

New ISO 80369 Product Line

Promoting patient safety by preventing misconnections

Luer connector misconnections are an under-recognized, but common dangerous events. The objective of the new ISO 80369 Standards that are gradually being implemented is to prevent these adverse events so crucial to patient safety.



Elcam Medical has taken a proactive approach to the implementation of the new ISO 80369 standard regulations and is in the process of implementing those standard drafts well in advance allowing our customers to prepare themselves for the upcoming change.



New ISO 80369

 Elcam Devices  Elcam Stopcocks  Elcam Components

The ISO 80369 -3 Standard, Enteral Feeding applications.

The transition has started in 2015 and is scheduled to be continued in 2017.

Elcam Medical has launched a new Enteral Feeding Stopcock that includes the new Enfit connector design that fully complies with the new standard.

This product is available for sale.



ISO 80369-6:2016 Standard, Neuraxial applications.

This standard will eventually be adopted by the medical device industry following a new State of California legislation requiring, from January 2017, the use of an epidural connector that would not fit into a connector other than the type it is intended for.

Among relevant devices that will be affected by this new standard are: epidural devices, pain pumps and their administration sets, regional anesthesia catheters and needles.



This line of connectors will include both male and female versions and also vented and non-vented caps for both connectors. The connectors will be made of clear **Tritan™** material from Eastman, which was shown in laboratory tests to have improved lipid resistance, high clarity and the BPA-free benefit.

ISO 80369- 7 Standard, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.

Elcam Medical's luers comply with ISO 80369-7:2016/2017. Elcam Medical Italy luers are considered as well to comply with the ISO 80369-7:2016/2017. They will be tested and verified during 2019.

Some of Elcam Italy's ISO 80369- 7 luers are also available with **Tritan™**, renown for its improved heat and chemical resistance properties.



The ISO/ DIS 80369 -2 Standard, Respiratory applications.

Recently, the breathing systems connectors' standard has been removed by the ISO organization; however, its final destiny is still ambiguous. Elcam is closely monitoring the developments in this area, in order to be ready with compatible connectors on time.



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