



**RyMed**  
*TECHNOLOGIES, INC.*

RyMed's patented disruptive technology provides the only clinically-proven solution in combating both Catheter-related Bloodstream Infections (CR-BSIs) and Intraluminal Thrombotic Catheter Occlusions (Blood Clots), two of the most severe patient issues plaguing Healthcare today.

Investor Presentation  
February 2012

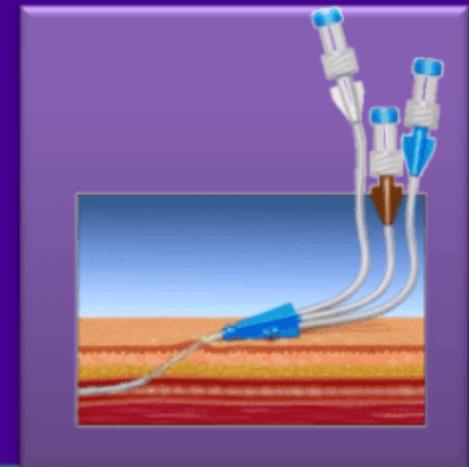


Middlebury  
Group

# Safe Harbor Statement

All statements other than statements of historical facts included herein regarding the Company's financial position, business strategy, growth strategy and other plans and objectives for future operations, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "plan" and similar expressions that may tend to suggest a future event or outcome are not guarantees of performance and are inherently subject to numerous risks and uncertainties, many of which cannot be predicted or anticipated. Future events and actual results, financial or otherwise, could differ materially from those contained herein. Potential investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve significant risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements as a result of various factors. Potential investors are urged to carefully consider all risk-factors highlighted in the private placement memorandum. All forward-looking statements are expressly qualified in their entirety by the foregoing cautionary statement. This is not a solicitation to sell nor offer to buy.

**RyMed Technologies, Inc.**  
**137 Third Avenue North**  
**Franklin, TN 37064**  
**[www.rymedtech.com](http://www.rymedtech.com)**



# Creation of a Problem

Prior to RyMed's InVision-Plus® technology introduction in May 2004, Needleless I.V. Connector Systems were designed to protect healthcare professionals from accidental needle stick injuries, AIDS and hepatitis transmission.

Unbeknown to the design engineers, they solved one problem by protecting the healthcare worker from accidental needle stick injuries, BUT created a new patient safety problem.

## Vascular Access Healthcare Crisis

- ❖ 250,000 – 500,000 catheter-related bloodstream infections yearly in US \*
- ❖ 12-25% mortality rate associated with an intravascular-related BSI\*
- ❖ ICU Length of Stay can increase by as much as 20 days; hospitals by 22 days\*
- ❖ \$2.3 – \$28 Billion/year spent to treat CR-BSIs\*

*\*Maki, D. G., Kluger, D.M., & Crnich, C.J. (2006). May Clinic Proceedings, 81(9), 1159-1171.*

## Needleless I.V. Connector Product Design Flaws

All competitive (Negative & Positive) needleless I.V. connector designs exhibit one or more fluid pathway concerns:

Negative Fluid Displacement  
Fluid Pathway Dead Space

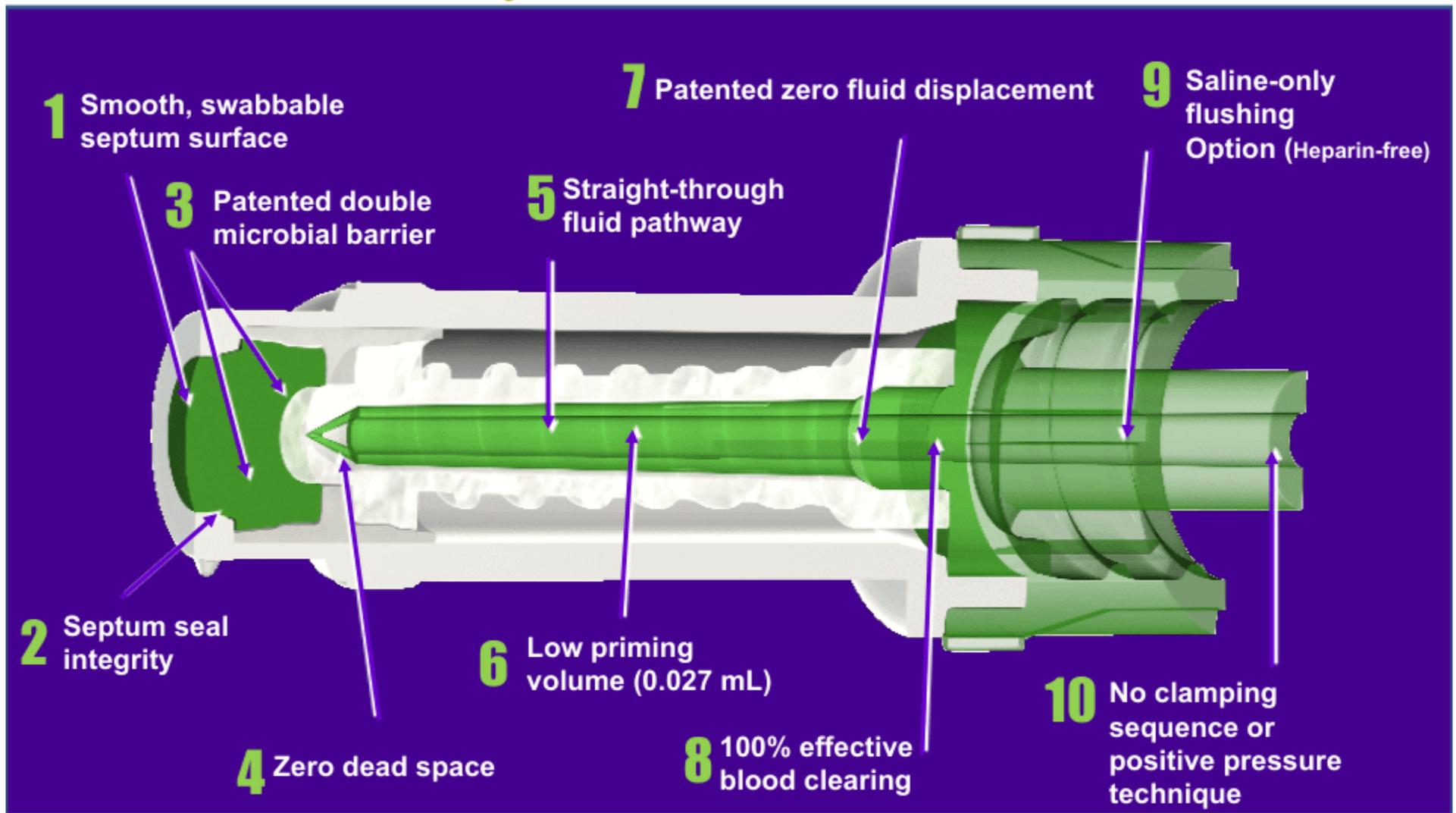
Lack of Septum Seal Integrity  
Ineffective Septum Surface Design

Tortuous Fluid Pathways



# Neutral Advantage™ technology

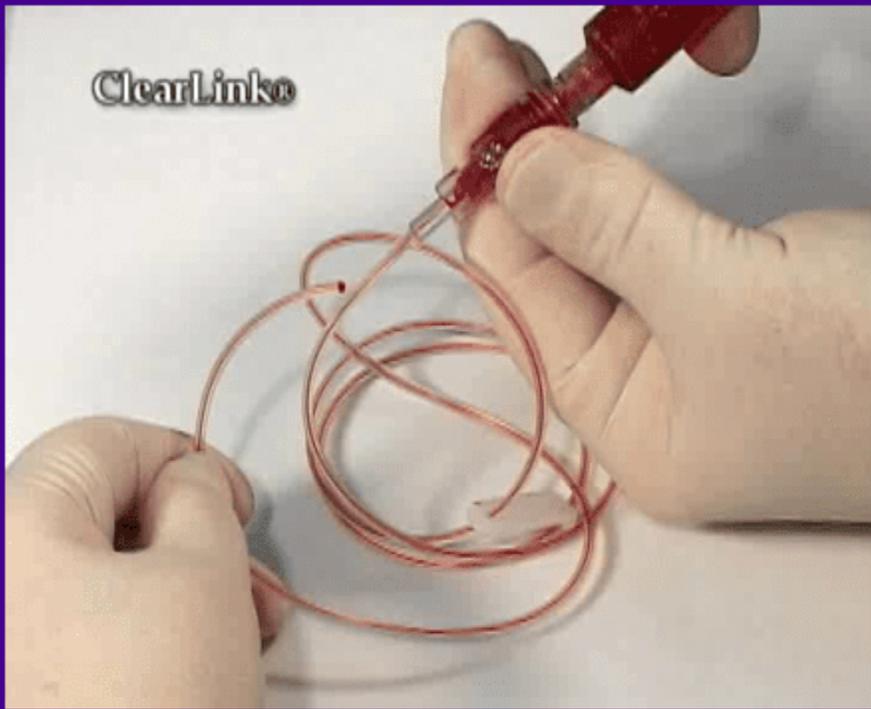
RyMed's "10-Point Standard"



