

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					