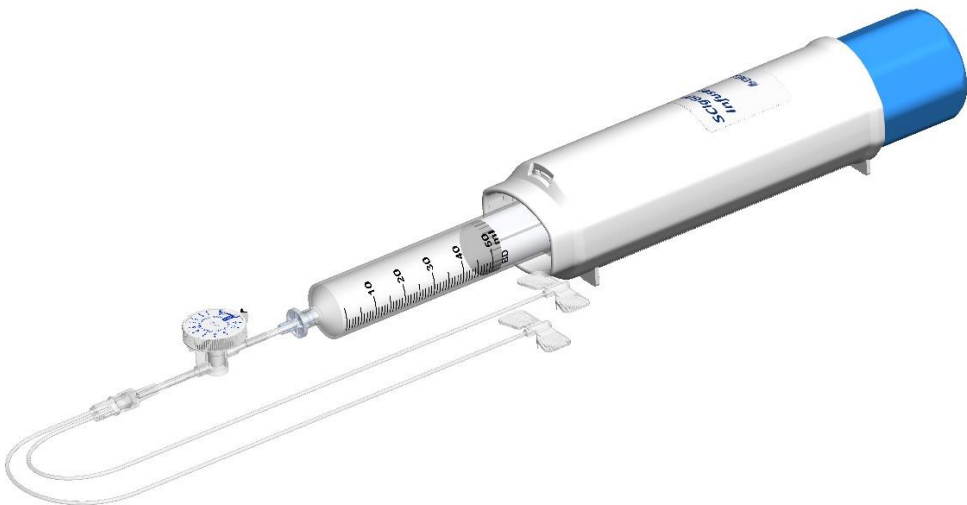




User Manual

SCIg60® Infusion System

USA Users



SClg60® Infusion System

Contact Information



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NOTE:

In the event any serious incident occurs due to the use of this product, the healthcare provider, user or patient shall report the incident to EMED Technologies at +1-916-932-0071 and the competent authority in your region.

SCIg60® Infusion System

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SCIg60® Infusion System

Important Information

Please contact EMED Technologies if you have any questions or concerns regarding the use of the SCIg60 Infusion System.

Document Conventions

The below text and color code convention is used throughout this document to highlight warnings, cautions, and notes:

WARNING:

A **Warning** is an alert to a potential hazard which could result in serious personal injury or product damage if proper procedures are not followed.

CAUTION:

A **Caution** is an alert to a potential hazard which could result in minor personal injury or product damage if proper procedures are not followed.

NOTE:

A **Note** provides additional information or recommendation.

Terms and Abbreviations

The following terms are defined below and referenced throughout the document:

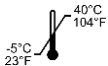
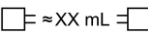
Defined Term	Meaning
Infuset	Infuset® fixed rate flow control accessory
IFU	Instructions for Use
Pump	SCIg60® Infuser
SCIg60	SCIg60® Infusion System
SUB-Q Set	Subcutaneous Administration Set
VersaRate	VersaRate® Variable rate flow controller accessory
VersaRate Plus	VersaRate® Plus Variable rate flow controller accessory

SClg60® Infusion System

Symbols

EMED Symbol Glossary can be found at the following website: <https://www.emedtc.com/support>

The following symbols may be found on the SClg60 Infusion System labeling and packaging materials:

Symbol	Definition	Symbol	Definition
	Caution		Manufacturer
	Refer to instruction manual/booklet		EC Representative
	Medical Device		CE Mark
RxOnly	To sale by or on the order of a physician.		Importer
	Do not re-use		Reference number
	Don't use if package is damaged		Serial number
	Sterilized by Ethylene Oxide		Manufacturing date
	Single sterile barrier system with protective packaging outside		Country of Manufacture
	This product is not made with latex		Batch number
	Is not made with di(2-ethylhexyl) phthalate (DEHP)		Expiration date
	Non-pyrogenic		Quantity
	Fluid Path		Length
	Storage temperature limits		Approximate priming volume
	MR Unsafe		Single patient, multiple use

SCIg60® Infusion System

Introduction

The EMED SCIg60® Infusion System consists of the SCIg60 Infuser and carrying case, a flow rate controller (Infuset® fixed rate flow control extension set, VersaRate® variable flow rate controller, or VersaRate Plus® variable flow rate controller), and a subcutaneous patient administration set. The SCIg60 Infuser must be used with the BD 50 mL syringe (model no. 309653). The SCIg60 Infusion System provides a portable and effective way to subcutaneously infuse prescribed fluids.

Description

The SCIg60 Infuser is a reusable mechanical infusion pump that does not require batteries or any electrical source. The pump utilizes a spring as a source of energy to continuously deliver fluids at controlled flow rates when used as a system with the following components:

Component	Model Information
Pump with Carrying Case	SCIg60® Infuser (FP-0010002)
50 mL Syringe	BD 309653
Flow Controller	Infuset®, VersaRate®, or VersaRate® Plus (See table below)
Administration Set	SUB-Q, SAF-Q®, or OPTFlow®

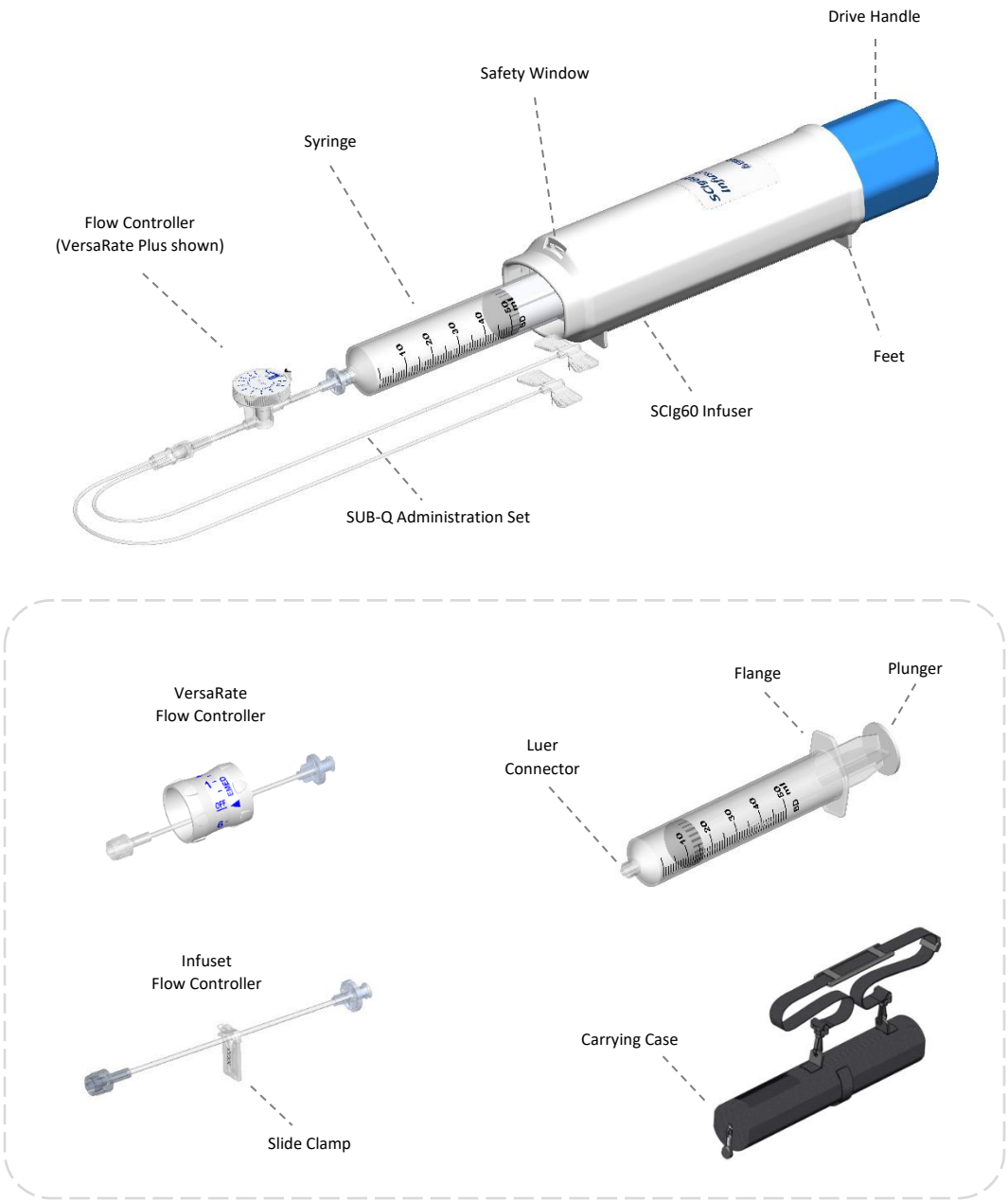
The SCIg60 Infuser is intended for single patient, multiple use only, while flow controllers and patient administration sets are single-use only. The syringe, flow controller and administration set are sold separately. The syringe component is not manufactured by EMED and is available for purchase from the manufacturer.

The flow controller accessory regulates the fluid flow rate into the SUB-Q set. The flow controller accessory should be selected based on the prescribing fluid’s administration instructions, the viscosity of the prescribed fluid, the type of SUB-Q administration set being used, and patient factors. See section *System Flow Rate Performance* for additional information. The following flow controllers are recommended for use with the SCIg60 Infuser System:

Description	Reorder Number
Infuset-45	FP-0010013
Infuset-80	FP-0010014
Infuset-120	FP-0010011
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
Infuset-3200	FP-0010027
Infuset-4000	FP-0010028
Infuset-4300	FP-0010029
VersaRate	FP-0010003
VersaRate Plus	FP-0010026

SCIg60[®] Infusion System

System Diagram



SCIg60® Infusion System

Indications

The SCIg60 Infusion System is intended for the subcutaneous infusion of the following immunoglobulin liquid medications:

- Hizentra, Immune Globulin Subcutaneous (Human) 20% (manufactured by CSL Behring),
- Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Takeda Pharmaceutical Company, formerly Baxalta),
- Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Takeda Pharmaceutical Company, formerly Baxalta),
- Gamunex-C Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.),
- Gammaked Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.)
- Xembify Immune Globulin Subcutaneous (Human), 20% (manufactured by Grifols Therapeutics Inc.), and
- Cutaquig Immune Globulin Subcutaneous (Human), 16.5% (manufactured by Octapharma AG)

with the BD 50 ml syringe (model no. 309653) in the home or hospital environment.

Contraindications

Administration of indicated immunoglobulin fluids is intended for subcutaneous infusion only. Infusion into other infusion sites, including blood vessels, should not be attempted.

Intended Population

The SCIg60 Infusion System is intended for adult or pediatric patients (2 years and older) that require subcutaneous infusion of fluid medication prescribed by a healthcare professional. The infusion system must be operated by an adult for use with pediatric patients.

Alarms

The SCIg60 Infuser is a mechanical infusion pump which does NOT have alarms or indicators.

Limitations

The principle of operation of the SCIg60 Infusion System is continuous infusion by applying a constant force to the syringe and regulating the fluid flow into the SUB-Q set using a flow controller. The system is passive and is therefore not able to compensate automatically for changes in environment or patient conditions. When using an Infuset flow controller, the rate is fixed and cannot be adjusted during infusion. When using a VersaRate flow controller, the rate can be adjusted manually if needed. For more information, reference the *Factors that Affect Flow Rate* and *Troubleshooting* sections.

The SCIg60 Infuser does not have any indications or alarms. The patient or healthcare professional must always monitor the infusion progress and determine when the infusion is complete by verifying the remaining volume in the syringe.

SCIg60® Infusion System

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.



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 SCIg60 Infuser to autoclaving or other 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.

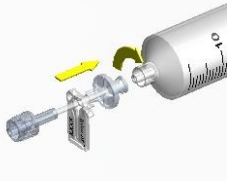
MRI Safety Information

The SCIg60 Infusion System is MR Unsafe.

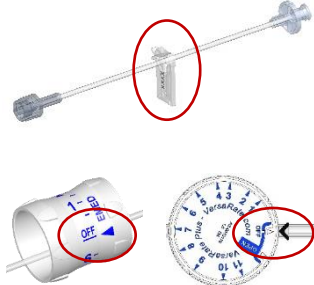
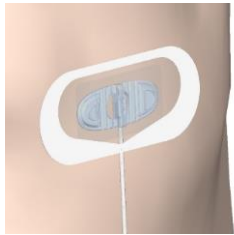
SCIg60® Infusion System

Instructions for Use

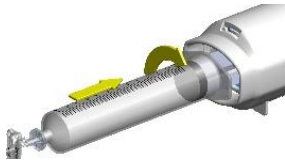
SCIg60 Infusion System IFU

Step	Instruction	Image
Prepare Infusion		
1	WASH HANDS thoroughly and dry hands before handling any supplies. Wear gloves if you have been instructed to do so. WARNING: Use aseptic technique throughout procedure.	
2	REMOVE Flow controller, administration set and syringe from sterile packaging. WARNING: Read and follow all instructions for the components prior to use.	
3	TRANSFER indicated fluid from vial(s) to 50 ml syringe (BD model no. 309653) according to the package insert or as instructed by your healthcare professional. Immediately proceed to next step. WARNING: Do NOT store indicated immunoglobulin fluid in the syringe prior to use.	
4	CONNECT syringe male Luer lock (MLL) to Infuset or VersaRate female Luer lock (FLL). The “Luer Locks” are the connectors at each end of the various components that allow interconnection between the components.	
5	CONNECT Infuset or VersaRate male Luer lock (MLL) to specified patient administration set female Luer lock (FLL).	

