Symbol Glossary for Johnson & Johnson Surgical Vision (JJSV) Products

This document specifies symbols used to express information supplied for a medical device. It provides information on the symbol including the standards title, reference, and description, where available. The order of appearance of symbols and the categories in which they are placed are not prioritized.

Please read the full Instructions For Use for detailed information on Directions For Use, indications, contraindications, warnings, precautions and adverse events. This document does not replace the Instructions For Use.

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ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — US FDA Recognized Consensus Standards Recognition Number 5-134

(This document [ISO 15223-1:2021] specifies symbols used to express information supplied for a medical device. This document is applicable to symbols used in a broad spectrum of medical devices, that are available globally and need to meet different regulatory requirements.

These symbols can be used on the medical device itself, on its packaging or in the accompanying information. The requirements of this document are not intended to apply to symbols specified in other standards.)

Image	Accompanying Text	Reference	Description
	*Manufacturer*	5.1.1	Indicates the *medical device manufacturer.* NOTE 3 The date of manufacture, as well as the name and address of the *manufacturer*, can be combined in one *symbol*.
	Authorized representative in the European Community/European Union	5.1.2	Indicates the authorized representative in the European Community/European Union.
	*Date of manufacture*	5.1.3	Indicates the date when the *medical device* was manufactured.
	Use-by date	5.1.4	Indicates the date after which the *medical device* is not to be used.
	*Batch code*	5.1.5	Indicates the *manufacturer's batch code* so that the batch or lot can be identified. NOTE (Synonyms for "*batch code"* are "*lot number",* "lot code" and "*batch number".)*
	*Catalogue number*	5.1.6	Indicates the *manufacturer's catalogue number* so that the medical device can be identified. NOTE (Synonyms for "*catalogue number"* are "reference number" or "reorder number".)
	*Serial number*	5.1.7	Indicates the *manufacturer's serial number* so that a specific *medical device* can be identified.
	*Importer*	5.1.8	Indicates the entity importing the *medical device* into the locale.

Image	Accompanying Text	Reference	Description
	*Distributor*	5.1.9	Indicates the entity distributing the *medical device* into the locale.
	*Model number*	5.1.10	Indicates the *model number* or type number of a product.
	Country of manufacture	5.1.11	To identify the country of manufacture of products. In the application of this symbol, the “CC” has been replaced by either the two-letter country code or the three letter country code defined in ISO 3166-1
	*Sterile*	5.2.1	Indicates a medical device that has been subjected to a sterilization process.
	Sterilized using aseptic processing techniques	5.2.2	Indicates a *medical device* that has been manufactured using accepted aseptic techniques.
	Sterilized using ethylene oxide	5.2.3	Indicates a *medical device* that has been sterilized using ethylene oxide.
	Sterilized using irradiation	5.2.4	Indicates a *medical device* that has been sterilized using irradiation.
	Sterilized using steam or dry heat	5.2.5	Indicates a medical device that has been sterilized using steam or dry heat.
	*Do not resterilize*	5.2.6	Indicates a *medical device* that is not to be re-sterilized.
	Non-*sterile*	5.2.7	Indicates a *medical device* that has not been subjected to a sterilization process.

Image	Accompanying Text	Reference	Description
	Do not use if package is damaged and consult *instructions for use*	5.2.8	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.
	Single *sterile* barrier system	5.2.11	Indicates a single *sterile* barrier system.
	Double *sterile* barrier system	5.2.12	Indicates two *sterile* barrier systems.
	Single *sterile* barrier system with protective packaging inside	5.2.13	Indicates a single *sterile* barrier system with protective packaging inside.
	Single *sterile* barrier system with protective packaging outside	5.2.14	Indicates a single *sterile* barrier system with protective packaging outside.
	Fragile, handle with care	5.3.1	Indicates a *medical device* that can be broken or damaged if not handled carefully.
	Keep away from sunlight	5.3.2	Indicates a *medical device* that needs protection from light sources.
	Keep dry	5.3.4	Indicates a *medical device* that needs to be protected from moisture.
	Lower limit of temperature	5.3.5	Indicates the lower limit of temperature to which the *medical device* can be safely exposed.
	Upper limit of temperature	5.3.6	Indicates the upper limit of temperature to which the *medical device* can be safely exposed.
	Temperature limit	5.3.7	Indicates the temperature limits to which the *medical device* can be safely exposed.

