



# Neutral Notes

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## WELCOME TO NEUTRAL NOTES

### Message from Dana Wm. Ryan, President & CEO, RyMed Technologies, Inc.

RyMed Technologies, Inc. is pleased to offer this first edition of our 2008 newsletter, *Neutral Notes*™. The focus of this edition is RyMed's *Net Zero*™ Catheter Management Program. This program is designed to provide a roadmap to dramatic reductions in your *catheter-related bloodstream infection (CRBSI)* and *intraluminal thrombotic catheter occlusion* rates.

In the healthcare industry today, over five million central venous catheters (CVCs) are placed yearly. CRBSI is a major hospital-acquired infection. As many as 10% to 25% of hospital admissions are related to CVC complications. Using conservative figures as many as 100,000 deaths annually can be attributed to CRBSIs. The Centers for Disease Control and Prevention (CDC) has set a goal of decreasing catheter-associated adverse events by 50% as one of its top patient safety challenges. The challenge of combating dangerous hospital-acquired infections is enormous and is currently an area of healthcare where multiple stakeholders are actively working together to significantly improve quality and safety. The Institute for Healthcare Improvement's (IHI) **5 Million Lives Campaign** and APIC's **Targeting Zero Initiative** are just two national programs that focus the mission, motivation, and educational resources into a professionally unified call-to-action to improve healthcare and save lives by driving CRBSI rates to zero. The Centers for Medicare & Medicaid's recent decision to eliminate reimbursement for treatment of certain infections in 2008, with private insurers sure to follow, adds additional financial incentive. Improving CRBSI outcomes today, product innovation must not only address infection potential but also support successful evidence-based clinician care and process.

Over the past thirty years IV technology has developed to improve patients' lives while enabling the clinician to provide more and more complex intravenous therapies. The vascular access specialty is unique in that technology is central to care delivery. The IV system includes an insertion site (extraluminal pathway), a catheter, and a connector protecting the intraluminal fluid pathway. A patient plan of care developed to promote positive vascular access outcomes must therefore address both the extraluminal and the intraluminal pathways with a combination of technology developed to reduce CRBSIs and assiduously followed clinician practices that insure aseptic insertion, care and maintenance. Many products and practices focused on the extraluminal catheter track have been individually studied and tried with mixed results. The intraluminal fluid pathway has relied on practice activities and has not been studied. The IHI spear-headed practice "bundles" as an approach to reducing hospital-acquired infections. As the word bundle implies, it is the combination of actions working synergistically that results in improvement where individual actions have failed. The bundle approach when applied to vascular access combines specific infection control developed technologies and practices for both the extraluminal and the intraluminal pathways. Once implemented, the bundle solidifies a successful approach that is clinically shown to achieve and sustain long-term reductions in CRBSI rates.

As hospitals incorporate "zero tolerance" methodologies into their practices, they become committed to doing whatever is necessary to achieve a zero CRBSI rate. With vascular access this requires the combination of extraluminal and intraluminal strategies in both product and practice which are the hallmark of the NET ZERO program. This Neutral Notes provides not only a bundle description but supporting documentation to assist you in developing your CRBSI reduction program: a program that makes zero a reality. I hope you find the information presented in this edition of Neutral Notes useful in your practice.

Dana Wm. Ryan

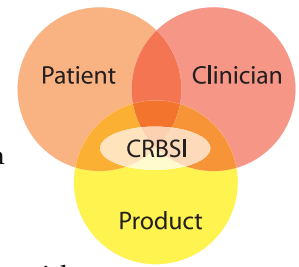
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# CRBSI

To develop an appropriate preventative care policy necessary to achieve zero CRBSI outcomes in today's complex care setting it is important to understand the bacterial migration to colonization cascade and how the patient, the clinician, and vascular access products are linked to intervention success or failure.



## PATIENT

The patient is central to vascular access assessment, device selection, care and maintenance. Patient risk factors are well known. Patient uniqueness and their associated risk factors cause significant outcomes variance. Developing a plan of care requires the clinician to determine which factors indicate implementation of alternative interventions to achieve positive outcomes. These risk factors potentially can pose enormous obstacles which require diligence, plan alteration and may contribute to suboptimal results.

