

## ANATOMIC WEDGES

### 1. Purpose

To establish the product features, its application, presentation, legal and normative information.

### 2. Medical device identification

#### 2.1 Commercial name

Anatomic Wedges

#### 2.2 Classification in compliance with ANVISA

Code	Name	Classification	ANVISA Registration
2101015	Dental Wedge	Rule 5, Class I	10291220032

#### 2.3 Classification in compliance with Regulation (UE) 2017/745

EMDN / GMDN Code	Name	Classification
16370	Kit: Assorted interdental wooden wedges Refill: Interdental wooden wedges	Class I

Legend: GMDN: numeric code / EMDN: alpha numeric code.

#### 2.4 General description

TDV wooden wedges are indicated for general use in procedures, with the mechanical function of adapting matrices and/or separating adjacent teeth. The wooden wedges do not require cuts or adjustments, because its shape allows an easy insertion into the interproximal areas and ensure a perfect adaptation of the matrices.

#### 2.5 Brief description

Wooden wedges, easy to adapt in the interproximal area. Available in five sizes codified by colors.

#### 2.6 Features and Benefits

- Anatomically shaped for a better fit in the interproximal area and to separate adjacent teeth
- Assists in restoring the tooth's natural anatomy, as it promotes an adequate adjustment of the matrix and proximal contact
- Available in 5 sizes

## 3. Technical Information

### 3.1 Composition

- **Information for printing:**

Natural: Wood

Colored: Wood and Non-toxic dyes

• **Registration information:**

Natural:

%	Component	Function	EMP
100	Wood	Structural	EMP0304000001

Colored:

%	Component	Function	EMP
99	Wood	Structural	EMP0304000001
1	Non-toxic reactive dyes	Identification of sizes	EMP0302000000

**3.1 Shapes and sizes**

Available in 5 sizes:  
 N°1 – Yellow (12mm)  
 N° 2 – Blue (13mm)  
 N°3 – Red (14mm)  
 N° 4 – Purple (15mm)  
 N° 5 – Natural (16mm)



**3.2 Physical-chemical principle of operation**

The shape of the wedge allows its easy insertion into the interproximal areas. The wedge provides a better adjustment of the matrix and separation of the adjacent teeth.

**3.3 Indication**

The wooden wedges TDV are generally used in restorative procedures, with the mechanical function of adapting the matrices and/or separation of the adjacent tooth.

**3.4 Use**

Select the most appropriate wedge size for the procedure.  
 Insert the wedge into the interproximal space.  
 Once the procedure is completed, the wedge must be removed.

**3.5 Warnings, precautions and restrictions**

Professional use only.  
 Single use. Its reuse can cause cross contamination.  
 To avoid an accidental swallowing of this product, it is necessary the application of a total isolation technique of the operatory filed.  
 The product has a sharp point and must be handled with caution to avoid risk of causing harm to the patient.  
 Any serious incident related to the device should be reported to the manufacturer and competent authority of the Member State in which the user and/or patient is established.

**3.6 Cleaning**

N/A.

**3.7 Sterilization**

N/A.

**3.8 Reprocessing Limits**

N/A.

**3.9 Inspection**

N/A.

**3.10 Connection with contra-angle**

N/A.

**3.11 Accessory**

N/A.

**3.12 Storage**

To be stored in a cool and dry place, protected from sunlight.














**3.13 Disposal**

Dispose in accordance with applicable local requirements.

**3.14 Shelf life date**

5 years

**3.15 Symbols**

 <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 Medical Device <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 Consult instructions for use <input checked="" type="checkbox"/> Label <input type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 Keep away from sunlight <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker
 Keep Dry <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 Do not re-use <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 Manufacturer <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 European Representative <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Instructions for use <input type="checkbox"/> Sticker	 Unique Device Identifier <input type="checkbox"/> Label <input type="checkbox"/> Instructions for use <input checked="" type="checkbox"/> Sticker	 Batch code <input type="checkbox"/> Label <input type="checkbox"/> Instructions for use <input checked="" type="checkbox"/> Sticker
 Use-by date					

<input type="checkbox"/> Label <input type="checkbox"/> Instructions for use <input checked="" type="checkbox"/> Sticker
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## 4. Efficiency and security description

