MAR - 6 1997

Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Premarket Approval of Millenium Medical Supply Incorporated
Needle-Ease™ 2501 - ACTION

The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

for Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Martha T. O'Lone, CDRH, HFZ-480, February 14, 1997, 443-8913

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

MILLENIUM MEDICAL SUPPLY INC.; PREMARKET APPROVAL OF NEEDLE-EASE™ 2501

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Louise N. Howe of the law firm HALE and DORR, as the U.S. Representative on behalf of Millenium Medical Supply Inc., Ontario, Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Needle-Ease™ 2501. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 6, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Dr. Chiu Lin,

Center for Devices and Radiological Health (HFZ-480),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-443-8913.

SUPPLEMENTARY INFORMATION: On December 6,, 1996, Louise N. Howe of the law firm HALE and DORR, as the US Representative on behalf of Millenium Medical Supply Inc., Ontario, Canada, N3T 5M1, submitted to CDRH an application for premarket approval of Needle-Ease™ 2501. This device is a sharps needle destruction device that is intended for home use by diabetics to reduce the incidence of needlesticks by the incineration of 28-30 gauge needles, 29 and 30 gauge diabetic "pen tips" and 23-26 gauge diabetic lancets.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the General Hospital and Personal Use Devices of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On March 6, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of

Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue

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to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Millenium Medical Supply Incorporated
C/O Ms. Louise N. Howe
HALE AND DORR
The Willard Office Building
1455 Pennsylvania Avenue North West
Washington, D.C. 20004

MAR 6 1997

Re: P960044
Needle-Ease™ 2501
Filed: December 6, 1996
Amended: February 3, 1997; February 14, 1997

Dear Ms. Howe:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Needle-Ease™ 2501. This device is a sharps needle destruction device that is intended for home use by diabetics to reduce the incidence of needlesticks by the incineration of 28-30 gauge needles, 29 and 30 gauge diabetic "pen tips" and 23-26 gauge diabetic lancets. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

FDA has determined that a preapproval GMP inspection will not be required. However, the device is still subject to the provisions of the GMP regulations (21 CFR Part 820) and will be subject to routine GMP inspections following approval.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

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You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

If you have any questions concerning this approval order, please contact Martha T. O'Lone at (301) 443-8913.

Sincerely yours,

for Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

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REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. **General Information**

Device Generic Name: Sharps Needle Destruction Device

Device Trade Name: Needle-Ease™ 2501

Applicant's Name and Address:

Millenium Medical Supply Inc.
408 Henry Street Suite 101
RR# 8 Brantford, Ontario
Canada N3T 5M1

Name and Address of Applicant's US Representative:

Ms. Louise N. Howe
C/O HALE AND DORR, L.L.P.
1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Premarket Approval Application (PMA) Number: P960044

Date of Notice of Approval to the Applicant: MAR - 6 1997

II. **Indications for Use**

Needle-Ease™ 2501 is a sharps needle destruction device that is intended for home use by diabetics to reduce the incidence of needlesticks by the incineration of 28-30 gauge needles, 29 and 30 gauge diabetic "pen tips" and 23-26 gauge diabetic lancets.

III. **Device Description**

Needle-Ease™ 2501 is a sharps needle destruction device that incinerates the 23 to 30 gauge sharps that diabetics use for injections/blood sampling by the delivery of a two volt, 2.5 amperage discharge from a two volt, 5 amp rechargeable battery across the width of the needle, between two 60/40 brass contacts. The Needle-Ease™ incinerates cross-sections of the needle from the tip to the hub as the needle is inserted vertically through the aperture on the top of the unit. The exterior surface is beige VO-94 flame retardant plastic with four rubber "feet" that secure it to a table top or other surface. The device dimensions are 5.25" x 2.5" x 2.25" and weighs slightly more than three pounds. The device has an aperture on top for needle or sharps insertion, a knob that protrudes from the top for the fuse access and a side port for a separate recharging unit to be adapted for recharging. The battery recharger is an EI-35

type recharger that meets UL and CSA specifications.

IV. Alternative Practices and Procedures

The home disposal of needles as practiced by diabetics is not subject to a structured or controlled methodology. The indications for use of sharps containers in the disposal of needles have been written for clinical settings. Local county or state regulations do not dictate the use of sharps containers for home use. Home disposal of sharps by diabetics may consist of dropping the needle and syringe in the trash or putting the needle and syringe in a bottle and then placing them in the trash.

V. Marketing History

Since 1995, the Needle-Ease™ 2501 has been marketed in Canada. In Canada, Millenium Medical Supply Inc. (Formerly known as At Point of Sale Enterprises Inc.) has sold approximately 750 units of various needle incineration models. Of these, 250 are the Needle-Ease ™ 2501 model. The needle incineration devices have not been withdrawn from marketing for any reason.

VI. Potential Adverse Effects of the Device on Health

The Needle-Ease ™ 2501 is a device that does not have direct patient contact when used as directed. The potential for electrical shock when the recharger is in use.

VII. Contraindications, Warnings, and Precautions

There are no contraindications or warnings to the use of this device.

Precautions: User precautions noted in attached labeling.

VIII. Summary of Studies

a. Non-clinical Studies

1. Test for Emission of Toxic Fumes: A test was conducted by CH2M Gore & Storrie Ltd. for determination of potential toxic fume emissions by this device. Their method utilized an impinger to collect the direct air exhaust of the device while incinerating needles. The background levels of the indoor air were then subtracted from the results of the direct air exhaust during incineration. This test measured concentrated emissions because the fumes would normally be dispersed in the air. The final data was expressed in micrograms/m^3 and found

to exhibit levels that for air concentration showed only Zn had a level greater than zero. The Zn level of 20 was well within the 5000 microgram/m^3 permissible exposure limit of the 1995-1996 American Conference of Governmental Industrial Hygienists. The levels of toxic fume emissions also were noted to be well below the levels found in a 1996 EPA sponsored study: "Personal Exposure to Airborne Particles and Metals".

2. Generation of heat: The temperature required to oxidize the iron in the needles is 3000° centigrade. Data demonstrated that the heat generated by the needle is confined to the contact points. Data was provided from UL and the Canadian Standards Association (CSA) that demonstrated that the electrical components used in and with the device had been subjected to the appropriate testing to assure protection from electrical shock and fire hazards.

3. Generation of noise: The data provided did not report excessive noise.

4. Formation of sparks: The data did support the lack of sparks when the appropriate gauge needles(28-30 gauge needles, 29-30 gauge diabetic "pen tips" and 23-26 gauge lancets) were incinerated. The potential of sparks with inappropriate gauge needles will be addressed in the labeling. Data from UL and CSA (Canadian Standards Association) demonstrated that the electrical components used in and with the device had been subjected to tests to assure protection from electrical shock and fire hazards.

5. Failure to completely destroy the needle: The device has the potential to fail to completely destroy the needle during the initial incineration. The result of failure to incinerate would require the home user to dispose of the needle by the current method, and should not impact the user.

6. Stability of the device: The data provided did not report problems with the ability of the device to stay in a level position during needle incineration.

7. Formation of infectious aerosols: Both B.stearothermophilus and S.marcescens were utilized in a study of possible aerosol contamination which resulted in a finding of "no growth".

8. Contamination of surrounding environment: The lack of aerosol contamination and toxic emissions from the incineration of the needles did not produce

contamination of the surrounding environment. The disposal of intact needles is recognized as a problem of medical waste management. There is no information to suggest that disposal of the incinerated needle ash would create further contamination of the environment.

b. Clinical studies:

A prospective questionnaire was sent to 52 current users as a means of obtaining clinical data for a device that is intended for home use. The information from the study of the Needle-Ease ™ 2501 users noted that the device was easy to use, incinerated the needles, did not produce electric shock, and did not generate excessive noise. Sparks were noted by two users without further incidence. A separate trial by the Canadian Diabetic Association noted successful incineration of 18,000 needles by this device without incidence of needlesticks.

IX. Conclusions Drawn from the Studies

The non-clinical studies demonstrated that this device does not contribute to environmental contamination either by aerosol of organisms or toxic fume emission, or by the generation of heat or excessive noise. The Needle-Ease ™ 2501 is a device that is designed for diabetics to incinerate their needles at home. Responses from the Clinical Survey showed that this device is easy to use, reduces needlesticks by the user, and is effective for destruction of needles. The Canadian Diabetics Association destruction of 18,000 needles did not report any problems with incineration of needles by this device. With the combination of these reports, there is sufficient information to establish a reasonable assurance of safety and effectiveness of the Needle-Ease ™ 2501 for home use by diabetics.

