SCIg60
Infusion System

EMED Technologies
The power of creative thinking

The Power of
CREATIVE THINKING

Contents

United States
User Manual
(Subcutaneous Infusion of Hizentra)

Introduction

The EMED SCIg60 Infusion system provides users with a portable way to subcutaneously infuse Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid. The SCIg60 Infuser is a reusable mechanical device and does not require batteries or any electrical source. The system utilizes a spring as a source of pressure that optimizes and controls the continuous delivery of Hizentra at desired flow rates using Infuset™ flow control infusion sets.

Indications

The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).

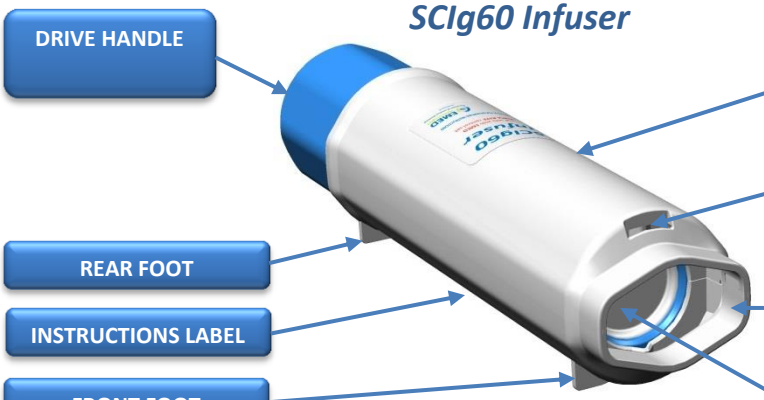
SCIg60 Infusion System Product Line

- SCIg60 Infuser
- User Manual
- Carrying Case
- Infuset Flow Control Infusion Sets (sold separately)

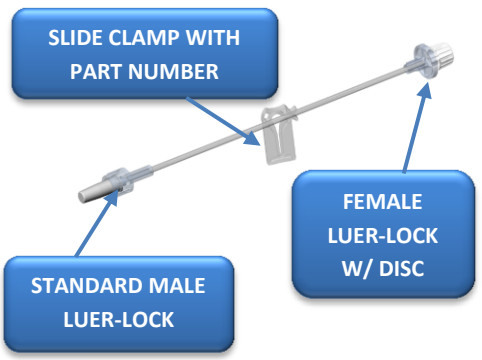
NOTE: EMED subcutaneous infusion administration sets and BD 60 ml syringes (model no. 309653) are not provided and may be purchased sold separately.

Getting to know your SCIg60 Infusion System

SCIg60 Infuser

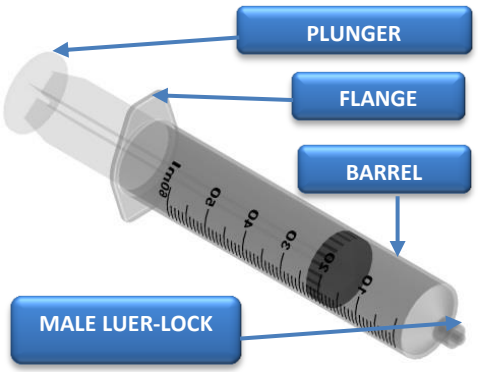


Infuset

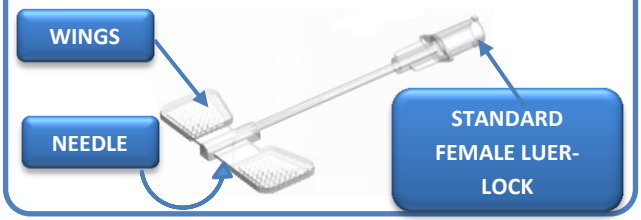


BD 60 ml syringe

(model no. 309653)



SUB-Q Set



Complete SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Available Infuset Flow Control Infusion Sets

Description	Reorder Number
Infuset-190	FP-0010008
Infuset-290	FP-0010007
Infuset-430	FP-0010010
Infuset-650	FP-0010009
Infuset-820	FP-0010006
Infuset-930	FP-0010005
Infuset-1850	FP-0010004

NOTE: Please review *SCIg60 Infusion System Setup for Hizentra Infusion Rates* section to determine which administration set is most appropriate for specific therapeutic needs and/or patient preferences.

Contraindications

Do not continue to use a SCIg60 Infuser that has been damaged, dropped, or if it has failed to perform as expected. If the infuser is dropped or damaged either in transit to you or during preparation for its use, or if any other damage is suspected, contact EMED Technologies.

Do not subject the Infuser to autoclaving or other similar methods of sterilization.

Do not use SCIg60 Infusion System while undergoing medical diagnostic procedures, such as MRI, x-ray, or CT scans.

Administration of Hizentra is for subcutaneous infusion only and infusion into other infusion sites, including blood vessels, should not occur.

Use only the listed administration sets for administration Hizentra with the SCIg60 Infusion System to obtain specified flow rates. Use of other infusion accessories may result in flow rates outside of what has been approved for Hizentra.

Physicians and users should read the Hizentra contraindications and warnings prior to initiating delivery of Hizentra

Warnings

Do not insert or remove the BD 60 ml syringe (model no. 309653) until the INNER DRIVE is fully opened, as indicated in the IFU section, step 17.

Do not use Infusets or BD 60 ml syringes (model no. 309653) more than once, as reuse may result in infection, cross contamination, or altered flow rate performance.