Image	Accompanying Text	Reference	Description
	Humidity limitation	5.3.8	Indicates the range of humidity to which the *medical device* can be safely exposed.
	Atmospheric pressure limitation	5.3.9	Indicates the range of atmospheric pressure to which the *medical device* can be safely exposed.
	Biological *risks*	5.4.1	Indicates that there are potential biological risks associated with the *medical device*.
	*Do not re-use*	5.4.2	Indicates a *medical device* that is intended for one *s i n g l e* use only.
	Consult *instructions for use* or consult electronic *instructions for use*	5.4.3	Indicates the need for the user to consult the *instructions for use*.
	Caution	5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Contains or presence of natural rubber latex	5.4.5	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.
	Contains hazardous substances	5.4.10	Indicates a *medical device* that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.
	*Single patient multiple use*	5.4.12	Indicates a *medical device* that may be used multiple times (multiple procedures) on a single patient.

Image	Accompanying Text	Reference	Description
	Non-pyrogenic	5.6.3	Indicates a *medical device* that is non-pyrogenic.
	Patient identification	5.7.3	Indicates the identification data of the patient.
	Patient information website	5.7.4	Indicates a website where a patient can obtain additional information on the medical product.
	Health care centre or doctor	5.7.5	Indicates the address of the health care centre or doctor where medical information about the patient may be found.
	Date	5.7.6	Indicates the date that information was entered or a medical procedure took place.
	*Medical device*	5.7.7	Indicates the item is a *medical device.*
	Unique device identifier	5.7.10	Indicates a carrier that contains unique device identifier information.

ISO 7000:2019 Graphical symbols for use on equipment — Index and synopsis — US FDA Recognized Consensus Standards Recognition Number 5-124

Image	Accompanying Text	Reference
	Foot-operated	1853
	Variability, rotational adjustment	1364

Image	Accompanying Text	Reference
	Ready (to operate)	1140
	This way up	0623
	Packaging unit Note: A number is inserted in the symbol to indicate the number of pieces in the package	2794
	Dangerous voltage	5036
	Nominal Dimension	0918
	Open here	3079

60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. – US FDA Recognized Consensus Standards Recognition Number 19-36

Image	Accompanying Text	Reference
	Alarm Low	Table D.1, 2
	Alarm Medium	Table D.1, 2

Image	Accompanying Text	Reference
	Refer to instruction manual/booklet for information related to safety	Table D.1, 11; Table D.2, 8
	Equipotentiality	Annex D, 8
	On/Off	Table D.1, 2
	Label, Emergency Stop	Part 2-22, Table D1
	Laser Radiation	IEC 60825-1:2014 Figure 3
	Electrical Hazard /High Voltage	ES60601-1:2005 & A1:2012
	Type B applied part	Table D.1, 19

IEC TR 60878:2015 Graphical symbols for electrical equipment in medical practice — US FDA Recognized Consensus Standards Recognition Number 5-104

Image	Accompanying Text	Reference
	Foot switch	5114
	Non-ionizing electromagnetic radiation	5140

	Fuse	5016

International Electrotechnical Commission (IEC) 60417:2002 — US FDA Recognized Consensus Standards Recognition Number 5-102

Image	Accompanying Text	Reference
	Alternating Current	5032
	Caution, hot surface	5041
	Stand-by or preparatory state for a part of equipment	5266
	Stand-by	5009
	Selection; affirmative acknowledgement; success; ACK	6334A
	"ON" (power)	5007
	"OFF" (power)	5008
	Type BF applied part	5333
	Model number	6050

Image	Accompanying Text	Reference
	Ground label (Protective ground)	5019
	Class II equipment	5172

ISO 7010:2019 Graphical symbols – Safety colors safety signs – Registered safety signs – US FDA Recognized Consensus Standards Recognition Number 5-130

Image	Accompanying Text	Reference
	Refer to instruction manual/booklet	M002
	General warning sign	W001
	Warning; Electricity	W012