X. Panel Recommendations

Based on the regulatory discretion provided in section 515(c)(2)(A) of the Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the General Hospital and Personal Use Devices panel, an FDA advisory panel, for review and recommendation.

XI. CDRH Decision

FDA determined that a preapproval Good Manufacturing

Practices (GMP) inspection was not required. The device will still be subject to the provisions of the GMP regulations (21 CFR 820) including routine GMP inspections.

Based on the data submitted, CDRH approved the PMA for the stated indication.

CDRH has determined that, based on the data submitted in the PMA, there is reasonable assurance that the Needle-Ease ™ 2501 device is safe and effective for its intended use. CDRH issued an approval order on MAR - 6 1997.

XII. **Approval Specifications**

Directions for use: See the labeling

Warnings, Hazards to Health from Use of the Device: See Indications and Precautions in the labeling

Postapproval Requirements and Restrictions: See approval order

DEVICE DESCRIPTION
The Needle-Ease™ 2501 is a battery operated sharps destruction device and comes with a battery recharger.

INDICATIONS FOR USE

This device is intended for home use by diabetics to reduce the incidence of needlesticks by incineration of 28 to 30 gauge needles, 29 & 30 gauge diabetic pen tips and 23 to 26 gauge diabetic lancets.

PREPARATION FOR USE

The *Needle-Ease* 2501 is ready to use right out of the box.

USING THE *Needle-Ease* 2501.

1. Insert the needle straight into the opening on the top of the *Needle- Ease.*

2. Gently push the needle into the opening slight rotating action as the needle is being incinerated.

3. The disposal process should take 1 to 2 seconds. When the disposal process is complete, remove the syringe from the *Needle- Ease.*

4. The unit is now ready to dispose of the next needle.

GETTING THE BEST PERFORMANCE FROM YOUR *Needle-Ease* 2501.

The *Needle-Ease* has been designed to operate quickly and efficiently. There are a few important precautions listed below which should be followed always.

Precautions

1. ***Do not attempt to dispose of any item other than 28,29, and 30 Gauge Diabetic Needles, Diabetic Pens and Diabetic Lancets in the Needle -Ease 2501.***

2. ***Avoid spilling liquids of any kind into the Needle-Ease 2501.***

3. ***Do not attempt to gain access to the inside of the unit.***

4. ***Use of the device by children should be under adult supervision.***

THIS MACHINE IS DESIGNED FOR DISPOSAL OF 28, 29, and 30 Gauge DIABETIC NEEDLES, DIABETIC PENS and DIABETIC LANCETS

***ONLY*.**

TROUBLE SHOOTING

Should a needle become jammed or stuck in the unit during the disposal process ..

While rotating the needle pull it straight out of the *Needle-Ease* giving it a slight twist as you are removing it. This should free the needle.

If a needle fails to incinerate completely or properly, dispose of it using your former method.

Should your *Needle-Ease* fail to perform, it may need to be recharged. Should recharging not correct the situation contact your retailer or call 1-800-387-4190

In rare instances sparks may occur during use. If excessive sparks occur, discontinue use and call 1-800-387-4190.

THE FUSE

On the top of the *Needle-Ease* 2501 there is a small black knob. It contains a fuse which is designed to protect the recharger. The cover comes off with a twist of the finger and thumb by pressing down slightly and twisting to the left. If the fuse contained within the fuseholder has a broken wire inside, replace it with a 2 Amp fast blow fuse.

CLEANING THE 2501

The *Needle-Ease* 2501 can be cleaned on the outside using alcohol and a soft cloth. The contact points can be cleaned using a cotton swab and alcohol. The ash from inside can be cleaned out by turning the 2501 upside down over a refuse container and shaking it gently

RECHARGING THE BATTERY

The *Needle-Ease* 2501 should dispose of 100 to 200 needles before it needs to be recharged.
Recharging the battery is a simple matter. Just plug in the recharger first to the *Needle- Ease* and then to the wall outlet. Allow the unit to charge overnight.

5. THE DEVICE HAS A POTENTIAL FOR SPARKING WHEN INCORRECT SIZE OR GAUGE OF NEEDLES ARE INCINERATED.
6. DO NOT ATTEMPT TO DISPOSE OF NEEDLES WHILE CHARGING THE UNIT. THIS MAY DAMAGE THE UNIT