

**Exclusive Distributor:****COMECER S.p.A.**

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1.1 Intended use:

Kit for the administration of solutions or radiopharmaceuticals to the patient.
Maximum Operating Pressure 3 bar = 40 psi
Suitable for use with the WIS equipment.

1.2 Description:

The kit is composed of :

- A. Spike with air vent for the connection to sodium chloride solution
- B. One way valve
- C. Double spike needles for the connection to the 10 ml syringe prefilled with radiopharmaceuticals.
- D. Peristaltic tube with thermoplastic elastomer (Pharmed / Santoprene)
- E. Air-eliminating filter, with the following characteristics: 0,2 µm Filter Media Supor (polyethersulfone) membrane - Effective Filtration Area = 4,5 cm² - Minimum Water Bubble Point = 3,1 bar (45 psi) - Vent: 0,02 µm supported PTFE. Priming Volume 0,7 mL.
- F. Tube for security sensors
- G. Extension coiled tube
- H. Swabable valve for the connection to patient kit.
- I. Pierceable cap for the By-pass of the double spike needles

Materials: Polyethylene, Polypropylene, TPE, ABS, PVC DEHP FREE, Polyurethane, PC, Silicone, PES, PTFE, stainless steel, Polysoprene.

The device is DEHP and LATEX FREE.

FOR THE USE FOLLOW THE MANUAL OF THE EQUIPMENT

1.3 Packaging:

The device is packed in pouch made of pharmaceutical grade paper and film, suitable to ETO sterilization. 50 pcs/box.

The product is supplied sterile and Pyrogen-free.

1.4 Sterilization:

The sterilization is individually performed through ETO exposition. The treatment is validated in conformity with Norms ISO 11135. The sterility is 5 years guaranteed. The product cannot be resterilized.

1.5 Quality Controls:

On receipt, each component is submitted to a dimensional and visual test for the verification of its conformity with the standards requirements, according to the internal quality procedures. On finished devices before the sterilization, following tests are performed: visual test, dimensional test, leak test, glueing sealing test and welding sealing test, according to internal quality procedures (IO01: glueing by solvent; IO02 single packaging; IC02: visual and dimensional test; IC03: air leak test; IC01: peeling test). The seal tests are performed by test machine at 1 bar pressure. Such test is performed by connecting the spike to the test machine and closing with caps the exits. The device is considered in conformity if within 10 seconds, has not a pressure decay major than 5 mmHg.

The devices just released by the sterilizer are tested for the packaging seal after the sterilization exposure. The sampling plans for above mentioned tests are in conformity with Norms UNI ISO 2859-1. The sterile finished devices are subjected to the sterility tests, pyrogen test, chemical toxicity test, ETO residue test in accordance with the monography E.P. IV ed. and ISO 10993-7 and biocompatibility test according to ISO 10993.

1.6 Manufacture and conformity:

The following device is manufactured according to GMP, moreover BTC Medical Europe has established and maintains a Quality System in conformity with the requirements of standards UNI EN ISO 9001 / ISO 13485. The device meets the essential requirements of the Directive 93/42/EEC concerning Medical Devices. The components are in conformity with ISO 594/1-2, E.P. current edition.

1.7 Classification:

Class IIa medical device, CE marked according to Directive 93/42/EEC, current editions and integrations concerning Medical Devices.

1.8 Disposal:

For the disposal, users have to apply the in force norms regulating the hospital waste disposal.

1.9 Storage:

Usual storage procedure, protect from moisture and keep away from light or heat sources.

1.10 Stability:

If correctly preserved and handled the medical device, maintains its own chemical – biological and physical characteristics all through its shelf life. The validity is reported on each single package. The expiry date is 5 years after release.