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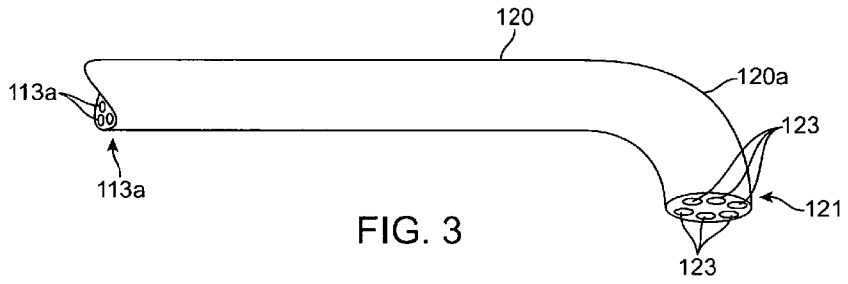

FIG. 3

(57) Abstract: Devices and methods are provided for performing microfracture surgery on an articular surface in a joint space. A surgical tool comprising an elongated body and a distal probe is provided. The probe is coupled to the elongated body and is adapted to be inserted in the joint space. The probe is positioned over the articular surface. A first and second channel through the subchondral bone into the marrow cavity are created with perforating elements, fluid jets, laser beams, or other channeling methods. The second channel is discrete from the first channel and is separated therefrom by a predetermined distance. The first channel and the second channel may be simultaneously created. In this way, a microfracture procedure is performed faster and with greater precision than existing techniques and with less risk of thermal damage and other complications.

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MICROFRACTURE DEVICE AND METHOD

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a non-provisional of, and claims the benefit of priority from U.S. Provisional Patent Application Nos. 61/218,147 (Attorney Docket No. 020979-004300US) filed June 18, 2009; and 61/218,148 (Attorney Docket No. 020979-004400US), also filed June 18, 2009. The entire contents of each of the above listed Provisional Patent Applications is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of Invention. The present disclosure relates to medical devices and methods, and more specifically to methods and devices used for orthopedic surgical procedures, such as articular cartilage repair, including microfracture surgery.

[0003] Cartilage is a type of tissue that can be found on the articular surfaces of the bones in human and animal joints. Articular cartilage enables a joint to move smoothly and with minimal friction. It also absorbs compressive, tensile, and shearing forces, protecting the tissue surrounding the joint, such as the ends of the bones in the joint.

[0004] Injuries and defects to articular cartilage may occur, for example, due to mechanical fatigue from athletic activities. Because cartilage is not vascularized, such injuries and defects heal very slowly if at all. If left untreated, many injuries can degenerate into osteoarthritis, causing pain and loss of mobility.

[0005] There are many known techniques to treat articular cartilage defects. Small defects can be treated with arthroscopic lavage and debridement. Loose debris is removed and the damaged cartilage is smoothed, thereby reducing pain, mechanical restriction, and inflammation and restoring mobility. This type of treatment, however, is typically only short-term and palliative.

[0006] Large defects can be treated by osteochondral grafting. The damaged section of articular cartilage, including a portion of the subchondral bone, is removed. Then, a replacement section of cartilage and bone is implanted. This replacement section can be taken from either the patient (i.e., an autograft) or a donor (i.e., an allograft). When an autograft is used, the replacement section is taken from low stress areas of a joint to minimize

any possible joint weakening. Depending on the size of the defect, a very large piece or multiple pieces of bone and cartilage may need to be used. The patient may not have enough spare tissue available. When an allograft is used, there may be issues of histocompatibility.

[0007] Large defects can also be treated by cell-based procedures, such as autologous chondrocyte implantation (ACI). In ACI, articular cartilage cells are arthroscopically harvested from the patient. The harvest cells are multiplied and cultured *in vitro*. When a sufficient number of cells have grown, usually after four to six weeks, the cells are implanted back into the patient in the treatment area. ACI, however, has its drawbacks. Growing cells outside the patient can be very expensive. Two surgeries are also required, the first to harvest cells and the second to implant them, and the second surgery typically needs to be an open procedure. Furthermore, the implanted cells may need several years to fully mature.

[0008] A promising surgical technique for treating articular cartilage defects which is gaining in popularity is microfracture surgery. Many professional athletes have undergone the procedure and have returned to their original form with much success. Microfracture surgery is most commonly performed on the knee, though it may be performed on the hip, shoulder, and other joints as well. In microfracture surgery, an articular cartilage defect is debrided and cleaned to remove any loose cartilage fragments. The calcified cartilage at the base of the defect is then removed using a curette to expose the subchondral bone plate. Next, a series of small, closely-spaced perforations are created in the bone plate throughout the area of the defect. These perforations are channels through the bone plate and into the underlying marrow space. Ideally, the perforations are spaced close together (e.g., 3-4 mm from each other) and angled orthogonally to the joint surface. Orthogonal placement of the perforations can enable the highest density of perforations to be made. The perforations are also orthogonally angled to prevent the perforations from breaking into or otherwise intersecting each other, which can weaken the underlying subchondral bone. Blood and marrow elements, which include mesenchymal stem cells, growth factors, and other healing factors and proteins, are released from the subchondral marrow space into the defect through the perforations to form a "super clot." The "super clot" provides an enriched environment for the formation of new chondral tissue in the defect.

[0009] Current devices and techniques for performing microfracture surgery may not be optimal. In most microfracture procedures today, the perforations are manually created with a specialized awl. Such awls are operated by positioning the sharp distal probe at the desired location in the defect and striking the proximal end of the awl with a mallet. Great care must be taken so that the perforations are positioned and aligned properly and that the perforations

do not penetrate too deeply into the subchondral bone, causing unwanted damage. Furthermore, because the perforations are created manually, great care must also be taken to ensure that the perforations have a consistent spacing, close enough together to create a continuous super clot, but not so close as to weaken the subchondral bone plate. Thus, the skill of a surgeon is heavily relied upon in typical microfracture procedures. Not all patients who may benefit from microfracture surgery have access to an orthopedic surgeon who has sufficient skill to perform the procedure successfully.

[0010] Also, currently available awls may not be ideal for creating perforations in a direction orthogonal to the joint surface. The angles at which an awl may be inserted into a joint are often quite limited, particularly if the awl is inserted into the joint through a small incision in a minimally invasive procedure or through a port or cannula in an arthroscopic procedure. Thus, the awl is often driven at an angle which is not orthogonal to the joint surface, resulting in the perforation being created at an oblique angle. In addition to the perforations not having the desired alignment, driving the awl at an oblique angle may also inadvertently skive off a portion of the subchondral bone plate or create an excessively large perforation, further damaging the subchondral bone plate.

[0011] Some currently available awls have an angled tip which is offset from the main body of the awl so that the tip can be positioned at an angle more orthogonal to the joint surface while the main body of the awl extends at a different angle. Such awls are usually driven by striking the proximal end along its longitudinal axis, which results in a force vector that is non-parallel to the angle of the tip. Other awls may be adapted to be struck in a transverse direction along a lateral surface of the awl, but this location is usually spaced substantially apart from the tip so the force may be significantly compromised by intervening tissue. Thus, current awls are inefficient, difficult to control, and may create an angled perforation which may be excessively large, ripped, and/or have ragged edges.

[0012] Current surgical techniques using currently available awls are also not well adapted for creating a large number of closely spaced perforations quickly. Each perforation is created individually. The manual process of positioning the awl, striking the awl, repositioning the awl, striking the awl, and repeating these steps can be very time consuming. Depending on the size of the defect, several hours may be required to create a large number of perforations, e.g., 25 to 100 perforations.

[0013] As an alternative to the use of specialized awls, mechanical drills and lasers have been proposed for microfracture surgery. However, these technologies have not gained favor

due for several reasons, including concerns over the risk of thermal necrosis in the bone resulting from the heat produced by such techniques.

[0014] In light of the challenges of currently available microfracture devices and techniques, improved devices and methods are desired. Such devices and methods should enable perforations of the subchondral bone plate to be made with a more precise and accurate size, depth and angle, with greater speed, and with minimal risk of inadvertent damage to the joint, such as from thermal necrosis or by compromising the mechanical strength of the subchondral bone. Such devices are also desirably much easier for a surgeon to use, reducing the heavy reliance on the skill of a surgeon and promoting the wide-spread use of microfracture surgery. At least some of these objectives will be met by the inventions disclosed herein.

[0015] 2. Description of the Background Art. Scientific publications which may be of interest include Philippon, MJ et al., *Can Microfracture Produce Repair Tissue in Acetabular Chondral Defect?*, Arthroscopy, 2008. 24(1): pp. 46-50; Steadman, JR et al., *Microfracture: Surgical Technique and Rehabilitation to Treat Chondral Defects*, Clinical Orthopaedics and Related Research, Number 391 S: pp. S362-S369; and Nixon, AJ et al., *Pulsed Carbon Dioxide Laser for Cartilage Vaporization and Subchondral Bone Perforation in Horses Part II: Morphologic and Histochemcial Reactions*, Veterinary Surgery, 1991. 20(3): pp. 200-208.

[0016] Patents which may be of interest include U.S. Patent Nos. 5,562,692; 5,620,414; 5,674,226; 5,853,384; 6,224,378; 6,423,028; 6,669,710; 6,960,214; 7,063,713; 7,067,123; 7,122,017; 7,232,446; and 7,431,711.

[0017] Patent publications which may be of interest include U.S. Publication Nos. 2002/0177802; 2004/0073223; 2004/0143269; 2004/0147932; 2007/0270870; 2008/0132932; 2008/0045964; and 2008/0268064 and PCT Publication Nos. WO 96/39952; WO 96/39953; WO 96/40476; WO 98/44853; WO 2007/106895; and WO 2008/022218.

[0018] Related applications include: U.S. Patent Application No. 12/776,177 (Attorney Docket No. 028357-000130US), the entire contents of which are incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

[0019] The present invention relates to medical devices and methods, and more specifically to methods and devices used for orthopedic surgical procedures. More specifically, the

invention relates to devices and methods for articular cartilage repair, in particular, microfracture surgery. The invention provides improved devices and methods for microfracture surgery which can enable a microfracture procedure to be performed faster and with greater precision than existing techniques and with less risk of thermal damage and other complications.

[0020] In a first aspect, embodiments of the invention provide a method for performing surgery on an articular surface in a joint space. The articular surface is disposed over a subchondral bone layer and a marrow cavity. A surgical tool comprising an elongated body and a distal probe is provided. The distal probe is coupled to the elongated body and is adapted to be inserted in the joint space. The distal probe comprises a first perforating element and a second perforating element. The distal probe is positioned over the articular surface. A first channel through the subchondral bone into the marrow cavity is created with the first perforating element. A second channel through the subchondral bone into the marrow cavity is created with the second perforating element. The second channel is discrete from the first channel and is separated therefrom by a predetermined distance. At least portions of the first channel and the second channel are simultaneously created.

[0021] The provided method may be used on various joints including the knee, the hip, the elbow, the shoulder, the ankle, or the wrist. Generally, the joint space to which the distal probe is inserted will comprises the hip joint. The articular surface on which channels are made may comprise the acetabulum of the hip and/or the femoral head.

[0022] The first channel and/or the second channel will typically be aligned generally orthogonally with the articular surface. The first and second channels may be parallel with one another. The first and second channels may be created at an angle transverse to the longitudinal axis of the distal probe.

[0023] In some embodiments, a third channel in the articular surface is created. The third channel is separated from the first channel and the second channel by the predetermined distance. The third channel may be created simultaneously with the first and second channels.

[0024] The first predetermined distance between the first perforating element and the second perforating element may be changed by various ways. It may be changed by deflecting at least one of the first perforating element or the second perforating element away from one another. It may be changed by axially translating a deflection member slidably disposed between the first perforating element and the second perforating element. The

deflection member may be axially translated by axially translating an actuation member slidably disposed within the elongated body and coupled to the distal probe. It may be changed by radially expanding a deflection member disposed between the first perforating element and the second perforating element.

[0025] In some embodiments, at least one of the first perforating element or the second perforating element comprises a high pressure fluid jet nozzle.

[0026] The channels through the subchondral bone may be created in many ways, for example, by directly striking the subchondral bone.

[0027] In some embodiments, at least one of the first perforating element or the second perforating element comprises a pin. The pin may comprise an elongated shaft having a sharp distal end.

[0028] In some embodiments, the first perforating element comprises a first pin and the second perforating element comprises a second pin. The first channel is created by driving the first pin into a first location in the articular surface. The second channel is created by driving the second pin into a second location in the articular surface. The second location is separate and discrete from the first location. At least one of the first pin or the second pin may be driven at an angle transverse to a longitudinal axis of the distal probe. The first and/or second pins may be actuated in many ways, including electromagnetically, pneumatically, hydraulically, and by a drive shaft axially movable in the distal probe.

[0029] In some embodiments, at least one of the first perforating element or the second perforating element comprises a drill bit. Typically, the drill bit will be advanced through cartilage into subchondral bone at an angle transverse to a longitudinal axis of the distal probe. In some embodiments, the temperature of the subchondral bone layer is maintained below that at which thermal necrosis occurs during the creation of the first and second channels, for example, by delivering a cooling fluid to the articular surface during the creation of the first and second channels.

[0030] Another way of creating the channels through subchondral bone is by irradiation. In many embodiments, at least one of the first perforating element or the second perforating element comprises an optical element. The optical element may comprise an ablative laser beam. The optical element may comprise a lens for focusing an ablative laser beam. Typically, the ablative laser beam is delivered at an angle transverse to the longitudinal axis of the distal probe. In some embodiments, the temperature of the subchondral bone layer is

maintained below that at which thermal necrosis occurs during the creation of the first and second channels, for example, by delivering a cooling fluid to the articular surface while the first and second channels are created.

[0031] The distal probe may comprise means to facilitate its positioning and/or repositioning over various locations on the articular surface. The distal probe may further comprise an indexing member. The step of positioning the distal probe over the articular surface may comprise positioning the indexing member on or adjacent to a reference structure on or near the articular surface. The first perforating element and/or second perforating element may be disposed away from the indexing member by the predetermined distance between the first and second channels.

[0032] In some embodiments, the distal probe is positioned at a second location over the articular surface after the first channel and the second channel have been created. The distal probe may further comprise an indexing member, and the step of positioning the distal probe at the second location may comprise positioning the indexing member on or adjacent to a second reference structure on or near the articular surface. The second reference structure may comprise the first channel and/or the second channel. In some embodiments, a third channel in the articular surface is created with the first perforating element and a fourth channel in the articular surface and discrete from the third channel is simultaneously created with the second perforating element.

[0033] The predetermined distance between the first and second channels may be about 0.5 mm to about 6 mm. In some embodiments, the predetermined distance is about 1.0 mm to about 4 mm. The first channel and the second channel may extend about 2 mm to about 10 mm into the subchondral bone. The first channel and the second channel may have a width of about 0.1 mm to about 4 mm, preferably being less than about 1.0 mm.

[0034] In many embodiments, the joint space is irrigated, for example, with a cooled liquid. The cooled liquid may be delivered to the articular surface through the distal probe. The cooled liquid may be delivered while the first and second channels are being created.

[0035] In some embodiments, a switch on the elongated body is pressed to simultaneously activate the first perforating element and the second perforating element to create the first channel and the second channel.

[0036] In some embodiments, the first perforating element is operable independently of the second perforating element. For example, the distal probe is repositioned over a second

location in the chondral lesion. Only the first perforating element is activated to create a third channel through the subchondral bone to the marrow cavity while the second perforating element remains inactive.

[0037] In another aspect, embodiments of the invention provide a device for performing surgery on an articular surface. The articular surface is disposed over a subchondral bone layer and a marrow cavity. The device comprises an elongated body having a longitudinal axis, a distal probe, a first perforating element, and a second perforating element. The distal probe is coupled to the elongated body and adapted to be inserted into a joint space. The first perforating element and the second perforating element are coupled to the distal probe. The first perforating element is for creating a first channel through the subchondral bone into the marrow cavity. The second perforating element is for creating a second channel through the subchondral bone into the marrow cavity. The second perforating element is separated from the first perforating element by a first predetermined distance. The first perforating element and the second perforating element are adapted to create the first channel and the second channel simultaneously. The first perforating element and the second perforating element may be adapted to create the first and second channels at an angle transverse to the longitudinal axis of the elongated body.

[0038] In some embodiments, the device further comprises a deflection member disposed between the first perforating element and the second perforating element. The deflection member is adapted to change the spacing between the first perforating element and the second perforating element. The device may further comprise an actuation member slidably disposed within the elongated body and the distal probe. The actuating member is adapted to move the deflection member when axially translated. The deflection member may comprise an expandable member, for example, a balloon. The deflection member may comprises a plate having a first aperture through which the first perforating element extends and a second aperture through which the second perforating element extends.

[0039] In some embodiments, the first perforating element and/or the second perforating element comprises a high pressure fluid jet nozzle configured to deliver a high pressure fluid jet to the articular surface.

[0040] In some embodiments, the first perforating element and/or the second perforating element comprises a pin adapted to be driven into the articular surface. The pin may be driven in many ways. The pin may be electromagnetically actuated, pneumatically actuated, hydraulically actuated, or mechanically actuated.

[0041] In some embodiments, the first perforating element comprises a first pin and the second perforating element comprises a second pin. The device may further comprise a first drive shaft and a second drive shaft. The first drive shaft is disposed in the distal probe and is coupled to the first pin. The second drive shaft is also disposed in the distal probe and is coupled to the second pin. The first drive shaft drives the first pin and the second drive shaft drives the second pin. In certain embodiments, the device further comprises a first hammer coupling the first drive shaft to the first pin and a second hammer coupling the first drive shaft to the second pin. The first hammer can convert an axial movement of the first drive shaft into a transverse movement of the first pin to drive the first pin. Likewise, the second hammer can convert an axial movement of the second drive shaft into a transverse movement of the second pin to drive the second pin.

[0042] In some embodiments, the first perforating element and/or the second perforating element comprises an optical element adapted to deliver an ablative laser beam to the articular surface. The optical element may comprise a focusing lens for focusing the ablative laser beam.

[0043] In some embodiments, the first perforating element and/or the second perforating element comprises a drill bit adapted to drill through into the subchondral bone layer with the temperature of the subchondral bone layer remaining below that at which thermal necrosis occurs.

[0044] In some embodiments, the elongated body further comprises an irrigation lumen having and outlet in the distal probe. The irrigation lumen is adapted to deliver a fluid to the articular surface while the first and second channels are created. The device may further comprise a cooler fluidly coupled to the irrigation lumen for cooling the fluid.

[0045] In some embodiments, the distal end further comprises at least one indexing member for facilitating the positioning of the distal tip. The indexing member may be spaced away from the first and/or second perforating elements by the same predetermined distance between the first and second perforating elements.

[0046] In some embodiments, the device further comprises an aspiration element coupled to the distal tip. The aspiration element may comprise a conical suction member. The device may further comprise an aspiration lumen extending through the elongated body and the distal probe. The aspiration lumen is in communication with an aspiration port at the distal end.

[0047] In some embodiments, the elongated body of the device is adapted to be handheld in a single hand of a user.

[0048] In some embodiments, the elongated body of the device comprises a switch for simultaneously activating the first perforating element and the second perforating element to create the first channel and the second channel.

[0049] In another aspect, embodiments of the invention provide a method for performing surgery on an articular surface disposed over a subchondral bone layer and marrow cavity. A surgical tool is provided. The surgical tool comprises an elongated body having a longitudinal axis and a distal probe coupled to the elongated body. The distal probe comprises an indexing member and at least one perforating element. The indexing member defines a discrete reference point in a predetermined location relative to the perforating element. The distal probe is positioned at a first location adjacent the articular surface. A first channel is created at the first location with the at least one perforating element. The first channel extends through the subchondral bone into the marrow cavity. The distal probe is repositioned such that the reference point is within the first channel and the distal probe is positioned at a second location adjacent the articular surface. The second location is separated from the first location by a predetermined distance. A second channel is created at the second location with the at least one perforating element. The second channel extends through the subchondral bone into the marrow cavity.

[0050] In some embodiments, the indexing member is referenced by placing the indexing member in the first channel.

[0051] In some embodiments, the indexing member comprises at least one wire extendable from the distal probe. The indexing member is referenced by extending the at least one wire from the distal tip and positioning the at least one wire in or adjacent to the first channel. In some embodiments, the at least one wire may comprise a ball coupled to a distal end of the at least one wire. In some embodiments, the at least one wire assumes a known angle with the distal probe when extended. The at least one wire is positioned in a lumen in the distal probe and has a pre-formed shape. The wire assumes the preformed shape when extended from the lumen and is forced into a second shape when retracted in the lumen.

[0052] In some embodiments, the indexing member comprises at least one optical indexing element coupled to the distal probe. The indexing member is referenced by emitting at least one light beam from the at least one optical indexing element toward a reference location in or near the first at least one channel. The light beam may comprise a laser beam. The at least

one optical indexing element may be steered to align the at least one light beam with the reference location.

[0053] In some embodiments, the at least one perforating element comprises a plurality of perforating elements adapted to create a first plurality of channels. Each channel of the first plurality of channels is simultaneously created with each perforating element of the plurality of perforating elements.

[0054] In some embodiments, the at least one perforating element comprises a plurality of perforating elements and the second group of channels comprises a second plurality of channels. Each channel of the second plurality of channels is simultaneously created with each perforating element of the plurality of perforating elements.

[0055] In some embodiments, the at least one perforating element comprises at least one high pressure fluid jet nozzle. The first channel is created by delivering at least one high pressure fluid jet to the first location. The second channel is created by delivering the at least one high pressure fluid stream to the second location.

[0056] In some embodiments, the at least one perforating element comprises at least one pin. The first channel is created by driving the at least one pin through the subchondral bone at the first location. The second channel is created by driving the at least one pin through the subchondral bone at the second location. The at least one pin may be driven in many ways, for example, the at least one pin may be electromagnetically actuated, pneumatically actuated, hydraulically actuated, or mechanically actuated.

[0057] In some embodiments, the at least one perforating element comprises a drill bit. The first channel is created by advancing the drill bit through subchondral bone at the first location. The second channel is created by advancing the drill bit through subchondral bone at the second location.

[0058] In some embodiments, the at least one perforating element comprises an optical element. The first channel is created by delivering an ablative laser beam from the optical element to the first location. The second channel is created by delivering an ablative laser beam from the optical element to the second location.

[0059] In some embodiments, the joint spaces comprises a joint selected from the group consisting of a knee, a hip, an elbow, a shoulder, an ankle, or a wrist. The articular surface may comprise the acetabulum of the hip and/or the femoral head.

[0060] In another aspect, embodiments of the invention provide a device for performing surgery on an articular surface disposed over subchondral bone and marrow cavity. The device comprises an elongated body having a longitudinal axis, a distal probe, at least one perforating element, and at least one indexing member. The distal probe is coupled to the elongated body and is adapted to be inserted into a joint space. The at least one perforating element is coupled to the distal probe and is adapted to create at least one channel at a first location on the articular surface. The at least one channel extends through the subchondral bone to the marrow cavity. The at least one indexing member is coupled to the distal probe for facilitating the positioning of the distal probe at a second location on the articular surface adjacent the first location. The at least one indexing member defines a discrete reference point spaced away from the at least one perforating element by a predetermined distance in a predetermined direction.

[0061] In some embodiments, the indexing member is configured to be positioned in a pre-made channel created by the perforating member such that the perforating element creates the at least one channel the predetermined distance from the pre-made channel.

[0062] In some embodiments, the at least one indexing member comprises at least one wire extendable from the distal probe. The at least one wire may be retractable into the distal probe. The at least one wire may comprise a ball coupled to a distal end of the wire. In some embodiments, the at least one wire assumes a known angle with the elongated body when extended. The wire may have a first shape when retracted in the distal probe and may assume a second shape when extended from the distal probe.

[0063] In some embodiments, the at least one indexing member comprises at least one light emitter for emitting a light beam into a previously created channel. The light beam may comprise a laser. The at least one light emitter may comprise at least one light emitting diode disposed on the distal tip. The light beam may have a cross-sectional shape comprising a circle, an ellipse, a ring, a cross, a cross hair, an X-shape, an asterisk shape, a triangle, a square, or a pentagon. The at least one light emitter may comprise at least one optical cable having an output end disposed on an end of the distal probe. The light emitter may be steerable.

[0064] In some embodiments, the at least one perforating element comprises a plurality of perforating elements. The at least one channel comprises a plurality of channels. The plurality of perforating elements are adapted to simultaneously create each channel of the plurality of channels.

[0065] In some embodiments, the at least one perforating element comprises a high pressure fluid jet nozzle configured to deliver a high pressure fluid jet to the articular surface.