Do not store Hizentra in the syringe prior to use. Prepare the SCIg60 Infusion System and initiate therapy immediately after transferring Hizentra to BD 60 ml syringes (model no. 309653).

Do not use multiple Infusets at one time because the flow rates provided in this Manual and the Infuset IFU are for a single Infuset only.

Do not open the infuser or attempt to modify its function in any way other than its intended use.

DO NOT use any syringe other than the BD 60 ml (model no. 309653) syringe. Doing so may result in unsafe conditions for patient or deviation from desired infusion rates.

Do not re-sterilize Infuset flow control infusion sets, doing so may cause serious health effects to patient.

Important Information

Read all instructions for the SCIg60 Infusion System.

Read all instructions for the Infuset flow control infusion set and specified administration set.

Use the SCIg60 Infusion System as prescribed by your healthcare provider and follow all the directions as prescribed.

Use aseptic technique when handling Infuset flow control infusion sets and specified subcutaneous administration set.

Place SCIg60 Infuser on a flat surface or in the provided carrying case during use.

BD 60 ml syringe (model no. 309653) damage and Hizentra loss could occur if system is dropped while loaded with syringe and Hizentra.

The SCIg60 Infusion System is intended for single patient use only.

Contact EMED if you have any questions regarding the use of the SCIg60 Infusion System.

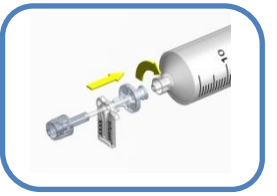
SCIg60 Infusion System Instructions for Use (IFU)

Note: Instructions for Use also appear on the underside of the Infuser

1. **WASH HANDS** thoroughly and dry hands before handling any supplies, and wear gloves if you have been instructed to do so.

2. **REMOVE** Infuset flow control infusion set, specified administration set and syringe from sterile packaging.

3. **TRANSFER** Hizentra from vial(s) to BD 60 ml syringe (model no. 309653) according to the Hizentra package insert or as instructed by your healthcare provider, and immediately proceed to next step.



4. **CONNECT** syringe male luer lock (MLL) to Infuset female luer lock (FLL).

5. **CONNECT** Infuset male luer lock (MLL) to specified patient administration set female luer lock (FLL).

6. **PRIME** the tubing by gently pushing on the syringe plunger to fill the tubing with Hizentra, or as instructed by your healthcare provider.

7. Use slide clamp provided with Infuset to prevent flow of Hizentra.

8. **PREPARE INJECTION SITES and INSERT NEEDLES** according to the Hizentra package insert, specified administration set instructions, or as instructed by your healthcare provider.

   NOTE: Before starting the infusion, attach a sterile syringe to the end of the primed administration tubing and gently pull back on the plunger to make sure no blood is flowing back into the tubing. If blood is present, remove and discard the needle and tubing.

9. **OPEN** SCIg60 Infuser drive by turning the handle **counterclockwise** until it stops.

Instructions for Use (IFU) – Continued

10. **LOAD** syringe into SCIg60 Infuser by inserting the syringe plunger into the SCIg60 infuser.

11. **LOCK** syringe into SCIg60 Infuser by turning the syringe 90° in either direction until you feel a click.

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

13. **CLOSE** SCIg60 Infuser drive by turning the handle clockwise until it stops.

    CAUTION: DO NOT ATTEMPT TO REMOVE THE BD 60 ml syringe (model no. 309653) BEFORE PERFORMING STEP 17.

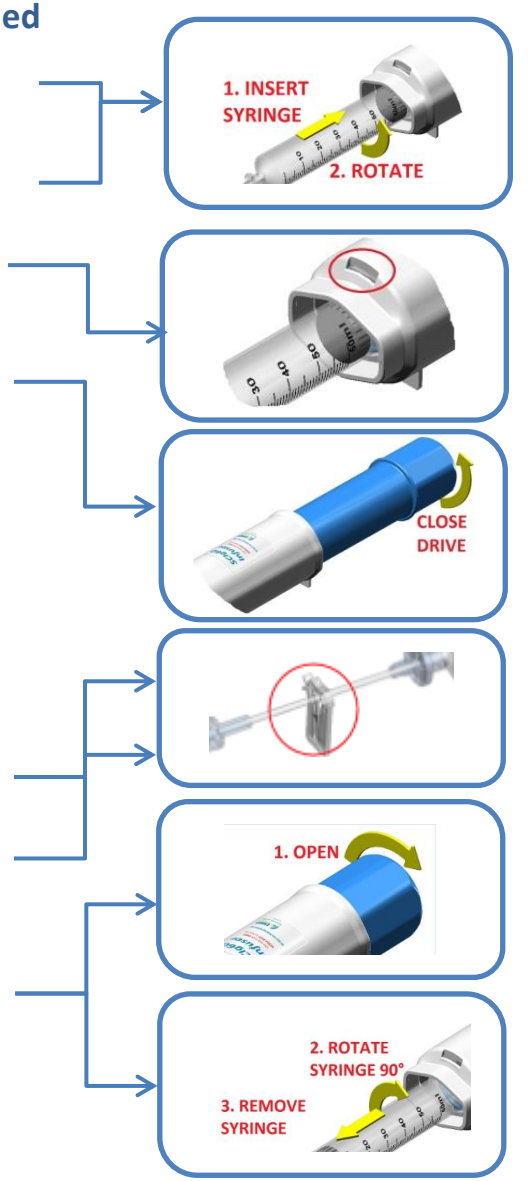
14. Place the SCIg60 Infuser, Infuset, and specified administration set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the SCIg60 Infuser Carrying Case Accessory* below for more details).

