Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

EMED Technologies
The power of creative thinking

K142319

FDA CDRH DOC
AUG 20 2014
Received

August 18, 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: 510(k) Premarket Notification
TRADITIONAL

SCIg60 Infusion System

EMED Technologies Corporation is submitting the enclosed application for a new device (SCIg60 Infusion System) intended for use in the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid with the BD 60 ml syringe. The indications for use and clinical applications are equivalent to current medical practice and existing legally marketed products.

(b)(4)

[redacted]

Accordingly, EMED Technologies is submitting this pre-market notification that contains additional testing data and relevant information that sufficiently supports the determination that the SCIg60 Infusion System, as defined and presented in this most recent pre-market notification, is as safe and effective as the identified legally marketed predicate devices.

We consider our intent to market the SCIg60 Infusion System as confidential commercial information and request that FDA consider it as such.

The submission and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

If you have any questions regarding this 510(k) submission, please contact the undersigned at your earliest convenience.

27 1CD 2CPY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.0071 • Fax 916.932.0074 • www.emedtc.com

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Administrative Information

Proprietary Name:	SCIg60 Infusion System
Common Name:	Infusion Pump and Administration Sets
Classification Name and Reference:	Pump, Infusion 21 CFR §880.5725 Intravascular Administration Set 21 CFR §880.5440
Intended Use:	The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).
Proposed Regulatory Class:	Class II
FDA Panel:	General Hospital
Device Product Code:	FRN and FPA

Design and Use of the Device

The EMED SCIg60 Infusion System provides users with a portable, safe, and effective way to administer subcutaneous immunoglobulin therapy. The SCIg60 Infuser is a reusable mechanical device that does not require batteries or any electrical source. System accessories include single use, sterile, and disposable fixed-rate infusion sets (Infuset).

The EMED SCIg60 Infusion System uses a spring as a source of pressure that optimizes and controls the delivery of Hizentra at desired flow rates. The EMED SCIg60 Infusion System can be connected to commercially available administration sets utilizing standard Luer lock connectors.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Design and Use of the Device

Table 3-1:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

* **Infuset accessories only**

Thank you for your expeditious review of this application.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510 (k) Premarket Notification – Traditional

SCIg60 Infusion System

Applicant: EMED Technologies Corporation

Peter Kollings

Director of Regulatory Affairs and Quality Assurance

1264 Hawks Flight Ct. Ste. 200

El Dorado Hills, Ca 95762

Phone: 916.632.0071 x114

Fax: 916.932.0074

pkollings@emedtc.com

Submission Date: August 18, 2014

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 1: Medical Device User Fee Cover Sheet

This section contains the Medical Device User Fee Cover Sheet (payment identifier (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

EMED TECHNOLOGIES CORPORATION
1264 HAWKS FLIGHT COURT, SUITE 200
EL DORADO HILLS
CA 95762
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****8533

2. CONTACT NAME
Peter Kollings

2.1 E-MAIL ADDRESS
pkollings@emedtc.com

2.2 TELEPHONE NUMBER (include Area code)
916-932-0071

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD145167

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted] 10-Feb-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 2: Administrative - FDA Forms

This section contains completed FDA forms 3674, *Certification of Compliance*, 3514, *CDRH Premarket Review Submission Coversheet*, and 3654, *Standards Data Reports for 510(k)s*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/18/2014	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☑ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: EMED Technologies Corporation	Establishment Registration Number *(if known)*: 2523167		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (916) 932-0071		
Street Address: 1264 Hawks Flight Ct, Ste. 200	FAX Number *(including area code)*: (916) 932-0074		
City: El Dorado Hills	State / Province: Ca	ZIP/Postal Code: 95762	Country: USA
Contact Name: Peter Kollings			
Contact Title: Director Regulatory Affairs and Quality Assurance	Contact E-mail Address: pkollings@emedtc.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRN	2	FPA	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K933652	1	Freedom 60 Syring Infusion Pump System with syringe set and tubing	1	Repro-Med Systems, Inc.
2	K140133	2	Infuset Flow Control Extension Set	2	EMED Technologies Corporation
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Infusion Pump and Administration Sets

	Trade or Proprietary or Model Name for This Device		Model Number
1	SCIg60 Infuser	1	FP-0010002
2	Infuset (multiple lengths)	2	FP-0010004 through FP-0010014
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K121358	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FRN

C.F.R. Section *(if applicable)*: 21 CFR 880.5725

Classification Panel: General Hospital

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☑ Contract Sterilizer ☑ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☑ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☑ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-7	ISO	Biological evaluation of medical devices - ethylene oxide sterilization residuals	2008	
2	ISO 11135-1	ISO	Sterilization of healthcare products - Ethylene oxide; Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	2007	
3	ISO 10993-1	ISO	Biological evaluation of medical devices - Evaluation and Testing	2009	
4	ISO 14971	ISO	Medical Devices - Application of risk management to medical devices	2007	
5	ISO 594-1	ISO	Conical Luer Fittings - General Requirements	1986	
6	ISO 594-2	ISO	Conical Luer Fittings - Lock Fittings	1998	
7	ISO 8536-8	ISO	Infusion Equipment for medical use - infusion equipment for use with pressure infusion apparatus	2004	

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form 3514, Utilization of Standards, Section 1 (continued)

8	Standards No. ASTM F1980-07	Standards Organization ASTM	Standards Title Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Version 2011	Date
9	Standards No. ASTM F756-13	Standards Organization ASTM	Standards Title Standard Practice for Assessment of Hemolytic Properties of Materials	Version 2007	Date
10	Standards No. 10993-5	Standards Organization ISO	Standards Title Biological evaluation of medical devices - Tests for in vitro cytotoxicity	Version 2009	Date
11	Standards No. 10993-10	Standards Organization ISO	Standards Title Biological evaluation of medical devices - Tests for irritation and skin sensitization	Version 2010	Date
12	Standards No. 10993-11	Standards Organization ISO	Standards Title Biological evaluation of medical devices - Tests for systemic toxicity	Version 2006	Date
13	Standards No. 10993-4	Standards Organization ISO	Standards Title Biological evaluation of medical devices - Selection of tests for interactions with blood	Version 2002	Date
14	Standards No. USP <85>	Standards Organization USP	Standards Title Bacterial Endotoxins Test	Version 2013	Date
15	Standards No. USP <161>	Standards Organization USP	Standards Title Transfusion and Infusion Assemblies and Similar Medical Devices	Version 2013	Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
EMED Technologies Corporation

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
8/18/14

3. ADDRESS *(Number, Street, State, and ZIP Code)*
1264 Hawks Flight Ct, Ste. 200
El Dorado Hills, Ca 95762

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 916.932.0071
(Fax) 916.932.0074

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

SCIg60 Infusion System
SCIg60 Infuser
Infusion Pump
EMED Infusion System
FP-0010002
EMED Infuser
Infuset

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Peter Kollings
(Title) Director RA/QA

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
1264 Hawks Flight Ct, Ste. 200
El Dorado Hills, Ca 95762

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 916.932.0071 x 114
(Fax) 916.932.0074

15. DATE OF CERTIFICATION
08/18/2014

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date -** This is the date of the application/submission which the certification accompanies.

3. & 4. **-** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification -** This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11. -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. & 14. **-** Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-7:2008, Biological evaluation of medical devices - ethylene oxide sterilization residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-335		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1:2007, ETO Sterilization

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-331		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2009, Biological evaluation of medical devices - Evaluation and Testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-179		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation a

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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Paperwork Reduction Act Statement

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1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007 - Medical Devices - Application of risk management to medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-40		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 594-1:1986 - Conical Luer Fittings - General Requirements

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 6-11		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
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Department of Health and Human Services
Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 594-2:1998 - Conical Luer Fittings - Lock Fittings

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 6-129		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 8536-8:2004 - Infusion Equipment for medical use - infusion equipment for use with pressure infusion apparatus

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF DEVIATION OR OPTION SELECTED ❖		
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JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-229		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F756-13, Standard Practice for Assessment of Hemolytic Properties of Materials

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
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JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5:2009, Biological evaluation of medical devices - Tests for in vitro cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-153		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
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JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10:2010, Biological evaluation of medical devices - Tests for irritation and skin sensitization

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-174		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11:2006, Biological evaluation of medical devices - Tests for systemic toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-176		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF DEVIATION OR OPTION SELECTED ❖		
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JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-4:2002, Biological evaluation of medical devices - Selection of tests for interactions with blood

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

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SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP <85>: 2013, Bacterial Endotoxins Test

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 14-416		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

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STANDARD TITLE

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TYPE OF DEVIATION OR OPTION SELECTED ❖		
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JUSTIFICATION		
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP <161>: 2013, Transfusion and Infusion Assemblies and Similar Medical Devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-418		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
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Section 3: 510k Cover Letter

This section contains completed FDA 510k Cover Letter

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EMED Technologies
The power of creative thinking

August 18, 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: 510(k) Premarket Notification
TRADITIONAL

SCIg60 Infusion System

EMED Technologies Corporation is submitting the enclosed application for a new device (SCIg60 Infusion System) intended for use in the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid with the BD 60 ml syringe. The indications for use and clinical applications are equivalent to current medical practice and existing legally marketed products.

(b)(4)

[redacted]

Accordingly, EMED Technologies is submitting this pre-market notification that contains additional testing data and relevant information that sufficiently supports the determination that the SCIg60 Infusion System, as defined and presented in this most recent pre-market notification, is as safe and effective as the identified legally marketed predicate devices.

We consider our intent to market the SCIg60 Infusion System as confidential commercial information and request that FDA consider it as such.

The submission and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

If you have any questions regarding this 510(k) submission, please contact the undersigned at your earliest convenience.

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.8700 • Fax 916.932.8074 • www.emedtc.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Administrative Information

Proprietary Name:	SCIg60 Infusion System
Common Name:	Infusion Pump and Administration Sets
Classification Name and Reference:	Pump, Infusion 21 CFR §880.5725 Intravascular Administration Set 21 CFR §880.5440
Intended Use:	The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).
Proposed Regulatory Class:	Class II
FDA Panel:	General Hospital
Device Product Code:	FRN and FPA

Design and Use of the Device

The EMED SCIg60 Infusion System provides users with a portable, safe, and effective way to administer subcutaneous immunoglobulin therapy. The SCIg60 Infuser is a reusable mechanical device that does not require batteries or any electrical source. System accessories include single use, sterile, and disposable fixed-rate infusion sets (Infuset).

The EMED SCIg60 Infusion System uses a spring as a source of pressure that optimizes and controls the delivery of Hizentra at desired flow rates. The EMED SCIg60 Infusion System can be connected to commercially available administration sets utilizing standard Luer lock connectors.

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Design and Use of the Device

Table 3-1:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X*	
Is the device intended for single use?	X*	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

* **Infuset accessories only**

Thank you for your expeditious review of this application.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 4: Indications for Use Form

This appendix contains the completed FORM FDA 3881, Indications for Use for the SCIg60 Infusion System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
SCIg60 Infusion System

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5: 510(k) Summary

K Number _____

Summary Prepared: August 19, 2014

General Information

Classification	Class II
Trade Name	SCIg60 Infusion System
Common Name:	Infusion Pump
Classification Name and Reference:	Pump, Infusion 21 CFR §880.5725
Submitter	Peter Kollings EMED Technologies Corporation 1264 Hawks Flight Ct El Dorado Hills, Ca Tel: 916.932.0071 Fax: 916.932.0074

Intended Use

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

Primary Predicate Device(s)

Repro-Med Systems, Inc.
Freedom 60 Syringe Infusion Pump System with syringe set and tubing
K933652

Secondary Predicate Device(s)

EMED Technologies Corporation
Infuset™ flow control extension sets
K140133

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

The EMED SCIg60 Infusion System consists of the SCIg60 Infuser and the Infuset™ flow control extension set which must be used with the BD 60 ml syringe (model no. 309653). The SCIg60 Infusion System has been designed to include the Infuset™ flow control extension sets also manufactured by EMED Technologies (see K140133). The EMED SCIg60 Infusion System can be used with commercially available administration sets utilizing standard luer lock connectors.

The SCIg60 Infuser is a reusable mechanical, non-electronic ambulatory infusion pump that does not require batteries or any electrical source. The EMED SCIg60 Infuser uses a spring as a source of pressure for the infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653) and the EMED Infuset™ flow control extension sets.

The Infuset™ flow control extension sets are assembled from standard luer lock components and specified lengths of PVC microbore tubing. The length and diameter of the tubing results in pre-determined flow rates when used with the SCIg60 Infuser, and include slide-clamps for stopping the flow of fluid. These fixed-rate flow control sets are individually sterile packaged and are essentially identical to those used in the Freedom 60 Infusion System predicate device (K933652) in appearance, design, and functionality.

Materials and Characteristics

The EMED SCIg60 Infusion system is equivalent in concept, technology, performance, basic physical properties, and having equivalent indications for use as the Freedom 60 Infusion System predicate device and its accessories (K933652).

The overall principle of action for the SCIg60 Infusion System and the Freedom 60 Infusion System are identical in that both consist of a constant pressure source acting upon a syringe filled with fluid, with the flow rate of that fluid being regulated by PVC tubing with fixed fluid path dimensions (i.e. tubing length and inner diameter). The flow control properties of the tubing follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid.

Table 5-1 aligns the functions of the SCIg60 and the Freedom 60 Infusion System predicate within the context of a functional system. Shaded blocks indicate already marketed medical devices for use with the SCIg60 Infusion System and the predicate Freedom 60 Syringe Infusion System.

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Table 5-1

	Pump/ Pressure Source	Reservoir	Flow Controller	Patient Administration Set
SCIg60 Infusion System	SCIg60 Pump	BD 60 ml Syringe	Infuset™	Patient administration set
Freedom 60 Infusion System	Freedom 60 Pump	BD or Sherwood 60 ml Syringe	Freedom 60 precision flow rate tubing	Patient administration sets

Table 5-2 below provides comparison of technological and other characteristics between the SCIg60 Infusion System and the Freedom60 Infusion System predicate.

Table 5-2:

	SCIg60 Infusion System	Freedom60 Infusion System
Indications for Use	The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).	The Freedom60 Syringe Infusion Pump is intended for use in the home or hospital environment using any intravenous fluids recommended for use with such syringes as the Becton Dickinson 309653 or Sherwood Medical 8881-560125. The Freedom 60 Syringe Infusion Pump is not indicated for the delivery of blood or blood products.
Infuser Material(s)	(b)(4) [redacted]	
Infuser Weight	1 lb	1 lb
Infuser Dimensions (l x h x d)	10.2” x 2.6” x 2.6”	9.5” x 4.9” x 2.5”
Syringe/Fluid	BD 60 ml syringe	BD 60 cc syringe, Sherwood

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	SCIg60 Infusion System	Freedom60 Infusion System
Container		Medical Monojet 60cc syringe
Principle of Action	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.
Pressure Source	Spring	Spring
Principle of Flow Control	Fixed flow rate due to fixed length and inner-diameter.	Fixed flow rate due to fixed length and inner-diameter.
Fluid Path Materials	PVC	PVC
Flow Controller Residual Volume	0.10 – 0.20 ml	0.13 – 0.15 ml
Flow Controller Sterilization	(b)(4) [redacted]	

All materials used in the manufacture of the SCIg60 Infusion System are suitable for this use and have been used in numerous, previously cleared products.

Performance Testing

Performance testing shows that the SCIg60 Infusion System is equivalent to the Freedom 60 Infusion System predicate. Table 5-2 below summarizes those testing results.

Table 5-2

	SCIg60 Infusion System	Freedom60 Infusion System
Maximum Operating Pressure	16.8 psi	16.1 psi
Average Operating Pressure	14.4 psi	13.5 psi
Flow Rate Accuracy (0.9% saline at RT)	+/- 10%	+/- 8%
Flow Rate Range (0.9% saline at 20°C - 25°C)	48 – 2089 ml/hr	47 – 1743 ml/hr
Vertical Sensitivity (for differential of 24”)	+/- 5.0%	+/- 6.6%

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Biocompatibility

In accordance with ISO 10993-1:2009 and based on the intended use of the SCIg60 Infusion System, studies were performed to establish biocompatibility of the Infuset™ Flow Control Extension Sets including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility. Table 5-3 presents a summary of testing and results indicating compliance with biocompatibility standards.

Table 5-3

Standard	Test Name	Test Result	Other Name
ISO 10993-5	Cytotoxicity	Pass	Neutral Red Uptake
ISO 10993-10	Sensitization	Pass	Kligman Maximization
ISO 10993-10	Irritation	Pass	Intracutaneous Injection
ISO 10993-11	Acute systemic toxicity	Pass	Systemic Injection
ISO 10993-11	Pyrogenicity	Pass	Rabbit Pyrogen
ISO 10993-4	Hemocompatibility	Pass	Unactivated Partial Throbmoplastin Time
ASTM 756	Hemocompatibility	Pass	Hemolysis (complete)
USP <85>	LAL Endotoxin Test	Pass	LAL Endotoxin Quantitation Test (Kinetic-QCL Method)

Sterility, Shelf-life, and Packaging

The Infuset™ Flow Control Extension Sets will be sterilized to a sterility assurance level (SAL) of 10^{-6} and with a shelf life of 5 years.

Summary of Substantial Equivalence

The EMED Technologies Corporation SCIg60 Infusion System is substantially equivalent to the predicate devices in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Any differences between the SCIg60 Infusion System and the predicate are considered minor and do not raise new questions of safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 6: Premarket Notification Truthful and Accurate Statement
[As Required by 21 CFR §807.87(k)]

I certify that, in my capacity as the Director of Regulatory Affairs and Quality Assurance of EMED Technologies Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Peter Kollings
(Typed Name)

8/18/14
(Date)

_____
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7: Class III Summary and Certifications

The EMED SCIg60 Infusion System is a Class II device and therefore this section is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 8: Financial Certification or Disclosure Statement

There is no clinical data supplied with this notification therefore this section is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9. Declaration of Conformity and Summary Reports

As required by 21 CFR §807.87(g)

I certify that, in my capacity as Director of Regulatory Affairs and Quality Assruance of EMED Technologies Corporation, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. The EMED Technologies Corporation manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CRF 820.30 and the records are available for review.

Peter Kollings

(Signature)

Peter Kollings

(Typed Name)

8/18/14

(Dated)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Responses to FDA's Letter

(b)(4) Responses to FDA's Letter

(b)(4) Responses to FDA's Letter

(b)(4) Responses to FDA's Letter

(b)(4) Responses to FDA's Letter

(b)(4) Responses to FDA's Letter

(b)(4) Responses to FDA's Letter

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Section 11: Executive Summary

The EMED SCIg60 Infusion System consists of the SCIg60 Infuser and the Infuset flow rate controller set which must be used with the BD 60 ml syringe (model no. 309653). The SCIg60 Infusion System has been designed to include the Infuset™ flow control extension sets also manufactured by EMED Technologies (see K140133). The EMED SCIg60 Infusion System can be used with commercially available administration sets utilizing standard luer lock connectors.

The SCIg60 Infuser is a reusable mechanical, non-electronic ambulatory infusion pump that does not require batteries or any electrical source. The EMED SCIg60 Infuser uses a spring as a source of pressure for the infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).

The Infuset™ flow control extension sets are assembled from standard luer lock components and specified lengths of PVC microbore tubing. The length and diameter of the tubing results in pre-determined flow rates when used with the SCIg60 Infuser, and include slide-clamps for stopping the flow of fluid. These fixed-rate flow sets are individually sterile packaged and are essentially equivalent to those used in the Freedom 60 Infusion System predicate device (K933652) in appearance, design, and functionality.

The EMED SCIg60 Infusion system is equivalent in concept, technology, performance, basic physical properties, and having equivalent indications for use as the Freedom 60 Infusion System predicate device and its accessories (K933652).

The overall principle of action for the SCIg60 Infusion System and the Freedom 60 Infusion System are identical in that both consist of a constant pressure source acting upon a syringe filled with fluid, with the flow rate of that fluid being regulated by PVC tubing with fixed fluid path dimensions (i.e. tubing length and inner diameter). The flow control properties of the tubing follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11-1 below provides comparison of technological and other characteristics between the SCIg60 Infuser device and the Freedom 60 Infusion system predicate as these devices share the majority of attributes.

Table 11-1:

	SCIg60 Infusion System	**Freedom60 Infusion System**
Indications for Use	The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).	The Freedom60 Syringe Infusion Pump is intended for use in the home or hospital environment using any intravenous fluids recommended for use with such syringes as the Becton Dickinson 309653 or Sherwood Medical 8881-560125. The Freedom 60 Syringe Infusion Pump is not indicated for the delivery of blood or blood products.
Infuser Material(s)	(b)(4) [redacted]	
Infuser Weight	1 lb	1 lb
Infuser Dimensions (l x h x d)	10.2” x 2.6” x 2.6”	9.5” x 4.9” x 2.5”
Syringe/Fluid Container	BD 60 ml syringe	BD 60 cc syringe, Sherwood Medical Monojet 60cc syringe
Principle of Action	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.
Pressure Source	Spring	Spring
Principle of Flow Control	Fixed flow rate due to fixed length and inner-diameter.	Fixed flow rate due to fixed length and inner-diameter.
Fluid Path Materials	PVC	PVC
Flow Controller Residual Volume	0.10 – 0.20 ml	0.13 – 0.15 ml
Flow Controller Sterilization	(b)(4) [redacted]	

See Section 13 for further information regarding substantial equivalence

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Table 10-2 below summarizes testing results performed to establish conformance of the EMED SCIg Infusion System to internal product specifications and requirements, as well as equivalence to the Freedom 60 Infusion System predicate device.

Table 11-2:

	SCIg60 Infusion System	**Freedom60 Infusion System**
Maximum Operating Pressure	16.8 psi	16.1 psi
Average Operating Pressure	14.4 psi	13.5 psi
Flow Rate Accuracy (0.9% saline at RT)	+/- 10%	+/- 8%
Flow Rate Range (0.9% saline at 20°C - 25°C)	48 – 2089 ml/hr	47 – 1743 ml/hr
Vertical Sensitivity (for differential of 24”)	+/- 5.0%	+/- 6.6%

See Section 19 for further information regarding bench testing equipment/apparatus, procedures, data, and conclusions.

The data and information presented in this pre-market notification will demonstrate that EMED SCIg60 Infusion System is substantially equivalent to the predicates in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Any differences between the SCIg60 Infusion System and the predicate are considered minor and do not raise new questions of safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 12: Device Description and Risk Management

Device Description

System Overview

The EMED SCIg60 Infusion System consists of the SCIg60 Infuser and the Infuset flow rate controller set which must be used with the BD 60 mL syringe. The SCIg60 Infusion System has been designed to use the Infuset™ flow control extension sets also manufactured by EMED Technologies (see K140133). The EMED SCIg60 Infusion System can be used with commercially available administration sets utilizing standard luer lock connectors.

The SCIg60 Infuser is a reusable mechanical, non-electronic ambulatory infusion pump that does not require batteries or any electrical source. The EMED SCIg60 Infuser uses a spring as a source of pressure for the infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).

The Infuset™ flow control extension sets are assembled from standard luer lock components and specified lengths of PVC microbore tubing. The length and diameter of the tubing results in pre-determined flow rates when used with the SCIg60 Infuser, and include slide-clamps for stopping the flow of fluid. These fixed-rate flow sets are individually sterile packaged, essentially identical to those used in the Freedom 60 Infusion System predicate device (K933652) in appearance, design, and functionality, and have been cleared for market distribution in K140133 for use with the Freedom 60 (K140133).

Diagram 12-1 below presents the SCIg60 Infusion System incorporating all of the functional system components, with each labeled A – E to correspond to detailed descriptions provided after the diagram.

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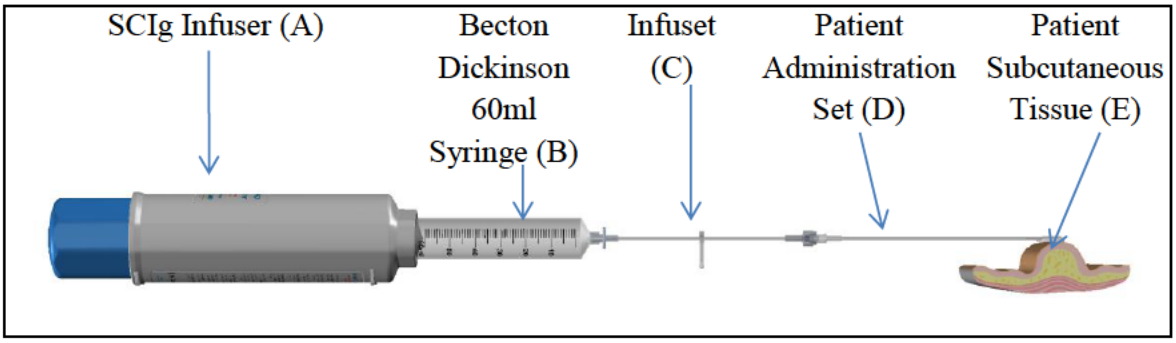
NOTE: Components B and D are currently marketed medical devices, and are not subjects of this pre-market notification.

Diagram 12-1



(A) <u>SCIg60 Infuser</u>

The SCIg60 Infuser is comprised of two outer housings that contain the inner drive, which in turn contains the spring and pump piston. The Infuser also includes a spring calibrator and inner drive end cap.

The pump inner drive and piston is designed to self-locate the inserted 60ml Becton Dickinson (BD) syringe plunger. The syringe plunger is in contact with the pump piston, which in turn is in contact with the calibrated stainless steel spring contained within the inner drive. The spring is retained and calibrated within the inner drive by the threaded spring calibrator. The end cap is attached to the Infuser to cover the opening in the inner drive and prevent user access to the spring calibrator.

The outer housings and spring calibrator are made of (b)(4), the inner drive and end cap of (b)(4), and the piston of Delrin. (b)(4) is used to secure the spring calibrator and end cap components of the device; the pump housings are secured via press-fit design elements.

The inner drive and outer housing are threaded allowing the inner drive to be unscrewed to allow insertion of a 60ml BD syringe, or to be screwed into the outer housing to compress the internal spring and apply pressure to the syringe plunger. This pressure forces Hizentra out of the syringe and into the Infuset flow control extension set.

(A) BD 60ml Syringe, model 309653

This is a general use piston-syringe manufactured by Becton-Dickenson (BD). These syringes feature a clear barrel with bold scale markings, tapered plunger rod for ease of aspiration, positive plunger rod stop, and an industry-standard luer lock connector for secure connection to downstream sets and/or accessories.

These devices are clearly labeled non-latex and provided empty and sterile for single use.

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In the context of the SCIg60 Infusion System, this syringe is the reservoir for liquid Hizentra medicine, and will only be connected to an Infuset flow control extension set.

(B) Infuset flow control extension set

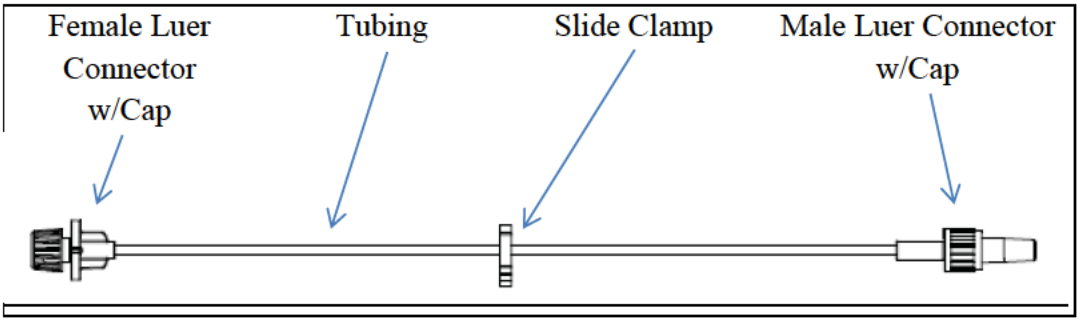
Infuset flow rate controllers are assembled from rigid PVC standard luer lock components and specified lengths of medium-density PVC. These sets include slide-clamps used to pinch the tubing and stop the flow of fluid. These fixed-rate flow sets are identical to those of the Freedom 60 system in appearance, design, and functionality, and are individually sterile packaged. (b)(4) [redacted] is used as an adhesive to attach components of the set.

