



# U.S. Department of Health & Human Services

---

Food and Drug Administration

## FOIA RESPONSE

**USER:** (acheng)

**FOLDER:** K982256 - 75 pages (FOI:10008079)

**COMPANY:** MCKINLEY, INC. (MCKINLEYA)

**PRODUCT:** PUMP, INFUSION, ELASTOMERIC (MEB)

**SUMMARY:** Product: OUTBOUND DISPOSABLE SYRINGE INFUSER  
OUTBOUND 2 DISPOSABLE PUMP

**DATE REQUESTED:** Mar 24, 2011

**DATE PRINTED:** Mar 24, 2011

**Note:** Releasable Version



# **Table of Contents**

<b>510KSUM_1 - 3 pages</b>	<b>1</b>
<b>510KSUM_2 - 3 pages</b>	<b>4</b>
<b>ADD TO FILE - AMBULATORY INFUSION PUMP - 3 pages</b>	<b>7</b>
<b>FOLDER - ELASTOMERIC VACUUM PUMP - 65 pages</b>	<b>10</b>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 3 1999

Ms. Suzanne Dennis  
Director, Regulatory Affairs/Quality Assurance  
McKinley, Incorporated  
4080 Youngfield Street  
Wheat Ridge, Colorado 80033 USA

Re: K982256  
Trade Name: Outbound Disposable Syringe Infuser/  
Outbound 2 Disposable  
Regulatory Class: II  
Product Code: MEB  
Dated: August 14, 1998  
Received: August 17, 1998

Dear Ms. Dennis:

This letter corrects our substantially equivalent letter of August 14, 1998, regarding the Indications for Use (enclosed).

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 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). 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.

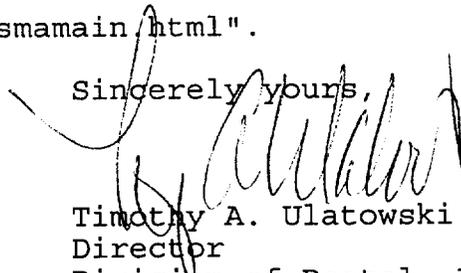
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Administration (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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

**Indications for Use**

510(k) Number (if known): K982256

Device Name: OutBound/OutBound II Disposable Infusion Pump

**Indications for Use:**

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

The OutBound pump 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

*Patricia Cruz*  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K982256



SEP 30 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Suzanne Dennis  
Director, Regulatory Affairs/Quality Assurance  
McKinley, Incorporated  
4080 Youngfield Street  
Wheat Ridge, Colorado 80033 USA

Re: K982256  
Trade Name: Outbound Disposable Syringe Infuser/  
Outbound 2 Disposable  
Regulatory Class: II  
Product Code: MEB  
Dated: August 14, 1998  
Received: August 17, 1998

Dear Ms. Dennis:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

Page 2 - Ms. Dennis

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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



69

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

Enclosure

Indications For Use

510(k) Number (if known) K982256

Device Name: Outbound Disposable Infuser

Indications For Use: The Outbound infuser is indicated for intravenous intra-arterial, subcutaneous, epidural, and (b)(4) (b)(4)

(b)(4) (b)(4) of medications or fluids requiring continuous delivery at controlled infusion rates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Patricia Cruz*

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

510(k) Number K982556

Prescription Use

OR

Over-The-Counter Use

(Optional Format 1-2-96)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 3 1999

Ms. Suzanne Dennis  
Director, Regulatory Affairs/Quality Assurance  
McKinley, Incorporated  
4080 Youngfield Street  
Wheat Ridge, Colorado 80033 USA

Re: K982256  
Trade Name: Outbound Disposable Syringe Infuser/  
Outbound 2 Disposable  
Regulatory Class: II  
Product Code: MEB  
Dated: August 14, 1998  
Received: August 17, 1998

Dear Ms. Dennis:

This letter corrects our substantially equivalent letter of August 14, 1998, regarding the Indications for Use (enclosed).

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 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). 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 (Pre-market 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug

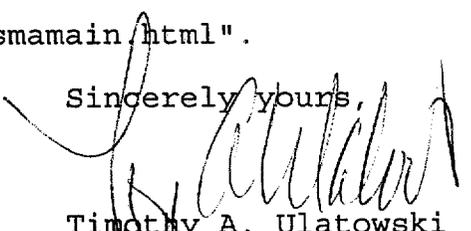
*Dme*  
*3-4-99*

Administration (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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain/html>".

Sincerely yours,



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

②

**Indications for Use**

510(k) Number (if known): K982256

Device Name: OutBound/OutBound II Disposable Infusion Pump

**Indications for Use:**

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

The OutBound pump 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

*Salvatore Crescente*  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K982256



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 30 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Suzanne Dennis  
Director, Regulatory Affairs/Quality Assurance  
McKinley, Incorporated  
4080 Youngfield Street  
Wheat Ridge, Colorado 80033 USA

Re: K982256  
Trade Name: Outbound Disposable Syringe Infuser/  
Outbound 2 Disposable  
Regulatory Class: II  
Product Code: MEB  
Dated: August 14, 1998  
Received: August 17, 1998

Dear Ms. Dennis:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

Page 2 - Ms. Dennis

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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



EG

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

Enclosure

Indications For Use

510(k) Number (if known) K982256

Device Name: Outbound Disposable Infuser

Indications For Use: The Outbound infuser is indicated for intravenous intra-arterial, subcutaneous, epidural, and (b)(4) (b)(4) (b)(4) of medications or fluids requiring continuous delivery at controlled infusion rates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Robert Chimento*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K982556

Prescription Use  OR Over-The-Counter Use

(Optional Format 1-2-96)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

To: Reviewer(s) - Name(s) HONG TRINH

Subject: 510(k) Number K952256/S1

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review \_\_\_\_\_
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- |   |   |  |
|---|---|--|
| Is this device subject to Postmarket Surveillance?                | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation?                | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Is this a prescription device?                                    | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO            |
| Was this 510(k) reviewed by a Third Party?                        | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |
| Special 510(k)?   | <input checked="" type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)?   | <input type="checkbox"/> YES            | <input checked="" type="checkbox"/> NO |

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

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

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

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):

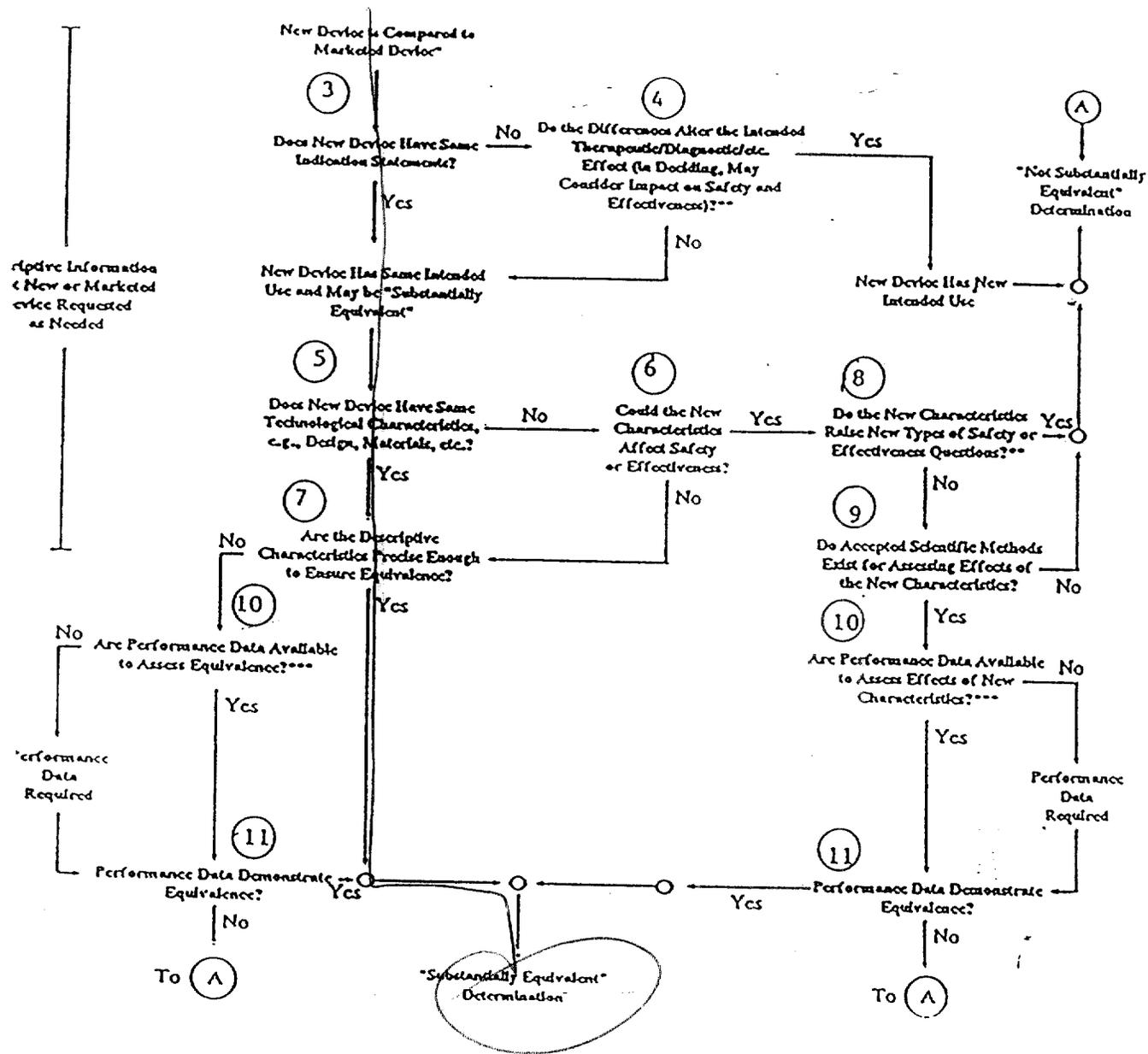
80 MEB Class II

By: Patricia Cuervo GHDB 9/30/98  
(Branch Chief) (Branch Code) (Date)

Reviewed by: Susan Puma 9/30/98  
(Division Director) (Date)

4

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



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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

50

**MEMO TO THE RECORD  
510(K) REVIEW**

**DATE:** 9/29/98  
**FROM:** Hung Trinh  
**DOCUMENT:** K982256  
**COMPANY NAME:** McKinley  
**DEVICE NAME:** OutBound

**OFFICE:** HFZ-480  
**DIVISION:**DDIG/GHDB

**Contact point:** Suzanne Dennis  
(303)420-9569

**NARRATIVE DEVICE DESCRIPTION**

**1. SUMMARY DESCRIPTION OF THE SUBMISSION UNDER REVIEW:**

The firm intends to expand their indication to include "...continuous infusion of a local anaesthetic directly into the intraoperative site for postoperative pain management." The firm has removed the previous claims regarding the (b) (4), (b) (5) (b)(4), (b)(5)

**2. INTENDED USE:**

The device is indicated for intravenous, intra-arterial, subcutaneous, and epidural infusion of medication or fluids requiring continuous delivery at controlled infusion rates.

