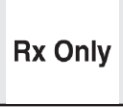
ORTHO Organizers
A HENRY SCHEIN® COMPANY

SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	SYMBOL DESCRIPTION	STANDARD REFERENCE	STANDARD TITLE
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	5.1.7	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Sterile	Indicates a medical device that has been subjected to a sterilization process.	5.2.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Sterilized using aspectic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.	5.2.2	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

	Sterilized using ethylene oxide	Indicates a medical device has been sterilized using ethylene oxide.	5.2.3	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.	5.2.5	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Do not resterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Sterile fluid path	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.	5.2.9	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	5.3.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	5.3.2	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Protect from heat and radioactive sources	Indicates a medical device that needs protection from heat and radioactive sources.	5.3.3	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Keep dry	Indicates a medical device that needs to be protected from moisture.	5.3.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	5.3.5	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	5.3.6	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirement
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	5.3.9	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Biological risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	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.	5.4.2	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be pre-sented on the medical device itself.	5.4.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Contains presence of natural rubber latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	5.4.5	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Sampling site	Indicates a medical device or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the medical device or blood container.	5.6.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Fluid path	Indicates the presence of a fluid path.	5.6.2	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.	5.6.3	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

	Drops per millilitre	Indicates the number of drops per millilitre.	5.6.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Liquid filter with pore size	Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.	5.6.5	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	One-way valve	Indicates a medical device with a valve that allows flow in only one direction.	5.6.6	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Importer	To indicate the entity importing the medical device into the locale.	—	—
	Patient number	Indicates a unique number associated with an individual patient.	5.7.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Single patient multiple use	To indicate that the medical device may be used multiple times (multiple procedures) on a single patient	—	—
	Contains human blood or plasma derivatives	To indicate that the medical device contains or incorporates human blood or plasma derivatives	5.4.6	ISO 15223-1:2021 Medical Devices - symbols to be used with information to be supplied by the manufacturer - Part 1: General Requirements
	Unique Device Identifier	The UDI symbol is optional. When multiple data carrier are present on the label, the symbol may be used.	5.7.1	ISO 15223-1:2021 Medical Devices - symbols to be used with information to be supplied by the manufacturer - Part 1: General Requirements
	Medical device	Indicates that a given product is a medical device.	5.7.7	ISO 15223-1:2021 Medical Devices - symbols to be used with information to be supplied by the manufacturer - Part 1: General Requirements
	N/A	An indication placed at the title of a section within the IFU that information has changed.	—	–
	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.	—	Requirement for medical products sold in the U.S.
	European conformity	CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements.	—	Required for products manufactured anywhere in the world that are then marketed in the EU.