

JS 20120116215A1

(19) United States

(12) Patent Application Publication Jones et al.

(10) **Pub. No.: US 2012/0116215 A1**(43) **Pub. Date:** May 10, 2012

(54) DEPLOYMENT OF POLYSACCHARIDE MARKERS FOR TREATING A SITE WITHIN A PATIENT

7,819,819, which is a continuation-in-part of application No. 10/374,915, filed on Feb. 24, 2003, now Pat. No. 7,189,206.

(76) Inventors: **Michael L. Jones**, San Clemente,

CA (US); Paul Lubock, Monarch

Beach, CA (US)

(21) Appl. No.: 13/301,024

(22) Filed: **Nov. 21, 2011**

Related U.S. Application Data

Continuation-in-part of application No. 12/070,786, filed on Feb. 21, 2008, which is a continuation-in-part of application No. 11/881,264, filed on Jul. 26, 2007, Continuation-in-part of application No. 13/155,628, filed on Jun. 8, 2011, which is a continuation of application No. 10/444,770, filed on May 23, 2003, now Pat. No. 7,983,734, Continuation-in-part of application No. 13/037,971, filed on Mar. 1, 2011, which is a continuation-in-part of application No. 10/753,694, filed on Jan. 7, 2004, now abandoned, which is a continuation-in-part of application No. 10/444,770, filed on May 23, 2003, now Pat. No. 7,983,734, Continuation-in-part of application No. 12/852,286, filed on Aug. 6, 2010, which is a continuation of application No. 10/990,327, filed on Nov. 16, 2004, now Pat. No. 7,792,569, which is a continuation of application No. 10/124,757, filed on Apr. 16, 2002, now Pat. No. 6,862, 470, which is a continuation-in-part of application No. 09/717,909, filed on Nov. 20, 2000, now Pat. No. 6,725,083, which is a continuation-in-part of application No. 09/343,975, filed on Jun. 30, 1999, now Pat. No. 6,347,241, which is a continuation-in-part of application No. 09/241,936, filed on Feb. 2, 1999, now Pat. No. 6,161,034, Continuation-in-part of application No. 12/592,020, filed on Nov. 18, 2009, which is a continuation of application No. 10/174,401, filed on Jun. 17, 2002, now Pat. No. 7,651,505, Continuationin-part of application No. 10/911,106, filed on Aug. 3, 2004, which is a continuation-in-part of application No. 10/642,406, filed on Aug. 15, 2003, now Pat. No. (60) Provisional application No. 60/835,740, filed on Aug. 4, 2006.

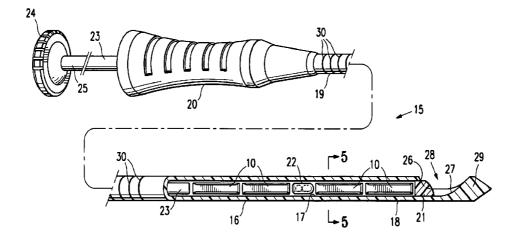
Publication Classification

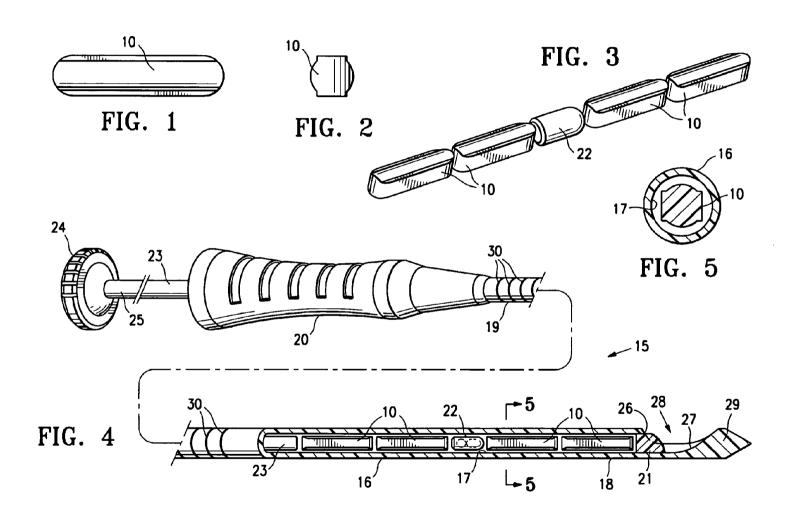
(51)	Int. Cl.	
	A61B 6/00	(2006.01)
	A61K 9/14	(2006.01)
	A61K 9/00	(2006.01)
	A61K 31/718	(2006.01)
	A61K 31/717	(2006.01)
	A61P 7/04	(2006.01)
	A61K 31/721	(2006.01)
	A61K 31/732	(2006.01)
	A61K 31/731	(2006.01)
	A61K 31/729	(2006.01)
	A61K 31/716	(2006.01)
	A61K 31/715	(2006.01)
	A61K 31/722	(2006.01)

