

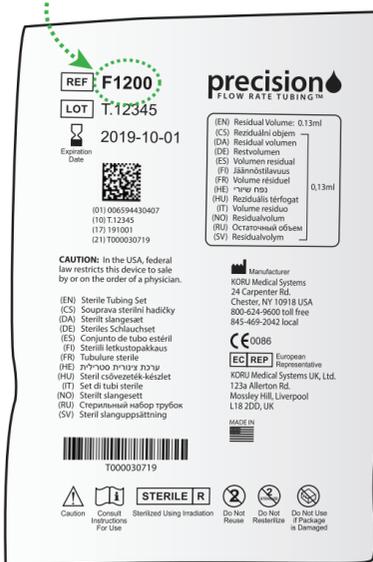
# FreedomEdge<sup>®</sup> Syringe Infusion System

## SCIg Infusion Mat

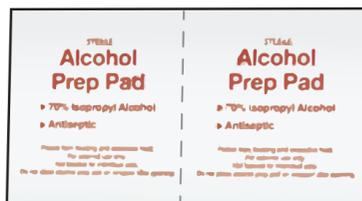
### Gather Supplies:

Be sure to use the complete protocol supplied by your healthcare provider. Wipe down infusion mat with alcohol pad prior to each use.

Precision Flow Rate Tubing™  
(check the F number of the tubing)



Alcohol/chlorhexidine pads



High-Flo Subcutaneous Safety Needle Sets™



Medication



Spike or needle



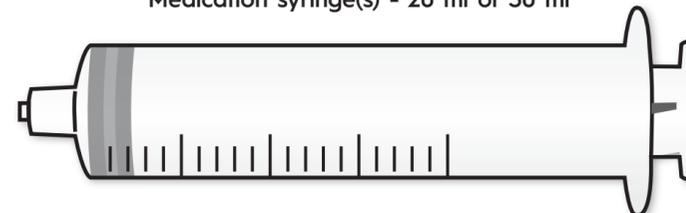
### Why SCIg?

Sub-q immunoglobulin is infused slowly into the fatty layer under the skin as opposed to IVIg, which is delivered through a vein. SCIg is typically administered on a more frequent basis than IVIg, which provides stable blood levels, decreases side effects and improves overall quality of life.



For larger volume infusions, FREEDOM60<sup>®</sup> pump has all of the performance and technology of the FreedomEdge<sup>®</sup>, in a design for 50 ml BD<sup>®</sup> syringes.

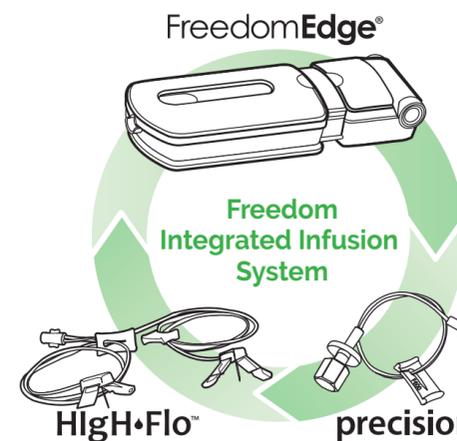
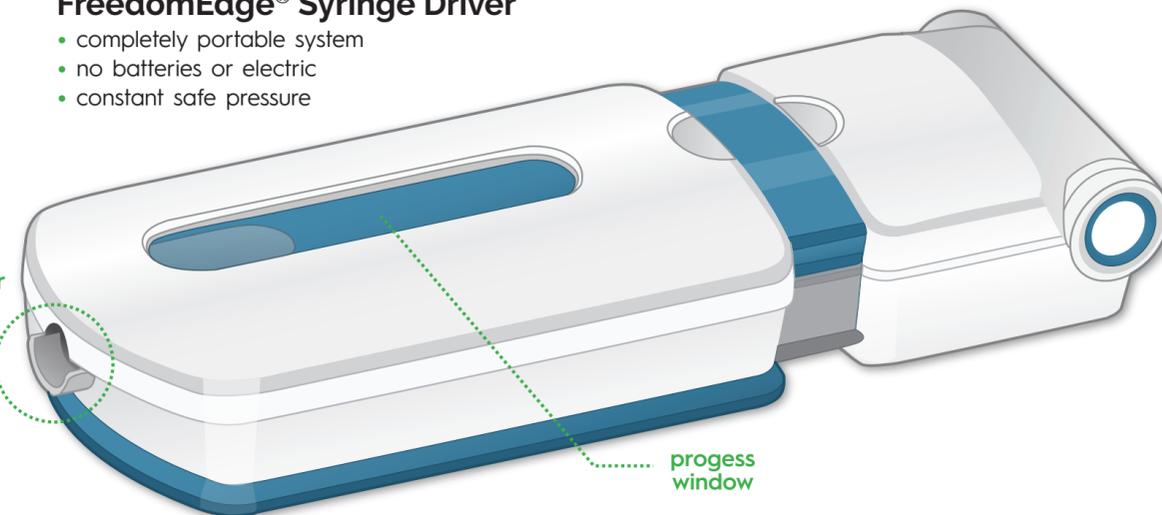
Medication syringe(s) - 20 ml or 30 ml



