PRODUCT TECHNICAL DATASHEET

icumedical
human connections

ITEM REF:	011-42338-01	REVISION:	02

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	**N/A**
INTENDED USE	MOUNTING BRACKET
ITEM DESCRIPTION	SAFESET™ MOUNTING BRACKET Reusable Device: Do Not Discard

PRIMING VOLUME (ml)	0	LENGTH (cm)	5	WEIGHT (g)	6.853	CASE QTY	30
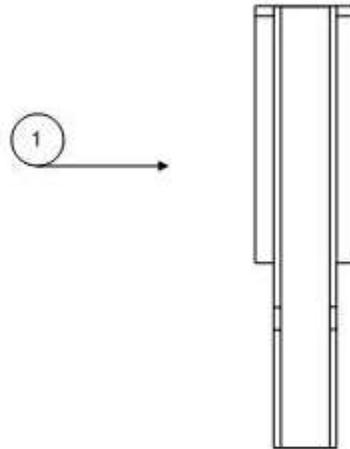
	MRI Compatibility	No Metal Components
	Chemical Compatibility	N/A
SPECIFIC ITEM DATA	Luer Compatibility	N/A
	Sterilization and Shelf Life	N/A

LIST OF COMPONENTS	1	RESERVOIR BRACKET, SAFESET	POLYCARBONATE

MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	This product is made of non-latex, and non-DEHP components.

ICU Medical B.V. • Hofspoor 3 • 3994 VZ Houten • The Netherlands
VAT: NL8537.83.664.B.01 • Chamber of Commerce: 60146591
www.icumed.com

Page **1** of 2

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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 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	• 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.		
QUALITY SYSTEM AND PRODUCT CERTIFICATION	Quality System complies to:	ISO 13485:2016	
	Product Certification:	N/A	
	CE Certificate Number:	N/A	
	Notified Body:	N/A	
	MDD Device Classification:	N/A	