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(54) Title: RADIOACTIVE MEDICAL DEVICES FOR INHIBITING A HYPERPLASTIC RESPONSE AND METHOD OF MAKING RADIOACTIVE MEDICAL DEVICES

(57) Abstract: This invention involves radioactive medical devices for inhibiting an undesirable hyperplastic response in biological tissue, and a method for making the radioactive medical devices. In a preferred embodiment, a medical device for inhibiting a hyperplastic response in biological tissue generally comprises polymeric hydrocarbon molecules forming the medical device and a salt or an acid of a radioactive isotope occluded within the polymeric hydrocarbon molecules. Also in a preferred embodiment, a method of creating a medical device according to the present invention comprises: providing a first solvent in a container; introducing a salt or an acid of a radioactive isotope into the first solvent; introducing a second solvent into the first solution so as to form a second solution; and introducing the medical device into the second solution, wherein the ionic components of the radioactive isotope migrate into the molecular structure of the medical device.



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**RADIOACTIVE MEDICAL DEVICES FOR INHIBITING
A HYPERPLASTIC RESPONSE AND METHOD
OF MAKING RADIOACTIVE MEDICAL DEVICES**

5

FIELD OF THE INVENTION

The present invention relates generally to medical devices and, more particularly, to a radioactive medical device having beta radiation emitting capabilities for inhibiting an undesired hyperplastic response to the healing of biological tissue, and a method for making and using the devices.

10

BACKGROUND OF THE INVENTION

In patients with arterial occlusive disease, vascular surgeons use sutures to anastomose autogenous vein, prosthetic grafts, or arteries to other arteries in order to bypass around or replace diseased arterial segments. At virtually all anastomotic sites between the arteries and autogenous vein, or prosthetic grafts, a condition of rapid cellular growth termed "intimal hyperplasia" may occur.

15

Intimal hyperplasia is the usual response to blood vessel injury. This rapid cellular growth, as a response to injury of the blood vessel cellular lining, begins to narrow the opening between the vessels and/or graft to the point where an occlusion may occur.

20

More specifically, intimal hyperplasia forms as a result of smooth muscle cell proliferation, migration, and extracellular matrix deposition. The interaction of platelets, macrophages, growth factors, and cytokines plays an important role in the process. Intimal hyperplasia is the primary cause of "restenosis" (narrowing) in the first year after

vascular bypass operations and may cause indwelling venous catheters to occlude as well.

Usually, the patient must have another operation to revise or replace the occluded graft.

If a major vein occludes (*e.g.* jugular or subclavian) massive edema of the upper extremity, face and neck may occur and if an artery occludes, it could possibly lead to potential limb loss.

Of course, intimal hyperplasia is merely a subset of a larger problem involving hyperplasia resulting from smooth muscle cell proliferation, migration, and extracellular matrix deposition. In general, when biological tissue begins grafting, or healing, an undesirable hyperplastic response may occur. It would be desirable to limit, or even prevent such an unwanted hyperplastic response.

The most frequently performed prosthetic graft operation is an arterial to venous conduit for dialysis in chronic renal failure patients. Renal dialysis patients require repetitive angioaccess to this arterial - venous graft for dialysis to rid their system of toxins. The most commonly used graft for dialysis is a synthetic graft made from teflon or ePTFE (expanded polytetrafluoroethylene). Unfortunately, these grafts rapidly fail and have a primary occlusion rate of 15% to 50% during the first year, with a mean patency of only 15 months. This failure in most cases is due to the development of intimal hyperplasia at the venous anastomosis. Again, there is a strong desire in the art to prevent this unwanted hyperplastic response.

Both of the examples of tissue grafting outlined above, surgery as a result of

arterial occlusive disease and an arterial to venous conduit for dialysis, prescribe the use of a suture to assist the healing of biological tissue. However, there are several devices currently used in the medical field for assisting the grafting of biological tissue. For example, sutures, "patches" and meshes are used to hold tissues in place and give the
5 tissues time to heal. Similarly, stents come in a variety of configurations for supporting blood vessel walls in an attempt to inhibit stenosis of the vessel.

Surgical sutures are used to bring together ends of biological tissue and hold them in place until the joining tissues have time to heal. As another example, in some types of medical operations, medical personnel may use "patches" or meshes to hold damaged
10 tissue in order to give the tissue appropriate time to heal. These "patches" function in a manner similar to sutures, but are much quicker to apply and may be effective where a suture would not be appropriate. Just as with vascular bypass operations and the restenosis that may occur, the tissue held by the "patch" or mesh may also exhibit signs of hyperplasia that are undesirable, if not harmful.

