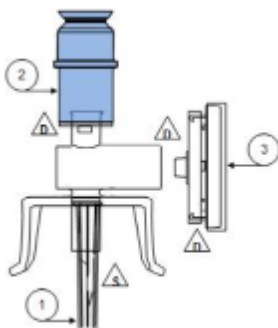


# PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-CL-80SXL	REVISION:	03
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**icumedical**  
human connections

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™ Vial Spike, 32mm						
PRIMING VOLUME (ml)	0.176	LENGTH (cm)	6.38	WEIGHT (g)	15.69	CASE QTY	50
							
ITEM SPECIFIC DATA	MRI Compatibility	No metal components					
	Chemical Compatibility	Lipids & Common Chemotherapeutics					
	Luer Compatibility	ISO 80369-7 Compliant.					
	Sterilization and Shelf Life	Radiation; 5-Year Expiration					

# PRODUCT TECHNICAL DATASHEET

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<b>CHEMOLOCK SPECIFIC DATA</b>	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
<b>LIST OF COMPONENTS</b> (Latex and DEHP Free)	1	SUB-ASSY, VIAL ADAPTER, LONG SPIKE, 32MM	POLYCARBONATE
	2	CHEMOLOCK™ PORT	SILICONE SILICONE LUBRICANT STAINLESS STEEL POLYCARBONATE POLYETHYLENE
	3	SUB-ASSY, ENTERPRISE FILTER	TAPE FILM SILICONE POLYCARBONATE FILTER MEMBRANE
<b>MATERIAL COMPLIANCE AND BIOCOMPATIBILITY</b>	Product has met the requirements of ISO 10993-1 and related standards for biocompatibility.		
<b>PRECAUTIONS</b>	Use aseptic techniques. Single-use only – Do not resterilize. Sterile, Non-Pyrogenic fluid pathway in unopened, undamaged package.		
<b>LABELS AND DIRECTIONS FOR USE</b>	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.		
<b>PACKING AND PACKAGING</b>	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.		
<b>TRACEABILITY</b>	Lot number provides full traceability of all components and manufacturing processes.		
<b>STORAGE</b>	Store in a dry and clean place. Product should be retained in packaging until ready for use.		
<b>DISPOSAL</b>	The user must dispose of the device according to hospital disposal policy.		

## PRODUCT TECHNICAL DATASHEET

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PRODUCTION AND ENVIRONMENT CONTROLS	<ul style="list-style-type: none"> <li>Product is manufactured in an environmentally controlled room. Floor, surfaces, and environment are monitored according to quality procedures.</li> <li>Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures.</li> <li>Production and release specific tests are performed according to quality procedures.</li> <li>Limulus amoebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures.</li> <li>Bioburden tests are performed on production samples to verify conformity of the microbial charge according to quality procedures.</li> </ul>	
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 I Sterile