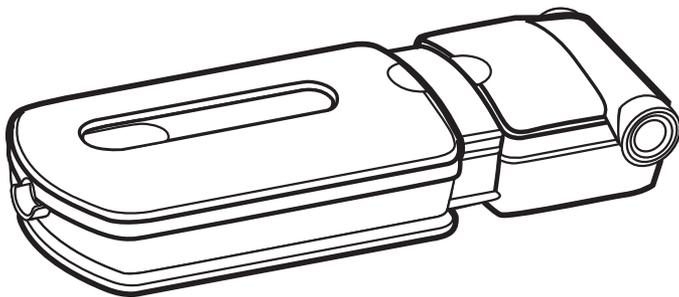


# FreedomEdge®

Syringe Infusion System



## Instructions For Use

### Contents

Introduction .....	2
Indications for Use.....	2
Caution .....	3
FreedomEdge Diagram .....	4
FreedomEdge Product Line.....	4
Syringes for Use with FreedomEdge .....	4
Preoperation Instructions.....	4
Instructions for Subcutaneous (SQ) Infusions .....	5
Instructions for Intravenous (IV) Infusions.....	7
Troubleshooting .....	9
Care and Maintenance .....	10
Technical Specifications .....	11
Residual Volumes .....	11
Selected Flow Rate Combinations .....	12
Warranty Information.....	13
Definition of Symbols .....	14
Notes .....	15

## **Introduction:**

The FreedomEdge® Syringe Infusion System is portable and easy to use, requiring no batteries or electricity. It starts to operate when the syringe driver is closed. KORU Precision Flow Rate Tubing™ sets are used to control the flow rate.

The FreedomEdge operates at a constant pressure, which automatically decreases the flow rate if there is an increase in resistance during the delivery. The system will find balance, known as Dynamic Equilibrium (or DynEQ®), between the increasing resistance and flow rate. It provides constant flow which tends to inhibit clots, and holds full pressure after an infusion is complete to prevent blood or drug return. The FreedomEdge also eliminates concerns of a bolus, overflow, overdose or runaway infusion.

## **Indications for Use:**

The Freedom Integrated Syringe Infusion System, which includes the FreedomEdge syringe driver, is indicated for the intravenous or subcutaneous infusion of medications and fluids in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. The Freedom System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used 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®); and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®). The Freedom System 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.

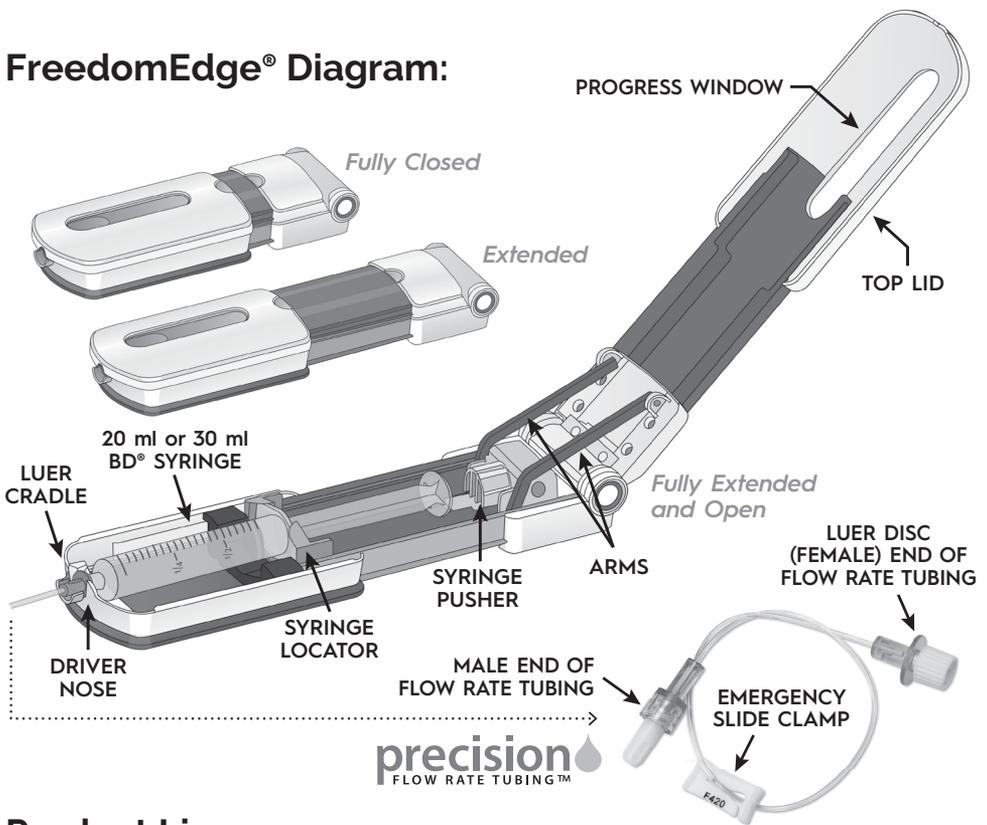
The FreedomEdge Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830) or BD® 30 ml syringe (US Reference number: 302832).