The length and diameter of the tubing results in pre-determined flow rates when the contents of the BD 60ml syringe are pressurized by the SCIg60 Infuser. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. There are no moving pieces or mechanics of these sets designed to alter flow rates.

These sets can be physically connected to the BD 60ml syringe and subcutaneous patient administrations sets using the standard luer lock connectors, and are provided sterile for single use.

Diagram 12-2 below represents the finished Infuset™ Flow Control Extension Set with references to the parts in the table 12-2 below.

Diagram 12-2



(C) Subcutaneous patient administration set

The subcutaneous patient administration sets provide a means for liquid immunoglobulin medicines to be introduced to the subcutaneous tissue of a patient. Subcutaneous patient administration sets may be assembled from rigid PVC standard luer lock components and specified lengths of medium-density PVC, as is the case with the EMED SUB-Q sets (K140131). These sets include slide-clamps used to pinch the tubing and stop the flow of fluid. Each set may provide a single fluid path terminating in a single small gage

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stainless steel hypodermic needle, or may be split into several paths with each terminating in a small gage hypodermic needle stainless steel. Additional design components may be present to facilitate handling before insertion and removal after infusion.

These sets can be physically connected to a Infuset flow control extension set using the standard luer lock connectors.

(D) Patient

Liquid immunoglobulin medicine is infused into the subcutaneous tissue of the patient via the SCIg60 Infusion system and patient administration set. Infused immunoglobulin medicine is absorbed by the patient's body over a period of time.

SCIg60 Infusion Pump – Functional Description

The inner drive and outer housing are threaded allowing the inner drive to be unscrewed to allow insertion of a 60ml BD syringe, or to be screwed into the outer housing to compress the internal spring and apply pressure to the syringe plunger.

(b)(4)

[redacted]

The pump is designed to interface with the BD 60ml syringe only. Syringe placement accomplished by the design of the pump mouth and the syringe-flange locking mechanism. The mouth is designed to allow the plunger and flanges of the BD 60ml syringe to enter the pump, and the locking mechanism accommodates the dimensions of the BD 60ml syringe to securely lock the syringe in place when inserted into the pump and rotated 90°. Syringes with different flange shapes or sizes cannot be inserted into the pump and securely locked in place.

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(b)(4)

[redacted]

The force of the SCIg60 pump is supplied by the compressed stainless steel spring. This spring is compressed when the user screws in the inner drive into the outer housing with a 60ml BD syringe in place and the tubing clamp closed to prevent liquid flow. The syringe plunger forces the pump piston into the spring, thereby compressing the spring and building infusion pressure.

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(b)(4)

[redacted]

Please see the Appendix A, User Manual and Labeling for additional general system information and method of operation.

Device Materials and Specifications

Tables 12-1 and 12-2 below list the components and materials used in the SCIg60 Infuser and Infuset.

Table 12-1: SCIg60 Infuser Components

Description	QTY	Units	Material(s)

(b)(4)

[redacted]

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(b)(4)

[redacted]

Table 12-2: Infuset Components

Description	QTY	Units	Material(s)	Additives
(b)(4) [redacted]				

*## several sets will be available in differing flow rate configurations; the tubing ID and length of each set is related to the target flow rate.

The fluid path contacting components of the luer locks and tubing are not manufactured with DEHP or natural latex rubber. See Appendix C for supporting declarations from the component manufacturer, device assembler, and final product packager and sterilizer.

See Section 16 for discussion of ISO 10993 biocompatibility testing of the single-use disposable Infuset™ flow control extension sets.

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See Appendix C for technical drawings and specifications for the SCIg60 Infuser device and the Infuset flow control extension sets.

See Appendix C for Material Safety Data Sheets for materials used to manufacture the components listed above or in the assembly process of either the SCIg60 Infusion Pump or the Infuset flow control extension sets.

Risk Management

General

Decisions made during the design and development of the SCIg60 Infusion System were carefully evaluated to assess and mitigate potential impact in the safety and effectiveness of the device and therefore have been documented per 21 CFR 820 Design Control requirements.

Risk Management Program

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4) Risk Management

[redacted]

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Section 13: Substantial Equivalence Discussion

Predicate Device Comparison

The following section describes the characteristics of the EMED SCIg60 Infusion System as compared to the Freedom 60 Infusion System predicate. A presentation of this information is provided in a tabular format first, with a discussion of relevant points and conclusion following. Discussion of the substantial equivalence between the Infuset™ flow control extension sets as part of the SCIg60 Infusion System and the K140133 subject device are also provided.

Table 13-1 below provides comparison of technological characteristics between the SCIg60 Infuser System and the Freedom 60 Infusion System predicate.

Table 13-1:

	EMED SCIg60 Infusion System	**Freedom60 Infusion System**
Indications for Use	The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).	The Freedom60 Syringe Infusion Pump is intended for use in the home or hospital environment using any intravenous fluids recommended for use with such syringes as the Becton Dickinson 309653 or Sherwood Medical 8881-560125. The Freedom 60 Syringe Infusion Pump is not indicated for the delivery of blood or blood products.
Infuser Material(s)	(b)(4) [redacted]	
Infuser Weight	1 lb	1 lb
Infuser Dimensions (l x h x d)	10.2” x 2.6” x 2.6”	9.5” x 4.9” x 2.5”
Syringe/Fluid Container	BD 60 ml syringe	BD 60 cc syringe, Sherwood Medical Monojet 60cc syringe

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	EMED SCIg60 Infusion System	**Freedom60 Infusion System**
Principle of Action	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.
Pressure Source	Spring	Spring
Principle of Flow Control	Fixed flow rate due to fixed length and inner-diameter.	Fixed flow rate due to fixed length and inner-diameter.
Fluid Path Materials	PVC	PVC
Flow Controller Residual Volume	0.10 – 0.20 ml	0.13 – 0.15 ml
Flow Controller Sterilization	(b)(4) [redacted]	

Technological Characteristics Discussion

Indications for Use

The SCIg60 Infusion System and the Freedom 60 Infusion System both share the same general intended use of infusion pumps, which is to pump fluids into a patient in a controlled manner. The indications for the SCIg60 Infusion system and the predicate are similar, with the exceptions being the SCIg60 Infusion System indicates for a specific liquid for infusion (i.e. infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid), specific route of administration (i.e. subcutaneous infusion), and a single fluid reservoir (i.e. BD 60ml syringe).

The difference regarding the specified drug for infusion does not raise any issues of safety or effectiveness because the SCIg60 Infusion System has been fully qualified for the indicated drug. Performance tests, labeling, and risk management activities for the SCIg60 Infusion Systems were based on the single indicated liquid medicine. These activities fully qualified the SCIg60 Infusion System for use with Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid, and satisfactorily mitigate any risks associated with a more specific indicated liquid medicine.

The difference regarding the route of administration does not raise any issues of safety or effectiveness because subcutaneous infusion is a type of infusion that falls within the more general route of administration indicated for the Freedom 60 Infusion System. SCIg60 Infusion System design, labeling, and risk management activities account for the subcutaneous infusion route of administration.

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The difference in indicated liquid medicine reservoirs is insignificant in that both the SCIg60 Infusion System and the Freedom 60 Infusion System indicate for the use of the BD 60 ml syringe (model no. 309653). This syringe is widely available to prescribing parties and end users alike as Becton Dickinson is a market leader for this product. In addition, indication for a single syringe allows pump calibration and validation activities to focus on the properties of a single syringe.. There is no risk to safety or effectiveness regarding the fluid reservoir due to the similarities between the SCIg60 and Freedom 60 reservoirs, and the mitigation steps in place for patient filling and preparation of these syringes.

The SCIg60 Infusion System shares the same Intended Use with the Freedom 60 Infusion system, and any differences of indications between the SCIg60 Infusion System and Freedom 60 Infusion System are minor and only serve to limit the scope of use of the SCIg60 Infusion System. Therefore, SCIg60 Infusion System can be considered substantially equivalent to the Freedom 60 in terms of intended use.

It is noted that K140133 states that the Infuset™ flow control extension set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to "provide flow rate control to administer fluids from a container to a patient's vascular system." The intended use of Infuset when used with the SCIg60 Infusion System is consistent with that found in K140133 in that in both cases it is intended to provide flow rate control to mechanical, spring driven infusion pumps. The difference between the indications for the Infuset™ flow control extension set as part of the SCIg60 Infusion System and that found in K140133 are consistent with the differences discussed above, are minor, and do not raise any new questions of safety or effectiveness

Materials

The materials that compose the SCIg60 Infuser were identified for their durability and performance characteristics. The plastics selected are widely used for medical device applications and are equivalent to those used for the Freedom 60 Infuser in consideration of the intended use and lifespan of the two devices.

The materials of the Freedom 60 precision flow rate tubing sets and the SCIg60 Infuset™ flow control extension sets are both PVC. Biocompatibility of all fluid path components of the Infuset™ flow control extension sets conform to ISO 10993-1 based on intended application (see Section 16). As noted earlier in this discussion, the Infuset™ flow control extension sets for use with the SCIg60 Infusion system are identical in design and materials to those that have already been cleared for commercial distribution in K140133 and are currently manufactured by EMED Technologies.

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Based on this information, the materials used in the SCIg60 Infusion System are considered safe for the intended use and substantially equivalent to those of the predicate.

Size and Weight

The size and weight of each component of the SCIg60 Infusion System and the Freedom60 System are essentially the same. Any dimensional or weight differences are insignificant and do not impact portability or usability of the device as compared to the predicate.

Device Design and Principles of Action

The overall principle of action for the SCIg60 Infusion System and the Freedom 60 Syringe Infusion System are identical in that both consist of a constant pressure source acting upon a syringe filled with fluid, with the flow rate of that fluid being regulated by PVC tubing with fixed fluid path dimensions (i.e. tubing length and inner diameter). The flow control properties of the tubing follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid.

The SCIg60 Infusion System has been designed to include the Infuset™ flow control extension sets also manufactured by EMED Technologies (see K140133). K140133 establishes that the Infuset™ flow control extension sets are substantially equivalent to the predicate Freedom 60 precision flow rate tubing sets when used with the Freedom 60 pump. The Infuset™ flow control extension sets provide the same function when used with the Freedom 60 pump as when used with the SCIg60 Infuser.

Due to the essentially identical purpose and function of the Infuset™ flow control extension set in the SCIg60 Infusion system (i.e. to regulate flow of liquids dispensed from a syringe when acted upon a spring-driven, constant pressure pump) and the pre-market clearance documented in K140133, one can conclude that the substantial equivalence of the Infuset™ flow control extension set as part of the SCIg60 Infusion System to the predicate flow control tubing may already be established.

The following discussion further details similarities between the SCIg60 Infusion System and the predicate in terms of design and principles of action, both of the system and system components. For clarity, Table 13-3 aligns the functions of the SCIg60 and the predicate within the context of a functional system. Diagrams of each system are provided below that indicate the key functional system components referenced Table 13-2.

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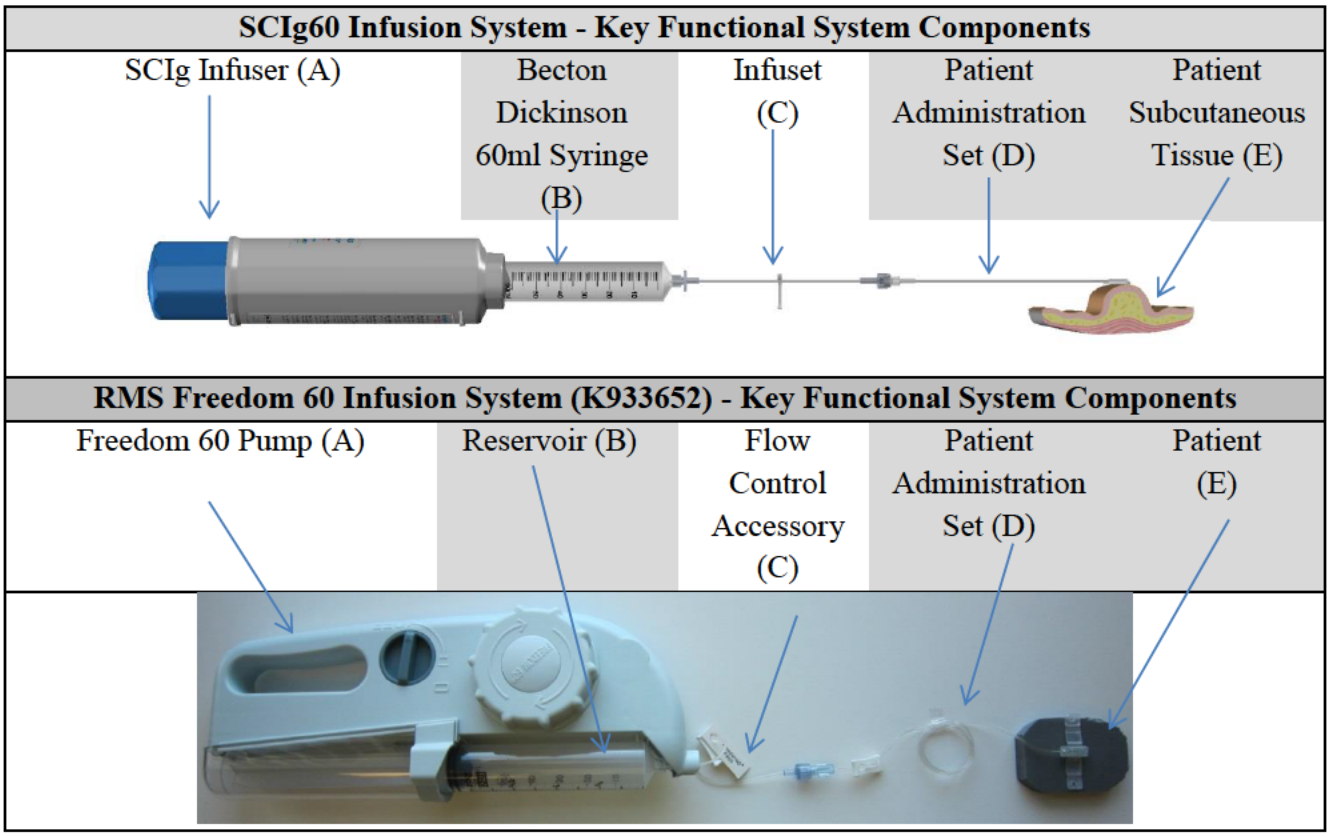
Table 13-2

	Pump/ Pressure Source (A)	Reservoir (B)	Flow Controller (C)	Patient Administration Set (D)	Patient
SCIg60 Infusion System	SCIg60 Pump	BD 60 ml Syringe	Infuset™ Flow Control Extension Set	Sub-cutaneous infusion sets with needles	N/A
Freedom 60 Infusion System	Freedom 60 Pump	BD or Sherwood 60 ml Syringe	Freedom 60 precision flow rate tubing	Patient administration sets	N/A

*NOTE: Shaded blocks indicate already marketed medical devices and/or components that are beyond the scope of this submission.

Diagram 13-1 below graphically identifies analogous components in both the SCIg60 Infusion System and the predicate. Following the diagram is a description of each including physical design, functional operation, and interface requirements.

Diagram 13-1



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(A) Pump/Pressure Source

The SCIg60 Infusion System and the Freedom 60 Infusion System are reusable infusion pumps that rely upon constant force springs to provide force upon the fluid reservoir (syringe) to infuse liquid medicines. The SCIg60 and the predicate pump require the user to compress the spring prior to infusion.

These pumps do not have alerts or alarms, are mechanical, do not require electricity to function, nor require any software to control flow. These pumps provide the user multiple ways to monitor infusion and stop flow as desired. The SCIg60 pump and the predicate pump are manufactured with plastics/composites, adhesives, and stainless steel springs widely used in industry; all materials are well characterized and do not pose any biocompatibility risks.

The SCIg60 Infusion pump shares basic construction, principles of action, and design with the Freedom 60 predicate infusion pump, and therefore there is no risk to safety or effectiveness.

(B) Reservoir

The reservoir used in by the predicate is essentially equivalent to that used in the SCIg60 Infusion System in that it provides the source for infusion fluids. The 60 ml BD syringe used by the SCIg60 infusion is also indicated for the Freedom 60 System, and therefore does not impact safety or effectiveness. Any risks inherent to patient filling and preparation of the syringes used in the SCIg60 and Freedom 60 infusion systems are sufficiently mitigated by comprehensive user manuals and training.

There is no risk to safety or effectiveness regarding the source of infusion liquids due to the similarities between the SCIg60 and Freedom 60 reservoirs, and the mitigation steps in place for patient filling and preparation of these syringes. Careful consideration of all factors is included in the Risk Management sections of this submission.

(C) Flow Rate Controller

The Infuset™ flow control extension sets used as part of the SCIg60 Infusion System are identical to the Freedom 60 precision flow rate tubing set accessories in function, general design, construction, an appearance to. Both flow control accessories contain clamps to stop the flow of liquid.

The flow control accessories of both systems rely upon standard Luer lock connectors to connect to other system components. The flow control accessories are manufactured with plastics and adhesives widely used in industry; all materials are well characterized and do not pose any biocompatibility risks.

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As noted earlier in this discussion, the Infuset™ flow control extension sets used in conjunction with the SCIg60 Infuser are the same as those that have already been cleared for commercial distribution in K140133 and are currently manufactured by EMED Technologies. The Infuset™ flow control extension sets have been found substantially equivalent to the precision flow rate tubing sets currently used with the Freedom 60 infusion system as documented in K140133.

Due to their equivalent functions, connectivity, assembly, and technology, any differences between the flow control accessories of the predicates and the SCIg60 Infusion System are insignificant and do not raise concerns of safety of effectiveness.

(D) Patient Administration Set

The Freedom 60 predicate and the SCIg60 Infusion System require the use of additional patient administrative sets to transfer liquid medicine into the patient.

Sterilization

Infuset™ Flow Control Extension Sets are ETO sterilized to a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1 standard, whereas the predicate flow rate controller set achieves necessary sterility levels via radiation.

See Section 15 and Appendix E for additional information regarding the validated ETO sterilization process for Infuset™ Flow Control Extension Sets.

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Bench Testing and Device Performance Discussion

Table 13-3 below summarizes bench testing that was performed to establish performance of the EMED SCIg60 Infusion System to evaluate conformance to product specification and equivalence to the predicate device.

Table 13-3:

	EMED SCIg60 Infusion System	**Freedom60 Infusion System**
Maximum Operating Pressure	16.8 psi	16.1 psi
Average Operating Pressure	14.4 psi	13.5 psi
Flow Rate Accuracy (0.9% saline at RT)	+/- 10%	+/- 8%
Flow Rate Range (0.9% saline at 20°C - 25°C)	48 – 2089 ml/hr	47 – 1743 ml/hr
Vertical Sensitivity (for differential of 24”)	+/- 5.0%	+/- 6.6%

See Section 19 for further information regarding bench testing equipment/apparatus, procedures, data, and conclusions.

Static Operating Pressure

Static pressure measurements were taken at several points during a simulated infusion session using the SCIg60 Infuser, a BD 60 ml syringe, and 0.9% saline solution. 0.9% saline is widely used by industry as a standard fluid for infusion activities, from which comparisons of infusion equipment attributes, properties, and performance can be made. Therefore, use of 0.9% saline solution is appropriate for use in performance comparison studies involving the SCIg60 Infusion System and the predicate.

The pressure results were averaged to obtain the values presented in Table 13-2 above. The maximum pressure result for the Freedom60 was acquired in a similar manner during a bench-top experiment (see Appendix F), while the average operating pressure can be found in Freedom60 User Manual Literature (see Appendix B).

It can be seen that the max and average pressure values are essentially the same. The differences between comparative values (0.7 psi for maximum operating pressure and 0.9 psi for average operating pressure) are insignificant in the scope of the overall functionality of the systems and would have insignificant impact on performance or safety of the systems.

Flow Rate Performance

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As mentioned in the Static Pressure discussion above, 0.9% saline is widely used by industry as a standard fluid to calibrate infusion apparatus, allowing for direct performance comparison of different flow regulating devices. For the purpose of comparing flow rate performance of the SCIg60 Infusion System against the predicate, 0.9% saline was chosen as an appropriate, established, and readily available fluid for performance testing.

Chart 13-1 below provides a summary of performance testing conducted to establish the equivalent flow rates of the Freedom 60 Infusion System and the SCIg60 Infusion System using select flow rate controlling accessories of similar nominal flow rates. Actual values are provided in Table 13-4.

Chart 13-1:

(b)(4)

[redacted]

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Table 13-4:

(b)(4)

[redacted]

It can be seen that the performance of the systems are essentially equivalent, which follows their nearly identical construction and principle of action. The Infuset™ flow control extension sets were designed to provide flow rates equivalent to that of the Freedom 60 Infusion System. Flow rate accuracy for the SCIg60 Infusion System using 0.9% saline and the Infuset flow controller devices is established as 10% from nominal (see Section 19 and Appendix F for description and test data), and the accuracy of the Freedom 60 System is provided in the User Manual as 8% from nominal. Comparison of the established flow rate accuracies for both systems underscores their similar infusion performance.

Actual flow rates can vary based on environmental factors, user conditions, and the viscosity of the fluid being transferred from the fluid source to the patient. This dynamic explains potential variances of actual flow rates during use from target values for the SCIg60 Infusion System, as well as all other infusion systems. Additional information and detail on this topic is provided in the SCIg60 User Manual, Appendix A.

Additional details on predicate device indications for use, design, principles of action, physical dimensions, materials, and performance are provided in Predicate Labeling (Appendix B).

Vertical Sensitivity

A known factor that could affect infusion flow rates of an infusion pump is the head height differential between the top of the infusion pump (including fluid reservoir) and point of infusion. To determine the influence of vertical differences between the SCIg60 infusion pump and the point of fluid exiting the Infuset™ flow control extension, benchtop performance testing was conducted. The conclusion drawn from

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this testing is that the SCIg60 Infusion System performance is influenced by head-height differentials to the same extent as the Freedom 60 Infusion System.

Summary of Substantial Equivalence

The design, principles of action, materials, performance, and materials of the EMED SCIg 60 Infusion System are essentially equivalent to the identified predicate. Both the SCIg60 Infuser and the Freedom 60 pump exert force from non-electric, mechanical actions to transfer medication to the patient from a medication reservoir through a flow-regulating set in a controlled and consistent manner. The component materials of each systems flow regulating accessories are well characterized and meet ISO 10993 biocompatibility requirements. Additionally, K140133 serves as supporting evidence that the currently marketed Infuset™ flow control extension set is substantially equivalent to the Freedom 60 precision flow rate tubing sets to provide flow rate control during infusion therapy.

The conclusions presented above, derived from design knowledge of the SCIg60 Infusion System, bench-top performance testing of the SCIg60 Infusion system and Freedom60 systems, and available literature pertaining to the predicate device, demonstrate similar technology, functionality, and performance of the SCIg60 Infusion system when compared to the Freedom 60 system that support the substantial equivalence of the SCIg60 Infusion System as compared to the predicate. Any differences between the SCIg60 Infusion System and the predicate are considered minor and do not raise any new questions of safety or effectiveness.

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Section 14: Proposed Labeling

The Instructions for Use, Product Labeling, and other proposed labeling is contained in Appendix A.

It is noted that the provided labeling for the Infuset™ Flow Control Extensions Set is consistent with that provided in K140133, with the exception to indications for use and flow rate performance information specific to use with the SCIg60 Infuser as part of the SCIg60 Infusion System.

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Section 15: Sterilization, Packaging and Expiration Dating

Sterilization

The SCIg60 Infuser will be supplied non-sterile.

Infuset™ Flow Control Extensions Sets will be sterilized to a sterility assurance level (SAL) of 10^{-6} and this process is in compliance with ISO 11355 requirements. Validation of the overkill approach to ETO sterilization (see ISO 11135-1, Annex B) is contained in Appendix E.

Table 15-1 below provides the daily exposure in mg for ETO, ethylene chlorohydrin (ECH), and ethylene glycol (EG) remaining from sterilization of the Infuset™ Flow Control Extensions Sets. It can be seen that these values are well below the thresholds indicated in ISO 10993-7 for prolonged exposure devices, therefore assuring that the sterilization of Infuset™ Flow Control Extensions Sets meets the criteria stipulated in ISO 10993-7 and use of Infuset™ Flow Control Extensions Sets as intended poses minimal risk to the patient.

Table 15-1

(b)(4) [redacted]

Information provided above regarding sterilization of the Infuset™ Flow Control Extensions Sets is identical to that found in K140133.

Packaging and Expiration Dating:

The SCIg60 Infuser will be supplied non-sterile with a shelf life of 5 years. This shelf-life is supported by simulated use testing of (b)(4) [redacted] equivalent to 5 years real-time storage at room temperature (b)(4) [redacted] (b)(4) [redacted]. See Appendix F for supporting performance testing reports.

Infuset™ Flow Control Extension Sets will be supplied in a sterilized package (sealed Dupont Tyvek pouch) with a shelf life of 5 years, identical to the packaging and expiration dating established in K140133. This shelf-life is supported by examination and bench testing of Infuset™ Flow Control Extension Sets aged (b)(4) [redacted] (b)(4) [redacted] and will be validated by testing of product stored at room temperature. This product will be marketed as a pyrogen-free medical device, as supported by pyrogenicity testing (rabbit pyrogen) as discussed in Section 16.

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Section 16: Biocompatibility

All patient-contacting materials are well-characterized and have been previously used in other medical applications. Fluid path materials are isolated to the Infuset™ flow control extension set. Full biocompatibility and extractable compound toxicological risk assessment information for the Infuset™ flow control extension set have been provided and evaluated in K140133. The Infuset™ devices discussed in this pre-market notification are identical in every aspect, including materials, processing, pouching, sterilization, and expected human exposure, to the subject devices of K140133, and therefore the biocompatibility results found in K140133 are applicable to this submission. Key points and conclusions documented in K140133 are provided below:

Device Description, Components, and Materials

Infuset™ Flow Control Extension Sets are assembled from rigid PVC standard luer lock components and specified lengths of medium-density PVC. These sets include slide-clamps used to pinch the tubing and stop the flow of fluid. Infuset™ Flow Control Extension Sets come in various configurations and lengths. Likely patient contacting surfaces include the inner fluid path of the tubing and luer lock connectors. Infuset™ Flow Control Extension Set components and materials are summarized in Table 16-1 below.

Table 16-1:

Description	QTY	Material(s)
(b)(4) [redacted]		

* Not included in surface area calculation or extraction procedure as these do not make contact with infused liquid during Infuset™ Flow Control Extension Set use.

The materials used in Infuset™ Flow Control Extension Sets are standard in industry for intravenous administrative sets, have well established safety profiles (they are used in other EMED products for several decades), and therefore it was determined that they do

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not likely pose significant risk to users. Biocompatibility tests were then performed to confirm these conclusions.

Biocompatibility Evaluation Considerations

Infuset™ Flow Control Extension Sets are designed to be used in connection with other products. Based on the design and intended use of the Infuset™ Flow Control Extension Sets, the following ISO 10993 category was deemed most appropriate external communicating device, with indirect blood path contact between 24 hours and 30 days in duration (i.e. prolonged exposure).

In accordance with ISO 10993-1:2009 and the intended use of Infuset™ Flow Control Extension Sets, the following studies were performed to establish biocompatibility of the finished devices:

- cytotoxicity
- Sensitization
- Irritation
- acute systemic toxicity
- pyrogenicity and endotoxins
- hemocompatibility

Biocompatibility Sample Preparation and Extraction Conditions

Infuset™ Flow Control Extension Sets samples manufactured under commercial conditions (FP-0010007, Lot 1206072 and Lot 1301089) were provided to the testing lab and extractions were performed per standard (b)(4) [redacted] procedure. For the majority of the testing (b)(4) [redacted]

(b)(4) [redacted]

Total surface area calculations were performed by EMED (b)(4) [redacted] for determination of the ratio of sample to extraction fluid. Calculations and images are presented in Figure 16-1 below.