[0066] In some embodiments, the at least one perforating element comprises an pin adapted to be driven into the articular surface. The pin may be electromagnetically actuated, pneumatically actuated, hydraulically actuated pin, or mechanically actuated.

[0067] In some embodiments, the at least one perforating element comprises an optical element adapted to deliver an ablative laser beam to the articular surface. The optical element may comprise a focusing lens for focusing the ablative laser beam.

[0068] In some embodiments, the at least one perforating element comprises a drill bit adapted to drill through the subchondral bone to the marrow cavity.

[0069] In another aspect, the invention provides a method for performing surgery on an articular surface in a joint space. A surgical tool comprising an elongated body having a longitudinal axis and a distal probe coupled to the elongated body is provided. The distal probe comprises a distal fluid jet nozzle. The distal probe is inserted into the joint space. The distal fluid jet nozzle is positioned adjacent to the articular surface. A high pressure fluid jet is delivered from the distal fluid jet nozzle against the articular surface to create a channel in the articular surface. The channel extends into subchondral bone below the articular surface. The articular surface may comprise the subchondral bone under articular cartilage in the joint space and/or the articular cartilage in the joint space.

[0070] Typically, the distal fluid jet nozzle is positioned generally orthogonal to the articular surface. Typically, the channel is generally orthogonal with the articular surface. In some embodiments, the distal fluid jet nozzle may be positioned by actively steering a distal portion of the surgical tool. The distal portion of the surgical tool may be axially steered by translating a pullwire slidably disposed within the elongated body and coupled to the distal probe to deflect the distal fluid jet nozzle.

[0071] In some embodiments, the distal probe has an aspiration port. Fluid and debris may be aspirated from the joint space through the aspiration port.

[0072] In some embodiments, the distal fluid jet nozzle comprises a plurality of distal fluid jet nozzles. Adjacent distal fluid jet nozzles are each spaced apart from each other. A plurality of high pressure fluid jets from the plurality of distal fluid jet nozzles are simultaneously delivered against the articular surface to simultaneously create a plurality of channels on the articular surface. Each channel extends into the subchondral bone below the

articular surface. Adjacent channels are separated from one another by a predetermined distance. In some embodiments, a high pressure fluid jet is delivered through one of the fluid jet nozzles while a high pressure fluid jet is not delivered through at least another of the fluid jet nozzles. In some embodiments, the predetermined distance comprises a distance of about 0.5 mm to about 6 mm. In some embodiments, the predetermined distance comprises a distance of about 1.0 mm to about 4 mm. Each channel will typically be aligned generally orthogonally with the articular surface. The channels will typically be parallel with one another.

[0073] In some embodiments, the distance between adjacent distal fluid jet nozzles may be changed. Adjacent distal fluid jet nozzles may be deflected, for example, by axially translating a deflection member disposed between the adjacent distal fluid jet nozzles. The deflection member may be axially translated by actuating an actuation member slidably disposed within the elongated body. Alternatively or in combination, the distance between adjacent distal fluid jet nozzles may be changed by expanding an expandable member between adjacent distal fluid jet nozzles.

[0074] In some embodiments, a fluid delivery tube within the elongated body is axially moved relative to the distal probe to expose the distal fluid jet nozzle distally of the distal probe. The fluid delivery tube is coupled with the distal fluid jet nozzle. The distal fluid jet nozzle may comprise a shape-memory material and can assume a pre-shaped curve when extended from the distal probe.

[0075] In some embodiments, the high pressure fluid jet comprises a pressure of about 3000 psi or greater. In some embodiments, the high pressure fluid jet comprises a pressure of about 5000 psi or greater.

[0076] In some embodiments, the high pressure fluid jet comprises a single pulse of high pressure fluid. In some embodiments, the pulse has a pulse duration in the range of about 100 milliseconds to about 500 milliseconds.

[0077] The channel may extend about 2 mm to about 10 mm into the articular surface. The channel may have a width of about 0.1 mm to about 4 mm, preferably being less than about 1.0 mm.

[0078] In various embodiments, the high pressure fluid jet comprises a fluid selected from the group consisting of water, saline solution, plasma, serum, calcium solution, or a

fluoroscopic dye solution. In some embodiments, the fluid further comprises hydroxyapatite which may enhance the cutting ability of the high pressure fluid jet.

[0079] In some embodiments, the high pressure fluid jet may be cooled.

[0080] In some embodiments, the joint space comprises a joint selected from the group consisting of a knee, a hip, an elbow, a shoulder, an ankle, or a wrist. The articular surface may comprise the acetabulum of the hip.

[0081] In some embodiments, the distal probe further comprises an indexing member. The step of positioning the distal fluid jet nozzle adjacent the articular surface may comprise positioning the indexing member on or adjacent to a reference structure on or near the articular surface to position the distal fluid jet nozzle at a second location over the articular surface. The second location is separated from the reference structure by a predetermined distance. The reference structure may comprise a previously-created channel in the articular surface.

[0082] In still another aspect, invention provides a device for performing a microfracture procedure on an articular surface in a joint space. The device comprises an elongated body having a longitudinal axis and a distal probe coupled to the elongated body. The distal probe is adapted to be inserted into the joint space and comprises at least one distal fluid jet nozzle. The at least one distal fluid jet nozzle is adapted to deliver at least one fluid jet at a sufficient velocity to perforate cartilage and bone to create a channel in the articular surface extending into through subchondral bone.

[0083] In some embodiments, the device further comprises an aspiration tube and the distal probe further comprises an aspiration port coupled to the aspiration tube for aspirating fluid from the joint space. The aspiration port may be concentric with the distal fluid jet. The aspiration port may be axially movable relative to the distal fluid jet nozzle. The aspiration reservoir may be coupled to the aspiration tube for collecting the aspirated fluid.

[0084] In some embodiments, the angle of the fluid jet nozzle relative to the longitudinal axis of the elongated body is changeable after insertion in the joint space.

[0085] In some embodiments, the device further comprises a steering mechanism adapted to change an angle between the distal probe and the elongated body. The steering mechanism may comprise a pullwire slideably disposed within the elongated body and coupled to the distal probe. Axially translating the pullwire articulates the distal probe.

[0086] In some embodiments, the at least one distal fluid jet nozzle is oriented transverse to the longitudinal axis of the elongated body.

[0087] In some embodiments, the at least one distal fluid jet nozzle comprises a plurality of distal fluid jet nozzles. Adjacent nozzles are each spaced apart from each other by a predetermined distance.

[0088] In some embodiments, the device may further comprise a first valve controlling fluid flow to the first of the fluid jet nozzles and a second valve controlling fluid flow to a second of the fluid jet nozzles. The first valve is controllable independently of the second valve.

[0089] In some embodiments, the device may further comprise a deflection member adapted to selectively change a distance between adjacent distal fluid jet nozzles. The device may further comprise an actuation member slidably disposed within the elongated body. The actuating member is adapted to axially translate the deflection member when actuated. In certain embodiments, the deflection member comprises an expandable member, for example, a balloon. In certain embodiments, the deflection member comprises a plate having a plurality of apertures through which the plurality of distal fluid jet nozzles extend. In certain embodiments, the deflection member comprises an axially translatable member disposed between adjacent distal fluid jets.

[0090] In some embodiments, the device further comprises at least one fluid delivery tube axially translatable relative to the distal probe and coupled to the at least one distal fluid jet. Moving the at least one fluid delivery tube relative to the distal probe extends the at least one distal fluid jet nozzle from the distal probe.

[0091] In some embodiments, the device further comprises a fluid source and a fluid pump coupled to the fluid source and the at least one distal fluid jet nozzle. The fluid pump is adapted to provide a high pressure stream of fluid to the at least one distal fluid jet nozzle. The fluid pump may be configured to deliver the high pressure stream of fluid at a pressure of at least about 3000 psi or more preferably at a pressure of at least about 5000 psi.

[0092] In some embodiments, the device further comprises a valve adapted to selectively deliver the high pressure stream of fluid to the at least one distal fluid jet nozzle. The valve may be adapted to deliver a short pulse of the high pressure stream of fluid. The valve may be configured to deliver a pulse of about 100 milliseconds to about 500 milliseconds in length.

[0093] In some embodiments, the fluid pump is disposed within the elongated body. The device may further comprise a second pump fluidly connected to the elongated body for delivering the fluid to the first pump.

[0094] In some embodiments, the fluid pump is configured to deliver a high pressure fluid pulse of fixed volume. The fluid pump may comprise a chamber having the fixed volume. The chamber has an inlet valve and an exit valve. The device may further comprise means for pressurizing the fluid in the chamber. The device may further comprise a second pump for delivering fluid to the chamber.

[0095] In some embodiments, the distal probe further comprises an indexing member for facilitating a repositioning of the distal probe at a predetermined spacing from a previously created channel.

[0096] In some embodiments, the indexing member may comprise a wire extendable distally from the distal probe and adapted to engage the previously created channel. The wire may be retractable into the distal probe. The wire may have a first shape when retracted in the distal probe and the wire may assume a second shape when extended from the distal probe.

[0097] In some embodiments, the indexing member may comprise a light emitter for emitting a light beam into the previously created channel. The light emitter may comprise an optical fiber. The light beam may comprises a laser.

[0098] In some embodiments, the elongated body may be adapted to be handheld in a single hand of a user.

[0099] These and other embodiments are described in further detail in the following description related to the appended drawings and figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0100] Figure 1 is a schematic diagram of a surgical device according to embodiments of the invention;

[0101] Figure IA shows the distal probe of the surgical device of Figure 1;

[0102] Figure IB shows the distal end of the distal probe of Figure 1;

[0103] Figure 1C shows a fluid jet nozzle according to embodiments of the invention;

[0104] Figure ID shows a hand-piece and a distal probe of a surgical device according to embodiments of the invention;

[0105] Figure IE shows a hand-piece and a distal probe of a surgical device according to embodiments of the invention;

[0106] Figure IF is a cross-sectional view of a safety switch of the distal probe of Figure ID;

[0107] Figure IG shows a hand-piece and a distal probe of a surgical device according to embodiments of the invention;

[0108] Figure IH shows a hand-piece and a distal probe of a surgical device having a recoil compensation mechanism according to embodiments of the invention;

[0109] Figure 11 shows a hand-piece and a distal probe of a surgical device having a sensor according to embodiments of the invention;

[0110] Figure 2 is a schematic diagram of a surgical device having an aspiration system according to embodiments of the invention;

[0111] Figure 2A shows the distal probe of the surgical device of Figure 2;

[0112] Figure 2B shows the distal end of the distal probe of Figure 2;

[0113] Figure 2C shows the distal end of a distal probe of a surgical device according to embodiments of the invention;

[01 14] Figure 3 shows a distal probe of a surgical device having multiple output nozzles according to embodiments of the invention;

[0115] Figure 3A shows a schematic diagram of a distal probe of a surgical device having multiple output nozzles according to embodiments of the invention;

[0116] Figure 3B shows a distal probe of a surgical device having multiple output nozzles and separate fluid deliver tubes according to embodiments of the invention;

[0117] Figure 4 shows a steerable distal probe of a surgical device according to an embodiment of the invention;

[0118] Figure 4A shows a distal probe of a surgical device which is steerable with an expandable member according to embodiments of the invention;

[0119] Figure 5 shows a distal probe of a surgical device having adjustable nozzles according to embodiments of the invention;

[0120] Figure 5A shows a front view of the distal probe of Figure 5 taken from line 5A-5A in Figure 5;

[0121] Figure 5B shows a side view of the distal probe of Figure 5 with an offset distal portion;

[0122] Figures 5C and 5D show a distal probe of Figure 5 delivering jets of fluid;

[0123] Figure 6 shows a distal probe of a surgical device having adjustable nozzles according to embodiments of the invention;

[0124] Figure 7 shows a distal probe of a surgical device having adjustable nozzles according to embodiments of the invention;

[0125] Figure 7A shows an end view of the distal probe of Figure 7 taken from line *IA-IA* in Figure 7;

[0126] Figure 8 shows a distal probe of a surgical device having an extendible nozzle according to embodiments of the invention;

[0127] Figure 8A shows a distal probe of a surgical device having multiple extendible nozzles according to embodiments of the invention;

[0128] Figure 9 shows a distal probe of a surgical device having extendible indexing pins according to embodiments of the invention.

[0129] Figure 9A shows an end view of the distal probe of Figure 9 taken from line 9A-9A in Figure 9;

[0130] Figure 9B shows a chondral lesion having microfracture perforations made by the distal probe of Figure 9;

[0131] Figure 10 shows a distal probe of a surgical device having an indexing wire and ball according to embodiments of the invention;

[0132] Figure 1OA shows a chondral lesion having microfracture perforations made by the distal probe of Figure 10;

[0133] Figure 10B shows a distal probe of a surgical device having an indexing wire and ball disposed in a separate tube from the remainder of the distal probe according to embodiments of the invention;

[0134] Figure 11 shows a distal probe of a surgical device having an indexing optical output element according to embodiments of the invention;

[0135] Figure 11A shows a chondral lesion having microfracture perforations made by the distal probe of Figure 11;

[0136] Figure 11B shows a distal probe of a surgical device having an annular indexing optical element according to embodiments of the invention;

[0137] Figure 11C shows the distal end of the distal probe of Figure 11B;

[0138] Figures 11D and 11E show cross-sectional views of a distal probe of a surgical device having a steerable indexing optical element according to embodiments of the invention;

[0139] Figure 12 is a schematic diagram of a surgical device according to embodiments of the invention;

[0140] Figure 12A shows an embodiment of the distal probe of the surgical device of Figure 12 having multiple fracture pins;

[0141] Figure 12B shows an embodiment of the distal probe of the surgical device of Figure 12 having a single fracture pin;

[0142] Figures 12C to 12H show mechanisms for driving the fracture pins of the surgical probe of Figure 12 according to embodiments of the invention;

[0143] Figure 121 shows a distal probe of a surgical device for performing microfracture with a drill bit according to embodiments of the invention.

[0144] Figure 12J shows a surgical device for performing microfracture with by electromagnetically driving a fracture pin according to embodiments of the invention.

[0145] Figure 13 shows a distal probe for performing microfracture surgery with ablative lasers according to embodiments of the invention;

[0146] Figure 13A shows a schematic diagram of a surgical device using the distal probe of Figure 13;

[0147] Figures 14 to 141 show an exemplary method of performing surgery on a chondral lesion according to embodiments of the invention;

[0148] Figures 15 to 15E show another exemplary method of performing surgery on a chondral lesion according to embodiments of the invention;

[0149] Figures 16 to 16D show a method of performing surgery on a chondral lesion in a hip joint according to embodiments of the invention; and

[0150] Fig. 17 illustrates another embodiment of a microfracture device.

DETAILED DESCRIPTION OF THE INVENTION

[0151] Fluid Systems. Embodiments of the invention provide improved devices and methods for articular cartilage repair, in particular, microfracture surgery. Many of these devices and methods can be applied to perform microfracture surgery by using high pressure fluid jets to create the requisite perforations in the subchondral bone plate of an articular cartilage lesion. The perforations created during microfracture surgery are channels through the exposed subchondral bony surface of the lesion and extending into the subchondral marrow space. By using fluid jets to create the perforations, the tissue and bone are cut more cleanly and precisely, and perforations of smaller diameter and with closer spacing may be made. In addition, debris, such as cartilage and bone particles, can be concurrently washed out and aspirated, leading to a cleaner, more effective procedure. Additionally, the use of fluid jets also lessens the risk of thermal damage. Moreover, multiple high pressure fluid jets may be delivered simultaneously, allowing microfracture procedures to be performed in less time and with greater precision and accuracy than current methods.

[0152] Fig. 1 shows a schematic diagram of a system 100 for performing microfracture surgery with a jet of high pressure fluid. The system 100 comprises a hand-piece 110, a distal probe 120, a fluid reservoir 130, a fluid accumulator or pump 140, a pressure regulator 150, a control valve 160, and a high pressure tube 180. In at least some cases, when it may be desired for the jet of high pressure fluid to be pulsed, the system 100 may further comprise a pulse inducer 170. The hand-piece 110 is typically ergonomically designed to be grasped by a surgeon's single hand. The hand piece 110 is coupled to the pump 140 and other system components by the high pressure tube 180. The distal probe 120 may comprise any of the distal probe embodiments for delivering high pressure fluid jets described herein. At least the distal portion of the distal probe 120 can be adapted to be arthroscopically inserted into a joint space, for example, in the knee, the hip, the shoulder, the ankle, the wrist, or other joint.

For example, it can have the appropriate dimensions and be made of biocompatible materials so that it can be arthroscopically inserted into the joint space. In exemplary microfracture procedures, the distal probe 120 is arthroscopically inserted into a joint space after a lesion in articular cartilage is identified, cleaned, debrided and/or aspirated. The distal probe 120 is adapted to deliver streams or jets of fluid, which can comprise high pressure fluid jets for creating perforations in the subchondral bone for microfracture surgery. The proximal end of hand piece 110 receives high pressure fluid from the high pressure tube 180.

[0153] The fluid reservoir 130 stores the fluid to be delivered. The fluid may comprise at least one of water, saline solution, plasma, serum, calcium solution, or a fluoroscopic dye solution for visualization during surgery. The fluid reservoir 130 is fluidly connected to the pump 140 which generates positive fluid pressure and can output the fluid as a high pressure stream. The output of the pump 140 is fed through the pressure regulator 150, then through an on-off control valve 160, and in at least some cases, to the pulse inducer 170 which can convert the high pressure fluid output into pulses of fluid. The pulse rate may be set from zero to continuous flow, e.g., the fluid jet may not be delivered at all, be delivered in single or repeating pulses, or be delivered as a continuous stream. The pressure regulator 150 may be used to reduce fluid pressure to a low setting for irrigation by the distal probe 120 and to increase fluid pressure to a higher pressure for soft tissue cutting, and yet a higher setting for cartilage and bone cutting or perforation by the distal probe 120.

[0154] Fig. IA shows an embodiment of the distal probe 120 of Fig. 1. The distal probe 120 comprises a fluid jet tube 113 having a fluid jet lumen 113a, which may be integrally formed in the distal probe 120 or be a separate element therein. The fluid jet tube 113 is coupled to the high pressure tube 180 and can receive high pressure fluid therefrom. As shown in Figs. IA and IB, the distal probe 120 has a distal end 121 and a fluid jet nozzle 123 at or near the distal end 121. The fluid jet nozzle 123 may be integral with or coupled to the fluid jet tube 113 or the distal probe 120 and receives fluid from the fluid jet tube 113. The fluid jet nozzle 123 will be of known construction and can concentrate the received fluid into a focused stream having a high enough pressure and velocity to cut through cartilage and bone. The fluid jet nozzle 123 as well as the other related components of the device 100 may be, for example, similar to the devices described in U.S. Patent Nos. 5,674,226 and 6,669,710, the contents of which are fully incorporated herein by reference. As shown in Fig. IA, the distal portion 120a of the distal probe 120 may be oriented transverse to the longitudinal axis 101 of the remainder of the distal probe 120 and/or the hand-piece 110, e.g., at an angle of about 45 degrees to about 90 degrees relative thereto. Having the distal portion

120a oriented as such can enable the distal probe 120 to be more easily positioned so that a high pressure fluid jet is delivered orthogonally to the exposed subchondral bony surface. In many embodiments, the body of the distal probe 120 is pre-formed so that the distal portion 120a is oriented transverse to the longitudinal axis of the remainder of the distal probe 120. Alternatively or in combination, the distal portion 120a may be deformable or steerable as discussed below and/or the distal fluid jet nozzle 123 may be positionally adjustable as discussed below.

[0155] The depth to which distal fluid jet nozzle 123 cuts bone and tissue will be carefully controlled. The microfracture channels should be deep enough to pass through the subchondral bone plate into the marrow cavity, but not so deep as to damage the marrow cavity or structures surrounding it. Usually channels are about 2-10 mm, more preferably 2-5 mm in depth from the chondral surface in the articular defect. Channel depth may be controlled by maintaining fluid pressure at appropriate levels to cut to the desired depth but no further. Alternatively, the apparatus may include a mechanism for creating turbulence or otherwise diffusing the fluid jet stream at distances beyond the desired cutting depth. For example, the apparatus may include two or more separate fluid jet nozzles, which may be similar to the various multi-nozzle embodiments describes below, directing two or more fluid jet streams at a converging angle toward each other, such that at the point of intersection the streams interfere and diffuse one another into a non-cutting flow pattern. In some embodiments, the cross sectional area of the lumen 123a of the distal fluid jet nozzle 123 can be increased or decreased to modify the speed and pressure of the delivered jet of fluid. As shown in Fig. 1C, a blocker 129 may be slidably disposed within the lumen of the distal fluid jet nozzle 123. The blocker 129 is coupled to a translatable shaft 128. Axially translating the translatable shaft 128 can translate the blocker 129 proximally or distally in directions 127. When the blocker 129 is distally advanced, the cross sectional area of the lumen 123a is decreased and the velocity and pressure of any delivered fluid can be increased, for example, to a speed and pressure sufficient to cut cartilage and bone. When the blocker is proximally retracted, the cross sectional area of the lumen 123a is increased and the velocity and pressure of any delivered fluid can be decreased, for example, to a speed and pressure only sufficient to irrigate tissue or to cut soft tissue..

[0156] Fig. ID shows the high pressure tube 180, hand piece 110, and the distal probe 120 of Fig. 1. The hand piece 110 may comprise an internal valve 111 and a finger switch 112. Having an internal valve 111 in the hand piece 110 allows the point where fluid flow is turned on or off to be closer to the fluid jet nozzle 123, minimizing pressure losses upstream

of the hand piece 110 and allowing the process of cutting cartilage and bone to be turned on and off almost instantaneously. The finger switch 112 is coupled to and can control the internal valve 111. The hand piece 110 may comprise finger switch control wires 115 coupling the finger switch 112 with the internal valve 111 and to a power supply located either in the hand piece 110 or remotely. The finger switch control wires 115 may alternatively lead back through the inside of hand piece 110 and over the high pressure tube 180 to couple to and/or control a more proximally placed fluid controller, for example, control valve 160. Alternatively or in combination, an on-off valve may be disposed upstream and outside of the hand piece 110. In some embodiments, for example, as shown in Fig. IE, the hand piece 110 may comprise a wireless receiver 117 coupled to the internal valve 111 and to a power supply located either in the hand piece 110 or remotely. The internal valve 111 may be configured to act in response to a wireless signal 119 from a more proximally placed external controller or interface, for example, a foot-operated switch electronically, hydraulically, or mechanically coupled to the internal valve 111. Or, a switch on the hand piece 110 may communicate wirelessly with a valve and/or pump located remotely.

[0157] The distal portion 120a of the distal probe 120 may also comprise a safety switch 125 which is coupled to safety switch control wires 116. The safety switch control wires 116 lead back through the inside of hand piece 110 and over the high pressure tube 180. In addition to the internal valve 111 being located in the hand piece 110, the safety switch 125 can add another layer of safety to ensure that fluid, e.g., high pressure fluid jets, are only delivered when the surgeon intends to and when the distal probe 120 is in the correct position and configuration.

[0158] Fig. IF shows the safety switch 125 in cross section. The safety switch 125 comprises a distal tube 125a, a first retainer 128 and a second retainer 129 each fixed to the fluid jet output nozzle 123, and a spring 127. The spring 127 is typically a coil spring and is concentric with the fluid jet output nozzle 123 and is disposed distal of the retainer 128. The spring 127 is disposed between the retainer 128 and the distal tube 125a. The distal tube 125a is concentric with the fluid jet output nozzle 123 and is slidable thereover and urged by spring 127 against the second retainer 129. The safety switch 125 further comprises a proximal contact ring 122a and a distal contact plate 122b. The proximal contact ring 122a is coupled to one end of the safety switch control wire 116a while the distal contact plate 122b is coupled to the other safety switch control wire 116b. When the distal tube 125a is moved proximally by pressing the distal tube 125a against the surface of a target portion of cartilage

or bone, the proximal contact ring 122a contacts the distal contact plate 122b, completing a circuit of the safety switch control wires 116a, 116b. The safety switch control wire 116 is coupled to the finger switch 112 and completing this circuit allows current to flow to switch open the valve 111 when the finger switch 112 is pressed. This ensures that the fluid jet nozzle 123 is pointing toward the target tissue and is fully enclosed by the distal tube 125a before it can be turned on. In some embodiments, the distal tube 125a may comprise at least one opening in its proximal end through which a vacuum may be applied through the distal probe 120 around the nozzle 123 and/or to allow excess fluid and debris to escape as a perforation is being made.