15. **USE SLIDE CLAMP** to start infusion once Infuser is fully loaded and needles are inserted and secured.

16. **USE SLIDE CLAMP** to stop flow as necessary during infusion session or when session is complete.

17. When session is complete, **REMOVE THE BD 60 ML SYRINGE (MODEL NO. 309653)** rotate the handle **counterclockwise** until it stops, then unlock the syringe by turning it 90° in either direction (refer to steps 9 - 11 above).

18. Dispose of THE BD 60 ML SYRINGE (MODEL NO. 309653) , Infuset, and SUB-Q set in an appropriate waste container



SCIg60 Infusion System Instructions for Use (IFU) – Continued

Using the SCIg60 Infuser Carrying Case

1. Open pouch and unfasten Velcro straps inside the pouch.
2. Insert SCIg60 Infuser with BD 60 ml syringe (model no. 309653) and Infuset into the pouch on top of Velcro straps.

   The Infuset should face away from the zipper pull, and exit the Carrying Case through the provided space below the zipper.
3. Fasten the Velcro straps around SCIg60 Infuser to secure it in place.
4. Close the case with the zipper - Use caution to prevent damage to the tubing.

SCIg60 Infusion System Setup for Hizentra Infusion Rates

EMED has conducted performance testing to ensure that the SCIg60 Infusion System provides Hizentra flow rates that fall within manufacturer's recommended dosage limits and accommodate each individual's needs for infusion comfort and convenience.

Use the tables below to identify the combination of the EMED SUB-Q set and the Infuset flow control set that will provide a Total Flow Rate that best meets therapeutic needs and/or patient preferences**.** The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits for a patient's **first infusion of Hizentra** and the second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

To choose a combination of Infuset and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the Infuset Reorder Number and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

First Infusion of Hizentra – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12	12	FP-0010008	SUB-109-G24 or SAF-Q-109-G24
	4	39	10	FP-0010009	SUB-409-G24
27	2	25	13	FP-0010005	SUB-260 or SAF-Q-209-G27
	4	49	12	FP-0010004	SUB-410 or SAF-Q-409-G27

Standard Infusions – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12	12	FP-0010008	SUB-109-G24 or SAF-Q-109-G24
		16	16	FP-0010007	SUB-109-G24
	2	26	13	FP-0010010	SUB-209-G24 or SAF-Q-209-G27
		35	18	FP-0010009	SUB-209-G24 or SAF-Q-409-G27
	3	39	13	FP-0010009	SUB-309-G24 or SAF-Q-309-G24
		51	17	FP-0010005	SUB-309-G24 or SAF-Q-309-G24
	4	39	10	FP-0010009	SUB-409-G24
		52	13	FP-0010005	SUB-409-G24
27	1	14	14	FP-0010009	SUB-109-G27 or SAF-Q-109-G27
		17	17	FP-0010004	SUB-109-G27 or SAF-Q-109-G27
	2	25	13	FP-0010005	SUB-260 or SAF-Q-209-G27
		30	15	FP-0010004	SUB-260 or SAF-Q-209-G27
	3	43	14	FP-0010004	SUB-320 or SAF-Q-309-G27
	4	49	12	FP-0010004	SUB-410 or SAF-Q-409-G27

SCIg60 Infusion System Setup for Hizentra Infusion Rates – Continued

The above Total Flow Rate values are based on bench testing of a single Infuset and EMED SUB-Q subcutaneous tissue infusion sets performed between 20°C - 25°C (68°F – 77°F). It is important to understand that flow rates of infused Hizentra can be affected by multiple factors such as ambient temperature, patient conditions, large height differences between the Infuser and infusion site, and variations in Hizentra viscosity.

Using a combination of Infuset and SUB-Q infusion set not found in the table above may result in a flow rate outside of what has been approved for Hizentra. Using more than one Infuset at a single time (i.e. connecting one Infuset to another) will impact resulting flow rates and is not recommended. Using other flow control accessories and/or subcutaneous tissue infusion sets may also result in a flow rate outside of what has been approved for Hizentra.

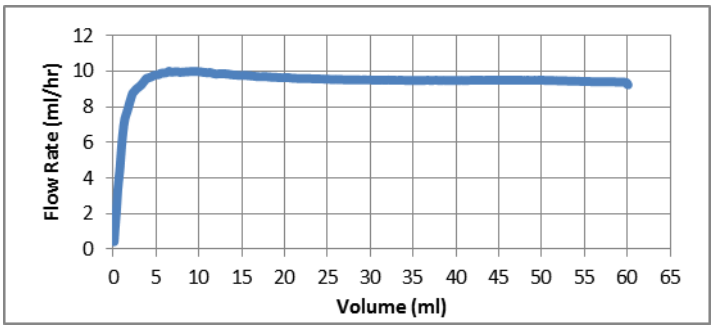
Please contact EMED Technologies at +1 (916) 932-0071 for additional information regarding selection of Infuset flow control infusion sets and SUB-Q sets to use to obtain a desired flow rate.

