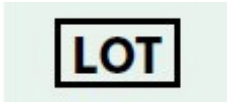
Symbol Glossary

This glossary provides the description of the labelling symbols which are used for Intersurgical products.

Symbol	Description of the symbol	Additional information
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.6. Title: Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified.	In Europe the manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it. This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this document.
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.5. Title: Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.	
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.7. Title: Serial number Indicates the manufacturer's serial number so that a specific device can be identified.	In Europe the manufacturer's serial number shall be placed after or below the symbol and adjacent to it. This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this document.
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.4. Title: Use-by date Indicates the date after which the medical device is not to be used.	In Europe the date could be a year, year and month, or year, month and day, as required by the relevant EU Directive; FDA 21 CFR 801 - the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.4.4. Title: 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.	

Symbol	Description of the symbol	Additional information
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.4.2. Title: 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.	
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.3. Title: Date of manufacture Indicates the date when the medical device was manufactured.	In Europe the date could be a year, year and month, or year, month and day, as required by the relevant EU Directive; FDA 21 CFR 801 - the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.1. Title: Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	This symbol shall be accompanied by the name and address of the manufacturer.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.1.2. Title: Authorised Representative in the European Community Indicates the authorised representative in the European Community.	This symbol shall be accompanied by the name and address of the authorised representative in the European Community, adjacent to the symbol.
	Standard: BS EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates Symbol: Figure 1. Title: Contains or presence of phthalate Meaning: Contains or presence of phthalate.	The type of phthalates is placed adjacent to the symbol. The type of phthalates will be indicated automatically in EFACS and IQR 22.
	Standard: BS EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates Symbol: Figure 1.- Annex B (Negation) Title: Does not contain phthalate Meaning: Does not contain phthalate.	

Symbol	Description of the symbol	Additional information
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.4.5. Title: Contains or 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.	In Europe, this symbol shall be explained in the information, supplied by the manufacturer.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.4.5. Title: Contains or presence of natural rubber latex and Annex B (Negation) Not made with natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	In Europe, this symbol shall be explained in the information, supplied by the manufacturer.
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.2.3. Title: Sterilized using ethylene oxide Indicates a medical device that has been sterilized using ethylene oxide.	
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.2.6. Title: Do not resterilize Indicates a medical device that is not to be resterilized.	
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.2.8. Title: Do not use if package is damaged Indicates a medical device that should not be used if the package has been damaged or opened.	In Europe, this symbol shall be explained in the information, supplied by the manufacturer.

Symbol	Description of the symbol	Additional information
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.2.7. Title: Non-sterile Indicates a medical device that has not been subjected to a sterilization process.	This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.
	Standard: Regulation (EC) No 1272/2008 [CLP] Symbol: GHS07 Toxic cat. 4 Irritant cat. 2 or 3 Warning Lower systematic health hazards Indicates product may cause less serious heath effects or damage ozone layer.	
	Standard: Regulation: (EC) No 1272/2008 [CLP] REF # GHS05 Symbol GHS05 Skin corrosion/irritation, Hazard Category 1A, 1B, 1C Title: Causes severe skin burns and eye damage Indicates product causes severe skin burns and eye damage.	
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.6. Title: Upper limit of temperature Indicates the upper limit of temperature to which the medical device can be safely exposed.	
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.7. Title: Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.	
	Standard: BS EN 62570-2015 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment Symbol: FIG. 5 MR Conditional Icon Geometry, Colour Option MRI conditional –an item with demonstrated safety in the MR environment within defined condition The symbol in BS EN 62570-2015 is identical to IEC 62570:2014 and ASTM F2503.	This can also be black and white.

