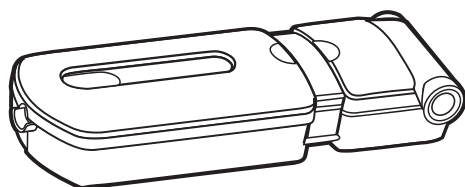


FreedomEDGE®

INFUSION SYSTEM



Instructions For Use

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KORU™
MEDICAL SYSTEMS

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Introduction

The FreedomEdge® Infusion System consists of the following components* manufactured by KORU Medical Systems, Inc. (KORU). See **page 5** for a complete system diagram and more details.

- **FreedomEdge® Infusion Pump** (referred to as “FreedomEdge™” or “pump”)
- **Precision™ Flow Rate Tubing** (referred to as “Precision tubing” or “tubing”)
- **High-Flo™ SubQ Needle Set** (referred to as “High-Flo needle set” or “needle set”)

CAUTION: Patients and their caregivers must be trained by their qualified healthcare provider prior to self-administration. Patients are advised to contact their healthcare provider for all questions related to their treatment.

Indications for Use

The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).

For Immunoglobulin Administration:

The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins in the home, hospital, or ambulatory settings when administered according to the FDA approved biologic labeling:

- **Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®);**
- **Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®);**
- **Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®)**
- **Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid 20ml Single-use pre-filled syringe (manufactured by CSL Behring®)**

For EMPAVELI™ (pegcetacoplan) Administration:

The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.

For RYSTIGGO (rozanolixizumab-noli) Administration:

The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of RYSTIGGO (rozanolixizumab-noli) in a clinical setting when administered according to the approved drug product labeling.

For Intravenous Antibiotic Administration:

The FreedomEdge Infusion System (FreedomEdge Infusion Pump and Precision Flow Rate Tubing) is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: Ertapenem, Meropenem, Oxacillin, and Tobramycin.



MRI Safety Information

The FreedomEdge® Infusion System is MR-unsafe. Do not use or store the FreedomEdge Infusion System or its components in or around an MRI machine.



WARNINGS

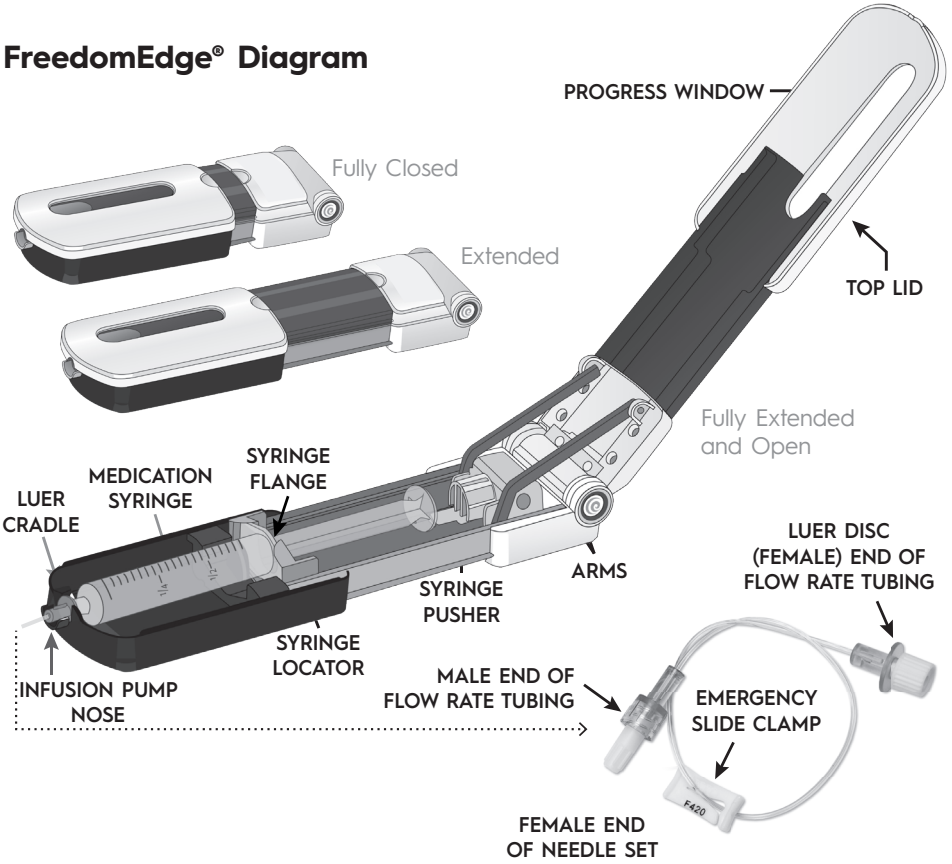
- Patient tolerance may vary. Potential side effects may include local site reactions such as swelling, redness, or soreness. If you are experiencing pain or discomfort, contact your healthcare provider. Refer to the medicinal product prescribing information for potential medicinal product reactions and side effects (e.g., paresthesia, headache, fever, dizziness, nausea, weakness, lethargy, etc.).
- Flow rates can be affected by multiple factors such as temperature, patient conditions, height differences between the system and infusion site, and variations in medicinal product viscosity. Refer to the device technical specifications for information on device performance.
- Do not connect the High-Flo needle set directly to the syringe. Connecting the needle set directly without the flow rate tubing can result in a flow rate that is too fast which can cause leakage or local site reactions, such as swelling, redness, or soreness.
- Do not re-sterilize or reuse the Precision tubing or High-Flo needle set. Re-using a single-use device may result in infection or malfunction of the pump.
- The FreedomEdge® syringe pusher operates at high force. Do not attempt to open the rear housing or interfere with the syringe pusher at any time.
- Do not place fingers inside the pump while opening or closing the FreedomEdge®.
- Do not attempt to remove the syringe or disconnect the tubing set without first fully opening the top lid of the FreedomEdge®.
- The FreedomEdge® Infusion Pump does not have an alarm. No alarm will sound if an interruption to flow occurs. There is no display of infusion status.
- If the FreedomEdge® Infusion Pump is submerged in any fluid, discontinue use and call or contact your healthcare provider for a replacement.
- Do not sterilize the infusion pump. Always follow the cleaning and disinfection instructions on page 14.
- The FreedomEdge® Infusion System is MR-unsafe. Do not use the FreedomEdge® Infusion System in or around an MRI Machine.



