

Glossary of Standard Symbols

SYMBOL	REF #	TITLE	DESCRIPTION
ISO 15233-1. Manufacturer			
	5.1.1	Manufacturer	Indicates the medical device manufacturer
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use-by-date	Indicates the date after which the medical device is not to be used. NOTE: Synonyms for “use-by date” are “use by”, “expiry date” and “expiration date”.
	5.1.5	Batch Code	Indicates the manufacturer’s batch code so that the batch or lot can be identified.
	5.1.6	Catalog number	Indicates the manufacturer’s catalogue number so that the medical device can be identified. NOTE: Synonyms for “catalog number” are “commercial product name”, “commercial product code”, stock keeping unit, “reference number” and “reorder number”.
	5.1.9	Distributor	Indicates the entity distributing the medical device into the locale.
ISO 15233-2. Sterility			
	5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	5.2.5	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.
	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	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. NOTE 1: This symbol can also mean, “Do not use if the product sterile barrier system or its packaging is compromised”.

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SYMBOL	REF #	TITLE	DESCRIPTION
ISO 15233-3. Storage			
	5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources. NOTE: This symbol can also mean "Keep away from heat".
	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.
	5.3.5	Lower temperature limit	Indicates the lower limit of temperature to which the medical device can be safely exposed.
	5.3.6	Upper temperature limit	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
ISO 15233-4. Safe Use			
	5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	5.4.5	Contains or presence of natural rubber latex	Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	5.4.12	Single patient, multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.

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SYMBOL	REF #	TITLE	DESCRIPTION
ISO 15233-7. Others			
	5.7.7	Medical device	Indicates the item is a medical device .
	5.7.10	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
ASTM F2503; Magnetic Resonance			
	7.3.1	MR Safe	An item which poses no known health hazards resulting from exposure to any MR environment.
	7.3.2	MR Conditional	An item which demonstrated safety in the MR environment with defined conditions.
	7.3.3	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
21 CFR 801.15; 21 CFR 801.109			
	21 CFR 801.15 (c)(1)(i)(F) 21 CFR 801.109 (b)(1)	Prescription Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

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