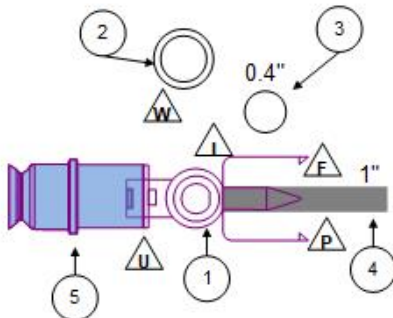


PRODUCT TECHNICAL DATASHEET

ITEM REF: 011-CL-72 REVISION: 08

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 Manadero Ensenada, Baja California, Mexico 22790						
CLASSIFICATION CODE	GMDN Code: 60539						
INTENDED USE	The ChemoLock Closed System Drug Transfer Device prevents the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system. The ChemoLock is needlefree and cannot be deactivated, which will passively aid in preventing needlestick injuries and the exposure to cytotoxic medications for healthcare personnel						
ITEM DESCRIPTION	ChemoLock™ Vented Vial Spike, 13mm						
PRIMING VOLUME (ml)	0.13	LENGTH (mm)	5	WEIGHT (g)	4.941	CASE QTY	50
							
ITEM SPECIFIC DATA	Chemical Compatibility		LIPIDS, COMMON CHEMOTHERAPEUTICS				
	Sterilization and Shelf Life		Radiation; 5-Year Expiration				
CHEMOLOCK SPECIFIC DATA	Connected Pressure Rating		45 psig / 2327 mmHG				
	Activations		10 Activations				
	Microbial Ingress and Disinfection Compatibility		Microbial barrier for seven days utilizing a 70% IPA disinfection				
LIST OF COMPONENTS	1	13MM VENTED VIAL SPIKE	COPOLYESTER				
	2	ULTRASONIC RING	ABS (NON-FLUID PATH)				
	3	FILTER	PTFE (NON-FLUID PATH)				
	4	TUBING CAP	POLYURETHANE (NON-FLUID PATH)				

PRODUCT TECHNICAL DATASHEET

ITEM REF: 011-CL-72 REVISION: 08



	5	CHEMOLOCK PORT	SILICONE POLYCARBONATE SILICONE LUBRICANT STAINLESS STEEL (NON-FLUID APTH)
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	This product is made of non-latex, and non-DEHP components. Product has met the requirements of ISO 10993-1 for biocompatibility.		
PRECAUTIONS	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.		
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 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.		
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	<ul style="list-style-type: none"> 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:	252.1002	
	Notified Body:	NSAI National Standards Authority of Ireland.	
	MDD Device Classification:	Class IS	