What is ISO 80369

Hospitals and other healthcare facilities depend on a variety of catheters, tubing and syringes to deliver medications and other substances to patients through vascular, enteral, respiratory, epidural and intrathecal delivery systems. These delivery systems frequently employ fittings called luer connectors to link various system components. Unfortunately, because luer connectors are ubiquitous, easy-to-use and compatible between different delivery systems, clinicians can inadvertently connect wrong systems together, causing medication or other fluids to be delivered through the wrong route. Such errors can cause serious patient injuries and deaths. To further reduce the occurrence of these misconnections, the FDA is actively participating in an international effort to develop and implement standards for noninterchangeable connectors for small bore medical connectors. A joint working group established by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) leads this effort to develop a series of standards for incompatible connectors. ISO 80369-1 is the first in the series of standards and establishes the applications specified below that will have their own unique connector geometries.

ISO 80369-2: Breathing Systems and Driving Gases
ISO 80369-3: Enteral and Gastric
ISO 80369-4: Urethral and Urinary
ISO 80369-5: Limb Cuff Inflation
ISO 80369-6: Neuraxial
ISO 80369-7: Intravascular (IV)

When will it come into effect?

Each section of the ISO 80369 standard is being defined separately. Currently, ISO 80369-2 and ISO 80369-7 are the farthest along in development, yet it is difficult to say when the entire standard will be complete.

How does it impact me?

Compliance with the ISO 80369 standard may require major changes on the part of medical device manufacturers. In the next few years, if these standards are approved it could mean new designs, new parts, new moldings and updating or replacing millions of components. While you may choose to manufacture your own custom fittings, you must consider the significant costs associated with such an endeavor. There is also the possibility that these custom fittings may inadvertently connect with other applications' fittings that are not yet defined.

It is important to note that if this standard passes, it does not mean that luers can no longer be used in the referenced markets. Until connectors are defined and approved for each market, no definitive action can be taken.

How can I prepare?

While the standards have not yet been completely established, the main precaution that medical device manufacturers can take to help prevent any future problems is to stay up-to-date on ISO 80369 news. Value Plastics is one of only a few connector companies worldwide actively participating on ISO 80369 committees. To keep the medical device community apprised of new developments, we have chosen to provide information in one web location. Value Plastics has set up an online resource to help medical device OEMs stay informed of the changes and updates to this standard.

To read the latest updates, subscribe to alerts, and view related resources, go to Value Plastics' online resource at **i8.valueplastics.com.**

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