## Caution:

- Use the FreedomEdge® Syringe Infusion System only for the patient for whom the device is prescribed and only for its intended use.
- Use only Freedom System accessories manufactured by KORU Medical Systems. Use of off-brand products may result in unknown flow rates.
- Directly connecting extension tubing or HIgH-Flo needle sets (without the luer disc) to the syringe may cause internal damage to the syringe driver.
- Use only BD® 20 ml or 30 ml syringes with the FreedomEdge.
- Using the same tubing set, BD 30 ml syringes will have slightly slower flow rates and slightly increased delivery times versus BD 20 ml syringes.
- Before use, carefully inspect the tubing and needle set packaging. Do not use the set if the package is opened or damaged.
- Do not re-sterilize tubing or needle sets.
- The slide clamp included on the Precision tubing and HIgH-Flo needle sets should only be used in the case of an emergency, to stop flow immediately. Use of the slide clamp may cause damage to the tubing and can affect the intended flow rate.
- Carefully inspect the FreedomEdge before use. Discontinue use of a syringe driver that has been damaged, exposed to severe impact, or which fails to operate properly.
- The FreedomEdge Syringe Infusion System does not have an alarm, therefore, no alarm will sound if an interruption to flow occurs. There is no display of infusion status.
- The syringe driver is not suitable for use with medication where delay or under-infusion could result in serious injury.
- If the syringe driver is submerged in any fluid, discontinue use and call your healthcare provider for a replacement.
- Do not autoclave the FreedomEdge.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Freedom infusion components (Precision tubing and HIgH-Flo needle sets) should not be assembled prior to shipping.
- The FreedomEdge Syringe Infusion System is not intended for blood transfusions.

## FreedomEdge® Diagram:



## Product Line:

Each FreedomEdge includes a travel pouch and user manual.

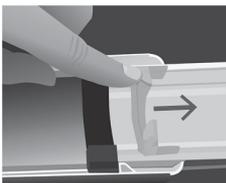
Product	Part #
FreedomEdge Syringe Driver	F10050
Replacement Travel Pouch	347400

## 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)

## Preoperation Instructions:

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



# Instructions for Subcutaneous Infusions:

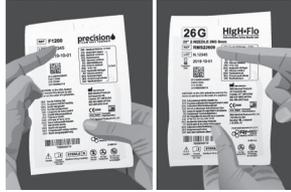
## Prepare and Prime Tubing:

### 1 Wash Hands



Gather supplies. Wash your hands thoroughly and, if required, put on disposable gloves.

### 2 Verify Tubing & Needles



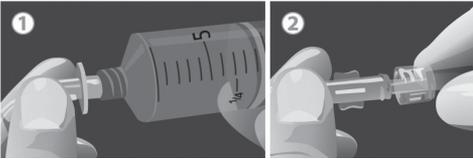
Verify that you are using the correct Precision tubing and High-Flo needle sets recommended and/or prescribed by your healthcare provider.