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Figure 16-1:

(b)(4)

[redacted]

Biocompatibility Testing Results

Biocompatibility test results indicate that the finished devices conform to ISO 10993-1:2009 and ASTM 756. Additionally, the LAL endotoxins test results fall under the limit established in USP <161> for transfusion and infusion assemblies (0.5 EU/mL or 20 EU/device). Therefore, Infuset™ Flow Control Extension Sets can be considered biocompatible and non-pyrogenic.

Tests and test results are summarized in Table 16-2 below.

Table 16-2: Summary of Testing Performed

Standard	Test Name	Other Name	Test Result	Report Reference
ISO 10993-5	Cytotoxicity	Neutral Red Uptake	Pass	(b)(4) [redacted]
ISO 10993-10	Sensitization	Kligman Maximization	Pass	
ISO 10993-10	Irritation	Intracutaneous	Pass	

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		Injection		(b)(4) [redacted]
ISO 10993-11	Acute systemic toxicity	Systemic Injection	Pass	
ISO 10993-11	Pyrogenicity	Rabbit Pyrogen	Pass	
ISO 10993-4	Hemocompatibility	Unactivated Partial Throbmoplastin Time	Pass	
ASTM 756	Hemocompatibility	Hemolysis (complete)	Pass	
USP <85>	Endotoxins	Limulus amebocyte lysate (LAL) Endotoxin	Pass	

Extractable Compounds and Toxicological Evaluation

In addition to the biocompatibility studies discussed above, studies were performed to identify and quantify potentially extractable compounds found in the Infuset™ flow control extension set. (b)(4) [redacted]

Extraction testing of the Infuset device fluid path components was performed (b)(4) [redacted]

Extracted compounds were identified and quantified (b)(4) [redacted] A toxicological risk assessment of the identified residues and theoretical values for non-detected compounds was then performed taking into account the intended use of the Infuset device.

Based on the analytical data from extractable testing and toxicological risk assessment of the identified extracted compounds and theoretical values for non-detected compounds, it was concluded that the Infuset™ flow control extension set does not pose undue risk to users considering its intended use. Additionally, it was concluded that the small level of residual risk is acceptable due to the low likelihood of adverse effects related to the

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identified compounds and because such residual risk is far outweighed by the clinical benefit of using the Infuset device.

Conclusion

All testing of Infuset™ Flow Control Extension Sets met requirements and/or passed the acceptance criteria for biocompatibility set forth in the applicable testing standards for a surface device, with mucosal membrane contact less than or equal to 24 hours in duration. Toxicological risk assessment also determined that the Infuset™ flow control extension set does not pose undue risk to users considering its intended use, and that any existing residual risk is acceptable due to the low likelihood of adverse effects related to the identified compounds and because such residual risk is far outweighed by the clinical benefit of using the Infuset device

Therefore, Infuset™ Flow Control Extension Set can be considered conforming to ISO 10993:2009, Biological Evaluation for Medical devices requirements for their intended use.

Full biocompatibility and extractable compound toxicological risk assessment discussions, conclusions, and supporting data for the Infuset™ flow control extension set have been provided and evaluated in K140133.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Section 17: Software

The EMED SCIg60 Infusion System does not include software and therefore this section is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Section 18: Electromagnetic Compatibility and Electrical Safety

The EMED SCIg60 Infusion System does not include any electrical components or elements and therefore this section is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Section 19: Performance Testing – Bench

Various performance tests were performed to verify the SCIg60 Infusion System successfully satisfied user and product requirements, and to establish substantial equivalency between the SCIg60 Infusion System and the Freedom 60 System. The following is a summary of the critical bench top performance tests performed and the conclusions drawn from those tests. Supplemental testing performed during the design and development of the SCIg60 Infusion System has been captured in the product Design History File per 21.CFR.820 and internal Design Control requirements. Test protocols and reports are provided in Appendix F.

Doc ID	Title/Description	Purpose	Results

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Doc ID	Title/Description	Purpose	Results

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Doc ID	Title/Description	Purpose	Results
(b)(4) [redacted]			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 20: Performance Testing – Animal

No animal testing was performed in support of this notification.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Section 21: Performance Testing – Clinical

No clinical testing was performed in support of this notification.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Appendix A: User Manual and Labeling

This appendix contains the following:

Exhibit	Part No.	Description
1	AS-0010015	SCIg60 Infuser IFU label
2	AS-0010021	SCIg60 Infuser User Manual
3	AS-0010037	Artwork, Pouch, Infuset-190 (representative example)
4	AS-0010041	Infuset IFU

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NOTES: Unless otherwise specified.

1. ENVIRONMENT: Indoors
2. LIFE EXPECTED: 5 years min. attached to device.
3. MATERIAL: 3 Mil Velvet Lexan®/S730/1.5 Mil Polyester
   a) Sub-Strate: FLEXmark V 400 F WHITE V-29 SPEC 50K-8
   b) Adhesive: S730 clear solvent acrylic permanent adhesive.
4. BACKGROUND TO MATCH SABIC PLASTICS NORYL GFN1 COLOR WHITE WH8F014
5. SIZE: 1.743in X 5.827in +.010 -.020
6. ALL MATERIALS AND INK TO BE RoHS COMPLIANT.
7. CERTIFICATE OF CONFORMANCE IS REQUIRED WITH EVERY SHIPMENT.

2X R.063"

SCIg60 Infusion System

Use only with EMED flow rate infusion sets and B-D 60ml syringe.

1) **FILL** syringe with desired fluid.

2) **CONNECT** flow rate infusion set to syringe and patient set.

3) **PRIME** flow rate infusion set and patient set per healthcare provider instructions.

4) **CLOSE** fluid path per flow rate infusion set instructions.

5) **REFER** to healthcare provider instructions to connect patient set to patient.

6) **OPEN** ***SCIg60 Infuser*** drive by rotating the knob counterclockwise until it stops.

7) **LOAD & LOCK** syringe into the ***SCIg60 Infuser*** by inserting the syringe plunger and rotating the syringe 90° until it clicks into place.

8) **VERIFY** syringe's proper placement into the ***SCIg60 Infuser*** by confirming that the syringe flange shows through the window marked in red (image above).

9) **CLOSE** the ***SCIg60 Infuser*** by rotating the knob clockwise until it stops (see image on step 6).

10) **COMPLETE INFUSION** as instructed by your health care provider.

11) **OPEN** the ***SCIg60 infuser*** drive before removing the syringe (see step 6).

SN XXXXXX

RxOnly

CE 0459

EMED Technologies Corporation
www.emedtc.com | Tel. 888.550.6500
AS 0010015 2 1

4

EACH LABEL TO BE SERIALIZED
STARTING AT **000600**
AND CONTINUE WITH SERIALIZATION
FOR EACH LABEL P.O.
FONT: ARIAL BOLD 10 PT. BLACK.
(REPLACE XXXXXX WITH SERIAL #)

Revision History

Rev	Description	DCR#
1.0	PILOT RELEASE	10122011 02
2.0	UPDATED IFU INSTRUCTIONS	12232011 01
2.1	UPDATED TYPO ON BLUE COLOR 385 TO 285	01122011 01
2.2	ADDED NOTE TO CONTINUE SERIALIZATION	10022012 01

C M Y K

285 396 426 485

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APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN BY:	Carlos G.	[ON FILE PER DCR]	01/12/2012
ENGINEERING:	Carlos G.	[ON FILE PER DCR]	10/15/2012
MFG.	Carlos G.	[ON FILE PER DCR]	10/15/2012
S&M	N/A	N/A	-
Q.A.	P. Rollings	See DCR 10022012-01	10/15/12

EMED Technologies
The power of creative thinking
EMED Technologies Corporation
1264 Hawks Flight Court Suite 200
El Dorado Hills, CA 95762
Tel. 916.932.0071
Website: www.emedtc.com

Desc. ARTWORK, SCIg60 INFUSER IFU LABEL
Rev. 2.2
Part No. AS-0010015
Size: A | Scale: 1:1 | Sheet 1 OF 1 | Template NO. MF 0006 REV 1.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SCIg60 Infusion System

EMED Technologies
The power of creative thinking

The Power of
CREATIVE THINKING

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Introduction

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

Indications

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

SCIg60 Infusion System Product Line:

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

NOTE: EMED subcutaneous infusion administration sets and BD 60 mL syringes are not provided and may be purchased sold separately.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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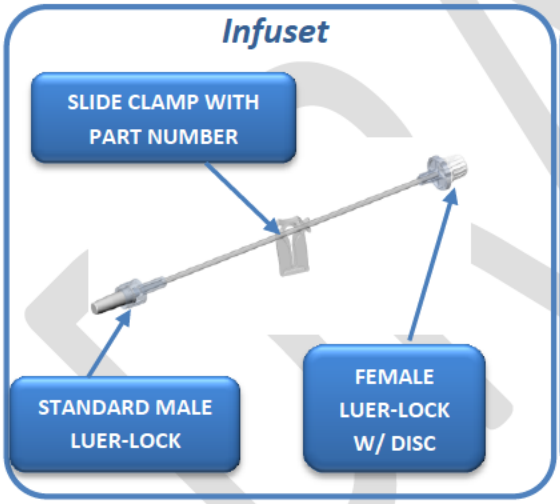
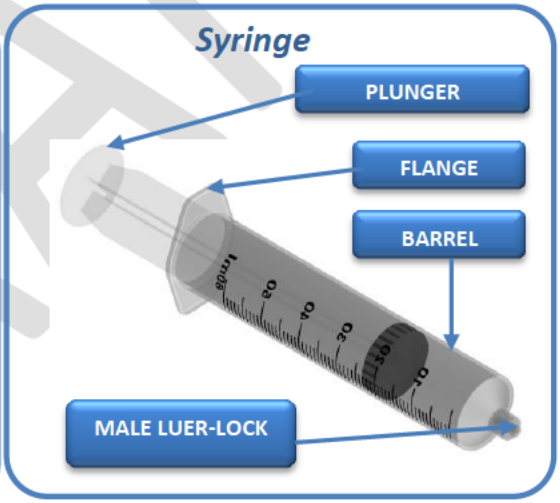
Getting to know your SCIg60 Infusion System





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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Complete SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Available Infuset Flow Control Extension Sets

Reorder Number	Description
FP-0010013	Infuset-45
FP-0010014	Infuset-80
FP-0010011	Infuset-120
FP-0010008	Infuset-190
FP-0010007	Infuset-290
FP-0010010	Infuset-430
FP-0010009	Infuset-650
FP-0010006	Infuset-820
FP-0010005	Infuset-930
FP-0010004	Infuset-1850

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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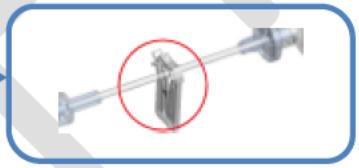
SCIg60 Infusion System Instructions for Use (IFU)

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

1. **WASH HANDS** before handling any supplies.
2. **REMOVE** Infuset flow controller, patient set and syringe from sterile packaging – Use caution to maintain the sterility of the fluid path.
3. **LOAD** syringe with drug.
4. **CONNECT** syringe and patient set to Infuset controller set.
5. **PRIME** set per your healthcare provider instructions.
6. Use slide clamp provided with Infuset to prevent flow of drug.
7. Select sites and insert needles as instructed by healthcare provider and/or subcutaneous administration set instructions.
8. **OPEN** SCIg60 Infuser drive by rotating the handle **counterclockwise** until it stops.
9. **LOAD** syringe into SCIg60 Infuser by inserting the syringe plunger into the SCIg60 infuser.
10. **LOCK** syringe into SCIg60 Infuser by rotating the syringe 90° in either direction until you feel a click.
11. **VERIFY** the syringe flange is in the window of SCIg60 Infuser to confirm the syringe is properly locked in place.



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instructions for Use (IFU) – Continued

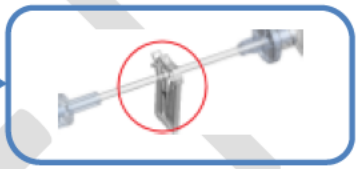
12. **CLOSE** SCIg60 Infuser drive by rotating the handle clockwise until it stops.

    CAUTION: DO NOT ATTEMPT TO REMOVE THE SYRINGE BEFORE PERFORMING STEP 16.

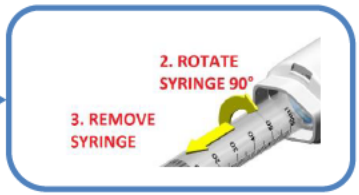
13. Place the SCIg60 Infuser, Infuset, and patient set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the SCIg60 Infuser Carrying Case Accessory* below for more details).

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

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



16. To **REMOVE THE SYRINGE** rotate the handle **counterclockwise** until it stops, then unlock the syringe by turning it 90° in either direction (refer to steps 8 - 10 above).



Using the SCIg60 Infuser Carrying Case Accessory

1. Open pouch and unfasten Velcro straps inside the pouch.
2. Insert SCIg60 Infuser with syringe and Infuset into the pouch on top of Velcro straps.

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

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Hizentra Dosage and Administration

EMED has conducted performance testing to ensure that the SCIg60 Infusion System provides Hizentra flow rates that fall within manufacturer's recommended dosages, decrease infusion time, and accommodate each individual's needs for infusion comfort and convenience. The following table indicates the Reorder Number of the Infuset flow control extension set and common 24g and 27g subcutaneous administration set configurations that that will provide patients with the shortest infusion duration while meeting Hizentra flow rate and administration guidelines.

24g Patient Administration Sets

	For Initial Infusion			For Subsequent Infusion		
# of Needles	Infuset Reorder Number	Avg Flow Rate (ml/hr) Total	Avg Flow Rate (ml/hr) Per Needle	Infuset Reorder Number	Avg Flow Rate (ml/hr) Total	Avg Flow Rate (ml/hr) Per Needle
1	FP-0010008	11.64	11.64	FP-0010010	22.54	22.54
2	FP-0010010	26.01	13.01	FP-0010009	35.11	17.56
3	FP-0010009	38.84	12.95	FP-0010005	51.49	17.16
4	FP-0010009	38.62	9.66	FP-0010005	51.59	12.90
5	FP-0010005	51.50	10.30	FP-0010004	100.37	20.07
6	FP-0010005	53.3	8.88	FP-0010004	117.00	19.50

27g Patient Administration Sets

	For Initial Infusion			For Subsequent Infusion		
# of Needles	Infuset Reorder Number	Avg Flow Rate (ml/hr) Total	Avg Flow Rate (ml/hr) Per Needle	Infuset Reorder Number	Avg Flow Rate (ml/hr) Total	Avg Flow Rate (ml/hr) Per Needle
1	FP-0010009	13.71	13.71	FP-0010004	17.27	17.27
2	FP-0010005	25.04	12.52	FP-0010004	29.56	14.78
3	FP-0010004	42.64	14.21	FP-0010004	42.64	14.21
4	FP-0010004	48.89	12.22	FP-0010004	48.89	12.22
5	FP-0010004	57.49	11.50	FP-0010004	57.49	11.50
6	FP-0010004	70.09	11.68	FP-0010004	70.09	11.68

Flow rates can be affected by multiple factors such as ambient temperature, patient conditions, large height differences between the Infuser and infusion site, and variations in Hizentra viscosity. The above flow rates are based on bench testing of a single Infuset and 36 inch subcutaneous tissue infusions set performed between 20°C - 25°C (68°F – 77°F) and are intended to be used as starting points to determine the flow rate for individual patient, as determined by a healthcare professional. Additional Infuset configurations are available and may be considered in order to meet each patient's unique therapeutic situation. Use of multiple components will impact resulting flow rates and is not recommended.

For further guidance in determining which Infuset flow control extension set to use, please contact EMED Technologies at +1 (916) 932-0071.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

SCIg60 Infuser Technical Information

Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 gr/ 14.5 oz
Storage Temperature	-5°C to +40°C (23°F to 104°F)
Syringe Volume	60 ml
Maximum Operating Pressure	16.8 psi
Average Operating Pressure	14.4 psi
Vertical Sensitivity	± 5.0% per 60 cm (24 in.)
Target Operating Temperature	20°C - 25°C (68°F – 77°F)

SCIg60 Infuser - Cleaning and Storage

- Clean the SCIg60 Infuser using alcohol wipes, isopropyl alcohol, or mild detergent and warm water.
- Clean only those areas that are exposed and external. Do not attempt to clean any part of the pump that is not easily accessible.
- Discontinue use of a pump that has been internally exposed to or immersed in fluid.
- Use a dry cloth to dry the exposed and external portions of the device, or allow the infuser to dry at room temperature. Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.
- 5 year shelf-life

SCIg60 Infuser Carrying Case – Cleaning and Storage

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting

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

- **SYRINGE POSITION**. Verify the syringe is properly positioned into the infuser as instructed in the IFU section; the syringe should be parallel to the infuser with the syringe flanges properly engaged and seen in the safety check window (shown in the diagram). If syringe 'pops out' of infuser when inner drive is activated/screwed in, it is an indication that the syringe was not properly positioned in the infuser. Unscrew the inner drive and properly position the syringe following the instructions for use.
- **TUBING CONNECTORS**. Verify the syringe is properly connected to the Infuset and that the Infuset is correctly connected to the subcutaneous administration sets.
- **NO FLOW.** Check the slide clamp on the Infuset and make sure it is not blocking the flow. Verify that no other clamp is blocking the flow and that the Infuset or administration set is not kinked in any way.
- **FLOW RATE IS TOO HIGH**. Verify that the correct Infuset is being used.
- **FLOW RATE IS TOO SLOW**. Verify that the correct Infuset is being used and that the Infuset or administration set is not kinked in any way.

  NOTE: Storage of the Infuset with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.
- **FLOW DOES NOT STOP**. Verify that the slide clamp on the Infuset is fully closed.
- **BROKEN PARTS**. Inspect infuser for any broken parts. If after following the instructions above the SCIg60 Infusion System does not appear to be working properly, or if you observe something unusual, discontinue use of the SCIg60 Infusion System and contact your healthcare provider or EMED Technologies Corporation.

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

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Contraindications/Warnings

DO	DO NOT
Read all instructions for the SCIg60 Infusion System.	Do not continue to use a pump that has been damaged, dropped, or if it has failed to perform as expected. If the infuser is dropped or damaged either in transit to you or during preparation for its use, or if any other damage is suspected, contact EMED Technologies.
Read all instructions for the Infuset flow controller and subcutaneous administration set.	Do not subject the Infuser to autoclaving or other similar methods of sterilization.
Use the SCIg60 Infusion System as prescribed by your healthcare provider and follow all the directions as prescribed.	Do not open the infuser or attempt to modify its function in any way other than its intended use.
Use only EMED Infusets to control the flow; using any other device/tubing to control the flow rate may result in unsafe conditions for patient.	DO NOT use any other syringe. Doing so may result in unsafe conditions for patient or deviation from desired infusion rates.
Use only BD 60 ml syringes (model no. 309653).	**Do not insert or remove the syringe** until the INNER DRIVE is fully opened, as indicated in the IFU section, step 16.
Use aseptic technique when handling Infuset flow control extension sets and **subcutaneous administration set.**	Do not use Infusets or syringes more than once, as reuse may result in infection, cross contamination, or altered flow rate performance.
Place SCIg60 Infusion pump on a flat surface or in the provided carrying case during use. Syringe damage and drug loss could occur if system is dropped while loaded with syringe and drug.	Do not re-sterilize Infuset flow control extension sets, doing so may cause serious health effects to patient.
The SCIg60 Infusion System is intended for single patient use only.	Do not use SCIg60 Infusion System while undergoing medical diagnostic procedures, such as MRI, x-ray, or CT scans.
Contact EMED if you have any questions regarding the use of the SCIg60 Infusion System.	Do not use multiple Infusets at one time because the flow rates provided in this Manual and the Infuset IFU are for use of a single Infusets.

Warranty

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- **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 Manufacturer's Representative.
- **Limited Warranty:** EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects in materials and workmanship under normal use, if used in accordance with device operating instructions and under the direction of authorized medical personnel. Failure to comply with these conditions will result in a void warranty.
- **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 one 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 one-year warranty period.
- **Disposable items (Infusets)**: In the event that a disposable item is found defective, it will be replaced with a new disposable item.

EMED Technologies Contact Information

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1264 Hawks Flight Court, Suite 200
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Email: info@emedtc.com
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sales@emedtc.com

EC REP
Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: +31 (0) 70 345 8570
Fax: +31 (0) 70 346 7299

CE 0459

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Symbols Definition Table

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

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions	-5°C 40°C	Storage temperature limits
	Do not re-use	SN	Serial number
	Don't use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide		Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date	Non-Pyrogenic	Non-pyrogenic fluid path

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

3.750 in

Peel Down

Infuset-190

Reorder No. / REF *FP-0010008*

Infusion extension set (en) Dispositif de perfusion (fr)
Equipo de infusión (es) Infusionset (de)
Set di infusione (it) инфузионный набор (ru)
Infusionsset (sv) Infuusionsetti (fi)
Infusionssæt (da) Infusjonssett (no)

51.76cm, ø0.3mm ID, ø2.4mm OD ≈ 0.14ml
Approximate priming volume.

QTY: 1 ea.
LOT XXXXXXX

Manufacture Date: DD.MMM.YEAR
Expiration Date: DD.MMM.YEAR

CAUTION. Consult the instructions for use. Do not use if package is damage.

STERILE EO Do not re-use. Non-Pyrogenic

This product is not made with di(2-ethylhexyl) phthalate (DEHP).

This product is not made with natural rubber latex.

40°C
-5°C
Storage temperature limits.

RxOnly CE 0459

CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

EC REP European Representative:
Meridian Medical Ltd.
Unit 1, Thorgate Road
Lineside Industrial Estate
Littlehampton, West Sussex BN17 7LU
Telephone: +44 (0) 1903 732 344
Fax: +44 (0) 1903 732 348
Email: admin@meridian-medical.com

Manufactured for:
EMED Technologies Corporation.
Assembled in Mexico from US components.
1264 Hawks Flight Ct. Suite 200
El Dorado Hills, CA 95762 USA
Telephone: +(1) 916.932.0071
Fax: +(1) 916.932.0074
Email: info@emedtc.com
Website: www.emedtc.com

EMED Technologies
The power of creative thinking

AS-0010037_3.0-B

REVISION HISTORY

REV	DCR#	CHANGE DESC.	DATE
1.0	12122011-01	INITIAL RELEASE	12/14/11
1.1	04182012-02	Updated REF# and Symbols	04/18/12
1.2	05182012-01	Changed MFG by to for: Added Assy in Mex.	05/18/12
2.0	10152012-01	Changed notes	11/15/12
3.0-A	12132013-02	Added symbols subtitles	12/13/12
3.0-B	03242014-02	Removed DEPH and Latex symbols.	12/13/12

Notes (Unless Otherwise Specified)
1. COLOR: ARTWORK TO BE PRINTED IN BLUE PMS 285.

2. PRINT ARTWORK ON TYVEK SIDE OF POUCH.

3. POUCH SIZE: 3.75" X 8.00"

4. PRINT MANUFACTURE AND EXPIRATION DATE AND LOT NUMBER PER EMED'S SPECIFICATIONS, (SAMPLE 01. JAN. 2012)

APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN.	Carlos G.	[ON FILE PER DCR]	03/24/14
ENG APPR.	Carlos G.	[ON FILE PER DCR]	03/24/14
CHECKED.			
MFG APPR.	Carlos G.	[ON FILE PER DCR]	03/24/14
Q.A.			

EMED Technologies
The power of creative thinking
EMED Technologies Corporation
1264 Hawks Flight Suite 200
El Dorado Hills CA, 95762
Tel. 916.932.0071
www.emedtc.com

TITLE: **Artwork, Pouch, Infuset-190**

ARTWORK # AS-0010037 REV. 3.0-B

SIZE: A SCALE: 1:1 SHEET 1 OF 1 TEMPLATE NO: MF-0013 REV 1.2

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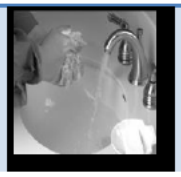
Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Infuset Flow Control Extension Set
Instructions for Use

WARNING:

- The Infuset™ Flow Control Extension Set is intended for home or hospital use with:
  - the SCIg60 Infuser for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).
  - the RMS Freedom 60 Syringe Infusion Pump System (K933652) and the BD 60 ml syringe (model no. 309653) to provide flow rate control to administer fluids from a container to a patient's vascular system, or
- Single use only; reuse may result in infection, cross contamination, or altered flow rate performance.
- Do not re-sterilize
- Use aseptic technique
- Follow pharmacy / physician instructions
- U.S. Federal Law restricts this device to sale by or on order of a physician

1		Wash hands before handling any supplies
2		Remove Infuset from packaging
3		Load BD 60 ml syringe (model no. 309653) syringe with drug
4		Connect syringe male luer lock (MLL) to Infuset female luer lock (FLL)
5		Connect Infuset male luer lock (MLL) to patient administration set male luer lock (FLL)
6		Prime set (be careful not to waste fluid) per your pharmacy / physician instructions.
7		Use provided slide clamp to prevent flow of fluid.
8		Load syringe into SCIg60 Infuser or Freedom60 Infusion Pump per pump User's Manual. **NOTE**: If using the Freedom60 Infusion Pump, be sure the female luer lock (FLL) disc is fully seated in the pump's nose.
9		Operate SCIg60 Infuser or Freedom 60 Infusion pump per User Manual and pharmacy / physician instructions directions.
10		Complete the infusion and disconnect Infuset from patient / equipment per your pharmacy / physician instructions
11		Dispose in appropriate waste container

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Corporate Headquarters: 1264 Hawks Flight Court, Suite 200 El Dorado Hills, CA 95762
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CE 0459

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Infuset Flow Control Extension Set
Instructions for Use

	SYMBOLS	ENGLISH
1		Warning
2		Read the instructions
3		Do not re-use
4		Don't use if package is damaged
5	STERILE EO	Sterilized by Ethylene Oxide
6		Manufacturer
7	EC REP	EC Representative
8	REF	Reference number
9		Manufacturing date
10	LOT	Batch
11		Expiration date
12		Quantity
13	40°C -5°C	Storage temperature limits
14	SN	Serial number
15	Ø	Diameter
16		Length
17	Rx ONLY	To sale by or on he order of a physician.
18	≈ XX ml	Approximate priming volume
19	CE	CE Mark
20	ID	Internal Diameter
21	OD	Outer Diameter
22	Non-Pyrogenic	Non-pyrogenic fluid path

Infuset Flow Rates
(0.9% saline at 20°C - 23°C)

		With SCIg60		With Freedom60	
Reorder Number	Description	Flow Rate (ml/hr)	Accuracy (%)	Flow Rate (ml/hr)	Accuracy (%)
FP-0010013	Infuset-45	45	+/- 10	Not Available	
FP-0010014	Infuset-80	80	+/- 10	Not Available	
FP-0010011	Infuset-120	120	+/- 10	Not Available	
FP-0010008	Infuset-190	190	+/- 10	202	+/- 10
FP-0010007	Infuset-290	290	+/- 10	305	+/- 10
FP-0010010	Infuset-430	430	+/- 10	444	+/- 10
FP-0010009	Infuset-650	585	+/- 10	610	+/- 10
FP-0010006	Infuset-820	750	+/- 10	817	+/- 10
FP-0010005	Infuset-930	875	+/- 10	939	+/- 10
FP-0010004	Infuset-1850	2100	+/- 10	2244	+/- 10

NOTE: Flow rates can be affected by ambient temperature and patient conditions. The above flow rates were determined at controlled room temperature (20°C - 23°C) without any patient sets or additional tubing downstream of the Infuset, and are intended to be used as starting points to determine the flow rate for individual patient, as determined by a healthcare professional.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B: Predicate Labeling

This appendix contains the following:

Exhibit	Description
1	Example RMS Precision Flow Rate Tubing Set
2	RMS flow controller accessory IFU
3	RMS Freedom60 Syringe Infusion System User Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FREEDOM60®
Syringe Infusion System

REF F2400

LOT 1.347/11

2016-12

CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

STERILE R

0297

- Sterile Tubing Set (en)
- Set di tubi sterile (it)
- Steriles Schlauchset (de)
- Conjunto de tubo estéril (es)
- Tubulure sterile (fr)
- Sterilt slangesett (no)
- Steril slanguppsättning (sv)
- Steriili letkustopakkaus (fi)
- Sterilt slangesæt (da)

