USER:	**WEEKS, SUSAN M (smw)**
FOLDER:	**K032642 - 120 pages (FOI:08006271)**
COMPANY:	**MCKINLEY, INC. (MCKINLEYA)**
PRODUCT:	**PUMP, INFUSION (FRN)**
SUMMARY:	**Product: BEELINE SYSTEM**

DATE REQUESTED:	**Wed Jan 19 24:00:00 2011**
DATE PRINTED:	**Wed Jan 19 15:07:46 2011**
Note:	**Releasable Version**

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McKinley Medical LLLP
4080 Youngfield Street
Wheat Ridge, CO 80033 USA
303.420.9569
303.420.8585 Fax

SEP 2 3 2003

K032642

McKinley

510(k) Summary—Special 510(k) for Modifications to the McKinley Beeline System

Date Prepared:	15 August 2003
Submitter:	McKinley Medical, LLLP 4080 Youngfield Street Wheat Ridge, CO 80033 Phone: 303-420-9569 Fax: 303-420-8585 Contact for questions: Andy Lamborne
Trade Name:	Beeline Motiv
Common Name:	Spring Pump & Kit
Classification Name:	Infusion Pump
Classification Panel:	General Hospital and Personal Use Device
Regulation Number:	Class II, 880.5725
Panel:	80
Procode:	FRN – Infusion Pump
Original cleared 510(k):	K990461
Establishment Registration:	1723533
Owner/Operator Number:	9027257

5. Summary of Safety and Effectiveness of the Beeline System

5.1 This submission is intended to notify the Food and Drug Administration that McKinley Medical, LLLP intends to market a modification to an existing device (K990461) called the Beeline system. Modifications to the existing device are extension of the flow rate range, addition of a larger reservoir volume, and addition of procedure kits.

5.2 The original cleared device demonstrating substantial equivalence is the McKinley Spring Pump Disposable Infusion Pump (K990461).

5.3 A supporting predicate device also demonstrating substantial equivalence is McKinley's Accufuser, Accufuser Plus & standard procedure kit (K023098).

5.4 The cleared indications for use for the Beeline system are as follows:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

5.5 Summary Description of the Beeline system

5.5.1 The Beeline device consists of a spring-pressurized, syringe-like medication reservoir with a flowrate-controlling administration set. Medication is held between the barrel and piston of the infuser. A spring applies force against the piston, pressurizing the medication. The administration set includes a flow restrictor component with controlled internal diameter and length. The flow rate at which medication is dispensed from the system is a function of the pressure applied to the medication and the dimensions of the flow restrictor component.

5.5.2 The size of the reservoir and the amount of flow restriction are varied during manufacturing to yield a variety of product codes with differing infusion volumes and flowrates.

5.5.3 A procedure kit provides various components that facilitate setup and use of the Beeline system. Examples of kit components include items such as a prep tray, sterile drape, transfer syringe, medication/chart labels, catheter & introducer, dressing, tape, gauze, prep pads/wipes, carrying case, etc. Multiple kit product codes are made, with the contents varied as applicable for the particular procedure.

5.5.4 The Beeline system is intended for single patient use.

5.5.5 Device Specifications

a. The Beeline system has fill volumes and flow rates substantially equivalent to the named predicate devices.
   - The nominal fill volume of the system is 100 mL (small infuser) or 275 mL (large infuser).
   - The nominal flow rate ranges from 0.4 to 10 mL/hr.
   - Flow rate accuracy is ±15% of nominal flow rate, for all product codes.
   - Residual volume is 5 mL or less.

b. Operating pressure averages approximately 6 psi.

c. As with the identified predicate devices, fluid viscosity, temperature, and head height affect flow rate.

- The device is calibrated to deliver at the nominal flow rate using D5W (5% dextrose in water) as the infusate. Changing from D5W to sterile water increases flow rate by approximately 10%.
- The device is calibrated to deliver at the nominal flow rate at skin temperature (86 °F). Flow rate changes by approximately 1% per °F.
- The device is calibrated to deliver at the nominal flow rate with the medication reservoir 18" below the infusion site. Raising the infuser will increase the flow rate by less than 1% per inch.

d. The fluid path materials are chosen from those commonly used in infusion devices.

- Examples of the types of material used include polypropylene; polyethylene; PVC; acrylic; polycarbonate; ABS; silicone, butyl, nitrile, or other latex-free rubber; polyimide; nylon; PTFE; cellulose acetate; glass; stainless steel. The actual materials used vary slightly, depending on the product code (e.g., different procedure kit components may use different materials).
- The Beeline system and the identified predicate devices control the flow rate with a length of micro-bore tubing made from glass, PVC, polyethylene or similar appropriate material.
- All fluid path materials of the Beeline system are in conformance with ISO 10993-1 biocompatibility standards.

e. There are currently no approved performance standards established for spring pumps under Section 514 of the Food, Drug and Cosmetic Act.

f. Packaging is suitable for both EtO and gamma radiation sterilization.

- For product codes sterilized with EtO, the EtO cycle is validated per ISO 11135 and residuals are validated per ISO 10993-7.
- For product codes sterilized with gamma radiation, the sterilization dose is validated per ISO 11137.

5.5.6 Device Safety Functions

a. The Beeline system provides a fixed flow determined by the applied force from the compressed spring and the flow restriction induced by the dimensions of the flow restrictor. The Beeline system is not subject to infusion runaway conditions as may occur with some electronic pumps.

b. The administration set includes a clamp, allowing the user to stop flow if necessary.
c. The administration set has a 1.2-micron or smaller air-eliminating filter.
d. The fluid path is clear or translucent, allowing visual inspection of the contents.
e. The medication reservoir has syringe-like graduation marks to provide an approximate indication of remaining volume, allowing the user to monitor the infusion progress.

5.6 Conclusion: The modified Beeline system does not raise any new safety and efficacy concerns when compared to the original device that is already legally marketed. The Beeline system is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2003

Mr. Andrew N. Lamborne
Director of Engineering
McKinley Medical, LLLP
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K032642
Trade/Device Name: Beeline Motiv Spring Pump & Kit
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 15, 2003
Received: August 27, 2003

Dear Mr. Lamborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use Statement

Applicant: McKinley Medical, LLLP

510(k) Number (if known): K032642

Device Name: Beeline System

Indications for Use:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cusante

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K032642

(Optional Format 3-10-98)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2003

Mr. Andrew N. Lamborne
Director of Engineering
McKinley Medical, LLLP
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K032642
Trade/Device Name: Beeline Motiv Spring Pump & Kit
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 15, 2003
Received: August 27, 2003

Dear Mr. Lamborne:

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Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use Statement

Applicant: McKinley Medical, LLLP

510(k) Number (if known): K032642

Device Name: Beeline System

Indications for Use:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K032642

(Optional Format 3-10-98)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 27, 2003

MCKINLEY, INC.
4080 YOUNGFIELD ST.
WHEAT RIDGE, CO 80033
ATTN: ANDY LAMBORNE

510(k) Number: K032642
Received: 27-AUG-2003
Product: BEELINE SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Premarket Notification

K032642

Special 510(k)

Modification to McKinley Medical Beeline System

FDA/CDRH/ODE/PMO
2003 AUG 27 P 12: 33

5K57

McKinley Medical LLLP
4080 Youngfield Street
Wheat Ridge, CO 80033 USA
303.420.9569
303.420.8585 Fax

McKinley

15 August 2003

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA/CDRH/ODE/PMO
2003 AUG 27 P 12: 33

Reference:	Special 510(k) Device Modification
Trade Name:	Beeline Motiv
Common Name:	Spring Pump & Kit
Classification Name:	Infusion Pump
Classification Panel:	General Hospital and Personal Use Device
Device Classification Regulation Number:	Class II, 880.5725
Panel:	80
Procode:	FRN – Infusion Pump
Original cleared 510(k):	K990461
Establishment Registration:	1723533
Owner/Operator Number:	9027257

Dear Madam/Sir:

McKinley Medical, LLLP hereby submits this Special Premarket Notification for modifications to our Beeline System, prior to introduction of the modified device into interstate commerce for commercial distribution in accordance with paragraph 510(k) of the Food, Drug and Cosmetic Act and in conformance with Title 21 CFR Part 807.81. The purpose of this premarket notification is to provide notice of modification of a device previously found substantially equivalent to marketed devices. The Beeline device was initially submitted as the SP Disposable Infusion Pump and received 510(k) number K990461.

McKinley Medical, LLLP intends to market the Beeline system, which includes:

- The Beeline spring-powered infusion pumps.
- Continuous flowrate-controlling administration sets.
- Procedure kits.

The Beeline system described in this submission is based on the basic spring-powered disposable infusion pump design that was previously approved. The modifications do not represent any changes to intended use of the device, the indications for use statement, or the fundamental scientific technology of the device. There are no significant changes in materials used in the device. The scope of this modification encompasses the following:

- Addition of flow rates up to 10 mL/hr. The original device included flow rates from 0.4 to 4 mL/hr.
- Addition of a 275-mL reservoir size. The original device included only a 100-mL reservoir size.
- Addition of procedure kits containing supplies and/or accessories to facilitate setup and use of the Beeline system.

The modified Beeline system is substantially equivalent to the original spring pump system (K990461) and to the Accufuser system (K023098) devices marketed by McKinley Medical LLLP.

Per Title 21 CFR Part 807.92, a 510(k) Summary is provided rather than a 510(k) Statement per Part 807.93.

All questions and comments concerning this document should be made to Andy Lamborne, 303-420-9569 x.276 or by email at alamborne@mckinleymed.com.

Sincerely,

Andrew N. Lamborne
Director of Engineering
McKinley Medical, LLLP
4080 Youngfield Street
Wheat Ridge, CO 80033
Phone: 303-420-9569 x.276
Fax: 303-420-8585

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)

Write the Payment Identification Number on your check.

See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.fda.gov/oc/mdufma.The following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. *(Note: In no case should payment be submitted with the premarket application.)* Also remember that the Payment Identification Number must be written on the check.
   If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314418-4821 if you have any questions concerning courier delivery.)
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

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

MCKINLEY MEDICAL
4080 YOUNGFIELD STREET
WHEAT RIDGE, CO 80033
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4)

2. CONTACT NAME
ANDY LAMBORNE

2.1 E-MAIL ADDRESS
alamborne@mckinleymed.com

2.2 TELEPHONE NUMBER (Include area code)
303-420-9569

2.3 FACSIMILE (FAX) NUMBER (Include area code)
303-420-8585

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/oc/mdufma)

Select an application type:

- [x] Premarket notification (510(k)); except for third party reviews
- [ ] Biologic License Application (BLA)
- [ ] Premarket Approval Application (PMA)
- [ ] Modular PMA
- [ ] Product Development Protocol (PDP)
- [ ] Premarket Report (PMR)

3.1 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.)

- [ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- [x] NO, I am not a small business

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

5. 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, parents, and partner firms
- [ ] This biologic 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

6. 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, theapplication is subject to the fee that applies for an original premarket approval application (PMA).)

- [ ] YES
- [x] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4)

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CDRH SUBMISSION COVER SHEET

Date of Submission: **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ☐ Traditional X Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B **Applicant or Sponsor**

Company/Institution Name: McKinley Medical, LLLP		Establishment registration number: 1723533	
Division Name (if applicable):		Phone number (include area code): 303-420-9569	
Street Address: 4080 Youngfield Street		Fax number (include area code): 303-420-8585	
City: Wheat Ridge	State/Province: CO	Zip code: 80033	Country: USA
Contact Name: Andy Lamborne			
Contact Title: Director of Engineering		Contact e-mail address: alamborne@mckinleymed.com	

Section C **Submission Correspondent (if different from above)**

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country
Contact Name:			

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5

Section D1 — Reason for Submission – PMA,PDP, or HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 — Reason for Submission - IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

- ☐ New Device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

☐ Change in technology
X Change in design

☐ Change in materials
☐ Change in manufacturing process

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Section E **Additional Information on 510(k) Submissions**

luct codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: X 510(k) summary attached ☐ 510(k) statement
80FRN	2 80MEB	3	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K990461	1 McKinley Spring Pump Disposable Infusion Pump	1 McKinley
2 K023098	2 Accufuser, Accufuser Plus, Standard Procedure Kit	2 Woo Young Medical
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name: Spring Pump/Kit

Trade or proprietary or model name	Model Number
1 Beeline	1 Various, see attached
2	2
3	3

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

K990461	2	3	4	5	6

Data included in submission: ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: 80FRN	C.F.R. Section 880.5725	Device Class: ☐ Class I X Class II ☐ Class III ☐ Unclassified
Classification Panel: 80, General Hospital and Personal Use Device		

Indications (from labeling): The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

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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:

ion H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

X Original ☐ Add ☐ Delete	FDA establishment registration number: 1723533	X Manufacturer ☐Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name: McKinley Medical, LLLP		Establishment registration number: 1723533
Division name (if applicable):		Phone number (include area code): 303-420-9569
Street address: 4080 Youngfield Street		FAX number (include area code): 303-420-8585

City Wheat Ridge	State/Province CO	Zip code: 80033	Country USA

Contact name: Andy Lamborne

Contact title: Director of Engineering

☐ Original X Add ☐ Delete	FDA Establishment registration number: (b) (4)	☐ Manufacturer ☐ Contract Sterilizer X Contract Manufacturer ☐ Repackager/relabeler
Company/Institution Name: (b) (4)		Establishment registration number: (b) (4)
Division name (if applicable):		Phone number (include area code): (b) (4)
Street address: (b) (4)		FAX number (include area code): (b) (4)

City: (b) (4)	State/Province: (b)	Zip code: (b) (4)	Country (b)

Contact name: Elvis Adams

Contact title: R.A. Manager	Contact e-mail address:

☐ Original X Add ☐ Delete	FDA Establishment registration number: (b) (4)	X Manufacturer X Contract sterilizer Contract Manufacturer Repackager/relabeler
Company/Institution name: (b) (4)		Establishment registration number: (b) (4)
Division name (if applicable): (b) (4)		Phone number (include area code): (b) (4)
Street address: (b) (4)		FAX number (include area code): (b) (4)

City: Allentown	State/Province: (b)	Zip code: (b)	Country: USA

tact name: (b) (4)

Contact title: Regulatory Affairs Specialist	Contact e-mail address: amy.smith@bbraun.com

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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:

'ion H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☐ Original X Add ☐ Delete	FDA establishment registration number: (b) (4)	Manufacturer X Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name: (b) (4)		Establishment registration number: (b) (4)
Division name (if applicable): (b) (4)		Phone number (include area code): (b) (4)
Street address: (b) (4)		FAX number (include area code):

City (b) (4)	State/Province (b)	Zip code: (b) (4)	Country USA

Contact name: (b) (4)

Contact title: Operations

☐ Original X Add ☐ Delete	FDA Establishment registration number: (b) (4)	☐ Manufacturer X Contract Sterilizer Contract Manufacturer ☐ Repackager/relabeler
Company/Institution Name: Steris Isomedix Services		Establishment registration number: (b) (4)
' 'sion name (if applicable):		Phone number (include area code): (b) (4)
Street address: (b) (4)		FAX number (include area code): (b) (4)

City: (b) (4)	State/Province: (b)	Zip code: (b) (4)	Country: USA

Contact name: (b) (4)

Contact title: Q.A. Manager	Contact e-mail address:

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2. Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of McKinley Medical, LLLP, 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.

(b) (6) [redacted]

(Signature)

Randy Hoffman, President
(Typed Name)

August 15, 2003
(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].

3. Indications for Use Statement

Applicant: McKinley Medical, LLLP

510(k) Number (if known): K032642

Device Name: Beeline System

Indications for Use:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

4. Declaration of Conformity with Design Controls

4.1 McKinley maintains a design control program (per SOP 200098, Design Control) that conforms to the Design Controls portion of the Quality System Regulation, 21 CFR 820.30. The modifications to the Beeline system are developed in accordance with these procedures. The design control records are on file at McKinley and available for review. Key design control documents for the Beeline system include the following:

- 4.1.1 Beeline System Project Plans, 202857 (100 mL), 203000 (275 mL)
- 4.1.2 Beeline System Functional Requirements Documents, 202858 (100 mL), 203001 (275 mL)
- 4.1.3 Beeline System Design Validation Plan, 202906
- 4.1.4 Beeline System Risk Analysis, 202859
- 4.1.5 Traceability Matrix (design verification activities), 202815
  - a. Design verification and in-house design validation testing includes tests and/or analysis to establish flow rate accuracy, leak integrity, drop/handling integrity, adequate protection from air embolus, biocompatibility, and sterile barrier integrity (the essential outputs).
- 4.1.6 Design Verification Report, 202908
- 4.1.7 Biocompatibility Report, 202909
- 4.1.8 Packaging Validation Report, 202846
- 4.1.9 Shelf Life Plan/Report, 202910/203021
- 4.1.10 Quality Plan & DMR, 202812
- 4.1.11 Pre- & Post-sterile Process Validation Reports (functional testing), 202885 & 202887
- 4.1.12 Field Evaluation Report, 202932
- 4.1.13 Design History File (including design reviews)

4.2 Risk analysis, evaluation, and control are incorporated into the design process, per ISO 14971, and documented in the Beeline System Risk Analysis (202859). Evaluation of risk associated with identified hazards includes clinical input/review.

- 4.2.1 All risk control measures are verified and/or validated, as appropriate. The risk analysis document and the traceability matrix identify the verification and/or validation activities associated with each risk control measure.
- 4.2.2 The design verification and validation activities have been performed and the results demonstrate that the predetermined acceptance criteria were met.

I certify that, in my capacity as Director of Engineering of McKinley Medical LLLP, I believe to the best of my knowledge that the above statements regarding

declaration of conformity with design controls are truthful and accurate and that no material fact has been omitted.

Andrew N. Lamborne

McKinley Medical LLLP
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Wheat Ridge, CO 80033 USA
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McKinley

510(k) Summary—Special 510(k) for Modifications to the McKinley Beeline System

Date Prepared:	15 August 2003
Submitter:	McKinley Medical, LLLP 4080 Youngfield Street Wheat Ridge, CO 80033 Phone: 303-420-9569 Fax: 303-420-8585 Contact for questions: Andy Lamborne
Trade Name:	Beeline Motiv
Common Name:	Spring Pump & Kit
Classification Name:	Infusion Pump
Classification Panel:	General Hospital and Personal Use Device
Regulation Number:	Class II, 880.5725
Panel:	80
Procode:	FRN – Infusion Pump
Original cleared 510(k):	K990461
Establishment Registration:	1723533
Owner/Operator Number:	9027257

5. Summary of Safety and Effectiveness of the Beeline System

5.1 This submission is intended to notify the Food and Drug Administration that McKinley Medical, LLLP intends to market a modification to an existing device (K990461) called the Beeline system. Modifications to the existing device are extension of the flow rate range, addition of a larger reservoir volume, and addition of procedure kits.

5.2 The original cleared device demonstrating substantial equivalence is the McKinley Spring Pump Disposable Infusion Pump (K990461).

5.3 A supporting predicate device also demonstrating substantial equivalence is McKinley's Accufuser, Accufuser Plus & standard procedure kit (K023098).

5.4 The cleared indications for use for the Beeline system are as follows:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

5.5 Summary Description of the Beeline system

5.5.1 The Beeline device consists of a spring-pressurized, syringe-like medication reservoir with a flowrate-controlling administration set. Medication is held between the barrel and piston of the infuser. A spring applies force against the piston, pressurizing the medication. The administration set includes a flow restrictor component with controlled internal diameter and length. The flow rate at which medication is dispensed from the system is a function of the pressure applied to the medication and the dimensions of the flow restrictor component.

5.5.2 The size of the reservoir and the amount of flow restriction are varied during manufacturing to yield a variety of product codes with differing infusion volumes and flowrates.

5.5.3 A procedure kit provides various components that facilitate setup and use of the Beeline system. Examples of kit components include items such as a prep tray, sterile drape, transfer syringe, medication/chart labels, catheter & introducer, dressing, tape, gauze, prep pads/wipes, carrying case, etc. Multiple kit product codes are made, with the contents varied as applicable for the particular procedure.

5.5.4 The Beeline system is intended for single patient use.

5.5.5 Device Specifications

a. The Beeline system has fill volumes and flow rates substantially equivalent to the named predicate devices.
   - The nominal fill volume of the system is 100 mL (small infuser) or 275 mL (large infuser).
   - The nominal flow rate ranges from 0.4 to 10 mL/hr.
   - Flow rate accuracy is ±15% of nominal flow rate, for all product codes.
   - Residual volume is 5 mL or less.

b. Operating pressure averages approximately 6 psi.

c. As with the identified predicate devices, fluid viscosity, temperature, and head height affect flow rate.

- The device is calibrated to deliver at the nominal flow rate using D5W (5% dextrose in water) as the infusate. Changing from D5W to sterile water increases flow rate by approximately 10%.
- The device is calibrated to deliver at the nominal flow rate at skin temperature (86 °F). Flow rate changes by approximately 1% per °F.
- The device is calibrated to deliver at the nominal flow rate with the medication reservoir 18" below the infusion site. Raising the infuser will increase the flow rate by less than 1% per inch.

d. The fluid path materials are chosen from those commonly used in infusion devices.

- Examples of the types of material used include polypropylene; polyethylene; PVC; acrylic; polycarbonate; ABS; silicone, butyl, nitrile, or other latex-free rubber; polyimide; nylon; PTFE; cellulose acetate; glass; stainless steel. The actual materials used vary slightly, depending on the product code (e.g., different procedure kit components may use different materials).
- The Beeline system and the identified predicate devices control the flow rate with a length of micro-bore tubing made from glass, PVC, polyethylene or similar appropriate material.
- All fluid path materials of the Beeline system are in conformance with ISO 10993-1 biocompatibility standards.

e. There are currently no approved performance standards established for spring pumps under Section 514 of the Food, Drug and Cosmetic Act.

f. Packaging is suitable for both EtO and gamma radiation sterilization.

- For product codes sterilized with EtO, the EtO cycle is validated per ISO 11135 and residuals are validated per ISO 10993-7.
- For product codes sterilized with gamma radiation, the sterilization dose is validated per ISO 11137.

5.5.6 Device Safety Functions

a. The Beeline system provides a fixed flow determined by the applied force from the compressed spring and the flow restriction induced by the dimensions of the flow restrictor. The Beeline system is not subject to infusion runaway conditions as may occur with some electronic pumps.

b. The administration set includes a clamp, allowing the user to stop flow if necessary.
c. The administration set has a 1.2-micron or smaller air-eliminating filter.
d. The fluid path is clear or translucent, allowing visual inspection of the contents.
e. The medication reservoir has syringe-like graduation marks to provide an approximate indication of remaining volume, allowing the user to monitor the infusion progress.

5.6 Conclusion: The modified Beeline system does not raise any new safety and efficacy concerns when compared to the original device that is already legally marketed. The Beeline system is substantially equivalent to the named predicate devices.