(52) **U.S. Cl.** **600/431**; 514/54; 424/400; 514/60; 514/57; 514/55; 514/59

(57) ABSTRACT

A method for treating a site within a patient from which tissue has been removed includes providing at least one press-formed marker body formed of polysaccharide and a suitable binder; and placing the at least one of the press-formed marker body within the site where tissue has been removed so as to provide hemostasis therein.





DEPLOYMENT OF POLYSACCHARIDE MARKERS FOR TREATING A SITE WITHIN A PATIENT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 12/070,786, entitled "DEPLOY-MENT OF POLYSACCHARIDE MARKERS", filed Feb. 21,2008, which is a continuation-in-part of U.S. patent application Ser. No. 11/881,264, filed Jul. 26, 2007, which is related to and claims priority from provisional application Ser. No. 60/835,740, filed on Aug. 4, 2006.

[0002] Also, this application is a continuation-in-part of U.S. patent application Ser. No. 13/155,628 entitled "FIBROUS MARKER AND INTRACORPOREAL DELIV-ERY THEREOF", filed Jun. 8, 2011, which is a continuation of U.S. patent application Ser. No. 10/444,770, filed May 23, 2003, now U.S. Pat. No. 7,983,734 B2.

[0003] Also, this application is a continuation-in-part of U.S. patent application Ser. No. 13/037,971 entitled "MARKER DELIVERY DEVICE WITH RELEASABLE PLUG", filed Mar. 1, 2011, which is a continuation-in-part of U.S. patent application Ser. No. 10/753,694, filed Jan. 7, 2004, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 10/444,770, filed May 23, 2003, now U.S. Pat. No. 7,983,734 B2.

[0004] Also, this application is a continuation-in-part of U.S. patent application Ser. No. 12/852,286 entitled CAV-ITY-FILLING BIOPSY SITE MARKERS, filed Aug. 6, 2010, which is a continuation of U.S. patent application Ser. No. 10/990,327, filed Nov. 16, 2004, now U.S. Pat. No. 7,792, 569, which is a continuation of U.S. patent application Ser. No. 10/124,757, filed Apr. 16, 2002, now U.S. Pat. No. 6,862, 470, which is a continuation-in-part of U.S. patent application Ser. No. 09/717,909, filed Nov. 20, 2000, now U.S. Pat. No. 6,725,083, which is a continuation-in-part of U.S. patent application Ser. No. 09/343,975, filed Jun. 30, 1999, now U.S. Pat. No. 6,347,241, which is a continuation-in-part of U.S. patent application Ser. No. 09/241,936, filed Feb. 2, 1999, now U.S. Pat. No. 6,161,034.

[0005] Also, this application is a continuation-in-part of U.S. patent application Ser. No. 12/592,020 entitled PLUGGED TIP DELIVERY TUBE FOR MARKER PLACEMENT, filed Nov. 18, 2009, which is a continuation of U.S. patent application Ser. No. 10/174,401, filed Jun. 17, 2002, now U.S. Pat. No. 7,651,505.

