
**USER:** GRAY, ILKA K (ixg)

**FOLDER:** K984638 - 83 pages (FOI:08003844)

**COMPANY:** I-FLOW CORP. (IFLOW)

**PRODUCT:** SET, ADMINISTRATION, INTRAVASCULAR (FPA)

**SUMMARY:** Product: PARAGON BOLUS ACCESSORY SET

**DATE REQUESTED:** Fri Jan 15 24:00:00 2010

**DATE PRINTED:** Tue Nov 16 14:09:44 2010

**Note:** Releasable Version

# Table of Contents

2/9/99

I-FLOW CORPORATION

20202 Windrow Rd.
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
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K984638

# SUMMARY OF SAFETY AND EFFECTIVENESS

December 30, 1998

**Trade Name:** Paragon Bolus Accessory Set

**Common Name:** Bolus Accessory

**Classification Name:** Set, Administration, Intravascular

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700
Fax: 949.206.2600

# 1.0 GENERAL INFORMATION

## 1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an accessory device for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus. This new accessory will be known as the Paragon Bolus Accessory Set, hereafter identified as the Bolus Accessory. No change will be made to the existing Paragon pump or administration sets.

1.1.2 Trade Name: Paragon Bolus Accessory Set

1.1.3 Common Name: Bolus Accessory Set

1.1.4 Classification Name: Set, Administration, Intravascular

1.1.5 Product Code: 80 FPA

1.1.6 Device Classification: Class II, 880.5440

1.1.7 Classification Panel: General Hospital and Personal Use Device

## 1.2 Statement of Equivalence

1.2.1 The Bolus Accessory is substantially equivalent to Patient Control Module (K884505) marketed by Baxter Healthcare Corporation and the I-Flow Bolus Dispenser (K935811).

# 2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

## 2.1 Description of the Bolus Accessory

Wherever the Paragon pump and administration set are mentioned, they may be replaced by any constant 6 psi pressure system.

2.1.1 The Bolus Accessory may connect to any Paragon administration set to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

2.1.2 The Bolus Accessory consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

2.1.3 The bolus button allows patient controlled administration of medication as needed.

## 2.2 Product Configuration

2.2.1 The Bolus Accessory is available in 0.5 ml bolus volume.

## 2.3 Components and Materials

2.3.1 All fluid path components of the Bolus Accessory are in conformance with ISO 10993 Part 1.

## 2.4 Power Requirements

2.4.1 The Bolus Accessory is a mechanical device that requires no external power.

## 3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions:**

| | |
|---|---|
| Bolus Volume: | 0.5 ml |
| Refill Time: | variable |
| Priming/Residual Volume: | <=4 ml |
| Operating Temperature: | 90 ± 2°F |
| Calibration Solution: | 0.9% NaCl |
| Operating Pressure: | 6.0 psi pressure source |
| Head Height: | 0" |
| Accuracy: | bolus volume: ±10% at 95% confidence interval at the identified lockout times. |

3.2 **Performance Data:** Testing occurred at standard operating conditions. All models performed within the specified accuracy when tested at nominal conditions.

3.3 **Safety / Alarm Funtions**

3.3.1 This device contains no alarms or indicators.

3.3.2 The non-linear refill adds additional patient safety if the bolus button is activated prior to the lockout time.

## 4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.

## 5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Bolus Accessory.

5.1.2 The Bolus Accessory is intended for general purpose drugs and pain medication.

## 6.0 INTENDED USE

6.1 The Bolus Accessory is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

6.2 The routes of administration intravenous, epidural, intramuscular and subcutaneous.

6.3 The Bolus Accessory is not intended for continuous delivery.

6.4 The Bolus Accessory is single patient use only.

6.5 The Bolus Accessory is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

6.6 No testing has been conducted to determine the efficacy of Bolus Accessory for the delivery of blood, blood products, lipids or fat emulsions. The Bolus Accessory is not intended for the delivery of blood, blood products, lipids or fat emulsions.

## 7.0 STANDARDS

7.1 There are currently no standards established for mechanical PCA infusion devices.

## 8.0 PACKAGING

8.1 Packaging is suitable for radiation or ETO sterilization.

## 9.0 STERILIZATION

9.1 The method of sterilization is gamma radiation (cobalt 60).

## 10.0 COMPARISON TO LEGALLY MARKETED DEVICES

10.1 The Bolus Accessory has the same intended use as the predicate Baxter Pain Control Module and the I-Flow Bolus Dispenser. The Bolus Accessory has similar bolus volumes and lockout times as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K984638
Trade Name: Paragon Bolus Accessory Set
Regulatory Class: II
Product Code: FPA
Dated: December 30, 1998
Received: December 31, 1998

Dear Mr. Bard:

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

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

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

Sincerely yours,

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

Enclosure

510(k) Number (if known): K984638

Device Name: Paragon Bolus Accessory Set

**Indications for Use**:

1. The Paragon Bolus Accessory Set is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider. The routes of administration are intravenous, epidural, intramuscular and subcutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR ~~Over~~-The-Counter Use

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

(Optional Format 1-2-96)

510(k) Number K984638

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

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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

Enclosure

2

510(k) Number (if known): K984638

Device Name: Paragon Bolus Accessory Set

**Indications for Use:**

1. The Paragon Bolus Accessory Set is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider. The routes of administration are intravenous, epidural, intramuscular and subcutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use 3

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984638

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service –
Food And Drug Administration

n: Reviewer(s) - Name(s) HUNG TRINH

Memorandum

ect: 510(k) Number K984638

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? | ☐ 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 |
| I 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)

erial of Biological Origin ☐ YES ☑ NO

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

Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

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

80 FPA Class II

Patricia Cuenca (Branch Chief) — (Branch Code) — (Date) 8/9/99

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iew: (Division Director) — (Date) 8/5/99

# Screening Checklist
## For all Premarket Notification 510(k) Submissions

| Device Name: Paragon Balue Accessory Set | K984638 |
|---|---|
| Submitter (Company): I-Flow Corp | |

| Items which should be included *(circle missing & needed information)* | SPECIAL YES | SPECIAL NO | ABBREVIATED YES | ABBREVIATED NO | TRADITIONAL YES | TRADITIONAL NO | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| **1. Cover Letter clearly identifies Submission as:** | | | | | | | |
| a) "Special 510(k): Device Modification" | GO TO # 2,4 | | GO TO # 3,4,5 | | GO TO # 4,5 | ✓ | |
| 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** | | | * If no - STOP not a special | | | | |
| c) *STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED** | | | * If no - STOP not a special | | | | |
| 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. | | | | | | | |

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→ → → CONTINUE TO SECTION 4 ← ← ←

| | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| | YES | NO | YES | NO | YES | NO | |
| **3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS** | | | | | | | |
| 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 | | | | | | | |

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→ → → CONTINUE TO SECTION 4 ← ← ←

| 4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| | YES | NO | YES | NO | YES | NO | |
| a) trade name, classification name, establishment registration number, address of manufacturer. device class | | | | | ✓ | | |
| b) OR a statement that the device is not yet classified | FDA - may be a classification request; see coordinator | | | | | | |
| c) identification of legally marketed equivalent device | NA | | | | ✓ | | |
| d) compliance with Section 514 - performance standards | NA | | | | ✓ | | |
| e) address of manufacturer | | | | | ✓ | | |
| f) Truthful and Accurate Statement | | | | | ✓ | | |
| g) Indications for Use enclosure | | | | | ✓ | | |
| h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)* | | | | | ✓ | | |
| i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)* | | | | | | | |
| j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals | | | | | ✓ | | |
| k) Proposed Labeling: | | | | | ✓ | | |
| i) package labeling (user info) | | | | | ✓ | | |
| ii) statement of intended use | | | | | ✓ | | |
| iii) advertisements or promotional materials | | | | | ✓ | | |
| i) MRI compatibility (if claimed) | | | | | | | |
| m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: | | | | | ✓ | | |
| i) labeling | | | | | ✓ | | |
| ii) intended use | | | | | ✓ | | |
| iii) physical characteristics | | | | | | | |
| iv) anatomical sites of use | | | | | | | |
| v) performance (bench, animal, clinical) testing | NA | | | | | | |
| vi) safety characteristics | NA | | | | | | |
| n) If kit, kit certification | | | | | | | |
| **5. Additional Considerations: (may be covered by Design Controls)** | | | | | | | |
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | | | | | | ✓ | |
| i) component & material | | | | | | ✓ | |
| ii) identify patient-contacting materials | | | | | | ✓ | |
| iii) biocompatibility of final sterilized product | | | | | | ✓ | |
| b) Sterilization and expiration dating information: | | | | | ✓ | | |
| i) sterilization method | | | | | ✓ | | |
| ii) SAL | | | | | ✓ | | |
| iii) packaging | | | | | ✓ | | |
| iv) specify pyrogen free | | | | | ✓ | | |
| v) ETO residues | | | | | ✓ | | |
| vi) radiation dose | | | | | ✓ | | |
| c) Software validation & verification: | | | | | | ✓ | |
| i) hazard analysis | | | | | | ✓ | |
| ii) level of concern | | | | | | ✓ | |
| iii) development documentation | | | | | | ✓ | |
| iv) certification | | | | | | ✓ | |

*Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.*

Passed Screening ✓ Yes ____ No

Date: JAN - 8 1999

Reviewer: _____

Concurrence by Review Branch: _____

1

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

## "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

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

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

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

9

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

**DATE:** 2/1/99
**FROM:** Hung Trinh HT 2/3/99
**DOCUMENT:** K984638
**COMPANY NAME:** I-Flow Corp
**DEVICE NAME:** Paragon Bollus Accessory set

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

**Contact point:** Robert Bard, VC Regulatory and Legal Affairs
949-206-2700
949-206-2600 (fx)

## NARRATIVE DEVICE DESCRIPTION

1. **SUMMARY DESCRIPTION OF THE SUBMISSION UNDER REVIEW:**
The firm intends to extend the administration set product line for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus, to include a bolus accessory set.

2. **INTENDED USE:**
The device is intended to allow patient controlled bolus delivery.

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?** yes
Gamma radiation (cobalt 60) or (b)(4), (b)(5) Gamma radiation validation methodology is by ANSI/AAMI ST32-1191/EN 552; dosage from 25 to 35 kGy (b)(4), (b)(5) sterilization complies with ANSI/AAMI/ISO (b)(4), (b)(5)
D. **Is the device for single use?** Single patient use
E. **Is the device for prescription use?** yes
**If yes, is prescription labeling included?** yes
F. **Is the device for home use or portable?** yes
G. **Does the device contain drug or biological product as a component?** no
H. **Is this device a kit?** no
I. **Software-driven:** no
J. **Electrically Operated:** no
K. **Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):** no
L. **Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:**
Baxter Basal/Bolus Infusor (K884505)
I-Flow Bolus Dispenser (K935811)
M. **Submission provides comparative specifications** yes
**comparative in vitro data** no
**performance data** yes

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| | |
|---|---|
| **animal testing** | no |
| **clinical testing** | no |
| **biocompatibility testing** | no (same material as predicate) |

**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 device consists of a plastic housing, medication reservoir, bolus button activator, and wrist band. The device can be connected to any Paragon administration set to deliver fixed boluses of medication upon demand by the patient or healthcare provider. This device **does not** deliver continuous medication. The refill time of the medication reservoir is determined by the flow control orifice of the Paragon administration set, and therefore, is inversely proportional to the flow rate (see page 16 of 19).

The Baxter Patient Control module is very similar to the subject device in that it is composed of a plastic housing, medication reservoir, bolus button activator, and wrist bands. It also requires a pressure source to fill the medication reservoir.

Comparative specs:

| Comparison Element | Paragon Bolus Accessory Set | Baxter Patient Control Module | I-Flow Bolus Dispenser |
|---|---|---|---|
| Bolus Volume | 0.5 ml; ±10% @ 95% confidence interval | 0.5 ml | 0-1.0 ml |
| Bolus Lockout time | 3.6, 9, 18, 35 and 70 min; ±15% @ 95% confidence interval | 6, 15, 60 min | 15, 30,, 60, 120 min |
| Pump Volume | 100 ml | 65 ml | 30 |
| Pressure source | Mechanical spring energy of the pump | Strain energy of elastomeric membranes | Mechanical Spring |
| Fluid Reservoir | PVC drug bag | Elastomeric membrane | PVC drug bag or polypropyplene syringe |

A more detailed comparison is available on page 22 of 23.

**O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based?** yes

**P. RECOMMENDATION:**

**I believe that this device is equivalent to:** 80 FPA

**Classification should be based on:**

11

880.5440 Intravascular (IV) administration set **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 with the type of device and a citation to the literature, or other sources of information, upon which they have based the description?** n/a

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## "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K984638

Reviewer: Hung Trinh

Division/Branch: DDIGD/GHDB

Device Name: Paragon Bolus Administration set

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

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

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

B

20202 Windrow Dr
Lake Forest, CA 92630
Tel: 949.206.2670
Fax: 949.206.2603

**I-Flow Corporation**

# Fax

| | | | |
|---|---|---|---|
| **To:** | Hung Trinh | **From:** | Robert J Bard, Esq. |
| **Fax:** | 301.480.3002 | **Pages:** | 6 |
| **Phone:** | 301.594.1287 x 130 | **Date:** | 02/02/99 |
| **Re:** | K984063, K984146, K984638 | **CC:** | |

x **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

● **Comments:** The documents accompanying this facsimile transmission contains information which may be legally privileged and confidential. The information is intended only for the use of the recipient named below. If you have received this facsimile in error, please immediately notify us by telephone to arrange for return of the original documents to us. Any disclosure, copying, distribution or the taking of any action in reliance on the contents of this faxed information is strictly prohibited.

N/

I-FLOW CORPORATION
20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

February 2, 1999

VIA FACSIMILE

Hung Trinh
Food and Drug Administration
Center for Devices and Radiological Health
Office Device Evaluation
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: K984063
K984146
K984638

Dear Mr. Trinh:

Pursuant to our conversation of February 2, 1999, I have made the following changes to the above referenced premarket notifications.

**K984063** The **Indications for Use** description has been changed to a single statement. Lines 3, 4 and 5 have been deleted and Line 2 has been incorporated into Line 1.

No other changes have been made to premarket notification K984063.

**K984146** A supplemental submission was made on January 13, 1999 to include synovial infusions as an additional indication for use. The basis of this supplemental submission was the finding of a predicate device (the McKinley Outbound K982256) that included (b)(4), (b)(5) as an indication for use.

I-Flow has agreed to remove the January 13 revision from our submission based on your statement that the McKinley will not be allowed to have an indication for use that includes (b)(4), (b)(5) Based on your statement, I-Flow believes the Office of Device Evaluation will require McKinley to modify their Indications for Use Statement and that the posting on the FDA 510(k) webpage will be changed.

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The **Indications for Use** description has been changed to a single statement including both Lines 1 and 2.

**K984638** The **Indications for Use** description has been changed to a single statement including both Lines 1 and 2.

No other changes have been made to premarket notification K984638.

If you have any additional issues specific to the above identified premarket notifications, either to the information provided or in general, I can be reached at 949.206.2670 or 800.206.2700.

