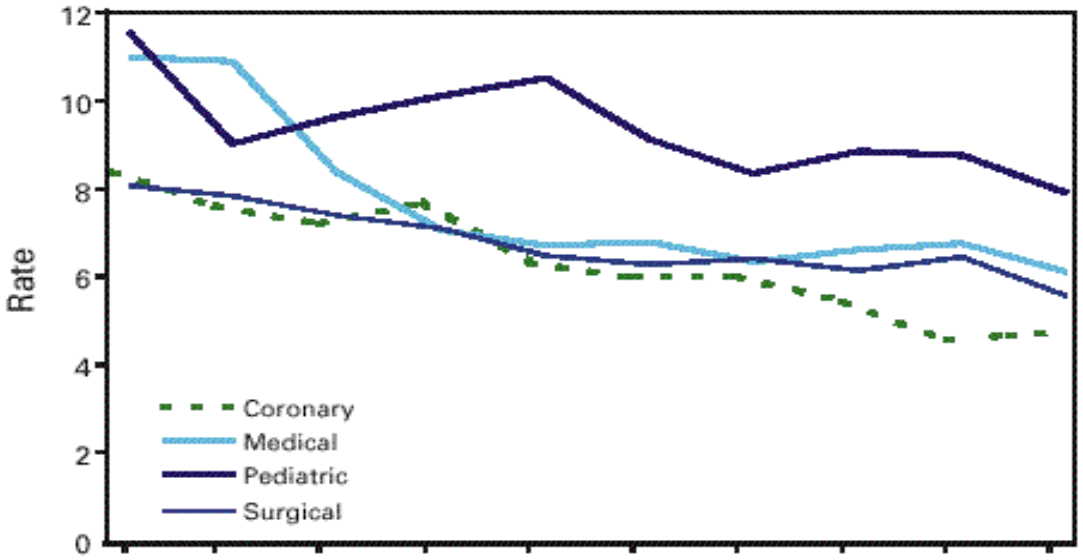
Health Care Worker Protection

- Risk of infection from contaminated sharp?[1]
  - **Hepatitis B – 1 in 5** (if you're not vaccinated)
  - **Hepatitis C – 1 in 50**
  - **HIV – 1 in 300**
- **$51 to $3,766-** average cost per exposure to the healthcare institution[2]
- **$71- $4,838-** 2004 study of 4 facilities showed a range of cost of exposure management[3]
- **$1 Million or more-** costs related to lost work time/disability payments due to serious infection[4]
- Intangible Costs of Exposure
  - Emotional Distress
  - Physical Distress
  - Family Impact
  - Co-Worker Impact

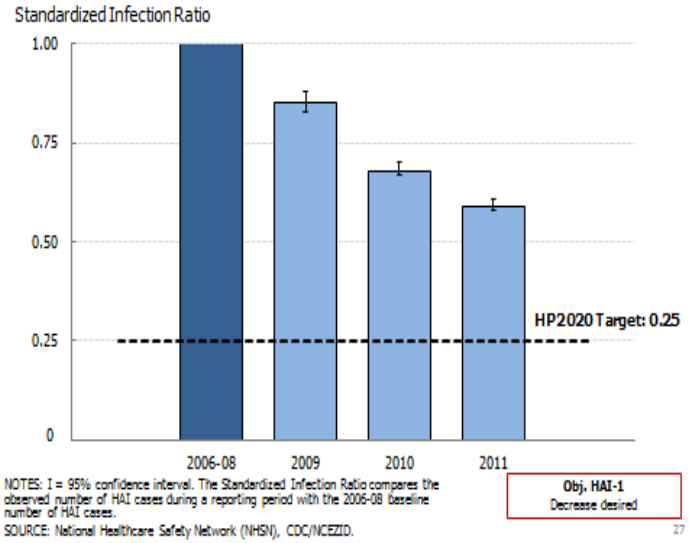
1. https://www.premierinc.com/needlestick/downloads/cdc-sharps-brochure-10-01-07.pdf
2. Lee J. et al, "A systematic review of the economic and humanistic burden of needlestick injury in the United States" American Journal of I
3. infection Control, May 2004
4. O'Malley EM, et al, "Costs of management of occupational exposures to blood and body fluids" Infection Control Hospital Epidemiology. 2007 Jul; 28 (7):774-783
5. American Hospital Association "Pugliese & Salahuddin" 1999

Nationwide Statistics of Interest

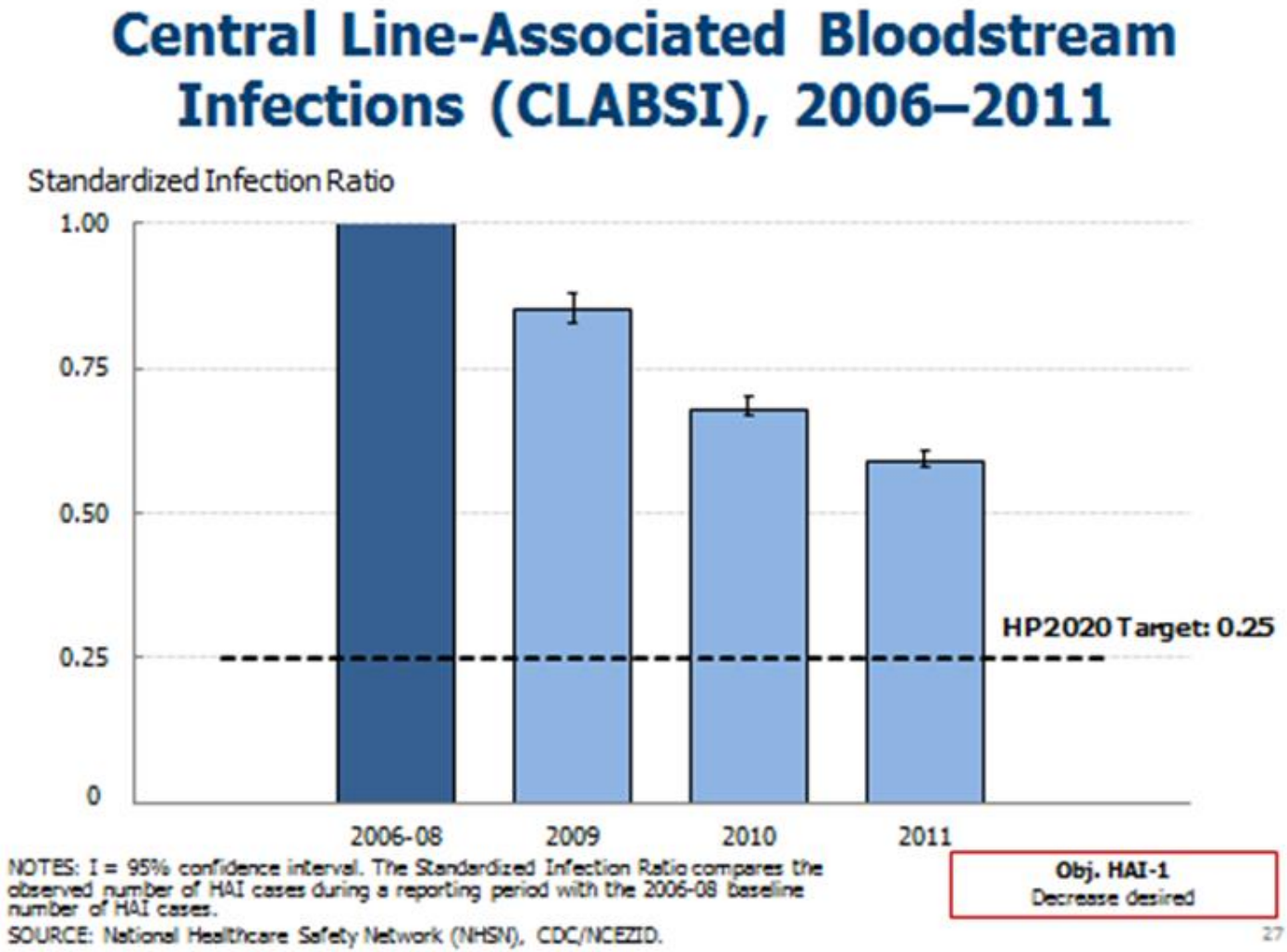
1990 → 1999



2006 → 2011



Contribution of Design to Contamination



Early Evolution

Now we understand the **Critical Features**:

