

# Instructions for Use

**BlueKit**  
MEDICAL

Document Ref: OPQC/IFU/014/3	Version: 3.1	Page: 1
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 SURGICAL INSTRUMENTS: Surgical Retractors and Skin Hooks

<b>Doc No.</b>	OPQC/IFU/014/3	<b>Rev.</b>	3.1	<b>Date of Issue</b>	20/08/22 Last doc review date: 19/12/23	<b>Condition:</b>	SINGLE-USE 	<b>Condition for Use:</b>	STERILE  
<b>Device</b>		Single use self-retaining surgical retractors Single use hand-held surgical retractors Single use periocular/lacrimal retractor, hand-held Single use hand-held endoscopic retractor Single use hand-held dental retractor Single use soft-tissue surgical hook							
<b>Intended Use</b>	For professional use. Intended for single use only. Surgical Retractors are hand-held, hinged, or simple Instruments used for grasping, holding and holding back objects, tissues and organs to provide surgical access and exposure. Self-Retaining Surgical Retractors offer a mechanism that allows them to hold back tissues in place without manually holding the instrument in place. Soft-Tissue Surgical Hooks are hand-held or simple instruments used to gently lift and manipulate skin.								
<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>	1. Store all instruments as packaged. 2. Do not use if packaging is damaged or open. 3. Ensure all packs are kept in a storage area free of dust, insects, chemical vapours and extreme changes in temperature and humidity.								
<b>Warnings/Cautions</b>		Surgical instruments may be damaged if used for unintended purposes. <b>NEVER:</b> <ul style="list-style-type: none"> <li>Misuse instruments or overstrain joints or racks.</li> <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> </ul>							

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	<ul style="list-style-type: none"> <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> </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>Use without Sterilisation/ Disinfection.</li> <li>Rusty conditions visually observed.</li> <li>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
<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 CE 1639

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<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

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