Sincerely,

Robert J. Bard, Esq., R.A.C.
Vice President, Regulatory and Legal Affairs

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510(k) Number (if known): K984638

Device Name: Paragon Bolus Accessory Set

**Indications for Use**:

1. The Paragon Bolus Accessory Set is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider. The routes of administration are intravenous, epidural, intramuscular and subcutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use 17

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

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

December 31, 1998

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD

510(k) Number: K984638
Received: 31-DEC-1998
Product: PARAGON BOLUS
ACCESSORY SET

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,

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

K984638

# CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
## Premarket Submission Cover Sheet

Date of Submission: 12/30/98

FDA Document Number:

### Section A — Type of Submission

- [X] 510(k)
- [ ] 510(k) Add'l information
- [ ] IDE
- [ ] IDE Amendment
- [ ] IDE Supplement
- [ ] IDE Report
- [ ] PMA
- [ ] PMA Amendment
- [ ] PMA Report
- [ ] PMA Supplement - Regular
- [ ] PMA Supplement - Special
- [ ] PMA Supplement - 30 day
- [ ] PMA Supplement - Panel Track

### Section B1 — Reason for Submission — 510(k)s Only

- [X] New device
- [ ] Additional or expanded indications
- [ ] Change in technology, design, materials, or manufacturing process
- [ ] Other reason (specify):

### Section B2 — Reason for Submission — PMAs Only

- [ ] New device
- [ ] Withdrawal
- [ ] Additional or expanded indications
- [ ] Licensing agreement
- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf life
  - [ ] Trade name
  - [ ] Other (specify below)
- [ ] Change in ownership
- [ ] Change in correspondent
- [ ] Other reason (specify):
- [ ] Change in design, component, or specification:
  - [ ] Software
  - [ ] Color Additive
  - [ ] Other (specify below)
- [ ] Process change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager
- [ ] Response to FDA correspondence (specify below)
- [ ] Request for applicant hold
- [ ] Request for removal of applicant hold
- [ ] Request for extension
- [ ] Request to remove or add manufacturing site
- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager
  - [ ] Distributor
- [ ] Report submission:
  - [ ] Annual or periodic
  - [ ] Post-approval study
  - [ ] Adverse reaction
  - [ ] Device defect
  - [ ] Amendment

### Section B3 — Reason for Submission — IDEs Only

- [ ] New device
- [ ] Addition of institution
- [ ] Expansion / extension of study
- [ ] IRB certification
- [ ] Request hearing
- [ ] Request waiver
- [ ] Termination of study
- [ ] Withdrawal of application
- [ ] Unanticipated adverse effect
- [ ] Emergency use:
  - [ ] Notification of emergency use
  - [ ] Additional information
- [ ] Other reason (specify):
- [ ] Change in:
  - [ ] Correspondent
  - [ ] Design
  - [ ] Informed consent
  - [ ] Manufacturer
  - [ ] Manufacturing
  - [ ] Protocol – feasibility
  - [ ] Protocol– other
  - [ ] Sponsor
- [ ] Report submission:
  - [ ] Current investigator
  - [ ] Annual progress
  - [ ] Site waiver limit reached
  - [ ] Final
- [ ] Response to FDA letter concerning:
  - [ ] Conditional approval
  - [ ] Deemed approved
  - [ ] Deficient final report
  - [ ] Deficient progress report
  - [ ] Deficient investigator report
  - [ ] Disapproval
  - [ ] Request extension of time to respond to FDA
  - [ ] Request meeting
- [ ] IOL submissions only:
  - [ ] Change in IOL style
  - [ ] Request for protocol waiver

| | FDA Document Number: |
|---|---|

## Section C — Product Classification

| Product code: 80 FPA | C.F.R. Section: 80.5440 | Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified |
|---|---|---|
| Classification panel: General Hospital and Personal Use Device | | |

## Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

| 1 | 2 | 3 | 4 |
|---|---|---|---|
| 80 FPA | 80 FRN | | |
| 5 | 6 | 7 | 8 |
| | | | |

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

| | 510(k) Number | Trade or proprietary or model name | Manufacturer |
|---|---|---|---|
| 1 | K884505 | Patient Control Module | Baxter Healthcare Corp. |
| 2 | K935811 | Bolus Dispenser | I-Flow Corp. |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |

## Section E — Product Information — Applicable to All Applications

Common or usual name or classification name:
Set, Administration, Intravascular

| | Trade or proprietary or model name | Model number |
|---|---|---|
| 1 | Paragon Bolus Accessory Set | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |

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

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

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):
The Paragon Bolus Accessory Set is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider. The routes of administration are intravenous, epidural, intramuscular and subcutaneous.

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| | FDA Document Number: |
|---|---|

## Section F — Manufacturing / Packaging / Sterilization Sites

| | | | |
|---|---|---|---|
| ☒ Original ☐ Add ☐ Delete | FDA establishment registration number: 2026095 | ☒ Manufacturer ☐ Contract manufacturer | ☐ Contract sterilizer ☐ Repackager / relabeler |

Company / Institution name: I-Flow Corporation

| | |
|---|---|
| Division name (if applicable): | Phone number (include area code): ( 949 )206-2700 ext. 2670 |
| Street address: 20202 Windrow Drive | FAX number (include area code): ( 949 )206-2603 |

| | | | |
|---|---|---|---|
| City: Lake Forest | State / Province: CA | Country: U.S.A. | ZIP / Postal Code: 92630 |

Contact name: Robert J. Bard, Esq., R.A.C.

Contact title: Vice President of Regulatory and Legal Affairs

| | | | |
|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer ☐ Contract manufacturer | ☐ Contract sterilizer ☐ Repackager / relabeler |

Company / Institution name:

| | |
|---|---|
| Division name (if applicable): | Phone number (include area code): ( ) |
| Street address: | FAX number (include area code): ( ) |

| | | | |
|---|---|---|---|
| City: | State / Province: | Country: | ZIP / Postal Code: |

Contact name:

Contact title:

| | | | |
|---|---|---|---|
| ☐ Original ☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer ☐ Contract manufacturer | ☐ Contract sterilizer ☐ Repackager / relabeler |

Company / Institution name:

| | |
|---|---|
| Division name (if applicable): | Phone number (include area code): ( ) |
| Street address: | FAX number (include area code): ( ) |

| | | | |
|---|---|---|---|
| City: | State / Province: | Country: | ZIP / Postal Code: |

Contact name:

Contact title:

21

| | FDA Document Number: |
|---|---|

**Section G** **Applicant or Sponsor**

| | |
|---|---|
| Company / Institution name: I-Flow Corporation | FDA establishment registration number: 2026095 |
| Division name (if applicable): | Phone number (include area code): ( 949 ) 206-2700 ext. 2670 |
| Street address: 20202 Windrow Drive | FAX number (include area code): ( 949 ) 206-2603 |

| | | | |
|---|---|---|---|
| City: Lake Forest | State / Province: CA | Country: U.S.A. | ZIP / Postal Code: 92630 |

Signature: Robert J Bard

Name: Robert J. Bard, Esq., R.A.C.

Title: Vice President of Regulatory and Legal Affairs

**Section H** **Submission correspondent (if different from above)**

| | |
|---|---|
| Company / Institution name: | |
| Division name (if applicable): | Phone number (include area code): ( ) |
| Street address: | FAX number (include area code): ( ) |

| | | | |
|---|---|---|---|
| City: | State / Province: | Country: | ZIP / Postal Code: |

Contact name:

Contact title:

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

22

I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

STJ

# Premarket Notification – 510(k)



Via Federal Express
December 30, 1998

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

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *Paragon Bolus Accessory Set* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to market an accessory device for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus. This new accessory will be known as the *Paragon Bolus Accessory Set*, hereafter identified as the *Bolus Accessory*. The *Bolus Accessory* is substantially equivalent to the Patient Control Module (K884505) marketed by Baxter Healthcare Corporation and the I-Flow Bolus Dispenser (K935811).

All questions and/or comments concerning this document should be made to:
Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Telephone: 949.206.2700
Fax: 949.206.2600

Sincerely,

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

23

I-FLOW
CORPORATION

20202 Windrow Rd.
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

# PREMARKET NOTIFICATION
# TRUTHFUL AND ACCURATE STATEMENT
# (As required by 21 CFR 807.87(j))

I certify that, in my capacity as the Vice President of Regulatory and Legal Affairs of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Paragon Bolus Accessory Set are truthful and accurate and that no material fact has been omitted.

Signature

Robert J Bard, Vice President of Regulatory and Legal Affairs
Name Title

I-Flow Corporation 12/30/98
Company Dated

Premarket Notification (510(k) Number)

24

I-FLOW
CORPORATION

20202 Windrow Rd.
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

510(k) Number (if known): _____

Device Name: Paragon Bolus Accessory Set

**Indications for Use**:

1. The Paragon Bolus Accessory Set is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider.
2. The routes of administration are intravenous, epidural, intramuscular and subcutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

25

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

## TABLE OF CONTENTS



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# 1.0 GENERAL INFORMATION

## 1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an accessory device for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus. This new accessory will be known as the Paragon Bolus Accessory Set, hereafter identified as the Bolus Accessory. No change will be made to the existing Paragon pump or administration sets.

1.1.2 Trade Name: Paragon Bolus Accessory Set

1.1.3 Common Name: Bolus Accessory Set

1.1.4 Classification Name: Set, Administration, Intravascular

1.1.5 Product Code: 80 FPA

1.1.6 Device Classification: Class II, 880.5440

1.1.7 Classification Panel: General Hospital and Personal Use Device

## 1.2 Statement of Equivalence

1.2.1 The Bolus Accessory is substantially equivalent to Patient Control Module (K884505) marketed by Baxter Healthcare Corporation and the I-Flow Bolus Dispenser (K935811).

## 1.3 Overview of the Existing Paragon Infusion System

1.3.1 The Paragon Infusion System consists of two main components, the Paragon pump and administration set. This premarket notification proposes a new accessory for use with the Paragon Infusion System, i.e. the Bolus Accessory. No change will be made to the existing Paragon pump or administration sets.

1.3.2 The Paragon Pump

1.3.2.1 The Paragon pump consists of two cylindrical shells. The top half of the pump has (b)(4) (b)(4) (b)(4) (b)(4) of the bottom half of the pump.

1.3.2.2 The top incorporates a (b)(4) (b)(4) which applies a load to the pliable drug bag. The load is applied to the drug bag by way of (b)(4) (b)(4) mechanism. The (b)(4) (b)(4) creates a near constant pressure in the drug bag.

1.3.2.3 The bottom half of the pump is slotted to allow for positioning of the administration set.

1.3.2.4 When the top and bottom halves of the pump are fully (b)(4) (b)(4) together, the (b)(4) (b)(4) contacts the drug bag and acts as the pressurizing element.

1.3.3 The Paragon Administration Set

1.3.3.1 The Paragon administration sets consist of a PVC drug bag attached to the administration line.

1.3.3.2 Each administration set has either flow control tubing or orifice to regulate the flow rate to the patient.

1.3.3.2.1 The delivery time characteristic is derived from the flow rate of the device which is in turn approximated by (b)(4), (b)(5)

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

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

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

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

equation provides an approximation of the actual delivery time.

## 2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

### 2.1 Description of the Bolus Accessory

Wherever the Paragon pump and administration set are mentioned, they may be replaced by any constant 6 psi pressure system. See Appendix A for drawings.

2.1.1 The Bolus Accessory may connect to any Paragon administration set to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

2.1.2 The Bolus Accessory consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

2.1.3 The bolus button allows patient controlled administration of medication as needed.

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

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

**Top View** **Side View**

## 2.2 Bolus Refill Cycle (i.e. Lockout Time)

2.2.1 The Paragon pump is the pressure source pushing fluid into the inlet port of the Bolus Accessory.

2.2.2 The flow control orifice of the Paragon administration set establishes a lockout period during which the patient cannot receive another full bolus of medication.

2.2.2.1 The time required to fill the bolus cavity is called the "lockout time" or "refill cycle".

2.2.2.2 Lockout times vary according to the flow rate of the Paragon administration set. See table below.

| Flow Rate of Paragon Set (ml/hr) | Lockout Time (min.) |
|---|---|
| 0.5 | 70.0 |
| 1.0 | 35.0 |
| 2.0 | 18.0 |
| 4.0 | 9.0 |
| 10 | 3.6 |

The lockout time is approximated as follows:

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

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

2.2.3 As fluid flows into the bolus cavity, the diaphragm is continuously displaced until the cavity is full.

2.2.3.1 As a safety feature, the bolus cavity is filled non-linearly, slower in the beginning and more rapidly towards the end of the refill cycle. See chart #6 for the pressure profile.

2.2.3.2 The bolus reservoir is 0.5 ml volume.

## 2.3 Bolus Activation

2.3.1 On the opposite side of the diaphragm is a bolus button. The button moves with the diaphragm as it is displaced.

2.3.2 At any time while the bolus cavity is filling, the button can be activated by the user. Only when the bolus cavity is full will the patient receive the entire bolus.

2.3.3 When the button is activated, the fluid in the bolus cavity is pushed out and forced through a check valve. At this point, the refill cycle begins.

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## 2.4 Product Configuration

Bolus Accessory Model

2.4.1 B000000: 0.5 ml bolus volume.

## 2.5 Components and Materials

No change will be made to the Paragon pump or administration set. The Paragon pump and administration set components remain the same as K923875.

The Bolus Accessory is a disposable device intended for single patient use.

2.5.1 Non-fluid path components (bolus component only)

2.5.1.1 Bolus Button: (b)(4), (b)(5)

2.5.1.2 Outer Housing: (b)(4), (b)(5)

2.5.1.3 Luer Cap: (b)(4), (b)(5)

2.5.2 Fluid path components (bolus component only)

2.5.2.1 Inner Housing: (b)(4), (b)(5)

2.5.2.2 Diaphragm: (b)(4), (b)(5)

2.5.2.3 Check Valve: (b)(4), (b)(5)

2.5.2.4 Male Luer Adapter: (b)(4), (b)(5) or equivalent.

2.5.2.5 Female Luer Adapter: (b)(4), (b)(5) or equivalent.

2.5.2.6 Tubing (Make-up): (b)(4), (b)(5)

2.5.2.7 Solvent Bonding: (b)(4), (b)(5) or equivalent.

## 2.6 Power Requirements

2.6.1 The Bolus Accessory is a mechanical device that requires no external power to operate.

# 3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

## 3.1 Standard Operating Conditions:

| | |
|---|---|
| Bolus Volume: | 0.5 ml |
| Refill Time: | variable |
| Priming/Residual Volume: | <=4 ml |
| Operating Temperature: | 90 ± 2ºF |
| Calibration Solution: | 0.9% NaCl |
| Operating Pressure: | 6.0 psi pressure source |
| Head Height: | 0” |
| Accuracy: | bolus volume: ±10% at 95% confidence interval at the identified lockout times. |

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3.2 **Performance Data:** (b)(4), (b)(5)

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

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

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

3.2.5

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

3.2.6

3.3 **Safety/Alarm Functions**

3.3.1 The Bolus Accessory will not be recommended for any application that exceeds the minimum internal pressure of the system.

3.3.2 If for any reason the patient needs to stop his or her infusions, each administration set is supplied with a pinch clamp to stop the infusion.

3.3.3 This device contains no alarms or indicators for flow other than visual.

3.3.4 This device contains no alarms or indicators to detect air in line or an occlusion; however, each set may include an integrated air-eliminating filter.

3.3.5 The non-linear refill adds additional patient safety if the bolus button is activated prior to the lockout time.

## 4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.

4.2 The Bolus Accessory is categorized as follows:

4.2.1 Device Category: External Communicating Device.

4.2.2 Body Contact: Blood Path, Indirect

4.2.3 Contact Duration: Prolonged

32

Chart #1
Bolus Accessory
**Bolus Volume Accuracy**
various lockout times

| Bolus # | Volume (ml) 3.6 min. lockout | 9 min. lockout | 18 min. lockout | 35 min. lockout | 70 min. lockout |
|---|---|---|---|---|---|
| 1 | (b)(4), (b)(5) | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| Min | | | | | |
| Max | | | | | |
| N | | | | | |
| **Average** | | | | | |
| Std. Dev. | | | | | |

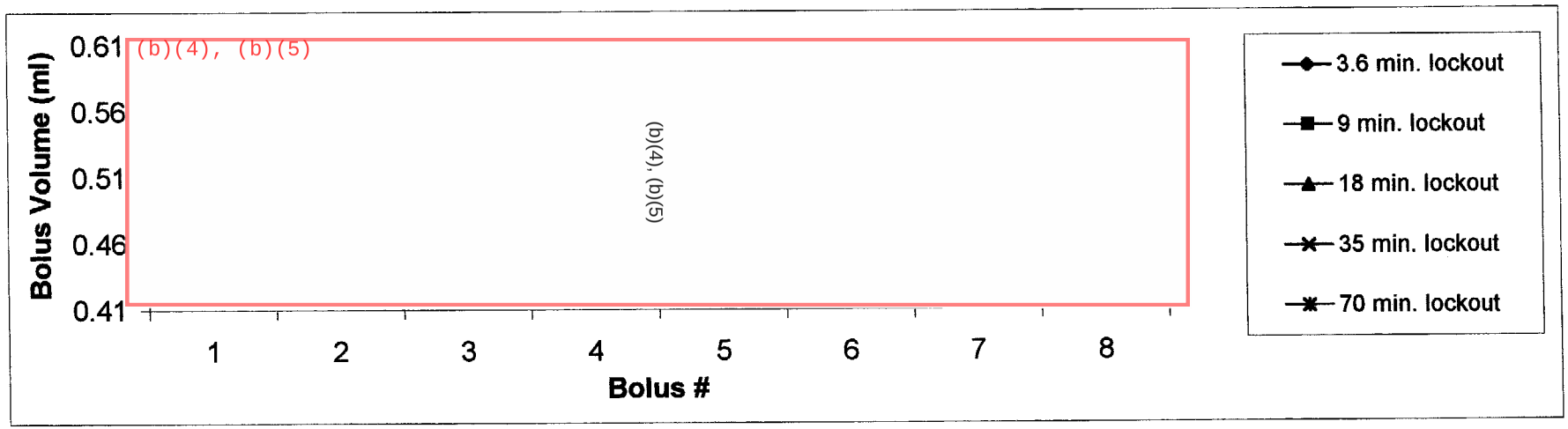

Chart #2
Bolus Accessory
**Bolus Volume Accuracy**
3.6 and 70 min. lockout

| Bolus # | Volume (ml) 3.6 min. lockout | 70 min. lockout |
|---|---|---|
| 1 | (b)(4), (b)(5) | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | | |
| 16 | | |
| 17 | | |
| Min | | |
| Max | | |
| N | | |
| **Average** | | |
| Std. Dev. | | |