7051

RMS® MEDICAL PRODUCTS

EC REP

RMS UK Ltd,
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Nailsea, Somerset
BS48 4NU, UK

RMS Medical Products
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Chester, NY 10918 USA
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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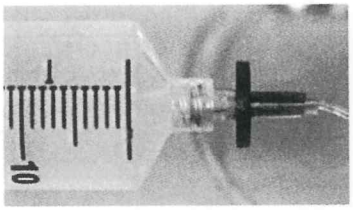
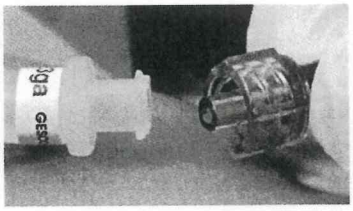
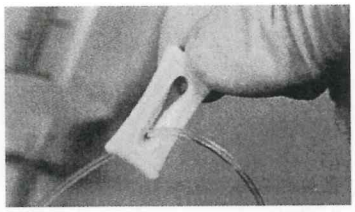
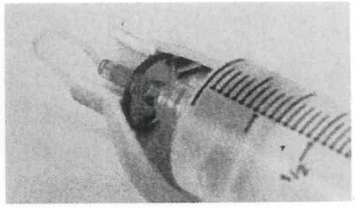
Freedom60® Sterile Tubing Set

Instructions • Istruzioni • Gebrauchsanleitung • Instrucciones • Instructions • Instruksjoner • Instruktioner • Ohjeet • Vejledning









Connect the luer disc end of the tubing set to the syringe.	Connect the male end of the tubing set to the indwelling catheter (IV) or needle set (Sub-q).	To immediately stop flow in the case of an emergency, pull the tubing through the slide clamp.	When inserting the syringe into the pump, make sure the tubing luer disc is fully seated in the pump's nose.
Collegare alla siringa l'estremità del disco luer del set di tubi.	Collegare l'estremità maschio del set di tubi al catetere a dimora (endovenoso) o al set di aghi (Sub-q).	Per arrestare immediatamente il flusso in caso di emergenza, tirare i tubi attraverso il morsetto scorrevole.	Quando si inserisce la siringa nella pompa, accertarsi che il disco luer dei tubi sia completamente alloggiato nell'estremità anteriore della pompa.
Den Luer-Anschluss des Schlauchsets an die Spritze anschließen.	Den Stecker des Schlauchsets mit dem Verweilkatheter (IV) oder dem Nadelset (Sub-Q) verbinden.	Um im Notfall den Fluss sofort stoppen zu können, ziehen Sie den Schlauch durch die Schiebeklemme.	Beim Einführen der Spritze in die Pumpe unbedingt sicherstellen, dass der Luer-Anschluss des Schlauchs vollständig und sicher in der Pumpennase sitzt.
Conecte el extremo del disco luer del conjunto de tubos a la jeringa.	Conecte el extremo macho del conjunto de tubos al catéter permanente del paciente (IV) o al juego de agujas subcutáneas.	Para detener inmediatamente el flujo en caso de una emergencia, tire del tubo a través de la pinza deslizante.	Cuando inserte la jeringa en la bomba, asegúrese de que el disco luer del tubo se queda completamente asentado en la nariz de la bomba.
Connecter l'extrémité du disque Luer de la tubulure sur la seringue.	Connecter l'extrémité mâle de la tubulure au cathéter à demeure (IV) ou à l'aiguille (sous-cutanée).	Pour interrompre immédiatement le débit en cas d'urgence, tirer la tubulure au travers du clamp coulissant.	Lors de l'insertion de la seringue sur la pompe, s'assurer que le disque Luer de la tubulure soit correctement positionné sur le bec de la pompe.
Koble endestykket av luerskiven til rørsettet på sprøyten.	Koble hanndelen av rørsettet til det intravenøse kateteret (IV) eller nålsettet (Sub-q).	For å umiddelbart stoppe gjennomstrømning i nødstilfelle, dras slangen gjennom skliklemmen.	Når sprøyten settes inn i pumpen, må det påses at rørets luerskive er godt festet i nesen på pumpen.
Anslut luerskivans ända av slangen till sprutan.	Anslut slangens hanända till den kvarliggande katetern (IV) eller nåluppsättningen (Sub-q).	Om du behöver stoppa flödet vid nödfall, drardu slangen genom glidklämman.	När du för in sprutan i pumpen kontrollerar du att slangens luerskiva sitter helt på plats i pumpens nos.
Liitä letkuston luer-laippapää ruiskuun.	Liitä letkuston koiraspää kestokatetriin (IV) tai neulasarjaan (Sub-q).	Hätätilanteessa virtaus loppuu välittömästi, kun vedät letkun liukupuristimen läpi.	Varmista asettaessasi ruiskua pumppuun, että letkun luer-laippa on sovitettu hyvin pumpun kärkeen.
Monter enden af luerskiven på slangesættet, til sprøjten.	Tilslut han-enden af slangesættet til det fastliggende kateter (IV) eller nålesæt (sub-q).	Gennemstrømningen standses i nødstilfælde ved at trække slangen igennem skydeklemmen.	Når sprøjten indsættes i pumpen, skal det kontrolleres at slangens luerskive sidder korrekt i spidsen af pumpen.

EC REP **RMS Medical Products** • Chester, NY 10918 USA • Ph: 800-624-9600 or 845-469-2042
RMS UK Ltd, Nailsea, Somerset BS48 4NU, UK

CE 0297

www.freedom60.com

342101

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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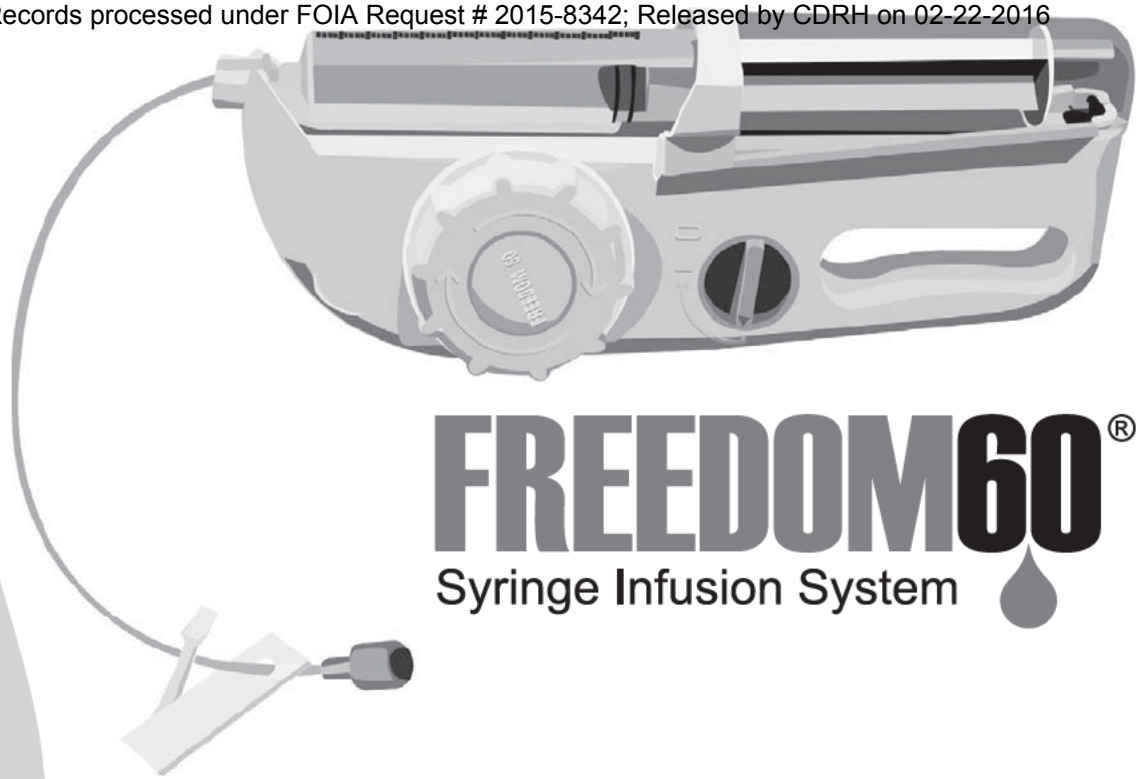

FREEDOM60®

Syringe Infusion System

Instructions For Use

Introduction 2
Indications for Use 2
Contraindications 2
Caution 3
FREEDOM60® Pump Diagram 4
FREEDOM60® Product Line 4
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Testing FREEDOM60® Syringe Infusion Pump 5
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8108

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Introduction:

The FREEDOM60® Syringe Infusion System is portable and easy to use, requiring no batteries or electric. There are only two operating knobs and special precision tubing sets are used to control the flow rate.

The FREEDOM60® operates at a constant safe pressure of 13.5psi. The constant pressure developed in the FREEDOM60® automatically decreases the flow rate if there is an increase in resistance during the delivery. The system will find equilibrium between the increasing resistance and flow rate. It provides constant flow which tends to inhibit clots, and holds full pressure after an infusion is complete to prevent blood or drug backflow. The FREEDOM60® also eliminates concerns of a bolus, overflow, overdose or runaway infusion.

Indications for Use:

The FREEDOM60® Syringe Infusion System is indicated for the infusion of prescribed liquid medicines.

Contraindications:

The FREEDOM60® is not intended for the delivery of blood, critical* or life-sustaining medications, or for the infusion of insulin.

*Critical may be defined as medication requiring greater accuracy of delivery, such as CNS opiate depressants which in certain countries, e.g. UK, may be limited by local regulations. CONSULT LOCAL REGULATORY AUTHORITIES.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Caution:

- Use the FREEDOM60® Syringe Infusion System only for the patient for whom the device is prescribed and only for its intended use.
- Use only FREEDOM60 Precision Flow Rate Tubing™ sets manufactured by RMS Medical Products. Use of any other tubing set may cause the syringe to eject from the pump and eventually cause internal damage to the pump. Use of any other tubing set may also cause over delivery of fluids or medication to the patient.
- Use only recommended 60ml syringes with the FREEDOM60®. Do not use Terumo® syringes.
- Do not use syringes smaller than 60ml. The use of a smaller syringe may cause high pressures unsafe for the patient.
- Before use, carefully inspect the tubing set package. Do not use the tubing set if the package is opened or damaged.
- Do not re-sterilize tubing sets.
- Overuse of the slide clamp or storing tubing sets with the slide clamp engaged for long periods of time* may damage the tubing and affect the infusion rate.
- The black tab that pushes on the syringe plunger operates under high force. Do not place fingers on the black tab or inside the syringe shield at any time. Do not attempt to interfere with the movement of the black tab at any time.
- Carefully inspect the FREEDOM60® Syringe Infusion Pump before use. Verify its condition and test. If repeated testing indicates the pump is not operating properly or at the appropriate rate of flow, immediately discontinue use.
- Do not attempt to open the pump housing or remove the syringe shield. Do not operate if the syringe shield has been removed.
- Do not attempt to remove the syringe or disconnect the tubing set without first turning the pump OFF and fully winding the large knob clockwise until the black tab has reached the end of its track.
- The FREEDOM60® Syringe Infusion System does not have an alarm, therefore no alarm will sound if an interruption to flow occurs. There is no display of infusion status. The pump is not suitable for use with medication where delay or under-infusion could result in serious injury.
- Discontinue use of a pump that has been damaged, exposed to severe impact, or which has failed to test properly.
- Discontinue use of a pump that has been submerged in fluid. If any fluid is allowed to enter the pump, it should be replaced immediately.
- Do not autoclave the FREEDOM60®. It will melt the ABS plastic and damage the pump.
- Federal law (USA) restricts this device to sale by or on order of a physician.
- Priming and shipping of tubing sets, packaged at temperatures below freezing, is not recommended. This may damage the tubing.

*For example, generally greater than about 2 hours.

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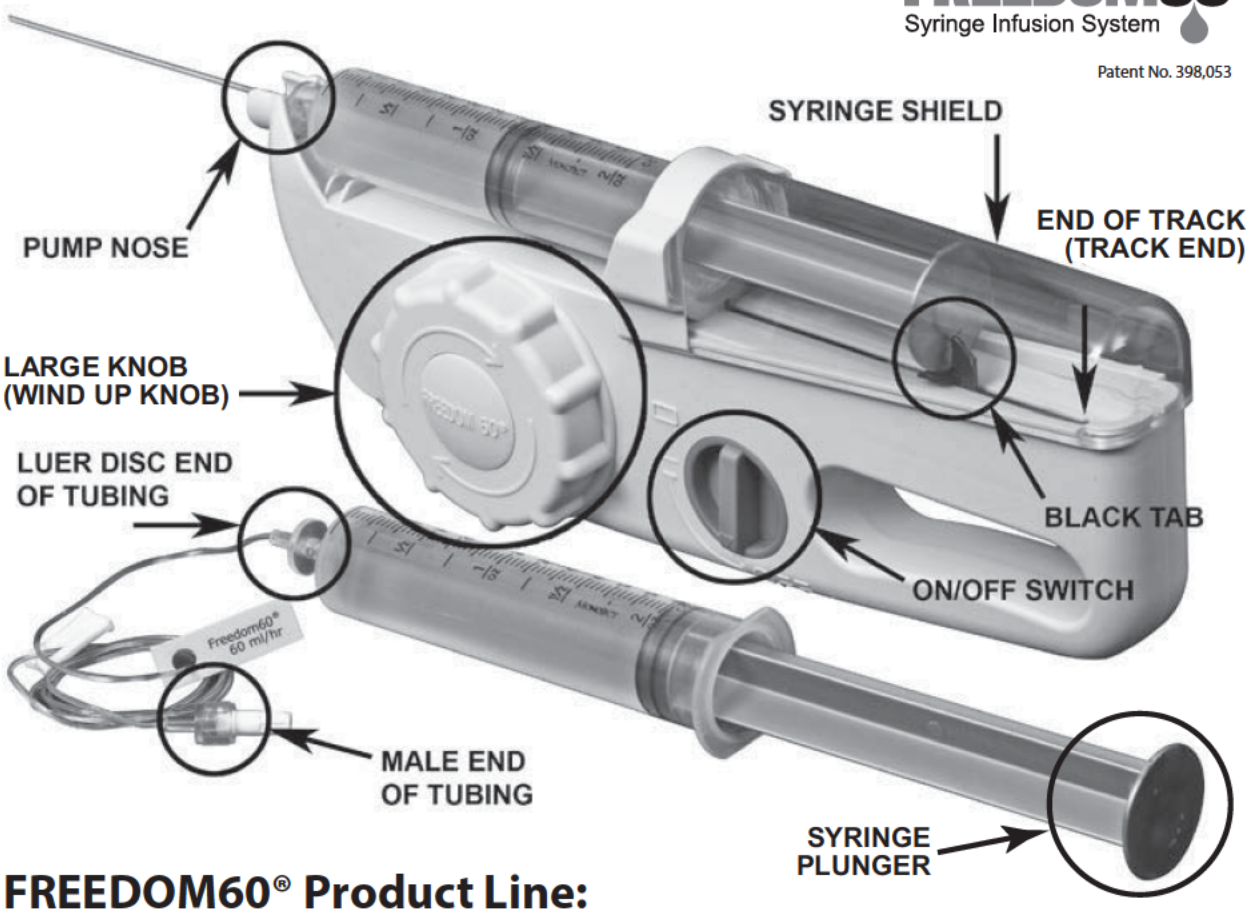
FREEDOM60® Pump Diagram:

FREEDOM60® Syringe Infusion System

Patent No. 398,053



FREEDOM60® Product Line:

Each FREEDOM60® Syringe Infusion System includes a travel pouch and user manual.

Product	Part #
FREEDOM60® Syringe Infusion Pump	F10050
Travel Pouch	F10090

Rate Controlled Tubing (case of 50)

Part #	Flow Rate	Part #	Flow Rate
F0.5	0.5ml/hr[1]	F45	45ml/hr[2]
F1	1ml/hr[1]	F60	60ml/hr[2]
F2	2ml/hr[1]	F120	120ml/hr[2]
F3	3ml/hr[1]	F180	180ml/hr[3]
F3.8	3.8ml/hr[1]	F275	275ml/hr[3]
F5	5ml/hr[1]	F420	420ml/hr[3]
F8	8ml/hr[1]	F500	500ml/hr[3]
F10	10ml/hr[1]	F600	600ml/hr[3]
F15	15ml/hr[1]	F900	900ml/hr[3]
F20	20ml/hr[1]	F1200	1200ml/hr[3]
F30	30ml/hr[2]	F2400	2400ml/hr[3]

FREEDOM60 precision™ FLOW RATE TUBING

[1] Sterile water for injection (SWFI) direct flow rates.
[2] Adjusted for antibiotic use, for actual flow rates see examples on pages 10-11.
[3] SWFI flow rates will be reduced from stated values. Typically used for viscous drugs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Syringes for use with the FREEDOM60®:

- Becton Dickinson & Co. BD® Luer-Lok® 60ml (US Reference #309653; EU Reference #300865)
- Sherwood Medical Monoject® 60ml (Reference #8881-560125)

Testing the FREEDOM60® Syringe Infusion Pump:

1. Examine the inside of the syringe shield and ensure it is free of debris or contamination.
2. Make sure that the pump's on/off switch is in the OFF position and that the black tab within the syringe shield is at the end of its track. If the black tab is not at the end of its track, fully wind the large knob clockwise.
3. Turn the pump ON (–) and watch that the tab moves smoothly along the full length of its track; listen for the following sounds:
    - a 'click' as the pump is turned ON (–)
    - a 'whirring' sound as the black tab moves forward
    - a 'click' as the tab reaches the end of its travel
4. Test to make sure the syringe tension tab (the one-inch long tab located at the entry of the syringe shield) operates freely by adjusting it up and down with your finger.

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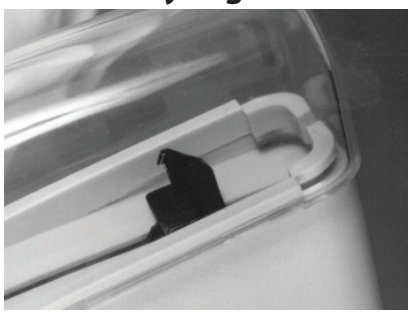
Syringe Loading and Removal Instructions:

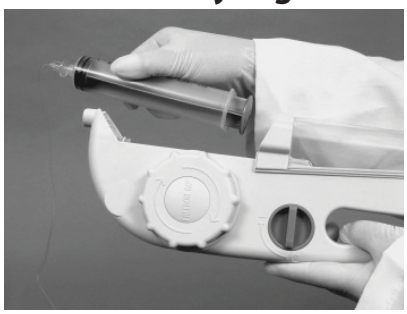
To load a syringe:



Make sure that the pump's on/off switch is in the OFF position and that the black tab within the syringe shield is at the end of its track. If the black tab is not at the end of its track, wind the large knob clockwise.

With the tubing attached and gradations facing up, load the pre-filled syringe, plunger first, into the syringe shield. Make sure the tubing luer disc is fully seated in the pump's nose.

To remove a syringe:



After the infusion is complete, turn the pump OFF and wind the large knob clockwise until the black tab is at the end of its track. Remove the empty syringe by gently pushing it back to disengage the nose, then lifting it up out of the pump.

Note: You will never need to use force to load or remove a syringe. If you're having trouble loading or removing, stop and make sure the black tab is at the end of its track.

Selected Flow Rates vs Time:

Note: For assistance in determining which flow rate tubing set to use, please contact RMS Medical Products at 800-624-9600.

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Flow Rate vs Time Chart

Syringe Volume	1ml/hr	2ml/hr	30ml/hr	45ml/hr	60ml/hr	120ml/hr
5	5 hrs.	2 hrs. 30 min.	10 min.	6 min. 42 sec.	5 min.	2 min. 30 sec.
10	10 hrs.	5 hrs.	20 min.	13 min. 18 sec.	10 min.	5 min.
15	15 hrs.	7 hrs. 30 min.	30 min.	20 min.	15 min.	7 min. 30 sec.
20	20 hrs.	10 hrs.	40 min.	26 min. 42 sec.	20 min.	10 min.
25	25 hrs.	12 hrs. 30 min.	50 min.	33 min. 18 sec.	25 min.	12 min. 30 sec.
30	30 hrs.	15 hrs.	60 min.	40 min.	30 min.	15 min.
35	35 hrs.	17 hrs. 30 min.	70 min.	46 min. 42 sec.	35 min.	17 min. 30 sec.
40	40 hrs.	20 hrs.	80 min.	53 min. 18 sec.	40 min.	20 min.
45	45 hrs.	22 hrs. 30 min.	90 min.	60 min.	45 min.	22 min. 30 sec.
50	50 hrs.	25 hrs.	100 min.	66 min. 42 sec.	50 min.	25 min.
55	55 hrs.	27 hrs. 30 min.	110 min.	73 min. 18 sec.	55 min.	27 min. 30 sec.
60	60 hrs.	30 hrs.	120 min.	80 min.	60 min.	30 min.

Starting the Infusion:

Before loading the syringe verify the following:

- Make sure that the pump's on/off switch is in the OFF position.
- Make sure that the black tab inside the syringe shield is at the end of its track. If the black tab is not at the end of its track, wind the large knob clockwise.
- Verify that you have the correct rate controlled tubing set.

1. Using sterile technique, remove the sterile cap from the luer disc end of the rate controlled tubing set and connect the tubing to the pre-filled syringe.
2. With syringe gradations facing up, insert the syringe, plunger first into the syringe shield. Make sure the luer disc is fully seated in the pump's nose.

Note: You will never need to use force to load or remove a syringe. If you are having trouble loading/removing, make sure the pump is in the OFF position and that the black tab is at the end of its track. If the black tab is not at the end of its track, fully wind the large knob clockwise.

3. Using sterile technique, prime the tubing with the pump by loosening the cap on the male end and turning the pump ON (–). You will immediately hear a "whirring" sound as the black tab searches for the syringe plunger. When the tab finds the plunger, it will "click" indicating that that the tab is now applying pressure onto the plunger. Medication is now being pumped through the tubing set. When all air and air bubbles are gone and medication starts to drip, tighten the cap.

NOTE: *Tubing that is pre-primed for antibiotic use and shipped at temperatures below freezing could be damaged.*

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4. Remove the cap from the male end of the tubing and connect the tubing to the patient's indwelling needle or catheter.
5. Turn the pump on to begin the infusion.

Note: Once the black tab finds the syringe plunger and the 'click' sound is heard, the pump will then be totally silent for the entire infusion.

Checking Infusion Progress:

Periodically check infusion progress by taking note of the time the infusion started and checking movement of the syringe plunger. The approximate rate for antibiotics or other non-viscous solutions can be found on the waterproof label attached to the tubing. (i.e. F60 will flow at 60ml/hr, F30 will flow at 30ml/hr, etc.)

End of Infusion:

1. Confirm that the syringe is empty.
2. Turn the pump OFF and wind the large knob clockwise until the black tab is at the end of its track.
3. Disconnect the tubing from the patient.
4. Gently lift the syringe back and up out of the pump.

Note: If the dose is greater than 60ml and an additional syringe is required, load the additional syringe by repeating section titled, 'Starting the Infusion'.

Troubleshooting:

If the suggestions in this section do not solve your problem, or if problems persist, discontinue use and consult RMS Medical Products and/or your medical provider.

Syringe will not load or remove from pump

- You will never need to use force to load or remove a syringe.
- Make sure the pump is in the OFF position and that the black tab is at the end of its track. If the black tab is not at the end of its track, fully wind the large knob clockwise and try again.
- Verify that you are using the proper BD® or Monoject® brand 60ml syringe.

Syringe will not stay inside in the pump

- Make sure you are using the proprietary FREEDOM60 Precision Flow Rate Tubing™ sets with the luer disc.
- Make sure the luer disc end of the tubing has been connected to a 60ml syringe and that it is seated properly in the nose of the pump.

No flow

- Assure that the pump is in the ON (–) position.
- Make sure the slide clamp is unclamped, and has not been used for an extensive period of time. If the slide clamp is overused it can damage the tubing.

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- Test the tubing: While the pump is in the ON (–) position, use sterile procedures to disconnect the rate controlled tubing set from the indwelling needle or catheter; check for medication drip. If medication does not drip, replace the tubing as it may be blocked or damaged. If medication does drip from the rate controlled tubing, then it's most likely a problem with the indwelling needle, catheter, or any fluid path accessories such as a clave connector or needle-free adapter.

Slow flow

- If a slide clamp is used for an extensive period of time, it can damage the tubing and affect the flow rate. Try using another tubing set and measure the flow. For 60ml/hr tubing, the syringe plunger should move 10ml in 10 minutes (1ml/min). For 120ml/hr tubing, the plunger should move 10ml in 5 minutes (2ml/min).

Continuous flow even when the pump is turned OFF

- This is a normal function of the pump. The pump is designed to maintain pressure during and after the infusion to prevent blood/drug backflow.
- To stop the flow turn the pump OFF and wind the large knob clockwise so the black tab moves away from the syringe. This will release pressure on the plunger.
- You can also use the slide clamp. We recommend using the slide clamp to immediately stop the flow only in the case of an emergency. Overuse can damage the tubing.

Medication (5ml or less) left in the syringe

- Verify that you are using the proper BD® or Monoject® brand 60ml syringe. Do not use Terumo syringes.

Care and Maintenance:

The FREEDOM60® does not require any preventative maintenance. The FREEDOM60® works as a system, which means the tubing determines the flow rate, not the pump; therefore our pump needs no calibration. If you choose the correct tubing set the proper flow rate will be achieved. Our tubing sets are statistically verified during manufacture and will deliver the appropriate flow rate under controlled conditions.

Cleaning

Clean only those areas that are exposed and external. No attempt should be made to clean any part of the pump that is not easily accessible. Discontinue use of a pump that has been internally exposed to or immersed in fluid.

Wipe the surface with warm water and detergent or use any surface disinfectant compatible with acetyl-butyl-styrene (ABS) and polycarbonate (PC) plastics, such as household bleach or hydrogen peroxide. Avoid the use of alcohol or alcohol containing compounds, as these tend to make ABS plastic brittle. Wipe again with clean water to rinse.

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If absolutely necessary, you may clean the inside of the syringe shield by using a long swab or bottlebrush and any cleaning agent compatible with ABS and PC plastics. Alcohol is not recommended.

Storage:
The FREEDOM60® pump is recommended to be stored in a cool, dry place and packaged tubing sets at room temperature (approximately 16-30°C or 61-86°F).

Testing Flow Accuracy (if required by your local protocol):

1. Fill a new syringe with 60ml of sterile water
2. Remove all air from the syringe
3. Attach a sterile FREEDOM60 Precision Flow Rate Tubing™ set to the syringe
4. Remove all air from the tubing set
5. Load the syringe into the pump and turn the pump ON (–)
6. Monitor the syringe readings and elapsed time to derive an approximate flow rate
7. Compare your test results to the range of test rates listed in the table below:

Labeled Flow Rate	Bench-Rated Flow Rate[1]	Test Range[2]
60ml/hr	72ml/hr	60-84ml/hr
120ml/hr	134 ml/hr	115-153ml/hr

1. The FREEDOM60® infusion pump design accounts for the effects of standard clinical conditions on flow rate performance. Under bench test conditions, a 60ml/hr labeled tubing set is designed to generate a nominal infusion rate of 72ml/hr. A 120ml/hr labeled tubing set will generate a nominal bench test rate of 134ml/hr. The FREEDOM60® generates nominal bench test rates higher than the labeled rate accounting for the following standardized application criteria that affects actual delivery rates under normal clinical circumstances.

