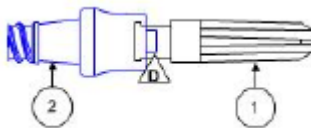


# PRODUCT TECHNICAL DATASHEET

ITEM REF: CS-53 REVISION: 18

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: 60539						
INTENDED USE	The ChemoClave is a needle-free CSTD that mechanically prohibits the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system during drug preparation and administration, thereby minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs.						
ITEM DESCRIPTION	Spike with Bonded Clave® Connector						
PRIMING VOLUME (ml)	0.16	LENGTH (cm)	4.7	WEIGHT (g)	3.62	CASE QTY	50
<div></div>							
ITEM SPECIFIC DATA	Chemical Compatibility			Lipids & Common Chemotherapeutics			
	Luer Compatibility			ISO 80369-7 compliant male luers > 1,55mm Internal diameter			
	Sterilization and Shelf Life			Radiation; 5-Year Expiration			
	Microbial Ingress and Disinfection Compatibility			Microbial barrier for seven days utilizing a 70% IPA disinfection			
LIST OF COMPONENTS	1	SPIKE, W/CAP		POLYCARBONATE ABS (NON-FLUID PATH)			
	2	CLAVE WHITE SPIKE		SILICONE SILICONE LUBRICANT ACRYLIC POLYESTER (PBT) (NON-FLUID PATH)			
MATERIAL COMPLIANCE AND BIOCOMPATIBILITY	This product is made of non-latex, and non-DEHP components. Product has met the requirements of ISO 10993-1 and related standards for biocompatibility.						

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<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.	
<b>PRODUCTION AND ENVIRONMENT CONTROLS</b>	<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>	
<b>QUALITY SYSTEM AND PRODUCT CERTIFICATION</b>	<b>Quality System complies to:</b>	ISO 13485:2016
	<b>Product Certification:</b>	The product is manufactured in compliance to Council Directive MDD 93/42/EEC as amended.
	<b>CE Certificate Number:</b>	252.1002
	<b>Notified Body:</b>	NSAI National Standards Authority of Ireland.
	<b>MDD Device Classification:</b>	Class I Sterile