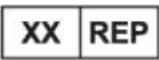


Title: Graphical Symbols for Medical Device Labeling

Owner: Tina O'Brien

Effective Date: 10/1/2025

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	➤ ISO 15223-1 (Clause 5.1.1) ➤ ISO 7000 (Symbol No. 3082)	Manufacturer	Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. Note: Can be used in combination with date of manufacture (Clause 5.1.1 note 5).
	➤ ISO 15223-1 (Clause 5.1.3) ➤ ISO 7000 (Symbol No. 2497)	Date of manufacture	Indicates the date when the medical device was manufactured
	➤ ISO 15223-1/Amd.1.2025 (Clause 5.1.2)	Authorized representative	Indicates the authorized representative.
	➤ ISO 15223-1 (Clause 5.1.4) ➤ ISO 7000 (Symbol No. 2607)	Use-by date	Indicates the date after which the medical device is not to be used.
	➤ ISO 15223-1 (Clause 5.1.6) ➤ ISO 7000 (Symbol No. 2493)	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	➤ ISO 15223-1 (Clause 5.1.7) ➤ ISO 7000 (Symbol No. 2498)	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	➤ ISO 15223-1 (Clause 5.1.5) ➤ ISO 7000 (Symbol No. 2492)	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	➤ NA - Zimmer Biomet internal symbology	Quantity	Indicates the packaged quantity.
	➤ ISO 15223-1 (Clause 5.1.8) ➤ ISO 7000 (Symbol No. 3725)	Importer	Indicates the entity importing the medical device into the local market.
	➤ ISO 15223-1 (Clause 5.1.9) ➤ ISO 7000 (Symbol No. 3724)	Distributor	Indicates the entity distributing the medical device into the local market.
	➤ ISO 15223-1 (Clause 5.2.2) ➤ ISO 7000 (Symbol No. 2500)	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.

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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT	
	➤ ISO 15223-1 (Clause 5.2.3) ➤ ISO 7000 (Symbol No. 2501)	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	
	➤ ISO 15223-1 (Clause 5.2.4) ➤ ISO 7000 (Symbol No. 2502)	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	
	➤ ISO 15223-1 (Clause 5.2.6) ➤ ISO 7000 (Symbol No. 2608)	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.	
	➤ ISO 15223-1 (Clause 5.2.7) ➤ ISO 7000 (Symbol No. 2609)	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	
	➤ NA - Zimmer Biomet internal symbology	Material	Indicates the material of the device	
	➤ ISO 15223-1 (Clause 5.2.8) ➤ ISO 7000 (Symbol No. 2606)	Do not use if package is damaged and consult instruction 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 instruction for use for additional information. Note: This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised."	
	➤ ISO 15223-1 (Clause 5.2.11 and 5.2.12) ➤ ISO 7000 (Symbol No.3707 and .3708)	Sterile barrier system	solid line indicates a sterile barrier The number of solid lines indicates the number of Sterile barriers present. For Example: Single solid line indicates single sterile barrier and double solid line indicates double sterile barriers.	
	➤ ISO 15223-1 (Clause 5.2.13 and 5.2.14) ➤ ISO 7000 (Symbol No.3708 and 3709)	Protective packaging for sterile barrier system	"The dotted line indicates the inclusion of protective packaging in the sterile packaging system, and is typically used with either a single solid line or a double solid line to indicate the number of sterile barriers. A dotted line inside the solid line(s) indicates the protective packaging is inside the sterile barrier system. A dotted line outside the solid line(s) indicates the protective packaging is outside the sterile barrier system."	
	➤ ISO 15223-1 (Clause 5.3.4) ➤ ISO 7000 (Reg No. 0626)	Keep dry	Indicates a medical device that needs to be protected from moisture.	
	➤ ISO 15223-1 (Clause 5.3.5) ➤ ISO 7000 (Symbol No. 0534)	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed. The temperature shall be indicated adjacent to the lower horizontal line.	