### FreedomEdge<sup>®</sup> Syringe Driver

- completely portable system
- no batteries or electric
- constant safe pressure

driver nose



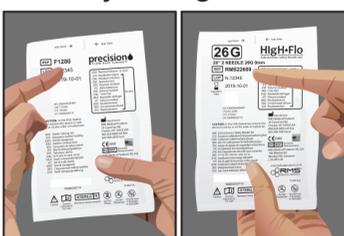
Use **ONLY** Freedom System accessories (Precision Flow Rate Tubing™ and High-Flo Subcutaneous Safety Needle Sets™) manufactured by KORU Medical Systems. Use of off-brand products may result in unknown flow rates.

### Prepare and Prime Tubing:

- 1 Wash Hands
- 2 Verify Tubing & Needles
- 3 Fill Syringe



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



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



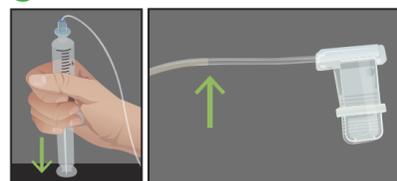
Be sure the product is at room temperature before you begin filling syringe with your required dose. Refer to the manufacturer's instructions or ask your provider for more detailed filling instructions.

### 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



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

Always follow your provider's protocol.

### Insert Needles/Check for Blood Return:

- 6 Prepare Sites
- 7 Insert



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



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

### 8 Secure



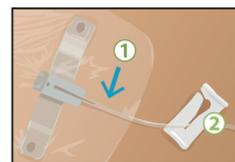
Secure the needle(s) by placing adhesive dressing in the center of the needle butterfly. Smooth it outward over skin.

### 9 Pull Back



Remove the syringe from the FreedomEdge<sup>®</sup>. Check for blood return by gently pulling back on the syringe plunger.

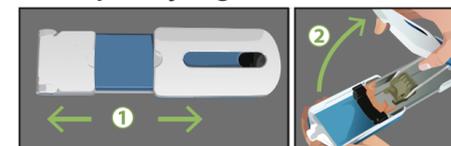
### 10 Watch



1. Watch to make sure no red/pink appears in tubing near your sites.
2. If blood return exists, clamp the flow to that site 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 of Prepare section.

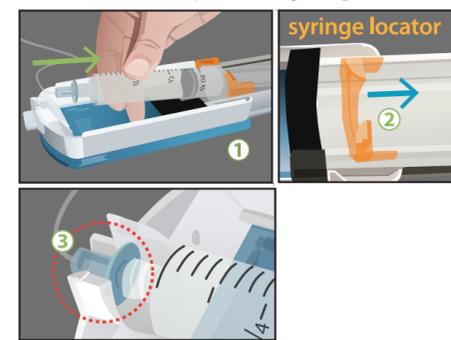
### Load Syringe Driver:

#### 11 Open Syringe Driver



To open the FreedomEdge<sup>®</sup>, 1. confirm that it is fully extended. 2. Then, open fully by lifting top cover.

