TruCath® Symbols Glossary

United States Title 21 of the Code of Federal Regulations (CFR) Section 801.109(b)(1)			
Symbol	**Symbol Title**	**Explanatory Text**	**Standard Reference**
Rx ONLY	Prescription Use Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.	21 CFR Section 801.109 (b) (1) and United States Food and Drug Administration Guidance for Industry – Alternative to Certain Prescription Device Labeling Requirements, Issued on January 21, 2000
Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements			
Symbol	**Symbol Title**	**Explanatory Text**	**Standard Reference**
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2021 5.1.6
	Do not use if package is damaged and Consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1:2021 5.2.8
	Consult instructions for use or consult electronic instructions for use.	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021 5.4.3
	Keep Dry	Indicates a medical device needs to be protected from moisture.	ISO 15223-1:2021 5.3.4
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1:2021 5.2.4
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1:2021 5.4.2
STERILE EO	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2021 5.2.3
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1:2021 5.2.4
	Not made with natural rubber latex	Indicates that neither the medical device nor the packaging of the medical device contains the presence of natural rubber latex.	ISO 15223-1:2021 5.4.5 and Annex B.2 and Guidance for Industry and US Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex; Issued on December 2, 2014
	Do Not Re-sterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1:2021 5.2.6
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021 5.1.5
	Use-by date	Indicates the date after which the medical device is not be used.	ISO 15223-1:2021 5.1.4
BS EN 15986:2011 – Medical devices – Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates			
	Does not contain DEHP	Indicates a medical device that does not contain the phthalate plasticizers DEHP.	BS EN 15986:2011 EN 15986:2011(E) Annex B
	Contains or presence of phthalate DEHP	Indicates presence of Bis (2-ethylexyl) phthalate (DEHP).	BS EN 15986:2011 Reference no. A.5

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