[0006] Also, this application is a continuation-in-part of U.S. patent application Ser. No. 10/911,106 entitled BIOPSY DEVICE WITH SELECTABLE TISSUE RECEIVING APERTURE ORIENTATION AND SITE ILLUMINATION, filed Aug. 3, 2004, which is a continuation-in-part of U.S. patent application Ser. No. 10/642,406, filed Aug. 15, 2003, now U.S. Pat. No. 7,819,819, which is a continuation-in-part of U.S. patent application Ser. No. 10/374,915, filed Feb. 24, 2003, now U.S. Pat. No. 7,189,206.

[0007] All the above from which priority is claimed are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0008] The invention is generally directed to remotely detectable, intracorporeal markers and devices and methods for the delivery of such markers to a desired location within a patient's body.

BACKGROUND OF THE INVENTION

[0009] In diagnosing and treating certain medical conditions, it is often desirable to mark a suspicious body site for

the subsequent taking of a biopsy specimen, for delivery of medicine, radiation, or other treatment, for the relocation of a site from which a biopsy specimen was taken, or at which some other procedure was performed. As is known, obtaining a tissue sample by biopsy and the subsequent examination are typically employed in the diagnosis of cancers and other malignant tumors, or to confirm that a suspected lesion or tumor is not malignant. The information obtained from these diagnostic tests and/or examinations is frequently used to devise a therapeutic plan for the appropriate surgical procedure or other course of treatment.

[0010] In many instances, the suspicious tissue to be sampled is located in a subcutaneous site, such as inside a human breast. To minimize surgical intrusion into a patient's body, it is often desirable to insert a small instrument, such as a biopsy needle, into the body for extracting the biopsy specimen while imaging the procedure using fluoroscopy, ultrasonic imaging, x-rays, magnetic resonance imaging (MRI) or any other suitable form of imaging technique or palpation. Examination of tissue samples taken by biopsy is of particular significance in the diagnosis and treatment of breast cancer. In the ensuing discussion, the biopsy and treatment site described will generally be the human breast, although the invention is suitable for marking biopsy sites in other parts of the human and other mammalian body as well.

[0011] Periodic physical examination of the breasts and mammography are important for early detection of potentially cancerous lesions. In mammography, the breast is compressed between two plates while specialized x-ray images are taken. If an abnormal mass in the breast is found by physical examination or mammography, ultrasound may be used to determine whether the mass is a solid tumor or a fluid-filled cyst. Solid masses are usually subjected to some type of tissue biopsy to determine if the mass is cancerous.

[0012] If a solid mass or lesion is large enough to be palpable, a tissue specimen can be removed from the mass by a variety of techniques, including but not limited to open surgical biopsy, a technique known as Fine Needle Aspiration Biopsy (FNAB) and instruments characterized as "vacuum assisted large core biopsy devices".

[0013] If a solid mass of the breast is small and non-palpable (e.g., the type typically discovered through mammography), a vacuum assisted large core biopsy procedure is usually used. In performing a stereotactic biopsy of a breast, the patient lies on a special biopsy table with her breast compressed between the plates of a mammography apparatus and two separate x-rays or digital video views are taken from two different points of view. A computer calculates the exact position of the lesion as well as depth of the lesion within the breast. Thereafter, a mechanical stereotactic apparatus is programmed with the coordinates and depth information is calculated by the computer, and such apparatus is used to precisely advance the biopsy needle into the small lesion. The stereotactic technique may be used to obtain histologic specimens. Usually at least five separate biopsy specimens are obtained from locations around the small lesion as well as one from the center of the lesion.

[0014] The available treatment options for cancerous lesions of the breast include various degrees of mastectomy or lumpectomy, radiation therapy, chemotherapy and combinations of these treatments. However, radiographically visible tissue features, originally observed in a mammogram, may be removed, altered or obscured by the biopsy procedure, and may heal or otherwise become altered following the biopsy.

