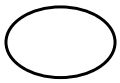
Symbol Glossary

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

Symbol	Description of the symbol	Additional information	Presence
REF	Standard: BS EN ISO 15223-1:2021 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 This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this document.	Individual product label. Product box labelling.
LOT	Standard: BS EN ISO 15223-1:2021 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.		Individual product label. Product box labelling.
SN	Standard: BS EN ISO 15223-1:2021 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 This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this document.	Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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. For use in Europe the full definition of "manufacturer" is given in EU Regulations 2017/745 and 2017/746. Other jurisdictions can have unique definitions.	This symbol shall be accompanied by the name and address of the manufacturer.	Instruction for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.	Individual product label — for sterile devices only. Product box labelling.

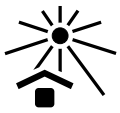
Symbol	Description of the symbol	Additional information	Presence
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.2.3. Title: Sterilized using ethylene oxide. Indicates a medical device that has been sterilized using ethylene oxide.		Instructions for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.2.11. Title: Single sterile barrier system. Indicates a single sterile barrier system.	This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10.	Individual product label
	Standard: BS EN ISO 15223-1:2021 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.		Instructions for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.	Instructions for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Individual product label.
	Standard: BS EN ISO 15223-1:2021 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.		Instructions for use. Individual product label. Product box labelling.

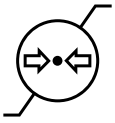
Symbol	Description of the symbol	Additional information	Presence
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.4.12. Title: Single patient multiple use . Indicates a medical device that may be used multiple times (multiple proce-dures) on a single patient.		Instrucions for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Individual and box labelling.
	Standard: BS EN ISO 7010:2012 + A6:2016 Graphical symbols – Safety colours and safety signs – Registered safety signs. Symbol: M002 Title: Refer to instruction manual/booklet – ISO Indicates to refer to instruction manual/booklet.	This symbol shall be explained in the information, supplied by the manufacturer.	Instructions for use. Individual product label.
	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.	Instructions for use. Individual product label.
	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.	Instructions for use. Individual product label. Product box labelling.

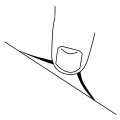
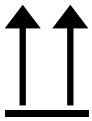
Symbol	Description of the symbol	Additional information	Presence
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.4.5. Title: Contains or presence of natural rubber latex. 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.		Instructions for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Individual product label. Product box labelling.
	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.	Instructions for use. Individual product label. Product box labelling.
	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.		Individual product label. Product box labelling.
	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, Color 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.		Product box labelling.

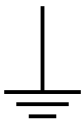
Symbol	Description of the symbol	Additional information	Presence
	Standard: BS EN 62570-2015 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment. Symbol: FIG. 5 MR Conditional Icon Geometry, Color Option. MRI conditional – an item with demonstrated 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.	Instructions for use. Individual product label. Product box labelling.
	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.	Instructions for use.
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.		Instructions for use. Individual product label. Product box labelling.
	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.		Individual product label. Product box labelling.
	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.		Instructions for use. Individual product label. Product box labelling.
	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.		Instructions for use. Individual product label. Product box labelling.
	Standard: IEC 60417 — Graphical Symbols for Use on Equipment. Symbol 6042, Title: Caution, risk of electric shock. Caution, risk of electric shock.		Instructions for use. Individual product label. Product box labelling.

Symbol	Description of the symbol	Additional information	Presence
	After colour change, dispose as per local regulations	This symbol shall be explained in the information, supplied by the manufacturer.	Individual product label. Product box labelling.
	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.		Individual product label. Product box labelling.
	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.		Individual product label. Product box labelling.
 **IPX1**	Ingress Protection. IP01 rating: Dripping water (vertically falling drops) shall have no harmfull effect.	This symbol shall be explained in the information, supplied by the manufacturer.	Individual product label. Product box labelling.
EC REP	Standard: BS EN ISO 15223-1:2021 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.	Instructions for use. Individual product label. Product box labelling.
CH REP	Indicates the Authorised Representative in Switzerland.	Authorised representative in Switzerland (Art. 4 para. 1 let. g MedDO, Art. 4 para. 1 let. f IvDO) Natural or legal person in Switzerland who receives and accepts a written mandate from a manufacturer located in another country, to act on the manufacturer's behalf in relation to specified tasks in accordance with MedDO.	Applicable for: ▪ EU MDR device – on label ▪ EU MDD devices – on the label or in the instructions for use or in a document accompanying the device
	Standard: BS EN ISO 15223-1:2021 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.	Individual product label. Product box labelling.

