

Symbols Glossary for Synthes






This document contains symbols that may appear on the product packaging or labeling. It provides information on the symbol including the standards title, reference, and description, where available. This document does not contain company created symbols, pictograms, or graphical images.







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






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ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

| Image | Accompanying Text | Reference | Description |
|---|------------------------------|-----------|---|
|  | Catalogue Number | 5.1.6 | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
|  | Batch code | 5.1.5 | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | Caution | 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. |
|  | Consult Instructions for Use | 5.4.3 | Indicates the need for the user to consult the instructions for use. |
|  | Manufacturer | 5.1.1 | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. NOTE 5 The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. |


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|---|--|-------|--|
|  | Use-by date | 5.1.4 | Indicates the date after which the medical device is not to be used. |
|  | Do not re-use | 5.4.2 | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
|  | 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. |

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|---|----------------------------------|-------|---|
|  | Non-sterile | 5.2.7 | Indicates a medical device that has not been subjected to a sterilization process. |
|  | 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. |
|  | Do not use if package is damaged | 5.2.8 | Indicates a medical device that should not be used if the package has been damaged or opened. |

ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

| Image | Accompanying Text | Reference |
|--|-------------------|-------------------|
|  | MR Conditional | Table 2, Figure 6 |
|  | MR Safe | Table 2, Figure 4 |
|  | MR Unsafe | Table 2, Figure 9 |

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. |