### 3 Fill Syringe



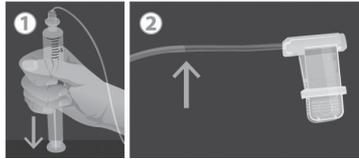
Be sure the medication is at room temperature before filling the BD® 20 or 30 ml syringe with your required dose. Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions.

### 4 Attach Syringe, Tubing & Needles



1. Remove the sterile cap from the luer disc end of the Precision tubing set and connect to syringe.
2. Remove sterile caps from opposite end of tubing set and High-Flo needle set and connect, using care not to contaminate ends.

### 5 Prime Needle Set



1. Grasp the syringe and gently press down with steady pressure.
2. Watch the tubing fill and try to stop the flow about 2" short of the needle(s). **NOTE:** To minimize site irritation, it is recommended to insert needles dry.

## Insert Needles/Check for Blood Return:

### 6 Prepare Sites



Select your site(s) and cleanse with alcohol (if advised by provider) and let dry. Carefully remove the shield from the needle tip, with care not to touch the needle.

### 7 Insert



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

### 8 Secure



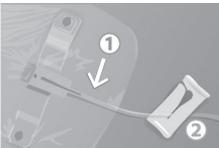
Secure the needle(s) by placing adhesive dressing in the center of the needle butterfly. Smooth it outward over skin.

### 9 Pull Back



Remove the syringe from the syringe driver. Check for blood return by gently pulling back on the syringe plunger.

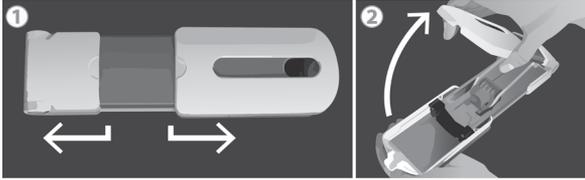
### 10 Watch



1. Watch to make sure no red/pink appears in tubing near your sites.
2. If blood return exists, clamp the flow to the sites and call your healthcare provider to determine if the dose can be run using the remaining sites. If so, continue. If not, remove all needles, attach a new needle set and start again from **Step 5**.

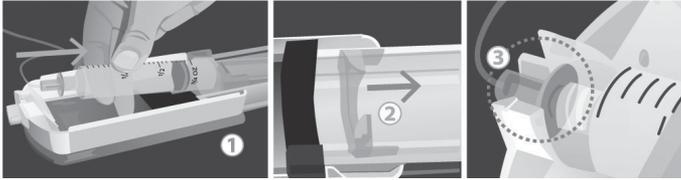
# Prepare FreedomEdge® and Begin Infusion:

## 11 Open Syringe Driver



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

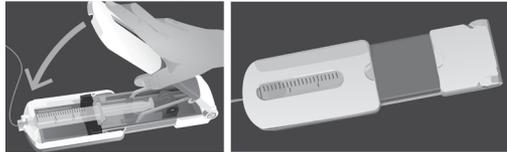
## 12 Load Syringe



1. With syringe gradations facing up, push the syringe against the syringe locator.
2. Seat the syringe flange into the syringe locator.
3. Verify that the Precision tubing (with the luer disc) is connected to syringe. Seat the luer disc inside the syringe driver nose so that the syringe is firmly attached inside the syringe driver.

**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.

## 13 Close Syringe Driver



To start the infusion, close the top lid. The infusion will begin immediately. Periodically monitor the infusion by checking the progress window, until syringe is empty.

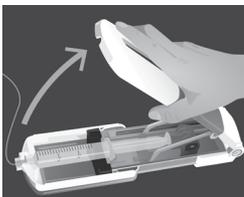
**To pause infusion:** Simply open the syringe driver. To continue, re-close the top lid.

**NOTE:** When closing the syringe driver, 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 syringe driver to turn off. Remove the syringe and connect additional syringe to the luer disc end of the Precision tubing set. Close the syringe driver to continue infusion.

