EMED

The Power Of Creative Thinking

Clinical Product Overview

www.emedtc.com

916.932.0071

1262 Haw ks Flight Court, Suite 200
El Dorado Hills, CA 95762

SCIg60® Infusion System

Soft-Glide® Safety SCIg Needle Sets

- Needle Lengths: 4, 6,9,12 and 14mm
- Optimized and coated needle bevel design reduces tissue damage and requires minimal insertion force.
- Proprietary ultra-flexible polyethylene tubing minimizing interaction with drugs and biologics.

VersaRate® and VersaRate® PLUS Variable Rate Control

- Intended to help offset the variations inherent to patient, setup and environmental conditions by allowing adjustment of flow rate through its dial to meet specific infusion requirements.

Infuset® Family of Fixed Rate Control

- Compatible with various mechanical infusion devices in the market.

SCIg60® Mechanical Syringe Infuser

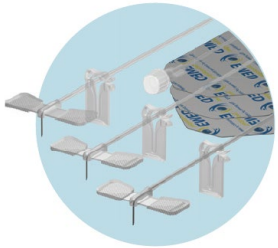
- Reusable, constant pressure, mechanical, non-electronic ambulatory infusion pump

Patents issued and other patents pending

SCIg60® Infuser

The SCIg60® Infuser is a reusable constant pressure, mechanical, non-electronic ambulatory infusion pump intended for use in the home or hospital environment. The SCIg60® Infusion System is cleared by the FDA specifically for infusion of Immunoglobulin G (IgG) into subcutaneous tissue. In addition, the SCIg60® Infusion System is approved for reimbursement by the Centers for Medicare and Medicaid Services under code E0779 (USA) along with multiple reimbursement systems worldwide, and is offered with a warranty. The SCIg60® Infuser is designed to work with EMED's family of devices while providing:

- Control of infusion therapy without high costs
- Ease of use for clinicians and patients for home use
- Stability and consistent long-term performance
- Portable, lightweight and quiet
- Biocompatibility to ISO 10993-1
- Virtually no maintenance



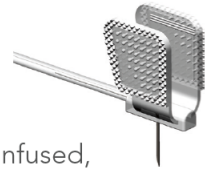
Soft-Glide® Subcutaneous Administration Sets

Soft-Glide® administration sets are a complete family of subcutaneous infusion sets with a proprietary design specifically for the subcutaneous administration of Immunoglobulin G (IgG). Working with leading clinicians in the field of immunology, EMED Soft-Glide® coating technology maximizes patient comfort throughout the infusion while providing:

Comfort

- EMED's Soft-Glide® administration sets with proprietary needle design and coating technology makes needle insertion virtually painless.
- Soft-Glide® SUB-Q sets assist patients to insert needles at the proper clinically preferred 90 degree insertion angle.
- Independent studies show that Soft-Glide® SUB-Q sets require the lowest needle penetration force when compared to other competitor needles.[1]

Safety

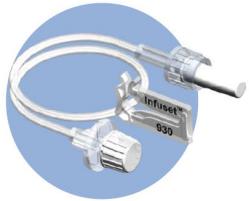


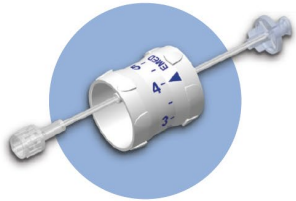
- EMED offers administration sets with features encapsulating the needle upon removal to provide safety at your fingertips, preventing the potential for injuries from needle sticks.

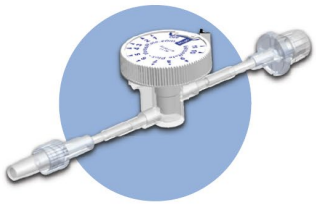
Priming Volume

- At EMED we realize that infusion drugs only add value when infused, so every drop counts. Soft-Glide® SUB-Q administration sets have been designed with this in mind to keep all priming volumes to a minimum.

