

# Instructions for Use



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Raised by (Name): Grant Porter Signature:	Position: Operations & Logistics Manager	Date: 01/04/2022
Authorised by (Name): Rebecca Porter Signature:	Position: Managing Director	Date: 01/04/2022

## SINGLE-USE PROCEDURE PACK: Carpal Tunnel Kit, Set TG

<b>Doc No.</b>	OPQC/IFU/017/1	<b>Rev.</b>	1.1	<b>Date of Issue:</b>	20/08/23	<b>Condition:</b>	SINGLE USE	<b>Condition for Use:</b>	STERILE
<b>Device</b>		Single Use Surgical Instrument Kit: Carpal Tunnel Kit, Set TG							
<b>Product Reference</b>		BKM-2047TG							
<b>Intended Use</b>	<p>For professional use. Intended for single use only. This sterile wrapped procedure pack contains a combination of the following items:</p> <ul style="list-style-type: none"> <li>1 x Sterile Wrap</li> <li>1 x Surgical Instrument Tray</li> <li>1 x Surgical Forceps</li> <li>1 x Surgical Dissector</li> <li>1 x Surgical Needle Holder</li> <li>1 x Surgical Retractor</li> <li>1 x Surgical Scissors</li> <li>1 x Disposable Scalpel</li> <li>1 x Sponge Stick</li> <li>1 x Gallipot</li> <li>1 x Fenestrated Drape</li> <li>5 x Nonwoven Swabs</li> </ul>								
<b>Sterilisation (R)</b>		<b>Method:</b>	Gamma Radiation Processed under ISO 13485: 2016 procedures		<b>Radiation Dose Range:</b>	25.00 Min – 35.00 Max kGy			
		<b>Instructions for Use:</b>	DO NOT USE if pack is damaged or open.						
<b>Storage</b>	<ol style="list-style-type: none"> <li>1. Store all instruments as packaged.</li> <li>2. Do not use if packaging is damaged or open.</li> <li>3. Ensure all packs are kept in a storage area free of dust, insects, chemical vapours and extreme changes in temperature and humidity.</li> </ol>								
<b>Warnings/Cautions</b>		<p>Surgical instruments and consumables may be damaged if used for unintended purposes.</p> <p><b>NEVER:</b></p> <ul style="list-style-type: none"> <li>▪ Misuse instruments or overstrain joints or racks.</li> </ul>							

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T 020 8224 2883 | E [info@bluekitmedical.com](mailto:info@bluekitmedical.com) | W [www.bluekitmedical.com](http://www.bluekitmedical.com)  
 A Unit 87 Capital Business Centre | 22 Carlton Road | South Croydon | CR2 0BS  
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	<ul style="list-style-type: none"> <li>▪ Handle instruments by their tips. These will have been cleaned by trained personnel only who will ensure the delicate working ends are adequately protected during storage or sterilisation.</li> <li>▪ Attempt to clean or use abrasives on instruments as this will spoil the surface finish and compromise sterility.</li> <li>▪ Store instruments with other heavier instruments on top. Always remember to store heavy instruments on the bottom and light instruments on the top.</li> <li>▪ Reuse a single use device as this may result in cross infection or functional failure.</li> <li>▪ Use surgical Instruments and consumables without the appropriate training and instruction.</li> </ul>
<b>Instructions</b>	<ul style="list-style-type: none"> <li>▪ Always store appropriately, ensuring storage is free of dust, insects, chemical vapours and extreme changes in temperature and humidity.</li> <li>▪ Always check packaging before use to ensure that packaging is not damaged or open.</li> <li>▪ Always check instruments for damage before use. Give special attention to microsurgical instruments: their fine tips can easily be damaged in transit or storage.</li> <li>▪ Ensure all instruments are only used for the purpose for which they were designed.</li> <li>▪ Handle all instruments gently. Never overstrain, drop, or misuse them.</li> <li>▪ Where any serious incident occurs as a result of use, this incident must be reported to the manufacturer and competent authority.</li> </ul>
<b>Contraindications</b>	<ol style="list-style-type: none"> <li>1. Use without Sterilisation/ Disinfection.</li> <li>2. Rusty conditions visually observed.</li> <li>3. Re-use of Single Use, whether used on a single patient, another patient, or another surgical procedure occurring at another time.</li> </ol>
<b>Shelf Life</b>	Refer to date of manufacture and date of expiration available on product label. Gamma Irradiation (R) provides sterility for 5 years.
<b>Disposal</b>	Single use surgical instruments should be disposed of after use. Used single use surgical instruments should be treated as clinical waste and should therefore be disposed of in accordance with and under the care and direction of the healthcare provider's full Policies and Procedures and must be managed strictly in accordance with local healthcare waste management policies and procedures. If decontaminated, stainless steel is recyclable in ordinary steel manufacturing units.
<b>Distributor</b>	BlueKit Medical Limited <a href="https://bluekitmedical.com">https://bluekitmedical.com</a> Unit 87 Capital Business Centre, 22 Carlton Road, South Croydon, CR2 0BS, England, United Kingdom
<b>Packing provided by</b>	Granton Medical Limited Parkway Close, Parkway Industrial Estate, Sheffield, S9 4WJ, United Kingdom

