
Sealed Source and Device Design Safety Testing

Technical Report on the Findings of Task 4

Investigation of a Failed Brachytherapy Needle Applicator

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Prepared by
S. J. Lukezich

MASTER

Southwest Research Institute
6220 Culebra Road
San Antonio, TX 78238-5166

T. H. Tiktinsky, NRC Project Manager


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ABSTRACT

As a result of an incident in which a radioactive brachytherapy treatment source was temporarily unable to be retracted, an analysis was performed on the needle applicator used during the treatment. In this report, the results of laboratory evaluations of the physical, mechanical, and metallurgical condition of the subject applicator and two additional applicators are presented.

A kink formed in the subject applicator during the incident. The laboratory investigation focused on identifying characteristics which would increase the susceptibility of an applicator to form a kink when subjected to bending loads. The results obtained during this investigation could not conclusively identify the cause of the kink. The subject applicator exhibited no unique features which would have made it particularly susceptible to forming a kink. The three applicators examined represent two methods of manufacturing. A number of characteristics inherent to the method used to manufacture the subject applicator which could lead to an increased susceptibility to the formation of a kink were observed. The use of an insertion device, such as the biopsy needle used during this incident, could also dramatically increase the likelihood of the formation of a kink if the applicator is subjected to bending loads.

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EXECUTIVE SUMMARY

This study was conducted in response to an incident which occurred at Medical Center Keesler in which a brachytherapy source was unable to be retracted at the completion of a treatment. Upon removal of the needle applicator from the patient during the incident, it was observed that the needle had formed a "kink". It was believed that the kink was responsible for the difficulty encountered in retracting the source.

The objective of this study was to determine if unique or inherent features of the needle applicator contributed to the formation of the kink. Of particular interest was a determination of whether the exposure to radiation during sterilization, or during the brachytherapy treatment, had embrittled the stainless steel alloy used in the needle. Three applicators were evaluated, including, 1) Subject Applicator (the applicator involved in the incident), 2) Unused Applicator (an applicator which had been gamma radiation sterilized in the same manner as the Subject Applicator, but never used for a treatment), and 3) Raw Applicator (a needle applicator which had not been intentionally exposed to any radiation).

Due to the supply of needles available from the brachytherapy equipment manufacturer, the Raw Applicator was from a different lot of needles than the other two specimens and had been manufactured using different processing steps. As a result, the physical characteristics of the Raw Applicator varied from the other two needles. The significant physical differences resulting from the two manufacturing processes are documented in this report.

No damage or other unique features of the Subject Applicator which may have detrimentally affected the resistance to forming a kink were observed. In particular, no evidence of embrittlement of the needles which had been exposed to radiation was detected. However, a number of differences were observed between the physical characteristics of the needles depending on the manufacturing processes used. The Subject and Unused Applicators had an irregular, relatively rough ID surface finish, and a pattern of finely spaced, shallow, circumferential scratches were present on the OD surface. Both of these features are expected to detrimentally impact the resistance of a needle to forming a kink when subjected to a bending load. The degree to which these features may have contributed to the kink which formed during the incident was not determined.

In addition to the physical and mechanical characteristics of the needles, the procedures used during the brachytherapy treatment were also reviewed. A biopsy needle was used as an insertion device to assist in positioning the needle applicator. It is likely that this led to the creation of a "hinge affect" for the needle applicator which would have localized any bending stresses experienced. Caution should be exercised when using insertion devices, such as a biopsy needle, to avoid the creation of undesirable sites of stress concentration.

The exact cause of the kink which formed in the needle applicator during the incident could not be conclusively identified from the results of this study. A number of contributing factors, including both physical characteristics of the needle and the procedures employed during the treatment, were identified. Since the level of bending stress generated by the movement of the patient which occurred during the treatment is unknown, it is not clear if elimination of any of these contributing factors could have prevented the incident.

INTRODUCTION

Background Information

The Nuclear Regulatory Commission (NRC) is responsible for investigation of incidents in which the public either was, or potentially could have been inadvertently exposed to levels of radiation which could be hazardous to human health. The jurisdiction of the NRC encompasses many fields in which radioactive sources are used, including the field of medicine.

In the Spring of 1994 an incident occurred at USAF Medical Center Keesler in which a radioactive source used to treat cancerous tumors, a procedure known as brachytherapy treatment, was unable to be retracted by the afterloader device to its storage chamber immediately after the completion of a treatment period. Steps were taken at the time of the incident to minimize the radiation exposure to the patient, and to prevent radiation exposure to the other Medical Center staff. The incident came to a conclusion when, without further direct intervention by the Medical Center staff, the afterloader device resumed operation and was able to retract the source into the storage chamber.

An investigation of the site and equipment, and interviews with the Medical Center staff involved with the incident, conducted by representatives of the NRC, raised questions concerning the physical and metallurgical condition of the needle applicators used during the brachytherapy treatment. It was subsequently decided by the NRC that the needle applicators involved with the incident should be subjected to a metallurgical analysis by a qualified third-party organization.

Program Objective

Southwest Research Institute (SwRI) was contracted to perform a metallurgical analysis of the needle applicator involved in the incident at Medical Center Keesler, as well as a number of other similar needle applicators. The results of the examination by the NRC of the needles involved in the incident indicated that a kink had formed in the needle applicator used during the treatment. The presence of the kink is believed to have contributed to the inability of the source to be retracted at the completion of the treatment. The specific goals of the analysis performed by SwRI were:

1. Determine if there were any unique physical features of the needle applicator involved in the incident which would have made it more susceptible to the formation of the kink than other needles of similar design.
2. Determine if there are inherent physical features in the design of the needle applicators which would make them particularly susceptible to the formation of a kink.

3. Determine if the mechanical properties of the needle applicators are adversely affected by the exposures to radiation. The needle applicators are subjected to radiation during manufacture, for sterilization purposes, and during the brachytherapy treatment.

Scope of Work

The scope of work conducted by SwRI included discussions with pertinent representatives of the NRC and the staff at USAF Medical Center Keesler to obtain an understanding of the procedures used and the physical conditions (positioning of the needles) which existed during the treatment at the time of the incident. A description of the damage sustained by the needle applicator during the incident, as opposed to that inflicted during subsequent examinations was also obtained.

Three needle applicators, the applicator involved with the incident, an applicator which had been sterilized but never used, and an applicator which had not yet been sterilized, were subjected to the following laboratory analyses:

- Optical microscopic examination
- Scanning electron microscopic examination
- Chemical analysis
- Microstructural analysis
- Dimensional analysis
- Hardness testing

In addition, a biopsy needle used as an insertion device during the incident was also subjected to the microscopic examinations.

By comparison of the characteristics of the three applicators, features unique to the subject applicator or inherent in the general design which may increase the susceptibility of the applicators to the formation of a kink could be identified. Changes in the mechanical properties of the needle applicator material as a result of the exposures to radiation could also be identified.

1.0 BACKGROUND

This report is a summary of the significant findings of a study performed on a series of needle applicators which are used during a medical procedure called brachytherapy. In a recent incident at USAF Medical Center Keesler (described in more detail below), difficulty was experienced in retracting the radiation source at the completion of a treatment. After an emergency withdrawal of the needles and sourcewire, it was observed that the needle applicator had suffered a bending collapse (kink). The objective of this study was to examine the needle involved in the incident, and compare it to other unused needles to determine if there were any unique features of the failed needle or inherent features of the needles in general, which may have contributed to the formation of the kink. The needle applicators are exposed to radiation during sterilization as well as during the brachytherapy treatment. A specific objective of this study was to determine if the radiation exposures to which the needle applicators are subjected had any affect on the susceptibility of the needle to forming a kink.

1.1 Brachytherapy Treatment

Brachytherapy treatment is a procedure which involves the insertion of a gamma-radiation source into a patient's body to provide direct radiation treatment to a cancerous tumor. The radiation source (Ir-192 is used by this manufacturer) is sealed in the tip of a wire, called the active sourcewire. Positioning of the source is performed by insertion of a closed end needle, called the needle applicator, into the appropriate position in the tumor, and then extending the active sourcewire through the needle applicator to that site. At the completion of the treatment, the sourcewire is retracted and stored. Storage, extension, and retraction of the active sourcewire is performed by an afterloader device, which is attached to the needle applicator by a catheter. An example of the needle applicator and catheter is shown in Figure 1-1a.

Standard procedure for performing a brachytherapy treatment involves insertion of the needle applicator, followed by the extension and retraction of a dummy sourcewire. The dummy sourcewire has the same dimensions as the active sourcewire, and is mounted in the afterloader device in the same manner as the active sourcewire. Prior to initiating the radiation treatment, the dummy sourcewire is extended to the treatment site and retracted to verify the integrity of the catheter connections and the sourcewire path. Once it is determined that the connections and sourcewire path are clear, the dummy sourcewire is removed from the needle applicator and the active sourcewire extended to the proper position to begin the treatment.

1.2 The Incident

The description of the incident which follows is a summary of discussions between staff members at Southwest Research Institute and the attending physician for the patient involved in the incident at USAF Medical Center Keesler. The tumor to be treated was located near the lung of the patient, and a 21 gage needle applicator was selected for the treatment. This is the thinnest needle applicator offered, and is specifically intended for

treatment of lung tumors since it minimizes the trauma and subsequent internal bleeding which can result from insertion of the needle. Internal bleeding caused by the insertion of needle applicators has been known to cause complications, particularly when treating tumors in the area of the lungs.

During the preparation for the treatment, the thin gauge needle applicator was unable to be properly positioned in the tumor. To assist in positioning of the needle applicator, a 19 gage open ended biopsy needle, which is much stiffer than the 21 gage needle applicator, was inserted into the tumor. The decision to use the biopsy needle as an insertion device was made by personnel at Medical Center Keesler. The needle applicator was then inserted through the biopsy needle. Once the needle applicator was in place, the biopsy needle was retracted approximately 4.7 cm to extract it from the tumor so it would not shield the radiation source. As recommended by the brachytherapy equipment manufacturer, a tungsten obturator wire was in place in the needle applicator, as a support, during the entire insertion procedure. Inspection of the needle applicator installation using the dummy sourcewire, prior to beginning the radiation treatment, indicated an unobstructed path. The installation was determined to be satisfactory.

The treatment schedule for the patient involved in the incident called for an 8:35 minute radiation exposure. The active sourcewire was extended to the end of the needle applicator and held for 145.7 seconds. The source was then retracted one centimeter and held for another 66.9 seconds. The procedure of retracting the source in one centimeter increments and holding for a specified time was repeated until a total of 8:35 minutes of exposure was achieved. The last treatment location was a position with the source wire retracted 4 cm from the tip of the needle applicator. The treatment progressed as planned through the fourth position of exposure, with the source located at a position 3 cm from the tip of the needle applicator. The source was retracted to a position 4 cm from the tip with no problems. During the fifth and final position of treatment, the patient, who had apparently fallen asleep during the procedure, awoke and twitched as though startled. Being temporarily disoriented, the patient began to turn his head (the patient was face down on the gurney) in an attempt to determine where he was. Observing the patient attempting to move, the personnel administering the treatment instructed the patient to be still for a while longer. After receiving those instructions, the patient reportedly stopped moving.

At the completion of the treatment at the fifth position, the afterloader attempted to retract the source wire to the shielded position and thereby terminate the treatment. To prevent failure of the sourcewire, the afterloader device measures the load required to retract the wire, and if excessive forces are required, the device ceases the attempt to retract the source and alarms are activated. As the afterloader attempted to retract the source from the patient, the load limit was reached. As it was designed to do, the afterloader ceased pulling on the sourcewire and the appropriate alarms were activated. To prevent overexposure of the patient to radiation, the attending staff made a decision to extract the entire needle assembly so the patient could be removed to a safe location away from the radiation source. That step was taken, and the treatment room evacuated and closed off until such time as the radiation danger could be assessed and proper corrective actions taken. Upon clearing the treatment room and turning attention back to the status of the

radiation source, it was observed that the afterloader was now successfully retracting, and the source wire was returned to a safe position in its shield. Inspection of the needle applicator after the incident revealed the presence of a bend or kink in the needle. The as-received condition of the needle assembly, including the needle applicator and the biopsy needle, is shown in Figure 1-1.

Based on the fact that the sourcewire was able to be retracted to the final treatment position only a short period of time (on the order of one minute), before the unsuccessful attempt to retract completely, and that unusual patient motion had occurred in the interim, it has been proposed that the patient motion caused a bending load to be applied to the needle applicator, creating the kink, and that led to the inability to retract the source wire. Subsequent examinations by representatives of the NRC have raised questions about the flexibility/ductility of the type 304 stainless steel needle applicators, and how the sterilization techniques used and the exposure to gamma radiation during a treatment may affect those properties.

1.3 Specimens

During this study, the following specimens were evaluated:

1.3.1 Subject Applicator

This is the 21 gage, 20 cm long closed end needle that was involved in the incident. This needle was supplied by Medical Center Keesler. The condition of this needle as it was received at SwRI is shown in Figure 1-1. The needle had been broken at a location approximately 1.7 cm from the tip. It was reported that this break, and the majority of the damage (kinks) visible in Figure 1-1, occurred during an evaluation of the needle applicator after the incident by representatives of the NRC, and are not related to the incident. Of the damage visually observable only Kink #3, at a location approximately 4 cm from the tip of the needle, was reported to be present immediately after the needle had been removed from the patient.

This needle is reportedly made from Type 304 stainless steel, and was sterilized by the manufacturer using gamma radiation. It has also been exposed to additional radiation during the treatment of the patient.

1.3.2 Unused Applicator

This is a 21 gage, 20 cm long closed end needle essentially identical to the Subject Applicator, except that it has never been used. This needle was supplied from the stock of needles at Medical Center Keesler. It had been sterilized by the manufacturer with gamma radiation using the same procedures as were used on the Subject Applicator. It has not intentionally been exposed to any additional radiation.

The results of the analysis of this needle will be compared to the results from the Subject Applicator to determine if any unusual mechanical features which may have increased the susceptibility of the Subject Applicator to kinking are present. Degradation of mechanical properties of the Type 304 stainless steel due to the radiation exposure during the treatment will also be able to be determined by this comparison.

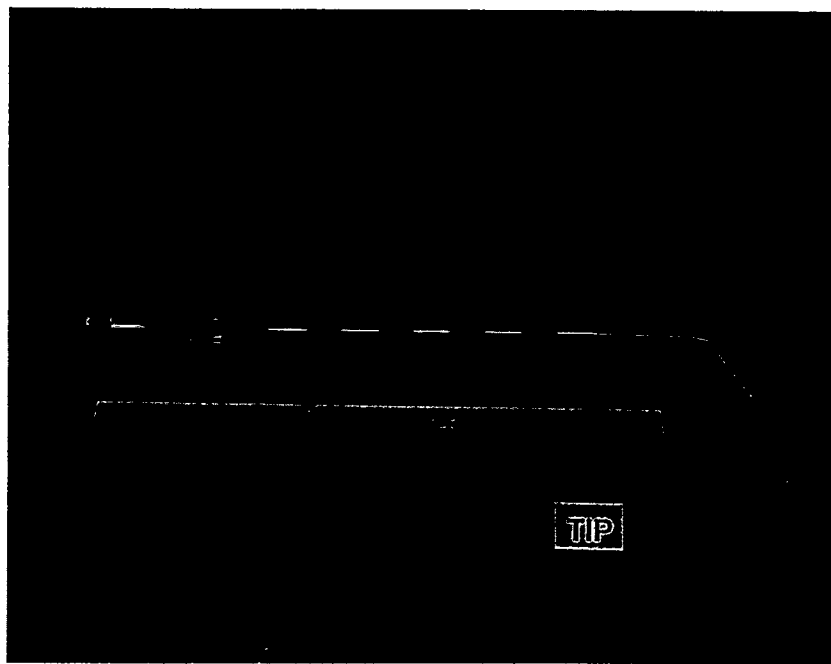
1.3.3 Raw Applicator

This is a 21 gage, 20 cm long closed end needle reportedly identical to the Subject and Unused Applicators, except that it has not been sterilized by any technique. This needle was supplied by the manufacturer of the brachytherapy equipment, from a new lot of needles, and has not intentionally been exposed to any radiation.

The physical characteristics of the Raw Applicator will be compared to the other two applicators. Degradation of the mechanical properties of the stainless steel due to the radiation exposure during sterilization will be able to be determined from this comparison.

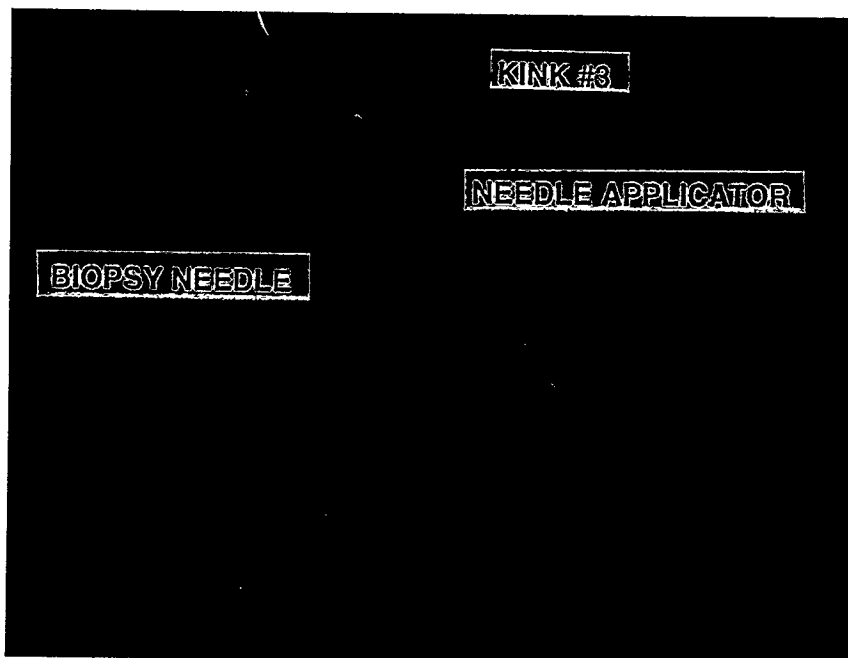
1.3.4 Biopsy Needle

This is a 19 gage, 10 cm long open ended needle. It was inserted into the tumor as a guide for the Subject Applicator during preparation for the brachytherapy treatment. During the treatment, the Subject Applicator extended beyond the end of the Biopsy Needle by approximately 4.7 cm. Due to the differences in stiffness between the two needles, the end of the biopsy needle could act as a hinge point against which the needle applicator could be bent. The open end of the biopsy needle was inspected to determine if any physical features were present which may have promoted the formation of a kink in the Subject Applicator at the point where it contacted the biopsy needle.



66730

(a)



66733

3-3/4X

(b)

Figure 1-1. As-Received Brachytherapy Needle Assembly. Consists of the needle applicator, biopsy needle, and associated fittings and catheter. A higher magnification of the needle applicator extending past the end of the biopsy needle is shown in (b).

2.0 LABORATORY EVALUATION — RESULTS AND DISCUSSION

2.1 Surface Examination

The physical condition of the needle specimens was examined using optical and scanning electron microscopy (SEM). The examination of the Biopsy Needle was limited to the open (outlet) end of the needle. The OD surfaces of the needle applicators were examined over their full length using an optical binocular microscope at magnifications of up to 40X. The OD surface and the ID surface of segments taken from the tip, 4 cm from the tip, and 15 cm from the tip from each of the needle applicators were examined using the SEM. The SEM provides the capability of examination of the needle surfaces at magnifications of many thousands of times. To expose the ID surface, specimens were mounted in wax, and a side of the needle ground off using a disc grinder. Once a sufficient opening was formed in the wall, the specimens were cleaned in acetone to remove the wax.

2.1.1 Optical Microscopic Examination

2.1.1.1 Subject Applicator

The condition of the OD surface of the Subject Applicator was very consistent over the entire length of the needle. It had a satiny finish which appeared to be a result of a high density of shallow circumferential scratches. There were a number of larger, isolated, longitudinally or nearly longitudinally oriented scratches, randomly located over the length of the needle, as well as spirally oriented scratches located at approximately 5-7 cm from the tip. All of these scratches appeared to be relatively shallow. Some slightly deeper, randomly oriented scratches were observed at the tip of the needle, and were most likely a result of grinding associated with forming the tip.

In addition to these surface scratches, six sites of significant damage were observed. These sites are identified below and in Figure 2-1.

- Kink #1 - Located 9 mm from the tip.
- Break - Located 17 mm from the tip.
- Kink #2 - Located 24.6 mm from the tip.
- Kink #3 - Located 38.5 mm from the tip.
- Kink #4 - Located 43.4 mm from the tip.
- Kink #5 - Located 45.3 mm from the tip.

Of these damage features, Kink #3 is the only one reported to have been present immediately following the emergency extraction of the needle assembly. The remainder of the damage, including the break at the 17 mm location, is believed to have been inflicted during an examination of the needle after the incident. The ease with which the needle could be broken during this post-incident examination led to questions concerning the ductility of the stainless steel material used in the needles.

2.1.1.2 Unused Applicator

The condition of the OD surface of the Unused Applicator was essentially identical to that of the Subject Applicator. The condition was uniform over the entire length of the needle. The finish was satiny as a result of the finely spaced shallow circumferential scratches, and a number of more longitudinally oriented but shallow scratches were also observed. Shallow, spiralling scratches were again present between 5 and 6 cm from the tip of the needle. No kinks were present in the Unused Applicator. Grinding marks at the tip of the needle were again observed.

2.1.1.3 Raw Applicator

The condition of the OD surface of the Raw Applicator was uniform over the entire length of the needle, but was different than the Subject and Unused Applicators. The grinding at the tip of this needle was deeper and more distinct than on the previous two applicators. The body of the remainder of the needle was more polished in appearance, and marred only by a relatively widely spaced series of shallow, randomly oriented scratches. No evidence of the circumferential pattern of scratches which caused the Subject and Unused Applicators to have a satiny appearance were observed. No other distinctive features were present.

