



Mechanical Initial Specimen Diversion of Whole Blood Using Active Negative Pressure

**Greg Bullington, CEO & Co-Founder,
Magnolia Medical Technologies, Inc.**

ICD-10 Coordination and Maintenance Meeting
Presentation

Introducing the New: Steripath® Micro Blood Collection System

- 510(k) clearance for Steripath® Micro received on October 8, 2020
- Indications for use:

“The Steripath® Micro Blood Collection System is indicated for use as a blood collection system that diverts and sequesters the initial specimen prior to collection of a subsequent test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion.”

Syringe Configuration



Direct-to-Media Configuration



Coding Issues Overview

- There are currently no ICD-10-PCS codes that uniquely describe use of the Steripath® Micro Blood Collection System
- A unique ICD-10-PCS Section X code is needed:
 - To identify Steripath® Micro for reporting purposes
 - To identify and track the use of Steripath® Micro for related outcomes data
 - If NTAP is granted, for claims processing for qualifying cases of Steripath® Micro
- Information on the use of the Steripath® Micro Blood Collection System could be found in the computerized provider order entry (CPOE) or entered into the patient's medical record via scanning a unique, serialized barcode included on the device.

Syringe Configuration

Designed for the most precious patients

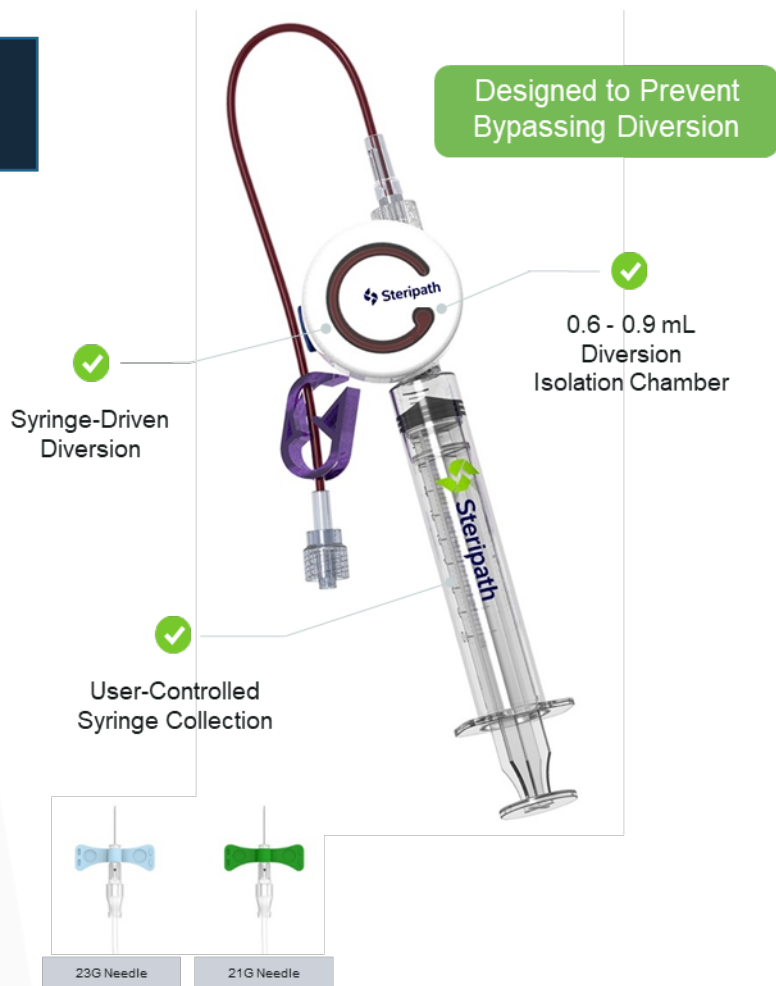
- Easy-to-use
- Syringe-driven diversion
- Precise user-controlled collection
- Optimized for patients with limited blood volume and difficult venous access – ‘hard sticks’

Configurations

- 7" Luer extension (for use with peripheral IV starts)
- 23G butterfly safety needle
- 21G butterfly safety needle

Syringe Volumes:

- 5 mL
- 10 mL
- 20 mL



Designed for the most precious patients (2)

