U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K992379 - 80 pages
COMPANY:	RADIONICS, INC. (RADIONICS)
PRODUCT:	SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS (JXG)
SUMMARY:	Product: RADIONICS XDC EXTERNAL VENTRICULAR CATHETER
DATE REQUESTED:	Aug 15, 2016
DATE PRINTED:	Aug 15, 2016
Note:	Printed

K992379

SEP 8 1999

Attachment VI: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER:	Radionics Inc, 76 Cambridge Street Burlington, MA 01803 Tel.: (781) 272-1233 Fax: (781) 272-2428 Contact: Kevin J. O'Connell Regulatory Engineer
PROPRIETARY NAME:	Radionics XDC Ventricular Catheter
COMMON OR USUAL NAME:	External Drainage Ventricular Catheter
CLASSIFICATION CODE:	Shunt, Central Nervous System and Components 21 CFR, Section: 882.5550
PREDICATE DEVICE:	Clinical Neuro System's MoniTorr ICP™ Ventricular Catheter, K922941 Medtronic Becker EDM Ventricular Catheters, 510(k) unk
DESCRIPTION:	The External Drainage Ventricular Catheter consists of a barium impregnated silicone tubing with flow holes at the distal end and a luer lock connector for attachment to an external drainage system. It is provided sterile for single use only.
INTENDED USE:	As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1999

Mr. Kevin J. O'Connell
Regulatory Engineer
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K992379
Trade Name: Radionics XDC Ventricular Catheter
Regulatory Class: II
Product Code: JXG
Dated: July 15, 1999
Received: July 16, 1999

Dear Mr. O'Connell:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 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) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 ODE Indications Statement:

510(k) Number (if known): K992379

Device Name: Radionics XDC Ventricular Catheter

Indications for use: As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992379

PRESCRIPTION USE X OR Over-The-Counter Use ____

(Per 21 CFR 801.109

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1999

Mr. Kevin J. O'Connell
Regulatory Engineer
Radionics, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K992379
Trade Name: Radionics XDC Ventricular Catheter
Regulatory Class: II
Product Code: JXG
Dated: July 15, 1999
Received: July 16, 1999

Dear Mr. O'Connell:

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.

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Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 ODE Indications Statement:

510(k) Number (if known): K992379

Device Name: Radionics XDC Ventricular Catheter

Indications for use: As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992379

PRESCRIPTION USE X OR Over-The-Counter Use ____

(Per 21 CFR 801.109

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memoran

From: Reviewer(s) - Name(s) JANINE MORRIS

Subject: 510(k) Number K992379

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review_____.
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive	☐ 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 NA
- ☒ The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin ☐ YES ☒ NO

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

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

Predicate Product Code with class:	Additional Product Code(s) with panel (optional):
JXG 84 Class II	HCA 94 Class II

Review: Neil R Ogden (Branch Chief) GSDB (Branch Code) 8/26/99 (Date)

Final Review: _____ (Division Director) 9/8/99 (Date)

Revised:6/2//98

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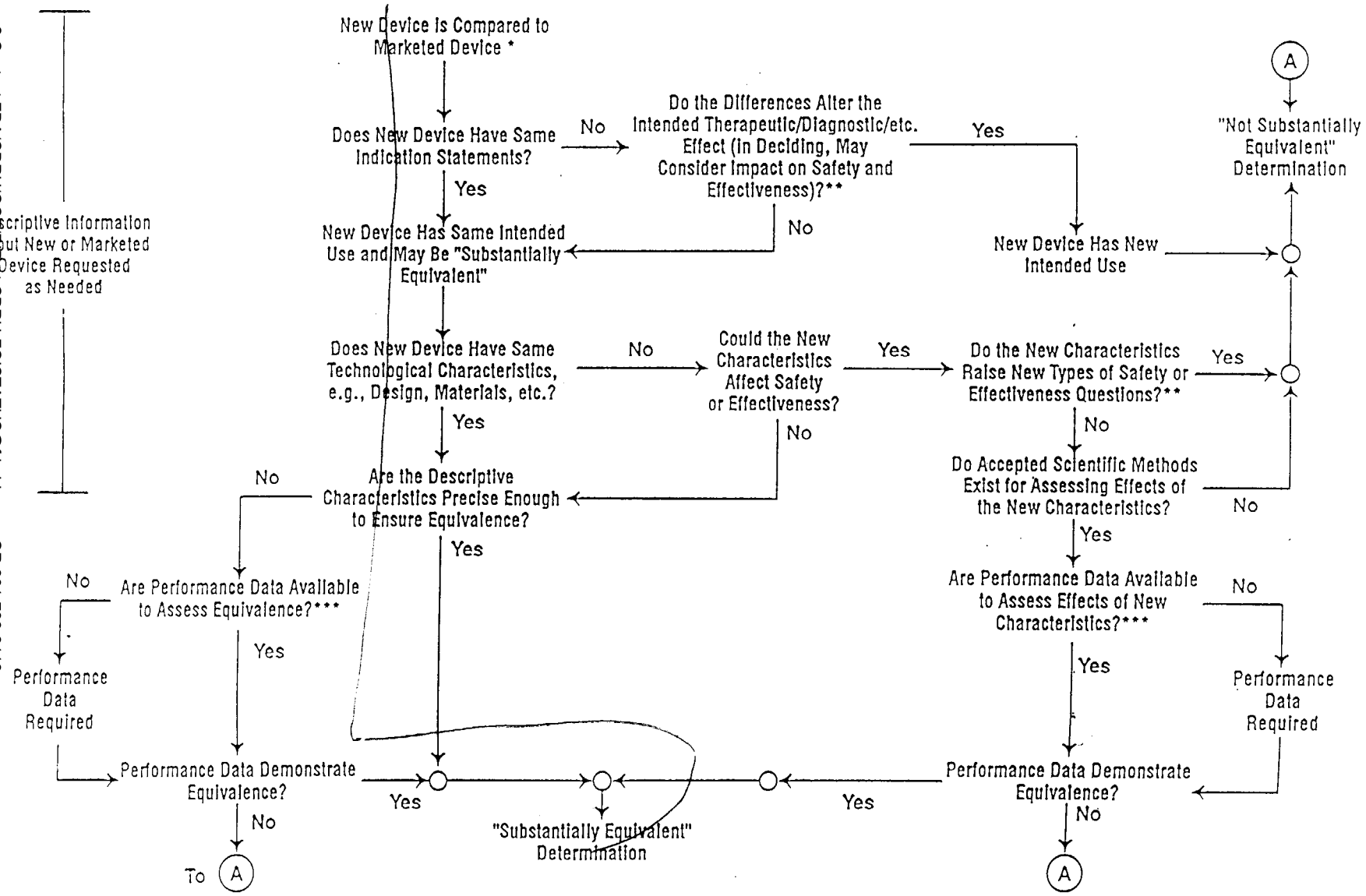
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(...ions Compare New Devices to Marketed Devices. FDA Requests Additiona... ...ormation if the Relationship Between Marketed and "Predicate"

** This D... ... Normally Based on Descriptive Information Alone, But Limite... ...n Information Is Sometimes Required.

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: XDC, Ventricular Catheters | K992379

Submitter (Company): Radionics

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" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5	✓	

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA (SPECIALS)		YES (ABBREVIATED)		NO (TRADITIONAL)		✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, 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)	✓						
l) 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				✓		
m) If kit, kit certification							

3. "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*			* If no - STOP not a special	6

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						

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					NA		
ii) identify patient-contacting materials					NA		
iii) biocompatibility of final sterilized product					NA		
b) Sterilization and expiration dating information:					✓		
i) sterilization method					✓		
ii) SAL					✓		
iii) packaging					✓		
iv) specify pyrogen free					✓		
v) ETO residues					NA		
vi) radiation dose					NA		
c) Software validation & verification:					"		
i) hazard analysis					"		
ii) level of concern					"		
iii) development documentation					NA		
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** **Reviewer:** _____

Date: 9/23/99 **Concurrence by Review Branch:** _____

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 992379

Reviewer: Janine Morris

Division/Branch: DGRD GSDB

Device Name: XDC Ventricular Catheters

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 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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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?	NA	
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	✓ ✓	✓
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	NA	✓

510(k) REVIEW
SUPPLEMENTAL SUMMARY SHEET

510K NUMBER: K992379
MANUFACTURER: Radionics Medical Products, Inc.
DEVICE NAME: XDC Ventricular Catheters

SUMMARY:
The subject of this 510k submission is for the Radionics XDC ventricular catheter intended to be used as the proximal component of the Radionics XDS External CSF Drainage and Monitoring System. The Radionics XDS External CSF Drainage and Monitoring System is currently the subject of 510(k) K992226.

Industry Contact

Kevin O'Connell
Regulatory Engineer
Radionics, Inc.
76 Cambridge Street
Burlington, MA 01803
Tel: (781) 272-1233
Fax: (781) 238-0643

Indications for Use
This 510(k) premarket notification represent a ventricular catheter intended to be used with an external CSF Drainage and Monitoring System for drainage of CSF from the lateral ventricles of the brain or monitoring of intracranial pressure (ICP).

Device Description
The ventricular catheter is the proximal component to the external drainage system and has direct patient contact. The ventricular catheters are supplied in two models consisting of two different sizes. The XDC-1 has a 2.5 mm diameter lumen and is 20 cm long and the XDC-2 is 3.0 mm in diameter and 35 cm long. Both models are manufactured from barium impregnated silicone tubing where the proximal end consists of a series of circular flow holes (4 rows of 4 each) and a molded bullet shaped tip. The distal ends of the catheters are connected to the external drainage system using a luer lock connection. The components and accessories supplied with the catheters under this 510(k) (K992379) are:

- Luer lock connector
- Red end cap
- Stylet (SST)
- Trocar needle
- Fixation anchor (silicone)

Labeling

The ventricular catheters are appropriately labeled as sterile, non-pyrogenic and single use only. Product label includes product and sterile lot numbers, sterilization date and expiration date. Instructions for use are provide and include relevant warnings, cautions, and contraindications.

Material Specification

The ventricular catheters represented under K992379 are manufactured from (b)(4) (catheter tubing) and (b)(4) (molded tip) silicone elastomer. The implant material is the most critical feature of these devices with respect to function and biocompatibility since this component has direct patient contact, i.e., CSF and brain parenchyma. The firm reports (page 9 under K992379) that these are the same materials used to manufacture their Siphon Limiting Device reviewed under K962990. This product involves the same patient contact therefore no additional data is necessary.

Sterilization

The ventricular catheters are sterilized by Ethylene Oxide to SAL of 10^{-6} using a validation method demonstrating a minimum 6-log reduction of microorganisms at half dwell time at minimum process parameters. The firm reports they will meet maximum ETO residues of (b)(4) . These values are the corrected values from original reference as per telecon dated 8/6/99 and documented by attached fax dated 8/10/99.

The packaging for the device is reported as the same double pouched Mylar/Tyvek packaging process used for the Radionics Contour Flex valve reviewed under K954285. Under K954285 the firm validated the packaging for package integrity and sterility from 4 year accelerated aging under conditions of shipping and handling stresses. The firm's 4 year expiration dating is based on this data.

The ventricular catheters are labeled as non-pyrogenic where the endotoxin limit is reported to be a maximum of (b)(4) ml as per telecon dated 8/6/99 and documented by fax dated 8/10/99.

Device Design

The critical features of the ventricular catheters, i.e., material, length, inner lumen diameter, diameter of drainage holes, number of holes, and hole configuration, are reported by the firm to be identical to predicate devices (see page 7 under K992379).

Qualification and Performance Testing

The firm references 2 tests conducted on the ventricular catheters: 1) leakage test and 2) integrity test. Both these tests were performed at the luer lock connection and provided reasonable results (see Attachment V).

Substantial Equivalence

The Radionics XDC ventricular catheter (K992379) is being compared with predicate devices including Clinical Neuro Systems MoniTorr System (K920156) and Medtronic Becker External Drainage and Monitoring System (K984053).

Based on the information provided the Radionics XDC ventricular catheter (K992379) has the same intended use as the predicate devices identified above. There seems to be no new technology or safety issues to consider in this design.

It is my recommendation that the Radionics XDC ventricular catheter (K992379) be found substantially equivalent to predicate devices as a component under **87 JXG, CNS Fluid Shunt and Components** and they be classified under **21 CFR 888.5550 class II.**

3/18/99

Janine M. Morris, Mechanical Engineer
Office of Device Evaluation
Center for Devices and Radiological Health

I concur

3/22/99

RADIONICS MEDICAL PRODUCTS INC.

Fax

To: Janine Morris, FDA **From:** Kevin O'Connell

Fax: (301) 594-2977 **Pages:** 2 including cover sheet

Phone: (301) 594-1190 **Date:** 08/10/99

Re: 510(k) K992379, Radionics XDC External Ventricular Catheter **CC:**

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

Dear Ms. Morris:

...our questions posed during our phone conversation of 8/5/99, I am

(b)(4)

[redacted]

Yes, Radionics has submitted a separate 510(k), that is currently under review, for the Radionics XDS External Drainage System(K992226).

If you have any additional questions, please feel free to contact me at (781) 272-1233.

Sincerely,

Kevin J. O'Connell
Regulatory Engineer

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

July 16, 1999

RADIONICS, INC.
22 TERRY AVE.
BURLINGTON, MA 01803
ATTN: KEVIN J. O'CONNELL

510(k) Number: K992379
Received: 15-JUL-1999
Product: RADIONICS XDC
EXTERNAL
VEENTRICULAR
CATHETER

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

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

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

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

15

K992379

RADIONICS®

Radionics Medical Products, Inc. 22 Terry Avenue, Burlington, MA 01803-2516 U.S.A.
Tel: (781) 272-1233
Fax: (781) 272-2428

July 15, 1999

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

Re.: Radionics XDC Ventricular Catheters 510(k)

Dear Sir/Madam:

These documents constitute a Premarket Notification [510(k) Notification] relating to the intention of Radionics Medical Products, Inc. to market Radionics XDC Ventricular Catheters.

It is our opinion that our product is substantially equivalent to another commercially available product described herein, and that the attached documents support this opinion.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at: (781) 272-1233.

Sincerely,
Radionics Medical Products, Inc.

Kevin J. O'Connell
Regulatory Engineer

/enc.

SK 3

16 NE II

Center for Devices and Radiological Health
Premarket Submission Cover Sheet

Date of Submission: July 15, 1999

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ 510(k) - Special
- ☐ 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

- ☒ New Device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials or mfg. process
- ☐ Other reason (specify): Device Modification

Section B2 — Reason for Submission - PMA's 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 add/delete mfg. 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 - IDE's 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
  - ☐ Emergency use notification
  - ☐ 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
- ☐ Other Reason (Specify):
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request time extension to respond
  - ☐ Request meeting
- ☐ IOL submissions only
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

FDA Document Number:

Section C — Product Classification

Product Code: JXG	C.F.R. Section: 882.5550	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel: Neurology Devices		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1. JXG	2.	3.	4.
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. K922941	1. MoniTorr ICP Ventricular Catheter	1. Clinical Neuro Systems.
2. unk	2. Becker EDM Ventricular Catheter	2. Medtronic PS Medical
3.	3.	3.
4.	4.	4.
5.	5.	5.
6.	6.	6.