ACCESS SURFACE is *solid and sealed*

- Could be effectively disinfected
- No crevices, slits, holes or gaps that can trap or allow contaminants to penetrate the connector

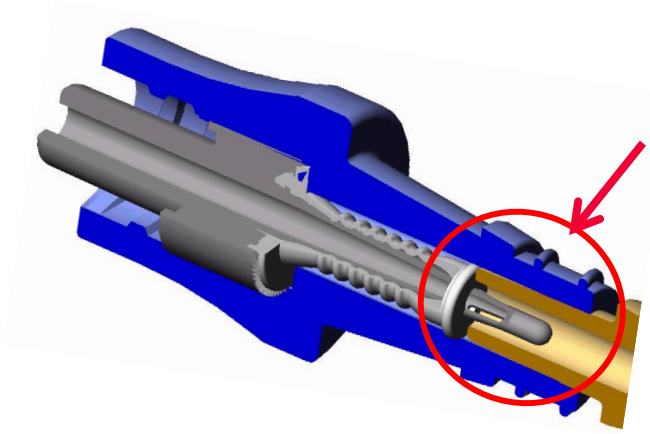
INTERNAL DESIGN is *simple*

- No internal cannulas or complex mechanisms
- **No** empty space within the fluid path ***OR*** the housing
  - This empty space is at risk for contamination, yet cannot be disinfected or flushed.

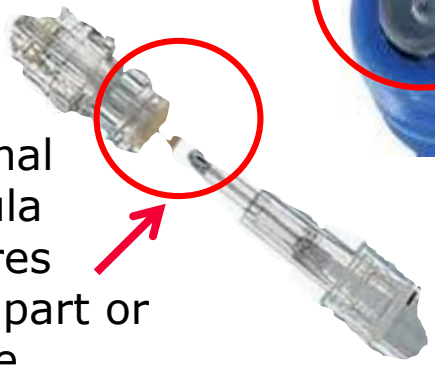
Luer Activated Design Introduced

These critical features were not recognized and luer designs eliminated them, replacing with:

- *Access surface with splits, slits, gaps, crevices and holes – non-solid surfaces through which contamination can penetrate*
  - *Internal cannula, springs and sleeves **created extra space outside the fluid path***
  - *Internal mechanism was concealed*



Internal cannula creates complex mechanism



External cannula requires extra part or needle

Total Confusion!

External vs internal cannula?

reflux

"Slit" septum vs. Split septum

Mechanical valve

Changes in technique

Interstitial space

Negative

Catheter Infections

Flush-ability

Catheter Occlusions

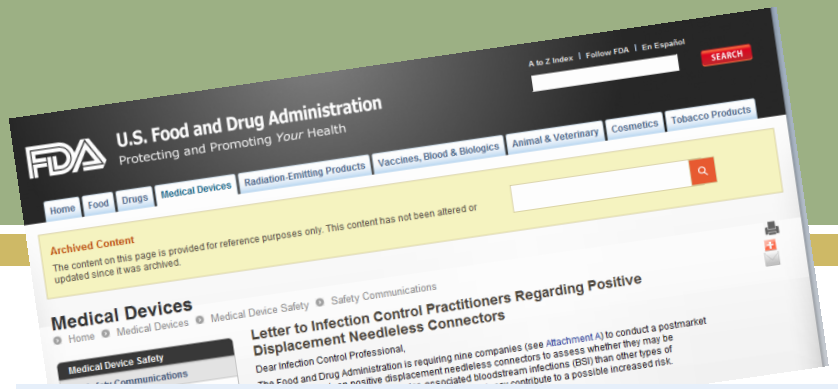
Neutral

Positive

disinfection

Residual volumes

Swab-ability



FDA Tells Makers of Positive-Displacement Needleless Connectors to Study Infection Risk

Robert Lowes
July 30, 2010

Comment Print

EDITORS' RECOMMENDATIONS

Rct Of Chlorhexidine vs. Soap & Water Bathing for Prevention of Hospital-acquired Infections in SICU

July 30, 2010 — The US Food and Drug Administration (FDA) is requiring 9 companies that make positive-displacement needleless connectors for intravenous (IV) therapy to assess whether these devices pose a higher risk for bloodstream infections than other types of needleless connectors, the agency announced yesterday.

Although needleless catheter connectors spare healthcare workers

Needleless Connectors and Bacteremia: Is There a Relationship?

November 1, 2005 0 Comments

Posted in Articles, Pathogens, Infections, Healthcare-Acquired Infections (HAIS), Research & Studies, Surveillance & Epidemiology

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Needleless Connectors and Bacteremia: Is There a Relationship?

By Marilyn Hanchett, RN, PhD

Abstract

Needleless connectors, used today as integral components of an infusion system, evolved in response to demands for enhanced healthcare worker safety and as part of the continuing development of infusion technology. At this time, there are three design categories among needleless connectors: split septum connectors, luer activated valves, and luer valves with positive displacement. Numerous branded products are available within each category. Although needleless connectors offer enhanced safety features, there have been recurrent concerns about an increased risk of bacteremia associated with their use. This article reviews the development of these devices, examines the available evidence base, identifies unresolved issues, and suggests strategies to facilitate optimum use of needleless connectors within infusion systems.

Introduction

Digital Issues | Galleries | Reports | Webinars | Whitepapers | HAI Prevention Imperatives D

Contamination Risk Related to Needleless Connector Design is Not a New Concept

"The internal mechanism of the valve contains moving parts which introduces irregularities in the fluid flow and may promote stagnation and create potential reservoirs for microbial growth."[2]

"difficulty in sterilizing the gap between the valve and the hub"[3]

"intricate access surfaces that are more difficult to disinfect"[4]

"mechanical valve could be more difficult to disinfect because of the complicated nature of the multi-part device"[5]

2. Rupp, M., et al., 2007, Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve Clinical Infectious Diseases, v. 44, p. 1408-14.
3. Field K., et al. Incidence of Catheter-Related Bloodstream Infection Among Patients with a Needleless, Mechanical Valve–Based Intravenous Connector in an Australian Hematology-Oncology Unit. ICHE 2007; 28:610-613.
4. Maragakis LL, et al. Increased catheter related bloodstream infection rates after the introduction a new mechanical valve intravenous access port. Infect Control Hosp Epidemiology 2006;27:67–70.
5. Salgado CD, et al., Increased Rate of Catheter-Related Bloodstream Infection Associated with Use of a Needleless Mechanical Valve Device at a Long-Term Acute Care Hospital. ICHE 2007; 28:684-688.

