

Saline Flush Recommendation for TEGO® Connector.

Document Review:

- **FDA Guidance for Industry on General/Specific Intended Use**, Published November 4, 1998. Section 513(i)(1)(F) Federal Food and Cosmetic Act (The Act).
- 510K 053106 TEGO Connector



Background

Traditional flushing procedures used in Hemodialysis typically include large concentrations of heparin to help prevent thrombotic occlusion with the Central Venous Catheter (CVC). This “Heparin Lock” Procedure is completed at the end of each Hemodialysis treatment before the patient goes home. Recent concerns about the use and availability of heparin have caused a crisis in the United States and abroad. There are substantial risks associated with the use of heparin such as Heparin Induced Thrombocytopenia which may occur in as many as 0.2% of patients.¹ Safety Alerts have been issued as far back as 2006 regarding fatal dosing errors involving Heparin.² Furthermore, in February 2008, a worldwide recall of Heparin was initiated by the largest supplier, Baxter Healthcare, which has resulted in global shortages. Below is an excerpt from the February 11, 2008 United States Food and Drug Administration (FDA) statement regarding the Baxter recall.

About 350 adverse events associated with the Baxter product have been reported since the end of last year compared to less than 100 reports in 2007. Most of the events have taken place at hemodialysis centers, almost exclusively involving patients receiving a bolus dose – which is a high dose administered over a short time. While most of the reports involve multiple-dose vials, several cases include patients who received a bolus dose after their health care professional combined heparin from single-dose vials. (FDA News; February 11, 2008).³

In an effort to improve the clinical outcomes for Hemodialysis Patients, the TEGO Connector was developed by ICU Medical. The TEGO is specifically designed for use in Hemodialysis which requires unique engineering to support the high flow rates of blood and fluids. The TEGO is a **Microbiologically and Mechanically Closed Connector** which has been proven to reduce Catheter Related Bloodstream Infection (CRBSI) in Pediatric Hemodialysis Patients.⁴ The TEGO is also designed as a **Neutral Displacement Connector** which means that when the blood tubing or a syringe is removed from the TEGO there is minimal reflux of blood into the catheter lumen, thus eliminating the need for a ‘Heparin Lock’. TEGO was approved with these *indications for use* which included the use of a Saline Flush to maintain the patency of Hemodialysis CVCs in the 510K documents.

Clinical Review

Beta Site studies have been performed using the TEGO and Saline Flush which resulted in no thrombotic occlusion events. Use of the TEGO and Saline Flush can drastically reduce manipulations of the CVC hub which offer benefit in the reduction of CRBSI and now, thrombotic occlusion. Reduction in CRBSI and Thrombotic occlusion can greatly improve patient outcomes.

Cost Review

There are substantial cost benefits to using the TEGO and Saline Flush as well. A host of procedures and materials can be eliminated beyond the cost of the drug itself. Procedures such as thrice weekly Betadine soaks can be reduced to only one; including the elimination of the associated materials. CRBSI carries significant cost, however the cost to treat a CRBSI in a Dialysis clinic may be considered cost neutral due to reimbursement practices. When a patient is hospitalized for CRBSI, which may be as often as two weeks in the year, there is however a significant loss of revenue for the clinic during this period. A cost worksheet is available from ICU Medical, to help demonstrate how the use of TEGO and Saline Flush can have cost benefits in all facilities.

Protocol

When using the TEGO and a Saline Flush it is important that certain protocols are adhered to. In order to properly disinfect the TEGO prior to access, an isopropyl alcohol swab using an aggressive circular motion for three seconds is required. The CVC must be properly flushed with normal saline after each use as well. In order to reduce manipulations, it is very important to utilize a complete 10mL or 20mL saline flush following the Dialysis treatment. It is not appropriate to use two 5mL syringes to achieve a 10mL flush as this increases the number of manipulations and therefore risk of CRBSI and thrombotic occlusion. The following points identify appropriate protocol elements to include the TEGO Connector and a Saline Only Flush. The follow table represents a week long protocol for the Dialysis patient.

<p>Day One:</p> <ol style="list-style-type: none"> 1. Aspirate 3-5mL to clear lumens and discard. 2. Remove TEGO Devices. 3. Perform Betadine soak on CVC hub. 4. Apply new TEGO to each lumen. 5. SWAB TEGO 6. Perform pre-treatment flush to verify CVC patency. 7. SWAB TEGO 8. Attach Bloodlines and perform Treatment. 9. Remove Bloodlines. 10. SWAB TEGO 11. Flush CVC using 10mL or 20mL Saline. 	<p>Day Three:</p> <ol style="list-style-type: none"> 1. SWAB TEGO 2. Aspirate 3-5mL to clear lumens and discard. 3. Perform pre-treatment flush to verify CVC patency. 4. SWAB TEGO 5. Attach Bloodlines and perform Treatment. 6. Remove Bloodlines. 7. SWAB TEGO 8. Flush CVC using 10mL or 20mL Saline. 	<p>Day Five:</p> <ol style="list-style-type: none"> 1. SWAB TEGO 2. Aspirate 3-5mL to clear lumens and discard. 3. Perform pre-treatment flush to verify CVC patency. 4. SWAB TEGO 5. Attach Bloodlines and perform Treatment. 6. Remove Bloodlines. 7. SWAB TEGO 8. Flush CVC using 10mL or 20mL Saline.
---	--	---

Conclusions

By reducing manipulations at the Catheter hub using a TEGO Connector, CRBSI and Thrombotic Occlusion may be reduced or eliminated. Use of Saline Flush in conjunction with the TEGO connector can also greatly reduce patient risks and reduce overall treatment time and costs. It is recommended that strict adherence to the disinfection and flush protocols be recognized in order to achieve optimal patient outcomes.

¹ Kadidal V, **Heparin-Induced Thrombocytopenia (HIT) Due to Heparin Flushes.** *Internal Medicine.* 1999;246, p.325-329.

² ISMP Safety ALERT: **Complications Associated with Heparin Vials.** 20-September, 2006.

³ FDA NEWS, **Baxter's Multiple-dose Vial Heparin Linked to Severe Allergic Reactions.** February 11, 2008.

⁴ McAfee N, **Use of Tego Connector to Prevent Hemodialysis Infections in Children.** ADC, March 2008, Poster Presentation .

