PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-CL4191	REVISION:	02

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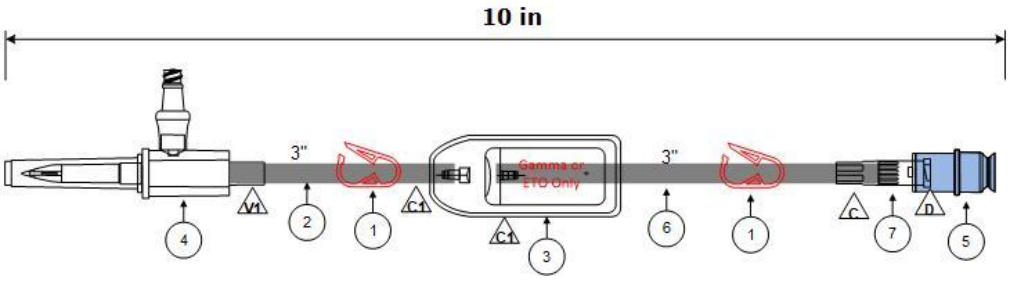
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA						
IMPORTER	**ICU Medical B.V.** Hofspoor 3, 3994 VZ Houten, The Netherlands						
EU AUTHORISED REPRESENTATIVE (EUAR)	**Medical Device Safety Service GmbH (MDSS)**, Schiffgraben 41, 30175 Hannover, Germany						
ASSEMBLY SITE	**ICU Medical de Mexico**, S.A. de C..**,** Avenida Cuarza No. 250, Colonia Rancho Santa Clara, Delegacion Manaedero Ensenada, Baja California, Mexico 22790						
CLASSIFICATION CODE	**GMDN** Code: 41222						
INTENDED USE	Medication transfer set A collection of sterile devices and supplies designed to transfer parenteral medications [e.g., intravenous (IV) fluids, drugs] between a first container(s) [e.g., a vial(s)] and a second container/administration line [e.g., an IV bag/line] in a non-powered closed system; it may also be used to compound and/or reconstitute medication for its preparation and administration. It is available in a variety of configurations and typically includes vials, tubulures, connectors, spikes, syringes, and caps. This is a single-use device.						
ITEM DESCRIPTION	Transfer Set, ChemoClave™ Bag Spike w/Port, ChemoLock™ Port						
PRIMING VOLUME (ml)	4.2	**LENGTH (cm)**	25,4	**WEIGHT (g)**	22.186	**CASE QTY**	50



ITEM SPECIFIC DATA	**Chemical Compatibility**	Lipids & Common Chemotherapeutics
	Luer Compatibility	ISO 80369-7 Compliant male luers > 1,55mm Internal diameter
	Sterilization and Shelf Life	Radiation; 5-Year Expiration
CLAVE SPECIFIC DATA	**Backpressure Rating**	60 psig / 3103 mmHG (Unactivated)
	Microbial Ingress and Disinfection Compatibility	Microbial barrier for seven days utilizing a 70% IPA disinfection

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CHEMOLOCK SPECIFIC DATA	**Extended Use**	600 repeat activations	
	Connected Pressure Rating	45 psig / 2327 mmHG	
	Activations	10 Activations	
	Needlefree Connector Compatibility	ChemoLock Port compatible with all known Needlefree Connectors	
	Pressure Rating	ChemoLock Injector = 45 psig / 2327 mmHG; ChemoLock Port = 20 psig / 1034 mmHG	
	Cytotoxic Drug Compatibility	Solvent and fat emulsion drugs including full strength etoposide and paclitaxel drugs.	
	Microbial Ingress and Disinfection Compatibility	Microbial barrier for seven days utilizing a 70% IPA disinfection	
LIST OF COMPONENTS *(Latex and DEHP Free)*	1	CLAMP, PINCH, RED	POLYPROPYLENE
	2	TUBING	PVC
	3	FILTER, 0.2 MICRON, ADULT IV-5	ACRYLIC, FILTER MEMBRANE
	4	SUBASSY, BAG SPIKE W/CLAVE	SILICONE SILICONE LUBRICANT ACRYLIC POLYESTER (PBT) POLYETHYLENE ABS
	5	CHEMOLOCK™ PORT	SILICONE SILICONE LUBRICANT STAINLESS STEEL POLYCARBONATE POLYETHYLENE
	6	TUBING, FROSTED	PVC
	7	FEMALE ADAPTER, LUER LOCK (0.138 OD TUBING)	PCTG POLYETHYLENE
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	Product has met the requirements of ISO 10993-1 and related standards for biocompatibility.		
PRECAUTIONS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.		

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LABELS AND DIRECTIONS FOR USE	Label and/or DFU contain information for proper use including any warnings or contraindications. Labels are applied on the individual package and on the outside of the cardboard box. Each sales package contains a Direction for Use where applicable.	
PACKING AND PACKAGING	The non-unit packaging is biodegradable as defined by Directive 94/62/EC. Packaging met the requirements of BS EN ISO 11607. The packaging for this product is Latex Free. This item is blister packed or pouched individually using medical grade materials.	
TRACEABILITY	Lot number provides full traceability of all components and manufacturing processes.	
STORAGE	Store in a dry and clean place. Product should be retained in packaging until ready for use.	
DISPOSAL	The user must dispose of the device according to hospital disposal policy.	
PRODUCTION AND ENVIRONMENT CONTROLS	• Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures. • Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures. • Production and release specific tests are performed according to quality procedures. • Limulus amebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures. • Bioburden tests are performed on production samples to verify conformity of the microbial charge according to quality procedures.	
QUALITY SYSTEM AND PRODUCT CERTIFICATION	**Quality System complies to:**	ISO 13485:2016
	Product Certification:	The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.
	CE Certificate Number:	252.602
	Notified Body:	NSAI National Standards Authority of Ireland.
	MDD Device Classification:	Class IIa