SCIg60 Infuser Technical Information

Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 g (14.5 oz)
Storage Temperature	-5°C to +40°C (23°F to 104°F)
Syringe Volume (BD 60 ml syringe (model no. 309653)	60 ml
Maximum Operating Pressure	16.8 psi
Average Operating Pressure	14.4 psi
Total System Accuracy (includes Infuset and SUB-Q set)	±15% from target flow rate
Vertical Sensitivity	
Each 30.5 cm (12 in.) above infusion site	+6% from target flow rate
Each 30.5 cm (12 in.) below infusion site	-4% from target flow rate
Maximum Vertical Difference	±61.0 cm (±24 in.)
Target Operating Temperature	20°C - 25°C (68°F – 77°F)
Infuset Residual Volume	
Infuset-190	≈ 0.14 ml
Infuset-290	≈ 0.16 ml
Infuset-430	≈ 0.13 ml
Infuset-650	≈ 0.12 ml
Infuset-820	≈ 0.11 ml
Infuset-930	≈ 0.13 ml
Infuset-1850	≈ 0.10 ml
Use-By Dating	5 years

Representative Hizentra Flow Rate Profile

Total Flow Rate vs Infused Volume at 20°C – 25°C under laboratory conditions
Achieved with SUB-320 and FP-001008



SCIg60 Infuser – Cleaning and Storage

- Outer surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak mixture 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.
- Clean only those areas that are exposed when the Infuser Inner Drive is completely screwed in. Do not attempt to clean any part of the SCIg60 Infuser that is not easily accessible.
- Discontinue use of a SCIg60 Infuser that has been internally exposed to or immersed in fluid.
- Use a dry cloth to dry the exposed and external portions of the device.
- Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.

SCIg60 Infuser Carrying Case – Cleaning and Storage

- Only clean surface with a clean damp cloth and let air dry.
- Do not machine wash the carrying case as it could damage the materials.
- Storage temperature: -5°C to +40°C (+23°F to +104°F).

Troubleshooting

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

- **SYRINGE POSITION**. Verify the syringe is properly positioned into the infuser as instructed in the IFU section; the syringe should be parallel to the infuser with the syringe flanges properly engaged and seen in the safety check window (shown in the diagram). If syringe 'pops out' of infuser when inner drive is closed/screwed in, it is an indication that the syringe was not properly positioned in the infuser. Unscrew the inner drive and properly position the syringe following the instructions for use.
  Use only the BD 60 ml syringe (model no. 309653).
- **TUBING CONNECTORS**. Verify the BD 60 ml syringe (model no. 309653) is properly connected to the Infuset and that the Infuset is correctly connected to the specified subcutaneous administration sets.
- **NO FLOW.** Check the slide clamp on the Infuset and make sure it is not blocking the flow. Verify that no other clamp is blocking the flow and that the Infuset or specified administration set is not kinked in any way.
- **FLOW RATE IS TOO HIGH**. Verify that the correct Infuset and SUB-Q set combination is being used.
- **FLOW RATE IS TOO SLOW**. Verify that the correct Infuset and SUB-Q set combination is being used, and that the Infuset or specified administration set is not kinked in any way.
  NOTE: Storage of the Infuset with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.
- **FLOW DOES NOT STOP**. Verify that the slide clamp on the Infuset is fully closed.
- **BROKEN PARTS**. Inspect infuser for any broken parts. If after following the instructions above the SCIg60 Infusion System does not appear to be working properly, or if you observe something unusual, discontinue use of the SCIg60 Infusion System and contact your healthcare provider or EMED Technologies Corporation.

If any of the above conditions persist or you feel the SCIg60 Infusion System is not performing as expected, please contact your healthcare provider or EMED Technologies Corporation.

Warranty

- **Parties Covered:** This warranty extends only to the Original Purchaser of the infusion infuser and it does not extend to subsequent purchasers or users. The "Original Purchaser" is the person purchasing the infusion infuser from the Manufacturer or Manufacturers Representative.

- **Limited Warranty**: EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects in materials and workmanship for three (3) years from the date of original purchase when used as intended and under the direction of authorized medical personnel. Failure to comply with these conditions will result in a void warranty.

  Use of accessories or components not specified in the SCIg60 Infusion System User Manual may impact Hizentra flow rates, result in a flow rate outside of what has been approved for Hizentra, and is not recommended. The Manufacturer does not represent that the SCIg60 Infusion System will operate in accordance with performance specifications if third party accessories are used.

- **Replacement**: 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 SCIg60 Infuser, or part thereof, which has been actually received by the Manufacturer or Manufacturers Representative within the three 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 three year warranty period.

- **Disposable items**: In the event that an EMED-branded disposable item is found defective, it will be replaced with a new disposable item by the Manufacture.

Contact Information

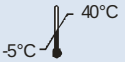
EMED Technologies
U.S.A. Headquarters
1264 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762
Tel. +1 (916) 932-0071
Fax: +1 (916) 932-0074
customerservice@emedtc.com
sales@emedtc.com
www.emedtc.com

EC REP Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

CE 0459

Symbols Definition Table

Some of these symbols may be found on your device labeling and packaging materials:

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions		Storage temperature limits
	Do not re-use	SN	Serial number
	Don’t use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide		Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date	Non-Pyrogenic	Non-pyrogenic fluid path
DEHP Free	Is not made with di(2-ethylhexyl) phthalate (DEHP)	Latex Free	This product is not made with latex

International Markets User Manual

Introduction

The EMED SCIg60 Infusion system provides users with a portable and effective way to subcutaneously infuse immunoglobulin. The SCIg60 Infuser is a reusable mechanical device and does not require batteries or any electrical source. The system utilizes a spring as a source of pressure that optimizes and controls the continuous delivery of fluids at desired flow rates using Infuset precision tubing sets and *VersaRate*® variable flow rate controlling sets.

Indications

The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of immunoglobulin liquid medicines with the BD 60 ml syringe (309653).