RyMed's patented InVision-Plus® Needleless I.V. Connector System is believed to be the first and only product of its kind that was created from the "ground up" in order to protect patients from the two critical vascular access catheter issues facing healthcare worldwide

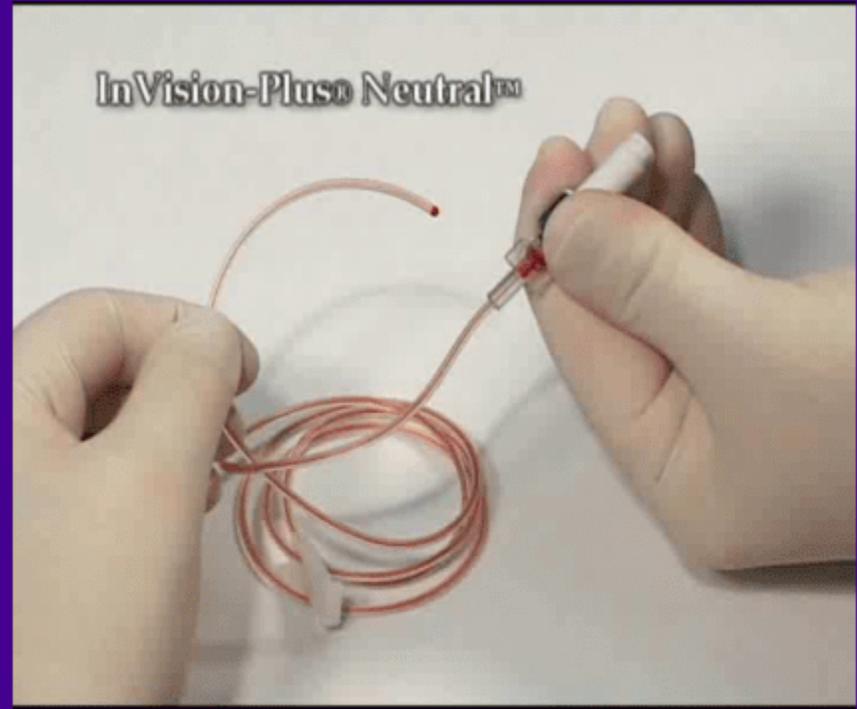
# The Advantage is Clear Statement

ClearLink®



**Negative Fluid Displacement**  
Baxter ClearLink®(example)

InVision-Plus® Neutral™



**RyMed Technologies**  
The ONLY Zero Fluid Displacement System

Negative fluid displacement, or blood refluxing into the catheter lumen, develops blood fibrin, a food source for micro-organisms that develops into biofilm colonization, a source of catheter bloodstream infections.



# Snapshot: RyMed

**HISTORY:**

- 1994 Company Founded
- 1997 InVision-Plus® Development Began
- 2004 Market Introduction
- 2006 Began hiring Direct Sales Force
- 2007 InVision-Plus® Red® Introduction
- 2008 InVision-Plus® Junior® Introduction
- 2009 InVision-Plus® Epi® Introduction
- 2010 Walgreens National Formulary (April)  
FDA Alert – Positive Pressure IV connectors  
FDA Clearance – InVision-Plus® CS™
- 2011 CS® beta site product trials began  
CVS Caremark (April)  
Amerinet - First GPO Contract

**HEADQUARTERS:** Franklin, TN  
**OPERATIONS:** Austin, TX  
**MANUFACTURING:** El Paso, TX/Juarez Mexico  
**EMPLOYEE COUNT:** 23

## Recent \*News\*

July 2011 iData Research , Vancouver British Columbia Canada stated RyMed Technologies is one of the major forces in Needleless IV Connectors in the U.S. Market

November US Army began purchasing

December Company received supply contract from Mayo Clinic's

January 2012 Two supportive peer-reviewed clinical poster presentations accepted by Oncology Nursing Society Europe Geneva – April

January B-D *Posi-Flo*® and Baxter *Flo-Link*® Positive Pressure Needleless IV Connector discontinued.

Guidance (000s)	2009A	2010A	2011A	2012E	2013E
Revenue	\$5,095	\$6,239	\$7,088	\$13,084	\$22,800
Net Income	(\$6,070)	(\$3,263)	(\$2,794)	\$890	\$6,851





# RyMed Snapshot

## 2012 U.S. Market Landscape

- **Clinical Proof of InVision-Plus® Safety & Efficacy – Exceeding Expectations**
- **New InVision-Plus® CS® with Chlorhexidine + Silver Ion Technology**
  - A NEW TRANSFORMATIONAL NEEDLELESS IV CONNECTOR SYSTEM
  - Received FDA 510(k) Approval
  - Kills the eight (8) common microorganisms associated with CR-BSIs
  - Full seven (7) day usage potential
  - A 7.0 log reduction of MRSA
  - All beta-sites reported “zero” CR-BSIs during their trial period in 2011
- **Medicare Non-Reimbursement for CR-BSIs**
- **VA Hospitals Alert Warning of Positive Pressure Needleless IV Connectors**
- **FDA Alert & Notification of Positive Pressure Needleless IV Connectors**
- **Dr. Jarvis M.D. – Clinical Journal Articles on potential risks for CR-BSIs**
- **Dr. Jarvis M.D. – Clinical Journal Article on competitive “Silver-only” Needleless IV Connectors – Blood Inactivates** (Reported to be published in 2012)
  - Baxter Healthcare V-Link®
  - Care Fusion Max-Guard™ (Positive Pressure)
  - B. Braun UltraSite Ag™ (Positive Pressure)



# RyMed Snapshot

## 2012 U.S. Market & Sales Landscape

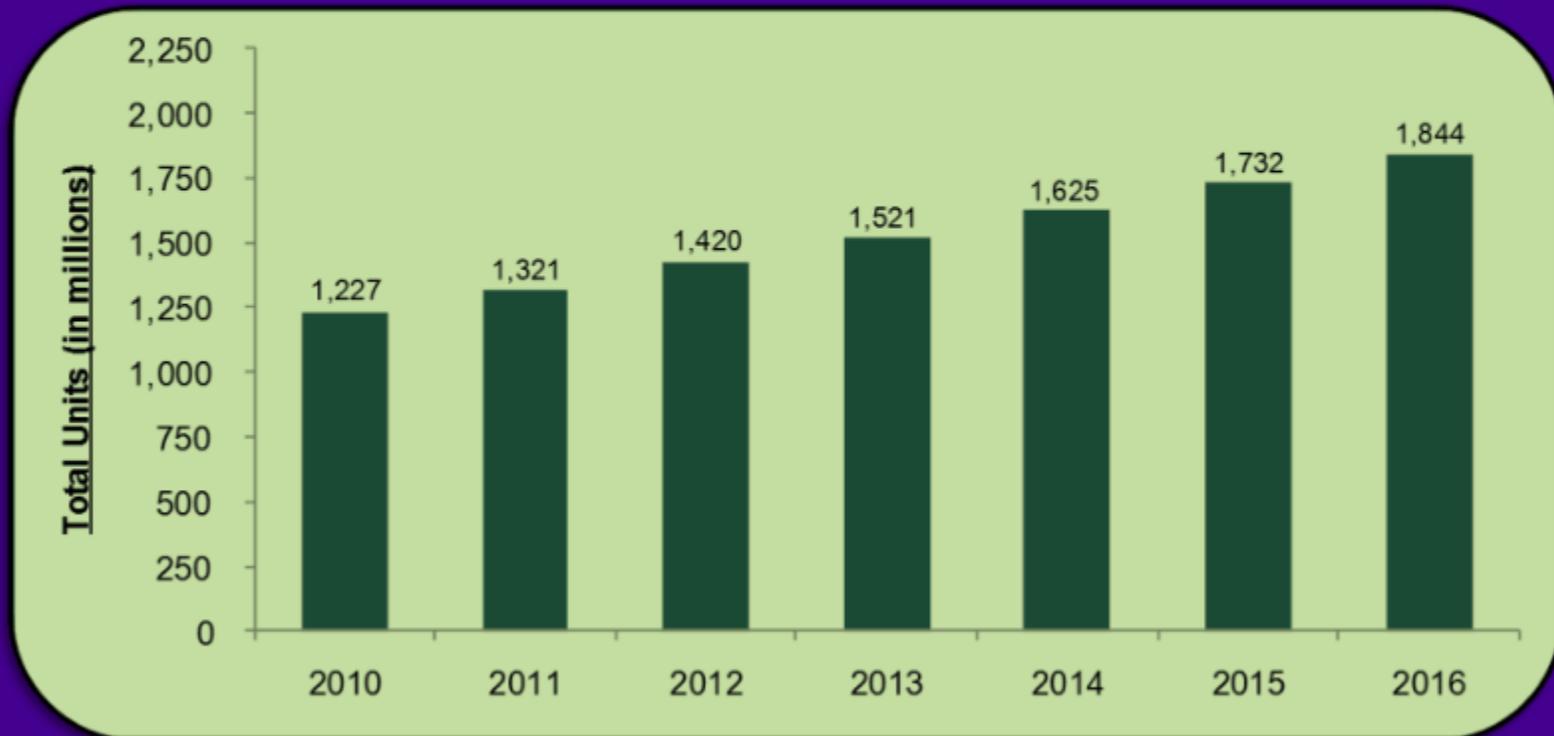
- **iData Research Study – U.S. Vascular Access Market**
  - Needleless IV Connectors will be the driving force within healthcare facilities
  - RyMed Technologies - One of the major forces in Needleless IV Connectors
  