Section E — Product Information - Applicable to All Applications

Common or usual name or classification name: External CSF Drainage and Monitoring System

Trade or proprietary or model name	Model number
1. Radionics XDC™ External Ventricular Catheter	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	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):

As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

	FDA Document Number:

Section F: Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration # 1219140	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler
Company / Institution name: Radionics Inc.			
Division name (if applicable): Radionics Medical Products Inc.			Phone number (include area code) (800) 466-6814
Street address: 22 Terry Avenue			FAX number (include area code) (781) 238-0643
City: Burlington	State / Province: MA	Country: US	ZIP / Postal Code: 01803
Contact name: Kevin J. O'Connell			
Contact title: Regulatory Engineer			

☐ Original ☐ Add ☐ Delete	FDA establishment registration #	☐ 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 #	☐ 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:			

	FDA Document Number:

Section C — Applicant or Sponsor

Company / Institution name: Radionics, Inc.			
Division name (if applicable): Radionics Medical Products Inc.			Phone number (include area code) (800) 466-6814
Street address: 22 Terry Avenue			FAX number (include area code) (781) 238-0643
City: Burlington	State / Province: MA	Country: US	ZIP / Postal Code: 01803
Signature: Kevin J. O'Connell			
Name: Kevin J. O'Connell			
Title: Regulatory Engineer			

Section D — 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:			

Center for Devices and Radiological Health
Premarket Notification for 510(k)
Refuse to Accept Checklist
(Revised 3-14-95)

K _____ Date DMC Received _____

Device Trade Name: Radionics XDC Ventricular Catheter

Reason for 510(k): New device

Division/Branch: Neurology

Administrative Reviewer Signature:_____Date_____

Supervisory Signature_____Date _____

Did the firm request expedited review? _____ Yes ____X____ No

Did we grant expedited review? _____ Yes _____ No

Truthful and accurate statement enclosed ?____X____ Yes _____ No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

_____ accepted

_____ refuse to accept

	Yes Present Omission Justified	No Inadequate Omitted
I. Critical Elements:		
A. Is the product a device?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Is the device subject to review by CDRH?	X	
D. (I) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?		X
E. (I) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer		X
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	NA	
F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(I) of the Federal Food, Drug, and Cosmetic Act(Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:		
1. Device trade or proprietary name	pg. 5	
2. Device common or usual name or classification name	pg. 5	
3. Establishment registration number (only applies if establishment is registered)	pg. 5	
4. Class into which the device is classified under (21 CFR Parts 862 to 892)	pg. 5	
5. Classification Panel	pg. 5	
6. Action taken to comply with Section 514 of the Act		
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #091-1)	Attachment III	

	Yes Present Omission Justified	No Inadequate Omitted
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	Attachment VI	
9. For class III devices only, a class III certification and class III summary	NA	
10. Photographs of the device	NA	
11. Engineering drawings for the device with dimensions and tolerances	Attachment II	
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	Attachment IV	
13. Statement of similarities and/or differences with marketed device(s)	pp. 7-911	
14. Data to show consequences and effects of a modified device(s)	NA	
15. Truthful and accurate statement	pg. 3	
I. Additional Information that <u>is</u> necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	pg. 5	
B. Contact person, telephone number and fax number	pg. 5	
C. Representative/Consultant if applicable		
D. Table of Contents with pagination	X	
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	pg. 5, Attachment I	
I. Additional Information that <u>may be</u> necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	pp. 7 - 8	
B. Action taken to comply with voluntary standards	NA	
C. Performance data	NA	
1. marketed device	NA	
bench testing	NA	
animal testing	NA	

	Yes Present Omission Justified	No Inadequate Omitted
clinical data	NA	
2. new device	X	
bench testing	Attachment V	
animal testing	NA	
clinical data	NA	
D. Sterilization information	Attachment I	
E. Software information	NA	
F. Hardware information	pp. 5-6	
G. If this 510(k) is for a kit, has the kit certification statement been provided?	NA	
H. Is this device subject to issues that have been addressed in specific guidance document(s)?		X
If yes, continue review with checklist from any appropriate guidance documents.		
If no, is 510(k) sufficiently complete to allow substantive review?	X	
I. Other (specify)		

Radionics XDC Ventricular Catheter
510(k)

Radionics Inc.
76 Cambridge Street
Burlington, MA 01803
Phone: (781) 272-1233
Fax: (781) 272-2428

Date: July 15, 1999

Table of Contents

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Attachments

I. Sterilization Information
II. Confidential Engineering Drawings
III. Proposed Labels/Labeling
IV. Commercially Available Device Information
V. Mechanical Test Results
VI. Summary of Safety and Effectiveness

1.0 Truthful and Accurate Statement:

Radionics XDC Ventricular Catheter

Truthful and Accurate Statement
(As Required by 21 CFR 807.87(j))

I certify that in my capacity as Regulatory Engineer for Radionics, Inc., that I believe to the best of my knowledge, all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Kevin J. O'Connell

7/15/99
Date

K992379
[Premarket Notification (510(k) Number]

2.0 ODE Indications Statement:

510(k) Number (if known): K992379

Device Name: Radionics XDC Ventricular Catheter

Indications for use: As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

.

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

PRESCRIPTION USE X OR Over-The-Counter Use ____

(Per 21 CFR 801.109

(Optional Format 1-2-96)

3.0 Regulatory Information:

3.1 Device Name

Classification:	Shunt, Central Nervous System and Components
Common/Usual:	External Drainage Ventricular Catheter
Proprietary:	Radionics XDC Ventricular Catheter

3.2 Device Sponsor

Manufacturer and Owner	Radionics, Inc. 76 Cambridge Street Burlington, MA 01803

Person to contact regarding questions about this 510(k) Notification:

Kevin J. O'Connell
Regulatory Engineer
Radionics Inc,
76 Cambridge Street
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 238-0643

3.3 Establishment Registration Number: 1219140

3.4 Classification: The classification of the Radionics XDC Ventricular Catheter is Class II, as per Title 21 of the Code of Federal Regulations, Section 882.5550: Central nervous system fluid shunt and components.

3.5 Performance Standards: No performance standards applicable to external drainage ventricular catheters have been established by the Food and Drug Administration.

4.0 Sterilization Information: The Radionics XDC Ventricular Catheter will be provided to the user sterile. See Attachment I for sterility information.

5.0 Description of the Device: The Radionics XDC Ventricular Catheter (XDC) is intended to be used as the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.

The XDC is manufactured from (b)(4) [redacted]. The distal end of the tubing will accept a luer lock connector that

is supplied with the system. The luer lock connector enables connection to a CSF drainage system. A red end cap is included to allow for temporary closure of the catheter.

A stainless steel stylet is included with the XDC to aid in inserting the catheter. The XDC-2 also includes a trocar needle to allow tunneling of the catheter under the scalp, and a silicone fixation tab to secure the catheter in place. The tab is made from the same barium impregnated silicone as the tubing.

Confidential engineering drawings can be found in Attachment II.

6.0 Proposed Labels/Labeling: A draft of the Instructions for Use and product labels can be found in Attachment III.

7.0 Packaging Integrity/Expiration Date: The product will be packaged using two heat sealed pouches, one within the other. Each pouch will be constructed of Tyvek/Mylar, a well recognized medical grade pouch construction to ensure sterility of the contained product (see attachment II for a drawing of the pouches). This is the same packaging material and process that has been validated for other Radionics products, such as the Contour Flex Valve cleared via K954285. For that submission, a validation was performed to confirm the package integrity and product sterility after 4 years of accelerated aging, shipping stress, and handling stress. Since, the XDC will also be packaged using the same process and tyvek pouches the package labels will reflect a 4 year expiration date.

8.0 Commercially Available Device Information: The Clinical Neuro System's MoniTorr ICP™ Ventricular Catheter was cleared via 510(k), K922941, on August 26, 1992. The 510(k) that covers the Medtronic Becker EDM Ventricular Catheters is not known. Additional information on these devices can be found in Attachment IV.

9.0 Comparison to Commercially Available Device(s): A comparison of Radionics XDC Ventricular Catheter to Clinical Neuro System's MoniTorr ICP™ Ventricular Catheter and Medtronic Becker EDM Ventricular Catheters follows:

	Radionics XDC Ventricular Catheters	CNS MoniTorr ICP Ventricular Catheters K922941	Medtronic Becker EDM Ventricular Catheters
Indications	As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.	As the proximal component for external CSF drainage and monitoring from the lateral ventricles of the brain.	As the proximal component for CSF drainage and/or monitoring from the lateral ventricles of the brain.
Dimensions	standard (XDC-1) diameter: 1.3/2.5 mm length: 20 cm large (XDC-2) diameter: 1.5/3.0 mm length: 35 cm	standard diameter: 1.3/2.5 mm length: 20 cm large diameter: 1.5/3.0 mm length: 35 cm	standard diameter: 1.3/2.5 mm length: 20 cm large diameter: 1.5/2.8 mm length: 35 cm
Flow Holes quantity orientation diameter	4 rows of 4 each rows are 90° apart standard: 1.27mm large: 1.4mm	4 rows of 4 each rows are 90° apart standard: 1.0 mm large: 1.4 mm	4 rows of 4 each rows are 90° apart standard: 1.0 – 1.3mm large: 1.3 – 1.4 mm
Distal tip configuration	Smooth bullet shaped barium-impregnated silicone tip molded to catheter	Smooth bullet shaped barium-impregnated tip molded to catheter	Bullet shaped silicone elastomer filled with tantalum
Length markers	5, 10 and 15 cm from tip	5,7.5, 10, and 15cm from tip	5, 10, and 15cm from tip
Proximal end	Luer lock connector and end plug.	Luer lock connector and end plug.	Luer lock connector and end plug.

3

	Radionics XDC Ventricular Catheters	CNS MoniTorr ICP Ventricular Catheters K922941	Medtronic Becker EDM Ventricular Catheters
Material:	barium impregnated silicone	barium impregnated silicone	barium impregnated silicone
Accessories			
Anchor	silicone fixation tab (large only)	silicone fixation tab	fixation collar (large only)
Stylet	stainless steel stylet	stainless steel stylet	stainless steel stylet
Trocar	large catheter only	large catheter only	large catheter only

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Determination of Substantial Equivalence: [ref. Office of Device Evaluation (ODE) Blue Book Memorandum #86-3, Attachment I "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)"]

New Device (Radionics XDC Ventricular Catheter (XDC)) **is Compared to Marketed Device** (Clinical Neuro System's MoniTorr ICP™ Ventricular Catheter (CVC) and Medtronic Becker EDM Ventricular Catheters (EDM)).

Does New Device Have Same Indication Statements? Yes, all of the catheters are used as the proximal component for external CSF drainage or monitoring from the lateral ventricles of the brain. See previous section.

New Device Has Same Intended Use and May be "Substantially Equivalent".

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.? Design: All three systems have a large and standard size catheters, the same diameter and length tubing, similar arrangement and number of flow holes and a luer lock connector with cap. The diameter of the flow holes on the XDC large catheters is the same as the diameter of the flow holes on the CVC large catheters. The diameter of the flow holes on the XDC standard catheters is within the range of the diameters of the flow holes of the EDM standard catheters.

Materials: Yes, all of the catheters are manufactured from a barium impregnated silicone elastomer. The formulation of the silicone for the XDC tubing is (b)(4) and the molded tip is (b)(4). These are formulations that were included in the Radionics Siphon Limiting Device cleared via 510(k) K962990.

Could the New Characteristics Affect Safety or Effectiveness? No. As stated above all the characteristics can be found in at least one of the predicate devices. In addition testing was completed to insure that the when the luer connector is attached to the catheter the junction will withstand 2 lbs. of force and the red end cap will not leak when the catheter is pressurized to (b)(4) water. A summary of the test and results can be found in Attachment V.

Substantial Equivalence Determination.

Summary of Safety and Effectiveness Information: Please see Attachment VI:

Confidentially Statement: We consider our intent to market this device to be confidential commercial information. Radionics has not disclosed the intent to market this device to others who are not collaborators and consultants. We have taken caution to protect the confidentiality of our intent.

Attachments

Attachment I:	Sterilization Information
Attachment II:	Confidential Engineering Drawings
Attachment III:	Proposed Labels/Labeling
Attachment IV:	Commercially Available Device Information
Attachment V:	Test Results Summary
Attachment VI:	Summary of Safety and Effectiveness Information [510(k) Summary]

Attachment I: Sterilization Information

The XDC will be supplied sterile for single use only. The XDC has been adopted into a validated sterilization process per the Association of the Advancement of Medical Instruments (AAMI) Guidelines.

The XDC will be sterilized by:
(b)(4)

The following information is provided according to the FDA Sterility Review guide [510(k) Memorandum #K90-1, dated 2/12/90].

1. METHOD: The method of sterilization of the product is by processing using an ethylene oxide (ETO) gas cycle.

2. STERILIZATION VALIDATION METHOD: The devices have been adopted into the current validated sterilization process that results in a minimum (b) reduction of microorganisms at half dwell time at minimum process parameters.

3. STERILIZATION ASSURANCE LEVEL (SAL): The Sterility Assurance Level (SAL) for the sterilized product will be 10^{-6}.

4. PROPOSED PACKAGING: The product will be placed into two heat sealed pouches, one within the other. Each pouch will be constructed of Tyvek/Mylar, a well recognized medical grade pouch construction to ensure sterility of the contained product. This is the same type of packaging as the commercially available Radionics Contour-Flex Valve (K954285).

5. RESIDUALS: ETO gas residuals in the validated sterilization process meet the standards outlined in the Federal Register, Vol. 44, No. 122, June 23, 1978, which follow: EO 250 ppm, ECH 250 ppm, and EGly 5000 ppm.

5. PYROGENIC: LAL testing performed on the samples of the validated sterilization process confirms that the product remains non-pyrogenic as labeled.

Attachment II: Confidential Engineering Drawings

(b)(4) Schematic drawing

(b)(4) Schematic drawing

(b)(4) Schematic drawing

(b)(4) Schematic drawing

Attachment III: Proposed Labels/Labeling

Radionics®

STERILE EO

XDC™ Latex Free
EXTERNAL VENTRICULAR CATHETER, 20cm

CATALOG No.: XDC-1 PROD LOT: XXXXX
Sterile Lot: XX.X.XX Exp. XX.XX
Sterilized (YR-MO-DA): XX/XX/XX

Contents are **STERILE** and **NON-PYROGENIC** provided that the package integrity is not compromised. CAUTION: United States federal law restricts this device to sale by or on the order of a physician.
Radionics, Inc., P.O. Box 438, 22 Terry Avenue, Burlington, MA 01803, U.S.A.
(781) 272-1233

Radionics®

STERILE EO

XDC™ Latex Free
EXTERNAL VENTRICULAR CATHETER, 35cm

CATALOG No.: XDC-2 PROD LOT: XXXXX
Sterile Lot: XX.X.XX Exp. XX.XX
Sterilized (YR-MO-DA): XX/XX/XX

Contents are **STERILE** and **NON-PYROGENIC** provided that the package integrity is not compromised. CAUTION: United States federal law restricts this device to sale by or on the order of a physician.
Radionics, Inc., P.O. Box 438, 22 Terry Avenue, Burlington, MA 01803, U.S.A.
(781) 272-1233

The following information will accompany the device as well:

(b)(4) draft document

(b)(4) draft document

Attachment IV: Commercially Available Device Information

PS MEDICAL

Pudenz-Schulte Medical Corporation
125-B Cremona Drive
Goleta, California 93117
(805) 968-1546
(800) 826-5603 USA/Canada
FAX (805) 968-6889

CAUTION: UNITED STATES FEDERAL LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Technical information on these products may be obtained from the PS Medical distributor in your area or by contacting PS Medical directly

10589-2 12/90

CSF–External Drainage and Monitoring Products

Instructions for Use

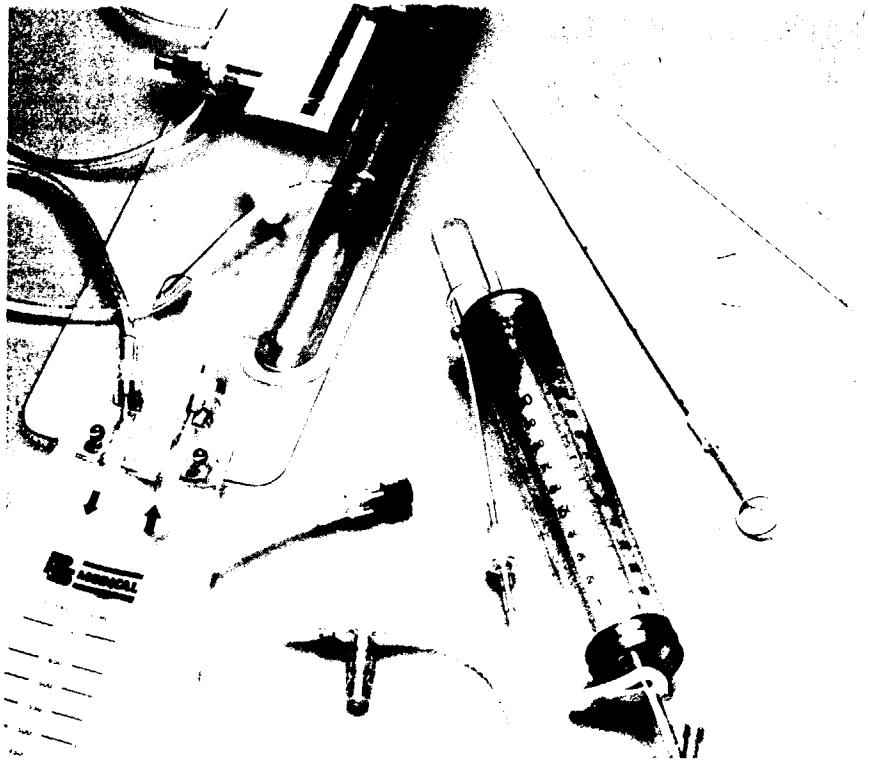

Fig. 1

PS Medical CSF-External Drainage and Monitoring (EDM) Products are designed to provide for the drainage of cerebrospinal fluid (CSF), and/or the monitoring of CSF pressure and flow rate from the lateral ventricles of the brain or the lumbar subarachnoid space.

Becker Ext. .al Drainage and Monitoring System

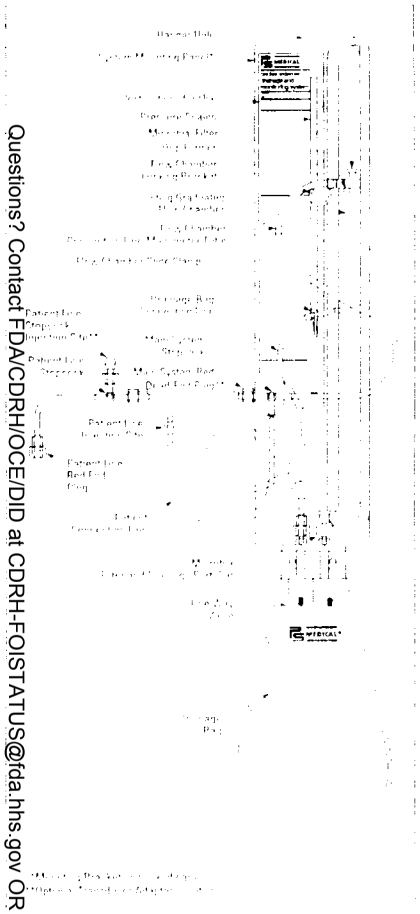

Fig. 2

The Becker External Drainage and Monitoring System (EDMS) provides the physician with a complete closed system for:

1. Draining cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space.

2. Monitoring CSF pressure and flow rate from the lateral ventricles of the brain and the lumbar subarachnoid space.

Description

Becker External Drainage and Monitoring System

As illustrated in Fig. 2 the system is comprised of:

A patient line stopcock with injection site and a nondistensible patient connection line with injection site.

The main system section located on the mounting panel includes:

a. Mounting bracket for height adjustment of system
b. Optional self-adjusting cord with lock for adjustment of system height
c. Main system stopcock with optional transducer location
d. Sliding graduated flow chamber with locking bracket
e. Flow chamber slide clamp
f. Drainage bag connection line

A removable drainage bag with approximate volumetric graduations and a microbial filter and drainage port.

