

Tierrett 1 Port Extension Tube

Instructions for use

Contraindicated to re-use

[WARNINGS]

<Using method>

Make sure to wipe and disinfect the connector, Y port and mixed injection part of this product before connecting to other medical devices.

[Bacteria may be mixed.]

[CONTRAINDICATIONS • PROHIBITION]

Do not reuse the product (single use only).

[1] Do not use for high-pressure injection lines such as angiography injection.

[The product may be broken.]

[2] Do not puncture the tube.

[The tube may cause air embolism.]

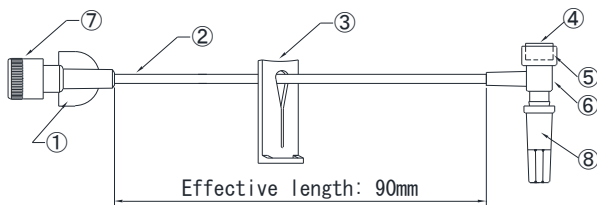
[3] Do not use for patients with intense physical activity.

[There is a risk of leakage, disconnection, and tube breakage from the connection.]

[Shape, structure, principle]

- This product is sterilized with ethylene oxide gas.
- This product uses polyvinyl chloride (plasticizer: di (2-ethylhexyl) phthalate).
- This product does not use natural rubber.

<Shape>



* Priming capacity: 0.3 ml

<Raw Materials>

- [1] Female luer connector: PC
- [2] PVC tube: PVC
- [3] Slide clamp: PE
- [4] Seal: Isoprene rubber
- [5] Ring: ABS
- [6] T port: PC
- [7] Female luer cap: ABS
- [8] Male luer cap: PP

<Principles>

This product is connected to an infusion set, an indwelling needle, etc.

[Intended purpose, efficacy or effect]

This product is a sterilized extension tube used by connecting to various infusion sets, indwelling needles, etc., is used for securing between medical devices, extending the tube, and mixed injection of drug solution.

[Operating or using method]

The below is a general procedure.

- [1] Open the package and take out the product.
- [2] Remove the protective cap and perform infusion or priming with saline to prevent air bubbles from remaining in the lumen of the product.
- [3] Make sure to check the connection status and flow path before start infusion.
- [4] Make sure that the connections are not loose during use.
- [5] After use, pay attention to infection prevention and dispose in a safe manner.

<When performing mixed injection of drug solution, etc.>

- [1] Disinfect the mixed injection part.

[2] The injection needle is punctured straight into the rubber stopper of the mixed injection part to inject the drug solution.

[3] After performing, pull out the injection needle and be careful of accidental puncture while holding the mixed injection part.

[Precautions]

<Important basic caution>

[1] Since the tensile strength of the product is 15N, do not apply an excessive load.
[There is a risk of leakage or breakage from the adhesive part.]

[2] Do not use the product for pressures above 150 kPa.
[There is a risk of leakage, breakage, or disconnection from the connection.]

[3] Do not pinch the device with forceps too strongly.
[The tube may be broken or lumen may be occluded.]

[4] Do not overtighten when connecting the connector.
[The connector may not come off or may be damaged.]

[5] Note that the connector and mixed injection part may crack by fat emulsions and pharmaceuticals containing fat emulsions, pharmaceuticals containing oily components such as castor oil, surfactants or solubilizers such as ethanol, and chemicals containing ethanol.

[6] Note that di (2-ethylhexyl) phthalate, which is a plasticizer for polyvinyl chloride, may elute in fat-soluble pharmaceuticals or drug solution.
[This product uses polyvinyl chloride for the PVC tube.]

[7] Make sure it is securely connected to other medical devices, and to check for damage, loose connections and leaks during use.
[There is a risk of leakage or disconnection from the connection.]

<Failures • Adverse events>

Failures

The following failures may be caused by use of the product:

- [1] Contamination, poor connection
[May cause infection.]
- [2] Deformation and rupture of tube
[Rupture by the following causes]
 - Damage caused by handling during insertion (damage caused by forceps, scissors, knife, other apparatuses)
- [3] Accidental or natural removal.
[Accidental or natural removal by the following causes]
 - A patient with intense physical activity.
 - Other complex causes caused by the above events.

Adverse events

The following adverse events may be caused by the use of the product:

- Sepsis

[Storage conditions and duration of use]

<Storage conditions>

Store the product hygienically, avoiding the direct sun light, high humidity and ultraviolet rays such as a sterilizing lamp and taking care of wetting.

<Expiration date >

See the expiration date given on each package provided that the device is stored appropriately.

[By self-authentication (our data).]

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