#### 12 Load Prepared Syringe

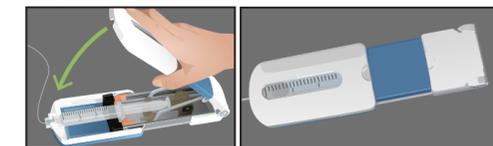


1. With syringe gradations facing up, push the syringe against the syringe locator.
2. Seat the syringe flange into the syringe locator.
3. Verify that the Precision tubing (with the luer disc) is connected to syringe. Seat the luer disc inside the syringe driver nose so that the syringe is firmly attached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

### Starting Infusion:

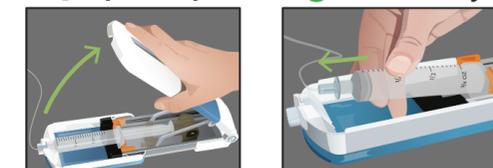
#### 13 Close Syringe Driver



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.

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

#### 14 Open Top Lid 15 Remove Syringe



Turn the FreedomEdge<sup>®</sup> OFF by opening the top lid.

Remove the empty syringe.

#### 16 Remove needles, discard sharps



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.

## Minimizing Site Reactions

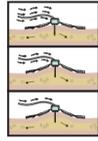
**NOTE:** Site reactions in new patients usually diminish over time as sub-q depots become more developed.

- Consider trying a longer needle
- Be sure needle is dry upon insertion
- Inquire about adding infusion sites
- Be aware of dressing/tape sensitivities
- Ask about trying a slower flow rate tubing



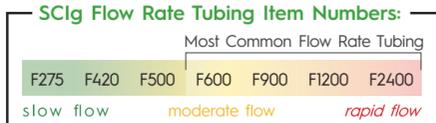
## A Balanced Infusion Through DynEQ®

Did you know the FreedomEdge® is designed to slow down the infusion based on how well the patient's body absorbs medication? This benefit, known as DynEQ (Dynamic equilibrium), responds to infusion site pressure build-up to deliver a safe pressure throughout the infusion.



## Precision Tubing

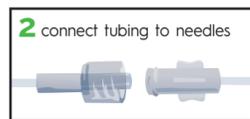
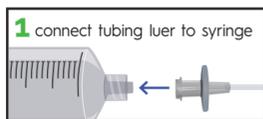
Precision Flow Rate Tubing™ controls your flow rate and infusion time. Each tubing set provides a different level of flow restriction. This, plus the viscosity of the drug, provides a precise delivery for predictable and consistent infusions.



We offer over twenty variations of Precision tubing, so that you can get the infusion rate you need. Ask your provider to help determine which flow rate tubing is best for you.

## Don't forget your Precision!

**Do not connect your HgH-Flo safety needle set directly to the syringe without a Precision flow rate tubing set attached.**



## FreedomEdge Q & A

### Q. Is my FreedomEdge® working? How can I tell if I am infusing?

**A.** Write down the time the infusion started and verify that you are using the correct control rate tubing and syringe recommended by your healthcare provider. Then, watch that the syringe plunger moves in accordance with your infusion time. If you expect dose to take 1 hour, then after 15 minutes, 1/4 of your dose should be complete. If there is any doubt, please ask your healthcare provider.

### Q. How can I find my best infusion sites?

**A.** Simply time your infusions! Note how long the first half of your dose takes, and then the second half. Compare both times. If the second half takes longer, you may be able to find sites that accept the drug more easily. If the two times are almost equal, it means your sites are accepting the drug well, and the site pressure is not increasing over the duration of your infusion.



### Q. What if I want to administer a smaller or larger amount of fluid?

**A.** For smaller volumes, the system will automatically adjust to whatever amount is contained in the syringe. If a dose is larger than 30 ml, you can load an additional syringe using the same tubing and needle set. We also offer the FREEDOM60®, which has the same performance as FreedomEdge®, but for 50 ml syringes.