Indications

Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

1. Reduce intracranial pressure (ICP), e.g. pre- intra- or postoperative;
2. Monitor CSF chemistry, cytology and physiology.
3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

The monitoring of the intracranial pressure (ICP) is indicated in selected patients with:

1. Severe head injury.
2. Subarachnoid hemorrhage graded III, IV or V preoperatively.
3. Reyes syndrome/similar encephalopathies.
4. Hydrocephalus.
5. Intracranial hemorrhage.
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver.

Monitoring can also be used to evaluate the status pre- and postoperative for space-occupying lesions.

Instructions for Use

Prior to use of the Becker EDMS, it is necessary for the attending physician and other responsible personnel to familiarize themselves with the use and function of the various components of the system. The following guidelines have been prepared by Dr. Donald P. Becker* and his staff.

System Set-Up

The system should be prepared under sterile conditions at least 30 minutes prior to placement of the ventricular catheter, lumbar catheter or subarachnoid bolt. The system should be removed from the opened pouch by an attendant wearing a surgical face mask and sterile gloves. Check to ensure that all components are assembled as illustrated in Fig. 2.

CAUTION: CHECK ALL CONNECTIONS TO ENSURE THAT FITTINGS ARE TIGHT AND LEAK-FREE.

A pressure transducer adapter may be attached at Position 4 on patient line stopcock or Position 3 on main system stopcock. See Fig. 3 and 4. If electronic pressure monitoring equipment is to be used, attach transducer to transducer adapter located on patient line or main system stopcock.

NOTE: Transducer adapters and transducers are not included with this system.

To attach a pressure transducer adapter at the main system stopcock, remove red end plug. The plug may then be used to cap a secondary inlet on the transducer adapter if necessary. To attach a transducer adapter at the patient line stopcock, remove injection site cap.

*This product was developed in cooperation with Donald P. Becker, M.D., Department of Surgery, Division of Neurosurgery, University of California, Los Angeles School of Medicine, Los Angeles, CA 90024

The system mounting panel incorporates a hanger hole and braided cord with cordlock for I.V. pole suspension and a panel bracket for manifold pole clamp mounting if more rigid mounting is desired. Locate the system mounting panel so that the main system stopcock is level with the patient's foramen of Monro or at the level of the exit of the lumbar catheter. Ensure that panel is properly aligned. The pressure head scales found on the panel label are referenced to zero at the main system stopcock. The main system stopcock must be correctly aligned with the patient for accurate pressure monitoring.

Pre-Filling System

The system must be pre-filled with sterile normal saline solution prior to connecting to patient.

Use of a 20 to 30ml syringe with a 25-gauge needle is recommended.

Inject at patient line stopcock injection site until all air has been flushed from patient line stopcock, patient line, main system stopcock, and flow chamber connection line into flow chamber.

If a transducer has been attached to the patient line stopcock, necessitating the removal of its injection site, inject at patient line injection site and fill per above.

Transducer adapter and patient line stopcock, red end plug and injection site fittings may be momentarily loosened to allow air to escape.

Check system for any residual air bubbles. Air can be removed by combined injection of saline and aspiration of air via a 25-gauge needle at injection sites on the patient line stopcock or patient line.

Ensure fluid drains from the flow chamber into the drainage bag. It may be necessary to manipulate the connection line or drainage bag one-way valve to establish drainage.

To Connect Catheter to System

After the catheter has been properly placed, the luerlock connector packaged with the catheter is inserted into the catheter. Care should be taken to allow only a minimal amount of CSF to escape. The catheter may be occluded at the scalp level by pinching or with an appropriate clamp to minimize fluid loss during the insertion of the connector.

The Becker EDMS Ventricular Catheter, 20cm, EDM Lumbar Catheter, 24cm and EDM Lumbar Catheter, 80cm include a catheter luerlock connector with an integral molded plug. This plug may be used to plug the catheter prior to connection to the patient line. The EDM Ventricular Catheter, 35cm includes a separate red end plug to allow temporary closure.

To connect the catheter to the pre-filled system, set the patient line stopcock to "Off" in Position 1 (See Fig. 3.1). Remove the red end plug from the patient line.

The catheter should now be occluded with an appropriate clamp (if not already in place) to minimize CSF loss during connection to the system. (Detach the plug from the catheter luerlock connector if used.) Attach luerlock connector to patient line. Care should be taken to ensure that the catheter and complete system is devoid of any air bubbles.

Set the patient line stopcock to the desired setting (see System Control). Remove the clamp from the catheter. The integral molded plug on the catheter luerlock connector should then be removed (cut off).

System Control

Patient Line Stopcock

The patient line stopcock is regularly positioned as depicted in Fig. 3. Arrows on handle indicate flow.

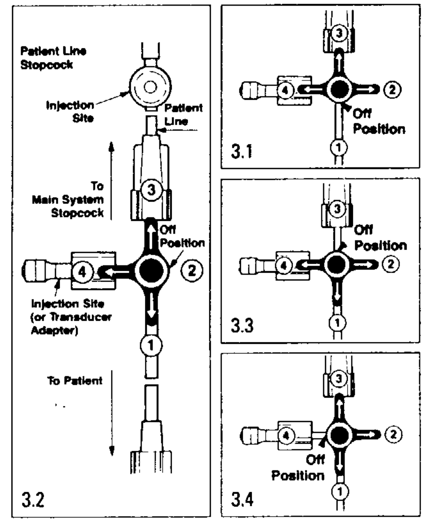

Fig. 3

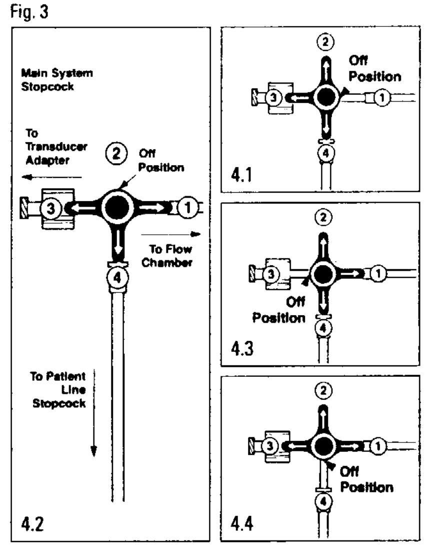

Fig. 4

When "Off" is at position number:

① Catheter does not communicate with patient line stopcock (Fig. 3.1).

② Catheter communicates with main system stopcock, patient line stopcock injection site (or transducer adapter) and patient line injection site. This is the regular setting for system use (Fig. 3.2).

③ Catheter communicates with patient line stopcock injection site (or transducer adapter). Catheter does not communicate with patient line injection site or main system stopcock (Fig. 3.3).

④ Catheter communicates with patient line injection site and main system stopcock only. Catheter does not communicate with patient line stopcock injection site (or transducer adapter) (Fig. 3.4).

Main System Stopcock

The main system stopcock is regularly positioned as depicted in Fig. 4. Arrows on handle indicate flow.

When "Off" is at position number:

① Patient line communicates with transducer adapter (if connected) only. Patient line does not communicate with flow chamber (Fig. 4.1).

② Patient line communicates with transducer adapter (if connected) and flow chamber. This is the regular setting for system use. (Fig. 4.2).

③ Patient line communicates with flow chamber only. Patient line does not communicate with transducer adapter (Fig. 4.3).

④ Patient line does not communicate with main system stopcock. Patient line does not communicate with flow chamber (Fig. 4.4).

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Flow Chamber Slide Clamp
(See Fig. 5)

The flow chamber will not communicate with the drainage bag when the slide clamp is closed or positioned to compress and securely occlude the drainage bag connection line (See Fig. 5.1). This position allows flow (CSF) to be collected in the graduated flow chamber.

The flow chamber will communicate with the drainage bag when the slide clamp is open or loosely positioned (See Fig. 5.2). This position allows flow (CSF) to communicate with the drainage bag.

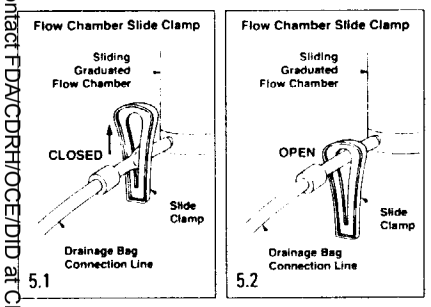

Fig. 5

To Calibrate System

To calibrate the transducer the instructions of the transducer manufacturer should be followed.

Initial system calibration should be done prior to connecting to patient.

The system provides several ways to perform the calibration. The transducer located on the patient line stopcock, or on main system stopcock may be referenced to atmospheric pressure through the microbial filter on the flow chamber. This can be done to zero the transducer.

The flow chamber connection line may be used as a manometer tube. The transducer is then referenced to the saline solution filled connection line. The saline solution in the connection line can be maintained at a constant height and provides a readily accessible standard pressure against which to calibrate the transducer.

To set the pressure, slide the flow chamber to the position where the flow chamber inlet tube aligns with the desired pressure setting on the cm H_2O or mm Hg scale. The scale is located on the system mounting panel adjacent to the flow chamber slide. A pressure setting of 27.2cm H_2O or 20mm Hg is recommended for transducer calibration.

To Drain CSF

Set patient line stopcock and main system stopcock to allow fluid to communicate from the drainage catheter to flow chamber. Open flow chamber slide clamp to allow fluid to communicate with drainage bag. The amount and rate of drainage will be partially dependent on the system pressure head setting (that is the height of the flow chamber inlet tube relative to the main system stopcock zero level).

CAUTION: DURING SYSTEM USE WITH THE FLOW CHAMBER SLIDE CLAMP OPEN TO ALLOW FLOW INTO THE DRAINAGE BAG, FLUID MAY ACCUMULATE IN THE FLOW CHAMBER BEFORE EMPTYING. FLOW MUST BE CAREFULLY MONITORED TO PREVENT COMPLETE FILLING OF THE FLOW CHAMBER. IT MAY BE NECESSARY TO MANIPULATE THE DRAINAGE BAG CONNECTION LINE TO RE-ESTABLISH DRAINAGE FROM THE FLOW CHAMBER TO DRAINAGE BAG. COMPLETE FILLING OF THE FLOW CHAMBER WILL PRECLUDE DRAINAGE OF CSF.

NOTE: During system use with the flow chamber slide clamp open to allow flow into the drainage bag, a small accumulation of fluid may occur in the flow chamber before emptying. When the periodic fluid accumulation empties a slight momentary reduction (0 to 4cm H_2O) in system pressure may occur.

To Set Pressure Head

Slide flow chamber so that flow chamber inlet tube aligns with desired graduation (in cm H_2O or mm Hg) on system mounting panel. Turn the thumb screw of locking bracket to unlock and lock sliding flow chamber in place.

To Monitor Pressure

Position patient line and main system stopcock so ventricular catheter or lumbar catheter communicates to transducer adapter.

Simultaneous drainage and pressure monitoring may result in artifacts in measured pressure as described by Wilkinson (53). If more accurate pressure monitoring is desired, the system should be temporarily closed to drainage by adjusting the patient line stopcock (Fig. 3.3) or main system stopcock (Fig. 4.4) so that the drainage catheter communicates *only* with the pressure transducer.

CAUTION: IF SYSTEM STOPCOCKS ARE TEMPORARILY CLOSED TO ALLOW FOR MORE ACCURATE PRESSURE MONITORING, CARE MUST BE TAKEN TO READJUST THE SYSTEM TO RE-ESTABLISH DRAINAGE OF CSF. FAILURE TO READJUST THE SYSTEM WILL PRECLUDE DRAINAGE OF CSF.

To Monitor Flow

Set patient line stopcock and main system stopcock to allow fluid to communicate to flow chamber. Slide flow chamber up to align flow chamber inlet tube with desired pressure setting.

Close flow chamber slide clamp to stop flow to the drainage bag (flow chamber does not communicate with the drainage bag). Record fluid accumulation over time per graduations (in ml) on flow chamber.

CAUTION: WITH THE FLOW CHAMBER SLIDE CLAMP SET TO MONITOR FLOW THERE IS NO FLOW INTO THE DRAINAGE BAG. FLOW MUST BE CAREFULLY MONITORED TO PREVENT COMPLETE FILLING OF THE FLOW CHAMBER. COMPLETE FILLING OF FLOW CHAMBER WILL PRECLUDE DRAINAGE OF CSF.

To empty the flow chamber, set main system stopcock to "Off" in Position 1 (see Fig. 4.1), then open flow chamber slide clamp (see Fig. 5.2). When the flow chamber is emptied, reset main system stopcock to desired position (see Fig. 4).

CAUTION: FAILURE TO ADJUST MAIN SYSTEM STOPCOCK TO ISOLATE PATIENT FROM FLOW CHAMBER DURING EMPTYING MAY RESULT IN A MOMENTARY REDUCTION IN SYSTEM PRESSURE.

To Flush System

Injection sites may be used to flush the system. Flush fluid into drainage bag.

CAUTION: ADJUST PATIENT LINE OR MAIN SYSTEM STOPCOCK TO ISOLATE PATIENT AND PRESSURE TRANSDUCER. INJURY TO PATIENT AND DAMAGE TO THE TRANSDUCER MAY OCCUR IF THE SYSTEM IS FLUSHED WITH AN OPEN PATH TO PATIENT AND/OR TRANSDUCER.

To Replace Drainage Bag

Close flow chamber slide clamp to prevent retrograde flow from the drainage bag connection line. Remove the bag from the system mounting panel (see Fig. 6). Using sterile handling technique to avoid contamination, disconnect the drainage bag connection line from the drainage bag. Discard drainage bag.

Connect sterile PS Medical Drainage Bag to the drainage bag connection line and attach to system mounting panel.

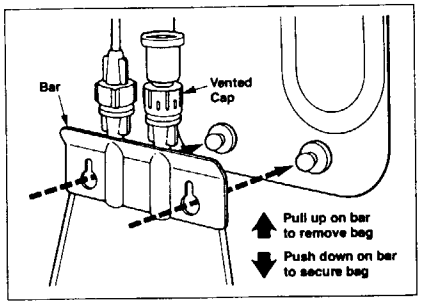

Fig. 6

4/9

CAUTION: THE FLOW CHAMBER SLIDE CLAMP MUST BE RESET TO OPEN POSITION TO ESTABLISH FLOW INTO THE DRAINAGE BAG. COMPLETE FILLING OF FLOW CHAMBER WILL PRECLUDE DRAINAGE OF CSF.

To Empty Drainage Bag

Replacement of the drainage bag is recommended by PS Medical. However, should the physician choose to empty and re-use the drainage bag, the following method may be used:

1. Remove the bag from the system mounting panel. **Do not disconnect the drainage bag from flow chamber connection line.**
2. Using sterile handling techniques, disconnect the vented port cap from the luerlock fitting.
3. With careful attention to avoid contamination of the open luerlock fitting, invert bag and empty.
4. Using sterile handling technique replace port cap.
5. Reattach bag to system mounting panel (see Fig. 6).

Irrigation, CSF Sampling and Intraventricular Medication

The system injection sites can be used for several purposes. A 25-gauge needle can be inserted through the injection site which has been cleaned and disinfected with alcohol. A clogged ventricular catheter may then be irrigated with 0.1ml of sterile saline. Similarly, the injection site can be used to withdraw a sample of CSF for laboratory analysis or to inject intrayentricular medication.

Volume/Pressure Relationship

A volume/pressure relationship (VPR) can be obtained with the system using the technique described by Miller et al. (31,32,33,34) and Marmarou and Shulman (25). Fill a 1.0ml syringe with a 25-gauge needle attached with sterile saline and insert the needle through patient line injection site. Physicians desiring to conduct these studies should be familiar with the techniques as described by Miller et al. and by Marmarou and Shulman.

Moving an EDMS Patient

If it is desired to move a patient who is undergoing external drainage and/or monitoring with a PS Medical Becker EDMS, the system should be kept upright and correctly aligned with the patient. If it is not possible for the system to be moved in an upright manner, the following steps must be performed:

1. Ensure that the flow chamber has completely drained;
2. Isolate patient from communication with the flow chamber by:
   a. Adjusting the patient line stopcock to "Off" Position 1 (Fig. 3.1).
   b. Adjusting main system stopcock to "Off" Position 4 (Fig. 4.4).
3. Move patient and system as required.
4. Realign and readjust system and stopcocks to initiate drainage when patient reaches new location.

CAUTION: FAILURE TO PERFORM STEPS 1-4, ABOVE, MAY RESULT IN IMPROPER VENTING BY FLOW CHAMBER MICROBIAL FILTER WHEN DRAINAGE IS RE-ESTABLISHED.

CAUTION: IF SYSTEM STOPCOCKS ARE TEMPORARILY CLOSED TO ALLOW FOR PATIENT TRANSPORT, CARE MUST BE TAKEN TO READJUST THE STOPCOCKS TO RE-ESTABLISH DRAINAGE OF CSF. FAILURE TO READJUST THE STOPCOCKS WILL PRECLUDE DRAINAGE OF CSF.