In order for the surgeon or radiation oncologist to direct surgical or radiation treatment to the precise location of the breast lesion several days or weeks after the biopsy procedure was performed, it is desirable that a biopsy site marker be placed in the patient's body to serve as a landmark for subsequent location of the lesion site. A biopsy site marker may be a permanent marker (e.g., a metal marker visible under x-ray examination), or a temporary marker (e.g., a bioresorbable marker detectable with ultrasound). While current radiographic type markers may persist at the biopsy site, an additional mammography generally must be performed at the time of follow up treatment or surgery in order to locate the site of the previous surgery or biopsy. In addition, once the site of the previous procedure is located using mammography, the site must usually be marked with a location wire which has a hook on the end which is advanced into site of the previous procedure. The hook is meant to fix the tip of the location wire with respect to the site of the previous procedure so that the patient can then be removed from the confinement of the mammography apparatus and the follow-up procedure performed. However, as the patient is removed from the mammography apparatus, or otherwise transported the position of the location wire can change or shift in relation to the site of the previous procedure. This, in turn, can result in follow-up treatments being misdirected to an undesired portion of the patient's tissue.

[0015] As an alternative or adjunct to radiographic imaging, ultrasonic imaging (herein abbreviated as "USI") or visualization techniques can be used to image the tissue of interest at the site of interest during a surgical or biopsy procedure or follow-up procedure. USI is capable of providing precise location and imaging of suspicious tissue, surrounding tissue and biopsy instruments within the patient's body during a procedure. Such imaging facilitates accurate and controllable removal or sampling of the suspicious tissue so as to minimize trauma to surrounding healthy tissue.

[0016] For example, during a breast biopsy procedure, the biopsy device is often imaged with USI while the device is being inserted into the patient's breast and activated to remove a sample of suspicious breast tissue. As USI is often used to image tissue during follow-up treatment, it may be desirable to have a marker, similar to the radiographic markers discussed above, which can be placed in a patient's body at the site of a surgical procedure and which are visible using USI. Such a marker enables a follow-up procedure to be performed without the need for traditional radiographic mammography imaging which, as discussed above, can be subject to inaccuracies as a result of shifting of the location wire as well as being tedious and uncomfortable for the patient.

[0017] Placement of a marker or multiple markers at a location within a patient's body requires delivery devices capable of holding markers within the device until the device is properly situated within a breast or other body location. Accordingly, devices and methods for retaining markers within a marker delivery device while allowing their expulsion from the devices at desired intracorporeal locations are desired.

[0018] In addition to marking functions, frequently it is desirable to provide treatments with the marker members such as hemostatic treatment and the like.

SUMMARY OF THE INVENTION

[0019] The invention is generally directed to a remotely imageable marker system suitable for deployment at a site

within a patient's body, particularly a biopsy site such as in a patient's breast. The imageable marker system has a plurality of marker members containing polysaccharide in sufficient amounts to provide hemostatic properties and has a molecular weight of about 3500 to about 200,000 Daltons. The polysaccharide containing marker members are preferably pressformed from a dry powder into a pellet shape. The polysaccharide and binder powder should have a particle size of about 10 to about 200 micrometers. The polysaccharide markers rapidly absorb body fluid and hydrate and in the process dehydrate blood at the site of deployment to rapidly initiate clotting.

[0020] The polysaccharide is preferably starch (corn starch or potato starch) but a variety of bioabsorbable polysaccharides are suitable, including glycogen, cellulose, chitin, chitosan, dextran, pectins, glucans, agar, alginate and carrageen. The binder is preferably methylcellulose but a variety of binders may be employed in lieu of or in addition to methylcellulose. Other suitable binders include hydroxyethyl cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrolidone.

[0021] The remotely imageable marker system preferably includes a marker body with a radiopaque element connected thereto or incorporated therein to provide long term identification of the intracorporeal site. Preferably, the radiopaque element is formed of non-magnetic material to avoid interference with magnetic resonance imaging (MRI). Suitable nonmagnetic materials include titanium, platinum, gold, iridium, tantalum, tungsten, silver, rhodium, non-magnetic stainless steel (316) and the like. The radiopaque element should have a shape that is readily recognized at the intracorporeal site when remotely imaged. The radiopaque element should have a maximum dimension of about 0.5 to about 5 mm, preferably about 1 to about 3 mm to ensure remote identification, particularly with MRI. The marker body having a radiopaque element is preferably formed of a bioabsorbable polymeric material such as polylactic-polyglycolic acid (polylactideco-glycolide) with a longer dissolution time than the polysaccharide pellets, although the latter may be used.