General Contraindications

The SCIg60 Infusion System is not intended for the delivery of whole blood or the infusion of insulin.

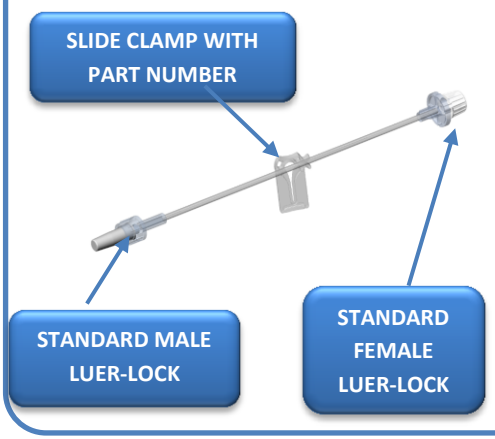
Getting to know your SCIg60 Infusion System

PACKAGE CONTENTS

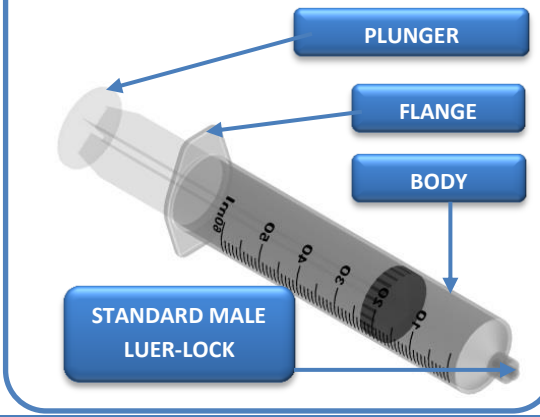
- SCIg60 Infuser
- User Manual
- Carrying Case
- (EMED Infuset and VersaRate® flow controllers are sold separately)
- (Syringe to be used: BD 60 ml Syringe Luer Lock Tip, product REF 309653)

SCIg60 Infuser

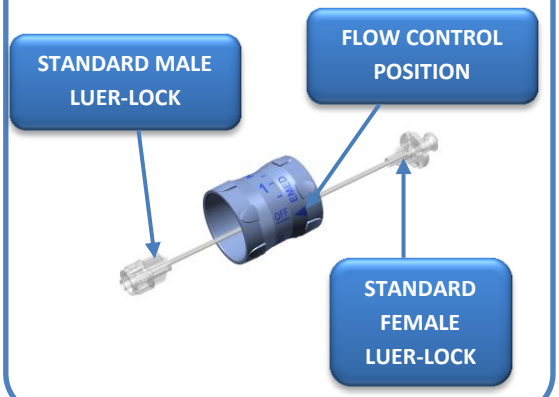
Infuset



Syringe



VersaRate®



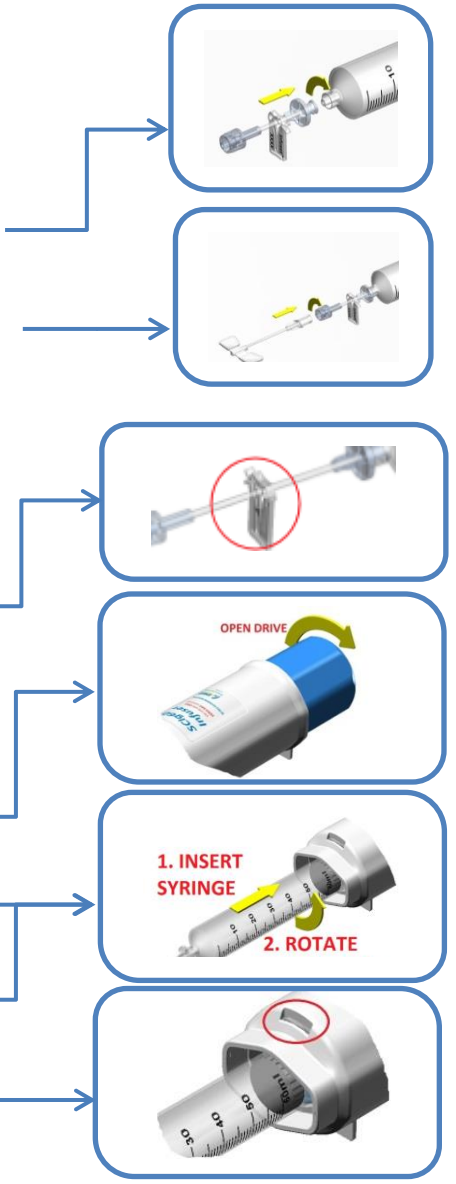
SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Instructions for Use (IFU): SCIg60 Infusion System with Infuset

1. **WASH HANDS** before handling any supplies.
2. **REMOVE** Infuset flow control infusion set, patient set and syringe from sterile packaging – Use caution to maintain the sterility of the fluid path.
3. **LOAD** syringe with medicine according to the immunoglobulin package insert or as instructed by your healthcare provider, and immediately proceed to next step.
4. **CONNECT** syringe male luer lock (MLL) to Infuset female luer lock (FLL).
5. **CONNECT** Infuset male luer lock (MLL) to patient set female luer lock (FLL).

   NOTE: see page 30 for instructions for using the *VersaRate®*
6. **PRIME** tubing per your pharmacy/ physician instructions.
7. Use slide clamp provided with Infuset to prevent flow of drug.
8. Select sites and insert needles as instructed by healthcare provider and/or SCIg patient set instructions.
9. **OPEN** SCIg60 Infuser drive by rotating the handle **counterclockwise** until it stops.
10. **LOAD** syringe into SCIg60 Infuser by inserting the syringe plunger into the SCIg60 infuser.
11. **LOCK** syringe into SCIg60 Infuser by rotating the syringe 90° until you feel a click.
12. **VERIFY** the syringe flange is in the window of SCIg60 Infuser to confirm the syringe is properly locked.



