AMERICAN ORTHODONTICS

FSN Reference Number: FSN_CAR40198_2026
Date: 2026-09-25

URGENT FIELD SAFETY NOTICE

Title: Labeling Update – Addition of "MR Unsafe" Symbol to Metallic Orthodontic Devices

Affected Devices:
This labeling update applies to metal orthodontic devices sold by American Orthodontics. A complete list of affected devices is provided in Appendix A. Specific lot or serial numbers are not applicable.

Purpose of the Notification:
The purpose of this notification is to inform customers that device labels were updated in 2024 to include the MR Unsafe symbol. Devices without this symbol may still be in distribution and/or clinical use. As part of American Orthodontics' proactive regulatory approach and commitment to providing quality products, the decision was made to add the symbol to the label to support labeling requirements under current medical device regulations. The addition of the MR Unsafe symbol reflects an inherent and well-known characteristic of orthodontic metal devices. There have been no changes to the design, materials, or performance of these devices.

Reason for the Notification:
One adverse event was reported where RF-induced heating occurred, ultimately resulting in delayed treatment to the patient.

Explanation of Risks:
The presence of orthodontic devices during MRI examinations may cause MR artifacts and/or heating of the device. This could result in reduced image quality and/or interruption, postponement, or rescheduling of the imaging procedure, potentially delaying patient diagnosis and/or treatment. **These risks are inherent to all metal orthodontic devices and are not unique to American Orthodontics' devices or materials.**

Actions by American Orthodontics:
Preventative / corrective actions have already been conducted.

Actions Required by Customers / Users:
Please share this notice with anyone in your organization, or other organizations, who may be affected. No acknowledgement of receipt of this letter or actions are required for product you may have in-stock.

Additional Information:
The appropriate Competent Authorities have been informed of this Field Safety Corrective Action where required. This is a New FSN with no follow-up FSN expected.

If you have any questions regarding this Field Safety Notice, please contact: vigilance@americanortho.com

We apologize for any inconvenience and thank you for your attention to this matter.
Sincerely,



Bruce Deemer
Quality Systems Manager

FSN Reference Number: FSN_CAR40198_2026

Date: 2026-09-25

Appendix A: Affected Metallic Orthodontic Products

Associated part numbers for all devices are maintained in EUDAMED.	
Device Name	**Basic UDI-DI**
Hard Line Band	01907460000100D7
Micro Band	01907460000102DB
Mini Skirt Crown	01907460000103DD
MR Band	01907460000104DF
MRX Band	01907460000105DH
Rollo Band	01907460000106DK
Standard Band	01907460000108DP
Lingual Sheath	01907460000101D9
Seating Lug	01907460000107DM
Weldable Elastic Lug	01907460000109DR
Weldable Eyelet	01907460000110DA
Weldable Gull Wing Cleat	01907460000111DC
Weldable Hook	01907460000112DE
Weldable Cleat	01907460000113DG
Forever Gold 24K Bracket	01907460000127DT
Iconix Bracket	01907460000128DV
LP Bracket	01907460000132DL
Master Series Bracket	01907460000134DQ
Mini Master Series Bracket	01907460000137DW
Mini Standard Edgewise Bracket	01907460000139E2
Mini Tweed Bracket	01907460000140DK
Stainless Steel Bracket	01907460000143DR
Empower Clear Bracket	01907460000125DP
Empower Bracket	01907460000124DM
Empower Tube	01907460000126DR
Iconix Tube	01907460000129DX
iFit Tube	01907460000130DG
Inconel Tube	01907460000131DJ
LP Tube	01907460000133DN
Master Series Tube	01907460000135DS
Mini Master Series Tube	01907460000138DY
Slim Tube	01907460000142DP
Stainless Steel Tube	01907460000144DT
Bite Blocks	01907460000115DL
Bondable Elastic Lug	01907460000116DN
Bondable Eyelet	01907460000117DQ
Bondable Gull Wing Cleat	01907460000118DS
Bondable Cleat	01907460000119DU
Bondable Retainer	01907460000120DD
Diastema	01907460000123DK
Metal Button	01907460000136DU
Tongue Director	01907460000145DV

Utility Traction Hook	01907460000146DX
Hanks Telescoping Herbst	01907460000166E5
Herbst Appliance	01907460000167E7
MiniScope Telescoping Herbst	01907460000172DY
Distal Jet	01907460000164DZ
Mesial Jet	01907460000171DW
Spring Jet	01907460000179EE
Uprighter Jet	01907460000180DX
Jones Jig	01907460000169EB
Gentle Jumper	01907460000165E3
Jasper Jumper	01907460000168E9
Lip Bumper	01907460000170DU
Palatal Arch	01907460000173E2
PowerBar	01907460000174E4
PowerScope	01907460000175E6
Quad Helix	01907460000176E8
Quick Fix	01907460000177EA
Rapid Molar Intruder	01907460000178EC
Protraction Facemask	01907460000204DL
Beta Titanium Wire	01907460000209DW
Chromium Cobalt Wire	01907460000210DF
Iconix NiTi Wire	01907460000211DH
NiTi Wire	01907460000216DT
NT3	01907460000217DV
Stainless Steel Wire	01907460000224DS
Tanzo	01907460000227DY
Therma-Ti	01907460000228E2
TriTanium	01907460000229E4
Kobayashi Hooks	01907460000212DK
Spooled Ligature Wire	01907460000222DN
Wire Ligature	01907460000230DM
Arch Lock	01907460000206DQ
Arch Stop	01907460000218DX
Ball Retainer Clasps	01907460000208DU
Arch Hook	01907460000205DN
Monkey Hook	01907460000213DM
Power Hook	01907460000219DZ
Power Pin	01907460000220DJ
Surgical Hook	01907460000225DU
Retainer Wire	01907460000221DL
ART Spring	01907460000207DS
NiTi Spring	01907460000215DR
Stainless Steel Spring	01907460000223DQ
Multi-Strand Wire	01907460000214DP