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	60 ml/hr Tubing	120 ml/hr Tubing
Bench Test Rate	72ml/hr	134ml/hr
Less Clinical Effects		
Catheter Gauge (20G PICC)	-7ml/hr	-8ml/hr
Fluid Viscosity	-2ml/hr	-3ml/hr
Venous Pressure	-3ml/hr	-3ml/hr
Label Flow Rate	60ml/hr	120ml/hr

2. To assure consistent test results, keep pump and tubing at the same approximate horizontal plane and monitor flow for a minimum of 20 minutes. The FREEDOM60® system is factory rated to deliver infusions under strict test conditions over a large number of pumps tested within 7% of nominal with a 95% statistical confidence interval. Under varying bench test and fluid conditions this range can be expected to vary approximately 15% of nominal. For more accurate monitoring, use a stopwatch and finely graduated burette. FREEDOM60® pump testing is based on ANSI/AAMI National Standard, ID 26-1992, Infusion Devices, August 24, 1992.

If test results in the range indicated cannot be approximated under bench testing conditions, factory refurbishment and full certification testing is available from the Manufacturer.

References:

1. Stuhmeier, Mainzer B. MD; Aspects of pressure build-up in the use of electronic infusion devices. II. Need for a pressure limit. Anasth Intensivther Notfallmed (1987 Aug.) 22(4): 185-190.
2. Anasth Intensivther Notfallmed (1987 Aug.) 22(4): 181-184. ANSI/AAMI National Standard, ID 26-1992, Infusion Devices, August 24, 1992.

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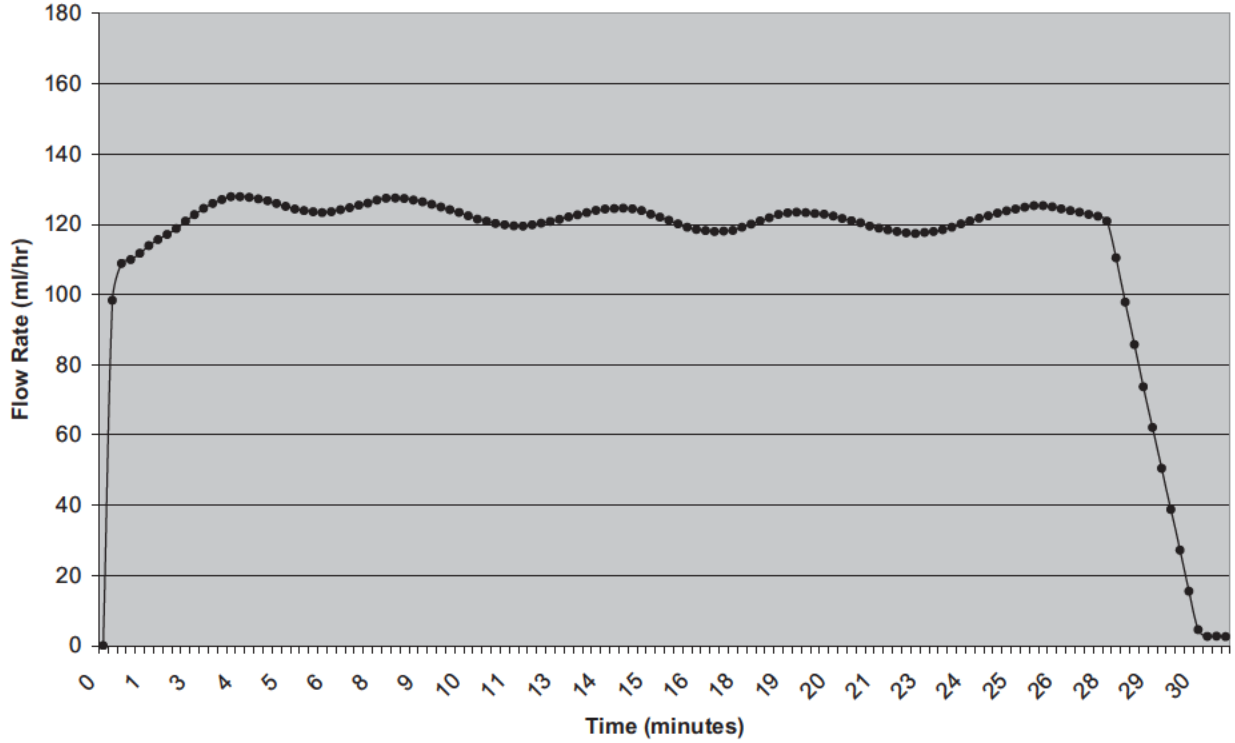
FREEDOM60® Flow Profile:

The FREEDOM60® flow profile shows that the flow rate is consistent throughout the delivery of medication.

FREEDOM60® Flow Rate vs. Time

Fluid: H_2O • Fluid Volume: 60ml • Tubing Measured: F120 – 120ml/hr



Technical Specifications:

System

Reservoir volume:	60ml (maximum)
Residual volume:	<0.4ml
Flow rate accuracy:	± 7%*
Operating pressure:	15psi (peak) 13.5psi (nominal)
Height sensitivity:	± 3% per 12" (30cm)
Constant force mechanism:	± 3%

*Flow rate data recorded at 22°C using 60ml of 0.9% NS. An overall accuracy of ±7% is expected at these values. At higher temperatures, which results in a decrease in viscosity, a higher flow rate is anticipated to occur. The flow rate variation due to changes in temperature is approximately linear and would vary from -20% at 14°C to +20% at 30°C. Fluids considerably more viscous than 0.9% NS are expected to slow the flow rate and consequently may result in longer infusion times. More viscous fluids may be tested before patient use by following the bench test procedures described in this manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-2108

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Pump

Weight:	14oz (0.4kg)
Length:	12" (304mm)
Width:	4.5" (114mm)
Height:	1.6" (41mm)

Rate Controlled Tubing

Length:	6" to 72" (152mm-1829mm)

Rate Controlled Tubing / Residual Volume (ml)

F0.5	0.09	F45	0.11
F1	0.08	F60	0.14
F2	0.10	F120	0.16
F3	0.09	F180	0.13
F3.8	0.09	F275	0.11
F5	0.08	F420	0.10
F8	0.08	F500	0.09
F10	0.14	F600	0.09
F15	0.11	F900	0.08
F20	0.10	F1200	0.13
F30	0.13	F2400	0.15

FREEDOM60 precision™ FLOW RATE TUBING

Warranty Information:

Limited Warranty: RMS Medical Products/Repro-Med Systems, Inc. ("Manufacturer") warrants the infusion pump to be free from defects in materials and workmanship under normal use, if used in accordance with device operating instructions. Warranty is limited to Original Purchaser for one year from date of purchase. The "Original Purchaser" is the person purchasing the infusion pump from the Manufacturer or Manufacturer's Representative. Warranty does not extend to subsequent purchasers. 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 infusion pump, or part thereof, which has been actually received by the Manufacturer or Manufacturer's Representative within the one 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 one-year warranty period. This warranty does not apply to accessories and disposable items. **The following conditions, procedures, and limitations apply to the Manufacturer's obligations under this warranty:**

- **Parties Covered by this Warranty:**
  This warranty extends only to the Original Purchaser of the infusion pump. This warranty does not extend to subsequent purchasers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8108

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- **Warranty Performance Procedure:** Notice of the defect must be made in writing to Customer Support Department, RMS Medical Products/Repro-Med Systems, Inc., 24 Carpenter Road, Chester, NY 10918, USA. Notice to RMS Medical Products/Repro-Med Systems, Inc. must include the model and serial number, date of purchase, and description of the defect in sufficient detail to facilitate repairs. Authorization must be obtained by the Original Purchaser from the Manufacturer or Manufacturer's Representative prior to returning the product to the Manufacturer. The defective pump must be properly packaged and returned to the Manufacturer, postage-prepaid. Any loss or damage during shipment is at the risk of the Original Purchaser.

- **Conditions of Warranty:** This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility in a way so as, in Manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, negligence or accident. Misuse includes, but is not limited to, use without compliance with the device operating instructions or use with non-approved accessories or disposable items.

- **Limitations and Exclusions:** Repair or replacement of an infusion pump or component part is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
    - No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied, or to change this limited warranty in any way.
    - THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF.
    - Manufacturer's liability under this Limited Warranty Agreement shall not extend to special, indirect, or consequential damages.
    - The infusion pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the infusion pump for a particular medical treatment.
    - All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

This warranty and the rights and obligations hereunder, shall be construed under and governed by the laws of the State of New York, USA.

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Definition of symbols:

_	On		Manufacturer
OFF	Off	QTY	Quantity
	Caution, consult accompanying documents	REF	Catalog number
	Consult instructions for use		Do not reuse
EC REP	Authorized representative in the European Community	SN	Serial number
	Use by YYYY-MM-DD or YYYY-MM	STERILE R	Sterilized using irradiation
LOT	Batch code		

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EC REP
RMS Medical
Products, UK Ltd.
146 Allerton Road
Mossley Hill
Liverpool
L18 2DH, UK

RMS Medical Products
24 Carpenter Road
Chester, NY 10918 USA
Ph. 800-624-9600 • 845-469-2042
www.rmsmedicalproducts.com

CE 0297

FREEDOM60® complies with Medical Device Directive 93/42/ECC as set forth by the European Commission.
RMS complies with the ISO 13485 Quality Management System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix C: Device and Component Specifications

This appendix contains device and component specifications for the SCIg60 Infuser listed in Table C-1 and for the Infuset™ Flow Control Extension Set as listed in Table C-2. Additionally, the MSDS documents for plasticizers, lubricants, bonding agents, or other materials used in the manufacture or assembly of the SCIg60 Infuser and Infuset™ Flow Control Extension Sets are listed in Table C-3.

Table C-1: Component Specifications for SCIg60 Infuser

Exhibit	Part No.	Description
(b)(4) [redacted]		

Table C-2: Component Specifications for Infuset™ Flow Control Extension Sets

Exhibit	Part No.	Component Description
(b)(4) [redacted]		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table C- 3: MSDS for SCIg60 Infuser and Infuset

Exhibit	Material Description	Material Use	Where Used
(b)(4) [redacted]			

(b)(4) [redacted]

Information provided above regarding component specifications, plasticizers, lubricants, bonding agents, or other materials used in the manufacture or assembly of the Infuset™ Flow Control Extensions Sets is consistent with that provided in K140133.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Schematic Drawings

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Appendix D: Risk Management

This appendix contains the following:

Exhibit	Title
1	SCIg60 Fault Tree Analysis
2	SCIg60 Infusion System RMM
3	Infuset RMM
4	TR-036, SCIg60 Infusion System Human Factors Validation Protocol and Report*
5	Safety Assurance Case Report
6	SCIg60 Infusion System Risk Management Report

*NOTE: Validation Records and Verification Test Reports are not included due to their large size but are maintained at EMED Technologies as part of the complete SCIg60 Human Factors Validation file.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EMED Technologies
The power of creative thinking

MEMORANDUM

To:	SCIg60 Infusion System Risk Management File, SCIg60 Infusion System DHF
From:	Peter Kollings, Director RA/QA
Date:	8/22/13
Subject:	Fault Tree Analysis for the SCIg60 Infusion System

This memorandum is intended to summarize critical aspects of the Fault Tree Analysis (FTA) performed for the SCIg60 Infusion System.

The scope of the FTA included design and usability considerations of the SCIg60 Infusion System. The focus of the FTA was narrowed to the SCIg60 Infuser, the BD 60 ml syringe, and the single-use disposable flow controller device. Patient interactions and system usability aspects were considered, with the patient's relation to potential faults/undesirable events included.

Inputs into the FTA included faults, failures, adverse events, and other undesirable conditions identified during design of the products and Risk Management activities. Such activities included hazards analysis, literature research, and post-market surveillance.

Ground Rules were established in an effort maintain a level of consistency and focus on relevant potential faults/undesirable events throughout the FTA. These Ground Rules including making all efforts to:

- Use common FTA symbols will be used (top level event, fault, lower level event, basic event, undeveloped event, AND gates, OR gates, and Inhibit gates.
- State events as faults, and included what and when.
- List event causes immediately preceding the event, and event causes will not be redundant to the resulting event.
- Ensure all inputs into gates will be fault or an event (no gate to gate connections)
- Purposefully exclude certain causes and event-types. Such types include:
    - QC test failures (assumes QC testing is accurate and sufficient)
    - improper storage or use environments when in EMED control (assumes processing and handling are appropriate)
    - human errors of commission (to limit the potentially infinite possibilities due to performing something NOT intended by manufacturing, handling, or usage instructions; human errors of omission may be included)
    - human error when training is considered to be present, appropriate, and effective

Quality Assurance and Engineering were responsible for developing, reviewing, and approving the FTA charts. Both Quality Assurance and Engineering will approve this memo as evidence that the FTA activity is complete. Upon approval of the FTA it will be evaluated and necessary entries and/or edits will be made to other components of the SCIg60 Infusion System Risk Management File.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix E: Sterilization Validation

This appendix contains the following:

Exhibit	ID	Description
1	(b)(4)	(b)(4) Sterilization Validation Protocol
2	(b)(4)	(b)(4) Sterilization Validation Report

*NOTE: Protocol and report attachments, supporting data, and supplemental information are not included due to their large size but are maintained at EMED Technologies as part of the complete (b)(4) validation file.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix F: Performance Testing – Bench

This appendix contains the following:

Exhibit	Doc ID	Title
1	(b)(4) Performance Testing	[redacted]
2	[redacted]	
3	[redacted]	
4	[redacted]	
5	[redacted]	
6	[redacted]	
7	[redacted]	
8	[redacted]	
9	[redacted]	
10	[redacted]	
11	[redacted]	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix G: Drug Information

This appendix contains the following:

- Exhibit 1: Hizentra Material Safety Data Sheet
- Exhibit 2: Hizentra Patient Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CSL Behring

Material Safety Data Sheet

Corresponding to EC Directive 93/112/EC

Product: **Immunoglobulin G**
Product Name: **Hizentra, IgPro20**

Date of issue: 21 April 2010
Replaces Version of: 28 January 2008

1. Identification of the product and of the company

Product Name: Hizentra
Immune Globulin Subcutaneous (Human), 20% Liquid for subcutaneous administration

Company name:
CSL Behring
Wankdorfstr. 10
3000 Bern 22
Phone: +41 31 344 44 44 Fax: +41 31 344 55 55

Emergency Phone number
Please contact the local CSL Behring representation in your country
Switzerland: Toxicological Information Center Switzerland: +41 01 251 51 51

U.S. CSL Behring (610) 878-4000
U.S. Emergency Response: (800) 424-9300
U.S. Emergency Product Information: (800) 504-5434

2. Composition / Information on ingredients

Trade names:
Hizentra
Chemical characterization of the substance / preparation:
Hizentra, IgPro20: 20% Proteins IVIG, amino acid L-proline / Polysorbat 80 / liquid

3. Hazards identification

According to the present state of knowledge, provided that this product is handled correctly, there is no known danger to humans.
No hazardous product as specified in Directive 67 / 548 / EEC.

4. First aid measures

After contact with the eyes:
Rinse eyes with running water.
After contact with the skin:
Rinse contaminated skin.
After inhalation:
Consult a physician if irritating symptoms develop and persist.
After ingestion or accident:
If feeling sick consult a physician.
Notes to physician:
Only effective when administered parenterally.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. Fire fighting measures

Extinguishing media, suitable:
all, suit to surrounding area
Extinguishing media, not to be used
no restrictions
Special advice in case of fire
Cool container and metallic parts with a water spray
Hazardous products of combustion:
Nitrogen oxide

6. Accidental release measures

After spillage, leakage, large amounts:
Must not be released into sewers, drains or wells.
Take up by mechanical means and dispose.
After spillage, leakage, small amounts:
Wash away remnants with plenty of water and detergents.
Cleaning of equipment:
Wash with plenty of water.

7. Handling and storage

Protect from (while storing)
Light
Max. storage temperature
Up to 25°C or 77°F (storage temperature for product quality reasons)
Protective measures, storage and handling:
Store protected from light, do not freeze

8. Exposure controls / personal protection

Personal protection for open handling:

Respiratory protection:	mask, dust filter in case of aerosol generation
Eye protection:	safety glasses
Hand protection:	required
Others:	change contaminated working clothes. Wash hands after finishing work.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9. Physical and chemical properties

Form:	liquid
Color:	colorless or pale yellow
Odour:	no
Melting point:	not applicable
Boiling point:	not applicable
Flash point:	not applicable
Density, Liquid:	approx. 1.061 g/mL (Hizentra, IgPro20)
Pallet packing density (depending on vial size):	approx. 750 kg / m^3
Viscosity (20°C):	<20 mPas
pH-value (20°C):	4.6 - 5.2

10. Stability and reactivity

Conditions to be avoided (for safety reason only):
None.
Substances to be avoided (for safety reason only):
None.
Hazardous decomposition products
None.

11. Toxicological information

No toxic effects are to be expected, when the product is handled appropriately.

12. Ecological information

Biological degradation:
Based on results of similar compounds good biodegradation can be expected.

Further ecological data:
No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Disposal considerations

Product:
Incineration in controlled furnaces.
Packaging
Must be disposed of in compliance with country-specific regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14. Transport information

Not subject to transport regulation

15. Regulatory information

Labeling according to EC Directives
Symbol: none
R-phrases: none
S-phrases: none

16. Other information

Product should be stored, handled and used in accordance with good industrial hygiene practice and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements; it should therefore not be construed as guaranteeing specific properties.

Revision Summary

4/21/10	U.S. Telephone contacts added

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HIZENTRA safely and effectively. See full prescribing information for HIZENTRA.

HIZENTRA®, Immune Globulin Subcutaneous (Human), 20% Liquid

Initial U.S. Approval: 2010

WARNING: THROMBOSIS

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

----------RECENT MAJOR CHANGES----------

Boxed Warning	09/2013
Dosage and Administration (2.2, 2.3)	09/2013
Warnings and Precautions (5.2)	09/2013

----------INDICATIONS AND USAGE----------

Hizentra is an Immune Globulin Subcutaneous (Human) (IGSC), 20% Liquid indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years of age and older (1).

----------DOSAGE AND ADMINISTRATION----------

For subcutaneous infusion only. Do not inject into a blood vessel.

Administer weekly or biweekly (every two weeks).

Dosage (2.2)

Before switching to Hizentra, obtain the patient's serum IgG trough level to guide subsequent dose adjustments.

Weekly: Start Hizentra 1 week after last IGIV infusion

$$\text{Initial weekly dose} = \frac{\text{Previous IGIV dose (in grams)}}{\text{No. of weeks between IGIV doses}} \times 1.53$$

- Biweekly: Start Hizentra 1 or 2 weeks after the last IGIV infusion or 1 week after the last weekly Hizentra infusion. Administer twice the calculated weekly dose.
- Adjust the dose based on clinical response and serum IgG trough levels *(see Dose Adjustment).*

Administration (2.3)

- Infusion sites – 1 to 4 injection sites simultaneously, with at least 2 inches between sites.
- Infusion volume – First infusion, up to 15 mL per site. Fifth infusion, up to 20 mL per site, then to 25 mL per site as tolerated.
- Infusion rate – Up to 15 mL per hr per site. Increase to 25 mL per hr per site as tolerated.

----------DOSAGE FORMS AND STRENGTHS----------

0.2 g per mL (20%) protein solution for subcutaneous injection (3)

----------CONTRAINDICATIONS----------

- Anaphylactic or severe systemic reaction to human immune globulin or components of Hizentra, such as polysorbate 80 (4)
- Hyperprolinemia (type I or II) (Hizentra contains the stabilizer L-proline) (4)
- IgA-deficient patients with antibodies against IgA and a history of hypersensitivity (4)

----------WARNINGS AND PRECAUTIONS----------

- IgA-deficient patients with anti-IgA antibodies are at greater risk of severe hypersensitivity and anaphylactic reactions (5.1).
- Thrombosis may occur following treatment with immune globulin products, including Hizentra (5.2).
- Aseptic meningitis syndrome has been reported with IGIV or IGSC treatment (5.3).
- Monitor renal function, including blood urea nitrogen, serum creatinine, and urine output in patients at risk of acute renal failure (5.4).
- Monitor for clinical signs and symptoms of hemolysis (5.5).
- Monitor for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]) (5.6).
- May carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent (5.7).

----------ADVERSE REACTIONS----------

The most common adverse reactions observed in ≥5% of study subjects were local reactions (i.e., swelling, redness, heat, pain, and itching at the injection site), headache, diarrhea, fatigue, back pain, nausea, pain in extremity, cough, rash, pruritus, vomiting, abdominal pain (upper), migraine, and pain (6).

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

The passive transfer of antibodies may interfere with the response to live virus vaccines (7.1), and lead to misinterpretation of the results of serological testing (5.8, 7.2).

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: No human or animal data. Use only if clearly needed (8.1).
- Pediatric: No specific dose requirements are necessary to achieve the desired serum IgG levels (8.4).

See 17 for PATIENT COUNSELING INFORMATION and the accompanying FDA-approved patient labeling.

Revised: September 2013

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
2.1 Preparation and Handling
2.2 Dosage
2.3 Administration
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Hypersensitivity
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*Sections or subsections omitted from the full prescribing information are not listed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hizentra®
Immune Globulin Subcutaneous (Human), 20% Liquid

FULL PRESCRIBING INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products[1-3], including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors *(see Warnings and Precautions [5.2], Patient Counseling Information [17]).***
- **For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity *(see Warnings and Precautions [5.2]).***

1 INDICATIONS AND USAGE

Hizentra is an Immune Globulin Subcutaneous (Human) (IGSC), 20% Liquid indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

2 DOSAGE AND ADMINISTRATION

For subcutaneous infusion only. Do not inject into a blood vessel.

2.1 Preparation and Handling

Hizentra is a clear and pale yellow to light brown solution. Do not use if the solution is cloudy or contains particulates.

- Prior to administration, visually inspect each vial of Hizentra for particulate matter or discoloration, whenever the solution and container permit.
- Do not freeze. Do not use any solution that has been frozen.
- Check the product expiration date on the vial label. Do not use beyond the expiration date.
- Do not mix Hizentra with other products.
- Do not shake the Hizentra vial.
- Use aseptic technique when preparing and administering Hizentra.
- The Hizentra vial is for single-use only. Discard all used administration supplies and any unused product immediately after each infusion in accordance with local requirements.

2.2 Dosage

- Hizentra can be administered as a weekly or biweekly (every two weeks) infusion.
- Individualize the dose based on the patient's clinical response to Hizentra therapy and serum immunoglobulin G (IgG) trough levels.
- Before receiving treatment with Hizentra:
  - Ensure that patients have received Immune Globulin Intravenous (Human) (IGIV) treatment at regular intervals for at least 3 months.
  - Obtain the patient's serum IgG trough level to guide subsequent dose adjustments (*see below under Dose Adjustment*).

For weekly dosing, start treatment with Hizentra 1 week after the patient's last IGIV infusion.

For biweekly dosing, start treatment 1 or 2 weeks after the last IGIV infusion or 1 week after that last weekly Hizentra infusion.

Weekly Dosing

Establish the initial weekly dose of Hizentra by converting the monthly IGIV dose into a weekly equivalent and increasing it using a dose adjustment factor. The goal is to achieve a systemic serum IgG exposure (area under the concentration-time curve [AUC]) not inferior to that of the previous IGIV treatment *[see Pharmacokinetics (12.3)]*.

To calculate the initial weekly dose of Hizentra, divide the previous IGIV dose in grams by the number of weeks between doses during the patient's IGIV treatment (e.g., 3 or 4); then multiply this by the dose adjustment factor of 1.53.

$$\text{Initial Hizentra dose} = \frac{\text{Previous IGIV dose (in grams)}}{\text{Number of weeks between IGIV doses}} \times 1.53$$

To convert the Hizentra dose (in grams) to milliliters (mL), multiply the calculated dose (in grams) by 5.

Biweekly (Every Two Weeks) Dosing

Biweekly dosing with Hizentra will result in systemic serum IgG exposure that is comparable to the previous IGIV or weekly Hizentra treatment *[see Pharmacokinetics (12.3)]*.

When switching to biweekly dosing, multiply the calculated Hizentra weekly dose by 2.

Dose Adjustment

Over time, the dose may need to be adjusted to achieve the desired clinical response and serum IgG trough level, irrespective of the frequency of administration. To determine if a dose adjustment should be considered, measure the patient's serum IgG trough level 2 to 3 months after switching to Hizentra.

Weekly dosing: When switching from IGIV to weekly Hizentra dosing, the target serum IgG trough level is projected to be approximately 25% higher than the last trough level during prior IGIV therapy *[see Pharmacokinetics (12.3)]*.

Biweekly dosing: When switching from IGIV to biweekly Hizentra dosing, the target serum trough level is projected to be approximately 15% higher than the last IGIV trough level. When switching from weekly to biweekly Hizentra dosing, the target trough is projected to be approximately 5% lower than the last weekly trough level *[see Pharmacokinetics (12.3)]*.

To adjust the dose based on trough levels, calculate the difference (in mg/dL) between the patient's serum IgG trough level and the target IgG trough level for weekly or biweekly dosing. Then find this difference in Table 1 (Column 1) and, based on the Hizentra dosing frequency (weekly or biweekly) and the patient's body weight, locate the corresponding adjustment amount (in mL) by which to increase (or decrease) the dose.

Use the patient's clinical response as the primary consideration in dose adjustment. Additional dosage increments may be indicated based on the patient's clinical response (infection frequency and severity).

Table 1: Incremental Adjustment (mL)* of the Weekly or Biweekly Hizentra Dose Based on the Difference (±mg/dL) from the Target Serum IgG Trough Level

Difference From Target Serum IgG Trough Level (mg/dL)	Dosing Frequency	Weight Adjusted Dose Increment (mL)*				
		Weight Group				
		>10 to 30 kg	>30 to 50 kg	>50 to 70 kg	>70 to 90 kg	>90 kg
50	Weekly	n/a	2.5	5	5	10
	Biweekly	5	5	10	10	20
100	Weekly	2.5	5	10	10	15
	Biweekly	5	10	20	20	30
200	Weekly	5	10	15	20	30
	Biweekly	10	20	30	40	60

n/a, not applicable.
* Incremental adjustments based on slopes of the pharmacometric model-predicted relationship between serum IgG trough level and Hizentra dose increments of 1 mg/kg per week.

For example, if a patient with a body weight of 70 kg has an actual IgG trough level of 900 mg/dL and the target trough level is 1000 mg/dL, this results in a difference of 100 mg/dL. Therefore, increase the weekly dose of Hizentra by 10 mL. For biweekly dosing, increase the biweekly dose by 20 mL.

Monitor the patient's clinical response, and repeat the dose adjustment as needed.

Dosage requirements for patients switching to Hizentra (weekly or biweekly) from another IGSC product: If a patient on Hizentra does not maintain an adequate clinical response or a serum IgG trough level equivalent to that of the previous IGSC treatment, the physician may want to adjust the dose. For such patients, Table 1 also provides guidance for dose adjustment if their desired IGSC trough level is known.

Measles Exposure

Administer a minimum weekly Hizentra dose of 200 mg/kg body weight for two consecutive weeks if a patient is at risk of measles exposure (i.e., due to an outbreak in the US or travel to endemic areas outside of the US. For biweekly dosing, one infusion of a minimum of 400 mg/kg is recommended. If a patient has been exposed to measles, ensure this minimum dose is administered as soon as possible after exposure.

2.3 Administration

Hizentra is for subcutaneous infusion only. Do not inject into a blood vessel.

Hizentra is intended for weekly or biweekly (every two weeks) subcutaneous administration using an infusion pump. Infuse Hizentra in the abdomen, thigh, upper arm, and/or lateral hip.

- Injection sites – A Hizentra dose may be infused into multiple injection sites. For weekly dosing, use up to 4 sites simultaneously or up to 12 sites consecutively per infusion. For biweekly dosing, increase the number of injection sites as needed. Injection sites should be at least 2 inches apart. Change the actual site of injection with each weekly administration.
- Volume – For the first infusion of Hizentra, do not exceed a volume of 15 mL per injection site. The volume may be increased to 20 mL per site after the fourth infusion and then to 25 mL per site as tolerated.
- Rate – For the first infusion of Hizentra, the recommended flow rate is 15 mL per hour per site. For subsequent infusions, the flow rate may be increased to 25 mL per hour per site as tolerated.

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Follow the steps below and use aseptic technique to administer Hizentra.

