

Product Specification Sheet

Model Number: FP-0010002

SCIg60™

Infusion System

(Patents pending and
other patents issued)

FDA • CE • CANADA

The SCIg60™ Infuser is a reusable constant pressure mechanical, non-electronic ambulatory infusion pump intended for use in the home or hospital environment. It is **the first mechanical syringe infusion system cleared by the FDA** specifically for infusion of Immunoglobulin G (IgG) into subcutaneous tissue. In addition, the SCIg60™ Infusion System is approved for reimbursement by the Centers for Medicare and Medicaid Services under code E0779 (USA) along with multiple reimbursement systems worldwide, and is offered with a warranty.

Features

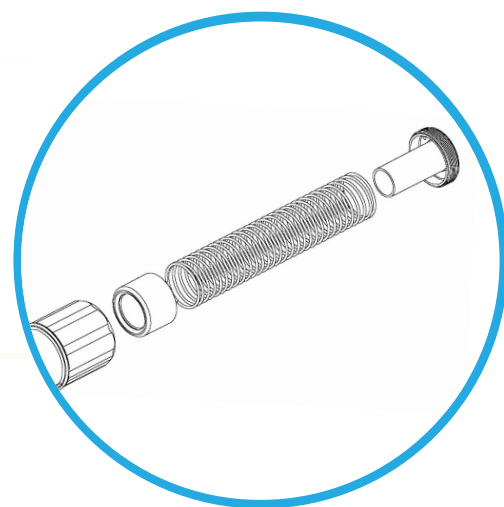
- Portable, lightweight and quiet
- Mechanically powered, non-electric, no batteries
- Designed for use with Infuset™ fixed rate sets
- Constructed with top grade materials
- Biocompatible to ISO 10993-1

Benefits

- Easy for clinicians to train patients for home use
- Multiple Infuset™ configurations available for situations that require a fixed flow rate

Advantages

- Offers control of infusion therapy without the cost of an electronic pump
- Is extremely robust and provides stable and consistent performance after long term use
- Flow rate charts are available for specific applications
- Is supported by a technical team
- Virtually no maintenance



**Versatility
you can
depend on.**



FDA Cleared, CE Marked. Clinically Engineered Comfort.



**Available
Worldwide**

SCIg60™ Infuser Technical Information

Specification	Parameter
Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 g (14.5 oz)
Storage Temperature	-5°C to +40°C (+23°F to +104°F)
Syringe Volume (BD 60 ml syringe (model no. 309653))	60 ml
Maximum Operating Pressure	16.8 psi
Average Operating Pressure	14.4 psi
Total System Accuracy (includes Infuset and SUB-Q set)	±15% from target flow rate
Vertical Sensitivity Each 30.5 cm (12 in.) above infusion site	+6% from target flow rate
Each 30.5 cm (12 in.) below infusion site	-4% from target flow rate
Maximum Vertical Difference	±30.5 cm (±24 in.)
Target Operating Temperature	20°C - 25°C (68°F - 77°F)
Residual Volume Infuset	Data available upon request
Usage Cycles	4200 cycles
Material Used	Stainless steel spring, Sabic Resin, Noryl plastic components, LNP Lubricomp, Acetal Resin

SCIg60™ Infuser Cleaning

(see user manual for additional information)

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).

SCIg60™ Infuser Summary

The SCIg60™ Infuser is extremely robust, providing consistent performance after long term test usage of **4,200 cycles**.

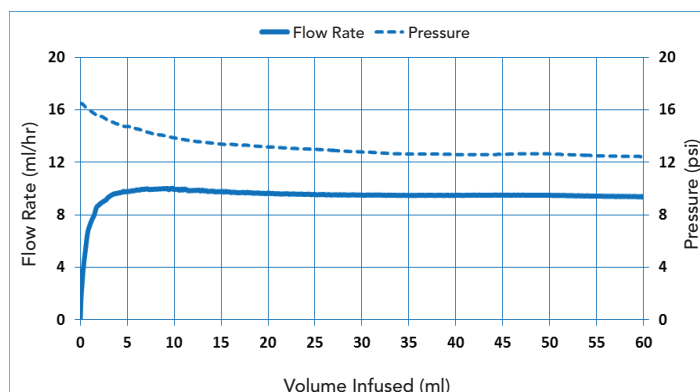
Prior to cyclic testing, each pump underwent accelerated aging at 55°C (131°F), to simulate the passage of time equivalent to 5 years of room temperature storage, based on Q10 test standards within ASTM F1980-07. The accelerated aging and storage was performed by an ISO9001-2008 certified medical device testing laboratory.

Cyclic testing was conducted to simulate intended usage of up to 4,200 cycles at a rate of 360 cycles per hour. The consecutive number of cycles and the high rotating speed exposed the device to a greater level of fatigue than normal use which provides a higher level of confidence that the device will meet the intended purpose even after excessive use.

Pre- and post cyclic testing/flow rate testing was conducted to evaluate if any changes in performance would occur as a result of excessive use during cyclic tests. Results indicated less than 1% change in flow rates demonstrating the SCIg60™ Infuser is extremely robust and provides consistent performance after long term usage.

Pressure and Flow Rate Profile

Representative Hizentra Total Flow Rate Profile vs. Infused Volume at 20°C - 25°C under laboratory conditions achieved with needle set SUB-320 and Infuset FP-001008.



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