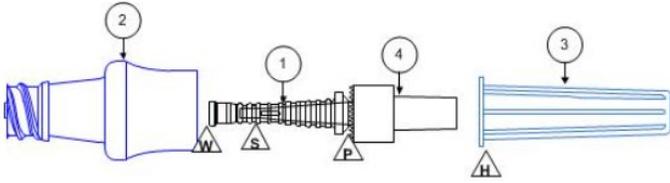


# PRODUCT TECHNICAL DATASHEET

<b>ITEM REF:</b>	<b>011-C1000NS</b>	<b>REVISION:</b>	<b>16</b>
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<b>LEGAL MANUFACTURER</b>	ICU Medical, Inc. 951 Calle Amanecer, San Clemente, CA 92673, USA						
<b>IMPORTER</b>	ICU Medical B.V. Hofspoor 3, 3994 VZ Houten, The Netherlands						
<b>EU AUTHORISED REPRESENTATIVE (EUAR)</b>	Medical Device Safety Service GmbH (MDSS), Schiffgraben 41, 30175 Hannover, Germany						
<b>ASSEMBLY SITE</b>	ICU Medical (Utah), Inc., 4455 Atherton Drive, Salt Lake City, UT 84123						
<b>CLASSIFICATION CODE</b>	GMDN Code: N/A						
<b>INTENDED USE</b>	<p>Neutral-pressure needleless valve-connector</p> <p>A small, sterile, stand-alone, Luer-activated needleless plastic valve intended to mate two related intravenous (IV) line devices [e.g., hypodermic syringe and catheter port or tubing from an IV administration set] and hold them in a secured, sealed, locked position until disconnection, at which point there is minimal fluid flow into or out of the catheter/tubing. It is intended to eliminate the use of needles for IV administration of medications. This is a single-use device.</p>						
<b>ITEM DESCRIPTION</b>	Clave® Connector, Non-Sterile						
<b>PRIMING VOLUME (ml)</b>	0.06	<b>LENGTH (cm)</b>	3.048	<b>WEIGHT (g)</b>	2.79	<b>CASE QTY</b>	2000
							
<b>ITEM SPECIFIC DATA</b>	<b>MRI Compatibility</b>		No metal components				
	<b>Chemical Compatibility</b>		Lipids & Common Chemotherapeutics				
	<b>Luer Compatibility</b>		ISO 80369-7 Compliant male luers > 1,55mm Internal diameter				
	<b>Sterilization and Shelf Life</b>		N/A Non-sterile				
<b>CLAVE SPECIFIC DATA</b>	<b>Power Injector Maximum Pressure</b>		≥ 400 psig / 20686 mmHG (activated)				
	<b>Backpressure Rating</b>		60 psig / 3103 mmHG (Unactivated)				
	<b>Microbial Ingress and Disinfection Compatibility</b>		Microbial barrier for seven days utilizing a 70% IPA disinfection				
	<b>Extended Use</b>		600 repeat activations				

# PRODUCT TECHNICAL DATASHEET

ITEM REF:	011-C1000NS	REVISION:	16
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<b>LIST OF COMPONENTS</b>	1	PLUG, SILICONE, STEPPED HEAD	SILICONE
	2	BODY, CLAVE, NO-STICK,	POLYBUTYLENE TEREPHTHALATE (PBT)
	3	CAP, BREATHER, FEMALE, BLUE	POLYPROPYLENE
	4	SPIKE, CLAVE, WHITE, CYREX	ACRYLIC
<b>MATERIAL COMPLIANCE AND BIOCOMPATIBILITY</b>	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.		
<b>PRECAUTIONS</b>	Use aseptic techniques. Single-use only – Non-sterile.		
<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>	N/A	
	<b>CE Certificate Number:</b>	N/A	
	<b>Notified Body:</b>	N/A	
	<b>MDD Device Classification:</b>	N/A	