GEDSA
Unite. Connect. Deliver.

Global Enteral Device Supplier Association
P.O. Box 250
Powell, OH 43065

(614) 800-5458
info@gedsa.org
www.stayconnected.org

A Conversation with the FDA on Irrigation Bag Connections

August 25, 2021

In a conversation with the FDA, GEDSA and its membership asked the following question in an effort to help those looking for advice on how to apply the ISO/IEC 80369 small bore connector standards series.

Question: What standard will cover the distal (patient) end of irrigation bag connections? There could be adverse events associated with an irrigation solution that is misconnected.

Answer:
The ISO 80369 series currently does not have a specific irrigation bag connector for the patient end or reservoir end (ISO 18250 series).

ISO 80369 asks manufacturers to assess and mitigate the risk of misconnection. In order to do this manufacturers need to ask themselves:

- What connector is currently being used?
- Could that connector's use bring potential harm to a patient?
- What steps are being taken to mitigate that risk?

While ISO 80369-7 does 'specify' its use under the scope for intervascular and hypodermic use, there is common and widespread knowledge that many other devices/clinical applications, irrigation for one, were not included or even envisioned for the ISO 80369 series for alternative use of the Luer connector.

There is an effort underway within the ISO 80369 series (ISO TC210/JWG4) to help manufacturers navigate that decision matrix and decide what approach a risk management process should take to determine if the continuance of such a connector is able to be appropriately justified.

The question for manufacturers is, what to do between now and then? The FDA's recommendation is that each manufacturer should make sure that its Risk Management File does in fact evaluate the known risks in a manner that supports the connector chosen. For new premarket submissions requiring the use of the ISO 80369-7 connector (vs. ISO 594), the recommendation is to consider a pre-submission before submitting a 510k to ask the FDA premarket review team if the approach used to support the use of the Luer, assuming that is what has been chosen, makes sense.

Finally, the FDA points out that this issue is will be discussed by the working group this fall in two scheduled meetings.

For more information click here and/or here.