

Symbols Glossary



Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard ¹
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used
LOT	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
STERILE R	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
8	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
*	5.3.7	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed
8	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
Â	5.4.4	Caution	Caution: Federal Law restricts this device to sale by or on the order of a physician
RxOnly	21 CFR 801.109(b) (1)	Prescription only	Requires prescription in the United States
¹ Reference numbers (e.g., 5.11, 5.1.4-5.1.6, 5.2.4, 5.2.8, 5.3.7, 5.4.2 and 5.4.4) and descriptions from ISO 15223-1:2016, Medical Devices – Symbols to be used with medical device labels, labelling and information to			

be supplied – Part 1: General requirements, FDA recognized standard # 5-118 unless otherwise noted.