EDM Drainage Assembly

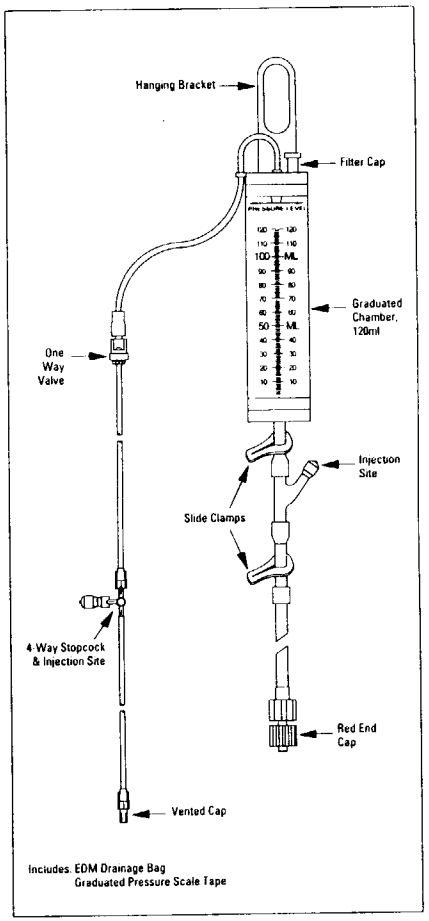

Fig. 7

The PS Medical EDM Drainage Assembly provides the physician with a complete closed system for:

1. Draining cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space.
2. Monitoring CSF pressure and flow rate from the lateral ventricles of the brain and the lumbar subarachnoid space.

Description

EDM Drainage Assembly

As illustrated in Fig. 7, the EDM Drainage Assembly includes:

a. A patient line stopcock with injection site and nondistensible patient connection line with one-way check valve.
b. A graduated chamber with drip former and hanging bracket for I.V. pole suspension.
c. A drainage bag connection line with 2 slide clamps and injection (sampling) site.
d. A removable vented drainage bag with approximate volumetric graduations and drainage port.
e. Pressure scale tape.

Indications

Draining CSF and monitoring CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

1. Reduce intracranial pressure (ICP), e.g. pre-intra- or postoperative;
2. Monitor CSF chemistry, cytology and physiology.
3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

The monitoring of the intracranial pressure (ICP) is indicated in selected patients with:

1. Severe head injury.
2. Subarachnoid hemorrhage graded III, IV or V preoperatively.
3. Reyes syndrome or similar encephalopathies.
4. Hydrocephalus.
5. Intracranial hemorrhage.
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver.

Monitoring can also be used to evaluate the status pre- and postoperative for space-occupying lesions.

Instructions for Use

Prior to use of the EDM Drainage Assembly, it is necessary for the attending physician and other responsible personnel to familiarize themselves with the use and function of the various components.

System Set-Up

The EDM Drainage Assembly should be prepared under sterile conditions at least 30 minutes prior to placement of the ventricular or lumbar drainage catheter.

The two components of the EDM Drainage Assembly (drainage assembly and drainage bag) are individually pouched. The two inner pouches should be opened, and their contents removed by an attendant wearing a surgical face mask and sterile gloves.

Remove the non-vented red end cap from the drainage bag connection line, and attach to the inlet connector of the drainage bag. Check to ensure that all components are assembled as illustrated in Fig. 7.

CAUTION: CHECK ALL CONNECTIONS TO ENSURE THAT FITTINGS ARE TIGHT AND LEAK-FREE.

A pressure transducer adapter may be attached at Position 4 on patient line stopcock. See Fig. 8. If electronic pressure monitoring equipment is to be used, attach transducer to transducer adapter located on patient line stopcock.

NOTE: Transducer adapters and transducers are not included with the EDM Drainage Assembly.

To attach a transducer adapter at the patient line stopcock, remove injection site fitting.

The graduated chamber assembly incorporates a hanging bracket for I.V. pole suspension. Affix the pressure scale tape onto the I.V. pole so that its zero line is level with the patient's foramen of Monro or with the exit of the lumbar catheter. The "Pressure Level" arrow on the graduated chamber is now used to read pressure head directly off the pressure scale tape. The tape must be correctly aligned with the patient for accurate pressure monitoring.

Pre-filling the Assembly

The EDM Drainage Assembly must be pre-filled with sterile normal saline solution prior to connecting to patient.

Use of 20 to 30ml syringe with a 25-gauge needle is recommended.

Inject at patient line stopcock injection site until all air has been flushed from patient line stopcock, patient line, one-way valve, and chamber connection line into graduated chamber.

Check drainage assembly for any residual air bubbles. Air can be removed by combined injection of saline and aspiration of air via a 25-gauge needle at the patient connection line stopcock injection site.

To Connect Catheter to the EDM Drainage Assembly

After the catheter has been properly placed, the luerlock connector packaged with the catheter is inserted into the catheter. Care should be taken to allow only a minimal amount of CSF to escape. The catheter may be occluded at the scalp level by pinching or with an appropriate clamp to minimize fluid loss during the insertion of the connector.

The Becker EDMS Ventricular Catheter, 20cm, the EDM Lumbar Catheter, 24cm and EDM Lumbar Catheter, 80cm include a catheter luerlock connector with an integral molded plug. This plug may be used to plug the catheter prior to connection to the EDM Drainage Assembly patient line. The EDM Ventricular Catheter, 35cm includes a separate red end plug to allow temporary closure.

To connect the catheter to the pre-filled drainage assembly, set the patient line stopcock to "Off" in Position 1 (See Fig. 8.1). Remove the vented cap from the patient line luer fitting.

The catheter should now be occluded with an appropriate clamp (if not already in place) to minimize CSF loss during connection to the drainage assembly. (Detach the plug from the catheter luerlock connector if used.) Attach catheter luerlock connector to patient line luer fitting. Care should be taken to ensure that the catheter and complete drainage assembly is devoid of any air bubbles.

Set the patient line stopcock to the desired setting (see Drainage Assembly Control). Remove the clamp from the catheter. The integral molded plug on the catheter luerlock connector should then be removed (cut off).

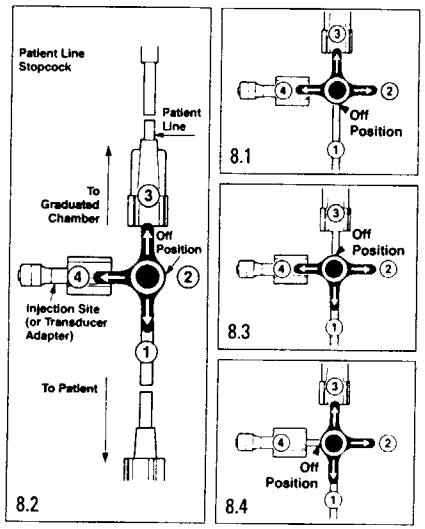

Fig. 8

Drainage Assembly Control
Patient Line Stopcock

The patient line stopcock is regularly positioned as depicted in Fig. 8. Arrows on the handle indicate flow.

When "Off" is at position number:

① Catheter does not communicate with patient line stopcock injection site (or pressure transducer) or graduated chamber (Fig. 8.1).

② Catheter communicates with graduated chamber and patient line stopcock injection site (or transducer adapter). This is the regular setting for system use (Fig. 8.2).

③ Catheter communicates with patient line stopcock injection site (or transducer adapter). Catheter does not communicate with graduated chamber (Fig. 8.3).

④ Catheter communicates with graduated chamber only. Catheter does not communicate with patient line stopcock injection site (or transducer adapter) (Fig. 8.4).

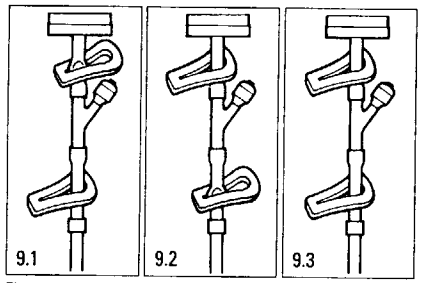

Fig. 9

Flow Chamber Slide Clamp
(See Fig. 8)

The graduated chamber will not communicate with the drainage bag when either of the two drainage line slide clamps are closed or positioned to compress and occlude the drainage bag connection line (See Fig. 9.1 and 9.2). These slide clamps may be used to preclude drainage from the graduated chamber into the drainage bag to:

1. Allow CSF to be collected in the graduated chamber to enable more accurate fluid volume determination (Fig. 9.1).
2. Allow for sampling of CSF using the drainage bag connection line injection (sampling) site (Fig. 9.2).
3. Allow for emptying or replacing a filled drainage bag (Fig. 9.1 and 9.2).

The graduated chamber will communicate with the drainage bag when both drainage line slide clamps are open or loosely positioned so as not to occlude the drainage bag connection line (See Fig. 9.3).

To Drain CSF

Set patient line stopcock to allow fluid to communicate from drainage catheter to the graduated chamber (Fig. 8.2). Open both drainage line slide clamps (Fig. 9.3) to allow the graduated chamber to communicate with drainage bag. The amount and rate of drainage will be partially dependent on the system pressure head setting (that is the height of the graduated chamber "Pressure Level" line relative to the patient).

CAUTION: THE DRAINAGE ASSEMBLY MUST BE PROPERLY ALIGNED AND NEVER LOWER THAN THE PATIENT TO PRECLUDE OVER-DRAINAGE OF CSF AND TO MAINTAIN CONTROL OF ICP.

To Set Pressure Head

Increase or decrease height of "Pressure Level" arrow on the graduated chamber relative to the patient. The pressure scale tape is graduated in both mm Hg and cm H_2O units and is provided for user preference.

To Monitor Pressure

Ensure that the patient line stopcock is positioned so that drainage catheter communicates with transducer adapter.

Simultaneous drainage and pressure monitoring may result in artifacts in measured pressure as described by Wilkinson (53). If more accurate pressure monitoring is desired, drainage should be temporarily ceased by adjusting the patient line stopcock so that the drainage catheter communicates *only* with the pressure transducer (Fig. 8.3).

CAUTION: IF THE PATIENT LINE STOPCOCK IS TEMPORARILY ADJUSTED TO ALLOW FOR MORE ACCURATE PRESSURE MONITORING, CARE MUST BE TAKEN TO READJUST THE PATIENT LINE STOPCOCK TO RE-ESTABLISH DRAINAGE OF CSF. FAILURE TO READJUST THE STOPCOCK WILL PRECLUDE DRAINAGE OF CSF.

To Monitor Flow

Set patient line stopcock to allow fluid to communicate to the graduated chamber. Adjust graduated chamber ("Pressure Level" arrow) height relative to the patient.

Close upper drainage line slide clamp (the one closest to the bottom of the graduated chamber, Fig. 9.1) to stop the flow of CSF to the drainage bag (graduated chamber will no longer communicate with the drainage bag). Record fluid accumulation over time per graduations (in ml) on graduated chamber.

CAUTION: WITH THE DRAINAGE LINE SLIDE CLAMP CLOSED TO MONITOR FLOW, THERE IS NO FLOW INTO THE DRAINAGE BAG. FLOW MUST BE CAREFULLY MONITORED TO PREVENT COMPLETE FILLING OF THE GRADUATED CHAMBER. COMPLETE FILLING OF GRADUATED CHAMBER WILL PRECLUDE DRAINAGE OF CSF.

To empty the graduated chamber, set patient line stopcock to "Off" in Position 1 (see Fig. 8.1), then open graduated chamber slide clamp so that the drainage bag connection line is no longer occluded (see Fig. 9.3). When the graduated chamber is emptied, reset patient line stopcock to desired position (see Fig. 8).

CAUTION: FAILURE TO ADJUST PATIENT LINE STOPCOCK TO ISOLATE PATIENT FROM GRADUATED CHAMBER DURING EMPTYING MAY RESULT IN A MOMENTARY REDUCTION IN SYSTEM PRESSURE.

To Flush Drainage Assembly

Injection sites may be used to flush the drainage assembly. Flush fluid into drain bag.

CAUTION: ADJUST PATIENT LINE STOPCOCK IN ORDER TO ISOLATE PATIENT AND PRESSURE TRANSDUCER. INJURY TO PATIENT AND DAMAGE TO THE TRANSDUCER MAY OCCUR IF THE DRAINAGE ASSEMBLY IS FLUSHED WITH AN OPEN PATH TO PATIENT AND/OR TRANSDUCER.

To Replace Drainage Bag

Occlude drainage bag connection line by closing either of the drainage line slide clamps (Fig. 9.1 or 9.2). Unhook the bag from its suspension location. Using sterile handling technique to avoid contamination, disconnect the drainage bag connection line from the drainage bag. Discard drainage bag.
Connect sterile PS Medical Drainage Bag to the drainage bag connection line and suspend using provided braided cord and cordlock.

CAUTION: THE DRAINAGE LINE SLIDE CLAMP MUST BE RESET TO THE OPEN POSITION TO ESTABLISH FLOW INTO THE DRAINAGE BAG. COMPLETE FILLING OF GRADUATED CHAMBER WILL PRECLUDE DRAINAGE OF CSF.

To Empty Drainage Bag

Replacement of the drainage bag is recommended by PS Medical. However, should the physician choose to empty and re-use the drainage bag, the following method may be used:

1. Unhook the bag from its suspension location. **Do not disconnect the drainage bag from the drainage bag connection line.**
2. Using sterile handling techniques, disconnect the vented port cap from the luerlock fitting.
3. With careful attention to avoid contamination of the open luerlock fitting, invert bag and empty.
4. Using sterile handling technique replace port cap.
5. Re-suspend drainage bag.

Irrigation, CSF Sampling and Intraventricular Medication

The EDM Drainage Assembly injection sites can be used for several purposes. A 25-gauge needle can be inserted through the patient line stopcock injection site, which has been cleaned and disinfected with alcohol. A clogged drainage catheter may then be irrigated with 0.1ml of sterile saline. The patient line stopcock injection site may also be used to inject intraventricular medication.

CSF sampling may be accomplished using the patient connection line stopcock injection site, or the drainage bag connection line injection (sampling) site. To sample from the drainage bag connection line injection site, close lower drainage line slide clamp (the one closest to the drainage bag, Fig. 9.2) to stop the flow of CSF to the drainage bag (graduated chamber will no longer communicate with the drainage bag). A syringe with a 25-gauge needle may now be used to sample CSF from the injection site.

CAUTION: THE DRAINAGE LINE SLIDE CLAMP MUST BE RESET TO THE OPEN POSITION TO ESTABLISH FLOW INTO THE DRAINAGE BAG. COMPLETE FILLING OF GRADUATED CHAMBER WILL PRECLUDE DRAINAGE OF CSF.

Volume/Pressure Relationship

A volume/pressure relationship (VPR) can be obtained with the EDM Drainage Assembly using the technique described by Miller et al. (31,32,33,34) and Marmarou and Shulman (25). Fill a 1.0ml syringe with a 25-gauge needle attached with sterile saline and insert the needle through patient line injection site. Physicians desiring to conduct these studies should be familiar with the techniques as described by Miller et al. and by Marmarou and Shulman.

Moving an EDM Patient

If it is desired to move a patient who is undergoing external drainage and/or monitoring with a PS Medical EDM Drainage Assembly, the system should be kept upright and correctly aligned with the patient. If it is not possible for the system to be moved in an upright manner, the following steps must be performed:

1. Ensure that the graduated chamber has completely drained;
2. Isolate patient from communication with the flow chamber by adjusting the patient line stopcock to "Off" Position 1 (Fig. 8.1) or "Off" Position 3 (Fig. 8.3).
3. Move patient and system as required.
4. Realign and readjust system to initiate drainage when patient reaches new location.

CAUTION: FAILURE TO PERFORM STEPS 1-4, ABOVE, MAY RESULT IN IMPROPER VENTING BY GRADUATED CHAMBER MICROBIAL FILTER WHEN DRAINAGE IS RE-ESTABLISHED.

CAUTION: IF PATIENT LINE STOPCOCK IS TEMPORARILY CLOSED TO ALLOW FOR PATIENT TRANSPORT, CARE MUST BE TAKEN TO READJUST THE STOPCOCK TO RE-ESTABLISH DRAINAGE OF CSF. FAILURE TO READJUST THE STOPCOCK WILL PRECLUDE DRAINAGE OF CSF.

EDM Drainage Kits with 120ml Graduated Chamber,
Ventricular and Lumbar

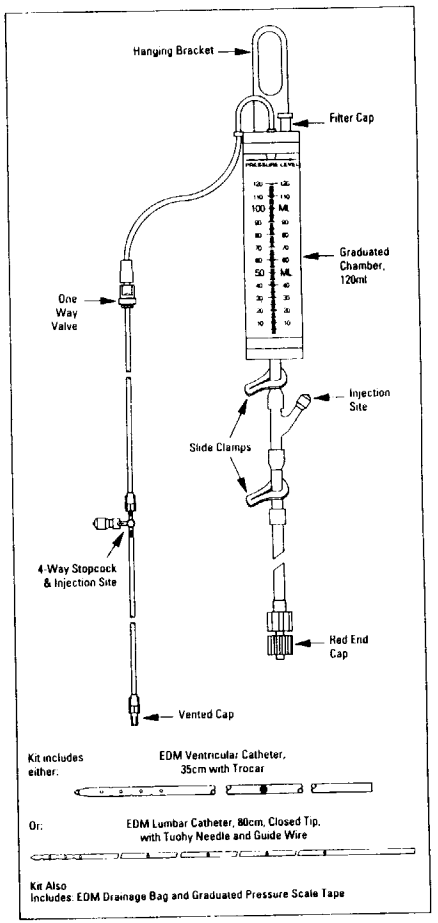

Fig. 10

The PS Medical EDM Drainage Kits provide the physician with a complete closed system for:

1. Draining cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space.
2. Monitoring CSF pressure and flow rate from the lateral ventricles of the brain and the lumbar subarachnoid space.

Description

EDM Drainage Kits

As illustrated in Fig. 10, the EDM Drainage Kits include:

a. An EDM drainage assembly with 120ml graduated chamber and 700ml drainage bag,
b. An EDM Ventricular Catheter, 35cm, Barium Impregnated with Trocar, or
c. An EDM Lumbar Catheter, 80cm, Barium Impregnated with Closed Tip.

The drainage assembly and catheter are packaged together in kit form for user convenience.