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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT	
	➤ ISO 15223-1 (Clause 5.3.6) ➤ ISO 7000 (Symbol No. 0533)	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed. The temperature shall be indicated adjacent to the upper horizontal line.	
	➤ ISO 15223-1 (Clause 5.3.7) ➤ ISO 7000 (Symbol No. 0632)	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	
	➤ ISO 15223-1 (Clause 5.4.2) ➤ ISO 7000 (Symbol No. 1051)	Do not re-use	Indicates a medical device that is intended for one single use only	
	➤ ISO 15223-1 (Clause 5.4.3) ➤ ISO 7000 (Symbol No. 1641) e-IFU ➤ ISO 15223-1 Annex A / A.15	Consult instructions for use Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use. Note: The e-IFU indicator can be a manufacture's website URL. (Annex A / A.15)	(e-IFU example)  IFUs, Patents & Symbol Glossary http://labeling.zimmerbiomet.com
	➤ ISO 15223-1 (Clause 5.4.4) ➤ ISO 7000 (Reg No. 0434A) ➤ ISO 15223-1 (Clause 5.4.4)	Caution 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 presented on the medical device itself. To indicate that Caution is necessary when operating the device or control close to where the <i>symbol</i> is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	
	➤ IEC 60825-1: 2014	Laser radiation	Warning label serves as a hazard symbol signifying that the device emits laser light	
	➤ IEC 60825-1: 2014	Do not stare into beam	Warning label not to look into the laser beam	
	➤ ISO 15223-1 (Clause 5.6.3) ➤ ISO 7000 (Symbol No. 2724)	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.	

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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	➤ ASTM F2503	Magnetic Resonance (MR) Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	➤ ASTM F2503	Magnetic Resonance (MR) Conditional	A medical device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the MR environment include static magnetic field strength; spatial gradient, time rate of change of the magnetic field (dB/dt), RF fields, and specific absorption rate (SAR). These conditions are identified on all appropriate product labeling.
	➤ ASTM F2503	Magnetic Resonance (MR) Safe	An item which poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic.
	➤ ISO 15223-1 (Clause 5.7.7)	Medical device	Indicates the item is a medical device. <i>On the implant card, this symbol is used to indicate the device name (MDCG 2019-8 v2 Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices).</i>
	➤ ISO 15223-1 (Clause 5.7.10)	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	➤ ISO 15223-1 (Clause 5.7.1) ➤ ISO 7000-2610	Patient number	Indicates a unique number associated with an individual patient. Note : The Hash Mark (#) is part of the symbol.
	➤ ISO 15223-1 (Clause 5.7.2) ➤ ISO 7000 (Symbol No. 3726)	Patient name	Indicates the name of the patient
	➤ ISO 15223-1 (Clause 5.7.3) ➤ ISO 7000 (Symbol No. 5664)	Patient identification	Indicates the identification data of the patient.
	➤ ISO 15223-1 (Clause 5.7.5) ISO 7000 (Symbol No. PI PF 044)	Health care center or doctor	To indicate the address of the healthcare centre or doctor where medical information about the patient may be found.
	➤ ISO 15223-1 (Clause 5.7.6) ➤ ISO 7000 (Symbol No. 5662)	Date	To identify the date that was entered or a medical procedure took place.

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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT	
	➤ ISO 15223-1 (Clause 5.7.4) ➤ ISO 7000 (Reg No. 3705)	Patient information website	Indicates a website where a patient can obtain additional information on the medical product.	
	➤ 21 CFR 801.15(c)(1)(i)F ➤ 21 CFR 801.109	Prescription Only	Caution: Federal law restricts this device to sale by or on the order of a physician. Title: ➤ Labeling-Medical devices; Prominence of required label statements. ➤ Labeling-Prescription Devices	Additional Example: 
	➤ European Medical Device Regulation 2017/745, Article 20	CE	The product conforms to European Medical Device Regulation 2017/745 and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified. Title: ➤ The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	Additional Example: 
	➤ MHRA Guidance: Regulating Medical Devices in the UK	UKCA	The UKCA (UK Conformity Assessed) marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market (England, Wales and Scotland).	Additional example 
	EN ISO 15223-1: 2021 (5.4.9)	Contains biological material of human origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of human origin	

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SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	EN ISO 15223-1: 2021 (5.1.11)	Country of Manufacture	Indicates the country of manufacture via the two-letter country code or the three-letter country code defined in ISO 3166-1.

STANDARD REFERENCE:

- ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- ISO 7000, Graphical symbols for use on equipment
- IEC 60417, Graphical Symbols for Use on Equipment
- ASTM F2503, Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment
- ISO 7010, Graphical symbols – Safety colours and safety signs
- IEC 60617, Graphical symbols for diagrams
- EN 15986, Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates
- IEC 80000-4, Quantities and Units
- ISO 5833, Implants for surgery – Acrylic resin cements

Note: Symbols not present within this symbol glossary are found within the Instruction for Use, defined and translated.

Note: Some symbols may not currently apply to Paragon 28 products or have yet to be adopted in product labeling.



Paragon 28[®], Inc.
14445 Grasslands Dr.
Englewood CO, 80112
+1 (855) 786-2828