



<b>RepairKit – Technical Data Sheet</b>		<b>Technical document A2</b>
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# Technical Data Sheet

**Product**      RepairKit  
**Class**        Ila

Emergency denture repair system

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08	Updated of the whole document	17.12.2014	BJ
09	Update of box and new article number/RD of IFU	03.12.2018	SA



## 1. General Information

<b>Article No.</b>	9.000.00.X.0.0.00
<b>Commercial name</b>	Denture-Repairfix
<b>Brands</b>	BonyPlus / Smile With Confidence
<b>Description</b>	<i>Denture-Repairfix</i> is a complete repair kit with a unique three component system that can be used to repair all removable acrylic resin dental appliances. When you use <i>Denture-Repairfix</i> to repair your broken dentures or to reattach a loose tooth it couldn't be simpler. The repair itself takes only minutes. There is no need for any additional tools or expert help, and the results are always reliable.
<b>Use, Toxicity &amp; safety</b>	<p>The application and respectively the handling of this product is described very carefully in the instructions. The mixing and application is done externally. The procedure is explained step by step with drawings so that it is easy to use - even for elderly people. In addition to this, the glue and all the ingredients are well known in the dental field and have been used for many years. The powder and the liquid is a cold cure polymerisation product and has the same mode of action as the major comparable dental brands (resin based dentures). The repair kit is only a temporary repair measure and the denture wearer must visit their dentist.</p> <p>The mixed but uncured powder/liquid itself can be irritant if it comes into contact with the skin, eyes or mucous membranes. This is due to the Methyl Methacrylate contained in the powder/liquid. Therefore, skin and eye contact must be avoided with the uncured powder/liquid. Swallowing of small amounts of the repair kit is not expected to be harmful. Generally, very rare allergic/sensitive reactions cannot be excluded for predisposed persons/patients. The most potential health risk is the misuse of the fast hardening cyanoacrylate glue. It can glue very quickly to the skin or the eyelid area. If the glue comes into contact with the skin or in the eyelid area you must seek medical advice immediately. Adequate warnings are mentioned in the instructions and on the outer packaging.</p> <p>Based on this data it can be concluded that if the product is applied according to the instructions, there is a limited health risk by use of the Denture-Repairfix. The risk lies within the misuse of the glue.</p>

<b>Composition/Indication</b>	<b>Glue:</b> Ethyl Cyanoacrylate <b>Powder:</b> Polymethyl Methacrylate <b>Liquid:</b> Methyl Methacrylate
<b>Shelf life</b>	3 Years

## 2. Regulatory & Legal aspects

<b>Classification Europe</b>	Medical Device Class IIa – CE0124
<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) and Technical Report CR 12401 (Dentistry. Guidance on the classification of dental devices and accessories) is a Class IIa product in accordance with Rule 5 for invasive devices.
<b>NBOG-Code</b>	MD 0402 Dental materials
<b>Target Audience</b>	Wearers of removable full & partial metal or acrylic dentures. Not intended for use on children.

### 3. Production

<b>Hygiene</b>	Hairnet Gloves Shoe covers Breathing mask Disinfectants Laboratory clothing		
<b>Components</b>	1 phial of Polymethyl Methacrylate - powder (1.80g) 1 phial of Methyl Methacrylate – liquid (2.10ml) 1 tube Cyanoacrylate - fast sticking glue (2g)		
<b>Machinery</b>	<b>BRAND</b>	<b>TYPE</b>	<b>PURPOSE</b>
	Cariba		Packaging
	Rota		Filling of phials
			Mixing liquid
<b>Packaging</b>			
<b>Size/Quantities</b>	1 pack Repairfix contains: 1.8g powder; 2.1ml liquid; 2g glue		
<b>Packaging of actual product</b>	2 glass phials, 1 metal tube, 1 spatula, 1 mixing dish, 1 rubber latex finger-protector and 1 piece of emery paper packed in a plastic tray		
<b>External packaging</b>	Pre-printed cardboard		
<b>Instructions for use</b>	1 page printed on one side (9.702.00.A.0.0.22 – R06112017D-PT)		
<b>Labelling</b>	Different languages available		
<b>Storage</b>	Standard Storage conditions – Cool & dry (<25°C)		
<b>Delivery</b>	4 Weeks		

### 4. Quality control

Tests		Passing value	
Type of test	Equipment used	Min	Max
Pressure test		<b>2.5Kg</b>	<b>n/a</b>
Weight test	<b>Scale</b>	<b>1.7g</b>	<b>1.9g</b>
Weight test	<b>Scale</b>	<b>2.0ml</b>	<b>2.2ml</b>
Seal test	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>