15 In recent years, studies have been conducted in animal models whose vessels have undergone angioplasty. It was found that the vessels response to injury from balloon angioplasty is similar to that observed at suture anastomotic lesions. Studies conducted at Emory University, Atlanta, Georgia, U.S.A., and Vanderbilt University, Nashville, Tennessee, U.S.A., suggest that restenosis results primarily from the migration and rapid
20 proliferation of a smooth muscle type cell after balloon angioplasty. It has been

demonstrated by these groups that very low levels of beta-particle irradiation introduced to the site of injury following angioplasty markedly inhibits smooth muscle cell proliferation and or migration. Numerous other studies have been conducted which have demonstrated and substantiated these early findings.

5 U.S. Patent No. 5,897,573, filed April 22, 1997, dealt with the problem of unwanted hyperplastic response in biological tissue by suggesting the irradiation of a suture material prior to its use in a patient. U.S. Patent No. 5,897,573 describes how a low-level beta-emitting radioisotope may be incorporated into the chemical structure of suture material in order to inhibit an unwanted hyperplastic response. U.S. Patent No.
10 5,897,573, filed April 22, 1997, is hereby incorporated by reference as if fully set out herein.

Similarly, U.S. Patent No. 6,042,600, filed January 25, 1999, dealt with the problem of unwanted hyperplastic response in biological tissue by suggesting the irradiation of various medical devices before use in a patient. U.S. Patent No. 6,042,600
15 was a continuation in part of U.S. Patent No. 5,897,573. U.S. Patent No. 6,042,600 describes how a low-level beta-emitting radioisotope may be incorporated into the chemical structure of a medical device. U.S. Patent No. 6,042,600, filed January 25, 1999, is hereby incorporated by reference as if fully set out herein.

Both of the two above-described patents generally prescribe chemically bonding
20 the radioactive element to the structure of the medical device. However, there may be

situations where it is not desirable to alter the chemical structure of the medical device to be used. Additionally, certain isotopes may not readily lend themselves to chemically attaching themselves to the molecules of the medical device.

Thus, there exists a need in the art for a radiation-emitting medical device where
5 the radioactive element is not chemically bonded to the structure of the device. There also exists a need in the art for a method of making such medical devices. The invention described below remedies any shortcomings of the prior art.

SUMMARY OF THE INVENTION

10 Generally described, the present invention provides a radioactive medical device having beta radiation emitting capabilities for inhibiting an undesired hyperplastic response to the healing of biological tissue, and a method for making and using the devices. It is known that smooth muscle cell proliferation may be inhibited by varying degrees and types of radiation, particularly low level beta radiation. This knowledge is
15 exploited by the radioactive medical devices and method described herein.

In a preferred embodiment, a method of creating a medical device that inhibits a hyperplastic response in biological tissue comprises the following steps: providing a first solvent in a container; introducing a salt or an acid of a radioactive isotope into the first solvent such that the salt or acid disassociates into ionic components so as to form a first
20 solution; introducing a second solvent into the first solution so as to form a second

solution; and introducing the medical device into the second solution, wherein the ionic components migrate from the second solution into the molecular structure of the medical device.

5 In a preferred embodiment, a medical device for inhibiting a hyperplastic response in biological tissue generally comprises polymeric hydrocarbon molecules forming the medical device and a salt or an acid of a radioactive isotope occluded within the polymeric hydrocarbon molecules. As a result of this structure, the radioactive isotope in the polymeric hydrocarbon molecules of the medical device inhibits a hyperplastic response in biological tissue.

10 Other systems, methods, features, and advantages of the present invention will be or will become apparent to one with skill in the art upon examination of the following drawings and detailed description. It is intended that all such additional systems, methods, features, and advantages be included within this description, be within the scope of the present invention, and be protected by the accompanying claims.

15

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention can be better understood with reference to the following drawings. The drawings are not necessarily to scale, emphasis instead being placed upon clearly illustrating the principles of the present invention. Moreover, like reference
20 numerals designate corresponding parts throughout the several views.

Fig. 1 is a cut-away side view of the first step used in the method of the preferred embodiment.

Fig. 2 is a cut-away side view of the second step used in the method of the preferred embodiment.