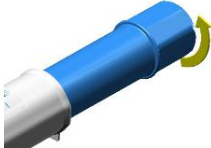
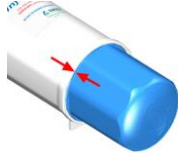
SCIg60® Infusion System

Step	Instruction	Image
6	PRIME the tubing (i.e., pre-load with the prescribed fluid) by gently pushing on the syringe plunger to fill the tubing with fluid or as instructed by your healthcare professional.	
7	CLOSE flow control accessory. Use slide clamp provided with Infuset or select the 'OFF' position on the VersaRate or VersaRate Plus to prevent flow of fluid.	
8	PREPARE INJECTION SITES and INSERT NEEDLES according to the indicated medication package insert, specified administration set instructions, or as instructed by your healthcare professional. NOTE: If instructed by your healthcare professional, before starting the infusion but after the needles are inserted, 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.	

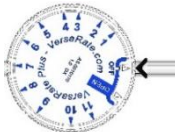
Load Pump

9	OPEN SCIg60 Infuser drive by turning the blue 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 turning the syringe clockwise until it stops.	

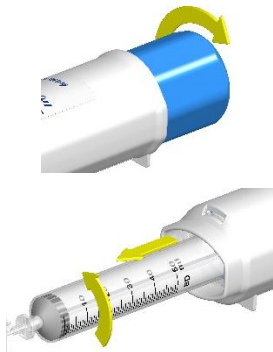
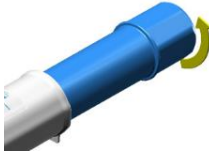
SClg60® Infusion System

Step	Instruction	Image
12	VERIFY the syringe flange is visible in the safety window of SClg60 Infuser to confirm the syringe is properly locked in place.	
13	CLOSE SClg60 Infuser drive by rotating the handle clockwise until the base of the handle touches the body of the pump, as shown in the second image. CAUTION: DO NOT ATTEMPT to remove the syringe before performing STEP 16.	 
14	PLACE the SClg60 Infuser, Infuset, VersaRate, or VersaRate Plus, and specified administration set on a stable, horizontal surface or use the Carrying Case Accessory (see Using the SClg60 Infuser Carrying Case Accessory below for more details).	

Start Infusion

15	When using Infuset: a) To START infusion, USE SLIDE CLAMP (release the slide clamp so that it doesn't compress the tubing) once pump is fully loaded and needles are inserted and secured. b) MONITOR infusion by viewing the syringe volume. c) To STOP infusion, USE SLIDE CLAMP as necessary during infusion session or when session is complete.	
	When Using VersaRate or VersaRate Plus: a) To START infusion, TURN dial to flow position as directed by your healthcare professional once pump is fully loaded and needles are inserted and secured. b) MONITOR infusion by viewing the syringe volume. c) To STOP infusion, TURN dial to 'OFF' position as necessary during infusion session or when session is complete.	 

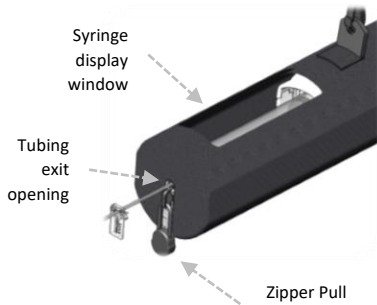
SClg60® Infusion System

Step	Instruction	Image
Stop Infusion		
16	When session is complete, to remove the syringe ROTATE the blue handle counterclockwise until it stops, THEN UNLOCK THE SYRINGE by turning it counterclockwise. NOTE: If the infusion protocol requires more than one syringe to be administered, repeat steps 3 – 16 in sequence. It is recommended to perform the infusions sequentially without a delay in time.	
17	DISPOSE of the syringe, Infuset or VersaRate, and SUB-Q set in an appropriate biohazard and/or sharps waste container according to your local regulations. WARNING: Read and follow all instructions for the components.	
18	CLOSE SClg60 Infuser drive by rotating the blue handle clockwise until the base of the handle touches the body of the pump. CLEAN and STORE SClg60 Infuser and Carrying Case for next use.	

NOTE:	• Instructions for Use also appear on the underside of the Infuser. • During infusion, an intermittent clicking sound may occur as the spring extends. This is normal. See <i>Troubleshooting</i> section for additional information.
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SClg60® Infusion System

SClg60 Carrying Case IFU

Step	Instruction	Image
Insert		
1	Place the carrying case on a level surface to prevent dropping.	
2	Open pouch by pulling the zipper.	
3	After loading the syringe and closing the inner drive per step 13 above, insert SClg60 Infuser with syringe and flow controller into the pouch oriented with the syringe to show from the display window. The syringe should face away from the zipper pull, and the tubing should exit the Carrying Case through the small opening below the zipper. CAUTION: Use caution not to drop the device.	
4	Close the pouch with the zipper CAUTION: Use caution to prevent damage to the tubing.	
5	Use belt loop or shoulder strap to hold and carry the system on the body.	
Remove		
6	Place the Carrying Case containing the SClg60 system on a level surface to prevent dropping	 Syringe display window Tubing exit opening Zipper Pull
7	Open the pouch by pulling the zipper.	
8	Remove the SClg60 System from the pouch using caution not to drop the device.	
9	Close the Carrying Case zipper.	

SClg60® Infusion System

Maintenance

The SClg60 Infuser 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 SClg60 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 SClg60 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 SClg60 Infuser Drive Handle is completely screwed in. Do not attempt to clean any part of the SClg60 Infuser that is not easily accessible.
- Discontinue use of an SClg60 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 SClg60 Infuser or carrying case to temperatures outside of recommended range.

Disposal

The SClg60 Infuser and Carrying Case can be disposed of in general waste collection systems. Please ensure compliance with local regulations.

WARNING:

Do NOT open the Infuser or attempt to modify its function in any way other than as instructed.

The administration set, flow controller, and syringe are single use only and should be disposed of in an appropriate biohazard and/or sharps waste container according to local regulations.

WARNING:

Read and follow all instructions for the components.

SCIg60® Infusion System

Specifications

SCIg60 Infuser Length	26.0 cm (10.2 in.)																										
SCIg60 Infuser Width	6.5 cm (2.6 in.)																										
SCIg60 Infuser Weight	412 g (14.5 oz)																										
SCIg60 Infuser Alarms	None																										
Syringe Volume	50 mL (BD model no. 309653)																										
Maximum Operating Pressure	1.16 bar (16.8 psi)																										
Average Operating Pressure	1.0 bar (14.4 psi)																										
Storage Temperature	-5°C – +40°C (23°F – 104°F)																										
Target Operating Temperature	20°C – 25°C (68°F – 77°F)																										
Total System Accuracy Using Infuset and SUB-Q set Using VersaRate and SUB-Q set: @ Position ½ Up to ±33% @ Position 1 Up to ±37% @ Position 2 Up to ±26% @ Position 3 Up to ±22% @ Position 4 Up to ±15% @ Position 5 Up to ±15% @ Position 6 Up to ±15% Using VersaRate Plus and SUB-Q set: @ Position 1-2 Up to ±41% @ Position 3-5 Up to ±21% @ Position 6-10 Up to ±20% @ Position 11-OPEN Up to ±14%	% Change from nominal flow rate: ±15%																										
Maximum Vertical Difference	±30.0 cm (±12 in.) Note: this is the vertical height of the SCIg60 Infuser above or below the infusion site on the patient																										
Vertical Sensitivity: 30.5 cm (12 in.) above infusion site 30.5 cm (12 in.) below infusion site	% Change from nominal flow rate: Up to +6% Up to -4%																										
Residual Volume	System residual volume depends on the combination of component residuals: Syringe: ≈ 0.2 mL, Note: this is the amount of fluid that will not be infused. Flow Controller: ≈ 0.05 – 0.25 mL depending on model, SUB-Q set: ≈ 0.18 – 1.87 mL depending on model. See individual component instructions for specific residual values.																										
Useful Life	4200 uses																										
Representative Flow Profile *The figure shows the Total Flow Rate vs. Infused Volume at 20°C – 25°C under laboratory conditions achieved with SUB-320 (3-needle, 27G 9-mm set) and FP-001008 (Infuset-190). Although realized flow rates are determined by the combination of Infuset and SUB-Q set used, the shape of the flow rate profile remains the same due to the design and principle of action of the SCIg60 Infusion System.	<table border="1"> <caption>Representative Flow Profile Data</caption> <thead> <tr> <th>Volume (mL)</th> <th>Flow Rate (mL/h)</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>6</td></tr> <tr><td>2</td><td>8</td></tr> <tr><td>3</td><td>9.5</td></tr> <tr><td>4</td><td>10</td></tr> <tr><td>5</td><td>10</td></tr> <tr><td>10</td><td>10</td></tr> <tr><td>20</td><td>10</td></tr> <tr><td>30</td><td>10</td></tr> <tr><td>40</td><td>10</td></tr> <tr><td>50</td><td>10</td></tr> <tr><td>60</td><td>10</td></tr> </tbody> </table>	Volume (mL)	Flow Rate (mL/h)	0	0	1	6	2	8	3	9.5	4	10	5	10	10	10	20	10	30	10	40	10	50	10	60	10
Volume (mL)	Flow Rate (mL/h)																										
0	0																										
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5	10																										
10	10																										
20	10																										
30	10																										
40	10																										
50	10																										
60	10																										

SClg60® Infusion System

Factors that Affect Flow Rate

System flow rate can be affected by various environmental factors, patient factors, and infusion equipment used. The following table shows some of the factors that influence the flow rate. The compounded effect of these variables should be considered during use of the SClg60 Infuser and selection of the appropriate Infuset or VersaRate accessories.

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, depending on the amount of time the fluid is in the ambient environment. The system flow rate will change approximately 1 to 1.5% for each degree Fahrenheit temperature change of the fluid, with higher temperatures resulting in faster flow rates. 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 is to change the dimensions of the fluid path. SClg60 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 settings (with VersaRate or VersaRate Plus) 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.

SCIg60® Infusion System

How to determine approximate flow rate during infusion:

1. Record the starting volume and time.
2. Wait an appropriate amount of time for volume to infuse (Examples: 10 minutes or after 5 mL infused).
3. Record the elapsed volume in mL and elapsed time in minutes.
4. Calculate flow rate using the equation:

$$\text{Flow Rate [mL/h]} = \frac{\text{Volume [mL]}}{\text{Time [minutes]}} \times 60$$

How to determine per site flow rate:

$$\text{Flow Rate Per Site [mL/h/site]} = \frac{\text{Total Flow Rate [mL/h]}}{\text{Number of Needles}}$$

System Setup for Infusion Rates

See www.VersaRate.com for an electronic version of the following information.

In the following pages you will find tables that can be used to identify the combination of the EMED administration needle set and the Infuset flow control accessory or VersaRate position that will provide a flow rate that may accommodate the patient's need for infusion while falling within drug manufacturer's recommended prescribing limits. Flow rate information for use with the Infuset, VersaRate and VersaRate Plus are presented separately for each of the indicated immunoglobulin fluids that are to be used with the SCIg60 Infusion System. In the case of Hizentra, separate flow rate tables have also been included for patients infusing for the treatment of Primary Immunodeficiency (PI) or Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

The flow rate values presented in the following tables are based on bench testing of a single Infuset or a VersaRate at a single position and EMED SUB-Q patient administration sets. Testing was performed between 20°C – 25°C (68°F – 77°F) without including the effect of the patient. It is important to understand that flow rates of infused immunoglobulin fluids can be affected by multiple factors. See previous section *Factors that Affect Flow Rate* for additional information.

To choose a system combination, first find the correct table according to the drug type and flow controller model. Select the table row that contains the needle gauge, needles model, needle length, number of needle sites, and/or flow rate that best meets therapeutic needs and/or patient preferences.

Total flow rate values are presented in the following tables. Flow rate per site can be determined by dividing the total flow rate by the number of needle sites.

CAUTION:

Using a combination of subcutaneous patient administration set and Infuset or VersaRate position not specified in the tables on the following pages may result in a flow rate outside of what has been approved for a specific immunoglobulin fluid.

NOTE:

Please contact EMED Technologies at +1-916-932-0071 for additional information regarding selection of flow controllers with SUB-Q sets to obtain a desired flow rate.