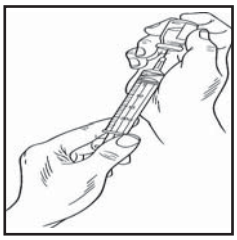
1. Assemble supplies – Gather the Hizentra vial(s), disposable supplies (not provided with Hizentra), and other items (infusion pump, sharps or other container, patient's treatment diary/log book) needed for the infusion.

2. Clean surface – Thoroughly clean a flat surface using an alcohol wipe.

3. Wash hands – Thoroughly wash and dry hands. The use of gloves when preparing and administering Hizentra is optional.

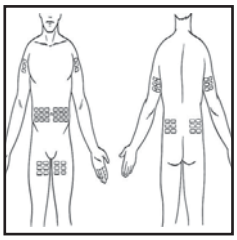
4. Check vials – Carefully inspect each vial of Hizentra. Do not use the vial if the liquid looks cloudy, contains particles, or has changed color, if the protective cap is missing, or if the expiration date on the label has passed.

5. Transfer Hizentra from vial(s) to syringe



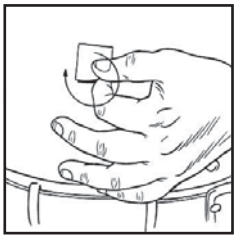
- Remove the protective cap from the vial to expose the central portion of the rubber stopper of the Hizentra vial.
- Clean the stopper with an alcohol wipe and allow it to dry.
  - If using a transfer device, follow the instructions provided by the device manufacturer.
  - If using a needle and a syringe to transfer Hizentra, follow the instructions below.
  - Attach a sterile transfer needle to a sterile syringe. Pull back on the plunger of the syringe to draw air into the syringe that is equal to the amount of Hizentra to be withdrawn.
  - Insert the transfer needle into the center of the vial stopper and, to avoid foaming, inject the air into headspace of the vial (not into the liquid).
  - Withdraw the desired volume of Hizentra.
  - When using multiple vials to achieve the desired dose, repeat this step.

6. Prepare infusion pump and tubing – Follow the manufacturer's instructions for preparing the pump, using subcutaneous administration sets and tubing, as needed. Be sure to prime the tubing with Hizentra to ensure that no air is left in the tubing.



7. Prepare injection site(s)

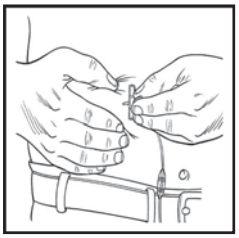
- The number and location of injection sites depends on the volume of the total dose Infuse Hizentra into a maximum of 4 sites simultaneously; or up to 12 consecutively per infusion. Injection sites should be at least 2 inches apart.
- Using an antiseptic skin preparation, clean each site beginning at the center and working outward in a circular motion. Allow each site to dry before proceeding.



8. Insert needle(s)

Grasp the skin between 2 fingers and insert the needle into the subcutaneous tissue.

- If necessary, use sterile gauze and tape or transparent dressing to hold the needle in place.
- Before starting the infusion, attach a sterile syringe to the end of the primed administration tubing and gently pull back on the plunger to make sure no blood is flowing back into the tubing. If blood is present, remove and discard the needle and tubing. Repeat the process beginning with step 6 (priming) using a new needle, new infusion tubing, and a different injection site.



9. Start infusion – Follow the manufacturer's instructions to turn on the infusion pump.

10. Record treatment – Remove the peel-off portion of the label from each vial used, and affix it to the patient's treatment diary/log book.

11. Clean up – After administration is complete, turn off the infusion pump. Take off the tape or dressing and remove the needle set from the infusion site(s). Disconnect the tubing from the pump. Immediately discard any unused product and all used disposable supplies in accordance with local requirements. Clean and store the pump according to the manufacturer's instructions.

For self-administration, provide the patient with instructions and training for subcutaneous infusion in the home or other appropriate setting.

3 DOSAGE FORMS AND STRENGTHS

Hizentra is a 0.2 g/mL (20%) protein solution for subcutaneous injection.

4 CONTRAINDICATIONS

Hizentra is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin or to components of Hizentra, such as polysorbate 80.

Hizentra is contraindicated in patients with hyperprolinemia (type I or II) because it contains the stabilizer L-proline *[see Description (11)]*.

Hizentra is contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity *[see Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Severe hypersensitivity reactions may occur to human immune globulin or components of Hizentra, such as polysorbate 80. In case of hypersensitivity, discontinue the Hizentra infusion immediately and institute appropriate treatment.

Individuals with IgA deficiency can develop anti-IgA antibodies and anaphylactic reactions (including anaphylaxis and shock) after administration of blood components containing IgA. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions with administration of Hizentra. Hizentra contains ≤50 mcg/mL IgA *[see Description (11)]*.

5.2 Thrombosis

Thrombosis may occur following treatment with immune globulin products[1-3], including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity *[see Boxed Warning, Patient Counseling Information (17)]*.

5.3 Aseptic Meningitis Syndrome (AMS)

AMS has been reported with use of IGIV[4] or IGSC. The syndrome usually begins within several hours to 2 days following immune globulin treatment. AMS is characterized by the following signs and symptoms: severe headache, nuchal rigidity, drowsiness, fever, photophobia, painful eye movements, nausea, and vomiting. Cerebrospinal fluid (CSF) studies frequently show pleocytosis up to several thousand cells per cubic millimeter, predominantly from the granulocytic series, and elevated protein levels up to several hundred mg/dL. AMS may occur more frequently in association with high doses (≥2 g/kg) and/or rapid infusion of immune globulin product.

Patients exhibiting such signs and symptoms should receive a thorough neurological examination, including CSF studies, to rule out other causes of meningitis. Discontinuation of immune globulin treatment has resulted in remission of AMS within several days without sequelae.

5.4 Renal Dysfunction/Failure

Renal dysfunction/failure, osmotic nephropathy, and death may occur with use of human immune globulin products, especially those containing sucrose.[5] Hizentra does not contain sucrose. Ensure that patients are not volume depleted and assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of Hizentra and at appropriate intervals thereafter.

Periodic monitoring of renal function and urine output is particularly important in patients judged to have a potential increased risk of developing acute renal failure.[6] If renal function deteriorates, consider discontinuing Hizentra. For patients judged to be at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure (such as those with diabetes mellitus or hypovolemia, those who are overweight or use concomitant nephrotoxic medicinal products, or those who are over 65 years of age), administer Hizentra at the minimum rate practicable.

5.5 Hemolysis

Hizentra can contain blood group antibodies that may act as hemolysins and induce *in vivo* coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin (Coombs') test result and hemolysis.[7-9] Delayed hemolytic anemia can develop subsequent to immune globulin therapy due to enhanced RBC sequestration, and acute hemolysis, consistent with intravascular hemolysis, has been reported.[10]

Monitor recipients of Hizentra for clinical signs and symptoms of hemolysis. If these are present after a Hizentra infusion, perform appropriate confirmatory laboratory testing. If transfusion is indicated for patients who develop hemolysis with clinically compromising anemia after receiving Hizentra, perform adequate cross-matching to avoid exacerbating on-going hemolysis.

5.6 Transfusion-Related Acute Lung Injury (TRALI)

Noncardiogenic pulmonary edema may occur in patients administered human immune globulin products.[11] TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Typically, it occurs within 1 to 6 hours following transfusion. Patients with TRALI may be managed using oxygen

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therapy with adequate ventilatory support.

Monitor Hizentra recipients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and patient's serum.

5.7 Transmissible Infectious Agents

Because Hizentra is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. The risk of infectious agent transmission has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current virus infections, and including virus inactivation/removal steps in the manufacturing process for Hizentra.

Report all infections thought to be possibly transmitted by Hizentra to CSL Behring Pharmacovigilance at 1-866-915-6958.

5.8 Laboratory Tests

Various passively transferred antibodies in immunoglobulin preparations may lead to misinterpretation of the results of serological testing.

6 ADVERSE REACTIONS

The most common adverse reactions (ARs), observed in ≥5% of study subjects receiving Hizentra, were local reactions (e.g., swelling, redness, heat, pain, and itching at the injection site), headache, diarrhea, fatigue, back pain, nausea, pain in extremity, cough, rash, pruritus, vomiting, abdominal pain (upper), migraine, and pain.

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, AR rates observed in clinical studies of a product cannot be directly compared to rates in the clinical studies of another product and may not reflect the rates observed in clinical practice.

US Study

The safety of Hizentra was evaluated in a clinical study in the US for 15 months (3-month wash-in/wash-out period followed by a 12-month efficacy period) in subjects with PI who had been treated previously with IGIV every 3 or 4 weeks. The safety analyses included 49 subjects in the intention-to-treat (ITT) population. The ITT population consisted of all subjects who received at least one dose of Hizentra *[see Clinical Studies (14)]*.

Subjects were treated with Hizentra at weekly median doses ranging from 66 to 331 mg/kg body weight (mean: 181.4 mg/kg) during the wash-in/wash-out period and from 72 to 379 mg/kg (mean: 213.2 mg/kg) during the efficacy period. The 49 subjects received a total of 2264 weekly infusions of Hizentra.

Table 2 summarizes the most frequent adverse reactions (ARs) (experienced by at least 2 subjects) occurring during or within 72 hours after the end of an infusion. Local reactions were assessed by the investigators 15 to 45 minutes post-infusion and by the subjects 24 hours post-infusion. The investigators then evaluated the ARs arising from the subject assessments. Local reactions were the most frequent ARs observed, with injection-site reactions (e.g., swelling, redness, heat, pain, and itching at the site of injection) comprising 98% of local reactions.

Table 2: Incidence of Subjects With Adverse Reactions (ARs)* (Experienced by 2 or More Subjects) and Rate per Infusion (ITT Population), US Study

AR (≥2 Subjects)	ARs* Occurring During or Within 72 Hours of Infusion	
	Number (%) of Subjects (n=49)	Number (Rate†) of ARs (n=2264 Infusions)
Local reactions‡	49 (100)	1322 (0.584)
Other ARs:		
Headache	12 (24.5)	32 (0.014)
Diarrhea	5 (10.2)	6 (0.003)
Fatigue	4 (8.2)	4 (0.002)
Back pain	4 (8.2)	5 (0.002)
Nausea	4 (8.2)	4 (0.002)
Pain in extremity	4 (8.2)	6 (0.003)
Cough	4 (8.2)	4 (0.002)
Vomiting	3 (6.1)	3 (0.001)
Abdominal pain, upper	3 (6.1)	3 (0.001)
Migraine	3 (6.1)	4 (0.002)
Pain	3 (6.1)	4 (0.002)
Arthralgia	2 (4.1)	3 (0.001)
Contusion	2 (4.1)	3 (0.001)
Rash	2 (4.1)	3 (0.001)
Urticaria	2 (4.1)	2 (< 0.001)

* Excluding infections.
† Rate of ARs per infusion.
‡ Includes injection-site reactions as well as bruising, scabbing, pain, irritation, cysts, eczema, and nodules at the injection site.

The ratio of infusions with ARs, including local reactions, to all infusions was 1303 to 2264 (57.6%). Excluding local reactions, the corresponding ratio was 56 to 2264 (2.5%).

Table 3 summarizes injection-site reactions based on investigator assessments 15 to 45 minutes after the end of the 683 infusions administered during regularly scheduled visits (every 4 weeks).

Table 3: Investigator Assessments* of Injection-Site Reactions by Infusion, US Study

Injection-Site Reaction	Number† (Rate‡) of Reactions (n=683 Infusions§)
Edema/induration	467 (0.68)
Erythema	346 (0.51)
Local heat	108 (0.16)
Local pain	88 (0.13)
Itching	64 (0.09)

* 15 to 45 minutes after the end of infusions administered at regularly scheduled visits (every 4 weeks).
† For multiple injection sites, every site was judged, but only the site with the strongest reaction was recorded.
‡ Rate of injection-site reactions per infusion.
§ Number of infusions administered during regularly scheduled visits.

Most local reactions were either mild (93.4%) or moderate (6.3%) in intensity.

No deaths or serious ARs occurred during the study. Two subjects withdrew from the study due to ARs. One subject experienced a severe injection-site reaction one day after the third weekly infusion, and the other subject experienced moderate myositis. Both reactions were judged to be "at least possibly related" to the administration of Hizentra.

European Study

In a clinical study conducted in Europe, the safety of Hizentra was evaluated for 10 months (3-month wash-in/wash-out period followed by a 7-month efficacy period) in 51 subjects with PI who had been treated previously with IGIV every 3 or 4 weeks or with IGSC weekly.

Subjects were treated with Hizentra at weekly median doses ranging from 59 to 267 mg/kg body weight (mean: 118.8 mg/kg) during the wash-in/wash-out period and from 59 to 243 mg/kg (mean: 120.1 mg/kg) during the efficacy period. The 51 subjects received a total of 1831 weekly infusions of Hizentra.

Table 4 summarizes the most frequent ARs (experienced by at least 2 subjects) occurring during or within 72 hours after the end of an infusion. Local reactions were assessed by the subjects between 24 and 72 hours post-infusion. The investigators then evaluated the ARs arising from the subject assessments.

Table 4: Incidence of Subjects With Adverse Reactions (ARs)* (Experienced by 2 or More Subjects) and Rate per Infusion, European Study

AR (≥2 Subjects)	ARs* Occurring During or Within 72 Hours of Infusion	
	Number (%) of Subjects (n=51)	Number (Rate†) of ARs (n=1831 Infusions)
Local reactions‡	24 (47.1)	105 (0.057)
Other ARs:		
Headache	9 (17.6)	20 (0.011)
Rash	4 (7.8)	4 (0.002)
Pruritus	4 (7.8)	13 (0.007)
Fatigue	3 (5.9)	5 (0.003)
Abdominal pain, upper	2 (3.9)	3 (0.002)
Arthralgia	2 (3.9)	2 (0.001)
Erythema	2 (3.9)	4 (0.002)
Abdominal discomfort	2 (3.9)	3 (0.002)
Back pain	2 (3.9)	2 (0.001)
Hematoma	2 (3.9)	3 (0.002)
Hypersensitivity	2 (3.9)	4 (0.002)

* Excluding infections.
† Rate of ARs per infusion.
‡ Includes infusion-related reaction; infusion-site mass; infusion/injection-site erythema, hematoma, induration, inflammation, edema, pain, pruritus, rash, reaction, swelling; injection-site extravasation, nodule; puncture-site reaction.

The proportion of subjects reporting local reactions decreased over time from approximately 20% following the first infusion to <5% by the end of the study.

Three subjects withdrew from the study due to ARs of mild to moderate intensity. One subject experienced injection-site pain and injection-site pruritus; the second subject experienced injection-site reaction, fatigue, and feeling cold; and the third subject experienced injection-site reaction and hypersensitivity. All reactions were judged by the investigator to be "at least possibly related" to the administration of Hizentra.

Biweekly (Every Two Weeks) Dosing

No data regarding ARs are available for the biweekly dosing regimen for Hizentra because no clinical trials using this dosage regimen were conducted. However, it is unlikely that the safety profile of Hizentra biweekly dosing is qualitatively different from that of weekly dosing.

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6.2 Postmarketing Experience

Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure.

Hizentra

The following adverse reactions have been identified during postmarketing use of Hizentra. This list does not include reactions already reported in clinical studies with Hizentra *[see Adverse Reactions (6.1)]*.

- *Infusion reactions:* Allergic-anaphylactic reactions such as swollen face or tongue and pharyngeal edema, pyrexia, chills, dizziness, hypertension/changes in blood pressure, malaise.
- *Cardiovascular:* Chest discomfort (including chest pain)
- *Respiratory:* Dyspnea
- *Neurological:* Tremor, burning sensation

The following adverse reactions have been reported during postmarketing use of immune globulin products[5]:

- *Infusion reactions:* Tachycardia, flushing, wheezing, rigors, myalgia
- *Renal:* Osmotic nephropathy
- *Respiratory:* Apnea, Acute Respiratory Distress Syndrome (ARDS), cyanosis, hypoxemia, pulmonary edema, bronchospasm
- *Cardiovascular:* Cardiac arrest, vascular collapse, hypotension
- *Neurological:* Coma, loss of consciousness, seizures, aseptic meningitis syndrome
- *Integumentary:* Stevens-Johnson syndrome, epidermolysis, erythema multiforme, dermatitis (e.g., bullous dermatitis)
- *Hematologic:* Pancytopenia, leukopenia, hemolysis, positive direct antiglobulin (Coombs') test
- *Gastrointestinal:* Hepatic dysfunction

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

7 DRUG INTERACTIONS

7.1 Live Virus Vaccines

The passive transfer of antibodies with immunoglobulin administration may interfere with the response to live virus vaccines such as measles, mumps, rubella, and varicella *[see Patient Counseling Information (17)]*.

7.2 Serological Testing

Various passively transferred antibodies in immunoglobulin preparations may lead to misinterpretation of the results of serological testing.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Hizentra. It is not known whether Hizentra can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hizentra should be given to pregnant women only if clearly needed.

8.3 Nursing Mothers

Hizentra has not been evaluated in nursing mothers.

8.4 Pediatric Use

Clinical Studies (Weekly Dosing)

The safety and effectiveness of weekly Hizentra have been established in the pediatric age groups 2 to 16, as supported by evidence from adequate and well-controlled studies. Hizentra was evaluated in 10 pediatric subjects with PI (3 children and 7 adolescents) in a study conducted in the US *[see Clinical Studies (14)]* and in 23 pediatric subjects with PI (18 children and 5 adolescents) in Europe. There were no differences in the pharmacokinetics, safety and efficacy profiles as compared with adult subjects. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels.

Pharmacokinetic Modeling and Simulation (Biweekly Dosing)

The biweekly (every two weeks) dosing regimen, developed from population PK-based modeling and simulation, included 57 pediatric subjects (32 from Hizentra clinical studies) *[see Pharmacokinetics (12.3)]*. No pediatric-specific dose requirements are necessary for biweekly dosing.

Safety and effectiveness of Hizentra in pediatric patients below the age of 2 have not been established.

8.5 Geriatric Use

Of the 49 subjects evaluated in the US clinical study of Hizentra, 6 subjects were 65 years of age or older. No overall differences in safety or efficacy were observed between these subjects and younger subjects. The clinical study of Hizentra in Europe did not include subjects over the age of 65.

11 DESCRIPTION

Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid, is a ready-to-use, sterile 20% (0.2 g/mL) protein liquid preparation of polyvalent human immunoglobulin G (IgG) for subcutaneous administration. Hizentra is manufactured from large pools of human plasma by a combination of cold alcohol fractionation, octanoic acid fractionation, and anion exchange chromatography. The IgG proteins are not subjected to heating or to chemical or enzymatic modification. The Fc and Fab functions of the IgG molecule are retained. Fab functions tested include antigen binding capacities, and Fc functions tested include complement activation and Fc-receptor-mediated leukocyte activation (determined with complexed IgG).

Hizentra has a purity of ≥98% IgG and a pH of 4.6 to 5.2. Hizentra contains approximately 250 mmol/L (range: 210 to 290 mmol/L) L-proline (a nonessential amino acid) as a stabilizer, 8 to 30 mg/L polysorbate 80, and trace amounts of sodium. Hizentra contains ≤50 mcg/mL IgA. Hizentra contains no carbohydrate stabilizers (e.g., sucrose, maltose) and no preservative.

Plasma units used in the manufacture of Hizentra are tested using FDA-licensed serological assays for hepatitis B surface antigen and antibodies to human immunodeficiency virus (HIV)-1/2 and hepatitis C virus (HCV) as well as FDA-licensed Nucleic Acid Testing (NAT) for HBV, HCV and HIV-1. All plasma units have been found to be nonreactive (negative) in these tests. In addition, the plasma has been tested for B19 virus (B19V) DNA by NAT. Only plasma that passes virus screening is used for production, and the limit for B19V in the fractionation pool is set not to exceed 10^4 IU of B19V DNA per mL.

The manufacturing process for Hizentra includes three steps to reduce the risk of virus transmission. Two of these are dedicated virus clearance steps: pH 4 incubation to inactivate enveloped viruses; and virus filtration to remove, by size exclusion, both enveloped and non-enveloped viruses as small as approximately 20 nanometers. In addition, a depth filtration step contributes to the virus reduction capacity.[12]

These steps have been independently validated in a series of *in vitro* experiments for their capacity to inactivate and/or remove both enveloped and non-enveloped viruses. Table 5 shows the virus clearance during the manufacturing process for Hizentra, expressed as the mean $\log_{10}$ reduction factor (LRF).

Table 5: Virus Inactivation/Removal in Hizentra*

	HIV-1	PRV	BVDV	WNV	EMCV	MVM
Virus Property						
Genome	RNA	DNA	RNA	RNA	RNA	DNA
Envelope	Yes	Yes	Yes	Yes	No	No
Size (nm)	80-100	120-200	50-70	50-70	25-30	18-24
Manufacturing Step	Mean LRF					
pH 4 incubation	≥5.4	≥5.9	4.6	≥7.8	nt	nt
Depth filtration	≥5.3	≥6.3	2.1	3.0	4.2	2.3
Virus filtration	≥5.3	≥5.5	≥5.1	≥5.9	≥5.4	≥5.5
Overall Reduction ($\log_{10}$ Units)	**≥16.0**	**≥17.7**	**≥11.8**	**≥16.7**	**≥9.6**	**≥7.8**

HIV-1, human immunodeficiency virus type 1, a model for HIV-1 and HIV-2; PRV, pseudorabies virus, a nonspecific model for large enveloped DNA viruses (e.g., herpes virus); BVDV, bovine viral diarrhea virus, a model for hepatitis C virus; WNV, West Nile virus; EMCV, encephalomyocarditis virus, a model for hepatitis A virus; MVM, minute virus of mice, a model for a small highly resistant non-enveloped DNA virus (e.g., parvovirus); LRF, $\log_{10}$ reduction factor; nt, not tested; na, not applicable.

* The virus clearance of human parvovirus B19 was investigated experimentally at the pH 4 incubation step. The estimated LRF obtained was ≥5.3.

The manufacturing process was also investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered a model for CJD and its variant (vCJD).[12] Several of the production steps have been shown to decrease infectivity of an experimental TSE model agent. TSE reduction steps include octanoic acid fractionation (≥6.4 $\log_{10}$), depth filtration (2.6 $\log_{10}$), and virus filtration (≥5.8 $\log_{10}$). These studies provide reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Hizentra supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. The mechanism of action in PI has not been fully elucidated.

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12.3 Pharmacokinetics

Clinical Studies

The pharmacokinetics (PK) of Hizentra was evaluated in a PK substudy of subjects (14 adults, 1 pediatric subject 6 to <12 years, and 3 adolescent subjects 12 to <16 years) with PI participating in the 15-month efficacy and safety study *[see Clinical Studies (14)]*. All PK subjects were treated previously with Privigen®, Immune Globulin Intravenous (Human), 10% Liquid and were switched to weekly subcutaneous treatment with Hizentra. After a 3-month wash-in/wash-out period, doses were adjusted individually with the goal of providing a systemic serum IgG exposure (area under the IgG serum concentration vs time curve; AUC) not inferior to that of the previous weekly-equivalent IGIV dose. Table 6 summarizes PK parameters for subjects in the substudy following treatment with Hizentra and IGIV.

Table 6: Pharmacokinetics Parameters of Hizentra and IGIV, US Study

	Hizentra	**IGIV*** (Privigen®)
Number of subjects	18	18
Dose* (mg/kg) Mean Range	 228 141-381	 152 86-254
IgG peak levels (mg/dL) Mean Range	 1616 1090-2825	 2564 2046-3456
IgG trough levels (mg/dL) Mean Range	 1448 952-2623	 1127 702-1810
AUC† (day x mg/dL) Mean Range	 10560 7210-18670	 10320 8051-15530
CL‡ (mL/day/kg) Mean Range	 2.2 1.2-3.7	 1.3§ 0.9-2.1

AUC, area under the curve; CL, clearance.
* For IGIV: weekly-equivalent dose.
† Standardized to a 7-day period.
‡ Apparent clearance (CL/F) for Hizentra (F = bioavailability)
§ Based on n=25 from the US Privigen PI study.

For the 19 subjects completing the wash-in/wash-out period, the average dose adjustment for Hizentra was 153% (range: 126% to 187%) of the previous weekly-equivalent IGIV dose. After 12 weeks of treatment with Hizentra at this individually adjusted dose, the final steady-state AUC determinations were made in 18 of the 19 subjects. The geometric mean ratio of the steady-state AUCs, standardized to a weekly treatment period, for Hizentra vs IGIV treatment was 1.002 (range: 0.77 to 1.20) with a 90% confidence limit of 0.951 to 1.055 for the 18 subjects.

With Hizentra, peak serum levels are lower (1616 vs 2564 mg/dL) than those achieved with IGIV while trough levels are generally higher (1448 vs 1127 mg/dL). In contrast to IGIV administered every 3 to 4 weeks, weekly subcutaneous administration results in relatively stable steady-state serum IgG levels.[13,14] After the subjects had reached steady-state with weekly administration of Hizentra, peak serum IgG levels were observed after a mean of 2.9 days (range: 0 to 7 days) in 18 subjects.

Table 7 summarizes PK parameters at steady state for pediatric subjects (age groups: 6 to <12 and 12 to <16 years) and adults subjects (>16 years) in the European Hizentra study following weekly treatment *[see Clinical Studies (14.2)]*. Pediatric PK parameters are similar to those of adult subjects; thus no pediatric specific dose requirements are needed for Hizentra dosing.

Table 7: Pediatric Pharmacokinetics Parameters of Hizentra, European Study

	Age Group			**Total (n=23)**
	6 to <12 years (n=9)	**12 to <16 years (n=3)**	**16 to <65 years (n=11)**	
Dose (mg/kg) Mean Range	 120 71-170	 115 72-150	 117 87-156	 118 71-170
IgG trough levels (mg/dL) Mean Range	 731 531-915	 764 615-957	 754 505-898	 746 505-957
$AUC_{0\text{-}7d}$ (day x mg/dL) Mean Range	 5230 3890-6950	 5491 4480-6750	 5452 3860-6810	 5370 3860-6950
CL (mL/day/kg) Mean Range	 2.19 1.57-3.05	 2.17 1.38-3.34	 2.30 1.82-3.01	 2.23 1.38-3.34

$AUC_{0\text{-}7d}$, area under the curve for the 7-day dosing interval; CL, apparent clearance (CL/F) (F = bioavailability).

Pharmacokinetic Modeling and Simulation

Biweekly (Every Two Weeks) Dosing

Pharmacokinetic characterization of biweekly administration of Hizentra was undertaken using population PK-based modeling and simulation. Serum IgG concentration data consisted of 3837 samples from 151 unique pediatric and adult subjects with PI from four clinical studies of IGIV (Privigen®) and/or Hizentra. Of the 151 subjects, 94 were adult subjects (63 from Hizentra clinical studies) and 57 were pediatric subjects (32 from Hizentra clinical studies). Compared with weekly administration, PK modeling and simulation predicted that administration of Hizentra on a biweekly basis at double the weekly dose results in comparable IgG exposure [equivalent AUCs, with a slightly higher IgG peak (C_{max}) and slightly lower trough (C_{min})]. See Table 8 (bottom row).

Prediction of Trough Levels Following Regimen Changes

Pharmacokinetic modeling and simulation also predicted changes in trough levels after switching from (a) monthly IGIV to weekly or biweekly Hizentra dosing, and (b) weekly to biweekly Hizentra dosing (Table 8). Steady-state trough levels three to four months after switching from IGIV to weekly Hizentra will be approximately 25% higher than trough levels with the previous IGIV treatment. When switching from IGIV to biweekly Hizentra, trough levels will be approximately 15% higher than previous IGIV trough levels. When switching from weekly to biweekly Hizentra, trough levels will be approximately 5% lower than previous weekly trough levels..

