SYMBOL GLOSSARY

American Orthodontics utilizes symbols that are in conformance to ISO 15223-1 Medical Devices - Symbols to be Used With Information to be Supplied by the Manufacturer - Part 1: General Requirements, and ISO 7010 Graphical Symbols - Safety Colours and Safety Signs - Registered Safety Signs. Other symbols deemed necessary, but not on the harmonized/ consensus lists are also found below. Symbols will appear on packaging/labeling and instructions for use where applicable.

	Manufacturer - Indicates the medical device manufacturer.		**Caution** Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	LATEX	**Contains or Presence of Natural Rubber Latex** Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
EC REP	**Authorized Representative in the European Community -** Indicates the authorized representative in the European Community / European Union		**Keep away from sunlight** Indicates a medical device that needs protection from light sources.		**Magnetic Field** Indicates interaction with metallic objects may produce Pinch Hazards.
CE	**CE Marking -** Medical Device Regulation (EU) 2017/745 Indicates that a product has been assessed and deemed to meet EU safety, health, and environmental protection requirements.	°C °C	**Temperature Limit** Indicates the temperature limits to which the medical device can be safely exposed.		**Pacemaker** Indicates product can be harmful to pacemaker wearers.
2797	**Notified Body Number** - Medical Device Regulation EU 2017/745		**Humidity Limitation** Indicates the range of humidity to which the medical device can be safely exposed.	STERILE	**Not Sterilized** Indicates product is not sterilized by the manufacturer
QTY	**Quantity**		**Consult Instructions for Use** Indicates the need for the user to consult the instructions for use.		**Date of Manufacture** Indicates the date when the medical device was manufactured.
REF	**Catalogue Number** Indicates the manufacturer's catalogue number so that the medical device can be identified.	LATEX	**Product is not made with Natural Rubber Latex**	MD	**Medical Device** Indicates that the product is a medical device
LOT	**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified	Rx Only	**Rx Only** 21 CFR801.109(b)(1) Caution: Federal law restricts this device to sale to or on the order of a dentist/ orthodontist		**Distributor** Indicates the entity distributing the medical device into the locale.
	Use By Date Indicates the date after which the medical device is not to be used.	Cr Ni	**Nickel-Chromium Warning** Indicates product contains Nickel and/or Chromium. Patients with an identified allergy to these metals should not use this product.		**Keep Dry** Indicates a medical device that needs to be protected from moisture.
UDI	**Unique Device Identifier** Indicates a carrier that contains unique device identifier information.	Cr Co Ni	**Chromium-Nickel-Cobalt Warning** Indicates product contains Chromium, Nickel, and/ or Cobalt. Patients with an identified allergy to those metals should not use this product.	MR	**MR Unsafe** ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
	Importer indicates the entity importing the medical device into the locale.	1	**Single Patient Multiple Use** Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.	2	**Do Not Re-use** Indicates a medical device that is intended for one single use only.
	Do not use if package is damaged and consult IFU Indicates a medical device that should not be used if the package has been damaged or opened.				