SCIg60® Infusion System

Infusing Cutaquig

The tables below only include combinations that will provide both total and per site flow rates that are within Cutaquig's dosage limits after system tolerances are applied. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions (Aged 2-16 years: up to 15 mL/h/site; Aged ≥ 17 years: up to 20 mL/h/site)
	Suitable for maintenance infusions only (Aged 2-16 years: up to 25 mL/h/site; Aged ≥ 17 years: up to 52 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 1a		Drug		Patient Information								Flow Controller					
		Cutaquig		Patients aged 2-16 years								Infuset					
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
26G	OPT12604	4	1		8	11	19										
	OPT12606	6	1		8	11	19										
	OPT12609	9	1		8	11	19										
	OPT12612	12	1		8	11	19										
	OPT12614	14	1		8	11	18										
	OPT22604	4	2				21	27	41								
	OPT22606	6	2				21	27	41								
	OPT22609	9	2				21	27	41								
	OPT22612	12	2				21	27	41								
	OPT22614	14	2				20	25	38								
	OPT32606	6	3					29	41								
	OPT32609	9	3					29	41								
	OPT32612	12	3					29	41								
	OPT32614	14	3					27	38	62							
	OPT42606	6	4					35	42	69							
	OPT42609	9	4					35	42	69							
	OPT42612	12	4					35	42	69							
	OPT42614	14	4					33	39	65							
	OPT52606	6	5						41	72							
	OPT52609	9	5						41	72							
OPT52612	12	5						41	72								
OPT62609	9	6						43	69		105						
OPT62612	12	6						43	69		105						
27G	SUB-104-G27	4	1				15	20									
	SUB-106-G27	6	1				15	19									
	SUB-109-G27	9	1				13	17	19								

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Table 1a		Drug		Patient Information								Flow Controller					
		Cutaquig		Patients aged 2-16 years								Infuset					
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	SUB-112-G27	12	1				12	16	18								
	SUB-204-G27	4	2					25	31								
	SUB-250	6	2					23	29	39							
	SUB-260	9	2					22	27	36							
	SUB-212-G27	12	2					20	24	33							
	SUB-310	6	3					26	35	51							
	SUB-320	9	3					24	32	47							
	SUB-312-G27	12	3					22	29	43							
	SUB-400	6	4					27	37	53							
	SUB-410	9	4					25	34	49							
	SUB-412-G27	12	4					22	31	45							
	SUB-414-G27	14	4					21	29	42							
	SUB-506	6	5					28	40	59							
	SUB-509	9	5					25	36	54							
	SUB-606	6	6					29	39	60							
	SUB-609	9	6					27	36	55							
	SAF-Q-106-G27	6	1				15	19									
	SAF-Q-109-G27	9	1				13	17	19								
	SAF-Q-112-G27	12	1				12	16	18								
	SAF-Q-206-G27	6	2					23	29	39							
	SAF-Q-209-G27	9	2					22	27	36							
	SAF-Q-212-G27	12	2					20	24	33							
	SAF-Q-306-G27	6	3					26	35	51							
	SAF-Q-309-G27	9	3					24	32	47							
	SAF-Q-312-G27	12	3					22	29	43							
	SAF-Q-406-G27	6	4					27	37	53							
	SAF-Q-409-G27	9	4					25	34	49							
	SAF-Q-412-G27	12	4					22	31	45							
	SAF-Q-509-G27	9	5					25	36	54							
	SAF-Q-609-G27	9	6					27	36	55							

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Table 1b				Drug		Patient Information								Flow Controller			
				Cutaquig		Patients aged 17 years or older								Infuset			
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
26G	OPT12604	4	1		8	11	19	26	34								
	OPT12606	6	1		8	11	19	26	34								
	OPT12609	9	1		8	11	19	26	34								
	OPT12612	12	1		8	11	19	26	34								
	OPT12614	14	1		8	11	18	25	32	43							
	OPT22604	4	2				21	27	41	60		84					
	OPT22606	6	2				21	27	41	60		84					
	OPT22609	9	2				21	27	41	60		84					
	OPT22612	12	2				21	27	41	60		84					
	OPT22614	14	2				20	25	38	56		79					
	OPT32606	6	3					29	41	65		86					
	OPT32609	9	3					29	41	65		86					
	OPT32612	12	3					29	41	65		86					
	OPT32614	14	3					27	38	62		81					
	OPT42606	6	4					35	42	69		101					
	OPT42609	9	4					35	42	69		101					
	OPT42612	12	4					35	42	69		101					
	OPT42614	14	4					33	39	65		95					
	OPT52606	6	5						41	72		106					
	OPT52609	9	5						41	72		106					
OPT52612	12	5						41	72		106						
OPT62609	9	6						43	69		105						
OPT62612	12	6						43	69		105						
27G	SUB-104-G27	4	1				15	20	22	26							
	SUB-106-G27	6	1				15	19	21	25							
	SUB-109-G27	9	1				13	17	19	23							
	SUB-112-G27	12	1				12	16	18	21							
	SUB-204-G27	4	2					25	31	42							
	SUB-250	6	2					23	29	39							
	SUB-260	9	2					22	27	36							
	SUB-212-G27	12	2					20	24	33							
	SUB-310	6	3					26	35	51							
	SUB-320	9	3					24	32	47							
	SUB-312-G27	12	3					22	29	43							
	SUB-400	6	4					27	37	53							
	SUB-410	9	4					25	34	49							
	SUB-412-G27	12	4					22	31	45							
	SUB-414-G27	14	4					21	29	42							
	SUB-506	6	5					28	40	59							

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Table 1b				Drug		Patient Information								Flow Controller			
				Cutaquig		Patients aged 17 years or older								Infuset			
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	SUB-509	9	5					25	36	54							
	SUB-606	6	6					29	39	60							
	SUB-609	9	6					27	36	55							
	SAF-Q-106-G27	6	1				15	19	21	25							
	SAF-Q-109-G27	9	1				13	17	19	23							
	SAF-Q-112-G27	12	1				12	16	18	21							
	SAF-Q-206-G27	6	2					23	29	39							
	SAF-Q-209-G27	9	2					22	27	36							
	SAF-Q-212-G27	12	2					20	24	33							
	SAF-Q-306-G27	6	3					26	35	51							
	SAF-Q-309-G27	9	3					24	32	47							
	SAF-Q-312-G27	12	3					22	29	43							
	SAF-Q-406-G27	6	4					27	37	53							
	SAF-Q-409-G27	9	4					25	34	49							
	SAF-Q-412-G27	12	4					22	31	45							
	SAF-Q-509-G27	9	5					25	36	54							
	SAF-Q-609-G27	9	6					27	36	55							

Table 2a		Drug		Patient Information				Flow Controller	
		Cutaquig		Patients aged 2-16 years				VersaRate	
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.									
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
27G	SUB-104-G27	4	1	16					
	SUB-106-G27	6	1	15					
	SUB-109-G27	9	1	14					
	SUB-112-G27	12	1	13	19				
	SUB-204-G27	4	2		34				
	SUB-250	6	2		32				
	SUB-260	9	2		30	38			
	SUB-212-G27	12	2		27	34			
	SUB-310	6	3	23		52			
SUB-320	9	3	21		48				

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Table 2a				Drug		Patient Information			Flow Controller	
				Cutaquig		Patients aged 2-16 years			VersaRate	
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.										
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)						
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	
	SUB-312-G27	12	3	19		43	60			
	SUB-400	6	4	24		60				
	SUB-410	9	4	22		55	81			
	SUB-412-G27	12	4	20		50	74			
	SUB-414-G27	14	4	19		47	69			
	SUB-506	6	5	26		68	94			
	SUB-509	9	5	24		62	86			
	SUB-606	6	6		47		102			
	SUB-609	9	6		43		94			
	SAF-Q-106-G27	6	1	15						
	SAF-Q-1Q09-G27	9	1	14						
	SAF-Q-112-G27	12	1	13	19					
	SAF-Q-206-G27	6	2		32					
	SAF-Q-209-G27	9	2		30	38				
	SAF-Q-212-G27	12	2		27	34				
	SAF-Q-306-G27	6	3	23		52				
	SAF-Q-309-G27	9	3	21		48				
	SAF-Q-312-G27	12	3	19		43	60			
	SAF-Q-406-G27	6	4	24		60				
	SAF-Q-409-G27	9	4	22		55	81			
	SAF-Q-412-G27	12	4	20		50	74			
	SAF-Q-509-G27	9	5	24		62	86			
	SAF-Q-609-G27	9	6		43		94			

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Table 2b				Drug		Patient Information				Flow Controller	
				Cutaquig		Patients aged 17 years or older				VersaRate	
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.											
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)							
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6		
27G	SUB-104-G27	4	1	16	23	28				36	
	SUB-106-G27	6	1	15	22	27				34	
	SUB-109-G27	9	1	14	20	24				31	
	SUB-112-G27	12	1	13	19	22				29	
	SUB-204-G27	4	2		34	43	55			78	
	SUB-250	6	2		32	41	53			74	
	SUB-260	9	2		30	38	48			68	
	SUB-212-G27	12	2		27	34	44			62	
	SUB-310	6	3	23		52	72	89		103	
	SUB-320	9	3	21		48	66	82		95	
	SUB-312-G27	12	3	19		43	60	74		86	
	SUB-400	6	4	24		60	89	115		154	
	SUB-410	9	4	22		55	81	105		141	
	SUB-412-G27	12	4	20		50	74	96		128	
	SUB-414-G27	14	4	19		47	69	89		120	
	SUB-506	6	5	26		68	94	138		187	
	SUB-509	9	5	24		62	86	127		172	
	SUB-606	6	6		47		102			227	
	SUB-609	9	6		43		94			208	
	SAF-Q-106-G27	6	1	15	22	27				34	
	SAF-Q-109-G27	9	1	14	20	24				31	
	SAF-Q-112-G27	12	1	13	19	22				29	
	SAF-Q-206-G27	6	2		32	41	53			74	
	SAF-Q-209-G27	9	2		30	38	48			68	
	SAF-Q-212-G27	12	2		27	34	44			62	
	SAF-Q-306-G27	6	3	23		52	72	89		103	
	SAF-Q-309-G27	9	3	21		48	66	82		95	
	SAF-Q-312-G27	12	3	19		43	60	74		86	
	SAF-Q-406-G27	6	4	24		60	89	115		154	
	SAF-Q-409-G27	9	4	22		55	81	105		141	
	SAF-Q-412-G27	12	4	20		50	74	96		128	
	SAF-Q-509-G27	9	5	24		62	86	127		172	
	SAF-Q-609-G27	9	6		43		94			208	

SClg60® Infusion System

Table 3a				Drug		Patient Information						Flow Controller				
				Cutaquig		Patients aged 2-16 years						VersaRate Plus				
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN	
27G	SUB-260	9	2			39										
	SUB-212-G27	12	2			36	39									
	SUB-312-G27	12	3			55										
	SUB-400	6	4			73										
	SUB-410	9	4			67	78									
	SUB-412-G27	12	4			61	71									
	SUB-414-G27	14	4			57	67	76								
	SUB-506	6	5			74										
	SUB-509	9	5			68	93									
	SUB-606	6	6			87										
	SUB-609	9	6			80	108									
	SAF-Q-209-G27	9	2			39										
	SAF-Q-212-G27	12	2			36	39									
	SAF-Q-312-G27	12	3			55										
	SAF-Q-406-G27	6	4			73										
	SAF-Q-409-G27	9	4			67	78									
	SAF-Q-412-G27	12	4			61	71									
	SAF-Q-509-G27	9	5			68	93									
	SAF-Q-609-G27	9	6			80	108									

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Table 3b		Drug		Patient Information								Flow Controller				
		Cutaquig		Patients aged 17 years or older								VersaRate Plus				
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN	
27G	SUB-104-G27	4	1			30	31	31	32	32	33	33	34	34	36	
	SUB-106-G27	6	1			29	29	30	30	31	31	32	32	32	34	
	SUB-109-G27	9	1			26	27	27	28	28	29	29	29	30	31	
	SUB-112-G27	12	1			24	24	25	25	26	26	26	27	27	28	
	SUB-204-G27	4	2			45	49	58	66	69	70	71	71	71	73	
	SUB-250	6	2			43	46	55	62	66	67	67	67	67	70	
	SUB-260	9	2			39	42	50	57	60	61	62	62	62	64	
	SUB-212-G27	12	2			36	39	46	52	55	56	56	56	56	58	
	SUB-310	6	3			66	75	82	88	93	97	101	105	108	116	
	SUB-320	9	3			60	68	75	80	85	89	93	96	99	107	
	SUB-312-G27	12	3			55	62	68	73	77	81	84	88	90	97	
	SUB-400	6	4			73	85	97	107	116	122	127	131	133	145	
	SUB-410	9	4			67	78	89	99	106	112	116	120	122	133	
	SUB-412-G27	12	4			61	71	81	90	97	102	106	109	111	121	
	SUB-414-G27	14	4			57	67	76	84	90	95	99	102	104	113	
	SUB-506	6	5			74	101	118	130	139	146	152	156	160	174	
	SUB-509	9	5			68	93	109	120	128	134	139	143	147	160	
	SUB-606	6	6			87	118	139	155	168	178	187	194	200	224	
	SUB-609	9	6			80	108	128	142	154	163	171	178	184	206	
	SAF-Q-106-G27	6	1			29	29	30	30	31	31	32	32	32	34	
	SAF-Q-109-G27	9	1			26	27	27	28	28	29	29	29	30	31	
	SAF-Q-112-G27	12	1			24	24	25	25	26	26	26	27	27	28	
	SAF-Q-206-G27	6	2			43	46	55	62	66	67	67	67	67	70	
	SAF-Q-209-G27	9	2			39	42	50	57	60	61	62	62	62	64	
	SAF-Q-212-G27	12	2			36	39	46	52	55	56	56	56	56	58	
	SAF-Q-306-G27	6	3			66	75	82	88	93	97	101	105	108	116	
	SAF-Q-309-G27	9	3			60	68	75	80	85	89	93	96	99	107	
	SAF-Q-312-G27	12	3			55	62	68	73	77	81	84	88	90	97	
	SAF-Q-406-G27	6	4			73	85	97	107	116	122	127	131	133	145	
	SAF-Q-409-G27	9	4			67	78	89	99	106	112	116	120	122	133	
	SAF-Q-412-G27	12	4			61	71	81	90	97	102	106	109	111	121	
	SAF-Q-509-G27	9	5			68	93	109	120	128	134	139	143	147	160	
	SAF-Q-609-G27	9	6			80	108	128	142	154	163	171	178	184	206	