5 Fig. 3 is a cut-away side view of the third step used in the method of the preferred embodiment.

Fig. 4 is a plan view of a mesh material of the preferred embodiment.

Fig. 5 is an exploded top depiction of the fibers of the mesh material depicted in Fig. 4.

10

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to conventional implantable medical devices that are designed to emit localized, low-level beta radiation while in or near biological tissue.

The present invention also relates to both a method of preventing hyperplasia in

15 biological tissue grafts and a method of creating medical devices that accomplish this goal. In other words, the present invention is a medical device having a radioactive

element occluded within the molecular structure of the medical device, and a method of making the medical device. In the present invention, the radioactive element is not

molecularly bonded to the molecular structure of the medical device. Rather, as will be

20 described in detail below, the radioactive element is "trapped" within the molecular

structure of the medical device.

Creation of the medical device of the present invention by the preferred method begins with the selection of a radioactive isotope to be occluded into the molecular structure of the medical device. The preferred radioisotopes for the present invention are

5 beta-emitting radioisotopes with relatively long half-lives. For purposes of this disclosure, a relatively long half-life is generally considered any half-life in excess of 150 days. Additionally, the preferred radioisotopes emit a relatively low level of beta radiation. For purposes of this disclosure, a low level of beta radiation is generally in the range of 10 uCi -- 1000 uCi. Of course, one with skill in the art can readily determine the

10 appropriate level of radiation to inhibit an undesired hyperplastic response. Such a level of radiation may not necessarily be within the above-specified range, and the present invention is not meant to exclude beta radiation values outside of this range. The range of radiation values is only illustrative and preferred for the particular embodiment described herein.

15 The following are examples of preferred radioisotopes: Calcium 45; Chlorine 36; Promethium 147; Strontium 90; and Technitium 99. All of the radioisotopes listed as examples have relatively long half-lives. Although radioisotopes with short half-lives may also be effective with the present invention, a long half-life is preferred mainly due to storage and shipping concerns. Over time, the quantity of radioactivity of a

20 radioisotope will decrease due to nuclear decay. The half-life is a measure of the rate of

this decrease in radioactivity. If the quantity of radioactivity of the radioisotope decreases too rapidly, the medical device must be used almost immediately after manufacturing. This leaves no time for shipping and no flexibility as to storage of the medical device. For example, Promethium 147, one of the above-listed radioisotopes, has a half-life of
5 approximately 2.5 years. If Promethium 147 is selected for the present invention, the 2.5 year half-life would provide ample time for manufacture, shipment, and storage. Then, when the medical device is needed, it still exhibits radioactive properties in adequate levels to provide the needed effect.

In the preferred embodiment 10 of the present invention, Calcium 45 is selected.
10 Calcium 45 is preferred for a variety of reasons. To begin, Calcium 45 has a half-life of about 163 days. This length of half-life is long enough to allow shipment and storage of the medical device. However, the fact that the half-life is not several years means that the medical device will not continue to be radioactive for many years after what is required to inhibit an undesirable hyperplastic response in a patient's biological tissue.

15 In the preferred embodiment 10 of the method described below, the radioactive isotope, Calcium 45, is not used alone. Rather, a salt or an acid of the radioisotope is preferred. So, for example, the preferred isotope of Calcium 45 is used in the form of its salt, radioactive Calcium Chloride ($^{45}\text{CaCl}_2$). Of course, Calcium 45 could also be used in its acid form, however, in the preferred embodiment described below, radioactive
20 Calcium Chloride is preferred. The other radioisotopes listed above can also be used in

their salt or acidic form. For example, Chlorine 36 is used in the form of either radioactive Calcium Chloride ($\text{Ca}^{36}\text{Cl}_2$) or radioactive Hydrochloric Acid (H^{36}Cl); Promethium 147 is used in the form of radioactive Promethium Chloride ($^{147}\text{PmCl}_3$); Strontium 90 is used in the form of radioactive Strontium Chloride ($^{90}\text{SrCl}_2$); and

5 Technitium 99 is used in the form of radioactive Technitium Fluoride ($^{99}\text{TcF}_5$).

Figs. 1-3 depict the preferred embodiment 10 of a method for creating a radioactive medical device according to the present invention. In Fig. 1, a container 11 is depicted with a solvent 12 in the container 11. The container has a body portion 13 and a neck portion 14. Initially, the solvent 12 is placed in the body 13 of the container 11.

