










SYMBOLS GLOSSARY

Control #: SMI-420- 100 Rev. A











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Symbol	Symbol Title	Standard Reference	Explanatory Text
	MANUFACTURER	ISO 15223-1:2012* Reference Number 5.1.1	Indicates the medical device manufacturer.
	DATE OF MANUFACTURE	ISO 15223-1:2012* Reference Number 5.1.3	Indicates the date when the medical device was manufactured.
	USE BY	ISO 15223-1:2012* Reference Number 5.1.4	Indicates the date after which the medical device is not to be used.
	BATCH CODE	ISO 15223-1:2012* Reference Number 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	CATALOGUE NUMBER	ISO 15223-1:2012* Reference Number 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	STERILIZED USING ETHYLENE OXIDE	ISO 15223-1:2012* Reference Number 5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
	DO NOT RESTERILIZE	ISO 15223-1:2012* Reference Number 5.2.6	Indicates a medical device that is not to be resterilized.
	NON-STERILE-	ISO 15223-1:2012* Reference Number 5.2.7	Indicates a medical device that has not been subjected to a sterilization process.
	DO NOT USE IF PACKAGE IS DAMAGED	ISO 15223-1:2012* Reference Number 5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.

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Symbol	Symbol Title	Standard Reference	Explanatory Text
	TEMPERATURE LIMIT	ISO 15223-1:2012* Reference Number 5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	HUMIDITY LIMITATION	ISO 15223-1:2012* Reference Number 5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.
	DO NOT REUSE	ISO 15223-1:2012* Reference Number 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 15223-1:2012* Reference Number 5.4.3	Indicates the need for the user to consult the instructions for use.
	CAUTION	ISO 15223-1:2012* Reference Number 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.
	CONTAINS OR PRESENCE OF NATURAL RUBBER LATEX	ISO 15223-1:2012* Reference Number 5.4.5	Indicates the presence of natural rubber or dry natural latex as a material of construction within the medical device or the packaging of a medical device.
	MR CONDITIONAL	ASTM F2503-13** Table 2, Figure 6	An item with demonstrated safety in the magnetic resonance environment within defined conditions.
	CONTAINS OR PRESENCE OF PHTHALATE	BS EN 15986:2011*** Reference Number A.5	Indicates the presence of di (2-ethylhexyl phthalate (DEHP), and/or benzyl butyl phthalate (BBP), and/or dibutyl phthalate (DBP).
<p>*ISO 15223-1:2012 Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied. ** ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment ***BS EN 15986:2016 Symbol for use in the labeling of medical devices. Requirements for labeling of medical devices containing</p>			

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Symbols Not from Standards

Symbol	Symbol Title	Reference	Explanatory Text
Rx only	PRESCRIPTION ONLY	21 CFR Part 801.109 and FDA Guidance for Industry: Alternative to Certain Prescription Device Labeling Requirements	Caution: Federal Law Restricts This Device to Sale by Or on The Order of a Licensed Healthcare Practitioner.
	QUANTITY	NOT APPLICABLE	This symbol followed by a numerical value indicates the quantity of medical devices contained in the package.
	NOT MADE WITH NATURAL RUBBER LATEX	NOT APPLICABLE	Indicates the medical device is not made with natural rubber latex.
	RECYCLE	NOT APPLICABLE	Indicates medical device may be saved for reprocessing.
	ORIGINAL EQUIPMENT MANUFACTURER'S CATALOGUE NUMBER	NOT APPLICABLE	Indicates the original manufacturer's catalogue number so that the medical device can be identified.
	DO NOT FOLD	NOT APPLICABLE	Indicates the medical device should not be folded.
	DO NOT ROLL	NOT APPLICABLE	Indicates the device should not be rolled.
	HOSPITAL ID	NOT APPLICABLE	Indicates the hospital identification number.