Pediatric Peripherally Inserted Central Catheters: Cracking the Code of Product Labeling

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Abstract

Clinicians placing peripherally inserted central catheters utilize a wide array of products from various manufacturers. To support appropriate use for patient safety, regulatory bodies require manufacturers to strive for some degree of uniformity in product labeling. This article describes and interprets the symbols used on product labeling for catheters and addresses a number of frequently voiced related clinical concerns.

Keywords: *product labeling, sterilization, product symbols, shelf life, catheter, gauge, PICC*

Introduction

In the current health care environment, peripherally inserted central catheters are placed routinely to provide necessary medications and parenteral nutrition for patients across the life span. A wide variety of products are utilized with pediatric and neonatal populations due to the varying size of patients. Numerous products are available from various manufacturers and each product carries its own instructions for use. Appropriate use to minimize undesired consequences includes careful consideration and a clear understanding of each product's label markings. Graphical symbols are favored due to their ability to convey concise significance in a multilingual market using limited label space. However, in a study of 293 participants representing 4 countries, only 50% correctly comprehended graphical symbols on medical device packaging.[1] Although label symbols are often assumed to be self-evident, improper understanding of label markings can have serious consequences. In 1 case, an infant's death resulted from improper labeling of a catheter.[2] Clinicians are responsible for verifying the appropriateness of medical devices, including deciphering label markings and reviewing instructions before use.[3] Unfortunately, in fast-paced clinical settings, the meaning of an important product label warning may not be discovered until after an event occurs. Clinicians with questions or concerns should contact the device's manufacturer for assistance. Many manufacturers have clinicians employed as educational resources. This article addresses common questions related to product labeling to promote safe practice for clinicians.

Who Regulates What Manufacturers Include in Product Labeling?

Product labeling is regulated by the regulatory body of the country, or countries, in which the product is registered. If a product is intended for global distribution, the manufacturer must apply product labeling specific to the recognized regulatory authority relevant to each country the product will reach. In the United States, the required elements of product labeling are dictated by the Food and Drug Administration (FDA). These elements accompany the product when it is submitted for premarket approval (510K) to the FDA.[4] The FDA labeling specifications pertinent to vascular access devices include useful length, inner diameter, outer diameter, priming volume, distance between markings, tip configuration description, indications for use, recommended access site, and final anatomical tip location. Catheters that are 3 Fr (ie, 1 mm or 0.039 in) or less in diameter are assumed to be applicable for pediatric patients and require additional instructions relative to use in pediatric patients. In the absence of such instructions, the device label must include the statement, "Not intended for pediatric or neonatal use."[4] Be aware that product labeling includes not only information affixed to the device and the package, but also the professional and patient inserts and any other instructions for use included with the product as well as information on product use posted on company websites. Products marketed in European Union countries must demonstrate compliance to Essential Requirements and the Medical Device Directive to earn a CE mark.[5,6] The CE mark must be 5 mm high and is usually followed by a 4-digit number indicating the specific notified body. Notified bodies are the agencies in European countries

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that review products and ensure that the products comply with established standards.

What Do the Symbols Mean?

A good symbol's meaning is immediately obvious. Its purpose is universal understanding. The International Organization for Standardization (ISO), a voluntary standards organization in Switzerland, publishes a list of label symbols called ISO 15223.[7] The European Union adopted the ISO standard and it is considered the European norm. ISO standards are internationally recognized and accepted in Europe and Asia, but individual countries may have additional requirements. See Figure 1.

Why Does the Labeling Present so Many Languages?

Manufacturers must present a label that is in compliance with the regulations for each country in which the product will be distributed. Tiny print is often employed to meet the challenge of presenting lengthy instructions for use in several languages in 1 document. It can be cumbersome and confusing for manufacturers to attempt to include instructions for use only in the prevailing languages of each country the product will reach.

What Does the Expiration Date on the Package Mean?

The expiration date on the package reflects the time limit that the manufacturer has validated the sterilization process to remain intact for the contents. Products that enter sterile tissue or the vascular system or through which blood will flow are considered critical, meriting the highest level of sterilization. Sterilization can be accomplished by steam, heat, gas, or chemicals to destroy microbial life.[8] A common method of sterilization for catheters is ethylene oxide.[9] Most manufacturers aim for a shelf life of 2 to 3 years, but this is dependent on the components in the product. If 1 of the items associated with the product carries a shorter shelf life than the sterilization boundary, for example, the shorter shelf life is adopted as the expiration date. However, the expiration date on a package specifies limits on the sterility of the contents and does not necessarily reflect limits on the integrity of the catheter product or its performance, which are specified in the product's initial regulatory approval. A clinician should always use or discard a product by the last day of the month and year indicated.

What Does Pyrogen Free or Nonpyrogenic Mean?

Pyrogens are bacterial substances that can cause fever. If a product is labeled pyrogen free, it contains no pyrogens. A product may be sterile but not pyrogen free. If a product is labeled nonpyrogenic it means that the levels of bacterial substances or endotoxins fall below the established specified concentrations. Manufacturers control the level of pyrogens

Symbol Guidance

CE	The CE mark, signifying compliance with European Medical Device Directive.		
REF	Catalogue number/ reference number/ re-order number	SN	Serial number
LOT	Lot number/batch code/batch number		Fragile
EC REP	Authorised representative in the European Community		Keep dry
STERILE EO	Sterilised using Ethylene Oxide	2	Do not re-use/single use/use only once
STERILE R	Sterilised using irradiation		Keep away from sunlight
	Use by		Do not use if package is damaged
	Date of manufacture		Green Dot - Recycle in Europe
	Manufacturer		Caution/attention/see instructions for use
	This way up		Temperature limitation
LATEX	Does not contain natural rubber latex	LATEX	Contains or presence of natural rubber latex

Figure 1. **International Organization for Standardization symbols chart. Reprinted with permission from Argon Medical Devices.**