There is More than Meets the Eye

It's what's under the surface that can do the most damage

Guidelines and Standards of Practice

CDC 2011 Guidelines

Needleless Intravascular Catheter Systems

Recommendations

1. Change the needleless components at least as frequently as the administration set. There is no benefit to changing these more frequently than every 72 hours. [39, 187–193]. Category II

2. Change needleless connectors no more frequently than every 72 hours or **according to manufacturers' recommendations**. Category II

Which recommendation do you follow?

Refer to device manufacturers' recommendations for use

Infusion Nursing Standards of Practice Revised 2016, S68

F. Perform a vigorous mechanical scrub for manual disinfection of the needleless connector prior to each VAD access and allow it to dry.

1. Acceptable disinfecting agents include 70% isopropyl alcohol, iodophors (ie, povidone-iodine), or > 0.5% chlorhexidine in alcohol solution. 7,16 (II)
2. **Length of contact time for scrubbing and drying depends on the design of the needleless connector** and the properties of the disinfecting agent.

For 70% isopropyl alcohol, **reported scrub times range from 5 to 60 seconds** with biocide activity occurring when the solution is wet and immediately after drying. 3,17,18 (II)

3. Use vigorous mechanical scrubbing methods even when disinfecting needleless connectors with antimicrobial properties (eg, silver coatings). 19-24 (IV)

INS Standards of Practice, 2016 Changing the Needleless Connector S68

Change the needleless connector no more frequently than 96-hour intervals. Changing on a more frequent time interval adds no benefit and has been shown to increase the risk of CLABSI.

1. When used within a continuous infusion system, the needleless connector is changed when the primary administration set is changed (eg, 96 hours)

3. Additionally, the needleless connector should be changed in the following circumstances: if the needleless connector is removed for any reason; if there is residual blood or debris within the needleless connector; prior to drawing a sample for blood culture from the VAD; upon contamination; per organizational policies, procedures, and/or practice guidelines; or **per the manufacturer's directions for use** (see Standard 49, Infection). 7,34,35 (IV)

Evolution of Needleless Technology

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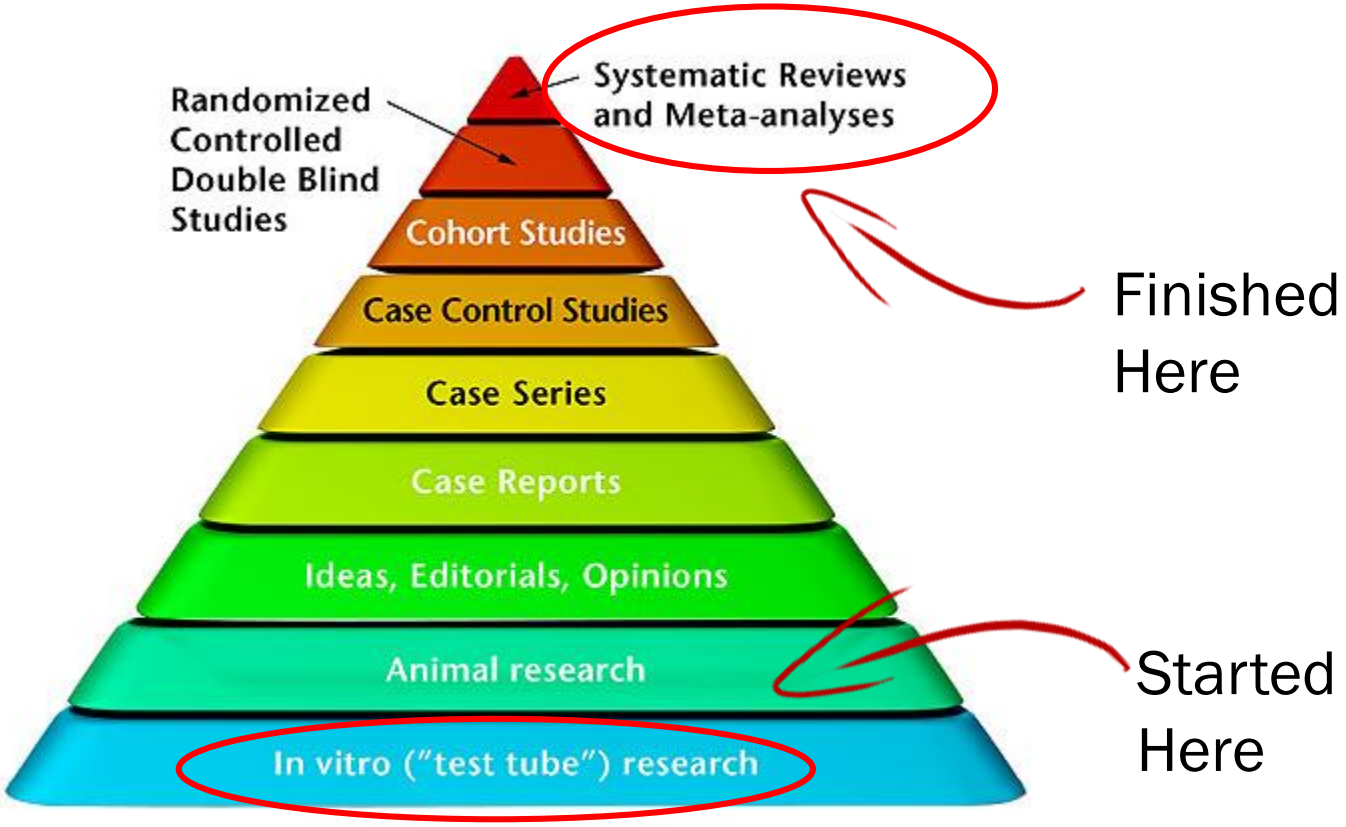
Bloodborne pathogen exposure risks gain greater attention	Occupational Safety & Health Administration (OSHA) recommends healthcare facilities use "engineering controls" to help protect Health Care Workers from these pathogens	Needlestick Safety and Prevention Act (Pub. L 106-430) signed into law	Engineered controls, including Needleless Connector (NC) systems mandatory under Needlestick Safety and Prevention Act	**FDA recognizes microbial risk** with NC's Testing should demonstrate disinfection procedures used are **effective for removing microorganisms from the device**	**FDA revises Guidance Testing** should demonstrate disinfection procedures are **effective during testing simulated clinical use with multiple accesses**
Healthcare Worker Protection				Patient Protection	

Manufacturers' Evidence

Strength of Evidence



In-Vitro Study Completed

Journal of Infusion Nursing January 2015 (Anna Casey et al)

Study Purpose:
Identify any differences between the rates of microbial ingress into different devices following contamination.

- Tested 5 second and 15 second disinfection protocols.
- 7-day clinical simulation = repeated microbial contamination of access surface and disinfection followed by saline flushes.
- Plus blood aspiration through the devices, mimicking blood discard and sampling, commonly carried out in clinical practice.

Anna Casey , PhD, BSc, Tarja Karpanen , PhD, BSc, RGN' Peter Nightingale , PhD, BSc, Tom Elliott, PhD, DSc, MRCP, BM, BS, BMedSci, FRCPath "An In Vitro Comparison of Microbial Ingress Into 8 Different Needleless IV Access Devices" Journal of Infusion Nursing, Volume 38, Number 1, January/February 2015

Interesting Conclusions

- **The MaxPlus was associated with ingress of significantly fewer microorganisms** compared with the other devices tested.