### Q. How do I clean the FreedomEdge®?

**A.** You can wipe the outside surface with warm water and detergent. Do not attempt cleaning any part of the device that is not easily accessible. Refer to the Instructions For Use for more information on how to clean the FreedomEdge®.

### Q. What if I want my infusion to go faster?

**A.** See the section above on the Precision Flow Rate Tubing™ choices available. Then talk with your provider to see if a change is appropriate.

### Q. Can the FreedomEdge® be used at high altitudes, such as in aircraft?

**A.** Yes. It can be used in any position, at any altitude.

### Q. Can the FreedomEdge® be used for applications other than SClg?

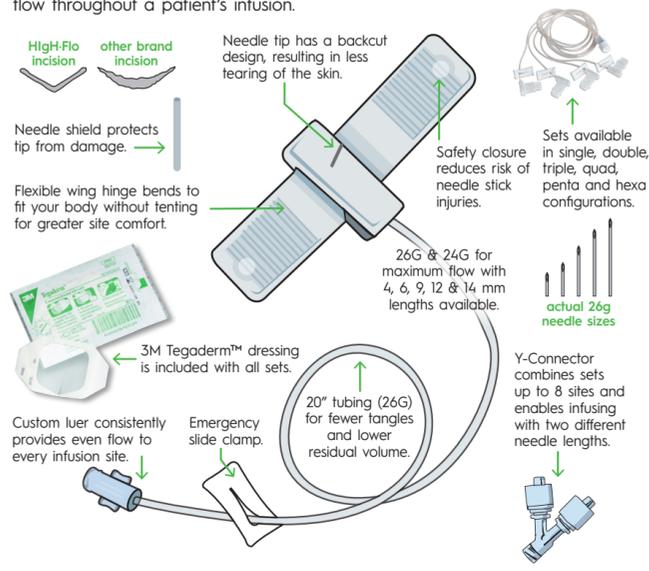
**A.** Yes. The FreedomEdge® can be used to administer most intravenous and subcutaneous medication that will fit in a 20 ml or 30 ml syringe.

### Q. Does the FreedomEdge® need maintenance?

**A.** The pump's design is made to withstand day-to-day home use without any scheduled maintenance. In addition, there are no user serviceable parts inside. You should never attempt to open the syringe driver. If you experience a problem with your pump, talk to your provider about a possible replacement.

## HgH-Flo Needles

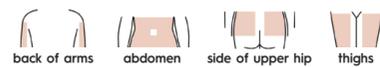
Specifically made for subcutaneous administration, HgH-Flo Subcutaneous Safety Needle Sets™ are designed for greater comfort and dependable flow throughout a patient's infusion.



HgH-Flo needles provide dependable, equalized flow through every needle, helping to fill your infusion site(s) at the same rate - reducing pain, swelling and oozing.

### Sub-q injection sites

The abdomen is the most common place to infuse, but ask your provider about your best site options.



Some medications require that sites be at least 2 inches apart - check your package insert. Needles should be dry and inserted at a 90° angle.

Talk to your healthcare provider about if and how to rotate infusion sites to find your best results.

## Troubleshooting

**NOTE:** For complete instructions, please refer to Instructions For Use included with your FreedomEdge®.

### Swelling, pain or redness at the site

According to continuing research, needles may play a significant role in adverse site reactions. Among the many factors which may contribute to infusion site reactions are: the quality of needles being used; needle tip design; sharpness; length; number of sites; flow rate; and, dressing/covering.

- 1) Verify that you are using HgH-Flo needles. If not, consult your provider to request them. For best results, use ONLY KORU Freedom accessories.
- 2) Be sure to insert your subcutaneous needles dry. IgG can irritate the skin.
- 3) Assure that the needles you are using are long enough to reach your sub-q layers.
- 4) Ask your provider about trying a slower rate tubing set, especially for your first few infusions.
- 5) If you have been having difficulty with rotating sites, you may want to return to the sites that work best for you. Talk to your provider about options.