SClg60® Infusion System

Infusing Cuvitru

The tables below only include combinations that will provide both total and per site flow rates that are within Cuvitru's dosage limits after system tolerances are applied. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 20 mL/h/site or 80 mL/h total)
	Suitable for maintenance infusions only (up to 60 mL/h/site or 240 mL/h total)
	No data available or may exceed prescribing information flow rate limits

Table 4				Drug						Flow Controller						
				Cuvitru						Infuset						
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
24G	SUB-109-G24	9	1				11	14	17			31				
	SUB-112-G24	12	1				10	13	16			28				
	SUB-209-G24	9	2						20	32		42	94			
	SUB-212-G24	12	2						18	29		38	85			
	SUB-309-G24	9	3							35		45	118			
	SUB-312-G24	12	3							32		41	107			
	SUB-409-G24	9	4									49	145			
	SUB-412-G24	12	4									44	132			
	SAF-Q-106-G24	6	1				12	15	19			33				
26G	SAF-Q-109-G24	9	1				11	14	17			31				
	SAF-Q-309-G24	9	3							35		45	118			
	OPT12604	4	1					15	19	26		31	48			
	OPT12606	6	1					15	19	26		31	48			
	OPT12609	9	1					15	19	26		31	48			
	OPT12612	12	1					15	19	26		31	48			
	OPT12614	14	1					14	17	25		29	45			
	OPT22604	4	2							32		45	94			
	OPT22606	6	2							32		45	94			
	OPT22609	9	2							32		45	94			
	OPT22612	12	2							32		45	94			
	OPT22614	14	2							30		42	88			
	OPT32606	6	3									51	122			
	OPT32609	9	3									51	122			
	OPT32612	12	3									51	122			
	OPT32614	14	3									48	114	148		
	OPT42606	6	4									52	146	194		
	OPT42609	9	4									52	146	194		
OPT42612	12	4									52	146	194			
OPT42614	14	4									49	137	183			

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Table 5				Drug			Flow Controller		
				Cuvitru			VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.									
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	11	17	26	35	47	
	SUB-112-G24	12	1	10	16	24	32	43	
	SUB-209-G24	9	2	11	20	33	50	87	
	SUB-212-G24	12	2	10	18	30	45	79	
	SUB-309-G24	9	3	11	21	35	58	107	
	SUB-312-G24	12	3	10	19	32	53	97	
	SUB-409-G24	9	4	12	23	37	65	141	
	SUB-412-G24	12	4	11	21	34	59	128	
	SAF-Q-106-G24	6	1	12	19	28	38		
	SAF-Q-109-G24	9	1	11	17	26	35	47	
SAF-Q-309-G24	9	3	11	21	35	58	107		
26G	OPT12604	4	1	13	20	28	33	47	
	OPT12606	6	1	13	20	28	33	47	
	OPT12609	9	1	13	20	28	33	47	
	OPT12612	12	1	13	20	28	33	47	
	OPT12614	14	1	12	19	26	31	44	
	OPT22604	4	2		24	38	54	83	
	OPT22606	6	2		24	38	54	83	
	OPT22609	9	2		24	38	54	83	
	OPT22612	12	2		24	38	54	83	
	OPT22614	14	2		23	35	51	78	
	OPT32606	6	3			41	65	106	
	OPT32609	9	3			41	65	106	
	OPT32612	12	3			41	65	106	
	OPT32614	14	3			39	61	100	
	OPT42606	6	4			43	70	119	
	OPT42609	9	4			43	70	119	
	OPT42612	12	4			43	70	119	
	OPT42614	14	4			40	66	112	

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Table 6				Drug					Flow Controller									
				Cuvitru					VersaRate Plus									
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																		
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)														
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN			
24G	SUB-109-G24	9	1		17	31	41											
	SUB-112-G24	12	1		16	29	38	44	48	50	50	50	50	50				
	SUB-209-G24	9	2		21	50	72	88										
	SUB-212-G24	12	2		19	46	66	80	90	95								
	SUB-309-G24	9	3		25	61	89	113	131									
	SUB-312-G24	12	3		23	55	81	103	119	132	141							
	SUB-409-G24	9	4		29	59	92	126	158	187								
	SUB-412-G24	12	4		26	54	84	114	144	170								
	SAF-Q-106-G24	6	1		19	34	45											
	SAF-Q-109-G24	9	1		17	31	41											
SAF-Q-309-G24	9	3		25	61	89	113	131										
26G	OPT12604	4	1	9	20	34	43											
	OPT12606	6	1	9	20	34	43											
	OPT12609	9	1	9	20	34	43											
	OPT12612	12	1	9	20	34	43											
	OPT12614	14	1	9	19	32	40	45										
	OPT22604	4	2		21	37	63	87										
	OPT22606	6	2		21	37	63	87										
	OPT22609	9	2		21	37	63	87										
	OPT22612	12	2		21	37	63	87										
	OPT22614	14	2		19	35	59	81										
	OPT32606	6	3		27	48	79	110	135									
	OPT32609	9	3		27	48	79	110	135									
	OPT32612	12	3		27	48	79	110	135									
	OPT32614	14	3		25	45	74	104	127	142								
	OPT42606	6	4			63	92	129	163	189								
	OPT42609	9	4			63	92	129	163	189								
OPT42612	12	4			63	92	129	163	189									
OPT42614	14	4			59	86	121	153	177									
27G	SUB-104-G27	4	1			15	17	18	19	20	20	20	21	21	21			
	SUB-106-G27	6	1			14	16	17	18	19	19	19	20	20	20			

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Table 6				Drug					Flow Controller						
				Cuvitru					VersaRate Plus						
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.															
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
	SUB-400	6	4			45	58	69	76	80	83	84	85	86	93
	SUB-410	9	4			41	53	63	70	74	76	77	78	79	85
	SUB-412-G27	12	4			38	49	58	64	67	69	70	71	72	77
	SUB-414-G27	14	4			35	45	54	59	63	65	66	67	67	72
	SAF-Q-106-G27	6	1			14	16	17	18	19	19	19	20	20	20
	SAF-Q-109-G27	9	1			13	15	16	16	17	17	18	18	18	18
	SAF-Q-112-G27	12	1			12	13	14	15	15	16	16	16	16	17
	SAF-Q-206-G27	6	2			27	32	35	38	39	40	41	42	42	45
	SAF-Q-209-G27	9	2			25	30	33	34	36	37	38	38	39	41
	SAF-Q-212-G27	12	2			23	27	30	31	33	34	34	35	35	37
	SAF-Q-306-G27	6	3			33	44	51	54	55	55	56	56	56	61
	SAF-Q-309-G27	9	3			30	41	47	49	50	51	51	51	51	56
	SAF-Q-312-G27	12	3			27	37	42	45	46	46	46	47	47	51
	SAF-Q-406-G27	6	4			45	58	69	76	80	83	84	85	86	93
	SAF-Q-409-G27	9	4			41	53	63	70	74	76	77	78	79	85
	SAF-Q-412-G27	12	4			38	49	58	64	67	69	70	71	72	77

SCIg60® Infusion System

Infusing Gammagard

The tables below only include combinations that will provide both total and per site flow rates that are within Gammagard dosage limits after system tolerances are applied. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions (Under 40 kg (88 lb) body weight: up to 15 mL/h/site; 40 kg (88 lb) and greater: up to 20 mL/h/site)
	Suitable for maintenance infusions only (Under 40 kg (88 lb) body weight: up to 20 mL/h/site; 40 kg (88 lb) and greater: up to 30 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 7a		Drug		Patient Information										Flow Controller			
		Gammagard		Patients <u>under</u> 40 kg (88 lb)										Infuset			
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
24G	SUB-109-G24	9	1	15													
	SUB-112-G24	12	1	14													
	SUB-209-G24	9	2		25	29											
	SUB-212-G24	12	2		23	26											
	SUB-409-G24	9	4			29											
	SUB-412-G24	12	4			26											
	SUB-512-G24	12	5				63										
	SUB-612-G24	12	6					95									
	SAF-Q-106-G24	6	1	16													
SAF-Q-109-G24	9	1	15														
26G	OPT12604	4	1	13													
	OPT12606	6	1	13													
	OPT12609	9	1	13													
	OPT12612	12	1	13													
	OPT12614	14	1	13													
	OPT22604	4	2	14	26												
	OPT22606	6	2	14	26												
	OPT22609	9	2	14	26												
	OPT22612	12	2	14	26												
	OPT22614	14	2	13	25												
	OPT32606	6	3			31											
	OPT32609	9	3			31											
	OPT32612	12	3			31											
	OPT32614	14	3			29											
	OPT42606	6	4			33											
	OPT42609	9	4			33											

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Table 7a		Drug		Patient Information										Flow Controller		
		Gammagard		Patients <u>under</u> 40 kg (88 lb)										Infuset		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
	OPT42612	12	4			33										
	OPT42614	14	4			31	64									
	OPT52606	6	5			32	67									
	OPT52609	9	5			32	67									
	OPT52612	12	5			32	67									
	OPT62609	9	6				65									
	OPT62612	12	6				65									
27G	SUB-104-G27	4	1	15												
	SUB-106-G27	6	1	14												
	SUB-109-G27	9	1	13												
	SUB-112-G27	12	1	12												
	SUB-204-G27	4	2			28										
	SUB-250	6	2			27										
	SUB-260	9	2			25										
	SUB-212-G27	12	2			22										
	SUB-312-G27	12	3				47									
	SUB-506	6	5				62									
	SUB-509	9	5				57									
	SUB-606	6	6					96								
	SUB-609	9	6					88								
	SAF-Q-106-G27	6	1	14												
	SAF-Q-109-G27	9	1	13												
	SAF-Q-112-G27	12	1	12												
	SAF-Q-206-G27	6	2			27										
	SAF-Q-209-G27	9	2			25										
	SAF-Q-212-G27	12	2			22										
	SAF-Q-312-G27	12	3				47									
	SAF-Q-509-G27	9	5				57									
	SAF-Q-609-G27	9	6					88								

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Table 7b		Drug		Patient Information								Flow Controller					
		Gammagard		Patients 40 kg (88 lb) and over								Infuset					
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
24G	SUB-109-G24	9	1	15	24												
	SUB-112-G24	12	1	14	21	25											
	SUB-209-G24	9	2		25	29											
	SUB-212-G24	12	2		23	26											
	SUB-309-G24	9	3				57										
	SUB-312-G24	12	3				52										
	SUB-409-G24	9	4			29		94									
	SUB-412-G24	12	4			26		86									
	SUB-512-G24	12	5				63										
	SUB-612-G24	12	6					95									
	SAF-Q-106-G24	6	1	16													
SAF-Q-109-G24	9	1	15	24													
SAF-Q-309-G24	9	3				57											
26G	OPT12604	4	1	13	25												
	OPT12606	6	1	13	25												
	OPT12609	9	1	13	25												
	OPT12612	12	1	13	25												
	OPT12614	14	1	13	24												
	OPT22604	4	2	14	26	36											
	OPT22606	6	2	14	26	36											
	OPT22609	9	2	14	26	36											
	OPT22612	12	2	14	26	36											
	OPT22614	14	2	13	25	34											
	OPT32606	6	3			31	66										
	OPT32609	9	3			31	66										
	OPT32612	12	3			31	66										
	OPT32614	14	3			29	62										
	OPT42606	6	4			33	68										
	OPT42609	9	4			33	68										
	OPT42612	12	4			33	68										
	OPT42614	14	4			31	64	98									
	OPT52606	6	5			32	67	103									
	OPT52609	9	5			32	67	103									
	OPT52612	12	5			32	67	103									
	OPT62609	9	6				65	109	135								
	OPT62612	12	6				65	109	135								

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Table 7b		Drug		Patient Information								Flow Controller					
		Gammagard		Patients 40 kg (88 lb) and over								Infuset					
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
27G	SUB-104-G27	4	1	15	23	25											
	SUB-106-G27	6	1	14	22	24											
	SUB-109-G27	9	1	13	20	22											
	SUB-112-G27	12	1	12	18	20											
	SUB-204-G27	4	2			28											
	SUB-250	6	2			27											
	SUB-260	9	2			25	47										
	SUB-212-G27	12	2			22	43										
	SUB-310	6	3				56										
	SUB-320	9	3				51	71									
	SUB-312-G27	12	3				47	64									
	SUB-400	6	4					87									
	SUB-410	9	4					80									
	SUB-412-G27	12	4					72									
	SUB-414-G27	14	4					68	96								
	SUB-506	6	5				62										
	SUB-509	9	5				57		121								
	SUB-606	6	6					96									
	SUB-609	9	6					88									
	SAF-Q-106-G27	6	1	14	22	24											
	SAF-Q-109-G27	9	1	13	20	22											
	SAF-Q-112-G27	12	1	12	18	20											
	SAF-Q-206-G27	6	2			27											
	SAF-Q-209-G27	9	2			25	47										
	SAF-Q-212-G27	12	2			22	43										
	SAF-Q-306-G27	6	3				56										
	SAF-Q-309-G27	9	3				51	71									
	SAF-Q-312-G27	12	3				47	64									
	SAF-Q-406-G27	6	4					87									
	SAF-Q-409-G27	9	4					80									
	SAF-Q-412-G27	12	4					72									
	SAF-Q-509-G27	9	5				57		121								
	SAF-Q-609-G27	9	6					88									

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Table 8a		Drug		Patient Information					Flow Controller	
		Gammagard		Patients <u>under</u> 40 kg (88 lb)					VersaRate	
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.										
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)						
Gauge	REF#	Length (mm)	# of Needles	½	1	2	3	4	5	6
26G	OPT32614	14	3	43						
	OPT42606	6	4	41						
	OPT42609	9	4	41						
	OPT42612	12	4	41						
	OPT42614	14	4	39						
	OPT52606	6	5	40						
	OPT52609	9	5	40						
	OPT52612	12	5	40						
	OPT62609	9	6		82					
OPT62612	12	6		82						
27G	SUB-320	9	3	42						
	SUB-312-G27	12	3	38						
	SUB-400	6	4	51						
	SUB-410	9	4	47						
	SUB-412-G27	12	4	43						
	SUB-414-G27	14	4	40	55					
	SUB-506	6	5	46						
	SUB-509	9	5	42						
	SAF-Q-309-G27	9	3	42						
	SAF-Q-312-G27	12	3	38						
	SAF-Q-406-G27	6	4	51						
	SAF-Q-409-G27	9	4	47						
	SAF-Q-412-G27	12	4	43						
	SAF-Q-509-G27	9	5	42						



The VersaRate flow regulator has markings around the circumference of the rotating dial denoting position settings that reference flow rates. Six markings have been designated with sequential numbers 1-6, with additional demarcations between each number. These demarcations between the numbers represent additional reference points that can be used to assist in controlling flow rates between the numbered position settings. The first of these reference points between OFF and Position 1, will be referred to as Position ½.

