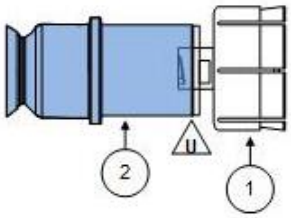
# PRODUCT TECHNICAL DATASHEET

| ITEM REF: | 011-CL-62 | REVISION: | 06 |
|---|---|---|---|

icumedical
human connections

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **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 ChemoLock Closed System Drug Transfer Device prevents the transfer of environmental contaminants, including bacterial and airborne contaminants into the system, and the escape of drug or vapor concentrations outside the system. The ChemoLock is needlefree and cannot be deactivated, which will passively aid in preventing needlestick injuries and the exposure to cytotoxic medications for healthcare personnel | | | | | | |
| **ITEM DESCRIPTION** | ChemoLock™ Vial Spike, 13mm | | | | | | |
| **PRIMING VOLUME (ml)** | 0.13 | **LENGTH (cm)** | 4.32 | **WEIGHT (g)** | 5.06 | **CASE QTY** | 50 |




| | | |
|---|---|---|
| | **Chemical Compatibility** | Lipids & Common Chemotherapeutics |
| | **Luer Compatibility** | ISO 80369-7 Compliant. |
| | **Sterilization and Shelf Life** | Radiation; 5-Year Expiration |
| **CHEMOLOCK SPECIFIC DATA** | Connected Pressure Rating | 45 psig / 2327 mmHG |
| | Activations | 10 Activations |
| | Needlefree Connector Compatibility | ChemoLock Port compatible with all known Needlefree Connectors |
| | Pressure Rating | ChemoLock Injector = 45 psig / 2327 mmHG; ChemoLock Port = 20 psig / 1034 mmHG |
| | Cytotoxic Drug Compatibility | Solvent and fat emulsion drugs including full strength etoposide and paclitaxel drugs. |
| | Microbial Ingress and Disinfection Compatibility | Microbial barrier for seven days utilizing a 70% IPA disinfection |

| PRODUCT TECHNICAL DATASHEET | | | |
|---|---|---|---|
| **ITEM REF:** | **011-CL-62** | **REVISION:** | **06** |

icumedical
human connections

| | | | |
|---|---|---|---|
| **LIST OF COMPONENTS** *(Latex and DEHP Free)* | 1 | DRIP CHAMBERS/SPIKES | COPOLYESTER |
| | 2 | CHEMOLOCK™ PORT | STAINLESS<br>POLYCARBONATE<br>SILICONE |

| | | |
|---|---|---|
| **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. | |
| **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.<br>• Each component is inspected during acceptance (example: visual; dimensional; functional) to verify conformity with the requirements according to quality procedures.<br>• Production and release specific tests are performed according to quality procedures.<br>• Limulus amebocyte lysate (LAL) testing is performed on production samples to verify conformity of the endotoxin charge according to quality procedures.<br>• 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:** | 252.1002 |
| | **Notified Body:** | NSAI National Standards Authority of Ireland. |
| | **MDD Device Classification:** | Class I Sterile |