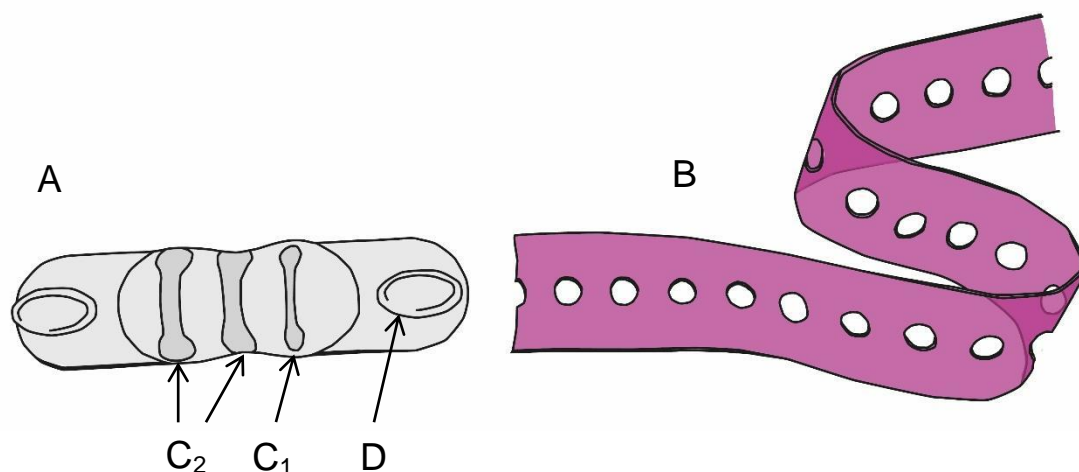


Instructions for Use - IV-bracelet

NOTE: Before using this product for the first time: Read the entire Instructions for Use and if uncertainties still remain, contact Medow AB for consultation. The Instructions for Use and the instructional video are also available on Medow's website www.medow.se.

The IV-bracelet is to be used on patients to affix intravenous tubes, so that these will follow the patient's movements and also to reduce the risk that a tug on the tube misplaces or pulls the vascular access device out. The product must only be used for these purposes.



| | |
|---|---|
| A | Tube fastener (fastener) - Reusable. Recommended to be used ca 100 times. Made of biocompatible material which is tested according to ISO 10993-5 and -10 and also USP class VI. |
| B | Elastic band (band) – For single use. Made of biocompatible TPE. An equivalent version has been tested according to ISO 10993-5 and -10 and also USP class VI. |
| C | Tube space (space) - The smaller tube space (C ₁) is used for tubes with an outer diameter of 3,5-4,5 mm, common size for infusion sets The two bigger tube spaces (C ₂) are used for tubes with an outer diameter of 6-8 mm, common size for dialysis tubes. |
| D | Foot - A part of the fastener to secure the elastic band. |



Instructions

The IV-bracelet

- is to be used as a complement to dressings that are used to affix venous access devices
- is to be used by health care professionals or users educated by the health care
- can be used for various kinds of intravenous treatments
- is to be attached to the patient's body part that is considered most appropriate
- is to be affixed so that it cannot change position. *NOTE: must not have an uncomfortable fit or restrict the blood flow.*

The IV-bracelet must NOT be used

- directly on top of the dialysis access or the venous access device's position
- around the neck
- on body part with edema
- on damaged skin
- on children under the age of three
- on suicidal patients
- if considered inappropriate by a responsible health care professional

Cleaning and disinfecting

After usage the fastener and elastic band should be separated.

Discard the band and clean the fastener in a washer disinfectant at a minimum of 90 degrees Celsius and for a minimum of 60 seconds (NOT sterilised).

If there is any risk of infections being transmitted, the effective guidelines for procedures at the specific unit should be followed.

Disposal

Discard unclean or impaired products.

The fastener is considered as combustible waste.

The elastic band is considered as plastic.

Risks

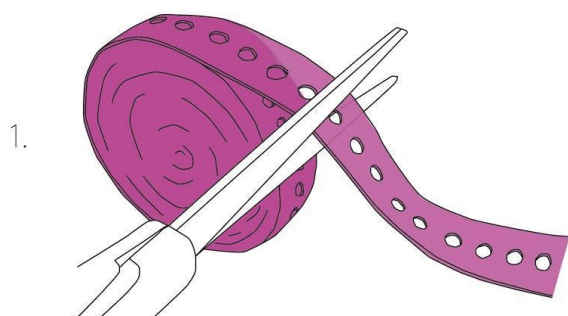
- If the body part that the bracelet is attached to becomes swollen, there is a risk that the band will fit too tight. This can cause discomfort for the patient and restrict the patient's blood flow.
- If the band is fitted too tightly there is a risk for wounds due to pressure or chafe.
- If the band, which is for single use, is reused there is a risk that
 - its length will not be sufficient for the next patient and it therefore will be put on too tightly
 - it is cleaned in a washer disinfectant and the material could consequently be affected by the heat
 - it will not be sufficiently cleaned and therefore transmits infections.
- The flow in the tube can be affected temporarily while the tube is pressed into the fastener's tube space.
- The flow can be affected if the tube is not correctly put in place.