[0022] The polysaccharide containing pellets will generally have a transverse dimension of about 0.02 to about 0.1 inch (0.5-2.5 mm), preferably about 0.035 to about 0.075 inch (0.9-1.9 mm), and typically about 0.056 inch (1.4 mm) The pellets will have a length of about 0.1 to about 0.4 inch (2.5-10 mm), preferably about 0.15 to about 0.35 inch (3.8-8.9 mm) The pellets provide sufficient column strength to facilitate introduction into and discharge thereof from the tubular delivery device. The markers are preferably arranged for delivery within the delivery tube with the marker having a radiopaque element between two adjacent marker members formed of polysaccharide. As presently contemplated, within the delivery tube there will be two polysaccharide marker members distal and two polysaccharide marker members proximal to the marker having a radiopaque element.

[0023] The marker member embodying features of the invention can be readily delivered to the desired location by suitable delivery systems such as disclosed in application Ser. No. 10/444,770, filed on May 23, 2003, now U.S. Pat. No. 7,983,734 B2, and Ser. No. 10/753,694, filed Jan. 7, 2004. The marker delivery system generally has an elongated cannula or tube with proximal and distal ports and an inner lumen extending between the ports. The marker member is slidably disposed within the inner lumen of the delivery cannula and a plunger slidably disposed within the inner lumen of the delivery.

ery cannula proximal to the markers. The plunger is movable from an initial position proximal to the markers within the tube, to a delivery position close to the discharge opening in the distal end of the cannula to push the marker members out of the discharge opening into the target tissue site.

[0024] Upon being discharged into the intracorporeal target site, the plurality of polysaccharide containing markers quickly take up body fluid at the site, initiating the clotting process and providing hemostasis. The other marker member with a radiopaque marker element enables short term detection (at least three weeks, preferably at least four weeks but less than a year) by remote USI and preferably long term detection by remote mammographic imaging or MRI identification by the radiopaque element. Typically, the polysaccharide bodies dissolve in situ in about five seconds to about 2 minutes and enzymatically degrade in about 2-5 days.

[0025] The cannula of the marker delivery device may be configured to fit within the guide cannula of a biopsy device, such as a Mammotome® (sold by Johnson & Johnson), the SenoCor 360TM biopsy device sold by SenoRx (the present assignee), the EnCorTM biopsy device sold by SenoRx and or a coaxial needle guide. The delivery cannula can also be configured to fit into the proximal end of a tubular cutting element such as found in the EnCorTM biopsy system sold by SenoRx which is the subject of co-pending application Ser. No. 10/911,106, filed on Aug. 3, 2004.

[0026] One suitable delivery system suitable for delivery through a tubular cutter (e.g. as with the EncorTM system) is a syringe-type delivery system described in co-pending application Ser. No. 10/911,106, filed on Aug. 3, 2004 having a tubular shaft with a flared guide on or integral with the distal tip to facilitate engagement with the proximal end of the tubular cutter. Another syringe-type delivery system has a plugged distal tip to prevent body fluids from engaging one or more markers which may be in the tubular shaft of the delivery system. Such fluid infusions can retard or restrict discharging the markers within the inner lumen of the delivery cannula by causing the markers to take up water or swell within the lumen of the delivery cannula. Delivery systems with plugged tips are described in co-pending application Ser. No. 10/444,770, filed on May 23, 2003, now U.S. Pat. No. 7,983,734 B2, and Ser. No. 10/753,694, filed Jan. 7, 2004, which are incorporated herein in their entireties. The plugged tip type delivery systems can have a side opening for marker deployment or a plugged needle-type distal tip both of which are disclosed in the above application Ser. No. 10/753,694.

[0027] A variety of therapeutic or diagnostic agents may also be incorporated into the marker bodies. Incorporated agents can include for example, anesthetic agents to control pain, chemotherapeutic agents for treating residual neoplastic tissue or coloring agents to facilitate subsequent visual location of the site. Antibiotics, antifungal agents and antiviral agents may also be incorporated into the marker bodies.