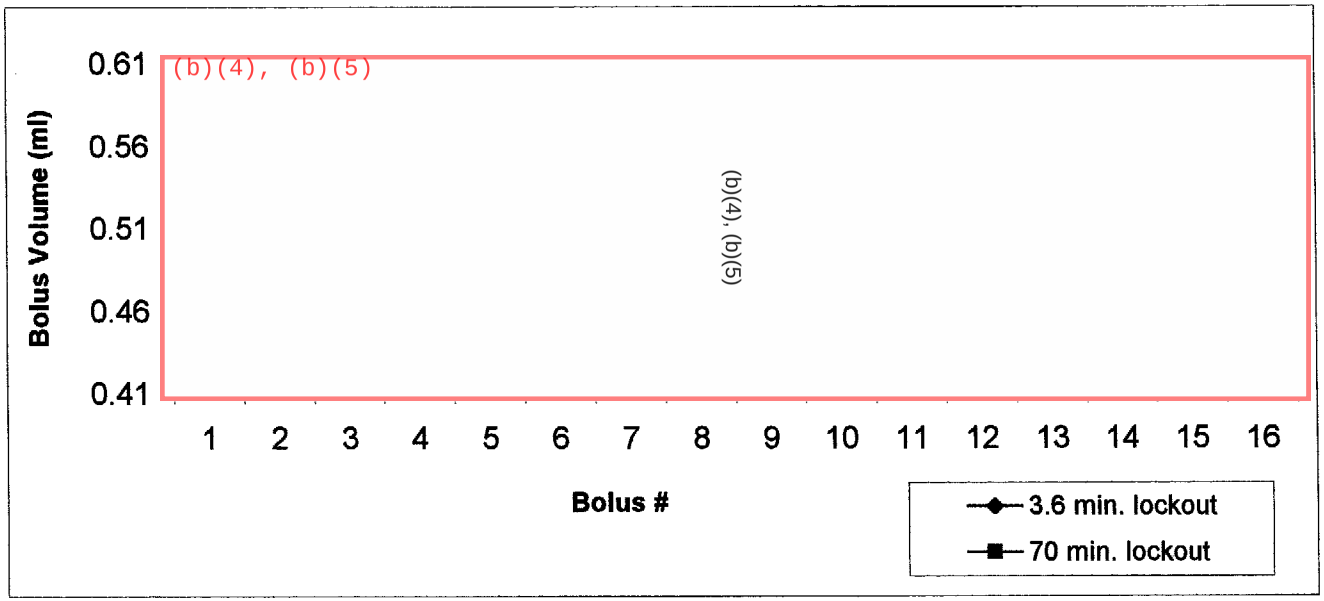

**Chart #3**
**Bolus Accessory**
**Bolus Volume Accuracy**
Life Test

(b)(4)

(b)(4)

35

**Chart #4**
Bolus Accessory
**Bolus Volume Accuracy**
Life Test

(b)(4)

(b)(4)

36

Chart #5
Bolus Accessory
**Bolus Refill Time Accuracy**
Life Test

(b)(4)

(b)(4)

37

Chart #6a
Paragon Bolus Accessory Set
**Pressure Profile**
During Refill Cycle
3.6 min. lockout

SOLTEC

(b)(4)

(b)(4)

58

Chart #6b
Baxter Patient Control Module
**Pressure Profile**
During Refill Cycle

(b)(4)

(b)(4)

## 5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Bolus Accessory.

5.1.2 The Bolus Accessory is intended for general purpose drugs and pain medication.

5.2 Drug Stability

5.2.1 There are no specific drugs referenced in the labeling for the Bolus Accessory.

## 6.0 INTENDED USE

6.1 The Bolus Accessory is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

6.2 The routes of administration intravenous, epidural, intramuscular and subcutaneous.

6.3 The Bolus Accessory is not intended for continuous delivery.

6.4 The Bolus Accessory is single patient use only.

6.5 The Bolus Accessory is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

6.6 No testing has been conducted to determine the efficacy of Bolus Accessory for the delivery of blood, blood products, lipids or fat emulsions. The Bolus Accessory is not intended for the delivery of blood, blood products, lipids or fat emulsions.

## 7.0 LABELS AND LABELING

7.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.2 The Bolus Accessory Directions for Use labeling:

7.2.1 Provides comprehensive directions for preparation and use for the Bolus Accessory.

7.2.2 Describes the routes of administration as it relates to intended use.

7.2.3 Contains warning information.

7.2.4 Contains the prescription statement required under 801.109 (b)(1).

7.2.5 Includes the specifications of the Bolus Accessory. The specifications include the priming volume, residual volume, accuracy and operating conditions.

7.3 Identification labels and labeling

7.3.1 I-Flow has developed product identification labeling for the Bolus Accessory. Refer to Appendix B for examples.

7.4 Packaging labels

7.4.1 Contains the prescription statement required under 801.109 (b)(1).

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7.5 Appendix C contains predicate labeling for the Patient Control Module marketed by Baxter Healthcare Corporation.

## 8.0 STANDARDS

8.1 There are currently no standards established for mechanical PCA infusion devices.

## 9.0 PACKAGING

9.1 The Bolus Accessory is packaged in a sealed Tyvek pouch, 12 pouches per case.

9.2 Packaging is suitable for radiation or ETO sterilization.

9.3 Package aging tests have been conducted on the Tyvek pouch. The results of (b)(4) (b)(4) testing has determined that the Tyvek pouches used to package the disposable Bolus Accessory maintains sterility in excess of three years.

## 10.0 STERILIZATION

10.1 The method of sterilization is gamma radiation (cobalt 60).

10.2 Sterilization validation methodology is by ANSI/AAMI ST32-1991 / EN552 Method 1 for gamma radiation.

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

10.3 The sterile product under review here will have a sterilization assurance level (SAL) of $10^{-6}$. Under AAMI Method 1 for Gamma sterilized product, no sterility test is required.

10.4 The Bolus Accessory is labeled pyrogen free and is tested for pyrogens using either the USP Rabbit Pyrogen Test or LAL test methods.

10.4.1 I-Flow products have been validated for LAL testing.

10.4.2 Either method may be used.

## 11.0 COMPARISON TO LEGALLY MARKETED DEVICES

See Table 1 that follows this section for more specific information.

11.1 Intended Use

11.1.1 The Bolus Accessory , the Baxter Patient Control Module and the I-Flow Bolus Dispenser have the same intended use:

11.1.1.1 To deliver fixed boluses of medication upon demand by the patient or healthcare provider.

11.2 Descriptions of the Paragon Bolus Accessory

Wherever the Paragon pump and administration set are mentioned, they may be replaced by any constant 6 psi pressure system.

11.2.1 The Bolus Accessory may connect to any Paragon administration set to deliver fixed boluses of medication upon demand by the patient or healthcare provider. The Bolus Accessory does not deliver continuous medication.

11.2.2 The Bolus Accessory consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

11.2.3 Bolus Refill Cycle (i.e. Lockout Time)

11.2.3.1 The Paragon pump is the pressure source pushing fluid into the inlet port of the Bolus Accessory.

11.2.3.2 The flow control orifice of the Paragon administration set establishes a lockout period during which the patient cannot receive another full bolus of medication.

11.2.3.3 The time required to fill the bolus cavity is called the "lockout time" or "refill cycle".

11.2.3.4 Lockout times vary according to the flow rate of the Paragon administration set. See table below.

| Flow Rate of Paragon Set (ml/hr) | Lockout Time (min.) |
|---|---|
| 0.5 | 70.0 |
| 1.0 | 35.0 |
| 2.0 | 18.0 |
| 4.0 | 9.0 |
| 10 | 3.6 |

11.2.3.5 As fluid flows into the bolus cavity, the diaphragm is continuously displaced until the cavity is full.

11.2.3.5.1 The bolus cavity is filled non-linearly, slower in the beginning and more rapidly towards the end of the refill cycle.

11.2.3.5.2 The bolus reservoir is 0.5 ml volume.

11.2.4 Bolus Activation

11.2.4.1 On the opposite side of the diaphragm is a bolus button. The button moves with the diaphragm as it is displaced.

11.2.4.2 At any time while the bolus cavity is filling, the button can be activated by the user. Only when the bolus cavity is full will the patient receive the entire bolus.

11.2.4.3 When the button is activated, the fluid in the bolus cavity is pushed out and forced through a check valve. At this point, the refill cycle begins.

11.3 Comparison to the Baxter Patient Control Module.

11.3.1 The Baxter Patient Control Module is very similar to the I-Flow Bolus Accessory.

11.3.2 The Patient Control Module may connect to any Baxter Infusor to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

11.3.3 The Patient Control Module consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

11.3.4 Bolus Refill Cycle (i.e. Lockout Time)

11.3.4.1 The Baxter Infusor is the pressure source pushing fluid into the inlet port of the Patient Control Module.

11.3.4.2 The time required to fill the bolus cavity is called the "lockout time" or "refill cycle".

11.3.4.3 Both the Patient Control Module and the Bolus Accessory determine the lockout time by the flow control orifice of the device they attach to. During the lockout time, the patient cannot receive another full bolus of medication.

11.3.4.4 Lockout times vary according to the flow rate of the Baxter Infusor. See table below.

| Flow Rate of Baxter Infusor (ml/hr) | Lockout Time (min.) |
|---|---|
| 0.5 | 60 |
| 2.0 | 15 |
| 5.0 | 6 |

11.3.4.4.1 The bolus cavity is filled linearly as opposed to non-linearly for the Bolus Accessory. See Charts #6a and #6b.

11.3.4.4.2 The bolus reservoir is the same as the Bolus Accessory (i.e. 0.5 ml volume).

11.3.5 Bolus Activation

11.3.5.1 For both the Baxter device and the Bolus Accessory, at any time while the bolus cavity is filling, the button can be activated by the user. Only when the bolus cavity is full will the patient receive the entire bolus.

11.3.5.2 When the button is activated, the fluid in the bolus cavity is pushed out and forced through a check valve. At this point, the refill cycle begins.

11.4 Comparison to the I-Flow Bolus Dispenser

11.4.1 The I-Flow Bolus Dispenser is a stand alone device that does not need to connect to an infusion pump such as the Paragon pump for the Bolus Accessory and the Baxter Infusor for the Patient Control Module.

11.4.2 The Bolus Dispenser consists of a reusable plastic dispenser, disposable medication reservoir (plastic syringe or mini-bag) and disposable administration set.

11.5 Specifications

11.5.1 The Bolus Accessory, the Baxter Patient Control Module and the I-Flow Bolus Dispenser have similar bolus volumes and lockout times. See Table 1.

11.6 Materials

11.6.1 All fluid path materials of the Bolus Accessory are in conformance with ISO 10993 Part 1.

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11.7 Based upon the data presented in this section 11.0 and Table 1, I-Flow Corporation has determined that the Bolus Accessory is substantially equivalent to the named predicate devices.

**Table 1**
Comparison to Legally Marketed Devices

| Comparison Element | Paragon Bolus Accessory Set (subject device) | SE[1] Baxter Patient Control Module (K884505) | SE[1] I-Flow Bolus Dispenser (K935811) |
|---|---|---|---|
| **Intended Use** | To deliver fixed boluses of medication upon demand by the patient or healthcare provider. | To deliver fixed boluses of medication upon demand by the patient or healthcare provider. | To deliver fixed boluses of medication upon demand by the patient or healthcare provider. |
| Route of Administration | Intravenous, epidural, intramuscular and subcutaneous | Intravenous, epidural, intra-arterial and subcutaneous | Intravenous, epidural, intramuscular and subcutaneous |
| Contraindications | Not intended for delivery of blood, blood products, lipids or fat emulsions. | | Not intended for delivery of blood or blood products. |
| Reuse Capability | Disposable, Single Patient Only | Disposable, Single Patient Only | Disposable, Single Patient Only |
| **Description** | | | |
| Bolus Volume | 0.5 ml | 0.5 ml | 0.25, 0.5 and 1.0 ml |
| Bolus Lockout Times | 3.6, 9, 18, 35 and 70 min. | variable (6 to 60 min.) | 15, 30, 60 and 120 min. |
| Pump Type | Available for use with any constant 6 psi pressure system such as the Paragon pump and administration set. | Available for use with Baxter Infusor pump | vacuum |
| Pump Volume | 100 ml | 65 ml | 30 ml |
| Power Requirements | None | None | None |
| Pressure Source | Mechanical spring energy of the Paragon Pump | Strain energy of elastomeric membranes | vacuum |
| Fluid Reservoir | PVC drug bag | Elastomeric membranes | PVC drug bag or polypropylene syringe |
| **Safety / Alarm Functions** | The Bolus Accessory attaches to fixed flow rate tubing which prevents fluid runaway conditions. The non-linear refill adds additional patient safety if the bolus button is activated prior to the lockout time. | The Patient Control Module attaches to fixed flow rate tubing which prevents fluid runaway conditions. | |

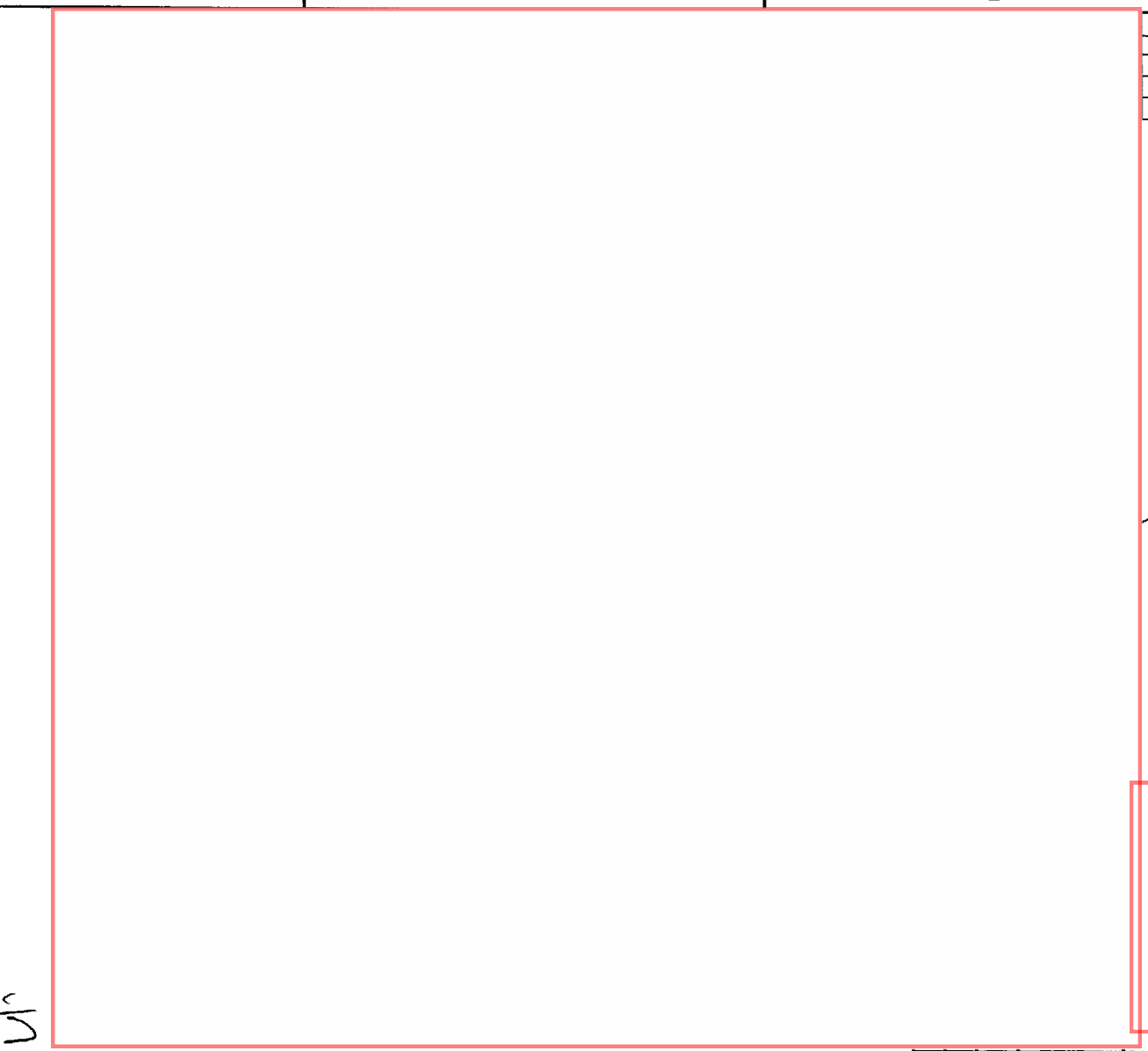
[1]SE = Substantially Equivalent

| Comparison Element | Paragon Bolus Accessory Set (subject device) | SE[1] Baxter Basal/Bolus Infusor (K884505) | SE[1] I-Flow Bolus Dispenser (K935811) |
|---|---|---|---|
| **Non-fluid Path Components** | | | |
| Outer Bolus Housing | (b)(4) | | |
| Bolus Button | | | |
| Luer Cap | | | |
| Pinch Clamp | | | |
| **Fluid Path Components** | | | |
| Inner Housing | (b)(4) | | |
| Diaphragm (bolus reservoir) | | | |
| Check Valve | | | |
| Luer Adapters | | | |
| Tubing (make-up) | | | |
| **Packaging (sterile pouch)** | | | |
| **Sterilization** | Gamma (b)(4) | ETO | Gamma or ETO |
| **Product Code** | 80 FPA | 80 FPA | 80 FPA |

