

IFU – Instructions for use

Version January 2016

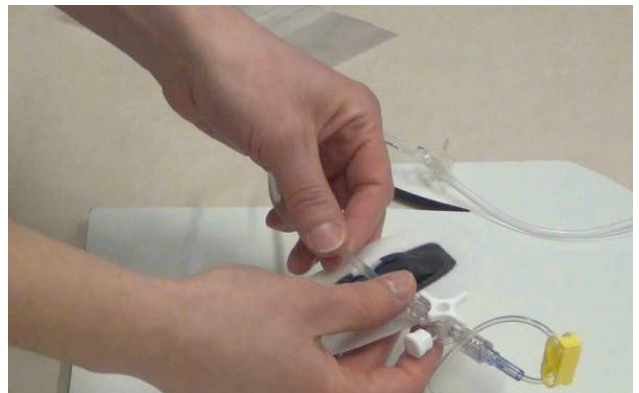
The application of the Bedalpatch is done by following the steps described in the section below:

- **Taking the Bedalpatch out of the packaging**

The Bedalpatch is individually packaged in a pouch, the 2 components of the Bedalpatch are included in 1 packaging. The pouch can be opened manually, and the Bedalpatch can be taken out.

- **Place the infusion line in the bottom part**

The infusion line should be placed in the opening of the bottom part. The diameter of the infusion line fits exactly in the opening of the bottom part. Make sure to select a part of the infusion line that is between 10cm and 40cm of the exit site. Do not select a part of the catheter that is between the exit site and the catheter hub, since these diameters can differ depending on the treatment of the patient.



- **Place the bottom part under the infusion line**

The bottom part has a double sided tape to fixate it on the skin. Remove the release liner of the tape, and position the bottom part on the skin, while the infusion line remains fixed in the bottom part of the snap. Make sure the position of the bottom part is within a distance of 10cm from the exit site. The position can be on the arm or on the chest of the patient, depending on the type of catheter. Note that it is also possible to click the top part on the bottom part before fixing the bottom patch to the skin (according to user preference).





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- **Place the top part over the bottom part, and click both parts of the snap over the infusion line**

Take the top part, and place the top part of the snap on top of the bottom part of the snap. The infusion line is now completely enclosed by the snap. Push the top part until you feel a click, this indicates that the snap is closed and applies sufficient pressure on the infusion line in order to create a watertight seal. Clicking the top part of the snap on the bottom part is indicated in the figure below. Please note that the top and bottom patch can also be clicked together before fixing the bottom patch to the skin (according to user preference).

For catheters that are disconnected, a standard closed infusion line of 40mm is included in the packaging. This short infusion line can be inserted in the snap part in order to provide a watertight closure of the snap part.

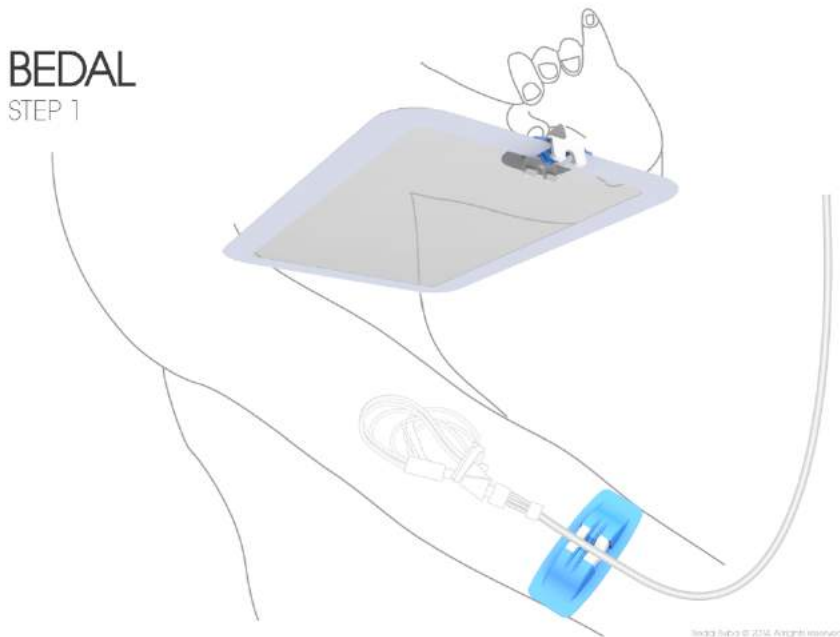
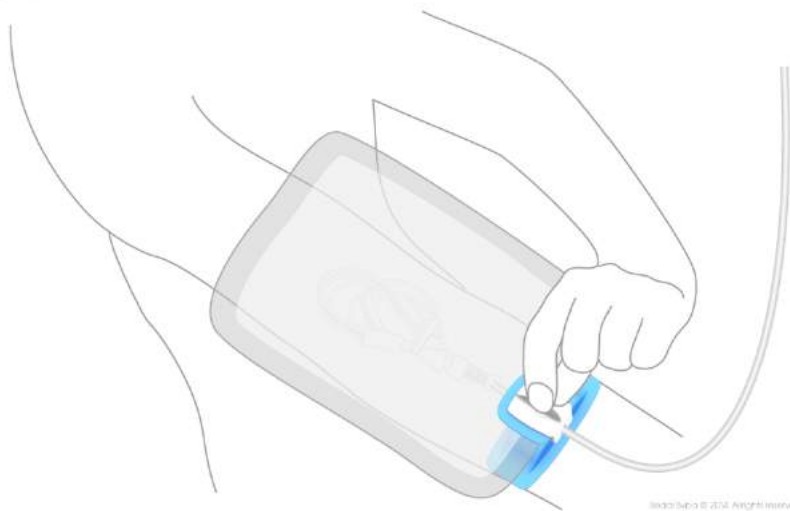


