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(54) Title: MINIATURE X-RAY DEVICE HAVING COLD CATHODE			
(57) Abstract Generally, the present invention provides a device for insertion into a body and delivery of x-ray radiation, and a method for fabricating such a device. The device includes a connector, the vacuum housing, an anode and a cathode having a granular surface and being composed of a material that allows it to act as a getter. The cathode may also contain diamond material in one embodiment.			

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MINIATURE X-RAY DEVICE HAVING COLD CATHODE**Field of the Invention**

The present invention is directed to an x-ray device having a cold cathode and a method of fabrication, and more particularly to a miniature x-ray device
5 having a cold cathode and method for fabrication for delivering radiation to vessels, lumen, or cavities of a body, such as cardiovascular tissue, to treat restenosis and other conditions.

Background of the Invention

In the medical sciences, doctors and scientists continually strive to find less
10 invasive ways to treat patients. By using treatments that are less intrusive to the body, doctors can greatly reduce the stress on the patient's system. For example, laparoscopic techniques enable physicians to explore the interior of the body and perform surgery through a small opening in the skin. Less intrusive medical techniques are extremely beneficial when applied to cardiovascular diseases, reflux
15 disease of the esophagus, and other diseases of vessels, cavities and lumens of the body.

Cardiovascular diseases affect millions of people, often causing heart attacks and death. One common aspect of many cardiovascular diseases is stenosis, or the thickening of an artery or vein wall, decreasing blood flow through the vessel.
20 Angioplasty procedures have been developed to reopen clogged arteries without resorting to a bypass operation. However, in a large percentage of cases, arteries become occluded again after an angioplasty procedure. This recurrent thickening of the vessel wall is restenosis. Restenosis frequently requires a second angioplasty and eventual bypass surgery. Bypass surgery is very stressful on the patient,
25 requiring the chest to be opened, and presents risks from infection, anesthesia, and heart failure.

Effective methods of preventing or treating restenosis could benefit millions of people. One approach uses drug therapy to prevent or minimize restenosis. For example, Heparin has been used as an anticoagulant and an inhibitor of arterial
30 smooth muscle proliferation. Dexamethasone is another drug which may prevent smooth muscle proliferation. It has been suggested that such anticoagulants and

antiproliferative agents may be effective at preventing restenosis after an angioplasty procedure thereby eliminating the necessity to repeat the procedure.

To be most effective and to reduce the associated risk, it is desirable to deliver such drugs directly to the region to be treated. In order to minimize the
5 invasiveness of the procedure, a drug delivery device that is adapted to traverse the human cardiovascular or circulatory system must be used. Such a device must be capable of entering small blood vessels with diameters of about two to four millimeters. Such a device must also be capable of making hairpin turns as it follows a tortuous path.

10 Many types of catheters have therefore been developed to deliver these and other effective drugs to the site of the restenosis. The major problem with local drug delivery is that the blood flow quickly washes away the drug so that only a small portion of the drug delivered is actually absorbed by the vessel wall. To address this problem, catheters frequently use pressure to drive the drug into the tissue or plaque,
15 potentially causing damage to the lumen wall. Techniques of delivery which do not use pressure use occlusion balloons to isolate the area from blood flow to enable sufficient absorption of the medication. However, the blood flow in an artery can only be occluded for a limited period of time while the drug is delivered. Due to these and other problems, localized delivery of drugs is not able to achieve sufficient
20 absorption in the treatment of restenosis.

Another treatment for restenosis that has been attempted is beta-irradiation of the vessel wall by positioning radioactive isotopes in the vessel at the site of the restenosis. However, the depth of the penetration of the radiation is impossible to control with this method. The depth of the penetration of the radiation is determined
25 by the type of the radio-isotope used. The radioactive source will also irradiate other healthy parts of the body as it is brought to the site to be treated. Another disadvantage is that medical personnel must take extensive precautions when handling the radioactive material.

Less intrusive techniques are also extremely beneficial when applied to the
30 esophagus. Tens of millions of Americans suffer from gastroesophageal reflux disease (GERD). GERD is characterized by a backward flow of the stomach and

duodenal contents into the esophagus. These conditions result when the valve at the junction between the esophagus and the stomach does not function properly. When this occurs frequently, it is termed chronic GERD or reflux esophagitis. The symptoms of this condition are dyspepsia, or discomfort in the esophagus after

5 meals, burning chest, upper abdominal pain, sour taste, and regurgitation.

Medical research has revealed that the acidic stomach contents cause anatomic abnormalities of the epithelium, or lining, of the esophagus during reflux. The cell type of the epithelium of the esophagus changes from a squamous, or circular-shaped cell, to a columnar, or rectangular-shaped, cell type. This cellular
10 damage of the epithelium is termed Barrett's esophagus.

