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First-of-its-Kind Randomized Clinical Trial Published in "The Lancet Infectious Diseases" Outlines Potential New Standard-Setting Best Practices for Peripheral IV Catheters

- There is robust evidence that the BD vascular care solution and skin antiseptic for peripheral intravenous catheters used in the CLEAN3 randomized clinical trial can help improve patient outcomes
- Compared with standard approaches, the BD vascular care solution reduced the relative risk of catheter failure by 27%, resulting in longer catheter dwell time without complications
- The use of 2% CHG 70% IPA single use, sterile applicator skin antiseptic reduced the risk of infectious complications (catheter colonization and local infection) by 92% compared with 5% povidone iodine (PVI) 69% ethanol

FRANKLIN LAKES, N.J., Feb. 2, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that new clinical data have found robust evidence that using a vascular care solution can help improve outcomes for patients requiring peripheral intravenous catheters (PIVCs).



The results of the CLEAN3 trial¹, [published in *The Lancet Infectious Diseases*](#), showed the use of the BD vascular care solution resulted in fewer PIVC failures compared with the standard group (34.8% vs. 47.5%, respectively) and extended the median time between catheter insertion and failure (50.4 hours vs 30.0 hours, respectively). PIVC failure was defined as any premature removal of PIVC before end of treatment – other than for routine replacement – and included phlebitis, infiltration, occlusion, dislodgment, local infection and catheter-related bloodstream infection (whichever occurred first).

The CLEAN3 trial also evaluated skin antiseptics with 2% chlorhexidine-gluconate (CHG) 70% isopropyl alcohol (IPA) single use, sterile applicator versus 5% povidone iodine (PVI) 69% ethanol applied with sterile gauze in preventing infectious complications related to the use of PIVCs (catheter colonization: 0.9% vs. 16.9%, respectively; local infection: 0% vs. 1.2%, respectively).

The trial, which involved approximately 1,000 patients from nine different medical wards within a single university hospital (Poitiers University Hospital, France), evaluated PIVC failure rates by comparing the BD vascular care solution for PIVCs, which included an integrated PIVC (BD Nexiva™), a positive displacement needle-free connector (BD MaxZero™), a disinfecting cap (BD PureHub™) and a sterile prefilled flush syringe (BD PosiFlush™) – compared with a standard group, which included a straight safety PIVC (BD Insyte™ Autoguard™ BC Winged), extension set three-way stopcock; the PIVCs were continuously infused with saline or polyionic solution, by gravity.

"The findings of the CLEAN3 trial support the use of an integrated solution as the best practice standard when peripheral IV catheter dwell time is expected to exceed 24 hours," said Professor Olivier Mimoz, head of the emergency department at Poitiers University Hospital, France, and principal investigator of the CLEAN3 trial. "Furthermore, the study shows that the use of 2% CHG-70% IPA single use, sterile applicator should become the first-line antiseptic for skin disinfection prior to PIVC insertion. We believe that the results can be extrapolated to all adult patients admitted to a medical ward requiring a PIVC placement and, by extrapolation, to those admitted to a surgical ward."

PIVCs are the most commonly used invasive medical devices in hospitals, where about 2 billion are placed annually worldwide.^{2,3} However, in hospitals, 35% to 50% of PIVCs do not meet their intended dwell time and need to be removed prematurely due to preventable complications, such as infection, occlusion, phlebitis, dislodgment and infiltration.² This can lead to longer hospital stays, higher inpatient costs, and greater risk of death than in patients without these preventable complications.⁴ In addition, unnecessary PIVC replacement can be painful to patients and lead to additional costs,⁵ as well as have an effect on health care professionals' ability to support other patients. Bloodstream infections can have an even greater impact, by prolonging hospitalization and increasing treatment costs and mortality.⁴

"Despite the extensive use of PIVCs in hospitals and the frequency and severity of complications that can be associated with them, CLEAN3 is the first large-scale, randomized clinical trial of its kind, looking at an integrated solution to prevent complications leading to catheter failure and assessing the efficacy of two skin antiseptics in preventing catheter-related complications," said Dr. Klaus Hoerauf, vice president, global medical affairs, Medication Delivery Solutions for BD. "The BD vascular care solution for peripheral IV catheters and skin antiseptic that were found to be efficacious in this trial are part of our integrated approach to help clinicians reduce complications and improve patient safety and care."

View the study publication in *The Lancet Infectious Diseases* here:

[http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30738-6/fulltext](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30738-6/fulltext).

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative

technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](https://www.bd.com).

This was an investigator-sponsored study (Poitiers University Hospital, France) supported by Becton Dickinson (BD). BD had no role in trial initiation, study design, choice of antiseptic products, data collection, data analysis, data interpretation, writing of the report, or the decision to submit. The authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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BD PureHub™ – BD Nexiva™ – BD Insyte™ Autoguard™ – BD MaxZero™ – BD PosiFlush™

These medical devices are CE marked and are CE certified by BSI Group The Netherlands B.V.

Product indications and registrations may vary by country and regions.

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