## PRACTICE

The nursing shortage, the increasing patient/nurse ratio, the lack of vascular access education in nursing schools, and the shrinking availability of vascular access nursing experts mean that greater potential exists for inconsistent central venous catheter care and maintenance. Additionally, lack of standardization of vascular access products within the healthcare setting affects routine selection. Therefore, insertion and care practices are performed with compromised and inconsistent results. Focusing only on practice, i.e. nursing behavior, places a huge burden on nursing. When complication rates are low, nurses are praised. But when spikes occur nurses are often singled out as the problem. Focusing on nursing behavior has proven to be labor intensive and extremely time consuming. Research has demonstrated that education improves outcomes (Eggimann 2000, Sherertz, 2000). But consistent results are elusively achieved with high nursing turnover rates and shortages.

## PRODUCT

Technology plays an enormous role in what devices are available, and what care and maintenance is required. Research has shown that device design directly impacts outcome. With new products have come changes in practice and, at times, increases in care and maintenance requirements. Syringe size was changed from 3mL to 10mL, with the advent of long-term silicone catheters, to prevent catheter damage. This change led to issues with pre-filled, low-volume syringes resulting in practice confusion. Before the transition to needle-free IV connector technology, fluid reflux with connection or disconnection using a steel needle and a latex injection port was not a problem. Needle-free "Split-Septum" and swabbable "Non-Positive Push" Luer connector designs have *negative fluid displacement* (blood reflux into the catheter lumen) immediately upon disconnecting from the IV connector. Practice was changed to include a "positive pressure" syringe technique along with clamping before disconnection sequence as a remedy. In the late 1990's a new needle-free IV connector design was introduced: a "Positive Push" IV connector. This new design had a "positive push" of fluid out of the catheter lumen immediately upon disconnecting from the IV connector. But to achieve this positive push upon disconnection, a *negative fluid displacement* (blood reflux into the catheter lumen) immediately upon connecting to the IV connector became reality. Practice again was changed to require a new clamping sequence: DO NOT clamp before disconnection from this type of IV connector. The end result was total clamping sequence confusion from the healthcare provider.

Through these product changes, healthcare workers were protected from accidental needle stick injuries but *catheter-related bloodstream injections* and *intraluminal thrombotic catheter occlusions* increased. Again the practice of when to clamp or not was driven by nursing behavior. A recent study of 100 nurses showed that **29% believe that all four intravenous connectors' designs (split-septum, non-positive push swabbable, positive push swabbable and neutral swabbable) are maintained the same way. (Casella 2007)** In fact, connector maintenance can vary greatly. This variance creates confusion and has led to suboptimal outcomes.

**CRBSI Risk Factors**

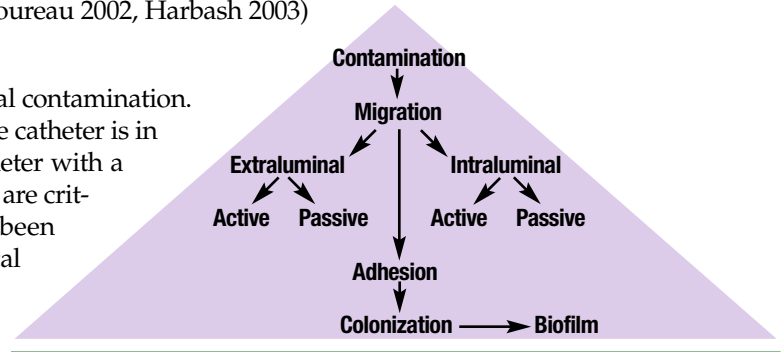
Patient	Clinical	Product
Extreme Age	Insertion Technique, Location	Catheter Type, Material, Lumens
Severe Illness	VAD Usage Blood Draws, TPN	Connector Septum Integrity
Underlying Disease	Site Management Dressing Change Hub Contamination	Fluid Pathway Integrity
Malnutrition	VAD Management Number of Entries Residual Blood	Reflux

## CRBSI OVERVIEW

*Catheter-related bloodstream infections* (CRBSIs) are caused by the migration of bacteria both actively and passively through the cutaneous insertion site and down the catheter track (extraluminal) and also through the fluid pathway (intraluminal). Previous studies indicate that approximately 50% of infections are extraluminal, whereas the remaining 50% are intraluminal. (Ryder, 2006) Once organisms gain access, infection occurs as a result of the bacteria's ability to adhere to the catheter surface, colonize, and develop biofilm. (Ryder 2006, Moureau 2002, Harbash 2003)