[0159] As shown in Fig. 1G, the hand piece 110 may comprise an internal accumulator or pump 141 and an internal control valve 161. The internal control valve 161 regulates the entry of fluid into the pump 141 and the internal valve 111 regulates the egress of fluid out of the pump 141. In this embodiment, fluid may be delivered at lower pressures to the hand piece 110 and the pump 141 may be used to generate bone-cutting pressures on demand within the hand piece 110. This minimizes pressure losses and delay upstream of the hand piece 110 and allows the process of cutting cartilage and bone to be turned on and off almost instantaneously. Additionally, the portion of the system 100 delivering high pressure fluid can be restricted to those components disposed between the pump 141 and the fluid nozzle 123, reducing the risk of rupture or leaks upstream of the hand piece 110.

[0160] Fig. 1H shows a further embodiment of a microfracture device according to the invention which includes a mechanism for reducing any tendency of the device to recoil away from the target site as a result of the pressure of the fluid jet. In this embodiment, the microfracture device includes a head having a first fluid jet nozzle 123 configured to deliver a focused high pressure fluid stream suitable for cutting tissue and/or bone to create microfracture channels. A first delivery lumen 123a delivers fluid to first fluid jet nozzle 123. A second fluid jet nozzle 133, connected to a second fluid delivery lumen 133a, is disposed on the opposite side of head and is adapted to deliver a more dispersed fluid stream of insufficient pressure to cut tissue in a direction opposite that in which the high pressure fluid stream is directed. The delivery of a lower pressure stream over a wider area may be adapted to produce the same overall force as that created by a more focused, higher pressure fluid jet. In this way, any recoil or kickback produced by delivering a high pressure fluid jet from first fluid jet nozzle 123 can be negated by simultaneously delivering fluid at lower pressure through the second fluid jet nozzle in the opposite direction.

[0161] As shown schematically in Fig. II, the distal probe 120 may further comprise a sensor 121s at the distal end 121. Such a sensor 121s may be an optical, infrared, ultrasonic, capacitance, chemical, or contact sensor and may sense parameters such as the distance from the distal end 121 to a target articular surface, the depth or thickness of the subchondral bone below the target subchondral bony surface in the defect site, the depth of a perforation which has been created, and/or the presence of fat droplets, blood, mesenchymal stem cells, and/or other fluids emerging from a perforation.

[0162] Fig. 2 shows a system 200 for performing microfracture surgery according to further embodiments of the invention. Like the system 100, the system 200 may comprise the hand-piece 110, the distal probe 120, the fluid reservoir 130, the fluid pump 140, the pressure-regulator 150, the control valve 160, the pulse indicator 170, and the high pressure tube 180. The system 200 can further comprise an aspiration system comprising a vacuum pump 220, a vacuum regulator 230, an aspirate reservoir 240, and a safety bypass 250. The distal probe 120, the hand-piece 110, and the high pressure tube 180 further comprise an aspiration lumen 223. The system 200 further comprises a controller 260 coupled to the vacuum regulator 230 and the control valve 160. The controller 260 may be coupled to and operated by a user interface 210, which may comprise, for example, a finger switch on the hand piece 110, a foot-switch, a control box, or a personal computer. The vacuum pump 220 generates negative fluid pressure and draws fluid from the concentric aspiration lumen 223 in high pressure tube 180. For example, the vacuum pump 220 may generate about 0.5 to about 5 atmospheres of negative pressure. The drawn fluid is directed through the safety bypass 250 and into the aspirate reservoir 240. The vacuum regulator 230 is coupled to the vacuum pump 220 and regulates the amount of negative pressure it generates. The aspiration system can be used to aspirate excess fluid and debris, e.g., debris from cut bone and cartilage, in the target joint space before, during, and after making a surgical perforation in a target portion of articular cartilage. Additionally, irrigation fluid may be delivered at low pressures through the aspiration system for irrigating the surgical site. The aspiration/irrigation system may be used in any of the embodiments described herein.

[0163] Fig. 2A shows the distal probe 120 of system 200. Fig. 2B shows the distal end 121 of the distal probe 120. As shown in Figs. 2A and 2B, the aspiration lumen 223 is concentric with the distal fluid jet nozzle 123. Fluid and debris, including bone and cartilage particles, can be aspirated through the aspiration lumen 223 before, during and/or after a surgical procedure using the system 200. Preferably, aspiration can be turned on and off separately from the delivery of high pressure fluid jets, although in some embodiments, aspiration may

be turned on and off automatically with the delivery of high pressure fluid jets. In some embodiments, a low pressure stream of fluid may be delivered through the aspiration lumen 223, for example, to irrigate or flush away excess or unwanted debris and particles and to exfoliate a calcified cartilage layer before a perforation is created. As shown in Fig. 2C, the distal portion 120a of the distal probe 120 may be include a soft and flexible suction cup coupled thereto to atraumatically engage and fluidly seal against the defect surface when the aspiration lumen 223 is used to aspirate fluid and debris as shown by arrows 235. The suction cup may be used to aspirate fluid and debris around and in the channel created by the fluid jet nozzle. Additionally, after channel formation, higher levels of negative pressure may be applied through the suction cup to the channel, e.g. -5 to -15 atmospheres, to draw out marrow components, stem cells, and blood from the marrow cavity into the chondral defect to accelerate formation of a super clot.

[0164] Fig. 3 shows a distal probe 120 according to yet further embodiments of the invention. As shown in Fig. 3, the distal probe 120 may comprise a plurality of fluid jet tubes 113, a plurality of fluid jet lumens 113a, and a plurality of distal fluid jet nozzles 123. Preferably, the distal fluid jet nozzles 123 are arranged so as to be spaced equally from each other, e.g., by about 1-4 mm. The distal probe 120 can be configured to simultaneously deliver a plurality of high pressure fluid jets from the distal fluid jet nozzles 123. Any number of separate fluid jet tubes 113 and nozzles 123 may be provided, from 2 up to 20 or more depending on size constraints. Thus, the distal probe 120 can simultaneously create multiple perforations in a target tissue during a surgical procedures. Simultaneous delivery of high pressure fluid jets and simultaneous creation of multiple perforations in a target tissue may be used with any of the systems, devices, and methods described herein. In one embodiment shown in Fig. 3A, each fluid jet tube 113 is coupled to a separate control valve 160, allowing independent control of fluid delivery through each fluid jet tube 113. This allows the operator to select the fluid jet nozzles 123 to be used at a particular location in an articular defect depending on its shape and size. The multi-nozzle distal probe 120 may comprise a single integral shaft with multiple internal lumens 113a as shown in Fig. 3, or a plurality of separate fluid delivery tubes 113 coupled together as shown in Fig. 3B. In either case, an aspiration lumen may also be provided either as a separate, parallel lumen or as a concentric lumen surrounding the fluid delivery lumens.

[0165] Fig. 4 shows a distal probe 120 according to yet further embodiments of the invention. As shown by the dotted outline in Fig. 4, the distal portion 120a of the distal probe 120 may be steered, deflected or articulated. Providing a steering mechanism in the distal

portion 120a allows the distal portion 120a to be straightened so as to reduce the profile of the distal portion 120a so that the distal probe 120 is more easily introduced into a joint space. The distal probe 120 comprises a pullwire 410 which is coupled to the distal end 121 at location 420. The pullwire 410 is slidable within the distal probe 120 and can be pulled in a direction 401 to adjust the angle the distal portion 120a forms with the longitudinal axis 101 of the distal probe 120. In some embodiments, the distal probe 120 may comprise multiple pullwires 410 to steer the distal portion 120a in multiple directions. The pullwire 410 may be actuated by an actuator mechanism such as a knob or slider mechanism located in the hand piece 110 and coupled to the pullwire 410, and pullwire 410 may be locked into desired position by locking mechanism located in the hand piece 110.

[0166] In some embodiments, as shown in Fig. 4A, the distal portion 120a of the distal probe 120 may be positioned or stabilized by the inflation of a laterally disposed expandable member 411 mounted to distal probe 120 on a lateral side opposite the fluid jet nozzle 123. The laterally disposed expandable member 411 may be an inflatable balloon coupled to an inflation tube 413 having an inflation lumen 413a. Fluid can be introduced into the expandable member 411 to expand it to its expanded configuration 411a to engage tissue structures within a joint space to reposition or stabilize the distal portion 120a. Expanding the expandable member 411 within a joint can also push the nozzle 123 against a target exposed subchondral bone surface and to stabilize the distal probe 120 at a desired position relative to the surface of the defect as it creates microfracture perforations. As shown in Fig. 4A, the inflation tube 413 may be separate and distinct from the distal probe 120. In certain embodiments, the inflation tube 413 may be integral with the distal probe 120, with the inflation lumen 413a being an additional lumen within the distal probe 120. In alternative embodiments, similar to the balloon 411 shown in Fig. 4A, a pad or foam block may be mounted to the distal end of distal probe 120 opposite the fluid jet nozzle 123 to minimize any trauma caused by recoil of the device when the fluid jet is activated.

[0167] Fig. 5 shows a distal probe 120 according to yet further embodiments of the invention. Fig. 5A shows a front view of the distal probe 120 taken from line 5A. As shown by the phantom lines in Figs. 5 and 5A, the distal fluid jet nozzles 123 can be deflected radially outward. As discussed below, by deflecting the fluid jet nozzles 123 radially outward, a plurality of microfracture perforations can be made at a selected spacing without changing the position of the distal probe 120. The distal probe 120 may comprise an expansible deflection member 500, for example, an inflatable balloon or an expandable mechanical basket, coupled to an actuation member 510 disposed within the distal probe 120.

The expansible deflection member 500 may be disposed between the distal fluid jet nozzles 123. When expansible deflection member 500 is expanded to its expanded form 500a, the expanded expansible member 500 deflects the distal fluid jet nozzles 123 radially outward. The expansible deflection member 500 may be expanded to different degrees of expansion to deflect the distal fluid jet nozzles 123 radially outward to different inter-nozzle spacings.

[0168] In other embodiments, for example, as shown in Fig. 6, in place of an expandable deflection member 500, an axially slidable cam member 600, e.g., a dish, plate or ball, is fixed to the actuation member or shaft 510 extending slidable through the distal probe 120 to an actuator in hand piece 110. Axially translating the actuation member 510 axially translates the cam member 600 to deflect the distal fluid jet nozzles 123 to a greater or lesser degree. In some embodiments, for example, as shown in Fig. 5B, the actuation shaft 510 is flexible and the distal portion 120a of the distal probe 120 including the distal fluid nozzles 123 are oriented transverse to the longitudinal axis 101 of the remainder of the distal probe 120. The expandable deflection member 500 or the axially slidable cam member 600 may be flexible as well.

[0169] In some embodiments, as shown in Fig. 5C, the distal fluid jet nozzles 123 maybe biased radially inward. The jets of high pressure fluid 1201 may be delivered along axes 511. As shown in Fig. 5C, when the expansible deflection member 500 is collapsed, the distal fluid jet nozzles 123 face radially inward and the delivered jets of high pressure fluid 1201 converge at a single point 555 to cut or perforate a chondral lesion CL. As shown in Fig. 5D, when the expansible deflection member 500 is expanded, the distal fluid jet nozzles 123 do not converge, allowing the creation of multiple, spaced-apart perforations, or the delivery of fluid at lower pressure to irrigate the chondral lesion CL.

[0170] Fig. 7 shows a distal probe 120 according to yet further embodiments of the invention. The distal probe 120 can comprise a deflection plate 700 coupled to an actuation member 510 disposed within the distal probe 120. As shown in Fig. 7A, the deflection plate 700 is in the form of a circular disc but may comprise other forms as well, for example, an elliptical disc, a polygonal disc, an elongate bar, to name a few. The deflection plate 700 comprises nozzle apertures 710. The distal fluid jet nozzles 123 extend through the nozzle apertures 710. Axially translating the actuation member 510, for example, proximally or distally as indicated by arrows 650, axially translates the deflection plate 700 to deflect the distal fluid jet nozzles 123 radially outward or inward to a greater or lesser degree. For example, retracting the deflection plate 700 can increase the angle between an individual distal fluid jet nozzle 123 and the longitudinal axis of the distal probe 120 while advancing

the deflection plate 700 can decrease the angle between the individual distal fluid jet nozzle 123 and the distal probe 120.

[0171] It should be noted that in any of the embodiments of Figs. 5-7, the distal fluid jet nozzles 123 may be bent at an angle or other suitable shape such that when deflected outward to a desired inter-nozzle spacing, the distal fluid jet nozzles 123 are generally orthogonal to the surface of the chondral lesion to be treated.

[0172] Fig. 8 shows a distal probe 120 according to still another embodiment of the invention. The distal fluid jet nozzle 123 has a pre-formed shape and can be axially extended or retracted from the distal end 121 of the distal probe 120. The fluid jet tube 113 can be axially translated, for example, as indicated by arrows 810, to extend or retract the distal fluid jet nozzles 123 from the distal end 121 of the distal probe 120. In some cases, the distal fluid jet nozzle 123 and the fluid jet tube 113 can also be rotated within the body of the distal probe 120 as indicated by arrow 808. Upon extension, the extended distal fluid jet nozzle 123 assumes a pre-formed shape in which its distal end is transverse to the longitudinal axis 101 of the distal probe 120. For example, the distal fluid jet nozzle 123 can comprise a flexible and resilient shape-memory or superelastic material such as Nitinol. When retracted, the distal fluid jet nozzle 123 is straightened by the more rigid outer shaft of the distal probe 120. Thus, the profile of the distal portion 120a of the distal probe 120 may have a low profile for introduction into the joint, but upon extension of the fluid jet nozzle 123 enables the delivery of high pressure fluid jets along an axis transverse to the longitudinal axis 101 of the distal probe 120. The extendable distal fluid jet nozzle 123 may also be biased in a curved shape so that the angle between the distal fluid jet nozzle 123 and the longitudinal axis 101 of the distal probe 120 increases as the distal fluid jet nozzle 123 is further axially advanced. In this way, a range of different angles between the fluid jet nozzle 123 and the longitudinal axis 101 of the distal probe 120 are possible. In some embodiments, as shown in Fig. 8A, the distal probe 120 can comprise a plurality of fluid jet tubes 113 and a plurality of distal fluid jet nozzles 123, each having a pre-formed shape, which can be axially extended or retracted from the distal end 121 of the distal probe 120. When extended distally from the distal probe 120, each fluid jet nozzle 123 assumes a desired pre-set configuration with a pre-determined spacing between the nozzles. Upon retraction into the distal probe 120, the distal fluid jet nozzles 123 are forced back into close spacing or direct engagement with one another to minimize the profile of the device.

[0173] In some embodiments, the distal probe 120 may comprise an indexing feature to facilitate the positioning and repositioning of the distal probe 120 to create multiple

perforations in a target portion of exposed subchondral bone plate in the chondral defect. The indexing feature can be used to ensure that the perforations are created with a known, predetermined uniform spacing between each other.

[0174] Fig. 9 shows a distal probe 120 according to yet further embodiments of the invention. Fig. 9A shows a bottom view of the distal end 121 of the distal probe taken from line 9A-9A. The distal probe 120 can comprise a plurality of distal fluid jet nozzles 123. As shown in Fig. 9A, the plurality of distal fluid jet nozzles 123 comprises a 3x3 matrix of fluid jet nozzles 123. An individual distal fluid jet nozzle 123 may be spaced away from an adjacent distal fluid jet nozzle 123 in the same column by the same distance as it is spaced away from the adjacent distal fluid jet nozzle 123 in the same row and vice versa. Other numbers and arrangements of a plurality of distal fluid jet nozzles 123, for example, a 2x2 matrix, a 2x3 matrix, a 3x2 matrix, a spiral pattern, an equilateral triangular pattern, a concentric circular pattern, to name a few, are also contemplated.

[0175] The distal probe 120 according to Fig. 9 further comprises indexing pins 900a and 900b. The indexing pins 900a and 900b are coupled to axially slidable indexing wires 902a and 902b, respectively, which are disposed within the distal probe 120. Axially translating the wires 902a and 902b in the directions shown by arrows 901, can extend or retract the indexing pins 900a and 900b to selectively expose them from the probe 120. The indexing pins 900a and 900b may be integral with or otherwise coupled to the axially slidable wires 902a and 902b. Although a variety of configurations are possible, as shown in Fig. 9A, the first indexing pin 900a can be positioned to the right of the bottom-most row of the 3x3 matrix while the second indexing pin 900b can be positioned below the left-most row of the 3x3 matrix. The first indexing pin 900a can be spaced away from the distal fluid jet nozzle 123 to its left by the same distance the distal fluid jet nozzles 123 are from the adjacent distal fluid jet nozzles 123 in the same row or same column. Likewise, the second indexing pin 900b can be spaced away from the distal fluid jet nozzle 123 above it by the same distance the distal fluid jet nozzles 123 are from the adjacent distal fluid jet nozzles 123 in the same row or same column. As explained below, the indexing pins 900a and 900b can help facilitate the positioning of the distal probe 120 during surgical procedures.

[0176] Fig. 9B shows a chondral lesion CL having a plurality of microfracture perforations 905 made therein by the distal probe 120 according to Figs. 9 and 9A. To make this plurality of microfracture perforations 905, the distal probe 121 is first positioned on an exposed region of subchondral bone plate in the chondral lesion CL with the first indexing pin 900a at a first spot 910. Multiple jets of high pressure fluid are then simultaneously delivered by the

plurality of distal fluid jets 123 of the distal probe 120, creating a first 3x3 matrix of perforations 906a. The distal probe 121 is next positioned on the exposed subchondral bone plate in chondral lesion CL with the first indexing pin 900a at a second spot 920, which coincides with the bottom-left most perforation of the first 3x3 matrix of perforations 906a. The first indexing pin 900a may be placed at the second spot 920 based on visual confirmation through an arthroscope and/or by tactile feedback to the surgeon. Multiple jets of high pressure fluid are then simultaneously delivered by the plurality of distal fluid jets 123, creating a second 3x3 matrix of perforations 906b. The distal probe 121 can next be positioned on the exposed subchondral bone plate in chondral lesion CL with the second indexing pin 900b at a third spot 930, which coincides with the top-left most perforation of the second 3x3 matrix of perforations 906b. Multiple jets of high pressure fluid can then be simultaneously delivered by the plurality of distal fluid jets 123, creating a third 3x3 matrix of perforations 906c. The distal probe 121 can next be positioned on the exposed subchondral bone plate in chondral lesion CL with the second indexing pin 900a at a fourth spot 920, which coincides with the top-left most perforation of the first 3x3 matrix of perforations 906a. Multiple jets of high pressure fluid can then be simultaneously delivered by the plurality of distal fluid jets 123, creating a fourth 3x3 matrix of perforations 906d. Similar steps can be performed to create more microfracture perforations.

[0177] Fig. 10 shows a distal probe 120 according to yet further embodiments of the invention. As shown in Fig. 10, the distal probe 120 may comprise a single distal fluid jet nozzle 123 and an indexing pin 900. The indexing pin 900 may comprise a distal ball 901a connected to the a pre-shaped wire 902. The single distal fluid jet nozzle 123 can deliver a high pressure fluid jet along a first axis 1010 while the indexing pin 900 extends along a second axis 1020. In some embodiments, the first axis 1010 is parallel with the second axis 1020 although it may also be at non-parallel angles thereto. The first axis 1010 and the second axis 1020, as well as the distal fluid jet nozzle 123 and the indexing pin 900, may be separated from each other by a predetermined distance 1030. While the lumens for fluid delivery and the wire lumen 903 are illustrated as being integral within the distal probe 120, these may also comprise separate tubes coupled to one another as shown in Fig. 1OB.

[0178] Fig. 1OA shows the distal probe 120 according to Fig. 10 being used to create a plurality of perforations on an exposed region of subchondral bone plate in a chondral lesion CL. To create the plurality of perforations, a first perforation 905a is created by a jet of high pressure fluid from the distal fluid jet nozzle 123. The distal probe 120 is then repositioned so that the indexing pin 900 is registered with the first perforation 905a. For example, the

indexing pin 900 may be placed adjacent to or even inserted into the first perforation 905a based on optical confirmation from an arthroscope or tactile feedback to the surgeon. A second perforation 905b is then created by a jet distal fluid jet nozzle 123. These steps can then be repeated. As the indexing pin 900 and the distal fluid jet nozzle 123 are separated from each other by a predetermined distance 1030, the distance between adjacent perforations can be uniform. The use of the indexing pin 900 can also make the step of repositioning the distal probe 120 easier and/or faster.

[0179] Fig. 11 shows a distal probe 120 according to yet further embodiments of the invention. As shown in Fig. 11, the distal probe 120 may comprise a single distal fluid jet nozzle 123 and an optical indexing element 1111. The single distal fluid jet nozzle 123 delivers high pressure fluid jets along a first axis 1110 while the optical indexing element 1111 emits a beam of light, e.g., a laser beam, along a second axis 1120. The source of this light may be in hand piece 110 or in a remote location and is coupled to the optical indexing element 1111 through an optical cable 1112 disposed within the distal probe 120. Alternatively, the optical indexing element 1111 may comprise a light emitting diode located at the distal end 121 of the distal probe 120 or in hand piece 110. In some embodiments, the first axis 1110 is parallel with the second axis 1120. The first axis 1110 and the second axis 1120, as well as the distal fluid jet nozzle 123 and the optical indexing element 1111, may be separated from each other by a predetermined distance 1030. Alternatively, the optical indexing element 1111 may direct a light beam on the same location at which the distal fluid jet nozzle 123 is directed, i.e., with axis 1110 intersecting axis 1120.

[0180] Fig. 1IA shows the distal probe 120 according to Fig. 11 being used to create a plurality of perforations on an exposed region of subchondral bone plate in the chondral lesion CL. To create the plurality of perforations, a first perforation 905a is created by a jet of high pressure fluid from the distal fluid jet nozzle 123. The distal probe 120 is then repositioned so that the beam of light from the optical indexing element 1111 is directed into the first perforation 905a. An arthroscope may be used to visualize the beam of light on the chondral lesion CL. A second perforation 905b is then created by a jet distal fluid jet nozzle 123. These steps can then be repeated. As the optical indexing element 1111 and the distal fluid jet nozzle 123 are separated from each other by a predetermined distance 1130, the distance between adjacent perforations will be uniform. The use of the optical indexing element 1111 can also make the step of repositioning the distal probe 120 easier and/or faster. In some embodiments, the projection of the beam from the optical indexing element 1111 on the chondral lesion CL can comprise a shape, for example, a cross, an X-shape, an asterisk

shape, to name a few. By observing the shaped projection, the surgeon can verify whether or not the second axis 1120 and thus the first axis 1110 are orthogonal to the exposed subchondral bone plate in the surface of the chondral lesion CL, and therefore also if a perforation made in the exposed subchondral bone plate of the chondral lesion CL will be orthogonal to the surface of the exposed subchondral bone plate. The optical indexing element 1111 may alternatively comprise an annular light pipe surrounding the distal fluid jet nozzle 123 as shown in Figs. 1IB to 11C so as to create an annular, donut-shaped light beam surrounding a location 1150 in which the fluid jet nozzle 123 will direct its fluid stream.

[0181] The distal probe 120 may further comprise a plurality of optical indexing elements (e.g., light emitters) which may be directed at different locations relative to the point at which the distal fluid jet nozzle 123 is directed. For example, a first light beam may be directed at the same point at which the distal fluid nozzle 123 is aimed, while a second light beam may be directed at a point spaced apart from the first light beam at a predetermined spacing, e.g., the desired spacing between perforations. The two light beams may be different colors or different shapes so the operator can discern which corresponds to each position. Preferably, the light beams may be activated independently of one another. In this way, the operator may turn on one of the light beams to illuminate the location where a new perforation is to be created, or he may turn on the other light beam and direct it at a previously created perforation in order to accurately position the distal probe at the desired spacing for a new perforation.

[0182] In another embodiment, the optical indexing element 1111 may be deflectable or steerable into a plurality of positions such that the operator may select where the light beam is directed relative to the fluid jet. For example, in Fig. 1ID, the distal probe 120 has an optical lumen 1155 in which an optical fiber 1160 is disposed. The tip 1161 of the optical fiber 1160 is deflectable laterally within the optical lumen 1155. A leaf spring 1165 coupled to the inner wall of the optical lumen 1155 urges the optical fiber 1160 toward a right wall of the optical lumen 1155. In this position, the optical fiber 1160 emits light along a first axis 1120a operably parallel to and at a pre-determined spacing relative to the axis 1110 of the fluid jet nozzle 123. A cam member 1170 is slidably disposed within the optical lumen 1155 and is moved axially via a wire 1175. The cam member 1170 has an enlarged portion 1171 which engages the optical fiber 1160. Optionally, the cam member 1170 may be tubular or may have an axial bore (not shown) through which the optical fiber 1160 may slidably extend. As the cam member 1170 is moved distally, the enlarged portion 1171 deflects the distal tip of the optical fiber 1160 toward the left wall of the optical lumen. In this position, the optical

fiber 1160 emits light toward the same location at which the fluid jet will be directed. The operator may thus select whether the light beam will shine upon the same location where a microfracture perforation is to be created, or upon a reference location (e.g., a previously created perforation) which is a predetermined spacing from where the fluid jet will be directed.

