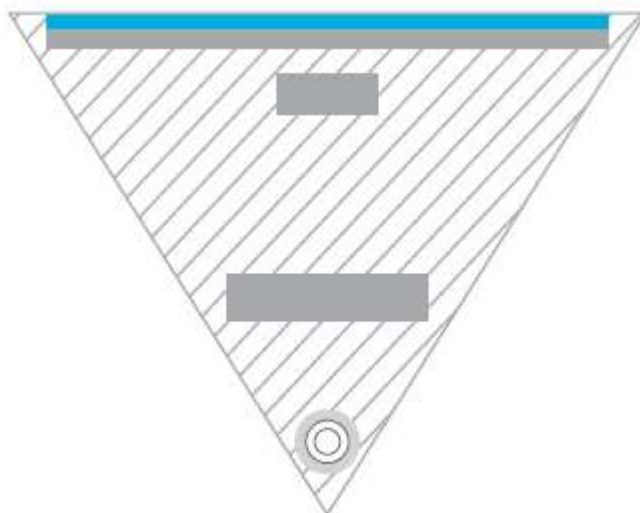


Fluid pouch, double filter and valve

Pouch with **filter and valve**

Functional fold that allows maintaining asepsis

Reference	Size	Color	Unit per box
AC.160003	80x55 cm	Transparent	50 un

Intended of use:

Medical devices in this subcategory are intended to create a sterile barrier to prevent transfer of infectious agents during surgical procedures. Therefore, the intended users of these medical devices are healthcare professionals and the patient population are persons undergoing surgical procedures.

Was designed for a single use for general procedures.

Product description:

Fluid pouch, double filter and valve, sterile for a single use.

Pouch also have a flex form for, which allows users to mold the bag to they needs, and self adhesive tape ideal for adjust to the surgical drape.

Standard performance.

Raw material:

Basic raw material in PE (polyethylene) – 110 my and filter in nonwoven 100% spunbound PP.
Low release of fibers, repellent to liquids and flammability.

Materials used are latex free.

Folding:

It's presented with functional fold that allows maintaining asepsis when correctly used by the medical staff during manipulation of sterile product

Final fold dimension:

Reference	Dimension
AC.160003	18x13 cm

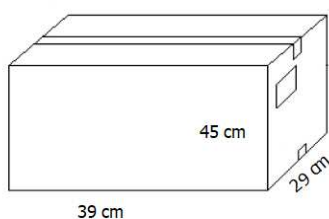


Packaging:

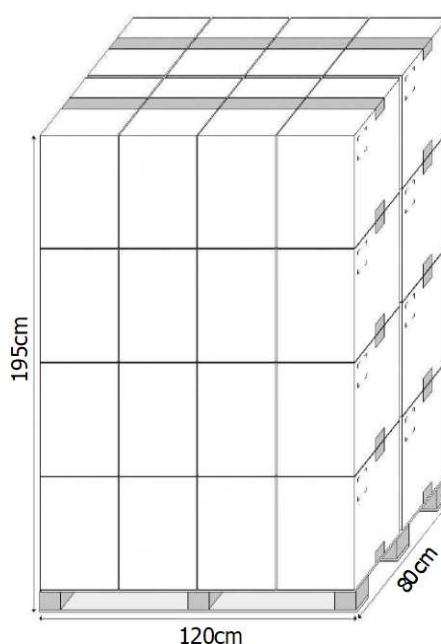
Easy-to-fit thermoformed single package, with four detachable labels in the primary package for full traceability.

Double packaging system with carton and polyethylene bag for added protection against dust, moisture and transport damage, handling and storage.

Outer box (39x29x45 cm)



Palletizing system: 32 boxes per pallet: 1.20x0.80x1.95 cm.



Labeling:

The product is identified with a label indicating size, image, performance and product description, as well as harmonized regulations according to applicable standards.

Contains two easily to removable traceability labels that contain product reference, expiration, lot and bath information.

Identification label in outer carton.

Sterilization:

Product sterilized by ethylene oxide.
According to applicable standards.

Shelf Life:

5 years if storage on the correct way.

Product should be protected from sunlight and kept dry.

Directive:

Medical device, class I sterile, rule 1.

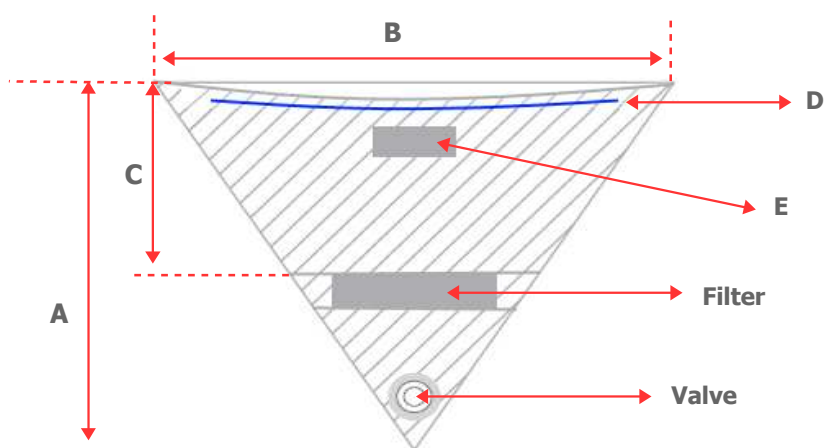
Product in compliance with the Essential Requirements of Directive 93/42 / EEC as amended by Directive 2007/47 / EC and applicable standards

Applicable Standards:

EN 868-5, EN 1041, EN ISO 11135, EN ISO 11607, EN ISO 11737, EN ISO 13485, EN 13795-1, EN ISO 14971, EN ISO 15223

General characteristics:

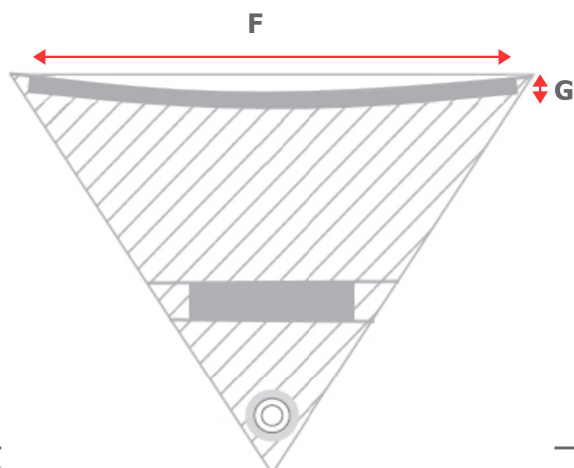
1. General dimensions / front side:



A	B	C	D = Flex Form	E = Tape
80	55	29	65	10x4

All dimension are represented in cm.

2. Back side:



F	G
55	4

All dimension are represented in cm.