1. Based on bench testing (MM-057)







Infuset Fixed Flow Rate Controller

Infusets are fixed flow rate control infusion sets developed to be compatible with various mechanical infusion devices in the market. Infusets are rated to operate within pressures of 1-30 PSI and ensure usability with a wide variety of therapies providing:

- Minimal priming volume
- Highly flexible tubing
- Accuracy levels above 90%
- Reduced waste of pharmaceutical fluid
- Simplified ambulatory use
- Flow rate data charts for specific applications

VersaRate® and VersaRate® Plus Adjustable Flow Rate Controllers

VersaRate® and VersaRate® Plus are adjustable flow rate control infusion sets designed to provide increased flexibility and comfort to optimize patients SCIg therapy. The devices are compatible with gravity infusion sets, mechanical and elastomeric infusion pumps. VersaRate® and VersaRate® Plus adjustable flow rate controllers offer the ability to dynamically choose an optimal flow rate (including low, medium and high flow rates) while providing:

- Easier priming with easier to rotate dial
- A range of adjustable flow rate position settings
- Flow stability in a given position setting
- Reduced waste of pharmaceutical fluid
- Off position to stop flow immediately
- Flow rate data charts for specific applications

Flow Rate Calculator

Our flow rate calculator provides ease of use for patients and clinicians. The flow rate calculator can be found at www.versarate.com. The website also features the ability for users to download the MS Excel version of the calculator directly at www.versarate.com/downloads after supplying their contact details. The flow rate calculator tools are based on bench test data and are user friendly while providing:

- Easy-to-use reference tool
- Runs directly in MS Excel, no installation needed
- Results summary in easy-to-print format
- Accurate flow rate estimates of drugs
- Clear warnings based on drug prescribing information

Factors that Affect Flow Rate

Factors That Affect Flow Rate:		
LARGE EFFECT	Ambient and Fluid Temperatures	Temperature of the fluid has a significant effect on drug viscosity, and therefore has a significant effect on flow rate. Ambient temperature may affect the fluid temperature given time to equilibrate. The system flow rate will change approximately 1 to 1.5% for each degree Fahrenheit temperature change of the fluid. Optimal operating temperate is between 20°C – 25°C (68°F – 77°F).
	Viscosity of Fluid	Differences in fluid viscosity significantly affect the system flow rate for a given system configuration. Various flow control accessories and SUB-Q set combinations are available to achieve flow rates according to specific clinical requirements.
MODERATE EFFECT	Administration Sets and Needle Gauge	The effect of the administration set and needle size depend on the dimensions of the fluid path. SCIg60 Infusion System is designed to work with a wide range of administration sets and needle gauges from 18 to 29G. Appropriate administration set and needle gauge should be selected for specific clinical requirements, then the appropriate flow controller should be selected to achieve the desired flow rate.
	Patient Factors	• Tissue back pressure • Tissue absorption rate • Body Mass Index • Age • Health
SMALL EFFECT	Infuser Relative Height	Difference in relative height between the infuser and the patient has a minimal effect on flow rate.
	Atmospheric Pressure	Difference in atmospheric pressure has minimal effect on flow rate.

Soft-Glide® / OPTflow® families

Soft-Glide® needle sets are a complete family of subcutaneous infusion sets with a proprietary design specifically for the subcutaneous administration of Immunoglobulin G (IgG).

OPTFlow® Subcutaneous Infusion Needle Set

EMED's Soft-Glide® technology has been incorporated in a family of subcutaneous needle sets branded under OPTFlow®.

Highest flow rate and lowest penetration force in the market

Patented easy-to-use wing closure

Self-aligning wings and inserter compatible

Designed to be best in class.

With comparable flow rates to EMED's SAF-Q® 24-gauge needles, OPTFlow® 26-gauge needle sets optimize patient comfort.

OPTFlow® needle sets have been engineered with a specific needle curvature designed to deliver maximum flow for optimal performance with a wide range of fluid viscosities while incorporating the Soft-Glide® coating technology for lower penetration force[1].

1. Based on bench testing (MM-057)

AND YOU THOUGHT YOUR INFUSION COULDN'T GET ANY BETTER

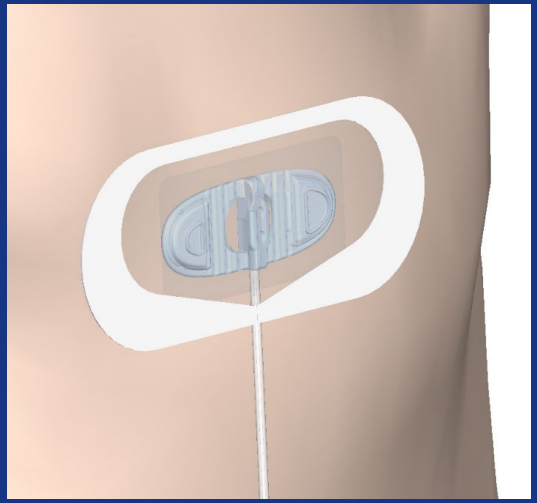
Included with the OPTFlow® needle sets is EMED's Soft-Site® Dressing featuring a non-adhesive window to cover the wings. This prevents the dressing from sticking to the wings upon removal and helps reduce adverse skin site reactions.