6. Description of the Beeline System

6.1 General Description & Performance Specifications

6.1.1 The Beeline spring pump system is disposable (for single use).

6.1.2 The major Beeline system component groups with fluid path contact are:

a. The spring pump, approximately 2 ½" diameter and 5-7" tall, depending on reservoir size

b. The administration set.

c. The transfer/filling syringe (for procedure kits containing a syringe)

d. The catheter (for procedure kits containing a catheter)

e. Extension set, Y-adapter, Tuohy-Borst adapter, and similar fluid line components (for procedure kits containing these items)

6.1.3 The major Beeline system component groups with no fluid path contact are:

a. The carrying pouch

b. The procedure kit and contents (except as noted above)

c. The packaging and labeling

6.1.4 The Beeline system does not require electrical power (the spring is the sole energy source) and does not include software, displays, alarms, etc. Proper delivery is visually confirmed by observing fluid dripping from the tubing when priming (during setup), and checking the progress of the infusion against the graduation marks on the barrel.

6.1.5 Flow rate accuracy is ±15% of nominal flow rate, for all product codes.

6.1.6 Nominal flow rate ranges from 0.4 to 10 mL/hr. Typical applications for continuous infusion at these flow rates include but are not limited to chemotherapy and pain management. For two-site sets (bifurcated distal end with a flow restrictor in each leg, typically used for pain management), the combined flow through both legs falls within this range.

6.1.7 Operating pressure averages approximately 6 psi.

6.1.8 The nominal fill volume of the system is 100 mL (small infuser) or 275 mL (large infuser).

6.1.9 Residual volume is 5 mL or less.

6.1.10 The device is calibrated to deliver at the nominal flow rate using D5W (5% dextrose in water) as the infusate. Changing from D5W to sterile water causes an increase in flow rate of approximately 10%.

6.1.11 The device is calibrated to deliver at the nominal flow rate at skin temperature (86 °F). Flow rate changes by approximately 1% per °F.

6.1.12 The device is calibrated to deliver at the nominal flow rate with the medication reservoir 18" below the infusion site. Raising the infuser will increase the flow rate by less than 1% per inch.

6.1.13 Flow rate is not affected by altitude/ambient air pressure.

6.1.14 Refer to Appendix 2 for graphs showing representative flow profiles of the Beeline device.

6.2 Detailed Description of the Beeline system

6.2.1 Refer to Appendix 3 for pictures of the Beeline system, including the infusers, representative sets, and representative procedure kit.

6.2.2 The medication reservoir is comprised of a barrel and piston, with an elastomeric sliding seal between the two.

a. The barrel and piston are molded from polypropylene. At least a portion of the barrel is clear, allowing the user to visually inspect the medication for air bubbles, particulate matter, solution color/clarity, etc.

b. The seal between the piston and barrel is formed by an elastomeric (e.g., butyl or nitrile) quad ring.

c. All materials are latex-free.

d. The fluid path materials are tested for compliance with ISO 10993-1 biocompatibility standards.

e. The barrel includes graduations, which allow the user to estimate the amount of medication in the reservoir. This is helpful for the user to gauge the progress of the infusion.

6.2.3 A compression spring applies force to the piston, pressurizing the fluid within the medication reservoir. This spring force provides the energy to infuse the fluid.

a. With a fixed flow restriction, the infusion flow rate is proportional to the output pressure of the pump. Because the spring force lowers as the spring expands (i.e., as the infusion progresses), the output pressure is highest when the medication reservoir is full and lowest when the reservoir is empty.

b. The spring parameters are specified to control the change in output pressure throughout the duration of the infusion. The resulting flow profile is an essentially even taper from a high point at the start of infusion to a low point and the end of infusion. The relative flatness of the flow profile (i.e., the change in flow rate throughout the infusion duration) is demonstrated to provide adequate delivery performance through user evaluations during design validation.

6.2.4 A rear cap mates to the barrel to form the outer housing of the pump. The cap engages the bottom of the compression spring. The walls of the cap, the walls of the barrel, and the engagement between the cap and the barrel carry the applied force of the compressed spring. The integrity of this outer housing is demonstrated to provide adequate strength to safely contain the spring energy through testing during design verification and validation.

6.2.5 The medication reservoir is filled with a syringe or pharmacy pump. The infuser has one of two fill port designs, depending on the product code.

a. Product codes with separate a pump and administration set utilize a female luer-lock fill port on the distal end of the barrel. This fill port incorporates a one-way valve to allow fluid to flow from the syringe or fill pump into the medication reservoir, but to prevent it from flowing back out (because once filled into the medication reservoir, the fluid is pressurized by the spring). Administration sets for these product codes incorporate a proprietary proximal connector with an extended tip to open the one-way valve, allowing flow only upon attachment of the flowrate-controlling set.

b. Product codes with an integral pump and administration set (where the tubing is bonded directly to the distal end of the barrel) incorporate a Y- or T-adapter style female luer-lock fill port near the proximal end of the set. This fill port incorporates a one-way valve to allow fluid to flow from the syringe or fill pump into the medication reservoir, but to prevent it from flowing back out the filling leg of the adapter.

6.2.6 The small (100 mL) infuser weighs approximately 180 g empty. The large (275 mL) infuser weighs approximately 240 g empty.

6.2.7 The administration set is comprised of tubing, connectors, flow restrictor(s), filter, clamp, and caps.

a. PVC, polyethylene, or similar plastic materials are used for the tubing. Acrylic, polycarbonate, ABS, silicone, PTFE, cellulose acetate, polyimide, glass, or similar appropriate materials are used for the components. The actual materials used vary slightly, depending on the product code.

b. All materials are latex-free.

c. Non-DEHP PVC tubing is used where possible. Where DEHP-plasticized tubing is required, the labeling indicates that it contains DEHP.

d. The fluid path materials are tested for compliance with ISO 10993-1 biocompatibility standards.

e. With a fixed pump output pressure, the infusion flow rate is proportional to the restriction in the flow restrictor. The flow restriction is proportional to the length of the flow restrictor bore and inversely proportional to the fourth power of the diameter of the bore (i.e., doubling the length halves the flow rate, increasing bore diameter by 10% increases flow by roughly 46%).

6.2.8 The tubing and components are typically attached via solvent bonds or adhesive bonds. Where bonding is not practical, glass flow restrictors are sealed into the fluid path with a silicone bushing compressed between the outer wall of the glass and the inner wall of a rigid connector component.

6.2.9 The distal end of the set terminates in a male luer-lock connector to facilitate attachment to the catheter/infusion site.

6.2.10 The set includes a clamp, allowing the user to stop flow if necessary.

6.2.11 The length of the set is specified to ensure adequate length for the application. For most product codes, this is between 60" and 90". Some product codes are made with shorter sets (e.g., local anesthesia models where a several-foot-long catheter will be connected to the distal end of the set).

6.2.12 When the Beeline system is packaged with accessories that comprise a kit, the kit includes components that are legally marketed—either pre-amendment devices, devices exempt from premarket notification, or devices found to be substantially equivalent through the premarket notification process for the intended use of the kit. Components may be utilized in the kit in finished form or they may be procured in bulk form and sterilized as part of the total kit.

6.2.13 The procedure kits may be sold separately or may be packaged together with the Beeline pump/set.

6.2.14 The contents of the procedure kits vary depending on the specific application (e.g., local anesthesia kit, regional anesthesia kit, IV infusion kit, etc.). Examples of procedure kit contents may include but are not limited to the following:

a. Drapes: such as a Kimberly Clark Kimguard Wrap (P/N 68424, 510(k) # K881471), an American Threshold Dexter CSR Wrap (P/N 21464, 11395, 510(k) not applicable), or other similar drape that can be used for laying out the kit contents within the sterile field

b. Prep trays: such as a Hospital Disposables Half Deep Tray (P/N 396-0952, 510(k) exempt per regulation 868.6100), an Alga Prep Tray (P/N 5761, 510(k) exempt per regulation 868.5150), or other similar tray that can be used to hold the kit

components and/or mix/transfer medication from vial to syringe

c. Syringes: such as a B-D 60cc syringe (P/N 301035, 510(k) # K980987), a Kendall Sherwood 5 cc syringe (P/N 8881-105-715, preamendment), or other similar syringe that can be used to transfer medication into the Beeline pump and/or flush the catheter/infusion line

d. Catheters: such as a Micor 20G Catheter (P/N KE17, 510(k) # K001717, thread assist 510(k) # K001940), a Micor 19G or 20G WundCath MultiPort Catheter (P/Ns KE32, KE33, 510(k) # K003966), a Micor fixed-hub catheter (510(k) # K001717), a Sims Portex 20G or 21G Epidural Catheter (P/Ns 4910-16, 4910-18, 510(k) # K992471), a Sims Portex 21G Anesthesia Catheter (510(k) # K994275), a B.Braun 20G Catheter (P/N 8455040, 510(k) # K840287), a B.Braun nerve block catheter (510(k) # K030830), a VistaMed UV-bonded catheter (P/N 417401, 510(k) # K014019), or other similar catheter (including larger or smaller gauge sizes to meet the needs of the specific application) that can be used to deliver the medication to the infusion site

e. Introducers: such as an Avid NIT 18G x 3.8" Needle (P/N 1164, 510(k) exempt per regulation 878.4800), a Manan Spinal Needle (P/N 3000-18-9), an AMI Epidural Needle (P/Ns 2317y71711-0, 2318y71784-2, 510(k) # K946047), a TFX OTN break-away sheath introducer (P/N T3372-02, 510(k) # K920908), a B.Braun Introcan Safety (P/N 15321387E, 510(k) #s K021094, K020785), a B-D Angiocath (P/N 381157, 510(k) #s K952861, K984059, K013073, K013800), or other similar introducer (including larger or smaller gauge size to fit the catheter, and longer or shorter length to meet the needs of the specific physician preference) that can be used to insert the catheter

f. Dressings, tape, etc.: such as a 3M Tegaderm dressing (P/N 1626WMS, 510(k) #s K811291, K812678, K901845), a J&J Healthcare Systems Bioclusive Dressing (P/N 2463, 510(k) # K923235), a 3M Steri-Strip card (P/N R1547NS, 510(k) # K813265), 3M EtO Tape (P/N 1224-1, 510(k) exempt per regulation 880.5240), or other similar materials for covering the infusion site and fixing the catheter/infusion line in place

g. Electrodes, sensor probes & needles, etc.: such as a Life-Tech Probloc Insulated Needle (510(k) # K926349), hookup wire, etc.

h. Extension sets, Y-adapters, stopcocks & valves, tamper-resistant fill port covers, luer caps, etc.: such as a TE ME NA Sarl, Tuohy Borst Adapter (P/N 91051, 510(k) # K990100), a

Medical Product Specialists Bifurcated Tubing Set (P/N MPS-BC006-04, 510(k) # K003476), a B.Braun stopcock (510(k) # K760383), a Merit Medical hemostasis valve (510(k) # K990975), or an International Medical Industries tamper-evident cap (510(k) # K861276)

i. Wipes, swabs (e.g., alcohol, iodine, etc.), gauze: such as B-D Persist Povidone Iodine Prep (P/N 386401), Norpak Alcohol Pads and Povidone Iodine Prep (K896835), or other similar materials for prepping the infusion site and/or wiping the medication vials

j. Medication labels, chart labels, etc.

k. Carrying pouches, hanging clips, etc.

6.3 Packaging Configuration

6.3.1 The Beeline system is packaged in sterile barrier packaging. The Beeline use is a single use device not intended for re-sterilization or reuse by the user.

6.3.2 The Beeline system uses a range of packaging configurations, depending on product code.

a. Pump/set packaged together in a single sterile barrier pouch (e.g., Tyvek/mylar pouch or header bag with heat-sealed edges) or tray (e.g., PS or PETG tray w/ heat-sealed Tyvek lid).

b. Pump or set packaged individually in single sterile barrier pouch or tray.

c. Pump/set and/or kit components packaged in blister tray, typically with inner pouch/tray and outer sterile barrier. This configuration allows the contents to be easily moved to a prep area in the sterile field, without the nurse/assistant making contact with the outer (non-sterile) packaging surfaces.

d. Sterile, individually-packaged kit components kitted together in a non-sterile external kit pack (e.g., zip-lock bag).

6.3.3 Product cases typically hold quantities of 5 or 10 product units, though other case quantities may be used to meet the needs of specific applications.

6.3.4 All packaging configurations are validated per ISTA 2A (for domestic and international shipping), including environmental conditions, drop shock, and shipping vibrations.

6.4 Design Controls

6.4.1 The Beeline system is developed in accordance with the Design Controls portion of the Quality System Regulation, 21 CFR 820.30.

6.4.2 Design verification and in-house design validation testing includes tests and/or analysis to establish flow rate accuracy, leak integrity, drop/handling integrity, adequate protection from air embolus, biocompatibility, and sterile barrier integrity (the essential outputs).

6.4.3 The shelf life for the Beeline system is determined through the design control process. An initial shelf life of two years has been established for Beeline, and the product labeling (case and pouch labels) indicate this expiration date. A real-time shelf life study to extend the expiration date is underway. The maximum shelf life that may be established under the ongoing study is 5 years (the proven shelf life of Tyvek sterile barrier packaging, per the Tyvek manufacturer).

6.4.4 Risk analysis, evaluation, and control are incorporated into the design process, per ISO 14971. Evaluation of risk associated with identified hazards includes clinical input/review.

6.5 Production & Process Controls

6.5.1 The Beeline system is produced in accordance with the Production & Process Controls portion of the Quality System Regulation, 21 CFR 820.70-75.

6.5.2 The manufacturing process is controlled through a quality plan and approved device master record. The DMR documents are controlled and include component/material specifications, assembly drawings and/or master samples, assembly procedures & equipment, test procedures & acceptance criteria, label and packaging specifications, sterilization procedures, and inspection plans & release criteria.

6.5.3 The assembly and packaging process is validated. This includes processes performed at contract manufacturers.

6.5.4 The sterilization process, performed at a contract sterilizer, is validated to demonstrate a 10^{-6} SAL.

a. Sterilization validation for EtO sterilized product codes is performed in accordance with ISO 11135 & EN 550. EtO residuals are validated to be less than the maximum allowable levels per ISO 10993-7.

b. Sterilization validation for gamma radiation sterilized product codes is performed in accordance with ISO 11137 & EN 552. The validated range for the radiation dose is 21.4 to 38 kGy.

c. The product is verified to be non-pyrogenic through Limulus Amebocyte Lysate (LAL) testing performed on each lot of product, using the kinetic turbimetric method (USP) with an endotoxin limit of 20.0 USP EU/device.

6.6 Safety Features of the Beeline System

6.6.1 The Beeline system provides a fixed flow determined by the applied force from the compressed spring and the flow restriction induced by the dimensions of the flow restrictor. The Beeline system is not subject to infusion runaway conditions as may occur with some electronic pumps.

6.6.2 The administration set has an on/off clamp. This allows the user to stop the infusion at any time, if necessary.

6.6.3 All fluid path materials of the Beeline system are in conformance with ISO 10993-1 biocompatibility standards.

6.6.4 The fluid path is clear or translucent, allowing visual inspection of the contents. This allows the user to inspect for trapped air or particulate matter in the system during setup.

6.6.5 The medication reservoir has syringe-like graduation marks to provide an approximate indication of remaining volume, allowing the user to monitor the infusion progress.

6.6.6 The administration set has a 1.2-micron or smaller air-eliminating filter.

6.6.7 There are currently no approved performance standards established for spring pumps under Section 514 of the Food, Drug and Cosmetic Act.

6.7 Product Codes

6.7.1 Refer to Figure 13 for a chart showing planned product codes. This chart describes the scope of product configurations, although actual marketed configurations will be based on market demand.

Figure 13: Planned Beeline product codes

(b) (4)

[redacted]

(b) (4)

[redacted]

7. Biological, Chemical and Drug Specifications and Data

7.1 Biological Specifications

7.1.1 The Beeline system is categorized as follows, per ISO 10993-1 biocompatibility guidelines:

a. Device Category: external communicating device

b. Body Contact: blood path, indirect

c. Contact Duration: prolonged

7.1.2 The Beeline fluid path materials are tested for compliance with ISO 10993-1 biocompatibility standards, as follows:

a. Cytotoxicity—passed

b. Sensitization—passed

c. Irritation/intracutaneous reactivity—passed

d. Acute systemic toxicity—passed

e. Hemocompatibility—passed

7.2 Chemical and Drug Specifications

7.2.1 Compatibility: There are no specific drugs referenced in the labeling for the Beeline system. The Directions for Use (see Labeling, section 9) caution the user to follow the drug manufacturer's information in preparing the drug and ensuring its compatibility with the Beeline fluid path materials.

7.2.2 Drug Stability: There are no drugs included in the Beeline system.

7.2.3 DEHP: Non-DEHP PVC tubing (i.e., TOTM-plasticized PVC tubing) is used where possible. Experience with other infusion devices has shown that slow-flowing product codes used with 5-flourouracil (chemotherapy agent) require DEHP plasticizer for the 2" section of PVC tubing between the filter and flow restrictor/distal luer assembly. In these cases, the labeling indicates that the set contains DEHP.

7.2.4 Latex: All materials in the Beeline system are latex-free.

8. Intended Use of the Beeline System

8.1 Indications for Use

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

8.2 Contraindications

The following contraindications are described in the Directions for Use (see Labeling, section 9):

8.2.1 Infusion of blood and blood products

8.2.2 Infusion of insulin

8.2.3 Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death

8.2.4 Infusion of any solution that is incompatible with the fluid path materials

8.2.5 Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual

8.3 Precautions

The following precautions are described in the Directions for Use (see Labeling, section 9):

8.3.1 Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.

8.3.2 The Beeline system is intended for single patient use only. Do not reuse. Do not resterilize.

8.3.3 It is the responsibility of the clinician using the Beeline system to ensure that the medications or fluids are used only according to the physician's infusion therapy prescription.

8.3.4 As with any infusion system, medications or fluids may interact with the components of the Beeline system. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

8.3.5 As with any infusion system, purge all air from the infusion line before connecting to the patient.

8.3.6 Do not fill the medication reservoir with more than the maximum reservoir volume. Filling beyond the maximum volume could damage the infuser and cause injury or fluid leakage.

8.3.7 Do not attempt to disassemble the Beeline infuser. Doing so could damage the infuser and cause injury or fluid leakage.

8.3.8 Do not drop the infuser, strike it against hard objects or otherwise subject it to extreme physical stress. Doing so could damage the infuser and cause injury or fluid leakage. If the infuser is subjected to any trauma, it must be checked for damage or leakage before use. If any problems are detected, discontinue use.

8.3.9 The device flow rate will vary according to the infusion set used. Use only the dedicated infusion sets authorized by McKinley for use with the Beeline infuser. [*Note this precaution only included where applicable, i.e. for product codes that incorporate a separate (rather than integral) infusion set*].

8.3.10 For models with an integrated set, the device flow rate is fixed and predetermined. Take care to select the appropriate nominal flow rate and reservoir size for the prescribed therapy. [*Note this precaution only included where applicable, i.e. for product codes that incorporate an integral (rather than separate) infusion set*].

8.3.11 Do not remove the Beeline infusion set after it has been connected to the infuser. Removal of a connected set may cause fluid leakage. [*Note this precaution only included where applicable, i.e. for product codes that incorporate a separate (rather than integral) infusion set*].

8.3.12 Do not use a microwave, oven, or water bath to warm the contents of the Beeline infuser.

8.3.13 The Beeline system should be stored in a clean, dry environment. It is the clinician's responsibility to instruct the patient on the proper storage of medications or fluids.

8.3.14 It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the Beeline system.

8.3.15 Do not use the Beeline system if the packaging has been previously opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.*

8.3.16 **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

8.3.17 **CAUTION**: Do not withdraw the catheter through the introducer. Doing so may damage the catheter or cause it to dislodge into the insertion site. [*Note this precaution only included where applicable, i.e. for procedure kits that incorporate a catheter and a sharp introducer that could cut the catheter if withdrawn*].

8.4 Specific Uses for the Beeline system

8.4.1 Typical applications for the Beeline system include but are not limited to pain management (including local anesthesia and regional anesthesia), chemotherapy, and antibiotic therapy.

8.4.2 The Beeline system will be used in hospitals, outpatient/surgery centers, clinics and physician's offices, and homecare settings.

8.4.3 Patients will typically be ambulatory while using the Beeline system.

9. Beeline System Labels and Labeling

9.1 McKinley Medical developed the proposed labels and labeling to meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

9.2 The following labels and labeling will be used:

9.2.1 Directions for Use, which includes:

a. An explanation of the intended use, including indications, contraindications, and precautions

b. The routes of administration as explained in the intended use

c. The device specifications, including reservoir volume, flow rate, accuracy, residual volume, and operating conditions (including the effects of varying conditions)

d. Comprehensive directions for preparation and use of the system, including the administration sets that determine the flow rate

e. Detailed fluid types that may be administered by the pump are not defined but are implied by the intended use statement, which is in DFU; the indications for use state "medications or fluids requiring continuous and/or intermittent delivery at controlled infusion rates"; the contraindications preclude infusion of insulin, blood or blood products, critical or life-supporting medications whose stoppage/interruption/over-delivery/under-delivery would likely cause serious injury or death, or any solutions not compatible with the fluid path materials

f. Instructions for cleaning and care of the device

g. The prescription statement required under Part 801.109 (b)(1)

9.2.2 Patient Quick Reference Card, which includes:

a. An overview of the device

b. Information for daily use (e.g., monitoring infusion, cleaning and care, etc.)

9.2.3 Product labels showing brand name, product code, etc.

9.2.4 Unit labels (on or visible through sterile barrier packaging) showing product code, volume & flow rate, lot number, expiration date, etc.

9.2.5 Case labels (on exterior packaging) showing product code, volume & flow rate, lot number, expiration date, etc.

9.2.6 Miscellaneous labels as appropriate for the specific application of each product code (e.g., chart & medication labels for procedure kits, etc.)

9.3 Refer to Appendix 1 for representative copies of labels and labeling. Product-code-specific and application-specific label information (e.g., product codes, drawings/pictures, flow rate values, etc.) will change as appropriate for each product code. The fixed content (e.g., intended use in DFUs) will remain the same for each product code.

10. Establishment Information

10.1 McKinley Medical, LLLP is the specification developer and the primary distributor of the Beeline System.

10.2 The Beeline system manufactured and sterilized by contract manufacturer(s) and contract sterilizer(s). Current contract manufacturer/sterilizer facilities are listed below. This information is provided for representative purposes only, as alternate contract manufacturer/sterilizer partners may be selected.

10.2.1 (b) (4) [redacted]

10.2.2

10.2.3

10.2.4

11. Substantial Equivalence Comparison to Legally Marketed Devices

11.1 The original cleared device demonstrating substantial equivalence is:

11.1.1 K990461; McKinley Medical; Spring Pump Disposable Infusion Pump

11.2 A supporting predicate device also demonstrating substantial equivalence is:

11.2.1 K023098; McKinley Medical; Accufuser, Accufuser Plus & standard procedure kit

11.3 Refer to Figure 14 for a table showing the detailed comparison to the predicate devices.

11.4 The existing device that is modified for this premarket notification is the Spring Pump Disposable Infusion Pump, 510(k) K990461. Additional product configurations added to the spring pump product line (now referred to under the brand name "Beeline") as part of this 510(k) premarket notification are as follows:

11.4.1 Extension of nominal flow rates to a range of 0.4 mL/hr through 10 mL/hr, for continuous-flow systems. This is determined to be substantially equivalent to the Spring Pump (K990461), which is cleared for flow rates from 0.4 to 4 mL/hr. This is also determined to be substantially equivalent to the Accufuser (K023098), which is cleared for flow rates up to 16 mL/hr.