Symbol	Description of the symbol	Additional information	Presence
CE	EU Conformity mark. Applicable for products which doesn't require the involvement of EU Notified Body in conformity assessment procedure.		Instructions for use. Individual product label. Product box labelling.
CE 1639	EU Conformity mark with identification number of EU Notified Body (SGS Belgium). Applicable for products which require the involvement of EU Notified Body in conformity assessment procedure.		Instructions for use. Individual product label. Product box labelling.
CE 1936	EU Conformity mark with identification number of EU Notified Body (TÜV Rheinland Italia). Applicable for products which require the involvement of EU Notified Body (TÜV Rheinland Italia) in conformity assessment procedure.		Instructions for use. Individual product label. Product box labelling.
CE 0598	EU Conformity mark with identification number of EU Notified Body (SGS Fimko,). Applicable for products which require the involvement of EU Notified Body (SGS Fimko) in conformity assessment procedure.		Instructions for use. Individual product label. Product box labelling.
UK CA	UK Conformity mark. Applicable for products which doesn't require the involvement of UK Approved Body in conformity assessment procedure.		Instructions for use. Individual product label. Product box labelling.
UK CA 0120	UK Conformity mark with identification number of UK Approved Body (SGS UK). Applicable for products which require the involvement of UK Approved Body in conformity assessment procedure.		Instructions for use. Individual product label. Product box labelling.
CLASSIFIED C UL US E358141	UL mark indicates compliance with Canadian and US authority safety requirements.		Instructions for use. Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Product box labelling.

Symbol	Description of the symbol	Additional information	Presence
	Standard: BS EN ISO 15223-1:2021 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.		Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.	Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.	Product box labelling.
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.7.7. Title: Medical device. This symbol indicated a product intended by the manufacturer to be used for human beings for specific medical purposes, such as diagnosis, prevention, monitoring, treatment or alleviation of disease.		Individual product label. Product box labelling.
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.1.8. Title: Importer. Indicates the entity importing themedical device into the locale.	This symbol shall be accompanied by the name and address of the importing entityadjacent to thesymbol. NOTE If multiple symbols (i.e. Authorized Representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	Instructions for use. Individual product label. Product box labelling.

Symbol	Description of the symbol	Additional information	Presence
	Standard: BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. Symbol: 5.1.9. Title: Distributor. Indicates the entity distributing the medical device into the locale.	This symbol shall be accompanied by the name and address of the importing entityadjacent to thesymbol. NOTE If multiple symbols (i.e. Authorized representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	Instructions for use. Individual product label. Product box labelling.
I	Length.		Individual product label. Product box labelling.
R	Resistance to flow.		Individual product label. Product box labelling.
R_I	Inspiratory limb resistance to flow.		Individual product label. Product box labelling.
R_E	Expiratory limb resistance to flow.		Individual product label. Product box labelling.
C	Compliance.		Individual product label. Product box labelling.
	Peel off.		Individual labelling.
	Do not open with sharp object.	This symbol shall be explained in the information, supplied by the manufacturer.	Product box labelling.
	Standard: BS EN ISO 15223-1:2021 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.		Product box labelling.
	Standard: ISO 7000 — Graphical symbols for use on equipment. Symbol: 0623 Title: This way up. To indicate correct upright position of the transport package.		Product box labelling.
	EU WEEE Directive. Symbol: SCHEDULE 6, Regulation 22 Title: Crossed out wheeled bin symbol. Dispose of according to EU WEEE Directive.		Product box labelling.

Symbol	Description of the symbol	Additional information	Presence
	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.		Instructions for use. Product box labelling.
	Standard: IEC 60417. Symbol: 5017 Title: Earth; ground. To identify an earth (ground) terminal in cases where neither the symbol 5018 nor 5019 is explicitly required.		Instructions for use. Individual product label. Product box labelling.
	Standard: IEC 60417. Symbol: 5041 Title: Caution, hot surface. To indicate that the marked item can be hot and should not be touched without taking care. Notes: 1. The inner symbol is standardized in ISO 7000-0535 “Transfer of heat, general”. 2. Warning signs are standardized in ISO 3864.		Instructions for use. Individual product label. Product box labelling.
	Standard: IEC 60417. Symbol: 5172 Title: Class II equipment. To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.		Instructions for use. Individual product label. Product box labelling.
	Standard: IEC 60417. Symbol: 5333 Title: Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.		Instructions for use. Individual product label. Product box labelling.
	Standard: IEC 60417. Symbol: 6042 Title: Caution, risk of electric shock. To identify a type BF applied part complying with IEC 60601-1. Notes: 1. ISO 3864-1 provides the rules for the application of this symbol as a safety sign. 2. ISO 7010-W012: “Warning; Electricity” is a related safety sign.		Instructions for use. Individual product label. Product box labelling.

INTERSURGICAL® COMPLETE RESPIRATORY SYSTEMS

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