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Table 8b		Drug		Patient Information				Flow Controller		
		Gammagard		Patients 40 kg (88 lb) and over				VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.										
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)						
Gauge	REF#	Length (mm)	# of Needles	½	1	2	3	4	5	6
26G	OPT22604	4	2	35						
	OPT22606	6	2	35						
	OPT22609	9	2	35						
	OPT22612	12	2	35						
	OPT22614	14	2	33						
	OPT32606	6	3	45						
	OPT32609	9	3	45						
	OPT32612	12	3	45						
	OPT32614	14	3	43						
	OPT42606	6	4	41	81					
	OPT42609	9	4	41	81					
	OPT42612	12	4	41	81					
	OPT42614	14	4	39	76					
	OPT52606	6	5	40	72					
	OPT52609	9	5	40	72					
	OPT52612	12	5	40	72					
OPT62609	9	6		82						
OPT62612	12	6		82						
27G	SUB-260	9	2	43						
	SUB-212-G27	12	2	39						
	SUB-310	6	3	46						
	SUB-320	9	3	42	60					
	SUB-312-G27	12	3	38	55					
	SUB-400	6	4	51	71					
	SUB-410	9	4	47	65					
	SUB-412-G27	12	4	43	59					
	SUB-414-G27	14	4	40	55					
	SUB-506	6	5	46	77					
	SUB-509	9	5	42	71					
	SAF-Q-209-G27	9	2	43						
	SAF-Q-212-G27	12	2	39						
	SAF-Q-306-G27	6	3	46						
	SAF-Q-309-G27	9	3	42	60					
	SAF-Q-312-G27	12	3	38	55					
	SAF-Q-406-G27	6	4	51	71					
	SAF-Q-409-G27	9	4	47	65					
	SAF-Q-412-G27	12	4	43	59					
	SAF-Q-509-G27	9	5	42	71					

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Table 9a		Drug		Patient Information								Flow Controller			
		Gammagard		Patients <u>under</u> 40 kg (88 lb)								VersaRate Plus			
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.															
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SUB-410	9	4	51											
	SUB-412-G27	12	4	47											
	SUB-414-G27	14	4	43											
	SUB-506	6	5	57											
	SUB-509	9	5	53											
	SUB-606	6	6	56											
	SUB-609	9	6	52											
	SAF-Q-409-G27	9	4	51											
	SAF-Q-412-G27	12	4	47											
	SAF-Q-509-G27	9	5	53											
SAF-Q-609-G27	9	6	52												

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Table 9b		Drug		Patient Information									Flow Controller		
		Gammagard		Patients 40 kg (88 lb) and over									VersaRate Plus		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.															
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SUB-212-G27	12	2	40											
	SUB-310	6	3	50											
	SUB-320	9	3	46											
	SUB-312-G27	12	3	42											
	SUB-400	6	4	56											
	SUB-410	9	4	51											
	SUB-412-G27	12	4	47											
	SUB-414-G27	14	4	43											
	SUB-506	6	5	57											
	SUB-509	9	5	53											
	SUB-606	6	6	56	112										
	SUB-609	9	6	52	102										
	SAF-Q-212-G27	12	2	40											
	SAF-Q-306-G27	6	3	50											
	SAF-Q-309-G27	9	3	46											
	SAF-Q-312-G27	12	3	42											
	SAF-Q-406-G27	6	4	56											
	SAF-Q-409-G27	9	4	51											
	SAF-Q-412-G27	12	4	47											
	SAF-Q-509-G27	9	5	53											
SAF-Q-609-G27	9	6	52	102											

SClg60® Infusion System

Infusing Gamunex-C or Gammaked

The tables below only include combinations that will provide both total and per site flow rates that are within Gamunex-C and Gammaked dosage limits after system tolerances are applied. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions For Adults: Up to 20 mL/h/site For Pediatrics: Under 25 kg (55 lb) body weight: up to 10 mL/h/site; 25 kg (55 lb) and greater: up to 15 mL/h/site
	Suitable for maintenance infusions only For Adults: Up to 20 mL/h/site For Pediatrics: Under 25 kg (55 lb) body weight: up to 10 mL/h/site; 25 kg (55 lb) and greater: up to 20 mL/h/site
	No data available or may exceed prescribing information flow rate limits

Table 10a				Drug				Patient Information				Flow Controller					
				Gamunex-C or Gammaked				Adults				Infuset					
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
24G	SUB-109-G24	9	1	15													
	SUB-112-G24	12	1	14													
	SUB-209-G24	9	2		25	29											
	SUB-212-G24	12	2		23	26											
	SUB-409-G24	9	4			29											
	SUB-412-G24	12	4			26											
	SUB-512-G24	12	5				63										
	SUB-612-G24	12	6					95									
	SAF-Q-106-G24	6	1	16													
SAF-Q-109-G24	9	1	15														
26G	OPT12604	4	1	13													
	OPT12606	6	1	13													
	OPT12609	9	1	13													
	OPT12612	12	1	13													
	OPT12614	14	1	13													
	OPT22604	4	2	14	26												
	OPT22606	6	2	14	26												
	OPT22609	9	2	14	26												
	OPT22612	12	2	14	26												
	OPT22614	14	2	13	25												
	OPT32606	6	3			31											
	OPT32609	9	3			31											
	OPT32612	12	3			31											
	OPT32614	14	3			29											

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Table 10a				Drug				Patient Information				Flow Controller					
				Gamunex-C or Gammaked				Adults				Infuset					
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	OPT42606	6	4			33											
	OPT42609	9	4			33											
	OPT42612	12	4			33											
	OPT42614	14	4			31	64										
	OPT52606	6	5			32	67										
	OPT52609	9	5			32	67										
	OPT52612	12	5			32	67										
	OPT62609	9	6				65										
OPT62612	12	6				65											
27G	SUB-104-G27	4	1	15													
	SUB-106-G27	6	1	14													
	SUB-109-G27	9	1	13													
	SUB-112-G27	12	1	12													
	SUB-204-G27	4	2			28											
	SUB-250	6	2			27											
	SUB-260	9	2			25											
	SUB-212-G27	12	2			22											
	SUB-312-G27	12	3				47										
	SUB-506	6	5				62										
	SUB-509	9	5				57										
	SUB-606	6	6					96									
	SUB-609	9	6					88									
	SAF-Q-106-G27	6	1	14													
	SAF-Q-109-G27	9	1	13													
	SAF-Q-112-G27	12	1	12													
	SAF-Q-206-G27	6	2			27											
	SAF-Q-209-G27	9	2			25											
	SAF-Q-212-G27	12	2			22											
	SAF-Q-312-G27	12	3				47										
SAF-Q-509-G27	9	5				57											
SAF-Q-609-G27	9	6					88										

SCIg60® Infusion System

Table 10b		Drug				Patient Information							Flow Controller				
		Gamunex-C or Gammaked				Pediatrics 25 kg (55 lb) and over							Infuset				
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
24G	SUB-109-G24	9	1	15													
	SUB-112-G24	12	1	14													
	SUB-209-G24	9	2		25	29											
	SUB-212-G24	12	2		23	26											
	SUB-409-G24	9	4			29											
	SUB-412-G24	12	4			26											
	SUB-512-G24	12	5				63										
	SUB-612-G24	12	6					95									
	SAF-Q-106-G24	6	1	16													
SAF-Q-109-G24	9	1	15														
26G	OPT12604	4	1	13													
	OPT12606	6	1	13													
	OPT12609	9	1	13													
	OPT12612	12	1	13													
	OPT12614	14	1	13													
	OPT22604	4	2	14	26												
	OPT22606	6	2	14	26												
	OPT22609	9	2	14	26												
	OPT22612	12	2	14	26												
	OPT22614	14	2	13	25												
	OPT32606	6	3			31											
	OPT32609	9	3			31											
	OPT32612	12	3			31											
	OPT32614	14	3			29											
	OPT42606	6	4			33											
	OPT42609	9	4			33											
	OPT42612	12	4			33											
	OPT42614	14	4			31	64										
	OPT52606	6	5			32	67										
	OPT52609	9	5			32	67										
OPT52612	12	5			32	67											
OPT62609	9	6				65											
OPT62612	12	6				65											
27G	SUB-104-G27	4	1	15													
	SUB-106-G27	6	1	14													
	SUB-109-G27	9	1	13													
	SUB-112-G27	12	1	12													
	SUB-204-G27	4	2			28											

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Table 10b		Drug				Patient Information								Flow Controller			
		Gamunex-C or Gammaked				Pediatrics 25 kg (55 lb) and over								Infuset			
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	SUB-250	6	2			27											
	SUB-260	9	2			25											
	SUB-212-G27	12	2			22											
	SUB-312-G27	12	3				47										
	SUB-506	6	5				62										
	SUB-509	9	5				57										
	SUB-606	6	6					96									
	SUB-609	9	6					88									
	SAF-Q-106-G27	6	1	14													
	SAF-Q-109-G27	9	1	13													
	SAF-Q-112-G27	12	1	12													
	SAF-Q-206-G27	6	2			27											
	SAF-Q-209-G27	9	2			25											
	SAF-Q-212-G27	12	2			22											
	SAF-Q-312-G27	12	3				47										
	SAF-Q-509-G27	9	5				57										
	SAF-Q-609-G27	9	6					88									

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Table 10c		Drug					Patient Information							Flow Controller		
		Gamunex-C or Gammaked					Pediatrics under 25 kg (55 lb)							Infuset		
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
24G	SUB-409-G24	9	4			29										
	SUB-412-G24	12	4			26										
26G	OPT22604	4	2	14												
	OPT22606	6	2	14												
	OPT22609	9	2	14												
	OPT22612	12	2	14												
	OPT22614	14	2	13												
	OPT42606	6	4			33										
	OPT42609	9	4			33										
	OPT42612	12	4			33										
	OPT42614	14	4			31										
	OPT52606	6	5			32										
	OPT52609	9	5			32										
	OPT52612	12	5			32										

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Table 11a		Drug			Patient Information			Flow Controller		
		Gamunex-C or Gammaked			Adults			VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.										
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)						
Gauge	REF#	Length (mm)	# of Needles	½	1	2	3	4	5	6
26G	OPT32614	14	3	43						
	OPT42606	6	4	41						
	OPT42609	9	4	41						
	OPT42612	12	4	41						
	OPT42614	14	4	39						
	OPT52606	6	5	40						
	OPT52609	9	5	40						
	OPT52612	12	5	40						
	OPT62609	9	6		82					
OPT62612	12	6		82						
27G	SUB-320	9	3	42						
	SUB-312-G27	12	3	38						
	SUB-400	6	4	51						
	SUB-410	9	4	47						
	SUB-412-G27	12	4	43						
	SUB-414-G27	14	4	40	55					
	SUB-506	6	5	46						
	SUB-509	9	5	42						
	SAF-Q-309-G27	9	3	42						
	SAF-Q-312-G27	12	3	38						
	SAF-Q-406-G27	6	4	51						
	SAF-Q-409-G27	9	4	47						
	SAF-Q-412-G27	12	4	43						
	SAF-Q-509-G27	9	5	42						



The VersaRate flow regulator has markings around the circumference of the rotating dial denoting position settings that reference flow rates. Six markings have been designated with sequential numbers 1-6, with additional demarcations between each number. These demarcations between the numbers represent additional reference points that can be used to assist in controlling flow rates between the numbered position settings. The first of these reference points between OFF and Position 1, will be referred to as Position ½.