11.4.2 Addition of a 275-mL reservoir size. This is determined to be substantially equivalent to the Spring Pump (K990461), which is cleared for a 100-mL reservoir. This is also determined to be substantially equivalent to the Accufuser (K023098), which is cleared for reservoir sizes from 60 to 550 mL.

11.4.3 Addition of procedure kits containing supplies and/or accessories to facilitate setup and use of the Beeline system.

a. Addition of the procedure kit does not change the intended use of the Beeline system. The clinician already will normally use the types of components contained in the procedure kit, but purchases them as separate items. The integrated procedure kit only provides more convenience to the user.

b. The Beeline procedure kit is determined to be substantially equivalent to the Accufuser (K023098), which includes a procedure kit providing supplies/accessories to facilitate setup and use of the infusion system.

c. The procedure kits may be sold separately or may be packaged together with the Beeline infuser.

d. Examples of procedure kit contents may include but are not limited to:

- Drapes
- Prep trays
- Syringes
- Catheters & introducers
- Dressings, tape, etc.
- Electrodes, sensor probes & needles
- Tuohy-Borst adapters, extension sets, Y-adapters, stopcocks & valves, tamper-resistant fill port covers, luer caps, etc.
- Wipes, swabs & gauze
- Medication labels, chart labels, etc.
- Carrying pouches, clips, etc.

Figure 14: Table showing comparison to legally marketed devices

System Element	Comparison Element	Subject (Modified) Device: Beeline system	Primary Substantially Equivalent (Original) Device McKinley SP Disposable Infusion Pump (K990461)	Supporting Substantially Equivalent Existing Device Accufuser, Accufuser Plus, Standard Procedure Kit (K023098)
System	Indications for Use	The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.	The McKinley SP is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. The McKinley SP is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.	The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery. The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous. The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.
System	Contraindications	• Infusion of blood and blood products • Infusion of insulin • Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death • Infusion of any solution that is incompatible with the fluid path materials • Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or	• Infusion of blood and blood products • Infusion of insulin • Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death • Infusion of any solution that is incompatible with the fluid path materials • Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or	• Infusion of blood and blood products • Infusion of lipids or fat emulsions • Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death • Infusion of any solution that is incompatible with the materials of the Accufuser system • Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or

System Element	Comparison Element	Subject (Modified) Device: Beeline system	Primary Substantially Equivalent (Original) Device McKinley SP Disposable Infusion Pump (K990461)	Supporting Substantially Equivalent Existing Device Accufuser, Accufuser Plus, Standard Procedure Kit (K023098)
		who are not under the care of a responsible individual	who are not under the care of a responsible individual	who are not under the care of a responsible individual
System	Safety Functions and Features	• Provides a fixed flow determined by the applied force from the compressed spring and the flow restriction induced by the dimensions of the flow restrictor, preventing infusion runaway conditions. • Administration set has an on/off clamp, allowing user to stop infusion at any time, if necessary. • All fluid path materials in conformance with ISO 10993-1 biocompatibility standards. • The fluid path is clear or translucent, allowing user to visualize the contents to inspect for trapped air or particulate matter in the system during setup. • Medication reservoir has syringe-like graduation marks to provide an approximate indication of remaining volume, allowing user to monitor the infusion progress.	• Provides a fixed flow determined by the applied force from the compressed spring and the flow restriction induced by the dimensions of the flow restrictor, preventing infusion runaway conditions. • Administration set has an on/off clamp, allowing user to stop infusion at any time, if necessary. • All fluid path materials in conformance with ISO 10993-1 biocompatibility standards. • The fluid path is clear or translucent, allowing user to visualize the contents to inspect for trapped air or particulate matter in the system during setup. • Medication reservoir has syringe-like graduation marks to provide an approximate indication of remaining volume, allowing user to monitor the infusion progress.	• Provides a fixed flow determined by the applied force from the elastomeric balloon reservoir and the flow restriction induced by the dimensions of the flow restrictor, preventing infusion runaway conditions. • Administration set has an on/off clamp, allowing user to stop infusion at any time, if necessary. • All fluid path materials in conformance with ISO 10993-1 biocompatibility standards. • The fluid path is clear or translucent, allowing user to visualize the contents to inspect for trapped air or particulate matter in the system during setup.
System	Reuse Capability	Disposable, single patient use	Disposable, single patient use	Disposable, single patient use
System	Accuracy	±15% of nominal	±15% of nominal	±10 to 15% of nominal
System	Flow Rates	0.4 to 10 mL/hr	0.4 to 4 mL/hr	0.5 to 16 mL/hr
Pump	Pump Filling	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.
Pump	Fill Volumes	100 & 275 mL	100 mL	60, 100, 275 & 550 mL
Pump	Pump Type	Spring pump	Spring Pump	Silicone Elastomeric pump
Pump	Power Requirements	None	None	None
Pump	Pump Mechanism	Compression of spring	Compression of spring	Strain energy of elastomeric membranes
Pump	Fluid Reservoir	Rigid barrel, movable rigid piston, elastomeric seal	Rigid barrel, movable rigid piston, elastomeric seal	Silicone elastomeric membrane

System Element	Comparison Element	Subject (Modified) Device: Beeline system	Primary Substantially Equivalent (Original) Device McKinley SP Disposable Infusion Pump (K990461)	Supporting Substantially Equivalent Existing Device Accufuser, Accufuser Plus, Standard Procedure Kit (K023098)
Pump	Fluid Path Materials	Polypropylene, butyl or nitrile, silicone	Polypropylene, butyl or nitrile, silicone	PET-G, ABS, polypropylene, silicone
Admin Set	Flow Control	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.
Admin Set	Flow Restrictor	Microbore glass tubing	Microbore glass tubing	Microbore glass tubing
Admin Set	Fluid Path Materials	PVC, PE, acrylic, polycarbonate, silicone, PTFE, cellulose acetate, glass	PVC, PE, acrylic, polycarbonate, silicone, PTFE, cellulose acetate, glass	PVC, acrylic, polycarbonate, ABS, silicone, PTFE, cellulose acetate, glass
Convenience Kit	Kit configuration	Inclusion of pump and administration set is optional with the kit accessories	None	Inclusion of pump and administration set is optional with the kit accessories
Convenience Kit	Kit Components	Pump/set, syringes, introducer needle, catheter & adapter, tape, dressing, prep tray, drape, instructions, chart & medication labels, etc.	None	Pump/set, syringes, introducer needle, catheter & adapter, tape, dressing, prep tray, drape, instructions, chart & medication labels

12. Appendix 1: Representative Copies of Beeline Labeling

12.1 The attached draft labels are illustrative of the proposed labeling for the Beeline system. The actual labels for each model will vary slightly (e.g., product code, flow rate values, etc.).

- 12.1.1 Draft Directions for Use for Beeline infuser & set (pp. 41-42)
- 12.1.2 Draft Directions for Use for local anesthesia kit containing Beeline infuser & set (pp.43-44)
- 12.1.3 Draft Patient Quick Reference Card for Beeline infuser & set (p. 45)
- 12.1.4 Example of draft product identification pouch insert label (p. 46)
- 12.1.5 Example of draft product identification case label (p. 47)
- 12.1.6 Example of draft product identification kit label from local anesthesia kit (p. 48)
- 12.1.7 Example of draft medication and chart labels from local anesthesia kit (p. 49)
- 12.1.8 Example of infuser brand label (p. 50)
- 12.1.9 Example of infuser caution label for models with separate infuser and tubing set (p. 51)

beeLINE® motIV®

Clinician Directions for Use

DESCRIPTION

The beeLINE motIV system is a completely disposable, non-electronic device that uses sustained pressure to deliver a continuous infusion of medications or fluids.

The beeLINE motIV consists of a clear Medication Reservoir that connects to a dedicated, flowrate-controlling Infusion Set. A one-way valve prevents medication flow until the Infusion Set is attached to the Medication Reservoir. Once the beeLINE motIV infuser is filled with medication, it is ready for use. Simply attach the Infusion Set, open the clamp, prime the tubing, and start delivery. A special carrying pouch protects the infuser during use.

INDICATIONS FOR USE

The beeLINE system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The beeLINE system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

CONTRAINDICATIONS

The beeLINE system is contraindicated for:

- Infusion of blood and blood products.
- Infusion of insulin.
- Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely case serious injury or death.
- Infusion of any solution that is incompatible with the fluid path materials.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- The beeLINE system is intended for single patient use only. Do not reuse. Do not resterilize.
- It is the responsibility of the ·ian using the beeLINE system to ensure that the medications c .ds are used only according to the physician's infusion therapy prescription.
- As with any infusion system, medications or fluids may interact with the components of the beeLINE system. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- Do not fill the medication reservoir with more than the maximum reservoir volume. Filling beyond the maximum volume could damage the infuser and cause injury or fluid leakage.
- Do not attempt to disassemble the beeLINE infuser. Doing so could damage the infuser and cause injury or fluid leakage.
- Do not drop the infuser, strike it against hard objects or otherwise subject it to extreme physical stress. Doing so could damage the infuser and cause injury or fluid leakage. If the infuser is subjected to any trauma, it must be checked for damage or leakage before use. If any problems are detected, discontinue use.
- The device flow rate will vary according to the infusion set used. Use only the dedicated infusion sets authorized by McKinley for use with the beeLINE infuser.
- For models with an integrated set, the device flow rate is fixed and predetermined. Take care to select the appropriate nominal flow rate and reservoir size for the prescribed therapy.
- Do not remove the beeLINE infusion set after it has been connected to the infuser. Removal of a connected set may cause fluid leakage.
- Do not use a microwave, oven, or water bath to warm the contents of the beeLINE infuser.
- The beeLINE system should be stored in a clean, dry environment. It is the clinician's responsibility to instruct the patient on the proper storage of medications or fluids.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the beeLINE system.
- Do not use the beeLINE system if the packaging has been previously opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.*
- **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

TECHNICAL SPECIFICATIONS

Fluid Path Materials:

Infuser: Polypropylene, silicone, butyl rubber, nitrile rubber. **Latex-free. DEHP-free.**

Set: PVC, polyethylene, acrylic, polycarbonate, silicone, glass, cellulose acetate, PTFE. **Latex-free. Set contains DEHP unless otherwise stated on product labels.**

Filter:

1.2-micron air-eliminating filter

Operating Pressure:

6 psi average

Fill Volume:

Small infuser (BL1N00) = 100 mL + 10 mL .ional overfill

Large infuser (BL2N00) = 275 mL + 20 mL optional overfill

System Residual Volume:

< 5 mL (includes medication reservoir and tubing set)

Flow Rates for Standard Sets:

0.6 to 8 mL/hr (use only flow sets approved by McKinley for use with the beeLINE motIV)

System Accuracy:

+/- 15% of nominal flow rate

Operating Temperature:

The system is calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the distal Luer is **86° F / 30° C** (skin temperature). Flow rate increases approximately 1% per 1° F / 0.56° C increase in temperature.

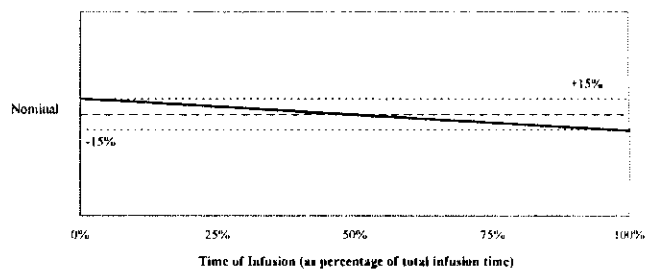
Fluid Viscosity:

The system is calibrated using **5% Dextrose in Water** (D5W) as the infusate. Flow rate increases as fluid viscosity decreases (e.g., sterile water will flow approximately 10% faster than D5W).

Head Height:

The system is calibrated with the infuser **18" / 45.7 cm** below the infusion site at the patient. Flow rate decreases approximately 6% for every 10" / 25 cm that the infuser is lowered.

Flow Profile:



DRAFT

FILLING TH IEDICATION RESERVOIR

CAUTION: As with any sterile product, use aseptic technique when preparing the beeLINE system for use.

Note: The beeLINE Medication Reservoir should never be filled beyond the maximum fill volume capacity referenced in the Technical Specifications section.

1. Inspect the beeLINE package to confirm that it has not been opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.* Using aseptic technique, remove the beeLINE Infuser from its package. Place it on a flat work surface with the Inlet/Outlet Reservoir Port pointing up. Save the non-vented Luer cap and beeLINE Infusion Set for later use.
2. Remove and discard the vented Luer cap from the Inlet/Outlet Reservoir Port.
3. Fill the beeLINE Medication Reservoir using a transfer syringe or other calibrated filling device. Connect the Luer Lock of the transfer device to the Inlet/Outlet Reservoir Port. Confirm that the connection is secure, but do not over-tighten. While filling, grasp the Infuser securely to keep it from moving.

   Note: The Volume Remaining marks printed on the beeLINE Medication Reservoir provide approximate volume indication only and are not intended to be used for precise measurements.
4. After filling, disconnect the transfer device. Then attach the non-vented Luer cap to the Inlet/Outlet Reservoir Port, or connect the Infusion Set as instructed in the section "Connecting The Infusion Set."

   Note: To remove air from the beeLINE Medication Reservoir, refer to the "Priming and Delivery Instructions" for the Infusion Set you have selected.
5. Label the filled Infuser with the appropriate patient identification and instruction information.

   Note: The beeLINE Infuser may be filled and stored at 40°F / 4°C for up to one week. Prior to use, the beeLINE Infuser and its contents must return to room temperature.

CONNECTING THE INFUSION SET

Note: Connecting the set is not required for the large infuser with integrated set.

1. Use only the appropriate Infusion Set dedicated for use with the beeLINE motIV Infuser. Confirm the flow rate, which is listed on the packaging and the Infusion Set tag.
2. Using aseptic technique, remove the Infusion Set from its package. Close the Infusion Set On/Off Clamp.
3. Place the beeLINE Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up. Remove and discard the Luer cap from the Infuser if present.
4. Remove and discard the cap from the Infusion Set Connector that has an extended male Luer and is located nearest to the On/Off Clamp.
5. Using a quick, continuous motion, insert the Infusion Set Connector with the extended male Luer into the Inlet/Outlet Reservoir Port while turni 'e Connector in a clockwise direction. Secure the con n, but do not overtighten it.

PRIMING AND DELIVERY INSTRUCTIONS

Note: The beeLINE System should be primed immediately before use. Do not store the **primed** beeLINE System for extended periods.

1. Examine the beeLINE Infuser for the presence of air bubbles. While rotating the Infuser, gently tap the bottom of the Infuser on your work surface until the small air bubbles have moved into a single bubble underneath the Inlet/Outlet Reservoir Port.
2. After the air bubbles are collected into a single bubble, place the beeLINE Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up.
3. Remove the Luer cap located at the patient end of the beeLINE Infusion Set. Save the Luer cap for recapping if short-term storage is required.
4. Open the On/Off Clamp to allow the fluid flow to expel any air present in the beeLINE Medication Reservoir and to prime the Infusion Set.

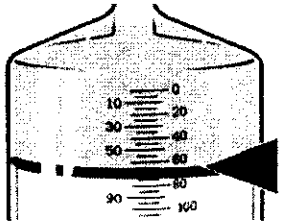
   IF THE INFUSION SET HAS A FILTER: To prime the filter, hold it so the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air.
5. When priming is complete, close the On/Off Clamp.

   Note: For short-term storage of primed Infusion Sets, reattach the Luer Cap to the Patient Access Connector.
6. Attach the primed Infusion Set to the patient's catheter.

   IF THE INFUSION SET HAS A FILTER: Tape the Patient Access Luer to the patient's skin. See the Technical Specifications section for appropriate operating temperature.
7. Open the On/Off Clamp to start infusion.

INFORMATION FOR DAILY USE

- Use the beeLINE Patient Quick Reference Card to assist with patient education and daily use instructions.
- Do not immerse the beeLINE Infuser in water or other fluids. When showering, the patient should keep the Infuser outside of the shower or place it in a waterproof bag.
- To protect the beeLINE Infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- During medication delivery, check for the following:
  - The beeLINE Infuser is emptying.
  - There is no leakage from the beeLINE System.
  - There is no air in the beeLINE System.
  - The beeLINE Infusion Set is not kinked.
  - All connections are secure.
  - The patient is not experiencing side effects, which may include but are not limited to:
    - Increased pain
    - Redness, swelling or discharge a catheter or incision site
    - Skin rash or hives
    - Metallic taste in patient's mouth
    - Light-headed or dizzy feeling
    - Excitation or restlessness
    - Excessive drowsiness
- To monitor the infusion progress, open the carrying pouch from time to time and read the position of the dark ring against the graduation scale on the beeLINE Medication Reservoir.



- The beeLINE Infuser is a disposable device and does not require periodic maintenance. If desired, the Infuser may be cleaned using a cloth dampened with water. To avoid damaging the Infuser, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the beeLINE Infuser. Do not disable the beeLINE Infuser.

DRAFT

Manufactured in Mexico for and distributed exclusively by:
McKinley, 4080 Youngfield Street, Wheat Ridge, CO 80033 USA
Telephone: 303-420-9569
Authorized Representative:
Priory Analysts, Ltd., P.O. Box 4030, Milton Keynes, MK13 OZG UK

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CE1275 ⚠ ② ☂ 0° C 40° C

beeLINE® motIV®

Local Anesthesia Kit
Clinician Directions for Use

DESCRIPTION

The beeLINE Local Anesthesia Kit is a completely disposable, non-electronic system that is designed specifically for pain management applications. The kit includes a beeLINE infuser, a catheter for infusion directly into the surgical site, and convenient accessories & prep materials to set up the device.

The beeLINE device uses sustained pressure to deliver a continuous infusion of medications. The infuser consists of a clear Medication Reservoir and a dedicated, flowrate-controlling Infusion Set.

INDICATIONS FOR USE

The beeLINE system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The beeLINE system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

CONTRAINDICATIONS

The beeLINE system is contraindicated for:

- Infusion of blood and blood products.
- Infusion of insulin.
- Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death.
- Infusion of any solution that is incompatible with the fluid path materials.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- The beeLINE system is intended for single patient use only. Do not reuse. Do not resterilize.
- It is the responsibility of the clinician using the beeLINE system to ensure that the medications or fluids are used only according to the physician's infusion therapy prescription.
- As with any infusion system [illegible]tications or fluids may interact with the components of the [illegible]NE system. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- Do not fill the medication reservoir with more than the maximum reservoir volume. Filling beyond the maximum volume could damage the infuser and cause injury or fluid leakage.
- Do not attempt to disassemble the beeLINE infuser. Doing so could damage the infuser and cause injury or fluid leakage.
- Do not drop the infuser, strike it against hard objects or otherwise subject it to extreme physical stress. Doing so could damage the infuser and cause injury or fluid leakage. If the infuser is subjected to any trauma, it must be checked for damage or leakage before use. If any problems are detected, discontinue use.
- The device flow rate will vary according to the infusion set used. Use only the dedicated infusion sets authorized by McKinley for use with the beeLINE infuser.
- For models with an integrated set, the device flow rate is fixed and predetermined. Take care to select the appropriate nominal flow rate and reservoir size for the prescribed therapy.
- Do not remove the beeLINE infusion set after it has been connected to the infuser. Removal of a connected set may cause fluid leakage.
- Do not use a microwave, oven, or water bath to warm the contents of the beeLINE infuser.
- The beeLINE system should be stored in a clean, dry environment. It is the clinician's responsibility to instruct the patient on the proper storage of medications or fluids.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the beeLINE system.
- Do not use the beeLINE system if the packaging has been previously opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.*
- **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

TECHNICAL SPECIFICATIONS

Fluid Path Materials:

Infuser: Polypropylene, silicone, butyl rubber, nitrile rubber. **Latex-free. DEHP-free.**

Set: PVC, polyethylene, acrylic, polycarbonate, silicone, glass, cellulose acetate, PTFE. **Latex-free. Set contains DEHP unless otherwise stated on product labels.**

Filter:

1.2-micron air-eliminating filter

Operating Pressure:

6 psi average

Fill Volume:

Small infuser (BL1N00) = 100 mL + 10 mL optional overfill

Large infuser (BL2N00) = 275 mL + 20 m[illegible] [illegible]tional overfill

System Residual Volume:

< 5 mL (includes medication reservoir and tubing set)

Flow Rates for Standard Sets:

0.6 to 8 mL/hr (use only flow sets approved by McKinley for use with the beeLINE motIV)

System Accuracy:

+/- 15% of nominal flow rate

Operating Temperature:

The system is calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the distal Luer is **86° F / 30° C** (skin temperature). Flow rate increases approximately 1% per 1° F / 0.56° C increase in temperature.

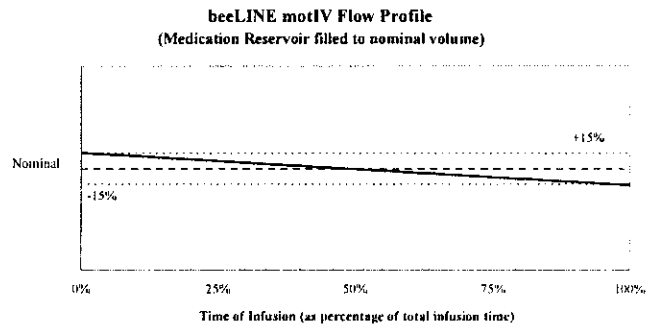
Fluid Viscosity:

The system is calibrated using **5% Dextrose in Water** (D5W) as the infusate. Flow rate increases as fluid viscosity decreases (e.g., sterile water will flow approximately 10% faster than D5W).

Head Height:

The system is calibrated with the infuser **18" / 45.7 cm** below the infusion site at the patient. Flow rate decreases approximately 6% for every 10" / 25 cm that the infuser is lowered.

Flow Profile:



USING THE LOCAL ANESTHESIA KIT

NOTES: All kit components are **latex-free** and **DEHP-free**.

Use the prep tray, designed to hold 300 mL, to transfer medication from the vials to the 60 cc transfer syringe.

1. Insert the Introducer approximately 3 –5 cm away from the intraoperative site, and advance the Introducer into the surgical wound site.
2. Remove the stylet from the Introducer.
3. Insert the marked tip of the Catheter through the Introducer and into the surgical wound site.

   CAUTION: Do not withdraw the Catheter through the Introducer. Doing so may damage the Catheter or cause it to dislodge into the insertion site.

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4. Remove the ›ducer while holding the Catheter securely in place.

   IMPORTANT:

   - To help avoid accidental needlesticks, follow your facility policies regarding safe use and disposal of medical sharps devices. Obtain prompt medical attention if injury occurs.
   - Unless directed otherwise by your facility policies, do not reshield a used Introducer. Discard unshielded Introducer in an approved sharps collector.
5. Insert the Catheter into the Tuohy-Borst Adapter and tighten (omit this step if using a fixed-hub catheter).
6. Using the 5 cc syringe, flush the catheter to verify patency.
7. Attach the Catheter/T-B Adapter to the beeLINE Infusion Set and tighten.
8. Secure the Catheter in place with Steri-strips or other securement device.
9. Apply dressing to the Catheter site if desired.

FILLING THE MEDICATION RESERVOIR

CAUTION: As with any sterile product, use aseptic technique when preparing the beeLINE system for use.