[0028] Upon delivery to the intracorporeal site, the markers are easily identifiable from surrounding tissue at the site by ultrasonic imaging (USI).

[0029] The polysaccharide containing markers embodying features of the present invention provide several advantages. The polysaccharide marker bodies quickly dissolve in the body fluids at the site to provide to provide rapid hemostasis therein even with serious bleeding. Moreover, the materials rapidly degrade so there is no long term irritation or inflammation at the site.

[0030] Thus, the invention, in one form thereof, is directed to a method for treating a site within a patient from which tissue has been removed, including providing at least one press-formed marker body formed of polysaccharide and a suitable binder; and placing the at least one of the press-formed marker body within the site where tissue has been removed so as to provide hemostasis therein.

[0031] The invention in another form is directed to a method for treating a site within a patient from which tissue has been removed, including providing at least one unitary marker pellet formed of polysaccharide powder and a suitable binder pressed into a desired shape; and placing each individual unitary marker pellet formed of polysaccharide powder within the site where tissue has been removed so as to provide hemostasis therein.

[0032] The invention in another form is directed to a method to facilitate treating a site within a patient from which tissue has been removed, including providing a plurality of marker members, each marker member of the plurality of marker members comprising a bioabsorbable polysaccharide and a binder, the bioabsorbable polysaccharide being in sufficient amounts to exhibit hemostatic properties, the plurality of marker members being disposed within an inner lumen of a tubular delivery member; and placing the plurality of marker members in a lumen of a delivery tube configured to deliver the plurality of marker members into the site within the patient from which the tissue has been removed.

[0033] These and other advantages of the invention will become more apparent from the following detailed description of embodiments when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] FIG. 1 is a plan view of a press-formed marker member embodying features of the invention.

[0035] FIG. 2 is an end view of the marker member shown in FIG. 1.

[0036] FIG. 3 is a perspective view of a plurality of markers arranged as they would be within a delivery tube (not shown).

[0037] FIG. 4 is a partly cut-away perspective view of a marker delivery assembly having a plurality of marker members embodying features of the invention.

 $[0038]~{\rm FIG.}~5$ is a transverse cross-sectional view taken along the lines 5-5 shown in FIG. 4.

DETAILED DESCRIPTION OF THE INVENTION

[0039] FIGS. 1 and 2 illustrate a press-formed marker member 10 embodying features of the invention which is formed of a mixture of polysaccharide powder and methylcellulose powder. The press-formed marker member 10 has sufficient polysaccharide powder so as to quickly form thrombus when coming into contact with blood at an intracorporeal site. Typically, the marker member 10 will have 65% (by wt.) polysaccharide and 35% (by wt.) methylcellulose. The marker member 10 is preferably formed by mixing polysaccharide powder (corn starch or potato starch) and methylcellulose powder in appropriate amounts, placing the mixed powder in a pellet die and subjecting the powder within the pellet die to a pressure of about 6 to 40 ksi, typically about 12 ksi.

[0040] One suitable polysaccharide material is U.S.P. Topical Starch. Alternatively, HemadermTM, which is available

from Medafor, Inc. located in Minneapolis, Minn., may also be used. This product is described at least in part in U.S. Pat. No. 6,060,461.

[0041] The marker member 10 may be formed in a variety of shapes and sizes, but generally the length of the marker member is at least twice, preferably five times that of the maximum transverse dimension. The marker member 10 should have sufficient column strength to allow it to be pushed within the delivery tube without significant damage. In some instances the marker member may be partially or completely coated with a bioabsorbable polymeric material such as polylactic acid, polyglycolic acid and copolymers thereof to control the dissolution of the material of the marker member.