PRECAUTIONS

- The FreedomEdge® Infusion System is for prescription use only. Use the FreedomEdge® Infusion System only for the patient for whom the device is prescribed and only for its intended use. Ensure that the patient and/or caregiver is trained by a qualified healthcare professional prior to use.
- Use only Freedom Infusion System components manufactured by KORU Medical Systems, Inc. Use of other products may result in unknown flow rates.
- Use only compatible syringes with the FreedomEdge® Infusion Pump. Using a different syringe may result in unknown flow rates.
- Before use, carefully inspect the Precision tubing and High-Flo needle set packaging. Do not use the set if the package is opened.
- Inspect tubing and needle sets for damage. If damaged, do not use replace and contact your healthcare provider.
- The slide clamp included on the Precision tubing and High-Flo needle set should only be used to stop flow immediately in the case of an emergency. Use of the slide clamp may cause damage to the tubing and can affect the intended flow rate.
- Carefully inspect the FreedomEdge® Infusion Pump before use. Discontinue use of a pump that has been damaged, exposed to severe impact, or which fails to operate properly. Inspect the device for signs of wear (including cracks, fractures, corrosion, discoloration, pitting, or cracked seals) and discontinue use if device is unacceptably deteriorated.
- Avoid placing High-Flo needle set over a mole, tattoo, scar, muscle, or hardened or bruised areas, where proper needle set insertion could be difficult.
- Only perform infusions while stationary or walking. Infusions with movement other than walking may result in faster, slower, or more variable flow rates than specified. Testing has been performed to simulate walking and its effect on flow rates; the FreedomEdge® Infusion System has not been tested with any other physical activity.
- To obtain maximum accuracy of the pump, position the height of the pump within $\pm 7,6$ cm (3") of the infusion site, whether infusing in a stationary position or in motion. If the pump is higher than the infusion site, flow rate may increase. If the pump is positioned lower than the infusion site, flow rate may decrease.
- Ambient temperature may impact the flow rate. For most accurate results, it is recommended to infuse at a temperature of 20°-25° C. Environmental pressure and humidity are not expected to significantly impact the flow rate.
- The shelf life of the device (prior to first use) has been verified as two (2) years after the manufacturing date when stored at 15°-30° C at a humidity of 45-55%. Storage outside of these conditions, or use of the device after two (2) years of aging, may result in reduced performance or loss of device function. Refer to the device label for the manufacturing date of the device.
- The FreedomEdge® has been verified to withstand transport conditions of temperatures (-29°C-60°C) $\pm 2^\circ\text{C}$ and humidity of (15%-85%) $\pm 5\%$ without compromising its functional performance. Transporting the device outside of these conditions may damage the device or result in unknown flow rate performance.

FreedomEdge® Diagram



Product Line

Each FreedomEdge includes a travel pouch and user manual.

Product	Part #
FreedomEdge Infusion Pump	F10020
Replacement Travel Pouch	347400

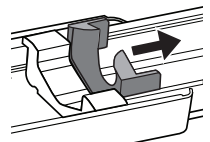
Syringes for use with the FreedomEdge

- Becton Dickinson & Co. BD® Luer-Lok® 20 ml (US Ref. Number: 302830)
- Becton Dickinson & Co. BD® Luer-Lok® 30 ml (US Ref. Number: 302832)
- Hizentra® 20 ml Single-Use Prefilled Syringe (NDC 44206-458-96)

Preoperation Instructions

The FreedomEdge Infusion Pump should be tested prior to any administration.

1. Examine the inside to ensure it is free of debris or damage.
2. Make sure the orange syringe locator moves freely by sliding it up and down the track with your finger.

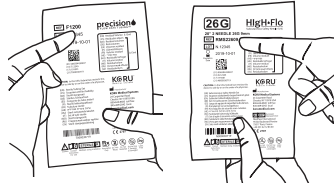
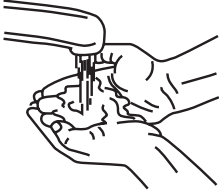


Step-by-Step Instructions for Subcutaneous Administration



Before subcutaneous self-administration, patients and/or caregivers should be properly trained by a qualified healthcare provider.

Infusion Preparation:

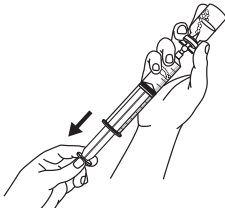


1. Gather Supplies & Sanitize

Clean your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly and, if required, put on disposable gloves. Lay out your supplies.

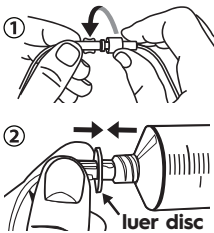
2. Verify Flow Rate Tubing & Needles

Verify that you are using the correct Precision Flow Rate Tubing and High-Flo Needle Sets prescribed by your healthcare provider. Inspect tubing and needle sets for damage. If damaged, replace and contact your healthcare provider.



3. Prepare Syringe(s)

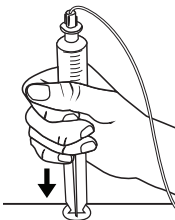
Ensure the medication is at room temperature (68-77°F or 20-25°C). Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions. If using a prefilled syringe, go to **Step 4**. If using vials, fill the BD 20 or 30 ml syringe(s) with the required dose.



4. Attach Tubing & Needles

Remove sterile caps from ends of the Precision Flow Rate Tubing set and High-Flo Subcutaneous Needle set and connect, using care not to contaminate the ends.

Remove the cap from the luer disc end of the flow rate tubing set with aseptic technique and connect to the syringe.



5. Prime (Fill) Tubing

Always follow your healthcare provider's protocol. Focus on a single needle and try to stop the flow when the fluid approaches the needle. Be careful not to prime to the needle tip.

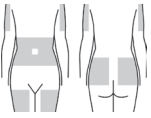
Push the syringe plunger and follow the medication as it flows through the tube. Release pressure from the plunger to stop the flow.

NOTE:

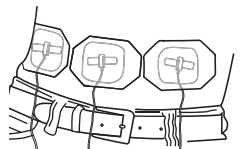
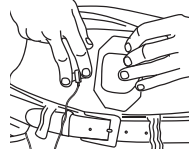
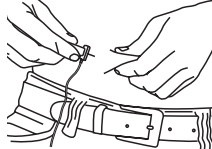
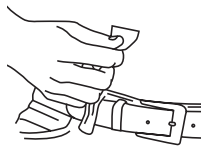
- It is recommended to insert the needles dry to minimize site irritation.
- To best see the medication, we suggest priming the tubing against a dark, solid-colored surface in a well-lit area.

Insert Needles and Check for Blood Return:

SC



NOTE: Always refer to the medical product manufacturer's prescribing information and recommendations from your healthcare provider for infusion site location(s). The most common areas for subcutaneous infusion include the abdomen, thighs, side of the upper hips and back of the arms.*



6. Prepare Sites

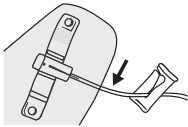
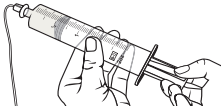
Select and clean site(s) before inserting needles. Carefully remove the shield from the needle tip, with care not to touch the needle.

7. Insert Needles

Pinch the skin and insert each needle into the subcutaneous tissue at a 90° angle.

8. Secure Needles

Peel the printed side from the dressing to expose adhesive. Secure the needle by placing the adhesive dressing in the center of the needle butterfly. Smooth it outward over skin.



9. Check for Blood Return

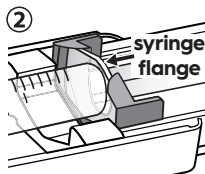
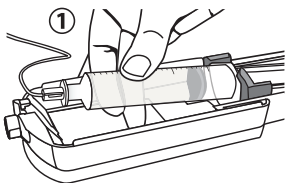
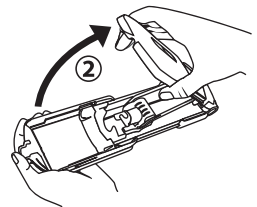
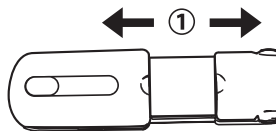
Check for blood return if instructed by your healthcare provider by gently pulling back on the syringe plunger. Watch to make sure no red/pink appears in tubing near your sites.

If blood return exists and if instructed by your healthcare provider, either clamp the flow to the needle site(s) or remove all needles, attach a new needle set, and start again from **Step 4**.

