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.

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

CE Marking
Complies with European Directives

EU Notified Body Number
Complies with European directives

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

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

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

Quantity
Indicates the amount of product included

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

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

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

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

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

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

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

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

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

Not made with Natural Rubber
21CFR801.437(d)
Product is not made with or contains natural rubber latex

Statement "Caution: Federal Law restricts this device to sale to or on the order of a dentist/orthodontist"
21CFR801.109(b)

Danger or Warning
(EC) No 1272/2008 [CLP] REF # GHS05
Corrosive cat. 1
Indicates product may cause corrosive damage to metals, as well as skin, eyes

Danger
(EC) No 1272/2008 [CLP] REF # GHS06
Toxic cat. 1-3
Indicates product can cause death or toxicity with short exposure to small amounts

Danger or Warning
(EC) No 1272/2008 [CLP] REF # GHS02
Flammable
Indicates fire hazard

Warning
(EC) No 1272/2008 [CLP] REF # GHS07
Toxic cat. 4
Irritant cat. 2 or 3
Lower systematic health hazards
Indicates product may cause less serious heath effects or damage ozone layer

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

Magnetic Field
ISO 3864-1 REF # LB0095
Indicates interaction with metallic objects may produce Pinch Hazards

No Pacemakers
FDA Consensus Standard ISO 7010 REF # P007
Indicates product can be harmful to pacemaker wearers

Health Hazard
GHS08 WHMIS 2015
Indicates product may cause or suspected of causing serious health effects

Not Sterilized
Indicates product is not sterilized by the manufacturer