### CRBSI Cascade

Insertion provides the first opportunity for extraluminal contamination. Bacteria attach to the catheter with any touch. Once the catheter is in place, the body's physiological response coats the catheter with a fibrin sheath. Insertion site and dressing management are critical. Extraluminal prevention strategies have been researched and include products that support clinical activities. In addition, some strategies interrupt and impede both the movement of bacteria through the insertion site and their successful colonization on the external catheter wall. The current issue is the consistent use of these practices and available products.



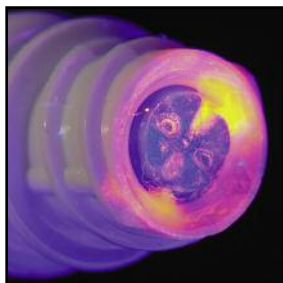
### Behavior Based

- Hand washing
- Skin disinfection
- Full barrier precautions for all central venous catheter insertions
- Routine and PRN dressing changes

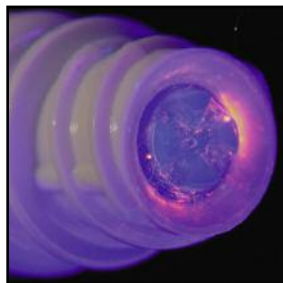
### Technology Based

- New antiseptic hand washing formulations
- New skin antiseptic formulations
- Impregnated external catheter surface with antibiotics, silver, chlorhexidine gluconate, heparin alone or in combination
- Chlorhexidine Gluconate impregnated foam disc
- Stabilization system to minimize catheter "pistoning" or movement

IV Connectors provide the barrier to the intraluminal catheter track. When IV connectors were covered with a latex seal, the fluid pathway was blocked when not in use. But these connectors required steel needles. For clinician safety from blood borne pathogens, IV connectors were designed to eliminate the need for steel needles and reduce the risk for accidental needle stick injury. Luer-access IV connectors have free floating septums that are compressed by the slip tip of the syringe or IV tubing sets. This system allows for gaps around the septum that harbor bacteria and allows both passive and active bacterial migration. Thorough septum surface disinfection has been reported to be unsuccessful in eliminating surface contamination. (Maki 2000)



Before swabbing



After Swabbing

Swabbable "Non-positive push" IV connectors, as well as 'Split-septum' designs, have negative fluid displacement (blood reflux into the catheter lumen) immediately upon disconnection from the IV connector. With a SASH flushing procedure, there are four blood reflux episodes per therapy. It is known that each blood reflux episode increases the potential for fibrin adhesion on the intraluminal catheter wall surface. The swabbable positive push IV connectors were designed to address thrombotic occlusion rates which resulted from the large blood reflux that occurred when disconnecting from split septums or swabbable "non-positive push" IV connectors.

However, with the positive push IV connector designs, the repeating blood reflux still occurs except it does so immediately at connection and not disconnection. Thus, repeated blood reflux episodes continue. It is documented that reflux is associated with increased partial and complete occlusion rates or intraluminal catheter track thrombosis. Thrombosis has been shown to enhance the risk of infection. (Mohammed 2000) Recently, in fact, research has linked the IV connector's intraluminal fluid pathway to CRBSI rates. (Jarvis 2005)

## Infection Rates with Luer Access Devices vs. Split Septum

Hospital	Location	SS Period	BSI Rate	Mechanical Valve	BSI Rate
A	HW - Peds	1-3/03	1.7	4-6/03	8.6
B	HW	10-12/03	1.5	2-4/04	5.1
C	HW	1-5/02	2.3	6/02-4/03	3.5
D	Ped ICU	1-3/04	5.4	7-9/04	17.3
E	All ICU's	7/00-6/03	5.7	7/03-6/04	8.6

HW = Hospital Wide MV = Mechanical valve SS = Split Septum BSI= Bloodstream Infection