Barrett's esophagus is a precursor for cancer of the gastroesophageal system. Barrett's-associated malignancies strike approximately 10,000 people per year. There is a high rate of progression from reflux disease to Barrett's esophagus. In fact, 90 percent of patients with reflux symptoms who have an endoscopic
15 examination show anatomic abnormalities of the epithelium.

Diagnosis of cancer in Barrett's esophagus ordinarily leads to removal of the diseased segment of the esophagus. However, an effective treatment of Barrett's disease could prevent the progression to cancer and could therefore reduce the need for this painful and drastic procedure. An effective treatment for Barrett's
20 esophagus could improve the lives of many people. Ultrasound and argon-ion plasma treatments have been suggested to treat Barrett's esophagus, but these techniques are in early experimental stages and have not been proven effective. It is believed that photodynamic therapy is also a possibility.

Many other disorders could be treated with small, effective medical devices
25 capable of accessing the interior of the body. For example, one disorder of the gastrointestinal system is pyloric strictures. Pyloric strictures occur in the pylorus, or distal aperture of the stomach. The pylorus is surrounded by a strong band of circular muscle, through which the stomach contents are emptied into the duodenum.

Pyloric strictures can be subjected to dilatation to open the pylorus passage.
30 However, the pylorus frequently thickens in response to the dilatation. Repeated dilatation has been used to treat pyloric strictures, but has not proven to be an

effective long-term solution. There is a need for treatments to prevent this recurrent thickening of the pylorus.

Thus, there is a need for miniature devices and effective methods to treat the interior of the body with minimal intrusion. Effective, less invasive techniques for treating stenosis and restenosis of a lumen, treating GERD, and treating pyloric strictures are especially needed.

Summary of the Invention

A device is described suitable for inserting into a body and delivering x-ray radiation, comprising a connector, including a proximal and a distal portion, a vacuum housing coupled to the distal portion of the connector, an anode disposed within the vacuum housing, and a cathode disposed within the vacuum housing. The cathode has a granular surface and is operative with the anode and the connector to produce the x-ray radiation. The cathode is composed of a material that also allows it to act as a getter. The cathode may also include diamond material.

A method is described for producing a device suitable for insertion into a body and delivering x-ray radiation, comprising forming a cathode from granular getter material, and combining the cathode with an anode, a vacuum housing, and a connector, so that the cathode is operative with the anode and connector to produce x-ray radiation.

Brief Description of the Drawings

The invention may be more completely understood in consideration of the detailed description of various embodiments of the invention which follows in connection with the accompanying drawings.

FIG. 1 shows a cross-sectional view of an embodiment of an x-ray emitter of the invention.

FIG. 2 shows a side view of one embodiment of a cathode and end cap of the x-ray device of the invention.

FIG. 3 shows a cross-sectional view of a cathode of an embodiment of the x-ray device of the present invention.

FIG. 4 shows a cross-sectional view of a cathode used in another embodiment of the x-ray device of the invention.

FIG. 5 shows a cross-sectional view of a cathode of another embodiment of the x-ray device of the invention.

FIG. 6 shows a cross-sectional view of a cathode of another embodiment of the x-ray device of the invention.

5 FIG. 7 shows a cross-sectional view of a cathode of an additional embodiment of the x-ray device of the invention.

FIG. 8 shows a cross-sectional view of a cathode of another embodiment of the x-ray device of the invention.

10 While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

15 **Detailed Description of the Various Embodiments**

The present invention is applicable to a variety of devices, and methods of fabrication thereof, which irradiate passages, lumens, vessels, cavities, or interior sites in a body with x-ray radiation. The invention is particularly advantageous in treating restenosis and stenosis of the cardiovascular vessels, gastroesophageal and
20 gastrointestinal systems, and other ailments where delivery of localized x-ray radiation to interior portions of the body has been discovered to be effective. While the present invention is not so limited, an appreciation of various aspects of the invention is best gained through a discussion of application examples operating in such environments.

25 Many disease states of the body involve the abnormal thickening of a lumen or passage. The inventors have found that the x-ray device of the present invention provides a very promising way to treat these types of conditions. The x-ray device produces ionizing radiation that penetrates to the first layers of cells on the surface of the passage or lumen. This radiation induces apoptosis, or programmed cell
30 death.

Apoptosis differs from another type of cell death, necrosis. In apoptosis, a disruption in the gene structure of the cell results in the cell failing to replicate, and in some cells, results in an induced cell death where the contents of the cell are utilized by adjacent cells. Cell death by apoptosis therefore reduces inflammation and the biochemical results of inflammation, as compared to necrosis, which results in scarring and thickening of the surface cells.

X-ray radiation has been found to reduce the occurrence of restenosis when x-ray radiation is applied to area of a blood vessel where an angioplasty or other expansion of the vessel has taken place. In coronary applications, it is desirable to have the x-ray radiation penetrate into the adventitia tissue of the blood vessels about 2mm deep. Penetration into the cardiac muscle tissue should be minimized. Further, it is desirable to deliver x-ray radiation with a peak energy of about 8-10 kiloelectron volts (keV) in coronary applications.