SClg60® Infusion System

Table 11b		Drug			Patient Information				Flow Controller	
		Gamunex-C or Gammaked			Pediatrics 25 kg (55 lb) and over				VersaRate	
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.										
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)						
Gauge	REF#	Length (mm)	# of Needles	½	1	2	3	4	5	6
26G	OPT32614	14	3	43						
	OPT42606	6	4	41						
	OPT42609	9	4	41						
	OPT42612	12	4	41						
	OPT42614	14	4	39						
	OPT52606	6	5	40						
	OPT52609	9	5	40						
	OPT52612	12	5	40						
	OPT62609	9	6		82					
OPT62612	12	6		82						
27G	SUB-320	9	3	42						
	SUB-312-G27	12	3	38						
	SUB-400	6	4	51						
	SUB-410	9	4	47						
	SUB-412-G27	12	4	43						
	SUB-414-G27	14	4	40	55					
	SUB-506	6	5	46						
	SUB-509	9	5	42						
	SAF-Q-309-G27	9	3	42						
	SAF-Q-312-G27	12	3	38						
	SAF-Q-406-G27	6	4	51						
	SAF-Q-409-G27	9	4	47						
	SAF-Q-412-G27	12	4	43						
	SAF-Q-509-G27	9	5	42						

Gamunex-C or Gammaked with VersaRate for Pediatrics Under 25 kg (55lbs)

For pediatric patients weighing less than 25kg, the infusion flow rate limit is 10mL/hr/site for both initial and maintenance infusions. All preceding configurations with VersaRate have flow rates that exceed this limit.

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Table 12a				Drug				Patient Information				Flow Controller			
				Gamunex-C or Gammaked				Adults				VersaRate Plus			
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SUB-410	9	4	51											
	SUB-412-G27	12	4	47											
	SUB-414-G27	14	4	43											
	SUB-506	6	5	57											
	SUB-509	9	5	53											
	SUB-606	6	6	56											
	SUB-609	9	6	52											
	SAF-Q-409-G27	9	4	51											
	SAF-Q-412-G27	12	4	47											
	SAF-Q-509-G27	9	5	53											
SAF-Q-609-G27	9	6	52												

Table 12b				Drug				Patient Information					Flow Controller			
				Gamunex-C or Gammaked				Pediatrics 25 kg (55 lb) and over					VersaRate Plus			
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.																
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN	
27G	SUB-410	9	4	51												
	SUB-412-G27	12	4	47												
	SUB-414-G27	14	4	43												
	SUB-506	6	5	57												
	SUB-509	9	5	53												
	SUB-606	6	6	56												
	SUB-609	9	6	52												
	SAF-Q-409-G27	9	4	51												
	SAF-Q-412-G27	12	4	47												
	SAF-Q-509-G27	9	5	53												
SAF-Q-609-G27	9	6	52													

Gamunex-C or Gammaked with VersaRate Plus for Pediatrics Under 25 kg (55lbs)

For pediatric patients weighing less than 25 kg, the infusion flow rate limit is 10 ml/hr/site for both initial and maintenance infusions. All preceding configurations with VersaRate Plus have flow rates that exceed this limit.

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Infusing Hizentra for Primary Immunodeficiency (PI)

The tables below only include combinations that will provide both total and per site flow rates that are within Hizentra dosage limits after system tolerances are applied for patients diagnosed with PI. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 15 mL/h/site)
	Suitable for maintenance infusions only (up to 25 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 13				Drug						Flow Controller							
				Hizentra (PI)						Infuset							
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
24G	SUB-109-G24	9	1				12	16									
	SUB-112-G24	12	1				11	15									
	SUB-209-G24	9	2						26	35							
	SUB-212-G24	12	2						24	32							
	SUB-309-G24	9	3							39	49	51					
	SUB-312-G24	12	3							35	45	47					
	SUB-409-G24	9	4							39	48	52					
	SUB-412-G24	12	4							35	44	47					
	SUB-512-G24	12	5							39		52	100				
	SUB-612-G24	12	6							39	47	53	117				
	SAF-Q-106-G24	6	1				13	17									
SAF-Q-109-G24	9	1				12	16										
SAF-Q-309-G24	9	3							39	49	51						
26G	OPT12604	4	1				11	17	19								
	OPT12606	6	1				11	17	19								
	OPT12609	9	1				11	17	19								
	OPT12612	12	1				11	17	19								
	OPT12614	14	1				11	16	17								
	OPT22604	4	2						22	36							
	OPT22606	6	2						22	36							
	OPT22609	9	2						22	36							
	OPT22612	12	2						22	36							
	OPT22614	14	2						21	33							
	OPT32606	6	3							38	55	55					
	OPT32609	9	3							38	55	55					
	OPT32612	12	3							38	55	55					
	OPT32614	14	3							36	51	52					
	OPT42606	6	4							42	58	57					
	OPT42609	9	4							42	58	57					
	OPT42612	12	4							42	58	57					

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Table 13				Drug						Flow Controller							
				Hizentra (PI)						Infuset							
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	OPT42614	14	4							39	55	53					
	OPT52606	6	5								62	65					
	OPT52609	9	5								62	65					
	OPT52612	12	5								62	65					
	OPT62609	9	6								65	66					
	OPT62612	12	6								65	66					
27G	SUB-104-G27	4	1							16	18		20				
	SUB-106-G27	6	1							15	17		19				
	SUB-109-G27	9	1							14	15		17				
	SUB-112-G27	12	1							12	14		16				
	SUB-204-G27	4	2									29	34				
	SUB-250	6	2									27	32				
	SUB-260	9	2									25	30				
	SUB-212-G27	12	2									23	27				
	SUB-310	6	3									36	46				
	SUB-320	9	3									33	43				
	SUB-312-G27	12	3									30	39				
	SUB-400	6	4									40	53				
	SUB-410	9	4									37	49				
	SUB-412-G27	12	4									33	44				
	SUB-414-G27	14	4									31	42				
	SUB-506	6	5									46	63				
	SUB-509	9	5									42	57				
	SUB-606	6	6								44	46	76				
	SUB-609	9	6									41	42	70			
	SAF-Q-106-G27	6	1								15	17		19			
	SAF-Q-109-G27	9	1								14	15		17			
	SAF-Q-112-G27	12	1								12	14		16			
	SAF-Q-206-G27	6	2										27	32			
	SAF-Q-209-G27	9	2										25	30			
	SAF-Q-212-G27	12	2										23	27			
	SAF-Q-306-G27	6	3										36	46			
	SAF-Q-309-G27	9	3										33	43			
	SAF-Q-312-G27	12	3										30	39			
	SAF-Q-406-G27	6	4										40	53			
	SAF-Q-409-G27	9	4										37	49			
	SAF-Q-412-G27	12	4										33	44			
	SAF-Q-509-G27	9	5										42	57			
	SAF-Q-609-G27	9	6									41	42	70			

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Table 14				Drug			Flow Controller		
				Hizentra (PI)			VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.									
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	14					
	SUB-112-G24	12	1	13					
	SUB-209-G24	9	2	15	27				
	SUB-212-G24	12	2	14	25	39			
	SUB-309-G24	9	3	17	27	50			
	SUB-312-G24	12	3	16	25	45			
	SUB-409-G24	9	4	17	30	49	80		
	SUB-412-G24	12	4	15	27	44	73		
	SUB-512-G24	12	5	16	31	49	79		
	SUB-612-G24	12	6	16	32	50	79		
	SAF-Q-106-G24	6	1	16					
	SAF-Q-109-G24	9	1	14					
SAF-Q-309-G24	9	3	17	27	50				
26G	OPT12604	4	1	13					
	OPT12606	6	1	13					
	OPT12609	9	1	13					
	OPT12612	12	1	13					
	OPT12614	14	1	13					
	OPT22604	4	2		26	39			
	OPT22606	6	2		26	39			
	OPT22609	9	2		26	39			
	OPT22612	12	2		26	39			
	OPT22614	14	2		25	36			
	OPT32606	6	3		28	43			
	OPT32609	9	3		28	43			
	OPT32612	12	3		28	43			
	OPT32614	14	3		26	41			
	OPT42606	6	4			47	75		
	OPT42609	9	4			47	75		
	OPT42612	12	4			47	75		
	OPT42614	14	4			44	71		
	OPT52606	6	5			48	82		
	OPT52609	9	5			48	82		
	OPT52612	12	5			48	82		
	OPT62609	9	6				81		
	OPT62612	12	6				81		
27G	SUB-104-G27	4	1	11	14	17	18	20	
	SUB-106-G27	6	1	11	13	16	17	19	20
	SUB-109-G27	9	1	10	12	15	16	17	18
	SUB-112-G27	12	1	9	11	13	14	16	16

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Table 14				Drug			Flow Controller		
				Hizentra (PI)			VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.									
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
	SUB-204-G27	4	2	12	19	26	32	36	
	SUB-250	6	2	12	18	24	30	34	39
	SUB-260	9	2	11	17	22	28	31	36
	SUB-212-G27	12	2	10	15	20	25	28	33
	SUB-310	6	3	14	23	33	40	50	
	SUB-320	9	3	13	21	30	37	46	59
	SUB-312-G27	12	3	11	19	27	33	42	54
	SUB-400	6	4	14	26	37	51	66	80
	SUB-410	9	4	13	24	34	47	61	73
	SUB-412-G27	12	4	A	22	31	43	55	67
	SUB-414-G27	14	4	11	20	28	40	52	62
	SUB-506	6	5	16	26	37	53	73	94
	SUB-509	9	5	15	24	34	49	67	87
	SUB-606	6	6	16	28	40	58	82	117
	SUB-609	9	6	14	25	37	53	75	108
	SAF-Q-106-G27	6	1	11	13	16	17	19	20
	SAF-Q-109-G27	9	1	10	12	15	16	17	18
	SAF-Q-112-G27	12	1	9	11	13	14	16	16
	SAF-Q-206-G27	6	2	12	18	24	30	34	39
	SAF-Q-209-G27	9	2	11	17	22	28	31	36
	SAF-Q-212-G27	12	2	10	15	20	25	28	33
	SAF-Q-306-G27	6	3	14	23	33	40	50	
	SAF-Q-309-G27	9	3	13	21	30	37	46	59
	SAF-Q-312-G27	12	3	11	19	27	33	42	54
	SAF-Q-406-G27	6	4	14	26	37	51	66	80
	SAF-Q-409-G27	9	4	13	24	34	47	61	73
	SAF-Q-412-G27	12	4	12	22	31	43	55	67
	SAF-Q-509-G27	9	5	15	24	34	49	67	87
	SAF-Q-609-G27	9	6	14	25	37	53	75	108

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Table 15				Drug					Flow Controller						
				Hizentra (PI)					VersaRate Plus						
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.															
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
24G	SUB-212-G24	12	2		33										
	SUB-309-G24	9	3		40										
	SUB-312-G24	12	3		36										
	SUB-409-G24	9	4		34	76									
	SUB-412-G24	12	4		31	69									
	SAF-Q-212-G24-70	12	2		33										
	SAF-Q-309-G24	9	3		40										
	SAF-Q-312-G24-70	12	3		37										
	SAF-Q-409-G24-70	9	4		43										
SAF-Q-412-G24-70	12	4		39	77										
26G	OPT12604	4	1	12											
	OPT12606	6	1	12											
	OPT12609	9	1	12											
	OPT12612	12	1	12											
	OPT12614	14	1	12											
	OPT22604	4	2	16	32										
	OPT22606	6	2	16	32										
	OPT22609	9	2	16	32										
	OPT22612	12	2	16	32										
	OPT22614	14	2	15	30										
	OPT32606	6	3		32										
	OPT32609	9	3		32										
	OPT32612	12	3		32										
	OPT32614	14	3		30										
	OPT42606	6	4		38	77									
	OPT42609	9	4		38	77									
	OPT42612	12	4		38	77									
	OPT42614	14	4		36	72									
	OPT52606	6	5			84									
	OPT52609	9	5			84									
OPT52612	12	5			84										
OPT62609	9	6				106									
OPT62612	12	6				106									
27G	SUB-104-G27	4	1		15	17	18	20	20						
	SUB-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SUB-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SUB-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SUB-106-G27-70	6	1		16	18									
	SUB-109-G27-70	9	1		15	17	18	19	20						
	SUB-112-G27-70	12	1		13	15	16	18	19	19	20	20	20	20	20

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Table 15				Drug					Flow Controller						
				Hizentra (PI)					VersaRate Plus						
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.															
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
	SUB-204-G27	4	2		23	29	34	37	38	39	39	39	40	41	
	SUB-250	6	2		22	28	32	35	36	37	37	37	38	38	40
	SUB-260	9	2		20	26	30	32	33	34	34	34	35	35	37
	SUB-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SUB-310	6	3		27	37	44	50	54	56	58	58	58	58	63
	SUB-320	9	3		25	34	41	46	49	52	53	53	54	54	58
	SUB-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SUB-400	6	4		34	47	57	65	70	74	77	79			
	SUB-410	9	4		31	43	52	59	64	68	71	73	75	78	82
	SUB-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SUB-414-G27	14	4		26	37	44	50	55	58	60	62	64	67	70
	SUB-506	6	5		20	45	63	77	86	92	96	98	101	103	
	SUB-509	9	5		19	41	58	70	79	84	88	90	92	95	99
	SUB-606	6	6		16	45	68	85	98	107	114				
	SUB-609	9	6		14	41	62	78	90	98	104	109	113	117	122
	SAF-Q-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SAF-Q-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SAF-Q-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SAF-Q-109-G27-70	9	1		15	17	18	19	20						
	SAF-Q-206-G27	6	2		22	28	32	35	36	37	37	37	38	38	40
	SAF-Q-209-G27	9	2		20	26	30	32	33	34	34	34	35	35	37
	SAF-Q-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SAF-Q-306-G27	6	3		27	37	44	50	54	56	58	58	58	58	63
	SAF-Q-309-G27	9	3		25	34	41	46	49	52	53	53	54	54	58
	SAF-Q-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SAF-Q-406-G27	6	4		34	47	57	65	70	74	77	79			
	SAF-Q-409-G27	9	4		31	43	52	59	64	68	71	73	75	78	82
	SAF-Q-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SAF-Q-509-G27	9	5		19	41	58	70	79	84	88	90	92	95	99
	SAF-Q-609-G27	9	6		14	41	62	78	90	98	104	109	113	117	122