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<b>Sterilisation provided by</b>	Swann-Morton Limited Owlerton Green, Sheffield, S6 2BJ, United Kingdom
<b>Regulatory Standards</b>	This product is packed in accordance with requirements set out within ISO 14644-1 and processed under ISO 13485: 2016 procedures. All contents are CE marked.
<b>Manufacturer</b>	Surgicrafts Muhammad Pura, Commissioner Road, Sialkot, Pakistan <b>CE 1639</b>
<b>EU Representative</b>	Mr. Manuel Mateos CMC Medical Devices & Drugs S.L, C/ Horacio Lengo n18, C.P 29006, Málaga-Spain
<b>Manufacturer</b>	S.R.R Surgical Airport Road, Kotli Behram, Sialkot, 51310, Pakistan <b>CE 1639</b>
<b>EU Representative</b>	CMC Medical Devices & Drugs S.L 19-21 Crawford Street, London, W1H 1PJ, United Kingdom
<b>Manufacturer</b>	Westfield Medical Limited Second Avenue, Westfield Trading Estate, Midsomer Norton, Radstock, BA3 4DP, United Kingdom
<b>EU Representative</b>	Sterimed SAS Route de Ceret, 66110, Amélie les Bains, France
<b>Manufacturer</b>	DLS Medical Premier House, Southgate Way, Orton Southgate, Peterborough, PE2 6YG, United Kingdom <b>CE 1639</b>
<b>EU Representative</b>	MedEnvoy Global BV 85 Great Portland Street, First Floor, London, W1W 7LT, United Kingdom
<b>Manufacturer</b>	Swann-Morton Ltd. Penn Works, Owlerton Green, Sheffield, S6 2BJ, United Kingdom <b>CE 2797</b>
<b>EU Representative</b>	EMERGO EUROPE Prinsessegracht 20, 2514 AP, The Hague, The Netherlands
<b>Manufacturer</b>	Jiangsu Jianyu Health Medical Co., LTD No.88 Longxi Avenue, Zhulin Town, Jintan District, Changzhou City, Jiangsu Province, People's Republic of China <b>CE 0123</b>
<b>EU Representative</b>	CMC Medical Devices & Drugs S.L 19-21 Crawford St, London, W1H 1PJ, United Kingdom
<b>Manufacturer</b>	Hefei C&P Nonwoven Products Co., Ltd. No. 22 Park Road, Feidong new city development area, Hefei, Anhui, People's Republic of China <b>CE 0197</b>
<b>EU Representative</b>	GENIMPEX S.R.L.S Viale Lombardia 143, 20816, Brugherio, Italy

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<b>Manufacturer</b> 	365 Healthcare Bunzl Retail & Healthcare Supplies Ltd. George House, Unit 6 Delta Park Industrial Estate, Millmarsh Lane, Enfield, London, EN3 7QJ, United Kingdom <b>CE 1639</b>
<b>EU Representative</b> 	Bunzl Ireland Limited Ten Earlsfort Terrace, Dublin D02 T380, Ireland

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