In one aspect of the present invention, an x-ray device positionable in the esophagus is used to treat Barrett's esophagus by inducing apoptosis in the abnormal cells of the epithelium. The use of the x-ray device of the present invention may therefore be used to reduce the escalation of this condition to cancer. Further, the x-ray device of the present invention may be used for preventing the thickening of the pylorus after dilatation of pyloric strictures.

When treating the interior of the body, it is desirable to use as small a device as possible. Very small devices are required when traversing the blood vessels of the cardiovascular system, for example. A smaller device will be more easily guided to the site of treatment. It is also important to minimize the occlusion of the blood vessel, in order to allow blood flow to the greatest extent possible.

FIG. 1 illustrates an x-ray emitter of a first embodiment in which a cathode 12 of an x-ray emitter 10 comprises a getter.

An x-ray emitter, as shown in FIG. 1, includes a cathode 12, an anode 14, a housing shell 18, and an end cap 16. The anode 14, endcap 16, and shell 18 define a vacuum chamber which encloses a vacuum space 24. In order to produce x-ray radiation, an electrical field is applied across the cathode and anode, resulting in the emission of electrons from the cathode and acceleration of these electrons toward the

anode. The anode 14 consists of a heavy metal that emits x-ray radiation when the high-speed electrons are incident upon the anode 14. The x-ray radiation is emitted from the anode 14 and travels through the shell 18 which is transparent to x-rays.

The anode and cathode are separated by a gap that varies depending on the requirements of the particular application. For many coronary applications, the gap may range from .20 to 1.5 mm.

The x-ray emitter 10 may be supplied with a high voltage by a connector, not shown in Fig. 1. The x-ray emitter 10 may be coupled to the connector at a distal end, which is disposed within the body during treatment. A proximal end of the connector emerges from the body and may be coupled to a voltage generator.

It is desirable to maintain a vacuum condition within the shell 18. In order to create the vacuum, frequently, the components are assembled within a vacuum or the chamber is pumped out by conventional methods. Further, a getter may also be disposed within the housing. The getter has an activation temperature at which it will react with stray gas molecules in the vacuum. The getter eliminates stray gas molecules, improving the quality of the vacuum within the shell.

In accordance with this invention, a getter may serve as an electron emitter when a voltage differential is applied. Therefore, the getter may be used as the cathode. This combination of elements results in a smaller x-ray device with a very simple design.

While attempting to produce x-ray radiation of about 8-10 keV in the body, it is important to keep the magnitude of the electrical fields at the surface of the cathode low enough to prevent arcing between the anode and the cathode. Just on the other side of the housing shell 18 from the anode and cathode, a conductive layer 19 is held at ground. An electrical discharge from the surface of the cathode to the anode along the inside surface of the shell is termed an electric flashover. An electric flashover must be prevented to keep the x-ray emitter operative. According to the present invention, as a weaker electrical field at the cathode surface is required for cold electron emission, the danger of electric flashover is reduced.

Because of concerns about flashover, dielectric strength should be considered when choosing a material for the housing. The dielectric strength is the maximum

electric field that a material can withstand before breaking down. However, surface discharge may occur at lower electrical field strengths. Many individual factors may affect the flashover voltage, such as the surface geometry, material contamination, the material history, and vacuum quality.

5 It is possible to have a safety switch mechanism that monitors power output to detect the occurrence of flashover. If flashover occurs, all remaining electrostatic energy in the cable may be quickly transferred to a resistor in the high voltage source outside the body.

10 The ability to lower the required electric field at the cathode results in a less expensive manufacturing technique. Small irregularities on the surface of the cathode result in an increase in the magnitude of the electrical field for an applied voltage, thereby increasing the chance of electrical flashover. The weaker the required electrical field at the cathode, the more imperfections can be tolerated on the cathode surface without risking flashover.

15 According to the invention, a cathode made of granular metal materials may not require an additional coating, such as diamond, in order to emit electrons at moderate electrical fields for x-ray applications. The granulated surface of the cathode provides multiple microprotrusions capable of efficient field emission of electrons at moderate electrical fields. Therefore, in accordance with the invention,
20 the cathode consists of granular getter materials. Using granular getter materials, field emission current densities of approximately 0.5-5 milliamps per square millimeter are observed at the cathode at electrical fields of 10-50 volts per micron. This level of emission current is similar to that found in diamond-coated cathodes at electrical fields that are moderate for x-ray production. However, a device using a
25 granular getter material as the cathode is considerably less complicated to manufacture. The cathode with microprotrusions may be formed by thermal diffusion bonding of granulated getter material, or getter powder, having granular sizes of .5 to 50 micrometers in diameter.