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

**3. DEVICE DESCRIPTION:**

**A. Life-supporting or life-sustaining:** no

**B. Implant (short-term or long-term):** no

**C. Is the device sterile?** yes

**If yes, is sterility information provided?** (b) (4), (b) (5) (b)(4), (b)(5)

**D. Is the device for single use?** yes

**E. Is the device for prescription use?** yes

**If yes, is prescription labeling included?** yes

**F. Is the device for home use or portable?** portable

**Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary?** (b) (4), (b) (5) (b)(4), (b)(5)

**G. Does the device contain drug or biological product as a component?** no

**H. Is this device a kit?** no

**If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent?** n/a

**I. Software-driven:** no

**Estimated level of concern: (Major, Moderate, Minor)?** N/a

6/5

**Has the firm provided a hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? n/a**

Software version: n/a

- J. Electrically Operated:** no  
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? n/a
- K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):** none  
If applicable, has test data been provided to demonstrate conformance (protocol, data, and results)? N/a
- L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:**  
I-Flow Pain Buster (K980558)
- M. Submission provides comparative specifications**
- |                                  |    |
|----------------------------------|----|
| comparative in <u>vitro</u> data | no |
| performance data                 | no |
| animal testing                   | no |
| clinical testing                 | no |
| biocompatibility testing         | no |
- N. 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. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.**  
The firm has expanded their indications which is currently available in the predicate device, I-Flow PainBuster.
- O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based?** no  
If not, does the submission include a certification that such information will be made available to interested persons upon request? yes
- P. RECOMMENDATION:**  
I believe that this device is equivalent to: 80 MEB  
Classification should be based on:  
868.5725 Infusion Pump                      Class: II  
If the device is substantially equivalent to a class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) a summary description of the types of safety and effectiveness problems associated

7  
to



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 18, 1998

MCKINLEY, INC.  
4080 YOUNGFIELD ST.  
WHEAT RIDGE, CO 80033  
ATTN: SUZANNE DENNIS

510(k) Number: K982256  
Product: OUTBOUND  
DISPOSABLE  
SYRINGE INFUSER  
OUTBOUND 2

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

9/8



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

July 22, 1998

MCKINLEY, INC.  
4080 YOUNGFIELD ST.  
WHEAT RIDGE, CO 80033  
ATTN: SUZANNE DENNIS

510(k) Number: K982256  
Product: OUTBOUND  
DISPOSABLE  
SYRINGE INFUSER  
OUTBOUND 2

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (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. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

*Marjorie Shulman*  
Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

11  
10

**Indications for Use**

**510(k) Number (if known):** K982256

**Device Name:** OutBound/OutBound II Disposable Infusion Pump

**Indications for Use:**

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

The OutBound pump 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 \_\_\_\_\_**

12  
H

## COMPARISON OF PREDICATE DEVICES

Characteristics	McKinley OutBound	I-Flow PainBuster (K980358)	Explanation of Differences
Volume	100 cc	85 - 100ml	No significant variation.
Flow Rate	0.6 - 4.0 ml/hr	0.5 - 2.0 ml/hr	The physician through the use of available infusion sets controls flow rate. OutBound has infusion sets available which would provide various flow rates as prescribed by the physician.
Positive Pressure	12 psi	6-7 psi	The OutBound infusion pump has a maximum positive pressure capability of 12 psi but fluids do not typically deliver at that rate at the site. The pump delivery is controlled by (b)(4) (b)(4) (b)(4) (b)(4) Therefore, there are no significant differences.
Delivery Accuracy	+/- 10%	+/- 15%	no significant variation
Function	Vacuum	Elastomeric Pump	Both are well known and approved technologies. Vacuum pumps tend to provide more accurate delivery.

13  
12

**Comparison of Predicate Device (continued)**

Labeling Differences	McKinley OutBound	I-Flow PainBuster (K889358)	Explanation of Differences
Indications	Indicated for intravenous, intra-arterial, subcutaneous and epidural infusion of medications	The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.	PainBuster is intended to perform one function, while OutBound has multiple uses. The company offers a variety of pump models, which are marketed for different indications
Contraindications	Infusion of (1) blood, (2) insulin, (3) critical or life supporting medications and (4) solutions incompatible with the infuser set and pump materials.	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products. Not for chemotherapy drugs	All pumps function in the same basic manner. McKinley believes (b)(4) (b)(4) (b)(4) (b)(4) (b)(4)

Note

1. Equivalent information for the Sgarlato SurgiPeace (K898422) infusion pump could not be obtained however available marketing materials are enclosed.

14  
+3

**IFLOW PAINBUSTER  
REFERENCE MATERIAL**

15  
H

# PainBuster™

## INTENDED USE

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

## CONTRAINDICATIONS

This system is not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use. Not for chemotherapy drugs.

## WARNINGS

- Single Use Pump. Do not refill. Discard after use.
- Do not overfill the pump.
- Medications being used with this system should be used in accordance with instructions provided from the drug manufacturer.

## DIRECTIONS FOR USE

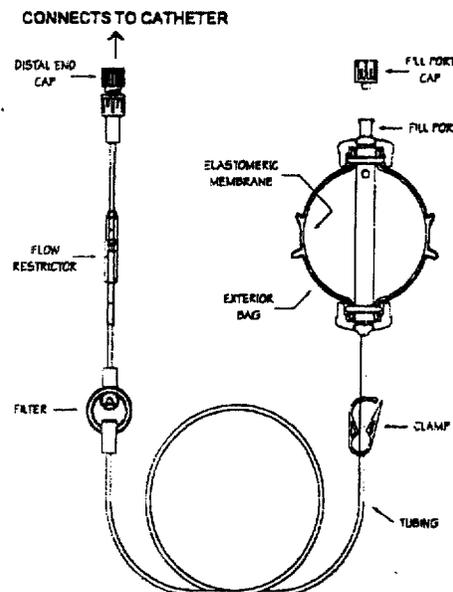
### Use Aseptic Technique

#### Filling the Elastomeric Pump

1. Close clamp on tubing.
2. Remove protective cap from filling port.
3. Attach filled syringe to the fill port and inject fluid into pump. Repeat if necessary. Do not fill over 65ml or 125ml as applicable (refer to table below). Replace fill port cap.
4. To prime the tubing, open the clamp on the tubing and allow fluid to fill the tubing. Close clamp until ready for use.

#### Placing the Catheter

1. Insert introducer needle through the skin (approximately 3-5cm away from wound site) then push introducer needle into the surgical wound site.
2. Insert the marked end of the catheter through the hub of the introducer needle into the wound site out the bevel of the needle.
3. Remove introducer needle while holding catheter tightly in place. Assure catheter placement in wound site.
4. Cut catheter to desired length.
5. Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed.
6. Attach the catheter connector to the pump tubing.
7. Tape catheter securely in place.
8. Apply appropriate dressing to catheter site.



16  
75

## Starting the PainBuster System

1. Open the clamp to begin delivering medication.
2. Secure flow restricter to skin and apply desired dressing.
3. Secure PainBuster Pump to the outer dressing with tape as desired.

### Delivery Time Information for the PainBuster

	P085005	P100020
NOMINAL FLOW RATE (ml/hr)	0.5	2.0
NOMINAL VOLUME (ml)	65	100
MAXIMUM VOLUME (ml)	65	125
RETAINED VOLUME (ml)	<5	<5
VOLUME (ml)		
APPROXIMATE DELIVERY TIME		
12 h		35
24 h/ 1 d		65
48 h/ 2 d	35	100
72 h/ 3 d	45	125
96 h/ 4 d	55	
120 h/ 5 d	65	
84 h/ 3.5 d		

Delivery accuracy is  $\pm 15\%$  (at a 95% confidence interval) of the labeled infusion period when delivering saline at 88° F (31° C).

### NOTES:

1. The infusion rate for each PainBuster Pump is indicated on each cap.
2. Actual infusion times may vary due to:
  - viscosity and/or drug concentration.
  - positioning the PainBuster pump above (increase) or below (decrease) the catheter site.
  - temperature: the PainBuster flow restricter (located distal to the filter) should be close to, or in direct contact with, the skin (31°C/88°F). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the PainBuster is used with the flow restricter at room temperature (20°C/68°F), delivery time will increase by 25%.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

**Infusion is complete when the PainBuster Pump is no longer inflated.**

### CAUTION

Federal (U.S.A.) law restricts this device to sale by or the order of a healthcare professional.

For Customer Service  
Call: 1.800.448.3569

A PRODUCT OF  
  
 I-FLOW CORPORATION  
 LAKE FOREST, CA 92630  
 U.S.A.

1301891B  
S/QB

17  
16

**SGARLATO LABORATORIES INC.  
REFERENCE MATERIAL**

18  
+7

**SGARLATO LABORATORIES, INC.**

250 ALMENDRA AVENUE, LOS GATOS, CA 95030 • 408/399-4638 • 800/421-5303 • FAX 408/354-4922

(b) (4) (b)(4)

Fax (b) (4) (b)(4)

Thank you for your recent inquiry about the PCIP.

The Pain Control Infusion Pump (formerly known as SurgiPEACE) is a disposable, ambulatory drug delivery system designed to provide continuous infusion of a local anesthetic directly into the surgical wound site for postoperative pain management. This form of therapy has proven to be extremely effective for pain relief and often reduces or eliminates the need for potent systemic analgesics. Since surgery is often used to correct problems, recovery is often painful and difficult. The PCIP is used to help alleviate pain and help speed the healing process. Both patient and physician response have been very positive for a variety of procedures. The device has also been used for numerous chronic pain treatments and for continuous epidural infusion.

The PCIP has a unique fail safe flow restrictor design which provides a continuous and constant flow rate. There are two models available. The flow rates are: 0.5 ml/hr & 2ml/hr. The 0.5ml flow rate has proven very effective for most small joint surgical procedures. The reservoir can contain up to 100 ml of medication. For larger or multiple wound sites, an additional "Y" adapter catheter can be inserted which will double the dosage. The Pump is lightweight and portable (approximately the size of a flashlight), and is easily attached to the patient for outpatient procedures. The device is easy to use and requires minimal staff or patient training. The PCIP package includes the pump, catheter, syringe, catheter introducer needle and carrying harness.

The PCIP is a very cost effective form of therapy compared to other pain control devices, drugs and/or treatments. The current list price is \$175.00. The physician's services for applying the device and catheter are reimbursable. The CPT code which most doctors use is 37202. Private insurance's have been reimbursing at approximately 85% of the billed amount. Surgery centers and hospitals have also been billing for the device.

Please feel free to call our customer service # at any time with further questions. 800.421.5303

Sincerely,

*Lisa Sgalko*

19  
18

# Finally, a Significant Reduction in Post-Surgical PAIN

## Take Aim at the Site of Post-Surgical Pain

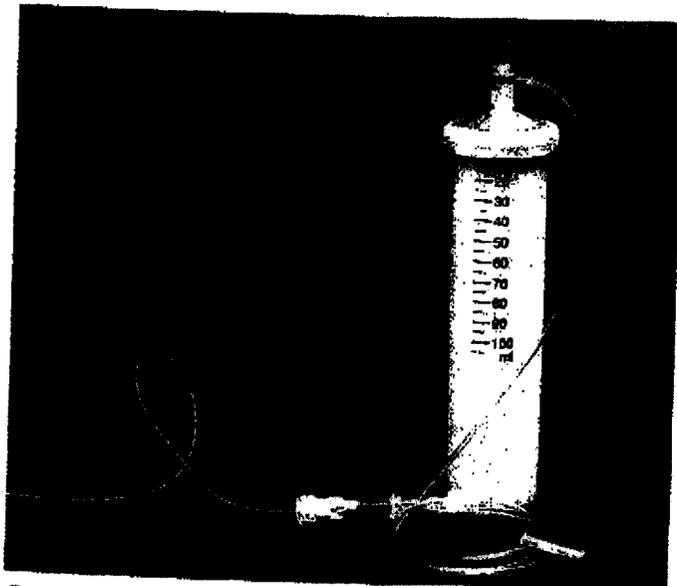
Now you can provide your patients with continuous infusion of a local anesthetic directly to the surgical site via Sgarlato Lab's new **SurgiPEACE™** system.

