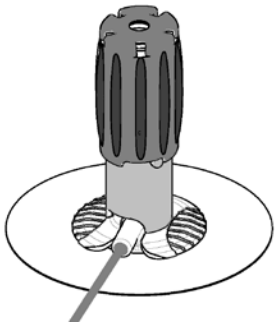
Saflo™ 90 Infusion Set – Instructions for Use

REF **SF90-109**, **SF90-069 SF90-106, SF90-066, SF90-P06, SF90-P09** Saflo 90 Infusion Set



Intended Use:

The Saflo™ 90 infusion sets are sterile devices for single use only.
They are intended for use in the administration of subcutaneous fluids or drugs for the treatment of a variety of clinical conditions.

Description:

The Saflo™ 90 infusion sets are manufactured with tri-layer tubing and have a priming volume of less than 0.2mL. The Saflo™ 90 infusion sets are equipped with a female luer lock connector at one end for connection to syringe or drug reservoir. Models designated SF90-P have a needle free swabbable port fitted for needle free intermittent injection applications. The infusion set incorporates a vertically aligned needle and a protective device to cover the introducer needle following insertion.

Contraindications:

These devices are not suitable for blood or blood derived products.

Precautions:

- Do not use if the primary packaging is damaged; this could compromise device integrity and/or sterility.
- Do not use after the use by date.
- The connection tubing must be primed before connection to the patient, **approximately 0.2mL.**
- Ensure that luer connector is secure and check for any indications of fluid leakage at the connection or infusion site.
- Observe for any possible drug reactions within the tubing, which may lead to precipitation and possible tube blockage.

Intended Users:

The Saflo™ 90 infusion sets are simple medical devices to be used by anyone familiar with standard procedures for the infusion of medical fluids. This may include healthcare professionals or individual patients fully trained in their use.

Duration of Use:

The Saflo™ 90 infusion set may be used for a duration of 72 hours or at healthcare provider's discretion.

Directions for Use:

1. Once the primary packaging has been opened, the external surfaces of the set will become non-sterile.
2. The infusion set tubing must be primed before connection to the patient, **approximately 0.2mL**.
3. Follow recommended procedures from the equipment manufacturer, or local hospital procedures, when attaching to an infusion pump or syringe driver.
4. Detailed instructions for proper insertion are provided on page 2.
5. Ensure that there are no leaks at the luer connection and patient infusion site once the infusion has started.
   After use, dispose of the set according to local hospital guidelines for contaminated sharps waste.

Conditions of Use and Storage

The device should be stored and transported in a normal environment, i.e. away from extreme temperatures and humidity. Do not use if the sterile packaging is damaged and/or open. For single use only; resterilization of this device jeopardizes sterility, can lead to product dysfunction and cross-contamination. The manufacturer will not be held liable in the case of re-use. Destroy after use according to the regulations in force regarding disposal of potentially infectious waste material.

Liability and Warranty

PROMEPLA and affiliates declare to the first purchaser, that reasonable care has been taken when designing and manufacturing this product. If damage is suspected, please contact PROMEPLA and affiliates. The present limited warranty dispenses all other warranties, express or implied, including but not limited to any implied warranties concerning usability or suitability for specific purposes. This limited guarantee ensures that the responsibility of Promepla and affiliated companies will be limited to the replacement of defective products. In no instance will Promepla and affiliates be held liable for direct, indirect, incidental and/or consequential damages of any kind arising from the use and/or handling of the device.

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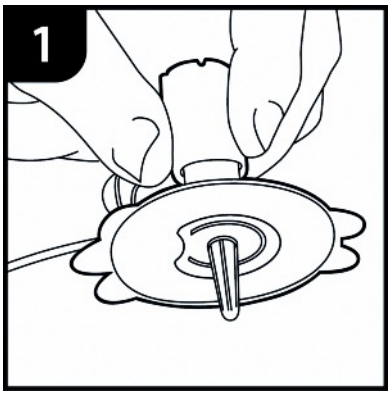
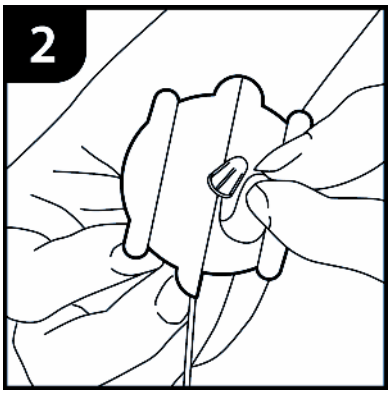


Remove the Saflo 90 from its packaging. Ensure that the needle protector is in place and there are no visible signs of damage to the product.

