

• REFERENCIA: 850.09

Filter Transfer Set

CE 0318

Description

The filter transfer set is a dispositive that is used to administrate medicin gas (ozone) to a autologous blood compiled in a vacuum glass container. The filter transfer set is a non-invasive single use sanitary product, sterile, latex free, DEHP free and single use.

Conformity

Sterile Class IIa product.

ISO certification: Oiarso S. Coop. (Bexen medical) has implemented and maintains a quality system that complies with the requirement of ISO 13485, ISO 9001 and ISO 14001.

CE mark from the European Directive 93/42/CEE.

Use

Sterile dispositive used to transfer medicinal gas (ozone) to a container with the patient's autologous blood.

Characteristics

Upper connection	Needle 35/165
Tube	Inner Diameter = 3mm
	Outer Diámetro = 4,1mm
	Length =330 cm
Flow regulation	Roller
Lower connection	Female Luer lock
	Hydrofobic and hemofobic 0,2 micron filter
	Protection Cap

Materials

Upper connection	Stainless Steel + PP+ silicone
Tube	Transparent vinyl polychloride (PVC DEHP free)
Roller	ABS
Lower connection	ABS Female Luer Lock
	Particle filter ABS and PTFE
	Male cap Polypropylene

Presentation

Individual unit: peelable sealed envelope.

Presentation: Box of 100 units.

Sterilisation

Process: STERILE EO.

Shelf life: 5 years from the date of sterilisation.

Recommendations for use

- Do not use if the blister is damaged
- Use a new Set for each ozone treatment
- Respect the asepsis rules
- Use gloves
- Never recover the connector with the protective cap after the use.
- After the use of each and all of the elements included in the envelope, throw them away in a hazardous waste container.
- Keep it in a dry place

Instructions for use

The filter transfer set is used with another sanitary products required for the intended use.

The ozone is produced by an ozone generator device and the ozone concentration dosage is administered by a syringe.

1. Close the roller and introduce the needle into the vacuum bottle, take out the cap.
2. Connect the syringe charge with ozone, open the roller and transfer pushing the plunger.
3. Disconnect and repeat the point 2 until reaching the ozone volume desired.

Reuse risks

Do not reuse. The reuse and re-sterilization of medical devices can cause:

- Sterility problems caused by biological contamination and pyrogenic reactions.
- Cross-contamination problems caused by the use of different fluids and/or preparations.
- Physicochemical alterations that can jeopardize the device's properties and benefits.

Verification of the connections

Before placing the device in its final position and after any additional connection and/or disconnection, verify the correct assembly and that all connected elements are properly secured. The ozone generator device is not supplied with the Set and the compatibility, verification and validation is responsibility of the user.

Period of use

The quality of our devices allows, in normal conditions, up to 24 hours of use. Past this period, we cannot guarantee the absence of alterations in the mechanical and/or technical properties of the device

Ref.	Código de barra Envase unitario (EAN 13)	Código de barra caja (DUN14)
850.09	8427860850095	18427860850092

MANUFACTURER
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Symbols

Símbolos	Descripción	Símbolos	Descripción
	Ítem code		Batch code
	Manufacturer		Manufacturing date
	Ethylene Oxide Sterilization		Expiry date
	Do not reuse		Do not use if the envelope is damage
	Latex free		DEHP free
	CE Marking		Spanish
	English		French

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