10 The solvent 12 of the preferred embodiment 10 is a protic solvent. More specifically, the preferred protic solvent for the present invention is Ethyl Alcohol ($\text{C}_2\text{H}_5\text{OH}$). Of course, other protic solvents may be used, such as ethyl acetate ($\text{CH}_3\text{COOC}_2\text{H}_5$) or toluene ($\text{C}_6\text{H}_5\text{CH}_3$). In the specific preferred embodiment described herein, the amount of Ethyl Alcohol is 0.5 milliliters. The amount of solvent 12 will

15 generally vary with the size of the medical device to be immersed in the radioactive solution and other practical considerations. One skilled in the art will be able to determine the appropriate amount of solvent 12 to be used for a specific application.

Although glass is the preferred material of the container 11, other types of containers may be used. Generally, it is desirable to use a container 11 that is relatively

20 non-reactive. Also, the shape of container 11 depicted in Fig. 1 is also not important to

the present invention. Any shape will suffice, as long as the opening of the container 11, as defined by the neck 14, is sufficiently large to accept a medical device to be exposed to a radioactive solution in the container 11. As will be outlined below, the container 11 of the preferred embodiment is also able to accept a lid, or to be sealed in some other way.

5 The preferred salt of a beta-emitting radioisotope, in this case radioactive Calcium Chloride ($^{45}\text{CaCl}_2$) 16, is added to the Ethyl Alcohol 12. See Fig. 1. In the preferred embodiment, 60 millicuries of radioactive Calcium Chloride 16 is added into the container 11 and allowed to dissolve in the Ethyl Alcohol 12. In this way, the Ethyl Alcohol 12 serves to reduce the radioactive Calcium Chloride 16 into solution. When
10 introduced into the Ethyl Alcohol 12, the radioactive Calcium Chloride 16 dissociates into its component ions: $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$. The radioactive Calcium Chloride 16 will remain dissociated into solution without any solid crystals in the container 11. Physically, the Ethyl Alcohol 12 forms a type of matrix around the $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions in order to keep the ions dissociated in solution form.

15 The solution 17 formed by the radioactive Calcium Chloride 16 and the Ethyl Alcohol 12 is depicted in the container 11 in Fig. 2. Once the radioactive Calcium Chloride 16 is dissolved into the Ethyl Alcohol 12, a second solvent 18 is added to the container 11, as depicted in Fig. 2. This second solvent 18 is preferably capable of expanding the molecular matrix of a polymer structure. To this end, the preferred second
20 solvent 18 is Methylene Chloride (CH_2Cl_2). However, dimethylformamide and

tetrahydrofuran would also function adequately, although they typically do not function as well as Methylene Chloride.

In the preferred embodiment 10, 19 milliliters of Methylene Chloride 18 is added to the container 11 in batches of less than 5 milliliters at a time. In the preferred
5 embodiment 10, a glass pipette 19 is used to hold and then dispense the 19 milliliters in four separate batches. In this way, the Methylene Chloride 18 is slowly added to the solution 17 in the container 11. The Methylene Chloride 18 is added slowly to the solution 17 in order to prevent causing the $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions to leave solution and form crystals of radioactive Calcium Chloride along the bottom of the container 11.

10 The combination of Methylene Chloride 18 and the Ethyl Alcohol/Calcium Chloride solution 17 form a new solution 21. Because Methylene Chloride 18 and Ethyl Alcohol 12 are miscible fluids, the new solution 21 will be a blend of Methylene Chloride 18 and Ethyl Alcohol 12. Because the $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions are in ionic suspension within the Ethyl Alcohol 12, the new solution 21 will generally comprise an homogenous
15 distribution of $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions.

Once all the Methylene Chloride 18 has been added to the container 11, a medical device 22 to be exposed to the radioactive solution 21 is placed in the container 11. In the preferred embodiment 10, the medical device 22 is a mesh material, as shown more clearly in Fig. 4. The mesh material 22 is preferably constructed of polypropylene. In
20 use, a medical practitioner may wrap this polypropylene mesh 22, once it is labeled with a

beta emitting radioactive substance, around a graft site in order to bathe the site with beta radiation. The use of this particular medical device 22 will be described in greater detail below.

Of course, many different types of medical devices may benefit from having the capacity to emit low level localized beta radiation, and the present invention is not intended to be limited to a polypropylene mesh. Generally, any place that a medical device with polymeric hydrocarbon molecules may be used in a body, the advantages afforded by the capability of emitting beta radiation may be helpful. For example, and without limitation, the medical devices of the present invention may comprise: surgical sutures, stents, surgical patches, anti-thrombogenic coatings, hydrophilic coatings, coverings or weavings over stents, fabric or mesh implants in the body, coatings on or woven into plastic catheters (*e.g.* dialysis catheters), and ocular lens implants.

As noted above, in the preferred embodiment 10, the mesh 22 is constructed of a polypropylene material. Polypropylene is a biocompatible material. However, in an alternative embodiment, the mesh material could be another biocompatible hydrocarbon material, such as polyethylene. In another alternative embodiment, the mesh material could comprise a biodegradable material, such as MarlexTM.

As depicted in Fig. 3, the mesh 22 is placed in the solution 21. The mesh 22 is preferably completely submerged within the solution 21. Once the mesh 22 is placed in the container 11, a covering 23, or lid, is placed on the neck 14 of the container 11 in

order to seal the container 11. If no lid 23 is used, the solution 21 will likely begin to evaporate. This may be undesirable if the mesh 22 is to stay in the solution 21 for several days.

Once the mesh 22 is in the solution 21, the Methylene Chloride 18 in the solution 21 expands the polypropylene matrix 24 and the $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions begin migrating into and among the molecular structure 24 of the polypropylene mesh 22. The mesh 22 is left in solution 21 until the desired concentration of radioactive Calcium is reached. In other words, the mesh 22 is left in solution 21 until it has incorporated the desired level of radiation-emitting characteristics. The migration of the radioactive Calcium may take anywhere from a day, to several days, to several weeks. The length of time necessary for migration of the radioactive ions into the molecular structure of the mesh 22 depends on the concentration of the radioactive ion present in the solution. In the preferred example, a one inch square of polypropylene mesh 22 is preferably left in the container 11 for 6-8 weeks.

One skilled in the art can readily determine the appropriate length of time to expose the mesh 22 to the radioactive Calcium in the solution 21. For example, small portions of the mesh 22 can be cut and tested to determine the level of radiation emitted by the irradiated mesh 22. If the level is too low, then the mesh 22 is left in solution 21. On the other hand, if the level of radioactive Calcium in the mesh 22 has reached equilibrium, or the desired level of radioactivity, then the mesh 22 is removed from the

solution 21.

After reaching the desired concentration of radioactive material in the mesh 22, the mesh 22 is removed from the container and permitted to dry. As the mesh 22 dries, the $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions re-form radioactive Calcium Chloride ($^{45}\text{CaCl}_2$) crystals 16, while still in the plastic mesh 22. It should be recalled that the Methylene Chloride caused the plastic fibers 24 to swell when the mesh 22 was placed in the solution 21. At the same time the $^{45}\text{Ca}^{(+)}$ and $\text{Cl}^{(-)}$ ions are re-forming radioactive Calcium Chloride 16, the drying process causes the polypropylene matrix 24 of the mesh 22 to shrink back to its original shape. This shrinkage causes the radioactive Calcium Chloride crystals 16 to become occluded in the polypropylene molecules 24. Fig. 5 depicts an exploded view of one strand of the mesh 22 in order to demonstrate the occlusion of the radioactive Calcium Chloride 16 in the polypropylene fibers 24 of the mesh 22. Thus, radioactive Calcium Chloride crystals 16 are dispersed throughout the plastic polymer structure and held in place by the polypropylene matrix 24.

In the preferred method 10, after drying is complete, the mesh 22 is rinsed several times with Ethyl Alcohol 16. Rinsing the mesh 22 removes any remaining Methylene Chloride 18 from the fibers and also removes any radioactive Calcium Chloride molecules that are not trapped within the molecular structure 24 of the mesh 22. Rinsing the mesh 22 with Ethyl Alcohol 16 also serves to clean and sterilize the mesh material.

Ethyl Alcohol is not the only liquid that may be used to rinse the mesh material.

If rinsing is desired, the mesh may be rinsed with a variety of other solutions which are equally effective at removing Methylene Chloride and free radioactive ions. Of course, rinsing the mesh material is not required by the present invention.