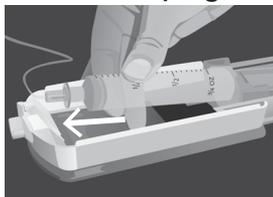
## End of Infusion: (When syringe is completely empty)

### 14 Open Syringe Driver



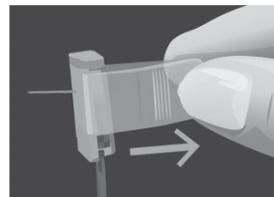
Turn the syringe driver OFF by opening the top lid.

### 15 Remove Syringe



Remove the empty syringe.

### 16 Remove Needles



Holding the needle in place, peel back the surrounding adhesive dressing. Remove the needle in a straight motion. Close the wings over the needle and snap shut. Remove set from the syringe. Discard all sharps and biologics as required.

# Instructions for Intravenous Infusions:

## Prepare and Prime Tubing:

### 1 Wash Hands



Gather supplies. Wash your hands thoroughly and, if required, put on disposable gloves.

### 2 Fill Syringe



Fill the BD® 20 or 30 ml syringe(s) with your required dose. Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions.

### 3 Attach Tubing



Verify that you are using the correct Precision tubing set recommended and/or prescribed by your healthcare provider. Remove sterile cap from luer disc end of the Precision tubing set and connect to the syringe.

### 4 Loosen Cap



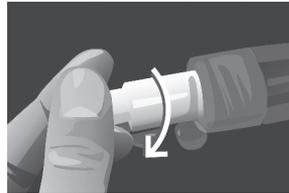
Loosen the cap on the Precision tubing set.

### 5 Push Plunger



Grasp the syringe, gently press down with steady pressure.

### 6 & Watch for Drip & Tighten Cap



When medication starts to drip, tighten the cap on the Precision tubing set.

**Flush:** Always follow your healthcare provider's protocol.

## 7 Use SASH technique

**S**

### Saline Flush

Ensure patency of the line and clear the line of residual medication

**A**

### Administer

Administer the medication (follow **Infuse Dose Steps 8 - 11** on the next page)

**S**

### Saline Flush

Ensure patency of the line and clear the line of residual medication

**H**

### Heparin (If required for patency)

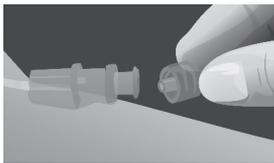
Minimize the potential of a blood clot forming inside the central line lumen

- Cleanse needleless connector with alcohol - 15 second scrub and allow to air dry.
- Aspirate for blood return to ensure line patency before each access.

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

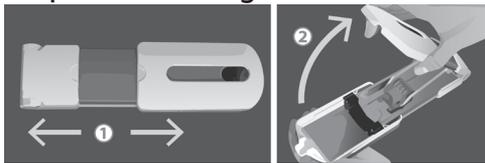
## Infuse Dose:

### 8 Connect



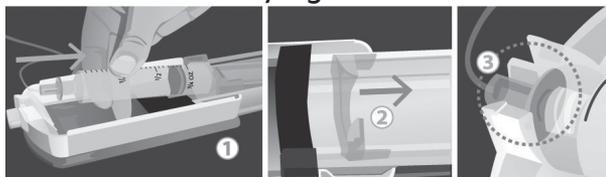
Uncap the Precision tubing set. Turning clockwise, connect the Precision tubing to the catheter end or needle-free connector.

### 9 Open FreedomEdge®



1. To open, confirm that the FreedomEdge is fully extended.
2. Then, open syringe driver fully by lifting top cover.

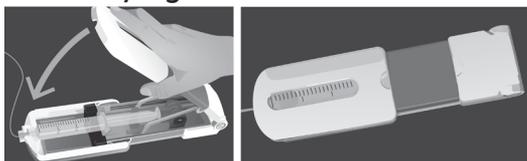
### 10 Load Medication Syringe



1. With syringe gradations facing up, push the syringe against the syringe locator.
2. Seat the syringe flange into the syringe locator.
3. Verify that the Precision tubing (with the luer disc) is connected to syringe. Seat the luer disc inside the syringe driver nose so that the syringe is firmly attached inside the syringe driver.

