













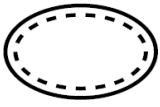







JENAVALVE

Symbols Glossary









Symbols Derived from References

Symbol	Reference	Reference Title	JenaValve Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Catalog number	Indicates the manufacturer's catalogue number so a specific medical device can be identified.
	ISO 15223-1, Reference 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so a specific medical device can be identified.
	ISO 15223-1, Reference 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so the batch or lot can be identified.
	ISO 15223-1, Reference 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Reference 5.1.11	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Country of manufacture/Country of Origin	To identify the country of manufacture of the products
	ISO 15223-1, Reference 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1, Reference 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Reference 5.7.10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Unique device identifier	Indicates a carrier that contains unique device identifier information
	ISO 15223-1, Reference 5.2.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Device is supplied sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 15223-1, Reference 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.








Symbols Derived from References

Symbol	Reference	Reference Title	JenaValve Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.2.14	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside
	ISO 15223-1, Reference 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Do not re-use	Indicates a medical device that is intended for one single use only
	ISO 15223-1, Reference 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Do not resterilize	Indicates a medical device that is not to be resterilized.
 www.eifu.jenavalve.com	ISO 15223-1, Reference 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Consult electronic instructions for use www.eifu.jenavalve.com	Indicates the need for the user to consult the electronic instructions for use (eIFU) at the specified website location.
	ISO 15223-1, Reference 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Consult instructions for use	Indicates the need for the user to consult the instructions for use (IFU)
	ISO 15223-1, Reference 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Caution, see instructions for use	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, Reference 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Temperature limitation	Indicates the upper and lower temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.3.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Keep away from sunlight	Indicates a medical device that needs protection from light sources.

Symbols Derived from References

Symbol	Reference	Reference Title	JenaValve Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Keep Dry	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1, Reference 5.4.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Device contains tissue of animal origin	Indicates a medical device that contains biological tissue cells or their derivatives, of animal origin
	ISO 15223-1, Reference 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Do not use if package or seal is damaged	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, Reference 5.7.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Medical device	Indicates that the item is a medical device.
	ISO 15223-1, Reference 5.1.2	Authorized representative in the European Community	European Authorized Representative	This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
	ASTM F2503 - 23 & FDA Guidance for Industry issued October 10, 2023	Nonbinding Recommendations Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment	MR Conditional	Conditions under which a medical device can safely enter the MR environment as described in ASTM F2503
	ASTM F2503 - 23 & FDA Guidance for Industry issued October 10, 2023	Nonbinding Recommendations Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment	MR Conditional	Conditions under which a medical device can safely enter the MR environment as described in ASTM F2503
	21 CFR 801.109	Labeling; Prescription devices	Prescription device only/for prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

Symbols Not Derived from References

Symbol	Symbol Title	Explanatory Text
	Sterilized using liquid chemical sterilants	Indicates a medical device that has been sterilized using liquid chemical sterilants
	Quantity per box	Number of parts in box
	Length	Length
	Valve diameter and system size	Valve diameter and system size
	CE Mark	CE Mark is Conformité Européenne (FR) or European Conformity. Indicates that the device fully complies with applicable European Union Acts.
	Code	Following this symbol is an access code to view or download related eIFU from the provided website
	Swiss Authorized Representative	Swiss Authorized Representative