

PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-41424-03	REVISION:	11
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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: 44833						
INTENDED USE	A device designed for accurate injection of an indicator solution (e.g., cooled saline, dye) into the blood stream that includes a mechanical mechanism used to inject the solution, in a closed loop, into a blood vessel through an indwelling catheter (e.g., Swan-Ganz cardiac catheter) mainly to assess heart blood flow and measure cardiac output. It may be used in conjunction with a densitometer or a thermodilution device to determine cardiac output. This is a reusable device						
ITEM DESCRIPTION	THERMOSET™ ROOM TEMPERATURE CLOSED-LOOP INJECTABLE DELIVERY SYSTEM WITH IN-LINE TEMPERATURE PROBE						
PRIMING VOLUME (ml)	15.2	LENGTH (cm)	37.75	WEIGHT (g)	72.8	CASE QTY	20
	Chemical Compatibility		Lipids & Common Chemotherapeutics				
	Luer Compatibility		ISO 80369-7 Compliant.				
	Sterilization and Shelf Life		ETO; 3-Year Expiration				
LIST OF COMPONENTS <i>(Latex and DEHP Free)</i>	1	LATEX FREE COHESIVE BELLY BAND	TAPE				
	2	DURA-CLAMP, SMALL TUBING	NATURAL RUBBER				

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	3	COVER, VENTED, WHITE, RG	ABS
	4	VENTED WHITE CAP, RG	ABS
	5	SUBASSEMBLY VALVE THERMOSET	POLYCARBONATE
	6	LUER LOCK NUT, POLYCARB. CLEAR	POLYCARBONATE
	7	SPARE PARTS, W/3 WAY STOPCOCK(HSP 67-1856)	ABS
	8	FLOW THROUGH HOUSING ASSEMBLY	PVC POLYCARBONATE STAINLESS STEEL
	9	SPIKE,BAG,NON VENTED, .170 TUBING	ABS POLYETHYLENE
	10	INSULATED SYRINGE, 10CC/SHEATH	ABS POLYCARBONATE UV ABSORBER POLYPROPYLENE SILICONE RUBBER POLYISOPRENE POLYCARBONATE
	11	TUBING, .122 X .170 , GTX FROSTED, 75 DUROMETER	PVC
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	<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 amoebocyte 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: 252.702
	Notified Body: NSAI National Standards Authority of Ireland.
	MDD Device Classification: Class IIa