Instructions for Use (IFU) – Continued

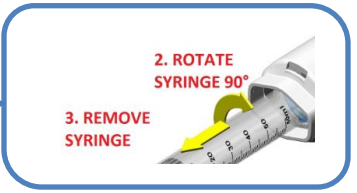
13. **CLOSE** SCIg60 Infuser drive by rotating the handle clockwise until it stops.
CAUTION: DO NOT ATEMPT TO REMOVE THE SYRINGE BEFORE PERFORMING STEP 17.

14. Place the SCIg60 Infuser, Infuset, and patient set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the Infuser Carrying Case Accessory* below for more details).

15. **COMPLETE INFUSION** as prescribed by your healthcare provider.

16. **USE SLIDE CLAMP** to stop flow as necessary during infusion session or when session is complete.

17. To **REMOVE THE SYRINGE** rotate the handle counterclockwise until it stops, then unlock the syringe by turning it 90° (refer to steps 9 - 11 above).



Using the SCIg60 Infuser Carrying Case Accessory

1. Open pouch and unfasten Velcro straps inside the pouch.
2. Insert SCIg60 Infuser with BD 60 ml syringe (model no. 309653) and Infuset into the pouch on top of Velcro straps.
   The Infuset should face away from the zipper pull, and exit the Carrying Case through the provided space below the zipper.
3. Fasten the Velcro straps around SCIg60 Infuser to secure it in place.

VersaRate® Adjustable Flow rate infusion set

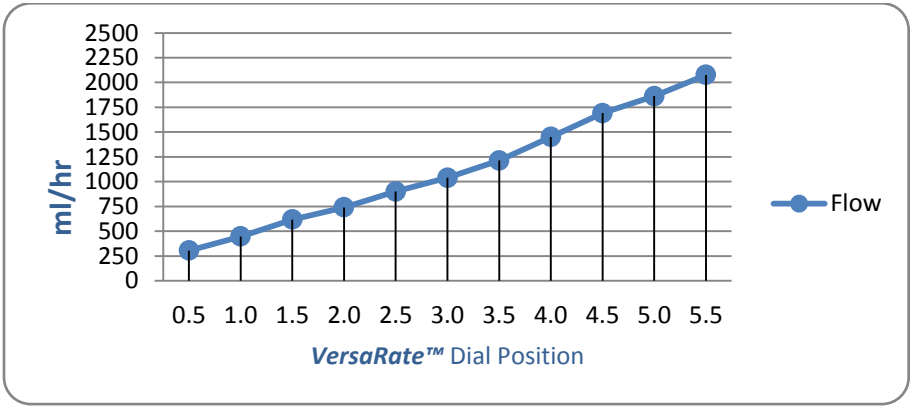
Flow control dials have been used for decades to provide a means to improve flow rate control in Home and Hospital settings. EMED has designed *VersaRate™*, a proprietary flow regulator **that enhances the performance of mechanical and elastomeric infusers.** *VersaRate*®was designed to eliminate multiple infusion sets with limited flow rates required by this category of infusers.

The *VersaRate*®control set has a dial with a scale from 1 to 6. The scale has been selected to avoid the confusion experienced with other rate sets labeled in ml/hr that do not correspond to actual flow rates. The *VersaRate*®scale is correlated with flow rates for specific fluids viscosities that allow patients to adjust the desired flow rate without the use of multiple sets.

Ambient conditions, equipment set up and patient parameters contribute to the actual flow rate during the use of mechanical and elastomeric infusion devices. *VersaRate®* provides a means to compensate for these factors by adjusting the settings to allow the clinician and patient to bring the actual flow rate to the desired level.

The chart below was developed based on 0.9% Sodium Chloride under controlled temperature conditions between 20°C - 25°C (68°F – 77°F) without a patient set. For specific fluid viscosities contact your healthcare provider.

***VersaRate*®Flow Rate chart (with 0.9% Saline solution and 15 PSI pressure)**



Note: *VersaRate*®Dial Position #6 is fully open.

VersaRate®Instructions for Use (IFU)

1. **REMOVE** *VersaRate*® flow controller, patient set and syringe from sterile packaging – Using caution to maintain the sterility of the fluid path.

2 **LOAD** syringe with medicine according to the immunoglobulin package insert or as instructed by your healthcare provider, and immediately proceed to next step.

3 **TURN** *VersaRate*® control set to the **OFF** position to block flow. The *VersaRate™* is packaged in the open position for sterilization purposes.

4 **CONNECT** syringe male luer lock(MLL) to *VersaRate*® control set female luer lock (FLL)

5 **CONNECT** *VersaRate*® control set male luer lock (MLL) to patient set female luer lock (FLL).

6 **TURN** *VersaRate*® control set to the desired position to allow flow.

7 **PRIME** tubing per your pharmacy/physician instructions.

8 **TURN** *VersaRate*® control set to the **OFF** position to block flow.