- **Continued standardization trend**
  - PICCs, CVCs and PIVs – (1) Needleless IV Connector
  - Shorter sales cycle time from introduction
  
- **New emphasis from “C-Suite” administrators**
  - New attitude on CR-BSIs - “Soft Savings” → “Hard Savings”
  - Eliminate CR-BSIs – Reduce Costs and Risks
  
- **First major GPO – Amerinet (September 2011)**
  - 2,700+ member hospitals, IDNs
  
- **Paul Blackburn – New Senior Director, Marketing & Clinical Education**
  - Starting Date: February 13, 2012
  - Coming from Bard-Access Systems
  - New President-elect – Association for Vascular Access (AVA – Sept 2012)
  
- **Jim Hinkel – New Controller**
  - Starting Date: February 1, 2012
  
- **ICU Medical Litigation**
  - Most Clave and MicroClave U.S. patents expired December 18, 2011;
  - Improved clarity with new trial – May 7, 2012;
    - One patent, one independent claim; literal infringement only
    - RyMed’s new “work around” component design



# Needleless I.V. Connectors - U.S. Market Size

2011: 1.32 Billion Units x \$2.65 = \$3.5 Billion  
2016: 1.84 Billion Units x \$3.50 = \$6.5 Billion  
CAGR ('11 - 16') - +7.1%

## Total U.S. UNIT Market Projections – Needleless I.V. Connectors



Source: iData Research Inc., Vancouver, Canada U.S. Market for Vascular Access Devices and Accessories, February 2010

# Design Evolution

## Needleless IV Connector Devices

- **Recessed needles (late 1980s)**
  - No negative fluid displacement
- **Split Septum or Blunt Cannula devices with Negative Fluid Displacement (early 1990s)**
  - Negative fluid displacement upon disconnection
  - Dr. William Jarvis MD article “Increased CR-BSIs associated with the use of Negative and Positive Displacement Needleless IV Connectors”
- **Luer-Activated devices with Negative Displacement (mid 1990s)**
  - Negative fluid displacement upon disconnection
  - Dr. William Jarvis MD article “Increased CR-BSIs associated with the use of Negative and Positive Displacement Needleless IV Connectors”
- **Luer-Activated devices with Positive Fluid Displacement (late 1990s)**
  - Negative fluid displacement upon connection
  - VA Administration Warning Letter – December 2007
  - FDA Alert & Notification Letter – July 2010
  - Dr. William Jarvis MD article “Increased CR-BSIs associated with the use of Negative and Positive Displacement Needleless IV Connectors”
- **RyMed’s InVision-Plus® (Introduction May 2004)**
  - **Neutral Fluid Displacement (Patent Issued)**
  - **Zero Fluid Displacement (Patent Issued – January 2012)**
  - **Double Microbial Barrier Design (Patented technology)**



# RyMed's Competitor's

Clinical Infectious Diseases 2009: 49-1821-7

**“Health care-associated, central venous catheter-related bloodstream infections (HA-BSIs) are a major cause of morbidity and mortality”**

**“Needless connectors are an important component of the intravenous system”**

**“Needless connectors initially were introduced to reduce health care worker needle stick injuries, yet some of these needless connectors may increase HA-BSI risk”**

**“The Centers for Disease Control and Prevention (CDC) estimates that, in US intensive care unit (ICU) patients, > 80,000 HA-BSIs occur, costing up to \$29 billion annually.”**

**Conclusions: “We found strong evidence that Mechanical Valve Needleless Connectors (MV-NCs) were associated with increased HA-BSI rates, despite similar BSI surveillance, definitions, and prevention strategies”**

## Health Care-Associated Bloodstream Infections Associated with Negative- or Positive-Pressure or Displacement Mechanical Valve Needleless Connectors

William R. Jarvis,<sup>1</sup> Cathy Muehle,<sup>2</sup> Karl K. Holt,<sup>3</sup> Pamela J. Fogle,<sup>4</sup> Soti B. Karkhanavala,<sup>5</sup> George Herington,<sup>6</sup> Cassandra Salgado,<sup>7</sup> Eva T. Giannetta,<sup>8</sup> Carol Cameron,<sup>9</sup> and Robert J. Stuebel<sup>10</sup>

<sup>1</sup>State and Jarvis Associates, Hilton Head Island, and <sup>2</sup>Medical University of South Carolina, Charleston, South Carolina, <sup>3</sup>University of Virginia Medical Center, Charlottesville, <sup>4</sup>Wake Forest University School of Medicine, Winston-Salem, North Carolina, and <sup>5</sup>Texas University and Infectious Control Inc, Gold Coast, and <sup>6</sup>North Health Services, Brisbane, Queensland, and <sup>7</sup>The Alfred, Sydney Health, Melbourne, Victoria, Australia

**Background.** Health care-associated, central venous catheter-related bloodstream infections (HA-BSIs) are a major cause of morbidity and mortality. Needleless connectors (NCs) are an important component of the intravenous system. NCs initially were introduced to reduce health care worker needlestick injuries, yet some of these NCs may increase HA-BSI risk.

**Methods.** We compared HA-BSI rates on wards or intensive care units (ICUs) at 5 hospitals that had converted from split septum (SS) connectors or needles to mechanical valve needleless connectors (MV-NCs). The hospitals (16 ICUs, 1 entire hospital, and 1 oncology unit) 3 hospitals were located in the United States, and 2 were located in Australia) had conducted HA-BSI surveillance using Centers for Disease Control and Prevention definitions during use of both NCs. HA-BSI rates and prevention practices were compared during the pre-MV period, MV period, and post-MV period.

**Results.** The HA-BSI rate increased in all ICUs and wards when SS-NCs were replaced by MV-NCs. In the 16 ICUs, the HA-BSI rate increased significantly when SS-NCs or needles were replaced by MV-NCs (6.15 vs 9.49 BSIs per 1000 central venous catheter [CVC]-days; relative risk, 1.54; 95% confidence interval, 1.37–1.74;  $P < .001$ ). The 14 ICUs that switched back to SS-NCs had significant reductions in their BSI rates (9.49 vs 5.77 BSIs per 1000 CVC days; relative risk, 1.65; 95% confidence interval, 1.38–1.96;  $P < .001$ ). BSI infection prevention strategies were similar in the pre-MV and MV periods.

**Conclusions.** We found strong evidence that MV-NCs were associated with increased HA-BSI rates, despite similar BSI surveillance, definitions, and prevention strategies. Hospital personnel should monitor their HA-BSI rates and, if they are elevated, examine the role of newer technologies, such as MV-NCs.

Each year in the United States, >450 million intravenous (IV) catheters are used. IV catheters are the major risk factor for health care-associated catheter-related bloodstream infections (HA-BSIs). HA-BSIs result in substantial morbidity and mortality and cost \$14,000–

\$56,000 per episode [1–5]. The Centers for Disease Control and Prevention (CDC) estimates that, in US intensive care unit (ICU) patients, >80,000 HA-BSIs occur, costing up to \$29 billion annually [1, 4, 5]. In October 2008, the Center for Medicare and Medicaid Services (CMS) and major US health insurance carriers discontinued increased payment for HA-BSIs, so HA-BSI prevention is even more critical for facility financial viability.