30 In accordance with one embodiment of the invention, x-ray radiation is produced while keeping the required electrical fields low by mixing diamond powder with the granulated getter materials before forming the cathode of the

present invention. Diamond materials display valuable properties as field emitters, losing electrons easily as a field is applied. Where a diamond powder is included in the cathode, an electrical field of 10-50 volts per micron will produce current densities in the range of 1-10 milliamps per millimeter square.

5 The diamond material may be purchased commercially from numerous sources. Most of the powder diamond material is obtained from CVD processes, although it may be produced from natural beds of diamond.

Heat is generated by the operation of the x-ray emitter of the present invention. Therefore, it is important that coefficients of thermal expansion (CTE)
10 are similar in all materials used to construct the x-ray emitter. If materials are used having inconsistent CTEs, then the integrity of the vacuum chamber of the x-ray emitter may be jeopardized. In one embodiment of the invention, the end cap 16 is composed of molybdenum, having a CTE of $4.9 \times 10^{-6} \text{ }^{\circ}\text{C}^{-1}$. The shell 18 of the x-ray emitter may be composed of isotropic boron nitride having a CTE of $3.8 \times 10^{-6} \text{ }^{\circ}\text{C}^{-1}$.
15 The CTE of the anode is also important because it seals the end of the shell 18 closest to the coaxial cable. The anode may be comprised of tungsten, having a CTE of $4.6 \times 10^{-6} \text{ }^{\circ}\text{C}^{-1}$.

Another consequence of heat generation is that cooling may be desirable in some situations. Where the x-ray emitter of the present invention is used in a blood
20 vessel, the blood flow past the emitter is sufficient to dissipate the generated heat. Where the device is used in the esophagus or other cavity, a fluid could circulate through a balloon surrounding the emitter to prevent damage to the body.

Now referring to FIG. 2, the end cap of the x-ray emitter is shown from a side view. In one embodiment, the elements of the x-ray emitter may be bonded
25 together using vacuum brazing. The brazing alloy 22 joins the cathode to the end cap. Further brazed alloy connects the end cap to the shell. Additional brazing alloy may bond the anode to the shell, shown in FIG. 1. The vacuum brazing techniques are important to maintaining the integrity of the vacuum chamber 24. Vacuum brazing as used in the x-ray emitter of the present invention may be provided by
30 Koral Labs, Minneapolis, Minnesota, for example. Two examples of preferred brazing alloys are AuSn and AuGe.

The getter cathode 12 may be composed of many different types of getter materials. The getter may include zirconium, aluminum, vanadium, iron, and/or titanium. In one embodiment, the getter materials may be composed of an alloy including vanadium, iron and zirconium. One successful choice for the getter cathode is a material produced by SAES and referred to as ST707. Getter alloy ST707 is produced by thermal diffusion bonding and is composed of 24.6% vanadium, 5.4% iron, and 70% zirconium.

The getter will be sufficiently conductive and capable of electron emission to serve as an effective cathode at moderate electrical fields, for example, 10 volts per micron to 60 volts per micron. Before the getter is activated, it is covered with a layer of oxidation that shields the getter material from the atmosphere at normal conditions. When the getter is heated to an activation temperature in a vacuum, the oxidation layer diffuses into the interior of the getter, revealing the active getter surface, which will react and bond with most gas molecules. Under vacuum conditions, the active getter surface reacts with most stray gas molecules and bonds them to the getter, thereby improving the quality of the vacuum. The SAES ST707 alloy getter has an activation temperature of 400-500°C.

The shape of the cathode affects the electron emission qualities of the cathode. FIG. 3 shows a cross-sectional view of the cathode shown in FIGs. 1 and 2. This cathode is cylindrically shaped with a half full sphere shape on one end. The diameter D is 0.75mm. The length of the cathode L is 1.30mm. A smaller catheter where D is 0.50mm and L is 1.30mm is shown at Fig. 4.

FIG. 5 illustrates a cathode 12 having a standard 118° drill point tip. For the cathode 12 shown in FIG. 5, D is 0.75mm and L is 1.30mm.

FIG. 6 shows a smaller cathode in the standard 118° drill point tip configuration. In FIG. 6, D is 0.50mm and L is 1.30mm.

FIG. 7 shows a cathode 12 having a sharp point. The angle Θ is 60°. For the cathode shown in FIG. 7, D is 0.50mm and L is 1.30mm.

The cathode shown in FIG. 8 is also a sharp point configuration where Θ is 60°. The diameter D is 0.75mm while the length L is 1.30mm.

In order to apply an electric field across the anode and cathode, a coaxial cable, not shown in the figures, may be used as the connector. The coaxial cable may be coupled to a high-voltage generator at a proximal end that remains outside the body. At the distal end, the coaxial cable may be coupled to the x-ray emitter.