[0042] One suitable marker delivery system 15 is depicted in FIGS. 4 and 5 which includes a delivery tube or cannula 16 with an inner lumen 17, a distal portion 18, and a proximal portion 19 with a handle 20. A releasable distal plug 21 and the press-formed markers 10 are shown disposed within the inner lumen 17. A marker body 22 formed of a bioabsorbable material other than a polysaccharide with a radiopaque element is disposed between at least two press-formed marker bodies 10. A plunger 23 is slidably disposed within the inner lumen 17 and is provided with a head 24 on the proximal end 25 configured to allow an operator to press the plunger further into the inner lumen and push both the releasable plug 21 and marker members 10 and marker body 22 out of the discharge port or opening 26 in the distal end 27 of delivery cannula 16. Cannula handle 20 allows an operator to hold the cannula steady while pressing plunger 23 to discharge the releasable plug 21 and marker members 10 and marker body 22.

[0043] Releasable plug 21, preferably formed of polyethylene glycol, may substantially fill the discharge opening 26, as shown in FIG. 4 or at least occupy or block a portion of the discharge opening. The exposed face of plug 21 is preferably provided with an inclined configuration. Releasable plug 21 is configured to be tight enough, e.g. press fit, in the inner lumen 17 to prevent its inadvertent release which might allow premature discharge of marker 10 from delivery cannula 16, but the plug must be easily released when the plunger 23 is pressed deeper into the inner lumen 17 of the delivery cannula 16. An adhesive or mechanical element(s) may be used to hold the releasable plug 21 in a position within the inner lumen 17 to occlude the discharge opening 26. Suitable adhesives include polyurethane or polyacrylic based adhesives, polyhydroxymethacrylate base adhesives, fibrin glue (e.g., TissealTM), collagen adhesive, or mixtures thereof. Suitable mechanical means for securing the releasable plug 21 are described in application Ser. No. 10/174,401, now U.S. Pat. No. 7,651,505. The distal end 26 of the delivery cannula 16 is provided with a ramp 27 which guides the discharged plug 21 and marker member 10 out of the side port 28 into the target site. The distal tip 29 may be tapered for delivery through a guide tube (not shown).

[0044] The delivery cannula 16 may be provided with markings 30 which serve as visual landmarks to aid an operator in accurately placing the distal portion 18 of the cannula 16 in a desired location within a patient's body for discharging the marker 10.

[0045] The exterior of the delivery cannula 16 is preferably configured to fit within a guide cannula sized to accept a SenoCor®, EnCor $^{\text{TM}}$, Mammotome® or Tru-Cut®, biopsy device. Typically, plug 21 and marker member 10 will have diameters determined by the size of the inner lumen 17 and

typically will be about 0.02 inch (0.5 mm) to about 0.5 inch (12 mm), preferably about 0.04 inch (1 mm) to about 0.3 inch (8 mm) Plug 21 may have slightly larger transverse dimensions to provide a tight fit.

[0046] When the marker member 10 contacts body fluid within a body cavity such as a lumpectomy or biopsy site, the binding agent is dissolved and the polysaccharide draws moisture away from the blood and other fluids at the site and the clotting cascade begins to form thrombus at the site resulting in hemostasis.

[0047] While one or more particular forms of the invention have been illustrated and described herein in the context of a breast biopsy site, it will be apparent that the device and methods having features of the invention may find use in a variety of locations and in a variety of applications, in addition to the human breast, where tissue has been removed. Moreover, various modifications can be made without departing from the spirit and scope of the invention. For example, while the polysaccharide bodies are primarily described herein as press-formed bodies, the polysaccharide materials by be encapsulated in a bioabsorbable body or be in other forms. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention to be defined by the scope of the appended claims as broadly as the prior art will permit, and in view of the specification if need be. Moreover, those skilled in the art will recognize that features shown in one embodiment may be utilized in other embodiments. Additional details of pellet or other marker members and delivery systems may be found in application Ser. No. 10/753,694, filed on Jan. 7, 2004, and Ser. No. 10/976,138, filed on Oct. 27, 2004.

[0048] Terms such as "element", "member", "device", "section", "portion", "step", "means" and words of similar import when used in the following claims shall not be construed as invoking the provisions of 35 U.S.C. §112(6) unless the following claims expressly use the term "means" followed by a particular function without specific structure or expressly use the term "step" followed by a particular function without specific action. All patents and patent applications referred to above are hereby incorporated by reference in their entirety.

