

For better dentistry®

**DENTSPLY**  
CAULK

**L.D. Caulk Division**  
38 West Clarke Avenue  
Milford, DE 19963-1805  
(302) 422-4511

**Palodent® V3 EZ Coat Sectional Matrix System**

**EC Declaration of Conformity**

**Manufactured for:** DENTSPLY Caulk  
**Name Address:** 38 West Clarke Avenue  
Milford DE 19963  
USA

**Authorized EC Representative** DENTSPLY DeTrey GmbH  
**Name and Address:** D-78467  
Konstanz Germany

**Unique Product Identification:** 659610v Palodent® V3 EZ Coat 3.5mm Matrices Refill  
659620v Palodent® V3 EZ Coat 4.5mm Matrices Refill  
659630v Palodent® V3 EZ Coat 5.5mm Matrices Refill  
659640v Palodent® V3 EZ Coat 5.5mm Matrices Refill (90)  
659650v Palodent® V3 EZ Coat 6.5mm Matrices Refill  
659660v Palodent® V3 EZ Coat 7.5mm Matrices Refill  
659670v Palodent® V3 EZ Coat Introductory Kit  
659680v Palodent® V3 EZ Coat Sample

**Description:** The Palodent® V3 EZ Coat Sectional Matrix System employs a nickel-titanium retaining ring, interproximal wedge, WedgeGuard and sectional matrices for placement of restorations in the posterior region. Sectional matrices are suitable for use with all posterior restorative materials. Palodent V3Plus EZ Coat matrices have a micro-thin, non-stick finish that minimizes the chance that bonding agent or composite sticks to the band, making matrix removal easier. The retaining rings are available in narrow, for most premolar and small molars or universal, for larger molars. Rings may be used either singly or in tandem, for simultaneous restoration of multiple surfaces. The advantages of the sectional matrices and rings include natural contours for better control of contact areas and embrasures, ease of placement, better visualization of the operative field, and more comfort for the practitioner and patient. Eliminating the leverage of a conventional matrix retainer allows the practitioner to use less tension, avoiding excessive compression of tooth and easier formation of anatomical proximal contact areas. When placed prior to preparation, the innovative WedgeGuard combination wedge and shield protects approximating surfaces from inadvertent damage during preparation. Using the pin tweezers, the shield easily slides away, leaving the wedge securely in place.

**GMDN Code(s):** P38786 – Dental matrix band, single use

**Product Classification** This product is classified as a Class I Medical Device under  
**Per Annex IX:** Annex IX Section III, rule 5, transient, invasive device.

For better dentistry®

**DENTSPLY**  
CAULK

**L.D. Caulk Division**  
38 West Clarke Avenue  
Milford, DE 19963-1805  
(302) 422-4511

**Palodent® V3 EZ Coat Sectional Matrix System**

**EC Declaration of Conformity**

**EC Declaration of Conformity:**

The above listed medical device(s) conform to the requirements of Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation.

This declaration is made on the basis of the Certificate of Conformity US97/10442 issued by SGS United Kingdom Ltd. Systems & Services Certification with Notified Body identification number 0120 in accordance with Annex VII of the Directive.

DENTSPLY Caulk Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820 & 211, ISO 13485:2003, CMDR, JPAL (MO 169) and the European Union Council Directive 93/42/EEC

**Authorized Signature:**

Name: Jackie Webb  
Jackie Webb  
Regulatory Assurance Specialist

Date of Issuance: March 5, 2015