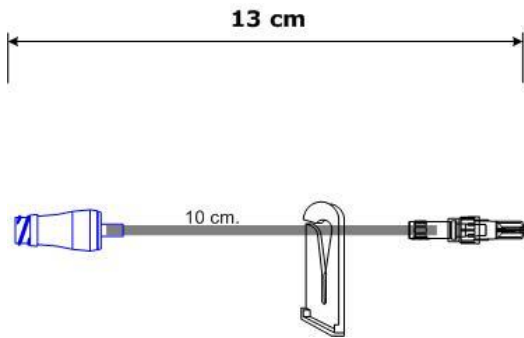


PRODUCT TECHNICAL DATA SHEET	
ITEM REFERENCE	011-H1976
LEGAL MANUFACTURER	ICU Medical, Inc. 951 Calle Amanecer, San Clemente, CA 92673, USA
ASSEMBLY SITE	- ICU Medical, Inc., 4455 Atherton Drive Salt Lake City, UT 84123 - ICU Medical S. de R.L. de C.V. Avenida Cuarza No. 250 Colonia Rancho, Santa Clara, Manáedero Ensenada, Baja California, Mexico 22790
ITEM DESCRIPTION	13 cm (5") Smallbore Ext w/MicroCLAVE®, Clamp, Rotating Luer Lock
INTENDED USE	IV Connector and Sets & Intravascular Administration Sets.
	
DEVICE GENERIC INFORMATION	Extension set with smallbore tubing, access by MicroCLAVE® Connector and Rotating male Luer Lock at the end. The device is compatible with the common chemotherapy/antiblastic drugs and diluents.
LIST OF COMPONENTS	MicroCLAVE® Connector, needle-free female valve, bi-directional self-sealing (Valox®, ABS, Silicone) Slide clamp, removable (Polyethylene) Rotating male Luer Lock with breather cap (Polycarbonate, PVC, Polyethylene) PVC Clear NO-DEHP Tubing, diameter (1.2 x 2.1) mm Priming Volume: approx. 0.20 ml The MicroCLAVE ® Connector is a neutral pressure needle-free female valve, bi-directional self-sealing and low dead-volume. The CLAVE® Connector can be used for infusion and/or withdrawal and venous/arterial long term access. The seal is automatically opened when it is access by a male Luer. This device, compared to conventional needle free connectors, allows not only to eliminate injuries from needle, thus protecting operators from the risk of infections (AIDS, hepatitis, etc..) and prevents microorganisms to access the system, minimizing the microbial contamination. The MicroCLAVE ® Connector System, if used according to the procedure, is easily disinfected due to its smooth surface. The MicroCLAVE ® Connector maintains a sterile barrier for 7 days and 700 activations. This information is collected in the archive of ICU Medical, Inc.. San Clemente, California 92673, USA. Do not use needles or Luer caps on CLAVE®connectors. The CLAVE® is compatible with Luer connectors with inside diameter between 1.55 mm and 2.8 mm.
PACKING AND PACKAGING	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.
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  Notified Body: NSAI (National Standards Authority of Ireland) Classification: Class IIa (Annex IX Directive 93/42/EEC).