Soft-Site®

A new dressing especially designed for SCIg.

(Patent pending)

- Window without adhesive to avoid unwanted adhesion of wings
- Edges able to be lifted for ease of removal
- Hypoallergenic



OPTFlow Patient Experience

https://bit.ly/3J1zj86

OPTFlow® Soft-Site® Dressing Survey Results[1]

94% of users reported that the Soft-Site® dressing improves usability and patient comfort.

97% of users reported that the site dressing was easy to remove from the skin.

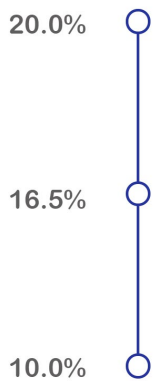
Over 90% of respondents recommended the Soft-Site® to maximize patient comfort.

1. Data based on internal customer survey from 2017

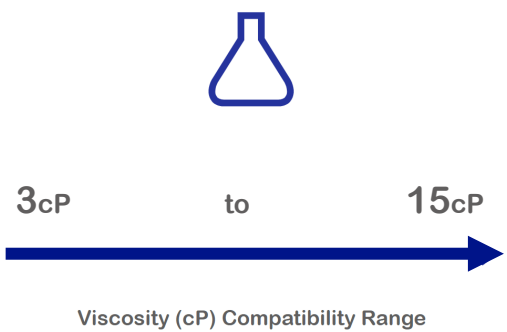
Designed for Higher Flow Rates

OPTFlow® and the SCIg60® Infusion Pump work with a variety of immunoglobulin concentrations and viscosities.

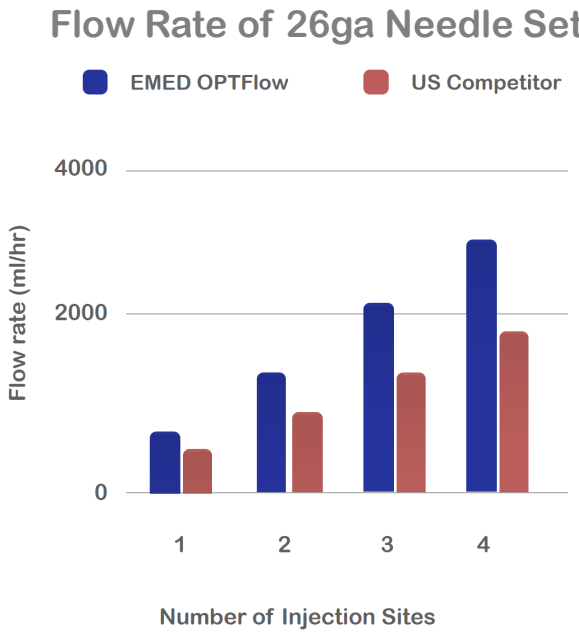
OPTFlow® Ig concentration range



OPTFlow® Ig viscosity range



Why high flow when you can OPTFlow®?



EMED OPTFlow® needle sets provide a solution for the increasing market demands of higher flow rates. OPTFlow® needle sets have higher maximum flow rates than subcutaneous device competitors.

1. Based on bench testing (MM-057)

Patented Wing Technology

OPTFlow®'s patented wing technology facilitates patient and clinician safety by securely enclosing the needle after use to maximize hygiene and reduce needle puncture risk. OPTFlow® wing technology also features a stabilizer lip, and grooves that contour to the patient and provide grip for easier insertion and removal.

Absorption & Tubing

Why PE lined tubing is important?

EMED devices are manufactured with superior polymers to minimize interaction with drugs and biologics. In practice, drug-plastic absorption can occur almost exclusively to polyvinyl chloride (PVC) material used by competition.

AccuSert®

PENDING FDA CLEARANCE

COMING SOON!!!!!!

EMED's AccuSert® Needle Insertion Device is pending FDA clearance.