Table 8: Predicted Ratios* [Median (5th, 95th percentiles)] of AUC, C_{max} and C_{min} and Changes in IgG Trough Levels Upon Switching Between IgG Dosing Regimens

IgG Dosing Regimen Switch		**AUC**	**C_{max}**	**C_{min}**	**Predicted Change in Trough†**
From:	**To:**				
IGIV	Weekly Hizentra‡	1.04 (0.96-1.12)	0.73 (0.65-0.81)	1.23 (1.13-1.33)	25% increase
IGIV	Biweekly Hizentra§	1.03 (0.96-1.11)	0.76 (0.69-0.85)	1.16 (1.07-1.25)	15% increase
Weekly Hizentra	Biweekly Hizentra§	1.00 (0.98-1.03)	1.06 (1.02-1.09)	0.95 (0.92-0.98)	5% decrease

* Ratios are based on comparison of second regimen vs. first regimen.
† Approximate change in trough based on predicted median C_{min} ratio.
‡ Weekly dose based on dose adjustment coefficient of 1.53 when switching from IGIV.
§ Biweekly dose = 2x weekly dose.
AUC, area under the curve, calculated as $AUC_{0\ 28days}$ for the IGIV to Hizentra switches and as $AUC_{0\ 14days}$ for the weekly to biweekly Hizentra switch; C_{max}, maximum IgG concentration; C_{min}, minimum IgG concentration during a 28-day period (for the IGIV to Hizentra switches) or a 14-day period (for the weekly to biweekly Hizentra switch).

Pediatric Pharmacokinetics

The population PK-based modeling and simulation results indicate that, similar to observations from the clinical study with weekly Hizentra dosing (Table 7), body weight-adjusted biweekly dosing accounted for age-related (>3 years) differences in clearance of Hizentra, thereby maintaining systemic IgG exposure (AUC values) in the therapeutic range.

13 NONCLINICAL TOXICOLOGY

13.2 Animal Toxicology and/or Pharmacology

Long- and short-term memory loss was seen in juvenile rats in a study modeling hyperprolinemia. In this study, rats received daily subcutaneous injections with L-proline from day 6 to day 28 of life.[15] The daily amounts of L-proline used in this study were more than 60 times higher than the L-proline dose that would result from the administration of 400 mg/kg body weight of Hizentra once weekly. In unpublished studies using the same animal model (i.e., rats) dosed with the same amount of L-proline with a dosing interval relevant to IGSC treatment (i.e., on 5 consecutive days on days 9 to 13, or once weekly on days 9, 16, and 23), no effects on learning and memory were observed. The clinical relevance of these studies is not known.

14 CLINICAL STUDIES

14.1 US Study

A prospective, open-label, multicenter, single-arm, clinical study conducted in the US evaluated the efficacy, tolerability, and safety of Hizentra in 49 adult and pediatric subjects with PI. Subjects previously receiving monthly treatment with IGIV were switched to weekly subcutaneous administration of Hizentra for 15 months. Following a 3-month wash-in/wash-out period, subjects received a dose adjustment to achieve an equivalent AUC to their previous IGIV dose *[see Pharmacokinetics (12.3)]* and continued treatment for a 12-month efficacy period. The efficacy analyses included 38 subjects in the modified intention-to-treat (MITT) population. The MITT population consisted of subjects who completed the wash-in/wash-out period and received at least one infusion of Hizentra during the efficacy period.

Although 5% of the administered doses could not be verified, the weekly median doses of Hizentra ranged from 72 to 379 mg/kg body weight during the efficacy period. The mean dose was 213.2 mg/kg, which was 149% of the previous IGIV dose.

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In the study, the number of injection sites per infusion ranged from 1 to 12. In 73% of infusions, the number of injection sites was 4 or fewer. Up to 4 simultaneous injection sites were permitted using 2 pumps; however, more than 4 sites could be used consecutively during one infusion. The infusion flow rate did not exceed 50 mL per hour for all injection sites combined. During the efficacy period, the median duration of a weekly infusion ranged from 1.6 to 2.0 hours.

The study evaluated the annual rate of serious bacterial infections (SBIs), defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess. The study also evaluated the annual rate of any infections, the use of antibiotics for infection (prophylaxis or treatment), the days out of work/school/kindergarten/day care or unable to perform normal activities due to infections, hospitalizations due to infections, and serum IgG trough levels.

Table 9 summarizes the efficacy results for subjects in the efficacy period (MITT population) of the study. No subjects experienced an SBI in this study.

Table 9: Summary of Efficacy Results (MITT Population)

Number of subjects (efficacy period)	38
Total number of subject days	12,697
Infections Annual rate of SBIs* Annual rate of any infections	 0 SBIs per subject year† 2.76 infections/subject year‡
Antibiotic use for infection (prophylaxis or treatment) Number of subjects (%) Annual rate	 27 (71.1) 48.5 days/subject year
Total number of subject days	12,605
Days out of work/school/kindergarten/ day care or unable to perform normal activities due to infections Number of days (%) Annual rate	 71 (0.56) 2.06 days/subject year
Hospitalizations due to infections Number of days (%) Annual rate	 7 (0.06)§ 0.2 days/subject year

* Defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.
† Upper 99% confidence limit: 0.132.
‡ 95% confidence limits: 2.235; 3.370.
§ Based on 1 subject.

The mean IgG trough levels increased by 24.2%, from 1009 mg/dL prior to the study to 1253 mg/dL during the efficacy period.

14.2 European Study

In a prospective, open-label, multicenter, single-arm, clinical study conducted in Europe, 51 adult and pediatric subjects with PI switched from monthly IGIV (31 subjects) or weekly IGSC (20 subjects) to weekly treatment with Hizentra. For the 46 subjects in the efficacy analysis, the weekly mean dose in the efficacy period was 120.1 mg/kg (range 59 to 243 mg/kg), which was 104% of the previous weekly equivalent IGIV or weekly IGSC dose.

None of the subjects had an SBI during the efficacy period, resulting in an annualized rate of 0 (upper one-sided 99% confidence limit of 0.192) SBIs per subject. The annualized rate of any infections was 5.18 infections per subject for the efficacy period.

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16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

- Hizentra is supplied in a single-use, tamper-evident vial containing 0.2 grams of protein per mL of preservative-free liquid.

Each product presentation includes a package insert and the following components:

Presentation	Carton NDC Number	Components
5 mL	44206-451-01	Vial containing 1 gram of protein (NDC 44206-451-90)
10 mL	44206-452-02	Vial containing 2 grams of protein (NDC 44206-452-91)
20 mL	44206-454-04	Vial containing 4 grams of protein (NDC 44206-454-92)
50 mL	44206-455-10	Vial containing 10 grams of protein (NDC 44206-455-93)

16.2 Storage and Handling

- Keep Hizentra in its original carton to protect it from light.
- Each vial label contains a peel-off strip with the vial size and product lot number for use in recording doses in a patient treatment record.
- When stored at room temperature (up to 25°C [77°F]), Hizentra is stable for up to 30 months, as indicated by the expiration date printed on the outer carton and vial label.
- Do not shake.
- Do not freeze. Do not use product that has been frozen.
- The components used in the packaging for Hizentra contain no latex.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Inform patients to immediately report the following signs and symptoms to their healthcare provider:

- Hypersensitivity reactions to Hizentra (including hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis) *(see Warnings and Precautions [5.1]).*
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body *(see Warnings and Precautions [5.2]).*
- Severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting *(see Warnings and Precautions [5.3]).*
- Decreased urine output, sudden weight gain, fluid retention/edema, and/or shortness of breath *(see Warnings and Precautions [5.4]).*
- Fatigue, increased heart rate, yellowing of the skin or eyes, and dark-colored urine *(see Warnings and Precautions [5.5]).*
- Severe breathing problems, lightheadedness, drops in blood pressure, and fever *(see Warnings and Precautions [5.6]).*

Inform patients that because Hizentra is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent *(see Warnings and Precautions [5.7] and Description [11]).*

Inform patients that Hizentra may interfere with the response to live virus vaccines (e.g., measles, mumps, rubella, and varicella) and to notify their immunizing physician of recent therapy with Hizentra *(see Drug Interactions [7]).*

Home Treatment for Primary Humoral Immunodeficiency with Subcutaneous Administration

- If self-administration is deemed to be appropriate, ensure that the patient receives clear instructions and training on subcutaneous administration in the home or other appropriate setting and has demonstrated the ability to independently administer subcutaneous infusions.
- Ensure the patient understands the importance of adhering to their prescribed administration schedule (weekly or every two weeks) to maintain appropriate steady IgG levels.

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- Instruct patients to keep a diary/log book that includes information about each infusion such as, the time, date, dose, lot number(s) and any reactions.
- Inform the patient that mild to moderate local injection-site reactions (e.g., swelling and redness) are a common side effect of subcutaneous therapy, but to contact their healthcare professional if a local reaction increases in severity or persists for more than a few days.
- Inform patients of the importance of having an infusion needle long enough to reach the subcutaneous tissue and of changing the actual site of injection with each infusion. Explain that Hizentra is for subcutaneous infusion only, and must not be injected into a blood vessel. Make sure patients know how to avoid blood vessels and check if the needle has entered a blood vessel.
- Inform patients to consider adjusting the injection-site location, volume per site, and rate of infusion based on how infusions are tolerated.
- Inform patients that they should be tested regularly to make sure they have the correct levels of Hizentra (IgG) in their blood. These tests may result in adjustments to the Hizentra dose.

Hizentra®

Immune Globulin Subcutaneous (Human), 20% Liquid

Information for Patients

This patient package insert summarizes important information about Hizentra. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare professional, and it does not include all of the important information about Hizentra. If you have any questions after reading this, ask your healthcare professional.

What is the most important information I should know about Hizentra?

Hizentra is supposed to be infused under your skin only. DO NOT inject Hizentra into a blood vessel (vein or artery).

What is Hizentra?

Hizentra (Hi – ZEN – tra) is a prescription medicine used to treat primary immune deficiency (PI). Hizentra is made from human plasma. It contains antibodies, called immunoglobulin G (IgG), that healthy people have to fight germs (bacteria and viruses).

People with PI get a lot of infections. Hizentra helps lower the number of infections you will get.

Who should NOT take Hizentra?

Do not take Hizentra if you have too much proline in your blood (called "hyperprolinemia") or if you have had reactions to polysorbate 80.

Tell your doctor if you have had a serious reaction to other immune globulin medicines or if you have been told that you also have a deficiency of the immunoglobulin called IgA.

Tell your doctor if you have a history of heart or blood vessel disease or blood clots, have thick blood, or have been immobile for some time. These things may increase your risk of having a blood clot after using Hizentra. Also tell your doctor what drugs you are using, as some drugs, such as those that contain the hormone estrogen (for example, birth control pills), may increase your risk of developing a blood clot.

How should I take Hizentra?

You will take Hizentra through an infusion, only under your skin. Make sure that the infusion is not into a blood vessel. You will place up to 4 needles into different areas of your body each time you use Hizentra. The needles are attached to a pump with an infusion tube. You will need to have infusions once a week or every two weeks. It usually takes about 1 to 2 hours to complete one infusion; however, the infusion may take longer depending on what your doctor has prescribed for you.

Instructions for using Hizentra are at the end of this patient package insert (see "How do I use Hizentra?"). Do not use Hizentra by yourself until you have been taught how by your doctor or healthcare professional.

What should I avoid while taking Hizentra?

Vaccines may not work well for you while you are taking Hizentra. Tell your doctor or healthcare professional that you are taking Hizentra before you get a vaccine.

Tell your doctor or healthcare professional if you are pregnant or plan to become pregnant, or if you are nursing.

What are possible side effects of Hizentra?

The most common side effects with Hizentra are:

- Redness, swelling, itching, and/or bruising at the injection site
- Headache/migraine
- Nausea and/or vomiting
- Pain (including pain in the chest, back, joints, arms, legs)
- Fatigue
- Diarrhea
- Stomach ache/bloating
- Cough
- Rash (including hives)
- Itching
- Fever and/or chills
- Shortness of breath
- Dizziness

Tell your doctor right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness, or fainting. These could be signs of a bad allergic reaction.

Tell your doctor right away if you have any of the following symptoms. They could be signs of a serious problem.

- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body. These could be signs of a blood clot.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of a brain swelling called meningitis.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a blood problem.
- Chest pains or trouble breathing.
- Fever over 100ºF. This could be a sign of an infection.

Tell your doctor about any side effects that concern you. You can ask your doctor to give you more information that is available to healthcare professionals.

How do I use Hizentra?

Infuse Hizentra only after you have been trained by your doctor or healthcare professional. Below are step-by-step instructions to help you remember how to use Hizentra. Ask your doctor or healthcare professional about any instructions you do not understand.

Instructions for use

Hizentra comes in single-use vials.

Keep Hizentra in the storage box at room temperature.

Step 1: Assemble supplies

Gather the Hizentra vial(s), the following disposable supplies (not provided with Hizentra), and other items (infusion pump, sharps or other container, treatment diary or log book):

Infusion administration tubing
Needle or catheter sets (for subcutaneous infusion)
Y-site connectors (if needed)
Alcohol wipes
Antiseptic skin preps
Syringes
Transfer device or needle(s)
Gauze and tape, or transparent dressing
Gloves (if recommended by your doctor)

Step 2: Clean surface

Thoroughly clean a table or other flat surface using one of the alcohol wipes.

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Step 3: Wash hands

- Thoroughly wash and dry your hands (Figure 1).
- If you have been told to wear gloves when preparing your infusion, put the gloves on.

Figure 1

Step 4: Check vials

Carefully look at the liquid in each vial of Hizentra (Figure 2). Hizentra is a pale yellow to light brown solution. Check for particles or color changes. **Do not use the vial if**:

- The liquid looks cloudy, contains particles, or has changed color.
- The protective cap is missing.
- The expiration date on the label has passed.

Figure 2

Step 5: Transfer Hizentra from vial(s) to syringe

- Take the protective cap off the vial (Figure 3).

Figure 3

Clean the vial stopper with an alcohol wipe (Figure 4). Let the stopper dry.

Figure 4

- Attach a needle or transfer device to a syringe tip, using aseptic technique. If using a transfer device, follow the instructions provided by the device manufacturer. If using a needle and a syringe to transfer Hizentra, follow the instructions below.
- Attach a sterile transfer needle to a sterile syringe (Figure 5).
- Pull out the plunger of the syringe to fill the syringe with air. Make sure the amount of air is the same as the amount of Hizentra you will transfer from the vial.
- Put the Hizentra vial on a flat surface. Keeping the vial upright, insert the transfer needle into the center of the rubber stopper.
- Check that the tip of the needle is not in the liquid. Then, push the plunger of the syringe down. This will inject the air from the syringe into the airspace of the vial.
- Leaving the needle in the stopper, carefully turn the vial upside down (Figure 6).
- Slowly pull back on the plunger of the syringe to fill the syringe with Hizentra.
- Take the filled syringe and needle out of the stopper. Take off the needle and throw it away in the sharps container.

Figure 5

Figure 6

When using multiple vials to achieve the desired dose, repeat this step.

Step 6: Prepare infusion pump and tubing

Prepare the infusion pump (following the manufacturer's instructions) and prime (fill) the infusion tubing. To prime the tubing, connect the syringe filled with Hizentra to the infusion tubing and gently push on the syringe plunger to fill the tubing with Hizentra (Figure 7).

Figure 7

Step 7: Prepare injection site(s)

- Select an area on your abdomen, thigh, upper arm, or side of upper leg/hip for the infusion (Figure 8).
- Use a different site from the last time you infused Hizentra. New sites should be at least 1 inch from a previous site.
- Never infuse into areas where the skin is tender, bruised, red, or hard. Avoid infusing into scars or stretch marks.
- If you are using more than one injection site, be sure the injection sites are at least 2 inches apart.
- During an infusion, do not use more than 4 injection sites at the same time.
- Clean the skin at each site with an antiseptic skin prep (Figure 9). Let the skin dry.

Figure 8

Figure 9

Step 8: Insert needle(s)

- With two fingers, pinch together the skin around the injection site. Insert the needle under the skin (Figure 10).
- Put sterile gauze and tape or a transparent dressing over the injection site (Figure 11). This will keep the needle from coming out.
- Make sure you are not injecting Hizentra into a blood vessel. To test for this, attach a sterile syringe to the end of the infusion tubing. Pull the plunger back gently (Figure 12). If you see any blood flowing back into the tubing, take the needle out of the injection site. Throw away the tubing and needle. Start the infusion over at a different site with new infusion tubing and a new needle.

Figure 10

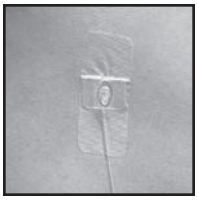

Figure 11

Figure 12

Step 9: Start infusion

Follow the manufacturer's instructions to turn on the infusion pump (Figure 13).

Step 10: Record treatment (Figure 14)

Peel off the removable part of the label of the Hizentra vial. Put this label in your treatment diary or log book with the date and time of the infusion. Also include the exact amount of Hizentra that you infused.

Figure 13

Step 11: Clean up

- When all the Hizentra has been infused, turn off the pump.
- Take off the dressing and take the needle out of the injection site. Disconnect the tubing from the pump.
- Throw away any Hizentra that is leftover in the single-use vial, along with the used disposable supplies, in the sharps container (Figure 15).
- Clean and store the infusion pump, following the manufacturer's instructions.

Figure 14

Be sure to tell your doctor about any problems you have doing your infusions. Your doctor may ask to see your treatment diary or log book, so be sure to take it with you each time you visit the doctor's office.

Figure 15

Call your doctor for medical advice about side effects. You can also report side effects to FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

Manufactured by:
CSL Behring AG
Bern, Switzerland
US License No. 1766

Distributed by:
CSL Behring LLC
Kankakee, IL 60901 USA

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K142319/S001/WD001

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January 23, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Request for withdrawal of K142319/S001 (EMED SCIg60 Infusion System)

This letter is intended to formally request withdrawal of the supplemental submission K142319/S001 received by the Document Control Center on 12/24/2014.

The submitted information is provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

Please contact the undersigned at your earliest convenience if there are any questions regarding this request.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

S.

Questions? Contact FDA/CDRH/OCE/DMD at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K142319/S001

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December 22, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Response to Request for Additional Information – SCIg60 Infusion System (K142319)

The following is the additional information requested on 10/17/14 to support the pre-market notification for the EMED Technologies Corporation SCIg60 Infusion System (K142319)

The submitted information and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

Please contact the undersigned at your earliest convenience if there are any questions regarding the responses or information provided.

Regards,

Peter Kollings

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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December 22, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Response to Request for Additional Information – SCIg60 Infusion System (K142319)

The following is the additional information requested on 10/17/14 to support the pre-market notification for the EMED Technologies Corporation SCIg60 Infusion System (K142319)

The submitted information and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

Please contact the undersigned at your earliest convenience if there are any questions regarding the responses or information provided.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 1: Updated Labeling

This appendix contains the following:

Exhibit	Doc ID	Description
1	AS-0010021_2.0_k	SCIg60 Infusion System User Manual
2	AS-0010015_3.0	SCIg60 Infuser IFU label
3	AS-0010041_1.3	IFU, Infuset

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SCIg60 Infusion System

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

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Introduction

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

Indications

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

SCIg60 Infusion System Product Line:

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

NOTE: EMED subcutaneous infusion administration sets and BD 60 mL syringes are not provided and may be purchased sold separately.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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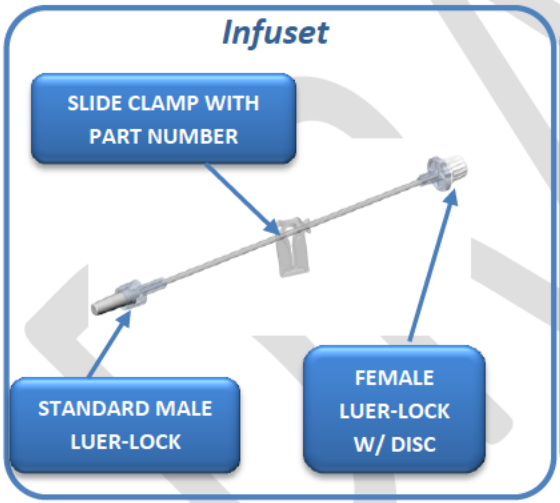
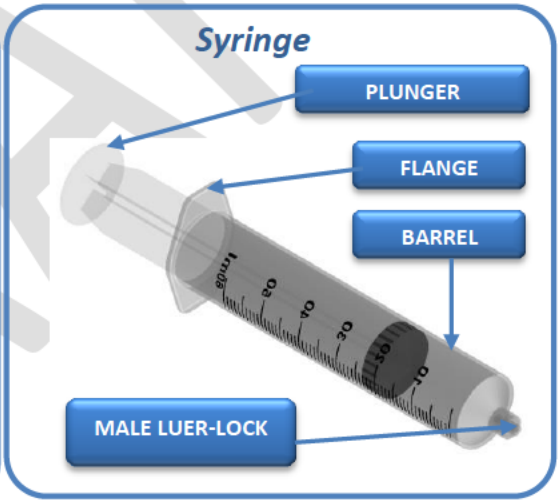
Getting to know your SCIg60 Infusion System





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Complete SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Available Infuset Flow Control Extension Sets

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

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SCIg60 Infusion System Instructions for Use (IFU)

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

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

2. **REMOVE** Infuset flow controller, administration set and syringe from sterile packaging.

3. **TRANSFER** Hizentra from vial(s) to BD 60 ml syringe (model no. 309653) according to the Hizentra patient insert or as instructed by your healthcare provider.

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

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

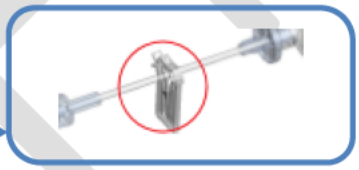
6. Use slide clamp provided with Infuset to prevent flow of Hizentra.

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

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

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

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



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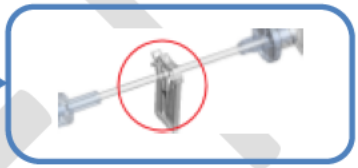
Instructions for Use (IFU) – Continued

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

    CAUTION: DO NOT ATTEMPT TO REMOVE THE SYRINGE BEFORE PERFORMING STEP 15.

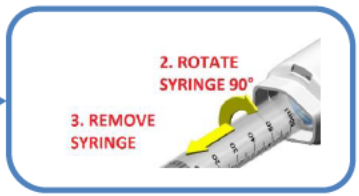
12. Place the SCIg60 Infuser, Infuset, and administration set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the SCIg60 Infuser Carrying Case Accessory* below for more details).

13. **PREPARE INJECTION SITES, INSERT NEEDLES,** and **START INFUSION** according to the Hizentra patient insert, administration set instructions, or as instructed by your healthcare provider.



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

15. To **REMOVE THE SYRINGE** rotate the handle **counterclockwise** until it stops, then unlock the syringe by turning it 90° in either direction (refer to steps 7 - 10 above).



Using the SCIg60 Infuser Carrying Case Accessory

1. Open pouch and unfasten Velcro straps inside the pouch.
2. Insert SCIg60 Infuser with syringe and Infuset into the pouch on top of Velcro straps.

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

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Hizentra Dosage and Administration

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

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

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

First Infusion of Hizentra – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12	FP-0010008	SUB-109-G24
	4	39	FP-0010009	SUB-409-G24
27	2	25	FP-0010005	SUB-260
	4	47	FP-0010004	SUB-410

Standard Infusions – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12	FP-0010008	SUB-109-G24
		16	FP-0010007	SUB-109-G24
	2	26	FP-0010010	SUB-209-G24
		35	FP-0010009	SUB-209-G24
	3	39	FP-0010009	SUB-309-G24
		51	FP-0010005	SUB-309-G24
	4	39	FP-0010009	SUB-409-G24
		52	FP-0010005	SUB-409-G24
27	1	14	FP-0010009	SUB-109-G27
		17	FP-0010004	SUB-109-G27
	2	25	FP-0010005	SUB-260
		30	FP-0010004	SUB-260
	3	43	FP-0010004	SUB-320
	4	47	FP-0010004	SUB-410

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

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

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

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SCIg60 Infuser Technical Information

Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 g (14.5 oz)
Storage Temperature	-5°C to +40°C (23°F to 104°F)
Syringe Volume	60 ml
Maximum Operating Pressure	16.8 psi
Average Operating Pressure	14.4 psi
Total System Accuracy (includes Infuset and SUB-Q set)	±15% from target flow rate
Vertical Sensitivity	
Each 30.5 cm (12 in.) pump above infusion site	+6% from target flow rate
Each 30.5 cm (12 in.) pump below infusion site	-4% from target flow rate
Maximum Vertical Difference	±61.0 cm (±24 in.)
Target Operating Temperature	20°C - 25°C (68°F – 77°F)
Shelf-life	5 years

SCIg60 Infuser – Cleaning and Storage

- Outer surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak mixture of mild detergent and warm water (approximately 1 part detergent to 50 parts water by volume). Clean exterior surfaces by gently pressing onto the SCIg60 Infuser and using circular motions with the alcohol wipe or damp cloth.
- Clean only those areas that are exposed when the Infuser Inner Drive is completely screwed in. Do not attempt to clean any part of the pump that is not easily accessible.
- Discontinue use of a pump that has been internally exposed to or immersed in fluid.
- Use a dry cloth to dry the exposed and external portions of the device.
- Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.

SCIg60 Infuser Carrying Case – Cleaning and Storage

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting

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

- **SYRINGE POSITION**. Verify the syringe is properly positioned into the infuser as instructed in the IFU section; the syringe should be parallel to the infuser with the syringe flanges properly engaged and seen in the safety check window (shown in the diagram). If syringe 'pops out' of infuser when inner drive is closed/screwed in, it is an indication that the syringe was not properly positioned in the infuser. Unscrew the inner drive and properly position the syringe following the instructions for use.
- **TUBING CONNECTORS**. Verify the syringe is properly connected to the Infuset and that the Infuset is correctly connected to the subcutaneous administration sets.
- **NO FLOW.** Check the slide clamp on the Infuset and make sure it is not blocking the flow. Verify that no other clamp is blocking the flow and that the Infuset or administration set is not kinked in any way.
- **FLOW RATE IS TOO HIGH**. Verify that the correct Infuset is being used.
- **FLOW RATE IS TOO SLOW**. Verify that the correct Infuset is being used and that the Infuset or administration set is not kinked in any way.

  NOTE: Storage of the Infuset with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.
- **FLOW DOES NOT STOP**. Verify that the slide clamp on the Infuset is fully closed.
- **BROKEN PARTS**. Inspect infuser for any broken parts. If after following the instructions above the SCIg60 Infusion System does not appear to be working properly, or if you observe something unusual, discontinue use of the SCIg60 Infusion System and contact your healthcare provider or EMED Technologies Corporation.

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

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Contraindications/Warnings

DO	DO NOT
Read all instructions for the SCIg60 Infusion System.	Do not continue to use a pump that has been damaged, dropped, or if it has failed to perform as expected. If the infuser is dropped or damaged either in transit to you or during preparation for its use, or if any other damage is suspected, contact EMED Technologies.
Read all instructions for the Infuset flow controller and subcutaneous administration set.	Do not subject the Infuser to autoclaving or other similar methods of sterilization.
Use the SCIg60 Infusion System as prescribed by your healthcare provider and follow all the directions as prescribed.	Do not open the infuser or attempt to modify its function in any way other than its intended use.
The provided flow rates represent expected performance of the SCIg60 Infusion System when used only with EMED Infuset and EMED SUB-Q infusion sets. Use of other infusion accessories may result in flow rates outside of what has been approved for Hizentra.	DO NOT use any other syringe. Doing so may result in unsafe conditions for patient or deviation from desired infusion rates.
Use only BD 60 ml syringes (model no. 309653).	**Do not insert or remove the syringe** until the INNER DRIVE is fully opened, as indicated in the IFU section, step 15.
Use aseptic technique when handling Infuset flow control extension sets and **subcutaneous administration set.**	Do not use Infusets or syringes more than once, as reuse may result in infection, cross contamination, or altered flow rate performance.
Place SCIg60 Infusion pump on a flat surface or in the provided carrying case during use. Syringe damage and Hizentra loss could occur if system is dropped while loaded with syringe and Hizentra.	Do not re-sterilize Infuset flow control extension sets, doing so may cause serious health effects to patient.
The SCIg60 Infusion System is intended for single patient use only.	Do not use SCIg60 Infusion System while undergoing medical diagnostic procedures, such as MRI, x-ray, or CT scans.
Contact EMED if you have any questions regarding the use of the SCIg60 Infusion System.	Do not use multiple Infusets at one time because the flow rates provided in this Manual and the Infuset IFU are for a single Infuset only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 Manufacturer's Representative.

