

# New ISO 80369 Product Line

Promoting patient safety by preventing misconnections

**Luer connector misconnections** are 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.

Elcam Medical is offering the **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 is gradually being 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.



Elcam's new **Neuraxial (NRFit) stopcock** is fully compliant with the new ISO 80369-6 standard and will soon be available for sale.

The **ISO 80369-6 connectors** include both male and female versions. The connectors are made of clear **Tritan™** material from Eastman, which was shown in laboratory tests to have improved lipid resistance, high clarity and offer the benefits of not being made with BPA.

## 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™**, renowned 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.



[www.elcam-medical.com](http://www.elcam-medical.com)

Head Office / Manufacturer  
Elcam Medical

BarAm 1386000,  
Israel  
Tel: 972 4 698 8120/1  
Fax: 972 4 698 0777  
sales@elcam.co.il

USA  
Elcam Medical Inc.

2 University Plaza, Suite 620  
Hackensack, NJ 07601  
Tel: +1 201 4571120  
Fax: +1 201 4571125  
info@elcam-medical.com

Europe  
Elcam Medical Europe

Via Emilia Romagna 15,  
41012 Carpi (Modena) Italy  
Tel: +39 059 697710  
Fax: +39 059 697705  
sales.eu@elcam-medical.com

China  
Elcam China Office

Room 3309, Jinhai Mansion  
No. 89 of Anshun Road,  
Shanghai, PRC. Zip: 200051  
Tel: +86 21 62829967  
Fax: +86 21 62829967  
johnliu02@126.com