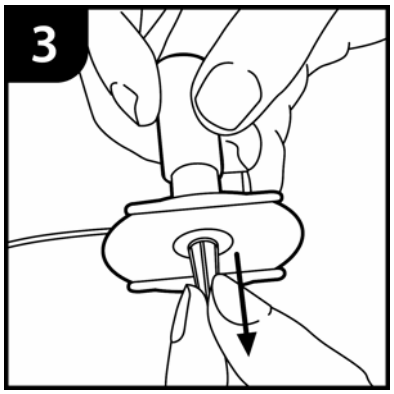
Note the product code and batch number if required for record keeping.

Prime the infusion set according to local procedures or, if used with an infusion pump, according to the pump manufacturer's instructions.

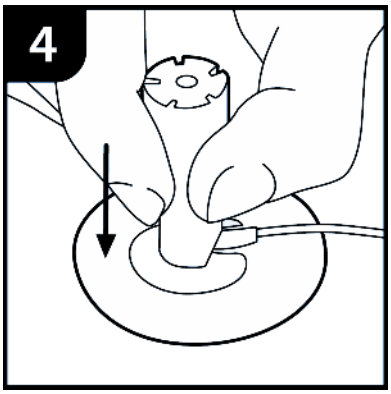
Prepare the infusion site according to local guidelines.



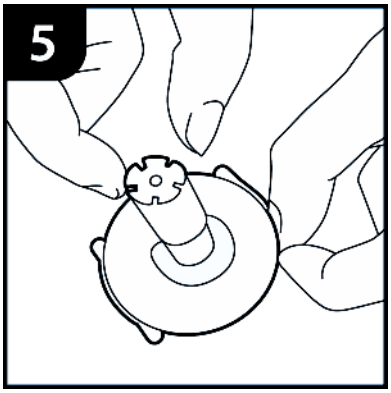
Remove the central portions of the tape from the infusion set.



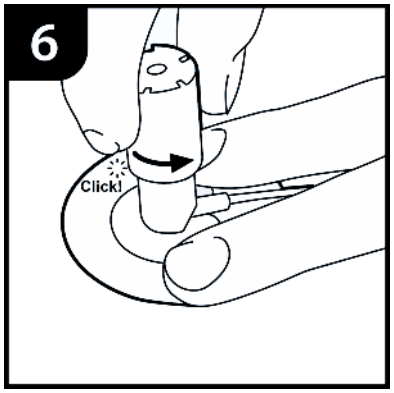
When ready to insert the infusion set, remove the needle protector with a gentle side to side motion.



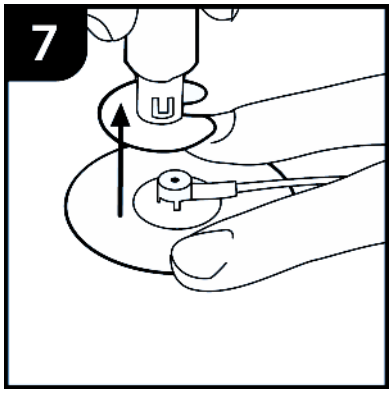
Insert the infusion set into the tissue with a smooth downward motion. Press the central portion of the tape to ensure the infusion set is firmly attached to the skin.



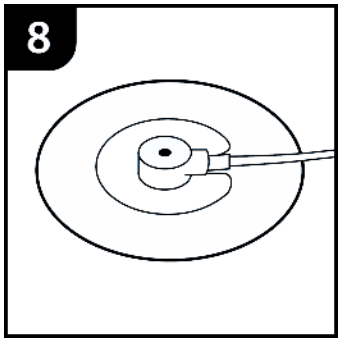
Remove the side portions of the tape backing and smooth the tape onto the skin surface.



Twist the cap of the device gently to the left through approximately ¼ turn. A click will be heard and a visible indicator will appear at the top of the cap to show that the needle has been withdrawn and is fully protected.



Hold down the tape of the infusion set and lift the needle assembly away from the site.



Move the protective cover along the tubing and press gently down onto the infusion site.

Dispose of the protected needle assembly in a container suitable for contaminated waste according to local procedures.