Many of the swabbable “non-positive push” and “positive-push” designs have tortuous fluid pathways resulting in various degrees of dead space within the internal pathway. Prior to infusing a required intravenous therapy, the IV connector on the catheter is accessed with a saline flush syringe. The syringe plunger is pulled back until the clinician visualizes blood within the syringe to verify catheter patency. Many of these IV connectors have various dead spaces or areas within the internal fluid pathway that are difficult to effectively flush or clear. Blood potentially is trapped within these areas. Research has shown that priming volume and dead space may be indicators of colonization and biofilm formation. (Cook 2007)

To overcome bacterial migration through the IV connector, minimize blood fibrin and microorganism adherence, *intraluminal prevention strategies* traditionally have been dependent on behavior practices. Some of these strategies have a research foundation such as aseptic technique and minimizing system entries. Other practices are based on recommendations but have no research basis. For instance, flushing volume or technique has not been studied. It is accepted that turbulent flow may work better than laminar flow at cleaning inner catheter wall surfaces. However, since it is now understood that bacteria know that wall surface is near when fluid flow decreases, constant fast flushing may prove to be more effective in limiting colonization. Because fluid follows the path of least resistance, IV connector fluid pathway design impacts flushing effectiveness.

### Behavior Based

- Use aseptic technique when changing tubing and/or IV connectors;
- Minimize breaks in the complete IV administration system;
- Cleanse the catheter hub with approved antiseptic before attaching a new replacement IV connector (routinely changed per CDC guidelines or institutional protocol);
- Flush the catheter after each use to clean the IV connector fluid pathway and intraluminal catheter track;
- Use “positive pressure” on the syringe plunger when disconnecting from a “split-septum” or “non- positive push” IV connector;
- Instill final heparin or normal saline only lock;
- Change IV administration set components and IV connectors at regular intervals (routinely changed per CDC guidelines or institutional protocol);
- Educate health-care providers on care and maintenance of central venous catheters.

In 2004, a new needle-free swabbable IV connector designed specifically to protect the fluid pathway became available. The *InVision-Plus® with Neutral Advantage™ technology* is available in a patented “Touch-Free™” package design that assists the clinician in preventing hand and catheter hub contamination during routine replacement. Its smooth, gap-less septum eliminates inaccessible areas that can not be disinfected. Thus, the potential for either passive or active bacterial migration into the fluid pathway with connection is minimized. When an IV tubing or syringe is connected to the *InVision-Plus®*, its two microbial barriers are compressed, opening the straight-through fluid pathway that has a 0.027mL priming volume and no dead space within the fluid pathway. To prevent fluid pathway contamination after disconnection, the second independent microbial barrier inside the *InVision-Plus®* covers the fluid pathway when the septum returns to the closed and compressed position. The “zero fluid displacement” feature of the *InVision-Plus®* eliminates repeated blood reflux episodes associated with connection or disconnection from the IV connector. As discussed earlier, the repetitive blood reflux coats the intraluminal surface of the catheter. Thus, a zero fluid displacement technology that is designed to eliminate repeated reflux episodes will minimize blood fibrin, microorganism adhesion, and also minimize biofilm colonization potential within the intraluminal catheter track lumen and IV connector fluid pathway. Additionally, the *InVision-Plus®* does not require a clamping sequence.

## Prevention Strategies

In order to lower CRBSI rates, prevention strategies must attack each point along the CRBSI cascade for both *extraluminal* and *intraluminal* catheter track pathways. These strategies must begin with device selection and insertion but also must include care and maintenance activities. Keeping in mind the healthcare setting today, prevention strategies must be a combination of behavior practices and new product technologies to promote sustainable improvements.

## CRBSI Bundle

One approach to decreasing hospital acquired infections has been the development of practice bundles. The Institute for Healthcare Improvement (IHI) defines a bundle as a structured way of improving the processes of care and patient outcomes: a small, straightforward set of practices that, when performed collectively and reliably, is proven to improve patient outcomes. A successful CVC bundle includes not only *extraluminal* and *intraluminal* clinical behavior practices that prevent contamination, migration, adhesion and colonization, but also innovative products that support current nursing practice. In order for the proposed CVC bundle to be widely acceptable, practices and products must be supported by research, require minimal change in the practice setting, be easy to duplicate consistently and be cost effective. Hospital education is the final critical component that must be developed to support the bundle and ensure compliance.