[0183] It will be understood that while the indexing features of the invention have been described in conjunction with the use of fluid jet nozzles for microfracture procedures, the indexing features may be used with any of various other means for creating microfracture perforations, including awls, picks, lasers, drills, and other devices. Further, the indexing feature may be part of a separate accessory device which may be attached to a fluid jet, awl, or other type of microfracture instrument to facilitate spacing between perforations. For example, the indexing feature may be mounted to a body having a clip or other attachment mechanism by which the body may be releasably attached to an awl or fluid jet microfracture instrument.

[0184] Mechanical Systems. In other embodiments, the invention provides devices and methods for performing microfracture surgery by mechanically penetrating, e.g., piercing, drilling, cutting, grinding, etc., articular cartilage and subchondral bone to create the requisite perforations.

[0185] Fig. 12 is a schematic diagram of a surgical device 300 for performing microfracture by mechanically penetrating articular cartilage. The surgical device 300 comprises a hand piece 310 coupled to a distal probe 320. At least the distal portion of the distal probe 320 is configured for insertion into a joint space. For example, it can have the appropriate dimensions and be made of biocompatible materials so that it can be arthroscopically inserted into the joint space. A common cannula used in arthroscopy has an inner diameter of approximately 5.5 mm and therefore the distal probe 320 should have an outer diameter small enough to freely move in the cannula, thus the distal probe 320 preferably has an outer diameter of about 5.4 mm or less. Additionally, the distal probe 320 should be long enough to extend into the treatment region such as a joint space; in an exemplary embodiment adapted for surgery of the hip joint, distal probe 320 preferably has a length of at least about 16.5 cm (6.5 inches long). These dimensions may be applied to any of the distal probes described herein.

[0186] The surgical device 300 can further comprise a driver 340 operably coupled to the hand piece 310 and a controller 360 operably coupled to the driver 340. The driver 340

provides electromechanical, pneumatic, hydraulic or other form of energy to drive a component in the distal probe 320 to create perforations in articular cartilage. The controller 360 comprises some form of user interface adapted to control the driver 360, such as a trigger, a pressable button, a control switch, a foot pedal, or other control mechanisms.

[0187] In many embodiments, the distal probe 320 may comprise at least one fracture pin 323 for creating a perforation in articular cartilage. As shown in Fig. 12A, the distal probe 320 may comprise a plurality of fracture pins 323. Each fracture pin 323 is cylindrical and has a sharp distal end for penetrating cartilage and bone. Fracture pins 323 may be solid needles or tubular coring-type needles having a hollow bore. Each fracture pin 323 is integral with or coupled to a translatable drive shaft 313 disposed within the distal probe 320. By advancing the translatable drive shafts 313 distally, the fracture pins 323 can be advanced distally as indicated by arrow 325. The fracture pins 323 may be advanced or driven at a velocity sufficient to fracture cartilage and bone. The microfracture pins 323 may be spaced away from each other by a predetermined distance which typically corresponds to the desired distance between perforations, for example, preferably about 1.5 mm to about 6 mm and more preferably about 2 mm to about 4 mm. In some embodiments, for example, as shown in Fig. 12B, the distal probe 320 may comprise a single translatable drive shaft 313 and a single fracture pin 323.

[0188] The distal portion 320a of the distal probe 320 may be oriented transverse to the longitudinal axis of the distal probe 320 and/or the hand piece 310. Having the distal portion 320a oriented as such can enable the distal probe 320 to be more easily positioned in the joint space so that the fracture pins 323 are driven orthogonally to the surface of the articular cartilage. In many embodiments, the body of the distal probe 320 is pre-formed so that the distal portion 320a is oriented transverse to the longitudinal axis of the remainder of the distal probe 320. Alternatively or in combination, the distal portion 320a may be steerable, for example, by using a pullwire or pullwires as previously described in reference to Fig. 4.

[0189] The fracture pins 323 may be driven in various ways. Driver 340 may be adapted to drive fracture pins 323 in a single continuous manner until the desired depth is reached, or the fracture pins may be driven in a series of repeating pulses similar to a jackhammer so as to incrementally progress deeper into the bone with each pulse. In a preferred embodiment, each drive shaft 313 is slidable within a curved lumen in distal probe 320 and is flexible so as to bend around the curve. Fracture pins may be integrally formed with the drive shafts or may be separate elements of a harder or more durable material capable of retaining a sharpened point.

[0190] Fig. 12C schematically illustrates an alternative embodiment of the distal probe 320 with a low profile right angle driver for driving a fracture pin 323. The fracture pin 323 is held at a perpendicular angle relative to the longitudinal axis of the distal probe 320. A hammer or striker 315 pivotably connected to the drive shaft 313 is used to transfer energy to fracture pin 323 from the axially movable drive shaft 313 that can be driven manually or by a pneumatic or hydraulic cylinder or other known means. As shown in Fig. 12C, this embodiment is used to drive a single fracture pin 323 but can be easily adapted to include multiple strikers 315 so that two or more fracture pins 323 may be driven individually or simultaneously into the articular cartilage and its subchondral bone. In some embodiments, in order to reduce profile of the distal probe 320 configured to drive multiple fracture pins 323, the distal probe 320 can be flexible or have a hinge or other articulation that allows multiple drivers to move closer together for introduction and then spread apart following introduction into the joint. While a 90 degree driver is shown, various other angles transverse to the longitudinal axis of shaft 320 are also possible.

[0191] Fig. 12D schematically illustrates another embodiment of an angled anchor driver. In this embodiment, the distal end 313a of the drive shaft 313 is angled to form a wedge that impacts striker 316, which has the corresponding angle on its proximal end 316b to interface with the drive shaft 313. Thus, as the drive shaft 313 moves axially, it drives the striker 316 down at a right angle to impact the fracture pin 323. As shown in Fig. 12D, the distal probe 320 is adapted to drive the fracture pin 323 into cartilage and bone at a 90 degree angle relative to the longitudinal axis of the distal probe 320. One of skill in the art can appreciate that this angle may be varied depending on the anatomy. Thus, in still other embodiments, the distal region of the distal probe 320 may be flexible, articulated or actively steered using steering means as described above so that the delivery angle can be varied. In still other embodiments, interchangeable tips for distal probe 320 may be used having predetermined angles ranging from 0 degrees to 90 degrees.

[0192] Figs. 12E and 12F illustrate still another embodiment of the distal probe 320. Fig. 12E shows an end view of the drive shaft 313 which rotates about the longitudinal axis of the distal probe. Fig 12F shows a side view of the distal probe 320 with the rotating drive shaft 313. The drive shaft 313 is operably coupled with a head 317. The head 317 is eccentrically attached to the rotating drive shaft 313. As the drive shaft 313 rotates and spins the head 317, the head 317 contacts a driver 318 that moves linearly in a direction transverse to drive shaft 313 to drive the fracture pin 323 into and penetrate cartilage and bone. The driver 318 may be spring loaded or may simply be forced back after driving the fracture pin 323 to the

original position for the next impact from the head mass 317. The distal probe 320 will usually include an outer housing (which is not shown in Figs. 12E and 12F for clarity) enclosing shaft 313 and operatively coupled to driver 318 and fracture pin 323. Fracture pin 323 will preferably be coupled to the housing and biased by a spring in an upward position so as to retract away from the target tissue following impact.

[0193] Fig. 12G illustrates an embodiment of the distal probe 320 in which the fracture pin 323 is pressure driven. Fig. 12G shows a cross section of the distal probe 320 which comprises the fracture pin 323, which may be actuated using high pressure fluid, for example, a high pressure liquid or a high pressure gas such as nitrogen. Instead of a drive shaft 313, the distal probe 320 comprises a high pressure fluid channel 314. The fluid flows through the channel 314 contained within the distal probe shown as P_{in} in Fig. 12G. The pressure in the channel 314, exerted in a direction 342, moves a driver 331 pivotably coupled to body of the distal probe 320. The driver 331 then impacts the fracture pin 323 at an angle transverse to the longitudinal axis of the distal probe 320 when pressure is applied. When the driver 331 travels the full distance, it moves past an exhaust orifice 341, and drives the fracture pin 323. Gas is exhausted through P_{out}. Torsion spring 332 forces the driver 331 back to the initial position. Preferably, fracture pin 323 is similarly biased back to an upward position following impact by a compression spring (not shown). By varying the dimensions of the driver 331, the velocity of the driver can change, resulting in different forces on the fracture pin 323. Additional porting and/or use of vacuum can create different frequencies and dampening within the driver chamber which would eliminate the need for or enhance the coilspring function.

[0194] Fig. 12H is a cross section of an alternative fluid pressure-driven embodiment in which a linearly movable piston 334 oriented transverse to longitudinal axis of the distal probe 320 is used instead of the pivotable driver 331. Pressure in the channel 314, exerted in a direction 342, forces the linearly movable piston 334 in a direction 336, which moves the fracture pin 323 at an angle transverse to the longitudinal axis of the distal probe 320. Fracture pin 323 may be coupled to piston 334 so as to move with it, or fracture pin 323 may be separate from piston 334 and driven by impact with it. A compression spring 333 can return the piston 334 and/or fracture pin 323 to their original positions.

[0195] Fig. 121 shows an embodiment of a distal probe 320 having a distal drill bit 324 for drilling into articular cartilage to create the requisite perforations for microfracture surgery. The distal drill bit 324 is coupled to the drive shaft 313 which in this embodiment is rotatable

within the distal probe 320. Rotating the drive shaft 313, for example, as shown by arrow 366, can rotate the distal drill bit 324. As shown in Fig. 121, the distal probe 320 comprises a single rotatable drive shaft 313 and a single distal drill bit 324. Other embodiments of the distal probe 320 may comprise multiple rotatable drive shafts 313 and multiple distal drill bits 324. In these embodiments, the distal drill bits 324 may be spaced away from each other by a predetermined distance which typically corresponds to the desired distance between perforations, for example, preferably about 1 mm to about 6 mm and more preferably about 2 mm to about 4 mm. Drill bit 324 is preferably rotated at very low speed, e.g. less than about 100 rpm, more preferably less than about 60 rpm, so as to minimize heat generated in the drilling process. Alternatively or additionally, a cooling fluid may be introduced through a fluid lumen (not shown) in distal probe 320 having an outlet near or surrounding drill bit 324 to allow irrigation and cooling of the target area during drilling. Introducing such a cooling fluid can keep the temperature of the drilled tissue at a temperature below that at which thermal necrosis occur. Cooling fluid may be introduced while drilling is occurring. Drill bit 324 may be specially adapted for creating microfracture penetrations while minimizing heat. For example, drill bit 324 may be tubular with a hollow central bore adapted to core out a circular column of tissue. Alternatively, drill bit 324 may comprise a spiral blade along its exterior which cuts through tissue rather than pulverizing or grinding tissue. In this embodiment, drill bit 324 may be rotated just enough to cut through subchondral bone to the desire depth, which may range from less than 360 degrees to 1, 2, or 3 or more complete rotations, depending on the pitch of the spiral blade and the desired depth of penetration.

[0196] Fig. 12J shows an embodiment of a surgical device 300 in which the fracture pin 323 is configured to be driven electromagnetically. The driver 340 may comprise a wire coil 341 surrounding the drive shaft 313. The drive shaft 313 may be ferromagnetic and the wire coil of the driver 340 may form an electromagnetic field repelling the drive shaft 313 and driving the fracture pin 323. The surgical device 300 may further comprise a spring coupling the drive shaft 313 to the driver 340 to resiliently return the drive shaft 313 to its original position after it has been repelled and the electromagnetic field has been turned off. In this way, by cycling current through coil 341, drive shaft 313 may be driven in an oscillating fashion to impact or otherwise drive fracture pin 323.

[0197] In any of the embodiments of Figures 12A-12J, or any other of the embodiments disclosed herein, it may be advantageous to include a pad or inflatable member mounted to the superior surface of the distal probe opposite the perforating element, similar to that illustrated in Fig. 4A described above. The pad or inflatable member may be placed in

engagement with tissue or bone opposite the chondral defect to stabilize the distal probe and maintain its position relative to the defect while minimizing trauma should the distal probe impact the tissue or bone as perforations are created.

[0198] Laser Systems. Embodiments of the invention can provide devices and methods for performing microfracture surgery by using a laser to ablate articular cartilage and subchondral bone to create the requisite perforations.

[0199] Fig. 13 shows a distal probe 420 for performing microfracture surgery with ablative lasers according to embodiments of the invention. The distal probe 420 comprises a plurality of optical cables 363 coupled to a plurality of optical output elements 373 at the distal end 421. Ablative laser beams are directed through the optical cables 363 to the optical output elements 373. The optical output elements 373 may comprise lenses for focusing ablative laser beams, e.g., excimer laser beams, onto the surface of a portion of articular cartilage. The optical output elements 373 may be spaced away from each other by a predetermined distance which typically corresponds to the desired distance between perforations, for example, preferably about 1.5 mm to about 6 mm and more preferably about 2 mm to about 4 mm. The plurality of optical output elements 373 may simultaneously deliver ablative laser beams to an articular surface or may sequentially deliver ablative laser beams. The distal probe 420 may also comprise a cooling fluid tube 364 ending at a cooling fluid output port 374 at the distal end 421. The distal probe 420 may deliver a cooled fluid to the articular surface as perforations are made by laser ablation. Introducing such a cooling fluid can keep the temperature of the drilled tissue at a temperature below that at which thermal necrosis occur. Cooling fluid may be introduced while ablation is occurring. The distal probe 420 may also further comprise an optical cable through which a surgeon can illuminate and/or view the treatment site while perforations are ablated onto articular cartilage and subchondral bone.

[0200] Fig. 13A shows a schematic diagram of an exemplary microfracture surgery system employing the distal probe 420, which is shown in cross-section. The distal probe 420 can comprise a first optical cable 363a, a second optical cable 363b, a third optical cable 363c, and a fourth optical cable 363d. At the distal end 421 of the distal probe, the first optical cable 363a, the second optical cable 363b, the third optical cable 363c, and the fourth optical cable 363d can be coupled to a first focusing lens 373a, a second focusing lens 373b, a third focusing lens 373c, and a fourth focusing lens 373d, respectively. The focusing lenses focus ablative laser beams onto the surface of a portion of articular cartilage. The first focusing lens 373a receives ablative laser energy from a first proximally placed laser source 460a. The

second, third and fourth focusing lenses 373b, 373c and 373d similarly receive ablative laser energy from second, third and fourth proximally placed lasers 460b, 460c and 46Od. A controller 466 is coupled to and can individually switch the laser 460a, 460b, 460c and 46Od on and off. For example, the controller 466 may cause ablative laser beams to be emitted from the first and third focusing lenses 373a and 373c while no ablative laser beams are emitted from the second and fourth focusing lenses 373b and 373d. In some embodiments, at least one of the optical cables 363a, 363b, 363c, and 363d may be coupled to a non-ablative laser so that the beam emitted onto an articular surface serves as a reference to determine the location of the distal probe 420. In certain embodiments, the particular optical cable may be switched back-and- forth between coupling to the non-ablative laser and coupling to an ablative laser. In some embodiments, at least one of the optical cables 363a, 363b, 363c, and 363d may be coupled to a light source to illuminate and/or view the treatment site.

[0201] The distal probe 420 shown in Fig. 13A further comprises a cooling fluid tube 364 ending at a cooling fluid output port 374 at the distal end 421. The cooling fluid tube 364 is coupled to a proximally placed irrigation system comprising a control valve 471, a pump 470, and a cooling fluid reservoir 480. The pump 470 and the control valve 471 may be coupled to the controller 466 which can switch the flow of cooling fluid on and off and control its flow rate.

[0202] The distal portion 420a of the distal probe 420 may be oriented transverse to the remainder of the distal probe 420 and/or a hand piece coupled to the distal probe 420. Having the distal portion 420a oriented as such can enable the distal probe 420 to be more easily positioned in the joint space so that the ablative laser beams are delivered orthogonally to the surface of the articular cartilage. In many embodiments, the body of the distal probe 420 is pre-formed so that the distal portion 420a is oriented transverse to the longitudinal axis of the remainder of the distal probe 420. Alternatively or in combination, the distal portion 420a may be actively steerable, for example, by using a pullwire or pullwires as previously described.

[0203] Particle Systems. In still another embodiment, shown schematically in Fig. 17, a microfracture device 1700 according to the invention is adapted to project particles 1706 at sufficient velocity to penetrate the subchondral bone to the marrow cavity. The distal probe 1702 may have one or more tubular barrels 1704 from which the particles are ejected. A chamber 1708 is connected to the barrels which holds multiple beads 1706 and feeds them into each barrel 1704. The particles 1706 may be a bioerodable polymer or other material that erodes after being driven into the marrow cavity, a durable metal or polymer suitable to

remain implanted in the marrow cavity, or frozen water, carbon dioxide or other suitable substance that is solid when cooled and which becomes liquid or gas at body temperature so at to become absorbed within the marrow cavity. If frozen particles are used, the device will include a cooler 1714 to maintain the particles at the desired solid state until they are projected into the bone. The particles will be of suitable size and shape to create perforations of desired depth and width, e.g. spherical beads about 0.05-0.5 mm in diameter. Preferably a pump 1712 is connected to the barrels with an intervening valve 1710, such that air or other gas may be delivered at sufficient pressure to accelerate the particles to the desired velocity. Alternatively, a pneumatic or electronic piston or ejector pin may be coupled to each barrel to mechanically push the particles through the barrels. In a further alternative, a reaction chamber may be connected to each barrel in which a chemical reaction may be used to create a burst of energy that drives the particles. In some embodiments a single particle is driven to create a perforation, while in others multiple particles are driven serially to create the perforation.

[0204] Microfracture Procedure. Embodiments of the invention may provide many procedures for using the above described surgical tools to perform microfracture surgery. Several exemplary procedures described below.

[0205] Figs. 14 to 141 show an exemplary method of performing microfracture surgery on a chondral lesion CL using a distal probe 120 configured to deliver jets of high pressure fluid as described above. Similar methods can be used to perform microfracture surgery with distal probes which are configured to create perforations by driving fracture pins or drill bits or by laser cutting according to other embodiments of the invention.

[0206] Fig. 14 shows a portion of articular cartilage CA having a chondral lesion CL. Below the articular cartilage is a corresponding portion of subchondral bone SB. The articular cartilage CA may be in any joint, including the knee, the hip, the shoulder, the ankle, the wrist, etc. As shown in Fig. 14, the chondral lesion CL may be a full-thickness lesion, i.e., it extends into the subchondral bone. The surgical procedure of Figs. 14 to 141 may be used for partial-thickness lesions as well.

[0207] Usually access to the joint will be aided by distracting the joint. Any known means of distraction may be used, but in preferred embodiments of the method, the joint will be distracted using an internal distraction device such as an inflatable balloon, as described in co-pending application Serial No. 12/483,446 (Attorney Docket No. 020979-003820US) filed June 12, 2009, the full disclosure of which is incorporated herein by reference. The use of

internal distraction devices rather than external distraction tables enhances joint access by allowing the joint to be easily repositioned in flexion, abduction and adduction, providing exposure of various locations of the joint that would otherwise be inaccessible. In addition, using internal distraction devices, the joint may be repositioned so as to reduce the tension in the ligaments and tendons comprising the joint capsule, thereby permitting easier introduction of instruments into the joint.

[0208] Fig. 14A shows the chondral lesion CL being smoothed and debrided by a debriding instrument 121 1 to expose the subchondral bony surface in the defect. Excess fluid and debris can be aspirated with an aspirator 1222. The surgical procedure of Figs. 14 to 141 may be arthroscopic, with the debrider instrument 121 1 and the aspirator 1222 being inserted through a cannula or port or through a small incision. The surgical procedure of Figs. 14 to 141 may alternatively be a mini-open or fully open procedure.

[0209] Fig. 14B shows the distal probe 120 as described above being inserted into the joint space so that the distal fluid jet nozzle 123 is adjacent to the exposed subchondral bony surface in the defect.

[0210] Fig. 14C shows the distal probe 120 being aligned so that the distal fluid jet nozzle 123 is generally orthogonal to the exposed subchondral bony surface of the chondral lesion CL. Generally, the distal probes of the invention are positioned so that the microfracture channels they make are orthogonal to the surface of the chondral lesion CL, whether such microfracture channels are made by high pressure fluid jets, fracture pins, drill bits, or ablative lasers.

[0211] Fig. 14D shows the distal fluid jet nozzle 123 of the distal probe 120 delivering a jet of high pressure fluid 1201 toward the surface of the exposed subchondral bony surface of the chondral lesion CL. The high pressure fluid jet 1201 may comprise a fluid comprising at least one of water, saline solution, plasma, serum, calcium solution, or fluoroscopic dye solution, to name a few and may include abrasive additives such as hydroxyapatite to enhance its cutting ability. The fluid of high pressure fluid jet 1201 may be also cooled to minimize any possible thermal damage. In some embodiments, the jet of high pressure fluid 1201 may be a single, discrete pulse of high pressure fluid, with a pulse duration of about 100 milliseconds to about 500 milliseconds which is usually sufficient to create a single perforation through the subchondral bone. Multiple discrete pulses may be repeated, or a rapid series of pulses, or continuous fluid flow for a longer period may also be used in some cases. In some embodiments, the jet of high pressure fluid 1201 may have a fluid pressure of

at least 3000 psi, more preferably at least about 5000 psi, which is usually sufficient to cut through bone. The delivered jet of high pressure fluid 1201 creates a first perforation or channel 905a in the chondral lesion CL that extends through the subchondral bone plate SB into the subchondral marrow cavity MC. The created perforation 905a will preferably be generally orthogonal to the surface of the chondral lesion CL. A perforation 905 will have a diameter (or transverse width) large enough to allow marrow components to pass from the marrow cavity into the defect, usually being about 0.1 mm to about 3 mm, but in particularly preferred embodiments the diameter will be less than about 1.0 mm, more preferably less than about 0.75 mm, so as to allow a higher density of perforations to be created without weakening the bone plate. While conventional awls typically produce perforations at least 1-2 mm in diameter with non-uniform dimensions and spacing, fluid jets are uniquely suited to creating uniform perforations of very low diameter consistently and accurately. Perforations 905 will usually have a depth of about 2 mm to about 10 mm, more preferably about 2 mm to about 6 mm. As shown in Fig. 14Dl, the distal probe 120 may comprise more than one distal fluid jet nozzles 123 and multiple jets of high pressure fluid 1201 can be delivered toward the exposed subchondral bony surface of the chondral lesion CL at one time to simultaneously create multiple perforations 905.

[0212] In some embodiments, for example, as shown in Fig. 14E, excess fluid and debris may be aspirated during or after a perforation 905 has been made. For example, as shown in Fig. 14E, the distal probe may comprise an aspiration lumen 223 as described above. Excess fluid and debris may be aspirated into the concentric lumen 223 as shown by arrows 235. Alternatively or in combination, the separate aspirator 1222 (Fig. 14A) may be used to aspirate excess fluid and debris.

[0213] Fig. 14F shows the distal probe 120 being horizontally repositioned at a desired spacing from the first perforation 905a and so that the distal fluid jet nozzle 123 is orthogonal to the exposed subchondral bony surface of the chondral lesion CL. An indexing feature as described above may be used to facilitate the repositioning of the distal probe 120 at the desired spacing. Preferably, perforations are spaced about 0.5 mm to about 6 mm apart, more preferably about 0.5 mm to about 2 mm apart, although the spacing will depend on various factors, including the diameter of the perforations and the strength of the subchondral bone SB. With conventional awls, due to the larger hole diameter and inability to accurately control spacing, perforations are typically placed 3-4 mm apart. However, using the fluid jets of the present invention, perforations may be made in substantially higher densities, with spacing as low as 0.5 mm. This closer spacing of perforations helps to ensure that marrow

components and blood are conveyed throughout the defect so that the resulting superclot extends over the entire defect without voids or openings.

[0214] Fig. 14G shows the distal fluid jet nozzle 123 of the distal probe 120 delivering a jet of high pressure fluid 1201 toward the exposed subchondral bony surface of the chondral lesion CL. The delivered jet of high pressure fluid 1201 creates a second perforation or channel 905b on the chondral lesion CL that extends through the subchondral bone plate SB. The created perforation 905b will typically and preferably be generally orthogonal to the surface of the chondral lesion CL.

