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New Study Published on Closed IV System as Baxter Produces One Billionth Viaflo Bag

A Milestone in IV Container Technology

Zurich, 3 December 2009 – Building on its well-established leadership developing innovative intravenous (IV) technologies, Baxter Healthcare SA, the regional headquarters of Baxter Europe, Middle East and Africa (EMEA), today announced that its one billionth Viaflo™ bag was manufactured at its plant in Sabiñánigo, Spain. This European milestone follows the printed publication of a new study¹ into the effects of open and closed IV infusion systems. The study adds further weight to the claim that closed systems, such as Baxter's Viaflo flexible IV solution bag, can significantly reduce the risk of central venous catheter-associated bloodstream infections (CVC-BSI) compared to open systems.

Baxter's Viaflo non-PVC flexible IV solution bag offers several advantages over conventional glass container systems. In addition to being lighter in weight and virtually unbreakable, Viaflo's closed system has also been shown to significantly reduce the risks of CVC-BSI*. The new study¹ led by Dr. Fabio Franzetti, Infectious Diseases Clinic, Sacco Hospital, Milan, Italy, involved 1173 adult patients in four intensive-care units. It investigated the effects of switching from open (glass) to closed (Viaflo) IV infusion containers on the rate and time to onset of CVC-BSI.

The results revealed that the CVC-BSI* rate during the open container period was significantly higher than during the closed container period (8.2 vs. 3.5 BSI/1000 CVC days or 0.43 relative risk, $p=0.01$). The probability of developing a CVC-BSI over time was also significantly higher during the open container period (2% at days 1–3 and 5.8% at days 7–9 compared with 0.8% and 1.4% respectively for the closed system). Overall, the risk of acquiring a CVC-BSI was 61% lower during the closed container period ($p=0.004$).

"Switching from conventional open IV infusion containers to Viaflo flexible bag, can significantly reduce the risk of contracting central venous catheter-associated bloodstream infections. Particularly where IV therapy is administered over several days, Viaflo has been shown to be a much better option for patients," said Dr. Franzetti.

In addition to excellent patient safety, Viaflo offers extensive drug compatibility² thanks to its high stability and resistance to leaching and absorption. The triple-layer bag, made from a unique co-extruded polyolefin film, allows for minimal interaction between container and solution, resulting in a high compatibility with a wide range of drugs. Viaflo also supports IV drug admixture, which means that a high volume of drugs can be admixed to the solution in the bag, with the added advantage of a low residual volume after administration.

"The manufacture of Baxter's one billionth Viaflo bag represents a significant achievement for a company that has been dedicated to saving and sustaining lives for more than seventy-five years," said David Pidduck, Vice President Marketing, Medication Delivery, Baxter EMEA. "The fact that Baxter started as the first manufacturer of commercially prepared intravenous solutions in glass containers, then evolved to PVC flexible bags, followed by non-PVC flexible bags illustrates our ongoing commitment to respond to the changing needs of our customers by pioneering the latest techniques and setting the standard for quality."

"With more than 400 employees, the Sabiñánigo plant is devoted solely to the production of Viaflo bags mainly distributed throughout Europe. We are very proud to be a part of this milestone for Baxter," said Santiago Castan, Sabiñánigo Plant Manager, Baxter Spain.

Baxter's reputation for innovation and research goes hand in hand with setting and adhering to the highest standards in patient safety. This commitment was solidified with Baxter's signing of the Vienna Declaration on "Patient Safety in Intensive Care Medicine" at the annual conference of the European Society of Intensive Care Medicine (ESICM) on 11 October 2009. The declaration represents a firm industry commitment to patient safety and outlines a number of measures that can be used by intensive care units around the world to improve the quality of care.³

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About Baxter International Inc.

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with haemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide. More information can be found at www.baxter.com

References

- 1 F. Franzetti et al. "Impact on rates and time to first central vascular-associated bloodstream infection when switching from open to closed intravenous infusion containers in a hospital setting." In: *Epidemiology and Infection*, 137 (2009): 1041-8.
- 2 For more information about the compatibility of certain drugs with Viaflo, please visit www.stabforum.com. This web tool provides online access to a secure, Good Automated Manufacturing Practice (GAMP) 5 validated database compiling specific, experimental compatibility and stability data.
- 3 See <http://patientsafety.esicm.org/declaration.asp> for the full "Declaration of Vienna" text. See also Rui P. Moreno et al. "Patient safety in intensive care medicine: the Declaration of Vienna." In: *Intensive Care Medicine*, 35 (2009): 1667-72.

* CVC-BSI defined in the study as laboratory-confirmed bloodstream infections (LCBI) and clinical primary nosocomial sepsis (CSEP).