Needles used with IV catheters are a source of health care worker (HCW) needlestick injuries (NSIs). In 1992, the US Occupational Safety and Health Administration recommended that health care facilities use safer IV devices to protect HCWs. The first generation of these devices introduced were needle devices with

Received 21 July 2008; accepted 28 May 2009; electronically published 15 November 2009.  
Presented in part: The Annual Meeting of the Association for Professionals in Infection Control and Epidemiology, May 2008.  
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Corresponding Author: William R. Jarvis, MD, State and Jarvis Associates, 1000 4th Street, Hilton Head Island, SC 29928 (wjarvis@sjarvis.com).  
Clinical Infectious Diseases 2009;49:1821–7  
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DOI: 10.1093/cid/cin581  
ISSN: 1093-9863

Mechanical Valve Connector-Associated BSI • CID 2009;49 (15 December) • 1821



# Federal Medicare Mandates

## October 2008

*Medicare stopped paying hospitals for treating the following conditions:*

- Catheter-associated urinary tract infections
- Pressure ulcers
- Vascular catheter-associated infections (CR-BSIs)
- Mediastinitis after coronary artery bypass
- Fractures, dislocations, or other injuries
- Objects left in during surgery
- Air embolisms
- Blood incompatibilities

## July 2010

**FDA notifies Infection Control Officer's and Manufacturers via the ALERT & NOTIFICATION LETTER on Positive Displacement I.V. Connectors**

**RyMed is believed to be the ONLY MANUFACTURER selling in the U.S. not cited in this FDA Alert**



# Product Technology



# Segmentation Strategy

## The Spectrum of Protection® Line of Products



**Designed for all I.V. and Blood Administration/Blood Sampling**



**Designed for Visual Identification of Non-Venous Catheters**



**Designed for Neonatal & Pediatric Patients**



**Designed for use with Pain Management Catheters**



**RyMed/Bacterin International Chlorhexidine+Silver Ion**  
***A new transformational technology***

# A new transformational technology

## **InVision-Plus® CS®**

RyMed Technologies new anti-bacterial InVision-Plus® CS® with Chlorhexidine + Silver Ions within its patented “Double Microbial Barrier” design does not come in contact with the patients blood. It is the first and only Needleless I.V. Connector System in the world that has received FDA or other regulatory body approval clearance with Cag and up to 7 days of usage.

Kills the 8 common microorganisms associated with CR-BSIs  
Up to a 7.0 Log (99.99999%) Reduction MRSA – 7 days

### RyMed’s Competition:

In a recent *in-vitro* study by Nelson Laboratories, Salt Lake City, UT on the “silver only” anti-bacterial I.V. connectors, it was discovered that competitive products shield the silver from the micro-organisms with a coating of blood fibrin. Each of the competitive connectors actually grew micro-organisms as reported in the study.

#### Baxter Healthcare V-Link®

- Silver only coated fluid pathway
- 96 hour effectiveness
- Negative Fluid Displacement

#### B. Braun UltraSite Ag®

- . Silver only impregnated fluid pathway components
- . 96 hour effectiveness
- . Positive Pressure Displacement (FDA Alert)

#### CareFusion MaxGuard®

- . Silver only impregnated fluid pathway components
- . 24 hour effectiveness
- . Positive Pressure Displacement (FDA Alert)



# Beta Site Trials

## InVision-Plus® CS® with Chlorhexidine + Silver Ions

2011

### 4 Beta Site Product Trials

#### Phoenix Children's (PICU), Phoenix, AZ

- . 90 day trial – All patients, all lines
- . Product trial completed – Reported “Zero” CR-BSIs

#### Los Angeles Medical Center (NICU) – Kaiser Permanente

- . 90 day trial - Neonatal patients
- . Product trial completed – Reported “Zero” CR-BSIs

#### Methodist Long-Term Care Hospital, Memphis, TN

- . 90 day trial – All patients, all lines
- . Product trial completed – Reported “Zero” CR-BSIs

#### Duke University Medical Center, Durham, NC

- . 120 day trial – All patients, all lines – Oncology Department
- . Product trial completed – Reported “Zero” CR-BSIs

ACTION PLAN: HIGH VOLUME SCALE-UP PROCESS IS BEING FINALIZED



# Intellectual Property

- **Nine (9) U.S. Patents Issued**  
(Five U.S. Patents Issued on InVision-Plus technology)  
(InVision-Plus current IP runs from 2023 through 2032)
  - *Double Microbial Barrier*
  - *3 Piece Valve System*
  - *Neutral Fluid Displacement*
  - *Zero Fluid Displacement*
- **Foreign Patents Issued**
  - *All major markets*
  - *Additional pending*
- **Numerous Trademarks Registered & Pending**



# Positive Patient Results

## MD Anderson Cancer Center (Monthly Average Occlusion Incidence)

	<u>ICU</u>	<u>Pediatric In-Patient</u>	<u>Pediatric Out-Patient</u>
Split-Septum:	15.3	8.3	4.7
InVision-Plus®:	12.3	4.5	0.8
Reduction %:	20%	46%	84%

**RyMed InVision-Plus®  
Reduced MD Anderson Cancer Center  
catheter infections by 10-fold within  
Intensive Care Unit**

## Sutter Hospital Roseville, CA 200 Bed Community Hospital

**Before InVision-Plus® Implementation**  
2005 – 767      11 CR-BSI

**COST of caring for 1 CR-BSI – \$25,000 - \$56,000**

### After InVision-Plus®

2006 – 1,558	0 CR-BSI
2007 – 2,278	0 CR-BSI
2008 – 2,313	0 CR-BSI
2009 > 2,400	0 CR-BSI
2010 > 2,400	0 CR-BSI
2011 > 2,400	0 CR-BSI

**Texas Children’s Hospital**  
**Neonatal Intensive Care Department**  
The largest NICU department in the U.S.  
A total of 288 NICU beds

**Before InVision-Plus® is implemented**  
Monthly CR-BSI Rate -28  
**After InVision-Plus® is implemented**  
Monthly CR-BSI Rate – 1 (96% Reduction)



# 122,000 Catheter Days of Aggregated Data Participants in the study reported 178 infections were prevented and approximately \$6.2 million in savings to the hospitals

## 2011 Association for Professional in Infection Control & Epidemiology Conference (APIC)

### Clinical Comparisons of Split Septum Positive and Negative Mechanical Valve Intravenous Connectors to an Intraluminal Protection Connector on Infection Rates

Denise Macklin, BSN, RN-C, Consultant, Marietta, GA    Cynthia Chernecky PhD, RN, AOCN, FAAN, Georgia Health Sciences University, Augusta, Georgia  
William R. Jarvis MD, Jason & Jarvis Associates, LLC, Hilton Head Island, SC    Jennifer Waller, PhD, Georgia Health Sciences University, Augusta, Georgia  
APIC 2011 Baltimore, MD

**Background**  
CR-BSI elimination is a national priority. IV Connectors are the gatekeeper of the intraluminal fluid pathway. It has been hypothesized that IV connector design features may affect CR-BSI. One large multi-center study found that both positive and negative IV connectors may impact CR-BSI. Four studies that involved smaller populations and took place over shorter periods of time than our own study have found an increase in CR-BSI rates when positive pressure connectors were introduced into the institution. The HATS model and the IGLT have voiced concerns about positive pressure mechanical valves. All these studies compare findings to findings published in the 1990s. The use of resistor access devices was much more limited in the 90's than now. In 2006 a new designed IV connector that incorporated 2 identified preferred features that may positively affect CR-BSI rates became available.

**Theoretical Model**  
The model used in this study is the newly developed Healthcare & Technology Synergy (HATS) model which reflects the synergy of human variables, process, practice and product. The basis of the model is that technology must be considered in relation to human, particularly computer-related, characteristics. For this study, the human component consisted of the investigators and the technology consisted of the different IV connector designs. The complete list of findings can be found in the main manuscript which appears in the Health Care Infection Control and Prevention journal. The HATS diagram from this study is available at [www.hatsmodel.com](http://www.hatsmodel.com).  
The HATS model is a conceptual framework that includes the following components:  
- Human: The individual healthcare provider or patient.  
- Process: The clinical practice or procedure.  
- Practice: The application of knowledge and skills.  
- Product: The technology or device used.  
The model illustrates how these components interact to influence patient outcomes.

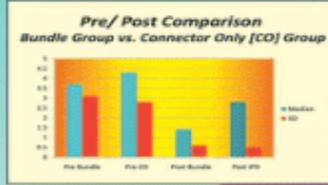
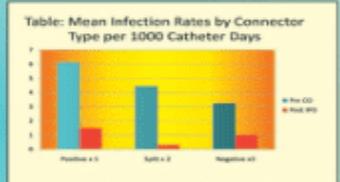
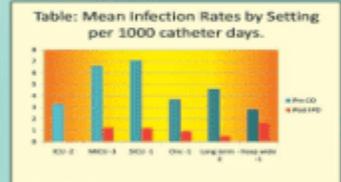
**Purpose**  
Using the Healthcare and Technology Synergy (HATS) Model the purpose of this multicenter study was comparison of bloodstream infection (BSI) rates associated with use of intravenous split septum, positive or negative pressure mechanical valves to a zero fluid displacement intraluminal protection device (IPD).

**Compare:**  
**Split Septum** (17,730 cath days - 2 states),  
**Positive** (10,067 cath days - 4 states),  
**Negative** (25,564 days - 3 states)  
for a total of 53,361 catheter days to an  
**IPD connector** (total of 68,752 catheter days) on infection rates per 1000 catheter days.