### No flow

- 1) Make sure all slide clamps are unclamped. **Note:** if a slide clamp has been overused, or left clamped for an extended time, it can damage the tubing.
- 2) Use sterile procedures to disconnect the tubing set from the needle set and check for medication drip. If medication drips from the tubing, it may be a problem with the needle set. If the medication does not drip, replace the tubing as it may be damaged.
- 3) With the FreedomEdge® empty, open and close the lid, watching that the syringe pusher slides freely and does not bind.

### Slow flow

- 1) Confirm you are using the correct size syringe. 30 ml syringes flow approximately 20% slower than 20 ml syringes on the same Precision flow rate tubing.
- 2) Administration may be slow, based on how well medication is absorbed through your tissue. If this is your first time with sub-q, it may take longer than expected because your body may need to create space in the subcutaneous layers in order to infuse in the time desired.
- 3) Avoid placing needles near areas of scar tissue or on top of muscle.
- 4) It is possible you may need more sites, longer needles or a faster flow rate tubing set.
- 5) Slow flow can also be a symptom of blocked or poor quality needles. If you are not using HgH-Flo Subcutaneous Safety Needle Sets™, talk to your healthcare provider about trying them.

## Precision Tubing Q & A

### Q. What makes Precision tubing so special?

**A.** Precision Flow Rate Tubing™ is made in the USA. Our manufacturing expertise, mastered through years of experience, ensures accurate and dependable infusions when used with Freedom syringe drivers, maximizing the benefits Dynamic Equilibrium.



### Q. What affects the flow rate of the KORU Freedom?

**A.** The two main factors are the diameter of the tubing and the viscosity of the fluid. Immunoglobulin, for example, will flow much slower than an antibiotic. Since temperature also affects the viscosity of fluid, when temperature is cold, the flow slows down; when temperature is warm, the flow rate increases.

### Q. Why can't I connect the needle set directly to the syringe?

**A.** You need a restrictive tubing with a disc luer. This ensures that your infusion is delivered at a controlled rate, and that the syringe stays properly seated in the driver.

### Q. What is the temperature range that I can infuse in?

**A.** For accuracy and safety, most medications must be delivered at room temperature, but make sure to check the drug's package insert.

## HgH-Flo Needles Q & A

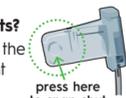
### Q. Why are they called "HgH-Flo"?

**A.** Made for sub-q, 26 and 24 gauge HgH-Flo (high performance flow) sets offer faster infusion rates than typical 27 gauge needle sets.

**NOTE:** If you are transitioning from 27 gauge, your provider might give you a different F-numbered Precision tubing set to keep your infusion time similar.

### Q. Why are they called HgH-Flo "safety" needle sets?

**A.** The butterfly wings 'snap shut' at the ends, to cover the needle after use. This feature is designed to help prevent accidental needle-stick injuries.



### Q. How can the smaller 26 gauge HgH-Flo sets flow at the same rate as other brand sets using larger 24 gauge needles?

**A.** HgH-Flo needle sets are carefully designed to optimize fluid flow for the most efficient handling of drugs. This efficiency translates into higher flowrates from smaller diameter needles.

### Q. I have heard HgH-Flo can improve how my sites fill. How so?

**A.** HgH-Flo needles are carefully designed and thoroughly tested to ensure equal flow to every needle. To our knowledge, no other manufacturer goes through these steps. Variations in flow rate may be due to: the quality of other sets, placement of the needle (e.g., in scar tissue, or over muscle), needle length or new site location.

### Q. When would I use HgH-Flo 24 gauge needles vs. HgH-Flo 26 gauge?

**A.** 26 G would be sufficient to administer 20% solution (Cuvitru® and Hizentra®), delivered between 20-25ml/h per site. In order to achieve faster flow rates, the 24 G needle would be required. Always refer to the drug manufacturer's package insert.

### Q. What is the least painful way to insert HgH-Flo needles?

**A.** Many patients tell us that they grab the wings above the needle, tightly pinch the skin at the site close together between their fingers, and insert the needle straight into the pinched area with a dart-like motion. You may notice that the HgH-Flo butterfly wings are very flexible, making this procedure easy. Each site should be about 2" apart and needles should be inserted at a 90° angle. Make sure any alcohol has evaporated off your sites, and insert all needles dry. You can also talk to your provider about premedication.