Use

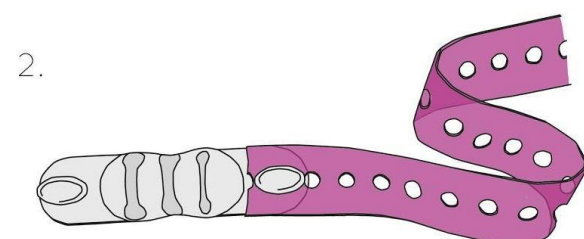
There is also an instructional video at www.medow.se/products

The IV-bracelet can be applied both before and during treatment.

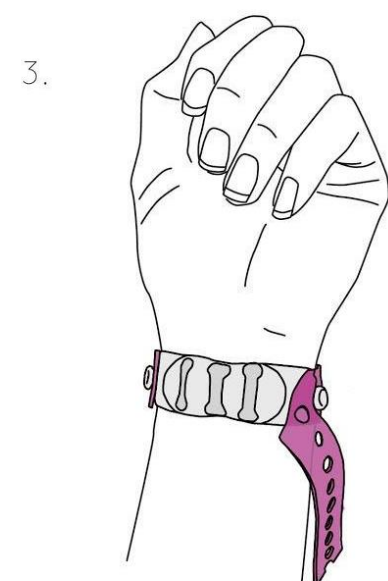


1. Take a tube fastener. Measure out as long piece of the elastic band that corresponds to the circumference of the chosen body part of the patient and **add approximately 5 centimetres**. Cut the band off through a hole.

Make sure that both the fastener and the elastic band are visibly clean and do not have any notable impairments that can affect the functionality. Do not use unclean or damaged products.



2. Take the fastener and put one of the fastener's feet completely through the hole at one end of the elastic band.



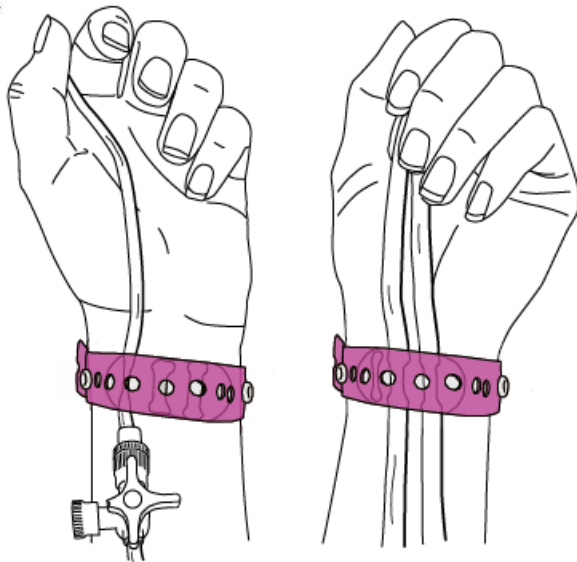
3. Place the fastener on the patient. Wrap the elastic band around the chosen body part. Choose the hole that makes the bracelet fit well and attach it to the fastener's other foot. If choosing between two holes, choose the hole that gives a slightly looser fit. The bracelet must however not fit so loosely that it can change its position. Make sure the holes stay round and do not become oval. If the holes are oval the band has been put on too tight and needs adjustment.

When attaching the tubes it is important to make sure that the part of the tube between the vascular access device and the bracelet is slack enough so that the tube cannot become fully stretched when the patient moves.

Support the fastener from underneath with a finger to avoid pressure against the patient, when attaching the tube. Start by pressing down the tube at the end of the tube space and continue pressing the tube along the tube space, all the way down. *NOTE: Do not start by pressing down the tube from straight above since the space is narrowest there.*



4.



Infusion

Dialysis

Do not use an empty tube space to turn the tube back around and make a U-turn. How to make a safe U-turn is shown in the instructional video.

4. When the tube is inside the tube space, **secure it further by covering the fastener with the remaining part of the elastic band and attaching it on the other side of the fastener.**

Cut off what is left of the elastic band but save at least one hole so that it is possible to adjust the fitting. Check so that the flow of the liquid inside the tube is as desired.

Checklist

- Measure out the length of elastic band needed for it to be able to reach one lap around the chosen body part of the patient and add approximately 5 centimetres. Cut the band off through a hole.
- Make sure that both the tube fastener and the elastic band are visibly clean and without notable impairments.
- Connect the elastic band to the fastener and attach them to the patient.
- Make sure that the product does not restrict the blood flow nor can change position.
- Make sure that the part of the tube between the vascular access device and the bracelet is slack enough so that the tube cannot become fully stretched when the patient moves.
- Attach the tube/tubes in the right tube space/spaces.
- Cover the fastener with the remaining part of the elastic band and attach it on the other side.
- Cut off what is left of the elastic band but make sure to save at least one hole so that it is possible to adjust the fitting. Cut right through a hole.
- Check the flow of the liquid inside the tube.



If any serious incidents occur in relation to the use of IV-bracelet these should be reported to Medow AB and the competent authority of the Member State in which the user and/or patient is established.

