INVUITY®

Symbols Glossary			
Standard: ISO 15223-1, Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements			
Symbol	**Title of Symbol**	**Description of Symbol**	**Standard/Symbol Reference Number**
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4
	Lot number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Do not reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure	5.4.2
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized	5.2.6
	Attention, see instructions for use	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	5.4.4
	Do not use if packaging is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Sterile (ethylene oxide)	Indicates a medical device was subjected to a sterilization process with ethylene oxide.	5.2.3
	Nonpyrogenic	Indicates a medical device that is non-pyrogenic	5.6.3
	Consult Instructions for Use and Symbols Glossary on this website: www.invuity.com/documentlibrary	Indicates the need for the user to consult the instructions for use.	5.4.3
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7
	Product is not made with natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging	5.4.5 and Annex B (Section B2)

Symbols not from Standard: ISO 15223-1			
Symbol	**Title of Symbol**	**Description of Symbol**	**Standard/Symbol Reference Number**
	Unit produces non-ionizing radiation	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests	IEC 60601-1-2:2007, Clause 5.1.1
	Quantity	Indicates quantity of medical devices contained within the packaging	N/A
	Prescription Device	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109)	21 CFR 801.109
	CE Marking of Conformity	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation	European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC) as described in Article 17 of the Directive