2.1.1.4 Biopsy Needle

The open end of the Biopsy Needle through which the end of the Subject Applicator extended during the treatment of the patient was also examined. This end of the needle was very clean, and no damage or surface scratching were observed.

2.1.2 Scanning Electron Microscopic (SEM) Examination

2.1.2.1 Subject Applicator

The condition of the OD surface at the tip of the Subject Applicator is shown in Figure 2-2. The circumferential scratches observed during the examination with the optical microscope can be seen clearly at these higher magnifications. Even at 200X, the scratches are seen to be relatively shallow and somewhat regularly spaced. A few longitudinally oriented very shallow scratches are also present. Surface discontinuities such as these are consistent with a surface which has been ground.

A similar examination of the OD surface of this needle at locations approximately 4 cm and 15 cm from the tip of the needle reveals a nearly identical surface condition (Figures 2-3 and 2-4). The specimen from 4 cm from the tip of the needle, shown in Figure 2-3, corresponds to the underside of Kink #3, the only kink reportedly present at the time of the incident. The needle was broken at that location in the laboratory by reverse bending, and the surface features at the exact location of the kink were examined at higher magnifications (Figure 2-5). No significant discontinuity which may have contributed to the formation of a kink was observed. Small surface dents, and limited evidence of

longitudinal scuffing can be seen (locations A and B in Figure 2-5). These features may be a result of impingement of the needle applicator against the edge of the biopsy needle in response to a bending moment being applied across the needles.

A potentially detrimental consequence of the circumferential scratches attributed to a grinding operation can be seen in Figure 2-5c. If the needle was loaded in bending, these scratches could act as stress concentration points potentially increasing the likelihood of forming either a kink, or as evidenced by the secondary cracking (arrows in Figure 2-5c) of initiating a fracture of the needle.

The condition of the ID surfaces of the Subject Applicator was somewhat unusual, although consistent over the entire length of the needle. Typical examples of the ID surface are shown in Figures 2-6 and 2-7. As opposed to the ground appearance of the OD surface, the ID surface was rugged and very irregular, similar to the bottom of a creek bed. Such an appearance is often associated with a rapidly solidified or recast surface, and is typical of a surface which has been electrodischarge machined (EDM). In discussions with the manufacturer of the brachytherapy equipment it was learned that they purchase these needles as standard hypodermic needle tubing and the manufacturing process used are predominantly left to the manufacturer. It was not clear why such a finish is present on the ID surface.

2.1.2.2 Unused Applicator

The condition of the OD surface at the tip of the Unused Applicator is shown in Figure 2-8. The condition of the tip of this needle is very similar to that of the Subject Applicator except for several isolated deeper scratches. The depth of the worst scratches was determined during the microstructural examination (discussed in Section 2.3.1) and found to be approximately 0.00015" deep which corresponds to 10% of the wall thickness at this location. These scratches are not expected to be detrimental to the performance of the needle. In addition to the deeper scratches, closely spaced very shallow circumferential scratches were again present, a feature which is consistent with a surface that has been ground.

The condition of the OD surface at locations 4 cm and 15 cm from the tip of the needle is shown in Figures 2-9 and 2-10. These two locations are essentially identical to each other, and to the comparable locations on the Subject Applicator. The surface is predominantly covered with an array of finely spaced, very shallow, circumferential scratches. Several isolated, somewhat deeper longitudinally oriented scratches were also observed. These longitudinal scratches are not expected to detrimentally affect the performance of the needle. The circumferential scratches, as was shown on the Subject Applicator, may act as areas of stress concentration for the initiation of either cracks or kinks if the needle is subjected to high levels of bending stress.

The condition of the ID surface of the Unused Applicator at the tip, and 4 cm and 15 cm from the tip of the needle are shown in Figures 2-11 through 2-13. The ID surface of this needle was identical to that of the Subject Applicator, exhibiting an irregular recast

appearance. This appearance is typical of a surface which has been electrodischarge machined.

The similarity in the condition of the OD and ID surfaces of the Subject and Unused Applicators was expected since both needles were from the same production lot, and therefore were manufactured from the same heat of steel and using the same fabrication techniques.

2.1.2.3 Raw Applicator

The condition of the OD surface near the tip of the Raw Applicator differed substantially from the previous two needles (Figure 2-14). The tip appeared to have been more heavily ground, and bands of circumferentially oriented grinding marks are present. Scattered scratches oriented either longitudinally or at approximately a 45° angle from the axis of the needle were also observed. These scratches had a depth similar to that of the circumferential grinding marks. The deepest grinding extends for a distance of 2 mm or less, and the lighter grinding of the tip is present over a distance of approximately 7 mm.

Beyond the first 7 mm from the tip, the OD surface condition of the needle is very consistent. As can be seen on the specimens from locations 4 cm and 15 cm from the tip (Figures 2-15 and 2-16), the OD surface is more polished than either the Subject or Unused Applicators. The majority of the surface is covered with fine longitudinally oriented scratches, combined with isolated but deeper, randomly oriented scratches. This surface condition is consistent with a tube that has been drawn through a polished external die.

The condition of the ID surfaces of the Raw Applicator were also very different from the ID surfaces of the Subject and Unused Applicators. Unlike the irregular recast appearance observed on the previous two needles, the ID surface of the Raw Applicator consisted of an array of finely spaced, shallow, longitudinal scratches (Figures 2-17 through 2-19). This type of surface finish is consistent with a tube which has been drawn over an internal mandrel.

The Raw Applicator which was examined during this program was only recently manufactured, and is from a different lot of needles than the Subject and Unused Applicators. It is SwRI's understanding that these needles are specified using dimensional and alloy criteria only, leaving the fabrication techniques to the discretion of the needle manufacturer. Based on the microscopic examinations of the surfaces of the needles, it is apparent that the fabrication techniques used for the two lots of needles were significantly different. Of the differences in the surface finish which resulted, the most significant is most likely the elimination of the circumferential external grinding of the entire length of the needle. As had been shown on the Subject Applicator, the circumferential scratches which resulted from this operation could act as stress concentrators which may adversely affect the resistance of the needle to fracture or kinking when subjected to high levels of bending stress.

2.1.2.4 Biopsy Needle

The open end of the biopsy needle, through which 4-5 cm of the tip of the Subject Applicator extended during the brachytherapy treatment, was examined in the SEM. As can be seen in Figure 2-20a, the overall condition of the end of the needle is very good. No significant distortion, burrs, or other features which may have contributed to the formation of a kink in the Subject Applicator were observed. There was a small region of deformed metal on the inside edge of the tip of the needle (Figures 2-20b and 2-20c). This distortion or smearing of the edge may be a result of the Subject Applicator impinging on the edge of the Biopsy Needle as would have occurred if the needle assembly were subjected to a bending load. The extent of the distortion is very limited, and is considered to more likely be an artifact of an impingement, and not expected to have contributed to the formation of the kink in the Subject Applicator.

2.2 Chemical Analysis

The chemical composition of the three needle applicators was determined using the Energy Dispersive X-Ray Spectroscopic (EDS) capability of the SEM. The results are presented in Table 2-1. For comparison purposes, the standard limits for the composition of an AISI Type 304 stainless steel are also listed. As can be seen, all three needles have compositions that are in accordance with the requirements for this alloy. The slightly low concentration of chromium (Cr) in the Subject Applicator (17.98% versus 18.00% minimum) is within the allowed tolerance for this element during a check analysis of a Type 304 stainless steel part.

The actual concentrations of carbon, sulfur, and phosphorus (C, S, and P, respectively) could not be conclusively determined due to the limits of detectability inherent in the EDS technique. The more sensitive techniques required for determining such low concentrations of a species were not applicable in this instance due to the relatively large volume of material required. Approximately six of the 21 gage, 20 cm long needles would have been required to provide sufficient material for these more sensitive analyses techniques.

Based on the results of the EDS analysis it can be concluded that all of the applicators are in general compliance with the compositional requirements of Type 304 stainless steel.

Table 2-1. Chemical Analyses Results

	Composition (% by weight) ⁽¹⁾						
	C	Mn	Si	S	P	Cr	Ni
AISI Type 304 Stainless Steel	0.08 Max	2.00 Max	1.00 Max	0.030 Max	0.045 Max	18.00- 20.00	8.00- 10.50
Subject Applicator	(2)	1.51	0.70	(2)	(2)	17.98	9.70
Unused Applicator	(2)	1.89	0.64	(2)	(2)	18.24	9.66
Raw Applicator	(2)	0.96	0.86	(2)	(2)	18.23	8.81

(1) These compositions were determined using the Energy Dispersive Spectroscopic capability of the SEM.

(2) The limits of detectability for elements when using EDS is on the order of 0.1%. The concentration of this element in the sample was below the limit of detectability of the instrument.

2.3 Microstructural Analysis

Specimens from the tip, 4 cm, and 15 cm from the tip of each of the three needle applicators were mounted in an epoxy mounting compound then ground and polished until a longitudinal cross section of the needle was exposed. These specimens were examined using an optical microscope at magnifications up to 1000X in both the etched and unetched conditions. Examination of these specimens enabled the configuration of the tip of the needles, the wall thickness, and the microstructure of the stainless steel, to be determined.

2.3.1 Unetched Specimens

2.3.1.1 Subject Applicator

Cross sections of the tip of the Subject Applicator and the wall thickness near the tip and 4 cm from the tip of the needle are shown in Figures 2-21 and 2-22. The tip of the needle is solid, and forms a nearly square corner with the remaining tube on the ID of the needle (Location A in Figure 2-21a). The ID surfaces of the needle both near the tip and at 4 cm from the tip are rough, which is consistent with the recast appearance observed during the examination with the SEM. The roughness associated with the recast surface finish causes the wall thickness of needle to fluctuate slightly, a feature which will be discussed in more detail in Section 2.4. The OD surface of the needle, particularly at 4

cm from the tip, is significantly smoother than the ID. These observations are consistent with the SEM examination results which revealed a more roughly ground finish on the OD surface near the tip. No appreciable wall thickness variation is attributable to the roughness of the OD surface.

The apparent relative smoothness of the OD surface, even at the higher magnifications, indicates that the circumferential scratches observed over the entire length of the needle (attributed to grinding), do not have appreciable depth. However, based on the secondary cracking which was observed during the SEM examinations at locations where this needle had been plastically deformed by bending, it must still be concluded that these scratches can be detrimental if sufficiently high bending stresses are applied.

2.3.1.2. Unused Applicator

Cross sections of the tip of the Unused Applicator and the wall thickness near the tip and 4 cm from the tip of the needle are shown in Figures 2-23 and 2-24. The transition from the tip to the inside diameter of the needle is nearly a square corner, as was the case for the Subject Applicator. The ID surface is relatively rough, which is again consistent with the recast appearance described earlier. The OD surface appears relatively smooth even at the highest magnifications used, except for several isolated circumferential scratches near the tip itself. These scratches penetrate to 10% or less of the wall thickness and are not expected to impact the performance of the needle since it is expected that the tip would provide mechanical support (stiffening) if a bending load were applied to this region of the needle.

2.3.1.3 Raw Applicator

Cross sections of the tip of the Raw Applicator and the wall thickness near the tip and 4 cm from the tip of the needle are shown in Figures 2-25 and 2-26. This needle is from a different manufacturing lot than the Subject and the Unused Applicators, and numerous differences were observed. The tip of the needle is larger and more elongated, and the transition from the tip to the inside diameter of the needle forms angles of less than 90° (Location A in Figure 2-25a). Within the first 7 mm adjacent to the tip of the needle the wall thickness was less than for the rest of the needle as a result of the grinding to finish the tip (Figure 2-25b). Both the ID and OD surfaces are very smooth, resulting in a uniform wall thickness over the remaining length of the needle. No scratches or other surface distortions are present which would be expected to impact the performance of the needle even if it were subjected to high levels of bending stress.

2.3.2 Etched Specimens

After examination in the unetched condition, the mounted cross sections of the three needle applicators were etched to reveal the microstructure of the stainless steel. The microstructural features observed during the examination of the etched specimens is described below.

2.3.2.1 Subject Applicator

The microstructure of the stainless steel needle at the tip, and 4 cm, and 15 cm from the tip of the Subject Applicator are shown in Figures 2-27 and 2-28. The microstructure of the actual tip of the needle (Figure 2-27a) consists of a mixture of austenite and ferrite, a structure which is common for solidified weld metal in a Type 304 stainless steel. In discussions with the brachytherapy equipment manufacturer, it was learned that the end of the stainless steel needle tubing is closed and the tip formed by welding. The microstructure observed is consistent with this manufacturing process.

The microstructure of the needle immediately adjacent to the tip consists of predominantly randomly oriented polygonal grains of austenite (Figure 2-27b). This is consistent with a Type 304 stainless steel in an annealed condition. The region of predominantly polygonal grain structure extends for a distance of approximately 2 mm from the tip of the needle, at which point a transition to a much finer structure is observed. Although individual grains are not discernible in the fine structure at the magnifications available on the optical microscope, there is a distinct orientation to the microstructure running parallel or nearly parallel to the longitudinal axis of the needle. This structure is typical of a heavily cold worked material, and is consistent with a cold drawn, thin walled tube such as a needle. This microstructure extends for the remaining length of the needle, and typical examples as observed in the specimens from locations 4 cm and 15 cm from the tip of the needle are shown in Figure 2-28.

The region with the polygonal grain structure adjacent to the tip of the needle is most likely a heat affected zone resulting from the thermal cycle associated with the weld used to form the tip. The elevated temperatures involved with the welding process itself, or any localized post weld stress relief were sufficient to cause a recrystallization of the heavily cold worked stainless steel. If a post weld stress relief treatment is part of the process of needle fabrication, it is apparently applied only locally, since the extent of the recrystallized microstructure is limited.

2.3.2.2 Unused Applicator

The microstructure of the stainless steel needle at the tip, 4 cm, and 15 cm from the tip of the Unused Applicator are shown in Figures 2-29 and 2-30. The microstructures and the distribution of the microstructures throughout this needle are the same as was described for the Subject Applicator. The tip of the needle consists of a mixture of austenite and ferrite and there is a recrystallized region which again extends for approximately 2 mm from the tip of the needle. The remainder of the needle consists of a microstructure of heavily cold worked stainless steel. This pattern of microstructures is consistent with a cold drawn tube which has been closed off and a tip formed on the end by welding. Again, any post weld stress relief which may have been applied was of limited extent.

2.3.2.3 Raw Applicator

The microstructure of the stainless steel needle at the tip, 4 cm, and 15 cm from the tip of the Raw Applicator are shown in Figures 2-31 and 2-32. The microstructures and the distribution of the microstructures throughout this needle are somewhat different than had been observed in the Subject and Unused Applicators. The tip of the needle exhibits a finer mixture of austenite and ferrite and the orientation of the microstructure of the heavily cold worked tube is more consistently parallel to the longitudinal axis of the needle. The most significant difference is associated with the region of recrystallization immediately adjacent to the tip. In this needle the recrystallized zone extends for only approximately 0.25 mm down the length of the needle, and even in that region there is only partial recrystallization. This limited extent of recrystallization indicates that less heat was put into this part during welding, and it is unlikely that any post weld stress relief was utilized during the manufacture of this needle.

Although the microstructure of the Raw Applicator varied somewhat from the Subject and Unused Applicators, it is expected that either microstructure should be capable of providing satisfactory service. The differences observed serve to further document that the Raw Applicator was from a different lot of needles than the other two, and that the manufacturing processes used to produce the two lots of needles were not the same.

2.4 Dimensional Analysis

2.4.1 Wall Thickness

The wall thickness of the applicators was determined at three locations along the length of the needles. These locations were, immediately adjacent to the tip, 4 cm, and 15 cm from the tip of the needle. The wall thickness was determined from the mounted longitudinal cross sections of the needles and measurements were made using a calibrated vernier scale on the optical microscope. The results of the wall thickness measurements are summarized in Table 2-2. Six measurements were made at randomly selected spots at each location, and the average and range of the measured values is reported.

The specified range for the wall thickness of a 21 gage needle is 2.0 mils, +0.0/-0.3 mils. This corresponds to an acceptable range of 1.7-2.0 mils. The measurement technique to be used, and the location and number of measurements to be made to determine the wall thickness of the needle for acceptance purposes is not known. Therefore, the wall thickness data reported here should not be considered grounds for acceptance or rejection of the tubing material used to make the needles, but is illustrative for discussion purposes.

Table 2-2. Wall Thickness of the Needle Applicators

	Wall Thickness (mils) ⁽¹⁾					
	Subject Applicator		Unused Applicator		Raw Applicator ⁽²⁾	
	Average	Range	Average	Range	Average	Range
Tip	1.5	1.3 - 1.7	1.8	1.5 - 2.0	1.9	1.8 - 2.0
4 cm	1.7	1.4 - 2.1	1.7	1.5 - 2.1	2.1	2.0 - 2.2
15 cm	1.6	1.2 - 2.0	1.9	1.6 - 2.0	1.9	1.8 - 2.0
Overall	1.6	1.2 - 2.1	1.8	1.5 - 2.1	1.9	1.8 - 2.2

(1) Average of six readings.

(2) A region of thinner wall thickness is present within the first 7 mm from the tip of the applicator (a result of the grinding to finish the tip). A wall thickness as low as 0.8 mils was measured in that region.

The Subject Applicator was found to have an average wall thickness of 1.6 mils with a range of 1.2-2.1 mils. The thinnest location of the three evaluated was adjacent to the tip of the needle where the wall thickness averaged 1.5 mils with a range of 1.3-1.7 mils. This is most likely a result of the additional grinding which was apparently performed during fabrication of the tip. The wall thickness at 4 cm from the tip of the needle, the site closest to where the kink occurred during the treatment of the patient, had an average wall thickness of 1.7 mils with a range of 1.4-2.1 mils. The average thickness is within the acceptable range, but the variations in wall thickness in this region were among the largest of any of the locations evaluated. The most significant contributor to the variations in wall thickness was the roughness of the ID surface associated with the recast appearance (described in Section 2.1.1).

The Unused Applicator was found to have an average wall thickness of 1.8 mils with a range of 1.5-2.1 mils. The thinnest of the regions evaluated from this needle was at 4 cm from the tip, but the wall thickness was still within the allowable range.

The Raw Applicator was found to have an average wall thickness of 1.9 mils with a range of 1.8-2.2 mils. This excludes measurements from the first 7 mm immediately adjacent to the tip of the needle, where the wall thickness had been reduced to as little as 0.8 mils as a result of grinding of the OD surface during the fabrication of the tip (Figure 2-25b). The uniformity of the wall thickness over the remainder of this needle was better than for the previous two needles, with the maximum variation from the average thickness at any location being +/- 0.1 mils. This improved uniformity is a result of the significantly smoother ID surface which was produced on this needle. The potential affect of the reduced wall thickness for the short distance immediately adjacent to the tip of the needle is unknown.

It is noteworthy that the average wall thickness of the Subject Applicator was the smallest and that this needle had the greatest variation of the three evaluated. The wall thickness of this needle at the site where the kink occurred during the treatment was close to the minimum of the allowable range for a 21 gage needle, and the variations were on the order of +/-15% of the nominal wall thickness. It cannot be conclusively determined from this study if the average or the variations in the wall thickness at this location were an important contributor to the formation of the kink, but changes in cross sectional area are a well known source of stress concentration.

2.4.2 Diameter

The outside diameter of the applicators was determined at three locations along the length of the needles. These locations were the tip, 4 cm, and 15 cm from the tip of the needle. The diameters were measured using a micrometer, and the results are summarized in Table 2-3. The outside diameter is very uniform over the entire length of each of the needles and is essentially the same for all three. All of the measured diameters are within the range of 0.0320-0.0325 inches specified by the manufacturer.

Table 2-3. Diameters of the Needle Applicators

	Diameters (inches)					
	Subject Applicator		Unused Applicator		Raw Applicator	
	OD	ID	OD	ID	OD	ID
Tip	0.0325	0.0295	0.0325	0.0289	0.0320	0.0282
4 cm	0.0320	0.0286	0.0320	0.0286	0.0320	0.0278
15 cm	0.0320	0.0288	0.0320	0.0284	0.0320	0.0282

The inside diameter of the needles at the same locations was determined by subtracting the measured wall thickness from the measured outside diameter. These results are also presented in Table 2-3. The inside diameter measurements determined in this manner are affected by the ID surface roughness in the same manner as the wall thickness measurements had been. Despite this, all of the inside diameters measured are within the range of 0.0280-0.0290 inches specified by the manufacturer.

The outside and inside diameters of the Subject Applicator are consistent with those measured for the other two needles, and in compliance with the dimensions specified by the manufacturer. The average diameters, or variations in the diameters should not have influenced the susceptibility of this needle to forming a kink.

2.5 Hardness

AISI Type 304 stainless steel is an austenitic alloy which achieves strength, and therefore hardness, primarily through cold working of the steel. As an austenitic stainless steel is cold worked, the strength and hardness will increase, and the remaining ductility will decrease. To address the concern that the Subject Applicator may have been embrittled either by the radiation to which it had been exposed, or some other mechanism, hardness measurements were made to enable the mechanical properties to be estimated.

The hardness of the needle applicators was determined by testing the mounted cross sections from the tip, 4 cm, and 15 cm from the tip. The measurements were made using a Knoop microhardness indenter and a 50 gram load. Four readings were taken at each location, and the measurements converted to the equivalent hardness on a Rockwell C scale (HRC). The results are summarized in Table 2-4. The normal hardness for the needles, as specified by the brachytherapy equipment manufacturer, is 20-40 HRC.

Table 2-4. Microhardness Test Results

	Hardness (HRC) ⁽¹⁾		
	Subject Applicator	Unused Applicator	Raw Applicator
Tip	95 HRB ⁽²⁾	27	25
4 cm	41	41	46
15 cm	37	43	46

(1) Average of 4 readings. Readings taken using a knoop indicator and a 50gm-load converted to Rockwell C hardness (HRC).

(2) This hardness is too low to be properly represented by values in the Rockwell C range. 95 HRB, however, is roughly equivalent to 16 HRC.