Starting & Ending Infusion:

10. Open Infusion Pump

1. Pull firmly to fully extend the infusion pump.
2. Then, open the infusion pump fully by lifting the top cover.



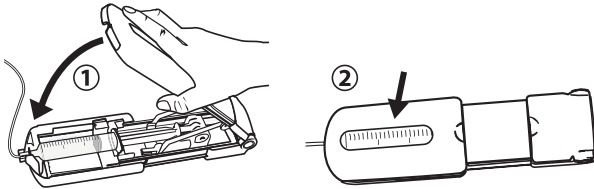
11. Load Syringe

1. With syringe gradations facing up, push the syringe flange against the orange syringe locator.
2. Make sure the syringe flange is seated within the front part of the orange syringe locator.
3. Verify that the Precision tubing (with the luer disc) is connected to syringe. Place the luer disc inside the infusion pump nose so that the syringe is firmly seated inside the infusion pump.

NOTE:



- You should not need to use significant force to load or remove the syringe. You can test proper fit by gently tugging on the syringe. It will stay in place if properly attached.
- When closing the infusion pump, make sure that the top lid is fully extended and aligns with the bottom portion.

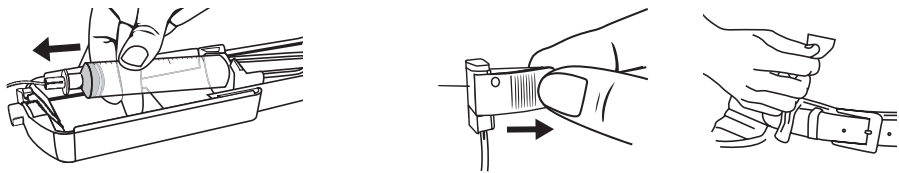


12. Begin Infusion

1. To start the infusion, close the top lid. The infusion will begin immediately. To reduce flow rate variability, try to keep the infusion pump level with your infusion sites.
2. Periodically monitor the infusion by checking the progress window, until syringe is empty.

To pause infusion: Simply open the infusion pump. To continue, re-close the top lid.

If using multiple syringes: Once the first syringe is empty, open the FreedomEdge. Remove the syringe from the infusion pump and disconnect from tubing. With aseptic technique, connect the additional syringe to the luer disc end of the Precision tubing set. Load the prepared syringe into the infusion pump. Close the top lid to continue infusion. Repeat until total dosage is complete.

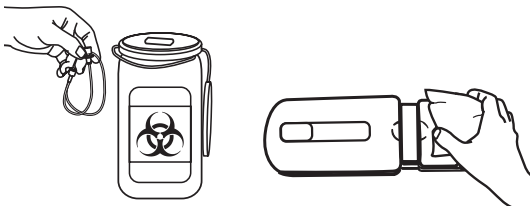


13. End of Infusion

When the syringe is completely empty and total dosage is administered, open the top lid of the infusion pump. Remove the empty syringe and its tubing.

14. Remove Needle(s) & Cleanse Sites

Holding the needle in place, peel back the surrounding adhesive dressing. Remove the needle in a straight motion, opposite of the direction you inserted it. To use safety feature, close wings over the needle and snap shut.



15. Discard Sharps & Clean

Discard all sharps and supplies as instructed by your healthcare provider. Remove visible soil as soon as possible after use of the device. Cleaning should be initiated as soon as possible after use of the device and delays between steps should be avoided. See **page 11** for full cleaning instructions.

Step-by-Step Instructions for Intravenous Administration

Before intravenous self-administration, patients and/or caregivers should be properly trained by a qualified healthcare provider.

Infusion Preparation:



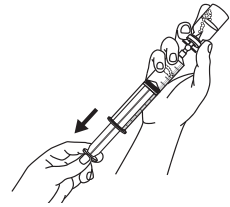
1. Gather Supplies & Sanitize

Clean your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly. Lay out your supplies.



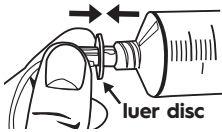
2. Verify Flow Rate Tubing

Verify that you are using the correct Precision Flow Rate tubing prescribed by your healthcare provider. Inspect the tubing set for damage. If damaged, replace and contact your healthcare provider.



3. Prepare Syringe(s)

Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions. If using a prefilled syringe, go to **Step 4**. If using vials, fill the BD® 20 or 30 ml syringe(s) with the required dose.

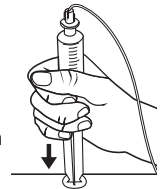


4. Attach Tubing

Remove cap from the luer disc end of the flow rate tubing set with aseptic technique and connect to the syringe.

5. Prime (Fill) Tubing

Always follow your healthcare provider's instructions. Loosen the cap on the Precision tubing set. Push the syringe plunger and follow the medicinal product as it flows through the tube. Release pressure from the plunger to stop the flow. When medication starts to drip, tighten the cap.



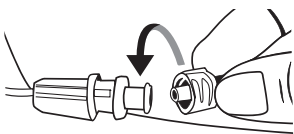
NOTE: To best see the medication, we suggest priming the tubing against a dark, solid-colored surface in a well-lit area.

Starting & Ending Infusion:

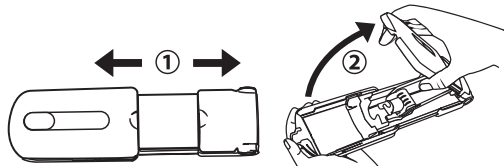
6. Begin Infusion

Follow the instructions of the healthcare provider for cleansing and preparing the vascular access device.

- Cleanse with alcohol – after 15 seconds scrub allow to dry completely.
- Aspirate for blood return to ensure the vascular access device is open and unobstructed before each access.

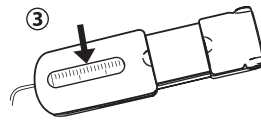
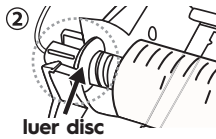
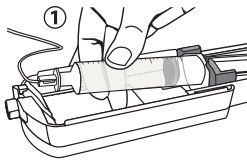


Uncap the Precision tubing set and connect to the vascular access device or needle-free connector.



Open the infusion pump:

1. Pull firmly to fully extend the infusion pump.
2. Then, open the infusion pump fully by lifting the top lid.



Load syringe and begin:

1. With syringe gradations facing up, push the syringe flange against the orange syringe locator.
2. Make sure the syringe flange is seated within the front part of the orange syringe locator. Place the luer disc inside the infusion pump nose so the syringe is firmly seated inside the infusion pump.
3. Close the top lid to start the infusion. Periodically monitor by checking the progress window, until syringe is empty. **To pause infusion:** Simply open the infusion pump. To continue, re-close the top lid.

NOTE:

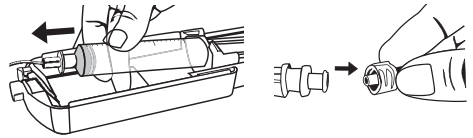
- You should not need to use significant force to load or remove the syringe. You can test proper fit by gently tugging on the syringe. It will stay in place if properly attached.
- When closing the infusion pump, make sure that the top lid is fully extended and aligns with the bottom portion.