[1]SE = Substantially Equivalent

# Appendix A
# Paragon Bolus Accessory Set
# Drawings

| Revisions | | | | | |
|---|---|---|---|---|---|
| Zone | Rev. | Description | Date | Chg. by | Ck. by |
| | | | | | |
| | | | | | |
| | | | | | |




| PARTS LIST | | | |
|---|---|---|---|
| ITEM NO. | QTY | PART NUMBER OR DESCRIPTION | |

3 LABEL TO CONTAIN LOT NUMBER (SEE TRAVELER) AND EXPIRY DATE. EXPIRY DATE TO BE 2 1/2 YEARS FROM DATE OF MANUFACTURER.

2. FINAL PRODUCT INSPECT PER QAOPXXX.

1. ASSEMBLE PER STANDARD PRODUCTION METHOD, SPMXXX

NOTES: UNLESS OTHERWISE SPECIFIED

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE:
FRACTIONS ± 1/32 DECIMALS .XX ± 0.01 .XXX ± 0.005 ANGLES ± 1/2

APPROVALS DATE
DRAWN
CHECKED
ENG.
QA/QC

MATERIAL
FINISH
DO NOT SCALE DRAWING

I-FLOW CORPORATION
Lake Forest, CA 92630

PARAGON BOLUS ACCESSORY

SIZE C | CAGE CODE | DWG NO. | REV A
SCALE NONE | FILE NAME | SHEET 1 OF 1

DWG NO. | SH 1 | REV A

(b)(4)

(b)(4)

| Revisions | | | | | |
|---|---|---|---|---|---|
| Zone | Rev | Description | Date | Chg by | Chk by |
| | | | | | |

| ITEM NO. | QTY REQD | INSERT NO. | PART OR IDENTIFYING NO. | NOMENCLATURE OR DESCRIPTION |
|---|---|---|---|---|
| 7 | A/R | | | |
| 6 | 1 | | | |
| 5 | 1 | | | |
| 4 | 1 | | | |
| 3 | 1 | | | |
| 2 | 1 | | | |
| 1 | 1 | | | |

PARTS LIST

(b)(4)

(b)(4)

⚠5 IDENTIFING MARK, USE PERMANENT INK MARKER, TO BE LOCATED IN THIS AREA.
4. (b)(4) TO Xpsi.
⚠3 DIMENSION FOR INSPECTION.
2. ASSEMBLE PER STANDARD PRODUCTION METHOD, SPMXXX.
1. INTERPRET DIMENSIONS AND TOLERANCES IN ACCORDANCE WITH ANSI Y14.5–1982.

NOTES: UNLESS OTHERWISE SPECIFIED

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE: DECIMALS .XX ± 0.01 .XXX ± 0.005 ANGLES ± 1/2°

MATERIAL ⚠5

Finish

DO NOT SCALE DRAWING

| APPROVALS | DATE |
|---|---|
| DRAWN ROHRDANZ | |
| CHECKED | |
| ENG. | |
| QA/QC | |

I-FLOW CORPORATION
Lake Forest, CA 92630

HOUSING ASSEMBLY, BOLUS ACCESSORY

SIZE D | CAGE CODE | DWG NO. | REV A

SCALE 4/1 | FILE NAME: | SHEET 1 OF 1

| Zone | Rev | Description | Date | Chg by | Chk by |
|---|---|---|---|---|---|
| | A | PRODUCTION RELEASE PER DCO | | RRR | |

(b)(4)

(b)(4)

| ITEM NO. | QTY REQD | INDENT NO. | PART OR IDENTIFYING NO. | NOMENCLATURE OR DESCRIPTION |
|---|---|---|---|---|
| 11 | | | | |
| 10 | A/R | | | |
| 9 | 1 | | | |
| 8 | 1 | | | |
| 7 | 1 | | | |
| 6 | 1 | | | |
| 5 | .67' | | | |
| 4 | .033' | | | |
| 3 | 1 | | | |
| 2 | 1 | | | |
| 1 | 1 | | | |

PARTS LIST

(b)(4)

7. BOLUS VOLUME TO BE .5ml ±.05ml @ Xpsi.
6. (b)(4)
5. (b)(4)
4.
3.
2. ASSEMBLE PER STANDARD PRODUCTION METHOD, SPMXXX.
1. INTERPRET DIMENSIONS AND TOLERANCES IN ACCORDANCE WITH ANSI Y14.5-1982.

NOTES: UNLESS OTHERWISE SPECIFIED

DO NOT SCALE DRAWING

I-FLOW CORPORATION
Lake Forest, CA 92630

BOLUS ACCESSORY

SIZE D | DWG NO. | REV A

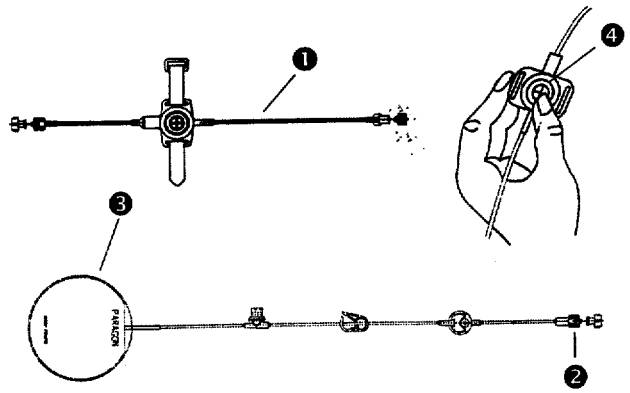
SCALE 1/1 | SHEET 1 OF 1

# Appendix B

# Paragon Bolus Accessory Set Labeling

# *PARAGON*
## *BOLUS ACCESSORY SET*

## Directions for Use




### NOMENCLATURE
1. Bolus Accessory Set ❶
2. Luer Lock ❷
3. PARAGON Administration Set ❸
4. Bolus Button ❹

### INTENDED USE
The Paragon Bolus Accessory Set, in combination with a Paragon Administration Set, is intended to allow patient controlled bolus delivery. The bolus component of the administration set enables fixed boluses to be delivered upon demand by the patient or healthcare provider. The routes of administration include intravenous, epidural, intramuscular and subcutaneous.

**DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED OR IF EITHER PROTECTOR CAP IN NOT IN PLACE. THE PARAGON BOLUS ACCESSORY SET IS STERILE AND NON-PYROGENIC.**

**DO NOT RESTERILIZE. SINGLE PATIENT USE.**

### CAUTION
1. Not for blood, blood products, lipids or fat emulsions delivery. It is recommended that the Bolus Accessory Set be changed in accordance with established guidelines.
2. Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic drug delivery. Do not use Y adapter with epidural delivery.
3. If the device is to be used for epidural analgesic drug administration, it should be labeled to differentiate from other routes of administration. When using this device for epidural drug administration, make certain only drugs recommended for this route of administration are used.
4. The Bolus Accessory Set does not provide basal flow rate. It should be used in conjunction with another infusion line providing a continuous delivery in order to keep the IV line patent.
5. Refer to the Directions for Use for the Paragon Administration Set for additional instructions.

### THE BOLUS ACCESSORY SET
The Paragon Bolus Accessory Set is designed to allow the patient or healthcare provider to administer a 0.5 ml bolus on demand. The refill time for the bolus depends on the Paragon Administration Set to which the Bolus Accessory Set is attached. See the Refill Time Table for specific refill times.

### PRIMING THE ADMINISTRATION SET
1. Prime the administration set first.
2. Attach the Bolus Accessory Set to the administration set.
3. Using appropriate aseptic technique, remove the cap from the Luer lock at the end of the set. Open the clamp on the administration set tubing. The medication will flow into the bolus chamber on the Bolus Accessory Set.
4. When the bolus button fills (button rises to top of housing), press the Bolus button to prime. Repeat until air is purged down stream from the bolus housing, which may take several pushes.
5. Pinch the clamp closed and replace the cap.

### STARTING THE INFUSION
1. Attach the Bolus Accessory Set to the infusion site. Secure the bolus housing against the skin, using either the strap provided or tape.
2. The Bolus button may be attached to the patient's wrist using the strap provided.
3. Opening the clamp on the administration set. A bolus can be delivered immediately.

### BOLUS ACTIVATION
1. To receive a bolus of medication, press firmly down on the bolus button until it stops. ❹
2. At any time during the infusion, the bolus button can be pushed to deliver a bolus of medication.
3. The next full bolus will be available after the refill time noted in the Refill Time Table.
4. Pressing the bolus button prior to the end of the refill time will result in a partial dose.

### IMPORTANT
1. Only *PARAGON* administration sets distributed by I-Flow Corporation are authorized for use with this product. I-Flow Corporation accepts no responsibility for performance, or the liability for damages, caused by the misuse of this product when used with unauthorized administration sets.
2. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the Bolus Accessory Set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

***The* PARAGON *Bolus Accessory Set Specifications***

**Bolus Volume:** 0.5 ml

**Refill Time:** 3.6 min. - 70 min., depending on the attached Paragon Administration Set.

**Accuracy:**

Bolus Volume: ±10% at 95% confidence interval at the identified lockout time.

**Priming volume:** Allow 1 ml for loss during priming.

**Residual volume:** Approximately 4 ml (including the Paragon Administration Set)

**Refill Time Table**

| Paragon Administration Set | Refill Time |
|---|---|
| 0.5 ml/hr | 70 min. |
| 1.0 ml/hr | 35 min. |
| 2.0 ml/hr | 18 min. |
| 4.0 ml/hr | 9 min. |
| 10.0 ml/hr | 3.6 min. |

**NOTES**

1. Actual refill times may vary from the specified range due to:
   - viscosity and/or drug concentration.
   - temperatures above or below the operating conditions.
   - the positioning of the *PARAGON* Infuser above or below the infusion site.

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

A PRODUCT OF

I-FLOW®

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

For Customer Service
Call: 1.800.448.3569
949.206.2700

CE 0123

European Representative:
MPS Medical Product Service GmgH
Borngasse 20, 35619 Braunfels, Germany

1302268A
12/98

A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE / UN PRODUCTO DE

I-FLOW®

CONTENTS / INHALT / CONTENU / CONTENIDO: 1

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

REF B000000

# Paragon Bolus Accessory Set
# 0.5 ml bolus volume



STERILE

LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

Manufactured by / Hersteller von / Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung / Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

130XXXXA

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A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE / UN PRODUCTO DE

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

CONTENTS / INHALT / CONTENU / CONTENIDO: 12

REF B000000

PART NO. 500XXXX

# Paragon Bolus Accessory Set
# 0.5 ml bolus volume

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL. SEE DIRECTIONS FOR USE.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE 0123

European Representative / Europaische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

130XXXXA

4

# Appendix C
## Predicate Labeling

Baxter

# Infusor Patient Control Module

## Description

The Patient Control Module is an accessory for Baxter's Infusors. When the medication demand button of the module is depressed, a small quantity of drug solution is delivered, **nominally** 0.5 mL. There is no infusion between depressions of the medication demand button.

Depression of the medication demand button empties the 0.5 mL reservoir of the Module. Upon release of the button, the reservoir again begins to fill with medication. The time to fill the Module's reservoir is determined by the Infusor selected. For example:

| Infusor | Flow Rate | Approximate Module Fill Time |
|---|---|---|
| 2C1070/2C1071 | 2 mL/hr | 15 minutes |
| 2C1073 | 5 mL/hr | 6 minutes |
| 2C1080 | 0.5 mL/hr | 60 minutes |
| 2C1954 | 0.5 mL/hr | 60 minutes |
| 2C1955 | 0.5 mL/hr | 15 minutes |

Note: All times reflect use of the Infusor as directed in the individual direction sheet.

## Indications and Usage

The Patient Control Module is intended for use with patients in both the hospital and home environment. It is convenient for use by ambulatory or nonambulatory patients. **This accessory can only be used with Baxter's Infusors.**

## Warnings

1. To ensure proper performance the device should be used as directed.
2. This accessory **must** be used with Baxter's Infusors to ensure safe operation.
3. Do not use if white shipping insert is not affixed to the medication demand button when received.
4. Remove white shipping insert prior to connection to patient. **Failure to remove shipping insert will cause continuous infusion.**

**Not intended for use for continuous infusion.**

## Directions For Filling

**Use aseptic technique throughout entire procedure**

A. Standard Method

1. Select the Infusor with the desired flow rate. Module filling time determines the maximum number of 0.5 mL doses available per hour.
2. Prepare the Infusor per its enclosed direction sheet. The drug concentration should be set so that the unit delivers the maximum dose/hr prescribed by the physician at either the 6, 15, or 60 minute dose interval. The patient can then use the Module to titrate the drug within the prescribed limits.
3. When the Infusor is ready for use, remove the tip protector and winged Luer cap from the Module. Do not remove white shipping insert at this time. Place the male Luer of Infusor into the female Luer of the Module. **Note: Avoid touch contamination of the Luer fittings.**
4. The Module will be primed by the flow of the Infusor. Priming time will depend upon the flow rate of the Infusor selected.
5. Observe the reservoir filling through the clear back plate. **When the liquid starts to flow from the male Luer, remove the white shipping insert. Failure to remove shipping insert will cause continuous infusion.** When the reservoir is filled, depress and release the medication demand button to complete the priming operation and expel any air in the reservoir.
6. Replace the winged Luer cap onto the male Luer of the Module.
7. Package the entire unit in the Infusor Dispenser Bag for transport to the patient.
8. Store in a clean area, protected from sunlight.

   Refer to drug manufacturer's package insert for storage requirements.

B. Optional Method

1. Proceed per standard method above, sections A.1 and A.2.
2. When the Infusor is ready for use, remove the tip protector and winged Luer cap from the Module. **Remove the white shipping insert from the Patient Control Module. Failure to remove shipping insert will cause continuous infusion.** Using a syringe containing a minimum of 2 mL of solution or diluent, attach the syringe to the female Luer of the Module. While filling the Module reservoir, cycle the Module medication demand button as needed to eliminate air in the reservoir or tubing. Disconnect the syringe from the female Luer of the Module.
3. Connect the male Luer of Infusor to the female Luer of the Module.
4. Proceed per standard method above, sections A.6 through A.8.

