


















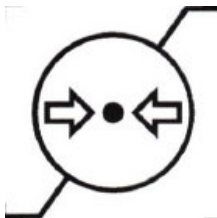

# Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
21 CFR 801.109		N/A	<b>Prescription device</b>	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
ISO 15223-1:2021		5.1.1	<b>Manufacturer</b>	Indicates the medical device manufacturer as defined in applicable medical device regulations
ISO 15223-1:2021 21 CFR Part 801.18 (applies to date format)		5.1.3	<b>Date of manufacture</b>	Indicates the date when the medical device was manufactured.
ISO 15223-1:2021 21 CFR Part 801.18 (applies to date format)		5.1.4	<b>Use-by date</b>	Indicates the date after which the medical device is not to be used.
ISO 15223-1:2021		5.1.5	<b>Batch code</b>	Indicates the manufacturer's batch code so that the batch or lot can be identified.
ISO 15223-1:2021		5.1.6	<b>Catalogue Number</b>	Indicates the manufacturer's catalogue number so that the medical device can be identified.
ISO 15223-1:2021		5.1.7	<b>Serial number</b>	Indicates the manufacturer's serial number so that a specific medical device can be identified







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ISO 15223-1:2021		5.1.8	<b>Importer</b>	Indicates the entity importing the <i>medical device</i> into the locale.
ISO 15223-1:2021		5.2.1	<b>Sterile</b>	Indicates a medical device that has been subjected to a sterilization process.
ISO 15223-1:2021		5.2.3	<b>Sterilized using Ethylene Oxide</b>	Indicates a medical device that has been sterilized using Ethylene Oxide.
ISO 15223-1:2021		5.2.4	<b>Sterilized using irradiation</b>	Indicates a medical device that has been sterilized using irradiation.
ISO 15223-1:2021		5.2.7	<b>Non-sterile</b>	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.
ISO 15223-1:2021		5.2.8	<b>Do not use if package is damaged</b>	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.
ISO-15223-1:2021		5.3.1	<b>Fragile, handle with care</b>	Indicates a medical device that can be broken or damaged if not handled carefully.



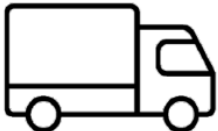

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Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
ISO-15223-1:2021		5.3.4	<b>Keep dry</b>	Indicates a medical device that needs to be protected from moisture.
ISO-15223-1:2021		5.3.7	<b>Temperature limit</b>	Indicates the temperature limits to which the medical device can be safely exposed.
ISO 15223-1:2021		5.3.8	<b>Humidity limitation</b>	Indicates the range of humidity to which the medical device can be safely exposed.
ISO 15223-1:2021		5.3.9	<b>Atmospheric pressure limitation</b>	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
ISO 15223-1:2021		5.4.2	<b>Do not re-use</b>	Indicates a medical device that is intended for one single use only.


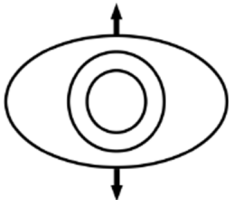
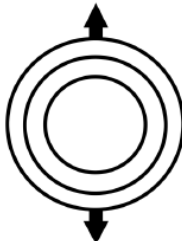
## Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
ISO 15223-1:2021		5.4.3	<b>Consult instructions for use</b>	Indicates the need for the user to consult the instructions for use.
ISO 15223-1:2021		5.4.4	<b>Caution</b>	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.
ISO 15223-1:2021		5.4.5	<b>Does not Contain natural rubber latex</b>	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.
ASTM F2503-23		N/A	<b>Magnetic Resonance (MR) Unsafe</b>	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
47 CFR Part 15		N/A	<b>Federal Communications Commission</b>	Meets FCC requirements per 47 CFR Part 15.
IEC 60417:2025		6414	<b>Waste electrical and electronic equipment</b>	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.

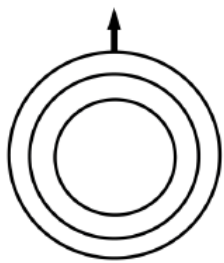
## Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
N/A		N/A	<b>This way up</b>	Instructs handlers to keep the package oriented with the arrows pointing upwards to prevent damage to contents.
N/A		N/A	<b>Storage facility</b>	Denotes storage facility, accompanied by environmental conditions to be maintained.
N/A		N/A	<b>Transportation</b>	Denotes transportation, accompanied by temporary environmental conditions during transportation.
N/A		N/A	<b>LIF NAV Primary Dilator stimulating, sterile</b>	Custom Alphatec Logo. Depicts LIF NAV Primary Dilator Stimulating, Sterile

## Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
N/A		N/A	<b>NAV Initial Dilator, Delta, Sterile</b>	Custom Alphatec logo. Depicts NAV Initial Dilator, Delta, Sterile
N/A		N/A	<b>SafeOp 3 Delta Dilator Kit, Sterile - Oval</b>	Custom Alphatec logo. Depicts SafeOp 3 Delta Dilator Kit, Sterile - Oval
N/A		N/A	<b>SafeOp 3 Delta Dilator Kit, Sterile - Circle</b>	Custom Alphatec logo. Depicts SafeOp 3 Delta Dilator Kit, Sterile - Circle

## Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
N/A	 The symbol consists of three concentric circles. A small upward-pointing arrow is positioned at the top center of the outermost circle.	N/A	<b>SafeOp 3 Insulated Dilator Kit, Sterile – Circle</b>	Custom Alphatec logo. Depicts SafeOp 3 Insulated Dilator Kit, Sterile – Circle.

\* Standard title and reference number (FDA recognition):

5-134: ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

8-602: ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment