Records processed under FOIA Request 2014-7433; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 1999

Mr. Tetsuharu Hirose
Manager, Corporate Quality Assurance &
Regulatory Affairs
JMS CO., LTD.
12-17 Kako-machi, Naka-ku
Hiroshima 730-8652 JAPAN

Re: K990470
JMS A.V. Fistula Needle Set
Dated: May 28, 1999
Received: June 8,1999
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FIE

Dear Mr. Hirose:

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

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

INDICATION FOR USE

510(K) Number : K990470

Device Name : Needle, Fistula

Indication for Use : Use for temporary cannulation for vascular access for extracorporeal blood treatment. This device is intended to single use only and is for temporary catheterization less than 30 days.

Regarding to pre-attached Anti-stick device, use for prevention of needlestick injury at the time of needle withdrawal after usage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over- The -Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990470/S001

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AUG 30 1999

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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.

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Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
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Center for Devices and
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Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

INDICATION FOR USE

510(K) Number : K990470

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Regarding to pre-attached Anti-stick device, use for prevention of needlestick injury at the time of needle withdrawal after usage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over- The -Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990470/S001

2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandu

From: Reviewer(s) - Name(s) Bn. Cool

Subject: 510(k) Number K990470/ S1

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Accepted for review 2/24/99.
- ☑ 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 N/A

☑ 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: 78 FIE 876.5820 Class II

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

Review: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 8/26/99 (Date)

Final Review: (Division Director) (Date)

Revised:6/2//98

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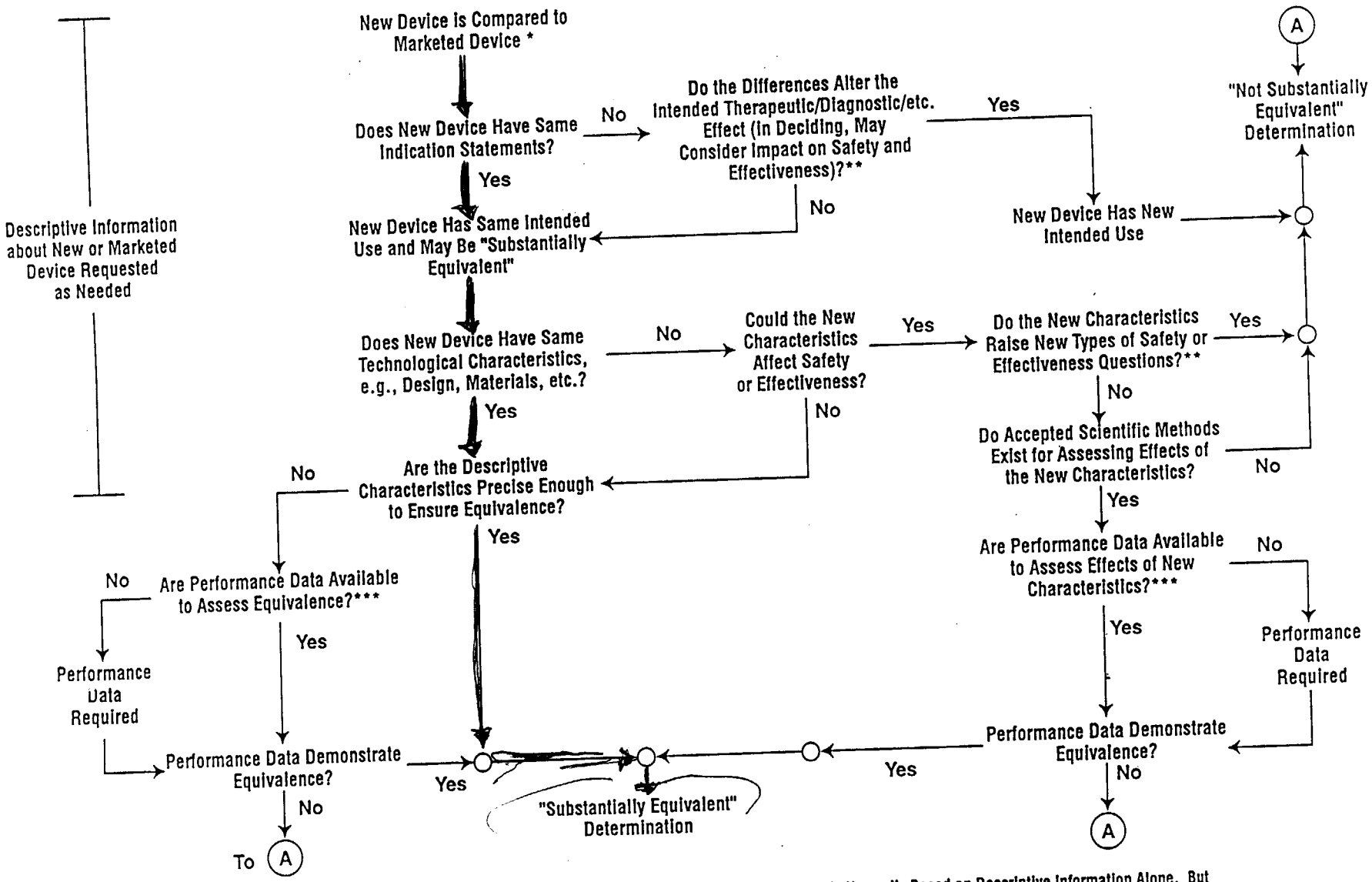
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

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



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be Obtained from 510(k)s, Other 510(k)s, The Center's Classification Files, or the Literature.

Questions? Contact FDA/CDRH/OCE/DID at DIS@cdrh.fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

K990470 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Reviewer: Barbara McCool, RN, MS Division/Branch: DRAERD/GRDB, HFZ-470

Trade Name: JMS CO., LTD.
510(k) Number: K990470/S1

Common Name: AV Fistula Single Needle Set and Anti-stick Device Guard

Classification: 21 CFR §876.5820 Class II, ProCode 78 FIE

Date: August 3, 1999

Product To Which Compared:
K970962 (AV Fistula Needle) & K~~990470~~ (Anti-stick Device)
K991404 cyd 8/26/99

Contact: Mr. Tetsuharu Hirose

Phone: (9-011)-81-82-234-5806

	YES	NO*	
1. IS PRODUCT A DEVICE?	X		IF NO STOP
2. DEVICE SUBJECT TO 51O(k)?	X		IF NO STOP
3. SAME INDICATION STATEMENT?	X		IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			IF YES STOP → NSE
5. SAME TECHNOLOGICAL CHARACTERISTICS	X		IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X		IF YES STOP → SE IF NO GO TO 10
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			IF YES STOP → NSE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			IF NO STOP → NSE
10. PERFORMANCE DATA AVAILABLE?			IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?			

* **"yes"** responses to 4, 6, 8, and 11, and every "**no**" response requires an explanation below

S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

This device is used to insert the needle into blood vessel, connect the bloodline, and consist a extracorporeal circuit. This device is used for hemodialysis, hemofiltration and hemodiafiltration. And there are applications in other treatments, requiring an extracorporeal circuit or blood to be drawn from a patient's circulation as in plasmapheresis, hemoperfusion, cell separation or hemopurification. Fistula needle is intended for one time use only.

2. DEVICE DESCRIPTION:

The Single Needle Set has 2 tubes in one product which are connected to one needle by the Y connector for a arterial side and venous side. The tubes have red and blue clamps respectively. All needles have oval back eye (slit) for better blood flow. The wing type has a rotating head . The Anti-stick Device can not be used with JMS AVF Single Needle Set due to its configuration. The firm has 5 variations of fistula needles which range in needle size, lengths, with or without eyes and either fixed wings or rotating wings. All of these designs can use the Anti-stick accessory. The Rotating Hub type is designed so that the needle bevel can be rotated or repositioned to permit optimum blood flow.

Life-supporting or life sustaining	NO
Implant (short or long term):	NO
Software driven:	NO
Sterile:	YES
Patient Contacting Device:	YES
Single Use:	YES
Home Use:	NO
Prescription Use:	YES
Drug or Biological Product:	NO
Kit	NO

Recommendation:

I recommend that since the firm has supplied the cleared (510k K991404 by DDIGD) as the additional information necessary to include the anti-stick device to their proposed needle device, be found substantially equivalent to other legally marketed devices as described in 21 CFR §876. Class II, ProCode 78.

* Supplement 1 was submitted to provide a revised Indications for Use Statement which includes the use of the anti-stick device. The original document was placed on telephone hold until the Anti-needle stick device which was to be included in this 510(k), was cleared for marketing under another 510(k) i.e. K991404. The K991404 was cleared SE on 5/17/99. This 510(k) was now complete and ready for review. 8/30/99

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

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

June 09, 1999

JMS CO., LTD.
12-17, KAKO-MACHI, NAKA-KU
HIROSHIMA,
JAPAN
ATTN: TETSUHARU HIROSE

510(k) Number: K990470
Product: JMS A. V. FISTULA NEEDLE SET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

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

Sincerely yours,

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

JMS CO.,LTD.

12-17 KAKO-MACHI, NAKA-KU
HIROSHIMA 730 JAPAN
PHONE: 81-(0)82-243-5806
FAX: 81-(0)82-243-5955

May 28, 1999

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

Re : Additional Information for K990470 and K990510

Attention : Document Mail Clerk

We have been advised by Ms. Barbara McCool, Lead Reviewer, Division of reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices that we need to re-submit new Indication for Use for both K990470 and K990510 including information of Anti-stick Device.

We have prepared the new Indication for Use for both K990470 and K990510 as attached and submit to you as additional information.

If you have any comment or questions, please feel free to contact me.

Thank you very much and Best Regards,

JMS Co., Ltd.

Keisuke Uratomi

Keisuke Uratomi
Assistant Manager,
Corporate Quality Assurance &
Regulatory Affairs
KU/mk

FDA/CDRH/OCE/OMC
JUN 8 2 24 PM '99

8

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

K990470

FDA/CDRH/OCE/DMC
JAN 8 2 25 PM '99

INDICATION FOR USE

510(K) Number : 990470

Device Name : Needle, Fistula

Indication for Use : Use for temporary cannulation for vascular access for extracorporeal blood treatment. This device is intended to single use only and is for temporary catheterization less than 30 days.

Regarding to pre-attached Anti-stick device, use for prevention of needlestick injury at the time of needle withdrawal after usage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over- The -Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

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

May 18, 1999

JMS CO., LTD.
12-17, KAKO-MACHI, NAKA-KU
HIROSHIMA,
JAPAN
ATTN: TETSUHARU HIROSE

510(k) Number: K990470
Product: JMS A. V. FISTULA NEEDLE SET

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

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

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

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

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
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10

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Records processed under FOIA Request 2014-7433; Released 10/23/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

.n: Reviewer(s) - Name(s) B M C Gal

Subject: 510(k) Number K990470

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

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept). Telephone Hold 5/14/99
- ☐ Accepted for review 2/23/99.
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)?	☐ YES	☐ NO

This 510(k) contains:

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

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

☐ The required certification and summary for class III devices

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

Material of Biological Origin ☐ YES ☐ NO

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

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

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

.eview: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 5/14/99 (Date)

Final Review: (Division Director) 8/27/99 (Date)

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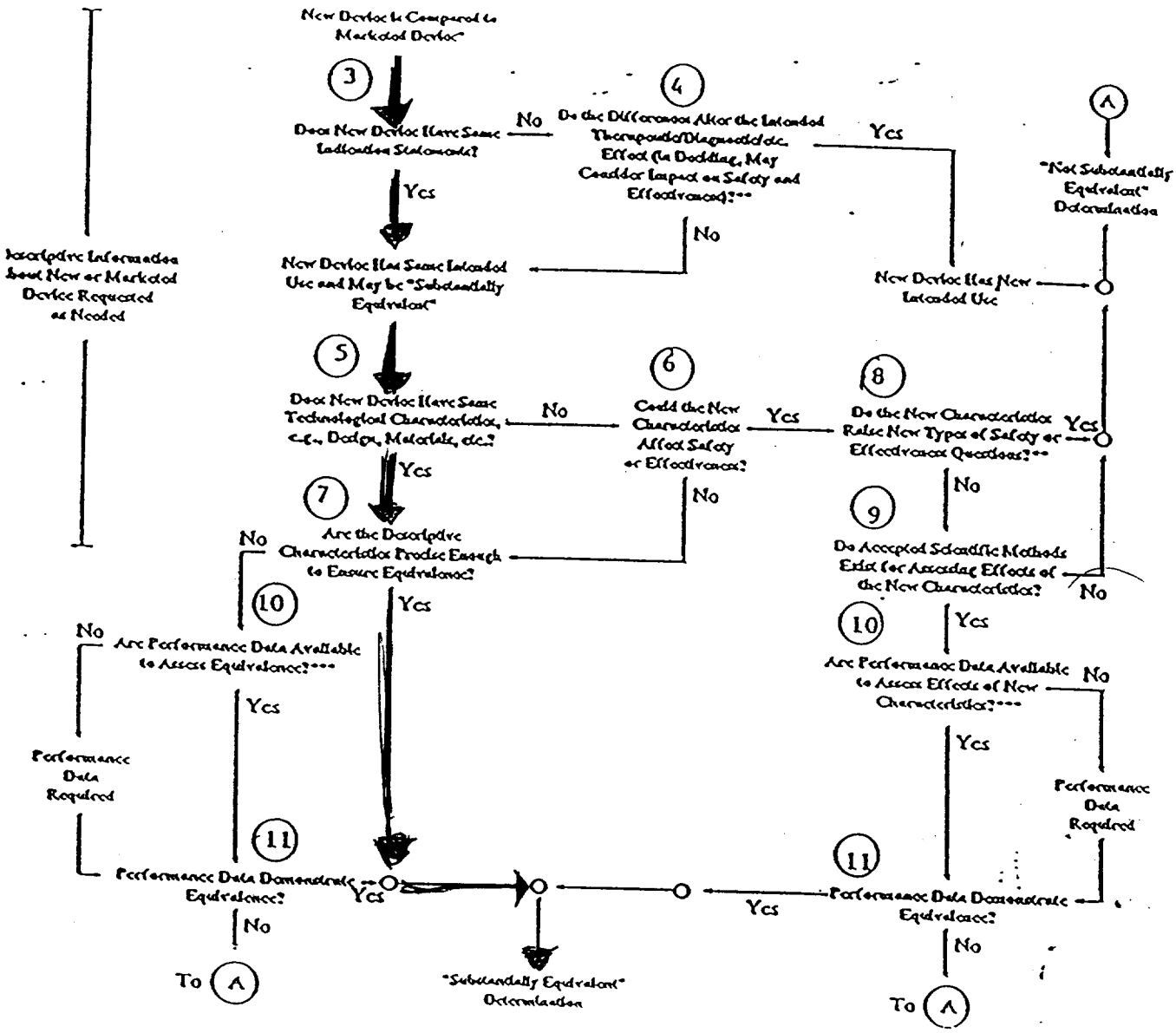
Revised:6/2//98

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

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



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

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

MEMORANDUM

From: Barbara McCool, RN, MS
DREARD/GRDB (HFZ-470) Nurse Consultant

Date: May 7,1999

Subject: AV Fistula Single Needle Set and Anti-stick device guard (Platypus)
K990470 JMS CO., LTD.

To: **RECORD**

BACKGROUND:

On February 16, 1999 JMS CO. LTD., submitted a notification to market a series of JMS A.V. Fistula needle Sets which is a predicate device holding 510(k) No. K970962. They now want to add a supplement A.V. "Single Needle Set" and add a Anti-stick Device to their other cleared A.V. fistula needles. The Substantial Equivalence for the single needle is the Althin A.V. single needle set which are manufactured for OEM (Original Equipment Manufacturing/Manufacturer) by Japan Medical Supply PTE. LTD., which is one of the manufacturing sites of the JMS AVF. Therefore, in comparing with this product and JMS AVF, their function, performance, parts, construction and materials are the identical and the intended uses are the same .

Description of JMS AVF Single Needle Set:

The Single Needle Set has 2 tubes in their AVF which are connected to one needle by the Y connector for a arterial side and venous side. The tubes have red and blue clamps respectively. All needles have oval back eye (slit) for better blood flow. The wing type has a rotating head.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Intended Use:

This device is used to insert the needle into blood vessel, connect the bloodline, and consist a extracorporeal circuit. This device is used for hemodialysis, hemofiltration and hemodiafiltration. Fistula needles are intended for one time use only.

Substantial Equivalence Comparison:

The Althin AV Fistula Needle Set is identical in function, performance, parts and construction. Their intended uses are also same and the predicate Single Needle Set have all the identical materials, specifications . They both have a Y-connector attached to one needle.

Device Description of the Platypus Anti-stick Device:

The Platypus plastic device contains an arrow on it's distal end which points toward the needle (it was designed to ensure the Platypus device would be oriented correctly for safety). The Platypus's design includes that it is to be clipped over the tubing (to ensure that the two tabs on the upper surface lock into the holders). This locking process produces an audible click. Once the needle is withdrawn a secondary lock is activated by squeezing the upper and lower surfaces of the Platypus together in the middle which then results in another audible click. The Platypus is labeled for single use only

At the end of a dialysis treatment (following removal of the needle) the whole assembly is to be disposed into an appropriate biohazard container. The Platypus is labeled for single use only. The device provides immediate shielding of needle upon withdrawal from vein or fistula. Because the needle shielding is always engaged from behind the needle assembly and features a secondary lock for added safety, it enables the safe withdrawal of needles at any angle. The "tongue-like" design encapsulates the needle, isolates any blood drops from the staff and prevents needle sticks.

Substantial Equivalence:

Was claimed by the firm to be K982126.

Intended Use:

The Anti-stick device is a needle guard designed for use with AV Fistula and apheresis needles to facilitate a fast and safe needle withdrawal, reduce risk of needle stick injury and reduce potential exposure to blood.

Note*: The Anti-stick Device can not be used with JMS AVF Single Needle Set due to its configuration. The firm has included 5 variations of fistula needles which range in needle size, lengths (ranging from 14G-18G and needle lengths of 20mm, 25, and 32 mm). They are

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available with or without eyes and have either fixed wings or rotating wings. Diagrams for all the AVF needles have been provided. (These needles were previously cleared - see K970962)

History:

The original K982126 for the Platypus device was received in our branch on 1/11/99 from DDIGD because it contained a claim that the device was to be used to aid in the prevention of needle-stick injuries for apheresis and hemodialysis fistula needles. The subject device was in fact only the protector and the apheresis/dialysis needle claim was removed. The firms' plan was that the device would be manufactured and marketed alone. We however were asked to do a consulting review of the instructions for use and device labeling.

Following our consulting review, where I suggested that they modify their labeling, DDIGD did request that a section of the labeling be revised to reflect the standard of care for withdrawal of needles associated with high-pressure vessels. The firm provided two separate instructions for the safe needle withdrawal (one for butterfly type needles and another for larger needles). Generally, a dialysis patient is only directed to apply pressure to a puncture site after the clinician has established that the patient is able to handle the venipuncture site safely. The firm did modify the instructions and cautions for removing these large (G15 , G16, G17 AV Fistula needles). Unbeknownst to us however, DDIGD found the Anti-stick device NSE shortly after our consulting review.

Meanwhile, two separate notifications were submitted to DREARD for two separate uses. This submission was for a modification to one of their fistula needles as noted above and a modification to add a accessory Anti-stick Device. On 4/23/99 a new submission was received for a Protector (AVFNP) device to be used for both apheresis and hemodialysis. Dr. Neuland rerouted it to General Hospital (and that's when we discovered that the predicate that was identified in this submission, were in fact not cleared). After several meetings with DDIGD and our upper management, we decided that we would place this submission on HOLD until the Platypus is cleared by DDIGD. We plan to call the firm to inform them (at this time) they have not identified a true predicate for their AVFNP.

Labeling:

Extensive labeling for all of their AVF needles and the new Single Needle AVF device has been provided and is adequate. Complete diagrams and Instruction For Use for the Anti-stick Device have also been provided.

The Performance Data for their AVF needles is complete and since there has been no changes to their previous cleared (K970962) AV Fistula needles, listing of these tests can be found in Attachment K in this submission and include package appearance, seal condition, color/shape, needle: cover, luer lock, needle retention, penetration, outer surface, point, inside and outside surface, OD dimension, and tube retention and air tightness.

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Sterilization Information:

(b)(4) sterilization

[redacted]

Residues and non Pyrogenicity information is complete.

RECCOMENDATION:

Place this submission on telephone HOLD until the Platypus is cleared by General Hospital. Their review should be complete within the next two weeks. (See Attached Fax)

This concludes my review of the single Fistula Needle Set and a preliminary review of JMS's Anti-stick needle device for hemodialysis.

BM C Cool

Barbara McCool, RN, MS

5/14/99

Date:

C. Newland
5/14/99

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****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1731
CONNECTION TEL	901181822435948
SUBADDRESS	
CONNECTION ID	
ST. TIME	05/14 17:46
USAGE T	00'29
PGS. SENT	1
RESULT	OK

Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
HFZ-470

DHHS/PHS/FDA/CDRH/ODE

9200 Corporate Blvd.
Rockville, MD 20850

Phone No.: (301) 594- 1220
FAX No.: (301) 594-2339

TO: Mr. Tetsuharu Hirose
JMS Co., LTD.

From: Barbara McCool, Lead Reviewer
(301) 594-1220

Comments: Ref: 510(k) K990470 and K990510

Your submissions will be placed on telephone hold on May 14, 1999, since your Anti-stick device (Platypus) has not been cleared K982126.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118.

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Division of Reproductive, Abdominal,
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Phone No.: (301) 594- 1220
FAX No.: (301) 594-2339

TO: Mr. Tetsuharu Hirose
JMS Co., LTD.

From: Barbara McCool, Lead Reviewer
(301) 594-1220

Comments: Ref: 510(k) K990470 and K990510

Your submissions will be placed on telephone hold on May 14, 1999, since your Anti-stick device (Platypus) has not been cleared K982126.

You can either contact the manufacturer for its status, or identify another predicate device to establish substantial equivalence.

Number of Pages: 1
(Including cover sheet)

Please advise if transmission is illegible.

"This document is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone and return it to us at the above address by mail. Thank you."

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Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: A.V. Fistula Needle Set | K990470

Submitter (Company): JMS Co., LTD.

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

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS YES	SPECIALS NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		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)*					N/A		
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					N/A		

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	

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USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted							

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

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

Passed Screening ✓ **Yes** ____ **No**
Date: 2/24/99

Reviewer: BMc Cool
Concurrence by Review Branch: C. Neuland

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

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

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use:

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

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

1. Explain why not a device:

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

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

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

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

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

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K990470

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		X
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?	X X	X
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)?		X
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.		X

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

February 16, 1999

JMS CO., LTD.
12-17, KAKO-MACHI, NAKA-KU
HIROSHIMA,
JAPAN
ATTN: TETSUHARU HIROSE

510(k) Number: K990470
Received: 16-FEB-1999
Product: JMS A. V. FISTULA NEEDLE SET

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K990470

JMS CO.,LTD.

12-17 KAKO-MACHI, NAKA-KU
HIROSHIMA 730 JAPAN
PHONE: 81-(0)82-243-5806
FAX: 81-(0)82-243-~~5955~~ 5948

12 February, 1999

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

FDA/CDRH/CDE/DMC
FEB 16 11 20 AM '99
RECEIVED

Re : 510(k) Notification

Attention : Document Mail Clerk

JMS CO., LTD. hereby submits notification that it intends to manufacture and market a series of JMS A.V. Fistula Needle Set.

JMS has marketed this product into USA under name of JMS A.V. Fistula Needle Set (thereinafter referred as "JMS AVF") which is predicated device holding 510(k), No. K970962. We make this time premarket notification 510(k) in order to supplement new type of JMS AVF specification whose product name is "Single Needle Set", and also an accessory which to be used with JMS AVF in order to prevent unintended sharps injury after using JMS AVF.
The accessory name is "Anti-stick Device". This "Anti-stick Device" is to be used after usage of AVF, when the needle is withdrawn, slide it up to the direction of the needle tip and fix it on Wings, and cover the needle.

This notification was prepared being added the new information on Single Needle Set and Anti-stick Device to the previous notification document, No. K970962. This submission document contains the information of not only the supplemental product/part but also that of No. K970962.

The following information is presented for your review in accordance with Section 510(k) of the Food, Drug and Cosmetic Act and 21 CFR 807. 87.

Applicant's name, Manufacturer name and street address, Tel. and Fax number :

Mr. Tetsuharu Hirose
JMS CO., LTD.
12-17, Kako-machi
Naka-ku, Hiroshima, 730-8652, Japan
9-011 – Tel. : +81-82-243-5806
Fax. : +81-82-243-5948

Signature of the applicant

Tetsuharu Hirose
Manager,
Corporate Quality Assurance &
Regulatory Affairs

SK 26

26 GU II

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Also, we have JMS AVF with/without "Anti-stick Device" on its tube.

3.2 Description of JMS AVF Single Needle Set

Single Needle Set has 2 tubes in one product which are connected to one needle by the Y-connector and these two tubes are used respectively for artery side and vein side. For the easy distinguish, those tubes have red and blue clumps respectively. Because of this configuration, only one insertion to the patient makes it possible to compose an extracorporeal circuit and there is no need to insert the needle twice. All needles have oval back eye (slit) for better blood flow. For wing type, we have only one type, RH type, for Single Needle Set. The Anti-stick Device will not go with JMS AVF Single Needle Set due to its configuration.

3.3 Description of Anti-stick Device

The "Anti-stick Device", Platypus™ is supplied from ITL Corp. and is submitting separate 510(K) No. K982126. This device is an effective needle guard designed for use on AV Fistula needle sets to facilitate a fast and safe needle withdrawal, reduce risk of needlestick injury and reduce potential exposure to blood drops. This device is pre-attached type and all Anti-stick Device is attached to JMS AVF previously.
For the further information, please refer to Attachment A "Information of pre-attached type Anti-stick Device".

4. Labeling

(a) Labeling
Each manufacturing site has its original individual package and middle box.

(JMS Singapore)
JMS Singapore roughly has two types of the individual packages and Inner boxes. One is labeled in 7 different languages and the other is labeled in English only. The individual package and Inner box which is labeled in only English is divided into four different types depending on the difference of sterilization method (Either "gamma irradiation" or "ethylene-oxide ") and manufacturing site identification (One contains the address of both JMS CO., LTD and JMS Singapore and the other contains only the address of JMS Singapore).

Also, JMS Singapore has two types of Middle carton and the difference is the manufacturing site identification (One contains the address of both JMS CO., LTD and JMS Singapore and the other contains only the address of JMS Singapore).

(JMS Miyoshi Plant)
JMS Miyoshi Plant has only one type of individual package and Inner box, which is labeled in 7 different languages.

(1) The label copy of individual package of the predicated device : **Attachment F**
(2) Draft label copies of individual packages (two types from JMS Singapore and one type from JMS Miyoshi Plant : **Attachment G**
(3) Draft label copies of Inner boxes and Middle carton(two types of Inner boxes and one type of Middle carton from JMS Singapore and one type from JMS Miyoshi Plant): **Attachment H**

(b)Instruction For Use : **Attachment I**
(c) Promotional Material : **Attachment J**
(d) Packaging Insert : None

5 Performance Data : Attachment K

6 Sterilization Information

We have (b)(4) sterilization [redacted]
(a) Sterilization Information : **Attachment L**
(b) Bioburden Monitoring : **Attachment M**
(c) Routine control of Pyrogen: **Attachment N**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Name and Address of the Manufacturing and Sterilization site
(Objective device will be manufactured and sterilized at two sites):

1) JMS CO., LTD.
12-17, Kako-machi, Naka-Ku, Hiroshima 730, Japan
Tel. : +81-82-243-5806
Fax. : +81-82-243-5948

(b)(4) [redacted]

1 General Information

(a) Classification Name / Number : Needle, Fistula / 78 FIE
(b) Trade Name : JMS A.V. Fistula Needle Set
(c) Common Name : Various types of sterile fistula needle
(d) Establishment Registration Number : 8031563
(e) Classification : Class II
(f) Performance Standard : None established under Section 514 of the FD & C Act
(g) Statement of Intended use ;
This device is used to insert the needle into blood vessel, connect the bloodline, and consist a extracorporeal circuit. This device is used for hemodialysis, hemofiltration and hemodiafiltration. And there are applications in other treatments, requiring an extracorporeal circuit or blood to be drawn from a patient's circulation as in plasmapheresis, hemoperfusion, cell separation or hemopurification.
Fistula needle is intended for one time use only.

2 Substantial Equivalence Comparison

The Althin A.V. Fistula Needle Set whose label is presented in Attachment F are manufactured for OEM by Japan Medical Supply (S) PTE. LTD., where is one of the manufacturing sites of the JMS AVF. Therefore, in comparing with this products and JMS AVF, their function, performance, parts and construction are same and the intended uses are also same, such the using for hemodialysis, hemofiltration and hemodiafiltration. However, the Althin A.V. Fistula Needle Set has only one type of wing, fixed, while the JMS AVF has two types of wing, fixed and rotating.

For Single Needle Set, all materials, specifications and intended use are identical to JMS AVF. The only difference is the configuration, which has Y-connector and 2 tubes are connected to one needle with the connector. The materials of Y-connectors are also identical to legally marketed device. For the details of materials, please refer to Attachment B, List of material.

3 Description of Device

(a) Variation Type and Diagram(1)(2), Information of Anti-stick Device: Attachment A
(b) List of Material: Attachment B
(c) Biocompatibility : Attachment C
(d) Expiry Date : Attachment D
(e) Product Specification : Attachment E

3.1 Description of JMS AVF

We have two types of wings on JMS AVF series. One type is ordinary one (Fixed Type) The other type is Rotating Hub type (RH Type) whose needle bevel can be rotated or repositioning and optimum flow.

For the types of needles, we also have two types. One type is standard needle that is basically used for vein side. The other type is one with oval back eye (slit) that is basically used for artery side.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7 Safe Medical Device Act of 1990

(a) Statement of Indication for Use : Attachment O

(b) 510(k) Statement : Attachment P

(b) Truthful and Accurate Statement : Attachment Q

8 Additional Information

Packaging Information

An individual package of JMS AVF contains either one set or two sets. In containing two sets, one is standard needle type and the other is slit needle type.

9 Reference Standard

Japan MHW standard, No. 494 for AVF (Dialyzer type artificial kidney apparatus approval standard, announcement No. 494, the Pharmaceutical Affairs Director, the Ministry of Health and Welfare, June 20, 1983) is exhibited in Attachment R

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Attachment A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Variation Type

1. Wing Color

Gage	14	15	16	17	18
Color	White	Blue	Green	Orange	Pink

2. Tube Dimension

ϕ3.0 x ϕ5.0mm x 80mm ± 15mm ~ ϕ3.0 x ϕ5.0mm x 400mm ± 15mm

3. Needle Dimension and Variation

Needle Size		Oval Back Eye	Tube Length	Clamp	Anti-stick Device
Gage Size	Needle Length				
14G (2.10mm)	x 4/5" (20mm)	With or Without	80mm± 15mm ~ 400mm± 15mm	With or Without	With or Without (For Single Needle Set, "Without")
	x 1" (25mm)				
	x 1 1/4" (32mm)				
15G (1.83mm)	x 4/5" (20mm)				
	x 1" (25mm)				
	x 1 1/4 (32mm)				
16G (1.65mm)	x 4/5" (20mm)				
	x 1" (25mm)				
	x 1 1/4" (32mm)				
17G (1.47mm)	x 4/5" (20mm)				
	x 1" (25mm)				
	x 1 1/4" (32mm)				
18G (1.24mm)	x 4/5" (20mm)				
	x 1" (25mm)				
	x 1 1/4" (32mm)				

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) diagram & specifications

(b)(4) diagram & specifications

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Information of pre-attached type Anti-stick Device

Description of the device
The "Anti-stick Device", Platypus™ is supplied from (b)(4) contractors which is submitting separate 510(K) No. K982126. This device is an effective needle guard designed for use on AV Fistula needle sets to facilitate a fast and safe needle withdrawal, reduce risk of needlestick injury and reduce potential exposure to blood drops and so on. Following is a part of this device's features :

- Immediate shielding of needle on withdrawal from vein or fistula
- The needle shielding is always engaged from behind the needle assembly
- Features a secondary lock for added safety
- Enables safe withdrawal of needles at any angle
- The "tongue-like" design encapsulates the needle and contains blood drops

Procedure for use of Anti-stick Device

(1)Assembly and venipuncture

This Anti-stick Device is previously attached to JMS AVF and the venipuncture can be performed as normal. Before use, ensure that the arrow is pointing towards the needle.

(2)Withdrawal of needle

- It is very important that this device must be held stationary while the needle is withdrawn into it.
- Slide this device froward and engage the wings.

(2-1)Needle withdrawal - unassisted haemostasis

- Place folded sterile gauze over puncture site and hold gauze in place without exerting pressure.
- Hold sides of the front grip point between the index finger and thumb.
- Pull the tubing smoothly into this device until needle is locked in position.
- Apply pressure on gauze as normal, to achieve haemostasis.

Confirm needle lock by :

- Listening for a "click" as the needle is fully retracted into this device.
- Ensuring the tubing cannot be pulled any further into this device.

(2-2)Needle withdrawal - assisted haemostasis

- Place folded sterile gauze over puncture site and ask patient/donor to hold gauze in place without exerting pressure.
- Hold the back (logo end) of this device between thumb and index finger of one hand and pull the tubing and needle assembly into the shielded position with the other hand.
- Instruct the donor/patient to apply pressure on gauze to establish haemostasis.

(3)Lock and disposal

- Activate the lock by squeezing both the sub-members together at the middle of this device. (confirmed by an audible "click").
- "Do not attempt to override or defeat the locking safety mechanism".
- "Single Use Only".
- Dispose of the whole assembly into and appropriate biohazard container.

Attached 3 pages are "Certificate on Pharmaceutical use" and "Safety Data Sheet" of the material of this device provided by the manufacturer.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) materials manufacturer

[redacted]

CERTIFICATE ON PHARMACEUTICAL USE

We certify that this product fulfils the requirements of the European Pharmacopoeia, Third Edition (19969, monograph 3.2.2. "Plastic containers and closures".

The product has passed the Class VI tests of the US Pharmacopeia XXI, and has the US FDA Drug Master File Nr: (b)(4) [redacted]

(b)(4) materials manufacturer

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) material data sheet

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PHARMACEUTICAL REGULATION

HD810P passes successfully the USP XXII tests including class VI. USP tests include:

- Toxicological test
- Cytotoxicological test

(b)(4) materials' manufacturer [redacted]

PHYSICAL PROPERTIES

	Typical Value	Unit	Test Method
Melt Flow Rate MFR (230°C/2.16kg)	(b)(4) testing [redacted]		
Density			
Tensile modulus (1mm/min)			
Stress at yield (50mm/min)			
Strain at yield (50mm/min)			
Rockwell hardness			
Heat Deflection Temp. (0.45 N/mm²)			
Charpy impact (notched +23°C)			

Values determined on injection moulded specimens acc. to ISO/DIS 1873-2 (94).

STORAGE AND HANDLING

HD810P should be stored in dry conditions at temperatures below 60°C and protected from UV light.

Improper storage can initiate degradation which results in odour generation and colour changes.

SAFETY

HD810P is not classified as dangerous preparation.

Dust and fines from the product may give a risk for dust explosion. All equipment should be properly earthed.

Inhalation of dust may irritate the respiratory system and should be avoided.

During processing of the product small amounts of fumes are generated, which require proper ventilation.

RECYCLING

The product is suitable for recycling using modern methods of shredding and cleaning. In-house production waste should be kept clean to facilitate direct recycling.

A Material Safety Data Sheet is available on request. Please contact your (b)(4) material representative for more details on various aspects of safety, recovery and disposal of the product.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment B

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

List of Material

1. Component

No.	COMPONENT	Material	Grade Name	Supplier Name	PREDICATE DEVICE and / or 510(k) NUMBER
①	Needle Cover	PP	(b)(4) materials specifications [redacted]	(b)(4) suppliers [redacted]	JMS Needles and JMS Syringes 510(k) K871965
					JMS AV FISTULA NEEDLES 510(k) K970962
		PE			JMS AV FISTULA NEEDLES 510(k) K970962
②	Needle	Stainless Steel			JMS AV FISTULA NEEDLES 510(k) K970962
③	Hub	PVC			JMS AV FISTULA NEEDLES 510(k) K970962
		PC			
④	Wing	PE (for RH Type)			JMS AV FISTULA NEEDLES 510(k) K970962
		PVC (for Fixed Type)			JMS AV FISTULA NEEDLES 510(k) K970962
⑤	Tube	PVC			JMS AV FISTULA NEEDLES 510(k) K970962
⑥	Clamp	PP			JMS AV FISTULA NEEDLES 510(k) K970962
⑦	Connector	PC			JMS AV FISTULA NEEDLES 510(k) K970962
⑧	Connector Cover	PP			JMS AV FISTULA NEEDLES 510(k) K970962
		PE			JMS DIALYZER PRIMING SET 510(k) K895882
⑨	Y-connector	PVC(for RH Type)			JMS VENTED I.V. SET 510(K) K960527
⑩	Anti-stick Device	PP			510(K) K982126

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. Colorant

No.	Component	Color	Grade Name	Supplier Name	PREDICATE DEVICE and / or 510(k) NUMBER
1	Wing (Material : PE)	White	(b)(4) materials specifications [redacted]	(b)(4) suppliers [redacted]	Not Applicable ; Not direct contact with human blood or fluid.
		Blue			
		Green			
		Orange			
		Pink			
	Wing (Material : PVC)	White			JMS AV FISTULA NEEDLES 510(k) K970692
		Blue			JMS AV FISTULA NEEDLES 510(k) K970692
					JMS AV FISTULA NEEDLES 510(k) K970692
		Green			JMS AV FISTULA NEEDLES 510(k) K970692
					JMS AV FISTULA NEEDLES 510(k) K970692
		Orange			JMS AV FISTULA NEEDLES 510(k) K970692
					JMS AV FISTULA NEEDLES 510(k) K970692
		Pink			JMS AV FISTULA NEEDLES 510(k) K970692
2	Clamp	White			Not Applicable ; Not direct contact with human blood or fluid.
		Blue			
		Red			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

3. Silicone

Grade Name	Supplier
(b)(4) materials	(b)(4) suppliers

4.Adhesive

No.	Affixed Components		Adhesive	Supplier Name	Predicate Device and / or 510(k) Number
1	Needle	Hub	Tetrahydrofuran	(b)(4) suppliers	JMS AV FISTULA NEEDLES 510(k) K970692
			Epoxy (b)(4) materials		JMS AV FISTULA NEEDLES 510(k) K970692
2	Hub	Tube	Cyclohexanone		JMS AV FISTULA NEEDLES 510(k) K970692
3	Tube	Connector	VC – 1※		JMS AV FISTULA NEEDLES 510(k) K970692
			VC – 5※		
			VCK - 1※		
4	Tube	Y-connector (PVC)	VC – 5※		JMS AV FISTULA NEEDLES 510(k) K970692

※Identification of the Adhesives by Chemical Composition

Unit (w/w%)

Chemical Composition	VC-1	VC-5	VCK-1
Methylethylketone	(b)(4) chemical composition	(b)(4) chemical composition	(b)(4) chemical composition
Cyclohexanone			
Dioctylphthalate			
Polyvinyl Chloride			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Biocompatibility

Used materials are identical to the legally marketed devices.
Please see the Corresponding Table below.