SClg60® Infusion System

Infusing Hizentra for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

The tables below only include combinations that will provide both total and per site flow rates that are within Hizentra dosage limits after system tolerances are applied for patients diagnosed with CIDP. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 20 mL/h/site)
	Suitable for maintenance infusions only (up to 50 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 16				Drug						Flow Controller							
				Hizentra (CIDP)						Infuset							
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
24G	SUB-109-G24	9	1				12	16	23	30		37					
	SUB-112-G24	12	1				11	15	21	27		33					
	SUB-209-G24	9	2						26	35	48	52					
	SUB-212-G24	12	2						24	32	44	48					
	SUB-309-G24	9	3							39	49	51					
	SUB-312-G24	12	3							35	45	47	124				
	SUB-409-G24	9	4							39	48	52	111				
	SUB-412-G24	12	4							35	44	47	101				
	SUB-512-G24	12	5							39		52	100				
	SUB-612-G24	12	6							39	47	53	117				
	SAF-Q-106-G24	6	1				13	17	25	32		40					
	SAF-Q-109-G24	9	1				12	16	23	30		37					
SAF-Q-309-G24	9	3							39	49	51						
26G	OPT12604	4	1				11	17	19	27	35	34					
	OPT12606	6	1				11	17	19	27	35	34					
	OPT12609	9	1				11	17	19	27	35	34					
	OPT12612	12	1				11	17	19	27	35	34					
	OPT12614	14	1				11	16	17	25	33	32					
	OPT22604	4	2						22	36	49	49					
	OPT22606	6	2						22	36	49	49					
	OPT22609	9	2						22	36	49	49					
	OPT22612	12	2						22	36	49	49					
	OPT22614	14	2						21	33	46	46					
	OPT32606	6	3							38	55	55					
	OPT32609	9	3							38	55	55					
	OPT32612	12	3							38	55	55					
	OPT32614	14	3							36	51	52					
	OPT42606	6	4							42	58	57	163				
	OPT42609	9	4							42	58	57	163				

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Table 16				Drug						Flow Controller							
				Hizentra (CIDP)						Infuset							
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																	
SUB-Q Set				Total flow rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	OPT42612	12	4							42	58	57	163				
	OPT42614	14	4							39	55	53	153				
	OPT52606	6	5								62	65	183				
	OPT52609	9	5								62	65	183				
	OPT52612	12	5								62	65	183				
	OPT62609	9	6								65	66	200				
	OPT62612	12	6								65	66	200				
27G	SUB-104-G27	4	1							16	18		20				
	SUB-106-G27	6	1							15	17		19				
	SUB-109-G27	9	1							14	15		17				
	SUB-112-G27	12	1							12	14		16				
	SUB-204-G27	4	2									29	34				
	SUB-250	6	2									27	32				
	SUB-260	9	2									25	30				
	SUB-212-G27	12	2									23	27				
	SUB-310	6	3									36	46				
	SUB-320	9	3									33	43				
	SUB-312-G27	12	3									30	39				
	SUB-400	6	4									40	53				
	SUB-410	9	4									37	49				
	SUB-412-G27	12	4									33	44				
	SUB-414-G27	14	4									31	42				
	SUB-506	6	5									46	63				
	SUB-509	9	5									42	57				
	SUB-606	6	6								44	46	76				
	SUB-609	9	6								41	42	70				
	SAF-Q-106-G27	6	1								15	17		19			
	SAF-Q-109-G27	9	1								14	15		17			
	SAF-Q-112-G27	12	1								12	14		16			
	SAF-Q-206-G27	6	2										27	32			
	SAF-Q-209-G27	9	2										25	30			
	SAF-Q-212-G27	12	2										23	27			
	SAF-Q-306-G27	6	3										36	46			
	SAF-Q-309-G27	9	3										33	43			
	SAF-Q-312-G27	12	3										30	39			
	SAF-Q-406-G27	6	4										40	53			
	SAF-Q-409-G27	9	4										37	49			
	SAF-Q-412-G27	12	4										33	44			
	SAF-Q-509-G27	9	5										42	57			
	SAF-Q-609-G27	9	6														

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Table 17				Drug			Flow Controller		
				Hizentra (CIDP)			VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.									
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	14	24	33			
	SUB-112-G24	12	1	13	22	30	40		
	SUB-209-G24	9	2	15	27	43	64		
	SUB-212-G24	12	2	14	25	39	58		
	SUB-309-G24	9	3	17	27	50	76	123	
	SUB-312-G24	12	3	16	25	45	69	112	
	SUB-409-G24	9	4	17	30	49	80	149	
	SUB-412-G24	12	4	15	27	44	73	136	
	SUB-512-G24	12	5	16	31	49	79	141	
	SUB-612-G24	12	6	16	32	50	79	156	
	SAF-Q-106-G24	6	1	16	26	36			
SAF-Q-109-G24	9	1	14	24	33				
SAF-Q-309-G24	9	3	17	27	50	76	123		
26G	OPT12604	4	1	13	21	30	38		
	OPT12606	6	1	13	21	30	38		
	OPT12609	9	1	13	21	30	38		
	OPT12612	12	1	13	21	30	38		
	OPT12614	14	1	13	20	28	36		
	OPT22604	4	2		26	39	59		
	OPT22606	6	2		26	39	59		
	OPT22609	9	2		26	39	59		
	OPT22612	12	2		26	39	59		
	OPT22614	14	2		25	36	56		
	OPT32606	6	3		28	43	67	116	
	OPT32609	9	3		28	43	67	116	
	OPT32612	12	3		28	43	67	116	
	OPT32614	14	3		26	41	63	109	
	OPT42606	6	4			47	75	140	
	OPT42609	9	4			47	75	140	
	OPT42612	12	4			47	75	140	
	OPT42614	14	4			44	71	132	
	OPT52606	6	5			48	82	144	
	OPT52609	9	5			48	82	144	
	OPT52612	12	5			48	82	144	
OPT62609	9	6				81	154		
OPT62612	12	6				81	154		
27G	SUB-104-G27	4	1	11	14	17	18	20	21
	SUB-106-G27	6	1	11	13	16	17	19	20
	SUB-109-G27	9	1	10	12	15	16	17	18

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Table 17				Drug			Flow Controller		
				Hizentra (CIDP)			VersaRate		
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.									
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
	SUB-112-G27	12	1	9	11	13	14	16	16
	SUB-204-G27	4	2	12	19	26	32	36	42
	SUB-250	6	2	12	18	24	30	34	39
	SUB-260	9	2	11	17	22	28	31	36
	SUB-212-G27	12	2	10	15	20	25	28	33
	SUB-310	6	3	14	23	33	40	50	64
	SUB-320	9	3	13	21	30	37	46	59
	SUB-312-G27	12	3	11	19	27	33	42	54
	SUB-400	6	4	14	26	37	51	66	80
	SUB-410	9	4	13	24	34	47	61	73
	SUB-412-G27	12	4	12	22	31	43	55	67
	SUB-414-G27	14	4	11	20	28	40	52	62
	SUB-506	6	5	16	26	37	53	73	94
	SUB-509	9	5	15	24	34	49	67	87
	SUB-606	6	6	16	28	40	58	82	117
	SUB-609	9	6	14	25	37	53	75	108
	SAF-Q-106-G27	6	1	11	13	16	17	19	20
	SAF-Q-109-G27	9	1	10	12	15	16	17	18
	SAF-Q-112-G27	12	1	9	11	13	14	16	16
	SAF-Q-206-G27	6	2	12	18	24	30	34	39
	SAF-Q-209-G27	9	2	11	17	22	28	31	36
	SAF-Q-212-G27	12	2	10	15	20	25	28	33
	SAF-Q-306-G27	6	3	14	23	33	40	50	64
	SAF-Q-309-G27	9	3	13	21	30	37	46	59
	SAF-Q-312-G27	12	3	11	19	27	33	42	54
	SAF-Q-406-G27	6	4	14	26	37	51	66	80
	SAF-Q-409-G27	9	4	13	24	34	47	61	73
	SAF-Q-412-G27	12	4	12	22	31	43	55	67
	SAF-Q-509-G27	9	5	15	24	34	49	67	87
	SAF-Q-609-G27	9	6	14	25	37	53	75	108

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Table 18				Drug				Flow Controller								
				Hizentra (CIDP)				VersaRate Plus								
Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.																
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN	
24G	SUB-109-G24	9	1		31											
	SUB-112-G24	12	1		28	38										
	SUB-209-G24	9	2		36	60										
	SUB-212-G24	12	2		33	54	73									
	SUB-309-G24	9	3		40	69	95	118								
	SUB-312-G24	12	3		36	62	86	107								
	SUB-409-G24	9	4		34	76	112	144								
	SUB-412-G24	12	4		31	69	102	131	155							
	SAF-Q-106-G24	6	1		33											
	SAF-Q-109-G24	9	1		31											
	SAF-Q-112-G24-70	12	1		29											
	SAF-Q-206-G24-70	6	2		39	66										
	SAF-Q-209-G24-70	9	2		36	60										
	SAF-Q-212-G24-70	12	2		33	55	72									
	SAF-Q-309-G24	9	3		40	69	95	118								
SAF-Q-312-G24-70	12	3		37	73	105										
SAF-Q-409-G24-70	9	4		43	84	123										
SAF-Q-412-G24-70	12	4		39	77	113	146									
26G	OPT12604	4	1	12	24											
	OPT12606	6	1	12	24											
	OPT12609	9	1	12	24											
	OPT12612	12	1	12	24											
	OPT12614	14	1	12	22											
	OPT22604	4	2	16	32	57	71									
	OPT22606	6	2	16	32	57	71									
	OPT22609	9	2	16	32	57	71									
	OPT22612	12	2	16	32	57	71									
	OPT22614	14	2	15	30	53	67									
	OPT32606	6	3		32	74	92									
	OPT32609	9	3		32	74	92									
	OPT32612	12	3		32	74	92									
	OPT32614	14	3		30	69	87									
	OPT42606	6	4		38	77	103	152								
	OPT42609	9	4		38	77	103	152								
	OPT42612	12	4		38	77	103	152								
	OPT42614	14	4		36	72	97	143	151							
	OPT52606	6	5			84	113	155	186							
	OPT52609	9	5			84	113	155	186							
OPT52612	12	5			84	113	155	186								
OPT62609	9	6				106	167	199								

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Table 18				Drug					Flow Controller						
				Hizentra (CIDP)					VersaRate Plus						
Values shaded in yellow are only suitable for maintenance infusions according to the drug’s prescribing information.															
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
	OPT62612	12	6				106	167	199						
27G	SUB-104-G27	4	1		15	17	18	20	20	21	21	21	22	22	22
	SUB-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SUB-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SUB-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SUB-106-G27-70	6	1		16	18	20	21	22	23	24	24	24	24	24
	SUB-109-G27-70	9	1		15	17	18	19	20	21	22	22	22	22	22
	SUB-112-G27-70	12	1		13	15	16	18	19	19	20	20	20	20	20
	SUB-204-G27	4	2		23	29	34	37	38	39	39	39	40	41	43
	SUB-250	6	2		22	28	32	35	36	37	37	37	38	38	40
	SUB-260	9	2		20	26	30	32	33	34	34	34	35	35	37
	SUB-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SUB-310	6	3		27	37	44	50	54	56	58	58	58	58	63
	SUB-320	9	3		25	34	41	46	49	52	53	53	54	54	58
	SUB-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SUB-400	6	4		34	47	57	65	70	74	77	79	82	85	90
	SUB-410	9	4		31	43	52	59	64	68	71	73	75	78	82
	SUB-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SUB-414-G27	14	4		26	37	44	50	55	58	60	62	64	67	70
	SUB-506	6	5		20	45	63	77	86	92	96	98	101	103	108
	SUB-509	9	5		19	41	58	70	79	84	88	90	92	95	99
	SUB-606	6	6		16	45	68	85	98	107	114	119	123	127	133
	SUB-609	9	6		14	41	62	78	90	98	104	109	113	117	122
	SAF-Q-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SAF-Q-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SAF-Q-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SAF-Q-109-G27-70	9	1		15	17	18	19	20	21	22	22	22	22	22
	SAF-Q-														