Figure 1: click the top part of the snap in the bottom part

BEDAL STEP 2

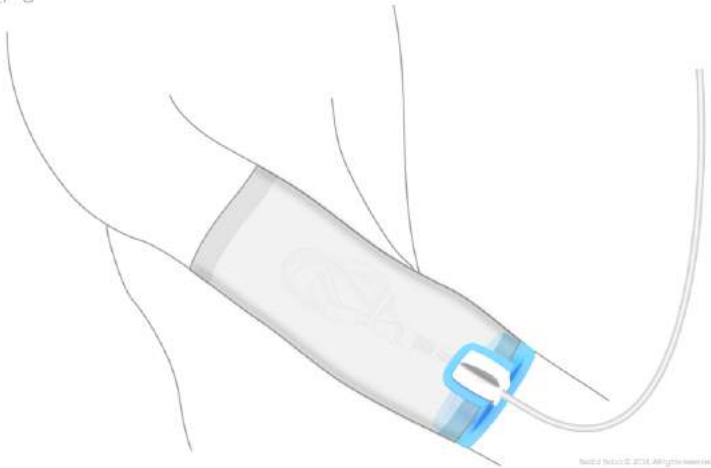


- **Attach the dressing to the skin with the adhesive layer**

The transparent film is positioned over the catheter exit site, make sure the transparent film covers the dressing that is used over the exit site.

Remove the release liner of the tape, and press on the edges of the Bedalpatch in order to fixate the patch on the skin. During the application of the pressure, move from the inside towards the outside with the hand, in order to avoid plies in the transparent film. Make sure the adhesive layer is straightly positioned to the skin, thus avoiding the formation of plies in the tape.

BEDAL STEP 3



- **The patient can take a shower or wash**

The Bedalpatch now provides a watertight seal of the exit site, and the patient is allowed to wash or take a shower. Please note that taking a bath or swimming with the Bedalpatch is not part of the intended use. The Bedalpatch is intended to be used for short durations of time, it should be applied before washing, and removed after washing.

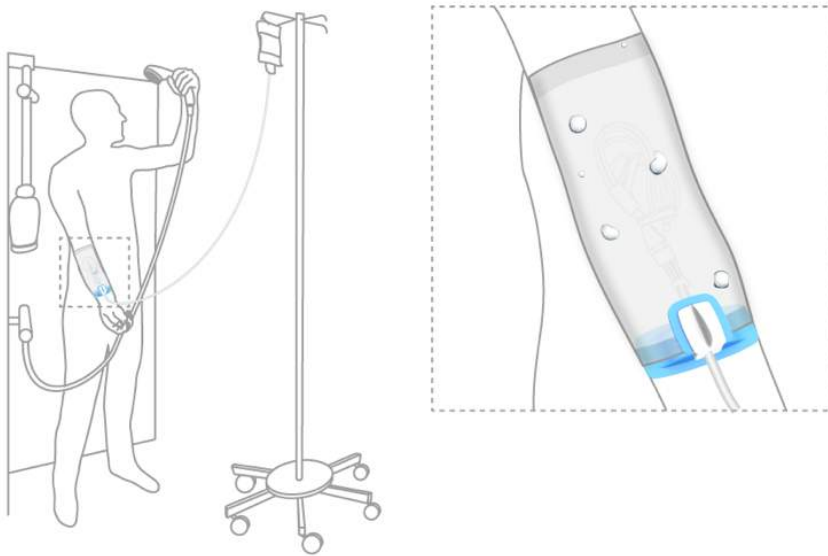




Figure 2: Bedalpatch worn by patient

- **Removing the Bedalpatch**

After the shower, the entire surface and surrounding of the film should be dried with a towel. This is done by gently sweeping the towel over the film and the surrounding skin of the patch. After the drying, the film can be removed by peeling of the adhesive layer. The peeling should be done in an angle of 180°, and not an angle of 90°, since this could cause a painful sensation upon removal.