Indications

Draining CSF and monitoring CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

1. Reduce intracranial pressure (ICP), e.g. pre-, intra- or postoperative.
2. Monitor CSF chemistry, cytology and physiology.
3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

The ventricular monitoring of intracranial pressure (ICP) is indicated in selected patients with:

1. Severe head injury.
2. Subarachnoid hemorrhage graded III, IV or V preoperatively.
3. Reyes syndrome or similar encephalopathies.
4. Hydrocephalus.
5. Intracranial hemorrhage.
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver.

Monitoring can also be used to evaluate the status pre- and postoperative for space-occupying lesions.

Instructions for Use

Prior to use, it is necessary for the attending physician and other responsible personnel to familiarize themselves with the use and function of the various components of the EDM Drainage Kit.

EDM Drainage Assembly Set-Up

The EDM Drainage Assembly should be prepared under sterile conditions at least 30 minutes prior to placement of the ventricular or lumbar drainage catheter.

EDM Lumbar Drainage Kit

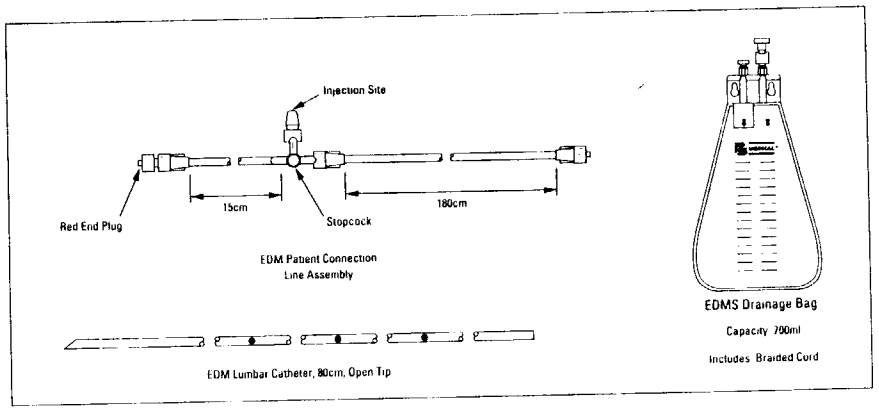

Fig. 11

The PS Medical EDM Lumbar Drainage Kit provides the physician with a closed system for:

1. Draining cerebrospinal fluid (CSF) from the lumbar subarachnoid space.

2. Monitoring CSF pressure from the lumbar subarachnoid space.

Description

As illustrated in Fig. 11, the EDM Lumbar Drainage Kit includes:

a. An EDM Lumbar Catheter, 80cm, Open Tip, Barium Impregnated,
b. An EDM Patient Connection Line Assembly, and
c. An EDMS Drainage Bag, 700ml, with braided cord for I.V. pole hook mounting.

The EDM Lumbar Catheter, 80cm, Open Tip, includes 14 gauge Tuohy needle, 2 each fixation tabs, luerlock connector with integral plug and 20 gauge blunt needle adapter.

The drainage assembly and catheter are packaged together in kit form for user convenience.

Indications

Draining CSF from the lumbar subarachnoid space is indicated in selected patients to:

1. Reduce intracranial pressure (ICP), e.g., pre-, intra-, or postoperative.
2. Monitor CSF chemistry, cytology and physiology.
3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

Monitoring of intracranial pressure (ICP) is indicated in selected patients with:

1. Severe head injury.
2. Subarachnoid hemorrhage graded III, IV or V preoperatively.
3. Reyes syndrome or similar encephalopathies.
4. Hydrocephalus.
5. Intracranial hemorrhage.
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver.

Monitoring can also be used to evaluate the status pre- and postoperative for space-occupying lesions.

Instructions for Use

Prior to use, it is necessary for the attending physician and other responsible personnel to familiarize themselves with the use and function of the various components of the EDM Lumbar Drainage Kit.

EDM Ventricular Catheters

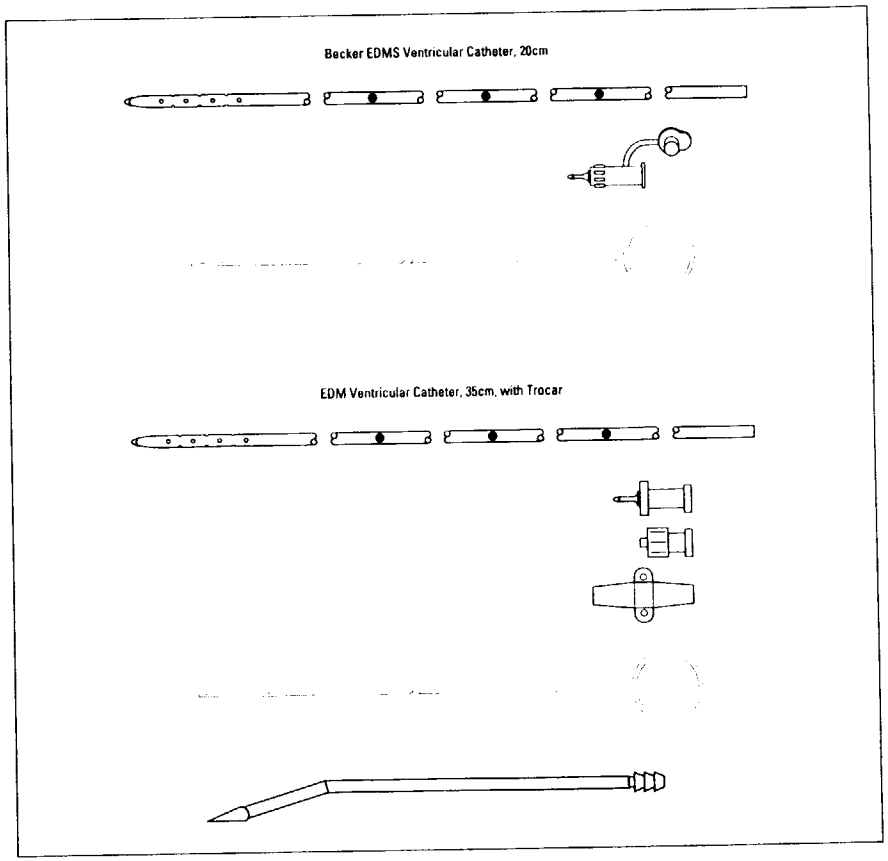

Fig. 12

Description

EDM Ventricular Catheters, Barium Impregnated

The PS Medical Becker EDMS Ventricular Catheter, 20cm and EDM Ventricular Catheter, 35cm with Trocar are fabricated from silicone elastomer tubing impregnated with white barium sulfate to provide radiopacity. Relatively firm tubing is incorporated in the catheter design to provide resistance to catheter kinking and compression. The tip of the catheter is bullet-shaped and is filled with radiopaque tantalum impregnated silicone elastomer. Black length markers made of graphite impregnated silicone elastomer are positioned on the catheter at points 5, 10 and 15cm from the proximal tip to enable the surgeon to gauge the depth of penetration of the catheter into the lateral ventricle.

A stainless steel stylet, packaged with each catheter, is designed to facilitate introduction of the catheter into the lateral ventricle. The catheter is packaged with the stylet inserted in the lumen.

Becker EDMS Ventricular Catheter, 20cm, Barium Impregnated

A barium impregnated silicone elastomer ventricular catheter 20cm in length with black length markers (at 5, 10 and 15cm from proximal tip), a luerlock connector and a stainless steel stylet to facilitate placement of the catheter in the lateral ventricle. The luerlock connector has an integral molded plug to facilitate its closure prior to connection to other drainage or monitoring system components.

EDM Ventricular Catheter, 35cm, Barium Impregnated with Trocar

A barium impregnated silicone elastomer ventricular catheter 35cm in length with black length markers (at 5, 10 and 15cm from proximal tip), a luerlock connector, a red end plug, a silicone elastomer fixation collar, a stainless steel stylet and a stainless steel trocar. The catheter is slightly larger in diameter and will allow insertion of a commercially available transducer-tipped fiber optic catheter.

Indications

The EDM Ventricular Catheters are designed for use as the proximal component for CSF drainage and/or monitoring from the lateral ventricles of the brain.

Instructions for Use

A variety of surgical techniques may be used in placing the catheters into the lateral ventricle. The site of placement is at the discretion of the surgeon.

Surgical Technique – Ventricular Catheter

The surgical technique for placement of the ventricular catheter has been provided by Dr. Donald P. Becker and his staff.

Prior to surgery, the balance of the drainage and/or monitoring system should be completely assembled in operational condition. The preoperative preparation of the patient is carried out with the standards of care appropriate for an intracranial operation. A broad-spectrum antibiotic is administered preoperatively and continued during the 24-hour postoperative period.

The head is completely shaved, cleaned and prepared in a manner appropriate for craniotomy. Using local anesthesia, a 2.5cm parasagittal incision is made just anterior to the right coronal suture in line with the medial margin of the iris. A self-retaining retractor is inserted and the skull is exposed by retracting the periosteum.

A twist drill hole directed slightly mesially is made with a 9/64" bit. Under ideal conditions, the twist drill should penetrate the dura without injuring the underlying brain. The dura may also be opened with a #11 surgical blade.

The ventricular catheter with stylet in place is directed from the twist drill hole toward the inner canthus of the ipsilateral eye. In the coronal plane, the penetration is directed in a plane aligned 2cm anterior to the external auditory canal. If the ventricle is not entered, a second pass is made directing the tip of the catheter toward the bridge of the nose. If this, too, is unsuccessful, a third and final pass is made directing the catheter toward the inner canthus of the contralateral eye. By following this sequence, even slit-like ventricles can be entered in the majority of cases. If the ipsilateral ventricle is not entered, the entire procedure is repeated on the opposite side. Should this also fail, the surgeon should consider the alternative of monitoring with a subarachnoid bolt (e.g.: Richmond Bolt).

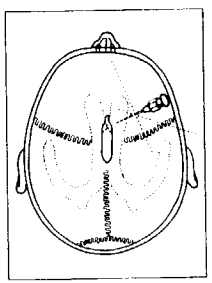

Fig.13

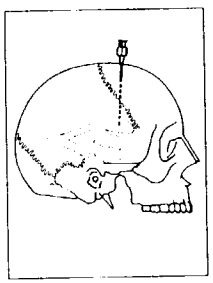

Fig.14

The landmarks for the incision site and directions for catheter insertion are illustrated in Fig. 13 and 14. If a subarachnoid bolt is to be used, it is recommended that it be placed in a new twist drill hole to decrease the possibility of clogging of the subarachnoid bolt with brain tissue.

When the ventricle is entered, the stylet is withdrawn and the catheter is occluded at the scalp level by pinching or with an appropriate clamp. Only a minimal amount of CSF should be permitted to escape. This is particularly important if the ICP is elevated. Over-draining may predispose to ventricular collapse.

The distal end of the occluded catheter is now tunneled under the scalp to emerge through a stab wound placed posterior to the ventriculostomy incision.

The EDM Ventricular Catheter, 35cm, includes a trocar which may be used to facilitate this placement. The trocar may be inserted into the distal end of the catheter for attachment. After desired placement of the catheter, cut the distal end of the catheter to detach the trocar.

The enclosed luerlock adapter may now be inserted into the catheter and attached to other components of the drainage and/or monitoring system. Specific details regarding catheter connection are found in the Instructions for Use sections for the Becker EDMS and EDM Drainage Assembly.

Secure the catheter to the connector with a tight double suture tie using 0 silk suture (Fig. 15).

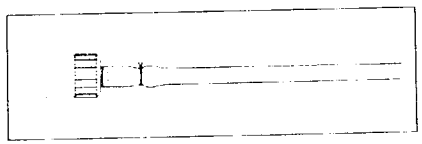

Fig.15

Care should be taken to ensure that the catheter and the balance of the drainage and/or monitoring system is filled and devoid of any air bubbles. If the catheter is properly placed, a satisfactory wave form should be visible on the monitoring equipment. Minor adjustments of the ventricular catheter position may be necessary to accomplish this.

After a satisfactory waveform is obtained, the ventriculostomy wound is closed with interrupted sutures and a full head dressing applied.

A silicone fixation collar is supplied with the EDM Ventricular Catheter, 35cm, with Trocar, and may be applied prior to completing the full head dressing. The fixation collar is applied to the catheter by spreading it open and positioning the catheter in the groove. The fixation collar may be positioned at the catheter or the catheter and luerlock adapter joint. The fixation collar is secured to the scalp by passing a ligature through the two holes in the flange of the fixation collar.

Connection of Catheter to Drainage and/or Monitoring System

Using the included luerlock connector, the EDM Ventricular Catheter may be directly attached to a PS Medical Becker EDMS or EDM Drainage Assembly.

EDM Lumbar Catheters

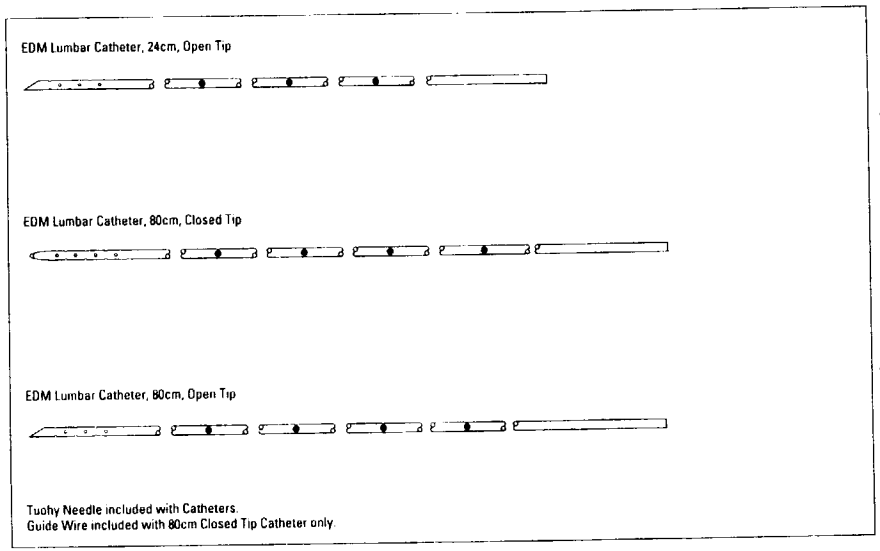

Fig. 16

Description

The PS Medical EDM Lumbar Catheter, 24cm and EDM Lumbar Catheters, 80cm are fabricated from silicone elastomer tubing impregnated with barium sulfate to provide radiopacity. Relatively firm tubing is incorporated in the catheter to provide resistance to kinking and compression. The open lumbar tips of the EDM Lumbar Catheter, 24cm and EDM Lumbar Catheter, Open Tip, 80cm, are trimmed at an angle (Fig. 17). The lumbar tip of the EDM Lumbar Catheter, Closed Tip, 80cm is bullet-shaped and filled with radiopaque tantalum impregnated silicone elastomer (Fig. 18). A Teflon coated stainless steel

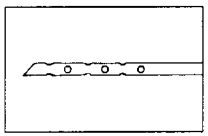

Fig. 17

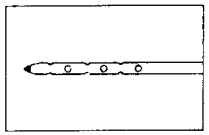

Fig. 18

guide wire with adjustable stop is provided with the Closed Tip 80cm EDM Lumbar Catheter to facilitate placement. All catheters have multiple inlet holes located within approximately 17mm of the lumbar tip. Length markers of graphite impregnated silicone elastomer are positioned on the catheters at points 11, 16 and 21cm from the lumbar tip (an additional 26cm length marker is included on the 80cm EDM Lumbar Catheters).

When the 11cm marker is aligned with the slot opening in the hub of the provided Tuohy needle, the lumbar tip of the catheter is aligned with the tip of the needle.

The lumbar catheter design, guide wire with adjustable stop (as applicable), and the 14-gauge Tuohy needle allow for percutaneous placement without need for laminectomy.

Separate silicone elastomer fixation tabs are included with the EDM Lumbar Catheter, 24cm (1 each) and EDM Lumbar Catheters, 80cm (2 each) to anchor the catheter as required.

Indications

The EDM Lumbar Catheters are designed for use as the proximal component for CSF drainage and/or monitoring from the lumbar subarachnoid space.

Instructions for Use

Surgical Technique – EDM Lumbar Catheter

The use of local or general anesthesia during the placement of the catheter is at the discretion of the surgeon.

Catheter patency prior to implantation may be verified by gently flushing a sterile saline solution through the catheter (a 20-gauge blunt needle adapter is provided with the EDM Lumbar Catheters, 80cm for this purpose. It may be placed into the open end of the catheter to facilitate flushing).

Catheter Placement

A variety of surgical techniques may be used to place a catheter in the lumbar subarachnoid space (23, 37). The surgical method is at the discretion of the surgeon.

NOTE: Refer to the "Guide Wire and Adjustable Stop" section for instructions on proper guide wire use during catheter implantation (EDM Lumbar Catheter, 80cm Closed Tip only).

Position the patient on one side with partial hip and knee flexion (Fig. 19). Prepare and drape the surgical areas (low back) as a sterile field.

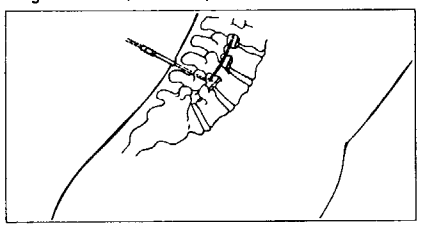

Fig. 19

Make a 2cm incision between the spinous processes of L4-L5 or L5-S1. Elevate the patient's head about 30° to increase intraspinal CSF pressure. Insert the 14-gauge Tuohy needle with the bevel cephalad, and advance into the lumbar subarachnoid space. Withdraw the needle stylet and lower the patient's head when a free flow of CSF is obtained. Introduce the lumbar catheter through the Tuohy needle. Insert 8cm of catheter into the subarachnoid space cephalad to the puncture site. Slowly remove the guide wire, if used. Slowly remove the Tuohy needle, leaving the catheter in place. Secure the catheter with fixation tab(s).

