










## Symbols Glossary Orthodontic Medical Devices

The symbols used on the product labeling are internationally recognized and provide important information regarding safe use, handling, and regulatory compliance. Refer to the glossary below for the definition of each symbol appearing on labeling, packaging, or Instructions for Use.


**1. The following are per ISO 15223-1 (References as indicated).**

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
 Ref. 5.1.1	<b>Manufacturer:</b> Indicates the medical device manufacturer.
 Ref. 5.1.2	<b>Authorized representative in the European Community / European Union</b> Indicates the authorized representative in the European Community / European Union.
 Ref. 5.1.3	<b>Date of manufacture:</b> Indicates the date when the medical device was manufactured.
 Ref. 5.1.5	<b>Batch Code:</b> Indicates the manufacturer's batch code so that the batch or lot can be identified.
 Ref. 5.1.6	<b>Catalogue or model number:</b> Indicates the manufacturer's catalogue number so that the medical device can be identified.
 <b>Single Use</b> Ref. 5.4.2	<b>Do not re-use/single patient use:</b> Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
 Ref. 5.4.3	<b>Consult instructions for use:</b> Indicates the need for the user to consult the instructions for use.
 Ref. 5.7.7 MDR 2017/745 Annex 1 23.2(q)	<b>Medical Device:</b> Indicates that the device is a medical device.


**2. The following are per MDR EU 2017/745 (References as indicated).**

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
 MDR 2017/745 Article 2 and Annex V	<b>CE Marking of Conformity:</b> Marking by which a manufacturer indicates that devices in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.

**3. The following are per ASTM F2503 (References as indicated).**

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
 ASTM F2503	<b>MR Unsafe:</b> Indicates that the device is not safe to be present in a Magnetic Resonance (MR) environment.  The devices are MR unsafe. When scheduling an MRI or other radiology services while wearing orthodontic appliances, always inform MRI or other radiology staff prior to the procedure so that proper coordination of care can be arranged. The devices have not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating, migration, or image artifacts in the MR environment. Scanning a patient who has this device may result in patient injury.

**4. Other symbols**

Symbols Not Derived from Standards	
 Contains Nickel and/or Chromium	<b>Product contains Nickel and/or Chromium</b> FDA 21 Part 872 Sec. 872.3710 Base metal alloy.

# 105-7310-01 (DOC-7598) Ver. 1

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**Approved By:**

[\(CO-927\) Pitts21 PRO IFU](#)

**Description**

Adding MR information to Pitts21 PRO IFU, adding MR unsafe symbol to Symbols Glossary.

**Justification**

Risk Information

**Assigned To:**

Josh Otto

**Initiated By:**

Josh Otto

**Priority:**

High

**Impact:**

Minor

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**Version History:**

Author	Effective Date	CO#	Ver.	Status
Josh Otto	March 26, 2026 9:15 AM PDT	<a href="#">CO-927</a>	1	Published
Maureen Janssen	September 5, 2025 7:53 AM PDT	<a href="#">CO-806</a>	0	Superseded