Generally, a solvent like Methylene Chloride will re-expand the polypropylene
5 fibers 24 of the mesh 22, thereby releasing the radioactive Calcium Chloride crystals 16. Water and bodily fluids are typically not of this nature and will not re-expand the molecular chain structure 24 of the polypropylene mesh 22 sufficiently to release the radioactive Calcium Chloride crystals 16. So, the radioactive calcium chloride molecules
10 16 stay trapped in the molecular structure 24 of the mesh 22 and will not migrate out of the mesh 22 when the mesh 22 is either handled or implanted into a patient's body.

The mesh 22 of the preferred embodiment 10 is typically used in surgical procedures in order to inhibit hyperplasia resulting from smooth muscle cell proliferation, migration, and extracellular matrix deposition. As noted above, when biological tissue begins healing, an undesirable hyperplastic response may occur, such as intimal
15 hyperplasia. The mesh material 22 of the preferred embodiment may be used to inhibit this undesirable hyperplastic response.

In order to use the mesh 22 to inhibit an unwanted hyperplastic response, a surgeon typically wraps the mesh 22 of the preferred embodiment around a site where tissues have been grafted, such as by a suture. Once the mesh 22 is placed around the
20 graft site, the surgeon simply stitches the ends 26, 27 of the mesh 22 together in order to

secure it in place. Of course, anywhere biological tissues are grafted together, the mesh

22 of the preferred embodiment will be very beneficial in preventing undesirable

hyperplasia. For example, the mesh 22 could be placed between the tissues to be grafted.

In this way, the device holding the tissue together, such as a suture, would also secure the

5 mesh 22 into place. One with skill in the art will be able to see many additional uses for the medical device 22 of the preferred embodiment 10.

The method of incorporating radioactive material into a medical device described

with regard to a polypropylene mesh 22 above could be used similarly to radioactively

label a whole host of medical devices. Such devices may include (without limitation):

10 surgical sutures, stents, surgical patches, anti-thrombogenic coatings, hydrophilic

coatings, a covering or weaving over stents, fabric or mesh implants in the body, coatings

on or woven into plastic catheters (*e.g.* dialysis catheters), and ocular lens implants. If

one of these other medical devices are radioactively labeled by the above-described

method, then these devices will also inhibit undesirable hyperplasia.

15 If certain medical devices are used with the present invention, such as suture

material for example, then it may be desirable to incorporate the preferred salt of a

radioactive isotope into a polymeric hydrocarbon material before the medical device is

actually made, or while the device is being made. For example, Calcium 45, or other beta

emitting isotope could be introduced into the polymeric hydrocarbon material during a

20 blending or extruding process used to make the medical device.

It would be apparent to one skilled in the art that many variations and modifications may be made to the preferred embodiments (*i.e.* preferred nonlimiting examples) as described above without substantially departing from the principles of the present invention. Such variations and modifications are intended to be included herein
5 and are within the scope of the present invention, as set forth in the following claims.

CLAIMS

Therefore, having thus described the invention, at least the following is claimed:

- 1 1. A method of creating a medical device that inhibits a hyperplastic response
2 in biological tissue, said method comprising the steps of:
 - 3 (a) providing a first solvent in a container;
 - 4 (b) introducing a salt of a radioactive isotope into said first solvent
5 such that said salt dissociates into ionic components so as to form a
6 first solution;
 - 7 (c) introducing a second solvent into said first solution so as to form a
8 second solution; and
 - 9 (d) introducing said medical device into said second solution, wherein
10 said ionic components migrate from said second solution into a
11 molecular structure of said medical device.
- 1 2. The method of claim 1, further comprising the steps of:
 - 2 (e) removing said medical device from said second solution;
 - 3 (f) drying said medical device; and
 - 4 (g) rinsing said medical device.

- 1 3. The method of claim 1, wherein said first solvent is a protic solvent.
- 1 4. The method of claim 3, wherein said protic solvent is Ethyl Alcohol.
- 1 5. The method of claim 1, wherein said second solvent has the capability of
2 expanding a molecular structure of said medical device.
- 1 6. The method of claim 5, wherein said second solvent comprises Methylene
2 Chloride.
- 1 7. The method of claim 1, wherein said container is a glass vessel.
- 1 8. The method of claim 1, wherein said medical device comprises a material
2 that may be molecularly expanded.
- 1 9. The method of claim 1, wherein said molecular structure of said medical
2 device comprises polymeric hydrocarbon molecules.
- 1 10. The method of claim 9, wherein said polymeric hydrocarbon molecules
2 comprise polypropylene.

