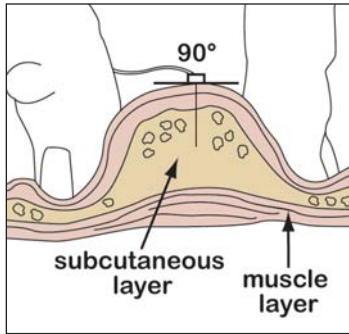


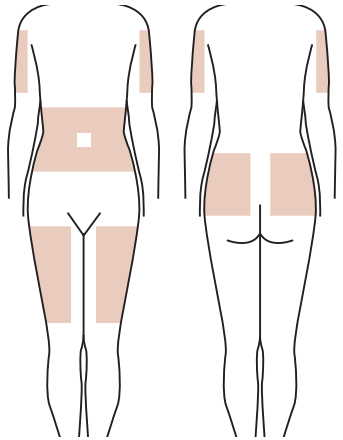
What is SCIg?

SCIg is a method for administering immunoglobulin through a small needle to the subcutaneous (sub-q) tissue, or fatty tissue just under the skin.



Patients that have received SCIg have experienced reduced adverse reactions that tend to occur during IVIg (intravenous delivery) including severe headache, nausea and vomiting. Because there is little blood flow to the sub-q layers medication is absorbed much slower eliminating large swings in IgG levels and decreasing side effects. This therapy is also an option for patients who may have poor venous access.

SCIg Injection Sites



Subcutaneous injections can be given in the arms, legs, or abdomen. Your home care provider or doctor will help you select the best sites to administer your medication.

Although the package insert recommends rotating sites in order to keep the skin healthy, some patients report

better results by returning to sites that have worked well for them in the past. Discuss trying both ways with your home care provider to see what works best for you. Sometimes repeated injections in the same spot can cause scarring and hardening of the fatty tissue that will interfere with absorption of medication. Remember each injection should be about 1" apart and needles should be inserted through pinched skin at a 90° angle.

Your home care provider is:

Contact Name _____

Contact Number _____

Drug _____

Dose (ml's) _____

Frequency _____

Number of Sites _____

Site Location _____

Freedom60 Tubing Set _____

SCIg Needle Set _____

The information and suggestions contained herein is supplemental and limited, and as such is provided only for your convenience to assist you in the use of the Freedom60 for use with IgG. Always consult your physician and/or your home care provider for any medical advice, current approved protocols and refer to the package insert that comes with your drug. This brochure should not be used to make any medical decisions or to supercede instructions from your medical professionals.

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Subcutaneous Immunoglobulin (SCIg)

Patient Information



FREEDOM60[®]
Syringe Infusion System

www.freedom60.com

737050 Rev B

With the Freedom60, your home care provider had your safety and comfort in mind, providing you with the most advanced and safest infusion system available for subcutaneous immunoglobulin (SCIg). Quality of infusion and unsurpassed safety make this pump ideal for any patient ages newborn to 99. It is also the only infusion pump reimbursed by Medicare for this application.



What is the Freedom60?

The Freedom60 is a completely portable syringe infusion system to give you the “freedom” to infuse anywhere - at home, while asleep, or on the go. It operates at a constant safe pressure and a wide variety of tubing sets are available to control the flow rate.

Your home care provider and physician have already determined how long your administration should take, and have provided you with a Freedom60 rate controlled tubing set best suited for your individual needs. If you find that this administration time is not ideal for you, and you wish to make a change, ask your provider about the different rate controlled tubing sets that are available.

Although you have been provided the Freedom60 for SCIg, it is also used to deliver other medications such as antibiotics, desferal, chemotherapeutics, pain management and cardiac medications.

Features & Benefits

- Easy to use - just 2 controls!
- Portable - gives you the freedom to live a normal life
- No batteries or electricity required
- Maximum safety
- Controlled pressure minimizes pain and complications
- Automatically adjusts to your tissue absorption
- Luer disc prevents contamination and overdose
- Slide clamp stops flow immediately
- Long life - tested for 4,000 infusions
- Reimbursed by Medicare (code E0779)

Freedom60 & SCIg

The Freedom60 is considered the pump of choice for SCIg because it is designed not only to maintain a constant safe pressure during your infusion, but it holds that pressure even after the infusion has completed to prevent drug backflow. It also adjusts to your particular tissue absorption by automatically slowing down to minimizing any pain or discomfort you might otherwise experience.

FREEDOM60[®]

Syringe Infusion System

Below is the typical list of supplies you should receive from your home care provider upon starting SCIg with the Freedom60.



1. Freedom60 pump
2. 60ml syringe
3. Freedom60 rate controlled tubing set
4. Subcutaneous needle set
5. Freedom60 travel pouch
6. Magnetic briefing card
7. User manual

SCIg Administration Instructions

Step 1



Wash your hands thoroughly and put on disposable gloves.

Step 2



Clean your work area with alcohol or disinfectant soap and water.

Step 3



Assemble your supplies.

Step 4



Fill the 60ml syringe with your required dose. (If your dose is refrigerated, be sure it is at room temperature before you begin.)

Step 5



Push on the syringe plunger to remove all air from the syringe.

Step 6



Verify that you are using the correct tubing recommended by your home care provider and prescribed by your doctor. (The ml/hr stated on some packages is not for use with SCIg.)

Be sure to use the complete protocol supplied by your home care provider.

Step 7



Remove the sterile cap from the luer disc end of the rate controlled tubing and connect the tubing to the syringe.

Step 8



Remove the sterile cap from the end of the sub-q needle set and attach it to the male end of the rate controlled tubing.