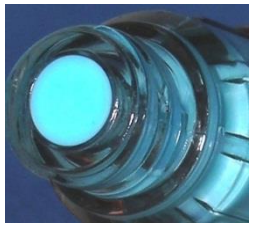
- **Significantly fewer CFU were recovered from needleless IV access devices with relatively large priming volumes, such as MaxPlus, than those with small priming volumes.**

- **The MaxPlus was associated with significantly fewer contaminated administration set male luers than the other devices tested, which supports the conjecture that the injection site design may protect the male luer sterility.**

Two Critical Features

ACCESS SURFACE is **solid and sealed**

- Can be effectively disinfected
- No crevices, slits, holes or gaps that can allow contaminants to penetrate the connector



INTERNAL DESIGN is **simple**

- No internal cannula or complex mechanism creating empty space in the connector outside the fluid pathway, where contamination can become trapped and cannot be flushed or disinfected.

This In-vitro study demonstrated the importance of these features for effective decontamination, 5 and 15 seconds were equally effective in reducing contamination on the MaxPlus.

This study also reported 5 and 15 second disinfection times were ineffective in reducing contamination of some other designs.

Meta-Analysis

ELSEVIER

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

AJIC American Journal of Infection Control

Sources searched for studies:

- MEDLINE
- ClinicalTrials.gov
- Embase
- Cochrane Database
- Studies using the positive-displacement study NC compared with negative- or neutral-displacement NCs were analyzed.

MedlinePlus® Trusted Health Information for You

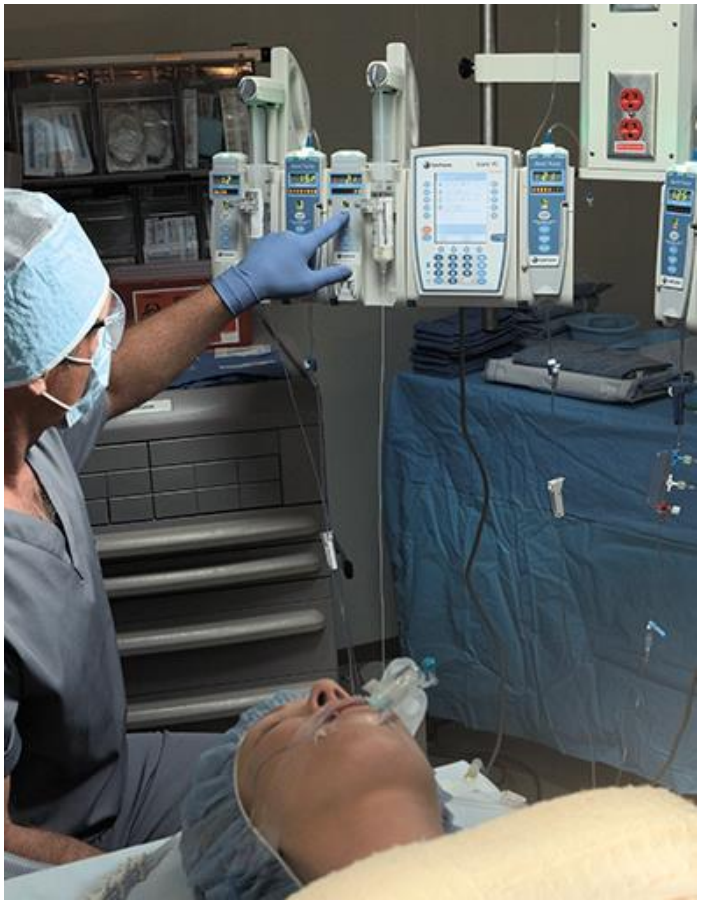
ClinicalTrials.gov A service of the U.S. National Institutes of Health

The Cochrane Library Evidence for healthcare decision-making

Studies included in Meta-Analysis

Seven studies met the inclusion criteria:

- 4 were conducted in intensive care units
  - One Pediatric Cardiac ICU
  - One Neonatal ICU
  - Two Medical ICU
- 1 in a home health setting
- 2 in long-term acute care settings.



Similarity in Conclusions

A Needleless Connector with improved engineering design that facilitates effective IV line care is associated with lower risk of bacterial contamination.

Many NCs have become complex in design. The complexities might have made some NCs harder to disinfect, flush completely, or use correctly, all of which could contribute to the risk of complications.

Feasibility of Using Existing Public and Private Data Sources for Nationwide Medical Device Post-marketing Safety Surveillance

In order to satisfy an FDA post-market surveillance request, **CareFusion undertook the largest analysis known to-date for needleless connectors.**

Used 2013 Center for Medicare and Medicaid Services Hospital Compare data

- 3,074 hospitals
- Nearly 11,000 recorded events
- Nearly 10 million catheter days
- Merged with Manufacturer's client database

Feasibility of Using Existing Public and Private Data Sources for Nationwide Medical Device Post-marketing Safety Surveillance

The advantages of using publicly reported outcome data such as used in this study include:

1) There is no sampling bias, because all eligible hospitals are included
2) There is no potential conflict of interest compared to data collected by manufacturers themselves
3) It is most current with minimal time lag
4) The comparison is concurrent, which eliminates potential bias inherent to pre-post period study designs.

Evidence from the Meta-Analysis and the CMS Data Analysis

CareFusion submitted data from the Meta-Analysis article (Jarvis et al) and the CMS Data Analysis to the FDA in response to a request for Post Market Surveillance.

Based on this data, the FDA provided input to CareFusion. CareFusion added the following statement to the MaxPlus DFU:

2013 CMS Hospital Compare data from 3,074 hospitals, accounting for nearly 11,000 CLABSIs associated with nearly 10 million catheter days show that hospitals using CareFusion MaxPlus needleless connector had lower unadjusted CLABSI rates, as well as lower standardized infection ratios, compared to hospitals not using MaxPlus needleless connector.

CareFusion

MaxPlus® needleless connector

Manufactured for
CareFusion
Switzerland 317 Sàrl
CH-1180 Rolle

Distributed by
CareFusion
San Diego, CA USA
1.800.854.7128

DEHP LATEX STERILE R

INDICATIONS FOR USE:
The MaxPlus is a sterile, single patient use, positive displacement connector for needleless access to the IV line and/or IV catheter during IV therapy. The MaxPlus connector can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

Description:
The MaxPlus needleless connector is a closed luer activated device. The accessing ISO male luer from standard administration sets, extension sets, and syringes activate the flow of fluid through the device. The MaxPlus features Tru-Swab® technology which provides a flat, smooth surface for optimum disinfection during pre-access swabbing. The positive displacement feature of the MaxPlus product produces a positive bolus of fluid to clear the catheter upon disconnection of the male luer.