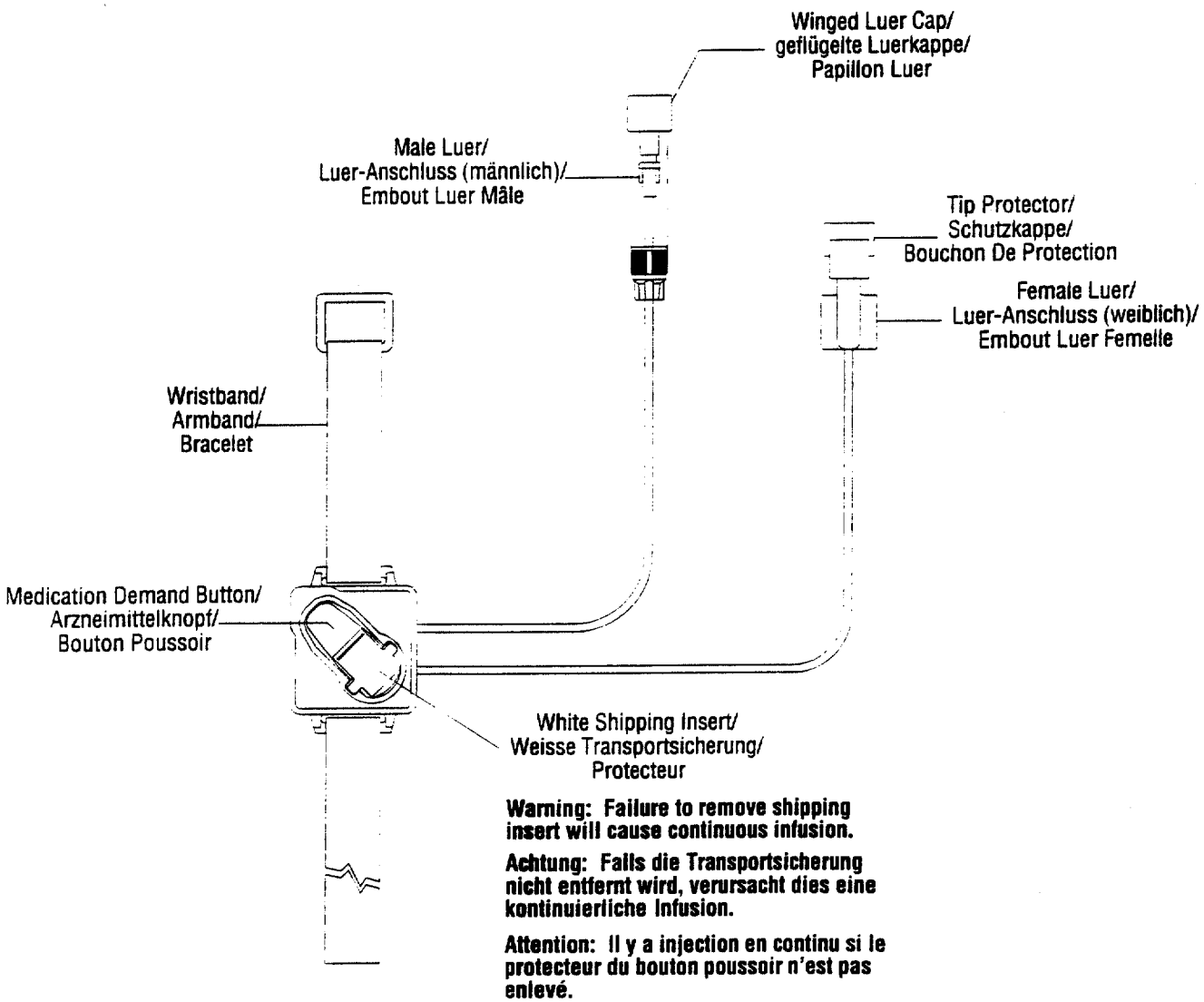
**Do not store above 38°C (100°F) or in direct sunlight.**

**Baxter Healthcare Corporation**
Deerfield, IL 60015 USA
Printed in USA



7-19-1-628
Rev. March 1992

# Infusor Patient Control Module/Module De Contrôle Pour L'Infuseur/Watch

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To Open Peel Down

**2C1079**

**Baxter**

## Infusor Patient Control Module

Sterile, nonpyrogenic fluid path.
Do not use if tip protectors are not in place.
The Patient Control Module is intended for use in both the hospital and home environment by ambulatory or nonambulatory patients.
**For use with Baxter's infusors only.**
**Not intended for use for continuous infusion.**
**Failure to remove shipping insert will cause continuous infusion.**
See accompanying directions for use.
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
**Do not store above 38°C (100°F) or in direct sunlight.**

**Baxter Healthcare Corporation**
Deerfield, IL 60015 USA

Made in USA

Patent Pending

## Module De Contrôle Pour L'Infuseur C1079

Circuit stérile et apyrogène.
Ne pas utiliser si les protecteurs des extrémités du circuit ne sont pas en place.
Vérifier l'intégrité du protecteur de stérilité avant usage.
N'ouvrir qu'au moment de l'emploi.
Mode d'emploi: Voir notice jointe: notamment, ne pas oublier de retirer le protecteur du bouton poussoir sous peine d'obtenir une injection en continu.
**Stocker à une température inférieure à 38°C et à l'abri de la lumière.**
Ne pas réutiliser—détruire après emploi.

Fabriqué par Baxter Healthcare Corporation, Deerfield, IL 60015, USA
Distribué par Baxter S.A. France—Avenue Louis Pasteur—
78311 Maurepas Cedex

## Watch 2C1079

**Für die bedarfsgesteuerte Therapie (on-demand)**
Flussweg ist steril und pyrogenfrei.
Zum einmaligen Gebrauch.
Bei beschädigter Verpackung, gelockerten oder fehlenden Schutzkappen nicht verwenden.
Beiliegende Gebrauchsanweisung beachten.
**Nicht über 38°C lagern. Vor direkter Sonneneinstrahlung schützen.**

Baxter Deutschland GmbH
D-8044 Unterschleissheim

Sterilized by gamma irradiation/Stérilisé aux rayons gamma.

Lot/Numéro de lot/Ch.-B.:/
Manufacture Date:/
Date of sterilization/Stérilisé le/sterilisiert:/
Expiration Date/Date de péremption/Verwendbar bis:
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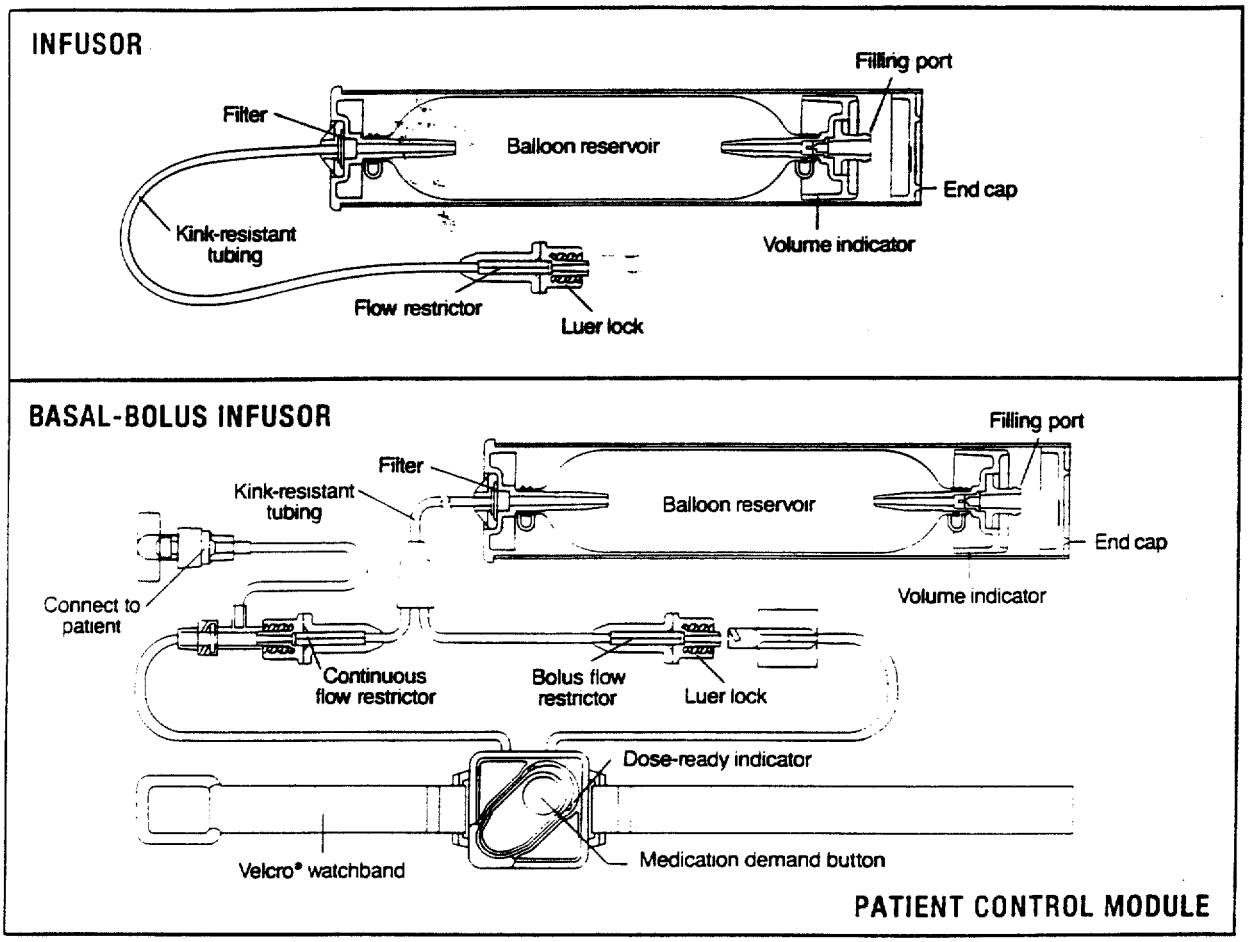
# PORTABLE INFUSION SYSTEMS
## WITH ELASTOMERIC TECHNOLOGY




| Model | Number | Flow Rate | Lockout Time | Bolus Dose | Capacity | Units Per Case |
|---|---|---|---|---|---|---|
| Singleday Infusor | 2C1071 | 2 mL/hr | 15 min* | 0.5 mL* | 65 mL | 6 |
| 12-hour Infusor | 2C1073 | 5 mL/hr | 6 min* | 0.5 mL* | 65 mL | 6 |
| Multiday Infusor | 2C1080 | 0.5 mL/hr | – | – | 65 mL | 6 |
| Basal-Bolus 15 | 2C1955 | 0.5 mL/hr | 15 min | 0.5 mL | 65 mL | 6 |
| Patient Control Module | 2C1079 | – | – | 0.5 mL | 0.5 mL | 12 |

*When used with Patient Control Module.

1. Carlson RW, Sikic BI. Continuous infusion or bolus injection in cancer chemotherapy. *Ann Intern Med.* 1983;99:823-833.

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Baxter

Baxter Healthcare Corporation. I.V. Systems Division. 1425 Lake Cook Road. Deerfield, IL 60015


3 91 10M Printed in U.S.A.

# The Infusor System (Baxter)

## DESCRIPTION

The Infusor System is a lightweight disposable device that uses a balloon reservoir to infuse medication. When filled, the Infusor System operates with a sustained internal pressure. Contents are delivered through a filter and a flow restrictor.

The Infusor System is designed to provide continuous flow of medication over the infusion period. Flow consistency is optimized when 5% Dextrose Injection (D5W) is used as the final diluent and the one-piece Luer body is in contact with the skin.

### Indications and Usage

The Infusor System is indicated for patients requiring slow, continuous intravenous, intra-arterial, epidural or subcutaneous administration of medications. It is convenient for use by ambulatory patients.

It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

### Epidural Administration

Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites.

It is strongly recommended that Infusors used for epidural drug delivery be clearly differentiated from Infusors used for other routes of administration.

## CONTRAINDICATIONS

Not designed for rapid infusion of medications.

## WARNINGS

1. Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
2. Discard Infusor after single use. The Infusor *must not* be refilled or resterilized.
3. Unfilled Infusors must be protected from direct sunlight and stored at temperatures less than 38°C (100°F).
4. Unfilled Infusors must be filled in accordance with the procedures described under DIRECTIONS FOR FILLING, in order to ensure proper performance.
5. Do not use unless solution is clear.
6. Do not fill with more than specified amount of solution. See directions accompanying Infusor.
7. Do not fill with more than maximum recommended fill volume.

## MIXING AND USE INFORMATION

1. The Infusor System is a fixed rate device designed to flow at a *nominal* rate as specified in the labeling of each Infusor. The quantity of solution for the Infusor is prepared by diluting the desired dose of drug in the recommended diluent to a volume determined by the desired infusion time.
2. Alteration of dosage is achieved by adjustments in concentration rather than flow rate.
3. Adhere to drug manufacturer's package insert if drug reconstitution is necessary.
4. The medication is prepared by diluting the desired dose of drug in a 60-mL syringe with Luer tip.
5. The Infusor System is designed to operate using 5% Dextrose Injection (D5W) as the final diluent to provide correct fluid viscosity. When using D5W, the Infusor will flow at the specified *nominal* rate. Although 0.9% Sodium Chloride Injection (NS) or Ringer's Injection may be used as an alternate diluent, these solutions will flow at approximately 10% above the *nominal* rate due to lower solution viscosity.
6. When empty, the Infusor will contain a 1 mL* residual volume.

   A. The fill volume for the Infusor is computed using the following equation:

   1. Using D5W as the final diluent.

      (Infusion time x nominal flow rate) + 1 mL* residual volume = fill volume.

   2. Using NS or Ringer's Injection as the final diluent.

      (Infusion time x 1.1 x nominal flow rate) + 1 mL* residual volume = fill volume.

   B. Compensate for the 1 mL* residual volume using the following equation:

$$\text{Desired patient dose} \times \frac{\text{fill volume}}{\text{fill volume} - 1^*} = \text{total dose placed in Infusor}$$

* For code 2C1082, substitute 2 mLs for residual volume.

U.S. Food and Drug Administration

# DETAILED INFORMATION

**Device Classification Name:** PUMP, INFUSION
**Regulation Number:** 880.5725
**510(k) Number:** K884505
**Device Name:** BASAL/BOLUS INFUSORS
**Applicant:** BAXTER HEALTHCARE CORP.
ROUTE 120 & WILSON ROAD
ROUND LAKE, IL 60073
**Contact:** PATRICIA S BARSANTI
**Product Code:** FRN
**Date Received:** 10/25/88
**Decision Date:** 07/14/89
**Decision:** Substantially Equivalent
**Classification Advisory Committee:** General Hospital
**Review Advisory Committee:** General Hospital
**Statemant/Summary/Purged Indicator:** Purged, no summary or statement

Return For Another Search

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*(Database Updated April 6, 1998)*

# Appendix D

## Reference Labeling

## Paragon Infusion System

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# PARAGON USER'S GUIDE

## Directions for Use

### NOMENCLATURE

1. PARAGON Infuser ❶
2. Fluid Level Indicator ❷
3. 1.2 micron air-eliminating filter ❸
4. PARAGON Administration Set ❹
5. Flow Rate Label ❺
6. Luer Lock ❻
7. End of Infusion Indicator ❼

### CAUTION

1. Do not use the administration set if the sterile pouch is opened or damaged. If either protective cap is missing or not in place, the sterility of the administration set is no longer guaranteed.
2. Not for blood or blood products delivery. It is recommended that the administration set be changed every 24–48 hours or in accordance with CDC guidelines or institutional policies.
3. Do not resterilize administration set. Administration sets are intended for single patient use only. The fluid pathway is sterile and nonpyrogenic.

### INTRODUCTION

The *PARAGON* is a drug delivery system consisting of a reusable mechanical infuser and specially designed administration sets. The *PARAGON* provides precise delivery of medications requiring slow and continuous infusions, such as chemotherapeutics and analgesics. The *PARAGON* also infuses medications which require faster delivery, such as antibiotics.

### THE *PARAGON* ADMINISTRATION SET

Administration sets are made of PVC. Each set is approximately 127 cm long. A 1.2 micron air-eliminating filter is built into all administration sets. The flow rate at which the drug flows to the patient is controlled by a flow restrictor built into the end of the set. Flow rates for each set are printed on the air-eliminating filter label. ❺

### FILLING THE *PARAGON* IV BAG - USE ASEPTIC TECHNIQUE

1. Remove the IV bag with attached administration set from its package.
2. Move the flow clamp next to the filling valve and close the clamp. ❻
3. Fill a sterile syringe with the solution to be dispensed into the IV bag.
4. Connect the tip of the syringe to the filling valve and inject the solution into the IV bag. ❼ Refill the syringe and repeat if necessary.

   NOTE: The *PARAGON* Infuser is designed to hold a total of 100 ml of fluid. The maximum fill volume is 110 ml. If the amount of fluid exceeds 110 ml, it may be difficult to engage the threads on the top and bottom of the *PARAGON* Infuser.
5. Remove air from the IV bag by aspirating with a syringe attached to the filling valve. Squeezing the sides of the IV bag when pulling back on the syringe will aid in removing the air.
6. Be certain to replace the cap on the filling valve.
7. Do not place labels on the IV bag. Labels may be wrapped around the set.

### LOADING THE IV BAG INTO THE *PARAGON* INFUSER

1. Twist open the top and bottom halves of the *PARAGON* Infuser. ❽
2. Before placing the IV bag into the *PARAGON* Infuser, slide the thin portion of the administration set through the slot found on the bottom of the infuser. ❾
3. Center the bag in the bottom and press all around the edge of the bag to fully seat the bag in the bottom. Make sure there are no wrinkles in the bag. ❿
4. Pull gently on the thick portion of the tubing so that it is fully extended and seated at the bottom of the slot. ⓫
5. Twist the top and bottom halves of the *PARAGON* Infuser together until they meet. ⓬

### PRIMING THE ADMINISTRATION SET

1. Using appropriate aseptic technique, remove the cap from the luer lock at the end of the set. Open the clamp on the IV tubing. The medication will flow toward the end of the luer lock.
2. Confirm that fluid is flowing by observing the formation of a drop at the end of the luer lock. It may take 10 minutes for a drop to form when priming the 0.5 ml/hr set. ⓭
3. Pinch the clamp closed and replace the cap.

