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 Stopcocks  Lucomed Medical Products  Injectech
The ISO 80369 -3 Standard, Enteral Feeding applications.
The transition has started in 2015 and is scheduled to be continued in 2016.
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.

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.
Products will be available for show and tell in June 2016.

In Q4 2016 Elcam also intends to launch an ISO 80369-6:2016 male Safe2 Rotator (S2R) version of connectors for minimizing disconnections and providing another safety layer for neuraxial fluid administration.

ISO/FDIS 80369- 7 Standard, Intravascular (IV) and Hypodermic applications for connectors with 6% (Luer) taper.
The Elcam ISO/FDIS 80369- 7 connectors will also address the need of drug resistance connectivity by cooperating with Eastman in implementing the well-known Tritan™ material with its properties of oncology drugs and lipid resistance and chemical compatibility and durability.
Products will be available for show and tell in June 2016

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. Nonetheless, Elcam has started developing connectors that will comply with this standard as part of its Patient Safety Roadmap. During 2017, Elcam will launch a series of connectors which comply with ISO/ DIS 80369-2.

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