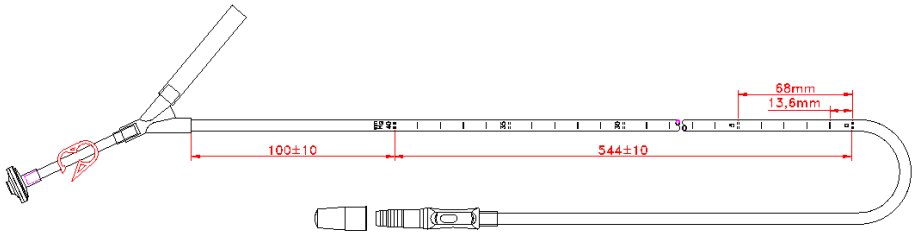
SecurMeter	
MANUFACTURER	**Bioengineering Laboratories Srl** Via Provinciale per Dubino 10 – 23014 Delebio (SO) Tel. +39 0342684693
INTENDED USE / INDICATIONS	The SecurMeter is a sterile single-use device for the monitoring of intra-abdominal pressure (“IAP”) via the bladder (“Pvescical”) in hospitalized patients. Accuracy: + 5% of pressure reading.
DEVICE DESCRIPTION	Securmeter is a device for the monitoring of intra-abdominal pressure (“IAP”) used with patients with a body weight of at least 10 Kg, with a Foley catheter, and at risk of developing intraabdominal hypertension.
CLASS	*Class Is*
CND CODE	U050401

Codes
SecurMeter

Code	mmHg scale length (mm)	Length (mm)	Ext diam (mm)	Int diam (mm)	Max pressure* (mmHg)	Min pressure* (mmHg)	RDM number
HM004	544	1030	6.8	**4.8**	**40**	**0**	2360751

Note: (*) L The indicated pressure refers to the maximum and minimum pressure that the device can read.

INFORMAZIONI

GENERAL CHARACTERISTICS	SecurMeter is a sterile, single-use non-invasive device used for intra-abdominal pressure detection. This device, which basically consists of a tubing that connects the Foley catheter to the urine collection bag, allowing the measurement of pressure. By elevating the tubing to a vertical position, a column of urine is generated which is an indication of the intra-abdominal pressure value; the reading of the pressure value in mmHg is made using a graduated scale printed directly on the tubing.
SUGGESTED TIME OF USE	From a clinical point of view, the time of use must not exceed 7 days and must be replaced whenever the Foley catheter, to which it is connected, is replaced.

PRODUCT CHARACTERISTICS

COMPONENT	MATERIAL	CHARACTERISTICS
TUBE WITH GRADUATED SCALE	PVC	Flexible catheter tube with centimeter scale for reading abdominal pressure. The centimeter scale, printed directly on the tube, has a range of use between 0 and 40 mmHg.
CONNECOTR	TPE, PVC, LDPE	Connector for connection to the Foley catheter with window for the injection of physiological solution.
Y CONNECTOR	PVC	Y connector for the connection between the tube with the graduated scale and the urine discharge tube.
FILTER CONNECTION TUBE	PVC	Connection tube to the filter for the passage of air.
CLAMP	PP	Clamp for closing the air passage tube. It is opened during the pressure measurement phase.
FILTER	PVC, Membrana	Hydrophobic filter 1.2 micrometers. It allows the passage of air, in order to bring the system to atmospheric pressure during the measurement phase.
URINE BAG CONNECTION TUBE	PVC	Tube into which urine flows during normal urine collection phases.

GENERAL INFORMATION ABOUT DEVICE AND PRODUCTION	
PACKAGING	Packaging validated according to the harmonized international standard ISO11607 STERILITY PACKAGING: - PE / paper 250x380 mm heat sealed pouch. MULTIPLE PACKAGING: - Cardboard box 410x290x160 mm (20 pieces per box) - Cardboard box 830x600x1020mm (480 pieces per box)
STERILIZATION	Sterilization with ethylene oxide (EtO). Process validated according to ISO11135-1.
EXPIRATION	3 years from the date of end of production if the packaging is intact and the device is properly detached. Single use device, reuse of the device can have a negative effect on functionality and sterility with consequences such as device malfunction and contamination.
BIOCOMPATIBILITY	All materials are biocompatible in accordance with ISO 10993.
LABELING	IDENTIFICATION DATA: manufacturer, product code, product description, production batch and quantity contained, expiry date of the product, are shown on the labels for each level of packaging. The symbols used are those required by the international standard harmonized EN ISO 15223-1.
PRODUCTION	All the phases of realization of the device are carried out in a qualified environment with particle and microbiological charge controlled in accordance with the ISO 14644 standards (clean room in ISO 8 class). All processes are carried out in accordance with ISO13485: 2016 quality system procedures (TÜV SUD).
TRACEABILITY	Bel guarantees complete traceability of the batches produced by identifying the medical device by the batch defined.
DISPOSAL	After use, disposing of the device according to the applicable regulations in place in the country of use and according to the procedures in place at the user center. The materials of which the device is made are specified in the "product characteristics" section.
STORAGE	Soft and space-saving primary packaging, suitable for storage and easy to dispose of. Store in a clean and dry warehouse.
WARNINGS	Follow aseptic techniques. Single use device. Do not resterilize.
PRODUCT CONTROLS	Systematic quality controls are implemented at various levels: acceptance of raw materials / components, production process, sterilization and final release of the product in accordance with the quality system procedures.
QUALITY AND PRODUCT SYSTEM CERTIFICATIONS	Quality System in compliance with the standards: UNI EN ISO 13485:2016 Notify Body: TUV SUD Product Service
	The product is a class Is medical device compliant with directive 93/42 EEC, to Legislative Decree 46/97 and their updates.