(Patent pending)

Currently not available for distribution

Instruction for Use Document Reference

SCIg60® Infusion System support documents and frequently asked questions are located online:

https://www.emedtc.com/support

Soft-Glide® Safety SCIG Needle Sets

- SUB-Q/SAF-Q® Infusion Set: AS-0010003
- OPTFlow® SUB-Q Infusion Set: AS-0010281
- Needle-Free Injection Site Sub-Q Set: AS-0010011

VersaRate® and VersaRate® PLUS Variable Rate Control

- VersaRate® - Adjustable Flow Rate Infusion Set: AS-0010040
- VersaRate® Plus - Adjustable Flow Rate Infusion Set: AS-0010169

Infuset® Family of Fixed Rate Control

- Infuset® Flow Control Infusion Set: AS-0010041

SCIg60® Mechanical Syringe Infuser

- SCIg60® Infusion System User Manual: AS-0010021

SCIg60® Infusion System Overview

Reference EMED Document Number AS-0010021 for the complete user manual.

Prepare the Work Area

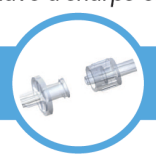
01. Wash and dry hands thoroughly before handling any supplies, and wear gloves if instructed by your healthcare professional.
02. Create a clean work area by wiping the entire surface of this mat with a small amount of disinfectant soap and water or alcohol.
03. Let the surface air-dry and clean your work area again if it becomes contaminated during use.

Gather Equipment

04. Refer to the steps in the instructions for use, user manuals and drug prescribing information to perform therapy treatment.
05. Make sure you have all the necessary supplies gathered in your work area prior to beginning. Generally, these supplies include:

1. SCIg60 Infuser
2. Prescribed Immune Globulin Medication
3. Needle or Spike
4. Alcohol Pads
5. BD Syringe (model no. 309653)
6. Patient Administration Set
7. Site Dressing
8. Preferred Flow Rate Control Infusion Set (Infuset, VersaRate® or VersaRate® Plus)

Have a sharps containter nearby for proper disposal.

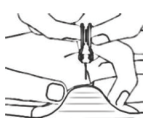


Prime and Prepare Needle Sets

06. Connect flow rate control infusion set to syringe and patient needle set.

07. Prime and close flow rate control set and patient needle set per healthcare provider instructions.

08. Refer to healthcare provider instructions to insert needle set to patient.



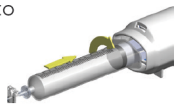
SCIg60® Infusion System Overview

Prepare Infusion Pump

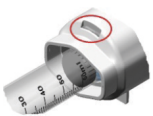
09. Open the SCIg60 Infuser by turning the handle counterclock-wise until it stops.

10. Ensure that the flow rate control infusion set is clamped for Infusets or is in the 'OFF' position for VersaRate® or VersaRate® Plus.

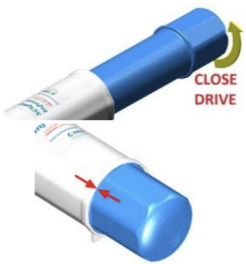
11. Load & lock the syringe into the SCIg60 Infuser by inserting the syringe plunger & rotating the syringe clockwise until it stops.



12. Verify the syringe flange is in the window of the SCIg60 Infuser to confirm the syringe is properly locked in place.



13. Close the SCIg60 Infuser by turning the handle clockwise until the base of the handle touches the body of the pump.



Infuse

14. Complete Infusion as instruced by your health care provider. Refer to the steps in the instructions for use, user manuals and drug prescribing infromation to perform therapy treatment.
15. Refer to flow rate calculators at www.versarate.com to estimate expected flow rates.

Completion

16. When infusions are complete, open the SCIg60 Infuser by rotating the handle counterclockwise until it stops, then unlock and remove the syringe by turning it counterclockwise and pulling it out. Dispose of needle set, syringes and flow rate control infusion set (Infuset, VersaRate® , or VersaRate® Plus) in appropriate waste or sharps containers.

Troubleshooting

Possible causes for the SCIg60® Infusion System to not perform properly are:

Problem	Possible Cause	Correction
Syringe not compatible	Use of non-recommended syringe model.	Use only recommended syringe model (BD 50 mL syringe model no. 309653).
Components will not connect	Incorrect assembly, incorrect components, or damage of components.	Verify the syringe is properly connected to the flow controller and that the flow controller is correctly connected to the SUB-Q set. Use only the recommended components with the SCIg60 Infuser.
Syringe disengages from the infuser when the inner drive is closed	Syringe was not properly loaded in the infuser.	Unscrew the inner drive and properly position the syringe following the instructions for use steps #9-13. Ensure handle is fully closed.
	Use of non-recommended syringe model.	Use only recommended syringe model.
Clicking sound	During infusion, the spring readjusts as it extends and may intermittently produce sound.	No correction necessary. This is normal and does not impact the function of the pump.
Fluid leak	Incorrect assembly or damage of components.	Verify Luer connectors are properly tightened. Do not overtighten as it may result in damage.