### Patient Benefits

- Reduced pain and increased comfort
- Improved compliance and satisfaction
- Reduced narcotic side effects
- Enhanced recovery period

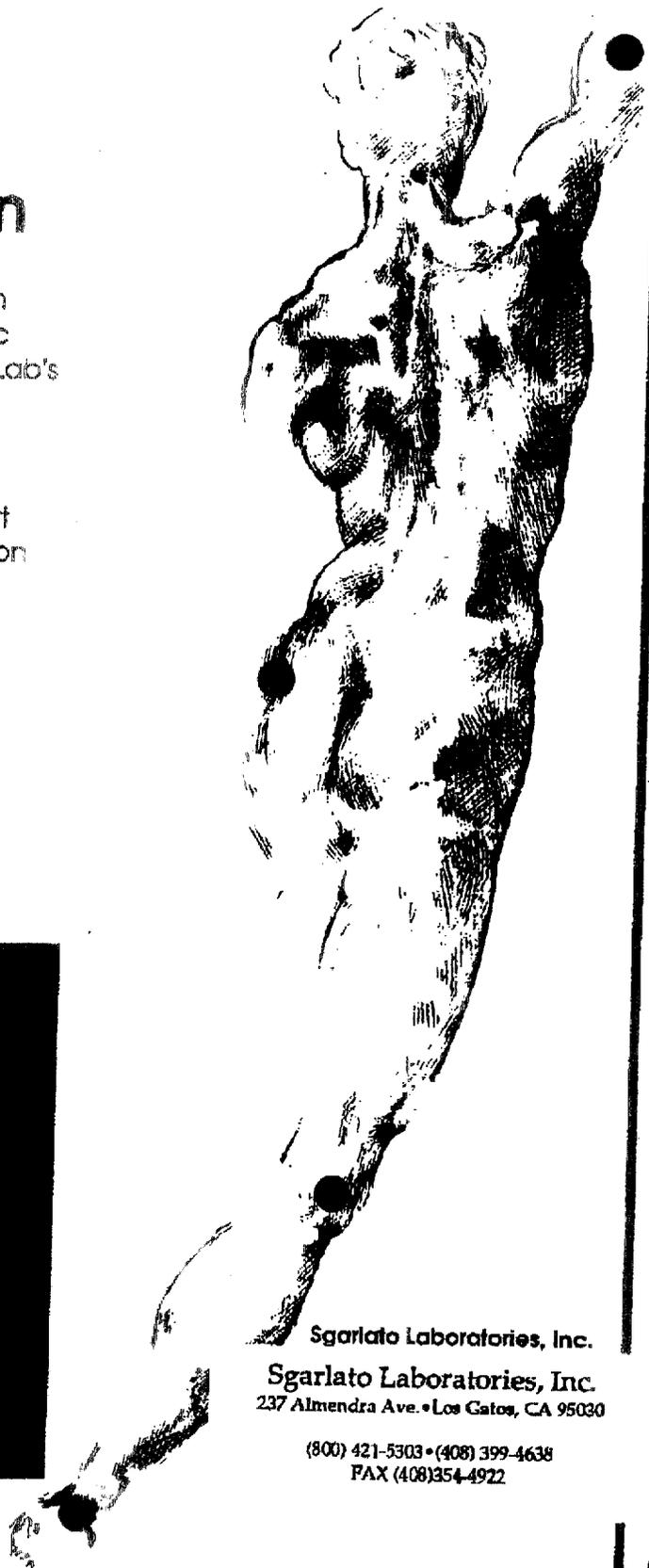
### Physician Benefits

- Safe, restricted dosing
- Easy to use
- Minimal patient in-servicing
- Improved patient relations
- Practice enhancement



Patent # 5,078,679

Patent # 4,997,420



Sgarlato Laboratories, Inc.  
**Sgarlato Laboratories, Inc.**  
 237 Alameda Ave. • Los Gatos, CA 95030

(800) 421-5303 • (408) 399-4638  
 FAX (408) 354-4922

19  
20

# Introducing SurgiPEACE Pain Control System

SurgiPEACE™ system utilizes a pump reservoir filled with a local anesthetic or the appropriate medication. The pump is connected to a microcatheter which is placed directly into the surgical wound site.

## SurgiPEACE™ Features and Benefits

### SAFE

- Continuous flow rate of approximately 0.5 ml per catheter.
- Restrictor (micro orifice) design prevents excessive delivery.
- Disposable after single use.

### EFFECTIVE

- Clinical studies indicate substantial reduction of pain.
- Allows earlier mobilization with less pain.
- Many potential applications for pain management.

### PRACTICAL

- Lightweight and portable
- Fully self contained

### COST EFFECTIVE

- Low cost
- May facilitate earlier patient discharge from hospital
- Should facilitate outpatient surgical procedures

### SurgiPEACE™ kit includes:

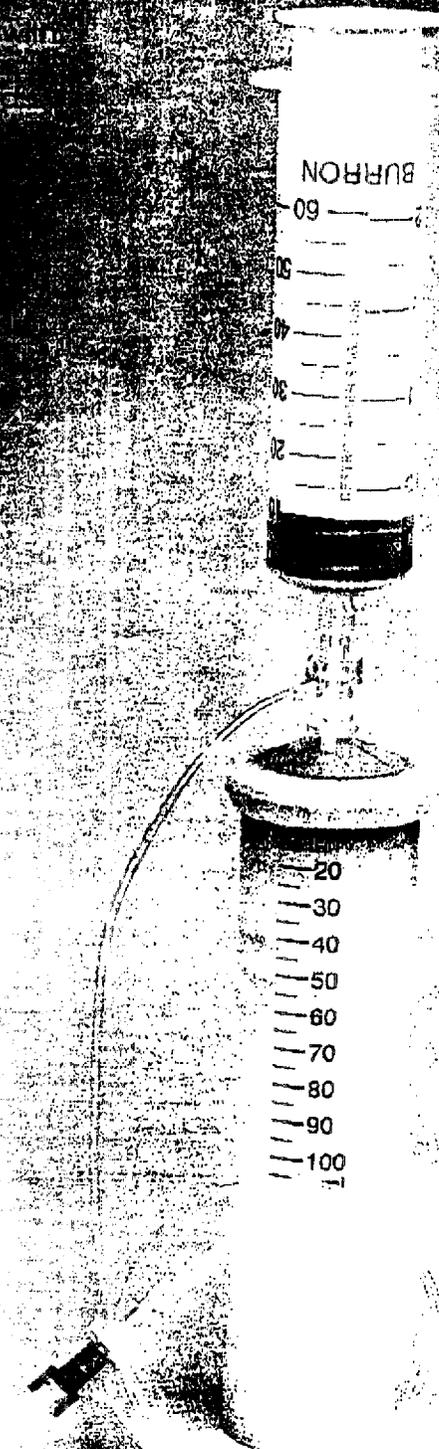
Drug reservoir pump (100 cc capacity), draw-up syringe with needle, introducer needle, flow regulator and catheter.

*\*Optional accessory kit includes additional flow regulator and catheter.*

**Sgarlato Laboratories, Inc.**

Sgarlato Laboratories, Inc.  
237 Alameda Ave. • Los Gatos, CA 95030

(800) 421-5303 • (408) 399-4638  
FAX (408) 354-4922



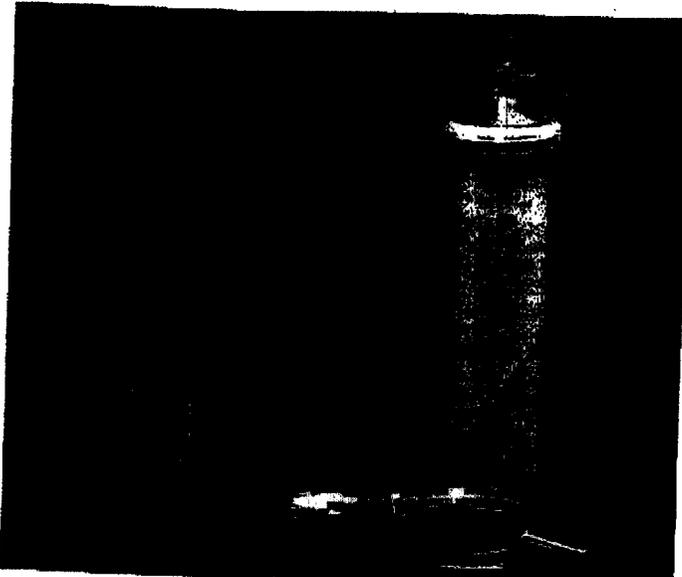
21  
20

# A Significant Improvement in Portable Infusion

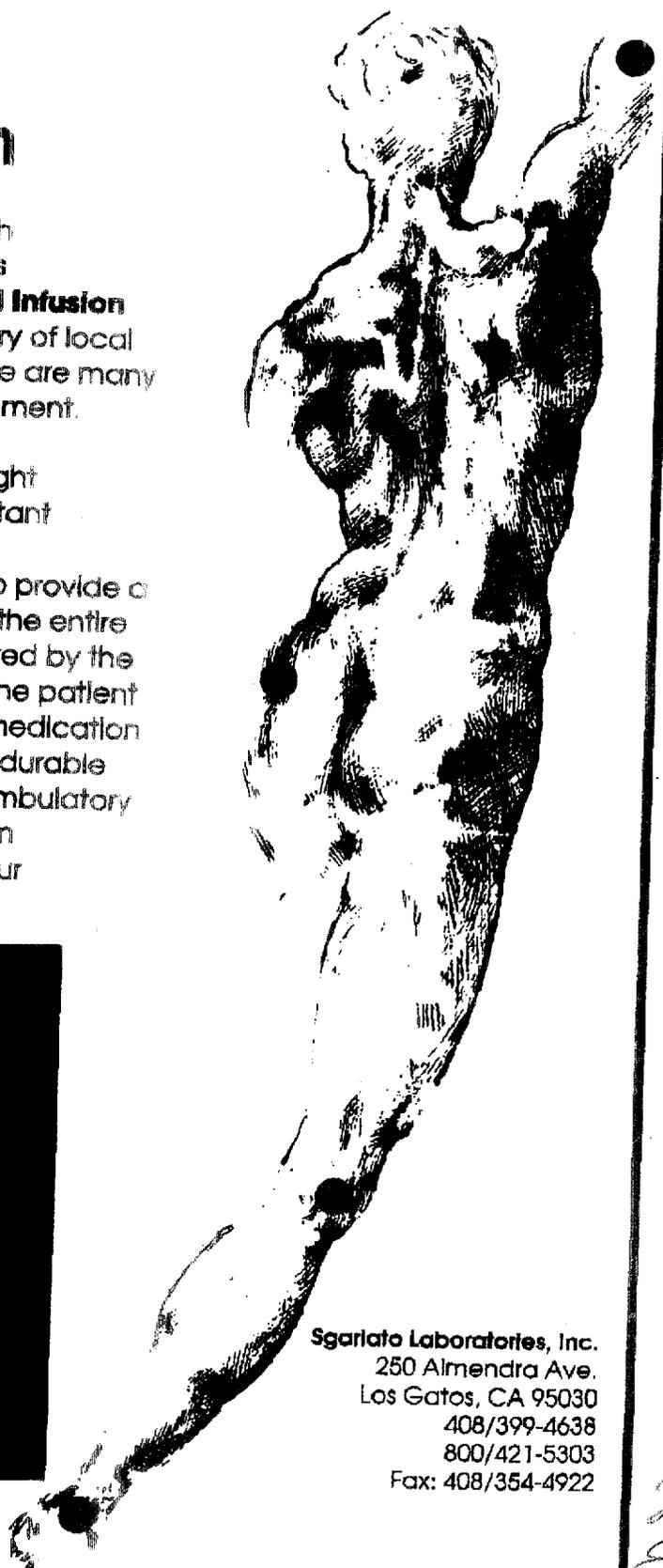
## Take Aim at the Site of Pain

Now you can provide your patients with safe, reliable, and accurate continuous infusion via Sgarlato Lab's **Pain Control Infusion Pump** system. PCIP is suitable for delivery of local anesthetic directly to the pain site. There are many potential applications for pain management.

The PCIP system is a complete, lightweight disposable device which provides constant internal pressure via a unique precision compression spring and a flow resistor to provide a consistent infusion flow rate throughout the entire course of therapy. The flow rate is selected by the physician and cannot be changed by the patient thus ensuring safety and efficacy. The medication reservoir is constructed of a high quality durable and stable plastic which is suitable for ambulatory use. This simple and practical system is an excellent low cost option for many of your pain treatment needs.



Patent # 4,997,420



Sgarlato Laboratories, Inc.  
250 Alameda Ave.  
Los Gatos, CA 95030  
408/399-4638  
800/421-5303  
Fax: 408/354-4922

22  
21

**Safe and Accurate**

- Consistent and reliable flow rate throughout therapy via a precision compression spring.
- Tamper resistant design and unique flow restrictor prevent excess drug delivery and rate manipulation.
- Sterile "closed" system design with integrated tubing reduces risk of contamination.
- Disposable after single use.