- 5 An internal conductor of the coaxial cable may be coupled to the anode at the appropriate voltage. An external conductive layer of the coaxial cable may be held at ground and coupled to the cathode base via a conductive solder. Other known methods may also be used to apply the electric field across the anode and cathode.

- The coaxial cable used in conjunction with the present invention must be
10 able to carry the required voltages, have sufficient flexibility to make sharp turns as it follows the path of an interior passage of the body, and have a sufficiently small diameter to traverse the area of the body to be treated. Standard high voltage coaxial cables are generally not flexible enough. However, the inventors have found that miniature high frequency coaxial cables with an outer diameter of approximately 1.0
15 millimeter to 3.0 millimeters are available which also exhibit sufficient flexibility. These types of cables are typically used in high frequency applications at voltages less than several kilovolts (kV). In connection with the present invention, the inventors have discovered that such cables can hold direct current voltages as high as 75-100 kV without breakdown. Therefore, these cables are well suited for use with
20 the x-ray device of the present invention. In one embodiment, a cable with an outer diameter less than or equal to 3.0 millimeters is used. In another embodiment, the cable has an outer diameter of 1-2 millimeters. Such cables are manufactured by, for example, New England Electric Wire Corporation, Lisborn, New Hampshire.

- The shell 18 of the x-ray emitter may be substantially transparent to x-rays in
25 order to allow the full dosage to reach the treatment site. The shell may also be an electrical insulator, capable of supporting the x-ray emitter without electrical discharge between the exterior of the shell at ground and the interior of the shell at high voltage. The shell may be comprised of chemical vapor deposition (CVD) boron nitride, CVD silicon nitride, beryllium oxide, aluminum oxide, or other
30 ceramic material. The shell may also be composed of a CVD diamond three-dimensional structure.

In one embodiment of the invention, the field emission properties of the cathode may be modified by a conditioning procedure that alters the surface of the cathode to achieve predetermined field emission parameters. Multiple applications of high voltage are carried out at different distances and relative positions of the electrodes, causing electrical discharges between electrodes. The discharges destroy unstable emitting sites at the cathode surface and drive the field emission parameters into the desired range. As a result, a conditioned cathode is capable of more consistent performance.

Conditioning of the cathode may be carried out according to the concepts set forth in High Voltage Vacuum Insulation: Basic Concepts and Technological Practice, R.V. Latham, Editor, Academic Press, 1995. For example, current conditioning includes applying a voltage over the cathode and a series resistor. The applied voltage is increased in small steps such that a "pre-breakdown" current in the cathode stabilizes before proceeding. The conditioning procedure is typically continued until the intended operating voltage is reached.

As another example, "glow-discharge" conditioning includes using the sputtering action of low-energy gas ions to remove contaminants from the cathode surfaces. A low-voltage AC glow discharge is allowed to occur between the cathode and an electrode by raising the pressure in the vacuum chamber while alternating current is provided to the cathode and the electrode.

Yet another example is gas conditioning, which includes progressively increasing the field at the gap near the cathode at currents of a few microampere and a pressure of about 10^{-5} mbar. The emission currents are allowed to quench for a 20 minute period to their asymptotic limit. The procedure is repeated at increasing field levels until the intended operating field of the cathode is reached.

As a final example, spark conditioning may be used, also known as "spot-knocking". The method may be carried out essentially as the current conditioning method; although a reduced series resistor may be necessary to increase the rate of dissipation of energy in the spark. In using this method, the external capacitance associated with the gap should be minimized so that only a limited amount of energy (≤ 10 J) is dissipated in the gap during sparking. A more sophisticated form of spark

conditioning includes using discharges in the nanosecond range under ultra high vacuum conditions.

Spark conditioning and current conditioning may be used to improve a cathode in one embodiment of the present invention. The slow application of voltage involved in current conditioning may be the most preferable method for conditioning the cathode of the present invention. As discussed above, current conditioning involves slow increases in the application of voltage across the cathode and an anode. Voltage application for the cathode of the present invention may begin at about 1 kilovolt per millimeter and gradually increase to about 60 kilovolts per millimeter, and perhaps as high as 100 kilovolts per millimeter. The voltage application may increase in increments of 1 kilovolt per millimeter in one embodiment of the present invention. The procedure for conditioning one cathode may take about thirty minutes. The conditioning process may be carried out before the cathode is assembled with the housing.

The slow application of increasing voltage gradually melts the microprotrusions present on the cathode. The sharpest field-emitting microprotrusions may be thermally blunted following excessive electron emission brought on by the current conditioning.

A method for producing a device suitable for insertion into a body and delivering x-ray radiation is also contemplated by the invention. First, a cathode structure including molded granular getter material is provided. The cathode and an anode are then enclosed in a vacuum housing so that the cathode is operative with the anode to produce x-ray radiation. This method of manufacture provides the advantage of simplicity because the cathode and getter components are present in the same structure.