### STARTING THE INFUSION

1. Attach the administration set to the IV site. Secure the connection against the skin.
2. Start the infusion by opening the clamp on the administration set. The infusion will begin immediately.

### THE FLUID LEVEL INDICATOR

1. The window with the markings on the side of the infuser is used to estimate how far the infusion has progressed. ⓮
2. When the *PARAGON* IV bag is filled to its capacity of 100-110 ml, the top of the pressure plate will be aligned with the top round marker. ⓯
3. As the infusion progresses, the plate will move to the bottom marker indicating the bag is nearly empty. ⓰

### THE END OF THE INFUSION

The infusion is complete when at least three (out of the six) small blue dots appear through the bottom of the *PARAGON* Infuser. ⓱

### THE CARRYING CASE

The carrying case can be worn on a belt, over the shoulder, or around the waist.

1. Place the *PARAGON* Infuser in the carrying case so that the bottom of the infuser can be seen through the clear plastic window. ⓲
2. Lift the Velcro strap and slide the administration set down so that the set exits the carrying case at the side window opening. ⓳ Close the strap. (Positioning the infuser in this way allows for the viewing of the Fluid Level Indicator.)
3. The front flap of the carrying case lifts up to reveal a clear plastic window, allowing for the viewing of the End of Infusion Indicator. ⓴
4. If necessary, a small lock can be placed through the larger of the two holes on the zipper, and then through the cloth loop on the side of the carrying case. (This may discourage tampering with the infuser during an infusion.) ㉑

### CARE OF THE *PARAGON*

The *PARAGON* Infuser is durable and is intended to be used for repeated drug deliveries. After each patient use, the exposed surfaces, except the threads, may be wiped clean using isopropyl alcohol or a 10% bleach solution.

NOTE: Do not submerge the *PARAGON* Infuser in a bleach solution. After cleaning, if the *PARAGON* is difficult to twist together, place a small drop of lubricating ointment (such as K-Y™ Jelly) on a small section of the threads on the bottom of the infuser. Twist the top of the infuser onto the bottom to spread out the ointment. ㉒

# *PARAGON* HINWEISE FÜR DEN BENUTZER

## Gebrauchsanweisung

### NOMENKLATUR

1. *PARAGON* Infuser ❶
2. Flüssigkeitsstandanzeige ❷
3. 1,2 Mikron Filter zur Luftentfernung ❸
4. *PARAGON* Injektionssatz ❹
5. Flußratenetikett ❺
6. Luer-Anschluß ❻
7. "Ende der Infusion"-Anzeige ❼

### ACHTUNG

1. Benutzen Sie das Verabreichungs-Set nicht wenn der sterile Beutel geöffnet oder beschädigt wurde. Wenn eine der Schutzkappen fehlt oder sich nicht an ihrer Stelle befindet, kann die Sterilität des Verabreichungs-Sets nicht mehr garantiert werden.
2. Nicht für die Zuführung von Blut oder Blutprodukten. Es wird empfohlen, dass die Verabreichungs-Sets alle 24–48 Stunden nach den CDC Richtlinien oder den Vorschriften des Institutes ausgewechselt werden.
3. Das Verabreichungs-Set darf nicht wieder Sterilisiert werden! Die Verabreichungs-Sets sind nur für den Einsatz mit je Einem einzelnen Patienten bestimmt. Der Flüssigkeitspfad ist Steril und nicht-Pyrogenisch.

### Einleitung

Das *PARAGON*-System ist ein Medikamentverabreichungssystem, das aus einem wiederverwendbaren mechanischen Infuser und speziell entwickelten Injektionssätzen besteht. Das *PARAGON*-System sorgt für ein exakte Verabreichung von Medikamenten, die langsame und kontinuierliche Infusionen verlangen, wie z.B. Chemotherapeutika und Analgetika. Das *PARAGON*-System dient auch für Infusionen von Medikamenten, die schneller verabreicht werden müssen, wie z.B. Antibiotika.

### DER *PARAGON* INJEKTIONSSATZ

Die Injektionssätze werden aus PVC hergestellt. Jeder Satz ist ca. 127 cm lang und enthält einen 1,2 Mikron Filter zur Luftentfernung. Die Flußrate, mit der das Medikament dem Patienten zugeführt wird, wird von einem am Ende des Satzes eingebauten Flußrestriktor gesteuert. Die Flußraten der einzelnen Sätze sind auf dem Etikett am Filter zur Luftentfernung angegeben. ❽

### FÜLLEN DES *PARAGON* IV-BEUTELS - KEIMFREIES VERFAHREN

1. Den IV-Beutel mit dem befestigten Injektionssatz aus der Verpackung nehmen.
2. Die Flußklemme zum Füllventil schieben und schließen. ❾
3. Eine sterile Spritze mit der in den IV-Beutel zu füllenden Lösung füllen.
4. Die Spitze der Spritze an das Füllventil anschließen und die Lösung in den IV Beutel spritzen. ❿ Ggf. die Spritze erneut füllen und den Vorgang wiederholen.
5. Hinweis: Der *PARAGON*-Infuser kann bis zu 100 ml Flüssigkeit aufnehmen. Die maximale Füllmenge beträgt 110 ml. Bei mehr als 110 ml Flüssigkeit kann es schwierig werden, das Gewinde oben und unten am *PARAGON* einzupassen.
6. Die Luft mit Hilfe einer am Füllventil angesetzten Spritze aus dem IV-Beutel absaugen. Ein Drücken auf die Seiten des IV-Beutels, während die Spritze zurückgezogen wird, beschleunigt den Vorgang.
7. Darauf achten, daß die Kappe wieder am Füllventil angebracht wird.
8. Keine Etikette auf den IV-Beutel kleben, sondern um den Injektionssatz wickeln.

### EINSETZEN DES IV-BEUTELS IN DEN *PARAGON*-INFUSER

1. Die obere und untere Hälfte des *PARAGON* Infusers auseinanderschrauben. ⓫
2. Vor dem Plazieren des IV-Beutels in den *PARAGON* Infuser den schmalen Teil des Injektionssatzes durch den Schlitz im Boden des Infusers schieben. ⓬
3. Den Beutel auf die Mitte des Bodens legen und anliegende des Beutelrandes drücken, um den Beutel im Unterteil zu sichern. Sicherstellen, daß der Beutel keine Unebenheiten aufweist und ganz glatt liegt. ⓭
4. Den dicken Teil des Schlauchs vorsichtig auf volle Länge gradeziehen und auf richtigen Sitz unten am Schlitz prüfen. ⓮
5. Das obere und untere Teil des *PARAGON*-Infusers wieder fest zusammenschrauben. ⓯

### VORFÜLLEN DES INJEKTIONSSATZES

1. Unter Verwendung eines keimfreien Verfahrens die Kappe vom Luer-Anschluß am Ende des Injektionssatzes abnehmen. Die Klemme am IV-Schlauch öffnen. Das Medikament beginnt zum Luer-Anschluß zu fließen.
2. Prüfen, ob sich am Ende des Luer-Anschlusses ein Tropfen bildet, um den Flüssigkeitsstrom zu bestätigen. Beim Vorfüllen des 0.5 ml/h Satzes kann die Tropfenbildung bis zu 10 Minuten dauern. ⓰
3. Die Klemme schließen und die Kappe wieder anbringen.

### STARTEN DER INFUSION

1. Den Injektionssatz am IV-Zugang befestigen und den Anschluß sichern. Das Verbindungsstück an der Haut befestigen.
2. Die Infusion durch Öffnen der Klemme am Injektionssatz starten. Die Infusion beginnt sofort.

### DIE FLÜSSIGKEITSSTANDANZEIGE

1. Das mit Markierungen versehene Fenster an der Seite des Infusers läßt erkennen, wie weit die Infusion ungefähr fortgeschritten ist. ⓱
2. Wenn der *PARAGON* IV-Beutel mit 100-110 ml voll gefüllt ist, steht die obere Kante der Druckplatte an der oberen runden Markierung. ⓲
3. Mit fortschreitender Infusion bewegt sich die Platte zur unteren Markierung hin, was auf einen fast leeren Beutel hinweist. ⓳

### DAS ENDE DER INFUSION

Die Infusion ist komplett, wenn mindestens drei (der sechs) kleine blaue Punkte unten am Boden des *PARAGON*-Infusers zu sehen sind. ⓴

### DIE TRAGETASCHE

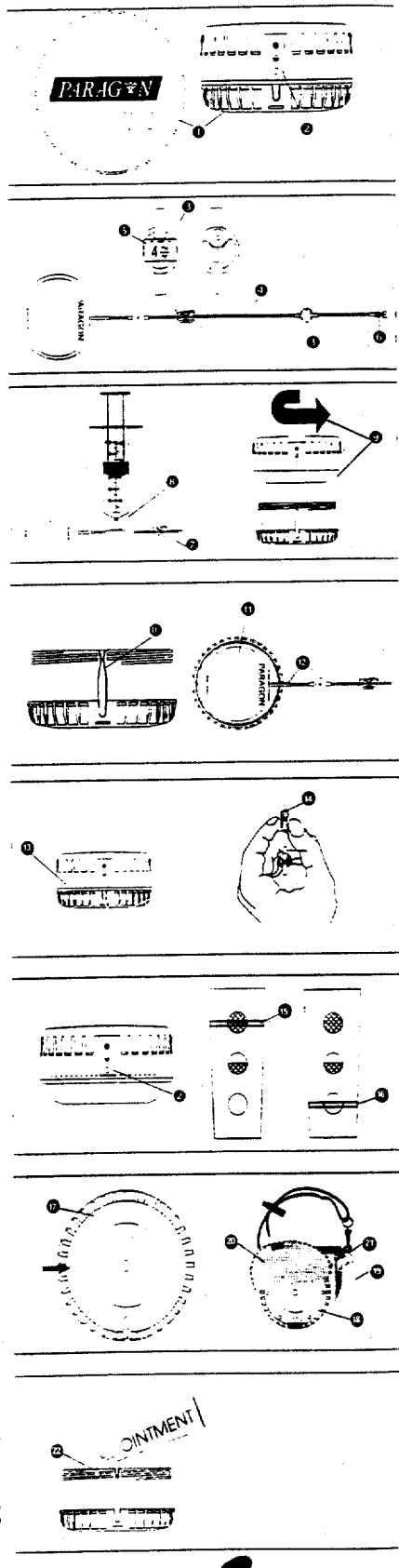
Die Tragetasche kann am Gürtel, über die Schulter oder um die Hüfte getragen werden.

1. Den *PARAGON*-Infuser so in die Tragetasche legen, daß die Unterseite des Infusers durch das durchsichtige Plastikfenster zu sehen ist. ㉑
2. Den Velcro-Verschlußstreifen öffnen und den Injektionssatz so nach unten schieben, daß er durch das Seitenfenster austritt. ㉒ Den Verschlußstreifen schließen. (Wird der Infuser so positioniert, ist die Flüssigkeitsstandanzeige erkennbar.)
3. Die vordere Klappe der Tragetasche läßt sich anheben, damit die "Ende der Infusion"-Anzeige durch das durchsichtige Plastikfenster eingesehen werden kann. ㉓
4. Bei Bedarf kann ein kleines Schloß durch das größere der zwei Löcher am Reißverschluß und dann durch die Stoffschlaufe an der Seite der Tragetasche geführt werden. (Damit läßt sich eine unzulässige Änderung der Infusionseinstellung verhindern.) ㉔

### REINIGEN DES *PARAGON*-INFUSERS

Der *PARAGON*-Infuser ist stabil und zur mehrfachen Verabreichung von Medikamenten vorgesehen. Nach jeder Verwendung an einem Patienten müssen die äußeren Oberflächen, mit Ausnahme der Gewinde, mit Isopropylalkohol oder einer 10%igen Bleichelösung abgewischt werden.

HINWEIS: Den *PARAGON*-Infuser nicht in eine Bleichenlösung eintauchen. Falls der *PARAGON* sich nach dem Reinigen nicht gut zusammenschrauben läßt, einen kleinen Tropfen Schmierpaste (z.B. K-Y™ Gel) auf einen kleinen Teil des Gewindes unten am Infuser auftragen. Das obere Teil des Infusers auf das untere Teil aufschrauben, um die Paste zu verteilen. ㉕

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# GUÍA DEL USUARIO DE *PARAGON*

## Modo de empleo

**MODO DE EMPLEO**

1. Dispositivo de perfusión *PARAGON* ❶
2. Indicador del nivel del fluido ❷
3. Filtro de aire de 1.2 micrones ❸
4. Tubo de administración *PARAGON* ❹
5. Etiqueta del caudal de flujo ❺
6. Cierre luer ❻
7. Indicador de la finalización de la perfusión ❼

**PRECAUCIÓN**

1. No utilice el juego para administrar si la bolsa esterilizada se encuentra abierta o dañada. Si la tapa protectora no está o si no se encuentra colocada en su lugar, la estanidad del juego para administrar ya no podrá ser garantizada.
2. No es apropiado para el suministro de sangre o de productos sanguíneos. Se recomienda que el juego para administrar sea cambiado cada 24 a 48 horas o de acuerdo a las pautas formuladas por el CDC de EE.UU. o de acuerdo a las políticas institucionales.
3. No vuelva a esterilizar el juego para administrar. Los juegos para administrar han sido fabricados para ser utilizados solamente en un paciente. La vía de administracion de líquido se encuentra esterilizada y no es pirogenica.

**INTRODUCCIÓN**

El sistema de administración de fármacos *PARAGON* consiste en un dispositivo de perfusion mecanico reutilizable y de tubos de administracion diseñados especialmente para su uso con el mismo. El sistema *PARAGON* facilita la administración de medicamentos que requieran una introducción lenta y continua, tales como quimioterapicos y analgesicos. Igualmente se puede utilizar para introducir con rapidez aquellos medicamentos que así lo requieran, tales como antibióticos.

**TUBO DE ADMINISTRACION PARAGON**

Los tubos de administración están hechos de PVC. Cada tubo tiene aproximadamente 127 cm de largo, y tiene incorporado un filtro de 1.2 micrones para la eliminación de aire. El fármaco fluye hacia el paciente con un caudal de flujo controlado a través de un reductor de flujo que se encuentra al final del tubo. En la etiqueta del filtro se especifican los caudales de flujo empleados para cada tubo. ❺

**LLENADO DE LA BOLSA INTRAVENOSA *PARAGON* - USE UNA TÉCNICA ASEPTICA**

1. Saque del paquete la bolsa intravenosa con su tubo de administracion acoplado
2. Mueva la pinza de flujo que está al lado de la válvula de llenado y cierre la pinza. ❽
3. Llene una jeringa estéril con la solucion a ser introducida en la bolsa intravenosa.
4. Conecte la punta de la jeringa a la válvula de llenado e inyecte la solución en la bolsa intravenosa. ❾ Si es necesario, vuelva a llenar la jeringa y repita el procedimiento.
5. Nota: El dispositivo de perfusión *PARAGON* está diseñado para almacenar un total de 100 ml de fluido. El volumen máximo de llenado es de 110 ml; si la cantidad de fluido es mayor de 110 ml, puede ser difícil engranar las roscas de la parte superior e inferior del *PARAGON*.
6. Saque el aire de la bolsa intravenosa apretándolo con una jeringa conectada a la válvula de llenado. Puede ayudarse apretando los lados de la bolsa cuando esté retrayendo la jeringa.
7. Asegúrese de volver a colocar el sombrerete de la válvula de llenado. No coloque etiquetas en la bolsa intravenosa, es mejor ponerlos alrededor del tubo.

**MODO DE CARGA DE LA BOLSA INTRAVENOSA EN EL DISPOSITIVO DE PERFUSION *PARAGON***

1. Rote las mitades superior e inferior del dispositivo de perfusión *PARAGON*. ❿
2. Antes de colocar la bolsa intravenosa en el dispositivo de perfusión *PARAGON*, introduzca la porcion delgada del tubo de administracion en la ranura que está en la parte inferior del dispositivo de perfusión. ⓫
3. Centre la bolsa en el fondo y haga presión alrededor de los bordes de la bolsa, de manera que esta quede totalmente asentada en el fondo. Asegurese de que no haya arrugas en la bolsa. ⓬
4. Con cuidado, tire de la porcion gruesa del tubo, de forma que se extienda y se asiente completamente en el fondo de la ranura. ⓭
5. Gire las mitades superior e inferior del dispositivo de perfusión *PARAGON* hasta que se junten. ⓮

**CEBADO DEL TUBO DE ADMINISTRACIÓN**

1. Usando una técnica aseptica apropiada, retire el sombrerete del cierre luer que está en el extremo del tubo. Abra la pinza de la tubería intravenosa; el fármaco fluirá hacia el extremo del cierre luer.
2. El fluido se está moviendo si se forma una gota del mismo en el extremo del cierre luer. Puede ser necesario esperar 10 minutos para que la gota se forme cuando se esté cebando el sistema a 0.5 ml/hr.
3. Cierre la pinza y vuelva a colocar el sombrerete. ⓯

**INICIO DE LA PERFUSION**

1. Acople el tubo de administracion al curso de la perfusión intravenosa. Asegure la conexión la piel.
2. Abra la pinza del tubo. El fármaco fluirá automáticamente.