No.	COMPONENT	Material	PREDICATE DEVICE and / or 510(k) NUMBER
①	Needle Cover	PP	Not applicable※
		PE	
②	Needle	Stainless Steel	JMS AV FISTULA NEEDLES 510(k) K970962
③	Hub	PVC	JMS AV FISTULA NEEDLES 510(k) K970962
		PC	
④	Wing	PE (for RH Type)	Not applicable※
		PVC (for Fixed Type)	JMS AV FISTULA NEEDLES 510(k) K970962
⑤	Tube	PVC	JMS AV FISTULA NEEDLES 510(k) K970962
⑥	Clamp	PP	Not applicable※
⑦	Connector	PC	JMS AV FISTULA NEEDLES 510(k) K970962
⑧	Connector Cover	PP	Not applicable※
		PE	
⑨	Y-connector	PVC(for RH Type)	JMS VENTED I.V. SET 510(K) K960527
⑩	Anti-stick Device	PP	Not applicable※

※) Not applicable : Not direct contact with human blood or fluid.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Attachment D

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

IDENTIFICATION OF THE EXPIRATION DATE FOR AVF

1. Summary

In order to indicate 5-year expiration is indicated ; therefore, using the preserve sample which was produced 5 years ago, the following test was conducted for two kinds of AVF because the sterilization method was different. (One was sterilized with (b)(4) sterilization [redacted] (b)(4) sterilization [redacted] Following is the results of the test.

2. Test Samples

(b)(4) sterilization [redacted]

3. Conclusion

All samples aged more than 5 years complied with product specification. According to these result, 5-year expiration will be indicated.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) specifications testing

(b)(4) specifications testing

Records processed under FOIA Request 2014-7433; Released 10/23/14

Attachment E

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) specifications

(b)(4) specifications

(b)(4) specifications

(b)(4) specifications

(b)(4) specifications

Records processed under FOIA Request 2014-7433; Released 10/23/14

Attachment F

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Althin

The Althin Group

Seraflo® A.V. Fistula Catheter Set

Peel Down

A.V. Fistula Catheter Set	1. Sterile, Non-pyrogenic Unit	Ultrathin wall, siliconized
Set d'Aiguilles à Fistule A.V.	1. Unité Stérile, Apyrogène	Paroi extra mince, siliconée
Punktionskanüle für A.V. Fistel	1. Sterile Einheit, Pyrogenfrei	Extra dünnwandig, silikonisiert
Ago Set Fistola Arteno-Venosa	1. Pezzo Sterile, Apirogeno	A parete ultrasottile siliconata
Equipo de Fistula Arterio-Venosa	1. Unidad Estéril, No Pirógenica	De pared ultrafina, siliconizada

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

Manufactured for:
Althin Medical, Inc.
14620 NW 60th Avenue
Miami Lakes, Florida 33014 U.S.A.

Althin Medical B. V.
Postbus 970
NL-3160 AD Rhoon, The Netherlands

® Registered Trademark of Althin Medical, Inc.

Made in Singapore

2506-1

Sterility note: Fluid pathway and area under protective caps are sterile and pyrogen free unless package is opened or damaged. An aseptic technique is required.
Caution: For one time use only.

Stérilité: Le parcours du liquide et la surface sous les capuchons protecteurs sont stériles et apyrogènes, sauf si l'emballage est ouvert ou endommagé. Des procédés aseptiques sont nécessaires.
Attention: A usage unique.

Sterilität: Schlauchsystem und Teile unter Schutzkappen sind steril und pyrogenfrei, wenn die Verpackung nicht geöffnet oder beschädigt ist. Aseptische Techniken sind erforderlich.
Achtung: Nur einmal verwenden.

Note sulla sterilità: La superficie interna delle linee e l'aree sotto i tappi protettivi sono sterili ed esenti da pirogeni a meno che la confezione non sia aperta o danneggiata. Deve essere adottato un metodo asettico.
Attenzione: Da usare solo una volta.

Nota sobre la Esterilidad: La trayectoria del líquido y la superficie inferior de las tapas han sido esterilizadas y están libres de pirógenos, a no ser que el envase se encuentre abierto o dañado. Se requiere una técnica asépica.
Precaución: Para usarse solo una vez.

CAT.NO.

GAUGE

TUBE LENGTH

DESCRIPTION

LOT NO.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment G

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Individual Package (1)
(JMS Singapore)

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TYPE:

SIZE

A.V. FISTULA NEEDLE SET

Single use only. Do not reuse. Sterilized by ethylene-oxide. Non-pyrogenic. **CAUTION :** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Do not use if package is damaged or cap is missing or not in place. Do not store in direct sunlight, at extreme temperatures, or in high humidity.

STERILE EO

Manufactured by / Fabriqué par / Hergestellt durch / Κατασκευάζεται από:
JAPAN MEDICAL SUPPLY (S) PTE. LTD.
440 Ang Mo Kio Industrial Park 1
Singapore 569620

SET D'AIGUILLES POUR FISTULES ARTERIO-VEINEUSES

SET DE AGUHAS DE FÍSTULA ARTERIO-VENOSA

EN SATS AV-FISTELNÅLAR

REF

LOT

MFG. DATE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

(individual Package(2)
(JMS Singapore)

FOR SINGLE USE ②

A.V. FISTULA NEEDLE SET

STERILE

JMS

Sterilized by
Non pyrogenic
Super thin wall and siliconized needle
Do not use if package is opened or damaged.
Do not store in direct sunlight, at extreme temperature, or in high humidity. Keep in a dry place.

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

TYPE
SIZE
LOT NO.
CODE NO.

Either 1. Or 2. will be labelled

1. JMS CO. LTD.
12-17 Kako-Machi, Naka-Ku, Hiroshima 730, Japan.
Manufactured by:
JAPAN MEDICAL SUPPLY (S) PTE. LTD.
440, ANG MO KIO, INDUSTRIAL PARK 1,
SINGAPORE 569620

2. Manufactured by:
JAPAN MEDICAL SUPPLY (S) PTE. LTD.
440, ANG MO KIO, INDUSTRIAL PARK 1,
SINGAPORE 569620

(b)(4) sterilization [redacted] is labeled.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Individual Package (3 (JMS Miyoshi Plant)

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A.V. FISTULA NEEDLE SET

Single use only. Do not reuse. Sterilized by gamma irradiation. Non-pyrogenic. **CAUTION** : Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Do not use if package is damaged or cap is missing or not in place. Keep in a dry place. Store between +5°C and +30°C.

STERILE R

CE 0123

JMS CO.,LTD.
12-15 KAKO-DOCHO, NAKA-KU
HIROSHIMA 730-8653 JAPAN

SET D'AIGUILLES POUR FISTULES ARTERIO-VEINEUSES
Ne pas utiliser si l'emballage est endommagé ou si les protecteurs de stérilité ne sont pas en place. Maintenir à l'abri de l'humidité. Stockage entre +5°C et +30°C.

DIALYSEKANÜLEN
Nicht verwenden bei beschädigter Verpackung oder abgefallener Schutzkappe. Trocken lagern. Lagertemperatur zwischen +5°C und +30°C.

SET DE AGUJAS DE FISTULA A-V
No utilizar si el envase ha sido dañado o si los tapones han desaparecido o no se encuentran en su lugar. Conservar en un lugar seco. Almacenar entre +5°C y +30°C.

SET DE AGUHAS DE FISTULA ARTERIO-VENOSA
Não utilizar, caso a embalagem esteja danificada, não seja encontrado o protetor ou o mesmo esteja fora de seu local. Manter em local seco. Armazenar entre +5°C e +30°C.

EN SATS AV-FISTELNÅLAR
Får ej användas om förpackningen är skadad eller om skyddshylsorna inte sitter på plats. Skall förvaras torrt. Lagras i en temperatur mellan +5°C och +30°C.

ΒΕΛΟΝΕΣ ΓΙΑ ΑΡΤΗΡΙΟΦΛΕΒΙΚΗ ΧΡΗΣΗ
Μη χρησιμοποιείτε (εάν η συσκευασία είναι κατεστραμμένη ή λείπει το κάλυμμα ή δεν βρίσκεται στη θέση του. Διατηρείστε σε στεγνό τόπο. Αποθηκεύστε σε μεταξύ +5°C και +30°C.

PART 62-16-270-22
ROTATING(A+V)
16G×1"(1.65×25mm)

LOT 981124

MFG DATE 1998-11

EXP. DATE 2003-11

2501474.2 4/98

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Attachment H

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Inner Box (1)
(JMS Singapore)

19

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1. JMS CO. LTD. 12-17 Kako-Machi, Naka-Ku, Hiroshima 730, Japan. Manufactured by: JAPAN MEDICAL SUPPLY (S) PTE. LTD. 440, ANG MO KIO, INDUSTRIAL PARK 1, SINGAPORE 569620	2. Manufactured by: JAPAN MEDICAL SUPPLY (S) PTE. LTD. 440, ANG MO KIO, INDUSTRIAL PARK 1, SINGAPORE 569620

FOR SINGLE USE

A.V. FISTULA NEEDLE SET

STERILE 50SETS

JMS

• Wing Color Code

gauge	14G	15G	16G	17G	18G
Wing Color	White	Blue	Green	Orange	Pink

Sticker

TYPE
SIZE
LOT NO.
CODE NO.

FOR SINGLE USE

A.V. FISTULA NEEDLE SET

STERILE 50SETS

JMS

Sterilized by

Non-pyrogenic.
Super-thin-wall and siliconized needle.
Read carefully "DIRECTIONS FOR USE" to use this device correctly.
Do not use if package is opened or damaged.
Do not store in direct sunlight, at extreme temperature, or in high humidity.
Keep in a dry place.

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

DIRECTIONS FOR USE
1. Remove A.V. Fistula Needle set.
2. Remove needle cover with care not to touch needle surface.
3. Loosen luer lock cap. Grip wings firmly and make venipuncture.
4. Clamp tubing after observing blood flash-back. Expel air completely from tubing.
5. Tape down wings firmly.
6. Connect with hemodialysis tubing set by aseptic technique.

Either "gamma irradiation" or "ethylene-oxide" is labeled.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

(inner Box (2)
(JMS Singapore)

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Next panel

TYPE:

SIZE

BATCH / LOT NO :

CODE NO :

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A.V. FISTULA NEEDLE SET

Single use only. Do not reuse. Sterilized by ethylene-oxide. Non-pyrogenic. **CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Do not use if package is damaged or cap is missing or not in place. Do not store in direct sunlight, at extreme temperatures, or in high humidity.

JMS

SET D'AIGUILLES POUR FISTULES ARTERIO-VEINEUSES

DIALYSEKANÜLEN

SET DE AGULHAS DE FISTULA A.V.

SET DE AGUJAS DE FÍSTULA ARTERIO-VENOSA

EN SATS AV-FISTELNÅLAR

ΣΕΑΟΝΕΣ ΓΙΑ ΑΡΤΗΡΙΟΦΛΕΒΙΚΗ ΧΡΗΣΗ

JMS

A.V. FISTULA NEEDLE SET

STERILE EO

Manufactured by / Fabriqué par / Fertigt / Fabricado por / Κατασκευάζεται από / Fabricato da /

JAPAN MEDICAL SUPPLY (S) PTE. LTD

440 Ang Mo Kio Industrial Park 1

Singapore 569630

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-7433; Released 10/23/14

Middle Carton (1)
(JMS Singapore)

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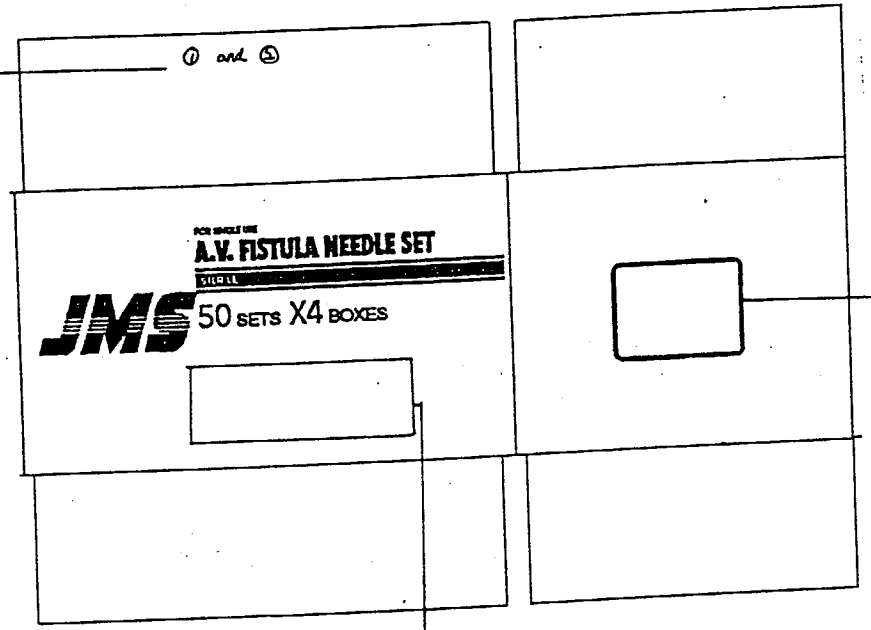
① CAUTION:
Federal (U.S.A) law restricts this device to sale by or on the order of a physician

② Do not store in direct sunlight, at extreme temperature, or in high humidity. Keep in a dry place.



Sticker

SIZE
LOT NO.
CODE NO.

① or ②

1. JMS CO. LTD. 12-17 Kako-Machi, Naka-Ku, Hiroshima 730, Japan. Manufactured by: JAPAN MEDICAL SUPPLY (S) PTE. LTD. 440, ANG MO KIO, INDUSTRIAL PARK 1, SINGAPORE 569620	2. Manufactured by: JAPAN MEDICAL SUPPLY (S) PTE. LTD. 440, ANG MO KIO, INDUSTRIAL PARK 1, SINGAPORE 569620

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Inner Box (3)
JMS Miyoshi Plant

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A.V. FISTULA NEEDLE SET

Single use only. Do not reuse. Sterilized by gamma irradiation. Non-pyrogenic. **CAUTION** : Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Do not use if package is damaged or cap is missing or not in place. Keep in a dry place. Store between +5℃ and +30℃

JMS

A.V. FISTULA NEEDLE SET

SET D'AIGUILLES POUR FISTULES ARTERIO-VEINEUSES
Ne pas utiliser si l'emballage est endommagé ou si les protecteurs de stérilité ne sont pas en place. Maintenir à l'abri de l'humidité. Stockage entre +5℃et +30℃.

DIALYSEKANÜLEN
Nicht verwenden bei beschädigter. Verpackung oder abgefallener Schutzkappe. Trocken lagern. Lagertemperatur zwischen +5℃und +30℃.

SET DE AGUJAS DE FISTULA A.V.
No utilizar si el envase ha sido dañado o si los tapones han desaparecido o no se encuentran en su lugar. Conservar en un lugar seco. Almacenar entre +5℃ y +30℃.

SET DE AGUHAS DE FÍSTULA ARTÉRIO-VENOSA
Não utilizar caso a embalagem esteja danificada, não seja encontrado o protetor ou o mesmo esteja fora de seu local. Manter em local seco. Armazenar entre +5℃e +30℃.

EN SATS AV-FISTELNÅLAR
Får ej anvandas om förpackningen är skadad eller om skyddshylsorna intesitter på plats. Skall förvaras torrt. Lagras i en temperatur mellan +5℃och +30℃.

ΒΕΛΟΝΕΣ ΓΙΑ ΦΛΕΒΟΑΡΤΗΡΙΑΚΗ ΧΡΗΣΗ
Μη χρησιμοποιείτε(το προϊόν) αν η συσκευασία είναι κατεστραμμένη ή λείπει το κάλυμμα ή δεν είναι στη θέση του. Διατηρείστε το σε ξηρό χώρο. Αποθηκεύστε το μεταξύ +5℃ και +30℃.

STERILE R

CE 0123

Manufactured by / Fabriqué par / Hergestellt durch / Fabricado por / Tillverkad av / Κατασκευάζεται από /
JMS CO.,LTD.
12-1 MACHI, NAKA-KU.
HIF 730-8652, JAPAN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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JMS

A.V. FISTULA NEEDLE SET

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Attachment I

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AGULHAS DE FÍSTULA ARTÉRIO-VENOSA

INSTRUÇÕES DE USO

INDICAÇÕES

Ler atentamente as instruções antes de utilizar o dispositivo.
AGULHAS DE FÍSTULA ARTÉRIO-VENOSA a utilizar nos seguintes tratamentos: hemodialise, hemofiltração e hemodiafiltração.
Dispositivo indicado para qualquer tratamento que necessite de um acesso à circulação sanguínea.

CONTRA-INDICAÇÕES

A simples utilização das agulhas não representa por si só um tratamento médico.
Não obstante, são possíveis contra-indicações geralmente associadas à introdução de agulhas e à ligação com o circuito extracorporal.
Por este motivo, a utilização destes dispositivos requer uma prescrição médica.
O dispositivo deve ser utilizado sob controlo médico.

RECOMENDAÇÕES E PRECAUÇÕES

1. DISPOSITIVO DESCARTÁVEL
   As Agulhas de Fístula são dispositivos descartáveis. NÃO REUTILIZAR.
2. ESTERILIDADE
   A embalagem em blisters separados garante a esterilidade do produto. Não utilizar agulhas contidas em blisters danificados ou não devidamente soldados, nem agulhas que não possuam as tampas protectoras ou se as mesmas não estiverem correctamente colocadas.
3. Utilizar em condições assépticas. NÃO TOCAR A AGULHA NEM A SUPERFÍCIE FINAL DO CONECTOR LUER.
4. INTRODUÇÃO DA AGULHA
   A preparação da agulha para a introdução deve ser feita em condições assépticas.
   Efectuar uma limpeza apropriada da área à volta do acesso vascular para evitar contaminações durante a fase de introdução da agulha.
5. Fazer a ligação entre a agulha de fístula e a linha sanguínea em condições assépticas para evitar a contaminação da cânula da agulha.
   Controlar atentamente a posição da agulha e todas as ligações antes de iniciar o tratamento. Verificá-las frequentemente mesmo durante a sessão de diálise para controlar e evitar possíveis fugas de sangue.
6. Podem haver pequenas diferenças no conector luer e/ou na agulha de fístula dependendo dos vários fabricantes. Estas diferenças podem originar fugas de sangue. Para prevenir a possibilidade de fugas de sangue, apertar bem os conectores macho e fêmea. Aconselha-se a utilizar um penso adesivo para fixar a ligação e a mantê-la visível durante o tratamento para possibilitar os eventuais controlos. O conector luer lock da JMS está em conformidade com a norma ISO 594.
7. FUGAS DE SANGUE
   Alguns desinfectantes ou valores de pressão excessivos na ligação podem provocar rachas nos materiais ou no conector luer. Estas avarias podem originar fugas de sangue ou aspiração de ar pela linha sanguínea, com a possibilidade de embolia gasosa. Portanto, recomenda-se a utilização contínua de um detector de ar. No fim da diálise, é também aconselhável restituir o sangue ao doente mediante uma reinfusão com linha cheia.
8. ENROLAMENTO
   Durante o tratamento é recomendável evitar a oclusão e/ou o enrolamento acidental do tubo de sangue. Uma pressão excessiva pode danificar o circuito extracorporal.
9. Para evitar os riscos de contágio de doenças infecciosas, tais como hepatite ou SIDA, as pessoas encarregadas pela introdução das agulhas e as encarregadas pela gestão do tratamento devem evitar o contacto directo com o sangue do doente. Utilizar continuamente os dispositivos de protecção, tais como luvas, máscaras, aventais e óculos protectores.
10. Afastar da sala de diálise imediatamente após o uso.
11. O operador deve tomar cuidado para não se picar acidentalmente com a agulha.

IMPORTANTE

1. CONDIÇÕES DE CONSERVAÇÃO
   Conservar nos cartões originais e num local limpo, seco e frio (5°C ~ 30°C, 20% ~ 80% de humidade relativa). NÃO MOLHAR. NÃO EXPOR DIRECTAMENTE À LUZ SOLAR.
2. DURAÇÃO
   A esterilidade das agulhas de fístula é garantida por 60 meses em condições apropriadas de conservação, dentro das embalagens triplas originais.
   A data de validade está indicada no blister e nas etiquetas dos cartões.
   Dar prioridade de utilização aos produtos com data de fabrico mais antiga.

INSTRUÇÕES DE USO

1. Utilizar em condições assépticas e manter a esterilidade.
2. Desinfectar completamente a área à volta do acesso vascular para evitar contaminações.
3. Verificar a presença de anomalias ou de partículas estranhas, após a agulha ter sido removida da embalagem. Controlar a tampa luer e apertá-la. Retirar a cobertura da agulha com cuidado para evitar contactos acidentais.
4. Lavar a agulha com solução salina (heparinizada).
5. Efectuar anestesia local se o doente pedir.
   Delimitar a área de injecção aplicando um laço hemostático.
6. Virar a secção oblíqua da ponta para cima, dobrar e segurar ambas as aletas durante as operações de introdução.
   (Nas agulhas com orifício lateral, este último representa um segundo canal, permitindo um maior fluxo sanguíneo).
   (Nas agulhas com aletas rotativas, o ponto preto na agulha indica que a secção oblíqua da ponta está ada para cima, enquanto que o ponto vermelho indica o posicionamento para baixo).
   roduzir a agulha de maneira não traumática no vaso sanguíneo (ângulo de introdução 25° ~ 40°).
   troduzir primeiro a agulha arterial e, de seguida, a venosa. Para prevenir a recirculação, a agulha venosa deve ficar a pelo menos 15 mm a jusante da agulha arterial.
   (A utilização da agulha simples requer uma única injecção).
8. Guiar a introdução da agulha no vaso.
9. Verificar a introdução correcta da agulha observando as pulsações; de seguida, encher a cânula com sangue.
10. Eliminar todo o ar presente na agulha e clampar a linha sanguínea.
11. Posicionar a agulha e fixar as aletas com um penso adesivo. Manter visível o ponto de introdução da agulha.
12. Retirar a tampa do conector luer e ligar a linha sanguínea em condições assépticas. Não ligar a linha arterial à agulha venosa e vice-versa.
13. Controlar atentamente a posição da agulha e de todas as ligações antes e durante os primeiros minutos do tratamento. Manter visível as ligações e o ponto de introdução da agulha durante a diálise e controlá-los constantemente para perceber e evitar possíveis fugas de sangue.

EN SATS AV-FISTELNÅLAR

BRUKSANVISNING

INDIKATION

LÄS BRUKSANVISNINGEN INNAN NÅLARNA ANVÄNDS
ARTERIOVENÖSA FISTELNÅLAR är avsedda att användas för hemodialys, hemofiltrering och hemodiafiltrering.
AV-fistelnålar används vid alla slags rutiner som kräver någon form av kontakt med blodflödet.

KONTRAINDIKATION

Användningen av fistelnålar är i sig ingen medicinsk behandling. Det kan dock finnas rutiner då kontakten med blod kan innebära en kontraindikation, vanligen förknippad med nålpunktion eller extrakorporeal krets.
Denna produkt får därför endast användas på läkarordination och enligt läkarens anvisningar.

VARNINGAR OCH SÄKERHETSFÖRESKRIFTER

1. ENGÅNGSBRUK
   Fistelnålar är endast avsedda för engångsbruk. FÅR EJ ÅTERANVÄNDAS.
2. STERILITET
   Endast nålar i hela blisterförpackningar är garanterat sterila för användning i blodbanan. Nålar i skadade eller öppna blisterförpackningar och nålar utan skyddshatt och nålskydd är troligen inte sterila och får därför ej användas.
3. Behandlingen måste utföras under aseptiska förhållanden. VIDRÖR INTE NÅLEN ELLER LUERKOPPLINGENS KONTAKTYTA.
4. PUNKTION
   Nålar för venpunktion skall förberedas enligt aseptiska rutiner. Tvätta noga huden över det valda kärlet för att undvika kontamination då nålen sticks in.
5. Tillämpa även aseptiska rutiner för att undvika kontamination av blodbanan då fistelnålar ansluts till blodslangar. Kontrollera nålarna och anslutningarna under de första minuterna av dialysen och sedan flera gånger medan behandlingen pågår, så att det inte uppstår läckor som kan orsaka blodförlust.
6. Det kan vara viss skillnad på luerkopplingar i blodslangar från olika tillverkare. Skillnader i storlek medför blodläckage eller att kopplingen lossnar. För att motverka sådana risker skall kopplingens hona och hane tryckas ihop ordentligt. Sätt gärna på en tape. Kopplingen skall kunna ses och kontrolleras under dialysen. JMS luerkopplingar uppfyller ISO 594.
7. LÄCKOR
   Trots att tillverkningen sker under noggrann kontroll, kan läckor hos fistelnålar inte helt uteslutas. Vissa desinfektionsmedel kan också orsaka materialsprickor. Kopplingarna brister om de utsätts för stor kraft. Skadade detaljer kan resultera i blodförlust eller att luft sugs in i blodslangen. Luft som kommer in i blodomloppet kan orsaka luftemboli. Använd därför alltid en detektor för luftläckage. Undvik att använda luft då blod återförs till patienten i samband med att dialysen avslutas. Alla kritiska ställen i en extrakorporeal krets skall vara tillgängliga för inspektion under behandlingen.
8. KINKAR
   Se till att slangen inte kinkar, snör sig eller täpps till under hemodialys eller liknande behandling. Ett alltför kraftigt tryck kan skada den extrakorporeala kretsen.
9. All exponering för blod och biprodukter av blod innebär risk för överföring av infektionssjukdomar, t ex hepatit och HIV, och den person som utför venpunktion och dialysen skall därför undvika direktkontakt med patientens blod. Skydd i form av handskar, rock, munskydd och ögonskydd skall användas rutinmässigt.
10. Efter användning skall det använda materialet kasseras på sådant sätt att det inte gör någon risk för spridning av infektionssjukdomar.
11. Den person som använder nålarna skall iaktta största försiktighet och undvika oavsiktliga nålstick.

VIKTIGT

1. FÖRVARING
   Fistelnålar skall förvaras i originalförpackningen i ett rent, torrt och svalt utrymme (5°C ~ 30°C, 20 ~ 80 % relativ fuktighet). FISTELNÅLAR FÅR EJ UTSÄTTAS FÖR FUKT OCH EJ EXPONERAS FÖR DIREKT SOLLJUS.
2. HÅLLBARHET
   Fistelnålarnas sterilitet garanteras i 60 månader. De måste dock förvaras på korrekt sätt i originalförpackningen som ger tredubbelt skydd. Sista förbrukningsdatum är tryckt på varje blisterförpackning samt på etiketten på ytterförpackningen. Produkterna skall användas omedelbart och enligt principen "först in, först ut".

BRUKSANVISNING

1. Denna produkt skall användas enligt aseptiska rutiner och med bibehållen sterilitet.
2. Tvätta noga det hudområde som skall punkteras, desinficera och se till att platsen för venpunktionen inte är kontaminerad.
3. Granska nålen när den tagits ur blisterförpackningen. Det får inte finnas några skador eller partiklar i lumen. Kontrollera och sätt på luerhatten. Dra av nålskyddet försiktigt så att nålen inte kontamineras.
4. Nålen kan spolas med saltlösning (saltlösningen kan vara heparinserad).
5. På patientens begäran kan lokalbedövning ges. Välj lämpligt ställe med hjälp av en proximalt placerad tourniquet.
6. Vik noga vingarna över centrum med den fasade sidan uppåt.
   [På nålar med bakre öga fungerar hålet som en ytterligare flödeskanal som ökar flödet.]
   [På nålar med roterande centrum, visar den svarta punkten på centrum att fasningen är vänd uppåt och den röda att den är vänd nedåt.]
7. Stick in nålen försiktigt i blodkärlet (insticksvinkel 25° ~ 40°). Sätt först i artärnålen och därefter vennålen. För att förhindra återcirkulation vid fasningen måste vennålen alltid placeras minst 15 mm längre ner i flödet än artärnålen. [Enkelnålar punkteras en gång.]
8. Led nålen varsamt in i blodkärlet och se till att den får en säker placering.
9. Kontrollera att blodet pulserar, fyll slangen med blod och saltlösning. Anslut slangen.
10. Avlägsna all luft i systemet.
11. Se till att nålen är placerad i kärlriktningen och fäst vingen med tape. Var noga med att inte täcka för nålöppningen med tapen.
12. Ta av hatten på kopplingen och anslut den till blodslangen. Arbeta aseptiskt. Artärslangen får ej anslutas till vennålen och vice versa.
13. Nålarnas lägen och kopplingarna måste kontrolleras noga före och under dialysens första minuter. Kontrollera också kopplingar och punkterade ställen medan dialysen pågår, så att läckor upptäcks i tid och blodförlust kan undvikas.

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ΒΕΛΟΝΕΣ ΓΙΑ ΦΛΕΒΟΑΡΤΗΡΙΑΚΗ ΧΡΗΣΗ

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

ΕΝΔΕΙΞΕΙΣ

Διαβάστε προσεκτικά τις οδηγίες πριν από τη χρήση.
ΒΕΛΟΝΕΣ ΓΙΑ ΦΛΕΒΟΑΡΤΗΡΙΑΚΗ ΧΡΗΣΗ για τις ακόλουθες θεραπείες: αιμοδιάλυση, αιμοδιήθηση, αιμοδιήθηση μέσω ημιπερατής μεμβρανής.
Προς χρήση σε οποιαδήποτε διαδικασία που απαιτεί πρόσβαση στην κυκλοφορία του αίματος.

ΑΝΤΕΝΔΕΙΞΕΙΣ

Η χρήση των βελονών δεν αποτελεί από μόνη της μια ιατρική θεραπεία.
Παρ'όλα αυτά μπορεί να παρουσιαστούν αντενδείξεις που εν γένει προέρχονται από την εισαγωγή των βελονών και από την σύνδεση του εξωσωματικού κυκλώματος.
Για το λόγο αυτό η χρηση αυτών των προϊόντων πρέπει να γίνεται κατόπιν ιατρικής συνταγής.
Πρέπει να γίνεται χρηση υπό την επίβλεψη του γιατρού.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ

1. ΜΙΑΣ ΧΡΗΣΕΩΣ
   Οι βελόνες είναι μιας χρήσεως. ΔΕΝ ΠΡΕΠΕΙ ΝΑ ΕΠΑΝΑΧΡΗΣΙΜΟΠΟΙΟΥΝΤΑΙ.
2. ΣΤΕΙΡΟΤΗΤΑ
   Η ειδική μονή αεροστεγής συσκευασία εξασφαλίζει τη στειρότητα. Μην χρησιμοποιείτε βελόνες που περιέχονται σε φθαρμένη ή αναιγμένη συσκευασία, ή βελόνες που δεν διαθέτουν ή που είναι κατεστραμμένο το προστατευτικό καπάκι.
3. Χρησιμοποιήστε τις βελόνες με μία ασηπτική μέθοδο.ΜΗΝ ΑΚΟΥΜΠΑΤΕ ΤΗ ΒΕΛΟΝΑ Η΄ ΤΗΝ ΕΠΙΦΑΝΕΙΑ ΤΗΣ ΑΠΟΛΗΞΗΣ ΤΟΥ ΣΥΝΔΕΤΗΡΑ LUER.
4. ΕΙΣΑΓΩΓΗ ΤΗΣ ΒΕΛΟΝΑΣ
   Προετοιμάστε τη βελόνα με ασηπτικές συνθήκες.
   Καθαρίστε κατάλληλα την περιοχή γύρω από την φλεβική είσοδο έτσι ώστε να αποφύγετε μολύνσεις κατά τη διάρκεια εισαγωγής της βελόνας.
5. Συνδέστε τη βελόνα στην αιματική γραμμή με μια ασηπτική μέθοδο έτσι ώστε να αποφύγετε μολύνσεις του εσωτερικού καναλιού της βελόνας. Ελέγξτε προσεκτικά την τοποθέτηση της βελόνας και όλες τις άλλες συνδέσεις πριν από την έναρξη της θεραπείας. Πραγματοποιήστε συχνό έλεγχο καθ'όλη τη διάρκεια της διάλυσης έτσι ώστε να προληφθούν ενδεχόμενες αιματικές διαρροές.
6. Πιθανόν να υπάρχουν μικρές διαφορές στο συνδετήρα luer και/ή στη βελόνα σύριγγας ανάλογα με τους διάφορους κατασκευαστές. Οι διαφορες αυτές μπορεί να προκαλέσουν αιματικές διαρροές. Για να προληφθεί η αιματική διαρροή συνδέστε σταθερά τα δύο ρακόρ. Συνιστάται η χρήση ενός τσιρότου για τη σταθεροποίηση της σύνδεσης και για να διατηρείται ορατή η σύνδεση κατά τη διάρκεια της θεραπείας για ενδεχόμενους ελέγχους. Ο συνδετήρας luer lock της JMS ανταποκρίνεται στις απαιτήσεις του κανονισμού ISO 594.
7. ΑΙΜΑΤΙΚΕΣ ΔΙΑΡΡΟΕΣ
   Μερικά απολυμαντικά ή υπερβαλικές πιέσεις κατά τη σύνδεση μπορεί να προκαλέσουν το σπάσιμο των υλικών ή του ρακόρ luer. Κατά συνέπεια μπορεί να προκληθούν αιματικές διαρροές ή αναρρόφηση αέρα στην αιματική γραμμή με πιθανότητα αεριώδους εμβολής. Συνιστάται, ως εκ τούτου, ή χρηση ενος ανιχνευτή αέρα. Στο τέλος της διάλυσης συνιστάται η επαναφορά του αίματος στον ασθενή μέσω πλήρους επανέγχυσης.
8. ΣΥΣΤΡΟΦΗ (KINKING)
   Κατά τη διάρκεια της θεραπείας σας συνιστούμε να αποφεύγεται την απόφραξη και/ή την τυχαία συστροφή του αιματικού σωλήνα. Η υπερβαλική πίεση μπορεί να καταστρέψει το εξωσωματικό κύκλωμα.
9. Για να αποφευχθεί ο κίνδυνος μόλυνσης από λοιμώδες νόσους, όπως Ηπατίτιδα και AIDS, το προσωπικό που ασχολείται με την εισαγωγή των βελονών καθώς και όσοι ασχολούνται με τον έλεγχο της θεραπείας, πρέπει να αποφεύγουν την άμεση επαφή με το αίμα του ασθενή. Θα πρέπει πάντως να χρησιμοποιούνται προστατευτικά μέσα όπως γάντια, μάσκες, ιατρικές ποδιές και προστατευτικά γυαλιά.
10. Απομάκρυνση από το χώρο διάλυσης αμέσως μετά τη χρήση.
11. Αποφεύγετε διατρήσεις εν κενώ.

ΣΗΜΑΝΤΙΚΟ

1. ΣΥΝΘΗΚΕΣ ΔΙΑΤΗΡΗΣΗΣ
   Διατηρήστε στα κουτιά τους και σε καθαρό χώρο, ξηρό και κρύο (5°C-30°C, 20%-80% σχετική υγρασία). ΔΕΝ ΠΡΕΠΕΙ ΝΑ ΒΡΕΧΕΤΑΙ ΟΥΤΕ ΝΑ ΕΚΤΙΘΕΤΑΙ ΑΠΕΥΘΕΙΑΣ ΣΤΙΣ ΑΚΤΙΝΕΣ ΤΟΥ ΗΛΙΟΥ)
2. ΔΙΑΡΚΕΙΑ
   Η στειρότητα των βελονών είναι εγγυημένη για 60 μήνες υπό τις κατάλληλες συνθήκες αποθήκευσης στα εσωτερικό της τριπλής αρχικής συσκευασίας (αεροστεγής συσκευασία, κουτί και χαρτοκιβώτιο). Η ημερομηνία λήξεως αναγράφεται στην αεροστεγή συσκευασία και στο χαρτοκιβώτιο. Πρέπει να δίδεται προτεραιότητα χρήσης σε προϊόντα παλαιότερης ημερομηνίας.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

1. Χρησιμοποιήστε σε ασηπτικό περιβάλλον και διατηρήστε τη στειρότητα.
2. Απολυμάνετε πλήρως την περιοχή γύρω από την φλεβική είσοδο έτσι ώστε να αποφευχθούν μολύνσεις.
3. Ελέγξτε αν έχει προκληθεί ζημιά ή αν υπάρχουν σωματίδια στο εσωτερικό της βελόνας μετά την απόσπαση της αεροστεγούς συσκευασίας. Ελέγξτε το luer και βιδώστε τα. Βγάλτε το κάλυμμα της βελόνας με προσοχή αποφεύγοντας τυχαίες επαφές.
4. Πλύνατε τη βελόνα με αλατούχο διάλυμα (με προσθήκη ηπαρίνης).
5. Πραγματοποιήστε τοπική αναισθησία αν το ζητήσει ο ασθενής.
   Οριοθετήστε την περιοχή με ένα αιμοστατικό λάστιχο.
6. Γυρίστε την πλάγια πλευρά της μύτης προς τα επάνω, διπλώστε τα πτερύγια και πιάστε τα και τα δύο μαζί (αν δεν υπάρχουν πτερυγια πιάστε τη βελόνα) κατά τη διάρκεια εισαγωγής της βελόνας.
   (Στις βελόνες με πλευρική οπή, προσφέρεται ένα ακόμη κανάλι και κατά συνέπεια μεγαλύτερη αιματική ροή).
   (Στις βελόνες με περιστρεφόμενα πτερύγια, το μαύρο σημείο στη βελόνα δείχνει όπ το πλάγιο τμήμα της μύτης είναι γυρισμένο προς τα επάνω, ενώ το κόκκινο δείχνει οτι το πλάγιο τμήμα της βελόνας είναι γυρισμένο προς τα κάτω).
7. Τοποθετείστε τη βελόνα αποφεύγοντας τραυματισμούς στο αγγείο (γωνία εισαγωγής 25° - 40°).
   Τοποθετείστε πρώτα την αρτηριακή βελόνα και στη συνέχεια τη φλεβική. Για να προλάβετε την ανακυκλοφορία, η φλεβική βελόνα πρέπει πάντα να βρίσκεται τουλάχιστον 15 χλστ. επάνω από την αρτηριακη βελόνα.
   (Η χρηση μονής βελόνας προϋποθέτει μια μόνο διάτρηση)
8. Καθοδηγήστε την είσοδο της βελόνας στο αγγείο.
9. Ελέγξτε τη σωστή εισαγωγή της βελόνας παρατηρώντας το σφυγμό και στη συνέχεια γεμίστε την κάνουλα με αίμα.
10. Βγαλτε εξ ολοκλήρου τον αέρα από τη βελόνα και μπλοκαρετε με ενα συνδετήρα την αιματική γραμμή.
11. Τοποθετηστε τη βελόνα και σταθεροποιήστε τα πτερύγια με ενα τσιροτο. Το σημείο εισαγωγής της βελόνας πρεπει να ειναι ορατο.
12. Βγαλτε το καπακι του συνδετηρα luer και συνδεστε την αιματικη γραμμη με ασηπτικό τροπο. Μην συνδέετε την αρτηριακη γραμμη με τη φλεβικη βελονα και αντιθετα.
13. Ελεγξτε προσεκτικα την θεση της βελονας και ολες τις συνδεσεις πριν και κατα τη διαρκεια των πρωτων λεπτων. Οι συν[illegible] κρυφα πρεπει να ελεγχονται συχνα ετσι ωστε να γινονται αντληπτες ενδεχομενες αιματικες διαρροες.

JMS

CE 0123

Manufactured by / Fabriqué par / Hergestellt durch / Fabricado por / Tillverkad av / Κατασκευάζεται από /

JMS CO.,LTD.
12-17 KAKO-MACHI, NAKA-KU,
HIROSHIMA 730-8652, JAPAN

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Questions? Contact DOA CDRH OCE/DRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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A.V. FISTULA NEEDLE SET

INSTRUCTION FOR USE

INDICATIONS

READ THIS INSTRUCTION BEFORE USE.

ARTERIOVENOUS FISTULA NEEDLES are indicated for hemodialysis, hemofiltration and hemodiafiltration.

A.V. fistula needles are indicated for use in conjunction with other procedures requiring access to the blood stream.

CONTRAINDICATIONS

The use of fistula needles is not in itself a medical treatment.

However, contraindication may be inherent in the procedures for which the access to the blood, generally associated with punctures by needles or in conjunction with extracorporeal circuit.

This therefore restricts this device to an order by a physician.

This device should be used to follow physician's instructions.

WARNINGS AND PRECAUTIONS

1. SINGLE USE
   Fistula needles are intended for single use only. DO NOT REUSE.
2. STERILITY
   The single blister packaging of the needle only assures sterility of the blood path.
   Needles in damaged or improperly sealed blister packages or those with detached or missing protector caps and needle covers may be non-sterile and should not be used.
3. An aseptic technique is required during treatment. DO NOT TOUCH THE NEEDLE AND THE END SURFACE OF LUER CONNECTOR.
4. PERFORMING PUNCTURE
   An aseptic technique is required when preparing fistula needles for venipuncture.
   Proper cleansing of the vessel access area must be performed to avoid contamination during the needle insertion process.
5. An aseptic technique is required to avoid contamination of the blood path when connecting the fistula needles to the blood lines.
   During the first minutes of operation and at several times during dialysis there should be visual inspections of the needles and connections to detect leaks and avoid blood loss.
6. There may be slight different luer connectors in blood lines provided by different manufacturers. These differences in size result in possible blood leakage or separation at the connector. To guard against these possibilities, join firmly male and female luer connectors each other. Taping assures connection. The connection should be visible at any time for visual inspections during dialysis. JMS luer lock connectors comply with ISO 594.
7. LEAKS
   In spite of great care in production, leaks of fistula needles cannot be excluded absolutely. Some disinfectants also may cause material cracks. Connectors break or crack under excessive force. These damages of the parts may result in blood loss or aspiration of air into the blood line. Air entering blood circuit can cause air embolism. Therefore use an air leak detector at all time. For return of blood to the patient at the termination of dialysis the use of air should be avoided. All critical areas of the extracorporeal circuit should be visually inspected during the treatment.
8. KINKING
   During hemodialysis or any other treatment, avoid kinking, twist or occluding of tubing. Excessive pressure may damage the extracorporeal circuit.
9. Since exposure to blood and blood-byproducts carries the risk of transfer of infectious diseases, for example Hepatitis and HIV AIDS, the person performing the venipuncture procedure and concerning the treatment of dialysis should avoid direct contact with the patient's blood. Protective equipment such as gloves, gowns, masks and eye shields should be utilized routinely.
10. After use, disposal should be done to protect infectious diseases for all concerning persons.
11. The person using needles should be careful to avoid accidental needle sticks.
12. Do not wipe this device with disinfectant such as alcohol, which may cause loosening of connection with blood line, or may cause leakage due to device damage.

IMPORTANT NOTICE

1. STORAGE
   Fistula needles should be stored in the original shipping carton, and in clean, dry and cool rooms. (5°C ~ 30°C, 20% to 80% relative humidity)
   PROTECT FROM WETNESS. DO NOT EXPOSE DIRECTLY TO THE SUN.
2. SHELF LIFE
   Sterility of the fistula needles is guaranteed for 60 months. It is necessary to store properly in the original packaging consisting of triple protection. The expiration date is printed on blister packs and carton labels. The products should be used according to the principle "first in-first out."

DIRECTION FOR USE

1. This device should be used aseptically and maintaining sterility.
2. After thoroughly cleanse the vessel area for puncture, carefully disinfect assuring the venipuncture area is not contaminated.
3. When the needle is removed from the blister pack it should be inspected for gross damages or particles in the lumen. The luer cap should be checked and tightened.
   The needle cover should be carefully removed to avoid touch contamination of the needle.
4. The needle may be flushed with saline (saline may be heparinized).
5. At a patient request local anesthesia may be used. With a tourniquet applied proximal a suitable puncture area is selected.
6. Fold wings over the hub securely with the bevel facing up.
   [In back eye type needles, the hole functions as an additional flow channel to permit sufficient flow rate.]
   [In rotating hub type, the black dot on the hub indicates bevel facing up and the red dot indicates down.]
7. Insert the needle smoothly into the blood vessel (insert angle 25° ~ 40°). It is recommended to place the arterial needle first and then the venous needle. To prevent recirculation on the bevel, the venous needle must always be at least 15mm downstream from the arterial needle.
   [Single needle type is punctured one time.]
8. Gently guides the needle into the blood vessel to achieve secure placement.
9. Observing pulsation of blood, fill the tube with blood and saline. Clamp the tube.
10. All air in the products should be eliminated entirely.
11. Secure the needle alignment and fix wing with tape. Using any taping method the needle entry site should be remain visible.
12. Detach the connector cap and connect with blood line aseptically.
    To connect the arterial blood line with the venous needle and the venous should be avoided.
13. Needle positions and all connections must be checked carefully prior to and during the first minutes of operation. During [illegible]

SET D'AIGUILLES POUR FISTULES ARTERIO-VEINEUSES

NOTICE D'UTILISATION

INDICATIONS

A LIRE ATTENTIVEMENT AVANT UTILISATION

LES AIGUILLES POUR FISTULES ARTERIO-VEINEUSES sont indiquées pour l'hémodialyse, l'hémofiltration et l'hémodiafiltration.

Les aiguilles pour fistules arteno-veineuses sont indiquées pour une utilisation dans toute procédure necessitant un acces au flux sanguin.

CONTRE-INDICATIONS

L'emploi d'aiguilles pour fistules ne constitue pas en soi un traitement médical.

Toutefois, des contre-indications peuvent exister dans le cadre des procédures d'accès au sang, généralement associées aux piqûres par des aiguilles ou en relation avec la circulation extra-corporelle.

C'est pourquoi ce produit doit être prescrit par un médecin.

Ce produit doit être employé conformement aux instructions du médecin.

AVRTISSEMENT ET PRECAUTIONS

1. USAGE UNIQUE
   Les aiguilles pour fistules sont prevues pour un usage unique. NE PAS REUTILISER.
2. STERILISATION
   L'emballage des aiguilles en blisters individuels garantit uniquement le caractère stérile du trajet sanguin. Ne pas utiliser toute aiguille dont l'emballage serait endommagé ou mal fermé, ou dont le capuchon protecteur et le couvercle d'aiguille seraient détachés ou manquants.
3. Une technique aseptique est requise pendant le traitement. NE PAS TOUCHER L'AIGUILLE ET LA SURFACE D'EXTREMITE DU CONNECTEUR LUER.
4. REALISATION DE LA PIQÛRE
   Une technique aseptique est requise lors de la preparation d'aiguilles pour fistules pour ponctions veineuses.
   Un nettoyage approprié de la zone d'accès au vaisseau doit être réalisé, afin d'éviter toute contamination lors du processus d'introduction de l'aiguille.
5. Une technique aseptique est requise pour éviter la contamination du trajet sanguin lors du raccordement du set d'aiguilles pour fistules aux vaisseaux sanguins.
   Pendant les premières minutes de fonctionnement et à plusieurs reprises au cours de la dialyse, il convient de vérifier visuellement les aiguilles et les raccords afin de détecter toute fuite éventuelle et d'éviter toute perte de sang.
6. Les connecteurs Luer des aiguilles pour fistules peuvent presenter de légères différences selon le fabricant. Ces différences de taille peuvent engendrer des fuites de sang ou une séparation au niveau du connecteur. Pour éviter ces phénomènes, maintenir fermement les connecteurs Luer mâle et femelle l'un contre l'autre. Fixer avec un ruban adhésif pour assurer la connexion. Celle-ci doit être visible à tout moment lors de la dialyse, afin de permettre des vérifications visuelles. Les connecteurs à verrouillage Luer JMS sont conformes à la norme ISO 594.
7. FUITES
   En dépit du grand soin apporté lors de la fabrication, les risques de fuite des aiguilles pour fistules ne peuvent totalement être-exclus. Certains désinfectants peuvent egalement causer des fissures dans les matériaux. Le connecteur peut se casser ou se fissurer s'il est soumis à une sollicitation excessive. Le fait que ces éléments soient endommages peut entraîner une perte de sang ou une introduction d'air dans les vaisseaux sanguins. La penétration d'air dans le flux sanguin peut causer une embolie gazeuse. Un détecteur de prise d'air est donc requis en permanence. Eviter l'emploi d'air pour le retour du sang vers le patient à la fin de la dialyse. Toutes les zones critiques de la circulation extra-corporelle doivent faire l'objet d'examens visuels au cours du traitement.
8. TORSION
   En cours d'hemodialyse ou de traitement comparable, éviter toute torsion, pli ou occlusion des tubes. Une pression excessive risque d'endommager le circuit extracorporel.
9. Etant donné que l'exposition au sang et aux sous-produits du sang entraine le risque de transfert de maladies infectieuses, comme l'hépatite, le virus HIV du Sida, la personne exécutant la procédure de ponction veineuse et assurant le traitement par dialyse doit éviter tout contact direct avec la sang du patient. Il convient de porter systématiquement les équipements de protection habituels : gants, tabliers, masques, lunettes de protection.
10. Après utilisation, la mise au rebut doit s'effectuer de façon à protéger toutes les personnes concernées contre des maladies infectieuses.
11. La personne employant les aiguilles doit veiller à ne pas se piquer avec celles-ci.

REMARQUES IMPORTANTES

1. STOCKAGE
   Les aiguilles pour fistules doivent être stockées dans leur carton d'emballage d'origine, dans des pièces propres, sèches et tempérées (5°C ~ 30°C, 20% à 80% d'humidité relative).
   NE PAS HUMIDIFIER, NI EXPOSER DIRECTEMENT A LA LUMIERE SOLAIRE.
2. DUREE DE CONSERVATION
   La stérilité des aiguilles pour fistules est garantie pendant 60 mois. Il est nécessaire de les stocker correctement, dans leur emballage d'origine à triple protection. La date de péremption est imprimée sur les sachets de blisters ainsi que sur les cartons. Les produits doivent être employés immédiatement et doivent se voir appliquer le principe "first in first out".

MODE D'EMPLOI

1. Ce produit doit être employé avec un aseptiqué et sa stérilité doit être préservée.
2. Après avoir nettoyé la zone de la piqûre, désinfecter soigneusement pour s'assurer que la zone de ponction veineuse ne soit pas contaminee.
3. Une fois l'aiguille retirée de l'emballage en blister, rechercher à la lumière d'éventuels dommages importants ou la présence éventuelle de particules. Le capuchon Luer doit être vérifié et serré. Retirer le couvercle de l'aiguille délicatement, afin d'éviter toute contamination de l'aiguille par contact.
4. L'aiguille peut être rincée au sérum physiologique (le sérum peut être héparinisé).
5. Une anesthésie locale peut être pratiquee à la demande du patient. Avec un garrot appliqué à proximité, une zone de piqûre appropriée est sélectionnée.
6. Replier les "ailes" par dessus la garde, avec le biseau orienté vers le haut.
   Pour les aiguilles de type "back eye", l'orifice fonctionne en tant que canal de flux supplémentaire afin de permettre un débit suffisant.
   Pour le type à garde rotative, le point noir figurant sur la garde correspond au côté superieur (biseau) et le point rouge au côté inferieur.
7. Introduire délicatement l'aiguille dans le vaisseau sanguin (angle d'introduction : 25° ~ 40°). Il est conseillé de placer d'abord l'aiguille artérielle, puis l'aiguille veineuse. Pour eviter la recirculation sur le biseau, l'aiguille veineuse doit toujours se situer à 15 mm minimum en aval de l'aiguille artérielle.
   Le type à aiguille simple est entonce une seule fois.
8. Guider l'aiguille dans le vaisseau sanguin de façon à assurer le placement de l'aiguille.
9. Observer les pulsations du sang, remplir le tube de sang et de serum physiologique. Clamper le tube.
10. Eliminer la totalité de l'air present dans les produits.
11. Fixer l'alignement de l'aiguille et l'aile avec un ruban adhésif. Quelle que soit la methode de fixation utilisée, le point d'entrée de l'aiguille doit toujours rester visible.
12. Enlever le capuchon du connecteur, puis le raccorder aseptiquement au circuit sanguin. Il convient d'éviter de raccorder la tubulure artérielle avec l'aiguille veineuse et inversement.
13. La position des aiguilles et l'ensemble des raccords doivent être verifiés avant le début du traitement et au cours des premières minutes de celui-ci. Au cours de la dialyse, les raccords et les points de piqûres doivent faire l'objet d'examens visuels, afin de detecter toute fuite éventuelle et d'éviter toute perte de sang.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DIALYSEKANÜLEN

Anwendungshinweise für Dialysekanülen

WICHTIGER HINWEIS

LESEN SIE DIESE ANWENDUNGSHINWEISE VOR BENUTZUNG

JMS-DIALYSEKANÜLEN sind für den Gefäßzugang bei Hämodialyse, Hämofiltration und Hämodiafiltration bestimmt. Sie können auch für andere extrakorporale Behandlungsverfahren eingesetzt werden, bei denen ein ergiebiger Zugang zum Blutkreislauf benötigt wird.

GEGENANZEIGEN

Der Einsatz von Dialysekanülen ist für sich betrachtet noch keine medizinische Behandlung. Dialysekanülen dürfen aber bei Patienten nur auf ärztliche Anordnung verwendet werden.

WARNUNGEN UND VORSICHTSMASSNAHMEN

1. EINMAL-VERWENDUNG
   Dialysekanülen sind für den Einmalgebrauch bestimmt.
   NICHT WIEDERVERWENDEN!
2. STERILITÄT
   Durch die Einfach-Blisterverpackung ist nur die Sterilität des Blutweges gewährleistet. Kanülen in beschädigter oder nicht einwandfrei verschlossener Verpackung oder mit abgefallenen oder fehlenden Schutzkappen, können unsteril sein und dürfen nicht verwendet werden.
3. Während der Handhabung der DIALYSEKANÜLE ist die Sterilität des produktes zu wahren. BERÜHREN SIE NICHT DIE NADEL UND DIE STIRNFLÄCHE DES LUER-KONNEKTORS.
4. PUNKTION
   Bei der Punktion einer DIALYSEKANÜLE ist eine aseptische Technik anzuwenden. Das Punktionsgebiet ist gründlich zu reinigen und zu desinfizieren, um eine Kontamination während der Punktion auszuschließen.
5. Beim Anschluß der Blutschläuche an die Dialysekanülen ist eine aseptische Technik ist erforderlich, um eine Kontamination auszuschließen. Während der ersten Minuten nach Start der Behandlung und während der Dialyse sollten das Punktionsgebiet und die Verbindungen wiederholt nach Undichtigkeiten überprüft werden um Lufteintritt und Blutverluste zu verhindern.
6. Die Pateintenkonnektoren der Blutschläuche können bisweilen vom internationalen Standard für medizinische Kegelverbindungen abweichen. Diese Abweichungen können zu Undichtigkeit und zum unbeabsichtigten Lösen der Verbindungsstücke führen.
7. Um ein unbeabsichtigtes Lösen der Blutschläuche während der Behandlung auszuschließen, sollten Sie die Gewindemutter festziehen und die Kupplungsteile zusätzlich mit Heftpflaster sichern. Die Verbindungsstellen sollten während der Dialyse für visuelle Kontrollen offen und jederzeit zugänglich sein. Die Luer-Konnektoren von JMS-Dialysekanülen entsprechen ISO 594, dem internationalen Standard für medizinische Kegelverbinungen (Luer-Konnektoren).
8. Undichtigkeiten
   Trotz größter Sorgfalt bei der Herstellung, können bei Dialysekanülen Undichtigkeiten nicht absolut ausgeschlossen werden. Bestimmte alkoholische Desinfektionsmittel können zu Spannungsrissen im Material der Konnektoren führen. Bei übermäßiger Kraftanwendung können die Konnektoren dann auch gesprengt werden. Diese Beschädigungen durch unsachgemäße Handhabung können zu Blutverlusten oder zum Ansaugen von Luft in den extrakorporalen Kreislauf führen. Luft im extrakorporalen Kreislauf kann Luftembolien verursachen. Während der Dialyse ist es deshalb zwingend erforderlich, einen auch auf Mikroschaum reagierenden Luft-Detektor einzuschalten. Beim Rückführen des Blutes am Ende der Dialyse sollte mit Infusionslösung substituiert werden, um den Eintritt von Luft in das System zu vermeiden. Alle kritischen Punkte des extrakorporalen Kreislaufs sollten während der Behandlung wiederholt visuell kontrolliert werden.
9. Während der Behandlung, ist das Abknicken, Verdrehen oder Abquetschen der Schläuche zu vermeiden. Bei übermäßigem Druck können sich Verbindungen im System lösen oder Teile geschädigt werden.
10. Da beim Kontakt mit Blut und Blut-Bestandteilen immer die Gefahr der Übertragung von Infektionskrankheiten, z.B. Hepatis oder AIDS, besteht, sollte die Person, die die Gefäßpunktion durchführt, den direkten Kontakt mit dem Blut des Patienten vermeiden. Schutzvorkehrungen wie das Tragen von Einmal-Handschuhen, Schutzkleidung, Gesichtsmaske oder Augenschutz sollten routinemaßig getroffen werden.
11. Nach Benutzung sind Dialysekanülen so zu entsorgen, daß alle betroffenen Personen ver Infektionen geschützt sind.
12. Das Pflegepersonal sollte mit größter Vorsicht arbeiten, um sich mit der Dialysekanüle nicht zu verletzen.

WICHTIGE HINWEISE

1. Lagerung
   Dialysekanülen sind in den geschlossenen Originalkartons in staubfreien, kühlen und trockenen Räumen zu lagern (5°C bis 30°C; 20% bis 80% relative Luftfeuchtigkeit).
   VOR FEUCHTIGKEIT UND DIREKTER SONNENBESTRAHLUNG SCHÜTZEN.
2. Verwendbarkeit
   Die Sterilität der Dialysekanülen wird für 60 Monate garantiert. Sie müssen in der Original-Verpackung, bestehend aus Blister, Spenderkarton und Versandkarton, gelagert werden. Das Verfalldatum ist auf der Blisterverpackung und auf den Kartonaufklebern aufgedruckt. Es sollte immer zuerst die ältere Ware verbraucht werden (First in-first out).

ANWENDUNGSHINWEISE

1. Das Produkt sollte unter aseptischen Bedingungen und unter Wahrung der Sterilität eingesetzt werden.
2. Nach gründlicher Reinigung dse Armes ist der Punktionsbereich sorgfältig zu desinfizieren.
3. Nach dem Entnehmen aus der Blisterverpackung ist die Dialysekanüle auf sichtbare Beschädigungen oder Fremdkörper im Lumen zu überprüfen. Der Festsitz der Drehverschlußkappe ist zu prüfen und gegebenenfalls nachzuziehen. Die Kanülenschutzkappe vorsichtig abnehmen, um eine Kontamination der Kanüle zu vermeiden.
4. Das komplette Gerät sollte mit steriler Kochsalzlösung durchgespült werden (die Kochsalzlösung kann heparinisiert sein).
5. Bei ängstlichen Patienten kann eine Lokalanästhesie durchgeführt werden.
6. Nach dem Zusammenfalten des Flügels wird der Anschliff entsprechend der Punktionstechnik ausgerichtet. Bei arteriellen Kanülen verhindert die Seitenöffnung ein Ansaugen des Anschliffes an der Gefäßwand. (Wenn eine Kanüle mit drehbarem Flügel bereits im Gefäß lieft, zeigt der schwarze Punkt auf dem Kanülenhalter die Ausrichtung der Anschliff-Öffnung an. Wenn der rote Punkt sichbar ist, ist die Anschliffüffnung nach unten gedreht).
7. Die Kanüle ist in einem Winkel zur Haut von 25° – 40° zu punktieren! Es wird empfohlen, zuerst die arterielle und dann die venöse Kanüle zu punktieren.
8. Zur Vermeidung von Rezirkulation sollte die venöse Kanüle in einem Mindestabstand von 15 mm punktiert werden (stromabwärts von der arteriellen Kanüle). Bei Single Needle Technik wird nur eine Spezialkanüle mit Y-Stück verwendet.
9. Kanüle ist vorsichtig in die gewünschte Position in das Gefäß vorzuschieben.
10. Bei guter Lage des Anschliffes im Blutstrom sollte die Blutsäule bei festgezogener Drehverschlußkappe im Anschlußschlauch pulsieren. Anschließend kann das Gerät mit steriler Kochsalzlösung gespült werden. Am Ende der Prozedur sollte die Luft im Schlauch vollständig durch Flüssigkeit verdrängt sein.
11. Die Kanülen sind in der gewählten Position mit Heftpflaster zu fixieren. Die Stellen, an denen die Kanülen die Haut perforieren, sollte aber offen bleiben.
12. Bei geschlossener Klemme und nach Entfernen der Drehverschluß-Kappe werden die Patienten-Konnektoren des Blutschlauchsystems und die Konnektoren der Dialysekanülen mit gleicher Farbkodierung verbunden. Ein irrtümliches Vertauschen [illegible] Rezirkulation und [illegible] Die Position der Kanülen und alle Verbindungen des extrakorporalen Systems müssen vor und bei Start der Dialyse

SET DE AGUJAS DE FISTULA A.V.

INSTRUCCIONES DE USO

INDICACIONES

LEA ESTAS INSTRUCCIONES ANTES DE SU UTILIZACIÓN

LAS AGUJAS DE FISTULA INTRAVENOSA están indicadas para su utilización en hemodiálisis, hemofiltración, hemodiafiltración.

Las agujas de fistula A.V. pueden ser utilizadas en combinación con cualquier procedimiento que requiera el acceso a circulación sanguinea.

CONTRAINDICACIONES

El uso de las agujas de fistula no constituye en sí mismo un tratamiento medico.

Sin embargo, pueden existir contraindicaciones inherentes a los procedimientos, generalmente asociados a puncion con agujas o a los circuitos extracorporeos.

Por lo tanto, su uso deberá ser prescrito por un medico.

Este dispositivo debe utilizarse siguiendo las instrucciones médicas.

ADVERTENCIAS Y PRECAUCIONES

1. UN SOLO USO
   Las agujas de fistula están diseñadas para un solo uso. NO SE DEBEN REUTILIZAR.
2. ESTERILIDAD
   El envase individual de la aguja, garantiza únicamente la esterilidad de la vía sanguinea. Las agujas procedentes embalajes dañados, incorrectamente sellados o aquellos cuyos tapones de protección esten sueltos o [illegible], pueden no conservar su esterilidad y no deben ser utilizadas.
3. Durante el tratamiento se requiere el uso de una técnica aséptica. NO TOQUE LA AGUJA NI LA SUPERFICI DEL EXTREMO DEL CONECTOR LUER.
4. PUNCION
   Cuando se preparen las agujas de fistula para la venopunción se requerirá el uso de una técnica aséptica. Se deb realizar una correcta limpieza del área de acceso al vaso, evitando así la contaminación durante la introducción de la aguja.
5. Se requiere el uso de una tecnica aséptica para evitar la contaminacion de la via sanguinea cuando se conecta la aguja de fistula con la línea sanguinea.
   Durante los primeros minutos del proceso, y varias veces durante la diálisis, se deben inspeccionar visualmente las agujas y las conexiones, con el objeto de detectar fugas y evitar pérdidas de sangre.
6. Pueden existir ligeras diferencias en los conectores Luer de las agujas de fistula suministradas por diferentes proveedores. Estas diferencias de tamaño pueden dar lugar a pérdidas de sangre o a la desconexión del sistema. Para evitarlo, una firmemente los conectores Luer macho y hembra. Para asegurar la conexión, dé unos ligeros golpes La conexión debe permanecer visible en todo momento, lo que permitirá la inspección visual durante la diálisis Los conectores Luer JMS se ajustan a la norma ISO 594.
7. FUGAS
   A pesar de las extremas precauciones de fabricación, es imposible descartar por completo la posibilidad de que se produzcan fugas. Algunos desinfectantes también pueden dañar los materiales de fabricación. Los conector romperse ò agrietarse si se aplica una fuerza excesiva. Estos daños en las piezas pueden provocar pérdida o la entrada de aire en el circuito de la linea sanguínea. La entrada de aire en el circuito podria causar un. gaseosa. Por ello, en todo momento debe utilizarse un detector de fugas de aire. Debe evitarse el empleo del aire para retornar la sangre al paciente una vez finalizada la diálisis. Todas las zonas criticas del circuito extracorpóreo deben ser inspeccionadas visualmente durante el transcurso del tratamiento.
8. PINZAMIENTOS
   Durante la hemodiálisis, u otro tratamiento similar, evite que el tubo utilizado sufra pinzamientos, acodamientos u oclusiones. Una presion excesiva puede dañar el circuito extracorpóreo.
9. Dado que la exposición a la sangre y a los componentes sanguineos conlleva el riesgo de transmisión de enfermedades infecciosas, por ejemplo hepatitis, HIV SIDA, la persona a cargo de la venopunción y del tratamiento de diálisis debe evitar el contacto directo con la sangre del paciente : Deben utilizarse rutinariamente sistemas de protección, como guantes, batas, mascarillas y protección ocular.
10. Después de su utilización, deseche el dispositivo para evitar el riesgo de enfermedades infecciosas en todas las personas implicadas en el tratamiento.
11. Las personas que manipulen las agujas deben extremar el cuidado para evitar pincharse accidentalmente.

AVISO IMPORTANTE

1. ALMACENAMIENTO
   Las agujas de fistula deben ser almacenadas en su embalaje original, en un recinto limpio, seco y fresco (5°C – 30°C, 20% a 80% de humedad relativa).
   NO MOJAR, NO EXPONER A LA LUZ SOLAR DIRECTA.
2. PERIODO DE VALIDEZ
   La esterilidad de las agujas de fistula está garantizada durante 60 meses. Es necesario almacenarlas adecuadamente en su embalaje original, que consta de una triple protección. La fecha de caducidad está impresa en el blister y en las etiquetas del envase. Los productos deben utilizarse inmediatamente y debe seguirse el principio "FIFO".

INSTRUCCIONES DE USO

1. Este dispositivo debe utilizarse asépticamente y manteniendo su esterilidad.
2. Despuès de limpiar minuciosamente el área del vaso en que se hará la punción, desinfecte cuidadosamente, asegurándose de no contaminar el área de venopunción.
3. Cuando se extrae la aguja del envase, debe ser inspeccionada en busca de posibles daños o particulas en el lumen. El tapón luer debe ser apretado y revisado visualmente. Se debe retirar cuidadosamente la cubierta de la aguja para evitar la contaminación de la misma.
4. La aguja debe lavarse con una solución salina (que puede contener heparina).
5. Si el paciente lo solicita, se puede utilizar anestesia local. Aplique un torniquete en posición proximal y seleccione un área adecuada para la punción.
6. Doble firmemente las aletas sobre la cánula de la aguja, con la parte biselada orientada hacia arriba.
   [En las agujas fenestradas, la ventana actua como un canal de flujo adicional que permitirá un caudal
   [En la aguja rotatoria, el punto negro en la cánula indica que la parte biselada está orientada hacia arri
   rojo que está orientada hacia abajo.]
7. Introduzca suavemente la aguja en el vaso sanguineo (angulo de inserción de 25° – 40°). Se recomienda colocar en primer lugar la aguja arterial y después la aguja venosa. Para evitar la recirculación en la parte biselada, la aguja venosa debe estar, al menos, 15 mm corriente abajo de la aguja arterial.
   [En el caso de la aguja de unipunción se realiza un solo pinchazo.]
8. Guie suavemente la aguja en el vaso sanguineo hasta conseguir un emplazamiento seguro.
9. Observando la pulsación de la sangre, llene el tubo con sangre y solución salina. Pince el tubo.
10. Se debe eliminar completamente el aire de los productos utilizados.
11. Una vez colocada la aguja adecuadamente, fije las aletas con esparadrapo. Independientemente del metodo utilizado para su fijación, el punto de entrada de la aguja debe permanecer visible.
12. Retire el tapon y conecte, asepticamente, al circuito sanguineo. Se debe evitar conectar la corriente arterial con la aguja venosa, y vice-versa.
13. [illegible] durante los primeros minutos del procedimiento, se deben revisar cuidadosamente la colocación de las agujas y todas las conexiones. Durante la diálisis, se deben inspeccionar visualmente las conexiones y los puntos de

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Attachment J

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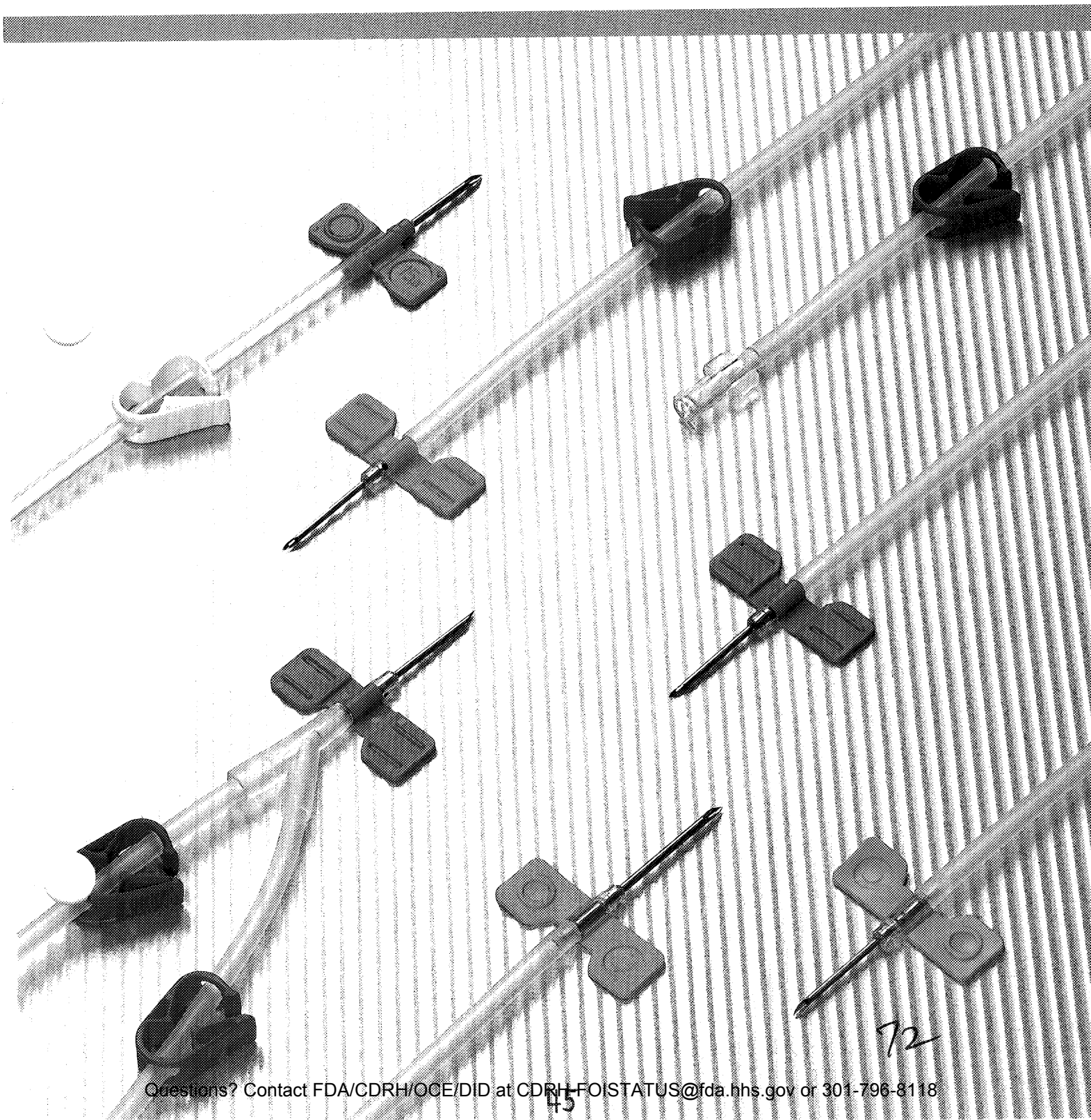
A.V. FISTULA NEEDLE SET

High tech with decades of experience

JMS CO.,LTD.



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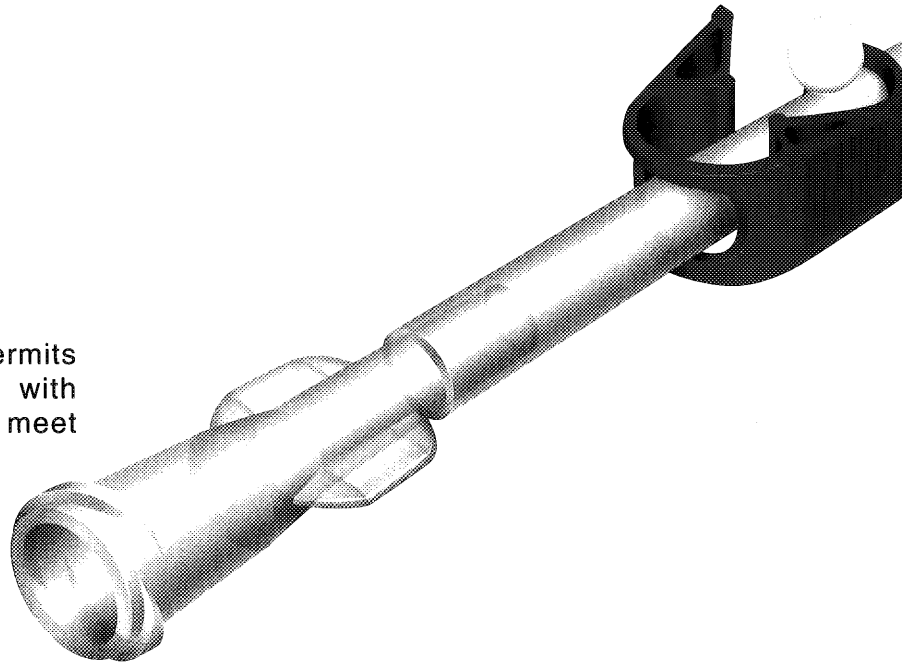
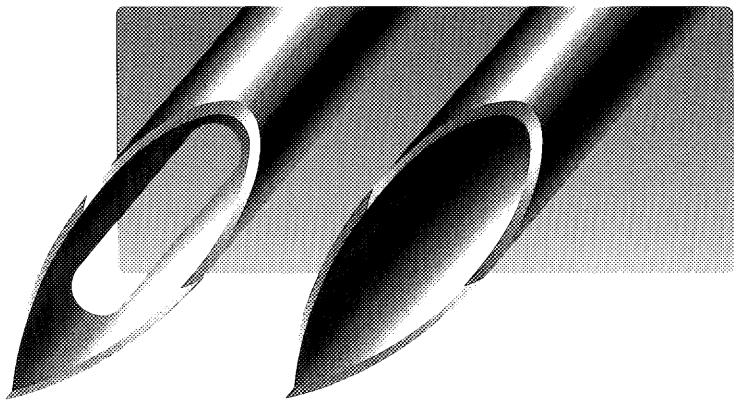


Winged Luer-Lock connector permits secure and easier connection with blood line. All the dimensions meet with ISO specification.

State-of-the-art JMS cannula making technology allows smooth and painless needle insertion with minimal trauma to the fistula, minimizing puncture site bleeding and post dialysis bleeding while allowing for better longevity of the fistula.
The ideal needle bevel geometry developed with our experience over the years and thorough clinical evaluation promises consistent superb sharpness and no coring effect.



JMS's original and unique oval back eye functions as an additional flow channel to permit a sufficient flow rate should the needle bevel adhere to the vein wall and obstruct the blood flow.

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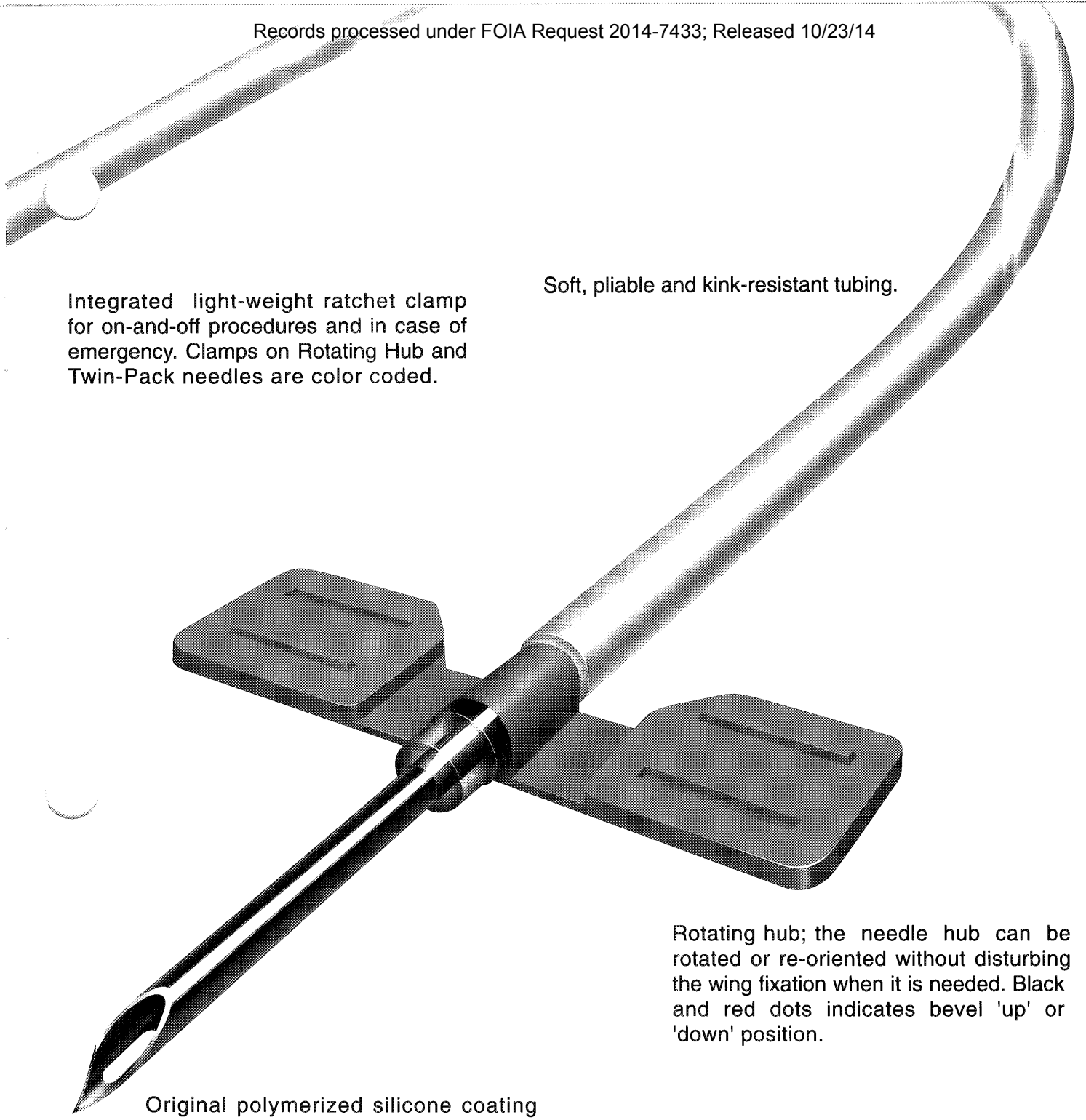

Integrated light-weight ratchet clamp for on-and-off procedures and in case of emergency. Clamps on Rotating Hub and Twin-Pack needles are color coded.

Soft, pliable and kink-resistant tubing.

Rotating hub; the needle hub can be rotated or re-oriented without disturbing the wing fixation when it is needed. Black and red dots indicates bevel 'up' or 'down' position.

Original polymerized silicone coating is the key to desirable lubrication. While it offers maximum ease of puncturing, silicone related risks are minimized; such as released silicone into blood stream and prolonged post-dialysis bleeding.