- Fast and easy-to-use
- Automatic active diversion
- Push-button collection

Configurations

- 7" Luer extension with peripheral IV starts)
- 23G butterfly safety needle
- 21G butterfly safety needle

(for use

Blood Culture Bottle Compatibility:

- BD
- BioMerieux
- Thermo Scientific

Designed to Prevent
Bypassing Diversion



Inaccurate Sepsis Testing is a Significant Problem

Multibillion-dollar problem that impacts over 1 million patients annually in the US

- Sepsis is a leading cause of death, readmissions and costs within the US acute care hospital system¹
- Standard of care blood test for sepsis (blood culture) is frequently wrong
 - 20% to >50% of positive blood culture results are false positive¹
 - “Blood culture contamination is a clinically significant problem that results in patient harm and excess cost.”²
- Extensive clinical evidence demonstrates that false positive blood culture results are preventable with Steripath Initial Specimen Diversion Device (ISDD)^{2,3}
 - Significant impact on antibiotic use, patient length of stay, HAI/HAC risk, 30-day readmission and morbidity/mortality
- Estimated 1.4M false positive blood cultures annually in US
 - Cost of >\$4,300 per patient-instance and average incremental avoidable length of stay of 2.2 days^{4,5}
 - Burden of >\$6B in completely avoidable costs and unnecessary consumption of ~3M in-patient bed days to US acute care hospital system annually

1 – Snyder, S., et al. Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis. Clinical Biochemistry (2012)

2 – Rupp, M., et al. Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. Clinical Infectious Diseases (July 2017)

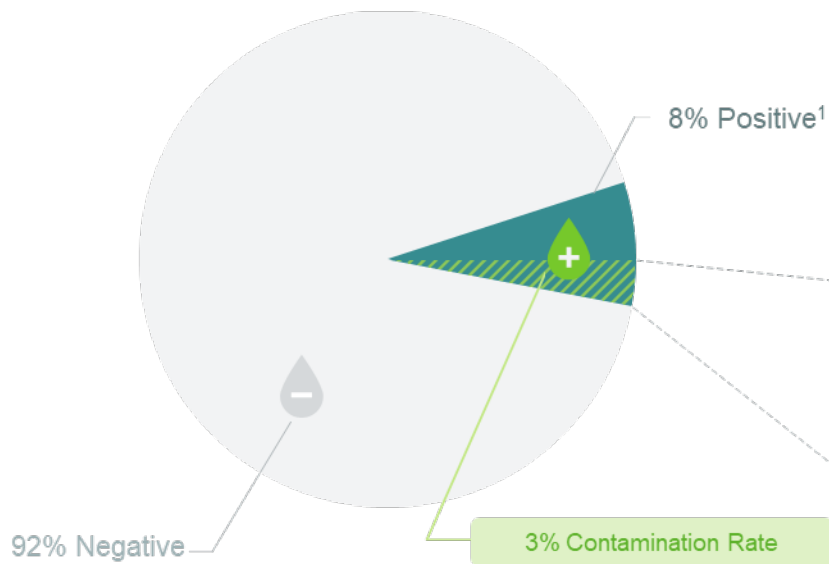
3 – See slide 21 for detailed overview of Steripath clinical performance data

4 – Skoglund, E., et al. Estimated Clinical and Economic Impact Through Use of a Novel Blood Collection Device (Steripath) to Reduce Blood Culture Contamination in the Emergency Department: A Cost-Benefit Analysis. J Clin Microbiol (January 2019)