The hardness of all three applicators was very similar. The region near the tip was the softest region of each needle, with hardnesses ranging from 95 HRB for the Subject Applicator, to 27 HRC for the Unused Applicator. The tip of the Subject Applicator is too soft to be properly described by the Rockwell C scale, so it is expressed as a hardness on the Rockwell B scale. The lowest hardness reportable on the Rockwell C scale is 20, however the measured hardness of 95 HRB would correspond to a hardness of approximately 16 HRC.

Based on the hardness measurements at 4 cm and 15 cm from the tip of the needles, the Subject Applicator is the softest, exhibiting a hardness of 37-41 HRC. This corresponds to a condition of approximately 40% cold work for this stainless steel, which should produce a remaining ductility on the order of 10-15%. The hardness of the Unused and

Raw Applicators is 41-43 HRC, and 46 HRC, respectively. These hardnesses correspond to a level of cold work in excess of 40%, and ductilities of less than 10% would be expected to result. These hardnesses are near or slightly above the normal hardness range reported by the manufacturer.

The softening of the needles near the tip is consistent with the recrystallized microstructure observed at this location for both the Subject and Unused Applicators. The comparable softening exhibited by the Raw Applicator indicates that even though the material appeared to be only partially recrystallized near the tip, a significant amount of recovery from the cold work must have occurred during the thermal cycle associated with making the tip.

Comparing the hardness of the needles to each other, the Raw Applicator, which has seen no radiation exposure, is the hardest (lowest ductility). The Unused Applicator, which has been exposed to a dose of gamma radiation during sterilization is slightly softer, and the Subject Applicator, which has seen an additional dose of gamma radiation during the brachytherapy treatment, was the softest.

A brief review of the literature indicates that it is generally reported that gamma radiation has little or no affect on the mechanical properties of annealed austenitic stainless steels. Mural' et al¹ reported a strengthening and embrittlement of a heavily deformed (cold worked) austenitic stainless steel after exposures of 3500 hours to a radiation source with an integral dose of 3.5×10^9 R. If a similar strengthening and embrittlement had occurred to an extent sufficient to measurably affect the properties of the stainless steel needles, an increase in hardness would have been expected. No such hardening was observed. It is most likely that the decrease in hardness measured as a function of radiation exposure is more likely related to normal variations in the manufacturing process, and should not be interpreted as a softening affect due to the limited radiation doses to which the needles have been exposed. It can be stated, however, that the hardness data provides no evidence of embrittlement of the needles due to the radiation exposure.

¹ Mural', V. V.; Shcherbedinskii, G. V.; γ -Radiation Aging of Deformed Austenite; Metal Science and Heat Treatment, Vol. 26, No. 5-6, May-June, 1984, p. 467.

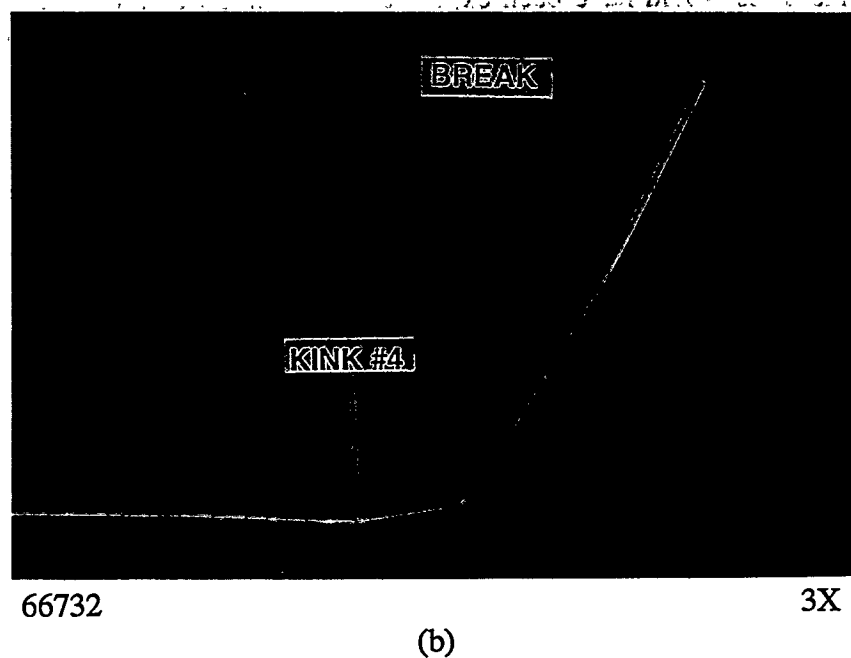
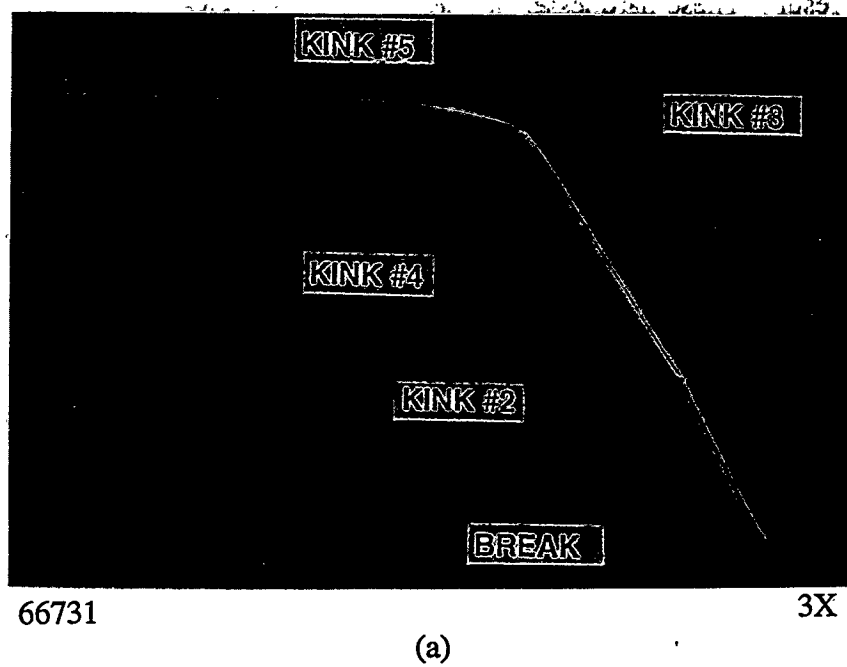
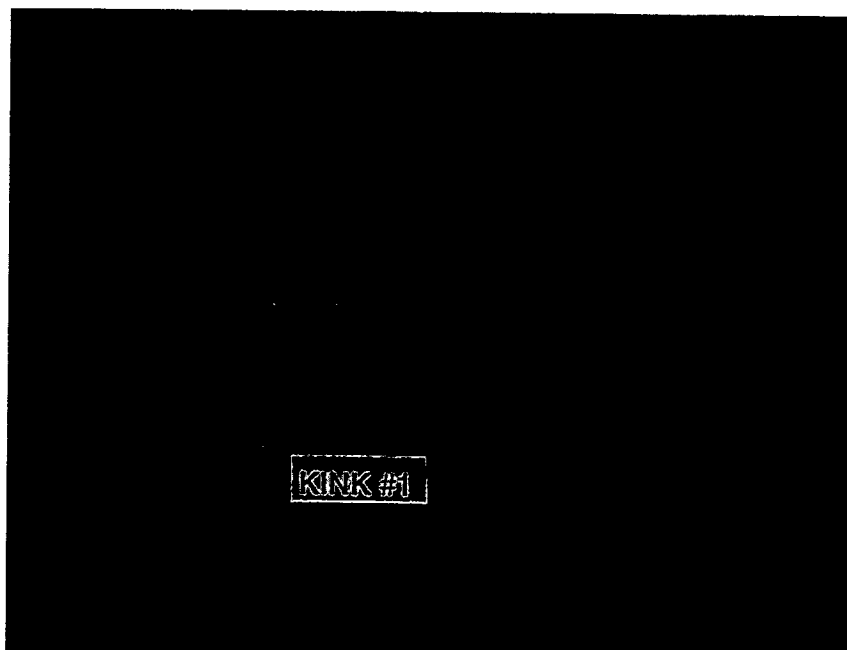


Figure 2-1. Subject Applicator. (a) and (b) are the damaged end of the needle.

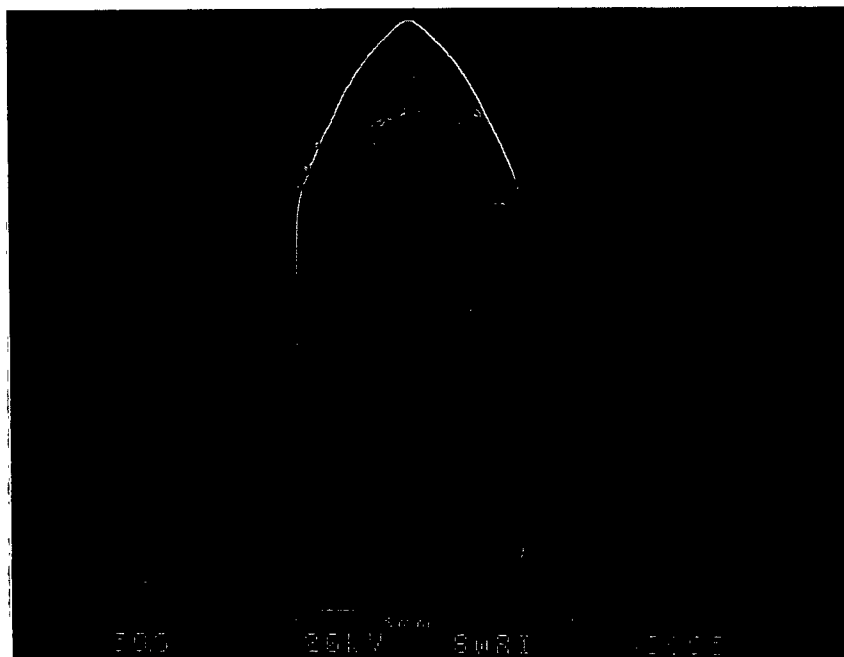


66734

5-1/2X

(c)

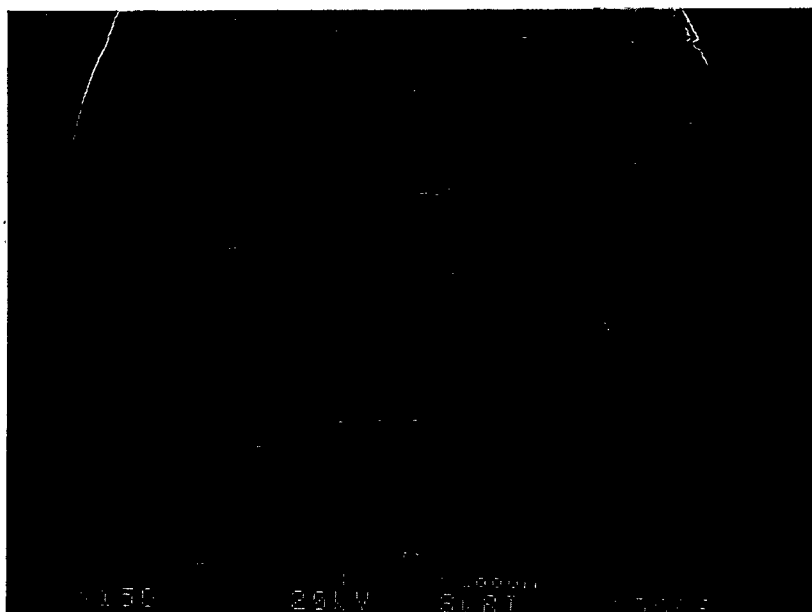
Figure 2-1 (continued). Subject Applicator. (c) the broken tip.



67293

50X

(a)

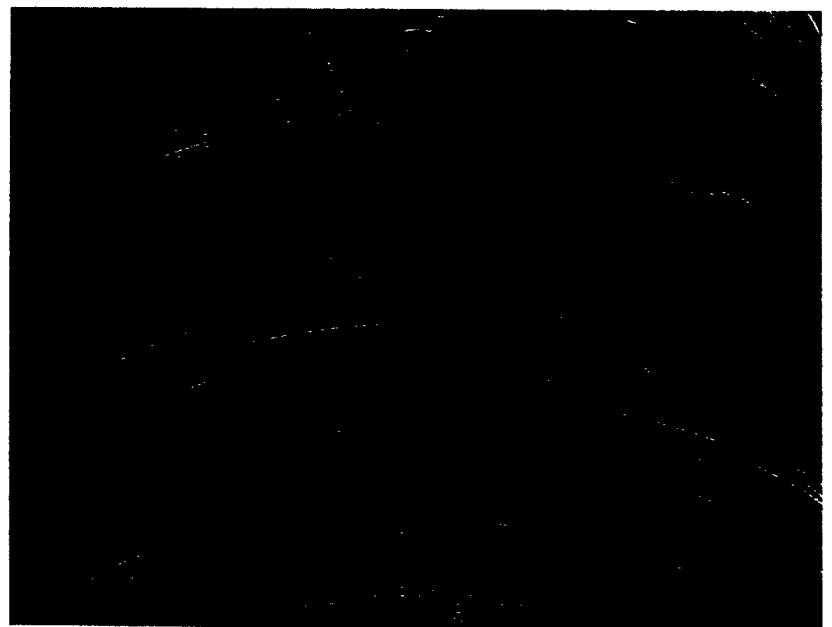


67294

150X

(b)

Figure 2-2. Subject Applicator. Condition of the OD surface near the tip.

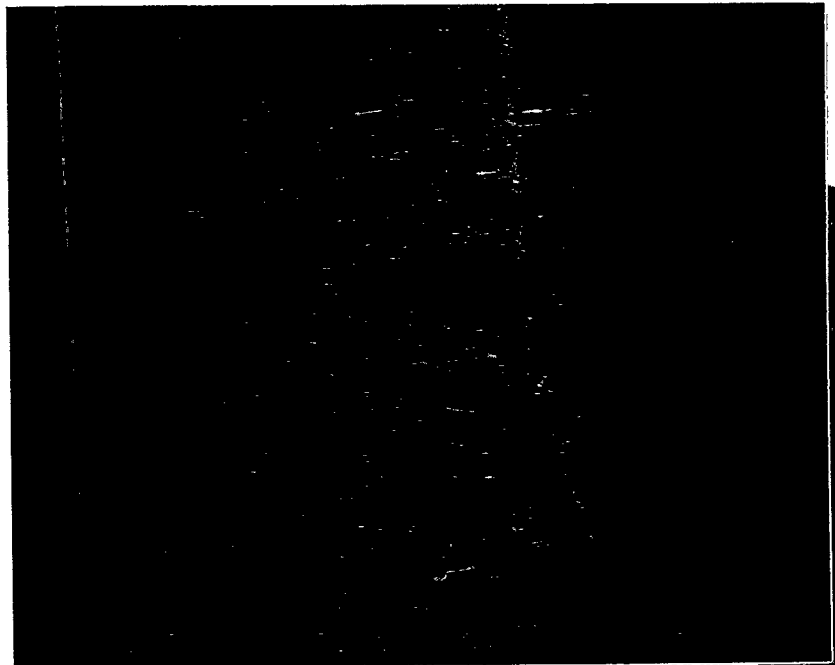


67292

200X

(c)

Figure 2-2 (continued). Subject Applicator. Condition of the OD surface near the tip.



67299

130X

(a)



67300

400X

(b)

Figure 2-3. Subject Applicator. Condition of the OD surface at 4 cm from the tip.

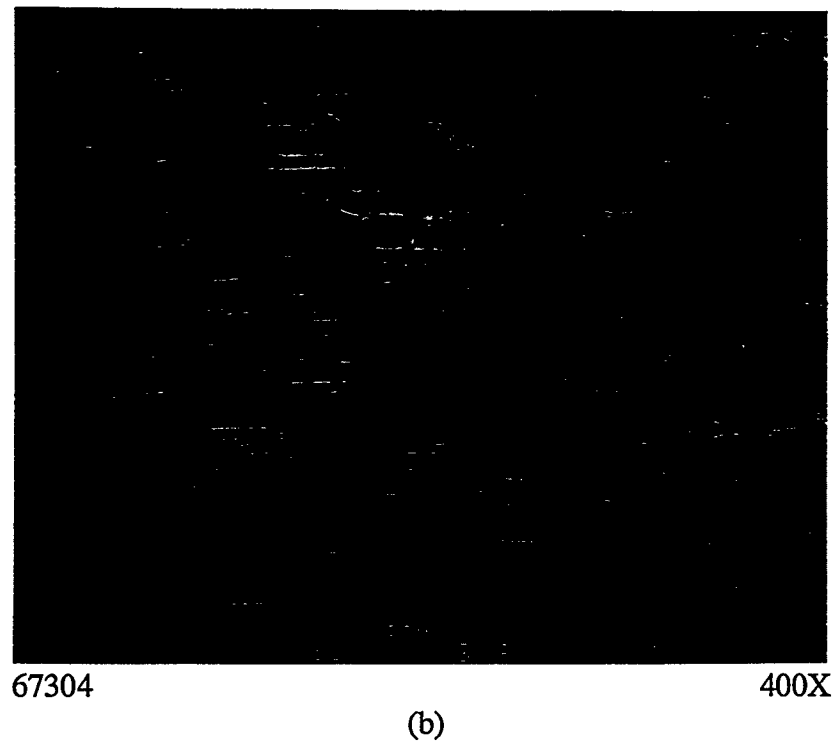
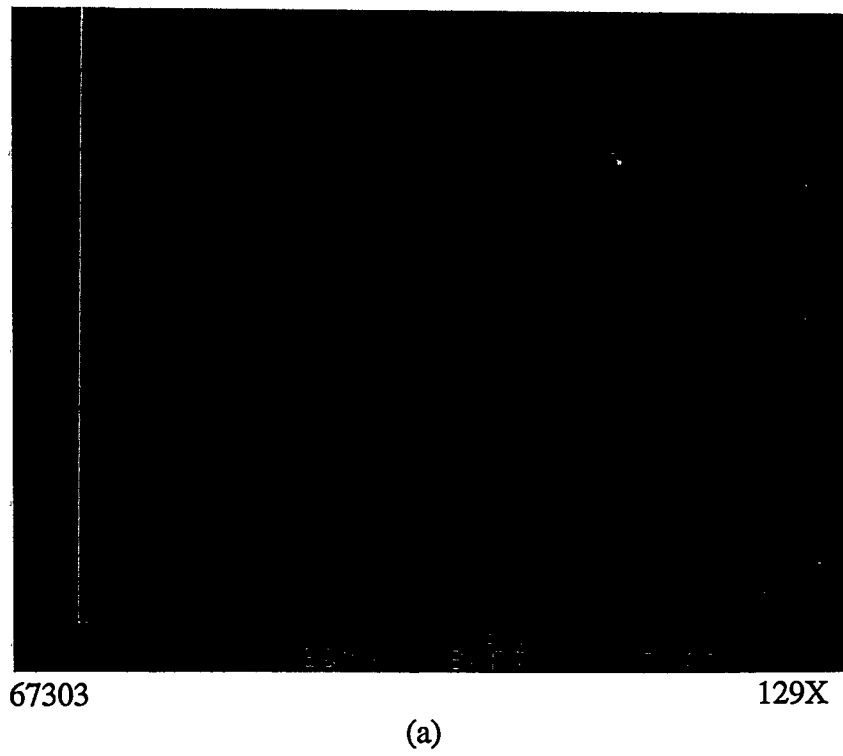


Figure 2-4. Subject Applicator. Condition of the OD surface at 15 cm from the tip.

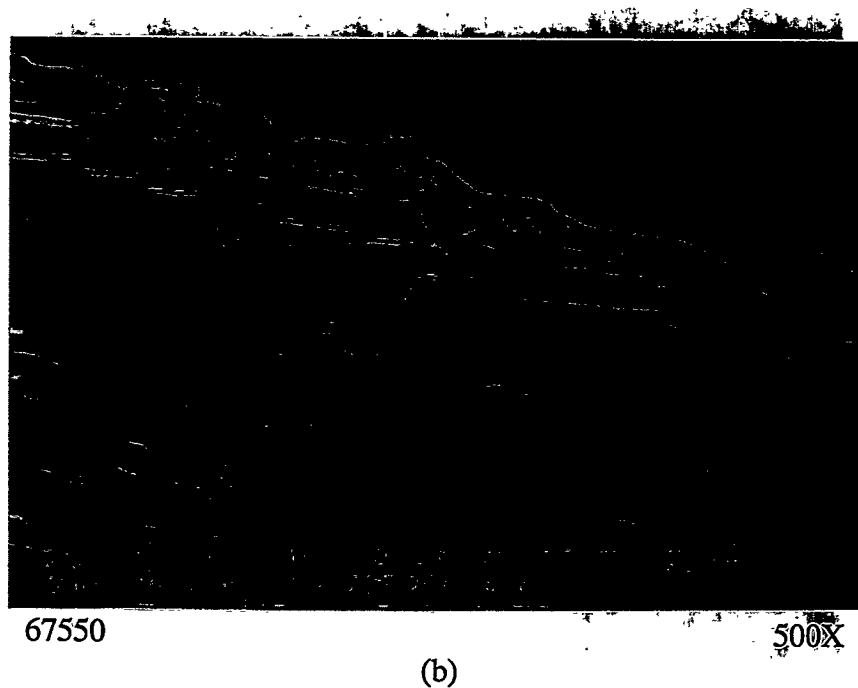
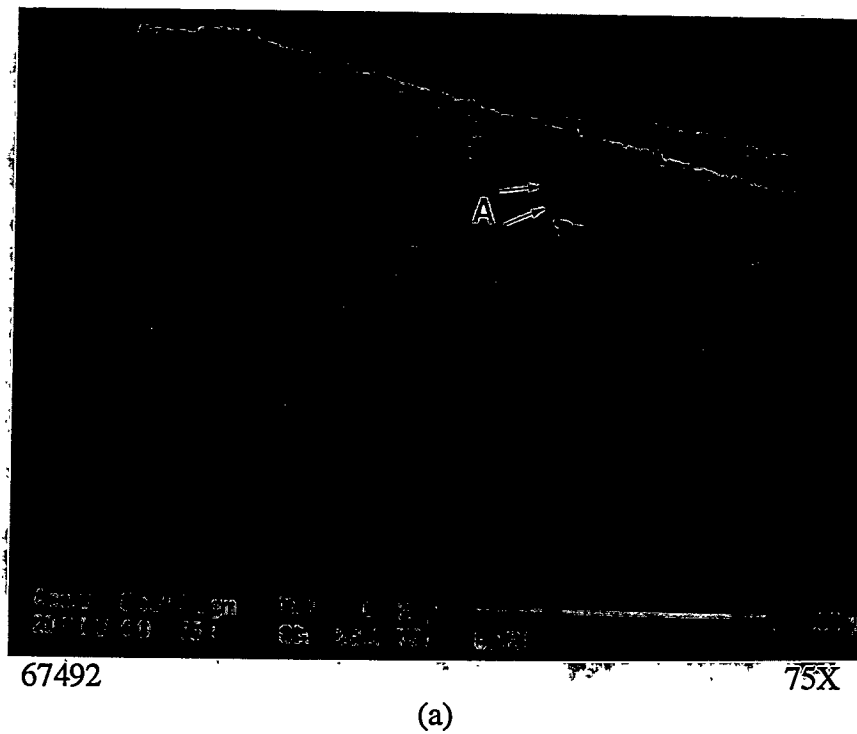


Figure 2-5. Subject Applicator. Condition of the OD surface at the inside edge of Kink #3. Note the surface dents (A), the scuff marks (B), and the secondary cracks (open arrows).