**INDICADOR DEL NIVEL DEL FLUIDO**

1. La ventanilla con marcas que se encuentra en la parte lateral del dispositivo de perfusión se utiliza para hacer un cálculo aproximado de la progresión de la perfusión. ❷
2. Cuando la bolsa intravenosa *PARAGON* se llene a su capacidad de 100-110 ml, la parte superior de la placa de presión se alineará con el marcador rellenado superior. ⓰
3. A medida que la perfusion progresa, la placa se desplazará al marcador del fondo, indicando que la bolsa está casi vacía. ⓱

**FINAL DE LA PERFUSION**

La perfusion se ha completado cuando al menos tres (de seis) puntos pequeños azules aparecen en el fondo del dispositivo de perfusión *PARAGON*. ⓲

**ESTUCHE PORTÁTIL**

El estuche portátil se puede llevar en un cinturón, sobre los hombros o alrededor de la cintura.

1. Coloque el dispositivo de perfusion *PARAGON* en el estuche portátil, de manera que el fondo del dispositivo pueda verse a través de la ventanilla plástica transparente. ⓳
2. Alce la banda de Velcro y deslice el tubo de administracion hacia abajo, de manera que éste salga del estuche a través de la abertura de la ventanilla lateral. ⓴ Cierre la banda; esta manera de colocar el dispositivo de perfusión permite observar el indicador del nivel del fluido.
3. La pieza frontal del estuche portátil se puede izar para mostrar una ventanilla plástica transparente, lo cual permite observar el extremo del indicador de perfusion. ㉑
4. Si es necesario se puede colocar un candado pequeño, haciéndolo pasar a través del agujero mas grande de la cremallera y del lazo de tela que está en la parte lateral del estuche (esto puede disminuir las posibilidades de que se causen daños en el dispositivo de perfusión durante una perfusion). ㉒

**CUIDADO DEL PARAGON**

El dispositivo de perfusion PARAGON es duradero y está diseñado para usos repetidos de perfusion de fármacos. Despues de cada uso con un paciente, se pueden limpiar las superficies expuestas (a excepcion de las roscas) con alcohol isopropílico o con una solucion de hipoclorito de sodio al 10%.

NOTA: No sumerja el dispositivo de perfusion *PARAGON* en hipoclorito de sodio. Despues de limpiarlo, si se dificulta hacer girar las mitades del *PARAGON* para juntarlas, ponga una pequeña gota de pomada lubricante (tal como gelatina K-Y) en una seccion pequeña de las roscas que están al fondo del dispositivo de perfusion. Rote la parte superior del dispositivo de perfusion sobre la inferior para distribuir la pomada. ㉓

# GUIDE D'UTILISATION *PARAGON*

## Mode d'emploi

**MODE D'EMPLOI**

1. Dispositif de perfusion *PARAGON* ❶
2. Indicateur de niveau ❷
3. Filtre à bulles d'air de 1,2 microns ❸
4. Tubulure de perfusion *PARAGON* ❹
5. Indicateur de débit ❺
6. Robinet Luer ❻
7. Indicateur de fin de perfusion ❼

**PRECAUTIONS**

1. Ne pas utiliser la tubulure d'administration si la poche de conditionnement stérile est ouverte ou endommagée. Si l'un des capuchons protecteurs vient à manquer ou n'est pas en place, la stérilité de la tubulure d'administration n'est plus garantie.
2. Ne pas utiliser le système pour les perfusions de sang ou de produits sanguins. Il est recommandé de changer la tubulure d'administration toutes les 24 à 48 heures ou conformement aux recommandations de C.D.C. des Etats-Unis ou des pratiques de l'établissement hospitalier.
3. Ne pas restériliser la tubulure d'administration. Les tubulures d'administration sont à usage unique. La voie d'administration du fluide est stérile et apyrogene.

**INTRODUCTION**

Le *PARAGON* est un système d'administration de médicaments composé d'un dispositif de perfusion mécanique réutilisable et de tubulures de perfusion spécialement conçues. Le *PARAGON* permet une administration précise des médicaments exigeant des infusions lentes et continues, tels que les produits chimiothérapeutiques et les analgésiques. Le *PARAGON* sert également à infuser les médicaments demandant une administration plus rapide, tels que les antibiotiques.

**LA TUBULURE DE PERFUSION *PARAGON***

Les tubulures de perfusion sont en C.P.V. Chaque dispositif fait environ 127 cm de long. Un filtre d'éliminaison des bulles d'air de 1,2 microns est incorporé à toutes les tubulures de perfusion. Le débit d'écoulement du médicament vers le patient est contrôlé par un système de limitation du débit intégré à une extrémité de l'appareil. Le débit de chaque dispositif est indiqué sur l'étiquette du filtre d'élimination d'air. ❺

**REMPLISSAGE DE LA POCHE DE PERFUSION *PARAGON* - UTILISER DES TECHNIQUES ASEPTIQUES**

1. Débloquer la poche de perfusion munie de sa tubulure de perfusion.
2. Placer le clamp d'écoulement près de la valve de remplissage et fermer la clamp. ❽
3. Remplir une seringue stérile de la solution à injecter dans la poche de perfusion.
4. Connecter l'extremité de la seringue à la valve de remplissage et injecter la solution dans la poche de perfusion. ❾ Remplir à nouveau la seringue et recommencer selon les besoins.
5. Remarque: Le dispositif de perfusion *PARAGON* a été conçu pour contenir une quantité maximum de 100 ml de liquide. Le volume de remplissage maximum est de 110 ml. Si la quantité de liquide dépasse 110 ml, l'enfilage du vissage en haut et en bas du *PARAGON* risque de se rendre difficile.
6. Evacuer l'air de la poche de perfusion par aspiration à l'aide d'une seringue reliée à la valve de remplissage. Une compression des parois de la poche de perfusion au moment du retrait de la seringue pourra faciliter l'expulsion de l'air.
7. Prendre bien soin de remettre le bouchon en place sur la valve de remplissage.
8. Ne pas placer d'étiquette sur la poche de perfusion. Les étiquettes pourraient s'enrouler autour du dispositif.

**CHARGEMENT DE LA POCHE DE PERFUSION DANS LE DISPOSITIF DE PERFUSION *PARAGON*.**

1. Desserrer les deux moitiés du haut et du bas du dispositif de perfusion *PARAGON*. ❿
2. Avant de placer la poche de perfusion dans le dispositif de perfusion *PARAGON*, faire glisser la partie étroite de la tubulure de perfusion dans la fente située dans la partie inférieure du dispositif de perfusion. ⓫
3. Centrer la poche dans la partie inférieure et appuyer tout autour de la poche de façon à ce qu'elle soit bien installée dans le dispositif de perfusion. Vérifier qu'il n'y ait aucune pissure de la poche. ⓬
4. Tirer doucement sur la partie épaisse du tube de manière à ce qu'il soit complètement détendu et qu'il repose au fond de la fente. ⓭
5. Rassembrer ensemble jusqu'à ce qu'elles se touchent les deux moitiés du haut et du bas du dispositif de perfusion *PARAGON*. ⓮

**AMORCAGE DE LA TUBULURE DE PERFUSION**

1. En suivant les techniques aseptiques qui conviennent, retirer le bouchon du robinet Luer situé à l'extrémité du dispositif. Ouvrir le clamp sur la tubulure de perfusion. Le médicament devrait s'écouler en direction de l'extrémité du robinet Luer.
2. Confirmer l'écoulement du liquide en observant la formation d'une goutte à l'extrémité du robinet Luer. Avec le dispositif de 0.5 ml/H, il faut quelquefois attendre jusqu'à 10 minutes pour qu'une goutte se forme après l'amorçage. ⓯
3. Serrer le clamp pour le fermer et remettre le bouchon en place.

**DAMARRAGE DE LA PERFUSION**

1. Fixer la tubulure de perfusion au point de ponction. Fixer la connexion contre la peau.
2. Commencer la perfusion en ouvrant le clamp sur la tubulure de perfusion. La perfusion doit démarrer immédiatement.

**INDICATEUR DU NIVEAU DE LIQUIDE**

1. La lucarne contenant des indications sur le côté du dispositif de perfusion sert à estimer la progression du déroulement de la perfusion. ❷
2. Lorsque la poche de perfusion *PARAGON* est remplie dans sa capacité de 100 - 110 ml, le haut de la plaque de pression se trouve dans l'alignement de la marque circulaire du haut. ⓰
3. Au fur et à mesure que la perfusion progresse, la plaque de pression descend vers la marque du bas, indiquant donc que la poche est presque vide. ⓱

**FIN DE LA PERFUSION**

La perfusion est terminée quand au moins trois (des six) petites pastilles bleues sont visibles sous la base du dispositif de perfusion *PARAGON*. ⓲

**LA POCHE DE RANGEMENT**

La poche de rangement peut se porter à la ceinture, sur l'épaule, ou autour de la taille.

1. Placer le dispositif de perfusion *PARAGON* dans sa poche de rangement de sorte que la base du dispositif de perfusion soit visible au travers de la lucarne en plastique transparent. ⓳
2. Soulever la bande de Velcro et faire glisser le dispositif d'administration vers le bas de sorte qu'il puisse sortir de la poche de rangement par l'ouverture du côté. ⓴ Refermer la bande de Velcro. (Quand le dispositif de perfusion se trouve dans cette position, il est possible de consulter l'indicateur du niveau de liquide.)
3. Le rabat avant de la poche de rangement se soulève sur une lucarne en plastique transparent qui permet de consulter l'indicateur de fin de la perfusion. ㉑
4. Au besoin, un petit verrou peut être introduit dans le plus gros de deux trous de la fermeture à glissière, puis au travers du passant en tissu sur le côté de la poche de rangement. (Afin de décourager quiconque voudrait toucher à le dispositif de perfusion pendant une infusion.) ㉒

# *PARAGON*. GUIDA PER L'UTILIZZATORE

## Istruzioni per l'uso

**LEGENDA**

1. Infusore PARAGON ❶
2. Indicatore di livello del fluido ❷
3. Filtro debollatore 1,2 u ❸
4. Set di infusione PARAGON ❹
5. Etichetta indicante il flusso del set ❺
6. Connettore Luer Lock ❻
7. Indicatore di fine infusione ❼

**AVVERTENZE**

1. Non usare il set se la confezione è aperta o danneggiata. Se il cappuccio protettivo manca o non è posizionato, la sterilità non è garantita.
2. Non adatto alla somministrazione di sangue. Si raccomanda di sostituire il set ogni 24-48 ore, o secondo le linee guida CDC, o secondo il protocollo dell'ospedale.
3. Non risterilizzare il set. I set si intendono monopaziente. La via di somministrazione è sterile e apirogena.

**INTRODUZIONE**

PARAGON è un sistema per l'infusione di farmaci costituito da un infusore meccanico riutilizzabile e da un set di somministrazione dedicato. PARAGON consente un accurata somministrazione di soluzioni che richiedono un infusione lenta e continua, quali chemioterapici e analgesici. PARAGON consente anche la somministrazione di farmaci che richiedono alta velocità di infusione come gli antibiotici.

**SET DI SOMMINISTRAZIONE PARAGON**

I set di somministrazione sono in PVC. Ciascuna linea è lunga circa 127 cm. Nella linea è compreso un filtro debollatore da 1,2 u. Il flusso è controllato da un capillare posto all'estremità distale del set. Un'etichetta sul filtro indica il flusso del set. ❺

**RIEMPIMENTO DELLA SACCA - USARE TECNICA ASETTICA**

1. Aprire la confezione
2. Portare la clamp vicino alla valvola di riempimento e chiuderla ❽
3. Riempire una siringa sterile con la soluzione da trasferire nel set
4. Connettere la siringa alla valvola di riempimento e inettare la soluzione nella sacca ❾. Riempire nuovamente la siringa e ripetere l'operazione se necessario.

**NOTA:** la sacca è disegnata per un volume totale massimo di 110 ml. Un accesso di volume può rendere difficoltosa la chiusura dell'infusore.

5. Rimuovere l'aria dalla sacca esperando con una siringa dalla valvola di rempimento. La rimozione dell'aria viene facilitata comprimendo dolcemente la sacca al momento di staccare la siringa.
6. Richiudere la valvola di riempimento con un tappino.
7. Non mettere alcuna etichetta sulla sacca, ma eventualmente intorno alla linea.

**POSIZIONAMENTO DELLA SACCA NELL'INFUSORE PARAGON**

1. Svitare completamente le due parti dell'infusore. ❿
2. Prima di posizionare la sacca nell'infusore, inserire il tubo nella fessura posta nella metà inferiore dell'infusore. ⓫
3. Alleggiare la sacca nell'infusore avendo cura di distenderla bene ed assicurandosi che non ci siano pieghe sul contorno. ⓬
4. Tirare dolcemente il tubo attraverso la fessura, distendendolo il meglio possibile. ⓭
5. Avvitare la metà superiore dell'infusore a quella inferiore amvando a fine corsa. ⓮

**RIEMPIMENTO DELLA LINEA DI SOMMINISTRAZIONE**

1. Usare tecnica asettica, togliere il tappo dall'estremità della linea. Aprire la clamp. La soluzione fluirà attraverso l'estremità luer lock.
2. Contenmere il riempimento della linea verificando la formazione di una goccia all'estremità luer lock. Occorrono 10 minuti con un set da 0.5 ml/h. ⓯
3. Chiudere la clamp e sostituire il tappo luer.

**INIZIO DELL'INFUSIONE**

1. Connettere la linea di somministrazione al paziente. Assicurare la connessione alla cute.
2. Iniziare l'infusione aprendo la clamp della linea di somministrazione. L'infusione inizierà immediatamente.

**INDICATORE DI LIVELLO DEL FLUIDO**

1. La finestra, posta sul lato dell'infusore, con appositi indicatori è usata per stimare la progressione dell'infusione. ❷
2. Quando la sacca PARAGON è riempita con 100-110 ml, il bordo superiore del piatto di pressione azzurro è allineato con il pallino più alto. ⓰
3. Col procedere dell'infusione, il piatto azzurro si muove verso il pallino inferiore indicando che la sacca è quasi vuota. ⓱

**FINE INFUSIONE**

L'infusione è completa quando sono visibili almeno tre (dei sei) pallini blu sul fondo trasparente dell'infusore PARAGON. ⓲

**BORSA PER IL TRASPORTO**

Può essere infilata nella cintura, messa a tracolla, o intorno alla vita.

1. Posizionare l'infusore PARAGON nella borsa in modo che il fondo trasparente della stessa sia visibile attraverso la finestra della borsa. ⓳
2. La linea di somministrazione deve fuoriuscire dalla finestra laterale della borsa, previa apertura dello strap Velcro. ⓴ Chiudere lo strap. (Posizionare in questo modo l'infusore consente di visualizzare l'indicatore di livello)
3. La parte frontale della borsa (rivestita da un aletta) è in plastica trasparente, visualizzando così l'indicatore di fine infusione. ㉑
4. Se necessario, la chiusura lampo della borsa può essere chiusa con un piccolo lucchetto (scoraggiando chiunque voglia manipolare l'infusore durante l'infusione). ㉒

**MANUTENZIONE DEL PARAGON**

L'infusore PARAGON è robusto e concepito per essere utilizzato per molteplici infusioni. Dopo ogni paziente, le superfici esposte, tranne la filettatura, possono essere pulite con alcool isopropilico o soluzione di ipoclorito di sodio al 10%

**Nota:** non immergere l'infusore PARAGON nell'ipoclorito di sodio. Se dopo la pulizia le due parti dell'infusore si avvitano con fatica, stendere un po' di crema lubrificante (tipo K-Y™ gel) su una piccola sezione della filettatura superiore e distribuirla nevvitando le due parti dell'unfusore. ㉓

**IMPORTANT**

1. Only administration sets distributed by I-Flow Corporation are authorized for use with this product. I-Flow Corporation accepts no responsibility for performance, or the liability for damages, caused by the misuse of this product when used with unauthorized administration sets.
2. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the IV administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
3. This device contains natural rubber latex. Individuals with known natural rubber latex sensitivities should not use this product.