Proper catheter placement in the lumbar subarachnoid space should be verified. This is verified by the flow of CSF from the catheter or through the use of appropriate imaging techniques. Occlude catheter with an appropriate clamp or finger pressure to ensure that as little CSF as possible is lost (23,37). Proper catheter placement allows lumbar subarachnoid drainage and pressure monitoring.

CAUTION: TO AVOID POSSIBLE TRANSECTION OF THE CATHETER, THE CATHETER SHOULD NEVER BE WITHDRAWN THROUGH THE TUOHY NEEDLE. IF THE CATHETER NEEDS TO BE WITHDRAWN, THE TUOHY NEEDLE AND CATHETER (WITH GUIDE WIRE IF USED) MUST BE REMOVED SIMULTANEOUSLY.

Silicone elastomer fixation tabs are provided to anchor the catheter at the incision site, as desired. The tabs wrap around the catheter and can be located at any point. The fixation tabs are applied to the catheter by spreading them open and positioning the catheter in the fixation tab groove (Fig. 20). The tabs are then closed (Fig. 21). To secure the fixation tab to the catheter a suture is passed through the two holes in the tab and tied. The tabs are then sutured to the exposed fascia at the lumbar incision. The catheter is left externalized at this point. The enclosed luerlock connector with integral plug may now be inserted into the catheter and secured. Secure the catheter to the connector with a tight double suture tie using 0 silk (Fig. 22). The integral plug on the luerlock connector will prevent loss of CSF when closed.

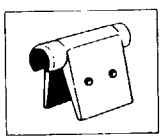

Fig. 20

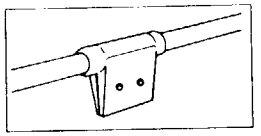

Fig. 21

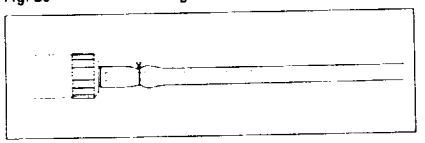

Fig. 22

Guide Wire and Adjustable Stop

A Teflon coated stainless steel guide wire with adjustable stop is provided with the EDM Lumbar Catheter, 80cm, Closed Tip, to increase the maneuverability of the silicone catheter.

To use the adjustable stop, loosen the luer cap. Partly withdraw the guide wire from the dispenser. Pass the flexible tip of the guide wire through the luer fitting of the adjustable stop, out the rounded end, and into the connector end of the lumbar catheter. Thread the guide wire through the connector end of the catheter so that the guide wire contacts the filled tip of the lumbar catheter. Slide the adjustable stop so that the rounded end is touching the connector end of the catheter. Tighten the cap to affix the adjustable stop to the guide wire. Discard the guide wire dispenser.

Connection of Catheter to Drainage and/or Monitoring System

Using the included luerlock connector, the EDM Lumbar Catheter may be directly attached to a PS Medical Becker EDMS or EDM Drainage Assembly.

NOTE: There is slight resistance to flow with use of the lumbar drainage catheter. The average resistance to flow at a constant flow rate of 23 ml/hour is 0.1cm H_2O per cm of catheter length. This resistance to flow may result in a reduction of system pressure as compared with actual in vivo pressure.

Accessory Products

Description

EDM Patient Connection Line Assembly
A nondistensible patient connection line assembly with stopcock, injection site and red end plug. This allows connection of a ventricular or lumbar drainage catheter directly to the drainage bag if complete system use with mounting panel is not desired (Fig. 23).

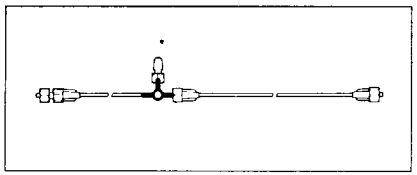

Fig. 23

Becker EDMS Drainage Bag
A vented 700ml drainage bag with approximate volumetric markings and anti-reflux valve for use when drainage of CSF is required. This bag is provided with the Becker EDMS, the EDM Drainage Assembly and the EDM Drainage Kits (Ventricular and Lumbar). The bag is also available separately as an individually packaged product. The drainage bag may be replaced if necessary, or may be emptied by removing the vented drain port cap (Fig. 24).

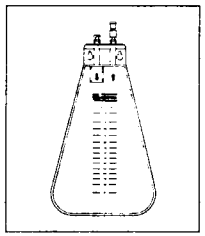

Fig. 24

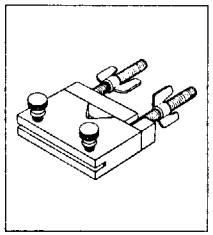

Fig. 25

The individually packaged drainage bag includes a braided cord. The bag may be mounted directly to the Becker EDMS panel as shown in Fig. 26. If complete system use with mounting panel is not desired, the drainage bag may be suspended with the cord and connected to the patient connection line or EDM Drainage Assembly.

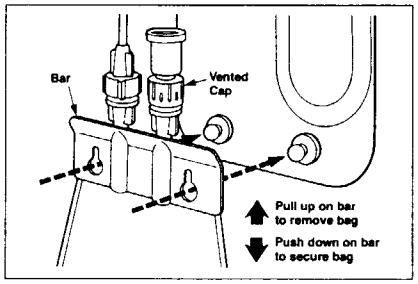

Fig. 26

EDM Drainage Bags (10-pack)
As an added convenience, EDM Drainage Bags are also available in a 10-pack box. Each drainage bag is individually sterile packaged and labeled, and includes a braided cord for suspension.

Becker EDMS Pole Clamp
The Becker EDMS Pole Clamp can be used to rigidly mount the Becker EDMS to an I.V. pole, if a rigid mounting is desired. The panel bracket incorporated into the Becker EDMS fits directly into the Becker EDMS Pole Clamp and most standard manifold clamps. The Becker EDMS Pole Clamp is reusable and is packaged non-sterile (Fig. 25).

Indications

The EDM patient connection line assembly is used to connect an EDM catheter to the balance of a drainage and/or monitoring system.

The Becker EDMS Drainage Bag is used to collect CSF drained from the lateral ventricles or lumbar subarachnoid space when connected to an EDM catheter via an EDM Patient Connection Line Assembly, an EDM Drainage Assembly or a Becker EDMS. The Becker EDMS Drainage Bag may also be used to approximate longer term CSF flow (the bag has approximate volumetric markings to 700ml). For convenience, individually packaged Becker EDMS Drainage Bags are available in a 10-pack box.

The Becker EDMS Pole Clamp may be used to rigidly mount a Becker EDMS to an I.V. pole, utilizing the bracket incorporated in the Becker EDMS mounting panel.

Instructions for Use

EDM Patient Connection Line Assembly
Under sterile conditions, remove the red end cap from the patient end of the assembly. Fill the assembly with sterile normal saline, and attach drainage end of assembly to the inlet connector of an EDM Drainage Bag (available separately).

NOTE: The drainage bag must not be placed lower than the patient as overdrainage of CSF may result. The height of the drainage bag helps to control the ICP when used separately.

The EDM Patient Connection Line Assembly is now ready to connect directly to the luerlock connector of a ventricular or lumbar EDM catheter. Ensure that all connections are tight and leak-free, and that the four-way stopcock is adjusted to allow drainage.

An injection site is provided on the four-way stopcock to sample CSF for laboratory analysis, inject intraventricular medication, flush a clogged drainage catheter or flush the assembly. A 25-gauge needle may be inserted through the injection site which has been cleaned and disinfected with alcohol. The four-way stopcock must be positioned to ensure proper communication between the injection site and the balance of the drainage and/or monitoring system.

CAUTION: ADJUST STOPCOCK TO ISOLATE PATIENT WHEN FLUSHING THE ASSEMBLY. INJURY TO THE PATIENT MAY OCCUR IF THE ASSEMBLY IS FLUSHED WITH AN OPEN PATH TO THE PATIENT. ENSURE STOPCOCK IS ADJUSTED TO RE-ESTABLISH DRAINAGE AFTER FLUSHING.

Becker EDMS Drainage Bag/EDM Drainage Bag (10-pack)
A Becker EDMS Drainage Bag is included with the Becker EDMS, the EDM Drainage Kits (Ventricular and Lumbar) and the EDM Drainage Assembly. EDM Drainage Bags (10-pack) are available separately for replacement, and for use with the EDM Patient Connection Line Assembly. **Replacement of the drainage bag is recommended, although it may be emptied and re-used at the physician's discretion.** Replacement and emptying of the drainage bag is outlined in the Instructions for Use sections for the Becker EDMS and the EDM Drainage Assembly.

NOTE: Isolate patient or balance of system from drainage line using sliding clamps or stopcocks when replacing or emptying the drainage bag. This will prevent retrograde flow of CSF from the drainage line. Ensure slide clamps or stopcocks are reset to establish flow into the drainage bag upon replacement or emptying. Failure to perform this will preclude drainage of CSF.

Becker EDMS Pole Clamp
The Becker EDMS Pole Clamp is designed to rigidly mount the Becker EDMS to an I.V. pole. To use the Becker EDMS Pole Clamp, loosen the wing-nuts, place clamp onto I.V. pole and tighten with fingers. Mount Becker EDMS to Pole Clamp by loosening thumbscrews and sliding system panel bracket into the slot. The thumbscrews may then be tightened to hold the Becker EDMS in place.

CAUTION: ENSURE THAT THE BECKER EDMS UNIT IS MOUNTED SO THAT THE MAIN SYSTEM STOPCOCK IS LEVEL WITH THE PATIENT'S FORAMEN OF MONRO OR AT THE LEVEL OF THE EXIT OF THE LUMBAR DRAINAGE CATHETER.

The system height may be changed by loosening the Pole Clamp wing-nuts and sliding the System/Pole Clamp up or down on the I.V. pole.

How Supplied

CSF-External Drainage and Monitoring Products
Component products for external drainage and monitoring are available separately, or as complete packaged systems. Products labeled **sterile** and **non-pyrogenic** are packaged in a single or double wrap package, and are intended for **single** (one time) **use only**. A complete drainage and monitoring set requires a drainage catheter (ventricular or lumbar), a patient connection line and a drainage bag.

Becker External Drainage and Monitoring System (EDMS)
The Becker EDMS is supplied **sterile** and **non-pyrogenic** in a single pouch and may be connected directly to a ventricular or lumbar drainage catheter (available separately). The system is preassembled. A drainage bag is included with the system. The Becker EDMS is intended for **single** (one time) **use only**.

EDM Drainage Assembly
The EDM Drainage Assembly is supplied **sterile** and **non-pyrogenic** in a double wrap package system. A drainage bag with braided cord is included with each EDM Drainage Assembly. The EDM Drainage Assembly is intended for **single** (one time) **use only**.

EDM Drainage Kits; Lumbar and Ventricular
The EDM Drainage Kits are complete drainage and monitoring systems, supplied **sterile** and **non-pyrogenic** in a double wrap package system. Drainage kits include an EDM Drainage Assembly, a drainage bag with braided cord, a drainage catheter (EDM Lumbar, 80cm, Closed Tip or Open Tip, or EDM Ventricular, 35cm) and accessories. The EDM Drainage Kits are intended for **single** (one time) **use only**. EDM Drainage Kits are available in five-pack cartons only.

EDM Ventricular and Lumbar Catheters
The EDM Ventricular and Lumbar Catheters are supplied as individual products, **sterile** and **non-pyrogenic** in double wrap packages. They are intended for **single** (one time) **use only**.

EDM Accessory Products Catheters
Accessory products available separately from PS Medical include the EDM Drainage Assembly, EDM Patient Connection Line Assembly, Becker EDMS Drainage Bag, EDM Drainage Bag (10-pack), and Becker EDMS Pole Clamp. All accessory products, except the Becker EDMS Pole Clamp, are supplied **sterile** and **non-pyrogenic** in a double wrap package system, and are intended for **single** (one time) **use only**. The Becker EDMS Pole Clamp is supplied **non-sterile** and is **reusable**.

Special Order Products
If this data sheet accompanies a **special order product** there will possibly be differences in the physical characteristics between the product enclosed and the product description in this data sheet. These differences will not affect the safety or efficacy of the special order product.

Special order products may be supplied **sterile** or **non-sterile** as indicated on the product package label. **Non-sterile products must be cleaned and sterilized prior to use.** The STERILIZATION procedure listed below may be used as a guide.

Materials

The silicone elastomer materials and polypropylene used in the fabrication of the EDM Ventricular and EDM Lumbar catheters have been shown to produce an acceptable level of tissue reaction by cell culture, hemolysis, USP extract tests, and intramuscular implant in rabbits. The tantalum powder and graphite materials used have been shown to be non-toxic by cell culture.

Sterilization

The PS Medical EDM products (other than the Becker EDMS Pole Clamp, as described above) are packaged **sterile** and **non-pyrogenic** and are intended for **single** (one time) **use only**.

Although PS Medical does not recommend resterilization of silicone products, the following guidelines are provided:

1. Only clean, unused products may be resterilized. After exposure to biological matter, cleaning is difficult and damage to the product may occur. However, if the product is removed from its package and sterility violated, or the package integrity compromised, steam sterilization of the catheter and the packaged components is possible.

CAUTION: DO NOT STERILIZE THESE PRODUCTS IN THEIR ORIGINAL PACKAGES.

However, the Becker EDMS, EDM Drainage Assembly, Becker EDMS Patient Connection Line, the Becker EDMS Drainage Bag and the adjustable stop (included with Guide Wire), are not to be autoclaved. Product damage will result.

2. In a clean environment and with gloved hands, remove the catheter and other components from their package. Remove the stainless steel stylet from the ventricular catheter and the luerlock adapter fitting. Remove the stylet from the Tuohy needle. Lint, glove talc, residue from direct skin contact, and other surface contaminants can cause an unacceptable level of tissue reaction if deposited on the silicone elastomer catheter surfaces. Avoid contacting the product with these contaminants.

3. The catheter and other components may be wrapped in effective packaging designed for steam sterilization.

4. Catheters should be pre-moistened (not fluid filled) just prior to packaging, then sterilized immediately. This is necessary so that steam can be generated from within.

5. Wrapped catheters and components should be steam autoclaved for 30 minutes at 250°F (121°C) and 15 psi.

NOTE: Although not recommended by PS Medical, ethylene oxide can be used to sterilize these products. If this method is chosen, it is recommended that the efficacy of the procedure be established with the user's own equipment by a method which includes sterilization of an intentionally contaminated product. Care must be taken to ensure that aeration is sufficient to allow adequate diffusion of ethylene oxide from the silicone elastomer material prior to implantation.

Contraindications

Intracranial pressure monitoring with a ventricular or lumbar catheter is contraindicated in patients receiving lumbar anticoagulants or who are known to have a bleeding diathesis. The ventricular catheter is contraindicated if scalp infection is present. The use of a ventricular or lumbar catheter is contraindicated where trained personnel are not available to supervise monitoring and drainage on a 24-hour-a-day-basis.

The use of a lumbar catheter for drainage and monitoring of cerebrospinal fluid is not recommended for patients with non-communicating hydrocephalus (1,2); where lumbar puncture is contraindicated; in the presence of large intracranial mass lesions, tumors, hematomas, or cysts (8); in the presence of infections in the surrounding area which includes the skin, subcutaneous tissue, bone, and the epidural space; and patients which have demonstrated blockage of cerebrospinal fluid to the subarachnoid space due to trauma, hematoma, fracture, or tumor. The use of a lumbar catheter under these conditions for external drainage and monitoring is at the discretion of the physician.

Monitoring pressure from the lumbar subarachnoid space can be done only in instances where lumbar puncture does not pose a danger to the patient (8).

Warnings

Patients undergoing intracranial pressure monitoring should be kept under close supervision in an intensive care unit staffed with trained personnel familiar with the use of intracranial and lumbar pressure monitoring techniques. Intracranial and lumbar pressure monitoring has been associated with intracranial infection, meningitis, and ventriculitis. This hazard has been quoted at less than 1% to more that 5%. The risk of infection is probably influenced both by the number of times a system is opened and by the duration of the monitoring. Prolonged steroid therapy can also increase the risk of infection. There is a less than 1% chance that the puncture of the ventricle or the opening of the dura will cause an intracranial hemorrhage. It is possible that if too much CSF is removed from the ventricles, either during a drainage procedure or when the ventricle is first punctured, the ventricle may collapse and occlude the catheter. It is possible that the monitoring system may give a false pressure reading either due to a pressure line becoming clogged or kinked or from an air bubble lodged in the system. An incorrect pressure reading may lead to the wrong therapy being given to the patient. The irrigation of the catheter or the performance of a VPR study may induce pressure waves in the patient. For this reason, irrigation or VPR studies should be done only by, or on the order of, a physician.

Precautions

Inform the patient or his representatives of possible complications associated with the use of the system.

In order to minimize the possibility of infection, meningitis, or ventriculitis, several steps should be observed. First, the injection sites should always be cleaned with alcohol and the alcohol allowed to dry before a needle is inserted into them. Second, sterile technique should be observed in setting up the system and in the placement of the catheter. Third, the ventricular catheter should be tunneled under approximately one to two inches of scalp. In order to ensure against ventricular collapse and the possible consequence of tentorial herniation, always perform a drainage maneuver against a positive pressure head on the order of 20cm H_2O or 15mm Hg. In addition, when the ventricle or lumbar subarachnoid space is first punctured during the insertion of the catheter, care should be taken so as little CSF as possible is lost.

