EN Instruction for use DivibaX 2.0®

Caution:
Read the instructions for use carefully prior to using the device.

Description:
DivibaX 2.0 is a medical device intended for making a closed connection an IV container and a vial containing active medication. DivibaX 2.0 supporting a safe mixing of involved ingredients before patient infusion.

DivibaX 2.0 is available in packaging form 21 pcs. blister tray with single sterile barrier system (REF. 63170041).

Intended purpose:
DivibaX 2.0 is a sterile mixing device intended for mixing medicinal products in vials with infusion fluid in infusion containers within a closed system. The preparation is to be used within 24 hours after mixing.

Intended use environment:
DivibaX 2.0 should only be used in environment, which is dedicated for infusion fluids preparation and infusion procedures.

Sterilization:
DivibaX 2.0 is supplied sterile and non-pyrogenic. Sterilization has been performed by radiation.

Precautions:
1. Prior to opening, the sterile package should be careful controlled to see if it is still intact.
2. Do not use the devices if the package is broken or damaged.
3. Do not use damaged device.
4. The blue safety ring needs to be pushed towards the IV container and locked in order to ensure a stable connection between the IV container and the DivibaX 2.0 device.
5. The device should only be used by experienced medical staff, trained in preparation of infusions fluids and familiar with the risks associated with IV infusions procedure.

Contraindication:
It is always the authorized medical staff responsibility to determine and ensure patient's suitability for the procedure where the DivibaX 2.0 is used.

Warnings:
1. SINGLE USE. This device is intended for single use only. Reusing the device involves high risk of contamination.
2. This device is provided in sterile condition. Do no re-sterilize or re-use the device.
3. Use before the expiry date stated on the package.
4. The user bears full responsibility for possible incompatibility between the DivibaX 2.0 device and liquids, powders and mixtures hereof used together with the device.

Storage and handling:
Store in original carton and dry conditions. Avoid direct sun light and keep away from heat. The cartons must not be subjected to bumps. Handle with care.

Directions for use:
DivibaX 2.0 is not intended to be connected to any active medical device. DivibaX is compatible with vials with a 20 mm standard neck (ISO 8362), standard infusion sets (ISO 8536) and some IV containers.

Correct usage of the DivibaX 2.0 device is illustrated on the next page of the Instruction For Use.

Potential side-effects:
Possible complications include but are not limited to embolization, allergy reactions, infection or inflammation.

Disposal:
Discard the device after use according to local instructions for hazardous waste. With purpose to avoid contamination of the environment with the medicinal product, do not try to disassemble the connected DivibaX 2.0 from the IV container and vial.

Serious incident:
Every serious incident that has occurred in relation to the device should be reported without delay to the manufacturer and the competent authority of the Member State where the incident has occurred.

Disclaimer of liability:
SP Medical A/S is not liable for defects/deterioration resulting from abnormal use or modifications made to the product and under these circumstances not covered by the guarantee. SP Medical A/S disclaims liability for direct or indirect injuries that may occur as a consequence of the product being modified or wrongly used.

Explanation of the symbols used on the package labels:

MD	Medical device
	Caution
	Contents
REF	Reference number
LOT	Lot number
	Do not resterilize
	Do not re-use
STERILE R	Sterilized by radiation
	Non-pyrogenic
	Expiry date
PL	Country of manufacturer (PL=Poland) and manufacturing date
	Manufactured by
UDI	UDI information
	Do not use if pack is open or damaged
	Keep away from sunlight
	Keep dry

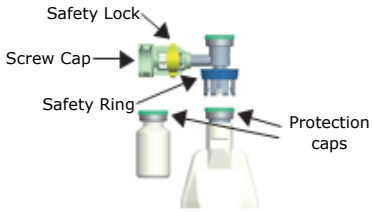
Manufacturer:
SP Medical A/S
Møllevej 1
DK - 4653 Karise
Denmark
Tel.: +45 56 76 60 00
Fax: +45 56 76 60 01
For further information please contact the manufacturer.

CE Mark:
CE
0197

Use of DivibaX 2.0®

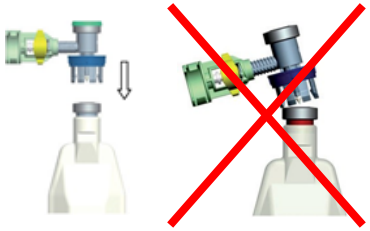
1. Remove the protection cap from the IV-container and the vial.

   Disinfect the rubber stoppers of the vial and the IV-container with alcohol. Unpack the DivibaX 2.0®.



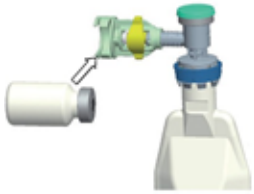
2. The blue safety ring must be pulled up as shown on the drawing.

   The DivibaX 2.0® **must** be fitted on the IV-container vertically and **not** at an angle or askew.



3. Push the blue safety ring downwards to lock it.

4. Push the vial into the green screw cap.



5. Turn the green screw cap clockwise ½ a round (2 clicks) to secure the vial.

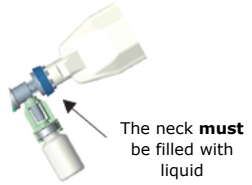
6. Remove the yellow safety lock with the thumb by pushing on the hinge on the yellow safety lock

7. Hold on to the green screw cap and turn it **clockwise** to the bottom of the thread.

8. Hold the IV-container at an angle – the vial pointing **downwards** as shown.

   Pump the liquid into the vial by squeezing the IV-container.

   Shake until the vial content is dissolved.

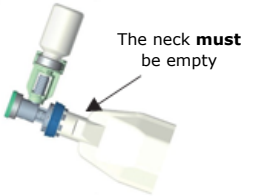


9. Hold the IV-container at an angle – the vial pointing **upwards** as shown.

   Pump the liquid back into the IV-container.

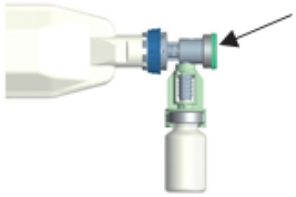
   Rinse by pumping the liquid back and forth from the vial to the IV-container.

   Repeat item 8 and 9.



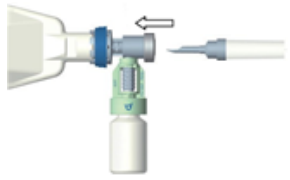
10. Remove the protection cap from the DivibaX 2.0®.

    Disinfect the rubber stopper with alcohol.



11. Insert the infusion set by turning and pushing the spike through the rubber stopper.

    Make sure the spike is inserted properly.



12. The infusion set closes for run-back of liquid to the vial. There may be some liquid left in the DivibaX 2.0® (appr. 1 ml).

    The vials stay on during the infusion procedure as documentation (patient safety).