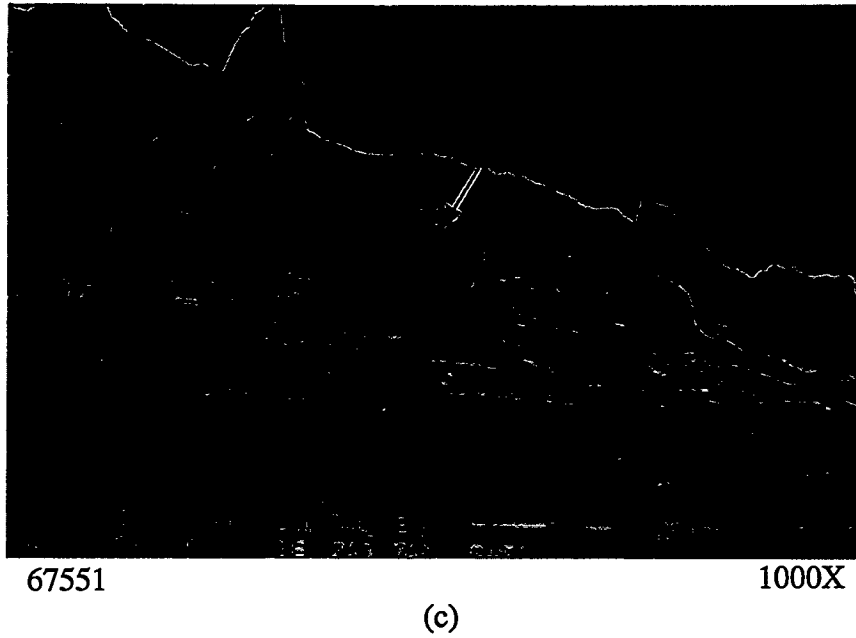


Figure 2-5 (continued). Subject Applicator. Condition of the OD surface at the inside edge of Kink #3. Note the surface dents (A), the scuff marks (B), and the secondary cracks (open arrows).

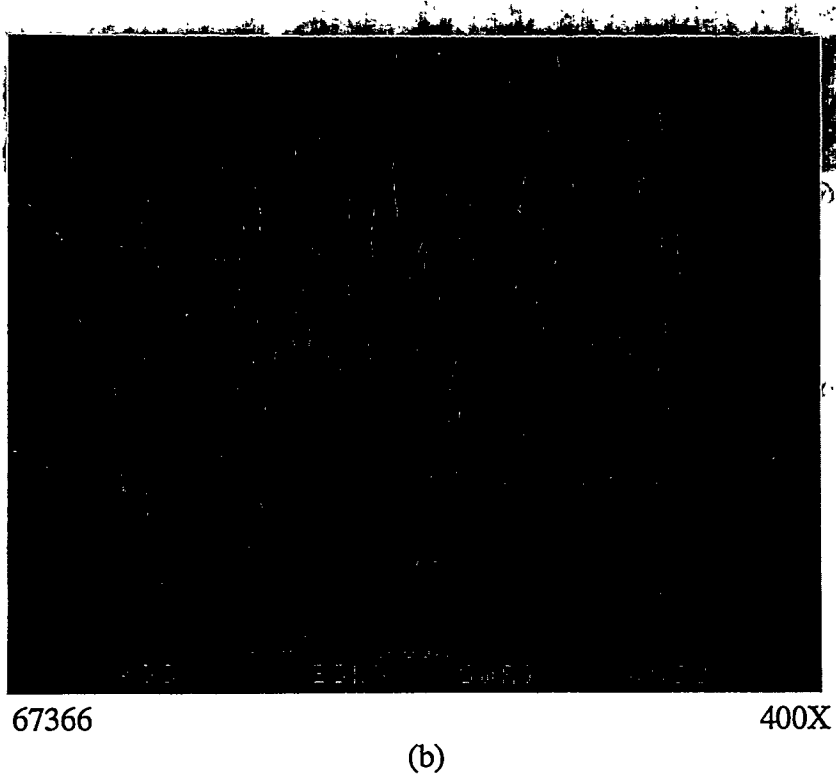
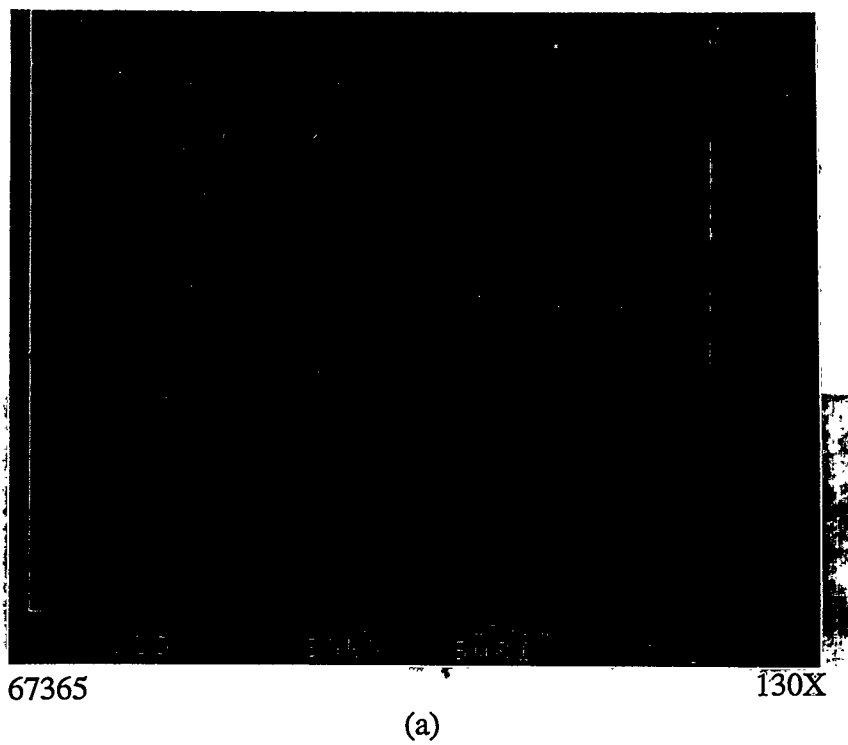
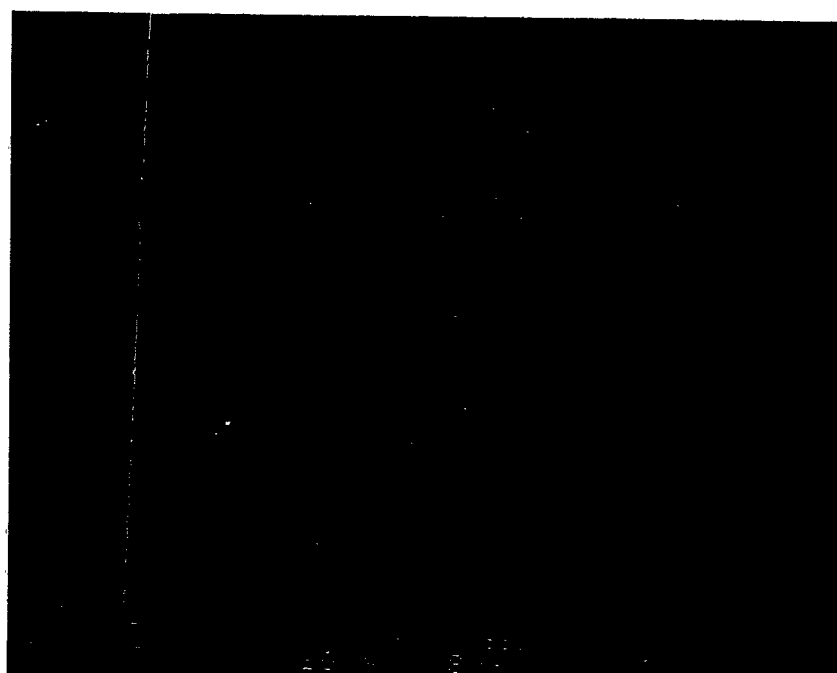
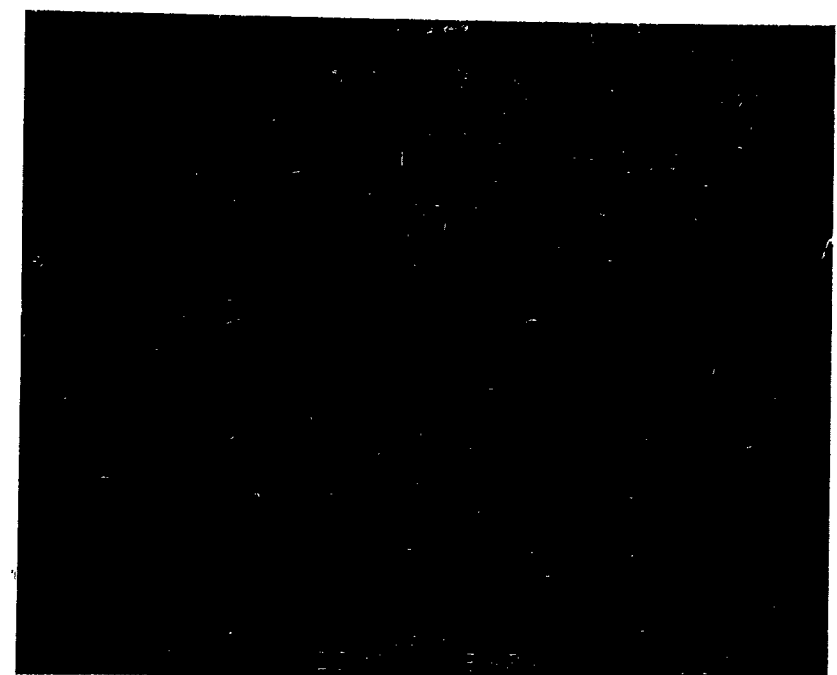


Figure 2-6. Subject Applicator. Condition of the ID surface at 4 cm from the tip.

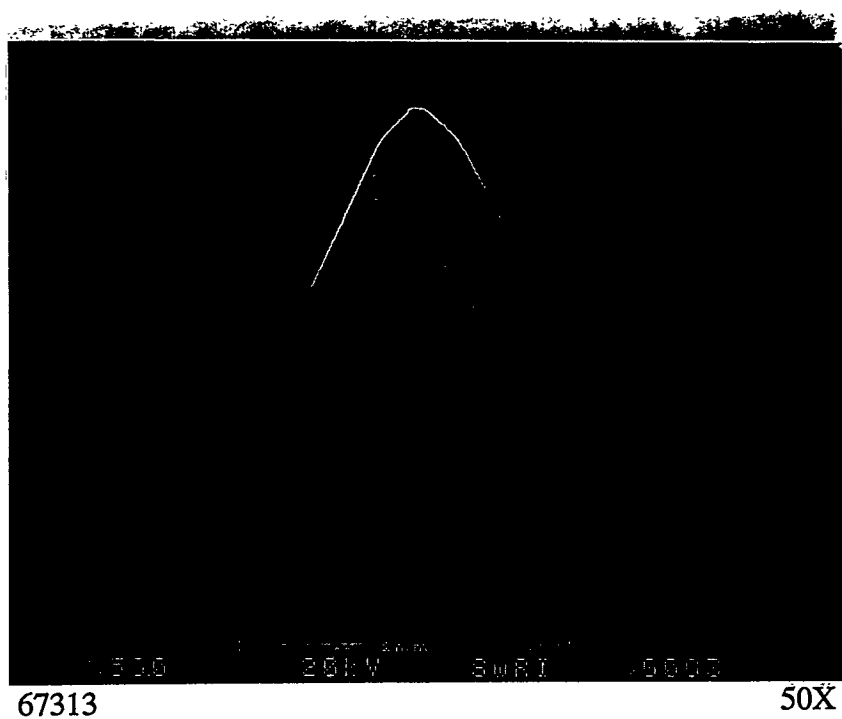


(a)

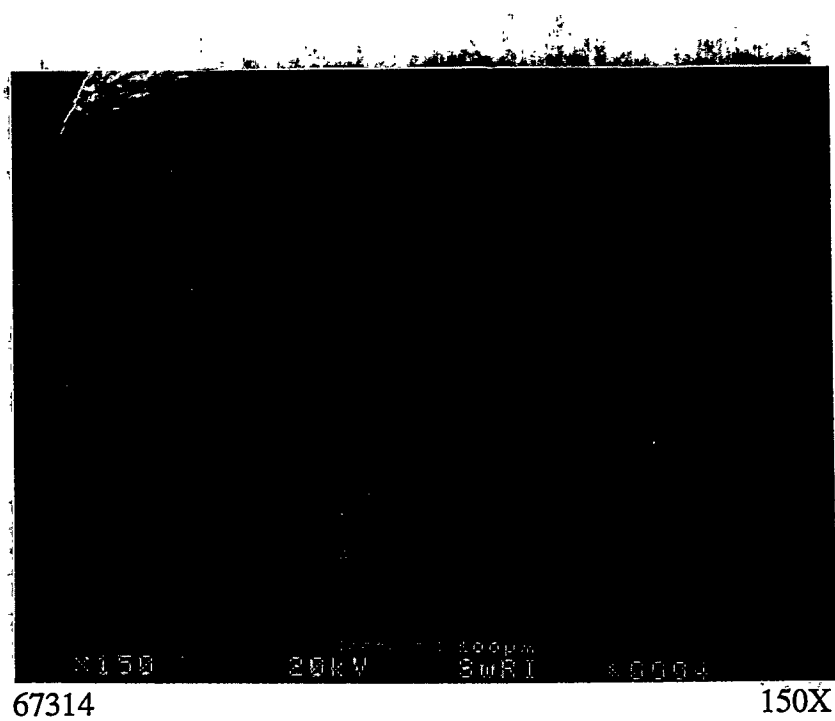


(b)

Figure 2-7. Subject Applicator. Condition of the ID surface at 15 cm from the tip.



(a)



(b)

Figure 2-8. Unused Applicator. Condition of the OD surface near the tip.

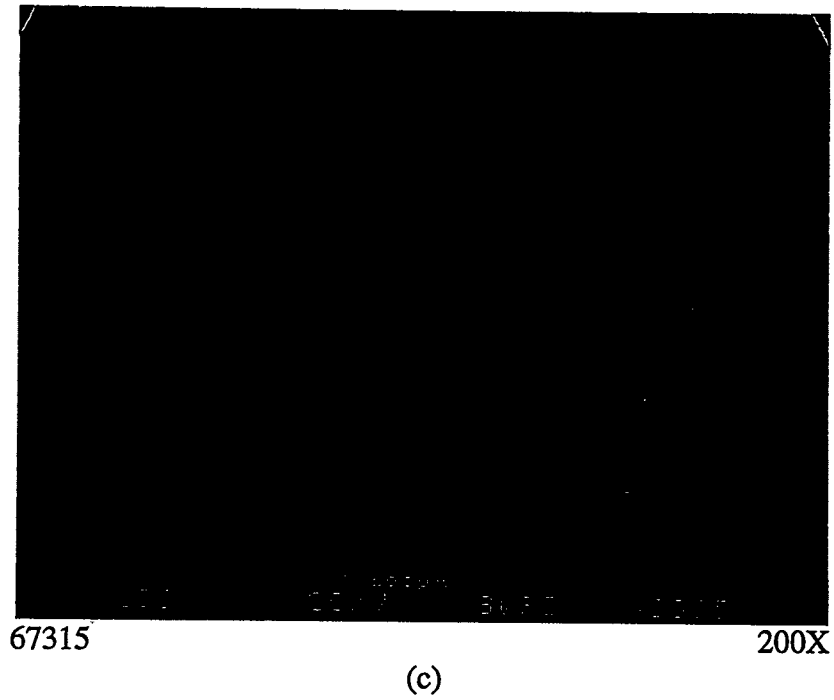


Figure 2-8 (continued). Unused Applicator. Condition of the OD surface near the tip.

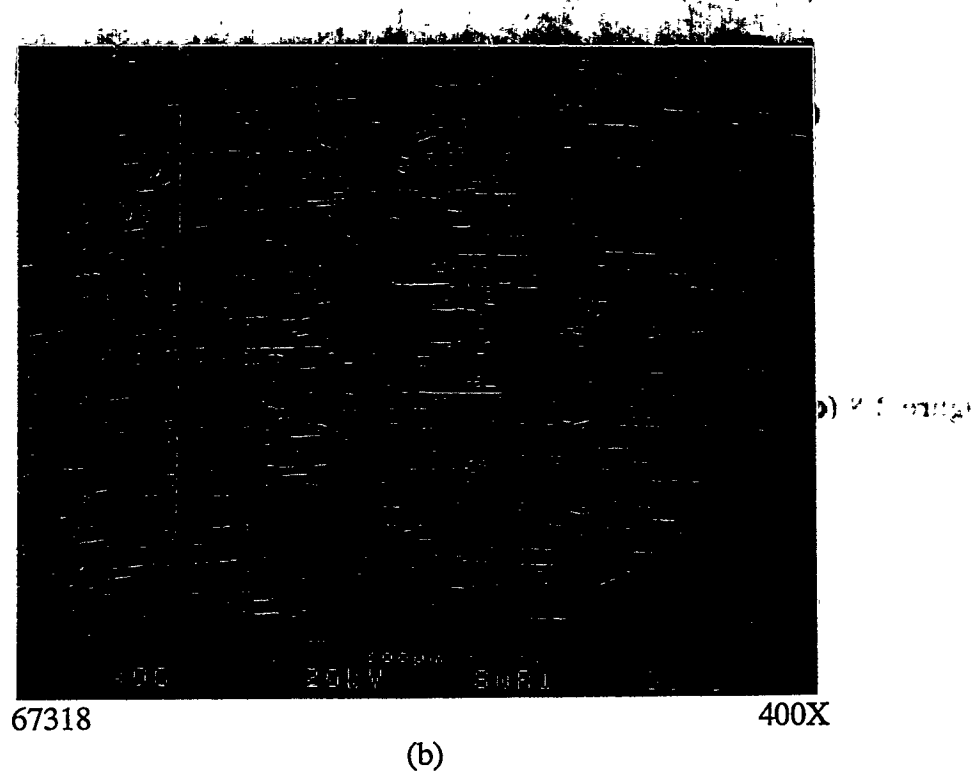
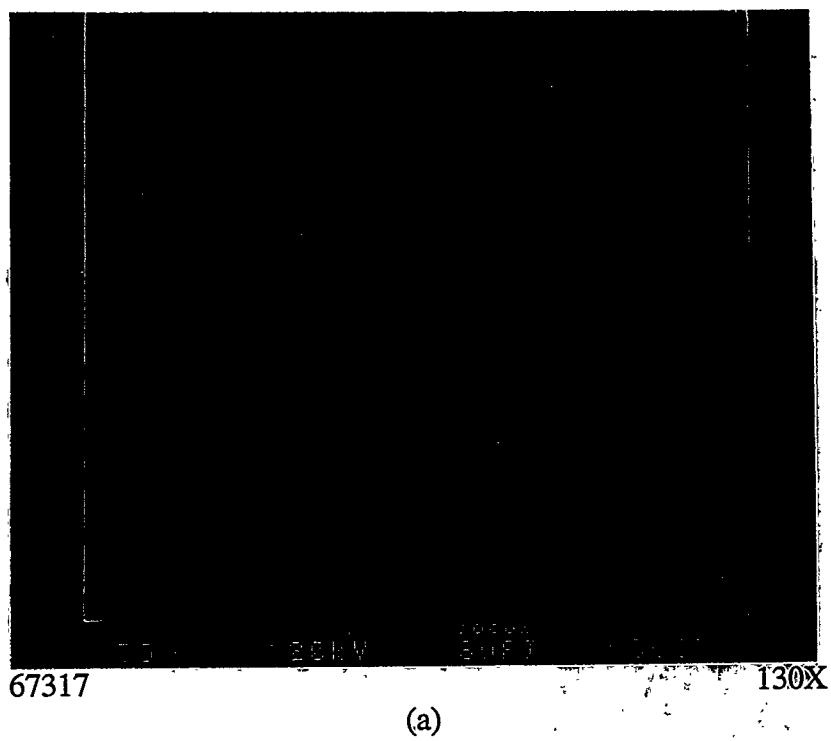


Figure 2-9. Unused Applicator. Condition of the OD surface at 4 cm from the tip.