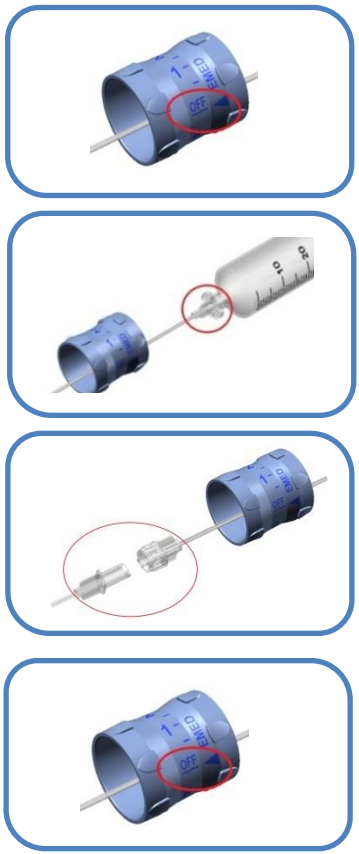
9 Select sites and insert needles as instructed by healthcare provider and/or SCIg patient set instructions.

10 **LOAD** syringe and prepare for infusion session by following steps 10 – 14 of the SCIg60 Infusion System with Infuset IFU.

11 **TURN** *VersaRate*® control set to the desired position to allow flow and begin infusion.

12 **COMPLETE INFUSION** as prescribed by your healthcare provider.

13 **TURN** *VersaRate*® control set to the **OFF** position to stop flow as necessary during infusion session or when session is complete.



Factors that Affect Flow Rate

The following are some of the factors that influence the flow rate of mechanical (non-electric) and elastomeric infusion devices. The compounded effect of these variables should be taken into account during use of the SCIg60 Infuser and selection of the appropriate Infuset or *VersaRate*® flow controller set.

FACTORS THAT AFFECT THE FLOW RATE	
Ambient temperature	Temperature has a significant effect on flow rate. The rate will change approximately 1 – 1.5% for each degree Fahrenheit in temperature changes.
Viscosity of solution	The SCIg60 Infusion System is designed to work with a wide range of fluid viscosities. The system was calibrated based on 0.9% Saline Solution. For specific data related to higher viscosities contact your healthcare provider.
Patient factors	➔ Venous Pressure / Sub-q tissue absorption ➔ Patient Body Mass Index (BMI), age and health
Catheters and needles	The effect of catheters and needles depends on their dimensions. SCIg60 Infusion System is designed to work with a wide range of gauges from 18 to 29.
Tubing obstruction	It is important to identify a comfortable position that prevents tubing obstruction.
Atmospheric pressure and infuser relative location	The force of gravity has a minimal effect on flow rate.

LARGE EFFECT	MODERATE EFFECT	SMALL EFFECT

SCIg60 Infuser Technical Information

Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 g (14.5 oz)
Storage Temperature	-5°C to +40°C (23°F to 104°F)
Syringe volume (BD 60 ml syringe (model no. 309653)	60 ml only
Maximum operating pressure	16.8 psi
CE	0459

Infuset Flow Control Infusion Set Performance Information

Infuset Part Number	Length	Residual Volume (ml)	Target Flow Rate (ml/hr) (0.9% saline at 25°C)	Flow rate accuracy (ml/hr) (0.9% saline at 25°C)
Infuset-45	37.9" (96.2 cm)	<0.2 ml	45	± 10%
Infuset-80	22.4" (56.8 cm)	<0.2 ml	80	± 10%
Infuset-120	33.4" (84.8 cm)	<0.2 ml	120	± 10%
Infuset-190	22.0" (55.8 cm)	<0.2 ml	190	± 10%
Infuset-290	23.5" (59.7 cm)	<0.2 ml	290	± 10%
Infuset-430	14.5" (36.8 cm)	<0.2 ml	430	± 10%
Infuset-650	9.6" (24.5 cm)	<0.2 ml	585	± 10%
Infuset-820	7.9" (20.1 cm)	<0.2 ml	750	± 10%
Infuset-930	6.9" (17.5 cm)	<0.2 ml	875	± 10%
Infuset-1850	3.4" (8.7 cm)	<0.2 ml	2100	± 10%
		CE	**0459**	

Flow rates can be affected by various environmental factors, patient factors, and infusion equipment used. The above flow rates were determined at controlled room temperature between 20°C - 25°C (68°F – 77°F) without any downstream patient sets or additional tubing, and are intended as starting points to determine the flow rate for each application, as determined by a healthcare professional.

Please contact EMED for additional flow rate information specific to your therapeutic application.

VersaRate® Technical Specifications

Length and width	**4.25" (10.8 cm) x 1.18" (3 cm)**
Tubing	Ø1.02mm ID x Ø2.4mm OD
Weight	0.4 oz / 13 gr
Storage Temperature	0°C to +40°C
Residual Volume	<0.3 ml
Maximum operating pressure	18.00 psi
Flow rate range	Adjustable 0-2100 ml/hr
CE	0459

SCIg60 Infuser – Cleaning and Storage

- Outer surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak mixture 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.
- Clean only those areas that are exposed when the Infuser Inner Drive is completely screwed in. Do not attempt to clean any part of the SCIg60 Infuser that is not easily accessible.
- Discontinue use of a SCIg60 Infuser that has been internally exposed to or immersed in fluid.
- Use a dry cloth to dry the exposed and external portions of the device.
- Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.

SCIg60 Infuser Carrying Case – Cleaning

- Only clean surface with a clean damp cloth and air dry.
- Do not machine wash the carrying case as it could damage the case.