### 4.1 Manufacturing Flow

FF0004020000

### 4.2 Risk Analysis

PLARA0004020000, RA0004020000 and REPRA0004020000

### 4.3 Technical Drawing


DP0204020111, DP0204020112, DP0204020113, DP0204020114 and DP0204020115

## 5. Presentation

5.1 Ref.	5.2 Code	5.3 Protheus Code	5.4 Content	5.5 Bars code	5.6 Available for IFU (price list)	5.7 Available for commercialization
-	00.04.02.00	0004020000	Anatomic wedge n°1 yellow – 5000 units	789799030205-3	-	ES/EN/FR
-	00.04.02.01	0004020001	Anatomic wedge n°2 blue – 5000 units	789799030206-0	-	ES/EN/FR
-	00.04.02.02	0004020002	Anatomic wedge n°3 red – 5000 units	789799030207-7	-	ES/EN/FR
-	00.04.02.03	0004020003	Anatomic wedge n°4 violet – 5000 units	789799030208-4	-	ES/EN/FR
-	00.04.02.04	0004020004	Anatomic wedge n°1 natural – 5000 units	789799030209-1	-	ES/EN/FR
-	00.04.02.05	0004020005	Anatomic wedge n° 2 natural – 5000 units	789799030210-7	-	ES/EN/FR
-	00.04.02.06	0004020006	Anatomic wedge n° 3 natural – 5000 units	789799030211-4	-	ES/EN/FR
-	00.04.02.07	0004020007	Anatomic wedge n° 4 natural – 5000 units	789799030212-1	-	ES/EN/FR
-	00.04.02.08	0004020008	Anatomic wedge n° 5 natural – 5000 units	789799030213-8	-	ES/EN/FR
0.4952 C	00.04.02.09	0004020009	Colored anatomic wedge– 500 units assorted	789799034952-2	PT/ES	PT/ES
0.4953	00.04.02.10	0004020010	Anatomic wedge n°1 yellow – 100 units	789799034953-9	PT/ES	PT/ES
0.4957 C	00.04.02.11	0004020011	Colored anatomic wedge– 100 units assorted	789799030214-5	PT/ES	PT/ES
0.4957	00.04.02.12	0004020012	Anatomic wedge - 100 units assorted	789799034957-7	PT/ES	PT/ES
-	00.04.02.13	0004020013	Anatomic wedge n°1 yellow – 1000 units	789799030215-2	-	ES/EN/FR
-	00.04.02.14	0004020014	Anatomic wedge n°2 blue – 1000 units	789799030216-9	-	ES/EN/FR

-	00.04.02.15	0004020015	Anatomic wedge n°3 red – 1000 units	789799030217-6	-	ES/EN/FR
-	00.04.02.16	0004020016	Anatomic wedge n°4 violet – 1000 units	789799030218-3	-	ES/EN/FR
-	00.04.02.17	000420017	Anatomic wedge n° 1 natural – 1000 units	789799030219-0	-	ES/EN/FR
-	00.04.02.18	0004020018	Anatomic wedge n°2 natural – 1000 units	789799030220-6	-	ES/EN/FR
-	00.04.02.19	0004020019	Anatomic wedge n°3 natural – 1000 units	789799030221-3	-	ES/EN/FR
-	00.04.02.20	0004020020	Anatomic wedge n°4 natural – 1000 units	789799030222-0	-	ES/EN/FR
-	00.04.02.21	0004020021	Anatomic wedge n°5 natural – 1000 units	789799030223-7	-	ES/EN/FR
0.4952 C	00.04.02.22	0004020022	Colored anatomic wedge – 500 units assorted	789799030224-4	EN/FR	EN/FR
0.4953	00.04.02.23	0004020023	Anatomic wedge n°1 yellow – 100 units	789799030225-1	EN/FR	EN/FR
0.4957 C	00.04.02.24	0004020024	Colored anatomic wedge – 100 units assorted	789799030226-8	EN/FR	EN/FR
0.4957	00.04.02.25	0004020025	Anatomic wedge – 100 units assorted	789799030227-5	-	EN/FR
0.4949 C	00.04.02.42	0004020042	Colored anatomic wedge – 100 units alternative assortments	789799031315-8	-	PT
0.4952	00.04.02.45	0004020045	Anatomic wedge – 500 units assorted	789799031317-2	-	EN/FR
-	00.04.02.48	0004020048	Anatomic wedge n°1 – 5000 units	789799032306-5	-	ES/EN/FR
-	00.04.02.50	0004020050	Anatomic wedge n°2 – 5000 units	789799032307-2	-	ES/EN/FR
-	00.04.02.51	0004020051	Anatomic wedge n°3 – 5000 units	789799032308-9	-	ES/EN/FR
-	00.04.02.52	0004020052	Anatomic wedge n°4 – 5000 units	789799032309-6	-	ES/EN/FR
-	00.04.02.53	0004020053	Anatomic wedge n°5 – 5000 units	789799032310-2	-	ES/EN/FR
0.4949 N	00.04.02.54	0004020054	Anatomic wedge – 100 units alternative assortments	789799032537-3	-	PT
-	00.04.02.57	0004020057	Anatomic wedge – 100 units (standard colors)	789799032710-0	-	EN
-	00.04.02.58	0004020058	Alternative anatomic wedge– 5000 units n°1 (standard colors)	789799032711-7	-	EN
-	00.04.02.59	0004020059	Alternative anatomic wedge– 5000 units n°2 (standard colors)	789799032712-4	-	EN
-	00.04.02.60	0004020060	Alternative anatomic wedge– 5000 units n°3 (standard colors)	789799032713-1	-	EN
-	00.04.02.61	0004020061	Alternative anatomic wedge– 5000 units n°4 (standard colors)	789799032714-8	-	EN
-	00.04.02.62	0004020062	Alternative anatomic wedge– 5000 units n°5 (standard colors)	789799032715-5	-	EN
-	00.04.02.63	0004020063	Colored anatomic wedge – 150 units assortments	789799032782-7	-	PT

## 6. Visual Identification Standard

PRINTED	COLOR	PAPER
Instructions for use	C = 0 M= 0 Y = 0 K = 80	Sulphite 63g/m <sup>2</sup>
Blister Paper Card	C = 100 M = 73 Y = 10 K = 48 C = 0 M = 87 Y = 84 K = 0 C = 0 M = 0 Y = 0 K = 80	Couché 90g/m <sup>2</sup>
PRIMARY PACKAGING		
		
EMP0500000000		PET 0,30mm

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