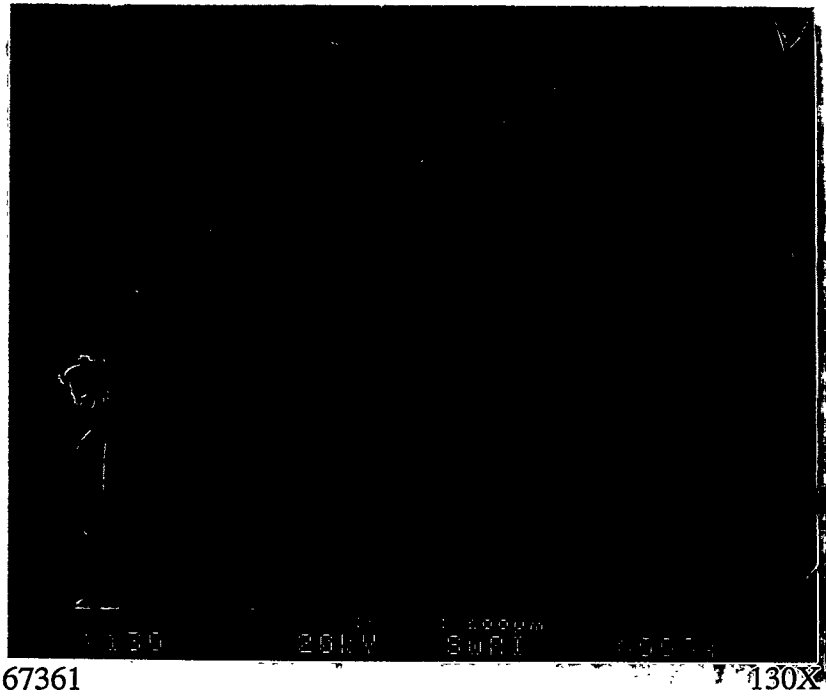


(a)

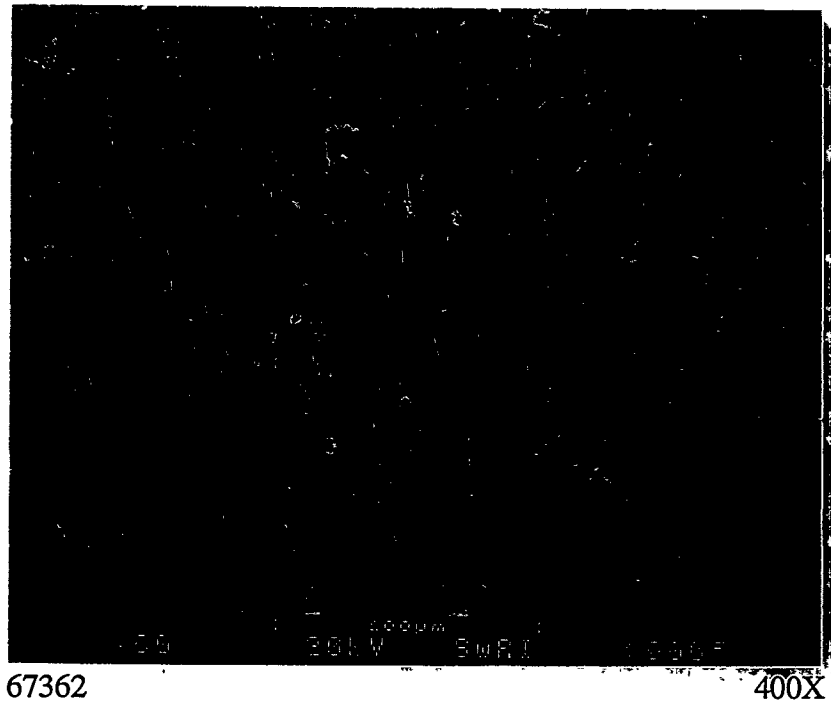


(b)

Figure 2-10. Unused Applicator. Condition of the OD surface at 15 cm from the tip.

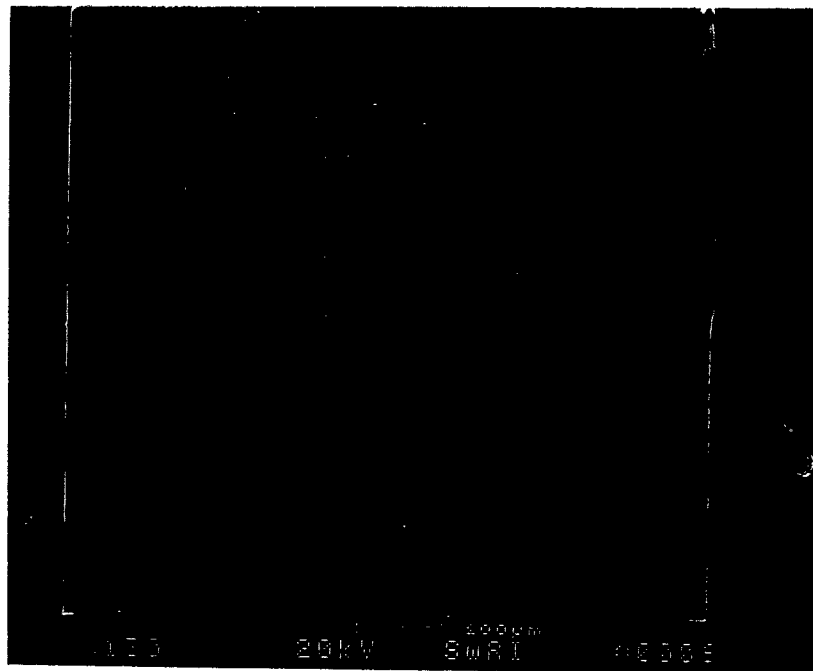


(a)



(b)

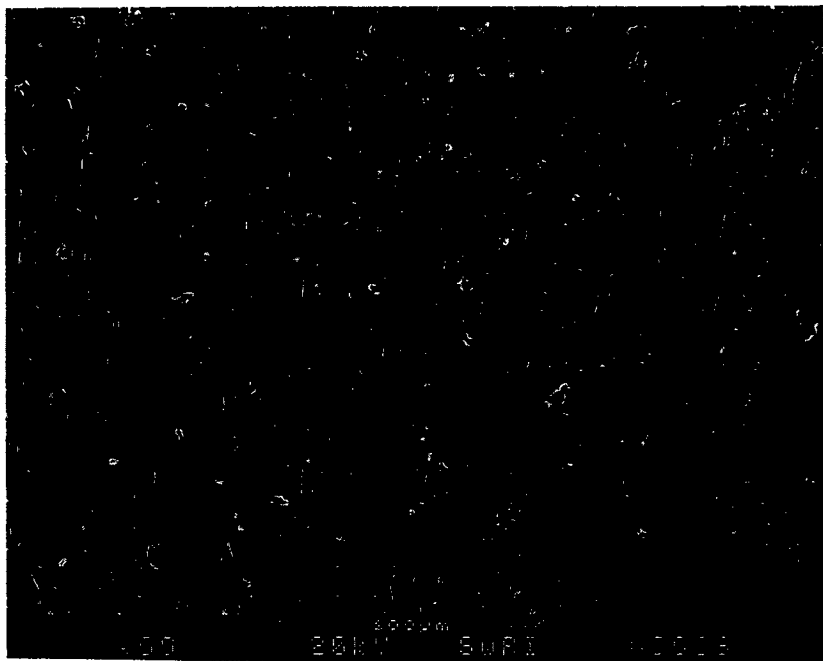
Figure 2-11. Unused Applicator. Condition of the ID surface at the tip.



67359

130X

(a)



67360

400X

(b)

Figure 2-12. Unused Applicator. Condition of the ID surface at 4 cm from the tip.

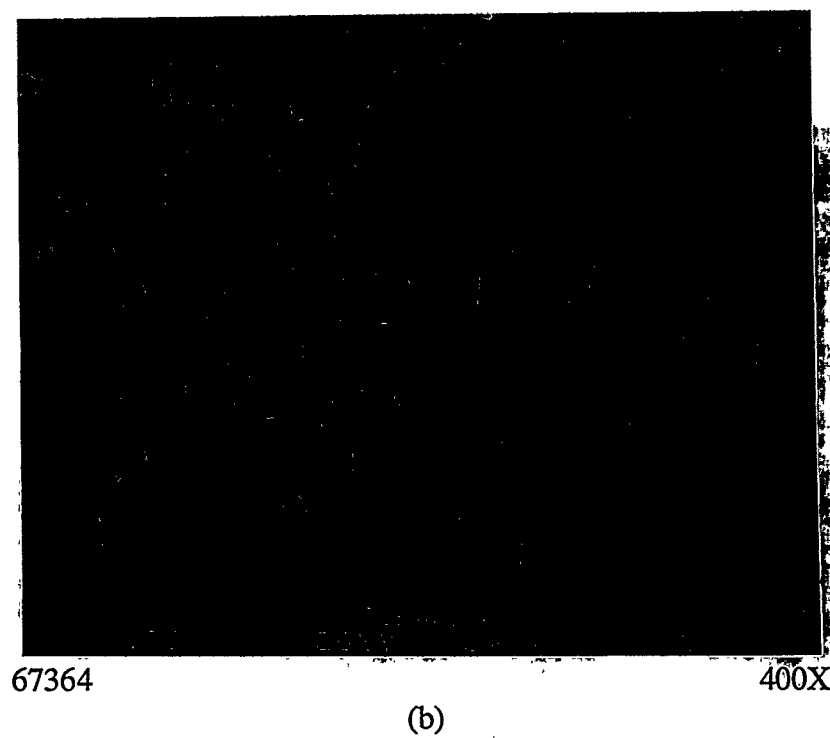
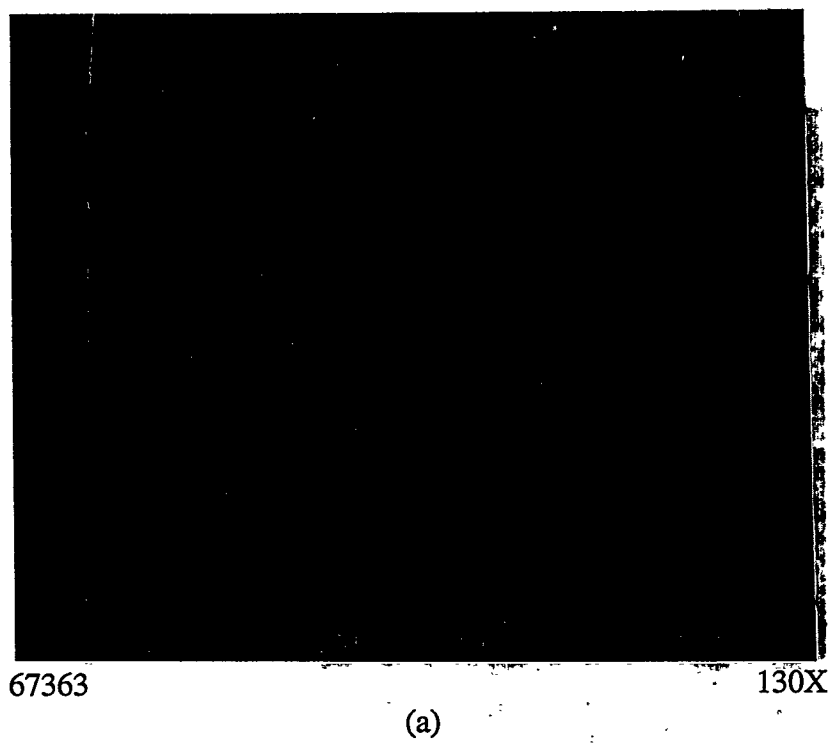


Figure 2-13. Unused Applicator. Condition of the ID surface at 15 cm from the tip.

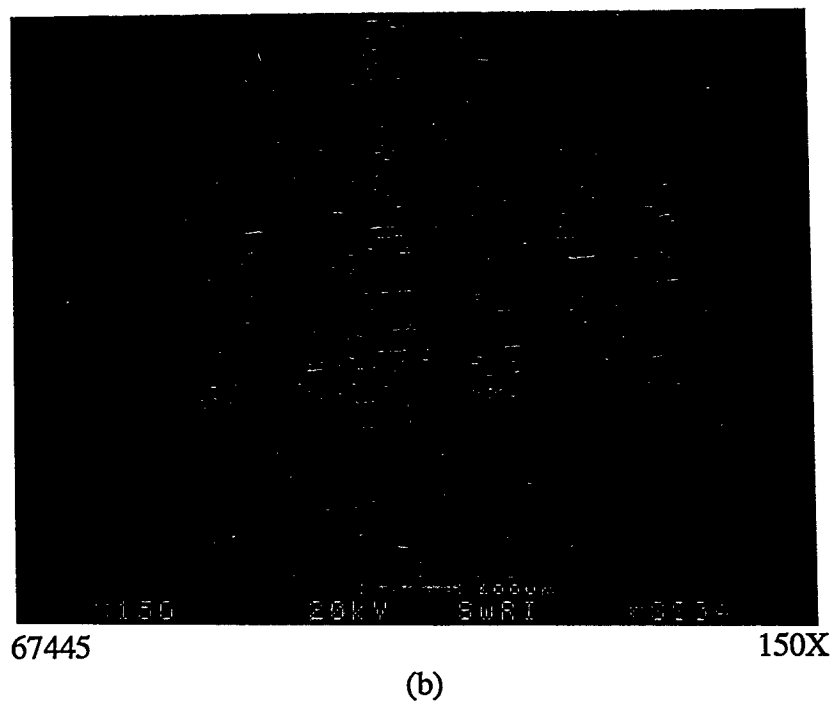
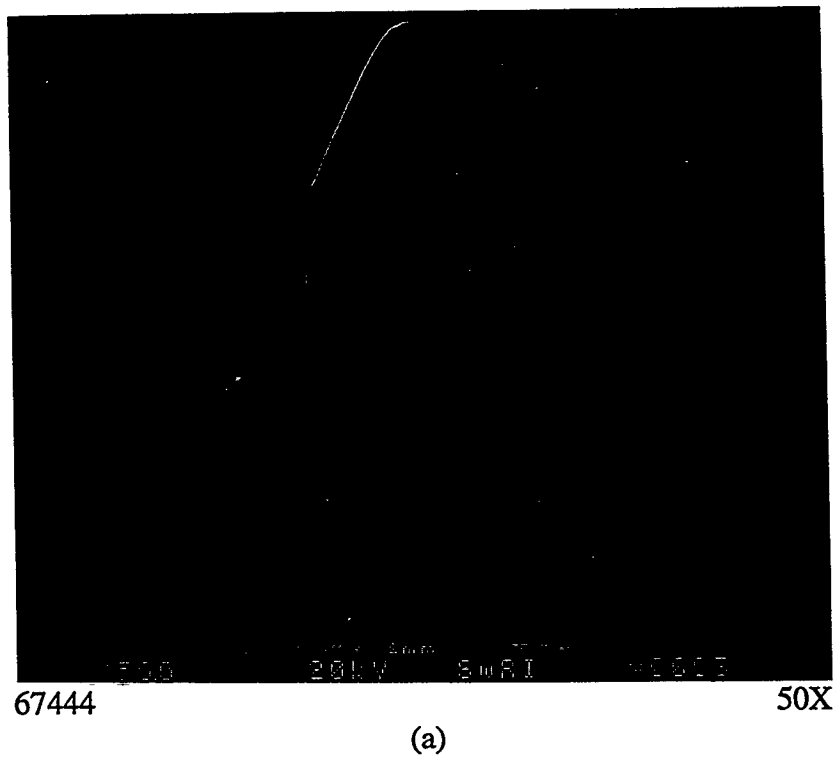
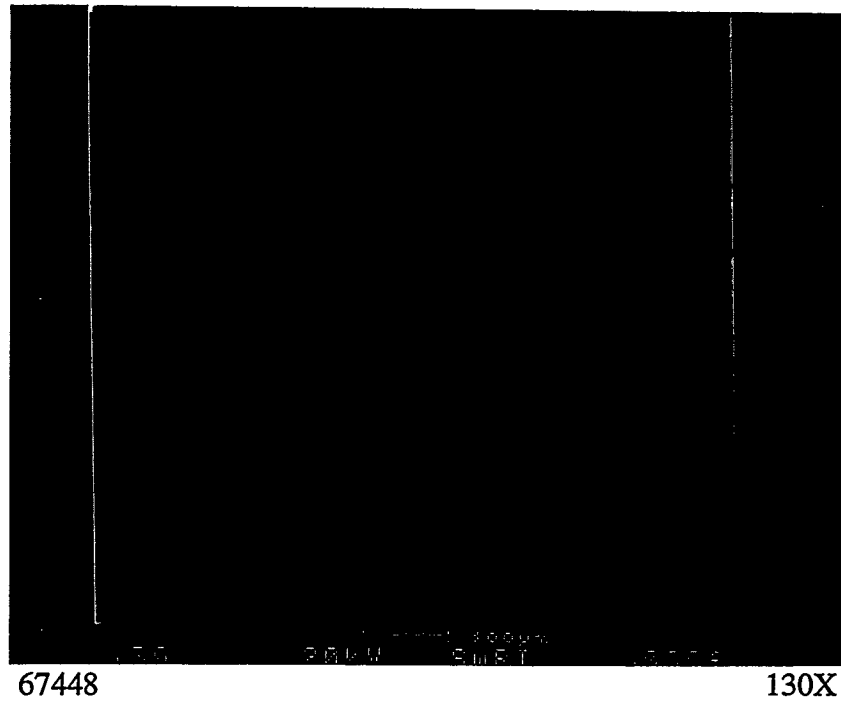


Figure 2-14. Raw Applicator. Condition of the OD surface near the tip.

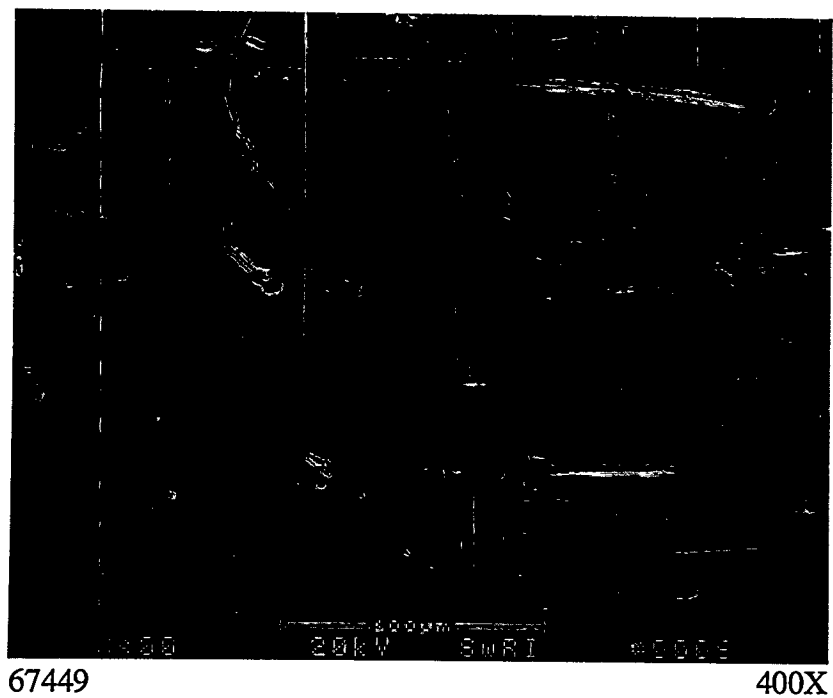


(c)

Figure 2-14 (continued). Raw Applicator. Condition of the OD surface near the tip.

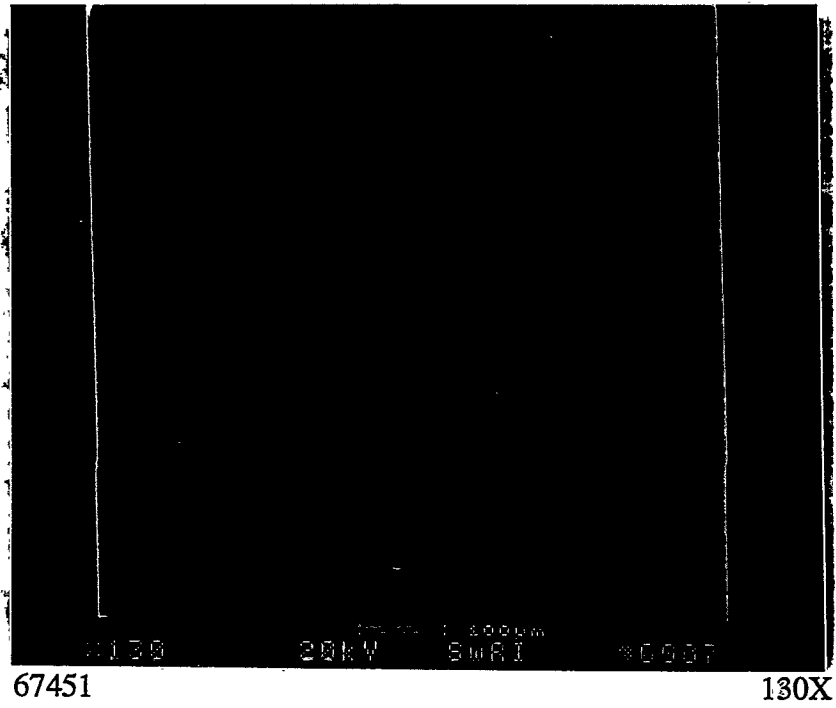


(a)



(b)

Figure 2-15. Raw Applicator. Condition of the OD surface at 4 cm from the tip.

