

# 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 and is in the process of implementing those standard 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 completed in 2019.

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 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/FDIS 80369- 7 Standard, Intravascular (IV) and Hypodermic applications for connectors with 6% (Luer) taper.

The Elcam ISO 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.



## The ISO/ NP 80369 -2 Standard, Respiratory applications.

The breathing systems connectors' standard is currently under proposal stage (Approval to New project approved), and is not yet available to the general public. Elcam continuously monitors the developments in this area in order to be prepared in advance for any needed changes.



[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