[0215] As shown in Fig. 14H, the above steps can be repeated to create a plurality of perforations 905 on the chondral lesion CL. Adjacent perforations 905 are usually spaced about 1 mm to about 6 mm apart from each other, more preferably about 1.5 mm to about 4 mm apart from each other. The perforations are preferably substantially parallel to one another.

[0216] As shown in Fig. 141, blood, fat droplets, and marrow elements, which include mesenchymal stem cells, growth factors, and other healing factors and proteins, release into the defect through the perforations 905 to form a "super clot" SC. The "super clot" SC provides an enriched environment for the formation of new tissue. The chondral lesion CL, which has been previously cleaned and debrided, provides clean and orderly location with defined borders for the "super clot" SC to form. In some embodiments, suction may be applied to one or more perforations 905 to assist and accelerate the flow of elements needed to form a "super-clot" from the marrow cavity MC into the chondral lesion CL. For example, the aspirator 1222, a suction cup, or an aspiration port on the distal probe 120 may be placed over a perforation 905 to apply suction thereto. Additionally or alternatively, a needle may be inserted through the subchondral bone SB into the marrow cavity MC and a fluid injected under pressure to force marrow components to flow through the perforations 905 into the chondral defect.

[0217] Figs. 14 to 141 show a method of creating multiple microfracture perforations in articular cartilage and subchondral bone either individually or simultaneously by delivering jets of high pressure fluid. Similar methods are contemplated for creating multiple microfracture perforations in articular cartilage and subchondral bone either individually or simultaneously by penetrating, drilling, and ablating articular cartilage and subchondral bone with different embodiments of the distal probe as described above.

[0218] Figs. 15 to 15E show a method of performing surgery on a chondral lesion CL with a distal probe 120 having deflectable distal fluid jet nozzles 123 according to embodiments of the invention.

[0219] As previously discussed, the chondral lesion CL in a joint space is typically first smoothed and debrided to expose the subchondral bony surface. The joint is typically first distracted and then the distal probe 120 is inserted into the joint space and then positioned adjacent to the exposed subchondral bony surface of the chondral lesion CL.

[0220] Fig. 15 shows a distal probe 120 having deflectable distal fluid jet nozzles 123 and comprising an expansible deflection member 500, for example, as in the embodiment of Figs. 5 to 5B. The methods of Figs. 15 to 15E can also be applicable for other embodiments of the distal probe 120 having deflectable distal fluid jet nozzles 123, for example, the embodiments of Figs. 6, 7 and 7A, deflectable fracture pins 323, deflectable drill bits 324, or extendible optic cables 363 which maybe deflected as described above.

[0221] As shown in Fig. 15, the distal fluid jet nozzles 123 of the distal probe 120 simultaneously deliver high pressure fluid jets 1201 toward the chondral lesion CL, simultaneously creating a first set of perforations 905.

[0222] As shown in Fig. 15A, after the first set of perforations 905 has been created, the expansible deflection member 500 is expanded to deflect the distal fluid jet nozzles 123. The distal fluid jet nozzles 123 then simultaneously deliver high pressure fluid jets 1201 toward the chondral lesion CL, simultaneously creating a second set of perforations 905. The distal probe 120 can be left in the same position, including the same horizontal and rotational position, when making the second set of perforations 905 as when making the first set of perforations 905.

[0223] As shown in Fig. 15B, after the second set of perforations 905 has been created, the expansible deflection member 500 is further expanded and/or retracted to further deflect the distal fluid jet nozzles 123. Alternatively or in combination, the expansible deflection member 500 can be expanded to further deflect the distal fluid jet nozzles 123. The distal fluid jet nozzles 123 then simultaneously deliver high pressure fluid jets 1201 toward the chondral lesion CL, simultaneously creating a third set of perforations 905. The distal probe 120 can be left in the same position, including the same rotational position, when making the third set of perforations 905 as when making the first and second set of perforations 905.

[0224] Alternatively or in combination, the distal probe 120 may be rotated between making different sets of perforations 905. For example, the distal probe 120 may be rotated by about 22.5 degrees to about 45 degrees between making successive sets of perforations 905 depending on the desired density of the perforations. As shown in Figs. 15Al and 15Bl, the distal probe 120 may be rotated as shown by arrow 1313 after making the first set of perforations 905 and rotated again after making the second set of perforations 905. Rotating the distal probe 120 between making different sets of perforations can more evenly distribute the perforations 905 if such an even distribution is so desired.

[0225] In some embodiments, the distal probe 120 may be rotated between making every other successive set of perforations 905. For example, a first set of perforations 905 can be made as in Fig. 15A. Then, the expansible deflection member 500 can be expanded and a second set of perforations 905 can be made as in Fig. 15B. Next, the distal probe 120 can be rotated, for example, by 45 degrees, and a third set of perforations 905 can be made. These steps can result in the perforation pattern as shown in Fig. 15C. Next, the expansible deflection member 500 can be expanded and/or retracted to further deflect the distal fluid nozzles 123 and a fourth set of perforations 905 can be made, which can result in the perforation pattern as shown in Fig. 15D. Afterward, the distal probe 120 can be rotated again and a fourth set of perforations 905 can be made, which can result in the pattern shown in Fig. 15E. In further embodiments, both the horizontal and rotational position of the distal probe may be changed between making successive sets of perforations 905.

[0226] Figs. 15 to 15E show a method of creating multiple microfracture perforations in articular cartilage and subchondral bone simultaneously by delivering jets of high pressure fluid. Similar methods are contemplated for creating multiple microfracture perforations in articular cartilage and subchondral bone simultaneously by penetrating, drilling, and ablating articular cartilage and subchondral bone with different embodiments of the distal probe as described above.

[0227] Embodiments of the invention may be used to perform microfracture surgery on various joints, including the hip, the shoulder, the knee, the elbow, the ankle, and the wrist to name a few. Figs. 16 to 16D show an exemplary method of performing microfracture surgery on the hip joint according to embodiments of the invention. Microfracture surgery may also be performed on the hip joint with other methods as described herein.

[0228] Fig. 16 illustrates the basic anatomy of a hip joint. The hip joint is formed between the head of the femur FH and the acetabulum A, a concave surface of the pelvis. The

acetabulum A is lined with a layer of articular cartilage CA. A blanket of ligaments cover the joint forming a capsule C. Additionally the acetabular labrum L, a fibrocartilaginous lip, surrounds the head of the femur FH, deepens the joint pocket and increases the surface area of contact. The ligamentum teres LT is a ligament attached to a depression in the acetabulum (the acetabular notch or fossa) and a depression on the femoral head (the fovea of the head).

[0229] As shown in Fig. 16A, after distraction of the hip joint, for example, by using methods known in the art, a distal probe 120, according to any of the embodiments described herein, can be arthroscopically inserted into the space between the femoral head FH and the acetabulum A. The distal probe 120 is positioned so that its distal end 121 is adjacent the chondral lesion CL. In many embodiments, a debriding instrument 1211 as previously described and an aspirator 1222 as previously described may be inserted into the space between the femoral head FH to debride, clean, and aspirate the chondral lesion CL.

[0230] As shown in Fig. 16B, the distal probe 120 can deliver a jet of high pressure fluid 1201 to create perforations 905 in the chondral lesion extending through the subchondral bone to the underlying marrow cavity MC. As described above, embodiments of the distal probe 120 may be selected so that perforations 905 are created one at a time or so that multiple perforations 905 are created simultaneously. As described above, the distal probe 120 may be repositioned after a set of perforations 905 have been made. After a number of perforations 905 is made, the distal probe 120 is removed and blood, fat droplets, and marrow factors are allowed to leak out of the perforations 905 to form a "super clot" as described above.

[0231] In at least some instances, the space between the femoral head FH and the acetabulum A may be very limited and repositioning the distal probe 905 after a set of perforations 905 have been made may be difficult. To create perforations 905 at different locations, the direction of the distal fluid jet nozzle 123 can be adjusted as seen in Fig. 16C. In some embodiments, the distal portion of the distal probe can be adjusted or deflected with a pullwire as described above to redirect the distal fluid jet nozzle 123. In other embodiments, a pullwire may similarly be used to redirect a fracture pin 323, a drill bit 324, or an optical output 373. In some embodiments, the distal fluid jet nozzle 123 can be extendable and pre-shaped in a curve, articulable, or steerable as described above, and the distal fluid jet nozzle 123 can be rotated in a direction 1414 and/or translated to change the angle of the distal portion 120a of the distal probe 120 as described above. As illustrated in Fig. 16D, a spiral pattern of perforations 905 may be created. A first, central perforation 905a can be created. Then, the distal fluid jet nozzle 123 can be deflected radially outward

and a second perforation 905b can be created. Next, the distal fluid jet nozzle 123 can be deflected further, the distal fluid jet nozzle 123 can be rotated, and a third perforation 905c can be created. Afterward, the distal fluid jet nozzle 123 can be deflected even further, the distal fluid jet nozzle 123 can be further rotated, and a fourth perforation 905d can be created. The steps can be repeated to create a fifth perforation 905e, a sixth perforation 905f, and so forth to create a spiral pattern of perforations that fills the chondral lesion.

[0232] Figs. 16 to 16D show a method of creating multiple microfracture perforations in articular cartilage and subchondral bone in a hip joint either individually or simultaneously by delivering jets of high pressure fluid. Similar methods are contemplated for creating multiple microfracture perforations in articular cartilage and subchondral bone in a hip joint either individually or simultaneously by penetrating, drilling, and ablating articular cartilage and subchondral bone with different embodiments of the distal probe as described above.

[0233] While Figs. 16 to 16C depict microfracture surgery on the acetabular surface, the procedure may also be performed on the articular cartilage surface of the femoral head, as well on articular defects in the knee, shoulder, ankle, and other joints.

[0234] While the methods and devices described above have involved the treatment of full thickness cartilage defects, the methods and devices are also applicable for treatment of partial thickness chondral defects where some cartilage is retained within the chondral defect and the perforations are created through the remaining cartilage and the subchondral boney plate.

[0235] In addition, the methods and devices may also be used for treatment of osteochondritis dissecans (OCD). OCD is a disease where blood supply to the subchondral bone is diminished or lost. The affected bone and its chondral surface may stay in place or a fragment may gradually loosen, separate and cause pain. For intact lesions, antegrade drilling through the chondral surface may be considered to stimulate healing of the subchondral bone. The methods and devices described above may be used to create perforations in the subchondral bone through the overlying cartilage layer to elicit a tissue repair response in the subchondral bone.

[0236] It should be appreciated that the exemplary steps illustrated in Figs. 14 to 141, Figs. 15 to 15E, and Figs. 16 to 16D provide exemplary methods of performing surgery on articular cartilage according to embodiments of the invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different

order. Moreover, the individual steps illustrated in Figs. 14 to 141, Figs. 15 to 15E, and Figs. 16 to 16D may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0237] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. The various features of the embodiments disclosed herein may be combined or substituted with one another. Therefore, the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

L A device for performing surgery on an articular surface, the articular surface being disposed over a subchondral bone layer and a marrow cavity, the device comprising:

an elongated body having a longitudinal axis;

a distal probe coupled to the elongated body and adapted to be inserted into a joint space;

a first perforating element coupled to the distal probe for creating a first channel through the subchondral bone into the marrow cavity; and

a second perforating element coupled to the distal probe for creating a second channel through the subchondral bone into the marrow cavity, said second perforating element being separated from the first perforating element by a predetermined distance,

wherein the first perforating element and the second perforating element are adapted to create the first channel and the second channel simultaneously.

2. The device of claim 1, wherein the first perforating element and the second perforating element are adapted to create the first and second channels at an angle transverse to the longitudinal axis of the elongated body.

3. The device of claim 1, further comprising a deflection member disposed between the first perforating element and the second perforating element, said deflection member being adapted to change the spacing between the first perforating element and the second perforating element.

4. The device of claim 3, further comprising an actuation member slidably disposed within the elongated body and the distal probe, said actuating member adapted to move the deflection member when axially translated.

5. The device of claim 3, wherein the deflection member comprises an expandable member.

6. The device of claim 5, wherein the expandable member comprises a balloon.

7. The device of claim 1, wherein at least one of the first perforating element or the second perforating element comprises a high pressure fluid jet nozzle configured to deliver a high pressure fluid jet to the articular surface.

8. The device of claim 1, wherein at least one of the first perforating element or the second perforating element comprises a pin adapted to be driven into the articular surface.

9. The device of claim 8, wherein the pin comprises an electromagnetically actuated pin.

10. The device of claim 8, wherein the pin comprises a pneumatically actuated pin.

11. The device of claim 8, wherein the pin comprises a hydraulically actuated pin.

12. The device of claim 8, wherein the pin comprises a mechanically actuated pin.

13. The device of claim 12, wherein the first perforating element comprises a first pin and the second perforating element comprises a second pin, and further comprising a first drive shaft disposed in the distal probe and coupled to the first pin for driving the first pin and a second drive shaft disposed in the distal probe and coupled to the second pin for driving the second pin.

14. The device of claim 13, further comprising a first hammer coupling the first drive shaft to the first pin and a second hammer coupling the first drive shaft to the second pin, wherein the first hammer converts an axial movement of the first drive shaft into a transverse movement of the first pin to drive the first pin and the second hammer converts an axial movement of the second drive shaft into a transverse movement of the second pin to drive the second pin.

15. The device of claim 1, wherein at least one of the first perforating element or the second perforating element comprises an optical element adapted to deliver an ablative laser beam to the articular surface.

16. The device of claim 15, wherein the optical element comprises a focusing lens for focusing the ablative laser beam.

17. The device of claim 1, wherein at least one of the first perforating element or the second perforating element comprises a drill bit adapted to drill through into

the subchondral bone layer with the temperature of the subchondral bone layer remaining below that at which thermal necrosis occurs.

18. The device of claim 1, wherein the elongated body further comprises an irrigation lumen having and outlet in the distal probe and adapted to deliver a fluid to the articular surface while the first and second channels are created.

19. The device of claim 18, further comprising a cooler fluidly coupled to the irrigation lumen for cooling the fluid delivered thereto.

20. The device of claim 1, wherein the distal end further comprises at least one indexing member for facilitating the positioning of the distal tip, the at least one indexing member being spaced away from the at least one perforating element by the predetermined distance.

21. The device of claim 1, further comprising an aspiration element coupled to the distal tip.

22. The device of claim 21, wherein the aspiration element comprises a conical suction member.

23. The device of claim 21, further comprising an aspiration lumen extending through the elongated body and the distal probe, the aspiration lumen being in communication with an aspiration port at the distal end.

24. The device of claim 1, wherein the elongated body comprises a switch for simultaneously activating the first perforating element and the second perforating element to create the first channel and the second channel.

25. A device for performing surgery on an articular surface disposed over subchondral bone and marrow cavity, the device comprising:

an elongated body having a longitudinal axis;

a distal probe coupled to the elongated body and adapted to be inserted into a joint space;

at least one perforating element coupled to the distal probe and adapted to create at least one channel at a first location on the articular surface, wherein the at least one channel extends through the subchondral bone to the marrow cavity; and

at least one indexing member coupled to the distal probe for facilitating the positioning of the distal probe at a second location on the articular surface adjacent the first location, the at least one indexing member defining a discrete reference point spaced away from the at least one perforating element by a predetermined distance in a predetermined direction

26. The device of claim 25, wherein the indexing member is configured to be positioned in a pre-made channel created by the perforating member such that the perforating element creates the at least one channel the predetermined distance from the pre-made channel.

27. The device of claim 25, wherein the at least one indexing member comprises at least one wire extendable from and retractable into the distal probe.

28. The device of claim 27, wherein the wire has a first shape when retracted in the distal probe and the wire assumes a second shape when extended from the distal probe.

29. The device of claim 25, wherein the at least one indexing member comprises at least one light emitter for emitting a light beam into a previously created channel.

30. The device of claim 29, wherein the light beam comprises a laser.

31. The device of claim 29, wherein the at least one light emitter comprises at least one light emitting diode disposed on the distal tip.

32. The device of claim 29, wherein the at least one light emitter comprises at least one optical cable having an output end disposed on an end of the distal probe.

33. The device of claim 29, wherein the light emitter is steerable.

34. The device of claim 25, wherein the at least one perforating element comprises a plurality of perforating elements, wherein the at least one channel comprises a plurality of channels, and wherein the plurality of perforating elements are adapted to simultaneously create each channel of the plurality of channels.

35. The device of claim 25, wherein the at least one perforating element comprises a high pressure fluid jet nozzle configured to deliver a high pressure fluid jet to the articular surface.

36. A device for performing a microfracture procedure on an articular surface in a joint space, the device comprising:

an elongated body having a longitudinal axis; and

a distal probe coupled to the elongated body and adapted to be inserted into the joint space, the distal probe comprising at least one distal fluid jet nozzle adapted to deliver at least one fluid jet at a sufficient pressure to perforate cartilage and bone to create a channel extending through subchondral bone.

37. The device of claim 36, further comprising an aspiration tube, and wherein the distal probe further comprises an aspiration port coupled to the aspiration tube for aspirating fluid from the joint space.

38. The device of claim 37, wherein the aspiration port is concentric with the distal fluid jet.

39. The device of claim 37, wherein the aspiration port is axially movable relative to the distal fluid jet nozzle.

40. The device of claim 37, further comprising an aspiration reservoir coupled to the aspiration tube for collecting the aspirated fluid.

41. The device of claim 36, wherein the angle of the fluid jet nozzle relative to the longitudinal axis of the elongated body is changeable after insertion in the joint space.

42. The device of claim 36, further comprising a steering mechanism adapted to change an angle between the distal probe and the elongated body.

43. The device of claim 42, wherein the steering mechanism comprises a pullwire slideably disposed within the elongated body and coupled to the distal probe, wherein axially translating the pullwire articulates the distal probe.

44. The device of claim 36, wherein the at least one distal fluid jet nozzle is oriented transverse to the longitudinal axis of the elongated body.

45. The device of claim 36, wherein the at least one distal fluid jet nozzle comprises a plurality of distal fluid jet nozzles, adjacent nozzles each being spaced apart from each other by a predetermined distance.

46. The device of claim 45, further comprising a first valve controlling fluid flow to the first of the fluid jet nozzles and a second valve controlling fluid flow to a second of the fluid jet nozzles, the first valve being controllable independently of the second valve.

47. The device of claim 45, further comprising a deflection member adapted to selectively change a distance between adjacent distal fluid jet nozzles.

48. The device of claim 47, further comprising an actuation member slidably disposed within the elongated body, said actuating member adapted to axially translate the deflection member when actuated.

49. The device of claim 47, wherein the deflection member comprises an expandable member.

50. The device of claim 49, wherein the expandable member comprises a balloon.

51. The device of claim 47, wherein the deflection member comprises a plate having a plurality of apertures through which the plurality of distal fluid jet nozzles extend.

52. The device of claim 47, wherein the deflection member comprises an axially translatable member disposed between adjacent distal fluid jets.

53. The device of claim 36, further comprising at least one fluid delivery tube axially translatable relative to the distal probe and coupled to the at least one distal fluid jet, wherein moving the at least one fluid delivery tube relative to the distal probe extends the at least one distal fluid jet nozzle from the distal probe.

54. The device of claim 36, further comprising:

a fluid source; and

a fluid pump coupled to the fluid source and the at least one distal fluid jet nozzle, said fluid pump being adapted to provide a high pressure stream of fluid to the at least one distal fluid jet nozzle.

55. The device of claim 54, wherein the fluid pump is configured to deliver the high pressure stream of fluid at a pressure of at least about 3000 psi.

56. The device of claim 54, further comprising a valve adapted to selectively deliver the high pressure stream of fluid to the at least one distal fluid jet nozzle.

57. The device of claim 55, wherein the valve is adapted to deliver a short pulse of the high pressure stream of fluid.

58. The device of claim 57, wherein valve is configured to deliver a pulse of about 100 milliseconds to about 500 milliseconds in length.

59. The device of claim 54, wherein the fluid pump is disposed within the elongated body.

60. The device of claim 57, further comprising a second pump fluidly connected to the elongated body for delivering the fluid to the first pump.

61. The device of claim 54, wherein the fluid pump is configured to deliver a high pressure fluid pulse of fixed volume.

62. The device of claim 61, wherein the fluid pump comprises a chamber having the fixed volume, the chamber having an inlet valve and an exit valve.

63. The device of claim 62, further comprising means for pressurizing the fluid in the chamber.

64. The device of claim 62, further comprising a second pump for delivering fluid to the chamber.

65. The device of claim 36, wherein the distal probe further comprises an indexing member for facilitating a repositioning of the distal probe at a predetermined spacing from a previously created channel.

66. The device of claim 65, wherein the indexing member comprises a wire extendable distally from the distal probe and adapted to engage the previously created channel.

67. The device of claim 66, wherein the wire is retractable into the distal probe.

68. The device of claim 67, wherein the wire has a first shape when retracted in the distal probe and the wire assumes a second shape when extended from the distal probe.

69. The device of claim 65, wherein the indexing member comprises a light emitter for emitting a light beam into the previously created channel.

