

Dear Members of the Value Analysis Committee,

My name is Dr. W. Frank Peacock. I am a Professor and Vice Chair of Research in Emergency Medicine at Baylor College of Medicine, as well as the Chief Medical Officer and a co-founder of AseptiScope. On behalf of our company, I am writing related to the recent Request for Proposal for The DiskCover System by your committee.

The DiskCover System is evidence-based and was developed in full alignment with the framework for assessing infection prevention products in healthcare published by the CDC's former Healthcare Infection Control Practices Advisory Committee (HICPAC) in the *Annals of Internal Medicine*.¹ In 2019, the CDC and HICPAC had recognized that infection prevention innovations in healthcare are essential to improving patient safety, and also that there is need for fair assessment of these innovations where supporting evidence is often limited.

To address these concerns and under CDC direction, HICPAC developed a process to meaningfully assess such innovation for use when formulating product-specific recommendations for implementation into healthcare settings. This framework outlines 14 criteria for consideration, all of which our data and evidence is consistent with, including key factors such as FDA registration status, clinically relevant human outcomes, including *proxy outcomes*, open-label performance, superiority to established alternatives (standard of care), and integration into a bundled approach.

The DiskCover System is an exempt FDA Class I medical device, the same classification as a standard stethoscope, and controlled studies demonstrate proxy outcomes that directly support its intended use in healthcare settings. These include evidence of pathogen barrier efficacy against a wide range of pathogens, including resistant pathogens such as *Clostridioides difficile*, and full acoustic performance with sound files statistically identical to an uncovered professional stethoscope.^{2, 3, 4} These studies indicate that use of disk cover barriers completely blocks pathogens on the stethoscope diaphragm which are commonly found on stethoscopes despite cleaning efforts and contribute to healthcare-associated infections (HAIs) for patients.

In addition, open-label registration studies conducted across multiple healthcare facilities covering a wide range of healthcare settings including emergency departments, ICUs, oncology, primary care, and urgent care, demonstrates both generalizability and clinician acceptance across diverse healthcare settings. These real-world evaluations capture both clinician and patient perspectives. Using a 5-point Likert scale survey, clinicians who tried The DiskCover System consistently responded favorably for ease of use, workflow integration, and perceptions of improved hygiene compliance and patient safety.⁵

Immunocompromised patients, including those being treated for cancer or burns, rated the stethoscope being clean before it touches them as the highest possible rating (100 out of 100, critically important), and responded that between cleaning the stethoscope before auscultation or applying a disk cover, The DiskCover System would be easier for their clinician to comply with.⁶

The aforementioned evidence also elucidates The DiskCover System's performance when benchmarked against established stethoscope hygiene methods (between-patient disinfection and use of disposable stethoscopes). Observational studies demonstrate between-patient stethoscope disinfection in multiple





healthcare settings was below 10%, and even when cleaned, up to 90% of stethoscopes may remain contaminated.^{7,8,9} In addition, disposable stethoscopes are poor-quality tools, which significant evidence suggests not only offer no value but are a detriment to patient safety due to their poor auscultation quality and lack of data on breaking transmission. The acoustics comparison study which found disk covers to be *acoustically invisible* with complete diagnostic accuracy, also found that clinicians who used disposable stethoscopes were attributed with a 10.9% misdiagnosis rate.⁴ This can be a grave danger to patients if important heart sounds are missed.

Finally, the technology has successfully been incorporated into bundled infection prevention protocols. Notably, its inclusion in a CLABSI bundle alongside standardized CHG dressing at the VA Memphis was followed by a prompt reduction in CLABSI rates to zero, while maintaining an 85% decline in baseline CLABSI rates for the next three years.¹⁰ While it could appear that one of two components in the bundle was solely responsible for the reduction of HAI, no prior study has ever before demonstrated the strength of a sustained reduction to zero CLABSI occurrences for over a year. In this study, that result followed the implementation of stethoscope hygiene policy and procedure and integration of The DiskCover System to protect patients.

Clinician and patient safety was our primary goal in founding AseptiScope and producing The DiskCover System. HAIs continue to harm patients in the US despite stringent hand hygiene efforts, and mounting data in the field of healthcare agrees that the stethoscope diaphragm is a significant vector of contamination. We thank you for your consideration of the evidence we have worked diligently on to articulate and produce.

Sincerely,

W. Frank Peacock, MD, FACEP, FACC, FESC
Chief Medical Officer
AseptiScope
100 W 35th St, Suite F
National City, CA 91950
Phone: (216) 312-3292
Email: frankpeacock@gmail.com



References

1. Chopra V, Janssen L, Bryant K, Fauerbach L, Talbot TR 3rd, Babcock HM. A Process for Assessing Products for Infection Prevention in Health Care Settings: A Framework From the Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention. *Ann Intern Med.* 2020;172(1):30-34. doi:10.7326/M19-2172
2. Vasudevan R, Shin JH, Chopyk J, et al. Aseptic Barriers Allow a Clean Contact for Contaminated Stethoscope Diaphragms. *Mayo Clin Proc Innov Qual Outcomes.* 2020;4(1):21-30. Published 2020 Feb 5. doi:10.1016/j.mayocpiqo.2019.10.010
3. Peacock WF, Kalra S, Vasudevan RS, Torriani F. Aseptic Stethoscope Barriers Prevent *C difficile* Transmission In Vitro. *Mayo Clin Proc Innov Qual Outcomes.* 2021;5(1):103-108. Published 2021 Jan 13. doi:10.1016/j.mayocpiqo.2020.10.002
4. Kalra S, Garri RF, Shewale JB. Aseptic Disposable Stethoscope Barrier: Acoustically Invisible and Superior to Disposable Stethoscopes. *Mayo Clin Proc.* 2021;96(1):263-264. doi:10.1016/j.mayocp.2020.10.029
5. Peacock W, Kipper S, Neath S-X. Stethoscope hygiene, workflow, and patient safety: The crux of healthcare-associated infections. *Antimicrob Steward Health Epidemiol.* 2022;2(S1):s55-s56. doi:10.1017/ash.2022.162
6. Siegmund, L.A., Peacock IV, W.F., Bena, J., Morrison, S., (September 17, 2024) "Patients and Healthcare Professionals' Perceptions of Stethoscope Barriers" *Online J Issues Nurs.* 2024;29(3). doi:10.3912/OJIN.Vol29No03PPT29
7. Alali SA, Shrestha E, Kansakar AR, Parekh A, Dadkhah S, Peacock WF. Community hospital stethoscope cleaning practices and contamination rates. *Am J Infect Control.* 2020;48(11):1365-1369. doi:10.1016/j.ajic.2020.04.019
8. Boulée D, Kalra S, Haddock A, Johnson TD, Peacock WF. Contemporary stethoscope cleaning practices: What we haven't learned in 150 years. *Am J Infect Control.* 2019;47(3):238-242. doi:10.1016/j.ajic.2018.08.005
9. Knecht VR, McGinniss JE, Shankar HM, et al. Molecular analysis of bacterial contamination on stethoscopes in an intensive care unit. *Infect Control Hosp Epidemiol.* 2019;40(2):171-177. doi:10.1017/ice.2018.319
10. Peacock WF, Vollman K, Cadwell C, Kupchik N. Eliminating CLABSI: Is stethoscope hygiene the missing piece? *J Infectiology & Epidemiol.* 2025. doi:10.29245/2689-9981/2025/4.1182