**Simple and Practical**

- Easy to use. System is not gravity dependent and does not require drop counting, rate setting or electronic pump programming.
- Minimal patient and staff training.
- No cords, outlets, batteries or I.V. poles needed.
- Lightweight and compact design encourages patient compliance.

**Flexible**

Currently there are three flow rates available.

Model #	Flow Rate	Max Volume	Infusion Time
SP500	0.5 ml/hr	100 ml	8 days
SP1000	1 ml/hr	100 ml	4 days
SP2000	2 ml/hr	100 ml	2 days

**Reliable and Durable**

- Outer markings on barrel show exactly how much fluid is in the reservoir at any point in time.
- Durable hard plastic pump design minimizes possibility of pump being damaged or crushed, especially for long term use.
- All polypropylene housing provides for greater drug stability and less sensitivities compared to elastomeric pumps. Drug stability information is available.

**Cost Effective**

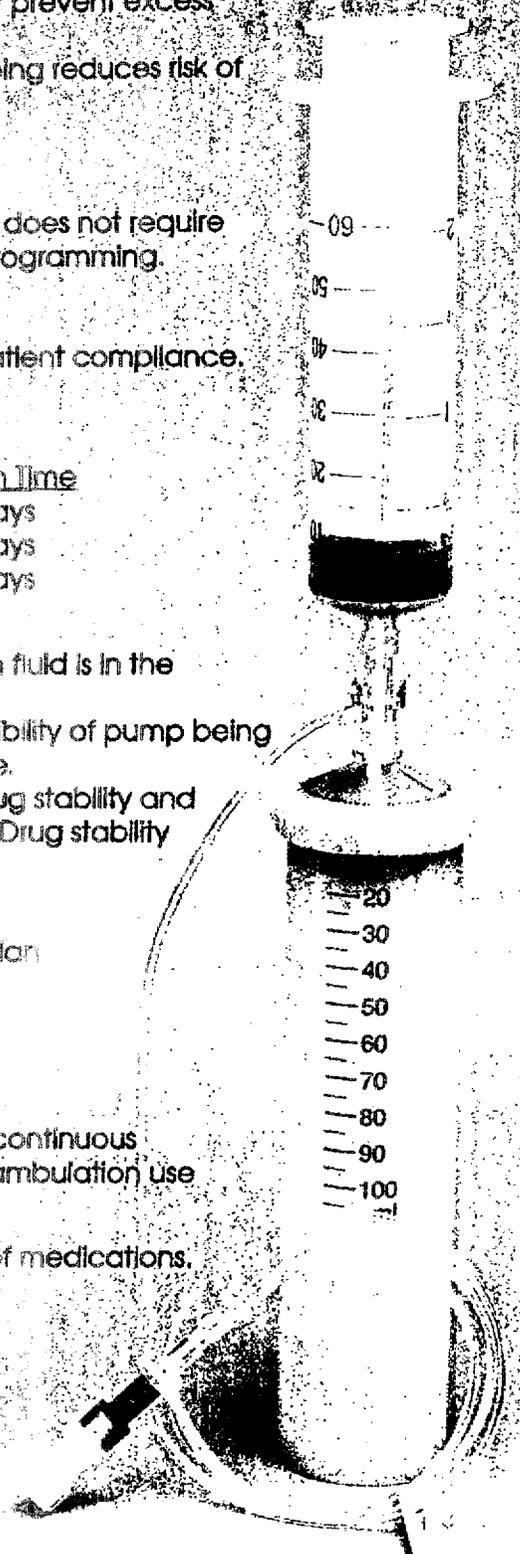
- Reduces or eliminates potentially expensive clinician intervention time.
- Low cost alternative to other more costly forms of pain treatment.
- Insurance billing available

**Indications and Usage:** For patients requiring slow continuous administration of medication. It is convenient for ambulation use for inpatients, outpatients or home care.

**Contraindications:** Not designed for rapid infusion of medications.

**Kit Options:** Catheter, needle, catheter connector, "Y" adapter for multiple catheters.

**Sgarlato Laboratories, Inc.**  
 237 Almendra Ave.  
 Los Gatos, CA 95030  
 408/399-4638  
 800/421-5303  
 Fax: 408/354-4922



23  
22

## SURGIPEACE PATIENT INSTRUCTIONS

The SurgiPEACE Pain Control System is a portable infusion pump designed to deliver medication directly to the surgical site for management of pain.

### How the System Works

SurgiPEACE administers local pain medication directly to the pain site via a tiny tube which is placed inside the wound by the physician during surgery. Pain relief is provided directly where it is needed. This is an alternative to other forms of therapy such as pain killers and narcotics taken orally which go throughout the entire body and sometimes cause side effects such as drowsiness, disorientation, nausea or other adverse reactions.

SurgiPEACE is comprised of a reservoir with internal spring pressure, tubing and a very precise flow regulator. The device has been filled with medication to flow continuously for a specific period of time. The system should remain completely intact for the duration of the period. Do not remove the blue cap or disconnect the device in any way.

### If Complications Arise

If you experience any problems with the SurgiPEACE unit such as leakage, the device becoming disconnected, the tube pulling out of the wound site, or if you experience discomfort or excessive pain, call your physician immediately. He/she may prescribe supplemental medication if necessary.

There is a white clamp on the thicker tubing to restrict the fluid flow if necessary. This should be done only upon the direction of your doctor. As a general rule, you do not have to do anything with the unit because it is fully self contained and automatic.

A full syringe will last approximately 2 days. You may remove all tape and pull the tubing out when the syringe is empty. Place all tubing and the syringe in a ziploc bag and bring it with you to your first office visit following your surgery.

24  
23

# Pain Control Infusion Pump

## Pain Control System

### DESCRIPTION

The Pain Control Infusion Pump is a complete, lightweight, disposable device which uses a constant internal pressure to infuse medication for control of pain. The system is designed to deliver medication continuously into the surgical wound site over the infusion period.

### INDICATIONS

The system is indicated for the relief of pain in patients following surgery, by the continuous administration of medication into the wound site. It is convenient for use by ambulatory patients.

### CONTRAINDICATIONS

Not intended for intravenous infusion.

### WARNINGS

**DISPOSABLE** - Destroy after single use. Do not refill or sterilize.  
Do not overfill device.  
Follow drug manufacturer's instructions for the medication being used.

### CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

### DIRECTIONS FOR USE:

Use Aseptic Technique.

### FILLING RESERVOIR PUMP

1. Close on/off clamp of medication tubing.
2. Remove protective cover from female luer lock filling port and discard.
3. Attach 60 ml syringe without needle to filling port at the top of the Pump Reservoir (refer to figure 1.). Fill reservoir with up to 100 ml of medication.
4. Once filling is complete, remove syringe. Securely attach blue replacement cap to filling port to maintain a sterile filling port.

### PRIMING SYSTEM (refer to figure 3a.)

1. Attach clear connector to medication catheter by pushing catheter into connector as deeply as possible. Twist connector as tightly as possible, use **MAXIMUM HAND FORCE** to screw connector components together to assure that the catheter will not pull out. It is almost impossible to constrict the catheter flow by maximum tightening.
2. Hold system reservoir and filter in upright position. Loosen proximal luer connector (green) to allow trapped air to exit.
3. Open on/off clamp (solution will automatically begin to flow into tubing and catheter). (Tighten proximal luer connector when fluid flow without air reaches connector.)
4. Hold the filter vertically and tap filter lightly to remove air bubbles.

5. Keep priming until all air has been purged from tubing, filter and catheter.
6. Allow 10 minutes before placing catheter in patient to see medication drops flow to the end of the medication catheter. If flow is not seen, attempt priming with 60 ml syringe filled with 10 ml or more of medication. Clamp off tubing with pinch clamp. Disconnect proximal luer connector and attach distal connection to syringe. Aspirate air bubbles and then force medication distally until drops of medication are seen at distal end of medication catheter. If flow is not seen, discard unit and repeat above steps with new Pain Control Infusion Pump unit. If flow is seen, reattach proximal connector and release pinch tubing clamp.

### PLACING CATHETER (refer to figure 2.)

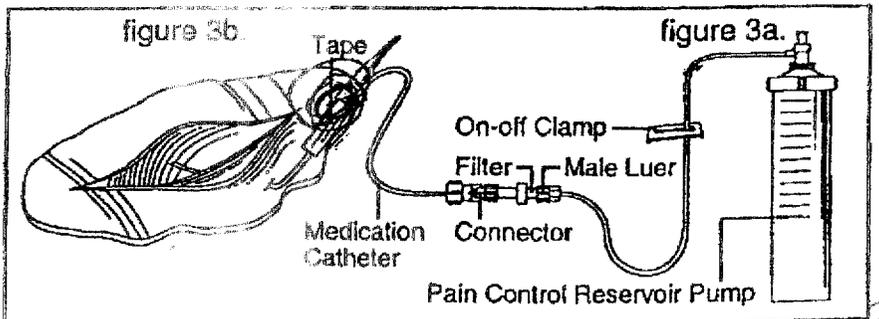
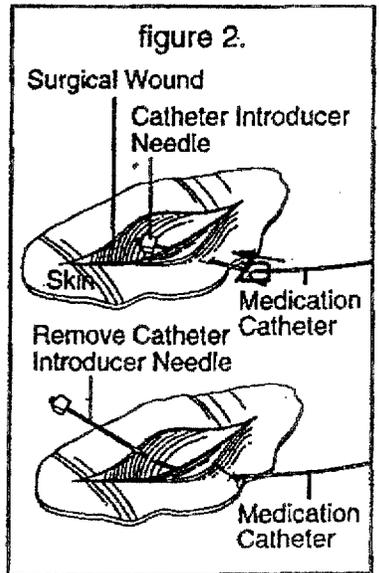
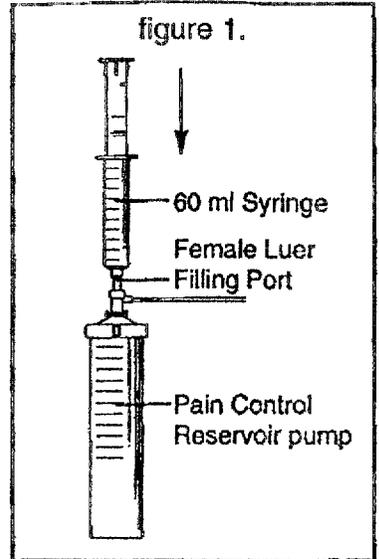
**NOTE:** Prime system completely prior to placing catheter.

### METHOD A: FROM INSIDE THE WOUND

1. Push introducer needle from the surgical wound site subcutaneously and puncture through skin at a desired location away from the surgical wound site.
2. Thread open end of catheter through the tip of the catheter introducer needle at the puncture site until the catheter is seen in the surgical wound site.
3. Place the end of the catheter in an appropriate location (not in a vessel) within the surgical wound site.
4. Tape catheter to the skin to prevent the catheter from pulling out of the wound site. It is most effective to tape in a linear parallel manner to the catheter (refer to figure 3.)
5. Remove introducer needle from wound site leaving catheter in place and dispose of needle in accordance with institutional protocol.

### METHOD B: INSERTION THROUGH SKIN

1. Puncture introducer needle through the skin at a desired location external to the surgical wound site; push the introducer needle subcutaneously into the surgical wound site.
2. The catheter is left free, unattached from the connector. Push catheter into the hub end of the needle and allow catheter to exit at the needle tip into the surgical wound site.
3. Remove introducer needle and tape catheter as described in Method A steps 4 and 5 above.
4. Attach catheter to clear connector per Priming System Procedure Step 1.



Manufactured for:  
**SGARLATO LABORATORIES, INC.**  
237 ALMENDRA AVE.  
LOS GATOS, CA 95030  
Phone 1-800-421-5303  
1-408-399-4638  
Fax 1-408-354-4922

25  
24

**ABBREY. PAIN CONTROL INFUSION PUMP INSTRUCTIONS**

Additional information is provided inside the sterile kit.