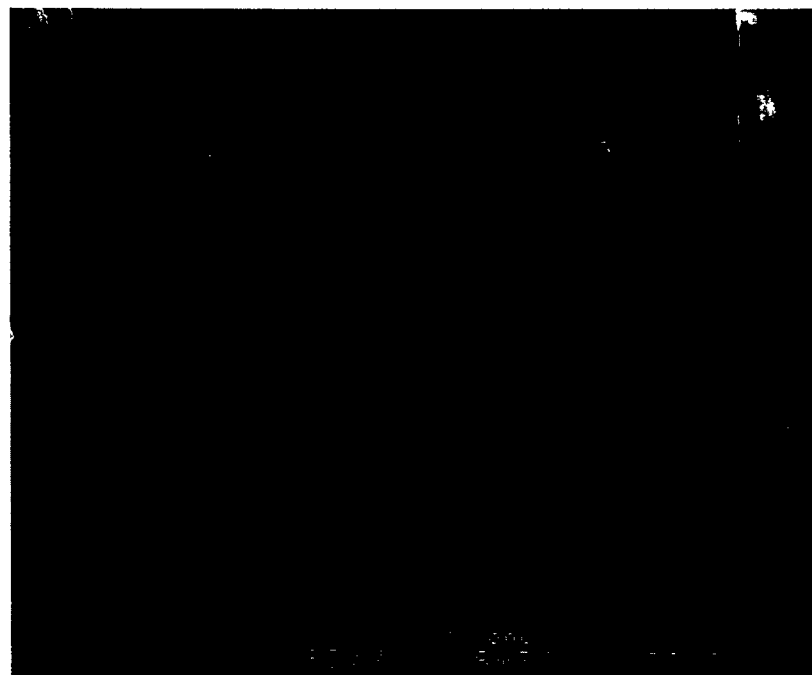


(a)



(b)

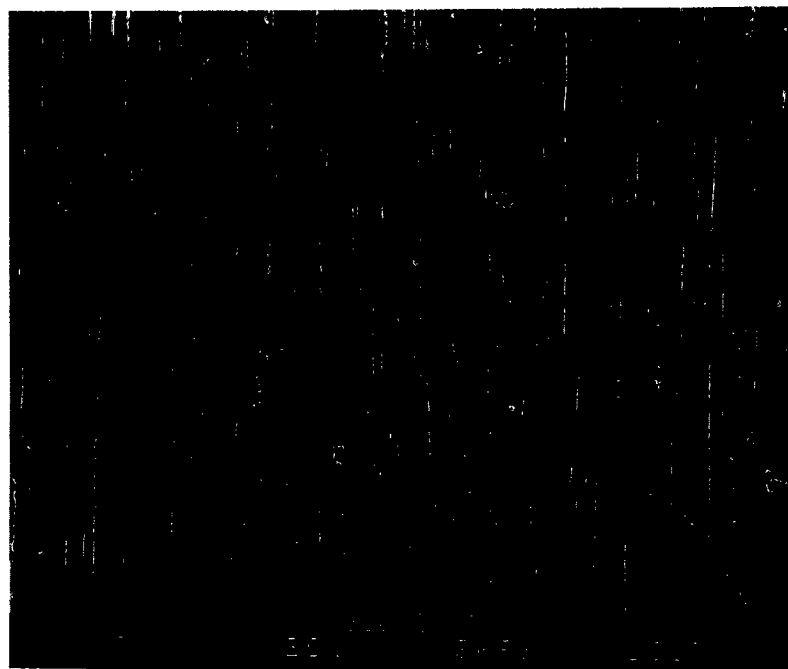
Figure 2-16. Raw Applicator. Condition of the OD surface at 15 cm from the tip.



67467

130X

(a)



67466

400X

(b)

Figure 2-17. Raw Applicator. Condition of the ID surface at the tip.

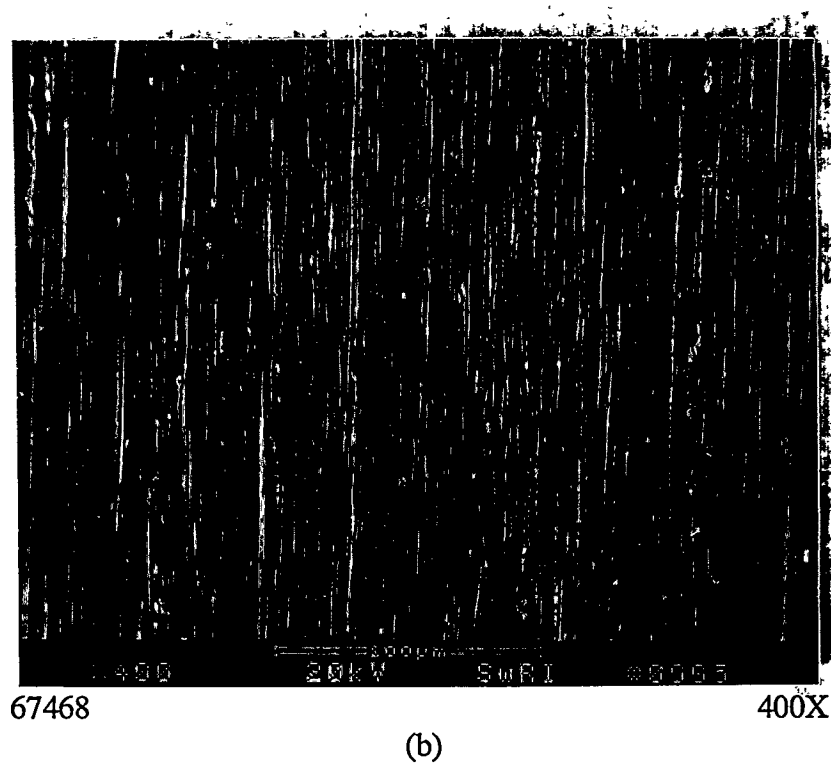
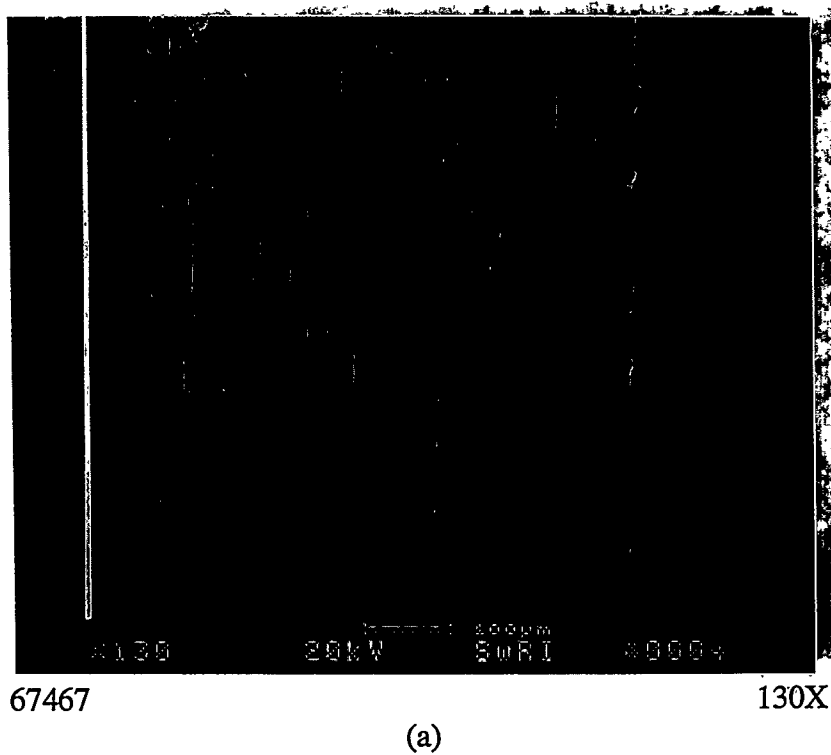
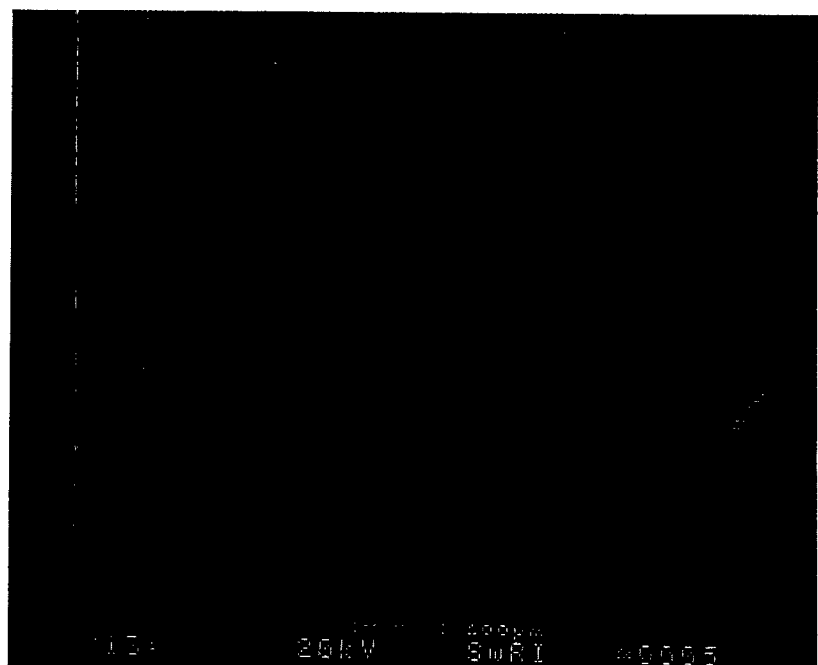


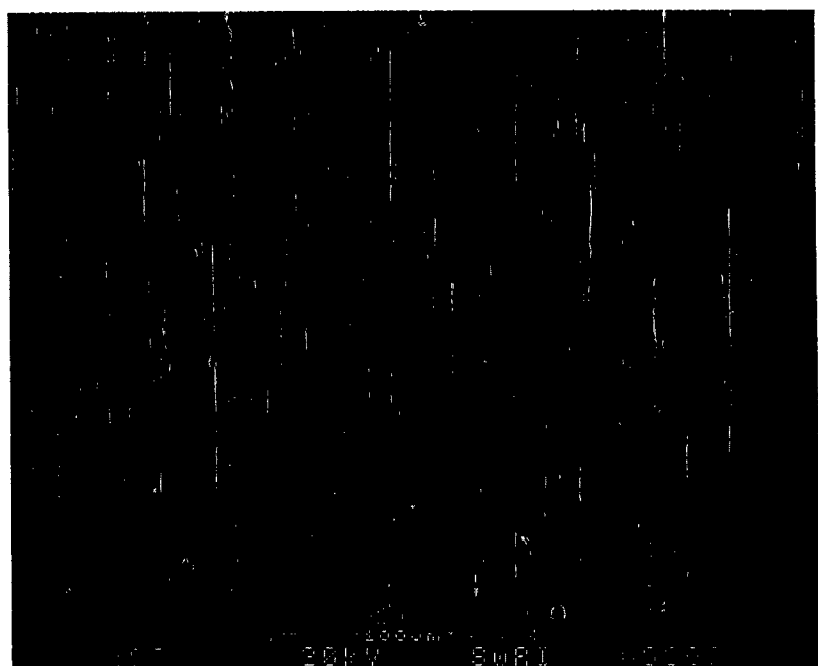
Figure 2-18. Raw Applicator. Condition of the ID surface at 4 cm from the tip.



67469

134X

(a)

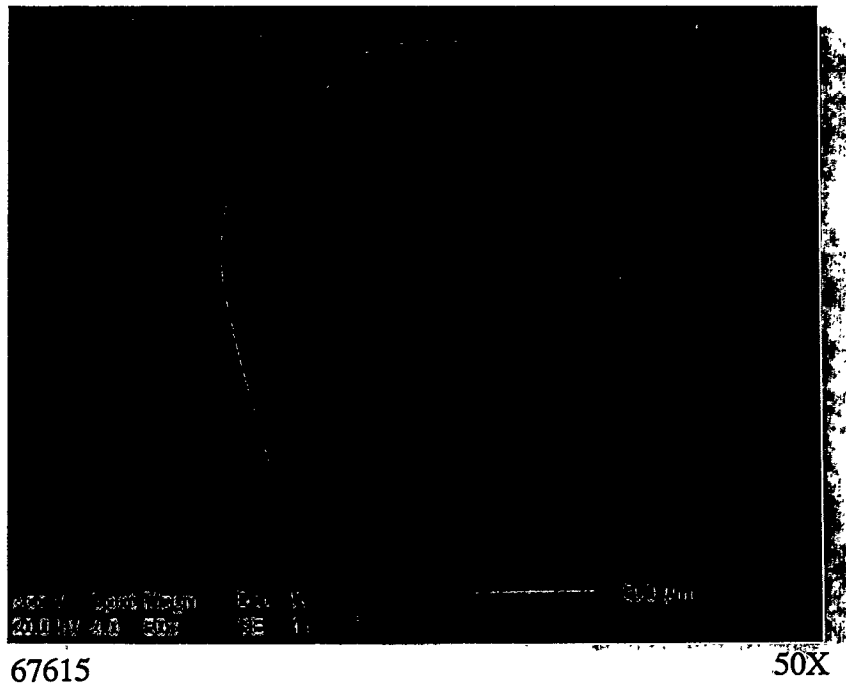


67470

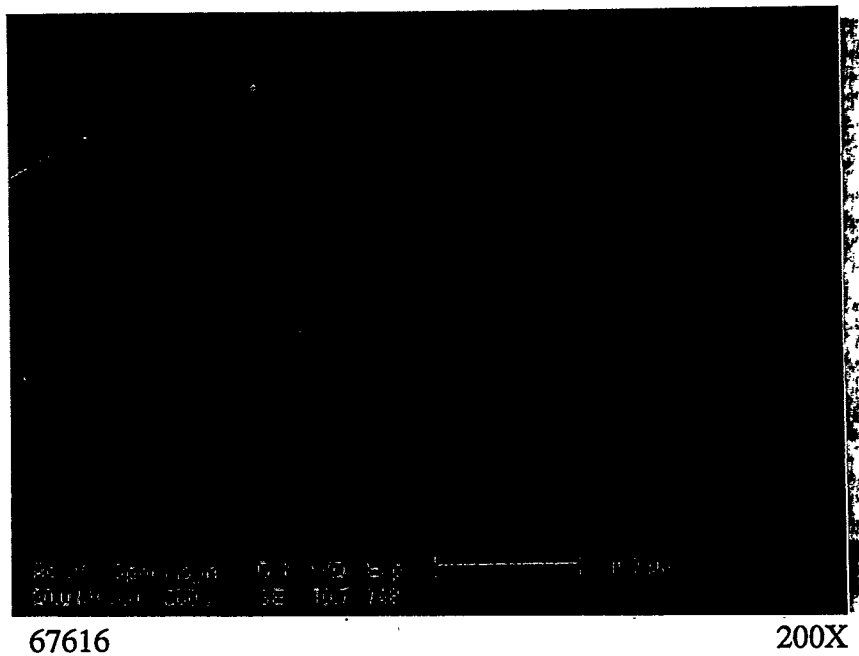
400X

(b)

Figure 2-19. Raw Applicator. Condition of the ID surface at 15 cm from the tip.

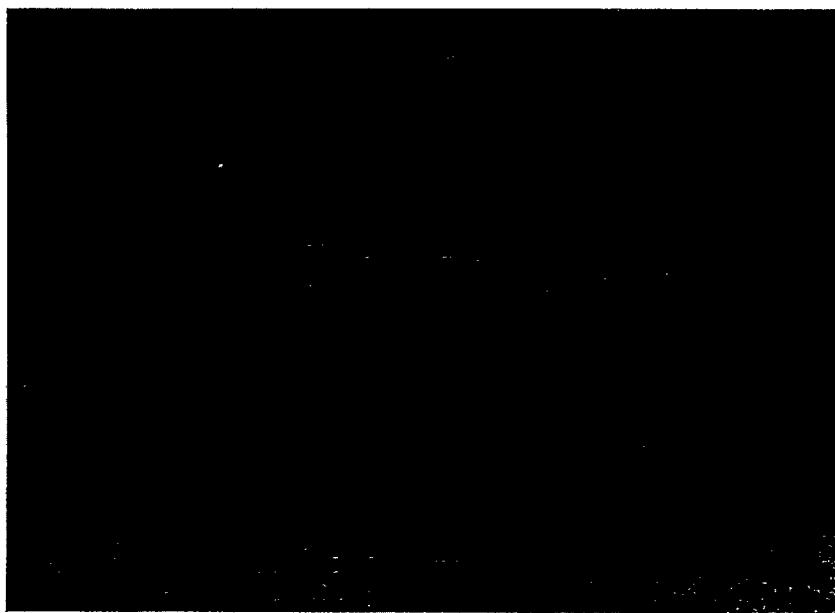


(a)



(b)

Figure 2-20. Biopsy Needle. Tip of the needle through which 4.5 - 5 cm of the needle applicator extended during the treatment. (b) and (c) are higher magnifications of Location A.



67617

800X

(c)

Figure 2-20 (continued). Biopsy Needle. Tip of the needle through which 4.5-5 cm of the needle applicator extended during the treatment. (b) and (c) are higher magnifications of Location A.

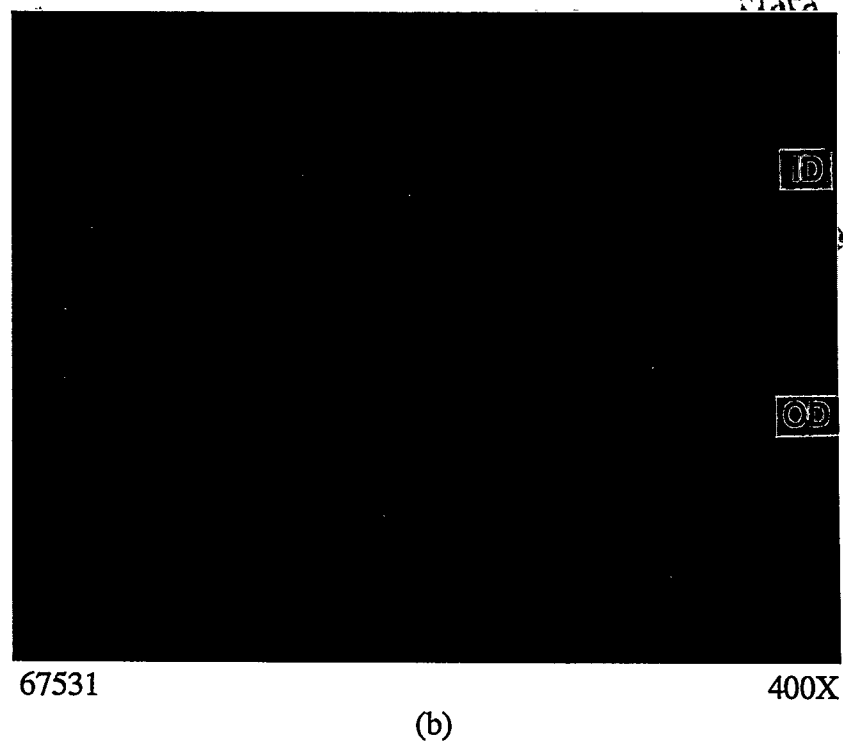
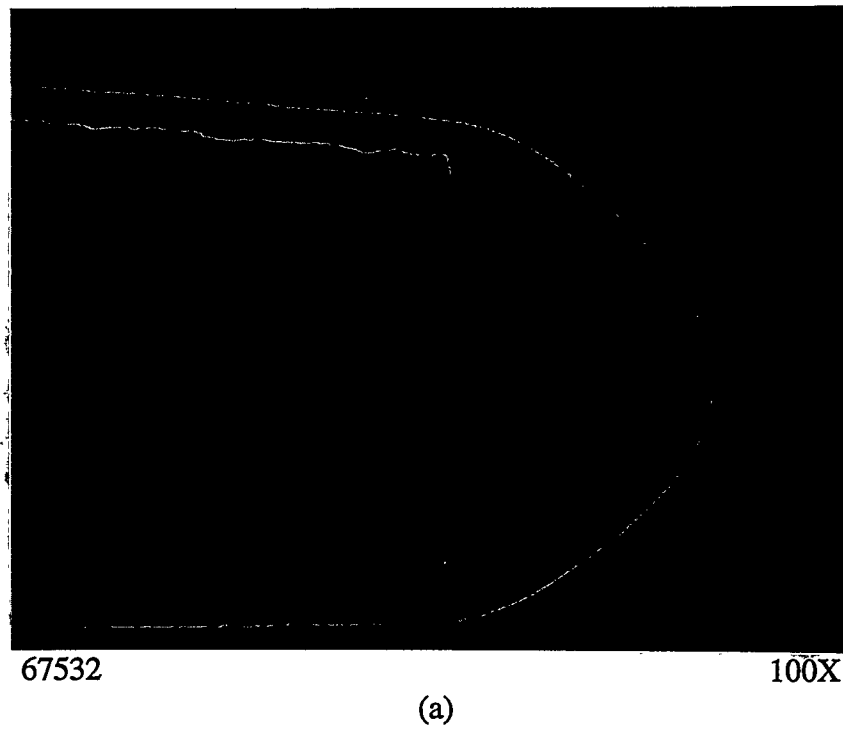


Figure 2-21. Subject Applicator. Unetched cross section of a) the tip, and b) the wall of the needle adjacent to the tip.

