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PRODUCT TECHNICAL DATASHEET

ITEM REFERENCE	**011-CL-70S**	**REVISION**	**06**
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		
ITEM DESCRIPTION	ChemoLock™ Vented Vial Spike, 20mm		
PRODUCT FAMILY	Vial Adapters		
CLASSIFICATION CODE	N/A		
INTENDED USE	Vial/bottle adaptor, non-hermetic: A sterile device intended to be fitted to a vial or bottle to enable the removal of its contents, (e.g., medication, nutritional solution for enteral feeding) into a syringe, for subsequent administration to a patient. It is typically a housing with a syringe connector that attaches to the container or replaces its lid; it does not allow for pressure equalization/airtight transfer of contents. This is a single-use device.		

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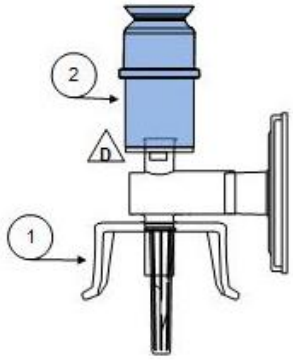

SPECIFIC ITEM DATA	**Priming Volume (ml)**	0.18	
	Length (mm)	63.50	
	Weight (g)	8.78	
CHEMOLOCK PERFORMANCE DATA	**Connected Pressure Rating**	45psig	
	Activations	10 Activations	
	Needlefree Connector Compatibility	ChemoLock Port with all known Needlefree Connectors	
	Pressure Rating	ChemoLock Injector = 45psig; ChemoLock Port = 20psig	
	Cytotoxic Drug Compatibility	Solvent and fat emulsion drugs including full strength etoposide and paclitaxel drugs. Also compatible with bendamustine HCL (Busulfan®) with specific products for compounding and with all products when diluted for administration.	
LIST OF COMPONENTS	1	SUB-ASSY, UNIVERSAL VIAL ACCESS W/SKIRT, LARGE FIL	POLYCARBONATE ABS PTFE
	2	CHEMOLOCK™ PORT	SILICONE STAINLESS STEEL POLYCARBONATE

	Sterile, non-pyrogenic fluid path in unopened undamaged package. This product is made of non-latex, non-DEHP 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 50 unit cartons.
STERILIZATION	Radiation.
EXPIRY – SHELF LIFE	5 years
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	• 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	**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