**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.

### 11 Close Syringe Driver



Check that all clamps are open. To start the infusion, close the top lid. The infusion will begin immediately. Periodically monitor the infusion by checking the progress window, until syringe is empty.

**To pause infusion:** Simply open the syringe driver. To continue, re-close the top lid.

**NOTE:** When closing the syringe driver, 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 syringe driver to turn off. Remove the syringe and connect additional syringe to the luer disc end of the Precision tubing set. Close the syringe driver to continue infusion.

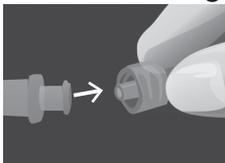
## End of Infusion: (When syringe is completely empty)

### 12 Open Syringe Driver



If needed, close clamp on the catheter. Turn the syringe driver OFF by opening the top lid.

### 13 Detach Tubing



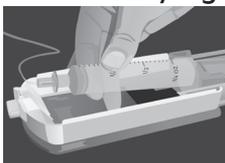
Disconnect the Precision tubing set from the catheter or needle-free connector.

### 14 Flush



Refer to **Step 7** on the previous page for **SASH** technique and follow your health-care provider's instructions.

### 15 Remove Syringe



Open the syringe driver and remove the empty syringe. Discard any biologics as required.

## Troubleshooting:

If the suggestions in this section do not solve your problem, or if problems persist, discontinue use and consult your healthcare provider.

### Syringe will not load or remove from syringe driver:

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

- Make sure the syringe driver is fully open, and that nothing is blocking the syringe locator.
- Confirm you are not filling the syringe to more than 30 ml, or using a syringe larger than 30 ml.
- If you still have difficulty, use one hand to slide the syringe locator all the way back, then place the syringe.

### Syringe will not stay inside in the syringe driver:

- 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.
- Make sure the luer disc is seated properly in the nose of the syringe driver.
- Make sure the flange shape of the syringe is correctly seated into the shape of the 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 sterile procedures to disconnect the tubing set from the needle set or catheter and check for medication drip.
  - If infusing subcutaneously and the medication does not drip from the tubing set, replace the tubing as it may be damaged.
  - If infusing intravenously, check the catheter patency.

### Slow flow:

- Verify that you are using the proper tubing.
- Verify that you are using the proper syringe. 30 ml syringes will flow approx. 73% of the rate of a 20 ml syringe (e.g. 120ml/hr tubing will flow at approx. 87.6ml/hr).
- If the slide clamp has been used, the tubing may be damaged.
- **For subcutaneous infusions:**
  - Administration may be slow based on how well medication is absorbed through the tissue. If it is your first infusion, it may take longer than expected because your body may need to adjust.
  - 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 syringe driver is designed to maintain pressure during and after the infusion to prevent blood/drug backflow.
- To stop the flow, fully open the lid to relieve pressure from the syringe plunger.
- The slide clamp can be used in the case of an emergency, when necessary to immediately stop the flow.

## Care and Maintenance:

The FreedomEdge® does not require any preventative maintenance. When used in combination with Precision Flow Rate Tubing™, KORU Freedom works as a system. This means the tubing determines the flow rate, not the syringe driver; therefore no calibration is needed.

### Cleaning

Clean only those areas that are exposed and external. No attempt should be made to clean any part of the syringe driver that is not easily accessible. Wipe the outside surface with warm water and detergent or use any surface disinfectant such as household bleach or hydrogen peroxide. Avoid excessive use of alcohol or alcohol containing compounds, as these tend to make ABS plastic brittle and degrade the product labeling. Wipe again with clean water to rinse.

### Storage

The FreedomEdge syringe driver is recommended to be stored in a cool, dry place at room temperature (approximately 16–30°C or 61–86°F).