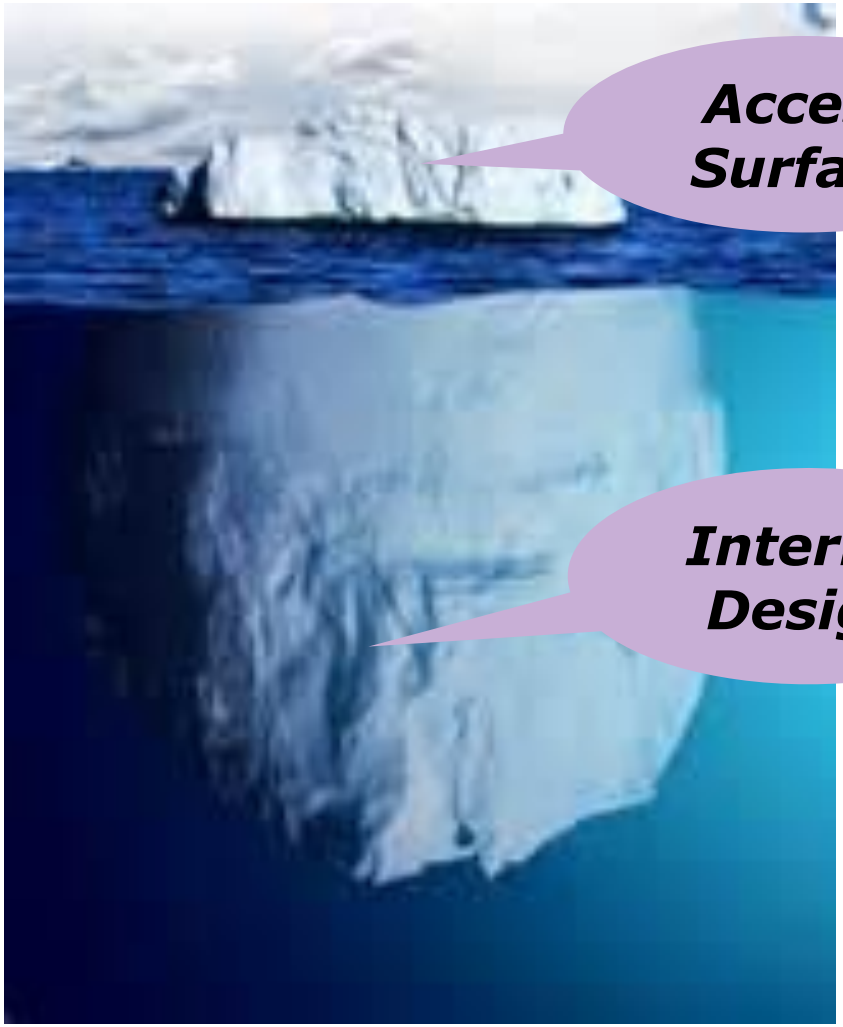
2013 CMS Hospital Compare data from 3,074 hospitals, accounting for nearly 11,000 CLABSIs associated with nearly 10 million catheter days show that hospitals using CareFusion MaxPlus needleless connector had lower unadjusted CLABSI rates, as well as lower standardized infection ratios, compared to hospitals not using MaxPlus needleless connector.

FDA Post Market Surveillance

This is the future for medical devices.


Lessons
Learned

There's more than meets the eye …



What should we be evaluating with needleless connectors?

What should we be looking at?

'Preferred Design[6]' & Extended Usage

OPPORTUNITIES TO IMPROVE DISINFECTION & PATIENT CARE

Features to improve disinfecting & flushing techniques:

- **Solid access surface**
- **Sealed between access surface and housing**
- **Completely fluid filled design with a one piece internal mechanism (*no internal cannula or complicated design*)**

Needleless Connectors
and the Improvement of Patient and Healthcare Professional Safety

By William R. Jarvis, MD

INTRODUCTION

When it comes to improving patient and healthcare safety, many factors are considered: time to treatment, antimicrobials and increased reporting standards to name a few. However, a small device – the needleless connector for intravenous systems – can have a big impact, particularly on protecting healthcare workers from needlestick injuries and in reducing bacterial contamination. There are numerous options for these devices, and there may be confusion on current guidelines, as well as protocols for appropriate disinfection and use. With all the variables and increasing time constraints, how can healthcare professionals – such as critical care nurses and infection preventionists – improve patient care and safety, as well as protect themselves? By understanding the differences between the device options, healthcare professionals can more easily tailor their patient care, improve adherence to clinical best practice and ensure their safety.

HISTORY

At the front line of patient interaction, hospital-based healthcare professionals have a great responsibility to provide quality patient care. But when it comes to protecting themselves, these professionals were at one time at a great risk for needlestick injury. A study by Jagger, et al., revealed that devices that required manipulation after use, such as intravenous (IV) tubing needles and disposable syringes, were associated with an increased rate of injury to the healthcare professional. At a rate of approximately 385,000 per year, sharps injuries posed a great issue to healthcare professionals, including an increased risk for bloodborne pathogen transmission.

To help protect the healthcare professional, the Needlestick Safety and Prevention Act mandated that the Occupational Safety and Health Administration (OSHA) clarify and revise the Bloodborne Pathogens Standard. The subsequent new provisions put forth in the Exposure Control Plan stated that, "Where engineering controls will reduce employee exposure either by removing, eliminating or isolating the hazard, they must be used."

A first-line strategy for compliance was to eliminate or reduce the unnecessary use of needles, primarily using a needle-free IV delivery system. While needleless connectors were initially developed to help improve healthcare professional safety, in recent years the use of needleless connectors may have contributed to improved patient care as well.

GUIDELINES

The Food and Drug Administration (FDA) has regulatory authority over the marketing of needleless connectors. The requirements for marketing have changed over time. In 2005, the FDA recognized that there is a microbial risk with needleless connectors. The guidance released that year said, "The testing should demonstrate that disinfection procedures you use are effective for removing microorganisms from the device." However, in 2008, this guidance changed and became less clear, stating "The testing should demonstrate that disinfection procedures you use are effective." Unfortunately, that allowed some laboratory studies to demonstrate the transfer of microorganisms, rather than validating the removal of them. This still leaves a concern of organism transfer, which would have been otherwise avoided if the organism were removed in the first place. FDA requirements should mimic the clinical situation and be straightforward and consistent for manufacturers.

It is imperative that the healthcare professional develop and adhere to manufacturer recommended disinfection protocols for their needleless connectors and use a sterile end cap on the male luer of the IV tubing during intermittent infusions to help reduce the risk of contamination. This disinfection process should specify the specific disinfecting agent, the method for disinfection (e.g., scrub the access surface) and the duration such disinfection should occur; such requirements may be needleless connector specific.

CHARACTERISTICS OF NEEDLELESS CONNECTORS

When identifying a disinfection protocol, it is important to consider the features of

At a rate of approximately 385,000 per year, sharps injuries posed a great issue to healthcare professionals, including an increased risk for bloodborne pathogen transmission.

www.infectioncontroltoday.com

2 ICT | December 2013

Jarvis WR. Needleless Connectors and improvement of Patient and Healthcare Professional Safety. Infection Control Today. December 2013