**The *PARAGON* Infuser Specifications**

**Size:** 5.8 cm high; 10.2 cm in diameter

**Weight:** 260 Gms

**Flow Rates:** 0.5, 1, 2, 4, and 10 ml/hr

**Delivery accuracy:** Accuracy is at ±10% at 95% confidence interval.

**Priming volume:** 1.5 ml

**Residual volume:** 5 ml or less

**NOTES**

1. The infusion rates for each administration set are indicated on the administration set label.
2. Actual infusion rates may vary from the specified range due to:
   - viscosity and/or drug concentration.
   - temperatures above or below the operating conditions.
   - the positioning of the *PARAGON* Infuser above or below the IV site.
3. The Paragon Drug Delivery System has been calibrated using Normal Saline (NS) as the diluent and skin contact temperature (32°C, 90°F) as the operating environment. When using NS and skin temperature the Paragon System will flow at the specified nominal rate. The use of other diluents or operating temperatures other than the above will affect the nominal flow rate. For example, if 5% Dextrose (D5W) is used as the final diluent, the Paragon System will flow at 10% below the nominal rate due to higher solution viscosity.

**CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFFESIONAL.**

**WICHTIG**

1. Dieses Produkt darf nur mit Injektionssätzen von I-Flow Corporation verwendet werden. I-Flow Corporation haftet weder für die Leistung noch Schadenersatzansprüche, die auf Mißbrauch dieses Produktes mit nicht zugelassenen Injektionssätzen beruhen.
2. Dieses Produkt benutzt DEHP plastisiertes PVC. Bestimmte Lösungen können möglicherweise mit dem PVC Material, das in den IV Verabreichungs-Sets benutzt wird, unverträglich sein. Wenden Sie sich an die Packungsbeilage und andere erhältliche Informationsquellen für ein besseres Verständnis möglicher Unverträglichkeits-Probleme.
3. Das Infusionsgerät besteht aus unbearbeitetem Gummilatex. Personen, die allergisch auf unbearbeiteten Gummilatex reagieren, wird vom Gebrauch dieses Produktes abgeraten.

**Technische Daten des *PARAGON*-Infusers**

**Abmessungen:** 5.8 cm hoch; 10.2 cm Durchmesser

**Gewicht:** 260 g

**Flußrate:** 0.5; 1; 2; 4; und 10 ml/h

**Verabreichungsgenauigkeit:** Die Genauigkeit liegt bei ± 10% bei einem 95%igen Vertrauensintervall.

**Vorfüllmenge:** 1.5 ml

**Rückstandsmenge:** Maximal 5 ml

**HINWEISE:**

1. Die Infusionsraten für jedes Verabreichungs-Set sind auf dem Etikett des Verabreichungs-Sets angegeben.
2. Die echten Infusionsraten können von den angegebenen Spanne aus den folgenden Gründen abweichen:
   - Viskosität und/oder Medikamentenzentration.
   - Temperaturen über oder unter den Betriebsbedingungen.
   - Anbringung des *PARAGON*-Infusers über oder unterhalb des IV-Zugangs.
3. Das Paragon Arznei Verabreichungs-System wurde mit normaler Salzlösung als Verdünnungsmittel geeicht und mit Hautkontakt-Temperatur (32°C, 90°F) als Verabreichungsklima. Beim Einsatz von Physiologischer Kochsalzlösung und der Hauttemperatur fließt das Paragon System zur angegebenen Nominalgeschwindigkeit. Der Gebrauch irgendwelcher anderer Verdünnungsmittel oder Einsätze außer den oben angegebenen beeinflußt die nominale Fließgeschwindigkeit. Wenn zum Beispiel 5% Dextrose (D5W) als abschließendes Verdünnungsmittel benutzt wird, fließt das Paragon System zu 10% unter der Nominalgeschwindigkeit auf Grund der höheren Lösungsviskosität.

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**IMPORTANTE**

1. Utilice unicamente tubos de administracion distribuidos por I-Flow Corporation. I-Flow Corporation no asume responsabilidad alguna por problemas de funcionamiento o por danos causados debido al maltrato de este producto cuando se usa con tubos de administracion no autorizados.
2. Este producto utiliza DEHP de cloruro de polivinilo plasticado. Ciertas soluciones podrian ser incompatibles con el material de cloruro de polivinilo utilizado en el juego para administrar de la intravenosa. Consulte con las indicaciones provistas en la caja de la droga y con otras fuentes de informacion disponibles para entender con mas detalle los posibles problemas de incompatibilidad.
3. Este dispositivo contiene latex de goma natural. Aquellos individuos que sufran de sensibilidad al latex de goma no deberan utilizar este producto.

**Especificaciones del dispositivo de perfusión *PARAGON***

**Tamaño:** Altura: 5.8 cm: diametro: 10.2 cm

**Peso:** 260 gr

**Flujo:** 0.5: 1: 2: 4: y 10 ml/hr

**Precision en la distribucion:** La precision es de ±10% a un intervalo de confianza de 95%.

**Volumen de cebado:** 1.5 ml

**Volumen residual:** 5 ml o menos

**NOTAS:**

1. El coeficiente de perfusión para cada juego para administrar se encuentra indicado en la etqueta del mismo.
2. Los coeficientes de perfusion actuales pueden variar del coeficiente especificado debido a::
   - viscosidad y/o concentración del fármaco.
   - temperaturas superiores o inferiores a las condiciones de operacion.
   - la colocacion del dispositivo de perfusion *PARAGON* por encima o por debajo del punto de perfusión intravenosa.
3. El Sistema de Suministro de Drogas Paragon ha sido calibrado utilizando Salinidad Normal (SN) como diluyente y la temperatura de contacto de la piel (32°C. 90°F) como el ambiente operativo. Al utilizar la SN y la temperatura de la piel, el Sistema Paragon fluirá a una razon nominal especifica. La utilizacion de otros diluyentes o temperaturas operativas que no sean las mencionadas anteriormente afectaran la razon nominal de fluido Por ejemplo, si se utiliza un 5% de Dextrosa como diluyente final, el Sistema Paragon fluirá a un 10% por debajo de la razon nominal debido a la viscosidad de la solucion mas alta.

**ENTRETIEN DU *PARAGON***

Le dispositif de perfusion *PARAGON* est solide et solide et a été conçu pour être utilisé de façon répétée pour des injections de médicaments. Après chaque patient, il est possible de nettoyer les surfaces visibles, à l'exception du filetage, en les essuyant avec de l'alcool isopropylique ou une solution de 10% d'eau de Javel.

**REMARQUE:** Ne pas tremper le dispositif de perfusion *PARAGON* dans une solution d'eau de Javel.

*Remarque:* Ne pas tremper le dispositif de perfusion *PARAGON* dans une solution d'eau de Javel.

Après le nettoyage, si le remontage du *PARAGON* est difficile, placer une petite goute de pommade lubrifiante (telle que de la vaseline K-Y™) sur une petite section du filetage dans-le bas du dispositif de perfusion. Revisser la moitié supérieure sur la moitié inférieure de manière à bien étaler la pommade.

**IMPORTANT**

1. Ne sont autorises avec ce produit que les tubulures de perfusion distribuées par I-Flow Corporation. I-Flow Corporation ne saurait accepter aucune responsabilité pour ce qui est des performances, ni aucune responsabilité pour ce qui est des dommages causés par une utilisation de ce produit avec des tubulures de perfusion non autorisées.
2. Ce produit est fabriqué avec du chlorure de polyvinyle plastifié au DEHP. Certaines solutions médicamenteuses peuvent être incompatibles avec le matériau en CPV utilisé dans la tubulure d'administration. Consulter la notice comprise dans le conditionnement du médicament et toutes les autres sources d'information disponibles pour obtenir le plus de renseignements possibles sur les problèmes d'incompatibilité éventuels.
3. Ce dispositif comprend du caoutchouc naturel au latex. Les personnes diagnostiquées avec une sensibilité naturelle (allergie) au caoutchouc latex doivent s'abstenir d'utiliser ce produit.

**Spécifications du dispositif de perfusion *PARAGON***

**Dimensions:** hauteur 5.8 cm: diamètre 10.2 cm

**Poids:** 260 Gms

**Débit d'écoulement:** 0.5: 1: 2: 4: et 10 ml/h

**Précision de l'administration:** La precision est de ±10% dans un intervalle de confiance de 95%.

**Volume d'amorçage:** 1.5 ml

**Volume résiduel:** 5 ml ou moins

**NOTES**

1. Les vitesses de perfusion de chaque dispositif d'administration sont indiquées sur l'étiquette du dispositif.
2. Les vitesses de perfusion reelles peuvent varier par rapport à la gamme spécifiée en raison de:
   - d'une viscosité et (ou) d'une concentration du médicament.
   - de températures superieures ou inférieures aux conditions d'utilisation.
   - du positionnement du dispositif de perfusion *PARAGON* au-dessus ou audessous du point de ponction.
3. Le système d'administration de substances médicamenteuses Paragon a été étalonné à l'aide de sérum physiologique salé (SN) comme solvant et de la température de la peau (32°C. 90°F) comme milieu ambiant d'intervention. Avec le solvant SN et la température de la peau, la circulation de fluide s'écoule dans le système Paragon à la vitesse nominale specifiée. L'emploi de solvants ou de temperatures d'intervention autres que celles mentionnees ci-dessus affectera la vitesse nominale de circulation. Sort, par exemple, si l'on utilise une solution à 5% de dextrose (D5W) comme solvant final, la circulation dans le système Paragon s'écoulera à une vitesse inférieure de 10% à la vitesse nominale en raison de la viscosité plus forte de la solution.

**IMPORTANTE**

1. Con PARAGON possono essere impiegati solo set di somministrazione prodotti da I-Flow Corporation. I-Flow Corporation declina ogni responsabilità per la prestazione o danni causati dall'impiego non corretto del prodotto con set di somministrazione non autorizzati.
2. Questo prodotto usa PVC plasticizzato con DEHP. Certe soluzioni possono essere incompatibili con il materiale usato nei set di somministrazione. Consultare il foglio istruzioni contenuto nella confezione del farmaco e altre fonti disponibili per la migliore informazione possibile sui possibili problemi di incompatibilità.
3. Questo dispositivo contiene lattice naturale. Soggetti con riconosciuta sensibilità al lattice non dovrebbero usare questo prodotto.

**SPECIFICHE DELL'INFUSORE PARAGON**

**Dimensioni:** altezza 5.8 cm: diametro 10.2 cm

**Peso:** 260 g

**Velocità di flusso:** 0.5-1-2-4-10 ml/h

**Accuratezza:** ±10% nell'intervallo di confidenza del 95%

**Volume di riempimento:** 1.5 ml

**Volume residuo:** 5 ml max

**NOTA:**

1. La velocità di flusso di ciascun set di somministrazione è indicata da un etichetta sul set stesso.
2. Le velocità di flusso possono variare da quanto indicato a causa di:
   - viscosità e/o concentrazione del farmaco
   - temperatura sopra o sotto le condizioni operative
   - posizionamento dell'infusore PARAGON sopra o sotto il punto di accesso al pazente.
3. Il Sistema di infusione Farmaci Paragon è stato calibrato usando Soluzione Saline (NS) come solvente e temperatura a contatto della cute (32°C, 90°F) come ambiente operativo. Quando si usano NS e temperatura a contatto della cute, il Sistema Paragon invera al flusso nominale specificato. L'impiego di altri solventi o temperature operative diverse da quelle indicate può produrre variazioni del flusso nominale. Ad esempio, se viene usato Destroso 5% come solvente finale, il Sistema Paragon ha un flusso del 10% al di sotto del valore nominale dovuto alla maggiore viscosità della soluzione.

Patentes Estadounidenses y extranjeras en procesamiento

Fabricado por
I-Flow Corp
Lake Forest, CA 92630
Impreso en EE.UU.

Representante Europeo
MPS Medical Product Service GmbH
Borngasse 20 35619 Braunfels Germany

Brevets Américains et étrangers/en cours

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Imprimé aux U.S.A.

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Prodotto Da
I-Flow Corp
Lake Forest, CA 92630

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CONTENTS / INHALT /CONTENU /
CONTENIDO / CONTIENE: 1

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

REF 5000937

# *Paragon* Administration Set
# 1 ml/hr (NS, 32°C)

STERILE EO

LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo /
Rappresentante Europeo:
MPS Medical Product Service GmbH
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CE 0123

Manufactured by / Hersteller von /
Fabrique par / Fabricado por / Prodoto Da:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

13018708

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I-FLOW®

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

CONTENTS / INHALT / CONTENU / CONTENIDO / CONTIENE: 12

REF 5000937

# *Paragon* Administration Set

# 1 ml/hr (NS, 32°C)



STERILE EO

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL. SEE DIRECTIONS FOR USE.

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European Representative / Europaische Vertretung / Représentant pour l'Europe / Representante Europeo / Rappresentante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

1301869B


Skin Contact - NS
1 ml/hr

# Appendix E

## Paragon Bolus Accessory Set

## Summary of Safety and Effectiveness

I-FLOW CORPORATION

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Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

# SUMMARY OF SAFETY AND EFFECTIVENESS

December 30, 1998

**Trade Name:** Paragon Bolus Accessory Set

**Common Name:** Bolus Accessory

**Classification Name:** Set, Administration, Intravascular

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700
Fax: 949.206.2600

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# 1.0 GENERAL INFORMATION

## 1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market an accessory device for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus. This new accessory will be known as the Paragon Bolus Accessory Set, hereafter identified as the Bolus Accessory. No change will be made to the existing Paragon pump or administration sets.

1.1.2 Trade Name: Paragon Bolus Accessory Set

1.1.3 Common Name: Bolus Accessory Set

1.1.4 Classification Name: Set, Administration, Intravascular

1.1.5 Product Code: 80 FPA

1.1.6 Device Classification: Class II, 880.5440

1.1.7 Classification Panel: General Hospital and Personal Use Device

## 1.2 Statement of Equivalence

1.2.1 The Bolus Accessory is substantially equivalent to Patient Control Module (K884505) marketed by Baxter Healthcare Corporation and the I-Flow Bolus Dispenser (K935811).

# 2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

## 2.1 Description of the Bolus Accessory

Wherever the Paragon pump and administration set are mentioned, they may be replaced by any constant 6 psi pressure system.

2.1.1 The Bolus Accessory may connect to any Paragon administration set to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

2.1.2 The Bolus Accessory consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

2.1.3 The bolus button allows patient controlled administration of medication as needed.

## 2.2 Product Configuration

2.2.1 The Bolus Accessory is available in 0.5 ml bolus volume.

## 2.3 Components and Materials

2.3.1 All fluid path components of the Bolus Accessory are in conformance with ISO 10993 Part 1.

## 2.4 Power Requirements

2.4.1 The Bolus Accessory is a mechanical device that requires no external power.

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## 3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions:**

| | |
|---|---|
| Bolus Volume: | 0.5 ml |
| Refill Time: | variable |
| Priming/Residual Volume: | <=4 ml |
| Operating Temperature: | 90 ± 2°F |
| Calibration Solution: | 0.9% NaCl |
| Operating Pressure: | 6.0 psi pressure source |
| Head Height: | 0" |
| Accuracy: | bolus volume: ±10% at 95% confidence interval at the identified lockout times. |

3.2 **Performance Data:** Testing occurred at standard operating conditions. All models performed within the specified accuracy when tested at nominal conditions.

3.3 **Safety / Alarm Funtions**

3.3.1 This device contains no alarms or indicators.

3.3.2 The non-linear refill adds additional patient safety if the bolus button is activated prior to the lockout time.

## 4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.

## 5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Bolus Accessory.

5.1.2 The Bolus Accessory is intended for general purpose drugs and pain medication.

## 6.0 INTENDED USE

6.1 The Bolus Accessory is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

6.2 The routes of administration intravenous, epidural, intramuscular and subcutaneous.

6.3 The Bolus Accessory is not intended for continuous delivery.

6.4 The Bolus Accessory is single patient use only.

6.5 The Bolus Accessory is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

6.6 No testing has been conducted to determine the efficacy of Bolus Accessory for the delivery of blood, blood products, lipids or fat emulsions. The Bolus Accessory is not intended for the delivery of blood, blood products, lipids or fat emulsions.

## 7.0 STANDARDS

7.1 There are currently no standards established for mechanical PCA infusion devices.

## 8.0 PACKAGING

8.1 Packaging is suitable for radiation or ETO sterilization.

## 9.0 STERILIZATION

9.1 The method of sterilization is gamma radiation (cobalt 60).

## 10.0 COMPARISON TO LEGALLY MARKETED DEVICES

10.1 The Bolus Accessory has the same intended use as the predicate Baxter Pain Control Module and the I-Flow Bolus Dispenser. The Bolus Accessory has similar bolus volumes and lockout times as its predicate devices.