**IMPORTANT:** Use aseptic technique.

**RECOMMENDED:** Administer prophylactic antibiotic.

**FILLING RESERVOIR PUMP:**

1. Disconnect flow regulator from tubing at green male luer.
2. Close on/off clamp at the very end of tubing (next to green male luer).
3. Draw medication into 60 ml syringe. Remove air bubbles.
4. Remove and discard protective cap on top of reservoir filling port.
5. Attach 60 ml syringe without needle to reservoir filling port and load up to 100 ml of medication.
6. Remove syringe and attach blue replacement cap to filling port.
7. Prime reservoir and tubing by briefly opening clamp to let air bubbles out.
8. Connect flow filter to tubing. Do not tighten excessively. Open clamp.

**PLACEMENT OF CATHETER:**

1. Puncture blue introducer needle through the skin external to the surgical wound site. Push needle subcutaneously into the wound cavity.
2. Feed micro catheter through needle and allow catheter to exit at the needle tip into the wound at the desirable surgical plane.  
**IMPORTANT:** Do not put catheter in blood vessel.
3. Remove and discard needle, leaving catheter in place.
4. Tape catheter to body very near to the insertion site utilizing the 3-4 loop technique in order to keep catheter securely in place.
5. Insert catheter as deeply as possible (apx. 1/2 inch) into connector. Twist connector as **TIGHTLY AS POSSIBLE** to assure that catheter will not pull out.
6. Tape connector below patient's knee (if procedure is below the knee). **RECOMMENDED:** Place gauze pad between body and connector for comfort.
7. Attach carrying harness to reservoir. Patients can wear or carry device however they prefer.

26  
28

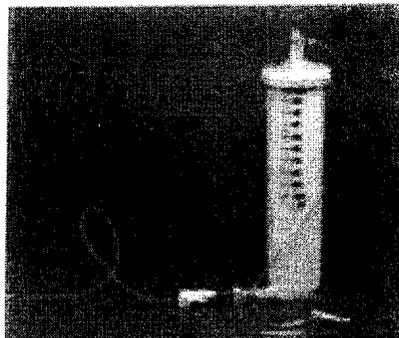


## A Significant Improvement in Portable Infusion Take Aim at the Site of Pain

- [About Sgarlato Labs](#)
- [Products](#)
- [Order Form](#)
- [Educational Workshops](#)
- [Email Us!](#)

Now you can provide your patients with safe, reliable, and accurate continuous infusion via Sgarlato Lab's **Pain Control Infusion Pump** system. PCIP is suitable for delivery of local anesthetic directly to the pain site. There are many potential applications for pain management.

The PCIP system is a complete, lightweight disposable device which provides constant internal pressure via a unique precision compression spring and a flow resistor to provide a consistent infusion flow rate throughout the entire course of therapy. The flow rate is selected by the physician and cannot be changed by the patient thus ensuring safety and efficacy. The medication reservoir is constructed of a high quality durable and stable plastic which is suitable for ambulatory use. This simple and practical system is an excellent low cost option for many of your pain treatment needs.



Next ⇨

---

Sgarlato Laboratories, Inc., 237 Alameda Ave., Los Gatos, CA 95030  
(800) 421-5303 • (408) 354-4922

---

27  
26



## Pain Management Pain Control Infusion Pump *Continued*

● **About Sgarlato Labs**

● **Products**

● **Pain Management**

● **Order Form**

● **Educational Workshops**

● **Email Us!**

**Safe and Accurate**

- Consistent and reliable flow rate throughout therapy via a precision compression spring.
- Tamper resistant design and unique flow restrictor prevent excess drug delivery and rate manipulation.
- Sterile "closed" system design with integrated tubing reduces risk of contamination.
- Disposable after single use.

**Simple and Practical**

- Easy to use. System is not gravity dependent and does not require drop counting, rate setting or electronic pump programming.
- Minimal patient and staff training.
- No cords, outlets, batteries or I.V. poles needed.
- Lightweight and compact design encourages patient compliance.

**Flexible**

Currently there are two flow rates available.

<u>Model#</u>	<u>Flow Rate</u>	<u>Max Volume</u>	<u>Infusion Time</u>
PCIP 500	0.5 ml/hr	100 ml	8 days
PCIP 2000	2 ml/hr	100 ml	2 days

**Reliable and Durable**

- Outer markings on barrel show exactly how much fluid is in the reservoir at any point in time.
- Durable hard plastic pump design minimizes possibility of pump being damaged or crushed, especially for long term use.
- All polypropylene housing provides for greater drug stability and less sensitivities compared to elastomeric pumps. Drug stability information is available.

**Cost Effective**

- Reduces or eliminates potentially expensive clinician intervention time.
- Low cost alternative to other more costly forms of pain treatment.
- Insurance billing available in some areas. Please call for details.

**Indications and Usage:** For patients requiring slow continuous administration of medication. It is convenient for ambulation use for inpatients, outpatients or home care.

**Contraindications:** Not designed for rapid infusion of medications.

**Kit Options:** Catheter, needle, catheter connector, "Y" adapter for multiple catheters.



Sgarlato Laboratories, Inc., 237 Almendra Ave., Los Gatos, CA  
95030  
(800) 421-5303 • (408) 354-4922

28  
27

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

July 22, 1998

MCKINLEY, INC.  
4080 YOUNGFIELD ST.  
WHEAT RIDGE, CO 80033  
ATTN: SUZANNE DENNIS

510(k) Number: K982256  
Product: OUTBOUND  
DISPOSABLE  
SYRINGE INFUSER  
OUTBOUND 2

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (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. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

29  
28



F. Reviewer(s) - Name(s) HUNG TRINH

Subject: 510(k) Number K982256

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

- Refused to accept.
- Requires additional information (other than refuse to accept). *phone hold*
- Accepted for review \_\_\_\_\_
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to 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)?  YES  NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

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

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

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):

Review: Peterson Cuervo GNDB 7/22/98  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)

30  
29



MEMORANDUM

Reviewer: Hung Trinh  
Date: 7/21/98

Division: GHDB/DDIGD  
Mail code: HFZ-480

Control number: K982256  
Company: McKinley  
Device name: Outbound  
Contact person: Suzanne Dennis (303)420-9569 ext 216

Summary of telephone conversation:

I contacted Ms. Dennis and told her that the predicate devices that (b)(4), (b)(5)

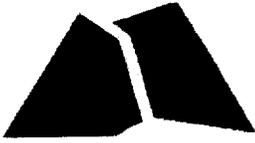
(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5) (b)(4), (b)(5). Ms. Dennis understands that the submission will be placed on hold pending the receipt of the additional information.

*Hung Trinh*

32  
31  
30



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

# McKinley

**FAX**

To: Hung TRINH  
Company: FDA  
From: Suzanne Dennis  
Date: 7/21/98  
CC:  
Subject: Predicate device

---

Fax Number: 301/480-3002

# Pages: 3

*Per our conversation. Hope this helps.*

*- 2nd FAX  
More Predicate info*

---

33  
34

Compare volume  
flow rate  
pressure  
route of administration

SE PCIP K898422

K930538

**Starting the PainBuster System**

1. Open the clamp to begin delivering medication.
2. Secure flow restricter to skin and apply desired dressing.
3. Secure PainBuster Pump to the outer dressing with tape as desired.

**Delivery Time Information for the PainBuster**

	P065005	P100020
NOMINAL FLOW RATE (ml/hr)	0.5	2.0
NOMINAL VOLUME (ml)	85	100
MAXIMUM VOLUME (ml)	85	125
RETAINED VOLUME (ml)	<5	<5
VOLUME (ml)		
APPROXIMATE DELIVERY TIME		
12 h		35
24 h / 1 d		65
48 h / 2 d	35	100
72 h / 3 d	45	125
96 h / 4 d	55	
120 h / 5 d	65	
84 h / 3.5 d		

Delivery accuracy is  $\pm 15\%$  (at a 95% confidence interval) of the labeled infusion period when delivering saline at 88° F (31°C).

**NOTES:**

1. The infusion rate for each PainBuster Pump is indicated on each cap.
2. Actual infusion times may vary due to:
  - viscosity and/or drug concentration.
  - positioning the PainBuster pump above (increase) or below (decrease) the catheter site.
  - temperature: the PainBuster flow restricter (located distal to the filter) should be close to, or in direct contact with, the skin (31°C/88°F). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the PainBuster is used with the flow restricter at room temperature (20°C/68°F), delivery time will increase by 25%.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

**Infusion is complete when the PainBuster Pump is no longer inflated.**

**CAUTION**

Federal (U.S.A.) law restricts this device to sale by or the order of a healthcare professional.

For Customer Service  
Call: 1.800.448.3569

A PRODUCT OF  
**I-FLOW**  
I-FLOW CORPORATION  
LAKE FOREST, CA 92630  
U.S.A.

1301891B  
C/98

32  
34

Models: P065005, P100020

298058

*Complete*  
**PainBuster™**

**INTENDED USE**

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

**CONTRAINDICATIONS**

This system is not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use. Not for chemotherapy drugs.

**WARNINGS**

- Single Use Pump. Do not refill. Discard after use.
- Do not overfill the pump.
- Medications being used with this system should be used in accordance with instructions provided from the drug manufacturer.

**DIRECTIONS FOR USE**

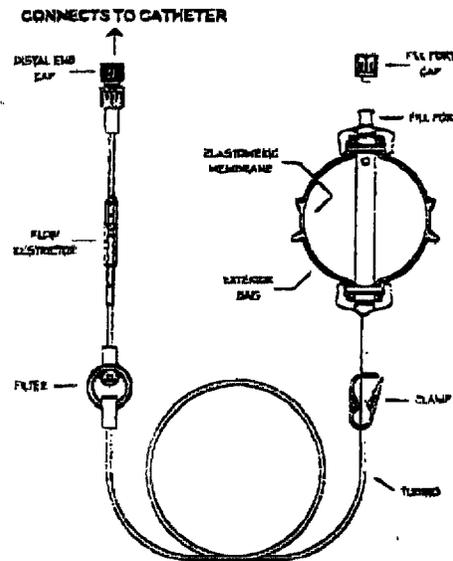
**Use Aseptic Technique**

**Filling the Elastomeric Pump**

1. Close clamp on tubing.
2. Remove protective cap from filling port.
3. Attach filled syringe to the fill port and inject fluid into pump. Repeat if necessary. Do not fill over 65ml or 125ml as applicable (refer to table below). Replace fill port cap.
4. To prime the tubing, open the clamp on the tubing and allow fluid to fill the tubing. Close clamp until ready for use.

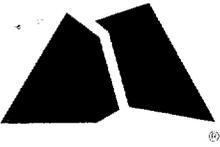
**Placing the Catheter**

1. Insert introducer needle through the skin (approximately 3-5cm away from wound site) then push introducer needle into the surgical wound site.
2. Insert the marked end of the catheter through the hub of the introducer needle into the wound site out the bevel of the needle.
3. Remove introducer needle while holding catheter tightly in place. Assure catheter placement in wound site.
4. Cut catheter to desired length.
5. Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed.
6. Attach the catheter connector to the pump tubing.
7. Tape catheter securely in place.
8. Apply appropriate dressing to catheter site.



35  
33

15982256-A1



▲ McKinley Medical, LLLP

4080 Youngfield Street  
Wheat Ridge, CO 80033 USA

303.420.9569  
Fax: 303.420.8585

**McKinley**

*New Values in Infusion*

RECORDED  
14 JUL 98 14 20  
FDA/CDRH/ODE/DMC

July 7, 1998

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
1390 Piccard Drive  
Rockville, MD 20850  
att: Document Control

RE: 510(k) Notification - OutBound Pumps

Dear Madam/Sir:

Per our telephone conversation of July 7, 1998, enclosed are the requested documents:

- Indications for Use form
- Truthful and Accurate Statement form

These documents have been faxed and are now being forwarded in hard copy. If there is additional information you require, please contact me.

Sincerely,

Suzanne Dennis  
Director, Regulatory Affairs/Quality Assurance

fax: (301) 480-3002

SK-43

60  
36  
24

Indications For Use

510(k) Number (if known) K982256

Device Name: Outbound Disposable Infuser

Indications For Use: The Outbound infuser is indicated for intravenous intra-arterial, subcutaneous, epidural, and (b)(4) (b)(4)

(b)(4) (b)(4) of medications or fluids requiring continuous delivery at controlled infusion rates.

