

**Product specification**

Device group: Matrix forms

Doc-id: TF13.1\_SPEC

Revision: 01

Pgs: 1 (2)

<b>Product specification</b>	
<b>Trade name(s)</b>	<b>CoForm™</b>
<b>Sample illustration</b>	
<b>Intended use</b>	<p>Pre-shaped matrix to form acrylic or composite fillings, to be removed after the material is set.</p> <p>Indication:</p> <ul style="list-style-type: none"> <li>- restoration of corners and edges, class IV composite restorations</li> </ul>
<b>Features</b>	<p>Anatomical design</p> <p>Transparent</p> <p>No chemical reaction to composite or acrylic.</p> <p>Tooth numbering system</p>
<b>Models</b>	Shapes as mesial (M) and distal (D)
<b>Dimensions</b>	<p>Sizes as per mould guides below.</p> <p>Each shape/model consists of 4 sizes.</p>
<b>Packages</b>	<p>Package per shape/model:</p> <ul style="list-style-type: none"> <li>- 8 pcs, 2 of each size.</li> <li>- Each size packed in individual compartment in plastic box with peel-open function. The perforation allows to open each individual compartment.</li> <li>- Colour coded, distal black and mesial red.</li> </ul>  <p>Assortment A:</p> <ul style="list-style-type: none"> <li>- 1 package of following shape/model: 11M, 21M, 12M, 22M, 13M, 23M, 31-32M, 41-42M, 11D, 21D, 12D, 22D, 13D, 23D, 31-32D, 41-42D</li> <li>- Placed on a plastic tray</li> <li>- Packed in a cardboard box.</li> </ul> <p>Assortment B:</p> <ul style="list-style-type: none"> <li>- 1 package of following shape/model: 11M, 21M, 12M, 22M, 11D, 21D, 12D, 22D</li> <li>- Placed on a plastic tray</li> <li>- Packed in a cardboard box</li> </ul>
<b>Single use/re-usable</b>	Single use
<b>Material</b>	Cellulose diacetate
<b>Shelf-life</b>	The device has no shelf-life restriction.
<b>Storing and transport conditions</b>	The device has no specified storage or transport conditions.
<b>Supply</b>	Supplied non-sterile.
<b>Hazards likely with re-use of single use medical devices</b>	Cross-contamination and function. Due to design, inability to clean and decontaminate properly. Further, it cannot be used as per intended use, as the device may have been cut off from its originally shape.

# Technical File TF13

## Product specification

































































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### Mould Guide

Model# and tooth#	Shape illustrations								Model# and tooth#
Mesial	Shape illustrations Mesial				Shape illustration Distal				Distal
11M									11D
21M									21D
12M									12D
22M									22D
13M									13D
23M									23D
31-32M									31-32D
41-42M									41-42D

### Revision history

Revision	Date	Completed by	Approved by	Remark
01	2021-05-17	Agneta Bengtsson, RA 	Sandra Peiponen, Product Manager 	Initial document