

Material and Chemical Characterization

The material and chemical characterization charts show the types of materials used in WCT’s orthodontic metal brackets and buccal tubes. The charts identify the main alloy components and trace elements.

1 Materials

1.1 Pitts21® PRO Bracket Body & Ligating Member, Pitts21® Brackets, H4 Brackets, BioMIM Mini-Twin Brackets, Phase 1 Eyelets, and Buccal Tubes

Table 1

Stainless Steel 17-4PH per ASTM B883 – 24		
Chemical Name	Min. (weight %)	Max. (weight %)
Iron (Fe)	Balance	Balance
Nickel (Ni)	3	5
Chromium (Cr)	15.5	17.5
Carbon (C)	-	0.07
Copper (Cu)	3	5
Silicon (Si)	-	1.0
Manganese (Mn)	-	1.0
Niobium; Tantalum (Nb+Ta)	0.15	0.45
Other	-	1.0

1.2 Pitts21® PRO Spring Member

Table 2

Nitinol per ASTM F2063-18		
Chemical Name	Min. (weight %)	Max. (weight %)
Titanium	Balance	Balance
Nickel	54.5	57
Carbon	-	0.04
Cobalt	-	0.05
Copper	-	0.01
Chromium	-	0.01
Hydrogen	-	0.005
Iron	-	0.05
Niobium	-	0.025
Nitrogen	-	0.005
Oxygen	-	0.04

Table 3

Coating “DLC (Diamond-Like Carbon)”

1.3 Static Immersion Test Ion Release Values

Table 4

Ion Release	
Element	µg / 20 brackets / 7 days
Ag	-
As	-
Ba	-
Be	-
Bi	-
Cd	-
Co	-
Cr	≤ 50
Cs	-
Cu	≤ 100
Fe	≤ 200
Ga	-
Ge	-
Hf	-
In	-
La	-
Li	-
Mg	-
Mn	-
Mo	-
Nb	≤ 50
Ni	≤ 50
Pb	-
Re	-
Sb	-
Se	-
Sn	-
Sr	-
Ta	-
Te	-
Ti	-
Tl	-
V	-
W	-
Zn	-
Zr	-
Sum	≤ 450

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Approved By:

[\(CO-967\) MR Unsafe - Brackets IFU](#)

Description

105-7300-09: Removed references to Table 1 Materials, Section 5 Materials, and Section 13 Explanation of Symbols. Changed the Warnings and Precautionary Measures table to bulleted list and updated verbiage. Updated the AR symbol to "EU REP". Added Section 13 Other Information – Supplementary Documents and Section 14 Request for IFU anmd/or Supplementary Documents in Paper Form. 105-7320-01: Added P21 brackets, H4 brackets, BioMIM brackets, and Phase 1 Eyelets to section 1.1.

Justification

MR Unsafe symbol is needed on labels for H4, P21, BioMIM, and eyelets. There is an updated MRI warning for metal brackets. Please refer to CO-931.

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