

TECHNOFLEX Empty Solution Container

This product is designed to allow the filling of a drug solution and its administration.

INSTRUCTIONS FOR USE - RECOMMENDED ORDER OF INFORMATION -

Intended user: The bag must be filled by a pharmaceutical expert and the administration performed by professionals as doctors and nurses.

Patient population: Adult and children.

Specific information intended for use:

The package of 10 containers must be opened in aseptic environment.

Customer must perform a compatibility study and stability studies with all drugs to be used with the device.

This product is already sterile. Do not irradiate a second time.

Side effects: No side effects identified with the empty bag.

Contra-indications:













Do not use if package is damaged or opened out of aseptic conditions.

Do not use if overwrap is opened.

This product is designed for a single use.

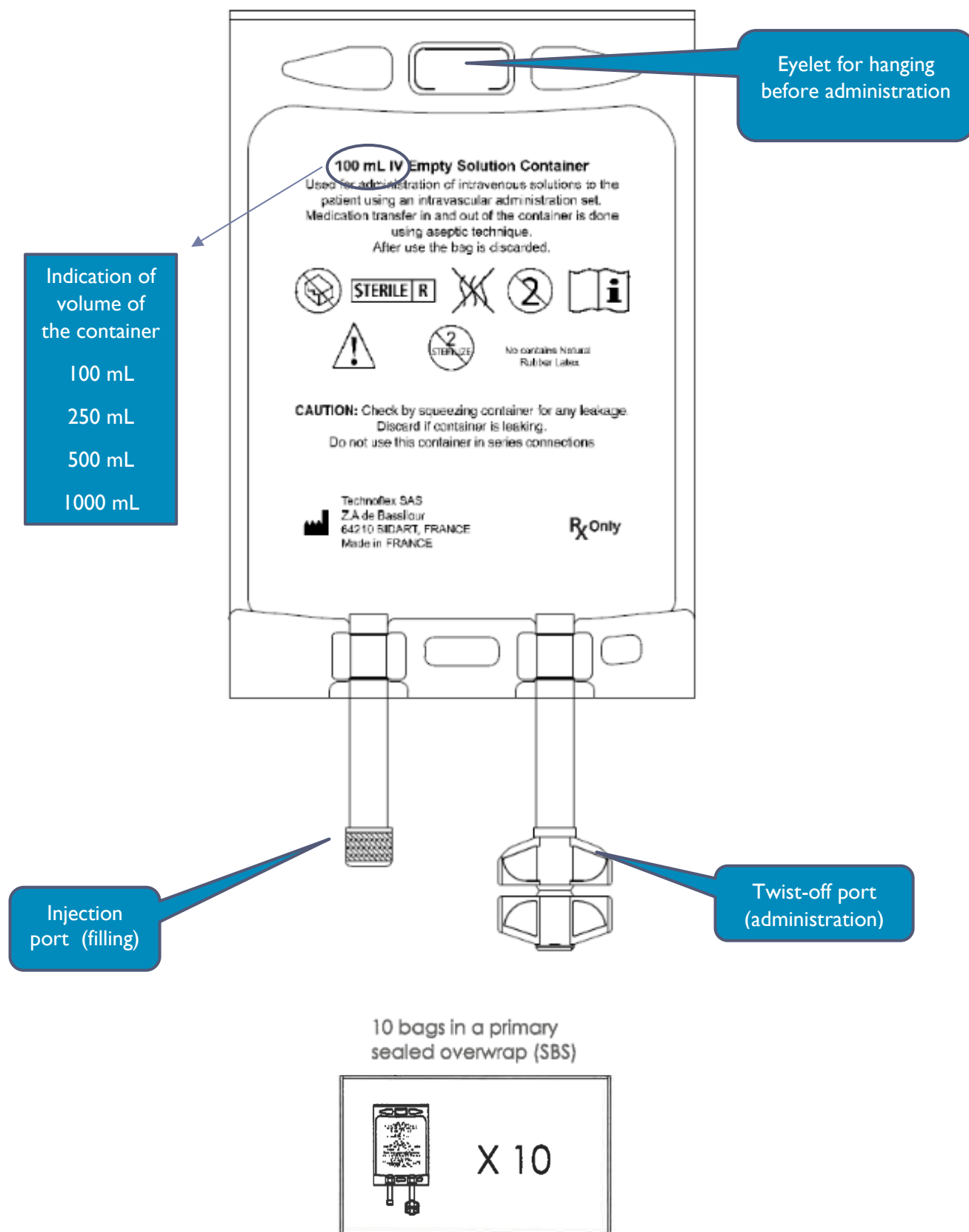
MRI Safety Information - The EMPTY SOLUTION CONTAINER has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of EMPTY SOLUTION CONTAINER in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.”

Symbols used on labels

		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Do not use if package is damaged and consult instructions for use
		
Sterilized using irradiation	Caution	Do not resterilize
		
Non-pyrogenic	Single sterile barrier system	Do not reuse
		
Date of manufacture	Batch code	Use-by date

These “Instructions for use” contain information on how to fill the Technoflex Empty Solution Container and administrate the solution once filled in Technoflex Empty Solution Container.

Description of the product



Important information you need to know before filling Technoflex Empty Solution Container.

- Use only container taken from its original packaging.
- Do not use if package is damaged or opened.
- Do not use if overwrap is opened.

Preparing to add solution into Technoflex Empty Solution Container.

1. Clean injection port with preferred antiseptic solution.
2. Access injection port, inject solution into solution container using aseptic technique with a hypodermic needle with 0,8mm maximal external diameter.
3. Repeat as necessary for admixing solutions.
4. Check by squeezing container for any leakage.

Preparing to administrate solution of Technoflex Empty Solution Container

1. Stir the solutions within the container.
2. Store the solution at the prescribed temperature, break the upper part of the twist-off port and insert administration set spike. For this action use administration set as per organizational policy
3. Administer the solution to the patient.
4. Properly discard solution container.

Storing Technoflex Empty Solution Container

- Empty Solution Containers are not sensitive to temperature.
- Can be stored between -5°C and +35°C.
- Can be stored during 3 years in original packaging.
- Do not expose to sunlight.
- Keep at ambient temperature 24h before use.

Disposing of Technoflex Empty Solution Container

Once used, the container must be discarded according to local procedures.

Additional information

Empty Solution Container are manufactured and distributed by

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