PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-41434-01	REVISION:	05

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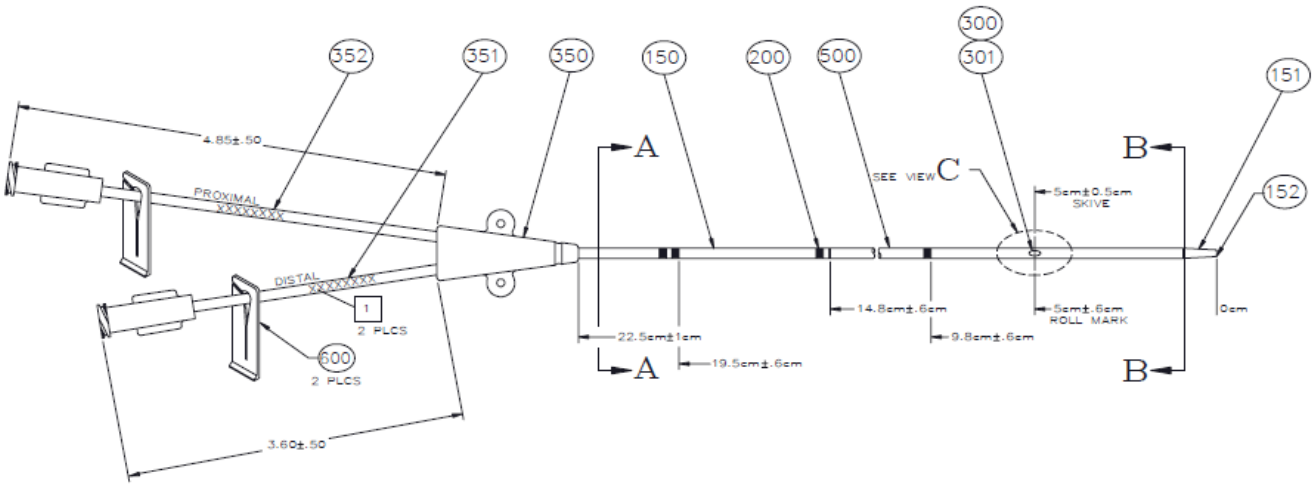
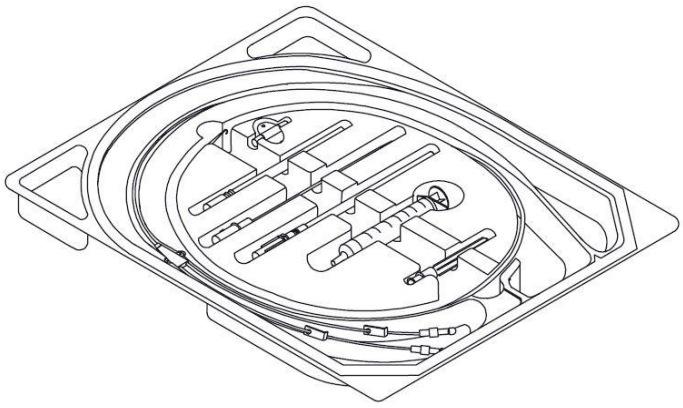
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA						
IMPORTER	**ICU Medical B.V.** Hofspoor 3, 3994 VZ Houten, The Netherlands						
EU AUTHORISED REPRESENTATIVE (EUAR)	**Medical Device Safety Service GmbH (MDSS)**, Schiffgraben 41, 30175 Hannover, Germany						
ASSEMBLY SITE	**ICU Medical (Utah), Inc.,** 4455 Atherton Drive, Salt Lake City, UT 84123						
CLASSIFICATION CODE	**GMDN** Code: 10729						
INTENDED USE	Catheter, intravascular, infusion, central venous. A central venous catheter is a device to infuse substances and/ or aspirate blood. It is a flexible tube usually introduced into the neck or thoracic vein, and is inserted into the superior vena cava.						
ITEM DESCRIPTION	Central Venous Catheter, Heparin Coated, 2 Lumen, 16/16 G, 20 cm, MAP, Basic Kit						
PRIMING VOLUME (ml)	N/A	**LENGTH (cm)**	20	**WEIGHT (g)**	N/A	**CASE QTY**	10





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ITEM SPECIFIC DATA		**Chemical Compatibility**	Lipids & Common Chemotherapeutics
		Luer Compatibility	ISO 80369-7 Compliant.
		Sterilization and Shelf Life	ETO; 2-Year Expiration
LIST OF COMPONENTS *(Latex and DEHP Free)*	150	TUBING, PU, 2L, 27CM, 16/16 GA	POLYURETHANE
	151	TUBING, PU, TIPPING, BLUE	POLYURETHANE
	200	BAND MARKS	INK
	300	BEADING, URETHANE, .022-.026"	POLYURETHANE
	301	ADHESIVE,URETHANE	POLYURETHANE ADHESIVE
	350	MANIFOLD	POLYURETHANE
	351	DISTAL LEAD TBG ASSY	URETHANE PCTG
	352	PROXIMAL LEAD TBG, ASSY	URETHANE PCTG
	500	HEPARIN COATING	HEPARIN BENZALKONIUM
	600	SLIDE CLAMP	ABS
	601	MALE ADAPTER PLUG	ACRYLIC ISOPRENE
	603	Abbocath-T Assembly 16 Gauge x 2.00 Inches ISO	STAINLESS STEEL ACRYLIC RADIOPAQUE TEFLON ABS
	604	DILATOR,8F X 4 INCHES	POLYETHYLENE
	605	CLAMP, CATHETER, INFUSION	TPE
	606	18 GAUGE THINWALL NEEDLE	STAINLESS STEEL ABS
	607	SYRINGE, ASSY,5.0ML,SL,W/O CAP	POLYPROPYLENE POLYISOPRENE
	608	CANNULA IN HUB, 22 GA X 1 1/2"	STAINLESS STEEL POLYPROPYLENE
	609	0.035 DOUBLE ENDED GUIDEWIRE AND DISPENSER	STAINLESS STEEL POLYPROPYLENE
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.		
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.		

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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:	252.129
	Notified Body:	NSAI National Standards Authority of Ireland.
	MDD Device Classification:	Class III