## SYMBOL GLOSSARY

American Orthodontics utilizes symbols that are in conformance to ISO 15223-1 and ISO 7010. 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.

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EC REP	Manufacturer  Authorized Representative in the European Community - Indicates the authorized representative in the European Community / European Union		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.
CE	Indicates that a product has been assessed and deemed to meet EU safety, health, and environmental protection requirements.	***	Keep away from sunlight Indicates a medical device that needs protection from light sources.	<b>(*)</b>	Warning (EC) No 1272/2008 [CLP] REF # GHS07 Toxic cat. 4; Irritant cat. 2 or 3 Lower systematic health hazards
2797	Notified Body Number	ړې	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed.	Cr	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.
REF	Catalogue Number Indicates the manufacturer's catalogue number so that the medical device can be identified.	<b>(%)</b>	Humidity Limitation Indicates the range of humidity to which the medical device can be safely exposed.	<u>⟨c</u>	Magnetic Field ISO 3864-1 Indicates interaction with metallic objects may produce Pinch Hazards.
LOT	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified	•1	Consult Instructions for Use Indicates the need for the user to consult the instructions for use.		Pacemaker Indicates product can be harmful to pacemaker wearers.
QTY	Quantity	LATEX	Product is not made with Natural Rubber Latex 21 CFR801.437 (d)	STERILE	Not Sterilized Indicates product is not sterilized by the manufacturer
	Use By Date Indicates the date after which the medical device is not to be used.	Ronly	Rx Only Caution: Federal law restricts this device to sale to or on the order of a dentist/ orthodontist	~~ <u></u>	Date of Manufacture Indicates the date when the medical device was manufactured.
UDI	Unique Device Identifier Indicates a carrier that contains unique device identifier information.	Ly Line	Danger or Warning (EC) No 1272/2008 [CLP] REF # GHS05 Corrosive cat. 1	MD	Medical Device Indicates that the product is a medical device
	Importer indicates the entity importing the medical device into the locale.		<b>Danger</b> (EC) No 1272/2008 [CLP] REF # GHS06 Toxic cat. 1-3		<b>Distributor</b> Indicates the entity distributing the medical device into the locale.
(1m)	Single Patient Multiple Use Indicates a medical device that may be used multi- ple times (multiple procedures) on a single patient.		<b>Danger</b> (EC) No 1272/2008 [CLP] REF # GHS02 Flammable		
2	Do Not Re-use Indicates a medical device that is intended for one single use only.		Health Hazard GHS08 WHMIS 2015 Indicates product may cause or suspected of causing serious health effects.		