What is claimed is:

- 1. A method for treating a site within a patient from which tissue has been removed, comprising:
 - providing at least one press-formed marker body formed of polysaccharide and a suitable binder; and
 - placing the at least one of the press-formed marker body within the site where tissue has been removed so as to provide hemostasis therein.
- 2. The method of claim 1, wherein the press-formed body is formed of a mixed powder of the polysaccharide and the binder.
- 3. The method of claim 2, wherein the powder has a particle size less than 0.01 inch.
- **4.** The method of claim **2**, wherein the powder has a particle size of about 10 to about 200 micrometers.
- 5. The method of claim 1, wherein each of the at least one press-formed body has a transverse dimension of about 0.02 to about 0.1 inch.
- $\pmb{6}$. The method of claim 1, wherein each of the at least one press-formed body has a transverse dimension of about 0.035 to about 0.075 inch.
- 7. The method of claim 1, wherein each of the at least one press-formed body has a length of about 0.1 to about 0.4 inch.

- **8.** The method of claim **1**, wherein each of the at least one press-formed body has a length of about 0.15 to about 0.35 inch
- 9. The method of claim 1, wherein the at least one pressformed marker body is including in a plurality of marker elements which comprise bioabsorbable polysaccharide in sufficient amounts to exhibit hemostatic properties and a binder, the plurality of marker elements being disposed within an inner lumen of a tubular delivery member and the plurality of marker elements are urged out a discharge port in the tubular delivery member.
- 10. The method of claim 9, wherein each marker element of the plurality of marker elements is about 10 to about 90% (by wt.) bioabsorbable polysaccharide.
- 11. The method of claim 1, wherein the polysaccharide selected from the group consisting of starch, glycogen, cellulose, chitin, chitosan, dextran, pectins, glucans, agar, alginate and carrageen.
- 12. The method of claim 11, wherein each of the at least one press-formed marker body is about 10 to about 90% (by wt.) binder.
- 13. The method of claim 12, wherein the binder selected from the group consisting of methylcellulose, hydroxyethyl cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrolidone.
- 14. The method of claim 1, wherein the polysaccharide is corn starch or potato starch.
- 15. The method of claim 14, wherein the binder comprises methylcellulose.
- 16. The method of claim 1, comprising a delivery tube with an inner lumen and a discharge port, and a plunger slidably disposed within the inner lumen of the delivery tube, the plunger having a proximal end and a distal end, the proximal end having a head configured to allow an operator to move the plunger within the inner lumen, and having the at least one

- press-formed marker body disposed in the inner lumen distal to the distal end of the plunger and a releasable plug positioned in the discharge port, further comprising moving the plunger in a distal direction to push all of the lat least one press-formed marker body and the releasable plug out of a discharge port and into the site within the patient.
- 17. A method for treating a site within a patient from which tissue has been removed, comprising:
 - providing at least one unitary marker pellet formed of polysaccharide powder and a suitable binder pressed into a desired shape; and
 - placing each individual unitary marker pellet formed of polysaccharide powder within the site where tissue has been removed so as to provide hemostasis therein.
- 18. The method of claim 17, wherein each of the at least one press-formed marker body is formed of a mixture of 65% (by wt.) powder of corn starch or potato starch and 35% (by wt.) methylcellulose binder, the mixture being placed in a pellet die and subjected to pressure to form a unitary marker pellet.
- **19**. A method to facilitate treating a site within a patient from which tissue has been removed, comprising:
 - providing a plurality of marker members, each marker member of the plurality of marker members comprising a bioabsorbable polysaccharide and a binder, the bioabsorbable polysaccharide being in sufficient amounts to exhibit hemostatic properties, the plurality of marker members being disposed within an inner lumen of a tubular delivery member; and
 - placing the plurality of marker members in a lumen of a delivery tube configured to deliver the plurality of marker members into the site within the patient from which the tissue has been removed.
- 20. The method of claim 19, wherein the bioabsorbable polysaccharide is corn starch or potato starch.

* * * * *