Troubleshooting

Problem	Possible Cause	Correction
NO fluid flow	Infuser drive is not completely closed.	Close inner drive by rotating the handle clockwise until the base of the handle touches the body of the pump. Refer to IFU step 13.
	Flow controller or administration set is in the OFF position or blocked by slide clamp.	For the Infuset, make sure that the slide clamp is not blocking the flow.
		For the VersaRate or VersaRate Plus, make sure that the dial is set to the intended position and not on the 'OFF' position.
		Verify that no other slide clamp is blocking the flow and that the tubing is not pinched or kinked.
	Occlusion of fluid path	Use new flow controller or administration set.
	VersaRate Plus at low position settings with viscous fluids and factors that affect flow rate.	When using the VersaRate Plus at the low position settings such as 1 to 3 with fluids having a viscosity greater than 8 cP, it is recommended to continually monitor the volume infused throughout the therapy and adjust the VersaRate Plus setting accordingly.
Flow rate is **HIGH**	Incorrect combination of SUB-Q set with flow controller or flow controller setting for the prescribed fluid.	Verify that the correct combination of SUB-Q set and Infuset or VersaRate position is being used. Consult the appropriate flow rate data sheet or calculator for expected flow rate.
		If using VersaRate or VersaRate Plus, turn the dial to a lower setting to reduce the flow rate.
	Patient or environmental factors	Refer to section *Factors that Affect Flow Rate*.

Troubleshooting

Problem	Possible Cause	Correction
Flow rate is **LOW**	Incorrect combination of SUB-Q set with flow controller or flow controller setting for the prescribed fluid.	Verify that the correct combination of SUB-Q set and Infuset or VersaRate position is being used. Consult the appropriate flow rate data sheet or calculator for expected flow rate.
		If using VersaRate or VersaRate Plus, turn the dial to a higher setting to increase the flow rate.
	Patient or environmental factors	Refer to section *Factors that Affect Flow Rate* and verify factors are within intended limits.
	Storage of the flow controller or SUB-Q set with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.	Do not store with slide clamp engaged for long periods of time.
	Partial occlusion of fluid path	Use new flow controller or administration set.
Flow does not **STOP**	Flow controller is not set to 'OFF' position or slide clamp is not clamped.	Verify that the slide clamp on the Infuset is fully closed or that the VersaRate is in the 'OFF' position.
		If the flow controller fails to stop the flow, turn the Drive Handle counterclockwise fully to stop fluid flow.

*The SCIg60® Infuser is a mechanical syringe pump with no electronic alarms, warnings or indications. As such it is recommended that the infusion be monitored and verified by reviewing the syringe volume during completion of the infusion.

*Flow rates can be affected by multiple factors such as ambient temperature, patient conditions, large height differences between the Infuser and infusion site, and variations in the immunoglobulin solution's viscosity.

Warnings and Precautions

Warnings:

- Use the SCIg60 Infusion System ONLY for its intended use and as prescribed by your healthcare professional.
- Read and follow all instructions for the SCIg60 Infusion System and applicable components prior to use.
- Healthcare professionals and users should read the indicated immunoglobulin fluid's contraindications, instructions, and warnings prior to initiating delivery of fluid.
- Do NOT use SCIg60 Infusion System while undergoing medical diagnostic procedures, such as MRI, X-ray, or CT scans.
- Use ONLY the listed administration sets, flow controllers and BD syringe (Model No. 309653) with the SCIg60 Infusion System. Use of other infusion accessories may result in unsafe conditions for patient or deviation from desired infusion rates.
- Do NOT store indicated immunoglobulin fluid in the syringe prior to use. Prepare the SCIg60 Infusion System and initiate therapy immediately after transferring indicated immunoglobulin fluids to the syringe.
- Use aseptic technique when handling fluid, syringe, flow controller, and subcutaneous administration set.
- Do NOT insert or remove the syringe until the DRIVE HANDLE is fully opened, as instructed in the Instructions for Use section.
- Do NOT use flow controller, administration set, or syringe components more than once, as reuse may result in infection, cross contamination, or altered flow rate performance. Do NOT attempt to re-sterilize components, doing so may cause serious personal injury.
- Do NOT open the Infuser or attempt to modify its function in any way other than its intended use.

