

## KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

**Wir / We**

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**erklären in alleiniger Verantwortung, dass**

declare on our own responsibility that

**das Medizinprodukt**  
the medical device

**Name:** Matrizenkeil,dental, UMDNS-Nr. 16-370

name : Fixing wedges

**Typ/ type** : siehe Anhang 1

**Serien Nr.** : siehe Anhang 2 serial nr.

**alien Anforderungen der Richtlinie 93/42/EWG entspricht.**

meets all the provisions of the Directive 93/42/EEC which apply to him.

**Angewandte harmonisierte Normen:** ISO 10993-3 : 2003

Applied harmonized standards:

DIN EN 14971 : 2001

DIN EN 1041 : 1998-04 DIN EN 980 :  
2,003-08

**Angewandte nationale Normen** : DIN V 13974 : 2003-10 Applied national standards :

**Benaim te Stelle (falls zutreffend):** für Klasse I nicht vorgeschrieben

Notified body (if applicable)

: for Class I not relevant

## KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

**Konformitätsbewertungsverfahren** :EG-Richtlinie 93/42/EWG ,AnhangVII ( Klasse I  
Conformity assessment procedure : Anhang IX, Regel 5 )

Council Directive : 93/42/ EEC, AnnexVII (Class I, AnnexIX, Rule 5 )

**Datum der Erstanbringung der CE Kennzeichnung** : 10. August 2005  
**Date of the first CE mark** : 10. August 2005

**Datum des erstmaligen Inverkehrbringen** : 25.October 2010  
**Date of the first lot:** 25.October 2010

Hersteller

Moscow, 25.10.2010  
**Ort, Datum**



Dr.Mikhalev O.I. CEO  
**Name und**

Hersteller  
Manufacturer  
**Funktion**

Heidelberg, 25.10.2010  
**place, date**



Gregor Kostunov  
**name and**

EG Bevollmächtigter  
EC Representative  
**function**

## **Beschreibung der Produktfamilie und deren Zweckbestimmung / Anwendung // Product Description and Application**

**Die Produktfamilie von Matrizenkeil, dental, besteht aus:**

**Product Family, Dental Matrices (Matrix Bands) and Fixing Accessories includes:**

### **Konstruktion E : Keile zum Fixieren / Construction E : Fixing Wedges**

**17. Holz-Keile / Wooden Wedges**

**18. Plastik-Keile / Plastik Wedges**

**19. Transparente Plastik-Keile / Transparent Plastic Wedges**

### **Zweckbestimmung/Anwendung der Produkte:**

#### **Application of Product:**

**1. Zur Fixierung der Matrize am Zahn während des Füllungsverfahrens / Matrix fixation upon tooth restoration**

**2. Wird zwischen den Zähnen plaziert, um die Matrize zu fixieren. Siehe auch Abbildungen und Beschreibung der Matrizen und Fixierhilfsmittel (Katalog Seite 6-10). Gebrauchsinformation in der entsprechenden Abteilung / To be inserted between teeth for matrix fixation. See figures and description of fixing wedges (Catalogue, Addendum 2, pages 6-10). Instruction see in the corresponding site.**

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**Anhang 1 zur EG-Konformitätserklärung: \ Matrizenkeil,dental /**  
**Addendum 1 to Declaration of Conformity Dental Matrices**

**Die Produktfamilie von Matrizenkeil, dental, besteht aus:**

**Product Family, Dental Matrices (Matrix Bands) and Fixing Accessories:**

<b>Komponenten / Product</b>	<b>Serien-Nr. (siehe Anhang 2) / Serial Number (see Addendum 2)</b>
<b>17. Holz-Keile / Wooden Wedges</b>	<b>Nr.17</b>
<b>18. Plastik-Keile / Plastic Wedges</b>	<b>Nr.18</b>
<b>19. Transparente Plastik-Keile / Transparent Plastic Wedges</b>	<b>Nr.19</b>

## Anhang 2 / Addendum 2

### Nr. 17

#### Wooden Wedges

		<b>№ 1.181</b>	<b>Wooden Wedges</b> superthin, short (orange) 100 pcs.	
		<b>№ 1.182</b>	<b>Wooden Wedges</b> thin, short (white) 100 pcs.	
		<b>№ 1.183</b>	<b>Wooden Wedges</b> thin, short (green) 100 pcs.	
		<b>№ 1.184</b>	<b>Wooden Wedges</b> thin, long (yellow) 100 pcs.	
		<b>№ 1.185</b>	<b>Wooden Wedges</b> medium, short (blue) 100 pcs.	
		<b>№ 1.186</b>	<b>Wooden Wedges</b> medium, long (pink) 100 pcs.	
		<b>№ 1.187</b>	<b>Wooden Wedges</b> thick, long (violet) 100 pcs.	
		<b>№ 1.080</b>	<b>Wooden Wedges.</b> <b>2 Types</b> 100 pcs. white (thin, short) 50 pcs. blue (medium, long) 50 pcs.	
		<b>№ 1.083</b>	<b>Wooden Wedges.</b> <b>4 Types</b> 200 pcs. white (thin, short) 50 pcs. yellow (thin, long) 50 pcs. blue (medium, short) 50 pcs. pink (medium, long) 50 pcs.	
		<b>№ 1.085</b>	<b>Wooden Wedges.</b> <b>6 Types</b> 400 pcs. orange (superthin, short) 100 pcs. white (thin, short) 100 pcs. yellow (thin, long) 50 pcs. blue (medium, short) 50 pcs. pink (medium, long) 50 pcs. violet (thick, long) 50 pcs.	
		<b>№ 1.281</b>	<b>Triangle Wooden Wedges</b> 100 pcs.	

Anatomically shaped



Made of maple wood

Clinical events



Date of issue October 25, 2010



# Nr. 18

## Wedges «Elastic»



**№ 1.801** Wedges «Elastic». Hard  
10 pcs.



**№ 1.802** Wedges «Elastic». Soft  
10 pcs.



**№ 1.808** Wedges «Elastic». 2 Types  
40 pcs.:  
hard wedges 20 pcs.  
soft wedges 20 pcs.

For installation of wedges «elastic» forceps № 1.099-2 with special stoppers (see p. 8) are preferable.

# Nr. 18

## Add-on Silicone wedges



**№ 1.861** Add-on Silicone Wedges  
40 pcs.

Holes for the tines of clamps and springclips

# Nr. 19

## Transparent Plastic Wedges



**№ 1.811** Transparent Wedges.  
Thin  
40 pcs.



**№ 1.810** Transparent Wedges.  
2 types  
40 pcs.  
thin wedges 25 pcs.  
medium wedges 15 pcs.

**№ 1.820** Transparent Wedges.  
2 types  
80 pcs.  
thin wedges 50 pcs.  
medium wedges 30 pcs.

# Nr. 18

## Non-Transparent Plastic Wedges



**№ 1.841** Non-transparent Plastic Wedges.  
Thin  
40 pcs.



**№ 1.840** Non-transparent Plastic Wedges.  
2 types  
80 pcs.  
thin wedges 50 pcs.  
medium wedges 30 pcs.

### Installation

1. Insert tines of forceps (see p.12) or of standard rubber dam clamp forceps into the wedge holes



2. Stretch the wedge by forcing apart the forceps and install it in interproximal space



Ready for restoration



- Anatomically shaped
- Transparent soft plastic
- Two thicknesses



- Anatomically shaped
- Soft plastic
- Two thicknesses



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