The main system stopcock of the Becker EDMS must be correctly aligned with the patient for accurate pressure monitoring. The system mounting panel must be securely mounted. If the panel is allowed to drop, reduction in system pressure will result and overdrainage of CSF may occur.

A tight double suture tie with 0 silk suture should be used to secure the ventricular or lumbar catheter to the connection fitting. Check to ensure that the connection is tight prior to use.

All connections must be checked during set-up to ensure that fittings are tight and leak-free.

Whenever irrigation of the catheter or the performance of the VPR is decided upon, great care must be used so that pressure waves are not initiated. Only a small volume of saline should ever be injected into the ventricular system, and this only done by, or on the order of, a physician. In general, in monitoring intracranial pressure, one should always be aware of the wave form on the oscilloscope. If the wave form begins to dampen out, it is important that the entire monitoring system be examined. Ensure that the line to the patient is not kinked and that all air bubbles or blood or other debris are removed from the system. Check to ascertain that the transducer is on the same level as the patient's ventricular system in order to ensure that the proper reference level in the manometer tube for use in calibration procedures. Pressure monitoring with the manometer may result in over drainage of the ventricles. Always ensure that the stopcocks are in the proper position for the maneuver being carried out. The improper positioning of a stopcock can put a patient in potential danger.

Complications

The major complication associated with ICP monitoring with a ventricular or lumbar catheter is the risk of infection, particularly meningitis and ventriculitis. The incidence of these infections can be reduced by care in inserting the ventricular catheter and stabilizing it by passing it through a subgaleal tunnel before it emerges. The lumbar catheter should be stabilized by use of the fixation tab (See Surgical Techniques – Lumbar Catheter). Wound infections may occur but usually subside when the catheter is removed.

Limiting the duration of monitoring from a single site to less than five days will reduce the infection rate. If monitoring must continue past five days, consider inserting a new catheter at a fresh site and changing the entire system.

Frequent punctures of the brain to insert the ventricular catheter can predispose to intracerebral hemorrhage and edema causing a further rise in ICP.

Poor recording of ICP will result if the catheter, patient line or other components of the monitoring system become clogged with blood clots, brain tissue fragments or fibrinous debris.

In patients with small ventricles, the ventricular walls may collapse around the tip of the catheter resulting in obstruction and predisposing to tentorial herniation. It is therefore extremely important to avoid excessive release of CSF before the catheter is attached to the patient line.

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling.

Determination of a product defect or mislabeling will be made by Pudenz-Schulte Medical Corporation (PS Medical), which determination will be final.

Products will not be accepted for replacement or credit if they have been in possession of the customer for more than 90 days.

Warranty

PS Medical warrants that reasonable care was used in the choice of materials and the manufacture of these Products. This warranty shall extend for a period of one year from the date of delivery of the Products and shall in no event extend beyond such term.

The Purchaser shall notify PS Medical by registered or certified mail, return receipt requested, of any claim of defect attributable to failure to use reasonable care in the choice of materials and the manufacture of the Product within 90 days of the discovery of such defect. Failure to notify PS Medical within the time and manner specified herein shall constitute a waiver of any such claim of defect or breach of warranty. This warranty shall extend to Purchaser only, and shall not be assignable or transferable to any other person.

DISCLAIMER OF WARRANTIES: THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OTHER THAN THOSE WARRANTIES SET FORTH IN THE PARAGRAPH ENTITLED "WARRANTY" ABOVE.

Purchaser's Remedies. The Purchaser's sole and exclusive remedy for breach of the warranty contained herein shall be the repair or replacement of the Product by PS Medical, free of charge. Reasonable costs for freight, insurance and any applicable taxes pertaining to the repair or replacement parts, shall be borne by PS Medical. If, for any reason, PS Medical is unable or unwilling to repair or replace the Product, or because of circumstances the exclusive remedy provided herein fails of its essential purpose or operates to deprive either party of the substantial value of its bargain, then the Purchaser's exclusive remedy will be the return of the purchase price for the Product. The liability of PS Medical shall in no

event be greater than the full amount of the purchase price of the Product. Any attempt by PS Medical to repair or replace any Product sold hereunder shall not constitute an admission that the Product or any part thereof, is defective within the meaning of the above warranty, nor that PS Medical has any legal responsibility to make such repair or effect such replacement. Any such attempts, if unsuccessful, shall not create any liability on the part of PS Medical, and the Purchaser is limited to the remedies set forth herein.

Limitations on Liability. PS Medical shall not, under any circumstances, be liable for direct, incidental or consequential damages for any breach of contract, breach of warranty or tort, including the negligence of PS Medical, including, but not limited to, damages resulting directly or indirectly from the use, or loss of use, of the Product sold hereunder, or the practices of the Purchaser wherein the Product is utilized.

The warranties contained herein, and the obligations of PS Medical hereunder, are expressly in lieu of, and the Purchaser expressly waives, any other liability of PS Medical based upon warranty, express or implied, contract, or the negligence of PS Medical, including, but not limited to, any additional warranties concerning the safety or efficacy of this Product in any medical procedure, negligence in the design of the Product or in choice of the materials therefore, or negligence in the repair or replacement of the Product whether such repair or replacement is required by the terms hereof, or if voluntary, upon the part of PS Medical.

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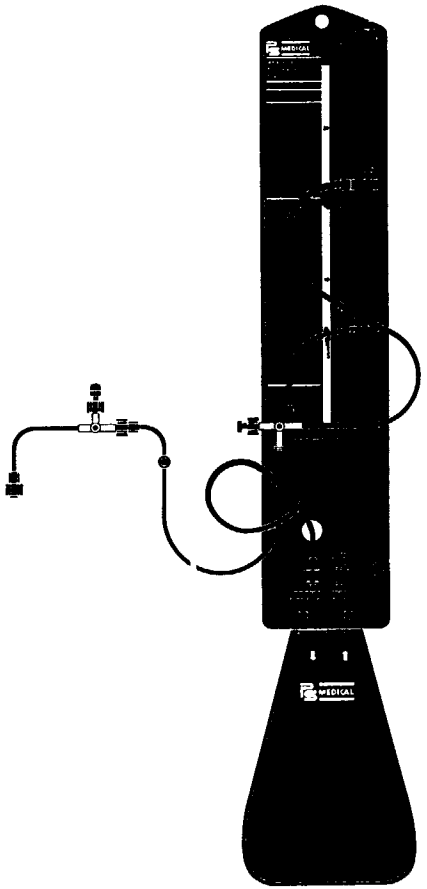
Dimensions (nominal):

Becker External Drainage and Monitoring System

Included with product:

- Patient Line Stopcock with Injection Site and Non-Distensible Patient Connection Line with Injection Site
- Mounting Bracket
- Optional Self-adjusting Cord with Lock
- Main System Stopcock with Optional Transducer Location
- Sliding Graduated Flow Chamber with Locking Bracket
- Flow Chamber Slide Clamp
- Drainage Bag Connection Line
- 700ml Drainage Bag with Microbial Filter and Drainage Port

Cat. No. 46121



6y

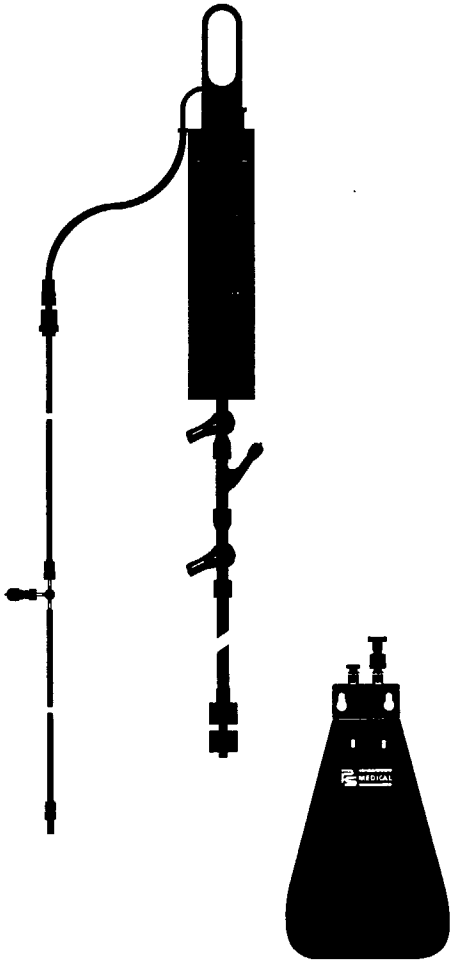
Dimensions (nominal):

EDM Drainage Assembly with 120ml Graduated Chamber

Included with product:

- Patient Line Stopcock with Injection Site and Non-Distensible Patient Connection Line with one-way Check Valve
- Hanging Bracket
- Graduated Flow Chamber
- Pressure Scale Tape
- 700ml Drainage Bag with Braided Cord, Drainage Port and Microbial Filter
- Drainage Bag Connection Line with 2 Slide Clamps and Injection Site

Cat. No. 46422



Dimensions (nominal):

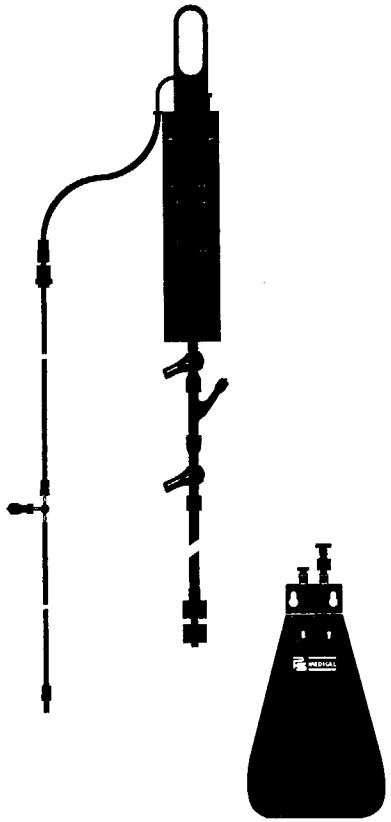
EDM Ventricular Drainage Kit with 120ml Graduated Chamber

Included with product:

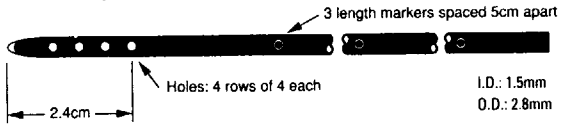
- EDM Drainage Assembly with 120ml Graduated Chamber and 700ml Drainage Bag (Cat. No. 46422)
- EDM Ventricular Catheter, 35cm, Barium Impregnated with Trocar, 15cm (Cat. No. 46118)
- Luerlock Connector
- Red End Plug
- Fixation Collar
- Stainless Steel Stylet, 39cm

Cat. No. 46141

Available in 5-Pack Cartons Only



EDM Ventricular Catheter, 35cm, Barium Impregnated with Trocar, 15cm



Dimensions (nominal):

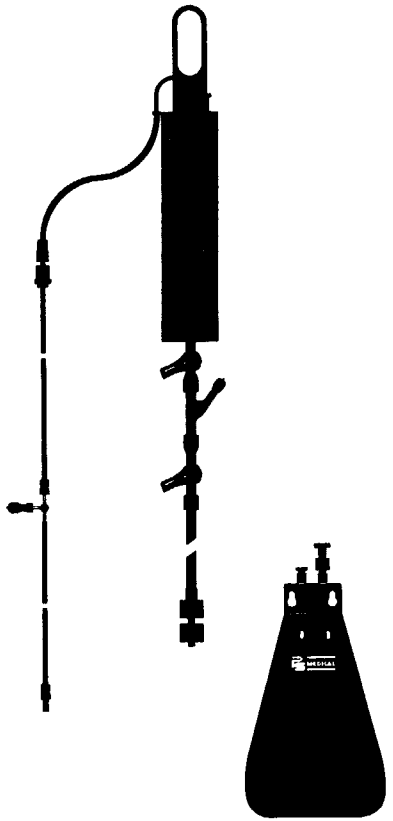
EDM Lumbar Drainage Kit with 120ml Graduated Chamber

Included with product:

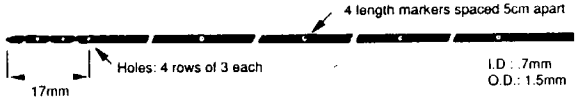
- EDM Drainage Assembly with 120ml Graduated Chamber and 700ml Drainage Bag (Cat. No. 46422)
- Lumbar Catheter, 80cm, Barium Impregnated, Closed Tip (Cat. No. 46419)
- Tuohy Needle, 14-gauge with Huber Tip
- Guide Wire with Adjustable Stop
- Fixation Tab (2 each)
- Luerlock Connector with Integral Plug
- Blunt Needle, 20-gauge

Cat. No. 46440

Available in 5-Pack Cartons Only



Lumbar Catheter, 80cm, Barium Impregnated, Closed Tip



Dimensions (nominal):

EDM Lumbar Drainage Kit

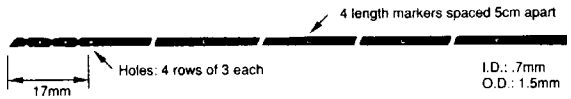
Included with product:

- EDM Lumbar Catheter, 80cm, Barium Impregnated, Open Tip (Cat. No. 46420)
- EDM Patient Connection Line Assembly (Cat. No. 46126)
- Becker EDMS Drainage Bag, 700ml (Cat. No. 46124)
- Tuohy Needle, 14-gauge with Huber Tip
- Fixation Tab (2 each)
- Luerlock Connector with Integral Plug
- Blunt Needle, 20-gauge

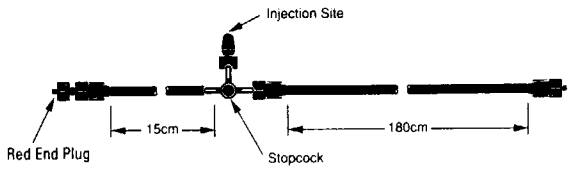
Cat. No. 46441

Available in 5-Pack Cartons Only

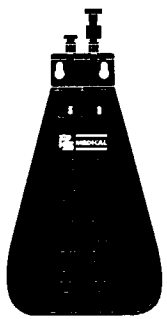
EDM Lumbar Catheter, 80cm, Barium Impregnated, Open Tip



EDM Patient Connection Line Assembly



Becker EDMS Drainage Bag, 700ml



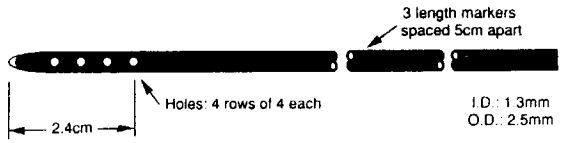
Dimensions (nominal):

Becker EDMS Ventricular Catheter, 20cm, Barium Impregnated

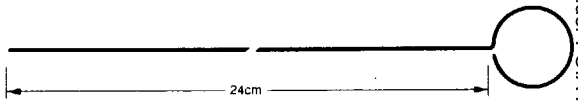
Included with product:

- Stainless Steel Stylet, 24cm
- Luerlock Connector with Integral Plug

Cat. No. 46115



Stainless Steel Stylet, 24cm



Luerlock Connector with Integral Plug

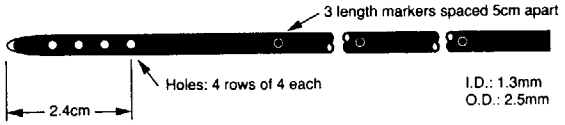
Dimensions (nominal):

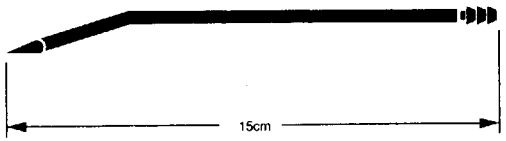
EDM Ventricular Catheter, 35cm, Barium Impregnated, with Trocar

Included with product:

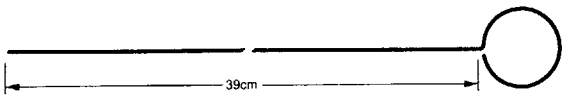
- Stainless Steel Stylet, 39cm
- Luerlock Connector
- Red End Plug
- Fixation Collar

Cat. No. 46118





Stainless Steel Stylet, 39cm



Luerlock Connector, Red End Plug, Fixation Collar

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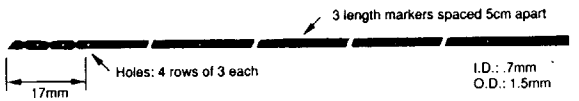
Dimensions (nominal):

EDM Lumbar Catheter, 24cm, with Open Tip, Barium Impregnated

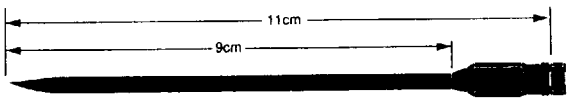
Included with product:

- Tuohy Needle, 14-gauge, with Huber Tip
- FixationTab
- Luerlock Connector with Integral Plug

Cat. No. 46418



Tuohy Needle, 14-gauge, with Huber Tip



Fixation Tab, Luerlock Connector with Integral Plug

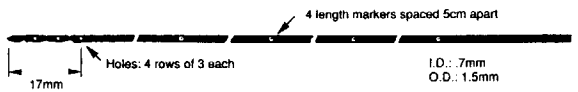
Dimensions (nominal):

EDM Lumbar Catheter, 80cm, with Closed Tip, Barium Impregnated

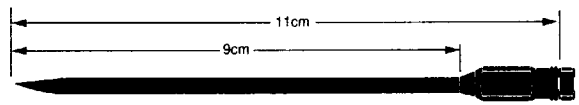
Included with product:

- Tuohy Needle, 14-gauge, with Huber Tip
- Guide Wire with Adjustable Stop
- Blunt Needle, 20-gauge
- Fixation Tab (2 each)
- Luerlock Connector with Integral Plug