70. The device of claim 69, wherein the light emitter comprises an optical fiber.

71. The device of claim 69, wherein the light beam comprises a laser.

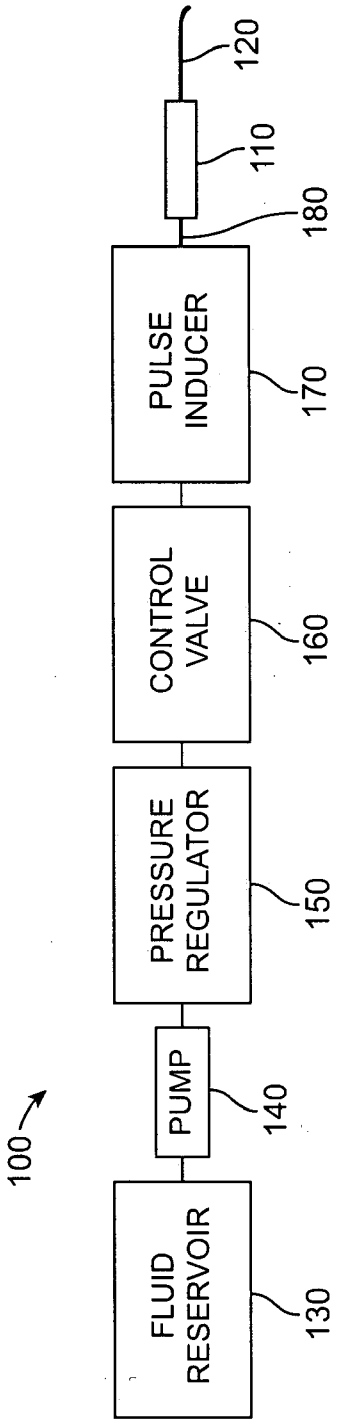


FIG. 1

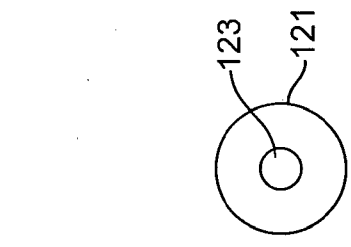


FIG. 1C

FIG. 1B

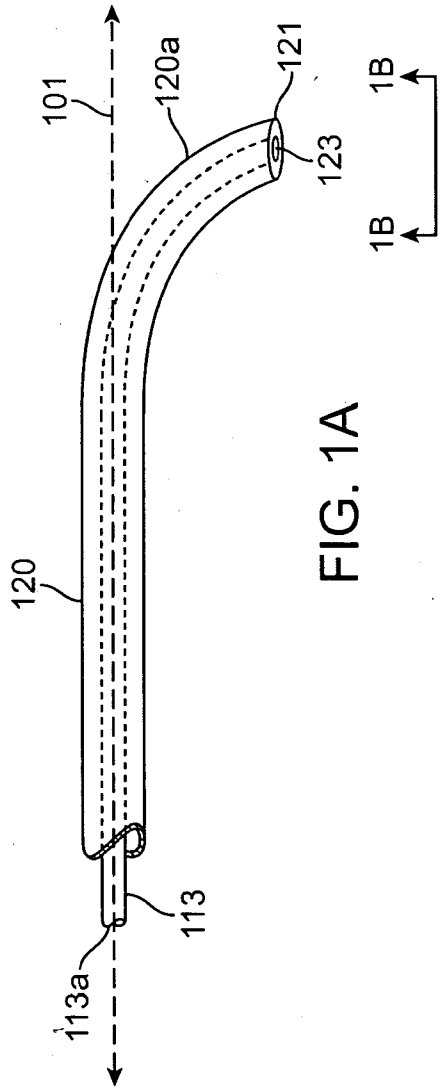


FIG. 1A

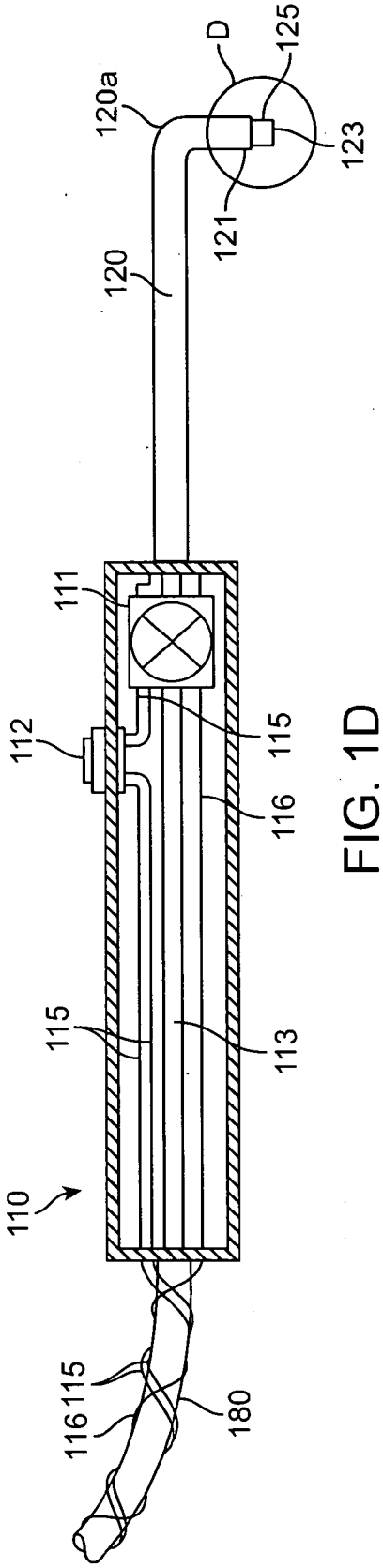


FIG. 1D

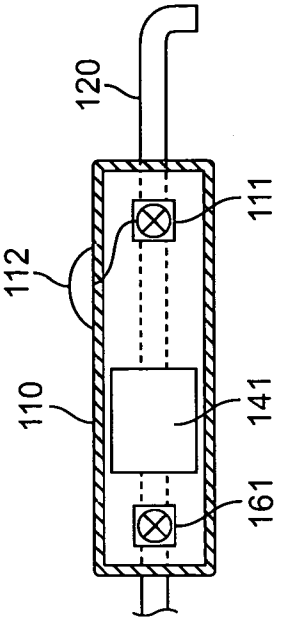


FIG. 1G

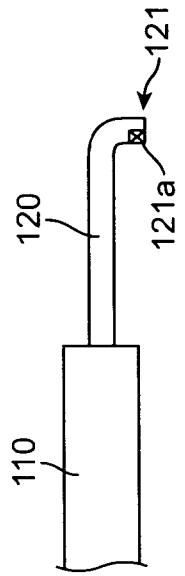


FIG. 1I

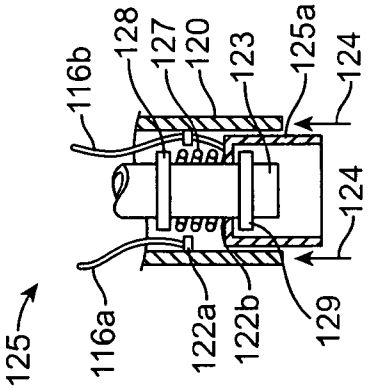


FIG. 1F

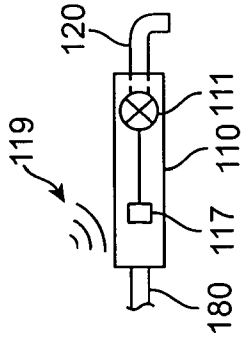


FIG. 1E

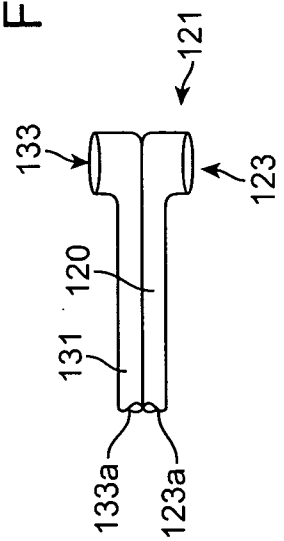


FIG. 1H

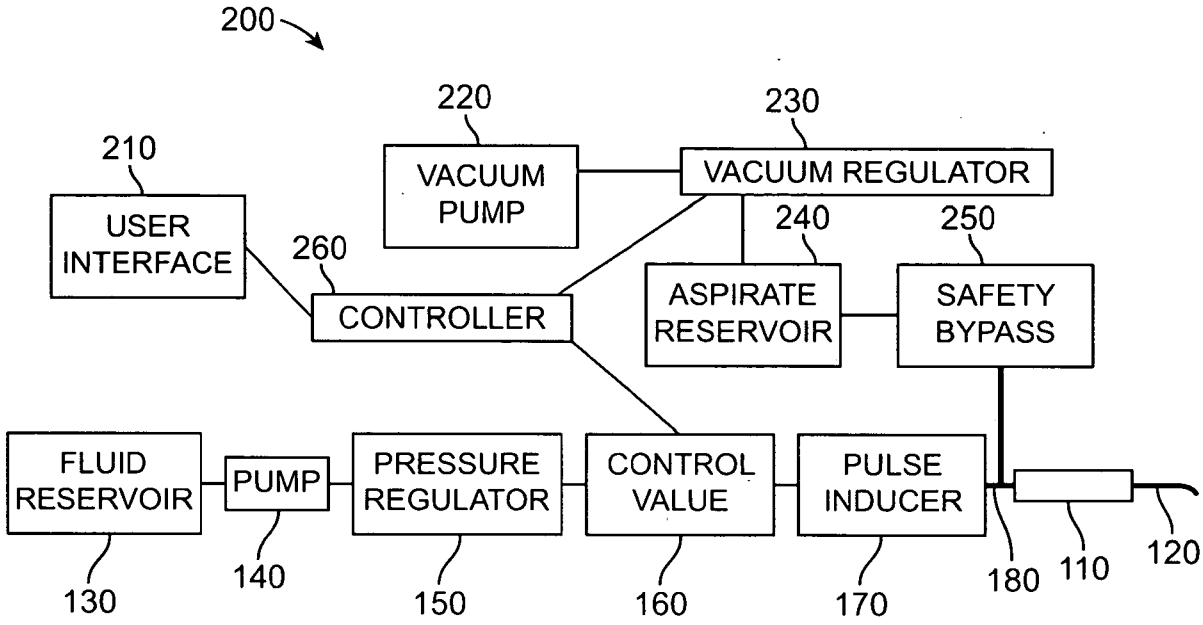


FIG. 2

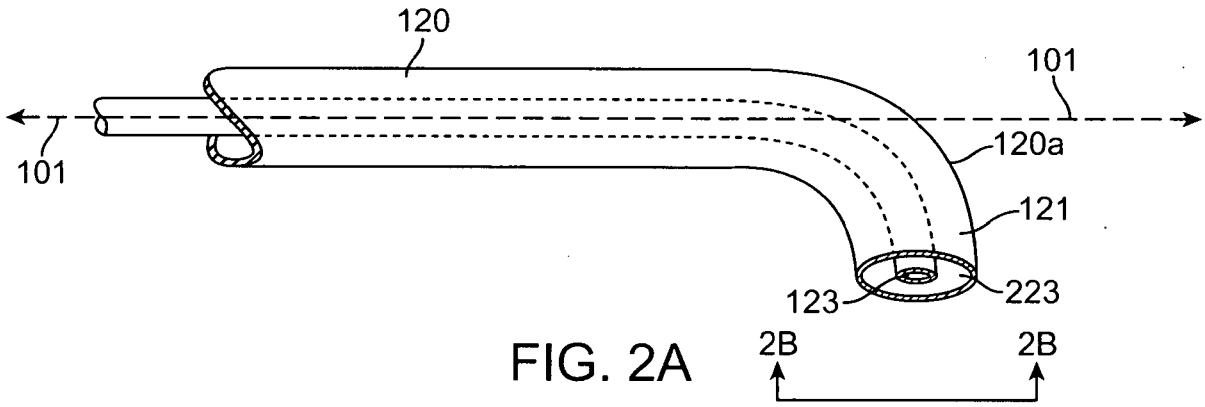


FIG. 2A

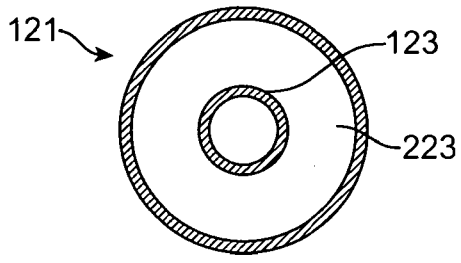


FIG. 2B

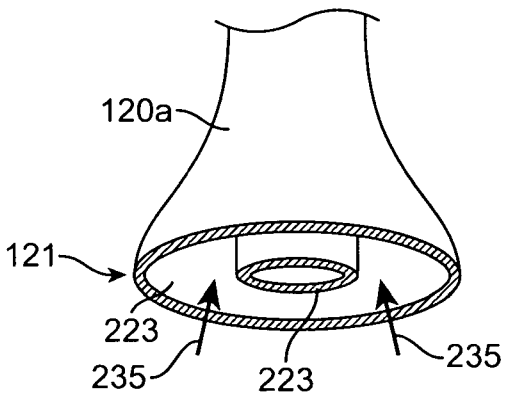


FIG. 2C

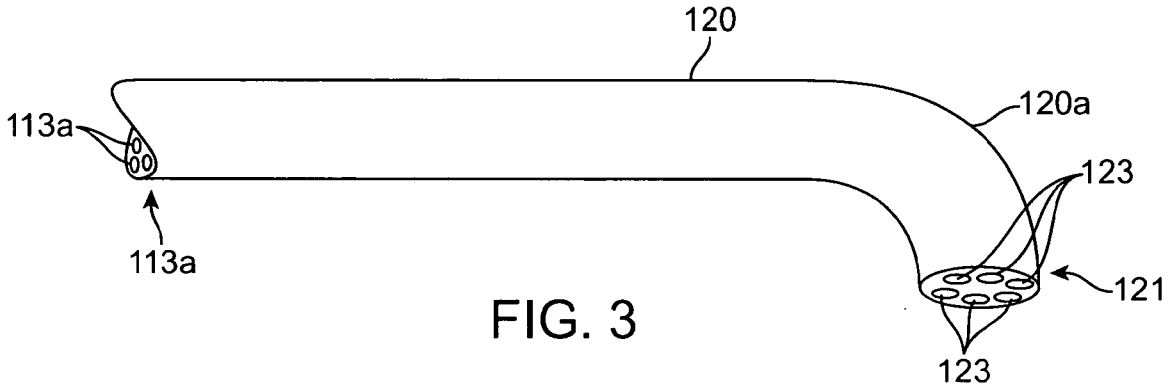


FIG. 3

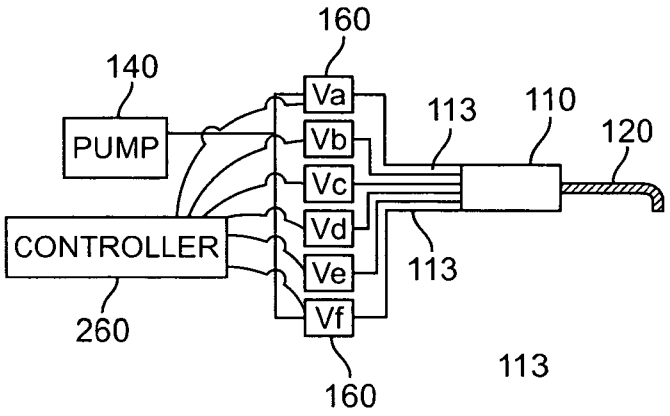


FIG. 3A

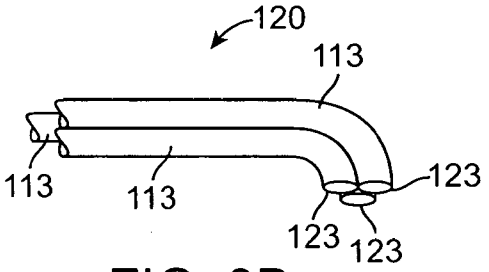


FIG. 3B

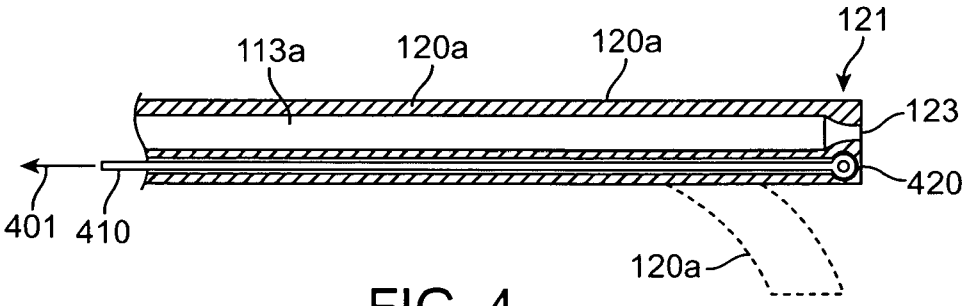


FIG. 4

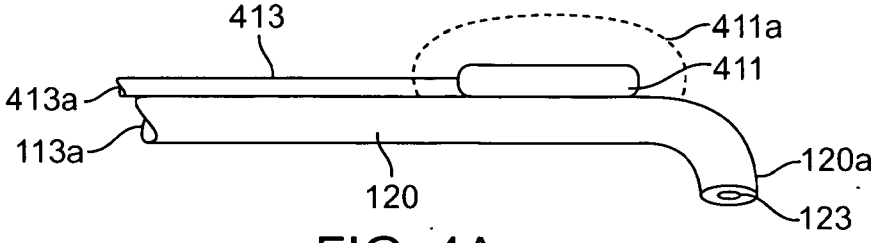


FIG. 4A

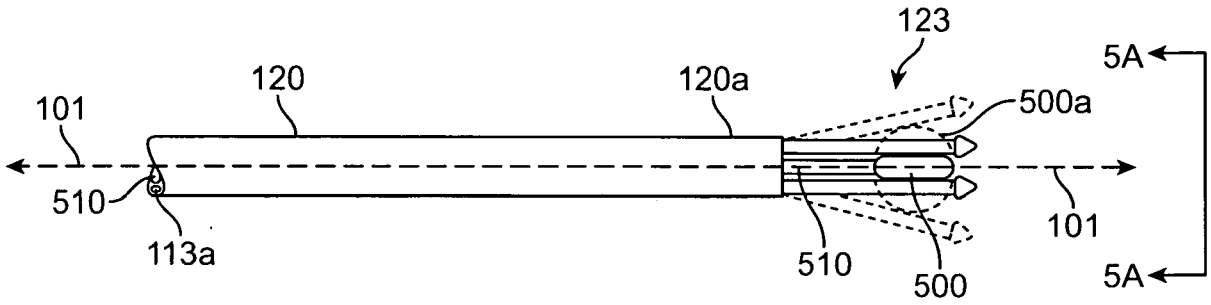


FIG. 5

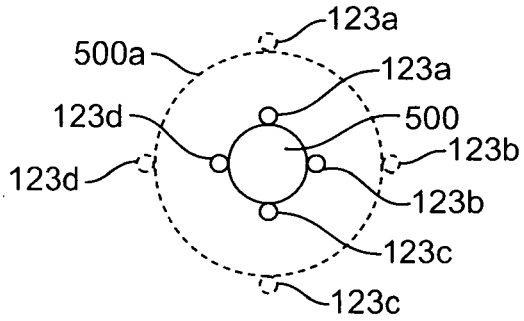


FIG. 5A

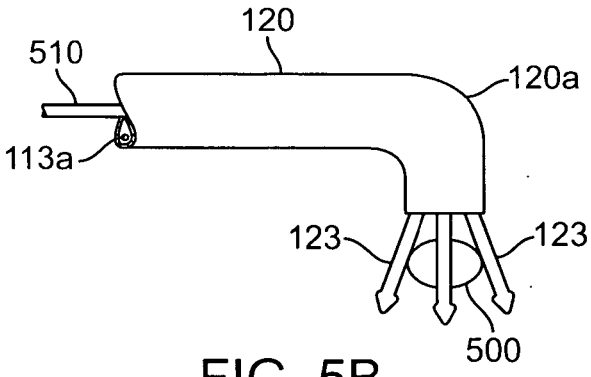
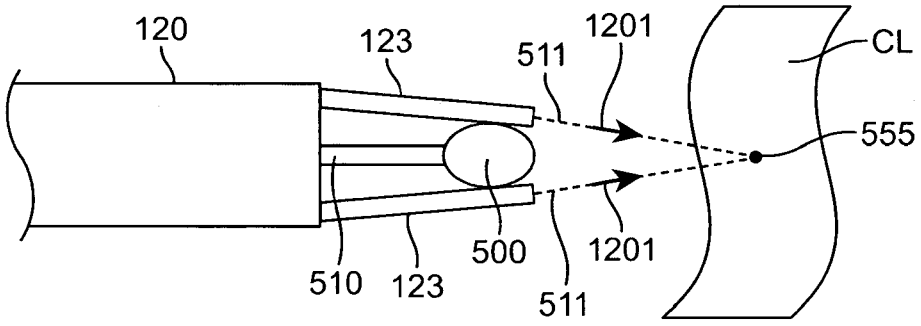


FIG. 5B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123
511
1201
CL
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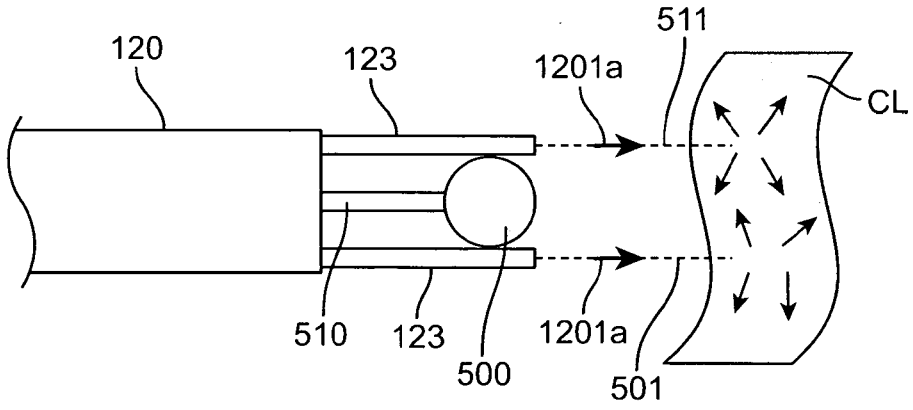
123
500
1201
511

FIG. 5C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123
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1201a
501

FIG. 5D

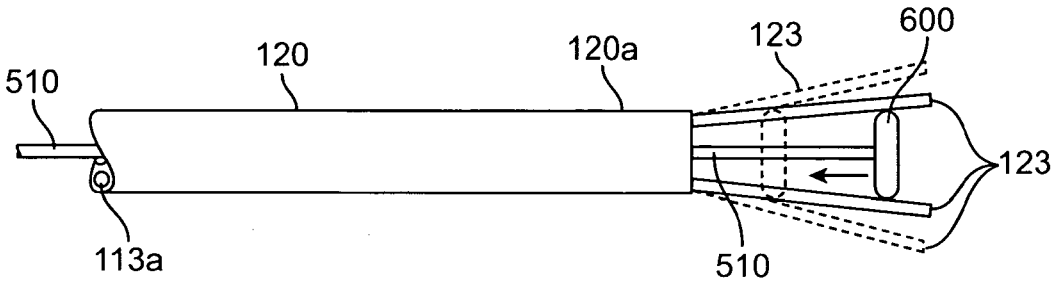

FIG. 6

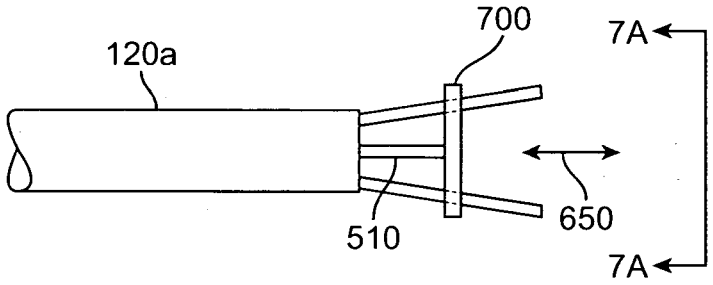

FIG. 7

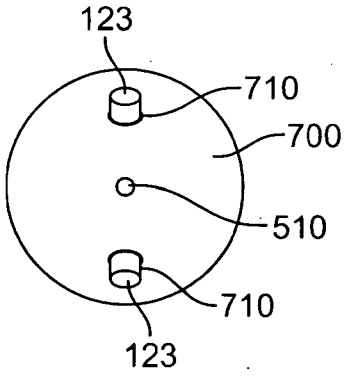

FIG. 7A

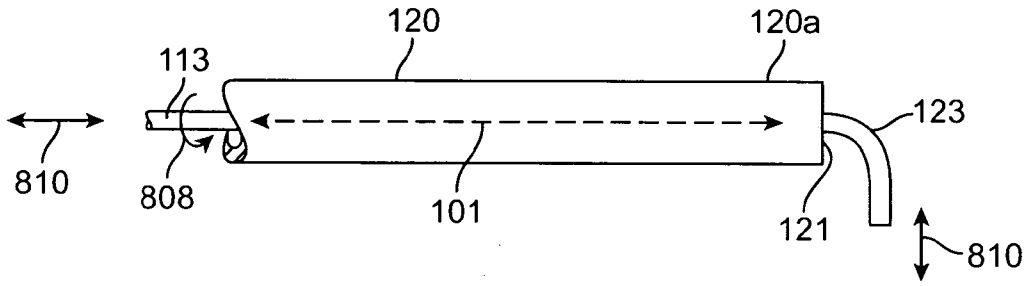
120
120a
113
123
810
808
101
121
810

FIG. 8

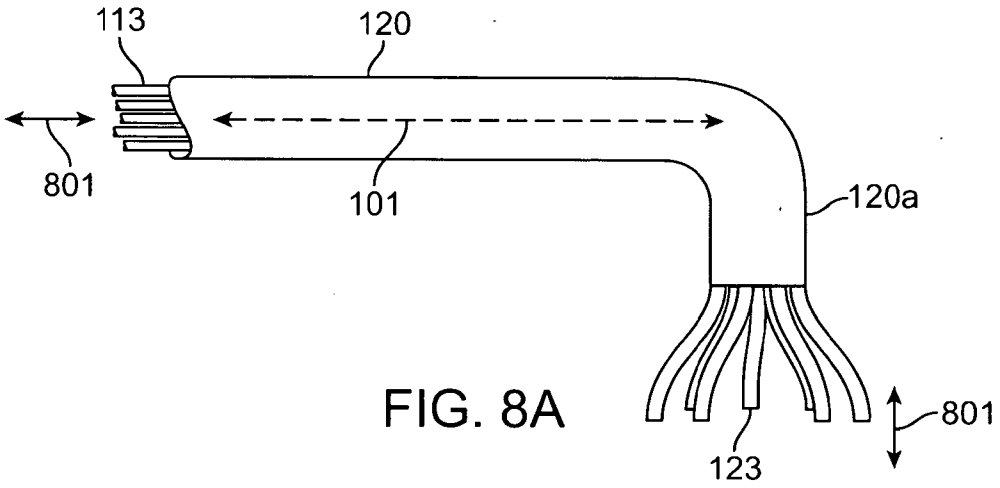
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FIG. 8A