Warnings and Precautions

Cautions:

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Place the SCIg60 Infusion pump on a flat surface or in the provided carrying case during use. Syringe damage and fluid loss may occur if the SCIg60 Infusion System is dropped while loaded.
- Do NOT continue to use an SCIg60 Infuser that has been damaged, dropped, or if it has failed to perform as expected. If any damage is suspected, contact EMED Technologies.
- Do NOT subject the Infuser to autoclaving or other similar methods of sterilization. Avoid exposing the SCIg60 pump or carrying case to temperatures outside of recommended range.
- Do NOT use multiple flow control accessories at one time (e.g., connecting one Infuset to another, connecting an Infuset to a VersaRate, etc.) because the flow rates provided in this manual are for a single Infuset or VersaRate only.

Maintenance and Storage

Maintenance

The infuser pump and carrying case are reusable parts of the infusion system and do not require any maintenance or calibration. Periodic cleaning of external surfaces is recommended.

Cleaning the infuser:

- External surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak solution of mild detergent and warm water (approximately 1 part detergent to 50 parts water by volume).
- Clean exterior surfaces by gently pressing onto the SCIg60 Infuser and using circular motions with the alcohol wipe or damp cloth.
- Use a clean, dry cloth to dry the exposed and external portions of the device.

CAUTION:	• Clean only those areas that are exposed when the Infuser Drive Handle is completely screwed in. Do not attempt to clean any part of the SCIg60 Infuser that is not easily accessible. • Discontinue use of an SCIg60 Infuser that has been internally exposed to or immersed in fluid. • Do not use heating devices to dry or expose infuser to high temperatures. Damage to the infuser may occur.

Cleaning the carrying case:

Only clean surface with a clean damp cloth and let it air dry.

CAUTION:	Do not machine wash the carrying case as it could damage the materials.

Storage

Store the pump and carrying case in a cool, dry place between the temperature range of -5°C to +40°C (+23°F to +104°F).

CAUTION:	Avoid exposing the SCIg60 pump or carrying case to temperatures outside of recommended range.

Patient Centric

Patients and clinicians have been and continue to be the core of EMED's focus. We're proud that our products are helping patients live better lives every day - and we're committed to ensuring that progress continues to be made to improve clinicians' jobs and patients' lives.

Improving the patient experience with innovative technologies

Why Convert Current Competitor Patients to EMED?

"VersaRate changed our infusion in a major positive way. Ethan was able to relax more as he no longer experienced stinging. Where usually he has anxiety, we saw him moving around and having fun even during the infusion. Something as small as a dial to have control of your body is a game changer. We have definitely found a new way of infusing that works better for him and our family."

- Mrs. Ayers, Ethan's mother

"I just finished my infusion and I have to say it felt like a whole different experience with the new needle set! I loved everything about it! The needles went in so much smoother (it didn't hurt as bad as it normally does)…It just felt like the medication went in smoother throughout the entire duration and taking the needles out didn't hurt at all! Normally it always hurts when I have to pull the needles out and the areas are tender. This was not the case at all this time!

– Mrs. Strnad, Patient

"I received the double needle set from EMED, and we did love it, especially with the rate control tubing. We've almost got Riley's infusions down to a science. It only took 2 years!! Joe and EMED have been amazing resources.

- Ms. Shanahan, Riley's mother

Why Convert Current Competitor Patients to EMED?

"When I first found out that I was going to have to give myself needles every week for the rest of my life, or else go to the hospital once a month for several hours for intravenous infusions, it seemed impossible.– I couldn't do it. And the needles hurt! With the EMED system, smaller needles are used and the pump does all the work. Even though I still don't like getting the needles, the pump makes it so much better. It is easy to use and seems to be fail proof. Everyone should have one."

- Ms. Cook, Patient

"I use the EMED needle sets with the Versarate regulator that I absolutely LOVE! Not only does it make priming my tubing a breeze. The needles are thin and so much easier to insert and remove than other brand sets I have used. But the most important thing about EMED in my opinion, is how you truly care for patients!"

– Ms. Haymans, Patient

"….these needles helped me! After using them I don't ever want to use the old ones again! I'm sure many others would feel the same!

- SCIG Patient

Contact Us

Joe Barbrie, VP of Sales and Marketing
jbarbrie@emedtc.com

Anne Cook, Product Manager | Sales and Operations Support
acook@emedtc.com

Phone: +1-916-932-0071
Website: www.emedtc.com

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