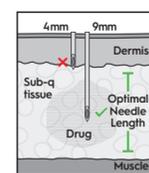
### Q. I heard I should insert the needles dry. What is the reason for this?

**A.** Patients have found that inserting needles wet with drug can be irritating to the skin, so inserting dry allows the needles to penetrate into the subcutaneous layer without impacting the mast cells. This may result in less pain. **If any medication ends up on the needle tip, do not touch the needle. Allow the needle to dry for a few minutes before insertion.**



### Q. How do I know if I am using the correct length needle?

**A.** Needle length should be determined according to how much sub-q tissue a patient has. 9 mm and 12 mm needles tend to work well with average sized patients; while 6 mm needles may be needed for very thin adults and children. Similarly, larger patients may require 14 mm needles.



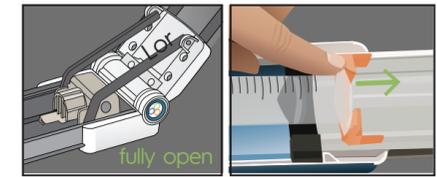
## Cannot stop flow

- 1) The best way to immediately stop flow is to fully open lid of the syringe driver.
- 2) We recommend using the tubing set slide clamp only in case of an emergency.

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

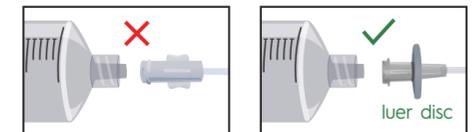
You will never need to use force to load or remove a syringe.

- 1) Make sure the top lid is fully open.
- 2) If you still have difficulty, use one hand to slide back the syringe locator.

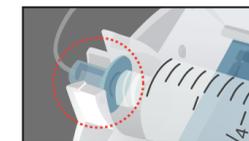


## Syringe is not properly seated in the driver nose

- 1) Make sure you have not attached the HgH-Flo needle set directly to the syringe.



- 2) Be sure you are using a Precision tubing set (with the luer disc).
- 3) Make sure that the luer disc at the end of the tubing is properly seated in the nose of the FreedomEdge®.



## Q. When using more than one needle, do I need to do anything special to be sure the drug is evenly distributed?

**A.** No special actions are necessary. Equal flow to each site reduces the risk that one site will over-fill. Dynamic Equilibrium automatically slows down the infusion to any site if pressure increases - to help prevent pain, swelling, and oozing. Sites that regularly fill more than others may be an indication that those subcutaneous layers have more space, or that different locations require different length needles.

## Q. Is there a best way to remove the needles and dispose of them when I am done with an infusion?

**A.** If you are unsure of how to handle used needles, ask your healthcare provider to demonstrate. HgH-Flo has built-in safety. Just 'snap shut' by pressing the wings together at ends to entrap the needle and then dispose of the set. Needle sets should be disposed of in a standard sharps container.

## Q. Can HgH-Flo needles be used with other syringe infusion devices besides the FreedomEdge?

**A.** Yes. Our needles are compatible with other syringe drivers, including KORU's FreedomEdge®. However, only the Freedom Systems, which include a Freedom syringe driver, Precision tubing and HgH-Flo needle sets, are cleared as an Integrated Infusion System and offer DynEQ™ (Dynamic Equilibrium), which automatically adjusts the flow rate if the tissues at the infusion site become saturated. Constant flow (electronic devices) and variable pressure (spring devices) cannot do this which may result in painful, adverse site effects.

## Q. Where can I get the FreedomEdge®, Precision tubing and HgH-Flo needles? What if I have more questions?

**A.** Ask your healthcare provider. Feel free to contact us for more information at 1-845-469-2042 or info@korumedical.com.

Also, feel free to ask about the Freedom60® Syringe Infusion System, for larger 50ml syringe infusions.

FreedomEdge SClg Training Video:  
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