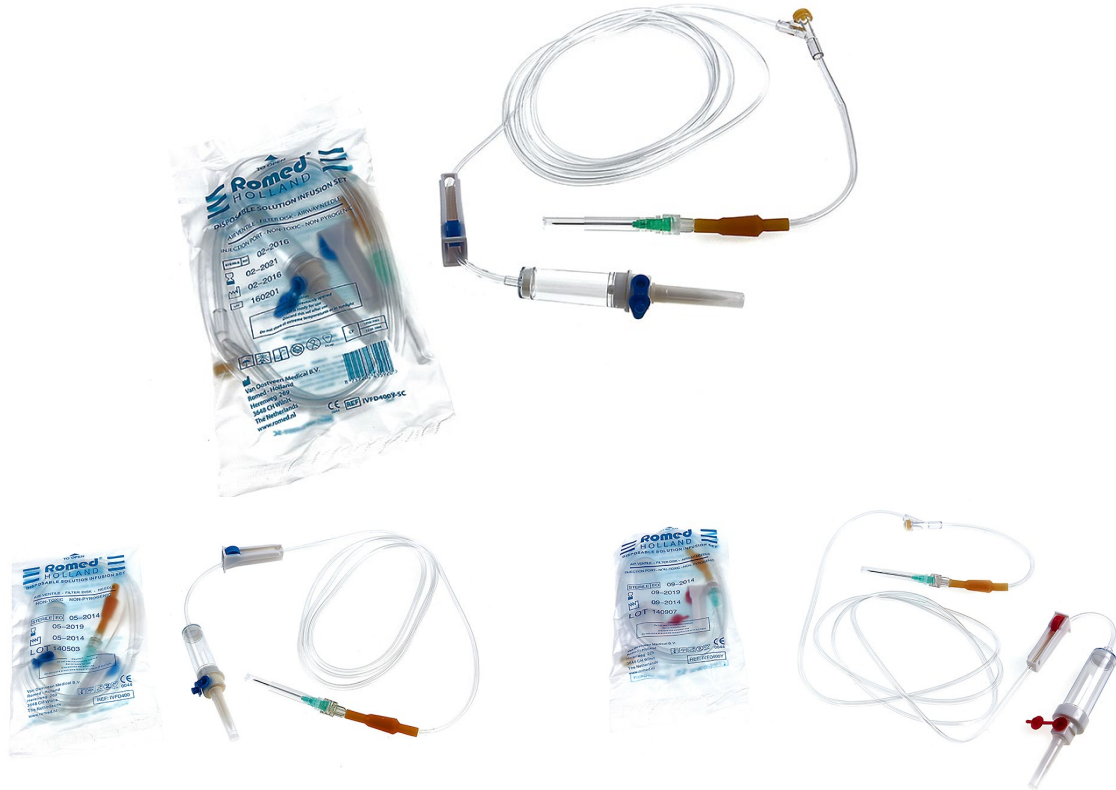


SPECIFICATIONS
ROMED DISPOSABLE INFUSION SETS
REF: IVFD-400, IVFD-400Y, IVFD-400Y-SC



Applicable harmonized standard: EN ISO 8536-4:2013
 Medical device conform MDD 93/42/EEC

Type and Chemical Composition of Raw Materials

Name of Parts	Name of Raw Material
Cover	Polypropylene
Spike	Acrylonitrile Butadiene Styrene
Air-inlet Cap	Polyvinyl Chloride
Air filter Membrane	Hydrophobic Medical Filter Paper
Chamber	Polyvinyl Chloride
Disc Filter (IV-6-1) 15-20 µm	Nylon 1010 & Acrylonitrile Butadiene Styrene
Tube Ø 4X3	Polyvinyl Chloride
Adjuster	Polypropylene
Wheel	Polypropylene
Connector Luer Lock	Polyvinyl Chloride

Hypodermic Needle 21Gx1.5

Cannula	Stainless steel Cr ₁₈ Ni ₉ Ti
Safety Cover	Polypropylene
Hub	Polypropylene
Latex Rubber Cone	Natural Rubber

Infusion sets contain phthalates (DEHP) and are DHP free.

Properties

Needle size:	21Gx1.5"
Length of tube	
IVFD400:	150 cm
IVFD400Y:	180 cm
IVFD400Y-SC:	180 cm
Size of chamber	
IVFD400:	6 ml
IVFD400Y:	10 ml
IVFD400Y-SC:	6 ml
Y valve	
IVFD400:	Absent
IVFD400Y:	Present
IVFD400Y-SC:	Present
Drop size: 20 drops per ml	

Recommendation

It is better to use the infusion set with a bottle or any container which is not soft than to use it with a soft bag. When there are 1000ml of liquid hanging on top, a soft bag brings so much pressure to the air valve of the infusion set that it has the risk to leak air into the valve.

Microbiological and Toxicological properties

<i>Toxicity:</i>	Non-toxic
<i>Pyrogenicity:</i>	Non-pyrogenic
<i>Poisonous:</i>	No abnormal poisonous
<i>Haemolysis:</i>	Haemolysis rate <5%
<i>Reducing matter:</i>	20 ml solution through an infusion set in comparison with 20ml of comparative liquid gives less than 2.0 ml consumption of 0.002mol/L K ₂ MnO ₄ .
<i>Heavy metals:</i>	An extract will not contain in total more than 1 µg/ml of barium, chromium, copper, lead and tin, and not more than 0.1 µg/ml of cadmium
<i>Acidity-Alkali degree:</i>	The pH difference between an infusion set solution in comparison with a comparative liquid is less than 1.5.
<i>Non-volatility matter:</i>	The weight of non-volatility matter is less than 2mg in 100ml solution through an infusion set.

Mechanical properties

<i>Liquid filter:</i>	Rate of liquid filter for insoluble particle which has a diameter of 15 µm in injecting liquid is less than 80%.
<i>Tightly connecting of circular cone in conical fitting:</i>	There is not a single water-drop from the combinator between circular and standard cone when axial pressure force of 27.5N acts on it for 5 seconds and it rotates at less than twisting force of 0.1 N at an angle of 90 under hydro-pressure of 3000 kPa.
<i>Injecting part:</i>	There is no leakage of any water-drop from punctured spot on injecting site when punctured by a 23G hypodermic needle (outer diameter: 0.65mm).
<i>Capacity:</i>	The flowing rate of an infusion set is not less than 1,000ml of 0.9% NaCl injecting solution at 1m static pressure within 10 minutes.
<i>Airtightness of infusion set:</i>	There is no leakage while 50kPa of air pressure is set on an infusion set for 15 seconds.
<i>Security between each joint:</i>	Each of the joints of an infusion set can withstand 15N static axial force.
<i>Membrane air filters:</i>	Rate of filterability for air-filter is less than 90%.

Sterilization

Ethylene oxide gas
Expiry date: 5 years

Packaging

Per piece in a peel pouch, 25 polybags in an inner bag, 16 inner bags (400 pieces) in an export carton.