- **Lifetime Warranty:** EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects, device degradation, or failure for the lifetime of the SCIg60 Infuser when used as intended. Lifetime is defined as the time from the original purchase date up to and including the 'Use by' date.

- **Replacement:** Subject to the conditions of and upon compliance with the procedures set forth in this lifetime 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 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 warranty period.

- **Disposable items (Infusets)**: In the event that a disposable item is found defective, it will be replaced with a new disposable item.

EMED Technologies Contact Information

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

EC REP
Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
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Fax: +31 (0) 70 346 7299

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Symbols Definition Table

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

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions	-5°C 40°C	Storage temperature limits
	Do not re-use	SN	Serial number
	Don't use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide	⟷	Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date	Non-Pyrogenic	Non-pyrogenic fluid path

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NOTES: Unless otherwise specified.

1. ENVIRONMENT: Indoors
2. LIFE EXPECTED: 5 years min. attached to device.
3. MATERIAL: 3 Mil Velvet Lexan®/S730/1.5 Mil Polyester
   a) Sub-Strate: FLEXmark V 400 F WHITE V-29 SPEC 50K-8
   b) Adhesive: S730 clear solvent acrylic permanent adhesive.
4. BACKGROUND TO MATCH SABIC PLASTICS NORYL GFN1 COLOR WHITE WH8F014
5. SIZE: 1.743in X 5.827in +.010 -.020
6. ALL MATERIALS AND INK TO BE RoHS COMPLIANT.
7. CERTIFICATE OF CONFORMANCE IS REQUIRED WITH EVERY SHIPMENT.
8. PRINT SERIAL NUMBER AND USE BY DATE AS NOTED.

2X R.125"

SCIg60 Infusion System

Use only with EMED flow rate infusion sets and B-D 60ml syringe.

1) FILL syringe with desired fluid.

2) CONNECT flow rate infusion set to syringe and patient set.

3) PRIME flow rate infusion set and patient set per healthcare provider instructions.

4) CLOSE fluid path per flow rate infusion set instructions.

5) REFER to healthcare provider instructions to connect patient set to patient.

6) OPEN ***SCIg60 Infuser*** drive by rotating the knob counterclockwise until it stops.

7) LOAD & LOCK syringe into the ***SCIg60 Infuser*** by inserting the syringe plunger and rotating the syringe 90° until it clicks into place.

8) VERIFY syringe's proper placement into the ***SCIg60 Infuser*** by confirming that the syringe flange shows through the window marked in red (image above).

9) CLOSE the ***SCIg60 Infuser*** by rotating the knob clockwise until it stops (see image on step 6).

10) COMPLETE INFUSION as instructed by your health care provider.

11) OPEN the ***SCIg60 infuser*** drive before removing the syringe (see step 6).

SN XXXXXX RxOnly

Use By: YYYY-MM

CE 0459

EMED Technologies Corporation
www.emedtc.com | Tel. 888.550.6500
AS 0010015 3.0a

4

2X R.063"

EACH LABEL TO BE SERIALIZED STARTING AT **000600** AND CONTINUE WITH SERIALIZATION FOR EACH LABEL P.O. FONT: ARIAL BOLD 10 PT. BLACK. (REPLACE XXXXXX WITH SERIAL #)

PRINT USE BY DATE FIVE (5) YEAR FROM MANUFACTURING DATE.

Revision History

Rev	Description	DCR#
1.0	PILOT RELEASE	10122011-02
2.0	UPDATED IFU INSTRUCTIONS	12232011-01
2.1	UPDATED TYPO ON BLUE COLOR 385 TO 285	01122011-01
2.2	ADDED NOTE TO CONTINUE SERIALIZATION	10022012-01
3.0a	ADDED USE BY DATE AND NOTE 8.	TBD

C M Y K

285 396 426 485

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APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN BY:	Carlos G.	[ON FILE PER DCR]	11/10/2014
ENGINEERING:	Carlos G.	[ON FILE PER DCR]	11/10/2014
MFG.	Carlos G.	[ON FILE PER DCR]	11/10/2014
S&M	N/A	N/A	-
Q.A.			

EMED Technologies
The power of creative thinking
EMED Technologies Corporation
1264 Hawks Flight Court Suite 200
El Dorado Hills, CA 95762
Tel. 916.932.0071
Website: www.emedtc.com

Desc. ARTWORK, SCIg60 INFUSER IFU LABEL
Rev. 3.0a
Part No. AS-0010015
Size: A | Scale: 1:1 | Sheet 1 OF 1 | Template NO. MF-0006 REV 1.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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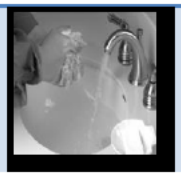
Infuset Flow Control Extension Set
Instructions for Use

WARNING:

- The Infuset™ Flow Control Extension Set is intended for home or hospital use with the SCIg60 Infuser for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).
- Single use only; reuse may result in infection, cross contamination, or altered flow rate performance.
- Do not re-sterilize
- Use aseptic technique
- Follow pharmacy / physician instructions
- U.S. Federal Law restricts this device to sale by or on order of a physician

1 
Wash hands before handling any supplies

2 Remove Infuset from packaging

3
Transfer Hizentra from vial(s) to BD 60 ml syringe (model no. 309653) according to the Hizentra patient insert.

4
Connect syringe male luer lock (MLL) to Infuset female luer lock (FLL)

5 Connect Infuset male luer lock (MLL) to patient administration set male luer lock (FLL)

6
Prime set (be careful not to waste fluid) per your pharmacy / physician instructions.

7
Use provided slide clamp to prevent flow of fluid.

8
Load syringe into SCIg60 Infuser per pump User's Manual.

9 Operate SCIg60 Infuser per User Manual and pharmacy / physician instructions directions.

10
Complete the infusion and disconnect Infuset from patient / equipment per your pharmacy / physician instructions

11
Dispose in appropriate waste container

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Infuset Flow Control Extension Set
Instructions for Use

	SYMBOLS	ENGLISH		SYMBOLS	ENGLISH		SYMBOLS	ENGLISH
1		Warning	9		Manufacturing date	17	Rx ONLY	To sale by or on the order of a physician.
2		Read the instructions	10	LOT	Batch	18	≈ XX ml	Approximate priming volume
3		Do not re-use	11		Expiration date	19	CE	CE Mark
4		Don't use if package is damaged	12		Quantity	20	ID	Internal Diameter
5	STERILE EO	Sterilized by Ethylene Oxide	13	-5°C 40°C	Storage temperature limits	21	OD	Outer Diameter
6		Manufacturer	14	SN	Serial number	22	Non-Pyrogenic	Non-pyrogenic fluid path
7	EC REP	EC Representative	15	Ø	Diameter			
8	REF	Reference number	16		Length			

Flow Rates with ***EMED SCIg60 Infusion System***

(Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid 20°C - 25°C)

First Infusion of Hizentra – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Total Flow Rate (ml/hr)	SUB-Q Set (# of needles)	Reorder Number
24	12	SUB-109-G24 (1 needle)	FP-0010008
	39	SUB-409-G24 (4 needle)	FP-0010009
27	25	SUB-260 (2 needle)	FP-0010005
	47	SUB-410 (4 needle)	FP-0010004

Standard Infusions – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Total Flow Rate (ml/hr)	SUB-Q Set (# of needles)	Reorder Number
24	12	SUB-109-G24 (1 needle)	FP-0010008
	16		FP-0010007
	26	SUB-209-G24 (2 needle)	FP-0010010
	35		FP-0010009
	39	SUB-309-G24 (3 needle)	FP-0010009
	51		FP-0010005
	39	SUB-409-G24 (4 needle)	FP-0010009
	52		FP-0010005
27	14	SUB-109-G27 (1 needle)	FP-0010009
	17		FP-0010004
	25	SUB-260 (2 needle)	FP-0010005
	30		FP-0010004
	43	SUB-320 (3 needle)	FP-0010004
	47	SUB-410 (4 needle)	FP-0010004

NOTE: Flow rates can be affected by multiple factors such as ambient temperature, patient conditions, large height differences between the Infuser and infusion site, and variations in Hizentra viscosity. The above flow rates were determined at controlled room temperature (20°C - 25°C) using only EMED SUB-Q subcutaneous administration sets downstream of the Infuset. Please refer to the SCIg60 Infusion System User Manual for more information, or contact EMED Technologies at +1 (916) 932-0071 for assistance regarding selection of Infuset flow control extension sets and SUB-Q sets to obtain a desired flow rate.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 2: Performance Testing

This appendix contains the following:

Exhibit	Doc ID	Description
1	(b)(4) Testing [redacted]	
2		
3		
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Appendix 3: Risk Management

This appendix contains the following:

Exhibit	Title
1	Usability Validation: Infuset-SUB-Q Combination Selection*
2	SCIg60 Risk Management Safety Assurance Case Report

*NOTE: Usability Test Forms are not included due to their large size but are maintained at EMED Technologies as part of the complete SCIg60 Human Factors Validation file.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K142319 | S002

FDA CDRH DMC
APR 14 2015
Received

April 13, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Response to Request for Additional Information – SCIg60 Infusion System (K142319)

The following is the additional information requested on 10/17/14 to support the pre-market notification for the EMED Technologies Corporation SCIg60 Infusion System (K142319)

The submitted information and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

Please contact the undersigned at your earliest convenience if there are any questions regarding the responses or information provided.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or 301-796-8118

1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.0071 • Fax 916.932.0074 • www.emedtc.com

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

EMED Technologies

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April 13, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Response to Request for Additional Information – SCIg60 Infusion System (K142319)

The following is the additional information requested on 10/17/14 to support the pre-market notification for the EMED Technologies Corporation SCIg60 Infusion System (K142319)

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Please contact the undersigned at your earliest convenience if there are any questions regarding the responses or information provided.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel: 916.932.8001 • Fax: 916.932.8017 • www.emedtc.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 1: Updated Labeling

This appendix contains the following:

Exhibit	Doc ID	Description
1	AS-0010015_3.0b	SCIg60 Infuser IFU label
2	AS-0010021_2.0_l	SCIg60 Infusion System User Manual
3	AS-0010041_1.3_j	IFU, Infuset

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NOTES: Unless otherwise specified.

1. ENVIRONMENT: Indoors
2. LIFE EXPECTED: 5 years min. attached to device.
3. MATERIAL: 3 Mil Velvet Lexan®/S730/1.5 Mil Polyester
   a) Sub-Strate: FLEXmark V 400 F WHITE V-29 SPEC 50K-8
   b) Adhesive: S730 clear solvent acrylic permanent adhesive.
4. BACKGROUND TO MATCH SABIC PLASTICS NORYL GFN1 COLOR WHITE WH8F014
5. SIZE: 1.743in X 5.827in +.010 -.020
6. ALL MATERIALS AND INK TO BE RoHS COMPLIANT.
7. CERTIFICATE OF CONFORMANCE IS REQUIRED WITH EVERY SHIPMENT.
8. PRINT SERIAL NUMBER AND USE BY DATE AS NOTED.

2X R.125"

SCIg60 Infusion System

Use only with EMED flow rate infusion sets and B-D 60ml syringe.

1) FILL syringe with Hizentra.

2) CONNECT flow rate infusion set to syringe and patient set.

3) PRIME flow rate infusion set and patient set per healthcare provider instructions.

4) CLOSE fluid path per flow rate infusion set instructions.

5) REFER to healthcare provider instructions to connect patient set to patient.

6) OPEN ***SCIg60 Infuser*** drive by rotating the knob counterclockwise until it stops.

7) LOAD & LOCK syringe into the ***SCIg60 Infuser*** by inserting the syringe plunger and rotating the syringe 90° until it clicks into place.

8) VERIFY syringe's proper placement into the ***SCIg60 Infuser*** by confirming that the syringe flange shows through the window marked in red (image above).

9) CLOSE the ***SCIg60 Infuser*** by rotating the knob clockwise until it stops (see image on step 6).

10) COMPLETE INFUSION as instructed by your health care provider.

11) OPEN the ***SCIg60 infuser*** drive before removing the syringe (see step 6).

SN XXXXXX RxOnly

Use By: YYYY-MM

CE 0459

EMED Technologies Corporation
www.emedtc.com | Tel. 888.550.6500
AS 0010015 3.0a

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2X R.063"

EACH LABEL TO BE SERIALIZED STARTING AT **000600** AND CONTINUE WITH SERIALIZATION FOR EACH LABEL P.O. FONT: ARIAL BOLD 10 PT. BLACK. (REPLACE XXXXXX WITH SERIAL #)

PRINT USE BY DATE FIVE (5) YEAR FROM MANUFACTURING DATE.

Revision History

Rev	Description	DCR#
1.0	PILOT RELEASE	10122011-02
2.0	UPDATED IFU INSTRUCTIONS	12232011-01
2.1	UPDATED TYPO ON BLUE COLOR 385 TO 285	01122011-01
2.2	ADDED NOTE TO CONTINUE SERIALIZATION	10022012-01
3.0a	ADDED USE BY DATE AND NOTE 8.	TBD
3.0b	Updated step #1 to fill the syringe with Hizentra	Date: 1/22/2015

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APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN BY:	Carlos G.	[ON FILE PER DCR]	01/22/2015
ENGINEERING:	Carlos G.	[ON FILE PER DCR]	01/22/2015
MFG.	Carlos G.	[ON FILE PER DCR]	01/22/2015
S&M	N/A	N/A	-
Q.A.			

EMED Technologies
The power of creative thinking
EMED Technologies Corporation
1264 Hawks Flight Court Suite 200
El Dorado Hills, CA 95762
Tel. 916.932.0071
Website: www.emedtc.com

Desc. ARTWORK, SCIg60 INFUSER IFU LABEL
Rev. 3.0b
Part No. AS-0010015
Size: A | Scale: 1:1 | Sheet 1 OF 1 | Template NO. MF-0006 REV 1.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SCIg60
Infusion System

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CREATIVE THINKING

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Introduction

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

Indications

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

SCIg60 Infusion System Product Line:

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

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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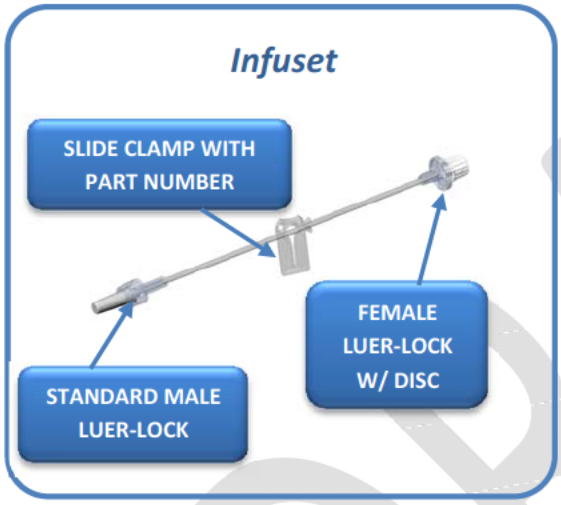
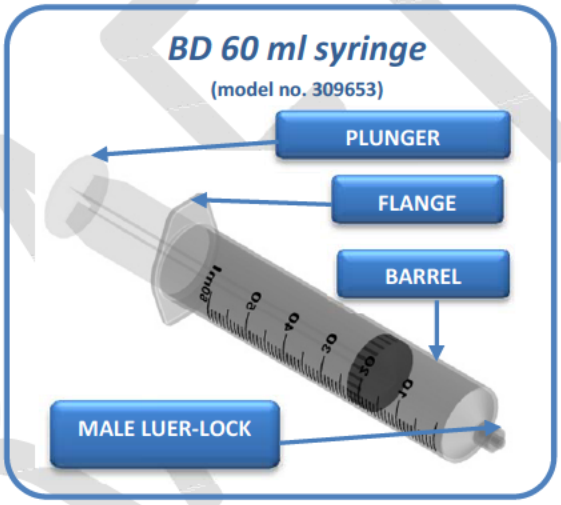
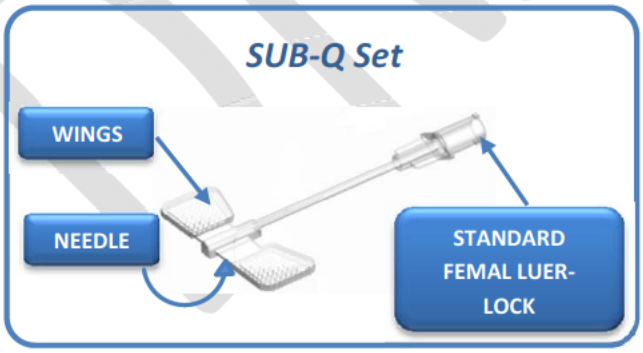
Getting to know your SCIg60 Infusion System







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Complete SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Available Infuset Flow Control Extension Sets

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

NOTE: Please review *Hizentra Dosage and Administration* section (page 8 of 14) to determine which administration set is most appropriate for specific therapeutic needs and/or patient preferences.

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⚠ Contraindications/Warnings

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

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

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

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

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

Do not insert or remove the BD 60 ml syringe (model no. 309653) until the INNER DRIVE is fully opened, as indicated in the IFU section, step 16.

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

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

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

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

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

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

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

Important Information

Read all instructions for the SCIg60 Infusion System.

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

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

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

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

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

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

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

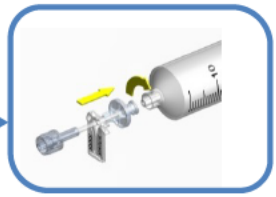
SCIg60 Infusion System Instructions for Use (IFU)

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

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

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

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



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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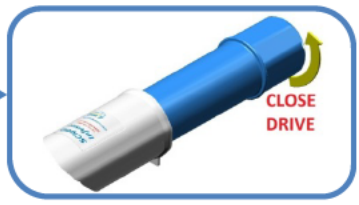
Instructions for Use (IFU) – Continued

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

    CAUTION: DO NOT ATTEMPT TO REMOVE THE BD 60 ml syringe (model no. 309653) BEFORE PERFORMING STEP 16.



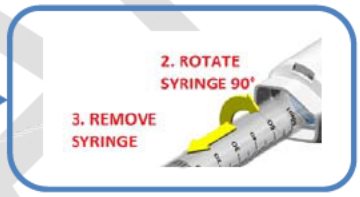
13. Place the SCIg60 Infuser, Infuset, and specified administration set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the SCIg60 Infuser Carrying Case Accessory* below for more details).

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

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

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

17. When session is complete, **REMOVE THE BD 60 ML SYRINGE (MODEL NO. 309653)** rotate the handle **counterclockwise** until it stops, then unlock the syringe by turning it 90° in either direction (refer to steps 7 - 10 above).



Using the SCIg60 Infuser Carrying Case

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

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

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hizentra Dosage and Administration

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

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

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

First Infusion of Hizentra – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12	12	FP-0010008	SUB-109-G24
	4	39	10	FP-0010009	SUB-409-G24
27	2	25	13	FP-0010005	SUB-260
	4	47	12	FP-0010004	SUB-410

Standard Infusions – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12	12	FP-0010008	SUB-109-G24
		16	16	FP-0010007	SUB-109-G24
	2	26	13	FP-0010010	SUB-209-G24
		35	18	FP-0010009	SUB-209-G24
	3	39	10	FP-0010009	SUB-309-G24
		51	17	FP-0010005	SUB-309-G24
	4	39	10	FP-0010009	SUB-409-G24
		52	13	FP-0010005	SUB-409-G24
27	1	14	14	FP-0010009	SUB-109-G27
		17	17	FP-0010004	SUB-109-G27
	2	25	13	FP-0010005	SUB-260
		30	16	FP-0010004	SUB-260
	3	43	14	FP-0010004	SUB-320
	4	47	12	FP-0010004	SUB-410

Hizentra Dosage and Administration – Continued

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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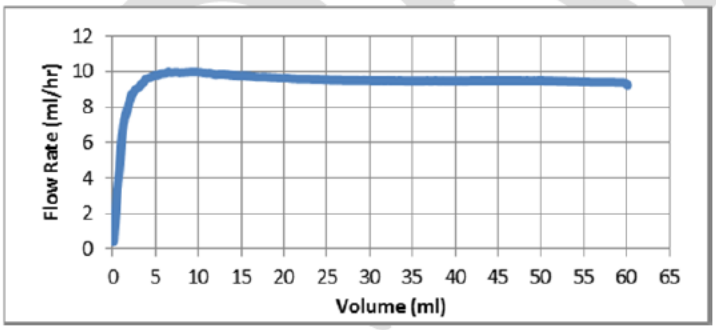
SCIg60 Infuser Technical Information

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

Representative Hizentra Flow Rate Profile

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



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

SCIg60 Infuser – Cleaning and Storage

- Outer surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak mixture of mild detergent and warm water (approximately 1 part detergent to 50 parts water by volume). Clean exterior surfaces by gently pressing onto the SCIg60 Infuser and using circular motions with the alcohol wipe or damp cloth.
- Clean only those areas that are exposed when the Infuser Inner Drive is completely screwed in. Do not attempt to clean any part of the pump that is not easily accessible.
- Discontinue use of a pump that has been internally exposed to or immersed in fluid.
- Use a dry cloth to dry the exposed and external portions of the device.
- Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.

SCIg60 Infuser Carrying Case – Cleaning and Storage

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting

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

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

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

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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 Manufacturer's Representative.

- **Lifetime Warranty:** EMED Technologies Corporation ("Manufacturer") warrants the SCIg60 Infuser to be free from defects, device degradation, or failure for the lifetime of the SCIg60 Infuser when used as intended. Lifetime is defined as the time from the original purchase date up to and including the 'Use by' date.

- **Replacement:** Subject to the conditions of and upon compliance with the procedures set forth in this lifetime 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 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 warranty period.

- **Disposable items (Infusets)**: In the event that a disposable item is found defective, it will be replaced with a new disposable item.

Contact Information

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Symbols Definition Table

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

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions	40°C -5°C	Storage temperature limits
	Do not re-use	SN	Serial number
	Don't use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide	↔	Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date	Non-Pyrogenic	Non-pyrogenic fluid path

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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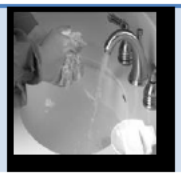
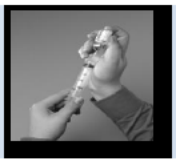
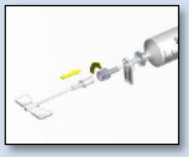
Infuset Flow Control Extension Set
Instructions for Use

WARNING:

- The Infuset™ Flow Control Extension Set is intended for home or hospital use with the SCIg60 Infuser for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring) with the BD 60 ml syringe (model no. 309653).
- Single use only; reuse may result in infection, cross contamination, or altered flow rate performance.
- Do not re-sterilize
- Use aseptic technique
- Follow pharmacy / physician instructions
- U.S. Federal Law restricts this device to sale by or on order of a physician

1		WASH HANDS thoroughly and dry hands before handling any supplies, and wear gloves if you have been instructed to do so.
2		REMOVE Infuset flow controller, specified administration set and syringe from sterile packaging.
3		TRANSFER Hizentra from vial(s) to BD 60 ml syringe (model no. 309653) according to the Hizentra package insert or as instructed by your healthcare provider
4		CONNECT syringe male luer lock (MLL) to Infuset female luer lock (FLL).
5		CONNECT Infuset male luer lock (MLL) to specified patient administration set male luer lock (FLL).
6		PRIME the tubing by gently pushing on the syringe plunger to fill the tubing with Hizentra, or as instructed by your healthcare provider.
7		Use slide clamp provided with Infuset to prevent flow of Hizentra. NOTE: Perform infusion within 30 minutes after priming set.
8		Load syringe into the SCIg60 Infuser and prepare the pump for infusion per SCIg60 Infusion System User Manual.
9		PREPARE INJECTION SITES and INSERT NEEDLES according to the Hizentra package insert, specified administration set instructions, or as instructed by your healthcare provider.
10		USE SLIDE CLAMP to start infusion as soon as pump is fully loaded and needles are inserted and secured by. USE SLIDE CLAMP to stop flow as necessary during infusion session or when session is complete.
11		When session is complete, REMOVE THE BD 60 ML SYRINGE (MODEL NO. 309653) and connected Infuset and SUB-Q set from the SCIg60 Infuser per SCIg60 Infusion System User Manual.
12		Dispose of THE BD 60 ML SYRINGE (MODEL NO. 309653) , Infuset, and SUB-Q set in an appropriate waste container

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Infuset Flow Control Extension Set
Instructions for Use

	SYMBOLS	ENGLISH		SYMBOLS	ENGLISH		SYMBOLS	ENGLISH
1		Warning	9		Manufacturing date	17	Rx ONLY	To sale by or on the order of a physician.
2		Read the instructions	10	LOT	Batch	18	≈ XX ml	Approximate priming volume
3		Do not re-use	11		Expiration date	19	CE	CE Mark
4		Don't use if package is damaged	12		Quantity	20	ID	Internal Diameter
5	STERILE EO	Sterilized by Ethylene Oxide	13	-5°C 40°C	Storage temperature limits	21	OD	Outer Diameter
6		Manufacturer	14	SN	Serial number	22	Non-Pyrogenic	Non-pyrogenic fluid path
7	EC REP	EC Representative	15	Ø	Diameter			
8	REF	Reference number	16		Length			

Flow Rates with ***EMED SCIg60 Infusion System***

(Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid 20°C - 25°C)

First Infusion of Hizentra – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Total Flow Rate (ml/hr)	SUB-Q Set (# of needles)	Reorder Number
24	12	SUB-109-G24 (1 needle)	FP-0010008
	39	SUB-409-G24 (4 needle)	FP-0010009
27	25	SUB-260 (2 needle)	FP-0010005
	47	SUB-410 (4 needle)	FP-0010004

Standard Infusions – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Total Flow Rate (ml/hr)	SUB-Q Set (# of needles)	Reorder Number
24	12	SUB-109-G24 (1 needle)	FP-0010008
	16		FP-0010007
	26	SUB-209-G24 (2 needle)	FP-0010010
	35		FP-0010009
	39	SUB-309-G24 (3 needle)	FP-0010009
	51		FP-0010005
	39	SUB-409-G24 (4 needle)	FP-0010009
	52		FP-0010005
27	14	SUB-109-G27 (1 needle)	FP-0010009
	17		FP-0010004
	25	SUB-260 (2 needle)	FP-0010005
	30		FP-0010004
	43	SUB-320 (3 needle)	FP-0010004
	47	SUB-410 (4 needle)	FP-0010004

NOTE: Flow rates can be affected by multiple factors such as ambient temperature, patient conditions, large height differences between the Infuser and infusion site, and variations in Hizentra viscosity. The above flow rates were determined at controlled room temperature (20°C - 25°C) using only EMED SUB-Q subcutaneous administration sets downstream of the Infuset. Please refer to the SCIg60 Infusion System User Manual for more information, or contact EMED Technologies at +1 (916) 932-0071 for assistance regarding selection of Infuset flow control extension sets and SUB-Q sets to obtain a desired flow rate.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Corporate Headquarters: 1264 Hawks Flight Court, Suite 200 El Dorado Hills, CA 95762
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Appendix 2: Performance Testing

This appendix contains the following:

Exhibit	Doc ID	Description
1	(b)(4) [redacted]	
2		
3		
4		
5		
6		
7		
8		

*NOTE: Study protocols and reports provided; appendices, attachments, supporting data, and supplemental information are not included due to their large size, but are maintained at EMED Technologies as part of the complete (b)(4) [redacted] (b)(4) [redacted] Report file.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 3: Risk Management

This appendix contains the following:

Exhibit	Title
1	Usability Validation: Infuset-SUB-Q Combination Selection*
2	SCIg60 Risk Management Safety Assurance Case Report

*NOTE: Usability Test Forms are not included due to their large size but are maintained at EMED Technologies as part of the complete SCIg60 Human Factors Validation file.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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