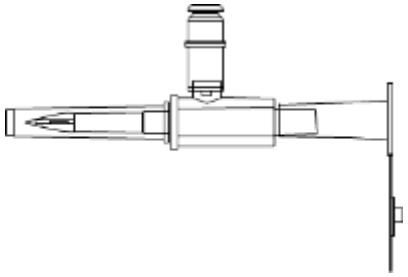
PRODUCT TECHNICAL DATA SHEET

ITEM REFERENCE	**011-CL-12**
LEGAL MANUFACTURER	**ICU Medical, Inc.** 951 Calle Amanecer, San Clemente, CA 92673, USA
ASSEMBLY SITE	• **ICU Medical, Inc.,** 4455 Atherton Drive Salt Lake City, UT 84123 • **ICU Medical S. de R.L. de C.V.,** Avenida Cuarza No. 250 Colonia Rancho, Santa Clara, Manaedero Ensenada, Baja California, Mexico 22790
ITEM DESCRIPTION	ChemoLock™ Bag Spike with Additive Port, Dry Spike
INTENDED USE	*IV Connector and Sets & Intravascular Administration Sets*
	
DEVICE GENERIC INFORMATION	Add on Bag Spike with ChemoLock™ The device is compatible with the common chemotherapy/antiblastic drugs and diluents.
LIST OF COMPONENTS	No-Vented spike with protecting cap (ABS, Polyethylene) ChemoLock™ Port, needle-free female valve, bi-directional self-sealing (Polycarbonate, Silicone, Stainless steel) Add on dry spike with closure cap (PVC no-DEHP) Priming Volume: approx 0.39 ml ChemoLock Port allows for a closed connection on vial spikes and bag spikes and for use on patient IV lines. The male end of the Port is compatible with all female ISO connections while the other side is only compatible with the ChemoLock to ensure compliance ChemoLock™ system is a Needlefree Mechanically and Microbiologically Closed System Drug Transfer Device (CSTD) with click to lock technology and passive self-sealing system to prevent the transfer of environmental contaminants into the system, and the escape of drug out of the system.
PACKING AND PACKAGIN	Individual packaged product using pouch/blister in medical paper and film. Cardboard boxes. Indivisible box composed by: 50 pcs. Packing and packaging according to UNI EN ISO 11607/1-2.
STERILIZATION	RADIATION: validated method according to UNI EN ISO 11137
EXPIRY – SHIELD LIFE	5 Year (from sterilization date) if undamaged package and properly stored Do not re-use, Reuse negatively impacts performance / sterility potentially resulting in product failure / contamination

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ICU MEDICAL EUROPE srl
A socio unico
Società soggetta ad attività di direzione e coordinamento di ICU Medical Inc. USA
Sede legale e operativa: Roncanova di Gazzo Veronese, Via Martiri della Libertà, 1/A, 37060 Roncanova (VR)
Registro Imprese di Verona: 03237150234 - REA di Verona: 320421 – CF e P.IVA: IT 03237150234
Tel. +39 0442 570106 – Fax +39 0442 570109

BIOCOMPATIBILITY	All the material are biocompatible according to ISO 10993
LABELS	Labels are applied on the individual bags and on the outside of the cardboard box. Product identification data according to Directive 93/42/EEC point 13.3 and the specific technical standards
INSTRUCTION FOR USE	Contained in each sales package (according to EN 1041 and further modifies and integrations)
PRODUCTION ENVIROMENT	Controlled production environments. Microbiological and particle controls are performed on environmental air and surfaces (UNI EN ISO 14644/1-2).
TRACEABILITY	ICU Medical guarantees full traceability of all the components used in the production of its devices
DISPOSAL	The user must dispose the device according to hospital disposal policy.
STORAGE	Store in a dry and clean place.
WARNINGS	Use aseptic techniques. Single-use only – Do not resterilize..
PRODUCTION CONTROLS	• Each component is inspected during acceptance (visual inspections, dimensional checks and functional tests) to verify conformity with the requirements according to ICU Medical internal quality procedures • During product production and release specific tests are performed according to ICU Medical internal quality procedures. • At least once a month a LAL test is performed on samples taken from production to verify conformity of the endotoxin charge on the products. • At least quarterly Bioburden tests are performed on samples taken from production to verify conformity of the microbial charge on the products.
QUALITY SYSTEM AND PRODUCT CERTIFICATION	**Quality System in compliance with** I.S.EN ISO 13485:2012 ➢ **Certificate** Number MD19.4496 **Notified body:** NSAI (National Standards Authority of Ireland) **Product certification:** in compliance with Directive 93/42/EEC (Annex II) and further modifies and integrations. **CE Certificate**: Number 252.602 CE 0050 **Notified Body:** NSAI (National Standards Authority of Ireland**)** **Classification:** Class IIa (Annex IX Directive 93/42/EEC).
PATENTS	US. PAT. 9089475; 9132062

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