Troubleshooting

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

- **SYRINGE POSITION**. Verify the syringe is properly positioned into the infuser as instructed in the IFU section; the syringe should be parallel to the infuser with the syringe flange properly engaged and seen within the safety check window (shown in the diagram). If syringe 'pops out' of infuser when inner drive is activated/screwed in, it is an indication that the syringe was not properly positioned in the infuser. Unscrew the inner drive and properly position the syringe following the instructions for use.
- **TUBING CONNECTORS**. Verify the BD 60 ml syringe (model no. 309653) is properly connected to the Infuset and that the Infuset is correctly connected to the specified patient sets.
- **NO FLOW.** Check the slide clamp on the Infuset and make sure is not blocking the flow, or if using the *VersaRate®*control set check to make sure it is not at the OFF position. If there is still no flow, verify the slide clamp is not closed on the patient tubing set and that the tubing is not kinked in any way.
- **FLOW RATE IS TOO HIGH**. Verify that the intended Infuset is being used or that the VersaRate dial is set to the intended position. If flow rate remains too high, contact your healthcare provider for alternative Infuset flow rate set, or if using *VersaRate®* control set, rotate the dial to a lower position or to the OFF position.
- **FLOW RATE IS TOO SLOW**. Verify that the intended Infuset is being used or that the *VersaRate®* dial is set to the intended position. If flow rate remains too slow, contact your healthcare provider for alternative Infuset flow rate set, or if using *VersaRate®*control set, rotate the dial to a higher position.
- **FLOW DOES NOT STOP**. Verify that the slide clamp on the Infuset is fully closed, or that the *VersaRate®* control set is fully turned to the OFF position. If flow does not stop disconnect the syringe from the SCIg60 Infuser by opening the Inner drive by rotating the handle counterclockwise until it stops.
- **BROKEN PARTS**. Inspect infuser for any broken parts. If this is the case contact EMED Technologies Corporation.

If after following the instructions above the SCIg60 Infusion System does not appear to be working properly, discontinue use of the SCIg60 Infusion System and contact your healthcare provider or EMED Technologies Corporation.

⚠ Contraindications/Warnings

DO	DO NOT
Read all instructions for the SCIg60 Infusion System and flow rate infusion set before use.	Do not use frozen solutions
Use only EMED Infusets or *VersaRate®* to control the flow; using any other device/tubing to control the flow rate will result in unsafe condition for patient.	Do not use Infuser if it is broken or damaged. If the infuser is dropped or damaged either in transit to you or during preparation for its use, or if water damage is suspected contact EMED Technologies.
Use the SCIg60 Infusion System as prescribed by your healthcare provider and follow all the directions as prescribed.	Do not subject the Infuser to autoclaving or other similar methods of sterilization
Use only BD 60 ml syringes (REF 309653) do not use any other syringe.	Do not open the infuser or attempt to modify its function in any way other than detailed in this User Manual.
If fluid source is disconnected during the infusion, stop the process and place a sterile non-vented cap on syringe and set	DO NOT use any other syringe. Doing so may result in unsafe conditions for patient or deviation from desired infusion rates
Use aseptic technique when handling Infuset and *VersaRate®* flow controllers	**Do not insert or remove the syringe** until the INNER DRIVE is fully opened, as indicated in the IFU section, step 17.
Place SCIg60 Infuser on a flat surface or in the provided carrying case during use. Syringe damage and drug loss could occur if system is dropped while loaded with syringe and drug.	Do not use this device if high accuracy is needed. Flow rates of all elastomeric or mechanical infusers are affected by multiple factors described in this manual. Alternative electronic infusers should be used in those cases
Use only one Infuset or VersaRate® at one time.	Do not use the Infuset, *VersaRate®*, or syringe more than once, as it may cause infection
Contact EMED if you have any questions regarding the use of the SCIg60 Infusion System.	Do not re-sterilize Infuset or *VersaRate®* flow controllers, doing so will cause serious health conditions to patient.

Caution: U.S. Federal Law restricts this device to sale by or on order of a physician.

Warranty

- **Parties Covered:** This warranty extends only to the Original Purchaser of the infusion infuser and it does not extend to subsequent purchasers or users. The "Original Purchaser" is the person purchasing the infusion infuser from the Manufacturer or Manufacturers Representative.

- **Limited Warranty**: EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects in materials and workmanship for three (3) years from the date of original purchase when used as intended and under the direction of authorized medical personnel. Failure to comply with these conditions will result in a void warranty.

  Use of accessories or components not specified in the SCIg60 Infusion System User Manual may impact Hizentra flow rates, result in a flow rate outside of what has been approved for Hizentra, and is not recommended. The Manufacturer does not represent that the SCIg60 Infusion System will operate in accordance with performance specifications if third party accessories are used.

- **Replacement**: 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 SCIg60 Infuser, or part thereof, which has been actually received by the Manufacturer or Manufacturers Representative within the three 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 three year warranty period.

- **Disposable items**: In the event that an EMED-branded disposable item is found defective, it will be replaced with a new disposable item by the Manufacture.

Contact Information

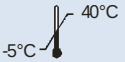
EMED Technologies
U.S.A. Headquarters
1264 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762
Tel. +1 (916) 932-0071
Fax: +1 (916) 932-0074
customerservice@emedtc.com
sales@emedtc.com
www.emedtc.com

EC REP Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

CE 0459

Symbols Definition Table

Some of these symbols may be found on your device labeling and packaging materials:

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions		Storage temperature limits
	Do not re-use	SN	Serial number
	Don't use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide		Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date	Non-Pyrogenic	Non-pyrogenic fluid path
DEHP Free	Is not made with di(2-ethylhexyl) phthalate (DEHP)	Latex Free	This product is not made with latex