Step 9



Make sure the pump is off and the black tab inside the clear view syringe shield is at the end of its track. If the black tab is not at the end of its track wind the large knob clockwise.

Step 10



With syringe gradations facing up, load the syringe and its tubing into the pump. (Make sure the luer disc is fully seated in the pumps nose.)

Step 11



Turn the pump on to prime the tubing but do not let drug drip out of the needles. To minimize site pain reactions, it is recommended to insert the needles dry. To stop flow



to the needles, turn the pump off and wind the large knob clockwise until the black tab is at the end of its track. This will release pressure on the plunger.

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

Step 12



Select your sites and cleanse with alcohol. Once dry, pinch the skin and insert each needle subcutaneously. Secure with adhesive dressing.

Step 13



Remove the syringe from the pump.

Step 14



With the syringe out of the pump, check for blood backflow by gently pulling back on the plunger. Make sure no red or pink exists in the tubing. If blood backflow does exist, clamp the flow to that



site and call your home care 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 8.

Step 15



Insert the syringe back into the pump and turn the pump on to begin the infusion.

Step 16



Once the infusion is complete turn the pump off, remove all needles, and wind the large knob until the black tab is at the end of its track. Remove the syringe. Cleanse each site and cover with a Band Aid.

Swelling, pain or redness at the site

To reduce pain or redness at the site: 1) Be sure to insert your subcutaneous needles dry. IgG tends to irritate the skin. 2) Assure that the needles you are using are long enough to reach your sub-q layers. 3) Talk to your home care provider about trying a slower rate tubing set as your flow rate may be too fast. 4) Think about site location. If you have been rotating your sites and have found locations that do not cause you pain, it may be preferable to return to the sites that work best for you.

No flow

1) Assure that the pump is in the on position. 2) Make sure the slide clamp is unclamped, or has not been used for an extensive period of time. (Sometimes if the slide clamp is overused it can damage the tubing.) If neither of the above, test the tubing. Use sterile procedures to disconnect the tubing from the needle set and check for medication drip. If medication drips from the tubing its

most likely a problem with the needle set. If the medication does not drip, replace the tubing as it may be damaged.

Slow flow

Administration may be slow based on how well your tissue absorbs the medication. If this is your first time with SCIG it may take longer than expected because your body may need to create space in the subcutaneous layers in order to absorb in the time desired. If you believe the rate is too slow, you should check the needle sites. It is best to avoid areas of scar tissue, or on top of muscle. It is also possible you may need more sites, longer needles or a faster flow rate tubing set.

Continuous flow even when the pump is turned off

This is a normal function of the pump. The pump is designed to maintain pressure during and after the infusion to prevent blood/drug backflow. To stop the flow: 1) Turn the pump off and wind the large knob clockwise so the black tab moves away from the syringe releasing pressure on

the plunger OR 2) Use the slide clamp. (We recommend only using the slide clamp in the case of an emergency. Overuse can damage the tubing.)

Syringe will not load or remove from pump

Remember, you will never need to use force to load or remove a syringe. Make sure the pump is in the off position and that the black tab is at the end of its track. If the black tab is not at the end of its track, wind the large knob all the way back and try again.

Syringe will not stay inside in the pump

1) Make sure you are using Freedom60 rate controlled tubing with the luer disc. 2) Make sure that the luer disc end of the tubing has been connected to a 60ml syringe and that it is seated properly in the nose of the pump. 3) Make sure you have not attached the syringe directly to the sub-q needle set.

How can I tell if the Freedom60 is working and that I am receiving my infusion?

Monitor use by taking note of the time the infusion started and verifying that you are using the correct rate controlled tubing recommended by your home care provider and prescribed by your doctor. Then, be sure that the syringe plunger moves in accordance to your infusion time.

What is the noise the pump creates noise when I first turn it on?

That is the black tab looking for the syringe. The pump is designed to search for the syringe, which could be filled anywhere from 60ml's down to 1ml. Once the black tab finds the syringe it makes a clicking sound and is then totally silent for the entire administration.

What if I want to administer a larger or smaller amount of fluid than 60ml?

If a dose is larger than 60ml, you can load an additional syringe using the same tubing and needle set. For

smaller volumes, the Freedom60 will adjust to whatever amount is contained in the syringe.

What happens if I turn the large wind-up knob during an infusion?

Nothing. The wind-up knob is disengaged while the pump is in the on position. There is no effect whatsoever by turning the knob in either direction.

Can I over wind and damage the Freedom60?

No. The Freedom60 wind-up knob is much like the gas cap on your car. If for any reason the pump will not wind, make sure it is in the off position. If it is off and still does not wind, the pump may be damaged. Send it back for repair.

How do I clean the Freedom60?

Any surface disinfectant can be used to clean the Freedom60, such as household bleach or hydrogen peroxide. Avoid the use of alcohol or alcohol containing compounds, as these tend to make ABS plastic somewhat brittle. To clean the syringe shield use a bottlebrush if absolutely

necessary. Make sure no fluid enters the inside of the pump. This will damage the pump. See user manual for more information.

How long will the Freedom60 last?

If used in accordance with recommended procedures, the Freedom60 will provide you with many years of trouble free service.

Can the Freedom60 be used at high altitudes, such as in aircraft?

Yes. It is not sensitive to ambient pressures and can be used in any position.

Can the Freedom60 be used for applications other than SCIG?

Yes. With flow rates from 0.5 to 1200ml/hr, the Freedom60 can be used to safely administer everything from antibiotics to epidural pain control. Other uses include percantine, use with MRI, desferal and just about anything that fit comfortably in a 60ml syringe.