NOTE: The beeLINE Medication Reservoir should never be filled beyond the maximum fill volume capacity referenced in the Technical Specifications section.

1. Inspect the kit to confirm that it has not been opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.* Confirm the nominal flow rate and reservoir capacity prior to opening the package.
2. Remove the Luer cap from the filling port. For models with an integrated set, close the tubing clamp.
3. Fill the sterile transfer syringe with the medication to be dispensed.
4. Connect the filled syringe to the infuser filling port and transfer the medication into the Medication Reservoir. Repeat until the desired volume of medication has been transferred into the infuser.

   NOTE: The Volume Remaining marks printed on the beeLINE Medication Reservoir provide approximate volume indication only and are not intended to be used for precise measurements.
5. After the Medication Reservoir has been filled, disconnect the transfer syringe and replace the Luer cap on the filling port. If using a tamper-evident cover, snap the cover over the filling port.
6. For models with a separate set:
   a) Remove and discard the cap from the proximal connector (the connector with an extended male Luer and located nearest to the tubing clamp).
   b) Close the tubing clamp.
   c) Using a quick, continuous motion, insert the proximal connector with the extended male Luer into the Medical Reservoir Port fill port while turning the connector in a clockwise direction. Secure the connection, but do not overtighten it.
7. Fill in the appropriate pati ›formation on the mediation label and affix to the Medicatio. ›servoir.

PRIMING AND DELIVERY

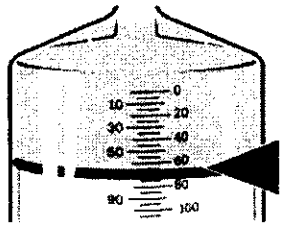
1. Leaving the clamp closed, examine the Medication Reservoir for air bubbles. While rotating the infuser, gently tap the bottom on your work surface until the small air bubbles have moved into a single bubble underneath the tubing outlet.
2. After the air bubbles are collected into a single bubble, place the infuser flat on a work surface with the tubing outlet pointing up.
3. Remove the cap from the distal end of the set and open the tubing clamp. Fluid will flow toward the patient end of the set, purging air from the system. As fluid reaches the filter, hold it so the outlet (toward patient) points up and tap the filter to eliminate residual air.
4. Confirm that fluid is dripping from the distal end of the tubing at the expected flow rate (1 mL/hr = approximately 1 drop every 3 minutes).
5. When priming is complete, close the clamp.

   NOTE: For short-term storage of the primed infuser, reattach the cap to the distal Luer connector.
6. Attach the primed system to the patient's catheter.

   IMPORTANT: Tape the distal luer connector to the patient's skin. See the Technical Specifications section for appropriate operating temperature.
7. Open the clamp to start the infusion.
8. Place the infuser in the protective carrying pouch during the infusion.

INFORMATION FOR DAILY USE

- Use the beeLINE Patient Quick Reference Card to assist with patient education and daily use instructions.
- Do not immerse the beeLINE Infuser in water or other fluids. When showering, the patient should keep the Infuser outside of the shower or place it in a waterproof bag.
- To protect the beeLINE Infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- During medication delivery, check for the following:
  - The beeLINE Infuser is emptying.
  - There is no leakage from the beeLINE System.
  - There is no air in the beeLINE System.
  - The beeLINE Infusion Set is not kinked.
  - All connections are secure.
  - The patient is not experiencing side effects, which may include but are not limited to:
    - Increased pain
    - Redness, swelling or discharge at the catheter or incision site
    - Skin rash or hives
    - Metallic taste in patient's mouth
    - Light-headed or dizzy feeling
    - Excitation or restlessness
    - Excessive drowsiness
- To monitor the infusion progress, open the carrying pouch from time to time and read the position of the dark ring against the graduation scale on the beeLINE Medication Reservoir.



- The beeLINE Infuser is a disposable device and does not require periodic maintenance. If desired, the Infuser may be cleaned using a cloth dampened with water. To avoid damaging the Infuser, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the beeLINE Infuser. Do not disable the beeLINE Infuser.

DRAFT

Manufactured for and distributed exclusively by:

McKinley, 4080 Youngfield Street, Wheat Ridge, CO 80033 USA

Telephone: 303-420-9569

Authorized Representative:

Priory Analysts, Ltd., P.O. Box 4030, Milton Keynes, MK13 OZG UK

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DRAFT

beeLINE® motIV®

Patient Quick Reference Card

Keep this card in a handy location. For complete guidance, refer to the instructions given to you by your health care provider.

PHONE NUMBERS FOR HELP

Daytime:_____

After hours:_____

Note: If you have any questions about the beeLINE system or your infusion therapy, contact you health care provider.

STARTING & STOPPING DELIVERY

- To start delivery, open the on/off clamp on the tubing attached to the beeLINE motIV infuser.
- To stop delivery, close the on/off clamp on the tubing attached to the beeLINE motIV infuser.

WHEN TO START/STOP DELIVERY:

_____

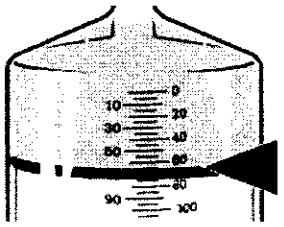
_____

_____

INFORMATION FOR DAILY USE

- Do not immerse the beeLINE infuser in water or other fluids. When showering, keep the infuser outside of the shower or place it in a waterproof bag.
- To protect the beeLINE infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- During medication delivery, check for the following:
  - The beeLINE infuser is emptying.
  - There is no leakage from the infusion system.
  - There is no air in the infusion system.
  - The tubing set is not kinked.
  - All connections are secure.
  - You are not experiencing side effects, which may include but are not limited to:
    - Increased pain
    - Redness, swelling or discharge at the catheter or incision site
    - Skin rash or hives
    - Metallic taste in patient's mouth
    - Light-headed or dizzy feeling
    - Excitation or restlessness
    - Excessive drowsiness

  IMPORTANT: If you notice any problems, contact your health care provider immediately.
- To monitor the infusion progress, open the carrying pouch from time to time and read the position of the dark ring against the graduation scale on the beeLINE Medication Reservoir.



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CLEANING & CARE

- If desired, the beeLINE infuser may be cleaned using a cloth dampened with water. To avoid damaging the infuser, do not use any cleaning agents.
- Take care to prevent entry of any foreign substances inside the beeLINE infuser.
- Do not disable the beeLINE infuser.

STORAGE

- The beeLINE infuser should be stored in a clean, dry environment. Avoid prolonged exposure to extreme temperatures above 104° F (40° C) or below 32° F (0° C).
- For proper storage of medications, refer to the instructions given to you by your health care provider.

ADDITIONAL INSTRUCTIONS

_____

_____

_____

(PRINT AS 2-SIDED CARD)

INFO ON:
MFG. SYMBOLS. P/N TRADEMARKS. ETC (PRINTED AT BOTTOM)

beeLINE® motIV®

REF. BL1N00

Part No. 202928

Disposable Infuser
110 ml maximum

Perfuseur jetable
110 ml max.

Einweg-Infusionspumpe
max. 110 ml

Infusore monouso
110 ml max.

Units
Unités
Einheiten
Unità

1

STERILE R

CE 0125

LATEX

LOT

40° C

0° C

Sterile and Non-pyrogenic. Do not use if package has been previously opened or damaged. For single use only. Do not resterilize.

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Stérile et apyrogène. Ne pas utiliser si le conditionnement a été ouvert ou endommagé. Produit à usage unique qui ne doit pas être restérilisé.

Steril und pyrogenfrei. Im Falle einer geöffneten oder beschädigten Verpackung darf das Produkt nicht verwendet werden. Nur zum einmaligen Gebrauch. Nicht neu sterilisieren.

Sterile ed apiretogeno. Non usare se la confezione è stata aperta in precedenza o danneggiata. Monouso. Non risterilizzare.

Authorized Representative:
Priory Analysts, Ltd., P.O. Box 4030, Milton Keynes, MK13 OZG UK

Assembled in Mexico for:
McKinley, Wheat Ridge, CO 80033 USA 303-420-9569

~~Quality System Certified ISO 9001 EN 46001~~

PN [redacted] Rev AA [redacted]

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beeLINE® *motIV®*

Non-pyrogenic. Do not use if package has been previously opened or damaged. Do not resterilize.

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Apyrogène. Ne pas utiliser si le conditionnement a été ouvert ou endommagé. Ne pas restériliser.

Pyrogenfrei. Im Falle einer geöffneten oder beschädigten Verpackung darf das Produkt nicht verwendet werden. Nicht neu sterilisieren.

Apiretogeno. Non usare se la confezione è stata aperta in precedenza o danneggiata. Non risterilizzare.

Authorized Representative:
Priory Analysts, Ltd., P.O. Box 4030
Milton Keynes, MK13 OZG UK

Manufactured in Mexico for:
McKinley, Wheat Ridge, CO 80033 USA
303-420-9569

REF. BL1D0/6 SET
203048

0.6 ml/hr Infusion Set

Tubulure de perfusion de 0.6 ml/h

0.6 ml/Std.-Infusions-Set

Gruppo di infusione da 0.6 ml/h

Units
Unités
Einheiten
Unità
10

STERILE EO CE1275

0°C 40°C LATEX

LOT **2MMYXXX**

YYYY-MM

203058 Rev AA 8/03

DRAFT DRAFT

beeLINE® Local Anesthesia Kit

275 mL Volume
5 mL/hr Continuous

McKinley
4080 Youngfield Street
Wheat Ridge, CO 80033 USA
303.420.9569

REF: BL2D005SK1

BARCODE

1 INSTRUCTIONS FOR USE	2 STERI-STRIP® CARDS
1 BEELINE PUMP/SET	1 TRANSPARENT DRESSING
1 CARRY CASE	4 CHART LABELS
1 SYRINGE, 60 cc L/L	1 MEDICATION LABEL
1 SYRINGE, 5 cc L/L	1 TRAY
1 CATHETER w/ ADAPTER	1 STERILE DRAPE
1 INTRODUCER	

LATEX

STERILE EO

LOT

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.
Contents sterile only if outer packaging is unopened and undamaged.
Avoid freezing and/or excessive temperatures.

Assembled in the USA for, and distributed exclusively by:
McKinley
Wheat Ridge, CO 80033 USA
Components made in USA, Mexico, Malaysia, Korea, and Germany.
beeLINE is a registered trade mark of McKinley. Steri-Strip is a registered trademark of 3M.
U.S. Patent D453,830.
PNxxxxx P-xxxx-0 REV. 8/03

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beeLINE® Pain Management

Patient: _____

Physician: _____

Medication: _____

Fill Volume: _____

Date/Time: _____

MEDICATION LABEL - PLACE ON INFUSER

DRAFT

beeLINE® Pain Management

REF. BL1D004SK1

Flow Rate: 4 mL/hr

LOT 6677889900 01-2006

Medication: _____

Fill Volume: _____

Start Date/Time: _____

CHART LABEL - PLACE ON PATIENT RECORD

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beeLINE® motIV®

REF. BL2N00 P/N 203037

DRAFT DRAFT

70 50

CAUTION

Once attached,
do not remove tubing
set from infuser.

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13. Appendix 2: Flow Profile Charts

13.1 The following flow profile charts demonstrate the performance of the Beeline system:

13.1.1 Figure 1: Representative Flow Profile of Standard Continuous-Flow Beeline Model, showing output pressure (proportional to flow rate) over the duration of the infusion (p. 53)

13.1.2 Figure 2: Representative Flow Profile of 2-Site Continuous-Flow Beeline Model, showing "instantaneous flow rate" over the duration of the infusion (p. 54)

13.1.3 Figure 3: Representative Flow Profile of 2-Site Continuous-Flow Beeline Model, showing cumulative delivered volume over the duration of the infusion (p. 55)

13.1.4 Figure 4: Representative Flow Profile of 275-mL Beeline Model, showing cumulative delivered volume over the duration of the infusion (p. 56)

Representative Flow Profile of Continuous-Flow Beeline System
(infuser output pressure throughout infusion)

(b) (4)

FIG. 1

73

53

(b) (4)

[redacted]

Representative Flow Profile of 2-Site Beeline System

24

FIG 7

(b) (4)

[redacted]

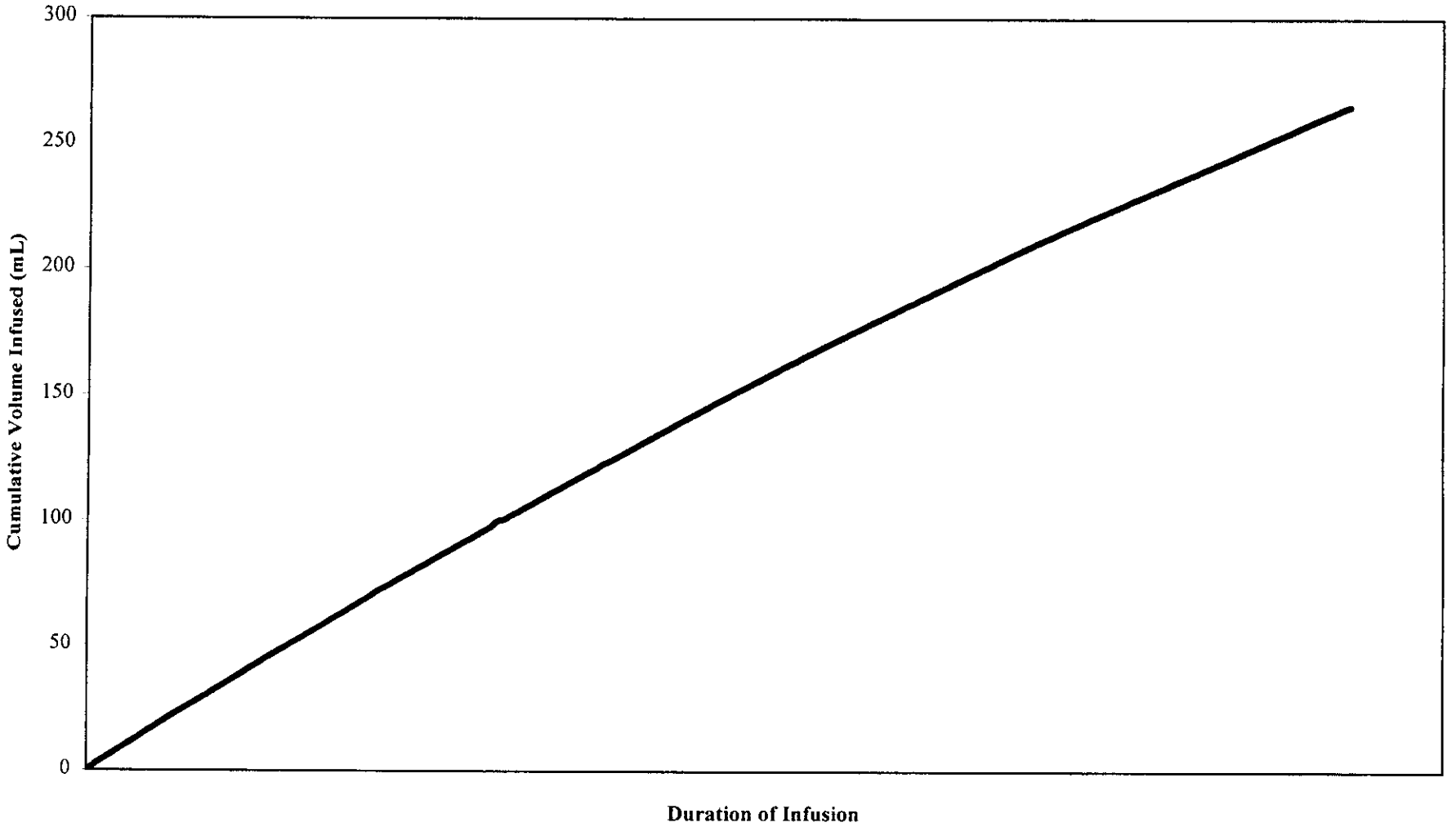
Representative Flow Profile of 2-Site Beeline System

75

FIG. 3

FIG. 4

Representative Flow Profile of Beeline System
(profile measured using 275 mL infuser)



14. Appendix 3: Pictures & Drawings

14.1 The following pictures, drawings and schematics illustrate the physical configuration of the various models within the Beeline system:

14.1.1 Figure 5: Picture of the 100-mL and 275-mL infusers (p. 58)

14.1.2 Figure 6: Picture of administration sets (standard set and two-site set) (p. 59)

14.1.3 Figure 7: Picture of an integral-set model (administration set is permanently bonded to the medication reservoir) (p. 60)

14.1.4 Figure 8: Picture of the 100-mL infuser in its carrying pouch (p. 61)

14.1.5 Figure 9: Picture of the kit contents from a representative procedure kit (for post-operative, local anesthesia) (p. 62)

14.1.6 Figure 10: Picture of additional, optional kit contents (fixed-hub catheter, split-sheath introducers, tamper-resistant fill port covers) (p. 63)

14.1.7 Figure 11: Drawing of standard continuous-flow infusion set with proximal infuser connector, micro-bore glass tubing flow restrictor, air-eliminating filter (p. 64)

14.1.8 Figure 12: Drawing of two-site continuous-flow infusion set with bifurcated distal end for continuous infusion into two sites (p. 65)