The various embodiments described above are provided by way of illustration only and should not be construed to limit the invention. Those skilled in the art will readily recognize various modifications and changes which may be made to the present invention without strictly following the exemplary embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the present invention which is set forth in the following claims.

We Claim:

1. A device suitable for insertion into a body and for delivery of x-ray radiation, comprising:
 - a connector, including a proximal and a distal portion;
 - 5 a vacuum housing coupled to the distal portion of the connector;
 - an anode disposed within the vacuum housing; and
 - a cathode disposed within the vacuum housing and having a granular surface,
 - the cathode being operative with the anode and the connector to
 - produce the x-ray radiation, the cathode being comprised of a
 - 10 material that also allows it to act as a getter.
2. The device of claim 1, wherein the granular surface of the cathode includes multiple protrusions capable of field emission of electrons when a moderate electrical field for x-rays is applied to the cathode.
- 15 3. The device of claim 1, wherein the cathode is formed from a granular material including granular sizes in a range of about 0.5 to 50 micrometers.
4. The device of claim 1, wherein the cathode is formed by thermal
20 diffusion bonding of a granular getter material.
5. The device of claim 1, wherein the anode and the cathode are separated by a distance ranging from about 0.2 to 1.5 millimeters.
- 25 6. The device of claim 1, wherein the connector is a flexible coaxial cable.
7. The device of claim 1, wherein the cathode includes at least one from the group consisting of vanadium, iron, zirconium, aluminum and titanium.

8. The device of claim 1, wherein the cathode is prepared by a conditioning process that reduces unstable emission sites at the cathode surface.

9. The device of claim 1, wherein the cathode further comprises
5 diamond powder mixed with a getter material.

10. The device of claim 9, wherein the granular surface of the cathode includes multiple protrusions capable of field emission of electrons when a moderate electrical field for x-rays is applied to the cathode.

10

11. A method for producing a device suitable for insertion into a body and delivering x-ray radiation, comprising:

forming a cathode from granular getter material; and

combining the cathode with an anode, a vacuum housing, and a connector, so

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that the cathode is operative with the anode and connector to produce x-ray radiation.

12. A cathode in a device suitable for insertion into a body and delivering x-ray radiation, wherein the cathode has a granular surface and is operative to
20 produce the x-ray radiation, and wherein the cathode is comprised of a material that also allows it to act as a getter.