If using multiple syringes: Once the first syringe is empty, open the FreedomEdge. If instructed, close the clamp on the vascular access device. Remove the syringe from the infusion pump and disconnect from tubing. With aseptic technique, connect the additional syringe to the luer disc end of the Precision tubing set and load back into the infusion pump. If closed, open the clamp on the vascular access device. Close the top lid to continue infusion. Repeat until total dosage is complete.

7. End of Infusion

When the syringe is completely empty and the total dosage is infused, open the FreedomEdge and remove the empty syringe.

If instructed, close the clamp on the vascular access device. Disconnect Precision tubing from the vascular access device or needle-free connector.



8. Flush

Always follow the healthcare provider's instructions on flushing the vascular access device. Refer to the **SASH** technique below.*

S **Saline Flush:** Ensure the vascular access device is open and unobstructed.

A **Administer:** Administer the medication.

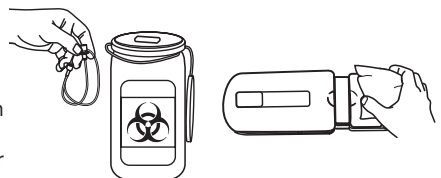
S **Saline Flush:** Clear the residual medication from the vascular access device and ensure the vascular access device is open and unobstructed.

H **Heparin** (If required for patency): Minimize the potential of a blood clot forming inside the vascular access device.

9. Discard Supplies & Clean

Discard all supplies as instructed by your healthcare provider.

Remove visible soil as soon as possible after use of the device. Cleaning should be initiated as soon as possible after use of the device and delays between steps should be avoided. See **page 11** for full cleaning instructions.



*Hadaway L. Technology of flushing vascular access devices. Journal of Infusion Nursing. 29(3):129-145, May 2006.

Troubleshooting

If the suggestions in this section do not solve your problem, or if problems persist, discontinue use and consult your healthcare provider. Any serious incident should be reported to your healthcare provider and KORU Medical Systems at **800-624-9600**.

Syringe will not load or remove from infusion pump:

NOTE: You should not need to use significant force to load or remove a syringe.

- Ensure the infusion pump is fully open, and that nothing is blocking the syringe locator.
- Confirm you are not overfilling the syringe (filling a 20 ml syringe with more than 20 ml of solution or a 30 ml syringe with more than 30 ml of solution), or using a syringe larger than 30 ml.
- If you still have difficulty, use one hand to slide the orange syringe locator all the way back, then place the syringe.

Syringe will not stay inside in the infusion pump:

- Make sure you are using the proprietary Precision Flow Rate Tubing™ sets and that the luer disc end of the tubing has been connected to a BD® 20 or 30 ml syringe or a Hizentra® 20 ml prefilled syringe.
- Make sure the luer disc is seated properly in the nose of the infusion pump.
- Make sure the flange shape of the syringe is correctly seated into the shape of the orange syringe locator.

No flow:

- Open and close the lid to ensure the syringe pusher slides freely and does not bind.
- Make sure all the slide clamps are unclamped. If vascular access device is being used, make sure its clamps, if any, are open.
- Use aseptic technique as recommended by the healthcare provider; disconnect the tubing set from the needle set, vascular access device or needle-free connector, and check for medication drip. If the medication does not drip:
 - **Subcutaneous administration:** replace the tubing as it may be damaged.
 - **Intravenous administration:** check that the catheter is open and unobstructed.

Slow flow:

- If the slide clamp has been used, the tubing may be damaged.
- Verify that you are using the proper syringe. 30 ml syringes will flow approx. 73% of the rate of a 20 ml syringe.
- Ensure the infusion pump is level with the infusion sites. If the infusion pump is positioned lower than the sites, the flow rate may be slower than expected.
- **Subcutaneous administration:**
 - Administration may be slow based on how well the medication is absorbed through the tissue. Some infusions may be faster than others. The first infusions may take longer than expected because the body may need to adapt.
 - Avoid placing needles on top of scar tissue or muscle.
 - It is possible you may need more sites, longer needles or a faster flow rate tubing set. Talk to your healthcare provider.

Stopping the flow quickly:

- The infusion pump is designed to maintain pressure during and after the infusion to prevent blood/drug backflow.
- To stop the flow, fully open the top lid to relieve pressure from the syringe plunger.
- The slide clamp can be used in the case of an emergency.

Medication (5 ml or less) left in the syringe:

- Verify that you are using a proper recommended syringe: BD® 20 or 30 ml, or Hizentra® 20 ml prefilled syringe.
- If the syringe does not completely empty, contact the healthcare provider.

Subcutaneous swelling, pain or redness at the site:

- It is recommended to insert subcutaneous needles dry as the medication may irritate the skin.
- Assure that the needles are long enough to reach the subcutaneous layer. If the selected needle is too short, leaking at the site may occur.
- Assure that the needles are not too long, as they may hit muscle.
- Try a slower flow rate tubing set as the rate may be too fast.
- Rotate infusion sites if recommended by your healthcare provider. Periodically returning to sites that worked well in the past may provide best results.

Care, Maintenance and Reprocessing

The FreedomEdge® does not require any preventative maintenance or calibration to be performed by the user

Between uses, the FreedomEdge infusion pump needs to be first thoroughly cleaned, and then disinfected.

After cleaning and disinfection, inspect the device for deterioration such as corrosion, discoloration, pitting, and cracked seals. Dispose of any devices that have reached the end of their lifetime according to your local disposal requirements.

Cleaning Procedure:

1. The FreedomEdge may be cleaned 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).
2. Using the prepared detergent solution and a clean non-linting wipe or soft cloth, wipe all the external surfaces of the infusion pump, including the driver nose and syringe tray up to the syringe shield for at least one (1) minute. During the one (1) 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.

Caution: Clean only those areas that are exposed and external. No attempt should be made to clean any part of the infusion pump that is not easily accessible.

3. 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 infusion pump, including the driver 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 infusion pump is thoroughly clean. Replace or re-wet cloth or wipes as needed, changing wipes when necessary to ensure that all surfaces are rinsed.
4. Dry the device using a clean non-linting wipe or soft cloth.
5. Inspect the device for any visible soil after the cleaning steps (but before the disinfection steps) to ensure that the device is thoroughly cleaned between uses prior to disinfection. If the device has remaining visible soil following cleaning, repeat the cleaning steps (1 through 4).

Disinfection Procedure:

1. Wipe the outside surfaces of the FreedomEdge® infusion pump with 70% Isopropyl Alcohol (IPA) and a non-linting cloth or wipe, or pre-saturated IPA wipe.
2. Use pre-saturated IPA wipes, or non-linting wipes saturated with 70% Isopropyl Alcohol (IPA) (wetted but not dripping) to thoroughly wipe all exterior surfaces of the device. Ensure all external surfaces of the infusion pump, including the driver nose, syringe tray and top lid are wiped. Pay special attention to the ridges and crevices during wiping. Allow all surfaces to remain visibly wet for a minimum of five (5) minutes.

Caution: Clean only those areas that are exposed and external. No attempt should be made to clean any part of the infusion pump that is not easily accessible.

3. During the five (5) minute contact time, use additional wipes to ensure all contacted surfaces remain wet for the full contact duration time.
4. Thoroughly dry the device using non-linting wipe(s) or allow to air dry.
5. Visually inspect devices for signs of damage or wear.

Storage:

The FreedomEdge infusion pump and infusion sets (Precision tubing sets and HigH-Flo needle sets) are recommended to be stored in a cool, dry place at room temperature (approximately 68-77°F or 20-25°C).