(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 \_\_\_\_\_

(Optional Format 1-2-96)

61  
37  
29

**PREMARKET NOTIFICATION**  
**TRUTHFUL AND ACCURATE STATEMENT**  
**(As Required by 21 CFR 807.87(j))**

I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance 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.

  
Signature

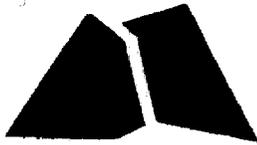
Suzanne Dennis, Director, RA/QA  
Typed Name and Title

McKinley Medical, LLLP  
Company

July 7, 1998  
Date

K982256  
[Premarket Notification (510(k)) Number]

38  
62  
37



**McKinley**

**▲ McKinley, Inc.**  
165 S. Union Blvd., Suite 800  
Lakewood, CO 80228 USA  
303.420.9569  
Fax: 303.420.8585

**FAX**

**To:** Linh O'Connell  
**Company:** FDA  
**From:** Suzanne Dennis  
**Date:** 7 July 98  
**CC:**  
**Subject:** Requested Statements for K982256

**Fax Number:** (301) 480-3002

**# Pages:** 4

---

Per your request, enclosed are the Indications for Use Form and the Truthful and Accurate Statement.

39  
24  
37



▲ McKinley Medical, LLLP

4080 Youngfield Street  
Wheat Ridge, CO 80033 USA

303.420.9669  
Fax: 303.420.8585

**McKinley**

*New Values in Infusion®*

July 7, 1998

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
1390 Piccard Drive  
Rockville, MD 20850  
att: Document Control

RE: 510(k) Notification - OutBound Pumps

Dear Madam/Sir:

Per our telephone conversation of July 7, 1998, enclosed are the requested documents:

- Indications for Use form
- Truthful and Accurate Statement form

These documents have been faxed and are now being forwarded in hard copy. If there is additional information you require, please contact me.

Sincerely,

Suzanne Dennis  
Director, Regulatory Affairs/Quality Assurance

fax: (301) 480-3002

40  
38

Indications For Use

510(k) Number (if known) K982256

Device Name: Outbound Disposable Infuser

Indications For Use: The Outbound infuser is indicated for intravenous intra-arterial, subcutaneous, epidural, and (b)(4) (b)(4) (b)(4) of medications or fluids requiring continuous delivery at controlled infusion rates.

(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 \_\_\_\_\_

(Optional Format 1-2-96)

41  
36  
39

**PREMARKET NOTIFICATION**  
**TRUTHFUL AND ACCURATE STATEMENT**  
**(As Required by 21 CFR 807.87(j))**

I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance 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.

  
 Signature

Suzanne Dennis, Director, RA/QA  
 Typed Name and Title

McKinley Medical, LLLP  
 Company

July 7, 1998  
 Date

K982256  
 [Premarket Notification (510(k)) Number]

*Handwritten notes:*  
 40  
 37  
 42

# Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?		✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?	✓	✓
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

43  
38 #1

# Screening Checklist

## For all Premarket Notification 510(k) Submissions

Device Name: outbound Disposable Syringe Infuser K982256

Submitter (Company): McKinley, Inc.

Items which should be included (circle missing & needed information)	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
		GO TO #2,4		GO TO #3,4,5		GO TO #4,5	
1. Cover Letter clearly identifies Submission as:					✓		
a) "Special 510(k): Device Modification"							
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							

**2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE**

a) Name & 510(k) number of legally marketed (unmodified) predicate device						
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*						
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*						
d) Design Control Activities Summary						
i) 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						
ii) 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						
iii) A declaration of conformity with design controls. The declaration of conformity should include:						
1) 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						
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.						

44  
#2  
39

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS</b>							
a) 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							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

45  
#3  
40



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

June 29, 1998

MCKINLEY, INC.  
4080 YOUNGFIELD ST.  
WHEAT RIDGE, CO 80033  
ATTN: SUZANNE DENNIS DENNIS

510(k) Number: K982256  
Received: 26-JUN-1998  
Product: OUTBOUND DISPOSABLE  
SYRINGE INFUSER  
OUTBOUND 2  
DISPOSABLE PUMP

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA 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  
Consumer Safety Officer  
Premarket Notification Staff

HS  
47

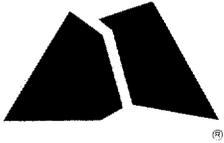
K982256

▲ McKinley, Inc.

4080 Youngfield Street  
Wheat Ridge, CO 80033 USA

303.420.9569  
Fax: 303.420.8585

RECEIVED  
26 JUN 98 11 14  
FDN/ODRN/ODE/DMC



McKinley

New Values in Infusion®

June 23, 1998

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
1390 Piccard Drive  
Rockville, MD 20850  
att: Document Control

RE: 510(k) Notification - OutBound Pumps

Dear Madam/Sir:

McKinley Medical LLLP hereby submits this 510(k) to request a labeling modification for the OutBound Family of disposable ambulatory infusion pumps.

The intended use of the pumps - *precisely-controlled infusion of medications or fluids* - (b)(4)  
(b)(4) (b)(4) The proposed modification is (b)(4) (b)(4)  
(b)(4) (b)(4)  
(b)(4) (b)(4)

The OutBound family of ambulatory infusion pumps provide Continuous, Intermittent and Patient Controlled Analgesia (PCA) infusion. The pump is indicated for intravenous, subcutaneous, enteral, epidural and arterial infusion of antibiotics, analgesics, chemotherapeutic agents and other medications. Detailed product information can be found in the previously submitted 510(k)'s listed in Section A.

The following information is being provided in compliance with CFR 807.87.

McKinley Medical considers our intent to market this device as confidential commercial information and requests that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please contact me (303) 420-9569 ext. 216.

Sincerely,

Suzanne Dennis  
Director, Regulatory Affairs and Quality Assurance

HO II #3 #6 48

SK 39

## TABLE OF CONTENTS

A. COVER PAGE.....	3
B. LABELING.....	5
C. STANDARDS.....	5
D. DEVICE DESCRIPTION.....	5
E. DESCRIPTIVE COMPARISON TO A LEGALLY MARKETED DEVICE.....	5
F. PERFORMANCE DATA.....	5
G. SOFTWARE.....	5
H. STERILIZATION INFORMATION.....	5
I. SMDA INFORMATION.....	5
APPENDIX 1 - LABELING.....	6
APPENDIX 2 - DESCRIPTIVE COMPARISON TO A LEGALLY MARKETED DEVICE ..	7
APPENDIX 3 - SMDA INFORMATION.....	8

### PRODUCT LABELING

- OUTBOUND DISPOSABLE SYRINGE INFUSER
- OUTBOUND-2 DISPOSABLE PUMP

#4  
#9  
#10

## A. COVER PAGE

### 1) Trade Name:

OutBound Disposable Syringe Infuser  
OutBound 2 Disposable Pump

### 2) Common Name:

OutBound Disposable Syringe Infuser - elastomeric vacuum pump  
OutBound 2 Disposable Pump - elastomeric vacuum pump

### 3) Classification Name:

Ambulatory Infusion Pump

### 4) Establishment Registration Number:

1723533

### 5) Class

#### Panel

General Hospital Panel

#### Code

80 FRN: Infusion Pump

### 6) Purpose of Submission:

Modified indications for use.  
The proposed modification does not affect the intended use of the device,  
and does not result in any negative consequences to the safety or efficacy of  
the device.

### Previous 510(k) Numbers:

K914148 - Oct. 5, 1992 - Prime CADI 120 (OutBound)  
K920637 - Jan 15, 1993 - Prime PCA (OutBound)  
K971844 - Jan. 23, 1998 - OutBound - 2 System

45  
48  
49  
50

**7) Substantial Equivalence:**

There have been no changes to the design of this product, therefore, the equivalency as determined and accepted in the previously referenced 510(k)s, remains unchanged.

**8) U.S. Contact**

Suzanne Dennis, Director Regulatory Affairs/Quality Assurance  
McKinley Medical LLLP  
4080 Youngfield Street  
Wheat Ridge, CO. 80033  
(303) 420-9569

50  
#6  
219  
51

**B. LABELING**

*See Appendix 1*

**C. STANDARDS**

Performance Standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

**D. DEVICE DESCRIPTION**

There have been no changes made to the device to accommodate the labeling modification.

**E. DESCRIPTIVE COMPARISON TO A LEGALLY MARKETED DEVICE**

The intended use of this device - to infuse various medications and fluids at a precisely-controlled infusion rate - has not changed. Therefore, the device remains substantially equivalent.  
*See Appendix 2*

**F. PERFORMANCE DATA**

The performance characteristics remain the same as previously submitted in 510(k)s listed in section A.6. There have been no changes made.

**G. SOFTWARE**

The software remains the same as previously submitted in 510(k)s listed in section A.6. There have been no changes made.

**H. STERILIZATION INFORMATION**

There have been no changes made to the sterilization process.

**I. SMDA INFORMATION**

*See Appendix 3*

## APPENDIX 1 - LABELING

CURRENT LABELING	PROPOSED LABELING
<p><b>OUTBOUND DISPOSABLE SYRINGE INFUSER:</b></p> <ul style="list-style-type: none"> <li>INDICATIONS FOR USE</li> </ul> <p>The OutBound infuser is indicated for intravenous, intra-arterial and subcutaneous infusion of medications or fluids requiring continuous delivery at controlled infusion rates.</p>	<ul style="list-style-type: none"> <li>INDICATIONS FOR USE</li> </ul> <p>The OutBound infuser is indicated for intravenous, intra-arterial, subcutaneous, epidural, and (b)(4) (b)(4) of medications or fluids requiring continuous delivery at controlled infusion rates.</p>
<p><b>OUTBOUND - 2 DISPOSABLE PUMP</b></p> <ul style="list-style-type: none"> <li>INDICATIONS FOR USE</li> </ul> <p>The McKinley OUTBOUND - 2 is indicated for patients requiring intravenous, interarterial [sic], subcutaneous or enteral administration of medication. It is convenient to use by ambulatory patients.</p> <p>It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the medication manufacturers [sic] package insert.</p>	

Current product labeling follows as Appendix 3

48  
53  
51  
52

## APPENDIX 2 - DESCRIPTIVE COMPARISON TO A LEGALLY MARKETED DEVICE

(b) (4)

(b)(4)

49  
50  
53  
54

## APPENDIX 3 - SMDA INFORMATION - 510(k) STATEMENT

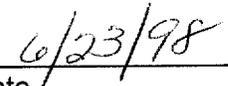
Follows on next page.

50  
55  
53  
54

## 510(k) STATEMENT

I certify that, in my capacity as the Director of Regulatory Affairs and Quality Assurance, of McKinley Medical LLLP, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

  
\_\_\_\_\_  
Signature

  
\_\_\_\_\_  
Date

54  
85  
56

## PRODUCT LABELING

- OUTBOUND DISPOSABLE SYRINGE INFUSER
- OUTBOUND-2 DISPOSABLE PUMP

510(k).doc

52  
56  
57

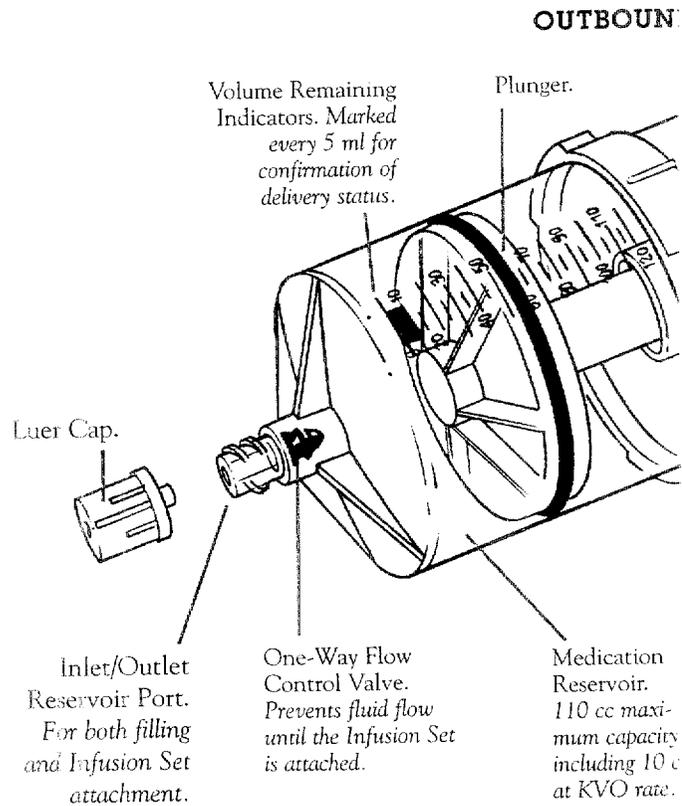
## FEATURES AND FUNCTIONS



# OutBound<sup>®</sup>

DISPOSABLE SYRINGE INFUSER

## CLINICIAN INSTRUCTIONS FOR USE



## DESCRIPTION

The OutBound<sup>®</sup> Disposable Syringe Infuser uses sustained vacuum pressure to deliver a continuous infusion of medications or fluids at controlled rates. This non-electronic device is designed for single use in the hospital or by the ambulating patient. It can be used for intravenous, intra-arterial and subcutaneous delivery.

