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HeRO® GRAFT NEWS BULLETIN

# CDC Removes HeRO Graft from CLABSI, CryoLife® Requests Correction to Dialysis Event Protocol

Some HeRO Graft customers may have recently received an email from the Centers for Disease Control and Prevention (CDC) containing a Central Line-Associated Bloodstream Infection (CLABSI)[1] document that called the HeRO Graft the HeRO "catheter"' and instructed them to include the HeRO Graft as a "central line" for purposes of reporting infections for dialysis in-patients.

The CDC also has a similar document called the Dialysis Event Protocol[2] for outpatient surveillance of infections that identifies the HeRO Graft in the "other access device" category (not meeting the definition of a graft).

The CDC was contacted to correct these errors and they stated the following on December 10, 2012:

> …We are in agreement that [the HeRO Graft] is different enough from historical central lines to justify removing it from this classification in the NHSN CLABSI surveillance protocol. Therefore beginning in January 2013 the [HeRO Graft] will no longer be included in CLABSI surveillance within the NHSN system. The 2013 NHSN manual will be updated to reflect this change and the change will be included in a document which highlights important surveillance changes for the year and is shared with NHSN users.[3]

CryoLife is very excited about this correction regarding the CLABSI. However, the Dialysis Event Protocol is another document that will need to be corrected by the CDC as well. Below are excerpts of what was emailed to the CDC requesting that they appeal their decision regarding how they identify the HeRO Graft:

> 1. HeRO Graft received Food and Drug Administration (FDA) clearance in January, 2008 and was FDA classified as a "vascular graft prosthesis" not a "catheter", not a "central line", and not an "other access device". The most recent FDA letter, dated June 22, 2012, still shows HeRO Graft in Regulatory Class II, and currently lists only one Product Code: DSY (prosthesis, vascular graft, of 6mm and greater diameter).[4]

1. CLABSI, Jan. 2012. http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf
2. Dialysis Event Protocol. Feb. 2012. http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf
3. Email from Division of Healthcare Quality Promotion CDC.
4. HeRO Graft 510(k) letters. www.MeritEMEA.com

## KEY TAKEAWAYS:

- FDA's Classification of HeRO Graft is vascular graft prosthesis
- CDC calling HeRO Graft a "catheter" and "central line" for infection surveillance in hospitals is not correct and will be corrected
- CDC categorizing HeRO Graft as an "other access device" for infection surveillance in outpatients is not correct



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