### 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 syringe driver.
6. Using a stop watch or similar time tracking device, start the timer when the top lid of the syringe driver 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:

## Syringe Driver:

Weight: 12oz (0.34kg)

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

Width: 3.25" (83mm)

Height: 1.5" (38mm)

## System:

Accuracy: +/-15%

## Syringe:

Reservoir volume: 20/30 ml  
 (BD® brand syringes)

## System Max Operating Pressure:

Tubing/Needle Combo	Pressure at the beginning of needle set (psi)	Measured Pressure at end of Needle set (psi)
F60 + 24G	0.3 psi	0 psi
F2400 + 24G	7.7 psi	0 psi

Data represents pressure changes through the Freedom System (Freedom syringe driver, Precision Flow Rate Tubing™, and HigH-Flo Subcutaneous Safety Needle Sets™) with the slowest flow rate parameter (F60) and the fastest flow rate parameter (F2400). The net effect: the pressure of the needle is significantly reduced from the initial head pressure.

## Residual Volumes - Precision Tubing and HigH-Flo Needle Sets



Item #	Res. Vol.	Item #	Res. Vol.	Item #	Res. Vol.
F0.5	0.09 ml	F10	0.14 ml	F275	0.11 ml
F1	0.08 ml	F15	0.11 ml	F420	0.10 ml
F2	0.10 ml	F30	0.13 ml	F500	0.09 ml
F3	0.09 ml	F45	0.11 ml	F600	0.09 ml
F3.8	0.09 ml	F60	0.14 ml	F900	0.08 ml
F5	0.08 ml	F120	0.16 ml	F1200	0.13 ml
F8	0.08 ml	F180	0.13 ml	F2400	0.15 ml



26 Gauge Sets Residual Volumes		
Needles	Item Number	Res. Vol.
1 needle	RMS126XX	0.1 ml
2 needles	RMS226XX	0.2 ml
3 needles	RMS326XX	0.3 ml
4 needles	RMS426XX	0.4 ml
5 needles	RMS526XX	0.5 ml
6 needles	RMS626XX	0.6 ml
26 Gauge with Y-Connector		
7 needles	RMS426XX + RMS326XX	0.9 ml
8 needles	RMS426XX + RMS426XX	1.0 ml

24 Gauge Sets Residual Volumes		
Needles	Item Number	Res. Vol.
1 needle	RMS124XX	0.4 ml
2 needles	RMS224XX	0.7 ml
3 needles	RMS324XX	1.1 ml
4 needles	RMS424XX	1.4 ml

## KORU Related Options

Product Code	Res. Vol.
LRVY (Low Residual Volume Y-Connector)	0.14 ml
FEXT (24" Extension Set)	0.4 ml

# Selected Flow Rate Combinations

Select Combinations of Flow Rates with High-Flo Subcutaneous Safety Needle Sets™ (Standard 26G and 24G) when used in combination with Precision Flow Rate Tubing™ for use with Hizentra, Cuvitru, and Gammagard Liquid.

**NOTE:** The following tables are only for the subcutaneous use of the immunoglobulin listed.

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	NOTES:
10	F120	RMS12609	8.2	8.2	10	1:12	Suggested start Peds
10	F180	RMS12609	10.5	10.5	10	0:57	Suggested start Peds
20	F275	RMS22609	17.1	8.5	10	1:10	Suggested start Peds
20	F600	RMS22609	29.6	14.8	10	0:40	Suggested start Peds
40	F600	RMS32609	33.9	11.3	13.3	1:10	Suggested start Adult
40	F900	RMS32609	44.3	14.8	13.3	0:54	Suggested start Adult
60	F900	RMS42609	49	12.3	15	1:13	Suggested start Adult
50	F2400	RMS32609	72.2	24.1	16.67	0:41	6 <sup>th</sup> Infusion of biologic and beyond
100	F2400	RMS42609	85.5	21.4	25	1:10	6 <sup>th</sup> Infusion of biologic and beyond (NEEDS TWO SYRINGES)
Hizentra - with FreedomEdge® with 30 ml syringe							
20	F600	RMS22609	22.5	11.2	10	0:53	Suggested start Peds
30	F900	RMS22609	28.3	14.2	15	1:03	Suggested start Adult
30	F2400	RMS22609	41.9	20.9	15	0:42	6 <sup>th</sup> Infusion of biologic and beyond