FIG. 1

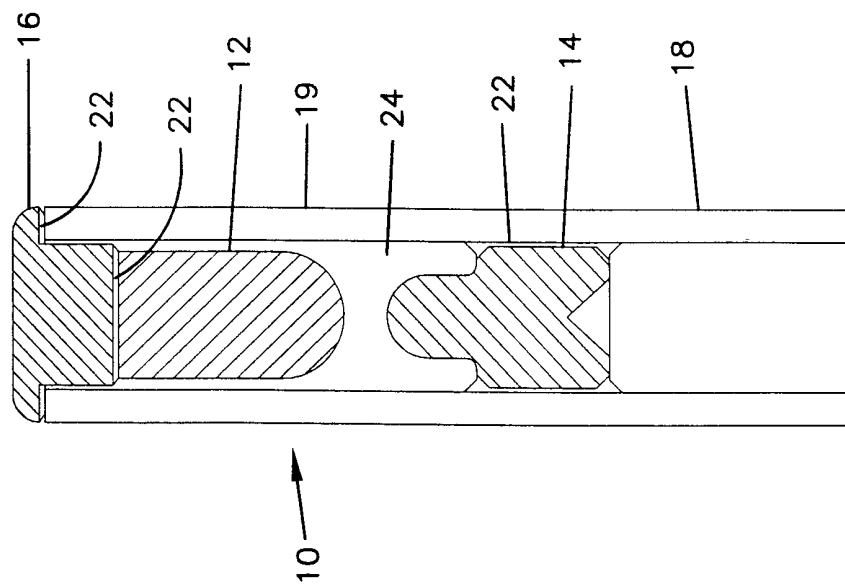


FIG. 2

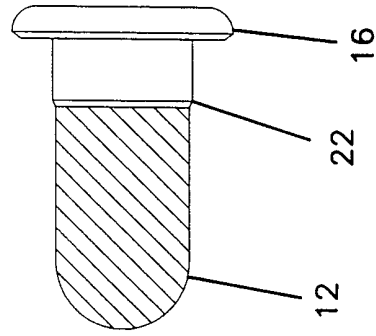


FIG. 3

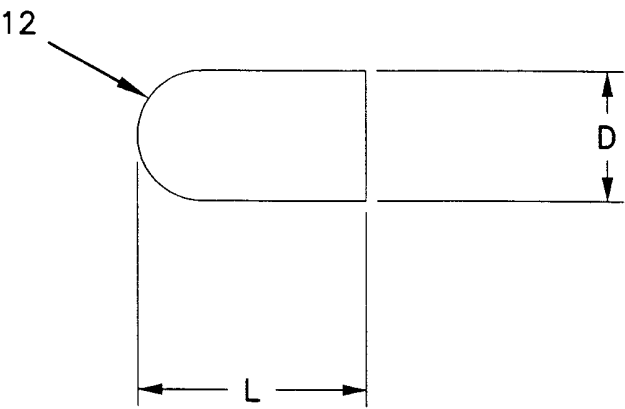


FIG. 4

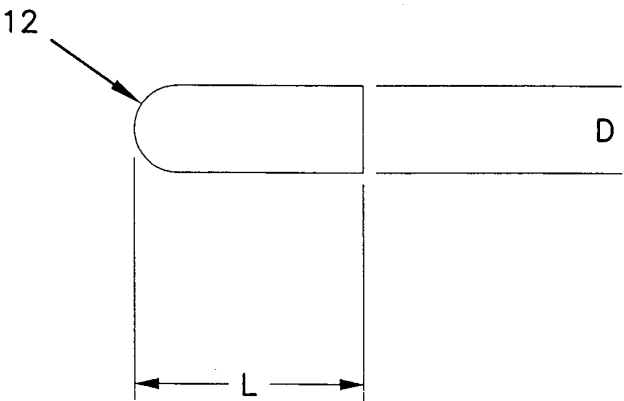


FIG. 5

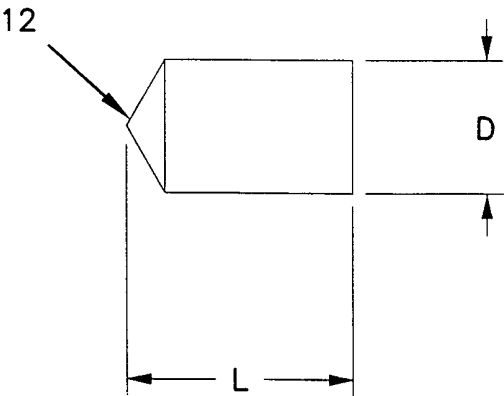


FIG. 6

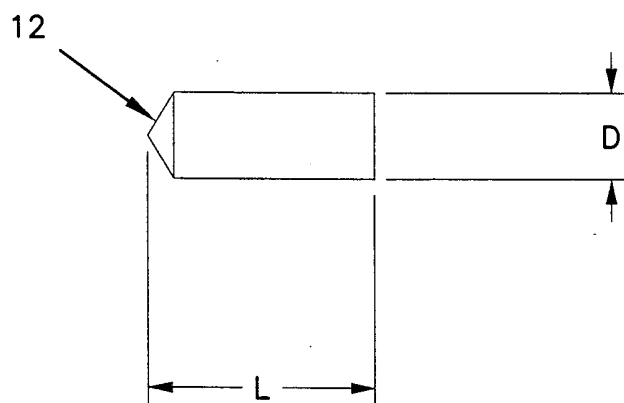


FIG. 7

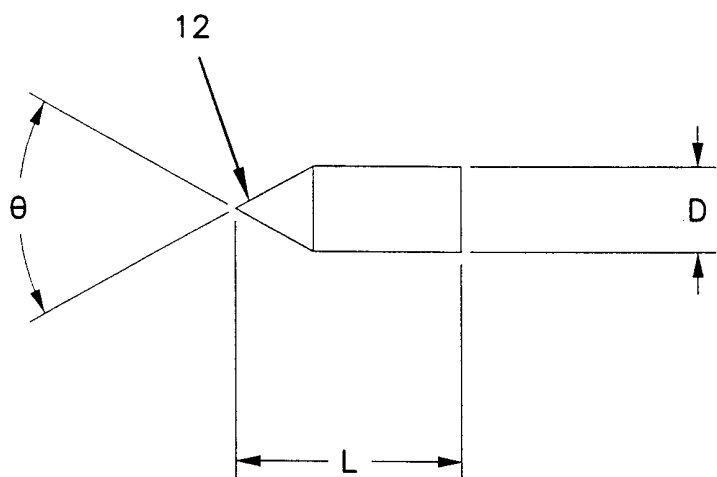
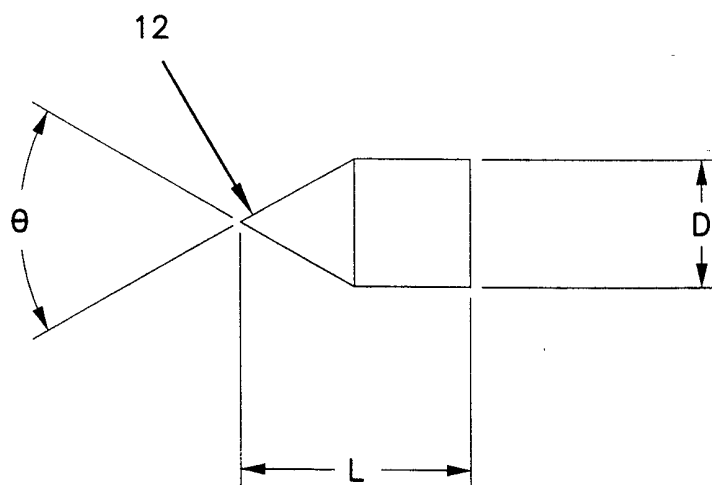


FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/14958

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 H01J35/32 H01J35/20 H01J35/06 A61N5/10

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 H01J A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 230 183 A (SAMUEL RUBEN) 2 April 1925 see claims 1,2 ---	1,12
Y	WO 97 07740 A (INTERVENTIONAL INNOVATIONS COR) 6 March 1997 see claims 1-18 ---	1,12
A	FR 2 672 734 A (FUTABA DENSHI KOGYO KK ;AGENCY IND SCIENCE TECHN (JP)) 14 August 1992 see claims 1-7 ---	1,7,12
A	WO 97 06549 A (TUCK RICHARD ALLAN ;LATHAM RODNEY VAUGHAN (GB); TAYLOR WILLIAM (GB) 20 February 1997 see claims 32-52 --- -/--	1

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

20 October 1998

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

national Application No
PCT/US 98/14958

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 164 680 A (VILLALOBOS HUMBERTO F) 14 August 1979 see column 9, line 31 - column 10 ---	9,12
A	EP 0 359 724 A (GETTERS SPA) 21 March 1990 see claim 4 ---	12
A	GB 997 352 A (INDUSTRIAL DISTRIBUTORS) 7 July 1965 ---	
A	EP 0 572 170 A (AMERICAN TELEPHONE & TELEGRAPH) 1 December 1993 ---	
A	US 3 582 702 A (ALMER FRIEDRICH HERMANN RAYMUN) 1 June 1971 ---	
A	US 2 173 258 A (A.LEDERER) 19 September 1939 ---	
A	PATENT ABSTRACTS OF JAPAN vol. 096, no. 010, 31 October 1996 & JP 08 153460 A (CANON INC), 11 June 1996 see abstract ---	12
A	EP 0 718 864 A (AT & T CORP) 26 June 1996 ---	
A	US 5 090 043 A (PARKER WILLIAM J ET AL) 18 February 1992 see claims 1,4 ---	1
E	EP 0 860 180 A (INTERVENTIONAL INNOVATIONS COR) 26 August 1998 see claims 1-10 ---	1
E	EP 0 860 181 A (INTERVENTIONAL INNOVATIONS COR) 26 August 1998 see column 7, line 28 - line 35; claims 1-4; figure 3 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/14958

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 230183 A		NONE	
WO 9707740 A	06-03-1997	AU 6857796 A EP 0847249 A	19-03-1997 17-06-1998
FR 2672734 A	14-08-1992	JP 2719239 B JP 4332423 A US 5469014 A US 5793154 A	25-02-1998 19-11-1992 21-11-1995 11-08-1998
WO 9706549 A	20-02-1997	AU 6626096 A EP 0842526 A GB 2304989 A,B GB 2306246 A,B	05-03-1997 20-05-1998 26-03-1997 30-04-1997
US 4164680 A	14-08-1979	US 4084942 A US 4273561 A	18-04-1978 16-06-1981
EP 0359724 A	21-03-1990	CN 1041240 A,B DD 288264 A DE 68920384 D DE 68920384 T JP 1864230 C JP 2117062 A KR 9711501 B MX 170949 B PL 162821 B US 4990828 A	11-04-1990 21-03-1991 16-02-1995 11-05-1995 08-08-1994 01-05-1990 11-07-1997 22-09-1993 31-01-1994 05-02-1991
GB 997352 A		NONE	
EP 0572170 A	01-12-1993	US 5283500 A DE 69301630 D DE 69301630 T JP 6089675 A	01-02-1994 04-04-1996 26-09-1996 29-03-1994
US 3582702 A	01-06-1971	NL 6804720 A BE 730961 A CH 495055 A DE 1913071 A	07-10-1969 02-10-1969 15-08-1970 23-10-1969

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/14958

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3582702 A		FR 2007388 A GB 1265881 A OA 3035 A SE 339962 B	09-01-1970 08-03-1972 15-12-1970 01-11-1971
US 2173258 A	19-09-1939	FR 845880 A	04-09-1939
EP 0718864 A	26-06-1996	US 5709577 A JP 8236010 A US 5796211 A	20-01-1998 13-09-1996 18-08-1998
US 5090043 A	18-02-1992	EP 0560906 A JP 6502559 T WO 9209998 A US RE34421 E	22-09-1993 24-03-1994 11-06-1992 26-10-1993
EP 0860180 A	26-08-1998	NONE	
EP 0860181 A	26-08-1998	NONE	