FIG. 5

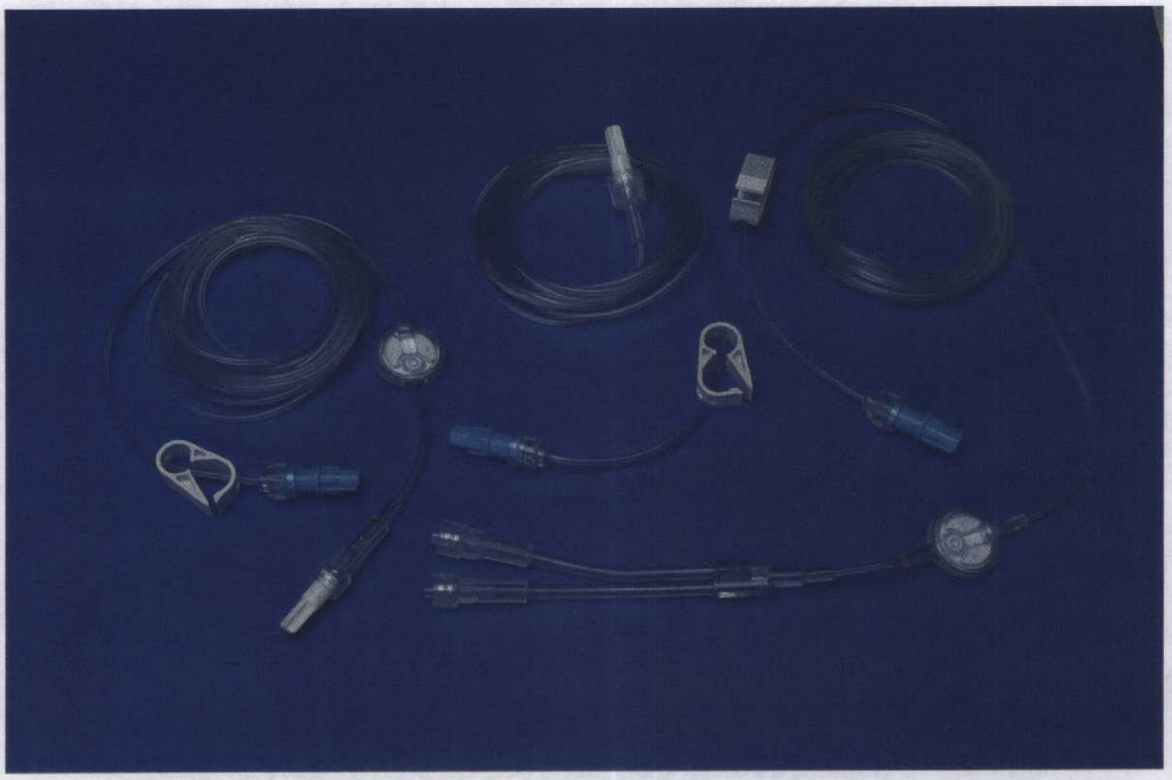


FIG. 6

79
59

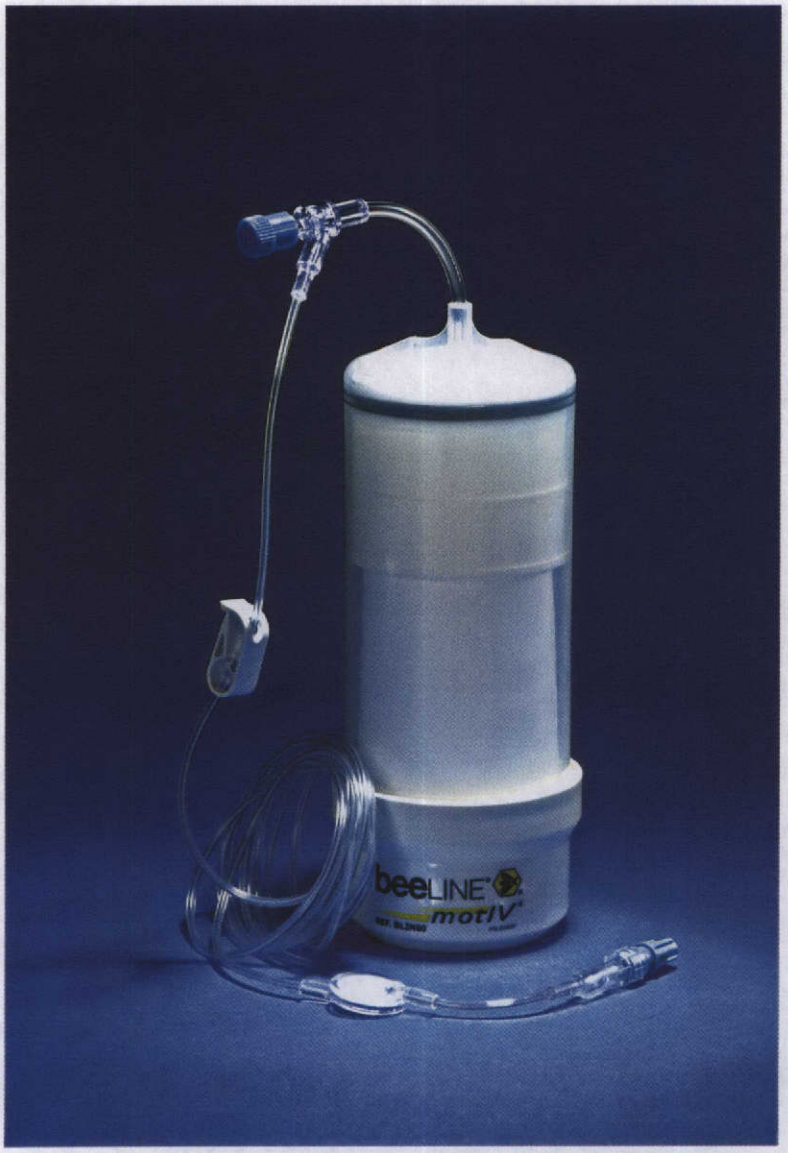


FIG. 7

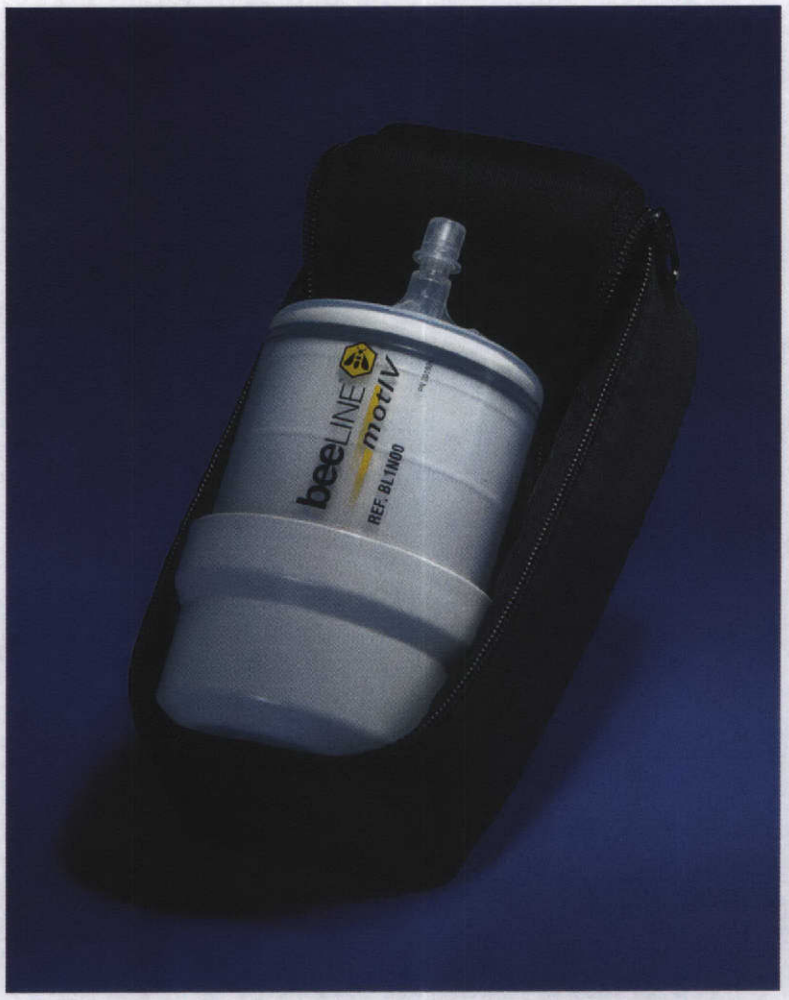


FIG. 8

FIG. 9

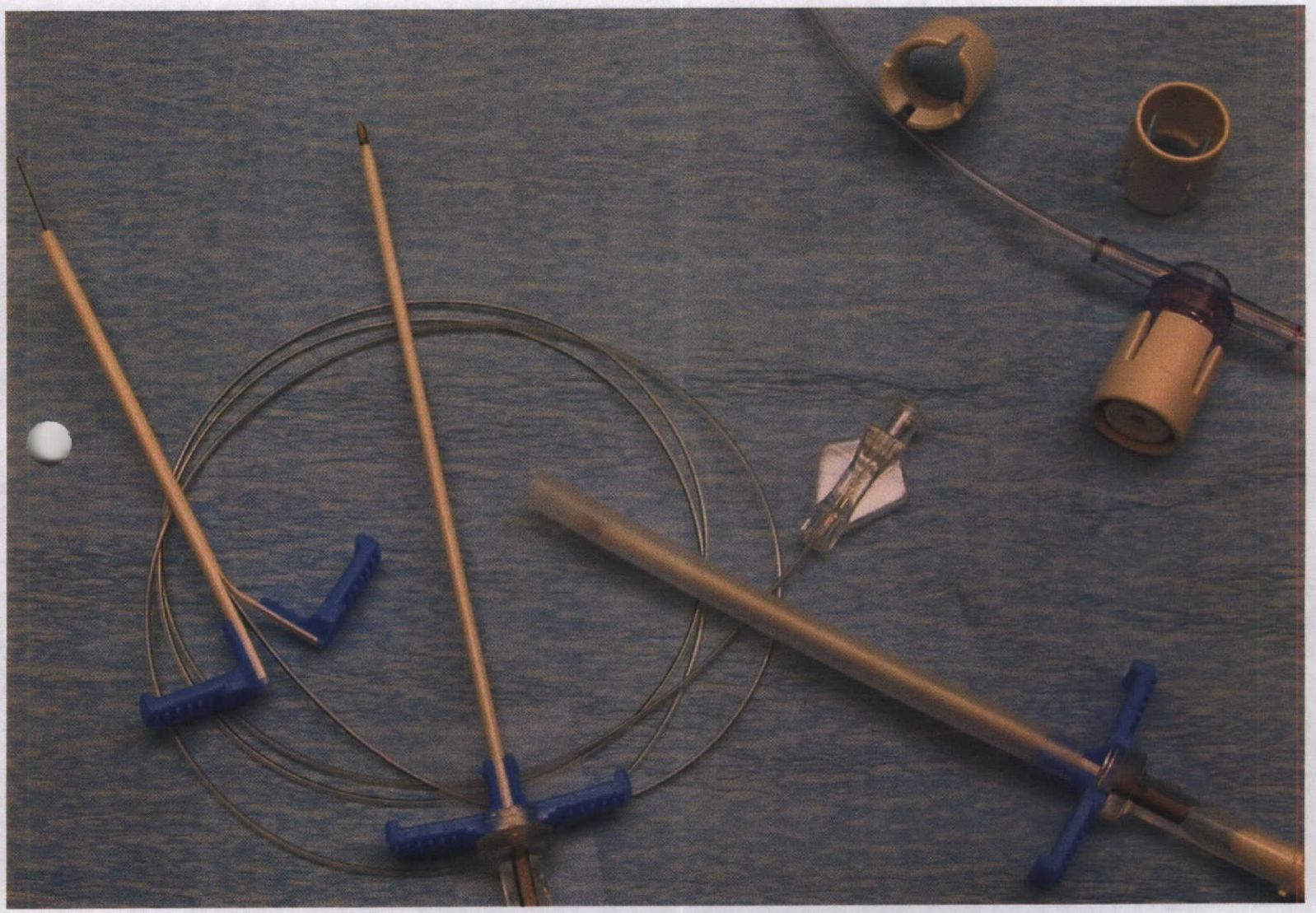


FIG.10

(b) (4)

FIG. 11

(b) (4)

[redacted]

15. Appendix 4: Representative Beeline Bills of Material

15.1 The following BOMs are representative of the Beeline device. The BOM for each product code varies slightly to provide the specified infuser size and flow rate.

15.1.1 BOM, BL1N00 110 mL infuser (packaged individually)

Item	P/N	Description	Qty
1	202826	Beeline infuser finished assembly	1 ea
1.1	200635	Vented cap	1 ea
1.2	202657	Compression spring	1 ea
1.3	202440	V.2 spring pump cap	1 ea
1.4	200266	Quad ring	1 ea
1.5	202943	V.2 spring pump piston	1 ea
1.6	202825	Siliconed barrel subassembly	1 ea
1.6.1	202438	V.2 spring pump barrel	1 ea
1.6.2	200201	Vernay valve	1 ea
1.6.3	202117	Valve retainer	1 ea
1.6.4	200208	Dow MDX silicone mixture	AR
1.6.5	200209	Stoddard solvent	AR
1.6.6	200210	Isopropyl alcohol	AR
2	200228	Non-vented luer cap	1 ea
3	201844	6.5" x 12" Tyvek/mylar pouch	1 ea
4	202425	Infuser lot label	1 ea
5	200988	Do Not Remove Set label	1 ea
6	201926	Infuser motIV label	1 ea
7	202929	Product ID pouch insert label	1 ea
8	202809	Clinician instructions for use	0.1 ea
9	202506	Patient quick reference card	0.1 ea
10	202930	Product ID case label	0.1 ea
11	201266	Cardboard shipping case	0.1 ea

15.1.2 BOM, 2 mL/hr completed set assembly (to be packaged in kit)

Item	P/N	Description	Qty
1	202379	Infuser connector	1 ea
2	202498	PVC tubing	6 ft
3	200256	Clamp	1 ea
4	200398	1.2 micron filter	1 ea
5	202291	PVC tubing	2 in
6	201638	PVC bushing	1 ea
7	201107	Silicone sleeve	1 ea
8	200470	Male luer adapter	1 ea
9	202578	2 mL/hr glass flow restrictor	1 ea
10	200226	Vented cap	1 ea
11	200227	Non-vented cap	1 ea
12	200206	Banding tape	3 in
13	200195	Cyclohexanone	AR
14	200213	Loctite 4014	AR
15	200207	Dow 360 silicone oil	AR
16	202433	Set lot & flowrate label	1 ea

16. Appendix 5: Predicate Device Information

16.1 Copies of the 510(k)'s and other relevant literature for the original device and the supporting predicate device demonstrating substantial equivalence are attached:

16.1.1 K990461; McKinley Medical; Spring Pump Disposable Infusion Pump (pp. 68-76)

16.1.2 K023098; McKinley Medical; Accufuser, Accufuser Plus & standard procedure kit (pp. 77-91)

U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

510(k) Premarket Notification Database

Device Classification Name	PUMP, INFUSION, ELASTOMERIC
Regulation Number	880.5725
510(k) Number	K990461
Device Name	MCKINLEY SP DISPOSABLE INFUSION PUMP
Applicant	MCKINLEY, INC. 4080 YOUNGFIELD ST. WHEAT RIDGE, CO 80033
Contact	JOHN MCINROY
Product Code	MEB
Date Received	02/12/1999
Decision Date	06/30/1999
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Statement only
STATEMENT	STATEMENT
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Database Updated 7/7/2003

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1999

Mr. John McInroy
Manager
Regulatory Affairs and Quality Assurance
McKinley Medical, LLLP
4080 Youngfield Street
Wheat Ridge, Colorado 80033 USA

Re: K990461
Trade Name: McKinley SP Disposable Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: May 10, 1999
Received: May 13, 1999

Dear Mr. McInroy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): _____

Device Name: McKinley SP Disposable Infusion Pump

Indications for Use:

McKinley SP
☐ The McKinley SP is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. ☐ The McKinley SP is also intended to provide continuous infusion of a local anaesthetic directly into the intraoperative site for postoperative pain management.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____	or	Over-The-Counter Use _____

Rebecca Cunningham

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K 970461

beeLINE® motIV®

Clinician Directions for Use

DESCRIPTION

The BeeLine® motIV® System uses sustained pressure to deliver a continuous infusion of medications or fluids. This non-electronic system is designed for single use in the hospital, outpatient, and home care settings. The BeeLine motIV System can be used for intravenous, intra-arterial, subcutaneous, and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. The BeeLine motIV System can also be used for intra-operative site infusion of a local anaesthetic.

The BeeLine motIV System consists of a 110 ml clear Medication Reservoir that connects to a dedicated Infusion Set. A one-way valve prevents medication flow until the Infusion Set is attached to the BeeLine motIV Infuser. Once the BeeLine motIV Infuser is filled with medication or fluid, it is ready for use. Simply attach the rate-controlling Infusion Set, open the clamp, prime the tubing, and start delivery. A special carrying pouch protects the BeeLine motIV Infuser during use.

INDICATIONS

The BeeLine motIV System is indicated for intravenous, intra-arterial, subcutaneous, and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates, and is also indicated for continuous infusion of a local anaesthetic directly into the intra-operative site for postoperative pain management.

CONTRAINDICATIONS

The BeeLine motIV System is contraindicated for:

- Infusion of blood and blood products.
- Infusion of insulin.
- Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death.
- Infusion of any solution that is incompatible with the materials of the BeeLine motIV Infuser or Infusion Sets.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.

  The BeeLine motIV Infuser and Infusion Sets are intended for single use only. Do not reuse. Do not resterilize.
- It is the responsibility of the clinician using the BeeLine motIV Infuser to ensure that the medications or fluids are used only according to the physician's infusion therapy prescription.
- BeeLine motIV Infusion Sets with flow rates ≤ 10 ml/hr are made of DEHP-plasticized PVC. As with any infusion system, medications or fluids may interact with the components of the BeeLine motIV Infuser and Infusion Set. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- DO NOT use "Y" injection sites for epidural drug administration.
- Do not fill the Medication Reservoir with more than 110 ml of fluid. Filling beyond 110 ml could damage the Infuser and cause serious injury or fluid leakage.
- Close the On/Off Clamp on the Infusion Set before delivering fluids into the patient's catheter. Failure to clamp the Infusion Set may cause fluid backflow into the BeeLine motIV Infuser.
- Do not attempt to disassemble the BeeLine motIV Infuser. Doing so could damage the Infuser and cause patient injury or fluid leakage.
- Do not drop the BeeLine motIV Infuser, strike it against hard objects or otherwise subject it to extreme physical stress. Doing so could damage the Infuser and cause serious injury or fluid leakage. If the Infuser is subjected to any trauma, it must be checked for damage or leakage before reuse. If any problems are detected, discontinue use.
- The device flow rate will vary according to the Infusion Set used. Use only the dedicated Infusion Sets authorized by McKinley for use with the BeeLine motIV Infuser.
- Do not remove the BeeLine motIV Infusion Set after it has been connected to the Infuser. Removal of a connected Infusion Set may cause fluid leakage.
- Do not use a microwave, oven, or water bath to warm the contents of the BeeLine motIV Infuser.
- The BeeLine motIV Infuser should be stored in a clean, dry environment. It is the clinician's responsibility to instruct the patient on the proper storage of medication or fluids.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the BeeLine motIV System.
- Federal (USA) law restricts this device to sale by, or on the order of, a physician.

TECHNICAL SPECIFICATIONS

BeeLine motIV Infuser:

Materials:	Polypropylene, butyl rubber and silicone rubber. **Latex-free.**
Fill Volume:	100 ml
Optional Overfill:	10 ml maximum
System Accuracy:	+/- 15%
Positive Pressure:	5.0 psi nominal / 258.6 mmHg
Weight (unfilled):	6.2 oz / 176.6 g
System Residual Volume:	< 5 ml, regardless of the Infusion Set used

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Standard Infusion Sets with Flow Rates > 10 ml/hr:

Materials:	Polyethylene, PVC, and acrylic. **Latex-free.**
Flow Rates:	25 ml/hr 50 ml/hr 100 ml/hr 200 ml/hr 250 ml/hr
Head Height:	The BeeLine motIV System is calibrated with the Infuser Inlet/Outlet Reservoir Port **18" / 45.7 cm** below the Patient Access Luer outlet of the Infusion Set. Flow rate decreases approximately 1% for every 1" / 2.5 cm that the Infuser is lowered.
Back Pressure:	The BeeLine motIV System is calibrated with **0 psi** back pressure downstream of the Luer output of the Infusion Set. Increased back pressure of 0.02 psi / 1 mmHG decreases flow rate by approximately 0.5%.
Operating Temperature:	The BeeLine motIV System is calibrated to deliver solution at the labeled flow rate using the referenced Infusion Sets when the temperature of the infusate in the tubing is **72°F / 22.2°C** (room temperature). Flow rate decreases approximately 1% per 1°F / 0.56°C decrease in temperature.
Fluid Viscosity:	The BeeLine motIV System is calibrated with the referenced Infusion Sets using **0.9% normal saline** as the infusate. Flow rate decreases as fluid viscosity increases.

Standard Infusion Sets with Flow Rates ≤ 10 ml/hr:

Materials:	Polyethylene, DEHP-Plasticized PVC, acrylic, cellulose acetate and PTFE. **Latex-free.**
Filter:	1.2 micron, air-eliminating, in-line filter.
Flow Rates:	0.5 ml/hr 1.0 ml/hr 2.0 ml/hr 4.0 ml/hr 8.0 ml/hr
Head Height:	The BeeLine motIV System is calibrated with the Infuser Inlet/Outlet Reservoir Port **18" / 45.7 cm** below the Patient Access Luer outlet of the Infusion Set. Flow rate decreases approximately 1% for every 1" / 2.5 cm that the Infuser is lowered.
Back Pressure:	The BeeLine motIV System is calibrated with **0 psi** back pressure downstream of the Luer output of the Infusion Set. Increased back pressure of 0.02 psi / 1 mmHG decreases flow rate by approximately 0.5%.
Operating Temperature:	The BeeLine motIV System is calibrated to deliver solution at the labeled flow rate when the temperature of the infusate in the patient-side Luer is **86°F / 30°C** (skin temperature). Flow rate decreases approximately 1% per 1°F / 0.56°C decrease in temperature.
Fluid Viscosity:	The BeeLine motIV System is calibrated with the referenced Infusion Sets using **5% Dextrose in Water** (D5W) as the infusate. Flow rate decreases as fluid viscosity increases.

Y-Site Infusion Sets:

Materials:	Polyethylene, DEHP-Plasticized PVC, acrylic, cellulose acetate and PTFE. **Latex-free.**
Filter:	1.2 micron, air-eliminating, in-line filter.
Head Height:	The BeeLine motIV System is calibrated with the Infuser Inlet/Outlet Reservoir Port **18" / 45.7 cm** below the Patient Access Luer outlet of the Infusion Set. Flow rate decreases approximately 1% for every 1" / 2.5 cm that the Infuser is lowered.
Back Pressure:	The BeeLine motIV System is calibrated with **0 psi** back pressure downstream of the Luer output of the Infusion Set. Increased back pressure of 0.02 psi / 1 mmHG decreases flow rate by approximately 0.5%.
Operating Temperature:	The BeeLine motIV System is calibrated to deliver solution at the labeled flow rate when the temperature of the infusate in the patient-side Luer is **86°F / 30°C** (skin temperature). Flow rate decreases approximately 1% per 1°F / 0.56°C decrease in temperature.
Fluid Viscosity:	The BeeLine motIV System is calibrated with the referenced Infusion Sets using **0.9% normal saline** as the infusate. Flow rate decreases as fluid viscosity increases.

MIXING AND USE INFORMATION

CAUTION: As with any sterile product, use aseptic technique when preparing the BeeLine motIV Infuser and Infusion Sets for use.

The BeeLine motIV System is designed for a 100 ml fill volume. The Medication Reservoir has a maximum capacity of 110 ml and should never be filled beyond this maximum capacity.

Note: For proper fluid or medication administration, you must fill the BeeLine motIV Infuser to at least 100 ml, but not more than 110 ml. Flow rates are based on a fill volume of 100 ml. Under-filling the Infuser will result in prolonged delivery (reduced flow rate).

FILLING THE MEDICATION RESERVOIR

1. Inspect the BeeLine motIV package to confirm that it has not been opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.* Using aseptic technique, remove the BeeLine motIV Infuser from its package. Place it on a flat work surface with the Inlet/Outlet Reservoir Port pointing up. Save the nonvented Luer cap and BeeLine motIV Infusion Set for later use.
2. Remove and discard the vented Luer cap from the Inlet/Outlet Reservoir Port.
3. Fill the BeeLine motIV Medication Reservoir using a transfer syringe or other calibrated filling device. Connect the Luer Lock of the transfer device to the Inlet/Outlet Reservoir Port. Confirm that the connection is secure, but do not over-

tighten. While filling, grasp the Infuser securely to keep it from moving.

Note: The Volume Remaining marks printed on the BeeLine Medication Reservoir provide approximate volume indication only and are not intended to be used for precise measurements.

4. After filling, disconnect the transfer device. Then attach the nonvented Luer cap to the Inlet/Outlet Reservoir Port, or connect the Infusion Set as instructed in the section "Connecting The Infusion Set."

   Note: To remove air from the BeeLine Medication Reservoir, refer to the "Priming and Delivery Instructions" for the Infusion Set you have selected.

5. Label the filled Infuser with the appropriate patient identification and instruction information.

   Note: The BeeLine motIV Infuser may be filled and stored at 40°F / 4°C for up to one week. Prior to use, the BeeLine motIV Infuser and its contents must return to room temperature.

CONNECTING THE INFUSION SET

1. Use only the appropriate Infusion Set dedicated for use with the BeeLine motIV Infuser. Confirm the flow rate, which is listed on the packaging and the Infusion Set tag.
2. Using aseptic technique, remove the Infusion Set from its package. Close the Infusion Set On/Off Clamp.
3. Place the BeeLine motIV Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up. Remove and discard the Luer cap from the Infuser if present.
4. Remove and discard the cap from the Infusion Set Connector that has an extended male Luer and is located nearest to the On/Off Clamp.
5. Using a quick, continuous motion, insert the Infusion Set Connector with the extended male Luer into the Inlet/Outlet Reservoir Port while turning the Connector in a clockwise direction. Secure the connection, but do not overtighten it.

PRIMING AND DELIVERY INSTRUCTIONS

Standard Infusion Sets:

Note: The BeeLine motIV System should be primed immediately before use. Do not store the primed BeeLine System for extended periods. Priming volume is < 3 ml.

1. Examine the BeeLine motIV Infuser for the presence of air bubbles. While rotating the Infuser, gently tap the bottom of the Infuser on your work surface until the small air bubbles have moved into a single bubble underneath the Inlet/Outlet Reservoir Port.
2. After the air bubbles are collected into a single bubble, place the BeeLine motIV Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up.
3. Remove the Luer cap located at the patient end of the BeeLine motIV Infusion Set. Save the Luer cap for recapping if short-term storage is required.
4. Open the On/Off Clamp to allow the fluid flow to expel any air present in the BeeLine Medication Reservoir and to prime the Infusion Set.

   IF THE INFUSION SET HAS A FILTER: To prime the filter, hold it so the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air.

5. When priming is complete, close the On/Off Clamp.

   Note: For short-term storage of primed Infusion Sets, reattach the Luer Cap to the Patient Access Connector.

6. Attach the primed Infusion Set to the patient's catheter.

   IF THE INFUSION SET HAS A FILTER: Tape the Patient Access Luer to the patient's skin.

7. Open the On/Off Clamp to start infusion.
8. Secure the BeeLine motIV Infuser in the protective carrying pouch during the infusion.

Y-Site Infusion Sets:

Note: The BeeLine motIV System should be primed immediately before use. Do not store the primed BeeLine System for extended periods. Priming volume is < 3 ml.

1. Examine the BeeLine motIV Infuser for the presence of air bubbles. While rotating the Infuser, gently tap the bottom of the Infuser on your work surface until the small air bubbles have moved into a single bubble underneath the Inlet/Outlet Reservoir Port.
2. After the air bubbles are collected into a single bubble, place the BeeLine motIV Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up.
3. If necessary, remove the cap from the Y-site extension to attach an injection port or needleless connector.

   Note: Take care to ensure that the Y-site cap, injection port, or needleless connector is attached securely. Tape may be used to reinforce the connection.

4. Remove the Luer cap located at the patient end of the BeeLine motIV Infusion Set. Save the Luer cap for recapping if short-term storage is required.
5. Open the On/Off Clamp to allow the fluid flow to expel any air present in the BeeLine Medication Reservoir and to prime the Infusion Set. To prime the filter, hold it so the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air. Invert and tap the Y-site to remove trapped air.
6. When priming is complete, close the On/Off Clamp.

   Note: For short-term storage of primed Infusion Sets, reattach the Luer cap to the Patient Access Connector.

7. Attach the primed Infusion Set to the patient's catheter and tape the Patient Access Luer to the patient's skin. Open the On/Off Clamp to start infusion.

   Note: Before starting medication flow from the piggyback line into the patient's catheter, close the On/Off Clamp on the BeeLine motIV Infusion Set to avoid possible backflow into the BeeLine Medication Reservoir.

