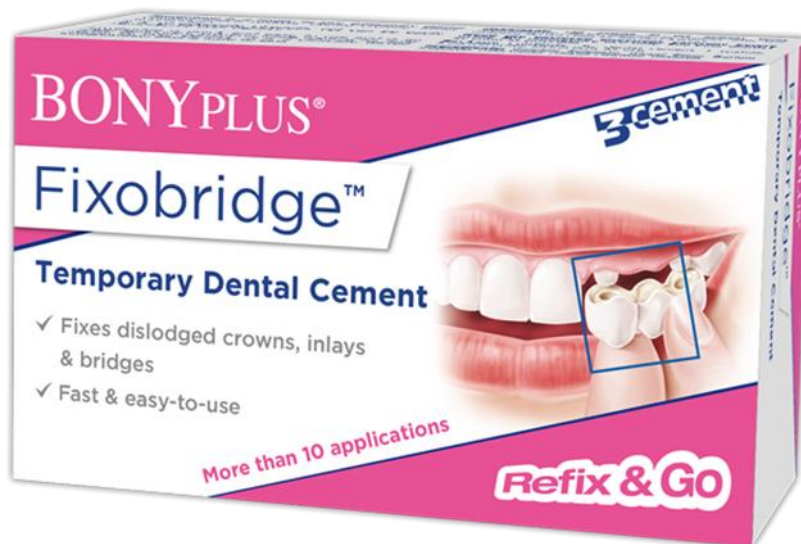


# Technical Data Sheet

**Product** Fixobridge  
**Class** IIa

Emergency temporary dental cement

Version History			
Version	Date	Comments	Author
05	27.02.2007	Old document	
06	13.11.2015	New template	IH



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	<b>Fixobridge – Technical Data Sheet</b>	<b>Technical document A2</b>
Version Number: 06	Version Date: 13.11.2015	Article Number: 4.000.00.X.0.0.00
		Authors: I. Hadded

## 1. General Information

<b>Article No.</b>	4.000.00.X.0.0.00
<b>Commercial name</b>	Fixobridge
<b>Brands</b>	BonyPlus / Smile With Confidence
<b>Description</b>	<p><i>Fixobridge</i> is a product designed to offer a sufficient, but temporary, solution for fixing dental bridges, metal, porcelain and synthetic crowns and post crowns. This must subsequently be dealt with by a dentist.</p> <p><i>Fixobridge</i> can be easily removed by a dentist and will not damage the bridge or crown. This product does not irritate the gums and it is easy to handle.</p>
<b>Use, Toxicity &amp; safety</b>	<p>The application and respectively the handling of this product are described very carefully in the instructions. The procedure is explained step by step with drawings so that it is easily used even by elderly people. The ingredients are well recognised and have been used for many years in the dental field. Fixobridge is only a temporary repair measure before consulting a dentist.</p> <p>Skin and eye contact must be avoided. Swallowing of small amounts of the 3Cement is not expected to be harmful. Generally very rare allergic/sensitive reactions cannot be excluded for predisponible persons/patients. Based on this data it can be concluded that if the product is applied according to the instructions there is a limited health risk in using the Fixobridge.</p>

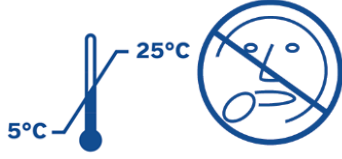
<b>Composition/Indication</b>	Calcium Sulphate Glycol Ether Barium Sulphate Zinc Oxide Acrylic Polymer Triacetin
<b>Shelf life</b>	3 Years

## 2. Regulatory & Legal aspects

<b>Classification Europe</b>	Medical Device Class IIa – CE0086
<b>Classification process</b>	<b>Classification according to Annex IX of Directive 93/42/EEC</b> The product is used in the oral cavity, always associated with removable dentures. According to Annex IX or MEDDEV (2.4 / 1 Guidelines for the Classification of Medical Devices) is a Class IIa product in accordance with Rule 8 (long term invasive use in the oral cavity).
<b>NBOG-Code</b>	MD 0402 Dental materials
<b>Target Audience</b>	Wearers of crowns or bridges.

## 3. Production

<b>Hygiene</b>	Hairnet Gloves Shoe covers Breathing mask Disinfectants Laboratory clothing Rf: SOP 165-Hygiene		
<b>Components</b>	1 tube of 3cement (7g) 1 spatula 1 plastic-rack 3 microbrushes		
<b>Machinery</b>	<b>BRAND</b>	<b>TYPE</b>	<b>PURPOSE</b>
	Cartonetta		Packaging

<b>Packaging</b>	
<b>Size/Quantities</b>	1 pack contains: 7g 3Cement
<b>Packaging of actual product</b>	1 tube, 1 spatula, 1 plastic-rack, 3 microbrushes
<b>External packaging</b>	Pre-printed cardboard
<b>Instructions for use</b>	1 page printed on both sides (Article Nr. 4.703.00.A.0.0.10 - 11.03.2015)  
<b>Labelling</b>	Different languages available
<b>Storage</b>	Store in a cool, dry place (5-25°C / 41-77°F).
<b>Delivery</b>	6 Weeks after initial order

#### 4. Quality control

Tests	
Type of test	Equipment used
Pressure test	Special instruments
Consistency test	Special instruments
Weight control	Scale

#### 5. References

Available literature	Safety Data Sheet Declaration of Conformity
Advertising	Samples on request