3M Tegaderm CHG I.V. Securement Dressing Receives FDA 510(k) Clearance for Expanded Indication to Reduce Catheter-Related Bloodstream Infection

Catheter-related bloodstream infections (CRBSI) are life-threatening for patients and costly for the medical professionals and facilities caring for them. 3M is pleased to announce that the U.S. Food and Drug Administration (FDA) has recognized the efficacy of 3M™ Tegaderm™ CHG Chlorhexidine Gluconate I.V. Securement Dressing in reducing CRBSI, expanding the product's 510(k) indication to include CRBSI reduction.

The expanded indication is supported by a randomized, multi-arm, controlled clinical trial of 1,879 subjects that found Tegaderm CHG I.V. Securement Dressing reduced CRBSI by 60 percent in patients with central and arterial lines (p=0.020).¹

"While we are making great strides in reducing CRBSI nationwide, these preventable infections are still responsible for significant morbidity, mortality and excess costs," stated Pat Parks, MD, PhD, medical director for 3M Critical and Chronic Care Solutions Division. "Successful CRBSI prevention practices rely on dedicated clinicians using proven technology, such as Tegaderm CHG I.V. Securement Dressing, in alignment with current best practice standards."

Tegaderm CHG I.V. Securement Dressing is the only transparent dressing indicated and proven to reduce CRBSI and vascular catheter colonization that aligns with evidence-based guidelines and practice standards. The dressing provides four essential elements to cover and protect patients' catheter sites and secure devices to skin.

Infection Reduction: Clinically proven to reduce CRBSI by 60 percent in patients with central and arterial lines. The dressing features an integrated gel pad containing 2 percent w/w CHG, a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity that maintains antimicrobial activity for 10 days. Site Visibility: Transparent film and gel pad allow for continual site observation, enabling early identification of complications at the insertion site.

Consistent Application: Integrated CHG gel pad and dressing design ensure standardized, correct application. Catheter Securement: Designed to minimize catheter movement and dislodgement.

"Providing effective, proven technology such as Tegaderm CHG I.V. Securement Dressing is just one of the ways that 3M partners with clinicians to help them achieve their infection prevention goals," said Parks. "We also provide clinical expertise and tools to support training and compliance, and engaging educational resources to help facilities implement the latest evidence-based guidelines and standards."

For more information about coordinating a Tegaderm CHG Dressing product trial, please visit <u>3M.com/TegadermCHG</u>.

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About 3M

At 3M, we apply science in collaborative ways to improve lives daily. With \$30 billion in sales, our 90,000 employees connect with customers all around the world. Learn more about 3M's creative solutions to the world's problems at www.3M.com or on Twitter @3M or @3MNewsroom.

¹ Timsit JF et al. *Randomized controlled trial of chlorhexidine dressing and highly adhesive dressing for preventing catheter-related infections in critically ill adults.* Am J Crit Care Med. 2012;186(12): 1272-1278 http://www.atsjournals.org/doi/pdf/10.1164/rccm.201206-1038OC.

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Multimedia Files:

M⢠Tegaderm⢠CHG Chlorhexidine Gluconate I.V. Securement Dressing (Photo: 3M) ownload:

ownload original 8 KB 400 x 240 ownload thumbnail 23 KB 200 x 120 ownload lowres 71 KB 400 x 240 ownload square 62 KB 250 x 250

M Tegaderm CHG I.V. Securement Dressing Receives FDA 510(k) Clearance for Expanded Indication to Reduce

RBSI (Photo: 3M)

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Additional assets available online: Photos (2)

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