

PRODUCT TECHNICAL DATASHEET			
ITEM REFERENCE	011-H2230		
LEGAL MANUFACTURER	ICU Medical, Inc. 951 Calle Amanecer, San Clemente, CA 92673, USA		
ASSEMBLY SITE	ICU Medical de Mexico, S.A. de C., Avenida Cuarza No. 250, Colonia Rancho Santa Clara, Delegacion Maneadero Ensenada, Baja California, Mexico 22790		
ITEM DESCRIPTION	221 cm (87") KR Ext w/3-Gang Stopcock Manifold, 3 White Stopcocks, 7 Clave®, Luer Lock		
PRODUCT CLASS	IV Connector and Sets & Intravascular Administration Sets		
<p>87 in</p> <p>70.75"</p> <p>6"</p> <p>Rev. 10 Capacity = 10.8 ml. Length = 87 in.</p>			
DEVICE GENERIC INFORMATION	IV Extension Sets / Clave® / MicroClave® / NanoClave™ Stopcocks		
LIST OF COMPONENTS	1	ADAPTOR, FLL, .170 TUBING FITMENT	COPOLYESTER

	2	TUBING, .090 X .162 , NON-DEHP	PVC
	3	STOPCOCK, 4 WAY(WHITE)	HDPE POLYCARBONATE POLYPROPYLENE
	4	STOPCOCK, 3 STOPCOCK MANIFOLD, COLORED W/ FLL	HDPE POLYCARBONATE POLYPROPYLENE
	5	ADAPTOR, FIXED MLL, 4.1MM	ABS
	6	SUB ASSY, CLAVE WHITE SPIKE	SILICONE ACRYLIC POLYESTER (PBT)
	7	FILTER CAP	POLYPROPYLENE FILTER MEMBRANE
	8	COHESIVE TAPE, LATEX FREE, 1/2" X 3" X 925 FT	TAPE
	9	BANDING TAPE, 1.125", WHITE W/RED TEXT	TAPE
	Sterile, non-pyrogenic fluid path in unopened undamaged package. This product is made of non-latex components.		
PACKING AND PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging is according to BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials in 25 unit cartons.		
STERILIZATION	Radiation.		
EXPIRY – SHELF LIFE	5 year(s).		
BIOCOMPATIBILITY	Product has been approved for use and has met the requirements for ISO 10993-1.		

LABELS / DIRECTIONS FOR USE	Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual bags and on the outside of the cardboard box. Each sales package contains a Direction for Use.
PRODUCTION ENVIRONMENT	Product is manufactured in an environmentally controlled room. Floor, surfaces and environment are monitored at defined frequencies to verify the controlled room conditions.
TRACEABILITY	ICU Medical guarantees full traceability of all the components used in the production of its devices.
DISPOSAL	The user must dispose the device according to hospital disposal policy.
STORAGE	Store in a dry and clean place. Product should be retained in provided packaging until ready for use.
WARNINGS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.
PRODUCTION CONTROLS	<ul style="list-style-type: none"> • Each component is inspected during acceptance (visual inspections, dimensional checks and functional tests) to verify conformity with the requirements according to ICU Medical internal quality procedures. • During product production and release specific tests are performed according to ICU Medical internal quality procedures. • At least once a month a LAL test is performed on samples taken from production to verify conformity of the endotoxin charge on the products. • At least quarterly Bioburden tests are performed on samples taken from production to verify conformity of the microbial charge on the products.
QUALITY SYSTEM AND PRODUCT CERTIFICATION	<p>Quality System is in compliance to: ISO 13485:2016</p> <p>Product Certification: The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.</p> <p>CE Certificate Number: 252.602</p> <p>Notified Body: NSAI National Standards Authority of Ireland.</p> <p>MDD Device Classification: Class IIa</p>