## Effective hand hygiene to prevent extraluminal and intraluminal contamination

Health care workers' hands have been identified as the primary source of organism transmission from patient to patient. Many studies have shown poor compliance with traditional soap and water hand-washing. Conversely, research has determined that incorporating a waterless, alcohol-based product improves compliance (Bischoff 2000) and is associated with significantly enhanced hand hygiene. (Kampf 2003). The CDC hand hygiene guideline recommends using an alcohol-based waterless product.

**Research has shown that PICCs have lower infection rates than jugular or subclavian insertion sites.**

(Safdar, Maki 2005; O'Grady 2002)

## Preventing extraluminal migration with insertion site selection

The skin has different resident flora and characteristics depending on body location. The upper chest, neck, and groin are warm, moist, and dark, while the arm is dry and light-exposed. The difference in normal skin bacteria counts between the subclavian/jugular location and the antecubital fossa is 1,000 fold (10,000 cfu/cm<sup>2</sup> vs. 10 cfu/cm<sup>2</sup>). Research has shown that PICCs have lower infection rates than jugular or subclavian insertion sites (Safdar, Maki 2005; O'Grady 2002). Evidence has demonstrated increased success rates and safety for central line insertions performed using ultrasound. Using an ultrasound process minimizes insertion site and vein wall trauma. This method is recommended by the Agency for Healthcare Research and Quality and the American College of Emergency.

## Preventing extraluminal contamination with skin antisepsis

The primary event for organism entry into the extraluminal pathway is when the catheter is pushed through the skin. The skin is populated by normal flora. Much research has demonstrated that a combination of 70% isopropyl alcohol and 2% chlorhexidine gluconate enhances skin disinfection. When wet, alcohol is active, kills rapidly and dries quickly. Chlorhexidine gluconate (CHG) is chemically active for a least 6 hours and is not affected by blood or other organic material (common with CVCs). In addition, CHG is persistent (effectiveness increases over time).

## Preventing extraluminal contamination by maintaining Good Aseptic Technique

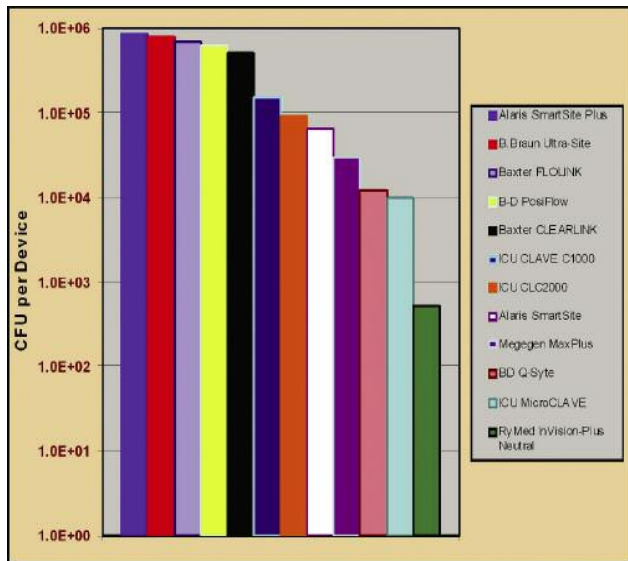
Bacteria are transferred to the skin surface by air, hands and clothes. Full barrier precautions including head cover, foot cover, and full surgical drape should be used with all CVC insertions including PICC. The CDC recommends that full barrier precautions be used with CVC insertion. Following an insertion checklist has proven to enhance procedure compliance. Integral to checklist usage is the ability of the nursing personnel to stop the process when breaks in technique occur.

## Preventing extraluminal bacterial migration

Because bacteria are distributed throughout the epidermis layers, the skin cannot be sterilized (repopulates in 18 hours). Current research determined that the use of a 2% chlorhexidine gluconate patch over the insertion site significantly reduces colonization of the insertion site (Hanazaki 1999, Maki 2000, Crawford 2004). The use of a sponge disc allows for dressing changes every 7 days without skin repopulation around the insertion site.