Symbol	Description of the symbol	Additional information
	Standard: BS EN 62570-2015 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment Symbol: FIG. 3 Black and White Option 1 MR Safe MR safe —an item that poses no known hazards resulting from exposure to any MR environment The symbol in BS EN ISO 62570-2015 is identical to IEC 62570:2014 and ASTM F2503.	This can also be black and white.
	Standard: BS EN 62570-2015 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment Symbol: FIG. 8 MR Unsafe, Colour Option MR Unsafe MR Unsafe—an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment The symbol in BS EN 62570-2015 is identical to IEC 62570:2014 and ASTM F2503.	This can also be black and white.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.2. Title: Keep away from sunlight Indicates a medical device that needs protection from light sources.	
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.1. Title: Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully.	
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.4. Title: Keep dry Indicates a medical device that needs to be protected from moisture.	
	Standard: BS EN ISO 7010:2012 + A6:2016 — Graphical symbols -- Safety colours and safety signs -- Registered safety signs Symbol: W017 Title: Warning, Hot surface This symbol warns of a hot surface.	

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Rx ONLY	21CFR801.109 Caution: federal law restricts this device to sale by or on the order of a physician or a properly licensed practitioner.	
	Standard: IEC 60417 — Graphical Symbols for Use on Equipment Symbol: 5333 Title: Type BF applied part To identify a type BF applied part complying with IEC 60601-1.	
	Standard: ISO 7000 / IEC 60417 Graphical symbols for use on equipment Symbol :5032 Title: Alternating current To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	
	Standard:IEC 60417 — Graphical Symbols for Use on Equipment Symbol 6042, Title: Caution, risk of electric shock Caution, risk of electric shock.	
	(Proposed Symbols For EN ISO 15223-1) Duration of Continuous Use.	In Europe, this symbol shall be explained in the information, supplied by the manufacturer.
	Standard : ISO 7000 — Graphical symbols for use on equipment Symbol :0623 Title: This way up To indicate correct upright position of the transport package.	
	EU WEEE Directive Symbol: SCHEDULE 6,Regulation 22 Title: Crossed out wheeled bin symbol Dispose of according to EU WEEE Directive.	
	Standard : ISO 7000 — Graphical symbols for use on equipment Symbol :1135 Title: General symbol for recovery/ recyclable To indicate that the marked item or its material is part of a recovery or recycling process.	

Symbol	Description of the symbol	Additional information
	Do not open with sharp object.	This symbol shall be explained in the information, supplied by the manufacturer.
	After colour change, dispose as per local regulations.	This symbol shall be explained in the information, supplied by the manufacturer.
	Standard: BS EN ISO 15223-1:2016 Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.4.3. Title: Consult instructions for use Indicates the need for the user to consult the instructions for use.	
	Ingress Protection IP01 rating: Dripping water (vertically falling drops) shall have no harmful effect.	This symbol shall be explained in the information, supplied by the manufacturer.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.9. Title: Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	In Europe, this symbol shall be explained in the information, supplied by the manufacturer.
	Standard: BS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements Symbol: 5.3.8. Title: Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.	In Europe, this symbol shall be explained in the information, supplied by the manufacturer.
	Standard: BS EN ISO 7010:2012 + A6:2016 Graphical symbols -- Safety colours and safety signs -- Registered safety signs Symbol: P002 Title: No smoking Indicates that smoking is prohibited.	This symbol shall be explained in the information, supplied by the manufacturer.

Symbol	Description of the symbol	Additional information
	Standard: BS EN ISO 7010:2012 + A6:2016 Graphical symbols -- Safety colours and safety signs -- Registered safety signs Symbol: P003 Title: No open flame; Fire, open ignition source and smoking prohibited Indicates not having an open flame or open ignition source and not smoking.	This symbol shall be explained in the information, supplied by the manufacturer.
CE	Complies with European Directives.	
CE 0120	CE mark including SGS (notified body) identification number. Product conforms with the essential requirements in the European Medical Devices Directive 93/42/EEC.	
CLASSIFIED C UL US E356141	UL mark indicates compliance with Canadian and US authority safety requirements.	
I	Length	
R_I	Inspiratory limb resistance to flow	
R_E	Expiratory limb resistance to flow	
C	Compliance	

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