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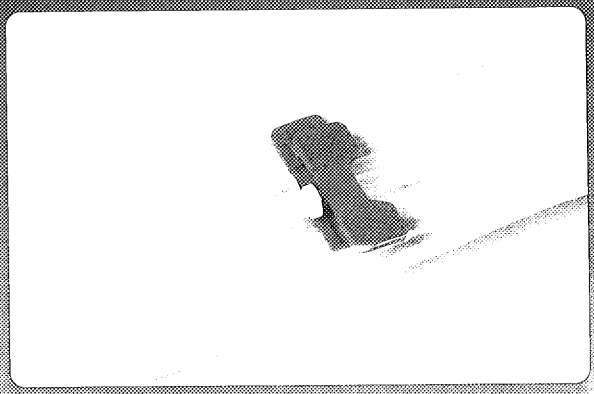
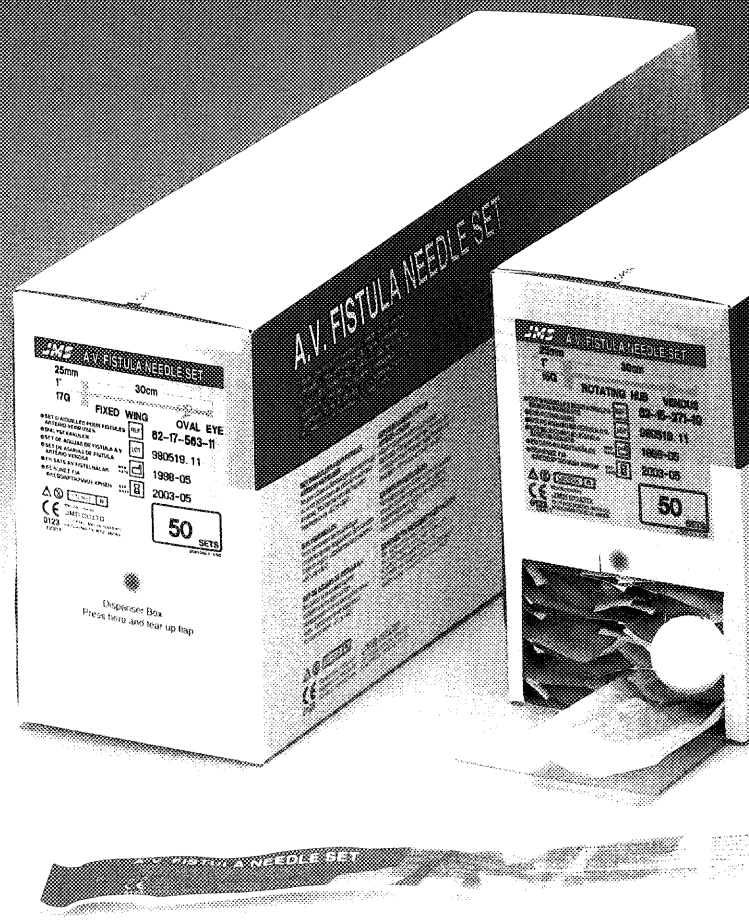
TWIN PACK

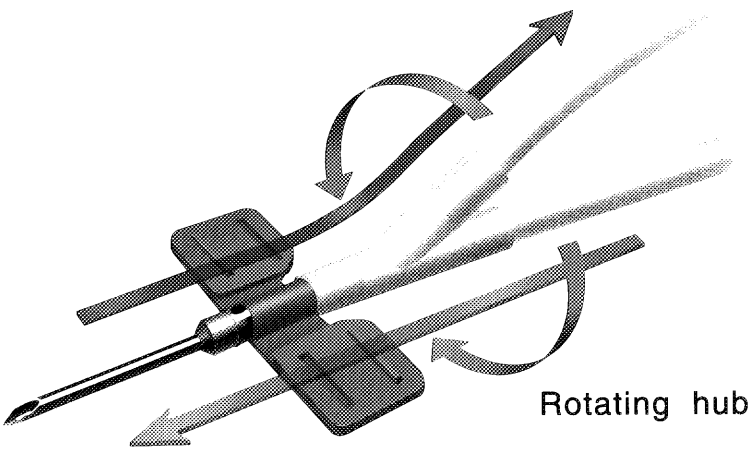
JMS recommends the use of a back eye needle for the arterial line and a without back eye for the venous line. JMS's Twin Pack (one arterial and one venous needles in a blister pack) offers stocking convenience and economy. Color coded red and blue clamps specify the lines and simply eliminate the risk of "reversed line" recirculation.





Single Needle Set

This set includes a carefully designed Y-piece joint and rotating hub. This combination permits the convenience of needle bevel rotation and secure compression free fixation as well as high dialysis efficiency by using minimal dead space which allows for a smooth flow without turbulence.



Rotating hub

Least dead space and smooth flow

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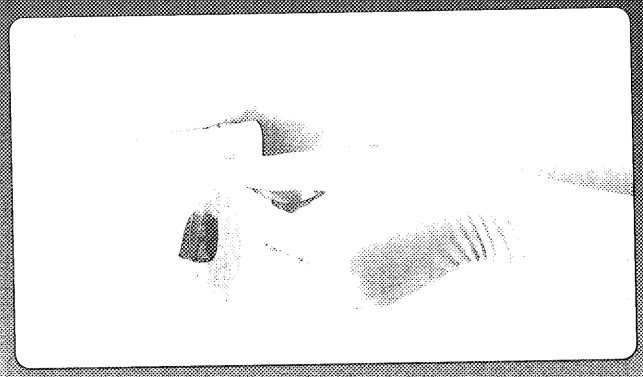
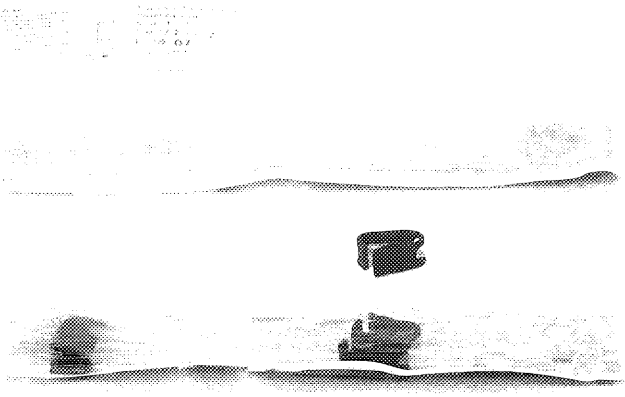
Packaging features :

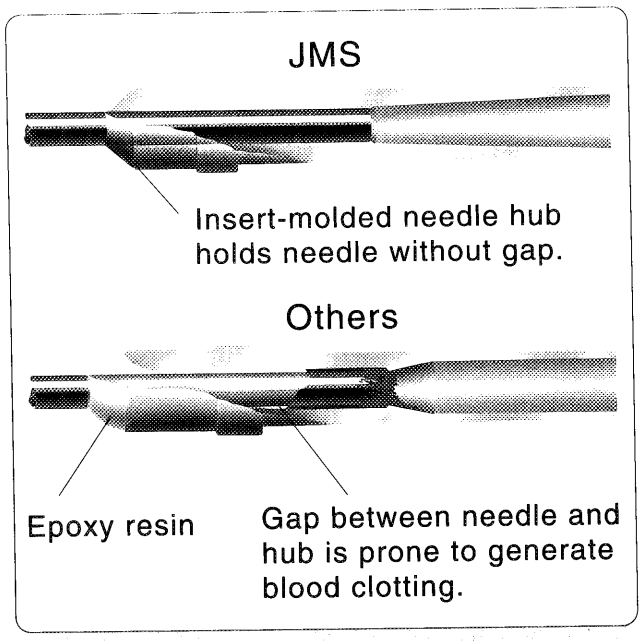
- Peel-to open blister package for proper sterile handling.
- Color coded and symbolized labeling on the shelf box.
- Choice of convenient dispenser opening on the side panel or fully opening top panel.



Other applications

JMS fistula needles are used mostly for arterio-venous fistula or graft in hemodialysis treatment, but are also widely used as blood access devices for other extracoporeal applications. Its laminar flow inner configuration without gap and siliconized inner lumen greatly reduce clot formation and damage to components. JMS needles are much appreciated for apheresis and automated blood components collection, where blood flow is low and higher quality of blood component are demanded.





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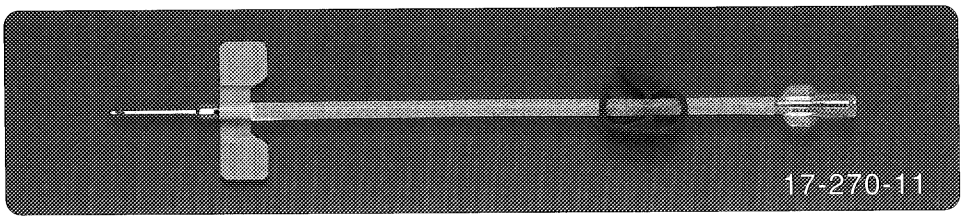
ROTATING HUB NEEDLE

Made in Japan

STERILE | R

Sterilized by gamma irradiation



Needle Size (Outer Diameter)	Needle Length	Tube Length 15cm (6")		Tube Length 30cm (12")	
		Arterial Back eye	Venous No back eye	Arterial Back eye	Venous No back eye
14G (2.10mm)	1" (25mm)	14-270-11	14-270-10	14-271-11	14-271-10
15G (1.83mm)	4/5" (20mm)	15-270-21	15-270-20	15-271-21	15-271-20
	1" (25mm)	15-270-11	15-270-10	15-271-11	15-271-10
16G (1.65mm)	4/5" (20mm)	16-270-21	16-270-20	16-271-21	16-271-20
	1" (25mm)	16-270-11	16-270-10	16-271-11	16-271-10
17G (1.47mm)	4/5" (20mm)	17-270-21	17-270-20	17-271-21	17-271-20
	1" (25mm)	17-270-11	17-270-10	17-271-11	17-271-10
18G (1.24mm)	4/5" (20mm)	18-270-21	18-270-20	18-271-21	18-271-20

Prefix 62 for JMS (Japan) product code (e.g. 62-14-270-11).
50 needles per dispenser. 10 dispensers (500 needles) per carton.

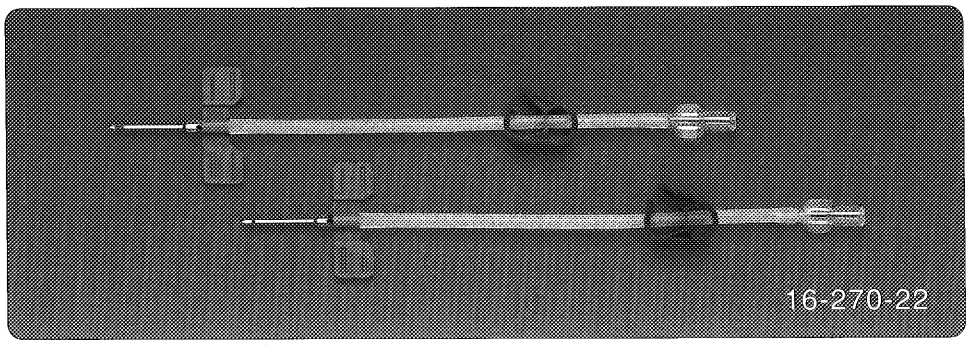
ROTATING HUB NEEDLE IN TWIN PACK

Made in Japan

STERILE | R

Sterilized by gamma irradiation

Arterial needle is with back eye and red clamp.
Venous needle is without back eye and blue clamp.



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Needle Size (Outer Diameter)	Needle Length	Tube Length 15cm (6")	Tube Length 30cm (12")
15G (1.83mm)	1" (25mm)	15-270-22	15-271-22
16G (1.65mm)	1" (25mm)	16-270-22	16-271-22
17G (1.47mm)	1" (25mm)	17-270-22	17-271-22

Prefix 62 for JMS (Japan) product code (e.g. 62-15-270-22).
One arterial and one venous needle in a pack. 40 packs per dispenser. 10 dispensers (400 packs) per carton.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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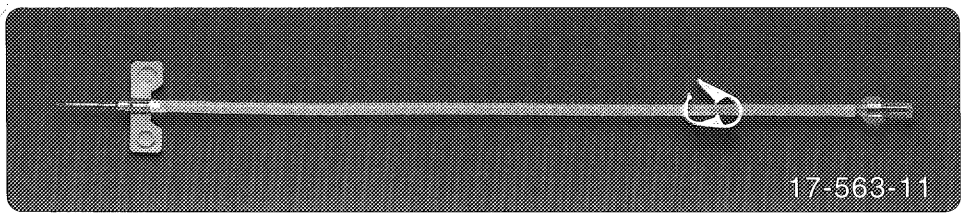
FIXED WING NEEDLE WITH CLAMP

Made in Japan

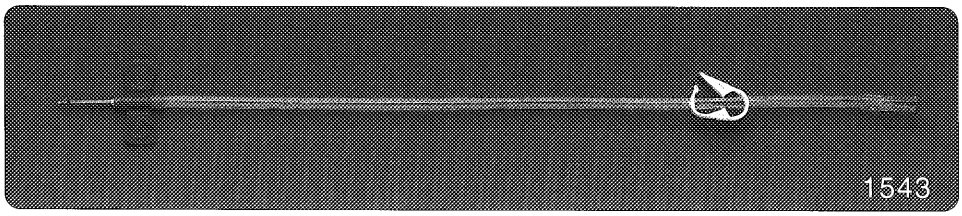
STERILE | R

Sterilized by gamma irradiation



Needle Size (Outer Diameter)	Needle Length	Tube Length 15cm (6")		Tube Length 30cm (12")	
		Arterial Back eye	Venous No back eye	Arterial Back eye	Venous No back eye
15G (1.83mm)	1" (25mm)	15-562-11	15-562-10	15-563-11	15-563-10
	11/4"(32mm)	15-572-11	15-572-10	15-573-11	15-573-10
16G (1.65mm)	1" (25mm)	16-562-11	16-562-10	16-563-11	16-563-10
	11/4"(32mm)	16-572-11	16-572-10	16-573-11	16-573-10
17G (1.47mm)	1" (25mm)	17-562-11	17-562-10	17-563-11	17-563-10
	11/4"(32mm)	17-572-11	17-572-10	17-573-11	17-573-10

Prefix 62 for JMS (Japan) product code (e.g. 62-15-562-11).
50 needles per dispenser. 10 dispensers (500 needles) per carton.



Made in Singapore

STERILE | EO

Sterilized by ethylene oxide gas

Needle Size (Outer Diameter)	Needle Length	Tube Length 15cm (6")		Tube Length 30cm (12")	
		Arterial Back eye	Venous No back eye	Arterial Back eye	Venous No back eye
14G (2.10mm)	1" (25mm)	—	—	1435	1436
	11/4"(32mm)	—	—	1437	1438
15G (1.83mm)	1" (25mm)	1541	1542	1543	1544
	11/4"(32mm)	1545	1546	1564	1565
16G (1.65mm)	1" (25mm)	1610	1611	1635	1636
	11/4"(32mm)	1654	1655	1676	1677
17G (1.47mm)	1" (25mm)	1743	1744	1745	1746
	11/4"(32mm)	1754	1755	1756	1757
18G (1.24mm)	1" (25mm)	—	—	1813	1814
	11/4"(32mm)	—	—	1815	1816

Prefix 820 for JMS (Singapore) product code (e.g. 820-1435).
50 needles per dispenser. 10 dispensers (500 needles) per carton.

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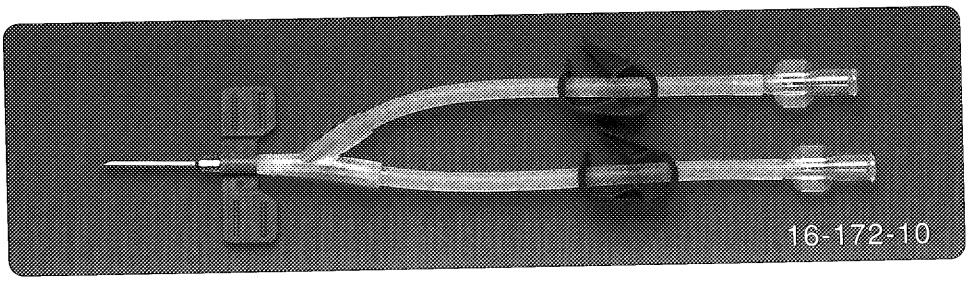
SINGLE NEEDLE SET

Made in Japan

STERILE | R

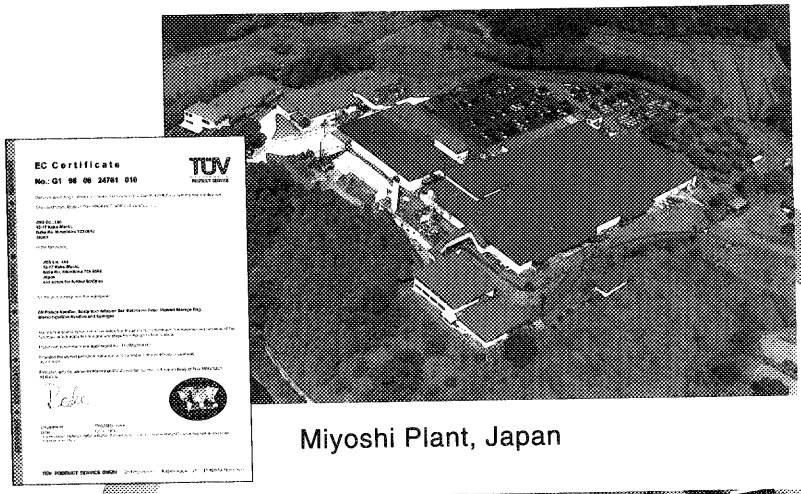
Sterilized by gamma irradiation

Needle with back eye. Rotating hub.
Two 11cm tubes with red and blue clamps.



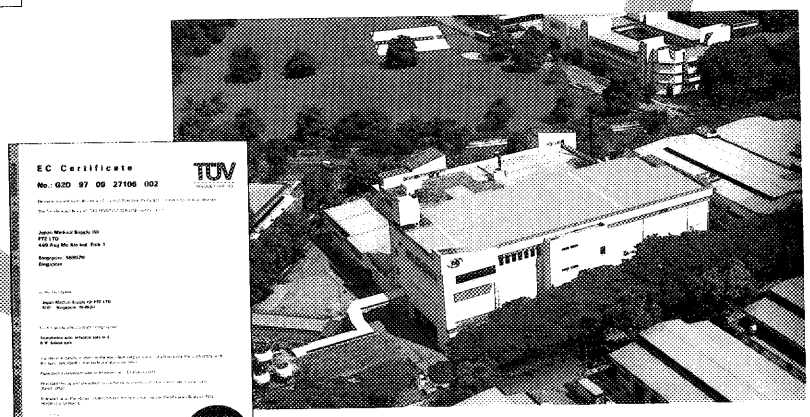
Needle Size (Outer Diameter)	Needle Length	Code No.
14G (2.10mm)	1" (25mm)	14-172-10
15G (1.83mm)	1" (25mm)	15-172-10
16G (1.65mm)	1" (25mm)	16-172-10
17G (1.47mm)	1" (25mm)	17-172-10

Prefix 62 for JMS (Japan) product code (e.g. 62-14-172-10).
50 needles per dispenser. 10 dispensers (500 needles) per carton.



Miyoshi Plant, Japan

JMS Fistula needles are manufactured at two locations, Singapore and Japan, to accomplish greater output and geograph convenience.
Cannulae, which are the most important component of fistula needles, are produced in-house at our Miyoshi plant for its through-production and also shipped for further assembly to our Singapore plant. These two plants combined together produce the world's largest output of fistula needles.