**Results**  
Paired t-tests used to examine differences.  
Alpha level of 0.05.

There were no statistically significant differences between total number of catheter days before and after adoption of the IPD.

Pre Connector Change Only	44,453	Post IPD Connector	41,707
Pre Bundle	8,508	Post Bundle	27,945
<b>Total</b>	<b>53,361 catheter days</b>	<b>Total</b>	<b>68,752 catheter days</b>



**Results**  
Statistically significant difference in rate of infection  
**p = 0.0008**

Group	Median	SD	Total Catheter Days
Pre Connector Only (CO)	4.3	2.8	
Post IPD Connector Only	2.8	0.5	
Pre Bundle	3.7	3.1	
Post Bundle	1.4	0.8	
Pre IPD Connector Adopted	4.2	2.44	
Post IPD Connector Adopted	0.8	0.52	

**Methods**

- Interview (telephone)
- 8 states (CA, CO, FL, NV, NY, PA, TN, TX), Range beds = 34-550
- 6 settings (ICU, MICU, SICU, long-term acute care, inpatient oncology and hospital wide)
- Total of 60 units (BANCU, 2HCU, 3SICU, 2ICAC, 1onc, 1 hosp wide)

Two Groups –  
1. One change - The IV connector  
2. Bundle approach: Practice Change + IV connector

**Conclusions**  
Catheter days were similar pre and post IPD adoption. There was a statistically significant higher BSI rate when negative (p = 0.0010) or positive (p = 0.0241) pressure mechanical valve MCs were used. Overall, a decrease in infections per 1000 catheter days was found after changing from any IV connector to the IPD connector (p = 0.0008).  
In this study clinically there were:  
Infections reported prior to changes: 228  
reported after changes: 56  
Change: 178  
\$35,000/ infection COST SAVINGS Over \$6.3 million

**Limitations**

- Not all marketed connectors were studied
- Different venous access device types were not separated out
- Catheter day totals do not reflect monthly fluctuations
- Data sets were not all matched.

**Nursing Implications**

- Supports HATS model
- Swabbing and Flushing protocols should be individualized based on product
- Achieving Zero CR-BSI rates can not depend entirely on nursing practice
- Further research needs to be done on products impact on nursing practice

**Disclosures**  
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4. CDC. National Nosocomial Infection Survey (NNIS) Report. Am J Infect Control. 2011;39:1-11.

# New Product Development Projects

## The Spectrum of Protection® Line of Products

### **InVision-Plus® HD™ with Chlorhexidine + Silver Ions for Hemodialysis Catheters**

Addressable U.S. Market Size – > 50 Million Units Annually

### **“Sentry CS® Project” Anti-Bacterial Protective End Caps for Needleless IV Connectors**

Addressable U.S. Market Size – > 3.0 Billion Units Annually

### **“Germinator Project” Cleaning/Disinfection System**

Designed to be used on Needleless I.V. Connectors/Catheter Lumens  
Addressable U.S. Market Size – > 3.0 Billion Units Annually

### **Anti-Bacterial Dead End Caps for IV Administration Line**

Designed to be used on I.V. Administration Lines  
Addressable U.S. Market Size – > 1.0 Billion Units Annually

### **“Sentry CS Project” Anti-Bacterial Protective End Caps for Hemodialysis Catheters**

### **IV Start Packs for Peripheral IV Catheter Placement**



# Distribution Venues

## Amerinet

- One of six major healthcare “super group” GPO’s
- Privately owned by Intermountain Healthcare and Administrative Resources, Inc.
- Headquartered in Saint Louis, formed in 1986 from smaller regional GPO’s
- Membership spans the full spectrum of healthcare provider facilities

### Membership Statistics - # of facilities

Acute Care Hospitals	2,714
Clinics	18,906
Long-Term Alternate Care Hospitals	5,722
Physicians (Hospital Based)	2,859
Surgery Centers	2,383
Emergency Medical Services	441
Other	18,347
<b>TOTALS:</b>	<b>51,372</b>

## Marquis Alternate Site Accounts

PharMerica National Account

Walgreens National Formulary

CVS Caremark Trials Began



# Manufacturing & Operations

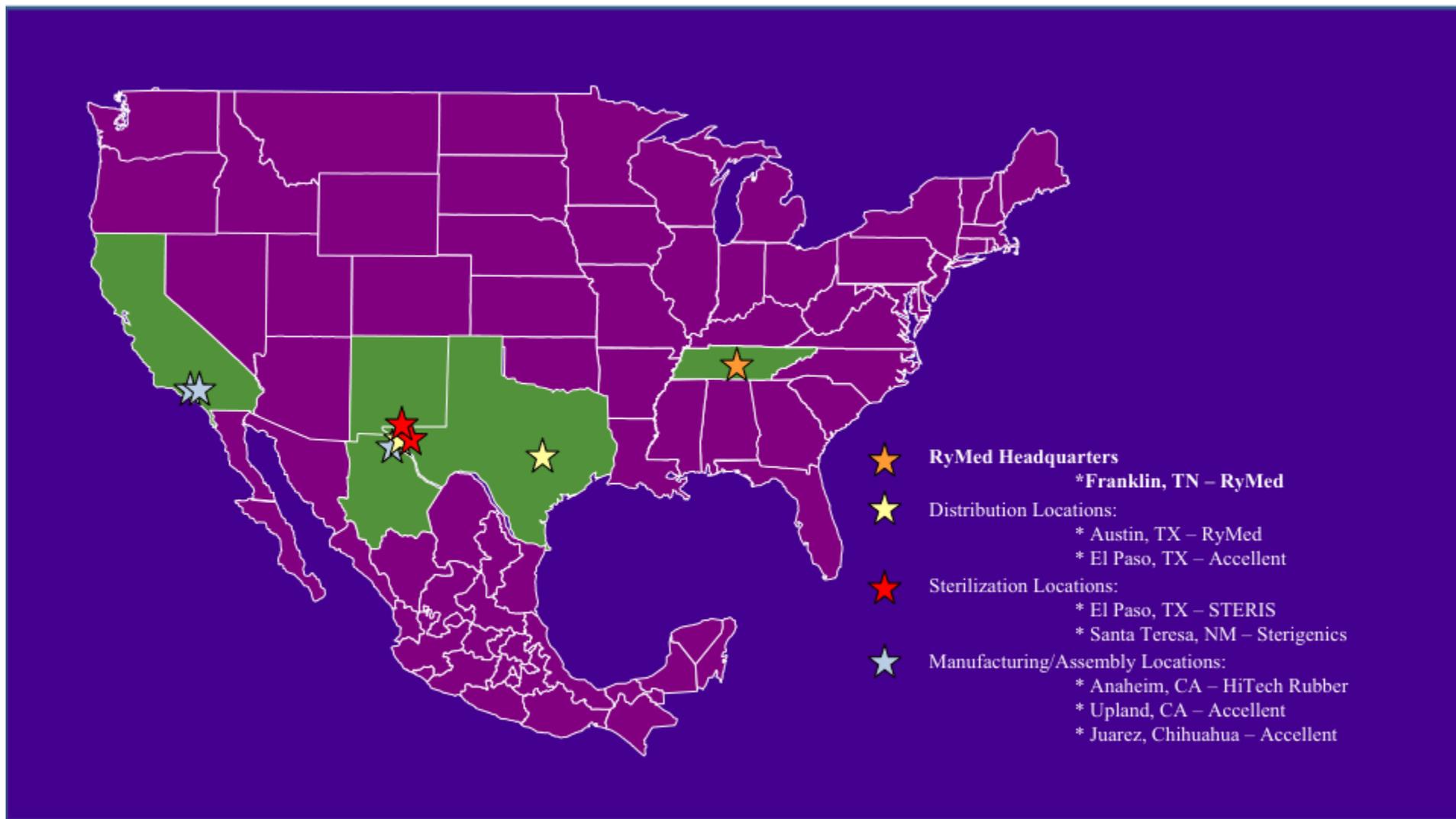


***Jim Kaiser***  
***Chief Operations Officer***

***Operations Office: Austin, TX***



# Corporate & Mfg./ Distribution Locations



# Manufacturing and Operations

## RyMed Agreements:

### Accellent

- Supply and Manufacturing of all products
- Distribution of Finished Goods
- Multi -Year Agreements
- Cancellation with 180 days notice without cause
- Benefits:
  - 60 day payment terms
  - Reduced infrastructure
    - Materials Planning
    - Vendor Audits
    - Warehousing Space and Operations
    - Payables (virtually one vendor)
  - Inventory Reduction Cost Savings
    - Inventory Valuation 12-31-2010: \$900,113
    - Inventory Valuation 12-31-2011: \$593,483

### Bacterin International

- Treatment of InVision-Plus® Septum component with Chlorhexidine + Silver Ions
- Worldwide, Exclusive Rights for Needle-Free IV Connectors
- Multi -Year with Automatic Renewal