8. Secure the BeeLine motIV Infuser in the protective carrying pouch during the infusion.

INFORMATION FOR DAILY USE

- Do not immerse the BeeLine motIV Infuser in water or other fluids. When showering, the patient should keep the Infuser outside of the shower or place it in a waterproof bag.

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- To protect the BeeLine motIV Infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- During medication delivery, check for the following:
  - The BeeLine motIV Infuser is emptying.
  - There is no leakage from the BeeLine motIV System.
  - There is no air in the BeeLine motIV System.
  - The BeeLine motIV Infusion Set is not kinked.
  - All connections are secure.
- To monitor medication or fluid delivery, open the carrying pouch from time to time and read the position of the dark plunger ring against the graduation scale on the BeeLine Medication Reservoir.
- Use the BeeLine Patient Quick Reference Card to assist with patient education and daily use instructions.

CLEANING AND CARE

The BeeLine motIV Infuser is a disposable device and does not require periodic maintenance. If desired, the Infuser may be cleaned using a cloth dampened with water. To avoid damaging the Infuser, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the BeeLine motIV Infuser. Do not disable the BeeLine motIV Infuser.

PROBLEM-SOLVING

Problem	Possible Causes	To Correct Problem
Delivery Rate Slowed	• **Prolonged change in head height, temperature, or medication viscosity** • **Improper Infusion Set used**	1. Confirm flow rate is within System accuracy specification. 2. For intermittent conditions, continue to monitor for progress of infusion. 3. For prolonged conditions, a faster-rate Infusion Set may be substituted. Contact the dispensing clinician.
Delivery Ends Early	• **Under-filled device** • **Prolonged changes in head height, temperature, or medication viscosity** • Improper Infusion Set used	1. Confirm fill volume 100 - 110 ml. 2. Evaluate environmental changes that may affect flow rate. 3. Confirm proper Infusion Set was used.
Occlusion	• **Patient's catheter is blocked** • **Clamp is closed on Infusion Set or patient's catheter** • **Infusion Set is pinched** • **Infusion Set or filter is clogged with medication**	1. Check for cause of occlusion. 2. Correct condition. 3. For clogged tubing or filters, return Infuser to pharmacy for handling. • Do not attempt to change the Infusion Set. • Do not store primed System for prolonged periods.
Leaking	• **Loose Luer connectors** • **Medication interaction with Infusion Set causing cracks**	1. Tighten connectors. Have patient routinely monitor for secure connections. 2. For sustained leaks, take device out of service immediately:
Leaking Set - continued	• **Improper use of cleaning methods or materials**	2. - continued • Have pharmacy confirm material compatibility with medication(s). • Educate patient on proper cleaning methods.
Air Detected in Infuser or Infusion Set	• **Improper priming of Infuser** • **Gas-producing medications used with Infuser** • **Y-site connector not secure**	1. Stop infusion and disconnect Infusion Set from patient's access device. Collect air at top of Infuser. 2. Open Clamp and vent air out of Infuser and Infusion Set. (This will take a long time.) 3. Contact pharmacy to determine impact on infusion duration. 4. After air is purged from Infuser, reconnect Infusion Set and resume infusion.
Backflow	• **Failure to clamp Infusion Set when Y-site is open**	1. If Y-site is used, ensure On/Off Clamp on Infusion Set is closed.
Dropped Infuser		1. Stop infusion. 2. Check system for damage or leakage. 3. If no problems are detected, resume infusion. Use protective carrying pouch. 4. If problems are detected, discontinue use.

CONTACTING MCKINLEY

Please note all **product reference and lot numbers** (on the Infusion Set or Infuser), which pertain to your inquiry, before contacting McKinley.

McKinley
4080 Youngfield Street
Wheat Ridge, CO 80033

(800) 578-0555 or (303) 420-9569 phone
(800) 254-6459 or (303) 420-4545 fax

Note: All product returns require prior authorization from McKinley.

Authorized Representative:
Priory Analysts, Ltd., P.O. Box 4030, Milton Keynes, MK13 OZG UK

Assembled in Mexico for:
McKinley, Wheat Ridge, CO 80033 USA

CE 0125

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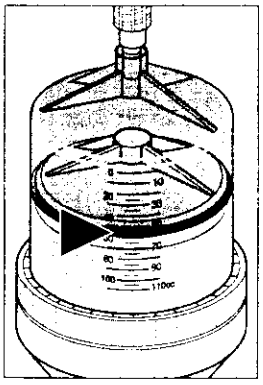
1/2002, PN 202809 Rev. AA.

INFORMATION FOR DAILY USE – continued

E[illegible] medication delivery, check for the following:

- [illegible] BeeLine motIV Infuser is emptying
- There is no leakage from the infusion system
- There is no air in the infusion system
- The tubing is not kinked
- All connections are secure

If you notice any problems, contact your health care provider immediately.



To check the progress of medication delivery, note the position of the black ring against the Volume Remaining scale on the side of the Infuser reservoir. You may not be able to see the black ring move because the Infuser delivers your medication very slowly. However, after waiting a period of time, check to see that the ring has moved from its earlier position. If you think that the ring has not moved, contact your health care provider.

Your health care provider should specify below how much medication or fluid should infuse over a period of time. Use this as a guide for checking the progress of your infusion.

Delivery Rate: _____

_____ Volume Infused Per _____ hour(s) of infusion

CLEANING AND CARE

The BeeLine motIV Infuser may be cleaned using a cloth dampened with water. To avoid damaging the Infuser, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the BeeLine motIV Infuser.

S[illegible]GE

The BeeLine motIV Infuser should be stored in a clean, dry environment. Avoid prolonged exposure to extreme temperatures above 104° F/40° C or below 32° F /0° C. For proper storage of medication or fluids, refer to the instructions given to you by your health care provider.

ADDITIONAL INSTRUCTIONS _____

_____

_____

PHONE NUMBERS FOR HELP

Daytime: _____

After hours: _____

Authorized Representative:
Priory Analysts, Ltd., P.O. Box 4030, Milton Keynes, MK13 0ZG UK

Manufactured for:
McKinley, 4080 Youngfield Street, Wheat Ridge, CO 80033 USA

CE 0125 — 0° C – 40° C

Quality System Certified: ISO 9001-EN46001

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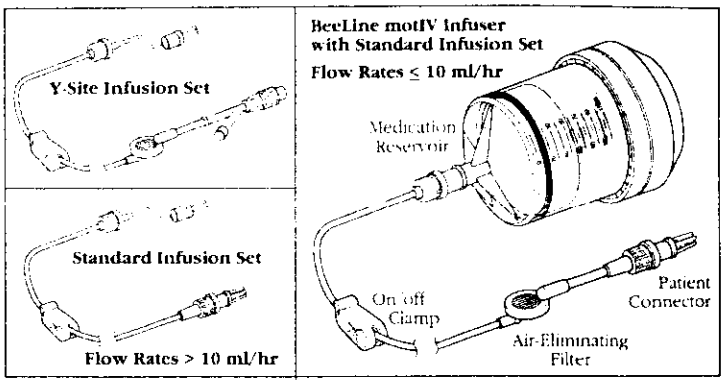
beeLINE® motIV™

PATIENT QUICK REFERENCE CARD

Keep this card in a handy location. For complete guidance, refer to the instructions given to you by your health care provider.

PRODUCT OVERVIEW



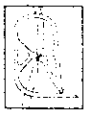
NOTE: Your health care provider should check the box (below) that corresponds to the type of Infusion Set you are using. If you have any questions about the BeeLine System or your infusion therapy, contact your health care provider.

❑ **Standard Infusion Set** ❑ **Y-Site Infusion Set**

STARTING DELIVERY

For Standard Infusion Sets

- To start delivery, open the on/off clamp on the tubing attached to the BeeLine motIV Infuser.



For Y-Site Infusion Sets

- Close the clamp on the piggyback (secondary) line if used. Open the on/off clamp on the tubing attached to the BeeLine motIV Infuser.
- To start piggyback delivery, close the on/off clamp on the BeeLine motIV tubing to avoid possible backflow. Then open the clamp on the piggyback line.

STOPPING DELIVERY

- To stop delivery, close the on/off clamp on the tubing attached to the BeeLine motIV Infuser.

For Y-Site Infusion Sets

- To stop piggyback delivery, close the clamp on the piggyback line. Open the on/off clamp on the tubing attached to the BeeLine motIV Infuser if necessary.

WHEN TO START / STOP DELIVERY

_____

_____

INFORMATION FOR DAILY USE

- Do not use a microwave, oven, or water bath to warm the contents of the BeeLine motIV Infuser.
- Do not immerse the BeeLine motIV Infuser in water or other fluids. While showering, keep the Infuser outside of the shower or place it in a waterproof bag.
- To protect the BeeLine motIV Infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- To monitor medication or fluid delivery, open the pouch from time to time and read the position of the dark plunger ring against the graduation scale on the BeeLine motIV Infuser.

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U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

510(k) Premarket Notification Database

Device Classification Name	PUMP, INFUSION, ELASTOMERIC
Regulation Number	880.5725
510(k) Number	K023098
Device Name	ACCUFUSER, ACCUFUSER PLUS, STANDARD PROCEDURE KIT
Applicant	MCKINLEY INFUSER 631 HOWARD #202 SAN FRANCISCO, CA 94105
Contact	JOHN CHAPPELL
Product Code	MEB
Date Received	09/18/2002
Decision Date	12/09/2002
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary only
SUMMARY	SUMMARY
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Database Updated 7/7/2003

K023098

Section D

Premarket Notification – 510(k)
Summary of Safety and Effectiveness
for Accufuser, Accufuser Plus and Standard Procedure Kit

DEC 0 9 2002

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Premarket Notification – 510(k)
Summary of Safety and Effectiveness
for Accufuser, Accufuser Plus and Standard Procedure Kit

Date Prepared: September 17, 2002

Trade Name: Accufuser; Accufuser Plus; Standard Procedure Kit

Common Name: Elastomeric Infusion Pump Kit

Classification Name: Pump, Infusion, Elastomeric

Classification Panel: General Hospital and Personal Use Device

Device Classification Regulation Number: 880.5725, Class II

Panel: 80

Procode: MEB

Existing Device Cleared 510(k): K003915, Accufuser and Accufuser Plus

Predicate devices demonstrating substantial equivalence include the following.

- K013928, Breg Corporation, Pain Care 3000 and 3200, and accessory Kit.
- K014091, Stryker Pain Pump and Accessory Kit.
- K020862, I-Flow, Infusion Pump and Administration Set.

Submitted by:

McKinley Infuser, LLC
631 Howard, #202
San Francisco, CA 94105 USA
Phone: 415-543-2196
Contact for questions: John Chappell, RAC
Establishment Registration Number: 3003468679
Owner/Operator Number: 9047569

This submission is intended to notify the Food and Drug Administration that McKinley Infuser, LLC intends to market a modification to an existing device (K003915) called the Accufuser/Accufuser Plus and Standard Procedure Kit. Modifications to the existing device include two new indications for use, expansion of the bolus delivery range, addition of two bolus lockout times, addition of one reservoir volume size through combining two reservoirs, addition of flow rates for bolus devices and addition of a standard procedure kit.

The Accufuser/Accufuser Plus system and its predicate device (K020862) are intended for use as follows.

> The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery.
>
> The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.
>
> The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

Description of the Accufuser System

> The Accufuser/Accufuser Plus system consists of a pump and an integrated administration set. The pump is a continuous silicone balloon type. The pump provides continuous fluid delivery with an attached, fixed rate administration set. The pumps are supplied as fixed flow rates. A silicone balloon is used as both the fluid reservoir of the device and the pressure (energy) source.
>
> The Accufuser/Accufuser Plus pump and administration set are intended for single patient use.
>
> The Accufuser Plus is the Accufuser with the addition of a Patient Medication Control Module (PCM). The PCM allows the patient to administer a bolus of a fixed volume with a fixed lockout (re-fill) time. The PCM in integrated into the administration set with a bolus button that allows the patient controlled administration of medication as needed.
>
> The Standard Procedure Kit is substantially equivalent to the predicate devices. The kit includes various kit components such as catheter, needle, syringe, y adapter, dressing, tape, gauze and carry case.

Device Specifications and Safety Functions

> The Accufuser/Accufuser Plus system has fill volumes and flow rates substantially equivalent to the pumps of the named predicate devices.
>
> The Accufuser/Accufuser pumps and the identified predicate device use either a glass orifice or PVC tubing to control the flow rate.

The Accufuser/Accufuser Plus provides a fixed flow and is not subject to fluid runaway conditions similar to that of some electronic pumps.

All fluid path materials of the Accufuser/Accufuser Plus system are in conformance with ISO 10993 Part 1.

There are currently no approved performance standards established for elastomeric infusion pumps under Section 514 of the Food, Drug and Cosmetic Act.

Packaging is suitable for ETO sterilization.

ETO is the validated sterilization method.

Product Configuration:

- Reservoir volume range is from 60 ml to 550 ml.
- Flow rate range is 0.5 ml/hr to 10.0 ml/hr.
- Bolus levels are 0.5 ml, 1.0 ml and 2.0 ml.
- Lockout times range from 6 minutes to 60 minutes and include increments of 6, 8, 15, 30 and 60 minutes.

Materials: PET-G, ABS, polypropylene, silicone, PVC, polycarbonate, cellulose acetate, PTFE, and acrylic. DEHP-Free. Plasticizer used is TOTM, Tri-Octyl Trimellitate. Latex-Free.

Filter: 1.2 Micron, air-eliminating, in-line filter

System Accuracy

Reservoir Volume	Accuracy
60 ml	+/- 10% of nominal flow rate at 95% confidence interval
100 ml	+/- 10% of nominal flow rate at 95% confidence interval
275 ml	+/- 15% of nominal flow rate at 95% confidence interval
550 ml	+/- 15% of nominal flow rate at 95% confidence interval

Operating Pressure: 5 to 6 psi

System Residual Volume: < 3 ml (includes tubing and reservoir)

Operating Temperature: The Accufuser and Accufuser Plus systems are calibrated to deliver solution at the labeled nominal

flow rate when the temperature of the infusate in the flow restrictor (distal end) is 32° C / 89.6°F (normal skin temperature). Flow rate increases approximately 1% per 1°F / 0.56°C increase in temperature.

Fluid Viscosity: The Accufuser and Accufuser Plus systems are calibrated using 5% Dextrose in Water (D5W) as the infusate. Flow rate increases as fluid viscosity decreases. (E.g., Using sterile water as diluent will increase the flow rate by approximately 10%.)

Head Height: The Accufuser and Accufuser Plus systems are calibrated with zero head height. Increased head height will cause increased flow rate. (E.g., +43 cm / +17" of head height will increase flow rate by approximately 12%.)

Conclusion:

The Accufuser/Accufuser Plus and Standard Procedure Kit does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. The Accufuser/Accufuser Plus system and accessory Standard Procedure Kit is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 9 2002

Mr. John Chappell
Regulatory Affairs
McKinley Infuser, LLC
631 Howard Street, Suite 202
San Francisco, California 94105

Re: K023098
Trade/Device Name: Accufuser, Accufuser Plus, Standard Procedure Kit
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: September 17, 2002
Received: September 18, 2002

Dear Mr. Chappell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: McKinley Infuser, LLC

510(k) Number (if known): K023098

Device Name: Accufuser, Accufuser Plus, Standard Procedure Kit

Indications for Use:

The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K023098

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(d) Inspect the system to ensure that it is fully primed and all air has been purged.

(e) Attach PCA button to patient using wristband

NOTE: The PCA button must be worn on the patient's skin to achieve proper operating temperature. (Refer to Operating Temperature in the Technical Specifications section for effect of temperature on flow rate.)

Confirm that the priming operation is complete and fluid is dripping from the distal end of the tubing at the expected flow rate (1 mL/hr = approximately 1 drop every 3 seconds).

In the event that the tubing does not completely prime, attach a stopcock to the distal Luer connector. Attach a syringe to the other side of the stopcock and pull plunger back to create suction.

6. After the system is fully primed, close the clamp on the tubing and connect the distal Luer to the patient's access device.
7. Tape the Luer to the patient's skin if using the *Accufuser* system. (Refer to Operating Temperature in the Technical Specifications section for effect of temperature on flow rate.)

INFORMATION FOR DAILY USE

- Use the clip to attach the medication reservoir to the patient's clothing (60 & 100 mL device only). A carry pouch is available for the 275 & 550 mL *Accufuser*.
- Do not immerse the *Accufuser* or *Accufuser Plus* in water or other fluids. When showering, the patient should keep the *Accufuser* or *Accufuser Plus* outside the shower or place it in a waterproof bag.
- During medication delivery, check for the following:
  - The *Accufuser* or *Accufuser Plus* is emptying.
  - There is no leakage from the *Accufuser* or *Accufuser Plus* system (i.e., connections, etc.).
  - There is no air in the *Accufuser* or *Accufuser Plus* system.
  - The tubing is not kinked.
  - All connections are secure.
- To monitor medication delivery, read the position of the black ring on the piston against the graduated scale on the medication reservoir housing. On the 550 mL device, the volume remaining in each side of the dual reservoir is read independently.
- If desired, the *Accufuser* or *Accufuser Plus* may be cleaned using a cloth dampened with water. To avoid damaging the device, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the *Accufuser* or *Accufuser Plus* system.

Manufactured by:
Woo Young Medical, Paju-City, Kyunggi-Do, Republic of Korea. 413-830

Distributed exclusively by:
McKinley, 4080 Youngfield Street, Wheat Ridge, CO 80033 USA
Telephone: 303-420-9569

NOTE: All product returns require prior authorization from McKinley.

0050

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PN xxxxxx 6/03

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Accufuser® and *Accufuser Plus*®
Clinician Directions for Use

INDICATIONS

The *Accufuser* and *Accufuser Plus* systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. The *Accufuser Plus* is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery.

The *Accufuser* and *Accufuser Plus* systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The *Accufuser/Accufuser Plus* system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

DESCRIPTION

The *Accufuser* and *Accufuser Plus* systems use an elastomeric silicone reservoir and are completely disposable and non-electronic. While the *Accufuser* is used for continuous infusion only, the *Accufuser Plus* offers a PCA capability designed specifically for pain management applications. The *Accufuser Plus* delivers continuous infusion plus optional bolus dosing, which can be activated by the patient using the convenient bolus button. The bolus button delivers a fixed volume of medication (0.5 ml, 1.0 ml, or 2.0 ml, depending upon the product selected) when fully depressed, and it features a predetermined lockout period for PCA security.

CONTRAINDICATIONS

The *Accufuser* and *Accufuser Plus* systems are contraindicated for:

- Infusion of blood and blood products.
- Infusion of lipids or fat emulsions.
- Infusion of critical or life-supporting medications whose stoppage, interruption, significant over-delivery or significant under-delivery would likely cause serious injury or death.
- Infusion of any solution that is incompatible with the materials of the *Accufuser* and *Accufuser Plus* systems.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

CAUTION: Please be aware that the actual rates at which medication is delivered and the total amount of medication the patient receives may vary as much as +/-15%, depending on the reservoir size and chosen flow rate. Please take the variance of the medication delivered into consideration in determining both the rate and duration of delivery of the medication in order to reduce the probability of an adverse event.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- The *Accufuser* and *Accufuser Plus* systems are intended for single patient use only. Do not reuse. Do not resterilize.

- It is the res[illegible]bility of the clinician using the *Accufuser* and *Accufuser Plus* systems to ensure that the me[illegible]ns or fluids are used only according to the physician's infusion therapy prescription.
- As with any infusion system, medications or fluids may interact with the components of the *Accufuser* and *Accufuser Plus* systems. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- Do not fill the medication reservoir with more than the maximum reservoir volume.
- Do not use the *Accufuser* or *Accufuser Plus* if the packaging has been previously opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.*
- The *Accufuser* and *Accufuser Plus* flow rates and reservoir volumes are fixed and pre-determined. Take care to select the appropriate nominal flow rate and reservoir volume for the prescribed therapy.
- The *Accufuser* and *Accufuser Plus* systems must be stored at room temperature and protected from direct sunlight.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the *Accufuser* and *Accufuser Plus* systems.
- **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

TECHNICAL SPECIFICATIONS

Materials:
PET-G, ABS, polypropylene, silicone, PVC, polycarbonate, cellulose acetate, PTFE, and acrylic. **Latex-Free. DEHP-free.**

Filter:
1.2 micron, air-eliminating, in-line filter

Flow Rates (Label colors apply to *Accufuser* tubing set only):

Flow Rate	Label Color	Flow Rate	Label Color
0.5 mL/hr	Red	4.0 mL/hr	Orange
1.0 mL/hr	Blue	5.0 mL/hr	Green
1.5 mL/hr	Sky Blue	8.0 mL/hr	Gray
2.0 mL/hr	Yellow	10.0 mL/hr	Violet

System Accuracy:

Reservoir Volume	Accuracy
60 mL	+/- 10% of nominal flow rate
100 mL	+/- 10% of nominal flow rate
275 mL	+/- 15% of nominal flow rate
550 mL (dual reservoir)	+/- 15% of nominal flow rate

Operating Pressure:
5 to 6 psi

System Residual Volume:
< 3 mL (includes tubing and reservoir)

Operating Temperature:
The *Accufuser* and *Accufuser Plus* systems are calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the distal end (*Accufuser*) or PCA button (*Accufuser Plus*) is **32° C / 89.6° F** (normal skin temperature). Flow rate increases approximately 1% per 1° F / 0.56° C increase in temperature.

Fluid Viscosity:
The *Accufuser* and *Accufuser Plus* systems are calibrated using **5% Dextro[illegible]Water** (D5W) as the infusate. Flow rate increases as fluid viscosity decreases (e.g., using ste[illegible]er as diluent will increase the flow rate by approximately 10%.)

Head Height:
The *Accufuser* and *Accufuser Plus* systems are calibrated with **zero** head height. Increased head height will cause increased flow rate (e.g., +43 cm / +17" of head height will increase flow rate by approximately 12%).

FILLING THE MEDICATION RESERVOIR

CAUTION: As with any sterile product, use aseptic technique when preparing the *Accufuser* and *Accufuser Plus* systems for use.

1. Confirm the nominal flow rate and reservoir capacity prior to opening package.

   NOTE: Flow rates for the *Accufuser* are indicated on the medication reservoir housing and on the flow restrictor with a color-coded label (see the Technical Specifications section for a color code matrix). The basal flow rate, bolus volume and lock-out period for the *Accufuser Plus* are indicated on the medication reservoir housing and on the bolus (PCA) button. The *Accufuser Plus* does not use color-coded labels.
2. Place clamp between filter and filling port (between filter and Y-connector on Accufuser 550). Close clamp. Remove Luer cap(s) from the filling port(s).
3. Fill a sterile transfer syringe with the medication to be dispensed into the medication reservoir.
4. Connect the filled syringe to the filling port and transfer the medication into the medication reservoir. (Repeat if necessary until desired volume of medication has been transferred into the medication reservoir.) Do not fill beyond the labeled capacity.
5. After the medication reservoir has been filled, disconnect the transfer syringe and replace the Luer cap(s) on the filling port(s).

   NOTE: When filling the *Accufuser* 550, one balloon may expand more than the other as pressure between the two reservoirs equilibrates. This is normal and does not affect device performance.