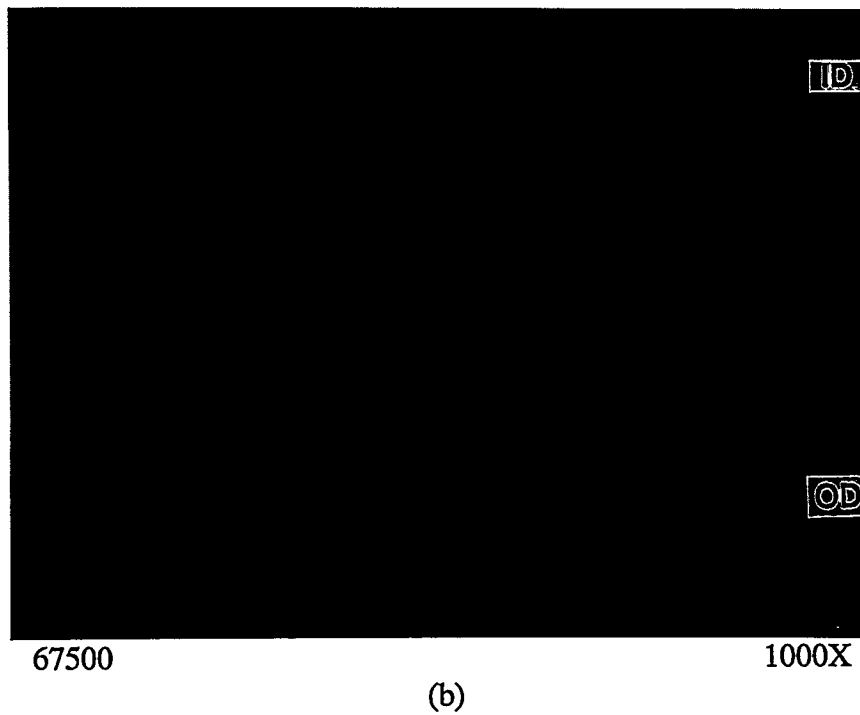
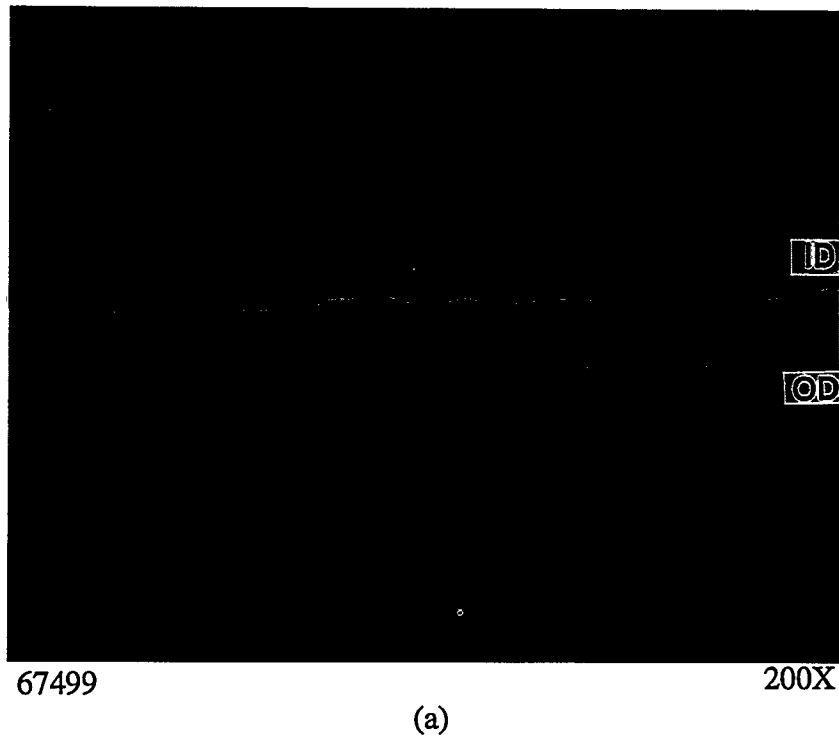


Figure 2-22. Subject Applicator. Unetched cross section of the wall of the needle at a location 4 cm from the tip.

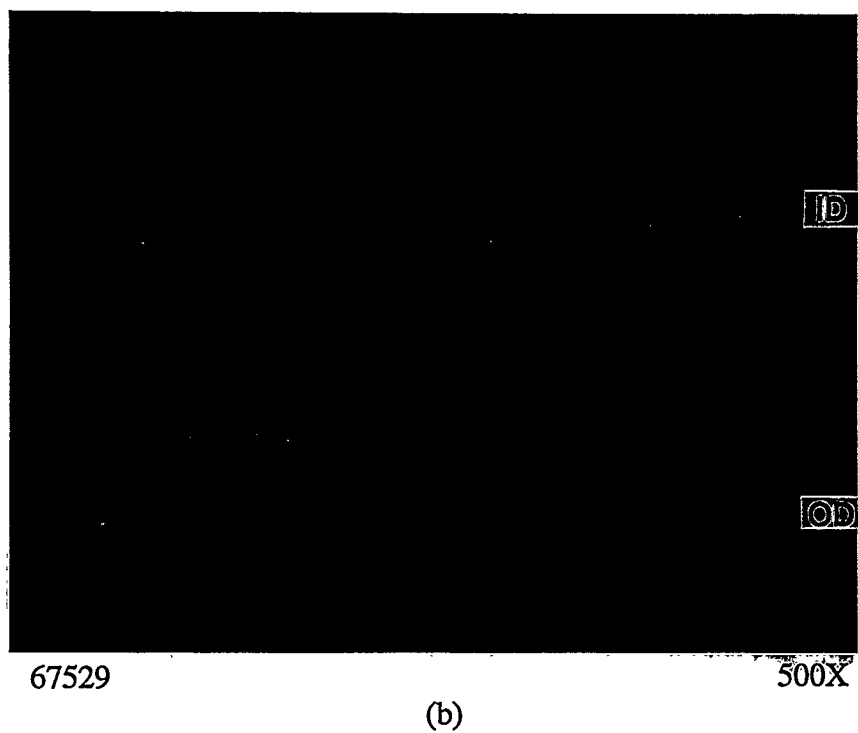
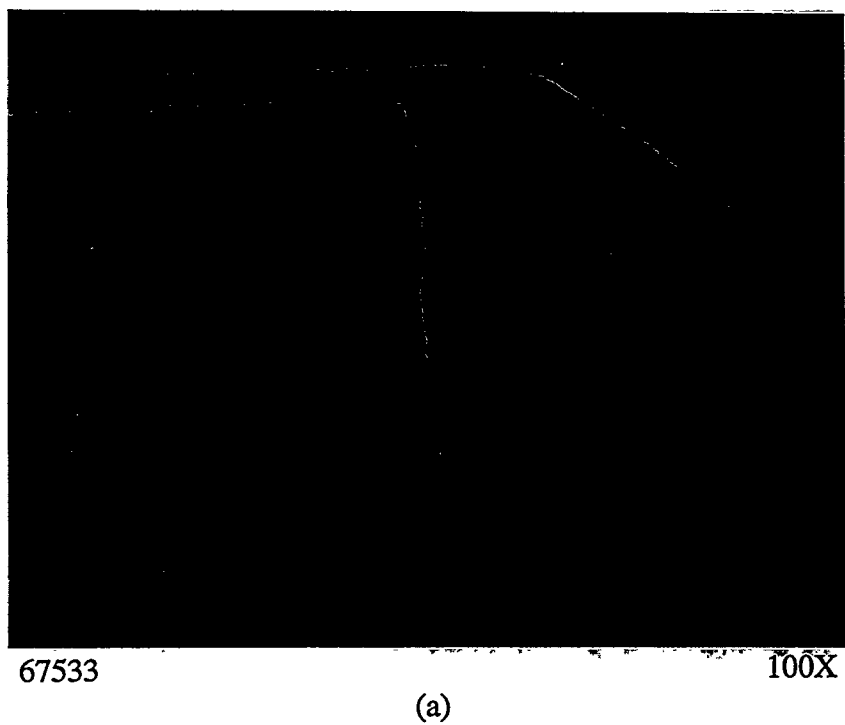
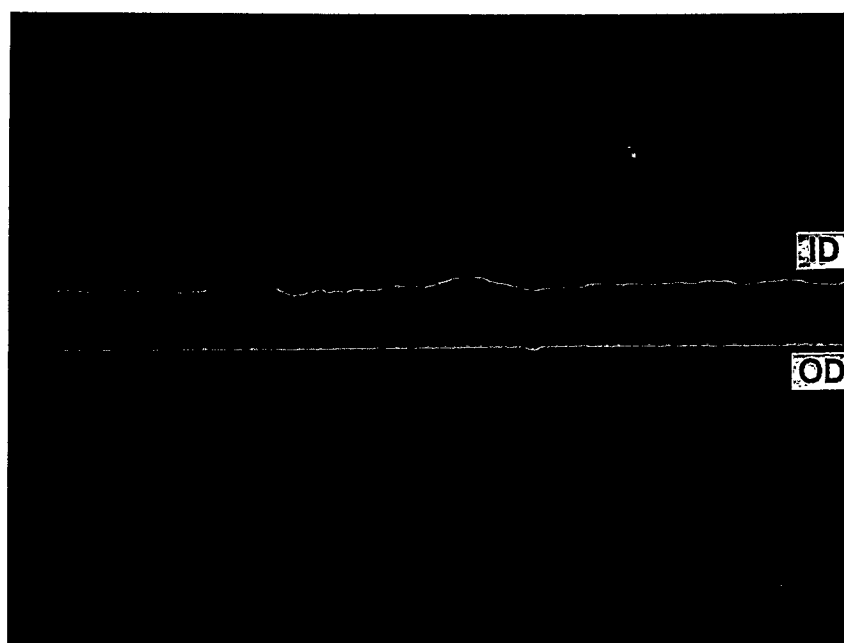


Figure 2-23. Unused Applicator. Unetched cross section of a) the tip, and b) the wall of the needle adjacent to the tip.



67497

200X

(a)



67498

1000X

(b)

Figure 2-24. Unused Applicator. Unetched cross section of the wall of the needle at a location 4 cm from the tip.

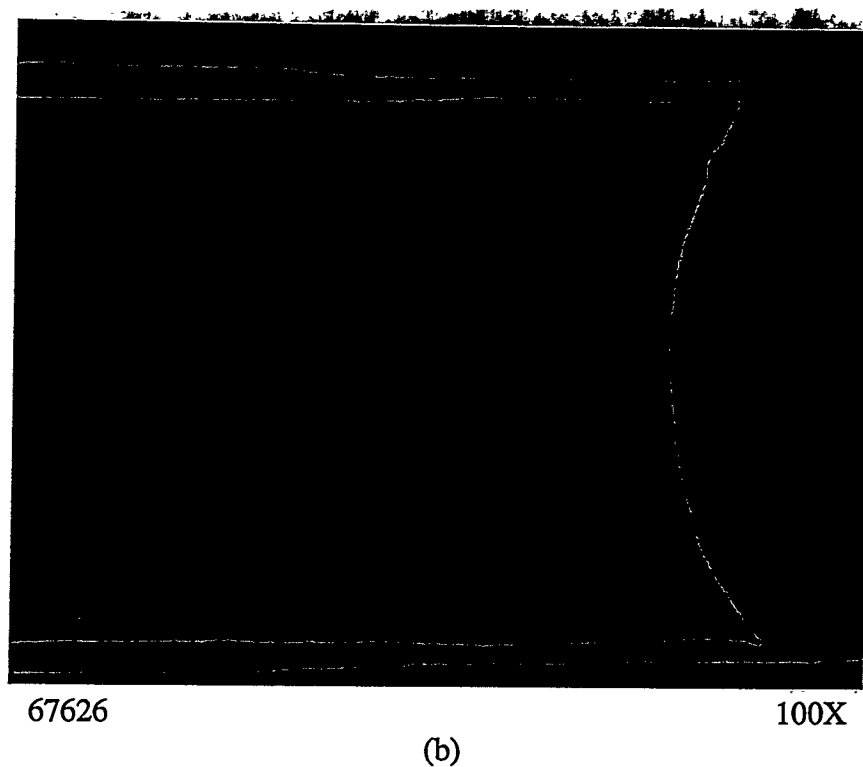
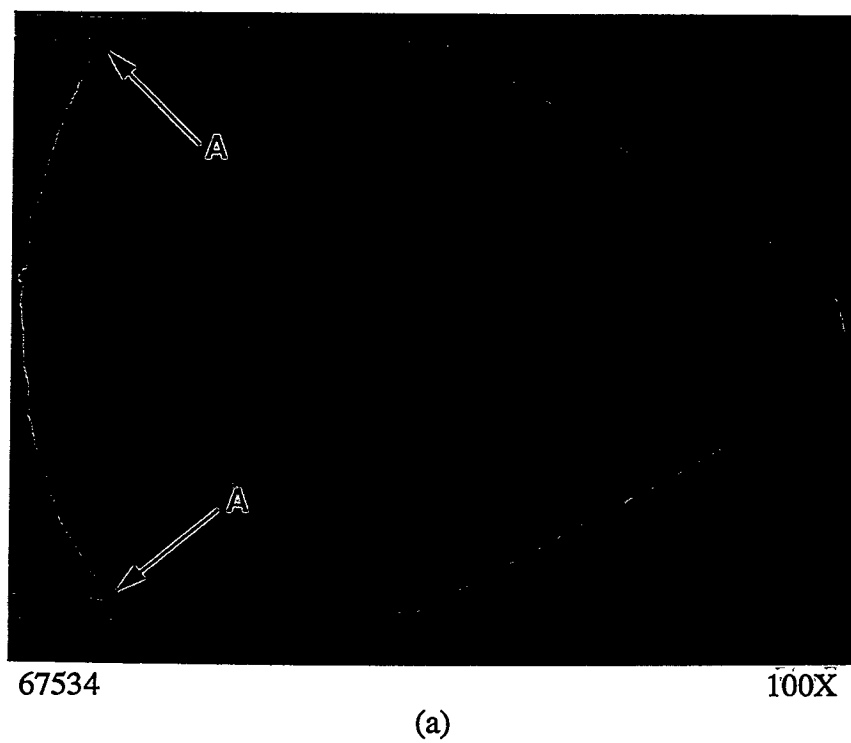


Figure 2-25. Raw Applicator. Unetched cross section of (a) and (b) the tip, and (c), the wall of the needle adjacent to the tip.

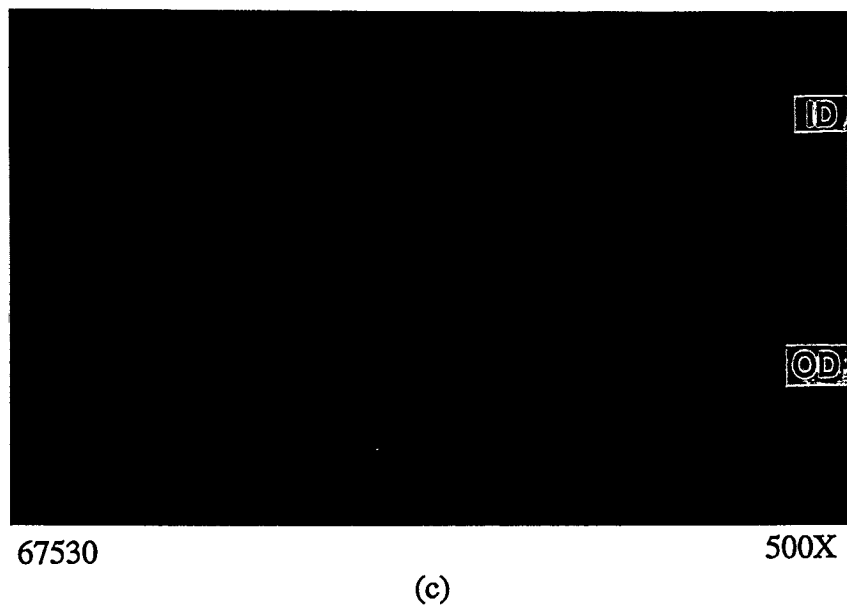
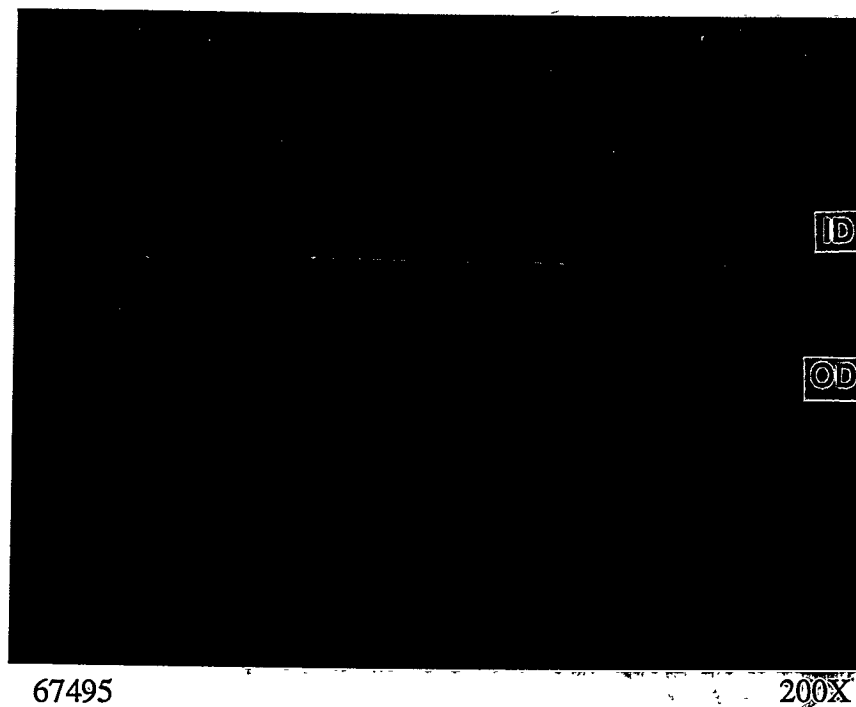
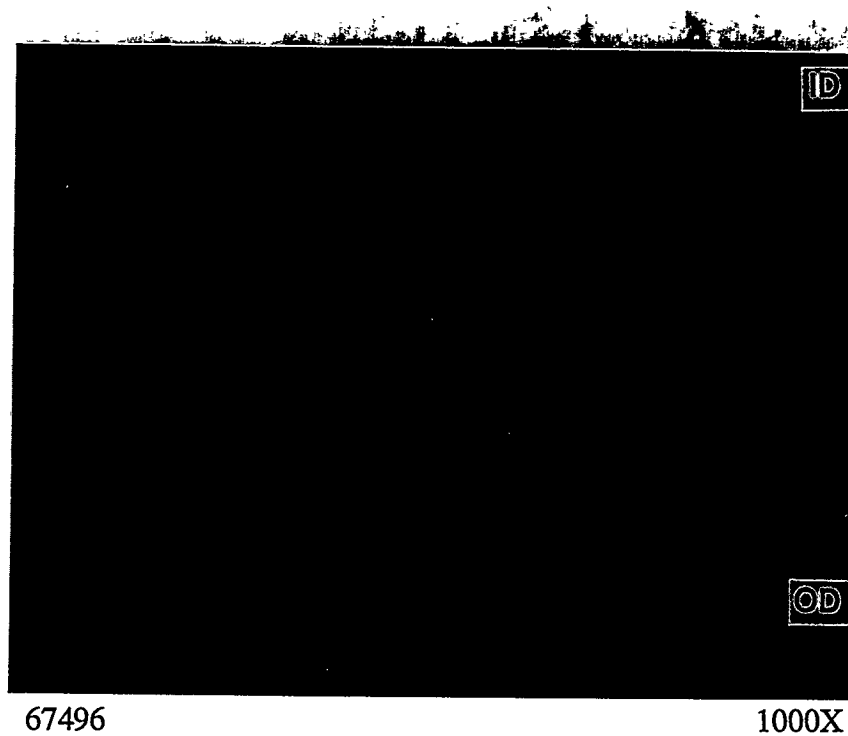


Figure 2-25 (continued). Raw Applicator. Unetched cross section (a) and (b) the tip, and (c) the wall of the needle adjacent to the tip.



(a)



(b)

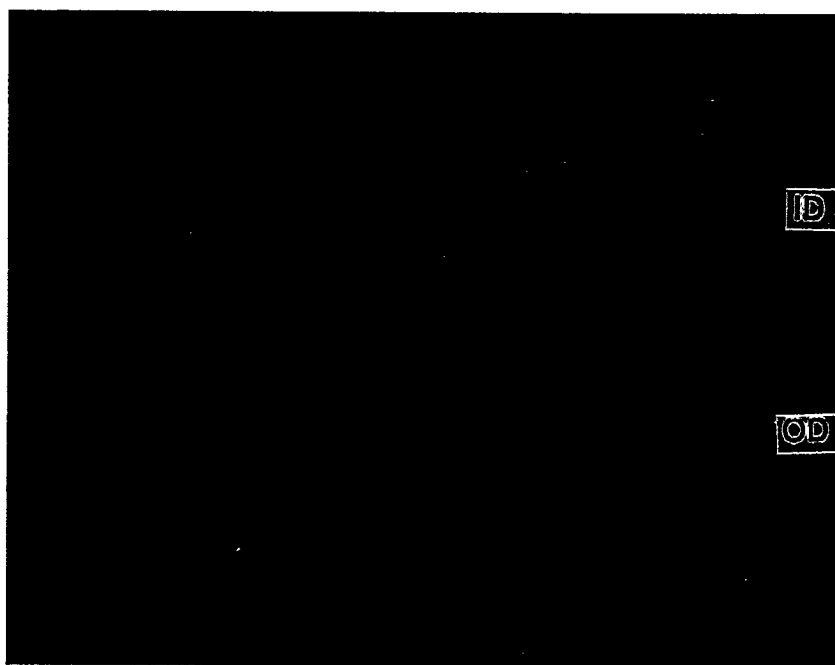
Figure 2-26. Raw Applicator. Unetched cross section of the wall of the needle at a location 4 cm from the tip.