## Preventing extraluminal adhesion with catheter stabilization

Catheter stabilization minimizes insertion site and catheter tract trauma. The physiological responses to this trauma are inflammation, edema, and interstitial fluid secretion. Secondary to inflammation is edema which causes the insertion site to enlarge. Interstitial fluid secretion acts as a buffer. This moisture plus the skin's natural moisture promote passive bacterial migration extraluminally down the catheter tract. Wall inflammation enhances the physiologic healing response leading to increasing the fibrin sheath. "Pistoning" (moving in and out of the insertion site) of the CVC occurs with patient movement. This movement moves pathogens on the skin into the catheter tract and intensifies wall trauma. Sutures were found to be a source of infection and did little to prevent pistoning. Using a catheter securement device has been shown to minimize catheter movement and significantly reduce CRBSI (Yamamoto, 2002).

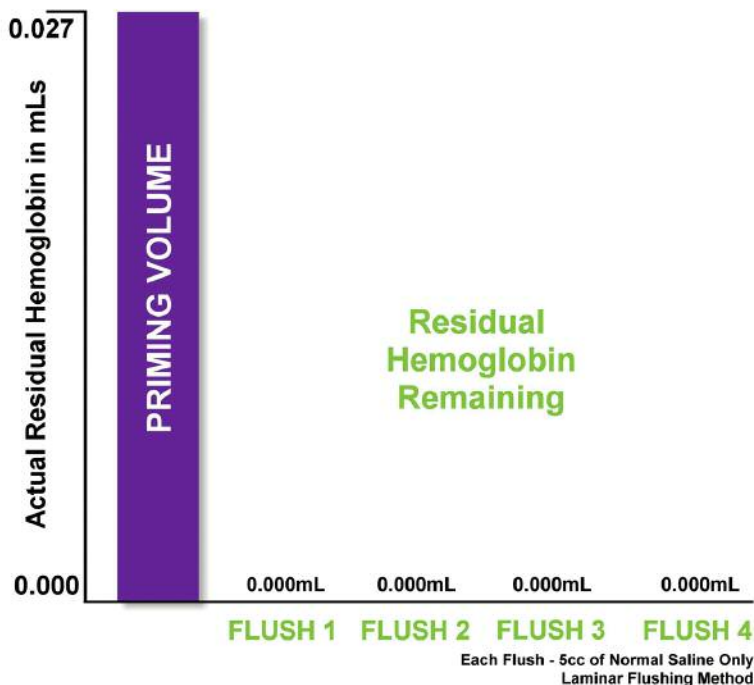


## Preventing intraluminal bacterial migration

**Septum Seal Integrity:** Research found that septums made of hard plastic show increased biofilm growth relative to more hydrophobic materials such as polyisoprene (Cook 2007 available rymedtech.com). Research has demonstrated a correlation between IV connector priming volume and the rate of microbial adhesion and subsequent biofilm formation and colonization. The higher priming volumes are associated with higher biofilm presence (Cook 2007 available rymedtech.com). The *InVision-Plus® I.V. Connector System* is 93.0% - 99.9% more effective at reducing the chance for biofilm formation than any other needle-free IV connector system tested (Cook 2007).

A blood-clearing study demonstrated complete removal of hemoglobin which support nursing flushing activities. In addition, the *InVision-Plus® I.V. Connector* has been shown to reduce thrombotic occlusion rates versus a "positive push" IV connector when eliminating heparin from the flushing procedure (saline only). (White 2006 available rymedtech.com)

## BLOOD CLEARING STUDY for the InVision-Plus® with Neutral Advantage™ technology



Because "zero fluid displacement" occurs at connection to or disconnection from the *InVision-Plus®*, it is not clamping sequence dependent. This feature is designed to eliminate repeated blood reflux episodes and nursing clamping confusion. It also increases consistent bedside success rate with central line management. *InVision-Plus® I.V. Connector* design features focus on all areas of the CRBSI cascade.

## Promoting septum disinfection with every access

Proper disinfection of access ports and IV connector external septums is crucial to preventing bacterial contamination of the patient's fluid pathway. The CDC recommends cleaning with 70% alcohol prior to each access. The length of time for swabbing and the correct technique have not been researched. It is widely accepted that friction should be used and that the entire surface including the threads should be cleaned. For consistent practice acceptance, this procedure must not require extended periods of time.

