

Freedom60[®] Prefilled Syringe Adapter - Instructions for Use

INFUSION SYSTEM

The Freedom60 Prefilled Syringe Adapter is intended for use with the Freedom60 Infusion Pump and the following prefilled syringes:

- Hizentra[®] 50 mL Pre-Filled Syringe

Precautions:

- U.S. Federal Law restricts this device to sale by or on the order of a physician.
- Only use the Freedom60 Prefilled Syringe Adapter and Freedom60 Infusion System for the patient for whom the device is prescribed, and only for its intended use.
- Only use Hizentra 50 mL prefilled syringes with the Freedom60 Prefilled Syringe Adapter.
- Do not use BD[®] 50 mL or Medline[®] 60 mL syringes with the Freedom60 Prefilled Syringe Adapter.
- Always refer to the Freedom60 Syringe Infusion System Instructions For Use (QR code on reverse side) and the immunoglobulin product's prescribing information for infusion instructions.
- Carefully inspect the syringe adapter before use. Discontinue use of a syringe adapter that is damaged, shows signs of deterioration (such as corrosion, discoloration, pitting, or cracking) or which fails to operate properly
- The Freedom60 Prefilled Syringe Adapter should be installed with the adapter placed into the pump collar and clicked into place as shown in the installation instructions. If the adapter is not assembled correctly, or the incorrect syringe is used, the syringe may be unintentionally expelled from the pump and may cause injury to the end user.
- Use only Freedom60 Infusion System accessories manufactured by KORU Medical Systems. Use of other products may result in unknown flow rates and possible site reactions such as swelling and redness.


Warnings:

- The black tab that pushes on the syringe plunger operates under high force. Do not place fingers on the black tab or inside the syringe shield at any time. Do not attempt to interfere with the movement of the black tab at any time
- Do not attempt to open the pump housing or remove the syringe shield. Do not operate if the syringe shield has been removed.
- Do not attempt to remove the prefilled syringe adapter without first turning the pump to the OFF position and fully winding the large knob clockwise until the black tab has reached the end of its track
- Do not sterilize the Freedom60 Infusion Pump or the Freedom60 Prefilled Syringe Adapter

Cleaning Procedure

1. Remove the Freedom60 Prefilled Syringe Adapter from the pump prior to cleaning.
2. Clean the adapter and pump with a soft cloth dampened with a weak mixture of mild detergent and warm water (minimum ratio of 1 part detergent to 50 parts water by volume).
3. Using the prepared detergent solution and a clean non-linting wipe or soft cloth, wipe all the external surfaces of the adapter and pump, including the pump nose and syringe tray up to the syringe shield for at least one (1) minute. During the one minute wipe, pay special attention to the ridges, crevices, raised lettering during wiping. Replace soiled cloths or wipes as needed, changing wipes when necessary to ensure that all surfaces are cleaned.
4. Using a clean non-linting wipe or soft cloth wetted with room temperature tap water (wet but not dripping), wipe all the external surfaces of the adapter and pump, including the pump nose and syringe tray up to the syringe shield. Pay special attention to the ridges, crevices, raised lettering during wiping. Continue wiping until all residue is removed to ensure the adapter and pump are thoroughly clean. Replace or re-wet cloth or wipes as needed, changing wipes when necessary to ensure that all surfaces are rinsed.
5. Dry the pump using a clean non-linting wipe or soft cloth.
6. Inspect the pump and adapter for any visible soil to ensure that the devices are thoroughly cleaned. If the device has remaining visible soil following cleaning, repeat the cleaning steps (1 through 4). Once all visible soil is removed, disinfect adapter and pump per the noted disinfection procedure.

Disinfection Procedure

1. Use pre-saturated IPA wipes, or a non-linting cloth or wipe saturated with 70% Isopropyl Alcohol (IPA) (wetted but not dripping) to thoroughly wipe all exterior surfaces of the Freedom60[®] Infusion Pump and Freedom60 Prefilled Syringe Adapter.
 - Ensure all external surfaces of the pump and adapter, including the pump nose and syringe tray up to the syringe shield are wiped. Pay special attention to the ridges, crevices, raised lettering during wiping.
-  **Caution:** Clean only those areas that are exposed and external. No attempt should be made to clean any part of the pump that is not easily accessible.
- Allow all surfaces to remain visibly wet for a minimum of five (5) minutes. During the five (5) minute contact time, use additional wipes to ensure all contacted surfaces remain wet for the full contact duration time.
2. Thoroughly dry the device using non-linting wipe(s) or allow to air dry.
 3. Visually inspect the device for signs of damage or wear.

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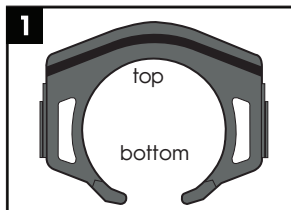
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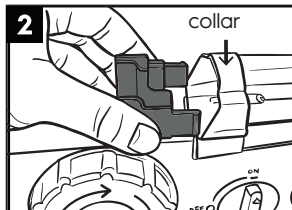
- Hizentra 50 mL Pre-Filled Syringe

Step-by-step instructions

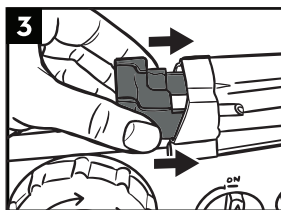
Installation Instructions for the Freedom60 Prefilled Syringe Adapter



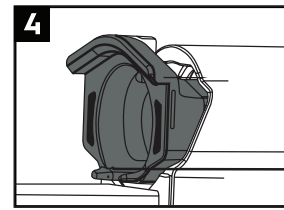
Make sure adapter is in the correct orientation, with opening at the bottom.



Line the adapter up with pump collar, placing fingers on the sides or retaining tabs of adapter as shown.

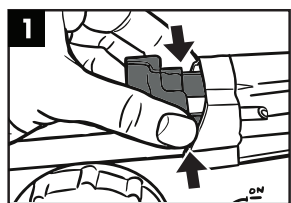


Lightly squeeze the sides of the adapter and begin to push it into the collar.

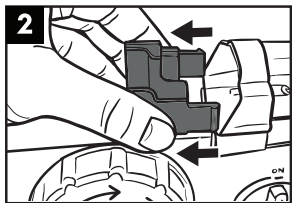


Continue pushing the adapter into the collar until it clicks into place.

Removal Instructions for the Freedom60 Prefilled Syringe Adapter



Pinch the two retaining tabs inward by applying pressure to them.



While pinching tabs, pull the adapter out of the collar, opposite the direction it was inserted.

For Instructions
for Use with the
Freedom60
Infusion System,
scan here:



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Manufacturer
KORU Medical Systems
100 Corporate Drive
Mahwah, NJ 07430 USA

800•624•9600
toll free

Store at room
temperature.



Caution



Consult
Instructions
For Use



Prescription
Only



Do Not Use
if Package
is Damaged



Latex Free