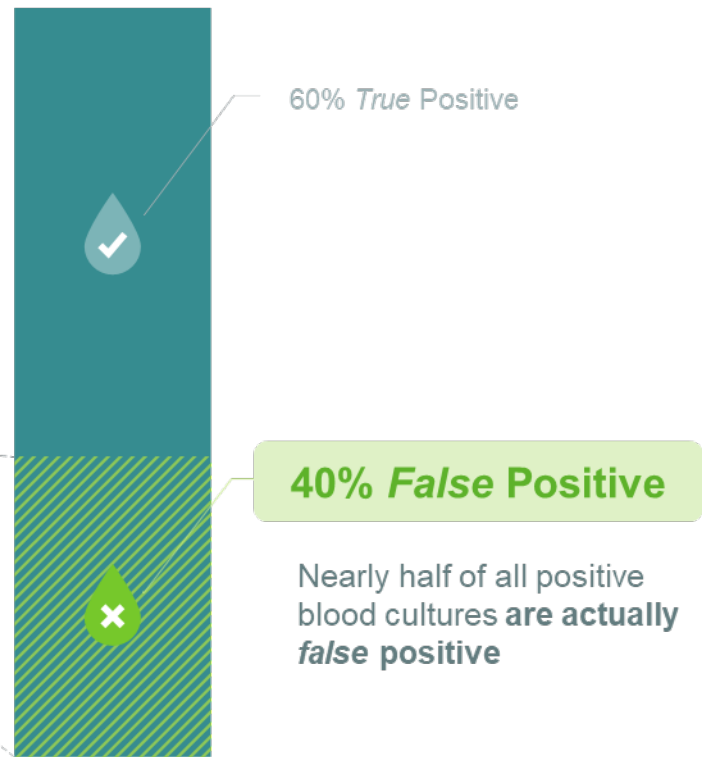
5 – Geisler, B., et al. Impact of Hospital-Based Interventions [Phlebotomy & Steripath® ISDD®] Targeting False-Positive Blood Cultures on Economic and Clinical Outcomes. Journal of Hospital Infection (March 2019)

Test Results for Sepsis are Frequently Wrong

ALL BLOOD CULTURES



POSITIVE BLOOD CULTURES



40% False Positive

Nearly half of all positive blood cultures are actually false positive

False positives are a *preventable error* and can lead to a misdiagnosis of sepsis

Current National 'Standard'

for blood culture contamination



**Current benchmark
for blood culture
contamination
rates in the U.S.¹**

BUT IS THIS 'STANDARD' GOOD FOR PATIENTS?

¹Clinical and Laboratory Standards Institute (CLSI). Principles and procedures for blood cultures: approved guideline, Vol. 46, No. 31. Wayne (PA): Clinical and Laboratory Standards Institute; 2007. CLSI document M47-A.

Proposed *New* National Standard

for blood culture contamination

Standard of Care Initiative



≤ 1%

**benchmark for
blood culture
contamination rates in
the U.S.**

*achieved by using Mechanical Initial
Specimen Diversion Device*

THE RIGHT 'STANDARD' FOR PATIENTS



Gary Doern, PhD
Professor Emeritus, Dept of Pathology
University of Iowa
Former Editor-in-Chief, J Clin Micro



Dan Sexton, MD
Professor, Infectious Diseases
Duke University
Chair, Duke IC and AMS Outreach Network



Clinical Microbiology
Reviews

“Comprehensive Update on the Problem of
Blood Culture Contamination and a Discussion
of Methods for Addressing the Problem”



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Dan Diekema, MD
Professor, Director Infectious Diseases
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Mark Rupp, MD
Professor, Chief Infectious Diseases
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“

It is the opinion of the authors that consideration should be given to the establishment of a **new universal threshold value of $\leq 1.0\%$.**”

“

When contamination rates **rise above 1%, objective, step-wise quality improvement programs designed to improve patient care and reduce unnecessary costs should be implemented.**”

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Clinical Microbiology
Reviews®

PRACTICAL GUIDANCE FOR
CLINICAL MICROBIOLOGY



A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem

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SUMMARY In this review, we present a comprehensive discussion of matters related to the problem of blood culture contamination. Issues addressed include the scope and magnitude of the problem, the bacteria most often recognized as contaminants, the impact of blood culture contamination on clinical microbiology laboratory function, the economic and clinical ramifications of contamination, and, perhaps most importantly, a systematic discussion of solutions to the problem. We conclude by providing a series of unanswered questions that pertain to this important issue.

KEYWORDS blood culture contamination

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Initial Specimen Diversion Device (Steripath Gen1 & Gen2): Peer-Reviewed Published Studies and Clinical Study Presentations & Submissions