## Eliminating bacterial food source

Since heparin is a protein, final heparin locks provide a food source for bacteria. Reducing the use of or totally eliminating heparin reduces the number of accesses associated with therapeutic regimens, the potential risk of heparin-induced thrombocytopenia (HIT), and provides significant cost savings to the healthcare provider. The common use of infusion pumps with continuous fluids and piggyback medications has resulted in manual flushing not being routinely done. Catheter clearance is accomplished with continuous primary fluid infusion. The continuous fluid rate may not provide a sufficient bolus volume and lacks turbidity necessary to clean the fluid pathway. Manual flushing permits the clinician to use a larger volume and provide a turbulent flushing episode. The clinician is able to assess the fluid pathway for resistance and institute interventions early.

## Proposed Catheter Bundle:

- Hand washing with approved antiseptic formulations before and after every CVC procedure
- Chloraprep®, (Medi-Flex Inc. (Enturia, Inc.) Leawood, KS) 2% Chlorhexidine Gluconate or 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol disinfection with every CVC insertion, and dressing change
- PICC selected as CVC of choice when possible; placed by ultrasound in the upper arm
- Full barrier precautions with every CVC (including PICC) insertion
- Biopatch® Antimicrobial Dressing (Johnson & Johnson Wound Management, Cincinnati, OH) applied at time of insertion and replaced weekly
- StatLock® Catheter Securement Device (Bard Medical Division, Covington, GA) placed at time of insertion and changed with dressing changes
- *InVision-Plus® with Neutral Advantage™ technology* (RyMed Technologies, Inc., Franklin, TN) applied to all CVC lumens 5-7 second alcohol swab with each IV connector access
- Normal Saline flush (manually at least each shift (Pre-filled syringes are recommended to minimize contamination)

## Initial Bundle application

Early results of bundle implementation have been very promising with CRBSI rates reduced to zero in two sites (three ICU units, total 48 beds). *One community hospital has remained at zero catheter-related bloodstream infections for 25 months. A second hospital has also achieved zero CRBSI for six months after adopting the full catheter bundle.* Both sites reported the need for intensive bundle implementation in-servicing. Research has shown that CVC education is extremely important to lowering CRBSI rates.

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## Conclusion

The CRBSI cascade is complex and has many points along the continuum requiring both *extraluminal* and *intraluminal preventative measures* be in place if *catheter-related bloodstream infections* are to be eliminated.

The proposed bundle of behaviors plus new product technologies have shown that reducing CRBSI rates to “zero” is achievable. Further multi-site bundle implementations need to be trialed to demonstrate both reliability and validity of the bundle. Since it is impossible to eliminate the role of products when managing IV therapy, combining behavior activities and innovative products provides a synergistic effect greater than when the same strategies are used individually.



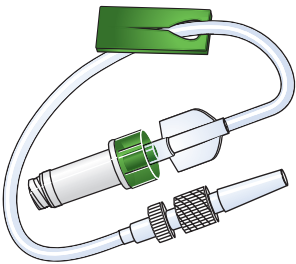
## Neutral Notes

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RyMed Technologies, Inc.  
137 Third Avenue North  
Franklin, TN 37064  
dryan@rymedtech.com