Testing Flow Accuracy (if required by your local protocol):

1. Remove all air from a new BD® 20 ml syringe with sterile water. Do NOT use a 30 ml syringe for this test.
2. Completely fill with 20 ml of sterile water.
3. Attach a sterile F120 Precision Flow Rate Tubing set to the syringe.
4. Remove all air from the tubing set.
5. Load the syringe into the infusion pump.
6. Using a stop watch or similar time tracking device, start the timer when the top lid of the infusion pump is fully closed (flow will begin).
7. Monitor and stop the timer when 10 ml of water has left the syringe.
8. The elapsed time should fall between 3:50-5:11 minutes.

NOTE: If the test results fall outside the range indicated in Step 8, factory refurbishment and testing are available. Please contact KORU Medical Systems at **800-624-9600**.

Technical Specifications

Testing was performed in a controlled test lab environment and as a result infusions should be administered within the same environmental conditions of 68-77°F (20-25°C) and atmospheric pressure of 1.01 bar (± 0.09).

Infusion Pump:

Weight: 12 oz (0.34 kg)

Length:

Closed: 9" (229 mm), *Extended:* 11.75" (299 mm)

Width: 3.25" (83 mm)

Height: 1.5" (38 mm)

Syringe: Reservoir volume: 20/30 ml

(BD® brand 20/30 ml syringes or Hizentra® prefilled 20 ml syringes)

Target Operating Temperature:

68-77°F (20-25°C)

Height Sensitivity:

Vertical Height (inches)	% Variation From Target Flow Rate
±3 inches from infusion site	Equivalent to Level
±6 inches from infusion site	up to ±1.2% from target flow rate
±12 inches from infusion site	up to ±2.4% from target flow rate
±24 inches from infusion site	up to ±4.8% from target flow rate

Ancillary Supply Product Information

Precision Flow Rate Tubing™ Sets:

Description	Item #	Residual Vol.	p/Box	Description	Item #	Residual Vol.	p/Box
Very Low Flow	F0.5	0.09 ml	50	Low Flow	F60	0.14 ml	50
Very Low Flow	F1	0.08 ml	50	Low Flow	F120	0.16 ml	50
Very Low Flow	F2	0.10 ml	50	Low Flow	F180	0.13 ml	50
Very Low Flow	F3	0.09 ml	50	High Flow	F275	0.11 ml	50
Very Low Flow	F3.8	0.09 ml	50	High Flow	F420	0.10 ml	50
Very Low Flow	F5	0.08 ml	50	High Flow	F500	0.09 ml	50
Very Low Flow	F8	0.08 ml	50	High Flow	F600	0.09 ml	50
Very Low Flow	F10	0.14 ml	50	High Flow	F900	0.08 ml	50
Very Low Flow	F15	0.11 ml	50	High Flow	F1200	0.13 ml	50
Low Flow	F30	0.13 ml	50	High Flow	F2400	0.15 ml	50
Low Flow	F45	0.11 ml	50				

Flow Rate Starter Kits:

Item Number	Description	Contents per Box
H20KT	High Flow Starter Kit	(2) F275, (5) F600, (5) F900, (4) F1200, (4) F2400
L20KT	Low Flow Starter Kit	(2) F30, (5) F45, (5) F60, (4) F120, (4) F180

KORU Related Accessories:

Item #	Description	Residual Vol.
LRVY	Low Residual Volume Y-Connector	0.14 ml
FEXT	24" Extension Set	0.4 ml

26G HiGh-Flo Subcutaneous Safety Needle Sets™:

Single-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
4 mm	RMS12604	0.1 ml	20
6 mm	RMS12606	0.1 ml	20
9 mm	RMS12609	0.1 ml	20
12 mm	RMS12612	0.1 ml	20
14 mm	RMS12614	0.1 ml	20

Two-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
4 mm	RMS22604	0.2 ml	10
6 mm	RMS22606	0.2 ml	10
9 mm	RMS22609	0.2 ml	10
12 mm	RMS22612	0.2 ml	10
14 mm	RMS22614	0.2 ml	10

Three-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
4 mm	RMS32604	0.3 ml	10
6 mm	RMS32606	0.3 ml	10
9 mm	RMS32609	0.3 ml	10
12 mm	RMS32612	0.3 ml	10
14 mm	RMS32614	0.3 ml	10

Four-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
4 mm	RMS42604	0.4 ml	10
6 mm	RMS42606	0.4 ml	10
9 mm	RMS42609	0.4 ml	10
12 mm	RMS42612	0.4 ml	10
14 mm	RMS42614	0.4 ml	10

Five-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
4 mm	RMS52604	0.5 ml	10
6 mm	RMS52606	0.5 ml	10
9 mm	RMS52609	0.5 ml	10
12 mm	RMS52612	0.5 ml	10
14 mm	RMS52614	0.5 ml	10

Six-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
4 mm	RMS62604	0.6 ml	10
6 mm	RMS62606	0.6 ml	10
9 mm	RMS62609	0.6 ml	10
12 mm	RMS62612	0.6 ml	10
14 mm	RMS62614	0.6 ml	10

24G HiGh-Flo Subcutaneous Safety Needle Sets™:

Single-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
6 mm	RMS12406	0.4 ml	20
9 mm	RMS12409	0.4 ml	20
12 mm	RMS12412	0.4 ml	20
14 mm	RMS12414	0.4 ml	20

Two-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
6 mm	RMS22406	0.7 ml	10
9 mm	RMS22409	0.7 ml	10
12 mm	RMS22412	0.7 ml	10
14 mm	RMS22414	0.7 ml	10

Three-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
6 mm	RMS32406	1.1 ml	10
9 mm	RMS32409	1.1 ml	10
12 mm	RMS32412	1.1 ml	10
14 mm	RMS32414	1.1 ml	10

Four-Needle Sets			
Length	Item #	Residual Vol.	p/ Box
6 mm	RMS42406	1.4 ml	10
9 mm	RMS42409	1.4 ml	10
12 mm	RMS42412	1.4 ml	10

Selected Flow Rate Tables

The following section is to guide healthcare providers in selecting the Precision Flow Rate Tubing™ and HIGh-Flo Subcutaneous Safety Needle Sets™* to achieve the desired flow rate based on the selected medication and number of infusion sites.

*HIGh-Flo Subcutaneous Safety Needle sets are only to be used for subcutaneous administration.

*All flow rate tables are based on bench top testing which was performed with 0 psi of back pressure.

How to Use Flow Rate Tables for Subcutaneous Administration:

- Select prescribed medication and refer to its prescribing information for recommended infusion flow rate and infusion time.
- Select the subcutaneous needle type – 26G or 24G needle. Verify the correct flow rate table.
- Evaluate and select flow rate tubing and number of needles based on the infusion phase and flow rate.

Refer to drug manufacturer’s prescribing information for maximum flow rate and/or volume per site and recommended parameters based on patient age and/or weight. Do not exceed drug manufacturer’s recommended infusion parameters.

EMPAVELI® (pegcetacoplan) Flow Rate Combinations:

The following table indicates the average, minimum, and maximum predicted infusion times with HIGh-Flo Subcutaneous Safety Needle Sets™ (Standard 26G) when used in combination with KORU Precision Flow Rate Tubing™ and FreedomEdge® Syringe Infusion System with a 20 ml BD syringe.