PRIMING AND DELIVERY

1. Place clamp between filter and distal end of tubing set. Leave clamp open.
2. Remove the female end cap on the distal Luer connector. The contents of the medication reservoir will flow toward the patient end of the set, expelling any air present in the system.
3. To prime the filter, hold it so the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air.

   Items (a) – (e) for *Accufuser Plus* only:

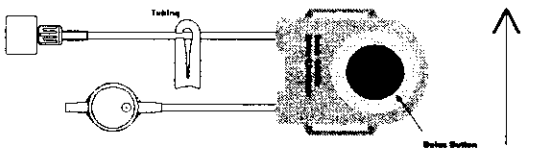
   Prime the PCA button reservoir as follows:

   (a) Allow fluid to flow into the PCA button reservoir.

   (b) Purge the air from the PCA button reservoir by depressing the bolus button.

   (c) Allow fluid to refill the PCA button reservoir over the specified lockout time. After the PCA button reservoir has refilled, depress and release the bolus button to complete the priming operation and to remove any air in the tubing and PCA button reservoir. (To facilitate air expulsion and priming, place the PCA button and tubing as below illustration) Repeat as needed until all air is purged from line.

PCA Button showing proper orientation for priming operation.



Accufuser® and Accufuser® Plus Local Anesthesia Kit

Clinician Directions for Use

INDICATIONS FOR THE *ACCUFUSER* SYSTEM

The *Accufuser* and *Accufuser Plus* systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue/body cavity) site. The *Accufuser Plus* is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery.

The *Accufuser* and *Accufuser Plus* systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The *Accufuser/Accufuser Plus* system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

DESCRIPTION

The *Accufuser* and *Accufuser Plus* systems use an elastomeric silicone reservoir and are completely disposable and non-electronic. While the *Accufuser* is used for continuous infusion only, the Accufuser Plus offers a PCA capability designed specifically for pain management applications. The *Accufuser Plus* delivers continuous infusion plus optional bolus dosing, which can be activated by the patient using the convenient bolus button. The bolus button delivers a fixed volume of medication (0.5 ml, 1.0 ml, or 2.0 ml, depending upon the product selected) when fully depressed, and it features a predetermined lockout period for PCA security.

CONTRAINDICATIONS

The *Accufuser* and *Accufuser Plus* systems are contraindicated for:

- Infusion of blood and blood products.
- Infusion of lipids or fat emulsions.
- Infusion of critical or life-supporting medications whose stoppage, interruption, significant over-delivery or significant under-delivery would likely cause serious injury or death.
- Infusion of any solution that is incompatible with the materials of the *Accufuser* and *Accufuser Plus* systems.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

CAUTION: Please be aware that the actual rates at which medication is delivered and the total amount of medication the patient receives may vary as much as +/- 15%, depending on the reservoir size and chosen flow rate. Please take the variance of the medication delivered into consideration in determining both the rate and duration of delivery of the medication in order to reduce the probability of an adverse event.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- The *Accufuser* and *Accufuser Plus* systems are intended for single patient use only. Do not reuse. Do not resterilize.
- It is the responsibility of the clinician using the *Accufuser* and *Accufuser Plus* systems to ensure that the medications or fluids are used only according to the physician's infusion therapy prescription.
- As with any infusion system, medications or fluids may interact with the components of the *Accufuser* and *Accufuser Plus* systems. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- Do not fill the medication reservoir with more than the maximum reservoir volume.
- Do not use the *Accufuser* or *Accufuser Plus* if the packaging has been previously opened or damaged. Sterility is not guaranteed for a product whose package has been opened or damaged.
- The *Accufuser* and *Accufuser Plus* flow rates and reservoir volumes are fixed and pre-determined. Take care to select the appropriate nominal flow rate and reservoir volume for the prescribed therapy.
- The *Accufuser* and *Accufuser Plus* systems must be stored at room temperature and protected from direct sunlight.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the *Accufuser* and *Accufuser Plus* systems.
- **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

ACCUFUSER TECHNICAL SPECIFICATIONS

Materials:

PET-G, ABS, polypropylene, silicone, PVC, polycarbonate, cellulose acetate, PTFE, and acrylic. **Latex-Free. DEHP-free.**

Filter:

1.2 micron, air-eliminating, in-line filter

Flow Rates (Label colors apply to *Accufuser* tubing set only):

Flow Rate	Label Color	Flow Rate	Label Color
0.5 mL/hr	Red	4.0 mL/hr	Orange
1.0 mL/hr	Blue	5.0 mL/hr	Green
1.5 mL/hr	Sky Blue	8.0 mL/hr	Gray
2.0 mL/hr	Yellow	10.0 mL/hr	Violet

System Accuracy:

Reservoir Volume	Accuracy
60 mL	+/- 10% of nominal flow rate
100 mL	+/- 10% of nominal flow rate
275 mL	+/- 15% of nominal flow rate

Operating Pressure:

5 to 6 psi

System Residual Volume:

<3 mL (includes tubing and reservoir)

Operating Temperature:

The *Accufuser* and *Accufuser Plus* systems are calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the distal end (*Accufuser*) or PCA button (*Accufuser Plus*) is **32° C / 89.6° F** (normal skin temperature). Flow rate increases approximately 1% per 1° F / 0.56° C increase in temperature.

Fluid Viscosity:

The *Accufuser* and *Accufuser Plus* systems are calibrated using **5% Dextrose in Water (D5W)** as the infusate. Flow rate increases as fluid viscosity decreases (e.g., using sterile water as diluent will increase the flow rate by approximately 10%).

Head Height:

The *Accufuser* and *Accufuser Plus* systems are calibrated with **zero** head height. Increased head height will cause increased flow rate (e.g., +43 cm / +17" of head height will increase flow rate by approximately 12%).

USING THE LOCAL ANESTHESIA KIT

NOTES: All kit components are **latex-free** and **DEHP-free.**

Use the prep tray, designed to hold 300 mL, to transfer medication from the vials to the 60 cc transfer syringe.

1. Insert the Introducer approximately 3 - 5 cm away from the intraoperative site, and advance the Introducer into the surgical wound site.
2. Remove the stylet from the Introducer.
3. Insert the marked tip of the Catheter through the Introducer and into the surgical wound site.

   CAUTION: Do not withdraw the Catheter through the Introducer. Doing so may damage the Catheter or cause it to dislodge into the insertion site.
4. Remove the Introducer while holding the Catheter securely in place.

Important:

- To help avoid accidental needlesticks, follow your facility policies regarding safe use and disposal of medical sharps devices. Obtain prompt medical attention if injury occurs.
- Unless directed otherwise by your facility policies, do not reshield a used Introducer. Discard unshielded Introducer in an approved sharps collector.

5. Insert the Catheter into the Tuohy-Borst Adapter and tighten (omit this step if using an integral-hub catheter).
6. Using the 5 cc syringe, flush the catheter to verify patency.
7. Attach the Catheter/T-B Adapter to the *Accufuser* Infusion Set and tighten.
8. Secure the Catheter in place with Steri-Strip® closures or other securement device.
9. Apply dressing to the Catheter site.

FILLING THE *ACCUFUSER* MEDICATION RESERVOIR

CAUTION: As with any sterile product, use aseptic technique when preparing the *Accufuser* and *Accufuser Plus* systems for use.

1. Confirm the nominal flow rate and reservoir capacity prior to opening package.

   NOTE: Flow rates for the *Accufuser* are indicated on the medication reservoir housing and on the flow restrictor with a color-coded label (see the Technical Specifications section for a color code matrix). The basal flow rate, bolus volume and lock-out period for the *Accufuser Plus* are indicated on the medication reservoir housing and on the bolus (PCA) button. The *Accufuser Plus* does not use color-coded labels.
2. Place clamp between filter and filling port. Close clamp. Remove Luer cap from the filling port.
3. Fill a sterile transfer syringe with the medication to be dispensed into the medication reservoir.
4. Connect the filled syringe to the filling port and transfer the medication into the medication reservoir. (Repeat if necessary until desired volume of medication has been transferred into the medication reservoir.) Do not fill beyond the labeled capacity.
5. After the medication reservoir has been filled, disconnect the transfer syringe and replace the Luer cap on the filling port.

ACCUFUSER PRIMING AND DELIVERY

1. Place clamp between filter and distal end of tubing set. Leave clamp open.
2. Remove the female end cap on the distal Luer connector. The contents of the medication reservoir will flow toward the patient end of the set, expelling any air present in the system.
3. To prime the filter, hold it so the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air.

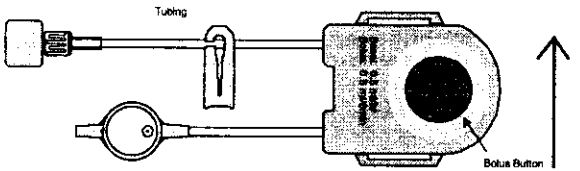
Items (a) - (e) for *Accufuser Plus* only:

Prime the PCA button reservoir as follows:

(a) Allow fluid to flow into the PCA button reservoir.

(b) Purge the air from the PCA button reservoir by depressing the bolus button.

(c) Allow fluid to refill the PCA button reservoir over the specified lockout time. After the PCA button reservoir has refilled, depress and release the bolus button to complete the priming operation and to remove any air in the tubing and PCA button reservoir. (To facilitate air expulsion and priming, place the PCA module and tubing as below illustration.) Repeat as needed until all air is purged from line.



PCA Button showing proper orientation for priming operation.

(d) Inspect the system to ensure that it is fully primed and all air has been purged.

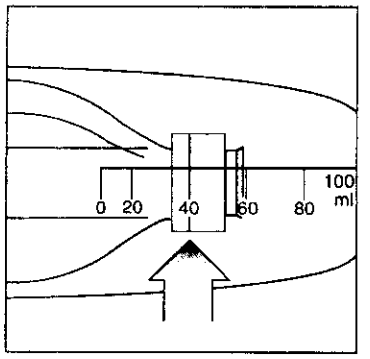
(e) Attach the PCA button to patient using wristband.

NOTE: The PCA button must be worn on the patient's skin to achieve proper operating temperature. (Refer to Operating Temperature in the Technical Specifications section for effect of temperature on flow rate.)

4. Confirm that the priming operation is complete and fluid is dripping from the distal end of the tubing at the expected flow rate (1 mL/hr = approximately 1 drop every 3 seconds).
5. In the event that the tubing does not completely prime, attach a stopcock to the distal Luer connector. Attach a syringe to the other side of the stopcock and pull plunger back to create suction.
6. After the system is fully primed, close the clamp on the tubing and connect the distal Luer to the patient's access device.
7. Tape the Luer to the patient's skin if using the *Accufuser* system. (Refer to Operating Temperature in the Technical Specifications section for effect of temperature on flow rate.)

INFORMATION FOR DAILY USE

- Use the clip to attach the medication reservoir to the patient's clothing (60 & 100 mL device only). A carry pouch is available for the 275 mL *Accufuser*.
- Use the *Accufuser* and *Accufuser Plus* Patient Quick Reference Card for patient training and reference during medication delivery.
- Do not immerse the *Accufuser* or *Accufuser Plus* in water or other fluids. When showering, the patient should keep the *Accufuser* or *Accufuser Plus* outside the shower or place it in a waterproof bag.
- During medication delivery, check for the following:
  - o The *Accufuser* or *Accufuser Plus* is emptying.
  - o There is no leakage from the *Accufuser* or *Accufuser Plus* system (i.e., connections, etc.).
  - o The catheter or tubing is not kinked.
  - o All connections are secure.
  - o The patient is not experiencing side effects, which may include but are not limited to:
    - · Increased pain
    - · Redness, swelling or discharge at the catheter or incision site
    - · Skin rash or hives
    - · Metallic taste in patient's mouth
    - · Light-headed or dizzy feeling
    - · Excitation or restlessness
    - · Excessive drowsiness
- To monitor medication delivery, read the position of the black ring on the piston against the graduated scale on the medication reservoir housing.



- If desired, the *Accufuser* or *Accufuser Plus* may be cleaned using a cloth dampened with water. To avoid damaging the device, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the *Accufuser* or *Accufuser Plus* system.

Manufactured for and distributed exclusively by:
McKinley, 4080 Youngfield Street, Wheat Ridge, CO 80033 USA
Telephone: 303-420-9569

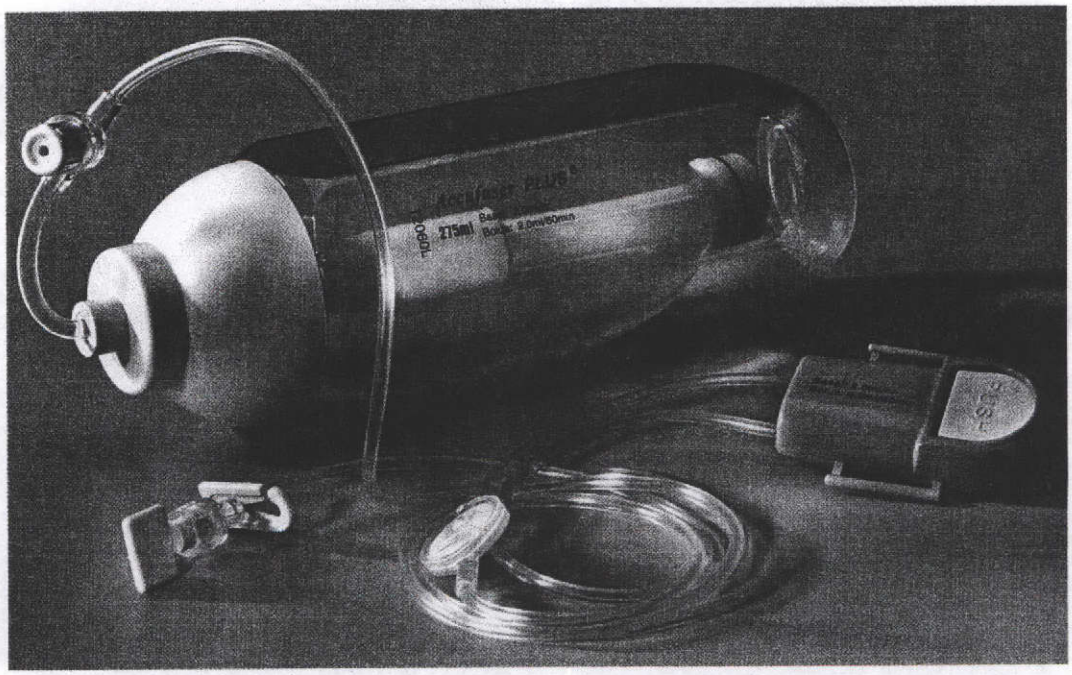
© 2002. All rights reserved. Accufuser is a registered trademark of McKinley. Steri-Strip is a registered trademark of 3M. U.S. Patent 6,024,724.

A4801151 P-6274-0 12/02

STERILE EO

New Breakthrough Technology!

The Only Disposable Infuser That Puts You [redacted]



ACCUFUSER™ Disposable Silicone Infuser

Optimize the clinical benefits of peripheral nerve blockade and surgical site infusion through the superior therapeutic control of Accufuser™ silicone balloon infusers. Accufuser and Accufuser Plus are the only disposable mechanical infusers that give you flexibility to fully manage safe, effective relief of post-operative pain.

Unique Piston For More Controlled Delivery
Accufuser stands apart from the rest with its patented piston for near-linear medication delivery. This innovative feature helps prevent sub-therapeutic dosing or toxic over-infusion.

Unequaled Choice in Basal/Bolus Options
No other disposable device matches Accufuser's flexibility to meet a variety of patient needs. Select from 8 basal rates, 3 bolus volume options (including 2.0 ml), and 3 lockout intervals to customize your patient's pain protocol.

Enhanced Control of Patient-Actuated Dosing
Only Accufuser Plus lets you combine continuous infusion with a range of optional bolus volumes and lockout intervals for better patient control of breakthrough pain. Preset parameters provide safety in the absence of clinician supervision.

Multi-Site Administration
McKinley's Y-Site administration set and multi-port catheter provide broad anesthesia coverage to better control incision pain and dual surgery sites.

Safe, Simple Set-Up
Unlike other disposable pumps, Accufuser fills quickly and easily without compromising sterile technique. After filling, the Accufuser system can be primed and ready for use in minutes. A 275 ml reservoir enables multi-day infusions with minimal follow-up.

Easy for Patients to Use
Monitoring Accufuser infusion is clearly intuitive. Patients and caregivers can confirm the device is properly operating with a simple check of its graduated markings.

Get the most out of disposable infusion technology. Choose Accufuser, the only disposable device that gives you full control to manage surgical pain.

ACCUFUSER™ Disposable Silicone Infuser

ACCUFUSER (Continuous only)*			
Model	Reservoir Volume (ml)	Basal Rate (ml/hr)	Maximum Duration (hr)
C0005M	100	0.5	200
C0010M	100	1	100
C0020M	100	2	50
C0050M	100	5	20
C0020L	275	2	138
C0040L	275	4	69
C0050L	275	5	55
C0080L	275	8	34
C0100L	275	10	28

ACCUFUSER and ACCUFUSER PLUS

Accuracy
100 ml reservoir: +/- 10% of nominal flow rate
275 ml reservoir: +/- 15% of nominal flow rate

Materials
Pet-G, ABS, polypropylene, silicone, PVC, polycarbonate, cellulose acetate, PTFE, acrylic. Latex-free.

ACCUFUSER PLUS (Continuous + Bolus)*						
Model	Reservoir Volume (ml)	Basal Rate (ml/hr)	Bolus Volume (ml)	Bolus Interval (min)	Max. Bolus Per Hour (ml)	Max. Hourly Volume (ml)
M1015M	100	1	1	15	4	5
M2015M	100	2	1	15	4	6
T2015M	100	2	2	15	8	10
M2060M	100	2	1	60	1	3
T2060M	100	2	2	60	2	4
T2015L	275	2	2	15	8	10
T2060L	275	2	2	60	2	4
T4030L	275	4	2	30	4	8
T4060L	275	4	2	60	2	6
T5015L	275	5	2	15	8	13
T5060L	275	5	2	60	2	7
T8015L	275	8	2	15	8	16
T8060L	275	8	2	60	2	10

* Additional Accufuser and Accufuser Plus models are available. Please contact your sales representative for information.

Manufactured for:
McKinley Infuser, LLC
631 Howard Street, Suite 202
San Francisco, CA 94105 USA
415.543.2196 (Voice) 415.543.5850 (Fax)
800.578.0555 (For Ordering and Customer Support)

CAUTION: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Erika Jordan

Subject: 510(k) Number K032642

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

BC FRN Class II 880.5725

Review: Patricia Cicerite GHDB 9/23/03
(Branch Chief) (Branch Code) (Date)

Final Review: Susan Runner 9/23/03
(Division Director) (Date)

Revised:4/2/03

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K032642

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

   Predicate devices: McKinley Spring Pump Disposable Infusion Pump - K990461
   Accufuser, Accufuser Plus, Standard Procedure Kit – K023098

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

   The indications/intended use, manufacturing and packaging of the modified have not changed from the predicate McKinley Spring Pump Disposable Infusion Pump (K990461). Both devices are indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. Both devices are also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The change was to increase the flow rates, reservoir size, and include procedure kits; modifications that were based on a previously approved device (K990461, K023098).

   The modifications are as follows:

   - Addition of flow rates up to 10 ml/hr (Available in previously cleared McKinley Spring Pump Disposable Infusion Pump - K990461).
   - Addition of a 275-mL reservoir size (Available in previously cleared McKinley Spring Pump Disposable Infusion Pump - K990461).
   - Addition of procedure kits containing supplies and/or accessories to facilitate setup and use of the Beeline system (kit is comprised of components that are devices exempt from premarket notification or devices found to be SE through the premarket notification process)

   A detailed description is provided on page 19.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

   Detailed comparison information can be found on pages 35 – 39.

5. A **Design Control Activities Summary** which includes:

5

a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
c) A declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Identification of Risk Analysis is provided on page 13.
Design Verification summary is provided on page 13.
Declaration of conformity is provided on page 13.

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Truthful and Accurate Statement provided on page 11.

510(k) Summary provided on page 15.

Indications for Use Enclosure provided on page 12.

Erika T. Jordan
(Reviewer's Signature)

9/22/03
(Date)

Comments
A concern was brought up by Pat Cricenti and Bill Burdick about the flow rate error of +/- 15% associated with this infusion pump. It was suggested that a caution statement be included in the labeling of the device explaining the possible variance in flow rate. The labeling for the predicate Accufuser pumps does contain the appropriate caution statement. McKinley will be contacted about this caution statement.
On Wednesday, September 17, 2003, Bill Burdick and I contacted Andrew Lamborne at McKinley Medical. He is out of the office until Sept. 22. He left the name and extension of Michelle Pratt to contact while he is away. Bill talked to her and informed her that the Caution statement needs to be included in the Instructions for Use of this device. He read the Caution statement word for word to her. He asked her to fax us a new copy of the Instructions for Use including the Caution statement. She said she would do that as soon as possible. The appropriate Caution statement reads as follows:

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Caution: Please be aware that the actual rate at which medication is delivered and the total amount of medication the patient receives can vary as much as +/- 15%, depending on the reservoir size and chosen flow rate. Please take the variance of the medication delivered into consideration in determining both the rate and duration of delivery of the medication in order to reduce the probability of an adverse event.

The fax of the updated Instructions for Use was received on September 17, 2003 as expected.