### 5. References

Available literature	Safety Data Sheet Declaration of Conformity
References for literature	<ol style="list-style-type: none"> <li><b>Emad M. Al-Khawam, Derek M. Brewis, Malcolm D. Glasse.</b> <i>Cyanoacrylate Adhesives of Potential Medical Use.</i> Leicester, U.K. : School of Chemistry, Leicester Polytechnic, 19.</li> <li><b>Braden, M.</b> <i>Report on BonyPlus Denture RepairFix Kit.</i> London : London Hospital, Dental School, September 1987.</li> <li><i>Der histologische Adpekt bei Unterfüllungen mit Cyanoacrylaten.</i> <b>al., König et.</b> 1990, Die Quintessenz, p. Seite 1495 ff.</li> <li><i>Denture self-repair: Experimental soft tissue response to selected commercial adhesives.</i> <b>al., M. Koudelka et.</b> February 1980, J. Prosth. Dent. Vol.43 , p. Page 143 ff.</li> <li><i>Bericht über einen Kunststoff auf Äthylcyanoacrylatbasis.</i> <b>Krause-Hohenstein, U.</b> January 1982, Die Quintessenz, p. Page 23 ff.</li> <li><i>Fractured denture repairs.</i> <b>al., M. H. Johnson et.</b> May 1982, JADA, Vol 104, p. Page 644 ff.</li> </ol>

	<p>7. <i>Cyanoacrylate hom denture repair: the problem and a solution.</i> <b>Clancy, J. S.</b> 1982, J. Prosth. Dent. Vol 62, p. Page 487 ff.</p> <p>8. <i>In-office permanent denture base correction technique.</i> <b>Ruffino, A. R.</b> 1985, J. Prosth. Dent. Vol 53, p. Page 437.</p> <p>9. <i>Simplified denture repair technique.</i> <b>al., D. A. Nitkiin et.</b> 1979, J. Prosth. Dent. Vol 41, pp. Pages 355-356.</p> <p>10. <i>Cytotoxicity of polymerized commercial cyanoacrylate adhesive on cultered human oral fibroblasts.</i> <b>al., V. Thumwanit et.</b> 1999, Australian Dental Journal Vol 44, pp. Pages 248-252.</p> <p>11. <i>Cytotoxic effects of cyanoacrylates used as retrograde filling materials: an in vitro analysis.</i> <b>De Azevedo CL, Marques MM, Bombana AC.</b> Apr-Jun 2003, Pasqui Odontol Bras., pp. 17(2):113-8.</p> <p>12. <i>Effect of different repair techniques on the accuracy of repositioning the fractured denture base.</i> <b>Goiato MC, Pesqueira AA, Vedovatto E., dos Santos DM, Gennari Filho H.</b> Sept 2009, Gerodontology, pp. 26(3):237-41.</p> <p>13. <i>Cyanoacrylates in dentistry: a review of literature.</i> <b>EL., Herod.</b> April 1990, J Can Dent Assoc. , pp. 56(4): 331-4.</p> <p>14. <i>Cytotoxicity of denture base acrylic resins: a literature reiew.</i> <b>Jorge JH, Giampaolo ET, Machado AL, Vergani CE.</b> Aug 2003, J Prosth. Dent., pp. 90(2):190-3.</p> <p>15. <i>Surgical applications of cyanoacrylate adhesives: a review of toxicity.</i> <b>Leggat PA, Smith DR. Kedjarune U.</b> ANZ J Surg., Apr 2007, pp. 77(4):209-13.</p> <p>16. <i>Surgical applications of methyl methacrylate: review of toxicity.</i> <b>Leggat PA, Smith DR. Kedjarune U.</b> Fall 2009, Arch Environ Occup Health, pp. 64(4):207-12.</p> <p>17. <i>In vivo qualitative analysis of the biocompatibility of different cyanoacrylate-based adhesives.</i> <b>Moretti Neto RT, Mello I, Moretti AB, Robazza CR, Pereira AA.</b> Jan-Mar 2008, Bra Oral Res, pp. 22(1):43-7.</p> <p>18. <i>Factors affecting the strength of denture repairs.</i> <b>Seo RS, Neppelenbroek KH, Filho JN.</b> Jul-Aug 2007, J Prosthodont., pp. 16(4):302-10.</p> <p>19. <i>Comparative study of suture and Cyanoacrylates in skin closure of rats.</i> <b>Souza SC, Oliveira WL, Soares DF, Briglia CH, Athanzio PR, Cerqueria MD, Guimaraes PH, Carreira MC.</b> Jul-Aug 2007, Acta Cir Bras., pp. 22(4):309-16.</p> <p>20. <i>A long term study on residual monomer release from denture materials.</i> <b>Zissis A, Yannikakis S, Polyzois G, Harrison A.</b> Jun 2008, Eur J Prosthodont Restor Dent., pp. 16(2):81-4.</p> <p>21. <b>bonyf AG.</b> MSDS for RepairFix.</p>
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