To determine the appropriate infusion time, please refer to the drug package insert. Only the specific combinations of Precision Flow Rate Tubing™ and HIGh-Flo Subcutaneous Safety Needle Sets™ identified in the table below are indicated for use with Empaveli.

The typical infusion time is approximately 30 minutes (if using two infusion sites) or approximately 60 minutes (if using one infusion site).

HIGh-Flo 26G with Precision Tubing
Average (Min-Max) Infusion Time for 20 ml Syringe (Minutes)

	F500	F600	F900	F1200	F2400
1 needle	47 (28-65)	44 (26-62)	38 (22-54)	37 (21-52)	30 (16-43)
2 needles	35 (22-48)	33 (20-45)	27 (16-37)	25 (14-36)	18 (10-26)

Cuvitru® Flow Rate Combinations: The following tables indicate the average predicted flow rates per site with High-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and FreedomEdge® Infusion Pump with a 20 or 30 mL BD syringe for the subcutaneous use of Cuvitru.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to the Cuvitru prescribing information for infusion parameters.

Cuvitru (<40 kg body weight)

- First 2 infusions: flow rate 10-20 mL/hr/site and volume ≤ 20 mL per site
- Subsequent infusions (i.e., after first 2 infusions): flow rate ≤60 mL/hr/site and volume ≤ 60 mL per site

Cuvitru - FreedomEdge® with 20 ml syringe						
Drug volume (mL)	Flow Rate Tubing	High-Flo Needle Set	Total flow rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time
10	F275	RMS12609	12.1	12.1	10	0:49
20	F275	RMS12609	12.1	12.1	20	1:39
20	F600	RMS22609	25.7	12.8	10	0:47
50	F600	RMS22609	25.7	12.8	25	1:57
60	F1200	RMS22609	37.1	18.6	30	1:37
60	F2400	RMS22409	110.5	55.4	30	0:32
60	F1200	RMS12409	55.3	55.3	60	1:05
100	F2400	RMS42409	132.8	33.2	25	0:45
Cuvitru - FreedomEdge® with 30 ml syringe						
20	F500	RMS22609	12.9	12.9	20	1:32
30	F900	RMS22609	24.6	12.3	15	1:13
30	F2400	RMS12609	21.2	21.2	30	1:24
30	F1200	RMS12409	42.1	42.1	30	0:42

Cuvitru (≥40 kg body weight)

- First 2 infusions: flow rate 10-20 mL/hr/site and volume ≤ 60 mL per site
- Subsequent infusions (i.e., after first 2 infusions): flow rate ≤ 60 mL/hr/site and volume ≤ 60 mL per site

Cuvitru - FreedomEdge® with 20 ml syringe						
Drug volume (mL)	Flow Rate Tubing	High-Flo Needle Set	Total flow rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time
10	F275	RMS12609	12.1	12.1	10	0:49
20	F275	RMS12609	12.1	12.1	20	1:39
20	F600	RMS22609	25.7	12.8	10	0:47
50	F600	RMS22609	25.7	12.8	25	1:57
60	F1200	RMS22609	37.1	18.6	30	1:37
60	F2400	RMS22409	110.5	55.4	30	0:32
60	F1200	RMS12409	55.3	55.3	60	1:05
100	F2400	RMS42409	132.8	33.2	25	0:45
Cuvitru - FreedomEdge® with 30 ml syringe						
20	F500	RMS22609	12.9	12.9	20	1:32
30	F900	RMS22609	24.6	12.3	15	1:13
30	F2400	RMS12609	21.2	21.2	30	1:24
30	F1200	RMS12409	42.1	42.1	30	0:42

Gammagard Liquid® Flow Rate Combinations: The following tables indicate the average predicted flow rates per site with 26G High-Flo Subcutaneous Safety Needle Sets™ when used in combination with Precision Flow Rate Tubing™ and FreedomEdge® Infusion Pump with a 20 or 30 mL BD syringe for the subcutaneous use of Gammagard Liquid.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to the Gammagard prescribing information for infusion parameters.

Gammagard Liquid (<40 kg body weight)

- Initial infusion: flow rate ≤ 15 mL/hr/site and volume ≤ 20 mL per site
- Subsequent infusions (i.e., after first infusion): flow rate ≤ 20 mL/hr/site and volume ≤ 20 mL per site

Gammagard Liquid - FreedomEdge® with 20 ml syringe						
Drug volume (mL)	Flow Rate Tubing	High-Flo Needle Set	Total flow rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time
20	F45	RMS12609	14.2	14.2	20	1:24
Gammagard Liquid - FreedomEdge® with 30 ml syringe						
20	F120	RMS22609	30	15	10	0:40
30	F180	RMS22609	39.8	19.9	15	0:45

Gammagard Liquid (≥40 kg body weight)

- Initial infusion: flow rate ≤ 20 mL/hr/site and volume ≤ 30 mL per site
- Subsequent infusions (i.e., after first infusion): flow rate ≤ 30 mL/hr/site and volume ≤ 30 mL per site

Gammagard Liquid - FreedomEdge® with 20 ml syringe						
Drug volume (mL)	Flow Rate Tubing	High-Flo Needle Set	Total flow rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time
20	F45	RMS12609	14.2	14.2	20	1:24
60	F120	RMS22609	39.8	19.9	30	1:30
100	F420	RMS42609	119.1	29.8	25	0:50
Gammagard Liquid - FreedomEdge® with 30 ml syringe						
20	F120	RMS22609	30	15	10	0:40
30	F180	RMS22609	39.8	19.9	15	0:45
30	F120	RMS12609	27	27	30	1:06

Hizentra® Flow Rate Combinations:

The following tables indicate the average predicted flow rates per site with 26G High-Flo Subcutaneous Safety Needle Sets™ when used in combination with Precision Flow Rate Tubing™ and FreedomEdge® Infusion Pump with a 20 or 30 mL BD syringe for the subcutaneous use of Hizentra for the treatment of Primary Immunodeficiency (PID) and Chronic Demyelinating Polyneuropathy (CIDP).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to the Hizentra prescribing information for infusion parameters.

Hizentra - Primary Immunodeficiency (PID)

- Initial infusion: flow rate ≤ 15 mL/hr/site and volume ≤ 15 mL per site
- Subsequent infusions (i.e., after first infusion): flow rate ≤ 25 mL/hr/site and volume ≤ 25 mL per site

Hizentra - Chronic Demyelinating Polyneuropathy (CIDP)

- Initial infusion: flow rate ≤ 20 mL/hr/site and volume ≤ 20 mL per site
- Subsequent infusions (i.e., after first infusion): flow rate ≤ 50 mL/hr/site and volume ≤ 50 mL per site

Hizentra - FreedomEdge® with 20 ml syringe						
Drug volume (mL)	Flow Rate Tubing	High-Flo Needle Set	Total flow rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time
10	F120	RMS12609	8.2	8.2	10	1:12
10	F180	RMS12609	10.5	10.5	10	0:57
20	F275	RMS22609	17.1	8.5	10	1:10
20	F600	RMS22609	29.6	14.8	10	0:40
40	F600	RMS32609	33.9	11.3	13.3	1:10
40	F900	RMS32609	44.3	14.8	13.3	0:54
60	F900	RMS42609	49.0	12.3	15	1:13
50	F2400	RMS32609	72.2	24.1	16.6	0:41
100	F2400	RMS42609	85.5	21.4	25	1:10
Hizentra - FreedomEdge® with 30 ml syringe						
20	F600	RMS22609	22.5	11.2	10	0:53
30	F900	RMS22609	28.3	14.2	15	1:03
30	F2400	RMS22609	20.9	20.9	15	0:42

Hizentra® 20ml Prefilled Syringe Flow Rate Combinations

Primary Immunodeficiency (PID)

The following tables indicate average (min-max) predicted flow rates per site with High-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and FreedomEdge® Infusion Pump for subcutaneous use with a Hizentra 20 mL prefilled syringe for the treatment of PID.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to the Hizentra prescribing information for infusion parameters.