# Current Manufacturing Capacity

## RyMed owns a total of 4 assembly machines

- Each Semi-automated module consists of
  - Two assembly machines ▶ Cost: < \$ 200,000
  - One set of production molds ▶ Cost: < \$ 700,000
- Current annual capacity: 30 million units
  - N.A.S.P. - \$ 1.58 each (2011)
  - Total Sales from current capacity: \$ 47.4 million
- Current overall Gross Margin is 53%
  - Gross Margin can be improved through:
    - Larger cavitation molds
    - Semi or full automation
  - 2012 Target Gross Profit: 60% - 65% with semi-automation
    - > 70% with full automation



# Leadership – Financials

## Growth Strategy



# Management Team

## **Dana Wm. Ryan, President & CEO (Founded 1994)**

Over 39 years of high volume, disposable medical device experience in sales, management, product marketing, development. Holds over 35 patents to date worldwide. 3M – sales engineer. Arbrook/Surkigos (J&J) – Head of New Products Department. Deseret Company (Warner-Lambert) – Director of Marketing. Ryan Medical – Founder/CEO – 14 patents in safety medical products in the field of blood collection and intravenous therapy. Small Business of the Year Award, Nashville, TN 1990, Company was sold in 1992. Symbiosis Corporation – Design, develop and manage. Symbiosis was sold to American Home Products in 1994. Major in mathematics (Arkansas State University). 1968-70 played professional baseball for the Chicago White Sox organization.

## **James M. Kaiser, Chief Operations Officer and Financial Director (1997)**

Over 40 years of high volume, disposable medical device manufacturing. Cutter Laboratories – manufacturing, sterilization, and materials management. Deseret Company – Production Superintendent (1,200 employees). Healthcare Group – Vice President of Operations. Ryan Medical – EVP Manufacturing. Isomedix, inc. – General Manager and later Group VP at HDQ. MBA (Southland University).

## **Tony Ryherd, Director of Engineering & Manufacturing (2007)**

Over 24 years of industrial manufacturing experience ranging from aerospace engineering to medical device development and expert in Operation Management Systems. Boeing Aerospace – Lead on China technology transfer. Accellent Endoscopy – head of engineering development. BS in Manufacturing Engineering (Bradley University).

## **Brandon D. Ryan, National Sales Director (2006)**

Over 12 years leadership experience in medical sales. Began as ABC news anchor, then CBS nightly news anchor/reporter hosting political roundtable “Behind the Headlines”. Bristol-Myers Squibb as Territory Manager. TAP Pharmaceuticals – Senior Specialty Sales Representative (top performer). BA in Broadcast Journalism (University of Mississippi).



# Management Team

## **D. Scott Chase, Director of Marketing (2006)**

Over 12 years of composite O.R.-based device sales experience. Techmedica/Sulzer Medica, Inc. (Camarillo, CA), TMJ Implants, Inc. (Golden, CO), and W. Lorenz Surgical/Biomet, Inc. (Jacksonville, FL), focusing primarily on the sale of titanium and resorbable craniofacial reconstructive implants, biomaterials and instruments to the neuro, plastic and reconstructive, ENT, oral/maxillofacial surgical specialties. BA in Mathematics (Vanderbilt University).

## **Anna McCutchen, Director of Quality Control & Regulatory Affairs (2005)**

7 years experience in quality assurance management of government regulated products. Expertise in quality systems, procedures, documentation and regulations. Triad Foods Group – Quality Assurance Manager. Cargill – Quality Assurance Manager plus plant level auditing of 7 facilities. BA in Food Science and Technologies (Texas [REDACTED]).

## **David Rogers, Director of Logistics & Operations Support (2006)**

Over 35 years leadership experience in strategic planning, human resources and budgetary controls. In 1967, began career as second military lieutenant rising to Chief of Staff of the Alaskan Air Command and three times as a Director of Personnel at a Major Air Command. Responsible for 3500 person staff with \$1.1 billion budget. Numerous military awards and distinctions. Masters Degrees - University of Arkansas 1974 (Management) and University of Oklahoma 1979 (Public Administration).

## **Paul L. Blackburn, RN, MNA, Senior Director, Clinical Education** (Starting date: February 13<sup>th</sup>)

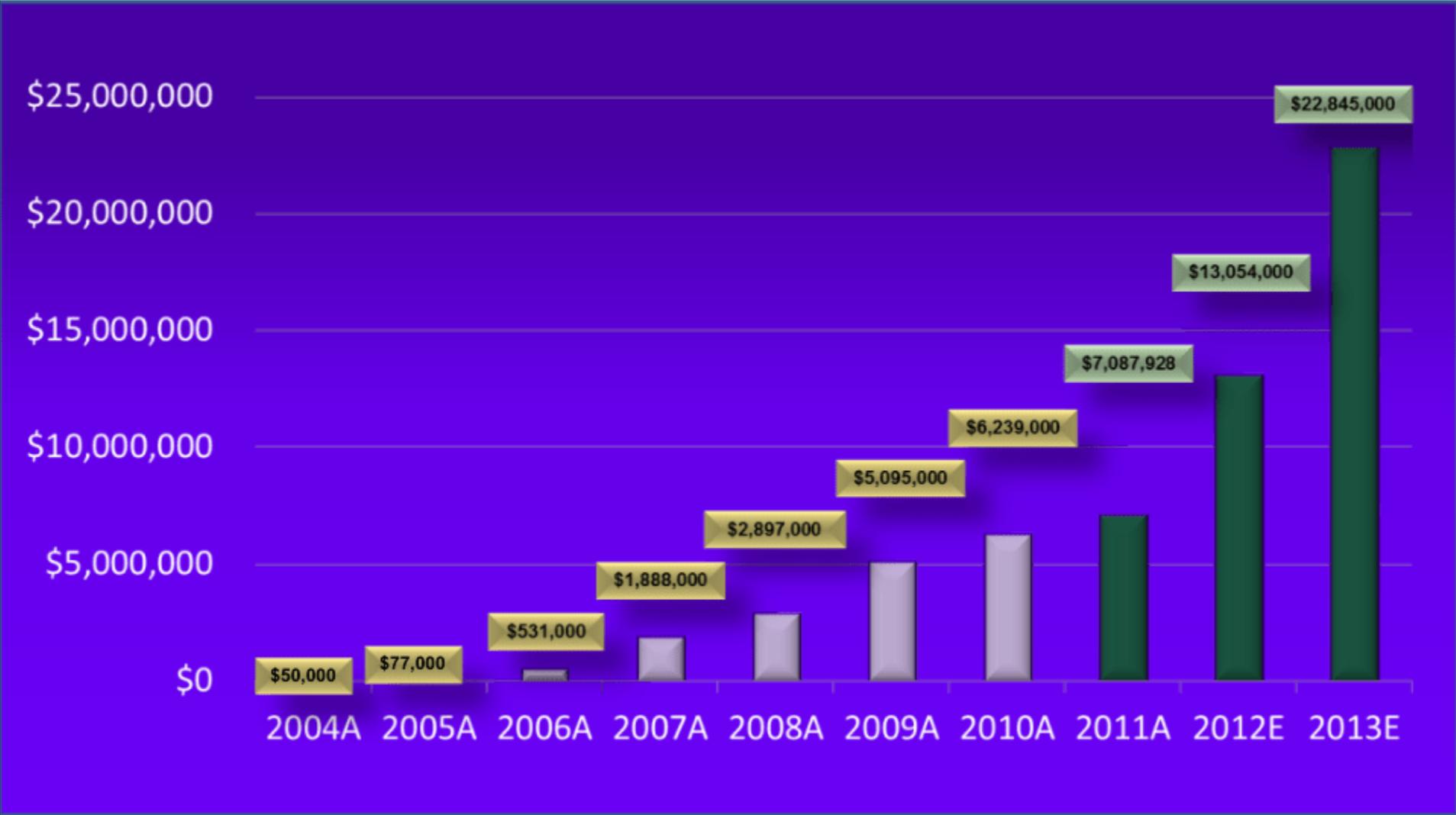
Over 20 years managerial and clinical education teaching experience. CR-Bard, Bard-Access Systems, Salt Lake City, UT, Director of Clinical Education. Managed over 150 clinical nurses and team developed all the clinical education programs for Bard-Access PICC catheter product lines. New President-elect of the Association for Vascular Access (AVA).

## **Jim Hinkel, Controller** (Starting date: February 1st)

Over 30 years of experience in operational accounting, financial analysis, audit responsibility, budgeting, and accounting control systems. His experience spans both large and small companies, including a start up company. Jim has a BBA in Accounting and received his CPA from the State of Illinois (non active).