1 11. The method of claim 1, wherein said medical device comprises a mesh.

1 12. The method of claim 11, wherein said mesh comprises a biocompatible
2 material.

1 13. The method of claim 12, wherein said biocompatible material comprises
2 polypropylene.

- 1 14. A medical device for inhibiting a hyperplastic response in biological
2 tissue, said medical device comprising:
- 3 (a) polymeric hydrocarbon molecules forming said medical device;
4 and
5 (b) a molecular form of a radioactive isotope occluded within said
6 polymeric hydrocarbon molecules, wherein said radioactive isotope
7 inhibits a hyperplastic response in biological tissue.
- 1 15. The medical device of claim 14, wherein said molecular form comprises a
2 salt of a radioactive isotope.
- 1 16. The medical device of claim 14, wherein said molecular form comprises
2 an acid of a radioactive isotope.
- 1 17. The medical device of claim 14, wherein said radioactive isotope
2 comprises a beta-emitting isotope with a half-life exceeding 150 days.
- 1 18. The medical device of claim 14, wherein said radioactive isotope
2 comprises Calcium 45.

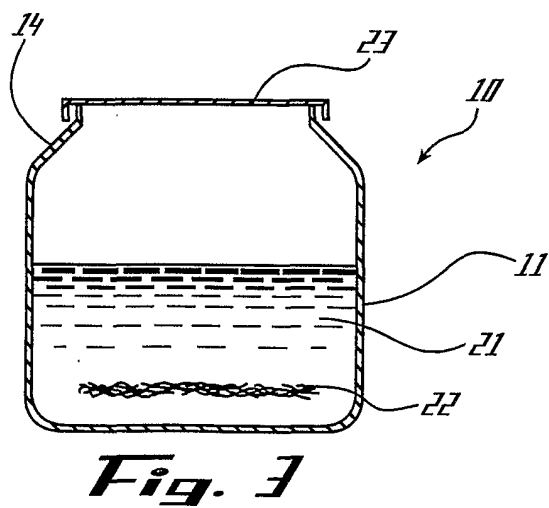
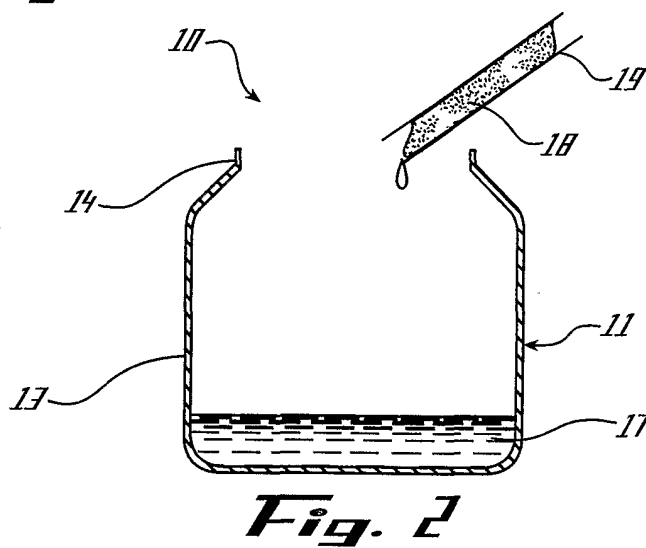
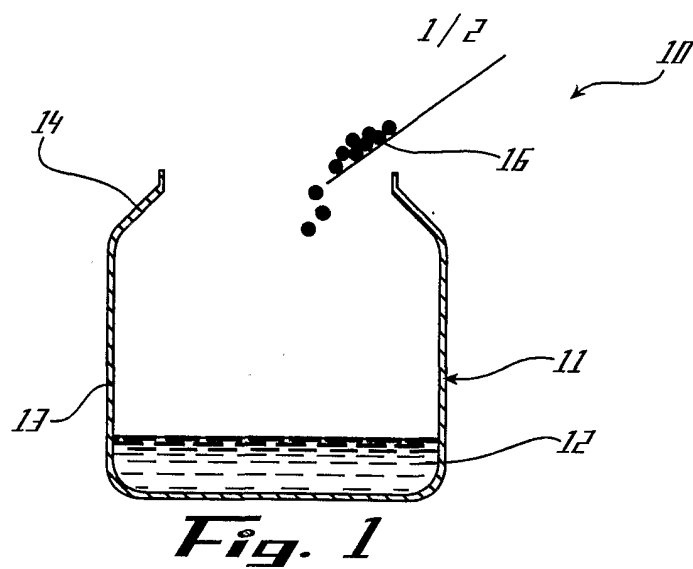
1 19. The medical device of claim 18, wherein said medical device comprises a
2 mesh.

