

SYMBOL GLOSSARY

American Orthodontics utilizes symbols that are in conformance to EN 980 as listed in the European Harmonized Standards list; ISO 15223-1 and ISO 7010 as listed in the US FDA's Consensus Standards. Other symbols deemed necessary, but not on the harmonized/consensus list are also found below. Symbols will appear on packaging/labeling and instructions for use where applicable.

	Manufacturer FDA Consensus Standard ISO 15223-1 REF # 5.1.1 EU Harmonized Standard BS EN 980 REF # 5.12 Indicates the medical device manufacturer, as defined in EU Directives 90/385-EEC, 93/42/EEC and 98/79/EC.		Use By Date FDA Consensus Standard ISO 15223-1 REF # 5.1.4 EU Harmonized Standard BS EN 980 REF # 5.3 Indicates the date after which the medical device is not to be used		Non-Sterile FDA Consensus Standard ISO 15223-1 REF # 5.2.7 EU Harmonized Standard BS EN 980 REF # 5.23 Indicates a medical device that has not been subjected to a sterilization process		Warning IEC No 1272/2008 (CLP) REF # GHS07 Toxic cat. 4 Irritant cat. 2 or 3 Lower systematic health hazards Indicates product may cause less serious health effects or damage ozone layer
	Authorized Representative in the European Community FDA Consensus Standard ISO 15223-1 REF # 5.1.2 EU Harmonized Standard BS EN 980 REF # 5.13 Indicates the Authorized representative in the European Community		Do Not Re-use FDA Consensus Standard ISO 15223-1 REF # 5.4.2 EU Harmonized Standard BS EN 980 REF # 5.2 Indicates a medical device that is intended for one use, or for use on a single-patient during a single procedure		Contains or Presence of Natural Rubber Latex FDA Consensus Standard ISO 15223-1 REF # 5.4.5 EU Harmonized Standard BS EN 980 REF # 6.2 Indicates the presence of natural rubber latex or dry natural rubber latex as a material of construction within the medical device or the packaging of the medical device		Nickel-Chromium Warning 21CFR801.109(c) Indicates product contains Nickel and/or Chromium. Patients with an identified allergy to these metals should not use this product
	CE Marking Complies with European Directives		Caution FDA Consensus Standard ISO 15223-1 REF # 5.4.4 EU Harmonized Standard BS EN 980 REF # 5.11 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		Not made with Natural Rubber 21CFR801.437(d) Product is not made with or contains natural rubber latex		Magnetic Field ISO 3864-1 REF # LB0095 Indicates interaction with metallic objects may produce Pinch Hazards
0843	EU Notified Body Number Complies with European directives		Keep away from sunlight FDA Consensus Standard ISO 15223-1 REF # 5.3.2 EU Harmonized Standard BS EN 980 REF # 5.20 Indicates a medical device that needs protection from light sources	Statement "Caution: Federal Law restricts this device to sale to or on the order of a dentist/orthodontist" 21CFR801.109(b)			No Pacemakers FDA Consensus Standard ISO 7010 REF # P007 Indicates product can be harmful to pacemaker wearers
	Catalogue Number FDA Consensus Standard ISO 15223-1 REF # 5.1.6 EU Harmonized Standard BS EN 980 REF # 5.1 Indicates the manufacturer's catalogue number so that the medical device can be identified		Temperature Limit FDA Consensus Standard ISO 15223-1 REF # 5.3.7 EU Harmonized Standard BS EN 980 REF # 5.17.3 Indicates the temperature limits to which the medical device can be safely exposed	Danger or Warning IEC No 1272/2008 (CLP) REF # GHS05 Corrosive cat. 1 Indicates product may cause corrosive damage to metals, as well as skin, eyes			Health Hazard GHS08 WHMIS 2015 Indicates product may cause or suspected of causing serious health effects
	Batch Code FDA Consensus Standard ISO 15223-1 REF # 5.1.4 EU Harmonized Standard BS EN 980 REF # 5.4 Indicates the manufacturer's batch code so that the batch or lot can be identified		Humidity Limitation FDA Consensus Standard ISO 15223-1 REF # 5.3.8 Indicates the range of humidity to which the medical device can be safely exposed	Danger IEC No 1272/2008 (CLP) REF # GHS06 Toxic cat. 1-3 Indicates product can cause death or toxicity with short exposure to small amounts			Not Sterilized Indicates product is not sterilized by the manufacturer
	Serial Number FDA Consensus Standard ISO 15223-1 REF # 5.1.7 EU Harmonized Standard BS EN 980 REF # 5.5 Indicates the manufacturer's serial number so that a specific medical device can be identified		Consult Instructions for Use FDA Consensus Standard ISO 15223-1 REF # 5.4.3 EU Harmonized Standard BS EN 980 REF # 5.18 Indicates the need for the user to consult the instructions for use - see www.americanortho.com	Danger or Warning IEC No 1272/2008 (CLP) REF # GHS02 Flammable Indicates fire hazard			
	Quantity Indicates the amount of product included						