Cuvitru – with 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	NOTES:
10	F275	RMS12609	12.1	12.1	10	0:49	1 <sup>st</sup> Two Infusions patients under 40kg
20	F275	RMS12609	12.1	12.1	20	1:39	1 <sup>st</sup> Two Infusions patients under 40kg
20	F600	RMS22609	25.7	12.8	10	0:47	1 <sup>st</sup> Two Infusions patients under 40kg
50	F600	RMS22609	25.7	12.8	25	1:57	1 <sup>st</sup> Two Infusions patients over 40kg
60	F1200	RMS22609	37.1	18.6	30	1:37	Subsequent Infusions
60	F2400	RMS22409	110.5	55.4	30	0:32	Subsequent Infusions
60	F1200	RMS12409	55.3	55.3	60	1:05	Subsequent Infusions
100	F2400	RMS42409	132.8	33.2	25	0:45	Subsequent Infusions
Cuvitru – with FreedomEdge® with 30 ml syringe							
20	F500	RMS22609	12.9	12.9	20	1:32	1 <sup>st</sup> Two Infusions patients under 40kg
30	F900	RMS22609	24.6	12.3	15	1:13	1 <sup>st</sup> Two Infusions patients under 40kg
30	F2400	RMS12609	21.2	21.2	30	1:24	Maintenance Infusions
30	F1200	RMS12409	42.1	42.1	30	0:42	Maintenance Infusions

Gammagard Liquid – with 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	NOTES:
20	F45	RMS12609	14.2	14.2	20	1:24	Patients under 40kg (Initial)
60	F120	RMS22609	39.8	19.9	30	1:30	Patients over 40kg (Initial)
100	F420	RMS42609	119.1	29.8	25	0:50	Patients over 40kg (maintenance infusions)
Gammagard Liquid – with FreedomEdge® with 20 ml syringe							
20	F120	RMS22609	30	15	10	0:40	Patients under 40kg(Initial)
30	F180	RMS22609	39.8	19.9	15	0:45	Patients over 40kg (Initial)
30	F120	RMS12609	27	27	30	1:06	Patients over 40kg (Maintenance)

\*High-Flo needle sets: The first number refers to the number of needles, the next two numbers refer to the needle gauge, and the last two numbers refer to the needle length (mm).

## 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/Repro Med Systems, Inc. (“Manufacturer”) warrants the syringe driver 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 syringe driver 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 syringe driver, 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 syringe driver. 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/Repro Med Systems, Inc., 24 Carpenter Road, Chester, NY 10918, USA. Notice to KORU Medical Systems/Repro Med Systems, Inc. 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 syringe driver 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 syringe driver 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 syringe driver can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the syringe driver 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:

	Caution		Use by YYYY-MM-DD or YYYY-MM
	Consult Instructions For Use		Manufacturer
	Authorized Representative in the European Community		Do Not Reuse
	Batch Code		Do Not Resterilize
	Quantity		Latex Free
	Catalog Number		Do Not Use if Package is Damaged
	Serial Number		Prescription Only
	Sterilized Using Irradiation		European Conformity



*formerly RMS Medical Products*



KORU Medical Systems    800-624-9600 toll free  
24 Carpenter Road    845-469-2042 local  
Chester, NY 10918 USA    korumedical.com



The FreedomEdge® and FREEDOM60® Syringe Infusion Systems, Precision Flow Rate Tubing™, HigH-Flo Subcutaneous Safety Needle Sets™, and DynEQ® are trademarks of KORU Medical Systems and are compliant with Medical Device Directive 93/42/EEC. All other trademarks are the property of their respective owners. KORU Medical Systems is ISO 13485 certified. ©2020 KORU Medical Systems; All Rights Reserved.