



TITAN STAPLER INSTRUCTIONS FOR USE

SYMBOLS

Symbol	Definition	Reference Standard/ Requirement
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801, Section 109
	Medical Device	ISO 15223-1, Reference # 5.7.7
	Refer to Instruction Manual	IEC 60601 Edition 3.1 2012-08, Table D.2, No. 10
	Consult Instructions for Use	ISO 15223-1, Reference # 5.4.3
	Caution, consult accompanying documents	ISO 15223-1, Reference # 5.4.4
	Manufacturer	ISO 15223-1, Reference # 5.1.1
	Distributor	ISO 15223-1, Reference # 5.1.9
	Catalogue Number	ISO 15223-1, Reference # 5.1.6 21 CFR 820.120
	Lot Number	ISO 15223-1, Reference # 5.1.5 21 CFR 820.65
	Do not re-sterilize	ISO 15223-1, Reference # 5.2.6
	Sterilized using gamma irradiation	ISO 15223-1, Reference # 5.2.4
	Do not re-use	ISO 15223-1, Reference # 5.4.2
	Not made with natural rubber latex	N/A
	Use by Date	ISO 15223-1, Reference # 5.1.4 21 CFR 801.18

Symbol	Definition	Reference Standard/ Requirement
	Date of Manufacture	ISO 15223-1, Reference # 5.1.3
	Applied Part Type B (TITAN SGS23R, Stapling End Effector and Shaft)	IEC 60601 Edition 3.1 2012-08, Table D.1, No. 19
	Magnetic Resonance (MR) Conditional	ASTM F2503-13
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Follow decontamination instructions before returning waste.	Article 11(2) of Directive 2002/96/EC
	Do not use if the package is damaged	ISO 15223-1, Reference # 5.2.8
	Keep Dry	ISO 15223-1, Reference # 5.3.4
	Storage Temperature Limitations: Upper Limit: 27°C (80°F) Lower Limit: 15°C (59°F)	ISO 15223-1, Reference # 5.3.7
	Storage Humidity Limitation: 15 – 90% Relative Humidity (RH)	ISO 15223-1, Reference # 5.3.8
Standards: Code of Federal Regulations (CFR) Title 21, Part 801 – Labeling Code of Federal Regulations (CFR) Title 21, Part 820 – Quality System Regulation ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied		


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