#	Institution	Publication or Conference Presentation	Date	Duration	Baseline or Control Rate	Steripath® Rate	BCC Reduction	Ann. Savings
1	Stanford Health Care	IDSA - IDWeek	2020	4 months	3.1%	0.0%	100%	NR
2	Univ. of Nebraska Medical Center	Clinical Infectious Diseases 	2017	12 months	1.8%	0.2%	88%	\$1,800,000
3	Kern Medical Center	IDSA - IDWeek	2020	19 months	3.4%	0.4%	88%	NR
4	Lee Health System (4 sites)	Journal of Emergency Nursing 	2018	7 months	3.5%	0.6%	83%	\$1,100,000
5	Brooke Army Medical Center	DOD Healthcare Quality Safety Award	2016	5 months	7.7%	0.6%	92%	\$564,000
6	Medical Univ. of South Carolina	Institute for Healthcare Improvement (IHI)	2016	8 months	4.2%	0.6%	86%	NR
7	Rush University Medical Center	IDSA - IDWeek	2017	3 months	4.3%	0.6%	86%	NR
8	Inova Fairfax Hospital	Emergency Nurses Association (ENA) 	2019	12 months	4.4%	0.8%	82%	\$932,000
9	SCL St. Mary's Medical Center	American Organization for Nursing Leadership (AONL)	2020	6 months	3.3%	0.8%	76%	NR
10	Beebe Healthcare	American Society for Microbiology (ASM)	2018	4 months	3.0%	0.8%	75%	NR
11	Medical Univ. of South Carolina	Institute for Healthcare Improvement (IHI)	2017	20 months	4.6%	0.9%	80%	\$447,000
12	Ascension Via Christi (3 sites)	Institute for Healthcare Improvement (IHI)	2020	3 months	5.8%	0.9%	85%	NR
13	VA Houston	Emergency Nurses Association (ENA)	2018	7 months	5.5%	0.9%	83%	NR
14	Shaare Zedek Medical Center	American Journal of Infection Control 	2019	6 months	5.2%	1.0%	81%	NR
15	Brooke Army Medical Center	Society for Healthcare Epidemiology of America (SHEA)	2017	14 months	37% reduction in vancomycin DOT (P=0.007)			
16	University of Houston	Journal of Clinical Microbiology 	2019	Steripath ISDD can save the hospital 2.0 bed days and \$4,739 per false positive blood culture event				
17	Mass General/ Harvard/ WingTech	Journal of Hospital Infection 	2019	Steripath ISDD can save the hospital 2.4 bed days, \$4,817 per false positive blood culture event and \$1.9M annually & prevent 34 HACs including 3 C.diff				



National Peer-Reviewed Publication



Best Evidence-Based Project

Journal of Hospital Infection
2019 (March)

Clinical Summary

- ✓ Reduction in false positives up to **92%**^{1,2}
- ✓ 12-month sustained contamination rate as low as **0.2%** (P=0.001)¹
- ✓ Positive predictive value as high as **97%**¹
- ✓ Reduction in vancomycin DOT as much as **37%** (P=0.007)^{2,3}
- ✓ Reduction in false positive CLABSI as much as **100%**⁴
- ✓ Shorten length of stay by average of **2-2.4 days** (P=0.0001)^{5,7}
- ✓ Reduce HAIs / HACs by as much as **23%**⁶
- ✓ Decrease annual costs by an average of **\$1.9M**⁷

1. M. Rupp, et al; Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. *Clinical Infectious Diseases* (August 2017). 2. C. Lanteri, et al; Reduction of Blood Culture Contamination in the Emergency Department. Department of Defense Healthcare Quality and Safety Award (2016). 3. D. Chang, et al; Impact of Blood Culture Diversion Device and Molecular Pathogen Identification on Vancomycin Use. *Society of Healthcare Epidemiology of America (SHEA) Conference* (Spring 2017). 4. Tompkins, L., et al.: "The Impact and Prevention of False Positive CLABSIs." AHA Health Forum Webinar (Dec. 2019) 5. Skoglund, E., et al. Estimated Clinical and Economic Impact Through Use of a Novel Blood Collection Device (Steripath) to Reduce Blood Culture Contamination in the Emergency Department: A Cost-Benefit Analysis. *J Clin Microbiol* (January 2019). 6. Data on file. 7. B. Geisler, et al. "Impact of Hospital-Based Interventions [Phlebotomy & Steripath® ISDD®] Targeting False-Positive Blood Cultures on Economic and Clinical Outcomes." *Journal of Hospital Infection* (March 2019)

A close-up, slightly blurred photograph of a person wearing a white surgical cap and a white face mask. The person's eyes are visible above the mask. The image has a dark blue overlay. The text 'Thank you' is written in white on the left side.

Thank you