# Revenue Growth Projection



# Summary Financial Statements

## Summary Income Statement 2011

Revenue	<b>\$ 7,081,019</b>
Cost of Goods Sold	<u>3,337,755</u>
Gross Profit	<b>3,721,767</b>
SG&A	<u>6,467,986</u>
Operating Profit/(Loss)	<b>(2,746,219)</b>
Other	<u>(47,895)</u>
Pre-Tax Profit/(Loss)	<b>(2,794,114)</b>
Taxes	<u>-</u>
Net Profit/(Loss)	<b><u>\$(2,794,114)</u></b>

## Condensed Balance Sheet Dec. 31 2011

<b>ASSETS</b>	
Cash	<b>\$ 68,500</b>
Accounts Receivable	<b>607,756</b>
Other Current Assets	<b>831,998</b>
Fixed Assets	<b>814,882</b>
Other Assets	<u>94,439</u>
<b>TOTAL</b>	<b><u>\$2,417,577</u></b>
<b>LIABILITIES</b>	
Current	<b>\$2,021,945</b>
Long Term	<u>4,302,360*</u>
Total	<b>6,324,305</b>
<b>EQUITY</b>	<b><u>(\$3,906,729)</u></b>
<b>TOTAL</b>	<b><u>\$2,417,577</u></b>



# 2011 Milestones

## Accomplishments

### January

- Began Beta Site Trials with InVision-Plus® CS™ with Chlorhexidine+Silver Ion Engineering

### February - March

- 11th National Conference on Cancer Nursing Research – Cynthia Chernecky, PhD
  - InVision-Plus® reduced infections and occlusions - Silver treated connectors show ineffectiveness in presence of blood
- Journal of Advanced Nursing – Comparative evaluation of five needleless I.V. connectors; Chernecky & Waller

### April - May

- SHEA Conference 2011 – Dallas, TX – Chernecky, Jarvis, Macklin;
  - Silver treated needleless connectors show ineffectiveness in presence of blood (abstract poster)
- 8-states; 122,000 catheter-days; comparative study - InVision-Plus® - Up to 92% reduction in CR-BSIs May
- Naval Hospital, Jacksonville, FL - InVision-Plus product trial
- VA Medical Center, San Antonio, TX – Reported “zero” CRBSIs in product trials
- Spaulding Hospital, Cambridge, MA (Partners) – InVision-Plus product trial\*

### June

- APIC Conference, Baltimore, MD
  - Clinical Poster Presentation – 122,000 Catheter Day Study
  - Clinical Poster Presentation – Texas Children’s Hospital NICU, Houston, TX
- AVA Conference – Accepted Clinical Poster Presentation – Methodist Extended Care Hospital
- CANS Conference, Washington, DC – Accepted Two Poster Presentations, Dr. Cynthia Chernecky PhD



# 2011 Milestones

## Accomplishments

### July

- VA Hospital, Jackson, MS - Conversion to InVision-Plus - All Lines
- Mayo Clinic, Jacksonville, FL – Straight conversion to InVision-Plus
- VA Hospital, Atlanta, GA - Began InVision-Plus product trial
- Duke University, Oncology Dept., Durham, NC – Began CS product trial (Oncology)
- Sutter Medical Center, Roseville, CA reported zero CR-BSIs for 5 ½ years with InVision-Plus

### August

- VA Medical Center, San Antonio, TX – Reported “zero” CRBSIs in product trials

### September

- APIC Conference, Baltimore, MD
  - . Clinical Poster Presentation – 122,000 Catheter Day Study
  - . Clinical Poster Presentation – Texas Children’s Hospital NICU, Houston, TX
- Danbury Hospital, Danbury, MA conversion to InVision-Plus

### October

- AVA Conference – Clinical Poster Presentation – Methodist Extended Care Hospital
- CANS Conference, Washington, DC – Two Poster Presentations, Dr. Cynthia Chernecky PhD
- Duke University, Oncology Dept., Durham, NC – Completed CS product trial – Zero CR-BSIs
- Spaulding Hospital, Cambridge, MA (Partners) – InVision-Plus successful product trial completed

### November-December

- Received supply agreement from Mayo Clinics
- Received supply agreement from Partners Alliance in Boston, MA
- U.S. Army purchasing InVision-Plus product line



# Strategic Goals

## I Quarter, 2012 goals

- **Complete \$10.0mm Growth Capital Financing**
- ✓ Engage new accounting firm and new audit firm
- ✓ Hire new Controller and Senior Director, Marketing & Clinical Education
- **Expand direct sales force and clinical team**
- ✓ Continue ISO Certification documentation to move international by early Q3 2012
- ✓ Begin semi-automation modification assembly machine project on to improve margins
- **Explore supply/distribution agreements and/or joint ventures**
- ✓ Continue developing Amerinet relationships across the U.S
- **Continue Balance Sheet improvement**
- ✓ Begin new Product Development programs to expand product lines



# Strategic Goals

## 12 month goals

- Expand board to five members
- Introduce product lines into targeted international markets
- Expand manufacturing capabilities and improve margins
- Execute worldwide sales, marketing & distribution agreements with major IV players
- Continue to expand GPO contracts in U.S.
- Further New Product Development programs to expand product lines
- Additional participation at industry conventions and analyst presentations
- Establish clinical advisory committee
- Successfully defend ourselves against ICU Medical litigation cases during 2012



# Potential Risks

- Ability to secure growth capital financings as needed
- Ability to keep and attract new sales and support team talent
- Ability to secure additional GPO contracts
- Continue to penetrate Needleless IV Connector markets
- Continue to successfully defend against ICU Medical current litigation cases
- Entry of new competition and technologies

# Strategic Growth Capital Finance Plan

Growth Capital Financing: \$ 10.0 Million

Use of Proceeds: Expansion of direct sales force and support personnel  
Cost of goods reduction program  
Expansion of manufacturing capacities  
Expand into targeted international markets,  
Increase industry and public market visibility

Breakdown:

Infrastructure	\$ 1.75
InVision-Plus® CS™ Expansion	\$ 0.50
Payoff targeted notes	\$ 2.00
Laboratory In-Vitro Testing	\$ 0.10
Assembly Machine Modification	\$ 0.25
Capital Equipment	\$ 0.50
ISO Certification/Mark	\$ 0.06
Patients/Patient Maintenance	\$ 0.05
Product Development	\$ 0.70
Litigation Reserve	\$ 0.80
Working Capital	\$ 3.29

Total Use of Funds \$10.00 Million



# Summary

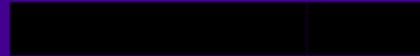
- Strong opportunities for high revenue growth:
  - 2012 introduction of new *transformation* InVision-Plus® CS® technology
  - New product developments into additional catheter care & maintenance product lines
  - Increased standardization by acute care hospitals, long-term care facilities and home infusion companies, to include PICCs, CVCs, Stopcocks, and PIVs
  - Strategic joint venture relationships and sales, marketing & distribution partners
  - Geographic expansion into targeted international markets
- Business model is capable of generating high margins (> 65%) and recurring revenue
- High barriers to entry (intellectual property, regulatory, product safety & efficacy features, and product development expenses) with limited competition and first to market advantage
- Strong executive, clinical, sales, marketing and manufacturing management team
- Continued focus of the FDA on RyMed's competitors products as they relate to increase in CR-BSIs (catheter-related bloodstream infections)



# Thank You for Your Time and Consideration

## RyMed Contact:

Dana Wm. Ryan, President & CEO



# Reference Slides Only



# FDA Alert & Notification Letter

The screenshot shows the FDA website interface. At the top, it says "U.S. Department of Health & Human Services" and "www.fda.gov". Below that is the "FDA U.S. Food and Drug Administration" logo and a search bar. A navigation menu includes "Home", "Food", "Drugs", "Medical Devices", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", "Radiation-Emitting Products", and "Tobacco Products". The main content area is titled "Medical Devices" and contains a sub-menu on the left with options like "Medical Device Safety", "Alerts and Notices (Medical Devices)", "Information About Hepatitis", "Laser Misconnections", "Safety Communications", "Public Health Notifications (Medical Devices)", "Tips and Articles on Device Safety", and "Patient Alerts (Medical Devices)". The main article is titled "Positive Displacement Needleless Connectors and Bloodstream Infections: Initial Communication". It includes sections for "Date Issued", "Audience", "Medical Specialty", "Summary of Issue and Scope", "Device", "Recommendations to Healthcare Professionals", "Postmarket Surveillance Studies", "Reporting Problems to FDA", "Contact Information", and "Additional Information".