The Whole Picture

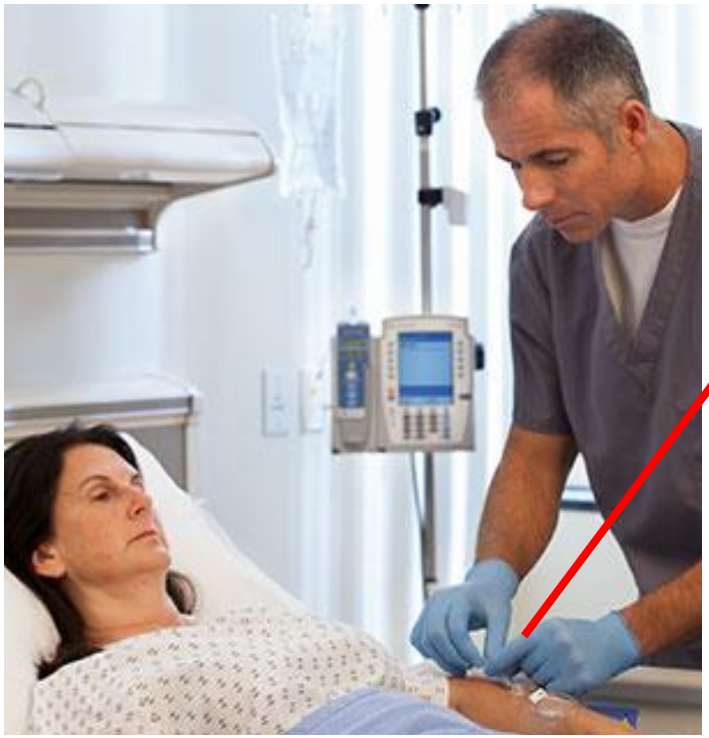
Great Two Bedroom Home

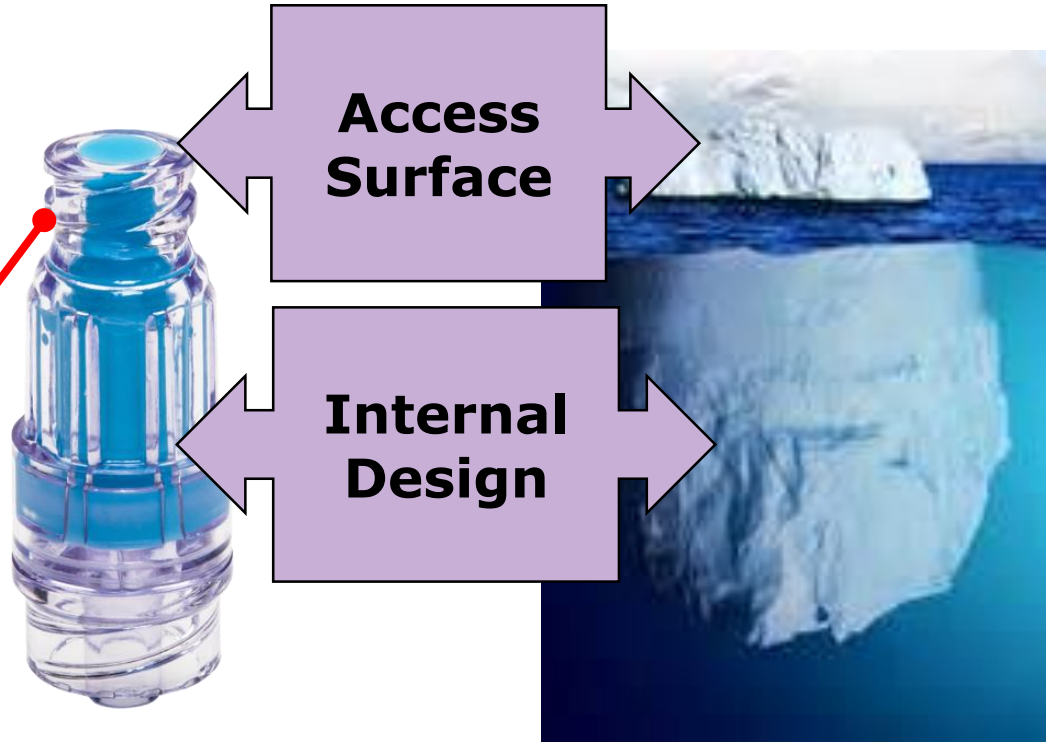
- Quiet neighborhood
- Attached garage
- Close to Shopping
- Beautiful view of the river

- Canoe Optional!!!!!!

Needleless Connectors

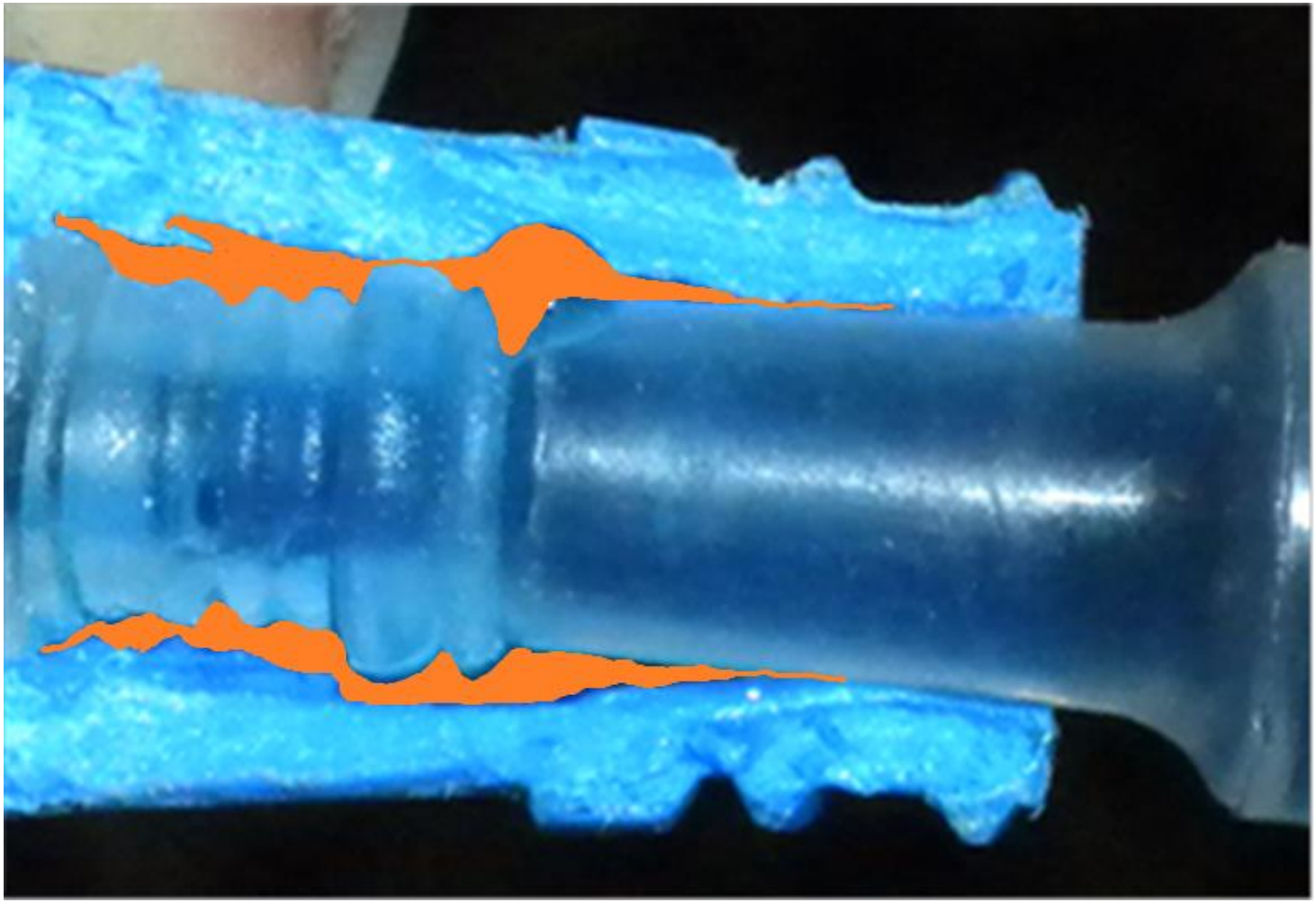
Preventing complications and contamination, and reducing costs





