












Labeling Symbols Glossary




 **Manufacturer:**
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Rx ONLY

Caution: Federal Law restricts this device to sale by or on the order of a physician.

The following is an explanation of symbols that may be used on Caldera Medical's product packaging:

Symbol	Title/ Meaning/ Referent	Function/ Description	ISO 7000 Reg. no.	ISO 15223-1 or Other
Manufacture				
	Manufacturer	Indicates the medical device manufacturer.	3082	5.1.1
	EU Authorized Representative	Indicates the authorized representative in the European community.	N/A	5.1.2
	Date of Manufacture	Indicates the date when the medical device was manufactured.	2497	5.1.3
	Use by Date	Indicates the date after which the medical device is not to be used.	2607	5.1.4
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	2492	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	2493	5.1.6
Sterility				
	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	2501	5.2.3
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	2608	5.2.6
	Do Not Use If Package Is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	2606	5.2.8
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	2609	5.2.7
Storage				
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	0626	5.3.4
Safe Use				
	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.	1051	5.4.2
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	1641	5.4.3
	Consult Instructions for Use, or For Instructions for Use Refer to	Indicates the need for the user to consult the instructions for use and where the electronic instructions for use (eIFU) and symbols glossary can be found.	1641	5.4.3
	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.	0434A	5.4.4

Symbol	Title/ Meaning/ Referent	Function/ Description	ISO 7000 Reg. no.	ISO 15223-1 or Other
Other				
	Packaging Unit	Indicates the number of pieces in the package.	2794	N/A
R ONLY	Prescription Only	Requires prescription in the United States of America.	N/A	21 CFR 801.109
	CE Marking of Conformity	Signifies European technical conformity – Class I (sterile, measuring), IIa, IIb, III devices	N/A	93/42/EE C, Annex XII
	CE Marking of Conformity	Signifies European technical conformity – Class I (non-sterile, non-measuring)	N/A	93/42/EE C, Annex XII

The most current version of the Labeling Symbols Glossary is available for viewing or download here:
www.calderamedical.com/medical-professionals/product-instructions-for-use

All Caldera Medical Instruction for Use (IFU) documents are available in print form at no additional cost upon request. If you would like to request a copy please contact us at 818.879.6555, fax 818.879.6556, or email info@calderamedical.com.

To learn more about our products, please contact Caldera Medical at 818.879.6555 or visit our website at www.calderamedical.com.