Revised:8/1/03

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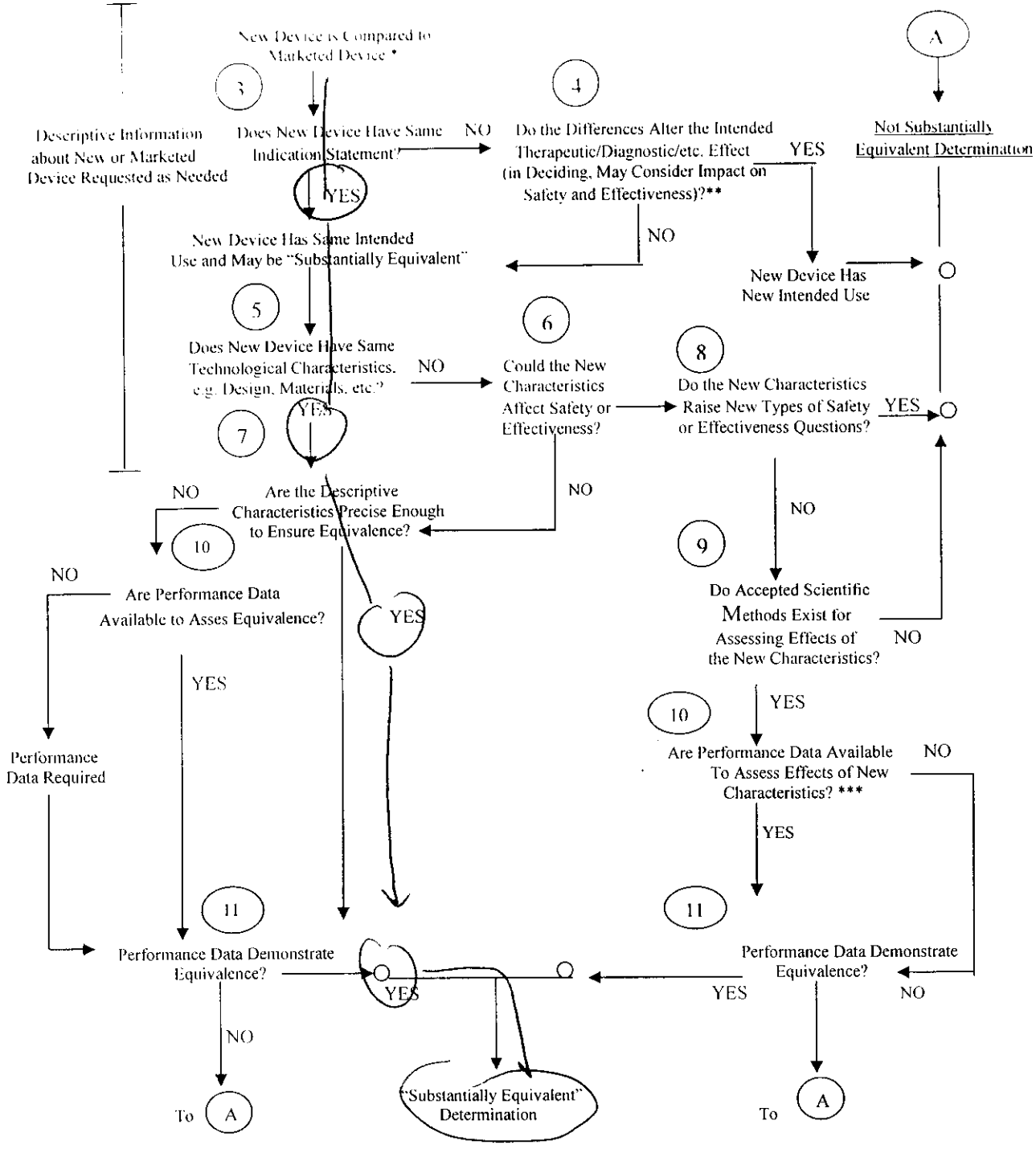
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K032642

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard**, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No

Reviewer: a. Jordan

Concurrence by Review Branch: AUG 28 2003

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Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K032642

Reviewer: Erika Jordan

Division/Branch: DAGID/GHDB

Device Name: Beeline System

Product To Which Compared (510(K) Number If Known): K990461, K023098

		YES	NO	
1.	Is Product A Device	Y		If **NO** = Stop
2.	Is Device Subject To 510(k)?	Y		If **NO** = Stop
3.	Same Indication Statement?	Y		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		N	If **YES** = Stop **NE**
5.	Same Technological Characteristics?			If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?				If **NO** = Request Data
11. Data Demonstrate Equivalence?				Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.
   The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the introperative site for postoperative pain management.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the

device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See Attached Review Memo.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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▲ **McKinley Medical LLLP**
4080 Youngfield Street
Wheat Ridge, CO 80033 USA
303.420.9569
Fax: 303.420.8585

McKinley

FAX

To:	Bill Burdick, Erica Jordan		
Company:	FDA	**Fax Number:**	301-594-2358
From:	Michelle Pratte		
Date:	9/17/03	**# Pages:**	5 (incl. Cover sheet)
CC:			
Subject:	Updated Instructions for Use for K032642		

Good Afternoon Bill and Erica,

Attached to this fax are the updated Instructions for Use for the special 510(k), Modication to McKinley Medical BeeLINE System, with the additional Caution statement that we discussed. Please contact me to affirm your receipt of this fax, and approval of the updated labeling.

Thank you,

Michelle Pratte

Phone: 303-420-9569 ext. 243

FAX FDA 510k doc

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motIV®

Clinician Directions for Use

DESCRIPTION

The beeLINE motIV system is a completely disposable, non-electronic device that uses sustained pressure to deliver a continuous infusion of medications or fluids.

The beeLINE motIV consists of a clear Medication Reservoir that connects to a dedicated, flowrate-controlling Infusion Set. A one-way valve prevents medication flow until the Infusion Set is attached to the Medication Reservoir. Once the beeLINE motIV infuser is filled with medication, it is ready for use. Simply attach the Infusion Set, open the clamp, prime the tubing, and start delivery. A special carrying pouch protects the infuser during use.

INDICATIONS FOR USE

The beeLINE system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The beeLINE system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

CONTRAINDICATIONS

The beeLINE system is contraindicated for:

- Infusion of blood and blood products.
- Infusion of insulin.
- Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death.
- Infusion of any solution that is incompatible with the fluid path materials.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- The beeLINE system is intended for single patient use only. Do not reuse. Do not resterilize.
- As with any infusion system, medications or fluids may interact with the components of the beeLINE system. Before use, consult the pharmaceutical manufacturer's precautions and guidelines, and ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- Do not fill the medication reservoir with more than the maximum reservoir volume. Filling beyond the maximum volume could damage the infuser and cause injury or fluid leakage.
- Do not attempt to disassemble the beeLINE infuser. Doing so could damage the infuser and cause injury or fluid leakage.
- Do not drop the infuser, strike it against hard objects or otherwise subject it to extreme physical stress. Doing so could damage the infuser and cause injury or fluid leakage. If the infuser is subjected to any trauma, it must be checked for damage or leakage before use. If any problems are detected, discontinue use.
- The device flow rate will vary according to the infusion set used. Use only the dedicated infusion sets authorized by McKinley for use with the beeLINE infuser.
- For models with an integrated set, the device flow rate is fixed and predetermined. Take care to select the appropriate nominal flow rate and reservoir size for the prescribed therapy.
- Do not remove the beeLINE infusion set after it has been connected to the infuser. Removal of a connected set may cause fluid leakage.
- Do not use a microwave, oven, or water bath to warm the contents of the beeLINE infuser.
- The beeLINE system should be stored in a clean, dry environment. It is the clinician's responsibility to instruct the patient on the proper storage of medications or fluids.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the beeLINE system.
- Do not use the beeLINE system if the packaging has been previously opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.*
- **CAUTION**: Please be aware that the actual rates at which medication is delivered and the total amount of medication the that patient receives can vary as much as +/- 15%, depending on the reservoir size and chosen flow rate. Please take the variance of the medication delivered into consideration in determining both the rate and duration of delivery of the medication in order to reduce the probability of an adverse event.
- **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

TECHNICAL SPECIFICATIONS

Fluid Path Materials:

Infuser: Polypropylene, silicone, butyl rubber, nitrile rubber. **Latex-free. DEHP-free.**

Filter:

1.2-micron air-eliminating filter

Operating Pressure:

6 psi average

Fill Volume:

Small infuser (BL1N00) = 100 mL + 10 mL optional overfill

Large infuser (BL2N00) = 275 mL + 20 mL optional overfill

System Residual Volume:

< 5 mL (includes medication reservoir and tubing set)

Flow Rates for Standard Sets:

0.6 to 8 mL/hr (use only flow sets approved by McKinley for use with the beeLINE motIV)

System Accuracy:

+/- 15% of nominal flow rate

Operating Temperature:

The system is calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the distal Luer is **86° F / 30° C** (skin temperature). Flow rate increases approximately 1% per 1° F / 0.56° C increase in temperature.

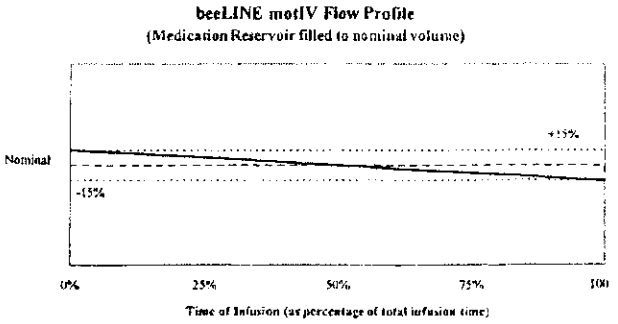
Fluid Viscosity:

The system is calibrated using **5% Dextrose in Water** (D5W) as the infusate. Flow rate increases as fluid viscosity decreases (e.g., sterile water will flow approximately 10% faster than D5W).

Head Height:

The system is calibrated with the infuser **18" / 45.7 cm** below the infusion site at the patient. Flow rate decreases approximately 6% for every 10" / 25 cm that the infuser is lowered.

Flow Profile:



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preparing the beeLINE system for use.

Note: The beeLINE Medication Reservoir should never be filled beyond the maximum fill volume capacity referenced in the Technical Specifications section.

1. Inspect the beeLINE package to confirm that it has not been opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.* Using aseptic technique, remove the beeLINE Infuser from its package. Place it on a flat work surface with the Inlet/Outlet Reservoir Port pointing up. Save the non-vented Luer cap and beeLINE Infusion Set for later use.
2. Remove and discard the vented Luer cap from the Inlet/Outlet Reservoir Port.
3. Fill the beeLINE Medication Reservoir using a transfer syringe or other calibrated filling device. Connect the Luer Lock of the transfer device to the Inlet/Outlet Reservoir Port. Confirm that the connection is secure, but do not over-tighten. While filling, grasp the Infuser securely to keep it from moving.

   Note: The Volume Remaining marks printed on the beeLINE Medication Reservoir provide approximate volume indication only and are not intended to be used for precise measurements.
4. After filling, disconnect the transfer device. Then attach the non-vented Luer cap to the Inlet/Outlet Reservoir Port, or connect the Infusion Set as instructed in the section "Connecting The Infusion Set."

   Note: To remove air from the beeLINE Medication Reservoir, refer to the "Priming and Delivery Instructions" for the Infusion Set you have selected.
5. Label the filled Infuser with the appropriate patient identification and instruction information.

   Note: The beeLINE Infuser may be filled and stored at 40°F / 4°C for up to one week. Prior to use, the beeLINE Infuser and its contents must return to room temperature.

CONNECTING THE INFUSION SET

Note: Connecting the set is not required for the large infuser with integrated set.

1. Use only the appropriate Infusion Set dedicated for use with the beeLINE motIV Infuser. Confirm the flow rate, which is listed on the packaging and the Infusion Set tag.
2. Using aseptic technique, remove the Infusion Set from its package. Close the Infusion Set On/Off Clamp.
3. Place the beeLINE Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up. Remove and discard the Luer cap from the Infuser if present.
4. Remove and discard the cap from the Infusion Set Connector that has an extended male Luer and is located nearest to the On/Off Clamp.
5. Using a quick, continuous motion, insert the Infusion Set Connector with the extended male Luer into the Inlet/Outlet

PRIMING AND DELIVERY INSTRUCTIONS

Note: The beeLINE System should be primed immediately before use. Do not store the **primed** beeLINE System for extended periods.

1. Examine the beeLINE Infuser for the presence of air bubbles. While rotating the Infuser, gently tap the bottom of the Infuser on your work surface until the small air bubbles have moved into a single bubble underneath the Inlet/Outlet Reservoir Port.
2. After the air bubbles are collected into a single bubble, place the beeLINE Infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up.
3. Remove the Luer cap located at the patient end of the beeLINE Infusion Set. Save the Luer cap for recapping if short-term storage is required.
4. Open the On/Off Clamp to allow the fluid flow to expel any air present in the beeLINE Medication Reservoir and to prime the Infusion Set.

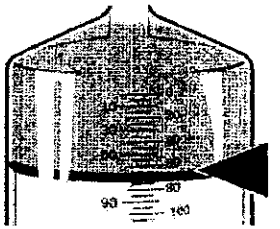
   IF THE INFUSION SET HAS A FILTER: To prime the filter, hold it so the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air.
5. When priming is complete, close the On/Off Clamp.

   Note: For short-term storage of primed Infusion Sets, reattach the Luer Cap to the Patient Access Connector.
6. Attach the primed Infusion Set to the patient's catheter.

   IF THE INFUSION SET HAS A FILTER: Tape the Patient Access Luer to the patient's skin. See the Technical Specifications section for appropriate operating temperature.
7. Open the On/Off Clamp to start infusion.

INFORMATION FOR DAILY USE

- Use the beeLINE Patient Quick Reference Card to assist with patient education and daily use instructions.
- Do not immerse the beeLINE Infuser in water or other fluids. When showering, the patient should keep the Infuser outside of the shower or place it in a waterproof bag.
- To protect the beeLINE Infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- During medication delivery, check for the following:
  - The beeLINE Infuser is emptying.
  - There is no leakage from the beeLINE System.
  - There is no air in the beeLINE System.
  - The beeLINE Infusion Set is not kinked.
  - All connections are secure.
  - The patient is not experiencing side effects, which may include but are not limited to:
    - Increased pain
    - Metallic taste in patient's mouth
    - Light-headed or dizzy feeling
    - Excitation or restlessness
    - Excessive drowsiness
- To monitor the infusion progress, open the carrying pouch from time to time and read the position of the dark ring against the graduation scale on the beeLINE Medication Reservoir.



- The beeLINE Infuser is a disposable device and does not require periodic maintenance. If desired, the Infuser may be cleaned using a cloth dampened with water. To avoid damaging the Infuser, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the beeLINE Infuser. Do not disable the beeLINE Infuser.

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Manufactured in Mexico for and distributed exclusively by:

McKinley, 4080 Youngfield Street, Wheat Ridge, CO 80033 USA

Telephone: 303-420-9569

Authorized Representative:

Priory Analysts, Ltd., P.O. Box 4030, Milton Keynes, MK13 0ZG UK

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motIV®

Local Anesthesia Kit
Clinician Directions for Use

DESCRIPTION

The beeLINE Local Anesthesia Kit is a completely disposable, non-electronic system that is designed specifically for pain management applications. The kit includes a beeLINE infuser, a catheter for infusion directly into the surgical site, and convenient accessories & prep materials to set up the device.

The beeLINE device uses sustained pressure to deliver a continuous infusion of medications. The infuser consists of a clear Medication Reservoir and a dedicated, flowrate-controlling Infusion Set.

INDICATIONS FOR USE

The beeLINE system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The beeLINE system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

CONTRAINDICATIONS

The beeLINE system is contraindicated for:

- Infusion of blood and blood products.
- Infusion of insulin.
- Infusion of critical or life-supporting medications whose stoppage, interruption, over-delivery or under-delivery would likely cause serious injury or death.
- Infusion of any solution that is incompatible with the fluid path materials.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- The beeLINE system is intended for single patient use only. Do not reuse. Do not resterilize.
- It is the responsibility of the clinician using the beeLINE system to ensure that the medications or fluids are used only according to the physician's infusion therapy prescription.

ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

- As with any infusion system, purge all air from the infusion line before connecting to the patient.
- Do not fill the medication reservoir with more than the maximum reservoir volume. Filling beyond the maximum volume could damage the infuser and cause injury or fluid leakage.
- Do not attempt to disassemble the beeLINE infuser. Doing so could damage the infuser and cause injury or fluid leakage.
- Do not drop the infuser, strike it against hard objects or otherwise subject it to extreme physical stress. Doing so could damage the infuser and cause injury or fluid leakage. If the infuser is subjected to any trauma, it must be checked for damage or leakage before use. If any problems are detected, discontinue use.
- The device flow rate will vary according to the infusion set used. Use only the dedicated infusion sets authorized by McKinley for use with the beeLINE infuser.
- For models with an integrated set, the device flow rate is fixed and predetermined. Take care to select the appropriate nominal flow rate and reservoir size for the prescribed therapy.
- Do not remove the beeLINE infusion set after it has been connected to the infuser. Removal of a connected set may cause fluid leakage.
- Do not use a microwave, oven, or water bath to warm the contents of the beeLINE infuser.
- The beeLINE system should be stored in a clean, dry environment. It is the clinician's responsibility to instruct the patient on the proper storage of medications or fluids.
- It is the responsibility of the clinician to ensure that the patient is educated in the proper use of the beeLINE system.
- Do not use the beeLINE system if the packaging has been previously opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.*
- **CAUTION**: Please be aware that the actual rates at which medication is delivered and the total amount of medication the that patient receives can vary as much as +/- 15%, depending on the reservoir size and chosen flow rate. Please take the variance of the medication delivered into consideration in determining both the rate and duration of delivery of the medication in order to reduce the probability of an adverse event.
- **CAUTION**: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

TECHNICAL SPECIFICATIONS

Fluid Path Materials:

Infuser: Polypropylene, silicone, butyl rubber, nitrile rubber. **Latex-free. DEHP-free.**

Set: PVC, polyethylene, acrylic, polycarbonate, silicone, glass, cellulose acetate, PTFE. **Latex-free. Set contains DEHP unless otherwise stated on product labels.**

Filter:

Fill Volume:

Small infuser (BL1N00) = 100 mL + 10 mL optional overfill

Large infuser (BL2N00) = 275 mL + 20 mL optional overfill

System Residual Volume:

< 5 mL (includes medication reservoir and tubing set)

Flow Rates for Standard Sets:

0.6 to 8 mL/hr (use only flow sets approved by McKinley for use with the beeLINE motIV)

System Accuracy:

+/- 15% of nominal flow rate

Operating Temperature:

The system is calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the distal Luer is **86° F / 30° C** (skin temperature). Flow rate increases approximately **1%** per 1° F / 0.56° C increase in temperature.

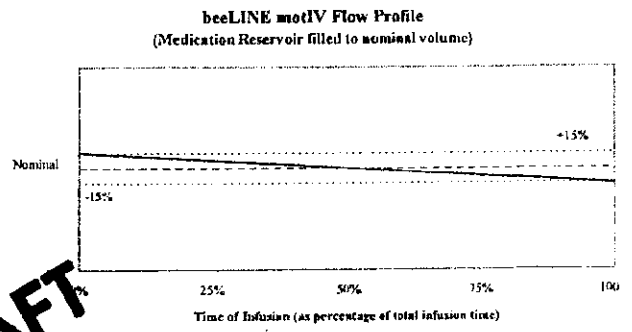
Fluid Viscosity:

The system is calibrated using **5% Dextrose in Water** (D5W) as the infusate. Flow rate increases as fluid viscosity decreases (e.g., sterile water will flow approximately 10% faster than D5W).

Head Height:

The system is calibrated with the infuser **18" / 45.7 cm** below the infusion site at the patient. Flow rate decreases approximately 6% for every 10" / 25 cm that the infuser is lowered.

Flow Profile:



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USING THE LOCAL ANESTHESIA KIT

NOTES: All kit components are **latex-free** and **DEHP-free**.

Use the prep tray, designed to hold 300 mL, to transfer medication from the vials to the 60 cc transfer syringe.

1. Insert the Introducer approximately 3 – 5 cm away from the intraoperative site, and advance the Introducer into the surgical wound site.
2. Remove the stylet from the Introducer.

introducer. Doing so may damage the Catheter or cause it to dislodge into the insertion site.

4. Remove the Introducer while holding the Catheter securely in place.

   IMPORTANT:

   - To help avoid accidental needlesticks, follow your facility policies regarding safe use and disposal of medical sharps devices. Obtain prompt medical attention if injury occurs.
   - Unless directed otherwise by your facility policies, do not reshield a used Introducer. Discard unshielded Introducer in an approved sharps collector.

5. Insert the Catheter into the Tuohy-Borst Adapter and tighten (omit this step if using a fixed-hub catheter).
6. Using the 5 cc syringe, flush the catheter to verify patency.
7. Attach the Catheter/T-B Adapter to the beeLINE Infusion Set and tighten.
8. Secure the Catheter in place with Steri-strips or other securement device.
9. Apply dressing to the Catheter site if desired.

FILLING THE MEDICATION RESERVOIR

CAUTION: As with any sterile product, use aseptic technique when preparing the beeLINE system for use.

NOTE: The beeLINE Medication Reservoir should never be filled beyond the maximum fill volume capacity referenced in the Technical Specifications section.

1. Inspect the kit to confirm that it has not been opened or damaged. *Sterility is not guaranteed for a product whose package has been opened or damaged.* Confirm the nominal flow rate and reservoir capacity prior to opening the package.
2. Remove the Luer cap from the filling port. For models with an integrated set, close the tubing clamp.
3. Fill the sterile transfer syringe with the medication to be dispensed.
4. Connect the filled syringe to the infuser filling port and transfer the medication into the Medication Reservoir. Repeat until the desired volume of medication has been transferred into the infuser.

   NOTE: The Volume Remaining marks printed on the beeLINE Medication Reservoir provide approximate volume indication only and are not intended to be used for precise measurements.

5. After the Medication Reservoir has been filled, disconnect the transfer syringe and replace the Luer cap on the filling port. If using a tamper-evident cover, snap the cover over the filling port.
6. For models with a separate set:
   a) Remove and discard the cap from the proximal connector (the connector with an extended male Luer and located nearest to the tubing clamp).
   b) Close the tubing clamp.

clockwise direction. [illegible] overtighten it.

7. Fill in the appropriate patient information on the medication label and affix to the Medication Reservoir.

PRIMING AND DELIVERY

1. Leaving the clamp closed, examine the Medication Reservoir for air bubbles. While rotating the infuser, gently tap the bottom on your work surface until the small air bubbles have moved into a single bubble underneath the tubing outlet.
2. After the air bubbles are collected into a single bubble, place the infuser flat on a work surface with the tubing outlet pointing up.
3. Remove the cap from the distal end of the set and open the tubing clamp. Fluid will flow toward the patient end of the set, purging air from the system. As fluid reaches the filter, hold it so the outlet (toward patient) points up and tap the filter to eliminate residual air.
4. Confirm that fluid is dripping from the distal end of the tubing at the expected flow rate (1 mL/hr = approximately 1 drop every 3 minutes).
5. When priming is complete, close the clamp.

   NOTE: For short-term storage of the primed infuser, reattach the cap to the distal Luer connector.

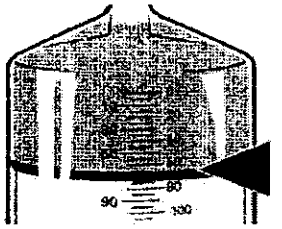
6. Attach the primed system to the patient's catheter.

   IMPORTANT: Tape the distal luer connector to the patient's skin. See the Technical Specifications section for appropriate operating temperature.

7. Open the clamp to start the infusion.
8. Place the infuser in the protective carrying pouch during the infusion.

INFORMATION FOR DAILY USE

- Use the beeLINE Patient Quick Reference Card to assist with patient education and daily use instructions.
- Do not immerse the beeLINE Infuser in water or other fluids. When showering, the patient should keep the Infuser outside of the shower or place it in a waterproof bag.
- To protect the beeLINE Infuser from damage during daily activities, use the specially designed protective carrying pouch at all times.
- During medication delivery, check for the following:
  - The beeLINE Infuser is emptying.
  - There is no leakage from the beeLINE System.
  - There is no air in the beeLINE System.
  - The beeLINE Infusion Set is not kinked.
  - All connections are secure.
  - The patient is not experiencing side effects, which may include but are not limited to:
    - Increased pain
    - Metallic taste in patient's mouth
    - Light-headed or dizzy feeling
    - Excitation or restlessness
    - Excessive drowsiness
- To monitor the infusion progress, open the carrying pouch from time to time and read the position of the dark ring against the graduation scale on the beeLINE Medication Reservoir.



- The beeLINE Infuser is a disposable device and does not require periodic maintenance. If desired, the Infuser may be cleaned using a cloth dampened with water. To avoid damaging the Infuser, do not use any cleaning agents. Take care to prevent entry of any foreign substances inside the beeLINE Infuser. Do not disable the beeLINE Infuser.

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