A thorough evaluation requires a look at the Whole Picture

Design Determines Protocol



Interstitial Space

Design determines protocol

Slits, Crevices, and Spaces

Design determines protocol

- Simple, fluid filled designs eliminate area outside the fluid path that can trap contamination, which can then be transferred to the luer and subsequently the fluid path.
- *The steps to contamination in* Complex Designs:
  1. Internal space outside fluid path traps contamination
  2. Contamination is passed to the male luer during access
  3. Repeated access passes contamination to the fluid path

Simple Designs:

Cannula Activated

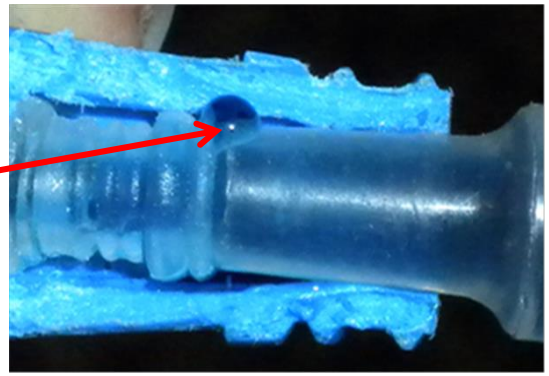
Luer Activated

Design determines protocol

Change
Out
Practice

- Multiple actuations
  - How many times can the device be accessed?
- Disinfection
  - Cleaning the injection surface to remove contamination and prevent contaminates from being pushed into internal space
- Fluid filled or internal space
  - Are there areas that are not part of the fluid path within the device that can trap contamination?

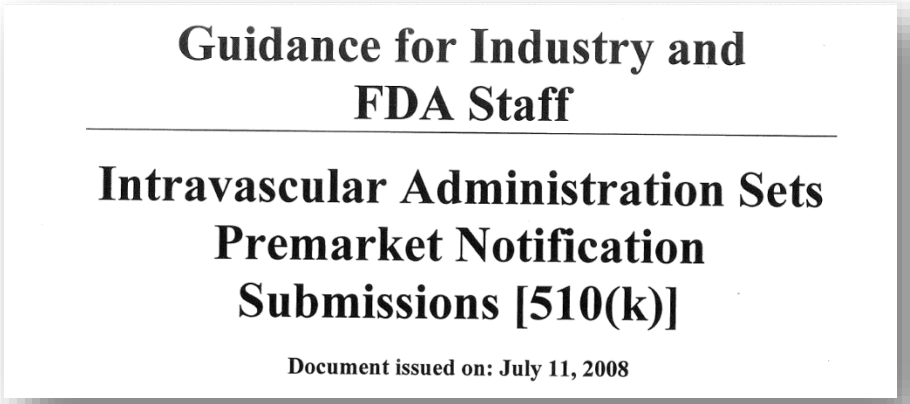
Split Top and interstitial space leads to contamination



Design determines protocol

GOOD CLINICAL PRACTICE

Change Out Practice



Guidance for Industry and FDA Staff

Intravascular Administration Sets Premarket Notification Submissions [510(k)]

Document issued on: July 11, 2008

8. Microbial Ingress Testing

- The FDA recommends that manufacturer's conduct microbial ingress testing of needleless connector devices. The testing is intended to simulate repeated access.
- Manufacturer's support dwell time recommendations with simulated clinical use testing which must demonstrate effective disinfection over multiple days of testing with multiple inoculations and multiple accesses.