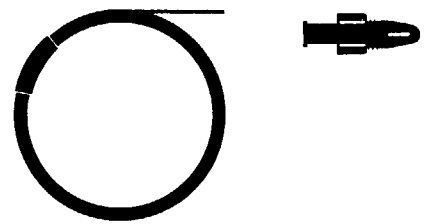
Cat. No. 46419



Tuohy Needle, 14-gauge, with Huber Tip



Guide Wire with Adjustable Stop



Fixation Tab, Luerlock Connector with Integral Plug, Blunt Needle

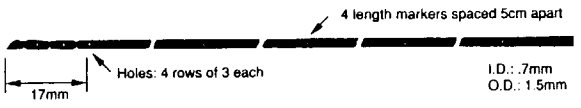
Dimensions (nominal):

EDM Lumbar Catheter, 80cm, with Open Tip, Barium Impregnated

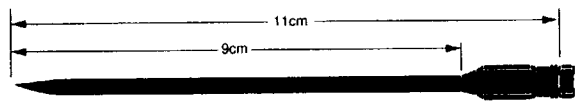
Included with product:

- Tuohy Needle, 14-gauge, with Huber Tip
- Blunt Needle, 20-gauge
- Fixation Tab (2 each)
- Luerlock Connector with Integral Plug

Cat. No. 46420



Tuohy Needle, 14-gauge, with Huber Tip



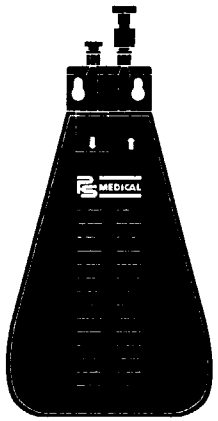
Fixation Tab, Luerlock Connector, Blunt Needle

Dimensions (nominal):

Becker EDMS Drainage Bag, 700ml

Included with product:
- Braided Cord

Cat. No. 46124

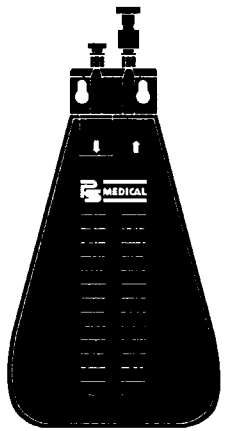


EDM Drainage Bag, 700ml

Included with product:
- Braided Cord

Cat. No. 46430

Available in 10-pack



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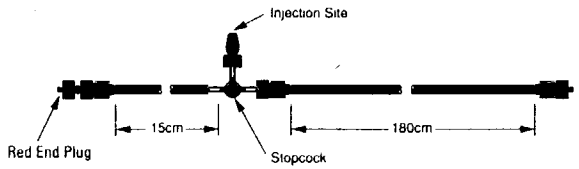
Dimensions (nominal):

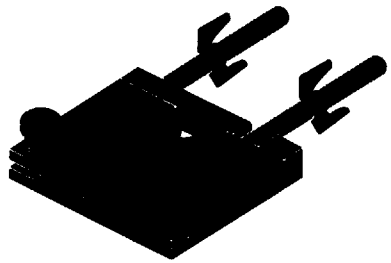
EDM Patient Connection Line Assembly

Cat. No. 46126



Becker EDMS Pole Clamp

Cat. No. 46131



CLINICAL NEURO SYSTEMS, INC

CLINICAL NEURO SYSTEMS, Inc.

309 Commerce Drive

Exton, PA 19341

(800) 220-7879

CAUTION: FEDERAL (USA) LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICAN

Technical information on these products may be obtained from the CNS distributor in your area or by contacting CNS directly.

10118-2 (Rev. 3)
7/97

CLINICAL NEURO SYSTEMS, INC

MoniTorr ICP™

Ventricular Catheters

The MoniTorr ICP™ Ventricular Catheter is available in a Large or Standard configuration and is fabricated from kink-resistant silicone elastomer tubing with a barium-sulfate impregnated stripe. The translucent tubing allows assessment of patency and fluid flow. The smooth bullet shaped barium-impregnated tip of the catheter is molded integral with the tubing. Numbered length markers are located at 5, 7.5, 10, and 15 cm from the tip. The CNS logo is printed on each catheter for ease of identification.

A stainless steel stylet is packaged with each catheter to facilitate insertion of the catheter into the lateral ventricle. The Large catheter also includes a trocar needle to allow tunneling of the catheter under the scalp. Each catheter also includes a luerlock connector with red end cap to facilitate connection to an external drainage system and a silicone fixation tab to allow anchoring of the catheter to the scalp.

Figure 1

FEATURES

1. Fabricated from translucent silicone elastomer tubing with a barium-sulfate impregnated stripe.
2. Kink and compression resistant tubing.
3. Stainless steel stylet.
4. Luerlock connector and red luerlock male/female end cap.
5. Numbered length markers.
6. Silicone fixation tab.
7. Stainless steel trocar (with Large catheter).
8. Large bore tubing and enlarged inlet holes to promote drainage (with Large catheter).
9. Smooth barium-impregnated tip integrally molded to catheter.

DESCRIPTION

The MoniTorr ICP™ Ventricular Catheter is illustrated in Figure 2. The Large catheter is 1.5 mm ID by 3.0 mm OD and is 35 cm long. The Standard catheter is 1.3 mm ID by 2.5 mm OD and is 20 cm long. There are 4 rows of 4 each holes. The tip of the catheter is bullet shaped and is integrally molded onto the tubing. Black numbered length markers are located at 5, 7.5, 10, and 15 cm from the tip.

The stainless steel stylet and trocar allow for ease of insertion and placement.

The plastic luerlock connector and red male/female luerlock end cap allow connection of the catheter to an external drainage system.

A silicone fixation tab may be wrapped around the catheter and may be anchored in place with a suture.

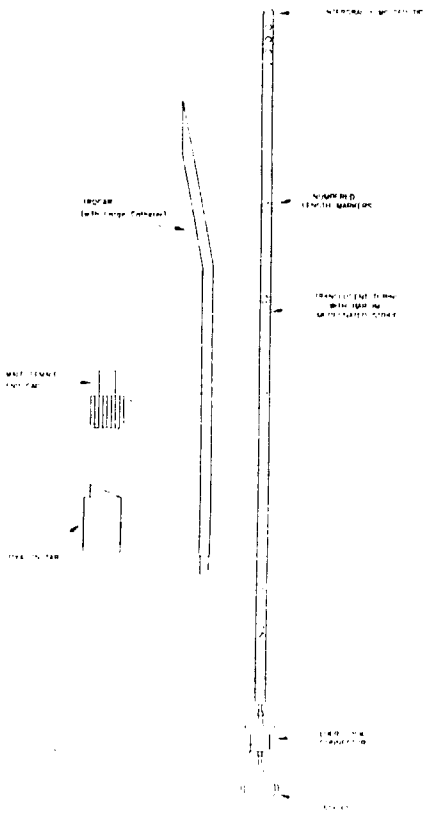


Figure 2

SPECIAL ORDER PRODUCTS

If this product is a Special Order product as requested by a physician, there may be differences between the enclosed product and the product description in this brochure. These differences will not affect the safety or efficacy of the special order product.

INDICATIONS

The MoniTorr ICP™ Ventricular Catheter is designed to be used as the proximal component for external CSF drainage and monitoring from the lateral ventricles of the brain.

CONTRAINDICATIONS

This product is not designed, sold or intended for use except as indicated.

External CSF drainage and monitoring system use is contraindicated where trained personnel are not available to supervise drainage and monitoring on a 24-hour-a-day basis.

ICP monitoring is contraindicated for patients receiving lumbar anticoagulants or are known to have bleeding diathesis.

Catheter placement is contraindicated in the presence of infections in the surrounding area including the scalp, skin, subcutaneous tissue, bone, and epidural space.

INSTRUCTIONS FOR USE

A variety of surgical techniques may be used in placing the catheter into the lateral ventricle. The site and placement is at the discretion of the surgeon.

This product includes a stainless steel stylet to facilitate insertion into the lateral ventricle of the brain. The stylet is packaged inserted into the catheter.

The Large catheter includes a stainless steel trocar to allow tunneling of the catheter under the scalp. The trocar may be connected to the catheter by inserting into the open end of the catheter. After desired placement, the distal end of the catheter may be cut to detach the trocar.

PREPARATION

The external CSF drainage and monitoring system should be prepared under sterile conditions prior to the placement of the ventricular catheter. Ensure that all system components are securely attached.

The system should be filled with sterile normal saline prior to connecting to the patient. Check to ensure that all connections are secure and leak-free. Check to ensure the absence of any residual air bubbles that may affect pressure transducer monitoring.

ALIGN SYSTEM

The system must be properly aligned relative to the patient for accurate drainage and monitoring.

SYSTEM CALIBRATION

Initial system calibration should be completed prior to connecting to the patient.

Instructions for transducer calibration should be followed from the transducer manufacturer.

CONNECTION OF CATHETER TO EXTERNAL CSF DRAINAGE SYSTEM

The catheter is packaged with a luerlock connector that may be inserted into the open end of the catheter. The catheter may be secured to the connector with a tight double suture of 1-0 silk. The connector provides a secure luerlock fitting to the external CSF drainage and monitoring system.

The product also includes a red male/female luerlock end cap. This allows the catheter luer connector to be temporarily capped prior to connection to the external CSF drainage and monitoring system.

ANCHORING CATHETER

A silicone fixation tab is included to anchor the catheter if desired. The fixation tab may be spread open and positioned at the desired location along the catheter. The tab may then be closed around the catheter. To anchor the tab in place, a suture may be passed through both wings of the tab and sutured to the scalp.

HOW SUPPLIED

The MoniTorr ICP™ Ventricular Catheter is supplied **sterile** and **non-pyrogenic** in a double wrap package. The catheter is intended for **single use only.**

The MoniTorr ICP™ Ventricular Catheter, Large is also available as a kit packaged with the MoniTorr ICP™ External CSF Drainage and Monitoring System. The catheter and system are supplied **sterile** and **non-pyrogenic** in separate double wrap packages.

Special Order products may be supplied **sterile** or **non-sterile** as indicated on the product package.

RESTERILIZATION

Clinical Neuro Systems does not recommend resterilization of these products.

WARNINGS

Patients undergoing external CSF drainage and ICP monitoring must be kept under close supervision with trained personnel familiar with the use of monitoring techniques. All personnel should be familiar with the information provided in this booklet.

Correct alignment of the system relative to the patient is critical for proper performance. Refer to the external CSF drainage system Instructions for Use for correct alignment procedure.

Pressure Level changes should only be made by qualified personnel on the orders of a physician.

PRECAUTIONS

Inform the patient or their representatives of possible complications associated with use of external CSF drainage and monitoring.

Sterile technique should be observed in preparing the system, connection of the catheter, replacement of the drain bag, and accessing the system.

Care should be taken that as little CSF is lost as possible during insertion of the catheter prior to connection to the system.

After desired placement of the catheter via the stainless steel trocar, the trocar should be cut from the distal end of the catheter and not pulled from the catheter. Pulling the trocar from the catheter may damage the distal end of the catheter resulting in CSF leakage after connecting to a drainage system.

All luer connections must be checked during the set-up of the system and prior to connecting to the patient. Ensure that all connections are secure and leak-free.

If pressure monitoring includes the use of transducers, all personnel should be familiar with the instructions from the manufacturer for proper calibration and performance.

COMPLICATIONS

The major complication associated with use of external CSF drainage and ICP monitoring is the risk of infection including meningitis and ventriculitis.

Excessive release of CSF prior to connection to the system may result in collapse of the ventricular walls and predisposing tentorial herniation.

Functional failure of the system resulting in a disconnection of the fluid path from the patient may result in serious complications including infection and overdrainage of CSF. Any failure of the system requires immediate replacement of the system or the affected component.

Improper use of the system including the failure to properly orient stopcocks may result in serious complications including infection, overdrainage of CSF, or increased ICP.

PRODUCT INFORMATION DISCLOSURE

Clinical Neuro Systems, Inc. has exercised reasonable care in the selection of materials and the manufacture of these products. **Clinical Neuro Systems, Inc.** excludes all warranties, whether express or implied, including but not limited to, any implied warranties of merchantability or fitness. **Clinical Neuro Systems, Inc.** shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of these products. **Clinical Neuro Systems, Inc.** neither assumes nor authorizes any person to assume for it, any other or additional liability or responsibility in connection with these products.

RETURNED GOODS POLICY

Products must be returned in unopened packages, with manufacturer's seals in tact to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling.

Determination of a product defect or mislabeling will be made by **Clinical Neuro Systems, Inc.** which determination will be final.

Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

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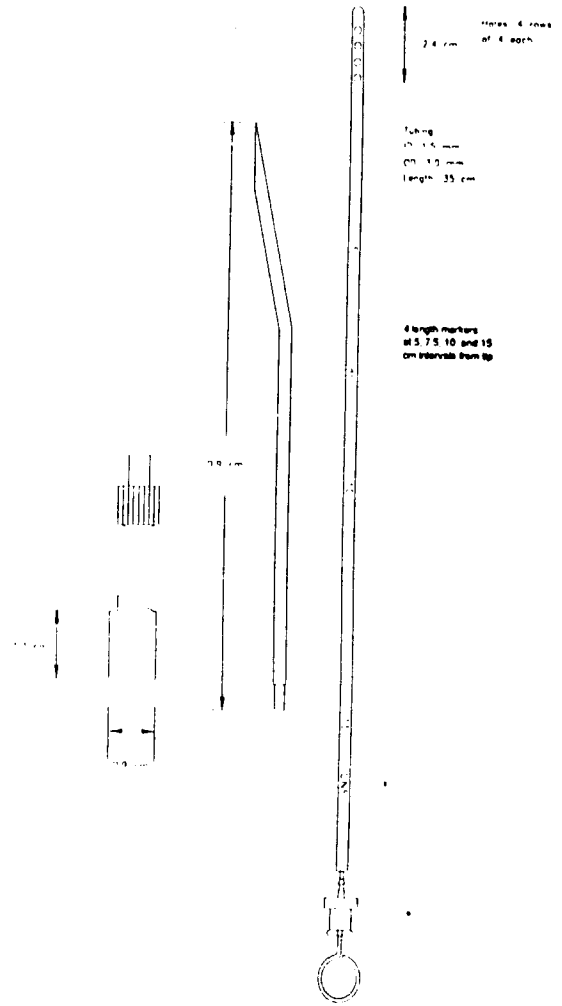
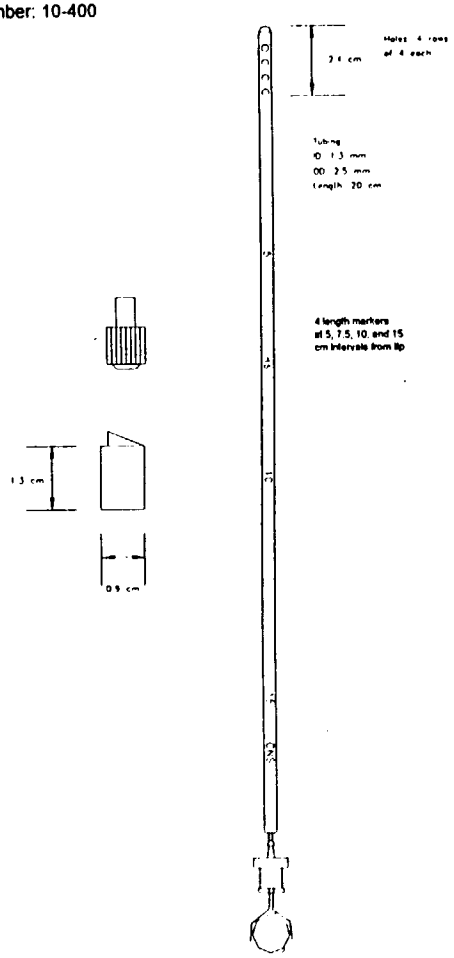
CATALOG PRODUCT OFFERINGS

MoniTorr ICP
Ventricular Catheter, Large
Catalog Number: 10-450



CATALOG PRODUCT OFFERINGS

MoniTorr ICP™
Ventricular Catheter, Standard
Catalog Number: 10-400



ALSO AVAILABLE AS A KIT:

MoniTorr ICP™
External CSF Drainage and Monitoring Kit
with Ventricular Catheter, Large
Catalog Numbe: 10-111

Includes:

- MoniTorr ICP™ Ventricular Catheter, Large (10-450)
- MoniTorr ICP™ External CSF Drainage and Monitoring System (10-110)

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Attachment V: Test Results Summary

Leak Test:

(b)(4)

[redacted]

Structural Integrity Test:

(b)(4)

[redacted]

Attachment VI: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER:	Radionics Inc, 76 Cambridge Street Burlington, MA 01803 Tel.: (781) 272-1233 Fax: (781) 272-2428 Contact: Kevin J. O'Connell Regulatory Engineer
PROPRIETARY NAME:	Radionics XDC Ventricular Catheter
COMMON OR USUAL NAME:	External Drainage Ventricular Catheter
CLASSIFICATION CODE:	Shunt, Central Nervous System and Components 21 CFR, Section: 882.5550
PREDICATE DEVICE:	Clinical Neuro System's MoniTorr ICP™ Ventricular Catheter, K922941 Medtronic Becker EDM Ventricular Catheters, 510(k) unk
DESCRIPTION:	The External Drainage Ventricular Catheter consists of a barium impregnated silicone tubing with flow holes at the distal end and a luer lock connector for attachment to an external drainage system. It is provided sterile for single use only.
INTENDED USE:	As the proximal component for CSF drainage or monitoring from the lateral ventricles of the brain.