Figure 3: removing of the Bedalpatch



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- **Unlocking the snap**

After removing the film, the snap is unlocked. This is done by gripping the fin to pull the snap up, and to release the snap. After unlocking of the snap, the infusion line can be taken out of the bottom part of the snap that is still attached to the skin.

- **Removing the bottom part of the snap from the skin**

The bottom part of the Bedalpatch is removed from the skin, by gripping a corner of the double sided tape, and pulling it of the skin. After removal of this bottom part, the full Bedalpatch is removed.



Figure 4: the bottom part is removed

1.1. Intended Performance of Device

The intended performance of the device is firstly the watertight function of the Bedalpatch. The water tightness requirement is to provide a watertight shielding during 1 washing of the patient.

The Bedalpatch is a consumable product, designed for single use.

Warnings and contra indications

The Bedalpatch is intended for patients with intravenous therapy with 0 or 1 connected infusion line. It can be used in connection with peripheral catheters, midline catheters, Central Venous Catheters and with ports, such as for example Port-a-Cath.

Warnings:

Some warnings are required in relation to the use of the Bedalpatch

- Use on infusion lines with an outer diameter of 4 mm, this means that the infusion line should be fixed in the snap, not the catheter, since this catheter can have a different diameter, depending on the French size. In order to communicate this warning, the user instructions on the label show the connection point of the snap, i.e. after the connection between the catheter and the infusion line.

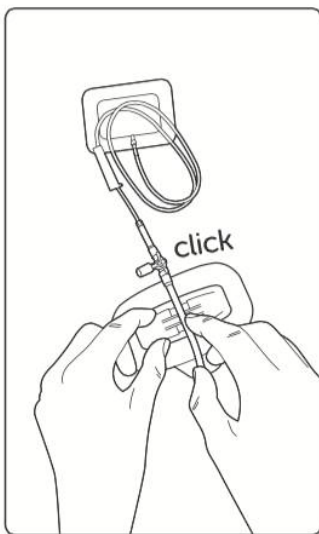


Figure 5: Instruction drawing on packaging, showing the connection of the snap part on the infusion line

- Verify that the snap has made a 'click' when connecting to the infusion line. When connecting the snap part to the infusion line, the user will feel a 'click' when the snap part is correctly fixed around the infusion line. This 'click' is shown on the user instructions, this is part of the product labeling.

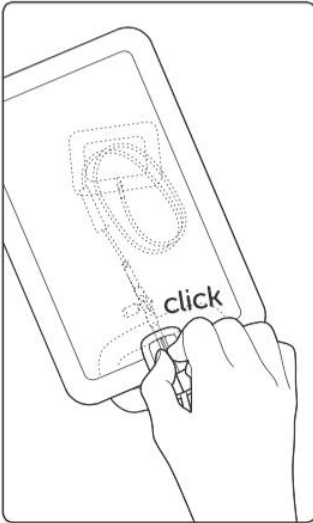


Figure 6: Instruction drawing on packaging, showing 'click' sound upon correct application of snap

- Position the snap part downward Whether the Bedalpatch is used on the chest position or the arm position, the orientation of the snap should be downwards, in order to limit the direct water exposure of the snap part. This warning is shown on the label of the product, which is part of the primary packaging.



Figure 7: Symbol on packaging to indicate that the snap should be positioned downwards

- Avoid direct water spraying from the shower head on the snap part. During washing or showering, the patient should avoid to directly spray water on the snap part, direct water spraying generates pressure on the snap part, which could lead to water intrusion. This warning is also visualized on the product label, and is shown on each product.



Figure 8: Symbol on packaging to indicate that direct water spraying on the snap should be avoided

- The Bedalpatch provides a sealing for 1 lumen, so it should only be used by patients with 1 connected lumen. Since the Bedalpatch has only 1 snap part, it can only accommodate 1 lumen for watertight sealing. The user instructions show only 1 lumen, no separate warning is made to limit the number of connected lumens to 1, since this is considered to be self-evident.

Contra indications

Known tape or adhesive allergies

Configurations and variants

The Bedalpatch is marketed in only 1 configuration and 1 variant.