67535

100X

(a)



67538

500X

(b)

Figure 2-27. Subject Applicator. Cross section of (a) the tip, and (b) the wall of the needle adjacent to the tip. Etchant: Oxalic Acid

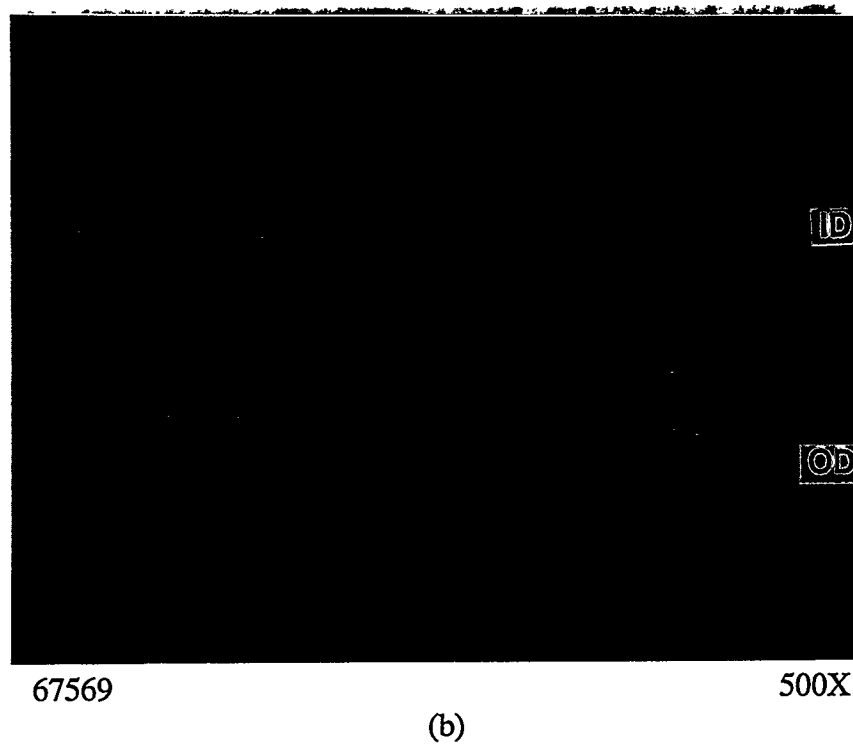
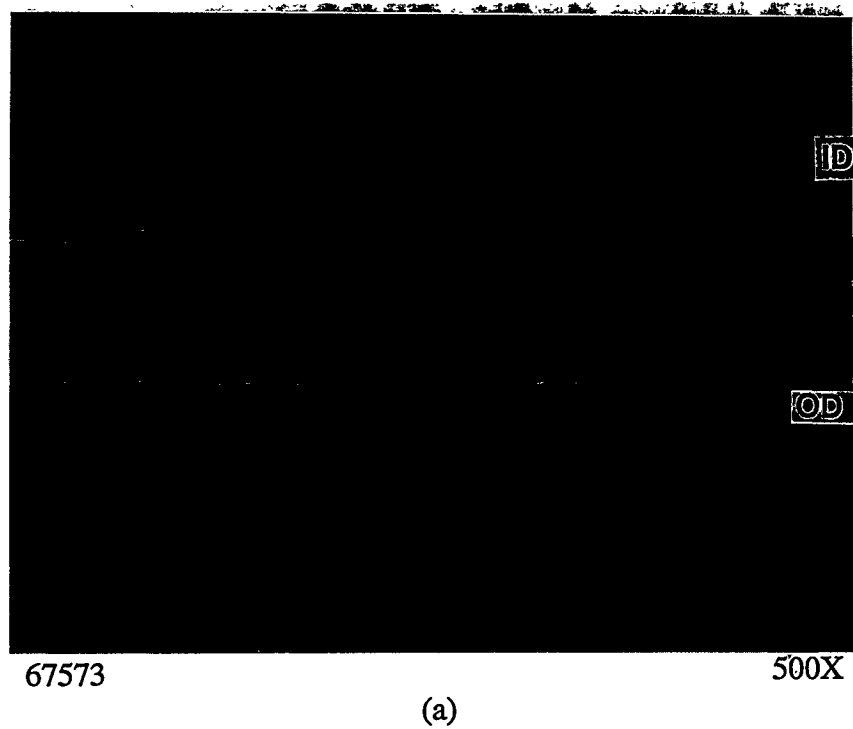
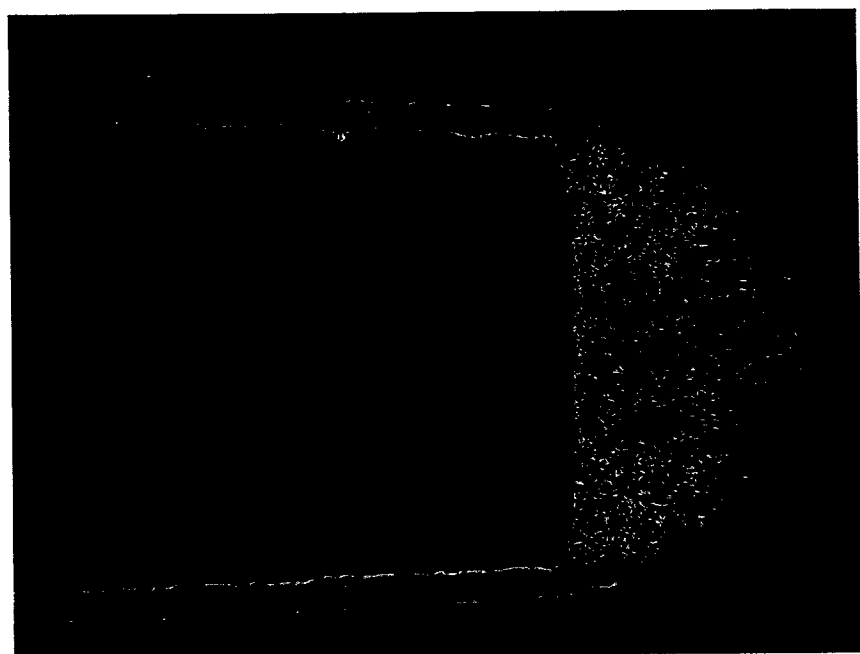


Figure 2-28. Subject Applicator. Cross section of the wall of the needle at a location (a) 4 cm, and (b) 15 cm from the tip. Etchant: Oxalic Acid.



67536

100X

(a)



67537

500X

(b)

Figure 2-29. Unused Applicator. Cross section of (a) the tip, and (b) the wall of the needle adjacent to the tip. Etchant: Oxalic Acid.

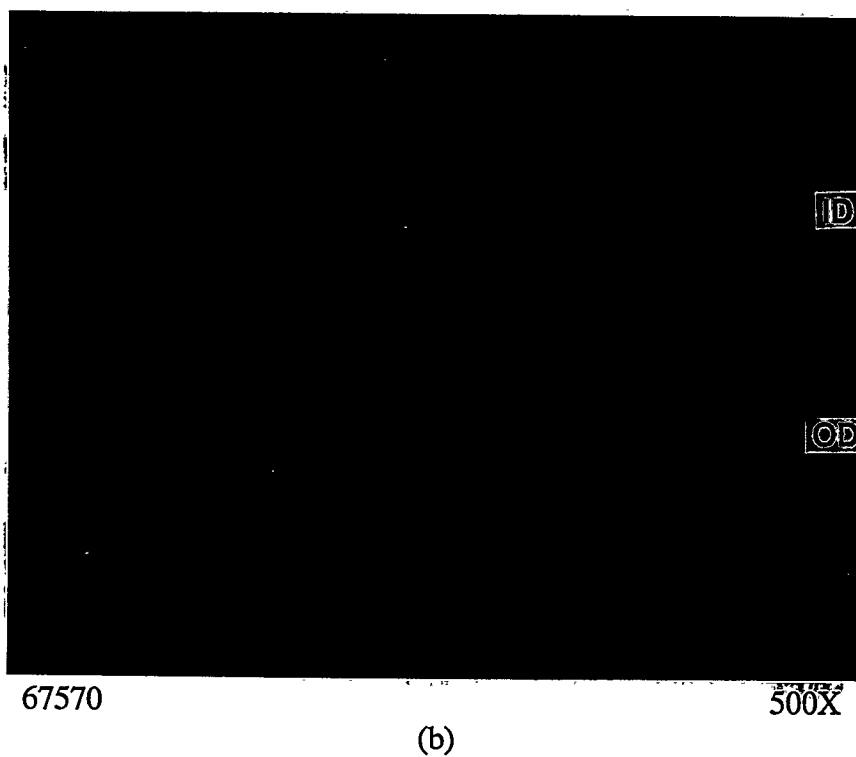
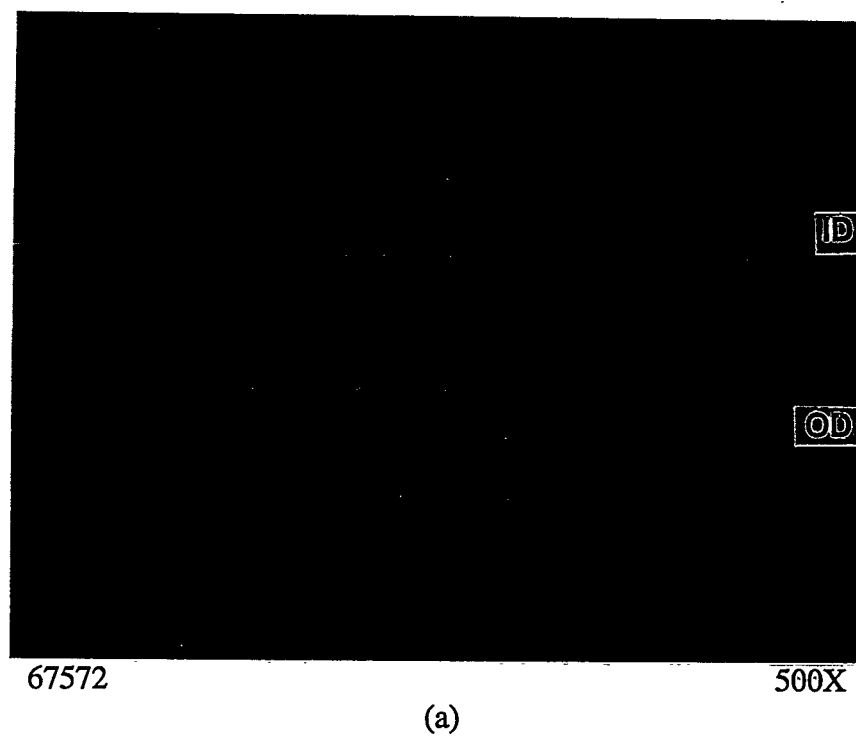
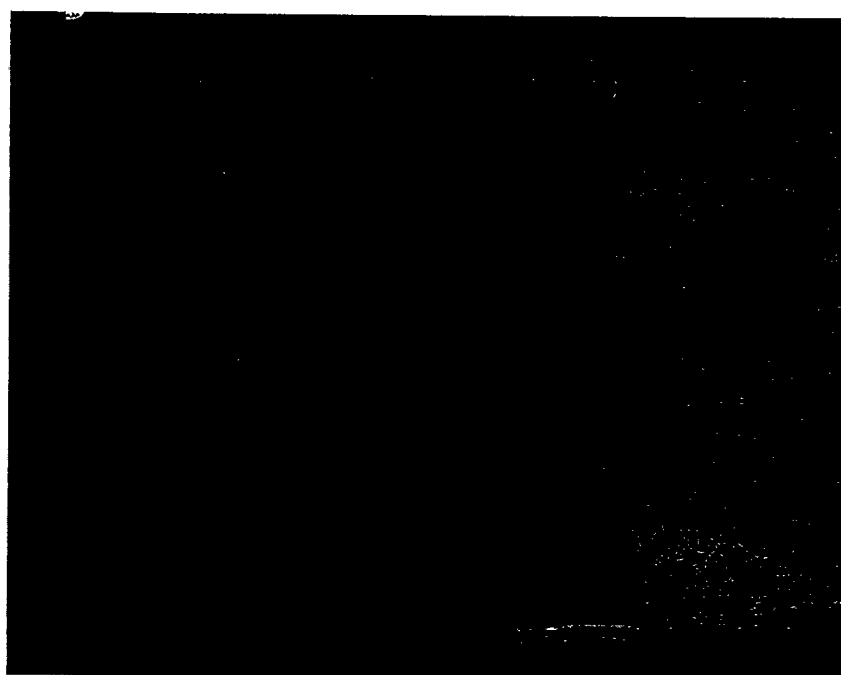


Figure 2-30. Unused Applicator. Cross section of the wall of the needle at a location (a) 4 cm, and (b) 15 cm from the tip. Etchant: Oxalic Acid.



67460

100X

(a)

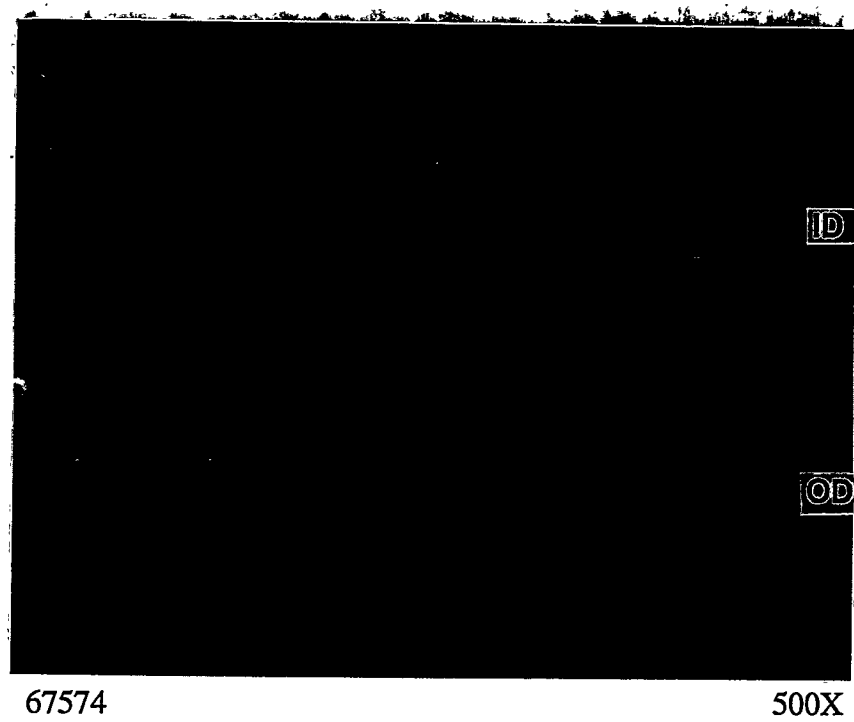


67539

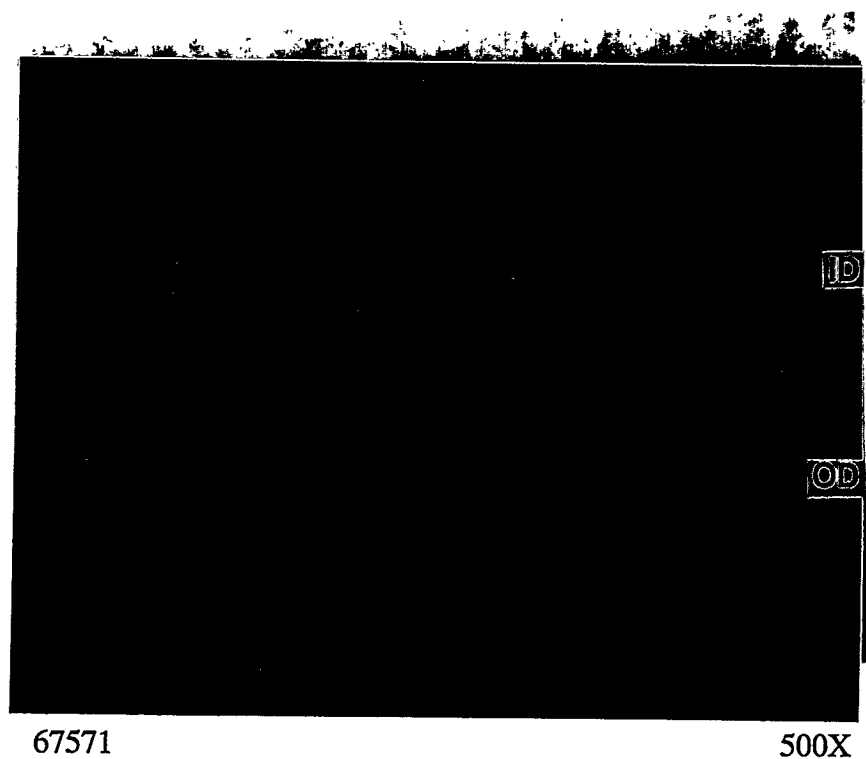
500X

(b)

Figure 2-31. Raw Applicator. Cross section of (a) the tip, and (b) the wall of the needle adjacent to the tip. Etchant: Oxalic Acid.



(a)



(b)

Figure 2-32. Raw Applicator. Cross section of the wall of the needle at a location (a) 4 cm, and (b) 15 cm from the tip. Etchant: Oxalic Acid.

3.0 SUMMARY

The laboratory evaluations conducted during this study revealed no physical or mechanical features unique to the Subject Applicator which would have rendered it unusually susceptible to the formation of a kink. Likewise, none of the inherent, general characteristics of the three needle applicators evaluated could be conclusively shown by this work to significantly affect the resistance of the needles to forming a kink when loaded in bending. There were, however, a number of differences between the Subject or Unused Applicators (manufactured using the same process), and the Raw Applicator (manufactured using different processing steps), which may affect the resistance of the needles to failure in bending.

In discussions with the brachytherapy equipment manufacturer, it was learned that the needles themselves are fabricated by subcontractors. Standard stainless steel hypodermic needle tubing is purchased and sent to a second vendor to have one end of the needle closed and a tip fabricated. The tubing and the needle tip are specified based on the final dimensions desired and the stainless steel alloy to be supplied. The processing steps used to produce the desired final dimensions are not specified by the brachytherapy equipment manufacturer. These details are left to the discretion of the hypodermic needle tubing supplier and the vendor producing the tip on the needles. Consequently, the brachytherapy equipment manufacturer was unable to provide details about the differences in the manufacturing processes used to produce the Raw versus the Subject and Unused Applicators.

The chemical composition of the stainless steel, and the outer and inner diameter of all three applicators was similar, and in accordance with the requirements for 21 gage needles as specified by the brachytherapy equipment manufacturer. Of the physical characteristics measured, the wall thickness and surface finish were the two features most significantly affected by the different manufacturing processes. The processing steps used for the Subject and Unused Applicators left a relatively irregular finish on the ID surface, and shallow, finely spaced, circumferential scratches on the OD surface. The irregular ID surface finish had a recast appearance typical of a surface created by electrodischarge machining. The pattern of shallow circumferential scratches on the OD surface is consistent with a surface which has been ground.

The significance of the irregular ID surface finish can be seen in Table 2-2, and in Figures 2-6 and 2-7, and 2-11 through 2-13. The irregularity causes variations in the wall thickness of on the order of $\pm 15\%$ of the nominal thickness. This irregular surface finish may not have significantly contributed to the formation of the kink which occurred. However, a needle with the same nominal wall thickness and without the irregular surface finish, such as the Raw Applicator, would be expected to be more resistant to a failure in bending.

In light of the fact that the problem encountered during the incident (i.e. an inability of the afterloader device to retract the active sourcewire), the degree of surface roughness on the ID may be detrimental in another way. By bending the needle applicator it may be

possible to "pinch" the active sourcewire sufficiently to exceed the load limit of the afterloader device without ever producing a kink in the needle. It is expected that an irregular surface finish on the ID of the applicator would make it easier to pinch the sourcewire in this manner.

The significance of the circumferential scratches on the OD surface of the Subject and Unused Applicators can be seen in Figure 2-5b and 2-5c. Although very shallow in depth, these scratches can act as sites of stress concentration which could increase the likelihood of forming a kink or initiating a fracture of the needle under high levels of bending stress. Once again, this failure mechanism cannot be conclusively shown to be the cause of the kink which formed during the incident, however, a needle such as the Raw Applicator, with a smoother OD surface finish, would be expected to have a greater resistance to failure by these mechanisms.

The ID and OD surface finishes on the Raw Applicator are considered an improvement over the finishes on the Subject and Unused Applicators. However, there was one aspect of the Raw Applicator which raises concern. During the grinding performed to shape the tip of the needle, a significant amount of the wall thickness was removed. A remaining thickness as low as 0.8 mils was measured in this region, which corresponds to only 42% of the average wall thickness. The reduced wall thickness extends for a distance of approximately 7 mm from the tip of the needle. The impact of this feature, if any, on the performance of the needle is not known.

Regarding the concern that the stainless steel needles may have become embrittled due to the radiation exposure during sterilization and/or the brachytherapy treatment itself, no evidence of embrittlement was detected during this study. It is likely that any significant embrittlement would be accompanied by an increase in strength and therefore hardness. As can be seen in Table 2-4, the Subject Applicator, which had been exposed to the most radiation of the three needles in this study, was the softest. This result is most likely due to normal variations in hardness and should not be interpreted as an indication of softening due to the exposure to radiation. However, it can be conclusively stated that no indication of strengthening or embrittlement of the stainless steel alloy was indicated by these hardness test results.

The microstructure of the needles was found to be primarily a heavily cold worked austenite. This is consistent with a manufacturing process involving cold drawing of a thin wall stainless steel tube. The tip of the needle has a microstructure which consists of a mixture of austenite and ferrite, a normal structure for austenitic stainless steel weld metal. Recrystallization of the cold worked microstructure occurred for a short distance adjacent to the tips of the needles. This correlated well with the reduced hardness measured at the tips of all three needles. The recrystallization and softening is most likely a result of the thermal cycles involved with the welding of the tip, and is not expected to detrimentally affect the performance of the needles.

In addition to the physical and mechanical features of the needles characterized during this study, the possible contribution to the formation of the kink by the procedures used to administer the brachytherapy treatment the day of the incident should also be noted. It

was reported by the staff at Medical Center Keesler that after insertion of the needle applicator into the tumor, the biopsy needle was retracted approximately 4.7 cm to withdraw it from the tumor. In this configuration, the applicator would have been supported at one end (the tip) by the relatively hard mass of the tumor, and at the other end by the biopsy needle. It appears likely that a short unsupported length of applicator existed between these two supported regions. Under a bending load, this unsupported length would act as a hinge and tend to localize the bending moment, increasing the likelihood of a failure at that location. It appears that the unsupported region was at approximately the same location as the kink that formed during the incident. It cannot be conclusively shown from this study that the needle configuration during the treatment contributed significantly to the formation of the kink, but engineering judgement dictates that caution be exercised when using an insertion device, such as the biopsy needle, to avoid the creation of an undesirable source of stress concentration.

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

As a result of an incident in which a radioactive brachytherapy treatment source was temporarily unable to be retracted, an analysis was performed on the needle applicator used during the treatment. In this report, the results of laboratory evaluations of the physical, mechanical, and metallurgical condition of the subject applicator and two additional applicators are presented. A kink formed in the subject applicator during the incident. The laboratory investigation focused on identifying characteristics which would increase the susceptibility of an applicator to form a kink when subjected to bending loads. The results obtained during this investigation could not conclusively identify the cause of the kink. The subject applicator exhibited no unique features which would have made it particularly susceptible to forming a kink. The three applicators examined represent two methods of manufacturing. A number of characteristics inherent to the method used to manufacture the subject applicator which could lead to an increased susceptibility to the formation of a kink were observed. The use of an insertion device, such as the biopsy needle used during this incident, could also dramatically increase the likelihood of the formation of a kink if the applicator is subjected to bending loads.

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