Title 21 Code of Federal Regulations Parts 801.109

Image	Accompanying Text
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Image	Accompanying Text
	Separate collection
	Separate collection
	Separate collection

EN 15986:2001 – Symbols for use in the labelling of medical devices — Requirements for labelling of medical devices containing Phthalates

Image	Accompanying Text	Reference
	Contains or presence of phthalate	A.5, Figure A.7
	Contains or presence of phthalate	A.2, Figure A.2

Standard of the Electronics Industry of the People's Republic of China SJ/T 11364-2014

Image	Accompanying Text
	Indicates that the Electrical and Electronic Product (EEP) contains toxic and hazardous substances or elements over the defined maximum concentration values. The names and content of the toxic and hazardous substances or elements shall be provided in the Chinese product instruction manual. The number "10" in the symbol refers to the environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system (People's Republic of China symbol for Restriction of Hazardous Substances (RoHS) in electrical and electronic products).
	Indicates that the Electrical and Electronic Product (EEP) contains toxic and hazardous substances or elements over the defined maximum concentration values. The names and content of the toxic and hazardous substances or elements shall be provided in the Chinese product instruction manual. The number "5" in the symbol refers to the environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system (People's Republic of China symbol for Restriction of Hazardous Substances (RoHS) in electrical and electronic products).
	Indicates that the Electrical and Electronic Product (EEP) contains toxic and hazardous substances or elements over the defined maximum concentration values. The names and content of the toxic and hazardous substances or elements shall be provided in the Chinese product instruction manual. The number "50" in the symbol refers to the environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system (People's Republic of China symbol for Restriction of Hazardous Substances (RoHS) in electrical and electronic products).
	Indicates that the Electrical and Electronic Product (EEP) does not contain toxic and hazardous substances or elements above the maximum concentration values, and that it is an environment-friendly product which can be recycled (People's Republic of China symbol for Restriction of Hazardous Substances (RoHS) in electrical and electronic products).

DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

Image	Accompanying Text	Reference
	Separate collection	Annex II

ISO 7001 — Graphical symbols — Public information symbols

Image	Accompanying Text	Reference	Description
	Information	PI PF 001	To indicate where information is to be obtained.

Occupational Safety and Health Standards CFR 1910.7

Image	Accompanying Text	Reference
	Underwriters Laboratories	29 CFR 1910.7

AS/NZS 4417.1 & 2 Regulatory Compliance Mark (RCM) Australia

Image	Accompanying Text	Reference
	Regulatory Compliance Mark	AS/NZS 4417.1 & 2

COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

Image	Accompanying Text	Reference
	www.e-ifu.com Manufacturer contact details	*Article 6 (3)*

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Image	Accompanying Text	Reference
CE	CE Mark (Conformité Européenne) with notified body number	Chapter II, *Article 14 (a)*

UK Product Conformity Marking

Image	Accompanying Text	Reference
UK CA	UKCA marking	Multi-directive

Ukraine National Symbol of Conformity

Image	Accompanying Text	Reference
	Class I	Decree 1184
 UA.TR.116	Class II, III	Decree 1184

ANSI Z136.1-2014 American National Standard for Safe Use Of Lasers

Image	Accompanying Text	Reference
	Laser Aperture	Control Measures *4.7.2*
	Laser Emission Indicator	Control Measures *4.7.2*
	Laser Emission Indicator	Control Measures *4.7.2*

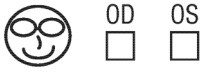
KC – Korea Certification

Image	Accompanying Text
	This device conforms with Korean electrical and electronic appliance safety requirements as well as Electromagnetic Compatibility (EMC) and Radio Frequency (RF) requirements.

FCC – Federal Communications Commission

Image	Accompanying Text
FC	FCC Mark

Additional Symbols

Image	Accompanying Text
 1-10 minutes	1-10 minutes (minimum time: 1 minute | maximum time: 10 minutes)
	IOL implant location (OD - right eye | OS - left eye)
D	Diopter
$\varnothing_T$	Overall diameter
$\varnothing_B$	Body diameter
EC	European Community / European Union
	“Period-After-Opening” Symbol (“Discard Date”) Example: “Discard any remaining solution XX days after opening”.