The OutBound Infuser combines a clear polypropylene syringe with a durable vacuum chamber. It connects to a dedicated Infusion Set for attachment to the patient's catheter. A one-way valve prevents medication flow until the Infusion Set is attached to the OutBound Infuser. Once the Infuser is filled with medication, it is ready for use. Simply attach the rate-controlling Infusion Set, open the clamp, prime the tubing and start medication delivery. The Infusion Sets dedicated for use with the OutBound Infuser are available in a variety of standard infusion durations and rates of flow. A specially designed carrying pouch available from McKinley protects the OutBound system during the patient's daily activities.

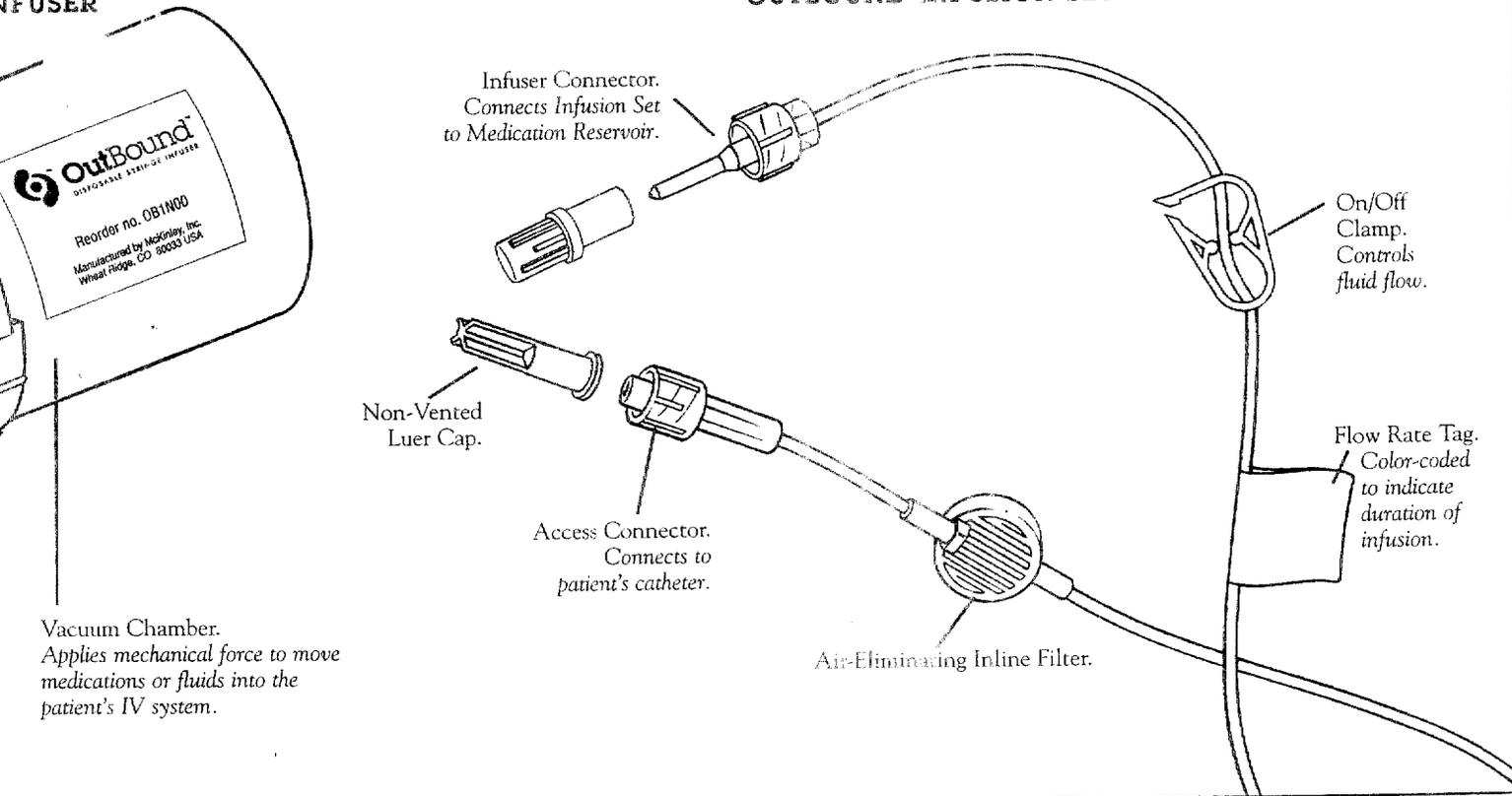
The OutBound Infuser is contraindicated for use in infusion regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy; or who are not under the care of a responsible individual.

## TECHNICAL SPECIFICATIONS

<b>Fill volume:</b>	100 cc
<b>Optional KVO volume:</b>	10 cc
<b>Flow rate accuracy:</b>	+/- 10%
<b>Positive pressure:</b>	12 psi nominal
<b>Weight (unfilled):</b>	3.7 oz / 105 g
<b>Dimensions:</b>	6.0" x 2.9" / 15.3 cm x 7.3 cm
<b>Detachable Infusion Sets:</b>	Use only dedicated Infusion Sets supplied by McKinley, Inc. for use with OutBound Infuser.
<b>Standard flow rates:</b>	Refer to individual Infusion Set package for infusion duration (for 100 cc) and flow rate.
<b>Materials:</b>	Infuser: Polypropylene, butyl rubber and silicone rubber. Latex-free. Infusion Set: PVC, acrylic, cellulose acetate, PTFE and polyethylene. Does not contain DEHP.
<b>Operating temperature:</b>	The OutBound Infuser is calibrated to deliver solution at the labeled flow rate when the temperature of the infusate in the patient-side Luer is 86° F (normal skin temperature). <span style="float: right;">33</span>
<b>Fluid viscosity:</b>	The OutBound Infuser flow rate is calibrated with D5W. <span style="float: right;">30</span>

INFUSER

### OUTBOUND INFUSION SET



Vacuum Chamber.  
Applies mechanical force to move medications or fluids into the patient's IV system.

### INDICATIONS

The OutBound Infuser is indicated for intravenous, intra-arterial and subcutaneous infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

### CONTRAINDICATIONS

The OutBound Infuser 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 OutBound Infuser or Infusion Sets.
- Use in infusion 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.

### WARNING

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

### CAUTIONS

As with any infusion system, medications or fluids may interact with the materials of the OutBound Infuser and Infusion Set, possibly causing damage or leakage. Before use, consult the pharmaceutical manufacturer's precautions and guidelines.

- Medications or fluids infused by the OutBound Infuser must be prescribed by the physician. It is the responsibility of the

clinician using the OutBound Infuser to ensure that the medications or fluids are used only according to the physician's infusion therapy prescription.

- The OutBound Medication Reservoir must not be filled with more than 120 cc of solution. Failure to follow the recommended filling procedure and filling beyond the specified volume could damage the OutBound Infuser and cause fluid leakage.
- Before connecting to the patient, purge all air from the infusion lines.
- Do not remove the Infusion Set after it has been connected to the OutBound Infuser. Removal of a connected Infusion Set may cause fluid leakage.
- Do not attempt to disassemble the OutBound Infuser. Doing so could damage the Infuser and cause fluid leakage.
- Do not drop the OutBound Infuser, strike it against hard objects or otherwise subject it to extreme physical stress. If the Infuser is dropped or subjected to extreme stress, it must be checked for damage or leakage before reuse. If any problems are detected, discontinue use. The OutBound Infuser should be kept in its protective carrying pouch during use.
- Do not cover the air vent on the bottom of the OutBound Infuser with a label. Sealing of the air vent may cause the Infuser to malfunction, resulting in under-delivery or non-delivery of medication to the patient.
- For proper performance, use only Infusion Sets authorized by McKirley for use with the OutBound Infuser.
- It is the responsibility of the healthcare provider to ensure that the patient is educated in the proper use of the OutBound Infuser.
- Federal (USA) law restricts this device to sale by, or on the order of, a physician.

SH

# INSTRUCTIONS FOR USE

## MIXING AND USE INFORMATION

The OutBound Infuser is a fixed-rate infusion system. Flow rate is controlled by the attached Infusion Set. Flow rate can only be altered by selecting a different OutBound Infusion Set.

- The OutBound Infuser and dedicated Infusion Sets are designed to deliver 100 cc of fluid over the duration stated on the Infusion Set Flow Rate Tag. An optional 10 cc of fluid can be added as a KVO volume. If you choose to use this optional feature, the final fill volume of the OutBound Infuser will be 110 cc. The medication dose should be concentrated to take into account the KVO volume.

**Note:** For proper fluid or medication administration, you must fill the OutBound Infuser to 100 cc. Filling it with less than 100 cc will result in delivery ending before the duration stated on the Infusion Set Flow Rate Tag.

- The OutBound Infusion Sets have been calibrated to deliver fluids or medications with viscosities equivalent to D5W. Changes in fluid viscosity will affect the OutBound flow rate performance. Increased solution viscosity will slow the rate of infusion. To complete delivery on schedule, you will need to fill the device with less than 100 ml. Solution viscosities less than D5W will cause the OutBound flow rate to run faster than stated on the Infusion Set Flow Rate Tag. Additional fluid volume can be added to the Medication Reservoir to complete delivery on schedule.

### Optional Mixing Procedure -- Adjusting Delivery Schedule with the Infusion Sets

- Delivery duration can be adjusted by under-filling the OutBound Infuser. To calculate the required fill volume for the new delivery schedule, divide the desired length of infusion by the duration stated on the Flow Rate Tag. Multiply that result by 100.

**Example:** You want to deliver a 3-day infusion regimen using a 5-day OutBound Infusion Set:

Normal Fill Volume for 5 days:	100 cc
Duration Desired:	3 days, or 60% of the 5-day tubing set specification
Fill Volume:	60 cc, or 3/5 of 100 cc

- You must add 10 cc additional volume if you intend to use the optional KVO feature.

## FILLING THE INFUSER

### CAUTION

As with any sterile product, use aseptic technique when preparing the OutBound Infuser and Infusion Sets for use.

- Prepare the transfer syringes to be used to fill the OutBound Infuser. It is recommended that Luer Lock syringes be used.
- Inspect the OutBound Infuser 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. Then open the package and remove the Infuser. Place it on a flat work surface with the Inlet/Outlet Reservoir Port pointing up.
- Remove the Luer cap from the OutBound Infuser Inlet/Outlet Reservoir Port.

Connect the Luer Lock of the transfer syringe to the Inlet/Outlet Reservoir Port. Confirm that the connection is secure. Do not over-tighten.