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Infusing Xembify

The tables below only include combinations that provide total flow rates that are within Xembify dosage limits after system tolerances are applied. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 25 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 19				Drug						Flow Controller						
				Xembify						Infuset						
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)												
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
24G	SUB-109-G24	9	1				12	16								
	SUB-112-G24	12	1				11	15								
	SUB-209-G24	9	2						26	35						
	SUB-212-G24	12	2						24	32						
	SUB-309-G24	9	3							39	49	51				
	SUB-312-G24	12	3							35	45	47				
	SUB-409-G24	9	4							39	48	52				
	SUB-412-G24	12	4							35	44	47				
	SUB-512-G24	12	5							39		52	100			
	SUB-612-G24	12	6							39	47	53	117			
	SAF-Q-106-G24	6	1				13	17								
	SAF-Q-109-G24	9	1				12	16								
SAF-Q-309-G24	9	3							39	49	51					
26G	OPT12604	4	1				11	17	19							
	OPT12606	6	1				11	17	19							
	OPT12609	9	1				11	17	19							
	OPT12612	12	1				11	17	19							
	OPT12614	14	1				11	16	17							
	OPT22604	4	2						22	36						
	OPT22606	6	2						22	36						
	OPT22609	9	2						22	36						
	OPT22612	12	2						22	36						
	OPT22614	14	2						21	33						
	OPT32606	6	3							38	55	55				
	OPT32609	9	3							38	55	55				
	OPT32612	12	3							38	55	55				
	OPT32614	14	3							36	51	52				
	OPT42606	6	4							42	58	57				
	OPT42609	9	4							42	58	57				
	OPT42612	12	4							42	58	57				
	OPT42614	14	4							39	55	53				

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Table 19				Drug						Flow Controller							
				Xembify						Infuset							
SUB-Q Set				Total Flow Rate for ALL sites with Infuset Flow Controller (mL/h)													
Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300	
	OPT52606	6	5								62	65					
	OPT52609	9	5								62	65					
	OPT52612	12	5								62	65					
	OPT62609	9	6								65	66					
	OPT62612	12	6								65	66					
27G	SUB-104-G27	4	1							16	18		20				
	SUB-106-G27	6	1							15	17		19				
	SUB-109-G27	9	1							14	15		17				
	SUB-112-G27	12	1							12	14		16				
	SUB-204-G27	4	2									29	34				
	SUB-250	6	2									27	32				
	SUB-260	9	2									25	30				
	SUB-212-G27	12	2									23	27				
	SUB-310	6	3									36	46				
	SUB-320	9	3									33	43				
	SUB-312-G27	12	3									30	39				
	SUB-400	6	4									40	53				
	SUB-410	9	4									37	49				
	SUB-412-G27	12	4									33	44				
	SUB-414-G27	14	4									31	42				
	SUB-506	6	5									46	63				
	SUB-509	9	5									42	57				
	SUB-606	6	6									44	46	76			
	SUB-609	9	6									41	42	70			
	SAF-Q-106-G27	6	1								15	17		19			
	SAF-Q-109-G27	9	1								14	15		17			
	SAF-Q-112-G27	12	1								12	14		16			
	SAF-Q-206-G27	6	2										27	32			
	SAF-Q-209-G27	9	2										25	30			
	SAF-Q-212-G27	12	2										23	27			
	SAF-Q-306-G27	6	3										36	46			
	SAF-Q-309-G27	9	3										33	43			
	SAF-Q-312-G27	12	3										30	39			
	SAF-Q-406-G27	6	4										40	53			
	SAF-Q-409-G27	9	4										37	49			
	SAF-Q-412-G27	12	4										33	44			
	SAF-Q-509-G27	9	5										42	57			
	SAF-Q-609-G27	9	6									41	42	70			

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Table 20				Drug			Flow Controller		
				Xembify			VersaRate		
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	14					
	SUB-112-G24	12	1	13					
	SUB-209-G24	9	2	15	27				
	SUB-212-G24	12	2	14	25	39			
	SUB-309-G24	9	3	17	27	50			
	SUB-312-G24	12	3	16	25	45			
	SUB-409-G24	9	4	17	30	49	80		
	SUB-412-G24	12	4	15	27	44	73		
	SUB-512-G24	12	5	16	31	49	79		
	SUB-612-G24	12	6	16	32	50	79		
	SAF-Q-106-G24	6	1	16					
	SAF-Q-109-G24	9	1	14					
SAF-Q-309-G24	9	3	17	27	50				
26G	OPT12604	4	1	13					
	OPT12606	6	1	13					
	OPT12609	9	1	13					
	OPT12612	12	1	13					
	OPT12614	14	1	13					
	OPT22604	4	2		26	39			
	OPT22606	6	2		26	39			
	OPT22609	9	2		26	39			
	OPT22612	12	2		26	39			
	OPT22614	14	2		25	36			
	OPT32606	6	3		28	43			
	OPT32609	9	3		28	43			
	OPT32612	12	3		28	43			
	OPT32614	14	3		26	41			
	OPT42606	6	4			47	75		
	OPT42609	9	4			47	75		
	OPT42612	12	4			47	75		
	OPT42614	14	4			44	71		
	OPT52606	6	5			48	82		
	OPT52609	9	5			48	82		
	OPT52612	12	5			48	82		
OPT62609	9	6				81			
OPT62612	12	6				81			
27G	SUB-104-G27	4	1	11	14	17	18	20	
	SUB-106-G27	6	1	11	13	16	17	19	20
	SUB-109-G27	9	1	10	12	15	16	17	18
	SUB-112-G27	12	1	9	11	13	14	16	16
	SUB-204-G27	4	2	12	19	26	32	36	
	SUB-250	6	2	12	18	24	30	34	39

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Table 20				Drug			Flow Controller		
				Xembify			VersaRate		
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Flow Controller (mL/h)					
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6
	SUB-260	9	2	11	17	22	28	31	36
	SUB-212-G27	12	2	10	15	20	25	28	33
	SUB-310	6	3	14	23	33	40	50	
	SUB-320	9	3	13	21	30	37	46	59
	SUB-312-G27	12	3	11	19	27	33	42	54
	SUB-400	6	4	14	26	37	51	66	80
	SUB-410	9	4	13	24	34	47	61	73
	SUB-412-G27	12	4	12	22	31	43	55	67
	SUB-414-G27	14	4	11	20	28	40	52	62
	SUB-506	6	5	16	26	37	53	73	94
	SUB-509	9	5	15	24	34	49	67	87
	SUB-606	6	6	16	28	40	58	82	117
	SUB-609	9	6	14	25	37	53	75	108
	SAF-Q-106-G27	6	1	11	13	16	17	19	20
	SAF-Q-109-G27	9	1	10	12	15	16	17	18
	SAF-Q-112-G27	12	1	9	11	13	14	16	16
	SAF-Q-206-G27	6	2	12	18	24	30	34	39
	SAF-Q-209-G27	9	2	11	17	22	28	31	36
	SAF-Q-212-G27	12	2	10	15	20	25	28	33
	SAF-Q-306-G27	6	3	14	23	33	40	50	
	SAF-Q-309-G27	9	3	13	21	30	37	46	59
	SAF-Q-312-G27	12	3	11	19	27	33	42	54
	SAF-Q-406-G27	6	4	14	26	37	51	66	80
	SAF-Q-409-G27	9	4	13	24	34	47	61	73
	SAF-Q-412-G27	12	4	12	22	31	43	55	67
	SAF-Q-509-G27	9	5	15	24	34	49	67	87
	SAF-Q-609-G27	9	6	14	25	37	53	75	108

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Table 21				Drug					Flow Controller						
				Xembify					VersaRate Plus						
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
24G	SUB-212-G24	12	2		33										
	SUB-309-G24	9	3		40										
	SUB-312-G24	12	3		36										
	SUB-409-G24	9	4		34	76									
	SUB-412-G24	12	4		31	69									
	SAF-Q-212-G24-70	12	2		33										
	SAF-Q-309-G24	9	3		40										
	SAF-Q-312-G24-70	12	3		37										
	SAF-Q-409-G24-70	9	4		43										
SAF-Q-412-G24-70	12	4		39	77										
26G	OPT12604	4	1	12											
	OPT12606	6	1	12											
	OPT12609	9	1	12											
	OPT12612	12	1	12											
	OPT12614	14	1	12											
	OPT22604	4	2	16	32										
	OPT22606	6	2	16	32										
	OPT22609	9	2	16	32										
	OPT22612	12	2	16	32										
	OPT22614	14	2	15	30										
	OPT32606	6	3		32										
	OPT32609	9	3		32										
	OPT32612	12	3		32										
	OPT32614	14	3		30										
	OPT42606	6	4		38	77									
	OPT42609	9	4		38	77									
	OPT42612	12	4		38	77									
	OPT42614	14	4		36	72									
	OPT52606	6	5			84									
	OPT52609	9	5			84									
	OPT52612	12	5			84									
OPT62609	9	6				106									
OPT62612	12	6				106									
27G	SUB-104-G27	4	1		15	17	18	20	20						
	SUB-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SUB-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SUB-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SUB-106-G27-70	6	1		16	18									
	SUB-109-G27-70	9	1		15	17	18	19	20						
	SUB-112-G27-70	12	1		13	15	16	18	19	19	20	20	20	20	20
	SUB-204-G27	4	2		23	29	34	37	38	39	39	39	40	41	

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Table 21				Drug					Flow Controller						
				Xembify					VersaRate Plus						
SUB-Q Set				Total Flow Rate for ALL sites with VersaRate Plus Flow Controller (mL/h)											
Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
	SUB-250	6	2		22	28	32	35	36	37	37	37	38	38	40
	SUB-260	9	2		20	26	30	32	33	34	34	34	35	35	37
	SUB-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SUB-310	6	3		27	37	44	50	54	56	58	58	58	58	63
	SUB-320	9	3		25	34	41	46	49	52	53	53	54	54	58
	SUB-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SUB-400	6	4		34	47	57	65	70	74	77	79			
	SUB-410	9	4		31	43	52	59	64	68	71	73	75	78	82
	SUB-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SUB-414-G27	14	4		26	37	44	50	55	58	60	62	64	67	70
	SUB-506	6	5		20	45	63	77	86	92	96	98	101	103	
	SUB-509	9	5		19	41	58	70	79	84	88	90	92	95	99
	SUB-606	6	6		16	45	68	85	98	107	114				
	SUB-609	9	6		14	41	62	78	90	98	104	109	113	117	122
	SAF-Q-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SAF-Q-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SAF-Q-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SAF-Q-109-G27-70	9	1		15	17	18	19	20						
	SAF-Q-206-G27	6	2		22	28	32	35	36	37	37	37	38	38	40
	SAF-Q-209-G27	9	2		20	26	30	32	33	34	34	34	35	35	37
	SAF-Q-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SAF-Q-306-G27	6	3		27	37	44	50	54	56	58	58	58	58	63
	SAF-Q-309-G27	9	3		25	34	41	46	49	52	53	53	54	54	58
	SAF-Q-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SAF-Q-406-G27	6	4		34	47	57	65	70	74	77	79			
	SAF-Q-409-G27	9	4		31	43	52	59	64	68	71	73	75	78	82
	SAF-Q-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SAF-Q-509-G27	9	5		19	41	58	70	79	84	88	90	92	95	99
	SAF-Q-609-G27	9	6		14	41	62	78	90	98	104	109	113	117	122

SClg60® Infusion System

Troubleshooting

Possible causes for the SClg60 Infusion System to not perform properly are:

Problem	Possible Cause	Solution
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 SClg60 Infuser.
Syringe disengages from the infuser when the inner drive is closed	Syringe was not properly loaded in the SClg60 Infuser.	Unscrew the inner drive using the blue handle and properly position the syringe following the instructions for use steps #9-13. Ensure blue handle is fully closed.
	Use of non-recommended syringe model.	Use only recommended syringe model (BD 50 mL syringe model no. 309653).
Clicking sound	During infusion, the spring readjusts as it extends and may intermittently produce sound.	No correction necessary. This is normal and does not affect 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.
NO fluid flow	SClg60 Infuser drive is not completely closed.	Close inner drive by rotating the blue 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 Infuset, make sure that the slide clamp is not blocking the flow.
		For VersaRate or VersaRate Plus, make sure that the dial is set to the intended position and not to 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.
	When using the VersaRate Plus at the lower position settings such as 1 to 3 to infuse 20% IG (viscous) fluids, it may result in slower than expected or stopped flow rate.	Monitor the fluid volume progress throughout the infusion. If flow rate is slower than expected, adjust the VersaRate Plus dial to a higher position setting to obtain the desired flow rate. If the flow rate completely stops, turn the VersaRate Plus dial to the OPEN position for a few seconds or until the fluid starts to flow,

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Problem	Possible Cause	Solution
		then rotate the dial back to the original position setting and continue to monitor the infusion progress. If the flow rate continues to stop, use a different VersaRate Plus device, or switch over to the VersaRate or Infuset flow controller devices.
Flow rate is HIGH	Incorrect combination of patient administration set with flow controller or flow controller setting for the prescribed fluid.	Verify that the correct combination of patient administration set and Infuset or VersaRate position is being used. Consult the appropriate flow rate table 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 <i>Factors that Affect Flow Rate</i> .
Flow rate is LOW	Incorrect combination of patient administration set with flow controller or flow controller setting for the prescribed fluid.	Verify that the correct combination of patient administration set and Infuset or VersaRate position is being used. Consult the appropriate flow rate table 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 <i>Factors that Affect Flow Rate</i> and verify factors are within intended limits.
	Storage of the flow controller or patient administration set with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.	Do not store patient administration 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 blue drive handle counterclockwise fully to stop fluid flow.

NOTE:

If any of the above conditions persist or the SClg60 Infusion System is not performing as expected, discontinue use and contact EMED Technologies +1-916-932-0071 and/or your healthcare professional.

SCIg60® Infusion System

Warranty

Parties Covered:

This warranty extends only to the Original Purchaser of the SCIg60 Infuser, and it does not extend to subsequent purchasers or users. The “Original Purchaser” is the person purchasing the SCIg60 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 immunoglobulin solution flow rates, result in a flow rate outside of what has been approved for immunoglobulin solution, 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.



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