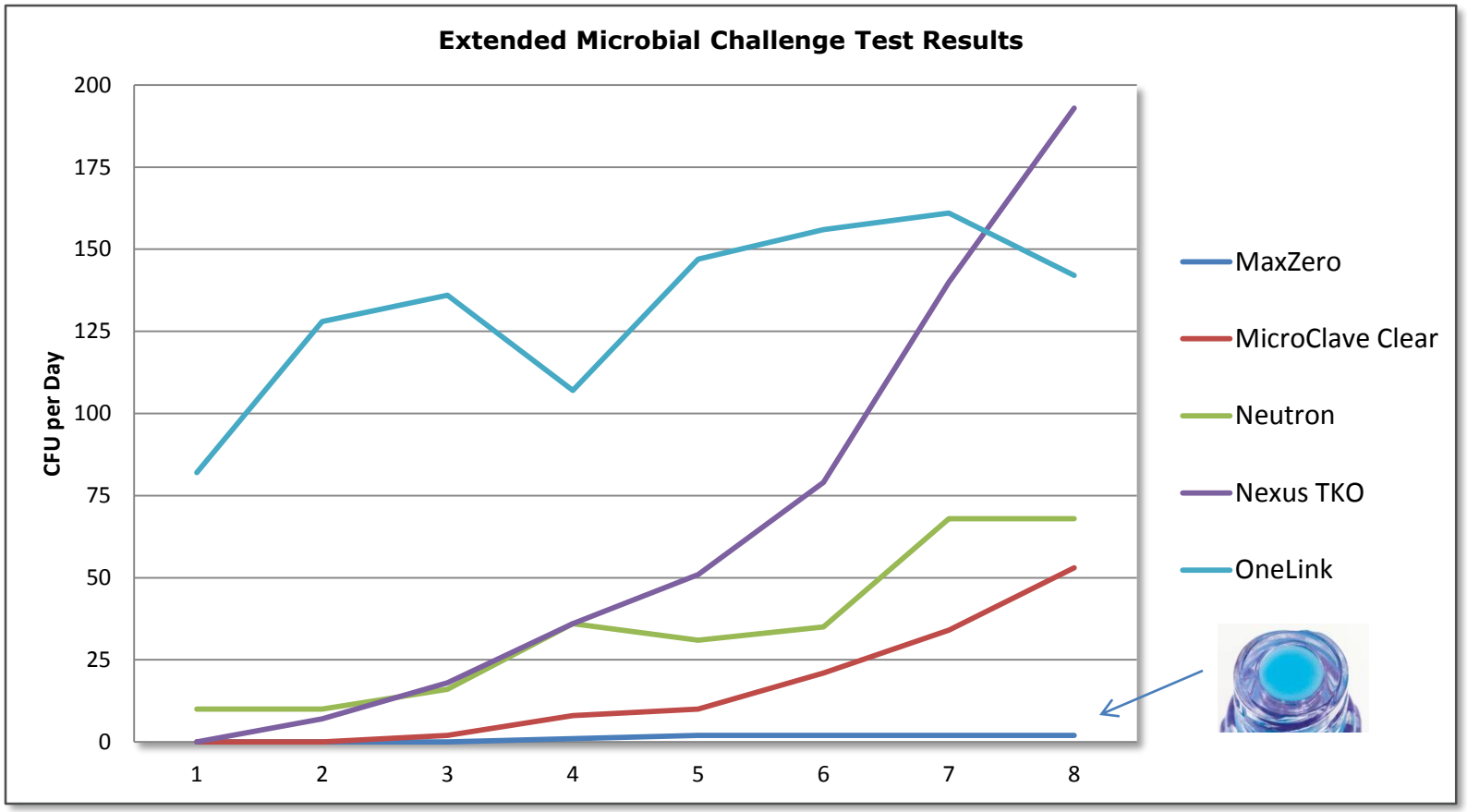
TESTING PROCEDURE

Round 1 Blood Aspiration	• Inoculate, allow to dry 30 minutes • Disinfect 3 seconds, allow to dry 30 seconds • Activation: flush each device with a new 10 mL saline flush syringe • Aspiration: Draw 5 mL of 10% (v/v) bovine blood through each device using the empty syringe by drawing the plunger back. Push the aspirated blood to waste. Repeat • Disinfect • Activation: flush each device with a new 10 mL saline syringe to waste
Round 2, 3, 4 Simulated IV Therapy	• Inoculate, allow to dry 30 minutes • Disinfect 3 seconds, allow to dry 30 seconds • Activation: flush each device with a new 10 mL saline flush syringe
Round 5 Simulated Intermittent Therapy using the same luer and prolong access	• Inoulate, allow to dry 3 minutes • Disinfect 3 seconds, allow to dry 30 seconds • Prolonged activation: connect a sterile 10 mL saline syringe to each device and flush approximately 8 mL from flush syringe and leave syringe attached to test device for one hour, then flush remaining 2 mL saline • With same syringe, repeatedly access test device without fully disconnecting luer 12 times
Eight Day Simulated Use	• Repeal rounds 1 through 5 once every 24 hours over eight (8) days • Final eluate flirtation is repeated at end of each day for each test device

Long Term Use: Extended Microbial Challenge Test

Test completed at independent third party laboratory, LGGS.

Simulated clinical use included blood draw, 25 accesses per day over 8 days, 5 inoculations per day with a 3 second disinfection protocol.



Design determines protocol

GOOD CLINICAL PRACTICE

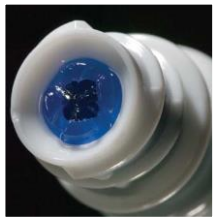
The ability to use a connector for an extended period to maintain a closed line varies depending on internal design and access surface design. The time is determined by microbial ingress testing following FDA Guidelines.

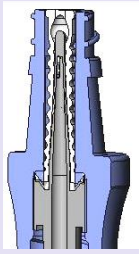
Simple designs with solid sealed access surface

- Solid sealed access surface can be easily and quickly disinfected, allowing little or no bacteria to enter the connector
- Evidence supports 7 day change out

Complex designs with splits, slits, crevices and internal cannula or other mechanisms

- Evidence demonstrates ineffective disinfection and areas inside connector that can trap contamination
- Evidence does not support 7 day change out





Design determines protocol

GOOD CLINICAL PRACTICE

Disinfection Practice

3-5 Second Disinfection

- Connector design has a solid, sealed access surface which can be effectively disinfected.
- Connector design is simple and all internal space is actively part of the fluid path.
- Manufacturer's testing demonstrates 3-5 second disinfection is effective and is not diminished over several days of use.
- **What does peer reviewed published data demonstrate?**

Is disinfection effective?

- Connector design has a split, slit or crevice in the access surface which does not support effective disinfection.
- Connector design permits contamination to fall into interior space created by complex design and the spaces cannot be flushed or disinfected.
- What does manufacturer's data demonstrate?
- **What does peer reviewed published data demonstrate?**

Design determines protocol

GOOD CLINICAL PRACTICE

Disinfecting Caps

No cap needed if:

- Connector design has a solid, sealed access surface which can be effectively disinfected.
- Connector design is simple and all internal space is actively part of the fluid path.
- Testing demonstrates effective disinfection in 3 to 5 seconds over extended 7-8 day testing.

Cap is needed if:

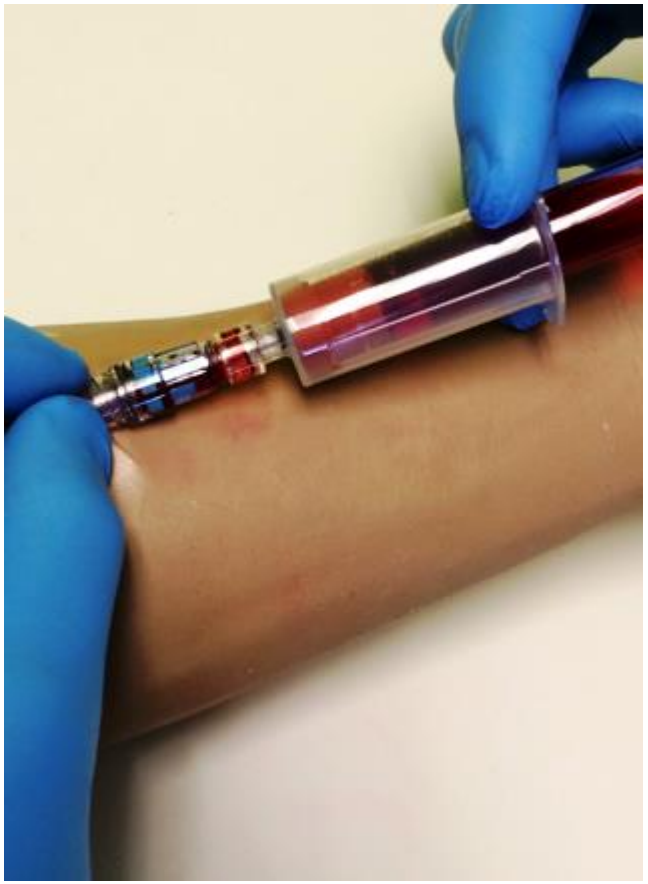
- Connector design has a split, slit or crevice in access surface which does not support effective disinfection.
- Connector design permits contamination to fall into interior space created by complex design and the spaces cannot be flushed or disinfected.
- Testing demonstrates ineffective disinfection, effectiveness diminishes over several day testing

Design determines protocol

GOOD CLINICAL PRACTICE

Blood Draws

- Is the connector INDICATED for aspiration of blood?
- How is this determined?
  - Review the Indications for use (IFU) of specific needleless connector on FDA website
- Using a connector that is indicated for aspiration protects the catheter hub, reducing change outs and blood exposure



Design determines protocol

Disinfection Practice

- Unresolved issue for developing one guideline
- Individual design of each connector dictates different practices
- Time required? Can the connector be disinfected?
- Method required? An alcohol swab or cap?
- Solution required? Alcohol alone or CHG?

- **Why does design matter?**
  - Quality of the surface seal
  - Complex internal mechanism eliminates a solid sealed access surface

Protocols Differ Based on Design

GOOD CLINICAL PRACTICE

- **Unresolved practice issues are caused by different connector designs**
  - One practice cannot be applied to all connector designs
- **Some practices are "Design Specific"**
  - It depends on the connector being used
  - Design specific practice should be established by the Manufacturer in the devices' Instructions for Use

Ultimately Protocols Affect Work Flow and Cost of Use

Connector Change Intervals

- Should the Needleless Connector be considered part of the line …?
- Or the part of the administrations set?

Important Practice Questions:

- Is the connector indicated for blood aspiration?
- Can bacteria be effectively removed via friction and scrubbing with a solution?
- Does the manufacture recommend covering the connector when showering, or changing when contaminated? How does that affect your practice? **How does that affect healthcare $$'s**

Call to Action

1. What is the impact of needleless connector design on performance outcomes in your clinical practice?
2. What steps have you taken to mitigate performance risks associated with needleless connectors?
3. How will you integrate a device risk reduction strategy into your catheter care protocols?
4. What is the best pathway to integrate technology solutions into your best clinical practices?

Questions