### CAUTION

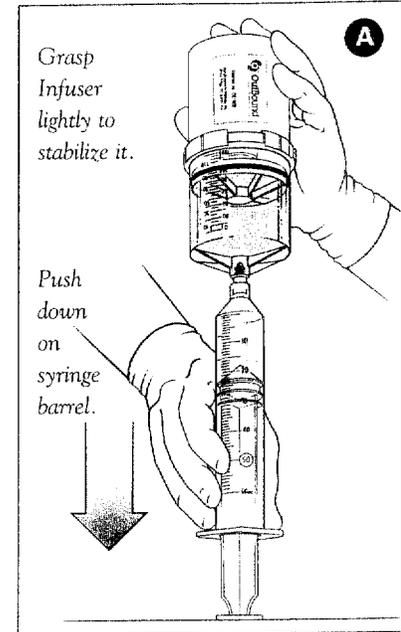
Do not attempt to penetrate the OutBound Infuser Inlet/Outlet Reservoir Port with a needle. Doing so may damage the one-way flow control valve, causing the unit to leak.

- Fill the OutBound Infuser Medication Reservoir with the contents of the transfer syringe using either of the following two methods:

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

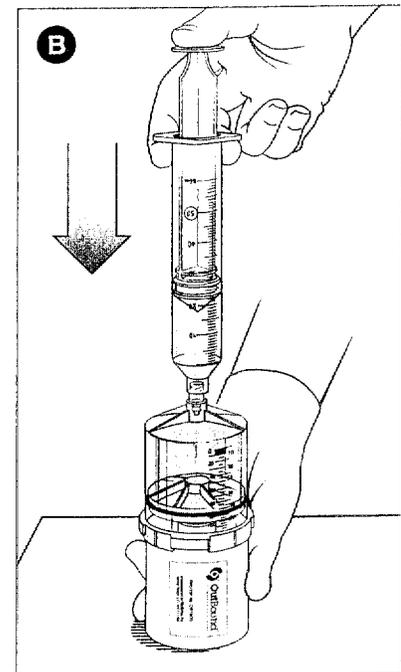
#### Method A:

With the transfer syringe connected to the OutBound infuser, turn the unit over so that the transfer syringe plunger rests on the work surface. Keeping the syringe-to-Infuser assembly perpendicular to the work surface, grasp the barrel of the transfer syringe and push it slowly down. Do not push on the OutBound infuser. Continue to push down on the transfer syringe barrel in order to push the medication into the Medication Reservoir.



#### Method B:

Keep the Infuser resting bottom-end down with the transfer syringe perpendicular to the work surface. With your fingers gripping the flanges of the syringe, push down with your thumb on the end of the syringe plunger to inject the medication into the Medication Reservoir. While filling, grasp the Infuser's Vacuum Chamber securely to keep the syringe-to-Infuser assembly in a stable perpendicular position. Do not move the Infuser unit from this position during filling.



**Note:** Filling the OutBound infuser by methods other than those described above could damage the Inlet/Outlet Reservoir Port.

- Repeat steps 4 and 5 for each additional transfer syringe required to achieve the desired OutBound Infuser fill volume. When the Infuser has been filled to its desired volume, remove the transfer syringe and either attach the Luer cap that was provided with the Infuser or connect the Infusion Set according to the instructions given in the next section.

**Note:** To remove air from the OutBound Infuser, refer to the instructions in the "Priming the Infusion Set" section.

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

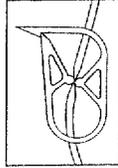
55  
58  
29  
00

## CONNECTING THE INFUSION SET

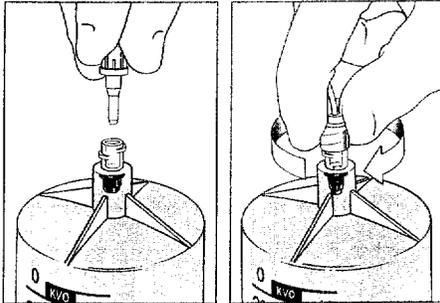
### CAUTION

With any sterile product, use aseptic technique when preparing the OutBound Infuser and Infusion Sets for use.

1. Select the appropriate Infusion Set dedicated for use with the OutBound Infuser. The duration of infusion is listed on the packaging and the tubing Flow Rate Tag. Also confirm that the Infusion Set package has not been opened or damaged. Sterility is not guaranteed for a product whose package has been opened or damaged.
2. Remove the Infusion Set from its package. Close the Infusion Set On/Off Clamp.
3. Place the OutBound 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 located nearest to the On/Off Clamp.



5. Using a quick, continuous motion, insert the extended male Luer Infuser Connector into the Inlet/Outlet Reservoir Port while turning it in a clockwise direction. Secure the connection. Do not over-tighten.



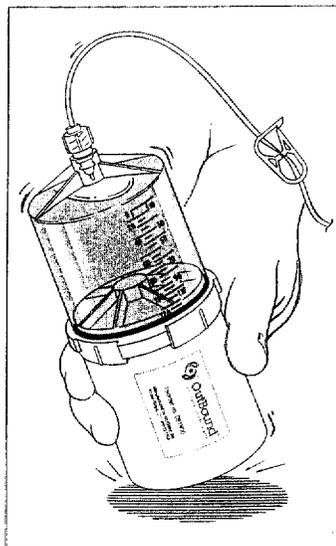
## PRIMING THE INFUSION SET

**Note:** The OutBound Infusion Set should be primed immediately before use. Do not prime and store the OutBound Infusion Set.

### CAUTION

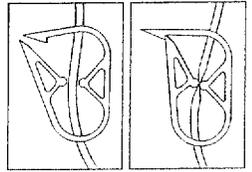
Do not remove the Infusion Set after it has been connected to the OutBound Infuser. Removal of a connected Infusion Set may cause fluid leakage.

1. Examine the Medication Reservoir for the presence of air bubbles. While rotating the Infuser, tap the bottom on your work surface until you've moved the small air bubbles into one large bubble underneath the Inlet/Outlet Reservoir Port.
2. When the air bubbles are collected, place the OutBound infuser flat on a work surface with the Inlet/Outlet Reservoir Port pointing up.



Remove and discard the Luer cap from the Access Connector located at the patient end of the Infusion Set (nearest the filter).

4. Open the On/Off Clamp to allow the fluid flow to prime the Infusion Set and expel any air present in the Medication Reservoir. To prime the filter, hold it so that the outlet (toward patient) points up. Allow a steady flow of fluid into the filter. Tap the filter to eliminate residual air. When priming is complete, close the Clamp.

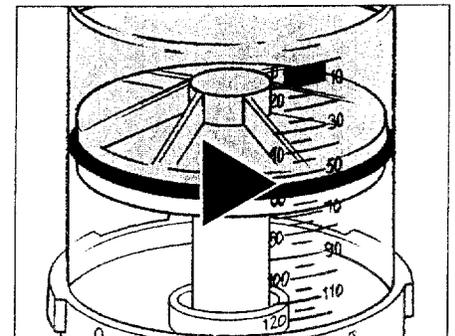
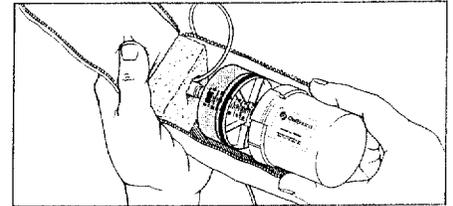


**Note:** The duration of priming will vary according to the Infusion Set selected.

5. Immediately attach the Infusion Set Access Connector to the patient's catheter. Open the On/Off Clamp to start infusion.

## INFORMATION FOR DAILY USE

- Do not immerse the OutBound 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 OutBound Infuser from damage during daily activities, use the specially designed OutBound carrying pouch at all times.
- During medication delivery, check for the following:
  - The Infuser is emptying.
  - There is no leakage from the infusion system.
  - There is no air in the infusion system.
  - The tubing is not kinked.
- To monitor medication delivery, open the carrying pouch from time to time and read the position of the dark plunger ring against the graduation scale on the Medication Reservoir.



**McKinley**

*New Values in Infusion®*

Manufactured by McKinley Medical, LLLP  
4080 Youngfield Street  
Wheat Ridge, CO 80033 USA  
303/420-9569

Customer Support Department:  
800/578-0555

© 1998 by McKinley Medical, LLLP. OutBound, the OutBound logo, the mountain logo and "New Values in Infusion" are registered trademarks of McKinley Medical, LLLP. U.S. Patent # 5135000.

3/98 PN 200724

Handwritten initials and numbers: 60, 50, 101

# DRAFT LABEL COPY

## McKinley OUTBOUND-2 Disposable Pump

### DESCRIPTION

The McKinley OUTBOUND -2 Disposable Pump is a lightweight device which operates by the sustained pressure created by filling the pump reservoir. This sustained pressure is the result of the bending of the flexible elastomeric wall of the reservoir. Maximum fill is as stated on the specific model and ranges from 25 to 1,000 cc. Flow rate accuracy, either +/-10% or +/-15%, is dependent upon the specific model, medication to be delivered and the separate rate controlling pump set.

The OUTBOUND-2 is designed to provide a continuous flow of medication, in a medication stable container, over the user selected infusion period. Nominal output flow rate is dependent on the special flow controlling tubing set, the viscosity of the medication, and the medication temperature. In general, increases in viscosity will reduce flow rate and increases in temperature will increase flow rate.

### INDICATIONS AND USAGE

The McKinley OUTBOUND-2 is indicated for patients requiring intravenous, interarterial, subcutaneous, or enteral administration of medication. It is convenient to use by ambulatory patients.

It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the medication manufactures package insert.

### CONTRAINDICATIONS

### WARNINGS

1. Discard after a single use. The unit **must not** be refilled or resterilized.
2. The user is responsible for selecting the correct flow rate tubing. **The correct flow rate tubing must be used for the rate prescribed. Use only McKinley OUTBOUND-2 rate controlling sets. Other sets will not work.**
3. Pumps must be filled in accordance with procedures described under DIRECTIONS FOR FILLING.
4. Do not fill beyond volume specified for model used.

### MIXING AND USE INFORMATION

1. The OUTBOUND-2 pump is a constant pressure device designed to flow at a nominal rate dependent upon the special flow control set used and the viscosity of the medication. Special sets are required for enteral nutritional fluids. Sets for I.V. infusion include an air eliminating filter. The quantity of solution for the pump is prepared in accordance with the manufacturers instructions.
2. Alteration of dosage is achieved by adjustments in concentration or by changing the rate controlling set.
3. Adhere to drug manufacturers package insert if drug reconstitution is necessary.
4. Labeled flow rate accuracy is specified for water at 70 F.

### DIRECTIONS FOR FILLING

**Use aseptic technique throughout entire procedure.**

The OUTBOUND-2 pump is filled by injecting the medication through the combined fill and delivery luer connection. A standard syringe with a locking luer or a pressure filler capable of up to 12 PSI pressure is required.

1. Remove the luer cap.
2. To fill the OUTBOUND-2 pump, connect the filling device to the combination fill and delivery luer port. Make sure that the connection is locked. **Do not attach a needle to the fill device.**

60  
60  
57  
62

3. After filling to the prescribed volume, recap the pump or attach the special flow control set INUSER CONNECTOR luer fitting to the pump luer connection. The INFUSER CONNECTOR is located at the label end of the flow control set prescribed. **Only the special INFUSER CONNECTOR end of the control tubing set will open the pump valve to begin flow.** Prime the set to remove air and clamp the tubing with the clamp provided on the set.
4. Apply the patient label to the pump and send to the patient.

#### **DIRECTIONS FOR USE**

**Use aseptic technique throughout entire procedure.**

**NOTE: Always check flow control tubing label to confirm flow rate!**

If the pump tubing set is connected to the pump, then connect the luer connection to the patient and open the clamp to begin infusion. If the tubing set is not connected to the pump, then connect the tubing per the INSTRUCTIONS FOR FILLING above and then connect to the patient.

#### **HOW SUPPLIED**

Pumps are supplied 20 per box. OUTBOUND-2 Flow Control Sets are separately packed 20 per box.

102  
58  
63  
61

FDA/CDRH IMAGING SYSTEM

Page Count Discrepancy Information

---

OCT 9, 1998  
Page between 33+34 was not  
numbered

Initials Verifier DL