Editor  
Denise C. Macklin, BSN, RNC

## New Product Introduction

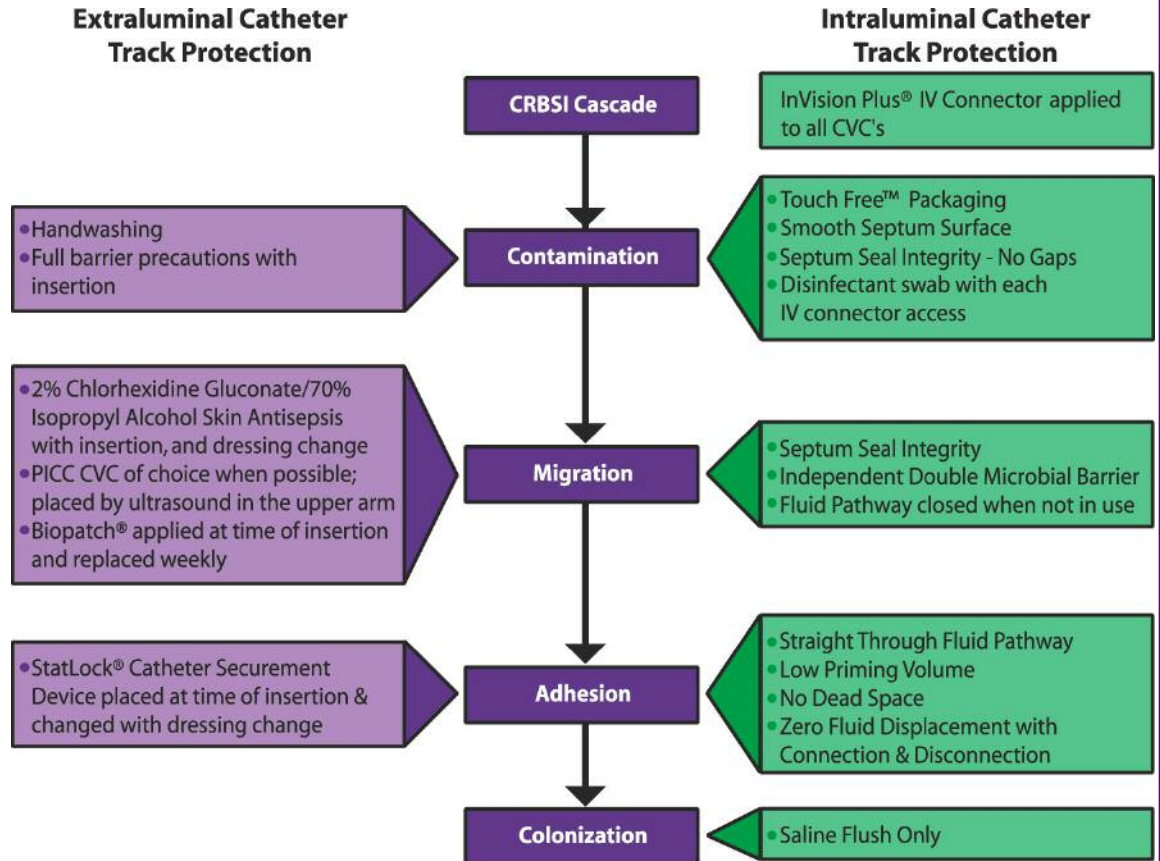
RyMed Technologies is pleased to announce the introduction of the new **RYM-5307 7" Macrobore Catheter Extension Set** (with pre-attached InVision-Plus® I.V. Connector)



For further information visit our website at [www.rymedtech.com](http://www.rymedtech.com)

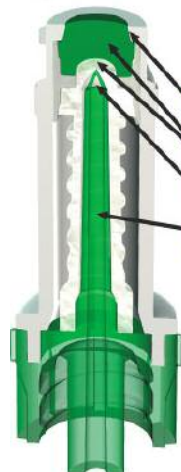
# NET ZERO™

## Catheter Management Program



The path to zero CRBSIs has now been revealed. The solution is using the InVision-Plus IV Connector in an approved catheter bundle which includes strategies to prevent contamination from the skin AND the fluid pathway.\*

The InVision-Plus is the only IV connector that combines septum seal integrity with a patented Double Microbial Barrier system, ZERO fluid displacement upon connection AND disconnection, ZERO fluid pathway deadspace, and a dedicated internal fluid pathway with a low priming volume of 0.027mL.



- A** Septum Seal Integrity
- B** Double Microbial Barrier
- C** No Fluid Pathway Deadspace
- D** Priming Volume 0.027mL

In an independent study presented at SHEA in 2007, the InVision-Plus showed a reduction of microbial colonization ranging from 93% to 99.9% compared to all other connectors tested with higher priming volumes.\*\* So as you advance your

own institution's mission to eliminate ALL hospital-acquired infections in 2008, let the InVision-Plus and its evidence-based success to eliminate CRBSIs lead the way. There are many connectors to choose from, but there's only one InVision-Plus®.

## InVision the Path to ZERO

RyMed Technologies, Inc. • 615-790-8093 • [www.rymedtech.com](http://www.rymedtech.com)

\*See study published in JAVA Winter 2007, "Achieving Zero Catheter Related Bloodstream Infections: 15 Months Success in a Community Based Medical Center."

\*\*Luer Activity Device Priming Volume as Predictor of BioFilm Formation in an InVivo Assay Clinical Poster (Cook, Meyer PhD, Luchinger PhD, April 2007)