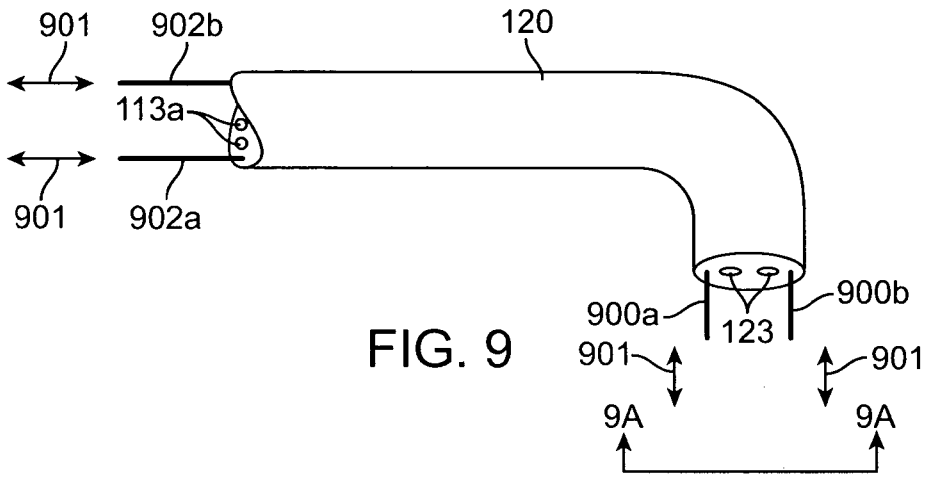

FIG. 9

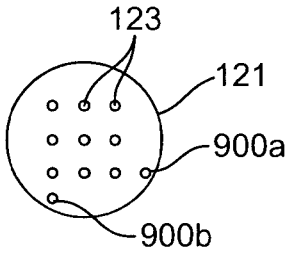

FIG. 9A

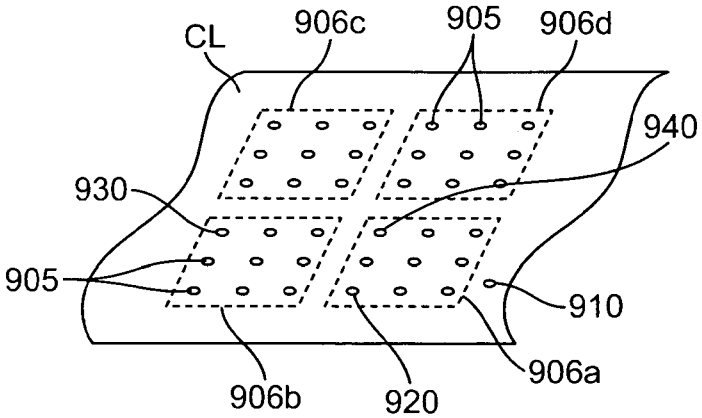

FIG. 9B

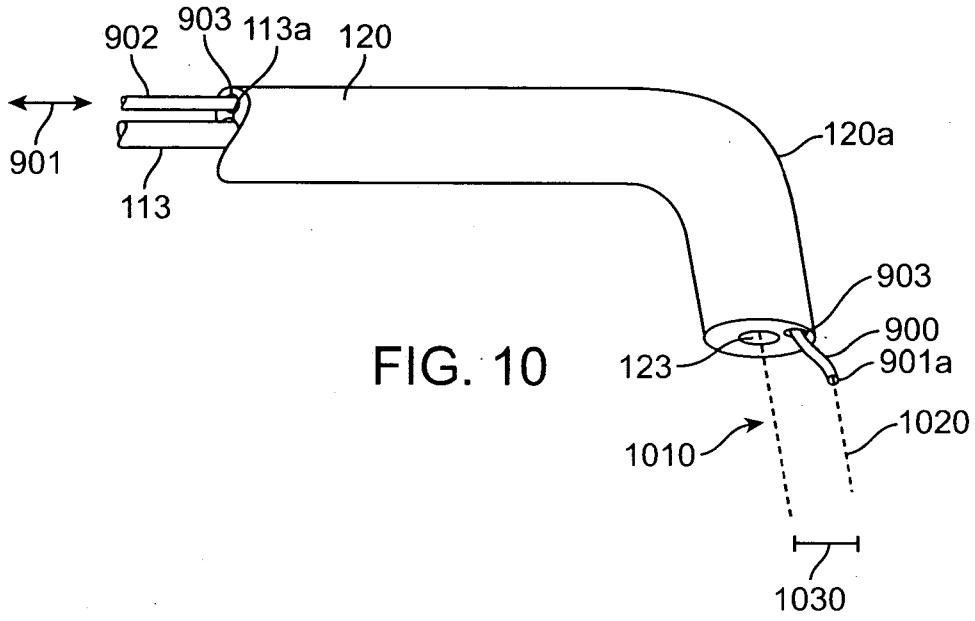

FIG. 10

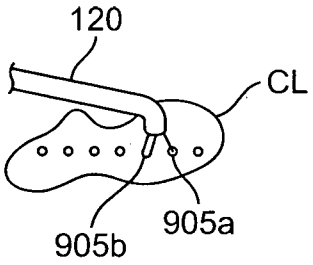

FIG. 10A

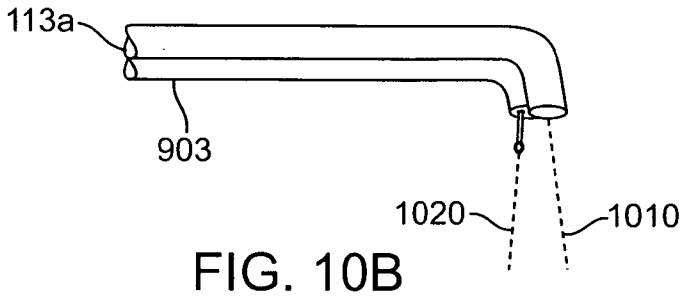

FIG. 10B

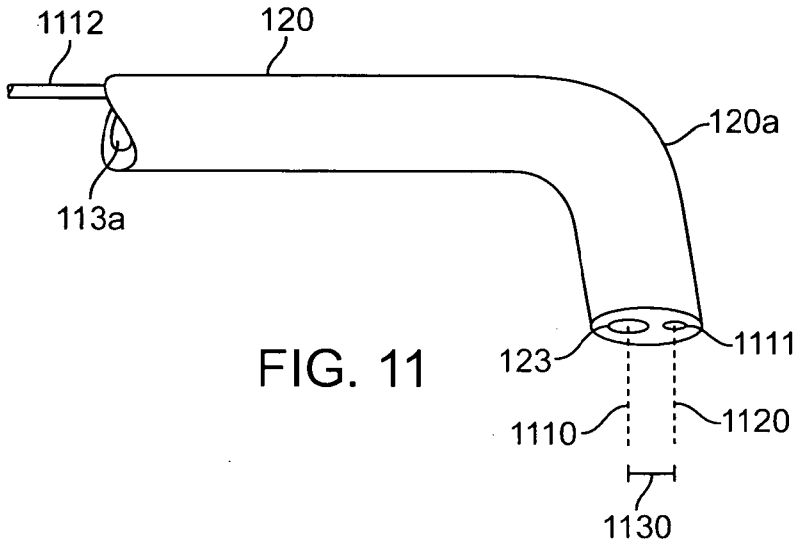

FIG. 11

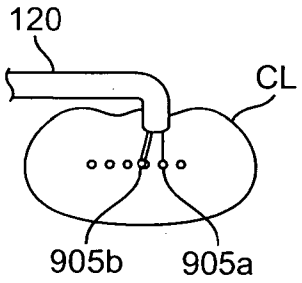

FIG. 11A

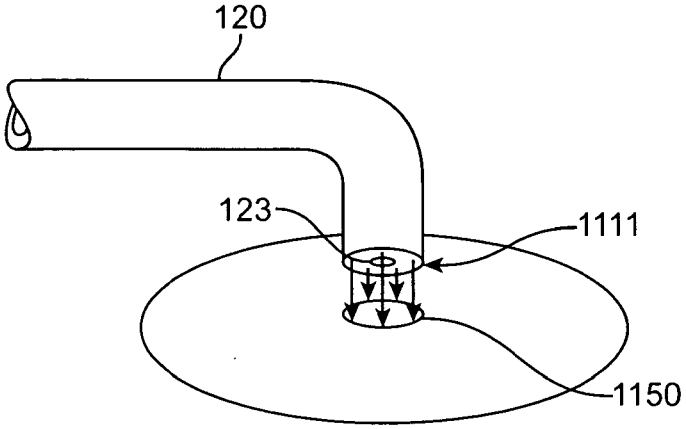

FIG. 11B

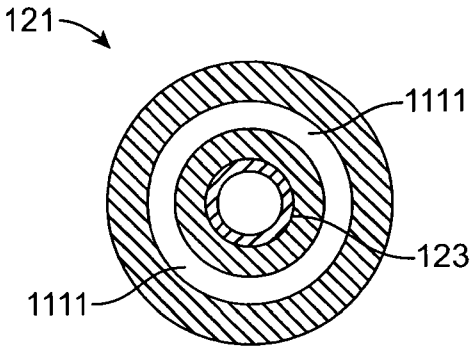

FIG. 11C

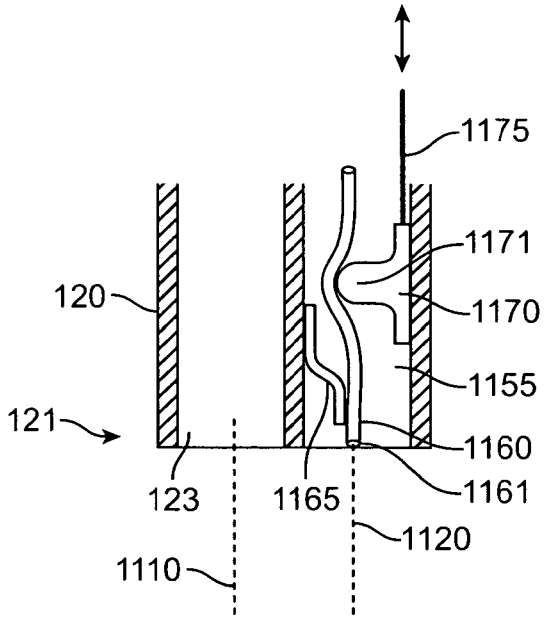

FIG. 11D

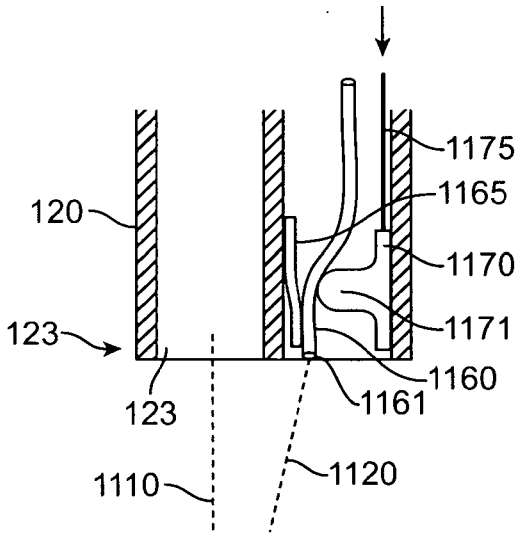

FIG. 11E

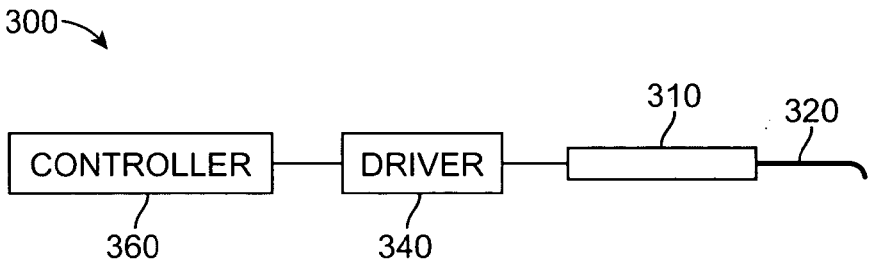

FIG. 12

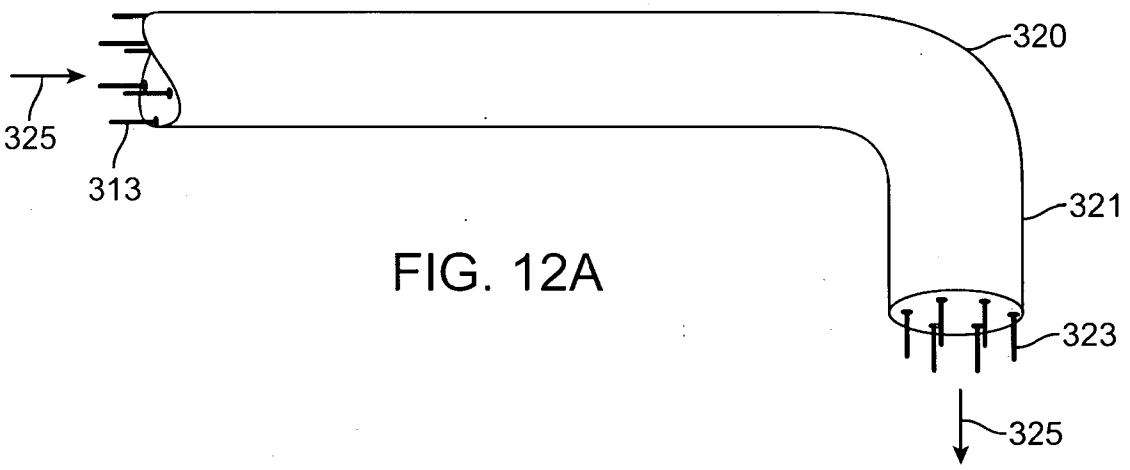

FIG. 12A

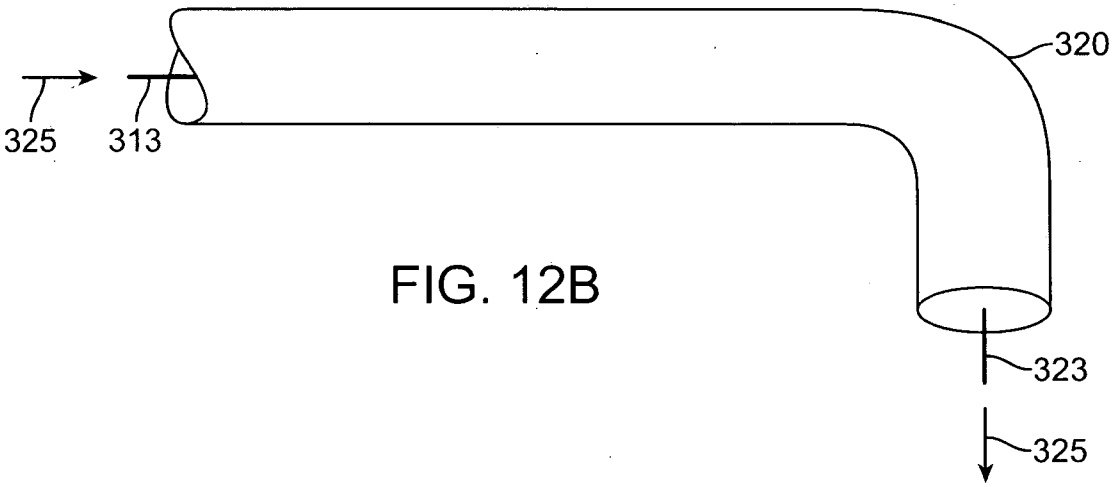

FIG. 12B

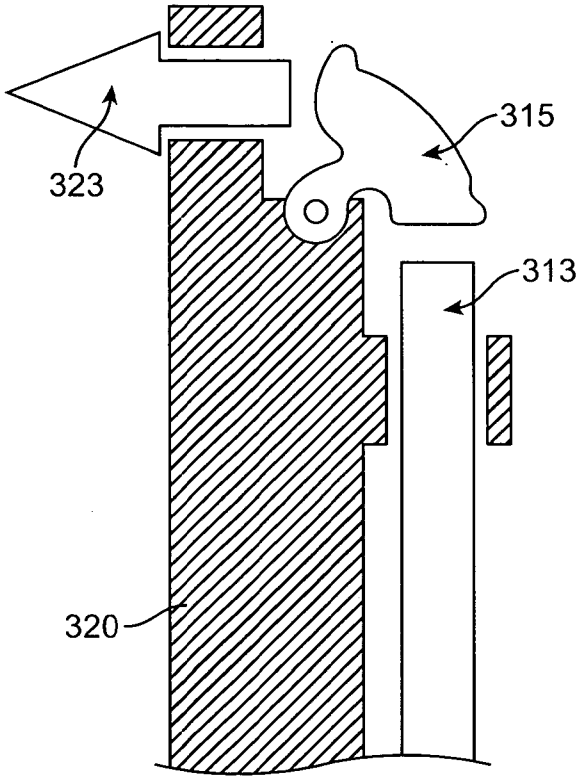

FIG. 12C

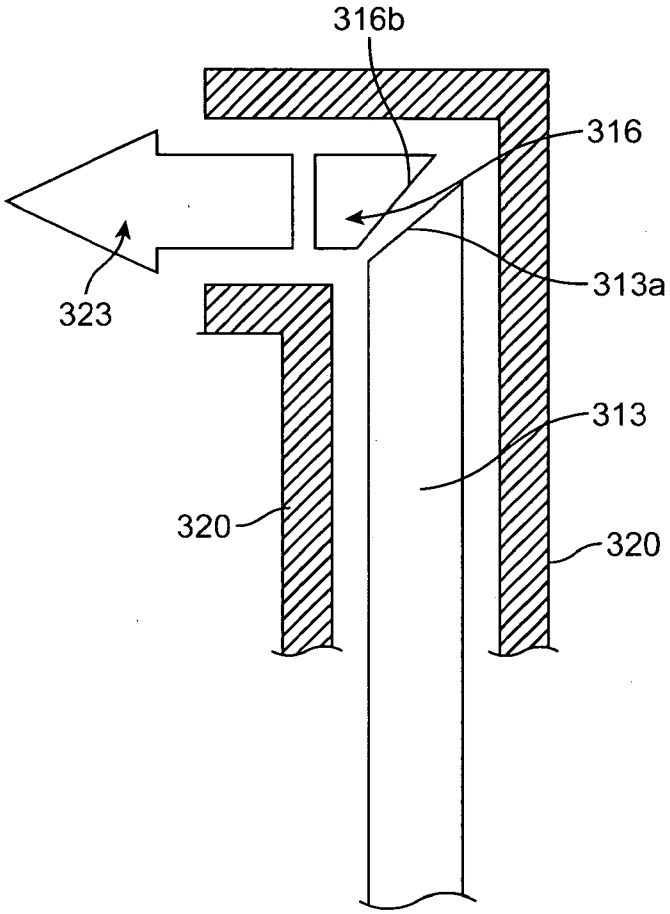

FIG. 12D

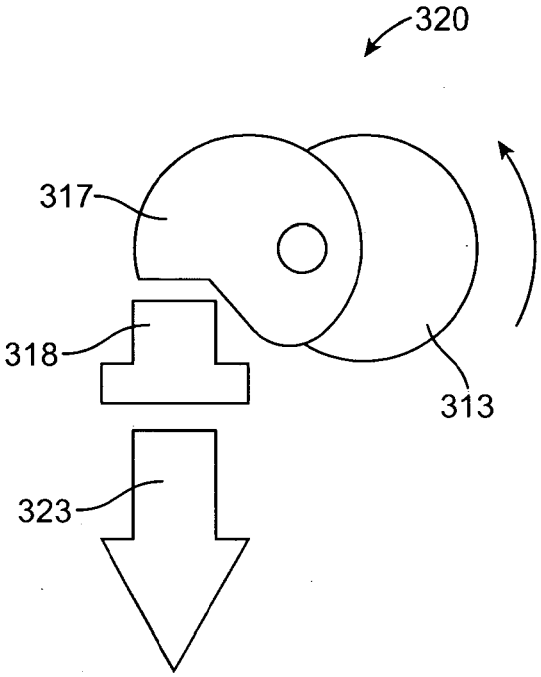

FIG. 12E

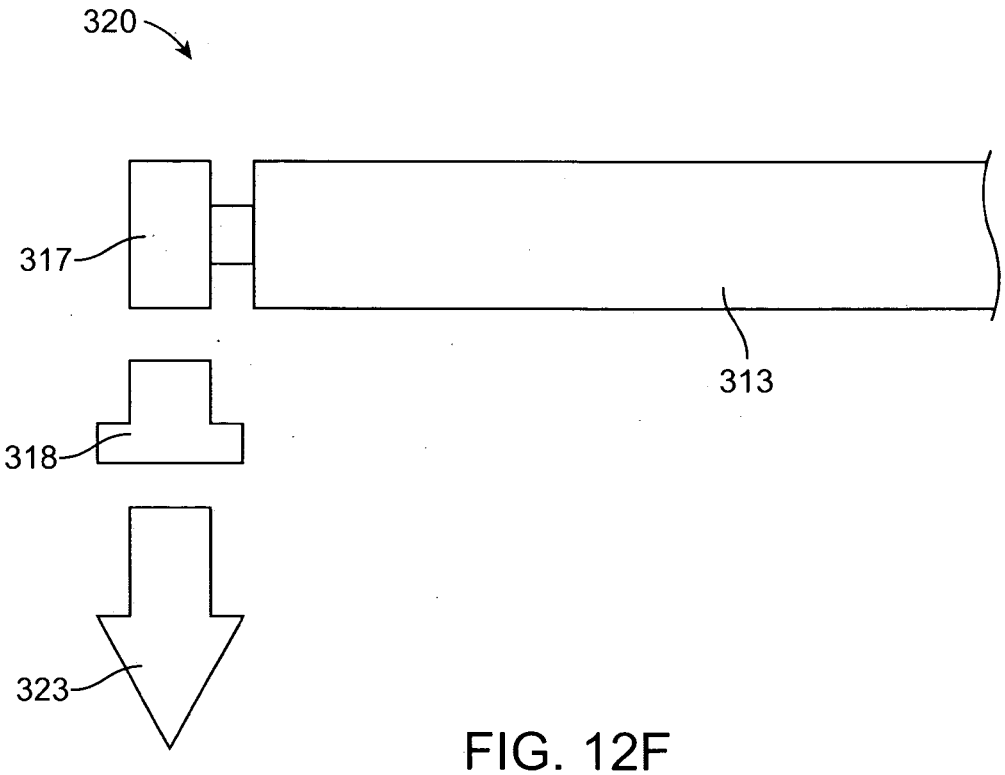

FIG. 12F

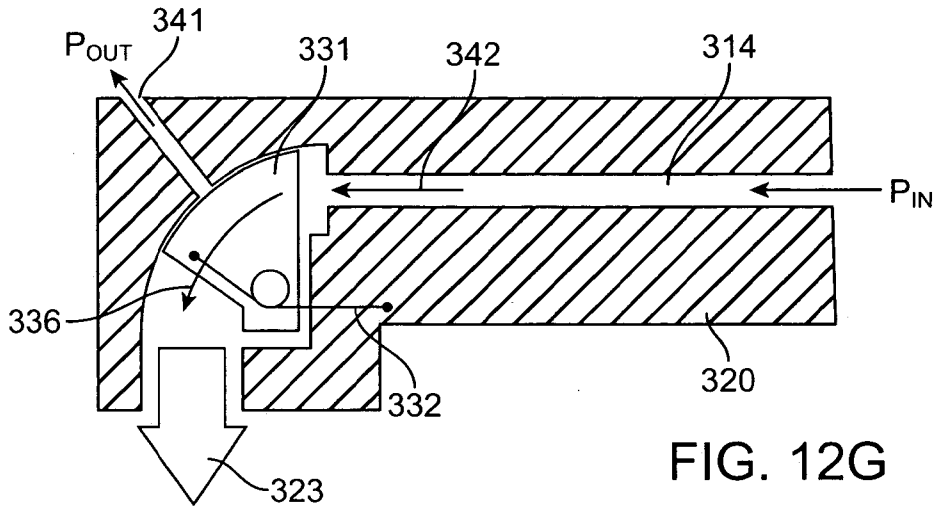

FIG. 12G

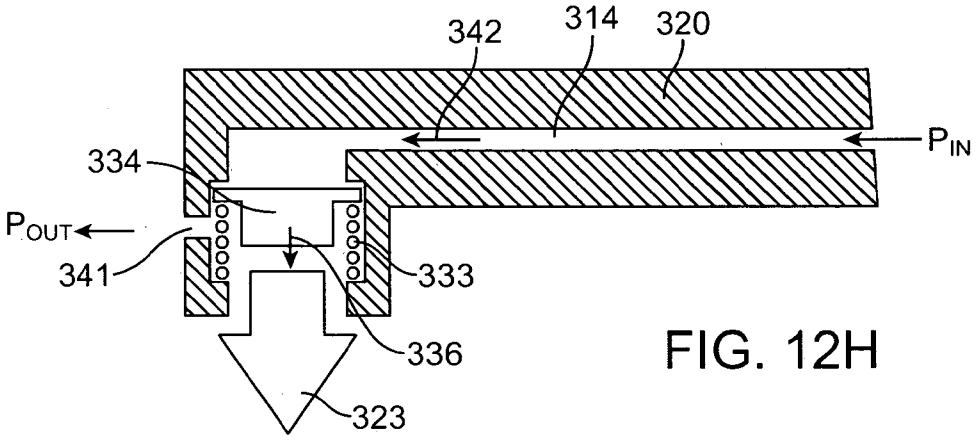

FIG. 12H

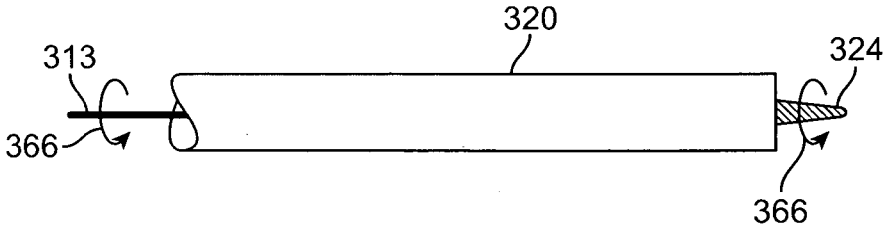

FIG. 12I

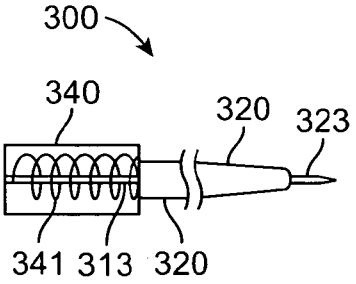

FIG. 12J