1 20. The medical device of claim 19, wherein said polymeric hydrocarbon
2 molecules comprise polypropylene.

1 21. The medical device of claim 14, wherein said polymeric hydrocarbon
2 molecules comprise a synthetic polymer.

1 22. The medical device of claim 14, wherein said medical device is
2 constructed of a biocompatible metal material and said polymeric hydrocarbon molecules
3 are distributed over said biocompatible metal.

- 1 23. A method of creating a medical device that inhibits a hyperplastic response
2 in biological tissue, said method comprising the steps of:
- 3 (a) providing a non-reactive container;
- 4 (b) introducing a protic solvent into an interior of said container;
- 5 (c) introducing a salt of a radioactive isotope into said protic solvent
6 such that said salt dissociates into ionic components so as to form a
7 first solution;
- 8 (c) introducing a second solvent into said first solution so as to form a
9 second solution;
- 10 (d) introducing said medical device into said second solution, wherein
11 said second solvent expands polymeric hydrocarbon molecules of
12 said medical device such that said ionic components migrate from
13 said second solution into a molecular structure of said medical
14 device;
- 15 (e) removing said medical device from said container;
- 16 (f) drying said medical device, wherein said drying step shrinks said
17 polymeric hydrocarbon molecules of said medical device and
18 permits said ionic components to form said salt occluded within
19 said molecular structure of said medical device.



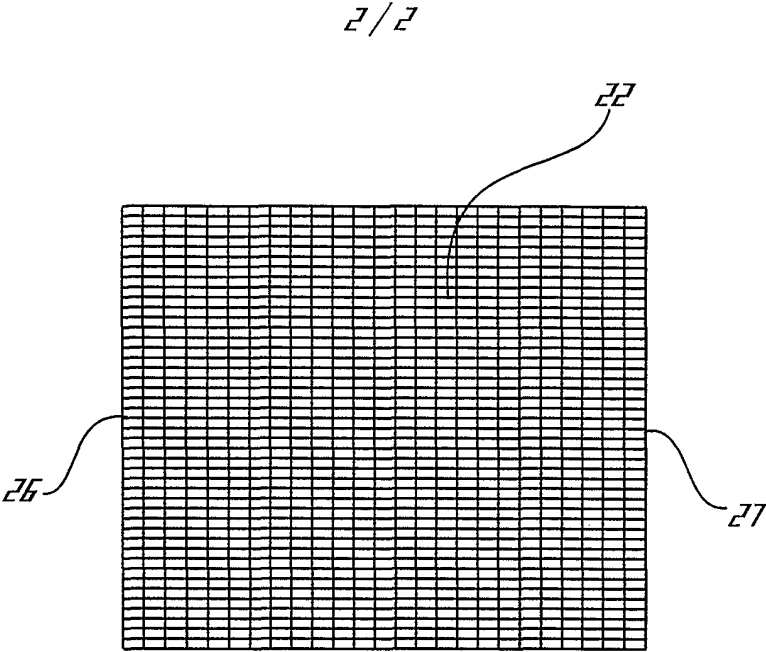


Fig. 4

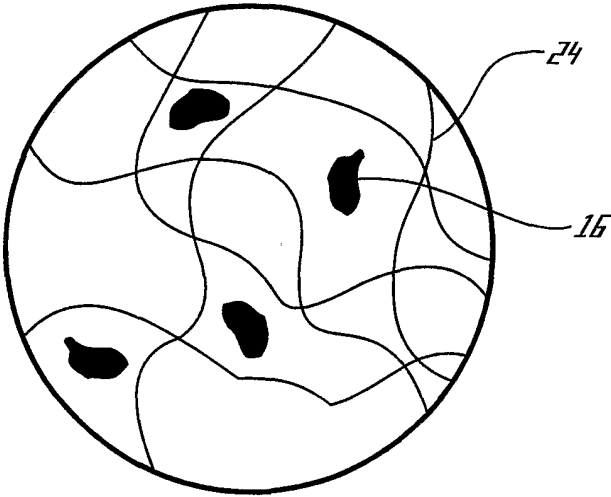


Fig. 5