
























SYMBOL GLOSSARY

| Symbol | Title | Standard | Ref No. | Description |
|---|---|--|---------|---|
|  | Do not re-use | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.4.2 | Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. |
|  | Consult instructions for use | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.4.3 | Indicates the need for the user to consult the instructions for use. |
|  | Caution | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.4.4 | 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. |
|  | Keep away from sunlight Note: This symbol can also mean "Keep away from heat," as referenced in ISO 7000:1989. | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.3.2 | Indicates a medical device that needs protection from light sources. |
|  | Keep dry | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.3.4 | Indicates a medical device that needs to be protected from moisture |
|  | Sterile | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.2.1 | Indicates a medical device that has been subjected to a sterilization process. |
|  | Sterilized using irradiation | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.2.4 | Indicates a medical device that has been sterilized using irradiation. |
|  | Sterilized using Ethylene Oxide | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.2.3 | Indicates a medical device that has been sterilized using ethylene oxide. |
|  | Sterilized using aseptic processing techniques | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.2.2 | Indicates a medical device that has been manufactured using accepted aseptic techniques. |
|  | Date of manufacture | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.1.3 | Indicates the date when the medical device was manufactured. |
|  | Manufacturer | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.1.1 | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. |
|  | Use-by date | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.1.4 | Indicates the date after which the medical device is not to be used. |
|  | Batch code | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.1.5 | Indicates the manufacturer's batch code so that the lot can be identified. |
|  | Fragile, handle with care | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.3.1 | Indicates a medical device that can be broken or damaged if not handled carefully. |
|  | Non-sterile | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.2.7 | Indicates a medical device that has not been subjected to a sterilization process. |
|  | Do not re-sterilize | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.2.6 | Indicates a medical device that is not to be re-sterilized. |
|  | Serial number | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.1.7 | Indicates the manufacturer's serial number so that a specific medical device can be identified. |
|  | Catalogue number | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.1.6 | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
|  | Do not use if package is damaged | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.2.8 | Indicates a medical device that should not be used if the package has been damaged or opened. This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised". |

SYMBOL GLOSSARY

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|  | Temperature limit | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. | 5.3.7 | Indicates the temperature limits to which the medical device can be safely exposed. |
|  | Prescription use only | N/A | N/A | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician, dentist, or licensed practitioner. |
|  | Type BF applied part | IEC 60417 Graphical symbols for use on equipment. | 5333 | To identify a type BF applied part complying with IEC 60601-1. |
|  | MR Conditional | ASTM F2503-13; Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment | N/A | An item with demonstrated safety in the MR environment within defined conditions. The conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields are addressed. |

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