- Initial infusion: flow rate ≤ 15 mL/hr/site and volume ≤ 15 mL per site
- Subsequent infusions (i.e., after first infusion): flow rate ≤ 25 mL/hr/site and volume ≤ 25 mL per site
- Exceeds drug manufacturer's infusion parameters >25 mL/hr/site

High-Flo 26G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	99 (7.0-12.9)	12.5 (9.7-15.4)	172 (131-212)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2 needles	5.4 (3.8-7.1)	7.0 (5.4-8.7)	10.1 (7.6-12.6)	14.2 (10.1-18.2)	16.1 (12.6-19.6)	18.3 (14.0-22.5)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3 needles	3.7 (2.6-4.9)	4.9 (3.7-6.0)	7.2 (5.4-8.9)	10.3 (7.3-13.3)	11.9 (9.3-14.5)	13.6 (10.3-16.9)	19.3 (14.8-23.7)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4 needles	2.9 (2.0-3.7)	3.7 (2.9-4.6)	5.5 (4.2-6.9)	8.1 (5.7-10.5)	9.4 (7.3-11.5)	10.9 (8.2-13.5)	15.8 (12.1-19.5)	18.2 (13.3-23.2)	<input checked="" type="checkbox"/>
5 needles	2.3 (1.6-3.0)	3.0 (2.3-3.8)	4.5 (3.4-5.7)	6.7 (4.7-8.7)	7.8 (6.0-9.5)	9.0 (6.8-11.2)	13.3 (10.2-16.5)	15.6 (11.2-19.9)	<input checked="" type="checkbox"/>
6 needles	1.9 (1.3-2.5)	2.5 (1.9-3.2)	3.8 (2.9-4.8)	5.7 (3.9-7.4)	6.6 (5.1-8.1)	7.7 (5.8-9.6)	11.6 (8.8-14.4)	13.6 (9.8-17.4)	<input checked="" type="checkbox"/>
7 needles	1.7 (1.1-2.2)	2.2 (1.7-2.7)	3.3 (2.5-4.1)	4.9 (3.4-6.4)	5.8 (4.5-7.1)	6.7 (5.1-8.4)	10.2 (7.7-12.7)	12.1 (8.6-15.5)	<input checked="" type="checkbox"/>
8 needles	1.5 (1.0-1.9)	1.9 (1.5-2.4)	2.9 (2.2-3.7)	4.4 (3.0-5.7)	5.1 (4.0-6.3)	6.0 (4.5-7.5)	9.1 (6.9-11.4)	10.8 (7.7-13.9)	18.7 (13.2-24.2)

High-Flo 24G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	11.5 (8.0-15.1)	15.1 (11.5-18.7)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2 needles	5.9 (4.0-7.7)	7.8 (5.9-9.6)	11.7 (8.7-14.7)	17.6 (12.2-23.0)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3 needles	4.0 (2.7-5.2)	5.2 (4.0-6.5)	7.9 (5.9-10.0)	12.0 (8.3-15.7)	14.2 (11.0-17.4)	16.7 (12.5-21.0)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4 needles	3.0 (2.0-3.9)	3.9 (3.0-4.9)	6.0 (4.5-7.5)	9.1 (6.3-11.9)	10.8 (8.3-13.2)	12.8 (9.5-16.0)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5 needles	2.4 (1.6-3.1)	3.2 (2.4-3.9)	4.8 (3.6-6.1)	7.3 (5.1-9.6)	8.7 (6.7-10.7)	10.3 (7.7-12.9)	16.3 (12.2-20.4)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6 needles	2.0 (1.4-2.6)	2.6 (2.0-3.3)	4.0 (3.0-5.1)	6.1 (4.2-8.1)	7.3 (5.6-8.9)	8.6 (6.4-10.8)	13.8 (10.3-17.2)	16.7 (11.7-21.8)	<input checked="" type="checkbox"/>
7 needles	1.7 (1.2-2.2)	2.3 (1.7-2.8)	3.5 (2.6-4.3)	5.3 (3.6-6.9)	6.3 (4.8-7.7)	7.4 (5.5-9.3)	11.9 (8.9-14.9)	14.5 (10.1-18.9)	<input checked="" type="checkbox"/>
8 needles	1.5 (1.0-2.0)	2.0 (1.5-2.5)	3.0 (2.3-3.8)	4.6 (3.2-6.1)	5.5 (4.2-6.7)	6.5 (4.9-8.2)	10.5 (7.8-13.1)	12.7 (8.9-16.6)	<input checked="" type="checkbox"/>

Hizentra® 20ml Prefilled Syringe Flow Rate Combinations

Chronic Demyelinating Polyneuropathy (CIDP)

The following tables indicate average (min-max) predicted flow rates per site with High-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and FreedomEdge® Infusion Pump for subcutaneous use with a Hizentra 20 mL prefilled syringe for the treatment of CIDP.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to the Hizentra prescribing information for infusion parameters.

- Initial infusion: flow rate ≤ 20 mL/hr/site and volume ≤ 20 mL per site
- Subsequent infusions (i.e., after first infusion): flow rate ≤ 50 mL/hr/site and volume ≤ 50 mL per site
- Exceeds drug manufacturer's infusion parameters >50 mL/hr/site

High-Flo 26G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	99 (7.0-12.9)	12.5 (9.7-15.4)	17.2 (13.1-21.2)	22.7 (16.7-28.7)	25.2 (19.9-30.5)	27.7 (21.6-33.9)	34.6 (27.3-42)	37.3 (28.8-45.9)	<input checked="" type="checkbox"/>
2 needles	5.4 (3.8-7.1)	7.0 (5.4-8.7)	10.1 (7.6-12.6)	14.2 (10.1-18.2)	16.1 (12.6-19.6)	18.3 (14.0-22.5)	24.8 (19.2-30.3)	27.6 (20.7-34.6)	37.8 (28.7-46.9)
3 needles	3.7 (2.6-4.9)	4.9 (3.7-6.0)	7.2 (5.4-8.9)	10.3 (7.3-13.3)	11.9 (9.3-14.5)	13.6 (10.3-16.9)	19.3 (14.8-23.7)	22.0 (16.2-27.7)	32.3 (24-40.6)
4 needles	2.9 (2.0-3.7)	3.7 (2.9-4.6)	5.5 (4.2-6.9)	8.1 (5.7-10.5)	9.4 (7.3-11.5)	10.9 (8.2-13.5)	15.8 (12.1-19.5)	18.2 (13.3-23.2)	28.2 (20.6-35.8)
5 needles	2.3 (1.6-3)	3.0 (2.3-3.8)	4.5 (3.4-5.7)	6.7 (4.7-8.7)	7.8 (6.0-9.5)	9.0 (6.8-11.2)	13.3 (10.2-16.5)	15.6 (11.2-19.9)	25.0 (18.1-32)
6 needles	1.9 (1.3-2.5)	2.5 (1.9-3.2)	3.8 (2.9-4.8)	5.7 (3.9-7.4)	6.6 (5.1-8.1)	7.7 (5.8-9.6)	11.6 (8.8-14.4)	13.6 (9.8-17.4)	22.5 (16.1-28.9)
7 needles	1.7 (1.1-2.2)	2.2 (1.7-2.7)	3.3 (2.5-4.1)	4.9 (3.4-6.4)	5.8 (4.5-7.1)	6.7 (5.1-8.4)	10.2 (7.7-12.7)	12.1 (8.6-15.5)	20.4 (14.5-26.4)
8 needles	1.5 (1-1.9)	1.9 (1.5-2.4)	2.9 (2.2-3.7)	4.4 (3.0-5.7)	5.1 (4.0-6.3)	6.0 (4.5-7.5)	9.1 (6.9-11.4)	10.8 (7.7-13.9)	18.7 (13.2-24.2)