Singapore Plant

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CE 0123

CT-98-5-6015-K

Printed in Japan

JMS

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JAPAN MEDICAL SUPPLY (S) PTE. LTD.
440 Ang Mo Kio Industrial Park 1, Singapore 569620
Phone : +65-4571144 Fax : +65-4599564

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Attachment K

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FINAL PRODUCT INSPECTION

a) Appearance, Dimensional And Functional Inspection

(i) Appearance Inspection

S/N	Description	Reject Tolerance	Results
(b)(4) [redacted]			

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(ii) **Dimensional Inspection**

Item	Method	Specification	Result
(b)(4) [redacted]			

(iii) **Functional Inspection**

Item	Method	Specification	Result
(b)(4) [redacted]			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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b) **Biological Test**

Item	Method	Specification	Result
(b)(4) [redacted]			

c) **Microbiological Test**

Item	Method	Specification	Result
(b)(4) [redacted]			

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Attachment L

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STERILIZATION INFORMATION

Sterilization Method

(b)(4)

[redacted]

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STERILIZATION INFORMATION

(b)(4)

[redacted]

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STERILIZATION INFORMATION

(b)(4)

[redacted]

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(b)(4) testing

(b)(4) testing

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(b)(4) testing

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Attachment O

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INDICATION FOR USE

510(K) Number :

Device Name : Needle, Fistula

Indication for Use : Use for temporary cannulation for vascular access for extracorporeal blood treatment. This device is intended to single use only and is for temporary catheterization less than 30 days.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over- The -Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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510(K) STATEMENT

I certify that in my capacity as Manager, Corporate Quality Management of JMS CO., LTD., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20. 61.

(Signature of Certifier)

Tetsuharu Hirose
(Typed Name)

Feb. 12, 1999
(Date)

*(Premarket Notification 510(k) Number)

* For a new submission, do not fill in the 510(k) number blank. FDA will fill in this blank with your 510(k) number when the number is assigned.

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR 807. 87(j)]

I certify that in my capacity as Manager, Corporate Quality Management of JMS CO., LTD., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature of Certifier)

Tetsuharu Hirose
(Typed Name)

Feb. 12, 1999
(Date)

*(Premarket Notification 510(k) Number)

* For a new submission, do not fill in the 510(k) number blank. FDA will fill in this blank with your 510(k) number when the number is assigned.

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Attachment R

JAPAN MOHW Standard, NO.494
(Dialyzer type artificial kidney apparatus approval standard,
announcement No. 494, the Pharmaceutical Affairs Director,
the Ministry of Health and Welfare, June 20, 1983)

Reference - Atomic Adsorption Spectrophotometry in Japanese Pharmacopoeia
- Pyrogen Test in Japanese Pharmacopoeia

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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QUALITY AND TEST METHOD OF I.V. CATHETER FOR ARTIFICIAL KIDNEY

(Dialyzer type artificial kidney apparatus approval standard, announcement No. 494, the Pharmaceutical Affairs Director, the Ministry of Health and Welfare, June 20, 1983)

(TRANSLATED BY JAPAN MEDICAL SUPPLY CO., LTD.)

SPECIFICATION AND TEST METHOD

TEST METHOD	SPECIFICATION
1. Material	
a. Needle	SUS 304, 304L, 321
b. Synthetic resin	
i) Lead Take 2.0 g of synthetic resin and cut into minute pieces. Put them into platinum or quartz crucible, moisten them with 2 ml of sulfuric acid, heat gradually to dryness, incinerate by ignition between 450 and 500°C. In case of silicone rubber, take 2.0 g of rubber and cut into minute pieces, put them into a platinum crucible and add 2 ml of sulfuric acid and heat gradually. After discomposition, add 5 ml of hydrofluoric acid in order to discompose and volatilize silicic acid and heat to dryness. If silicic acid still retains, add one or two drops of hydrofluoric acid and heat to dryness again. Then incinerate by ignition between 450 and 500°C, if necessary, repeat this procedure. After cooling, moisten the residue with water and add 2 to 4 ml of hydrochloric acid. Then evaporate it to dryness on a water bath; furthermore, add 1 to 5 ml of hydrochloric acid and dissolve with gentle ignition. Add 0.5 to 1 ml of a mixture of citric acid solution (1→2) and hydrochloric acid (1:1) and 0.5 to 1 ml of warmed ammonium acetate solution (2→5). If any insoluble residue remains, filter through grass filter. To the solution obtained add 10 ml of ammonium citrate solution (1→4) and 2 drops of bromothymolblue test solution. Add ammonia test solution until the color of solution changes from yellow to green, and add 10 ml of ammonium sulfate solution (2→5) and water to make 100 ml; moreover, add 20 ml of sodium.	The absorbance of the sample solution is not more than that of standard solution. (not more than 1 μg/g)

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diethyldithiocarbamate solution (1→20) and mix. Allow to stand a few minutes, add 20 ml of methylisobuthylketone and shake vigorously. Allow to stand, separate the methylisobuthylketone layer from the solution, filter, if necessary, and use as the sample solution.
On the other hand, take 2.0 ml of Stamdard Lead Solution and add water to make 10 ml accurately. Take 1.0 ml of the solution and add 10 ml of ammonium citrate solution (1→4) and 2 drops of bromothymolblue test solution, proceed in the same manner as the sample solution, and use this solution as the standard solution.
Perform the tests according to Atomic Absorption Spectrophotometry in JP under the following conditions, using the sample solution and standard solution.

Gas:	Combustible gas	Acetylene or hydrogen
	Supporting gas	Air
Lamp:	Lead hollow-cathode lamp	
Wave length:	283.3 nm	

ii) Cadmium
To 2.0 ml of Standard Cadmium Solution add 10 ml of ammonium citrate solution (1→4) and 2 drops of bromothymol-blue test solution, and proceed as the sample solution directed under i), and use the solution, as the standard solution. Perform the tests according to Atomic Absorption Spectrophotometry in JP under the following conditions, using sample solution obtained in i) and the standard solution.

The absorbance of the sample solution is not more than that of standard solution. (not more than 1 μg/g)

Gas:	Combustible gas	Acetylene or hydrogen
	Supporting gas	Air
Lamp:	Cadmium hollow-cathode lamp	
Wave length:	283.3 nm	

2. Needle

a. Outer and Inner Surface

i) Outer Surface
Observe visually.
Free of unevenness or scrach

ii) Inner Surface
Observe visually.
Free of toxic oxide or dust

iii) Point
Observe visually.
Free of hook

iv) Internal Cleanliness
Extrude glycerine through cannula.
Free of discoloration of glycerine.

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b. Dimention

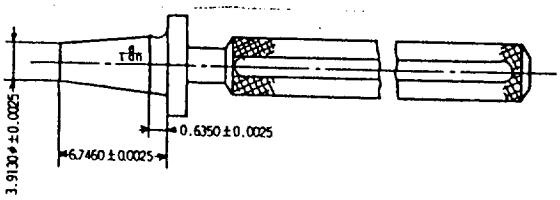
i) Outer Diameter (O.D.) of Cannula — Allowance +8 %, -3%

ii) Length of Cannula

Length (mm)	Allowance (%)
less than 20	±8
20-40	±7
40-60	±5
more than 60	±3

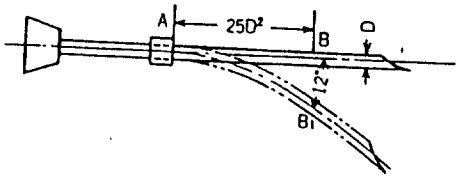
iii) Taper — Per JIS T-3101

Use a taper gauge.



c. Elasiticity (cannula O.D. does not exceed 1.0 mm). — Return to original shape

Fix cannula at the point A and press the point B to bent it at 12 degrees, and hold for 1 minute; as shown below.



d. Pull test — Needle must retain in hub during 1.5 Kg pull

3. Synthetic Resin Catheter

a. Strength of bending — No break.

Bind along 5 mm radius at 90 degrees.

b. Pull test — Catheter must retain in hub during 1.5 Kg pull.

4. Extractive Substances

Take the portion which is retained in body, cut into a piece about 2 cm in length. Place it in 100 ml of water cooled after boiling, extract at 50 ± 2°C for 24 hours. After cooling, transfer the solution, add water to make 100 ml, and proceed as the sample solution. Water cooled after boiling, as blank solution. Perform the following tests using sample solution and blank solution.

a. Appearance — Almost colorless and transparent. Free of foreign matter

Observe visually

b. Foam test — The form produced disappears within 3 minutes almost completely.

Place 5 ml of the sample solution in a glass-stoppered test tube of about 15 mm in inner diameter and 200 mm in length, and shake vigorously for 3 minutes.

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c. pH

To each 20 ml of the sample solution and the blank solution add 1.0 ml of potassium chloride solution, prepared by dissolving 1.0 g of potassium chloride in water to make 1,000 ml.

The difference of pH between the two solutions is not more than 1.5.

d. Zinc

To 10.0 ml of the sample solution add diluted dilute nitric acid (1→3) to make 20 ml , and use this solution as the test solution. Besides, to 1.0 ml of Standard Zinc Solution for Atomic Absorption Spectrophotometry, add diluted dilute nitric acid (1→3) to make exactly 20 ml, and use this solution as the standard solution. Perform the tests according to Atomic Absorption Spectrophotometry in JP, using these both solutions, under the following conditions.

The obsorbance of the sample solution is not more than that of the standard solution.

Gas:	Combustible gas	Acetylene
	Supporting gas	Air
Lamp:	Zinc hollow-cathode lamp	
Wave length:	213.9 nm	

e. Potassium permanganate-reducing substances

Measure 10.0 ml of the sample solution in a glass-stoppered Erlenmyer flask, add 20 ml of 0.01 N potassium permanganate solution and 1.0 ml of dilute sulfuric acid, and boil for 3 minutes. After cooling, add 0.10 g of potassium iodide, stopper, mix by shaking, then allow to stand for 10 minutes, and titrate with 0.01 N sodium thiosulfate (indicator: 5 drops of stareh test solution). Perform the blank test in the same manner, using 10.0 ml of the blank solution.

The difference in ml of 0.01 N potassium permanganate spent between both the tests is not more than 2.0 ml.

f. Residue on evaporation

Measure 20 ml of sample solution, evaporate to dryness on a water bath, and dry the residue at 105°C for 1 hour.

The weight of residue is not more than 1.0 mg.

5. Sterility Test

Perform sterility tests in JP, provided that all components must be disassembled. Cut tube and rubber stopper suitable length, and immerse them completely.

Pass

Test for	Medium	
	Type	Volume(ml)
Bacteria	Fluid thoglycollate Medium I	40
Fungi	Glucose-peptone Medium	40

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6. Biological Test

Take 5 pieces of product, sever between metalic part and synthetic resin part, and cut synthetic resin part into suitable length. Place them in a glass bottle, add 300 ml of saline, and extract at 70 ± 5°C for 24 hours. Allow to stand until solution temperature becomes room temperature, proceed as sample solution. Use saline as blank solution. Perform following tests using both sample solution and blank solution.

a. Acute systemic toxicity Use healthy male mice weighing 17 to 23 g and inject intravenously to groups of 10 mice 50 ml/Kg body weight of each solution.	No death for 5 days after injection
b. Intracutaneous test Use healthy 2 rabbits weighing more than 2.5 Kg, and inject intracutaneously 0.2 ml of TS at 10 sites on one side of each of 2 rabbits. Similarly, at 5 sites on the other side of each rabbit, inject 0.2 ml of the blank solution.	No erythema, eschar and edema for 72 hours after injection
c. Pyrogen test Perform the pyrogen test in JP.	Pass
d. Hemolysis test To 10 ml of sample solution add 0.1 ml of defibrinated blood of rabbit, allow to stand at 37°C for 24 hours. Besides, perform blank test in the same manner.	Negative
e. Implantation test This test is applied only synthetic resin which is retained in body. Prepare 8 sample strips by cutting the synthetic resin to the size of about 10 mm in length and 1 mm in width. Sterilize after rinsing with neutral detergent solution, water and Distilled Water for Injection successively. Prepare another 4 strips with negative control plastics for implantation test in the same manner. animals: Use 2 healthy male rabbits weighing not less than 2.5 Kg. Procedure: Insert each one test strip in a sterilized 15-gauge needles beforehand. Into the paravertebral muscles of one side of each of 2 rabbits, implant 4 strips of sample with stylet, placing the strips at the sites about 2.5 cm apart from each other and about 3.5 cm from the spinal column. In the same manner, implant 2 strips of control in the opposite side of each animal.	Keep the animals for a period of 72 hours after implantation, and sacrifice by anesthesia and then bleed. Examine the area of tissues surrounding the center portion of each implant strip macroscopically. Use magnifying glass if necessary. The tissues are free from changes such as hemorrhage or encapsulation as well as in the control, or the reaction is observed at less than 1 of 4 sites in each animal.

*) The test method of "Atomic Absorption Spectrophotometry in JP" and "Pyrogen test in JP" underlined in above is attached in next pages.

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Atomic Absorption Spectrophotometry

Atomic absorption spectrophotometry is a method to determine the amount or the concentration of an element in a sample specimen being examined, by utilizing the phenomenon that atoms being in the ground state absorb the light of specific wavelength, characteristic of the respective atom, when the light passes through an atomic vapor layer of the element to be determined.

Apparatus

Usually, the apparatus consists of a light source, a sample atomizer, a spectroscope, a photometer and a recording system. Some are equipped with a background compensation system. As a light source, usually a hollow cathode lamp specified for each element is used and sometimes a discharge lamp is also used. There are three types of sample atomizer: the flame type, the electrothermal type, and the cold-vapor type. The first one is composed of a burner and a gas-flow regulator, the second one is composed of an electric furnace and a power source, and the third one is composed of a mercury generator and an absorption cell. The third one is further classified into two subtypes, which differ in the atomizing method for mercury containing-compounds: one utilizes chemical reduction-vaporization and the other utilizes a thermal reduction-vaporization method.

For the selection of an appropriate analytical wavelength in a spectroscope, a grating for light diffraction or an interference filter can be used. A recording system is composed of a display and a recording device. A background compensation system is employed for the correction of atmospheric effects on the measuring system. Several principles can be utilized for background compensation, using continuous spectrum sources, the Zeeman splitted spectrum, the nonresonance spectrum, or self-inversion phenomena.

Procedure

Unless otherwise specified, proceed by any of the following methods.

(1) **Flame type**—Fit the specific light source to the lamp housing and switch on the instrument. After lighting the lamp and selecting the analytical wavelength specified in the monograph, set an appropriate electric current and slit-width. Next, a mixture of a combustible gas and a supporting gas is ignited and the gas flow rate and/or pressure should be adjusted to optimum conditions. The zero adjustment of the detecting system must be done through nebulizing the blank solvent into the flame. After setting up the measuring system, the sample solution prepared by the specified procedure is introduced into the flame and the light absorption at the characteristic wavelength of the element to be determined is measured.

(2) **Electrothermal type**—Fit the specific light source to the lamp housing and switch on the instrument. After lighting the lamp and selecting the analytical wavelength specified in the monograph, set an appropriate electric current and slit-width. Further, set an electric furnace to the appropriate temperature, electric current, and heating program, as directed separately in the monograph. When a suitable amount of sample is injected into the heated furnace with an appropriate stream of inert gas, the sample is dried and ashed, simultaneously with atomization of the metallic compound included in the specimen. The atomic absorption specified is observed and the intensity of absorption is measured. Details of the sample preparation method are provided separately in the monograph.

(3) **Cold vapor type**—Fit the mercury lamp to the lamp housing and switch on the instrument. After lighting the lamp and selecting the analytical wavelength specified in the monograph, set an appropriate electric current and a slit-width. In the chemical atomization-vaporization method, a mercury containing compound in the sample solution, prepared by the specified procedure, is chemically reduced to metallic mercury by adding a proper reducing reagent to the closed vessel and the generated mercury is vaporized and introduced into the absorption cell with a flow of inert gas. In the thermal atomization-vaporization method, the sample specimen on a quartz dish is heated electrically and the generated atomic mercury is vaporized and introduced into the absorption cell with a flow of inert gas. Thus, in both methods, the generated atomic mercury is carried into the absorption cell as cold vapor and the intensity of the characteristic atomic absorption of mercury is measured.

Determination

Usually, proceed by any of the following methods. In the determination, the possibility of interference for various reasons and the background effect must be considered and avoided if possible.

(1) Calibration curve method—Prepare standard solutions at more than 3 concentration levels, measure the specific absorption due to these standard solutions, and prepare the calibration curve of the atomic absorption against the concentration. Then measure the atomic absorption due to the sample specimen, in which the concentration of the element to be determined should be adjusted to be within the concentration range of the standard solutions, and determine the amount or the concentration of the element to be examined using the calibration curve.

(2) Standard addition method—To equal volumes of more than 3 sample solutions, prepared as directed in the monograph, add a measured quantity of the standard solutions to produce a series of solutions containing increasing amounts of the element to be examined, and further add a solvent to make up a constant volume. Measure the atomic absorption for the respective solutions, and plot the obtained values on a graph with the added amount or the concentration on the abscissa and the absorbance on the ordinate. Extrapolate the linear plot obtained by linking the data points, and determine the amount or the concentration of the element to be examined from the distance between the origin and the point where the plot intersects with the abscissa. This method is available only when the calibration curve obtained by Method (1) is confirmed to be linear and to pass through the origin.

(3) Internal standard method—Prepare a series of standard solutions of the element to be determined, each containing a definite amount of the internal standard element directed in the monograph. For these standard solutions, measure the atomic absorption due to the standard element and the internal standard element separately at the respective wavelengths under the same operating conditions, and obtain the ratio of absorbance by the standard element to that by the internal standard element. Prepare a calibration curve for the element to be determined, with the amount or the concentration of the standard element on the abscissa and the above-mentioned ratio of the absorbance on the ordinate. Then prepare sample solutions, adding the same amount of the internal standard element as contained in the standard solutions. Measure the ratio of the absorbance due to the element to be determined to that due to the internal standard element under the same conditions as employed for preparing the calibration curve, and determine the amount or the concentration of the element being examined by using the calibration curve.

Note: Reagents, test solutions, and gases used in this test should not interfere in any process of the measurement.

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Pyrogen Test

The Pyrogen Test is a method to test the existence of pyrogens by using rabbits.

Test animals

Use healthy mature rabbits each weighing not less than 1.5 kg which have not lost body weight when kept on a constant diet for not less than one week. Do not use the rabbits repeatedly in the same test unless as long a resting period as possible is taken. Animals should be excluded which have been used for a previous test that was decided as pyrogen-positive.

Record the rectal temperature four times at 2-hour intervals during 1 to 3 days prior to the test. House the animals individually during this period in an area free from disturbances likely to excite them, and exercise particular care to avoid disturbances on the day of the test.

Keep the temperature in an area of performing test uniform between 20°C and 27°C and preferably maintain constant humidity for at least 48 hours before the test.

Apparatus

(1) Thermometer—Use a rectal thermometer or any other temperature-recording devices of equal sensitivity for which the time necessary for reading the rectal temperature is known.

(2) Syringe and injection needle—Render the syinges and needles pyrogen-free by heating at 250°C for not less than 30 minutes.

Test procedures

(1) Quantity of injection—Unless otherwise specified, 10 mL of the sample per kg of body weight of the animals is used.

(2) Procedure—Perform the test at an environmental temperature similar to that of the room wherein the animals were housed. The test animals are usually fixed in a suitable type of holder. Insert the thermometer or other temperature-recording device into the rectum of the test animal to a constant depth in the range of 60 to 90 mm, and read the temperature after a sufficient period of time. Withhold food from the test animals beginning several hours before the first temperature recording and until the test is completed. Determine the temperature of the test animals three times at 1-hour intervals before the injection of the sample. When the second and third temperatures show little difference, the latter is taken as the "control temperature." Do not use animals whose second and third temperatures are not in accord or exceed 39.8°C even if these two values are similar. Warm the sample to 37°C before injection, and administer intravenously through an ear vein within 15 minutes after the third temperature recording. Hypotonic solution other than Water for Injection may be made isotonic by the addition of pyrogen-free sodium chloride before the test. Read the temperatures three times at 1-hour intervals after injection.

The difference between the control temperature and the highest temperature is taken to be the rise in body temperature.

Interpretation of results

The test is carried out on a group of three rabbits. If two or three rabbits show an individual rise of 0.6°C or more above the respective control temperature, the test shall be considered as positive. If only one animal shows a temperature rise of 0.6°C or more, or if the sum of the temperature rises of the three animals exceeds 1.4°C, repeat the test on a group of five other rabbits. The test shall be considered positive, if two or more of the five rabbits show an individual temperature rise of 0.6°C or more.

When the pyrogen test is positive, the sample is considered to be rejected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118