**Medical Device Safety**

**Alerts and Notices (Medical Devices)**

Information About Hepatitis

Laser Misconnections

Safety Communications

Public Health Notifications (Medical Devices)

Tips and Articles on Device Safety

Patient Alerts (Medical Devices)

## Positive Displacement Needleless Connectors and Bloodstream Infections: Initial Communication

**Date Issued:** August 11, 2010

**Audience:** Health Care Professionals

**Medical Specialty:** Infection Control

**Summary of Issue and Scope:**

Several peer-reviewed clinical studies report an increase in bloodstream infections following the introduction and use of positive displacement needleless connectors in healthcare facilities, as well as a reduction in infections after changing to another type of needleless connector. However, there is insufficient information to determine the magnitude of the risk of bloodstream infections with these devices as compared with other needleless connectors, or to determine whether the risk is associated with some or all positive displacement needleless connectors. FDA is ordering post-market surveillance to better understand the risk of bloodstream infections from use of positive displacement needleless connectors.

**Device:**

A positive displacement needleless connector is part of a needleless system used for intravascular access. These devices may also be referred to as "luer activated valves," "connectors," or "accesses," and may refer to "positive pressure" or "positive displacement" in their product descriptions.

**Recommendations to Healthcare Professionals:**

In 2008, two professional societies issued guidelines to minimize the risk of hospital acquired infections (<http://www.journals.uchicago.edu/toc/iche/2008/29/51>).<sup>1</sup> Those guidelines state, "Do not routinely use positive-pressure needleless connectors with mechanical valves before a thorough assessment of risks, benefits, and education regarding proper use." The FDA's initial evaluation supports this recommendation.

**Postmarket Surveillance Studies**

FDA is requiring companies that manufacture positive displacement needleless connectors to conduct postmarket surveillance studies. The studies will help clarify the infection risk associated with these devices and define more precisely their risks and benefits. Manufacturers will be required to collect data on bloodstream infections in patients who received their devices compared to patients who received other types of needleless connectors. More details can be found in FDA's letter to infection control professionals.

**Reporting Problems to FDA:**

Prompt reporting of adverse events can help FDA identify and better understand the risks associated with medical products. If you suspect problems with the use of positive displacement needleless connectors, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Healthcare personnel employed by facilities that are subject to FDA's device user facility reporting requirements should follow the reporting procedures established by their facilities.

Health care providers are also encouraged to notify their facility's infection control personnel if they suspect a positive displacement needleless connector contributed to a bloodstream infection.

**Contact Information:**

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at [DSMICA@FDA.HHS.GOV](mailto:DSMICA@FDA.HHS.GOV) or 800-638-2041.

**Additional Information:**

- FDA Website on Postmarket Surveillance Studies
- Letter to Infection Control Professionals

*This document reflects FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices. The nature, magnitude and possible public health impact of this situation are not yet clear.*

## July 2010

FDA notifies Infection Control Officer's and Manufacturers via the ALERT & NOTIFICATION LETTER on Positive Displacement I.V. Connectors

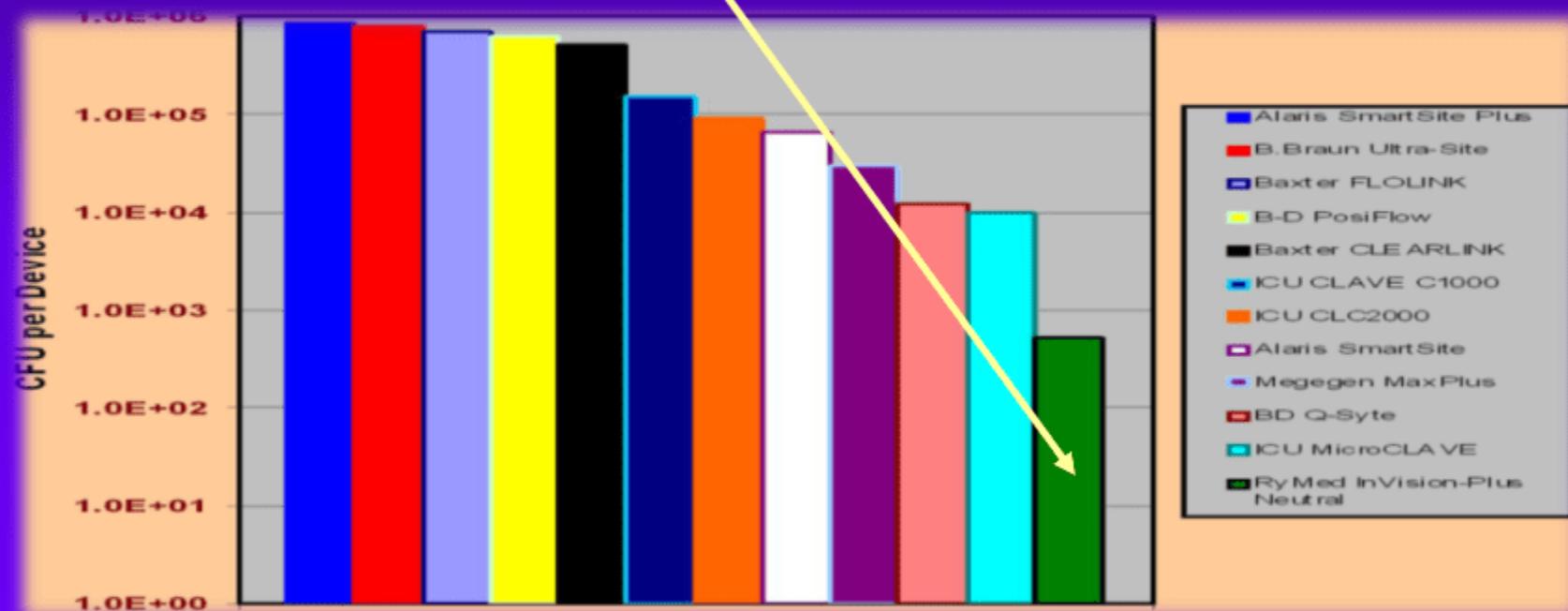
RyMed is the ONLY manufacturer not sited in this FDA Alert

# Negative Fluid Displacement

**\*\* Biofilm Colonization \*\***

RyMed's InVision-Plus® *in-vitro* test study results:

93.0% - 99.9 % reduction of biofilm colonization over other Competitive I.V. connectors tested



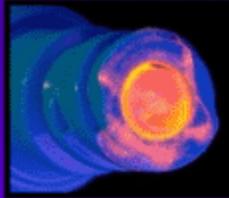
Bacterin International, Inc., Belgrade MT conducted the test study



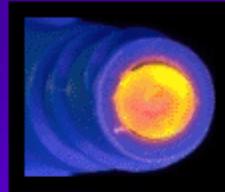
# Key Product Design Issues

## \* \* Septum Seal Integrity \* \*

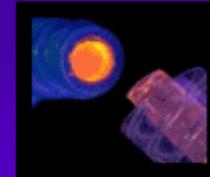
Large gaps, openings or certain septum surface designs compromise nursing swabbing and disinfection practice and contribute to downstream microbial ingress and biofilm colonization potential



Before Swabbing



After Aggressive Swabbing

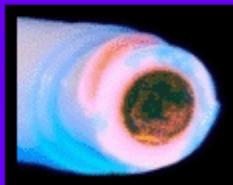


After Disconnect

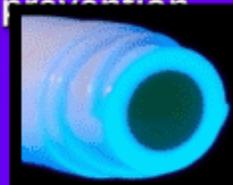
*Product shown is currently one of the market leaders*

## RyMed - InVision-Plus® with Neutral Advantage™

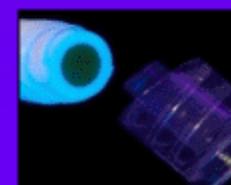
A fully compressed and tightly sealed septum surface design is important to fully support nursing swabbing and disinfection practice for effective downstream microbial ingress and biofilm colonization prevention



Before Swabbing



After 5 Second Swab



After Disconnect

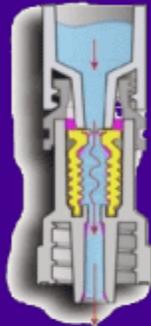


# Key Product Design Issues

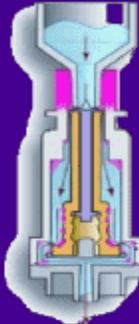
## \*\* Fluid Pathway \*\*

Most competitive I.V. connectors have large fluid dead space within the fluid pathway. Dead space entraps the patient's blood, contributing to biofilm colonization

CareFusion  
SmartSite®



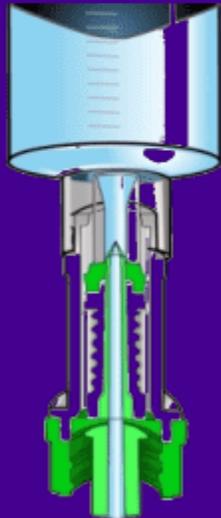
B. Braun  
UltraSite®



CareFusion®  
MaxClear™



Dead space (Pink) ~  
Complicated, ineffective  
flushing



## RyMed - InVision-Plus® with Neutral Advantage™

- Straight-through fluid pathway
- Zero dead space
- Zero fluid displacement
- Low priming volume (0.027mL)
- 99.94% effective blood clearing after 1 ml normal saline