FDA Revises Safety Alert –
Updates Guidance and Clears New/Additional Erbe 24-Hour Port Connector

May 23, 2019

On April 18, 2018, the FDA released a letter to health care providers regarding the use of 24-hour multi-patient use endoscope connectors. In this letter, it was stated that "the FDA has not received acceptable testing to demonstrate the safe use of these products, and recommends against their use." The FDA went on to recommend port connectors that "may be reprocessed and reused between procedures", or "single-use devices". They also specifically pointed out that Erbe's ERBEFLO® 24-hour port connector "does not include a backflow prevention feature".

Erbe strongly disagreed with the FDA's position for the following reasons:

1. The Erbe 24-hour multi-patient use endoscope connectors did in fact have a backflow prevention feature when used according to its Notes On Use (NOU), and in conjunction with FDA cleared ERBEFLO® tubing products. Erbe has backflow prevention valves permanently attached to every irrigation line/set.
2. To date, the Erbe 24-hour port connectors have been used in more than 18,000,000 procedures without any reported incident of cross-contamination.
3. Erbe had already provided additional testing pertaining to Erbe's 24-hour connectors to the FDA that Erbe maintains, met or exceeded FDA's published guidelines.

However, in the spirit of cooperation, on April 25, 2018, representatives from Erbe met with members of the FDA. The purpose of this meeting was to further demonstrate the safety and efficacy of the existing design and agree on a pathway that would alleviate the FDA's concerns regarding the safety of Erbe's 24-hour multi-patient use port connectors and the possibility of off-label use. As a result of that meeting, Erbe and the FDA agreed to the following:

1. In addition to the already completed "worst case" simulated use testing, Erbe would perform additional testing with the previously FDA cleared, 24-hour port connector (i.e., port connectors without a backflow valve but used with Erbe tubing sets that include a permanently attached backflow valve).
2. Erbe would perform Human Factors Testing to insure that it's Notes On Use could be properly followed when using ERBEFLO 24-hour port connectors.
3. Despite demonstrating safety and efficacy via direct clinical experience and the aforementioned testing, Erbe would add an additional back-flow valve to its 24-hour connector in order to mitigate FDA concerns of off-label use (i.e., Erbe connectors used with other manufacturer's tubing sets).

Upon successful completion of the above, we are pleased to announce that the FDA has updated its guidance and issued a new 510(k) for Erbe's updated 24-hour multi-patient use endoscope connector. Erbe will continue to offer both single-use and 24-hour port connector options, which will allow our customers to determine the most cost-effective and clinically appropriate device for use with their patients.

In summary, Erbe is the only manufacturer that has met FDA's requirements for 24-hour multi-patient use port connectors.

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