


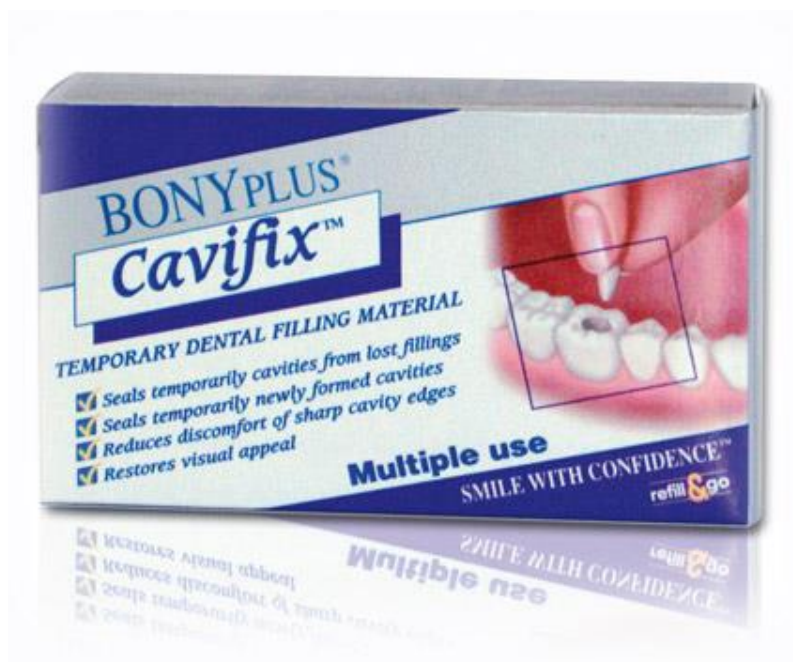
bonyf 	Cavifix – Technical Data Sheet		Technical document A2
Version Number: 08	Version Date: 12.11.2015	Article Number: 14.000.00.X.0.0.00	Authors: I. Hadded

Technical Data Sheet

Product Cavifix
Class IIa

Emergency temporary dental filling material

Version History			
Version	Date	Comments	Author
07	14.03.2007	Old document	
08	12.11.2015	New template	IH



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1. General Information

Article No.	14.900.00.A.0.0.00
Commercial name	Cavifix
Brands	BonyPlus / Smile With Confidence
Description	Cavifix is a product designed to replace a lost filling and to assist in cases of emergency. This must subsequently be dealt with by a dentist. Cavifix can be easily removed by a dentist and will not damage the tooth. This product does not irritate the gums and it is easy to handle.
Use, Toxicity & safety	The application and respectively the handling of this product is 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. Cavifix is only a temporary repair measure before consulting a dentist. Skin and eye contact must be avoided. Swallowing of small amounts of the product 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 3Cement is applied according to the instructions there is a limited health risk in using th Cavifix.

Composition/Indication	Calcium Sulphate Barium Sulphate Glycol Ether Zinc Oxide Acrylic Polymer Silica
Shelf life	3 Years

2. Regulatory & Legal aspects

Classification Europe	Medical Device Class IIa – CE0086
Classification process	Classification according to Annex IX of Directive 93/42/EEC 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).
NBOG-Code	MD 0402 Dental materials
Target Audience	Temporary care for persons with lost or broken fillings/inlays.

3. Production

Hygiene	Hairnet Gloves Shoe covers Breathing mask Disinfectants Laboratory clothing Ref: SOP 165-Hygiene
Components	1 tube Cavifix (7g) 1 dispensing key 1 plastic-rack 1 spatula 1 microbrush

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	1 glove		
Machinery	BRAND	TYPE	PURPOSE
	Cartonetta		Packaging
Packaging			
Size/Quantities	1 pack Cavifix contains : 7g Cavifix		
Packaging of actual product	1 tube, 1 dispensing key, 1 plastic-rack, 1 spatula, 1 microbrush, 1 glove		
External packaging	Pre-printed cardboard		
Instructions for use	1 page printed on both sides (Article Nr. 14.701.00.A.0.0.20 - 07.02.12)		
Labelling	Different languages available		
Storage	Store in a cool, dry place (5-25°C / 41-77°F).		
Delivery	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
Advertising	Samples on request