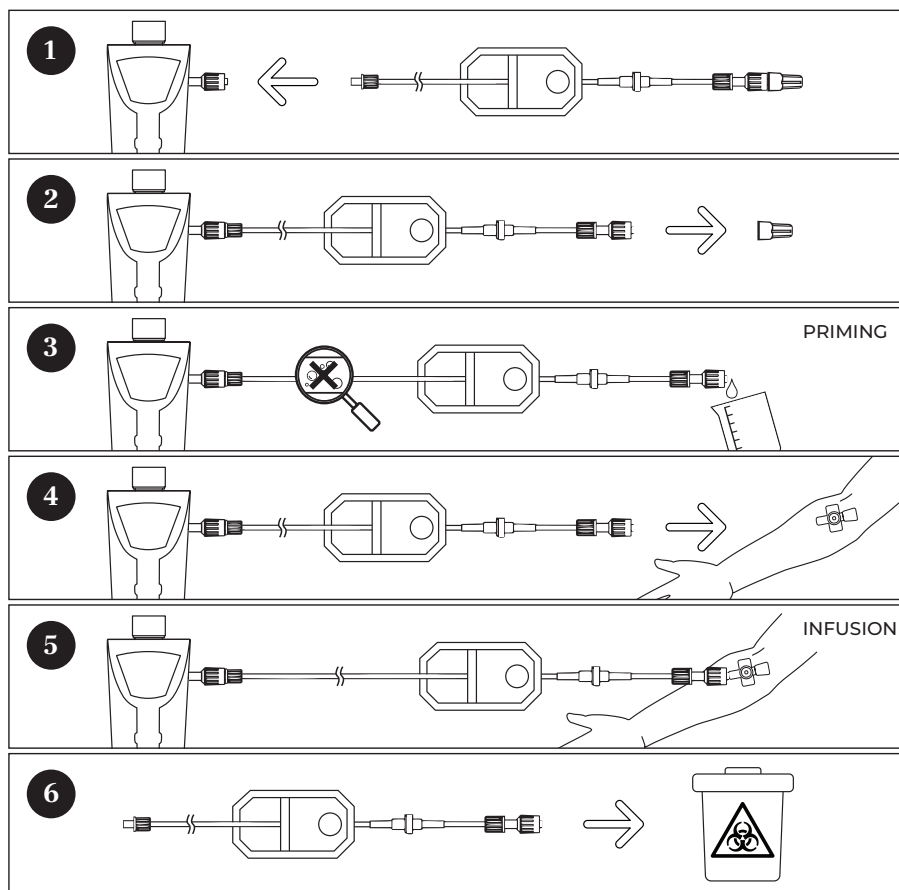




Manufacturer



Use-by date



Consult Instructions for Use



Sterilized using ethylene oxide



Do not use if package is damaged and consult IFU



Do not re-use



Batch code



Catalogue Number



Temperature limit

DESCRIPTION

Single use O15 H2O Patient Kits individually packaged per market unit. The device consists of tubing, a single way check valve, a 0.2 micron vented sterile filter and Luer connectors. The product is supplied sterile and pre-assembled. The device is to be used only with the P3 MT-100.

CONTENTS

REF MT-PAT-001, O15 H2O Patient Kits, 20 units
OR
REF MT-PAT-002, O15 H2O Patient Kit extended, 20 units.

INTENDED USE

Guiding a bolus of ^{15}O H₂O water for injection and the saline flush into the patient venflon.

INTENDED USERS

Trained healthcare professionals working in the field of nuclear medicine, trained in aseptic techniques.

PATIENT TARGET GROUP

Adult patients undergoing ^{15}O H₂O PET analysis.

STORAGE CONDITIONS

The device should be stored at temperatures between 10 to 25 °C.

INCIDENT REPORTING

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.



WARNINGS

- Do not reuse the Patient Kit, as it is single-use only. Resterilization or reuse of this device jeopardizes sterility and can lead to product dysfunction and cross-infection.
- Do not perform infusion without having primed the Patient Kit.
- Do not expose the ends of the Patient Kit to potential contamination.
- Do not use the Patient Kit if the sterile packaging is damaged or unintentionally opened before use.
- Do not use the Patient Kit if the label is unreadable or missing.
- Do not use the Patient Kit with other equipment than the Infusion kit (MT-INF-001), O15 H2O Production Kit (MT-PRO-001), and the P3 MT-100.
- Do not use anything other than Luer Locks in compliance with ISO 80369-7 to connect the Patient Kit to the patient's venflon.
- Used Patient Kits are bio-hazardous waste and should be handled accordingly. If assistance is needed for proper disposal of the device, please contact MedTrace.

INVESTIGATIONAL DEVICE

To Be Used by Qualified Investigators Only

INSTRUMENT DE RECHERCHE

Réservé uniquement à l'usage de chercheurs compétents

REF MT-PAT-001
MT-PAT-002



MedTrace Pharma A/S
Agern Allé 5A
DK-2970 Hørsholm
DENMARK