High-Flo 24G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	11.5 (8.0-15.1)	15.1 (11.5-18.7)	22.5 (16.8-28.2)	33.1 (23.2-43)	38.5 (29.9-47.1)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2 needles	5.9 (4.0-7.7)	7.8 (5.9-9.6)	11.7 (8.7-14.7)	17.6 (12.2-23.0)	20.7 (16.0-25.4)	24.4 (18.2-30.5)	37.5 (28.3-46.7)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3 needles	4.0 (2.7-5.2)	5.2 (4.0-6.5)	7.9 (5.9-10.0)	12.0 (8.3-15.7)	14.2 (11.0-17.4)	16.7 (12.5-21.0)	26.2 (19.7-32.7)	31.5 (22.2-40.9)	<input checked="" type="checkbox"/>
4 needles	3.0 (2.0-3.9)	3.9 (3.0-4.9)	6 (4.5-7.5)	9.1 (6.3-11.9)	10.8 (8.3-13.2)	12.8 (9.5-16.0)	20.1 (15.1-25.2)	24.3 (17.0-31.7)	<input checked="" type="checkbox"/>
5 needles	2.4 (1.6-3.1)	3.2 (2.4-3.9)	4.8 (3.6-6.1)	7.3 (5.1-9.6)	8.7 (6.7-10.7)	10.3 (7.7-12.9)	16.3 (12.2-20.4)	19.8 (13.8-25.8)	<input checked="" type="checkbox"/>
6 needles	2.0 (1.4-2.6)	2.6 (2-3.3)	4.0 (3.0-5.1)	6.1 (4.2-8.1)	7.3 (5.6-8.9)	8.6 (6.4-10.8)	13.8 (10.3-17.2)	16.7 (11.7-21.8)	32.7 (22.0-43.4)
7 needles	1.7 (1.2-2.2)	2.3 (1.7-2.8)	3.5 (2.6-4.3)	5.3 (3.6-6.9)	6.3 (4.8-7.7)	7.4 (5.5-9.3)	11.9 (8.9-14.9)	14.5 (10.1-18.9)	28.6 (19.2-38.0)
8 needles	1.5 (1.0-2.0)	2.0 (1.5-2.5)	3.0 (2.3-3.8)	4.6 (3.2-6.1)	5.5 (4.2-6.7)	6.5 (4.9-8.2)	10.5 (7.8-13.1)	12.7 (8.9-16.6)	25.3 (17.0-33.7)

Rystiggo® Flow Rate Combinations

The following tables indicate the average (min-max) predicted flow rates per site with HlgH-Flo Subcutaneous Safety Needle Sets™ (26G) when used in combination with KORU Precision Flow Rate Tubing™ and FreedomEdge® Syringe Infusion System with a 20 ml syringe for the subcutaneous use of Rystiggo for the treatment of Generalized Myasthenia Gravis (gMG).

Rystiggo should only be administered by a healthcare provider in a clinical environment. To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to the Rystiggo prescribing information for infusion parameters.

HlgH-Flo **26G** with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F180	F275
1 needle	9.2 (5.3-13.1)	12.5 (7.0-18.1)

Warranty Information

This warranty and the rights and obligations hereunder, shall be construed under and governed by the laws of the State of New York, USA.


























Limited Warranty: KORU Medical Systems (“Manufacturer”) warrants the infusion pump to be free from defects in materials and workmanship under normal use. Warranty is limited to Original Purchaser and covers the FreedomEdge® for a period of two years from the purchase date. This warranty is not valid for any damage caused by the use of non-KORU products. The “Original Purchaser” is the person purchasing the infusion pump from the Manufacturer or Manufacturer’s Representative. Warranty does not extend to subsequent purchasers. Subject to the conditions of and upon compliance with the procedures set forth in this limited warranty, the Manufacturer will repair or replace, at its option, any infusion pump, or part thereof, which has been actually received by the Manufacturer or Manufacturer’s Representative within the two-year warranty period, and which examination discloses, to the Manufacturer’s satisfaction, that the product is defective. Replacement product and parts are warranted only for the remaining portion of the original two-year warranty period.

KORU tests the FreedomEdge using KORU accessories to ensure that the FreedomEdge operates in accordance with published specification standards. If non-KORU accessories are used in conjunction with the FreedomEdge, KORU does not represent that the FreedomEdge will operate in accordance with published specification standards. The FreedomEdge warranty does not cover third-party products or accessories.

The following conditions, procedures, and limitations apply to the Manufacturer's obligations under this warranty:

- **Parties Covered by this Warranty:** This warranty extends only to the Original Purchaser of the infusion pump. This warranty does not extend to subsequent purchasers.
- **Warranty Performance Procedure:** Notice of the defect must be made in writing to Customer Support Department, KORU Medical Systems, 100 Corporate Drive Mahwah, NJ 07430 USA. Notice to KORU Medical Systems must include the model and serial number, date of purchase, and description of the defect in sufficient detail to facilitate repairs. Authorization must be obtained by the Original Purchaser from the Manufacturer or Manufacturer's Representative prior to returning the product to the Manufacturer. The defective infusion pump must be properly packaged and returned to the Manufacturer, postage-prepaid. Any loss or damage during shipment is at the risk of the Original Purchaser.
- **Conditions of Warranty:** This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility in a way so as, in Manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, negligence or accident.
- **Limitations and Exclusions:** Repair or replacement of a infusion pump or component part is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
 - No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied, or to change this limited warranty in any way.
 - THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF.
 - Manufacturer's liability under this Limited Warranty Agreement shall not extend to special, indirect, or consequential damages.
 - The infusion pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the infusion pump for a particular medical treatment.
 - All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

DEFINITION OF SYMBOLS

	Catalog Number		Consult IFU before use. IFU available electronically at the indicated location.
	Manufacturer		For Prescription Use Only
	Authorized Representative in the European Community		Device is not safe for use in a magnetic radiation environment
	Swiss Representative		Do Not Reuse
	UK Responsible Person		Do Not Re-sterilize
	Lot Number		Item is a medical device
	Serial Number		Single sterile barrier packaging system
	Unique Device Identification (GTIN)		Do not use if package is damaged
	Expiration Date		CE Mark Notified Body Number (BSI NL: 2797)
	Manufacturing Date		Not manufactured with natural rubber/latex
	Temperature Range to which device can be exposed		Importer
	Humidity Range to which device can be exposed		Caution required when using device. Refer to IFU
	Sterilized with Gamma Radiation		

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