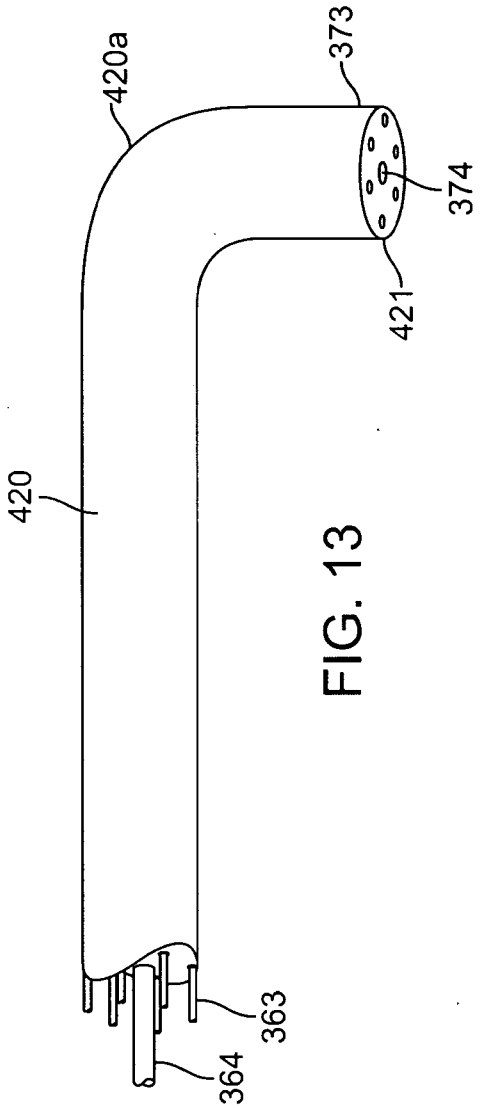

FIG. 13

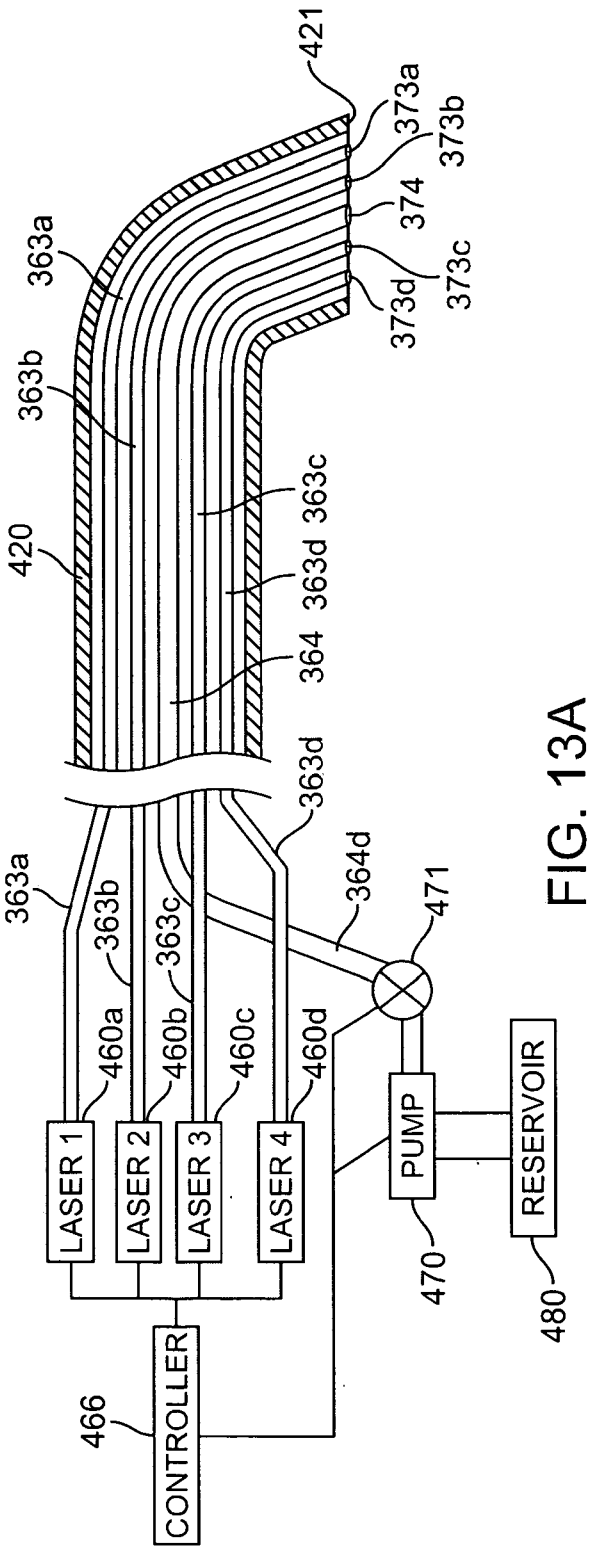

FIG. 13A

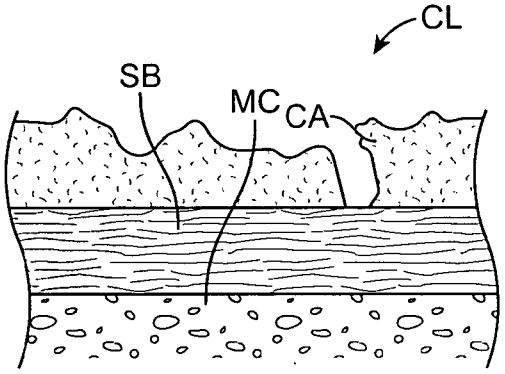

FIG. 14

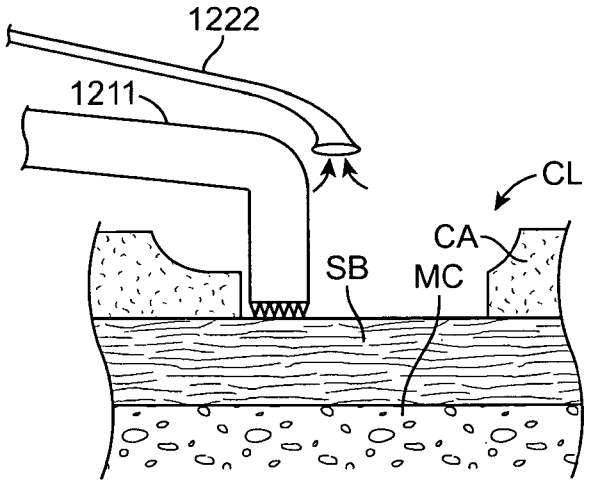

FIG. 14A

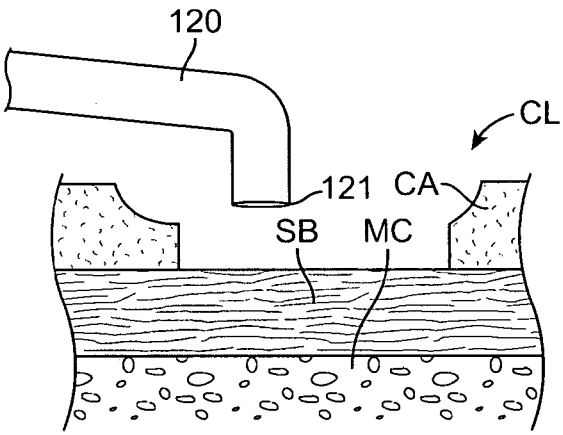

FIG. 14B

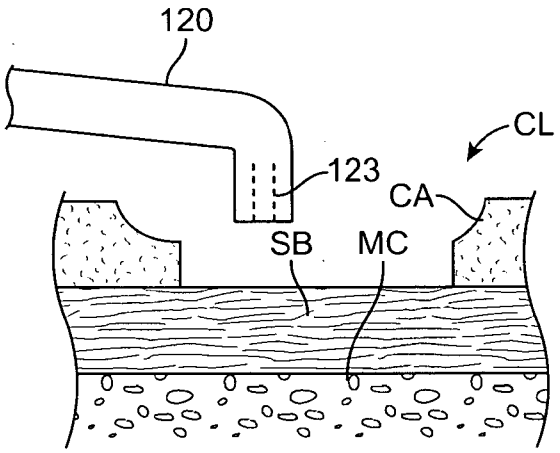

FIG. 14C

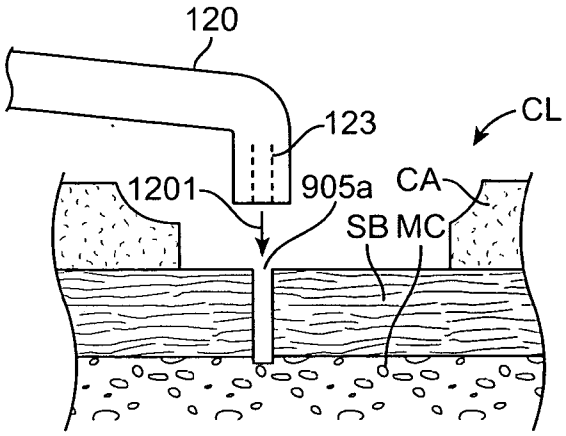

FIG. 14D

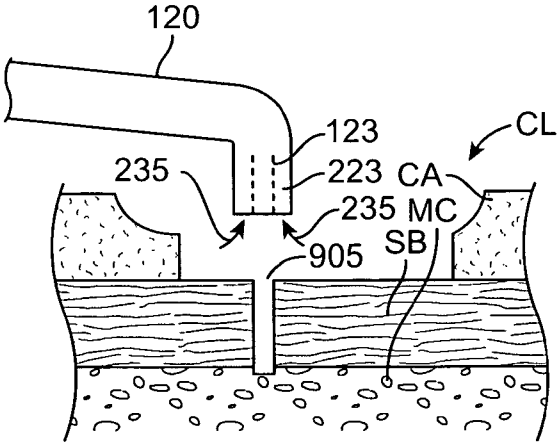

FIG. 14E

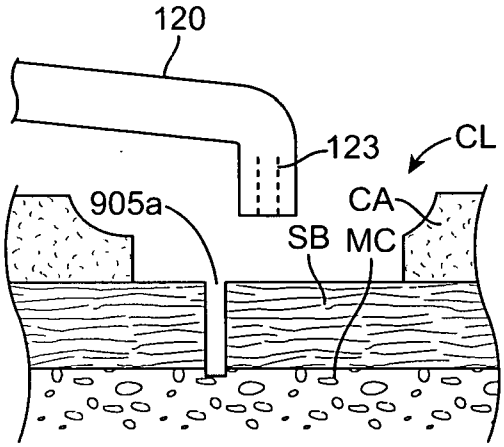

FIG. 14F

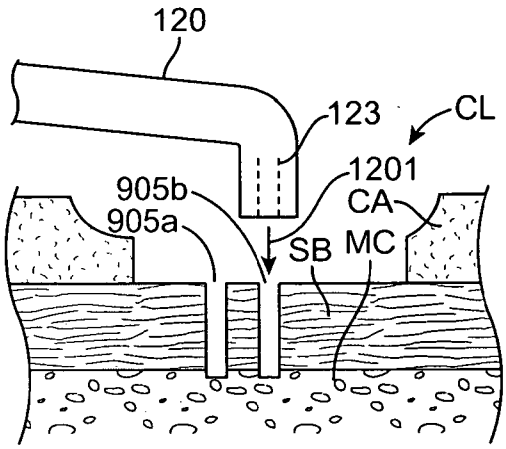

FIG. 14G

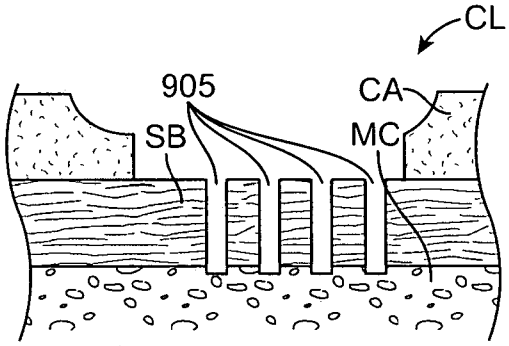

FIG. 14H

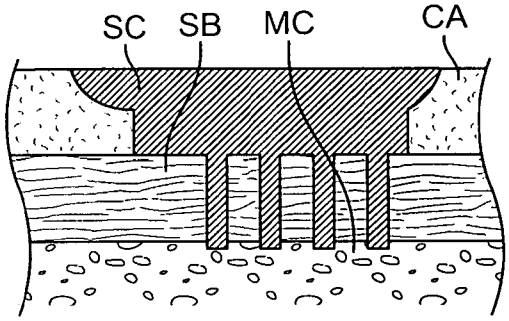

FIG. 14I

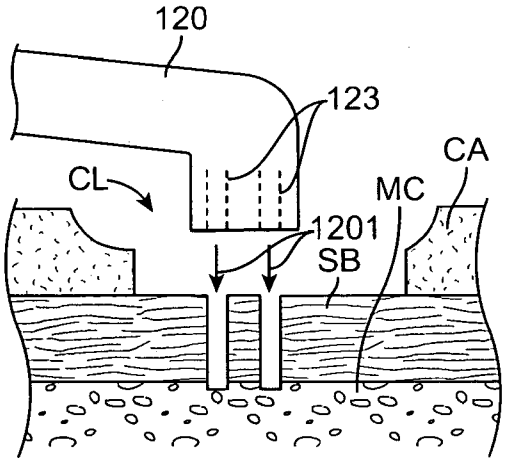

FIG. 14D1

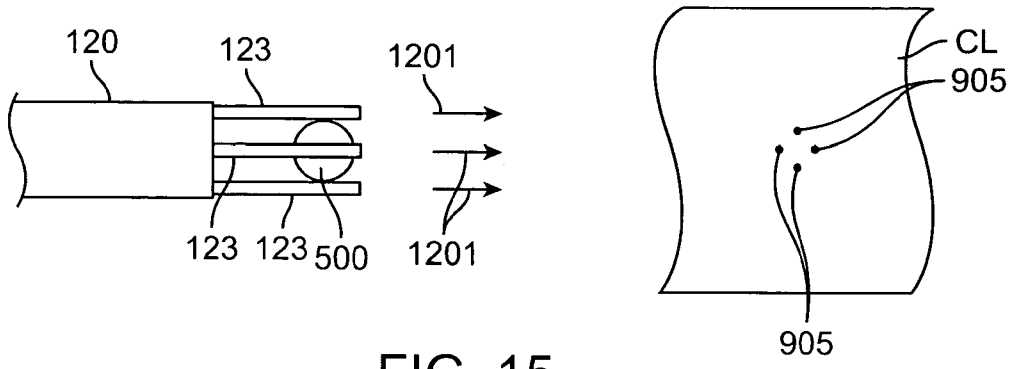

FIG. 15

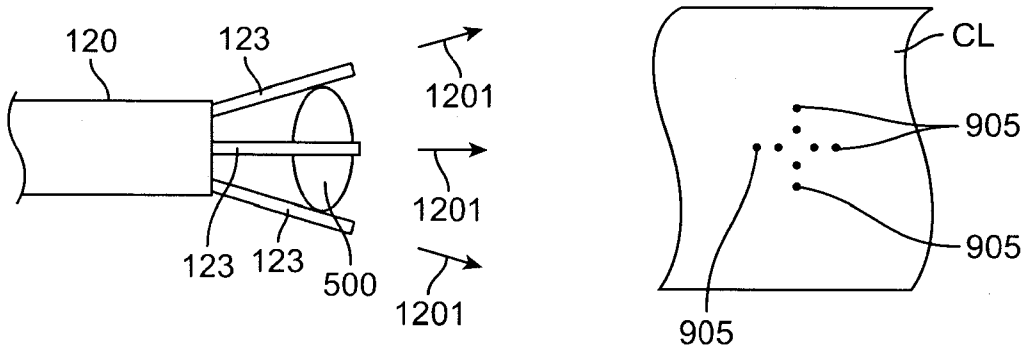

FIG. 15A

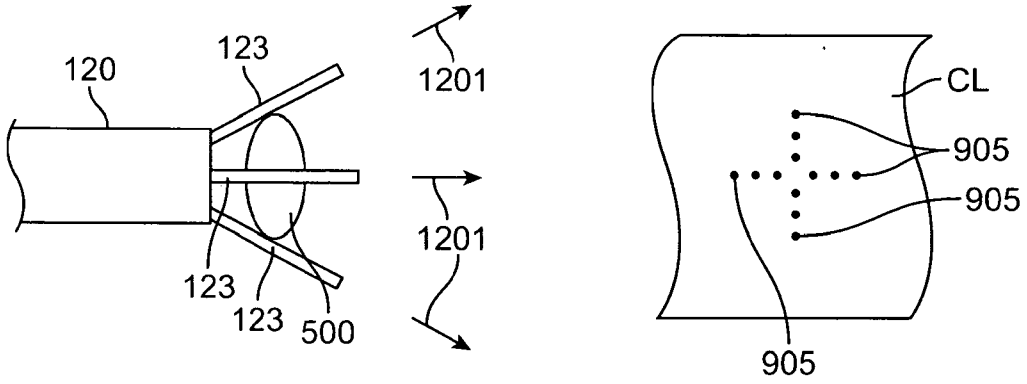

FIG. 15B

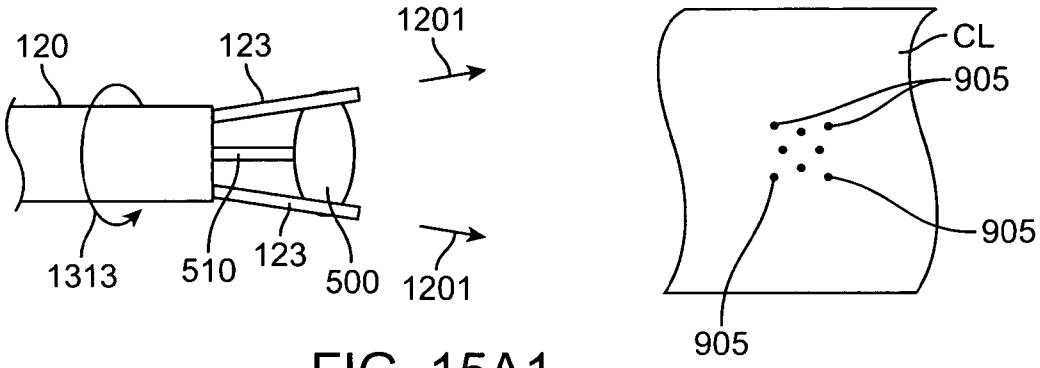

FIG. 15A1

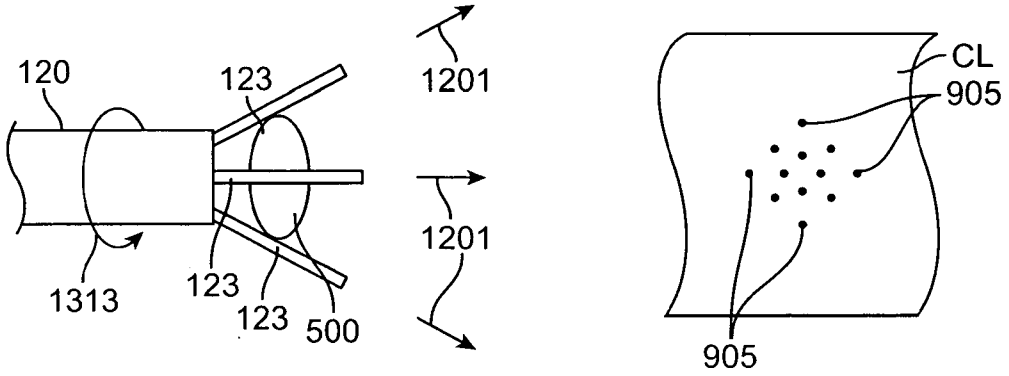

FIG. 15B1

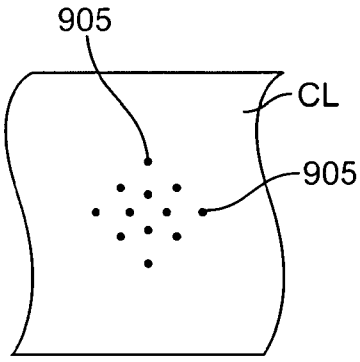

FIG. 15C

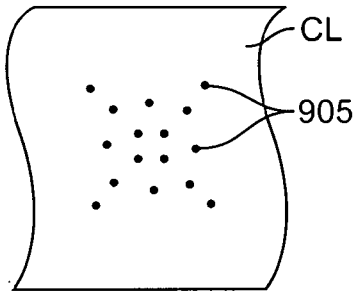

FIG. 15D

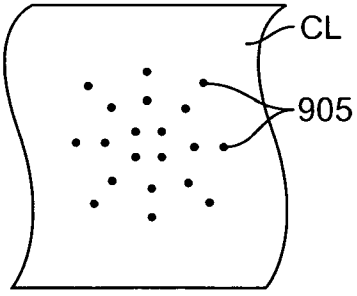

FIG. 15E

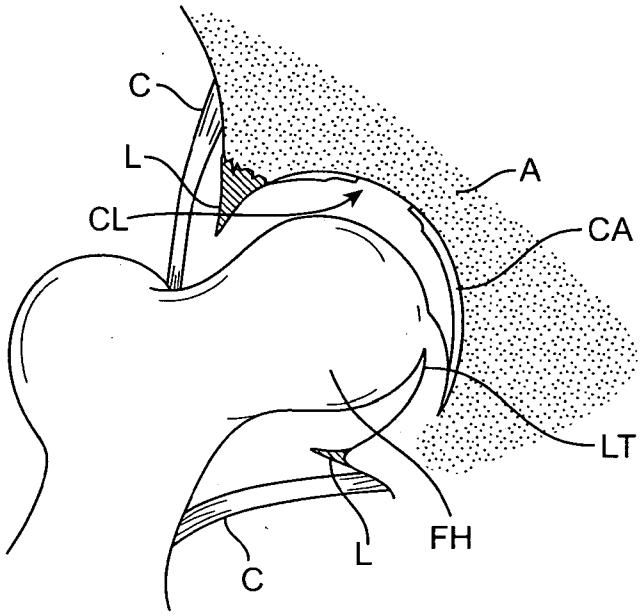

FIG. 16

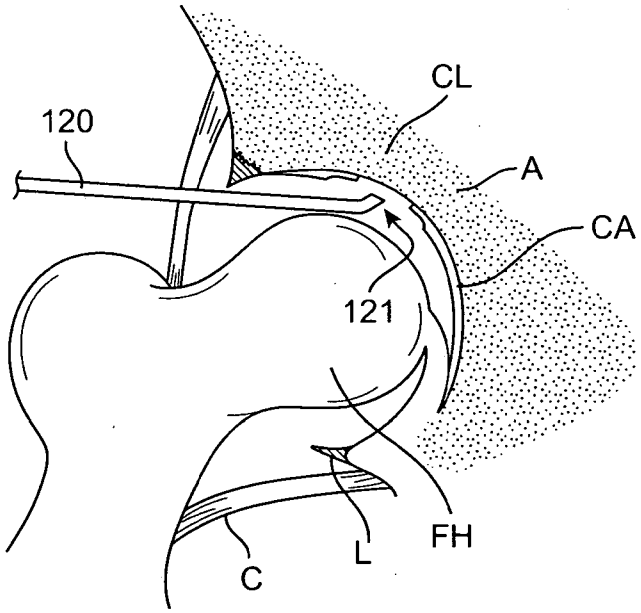

FIG. 16A

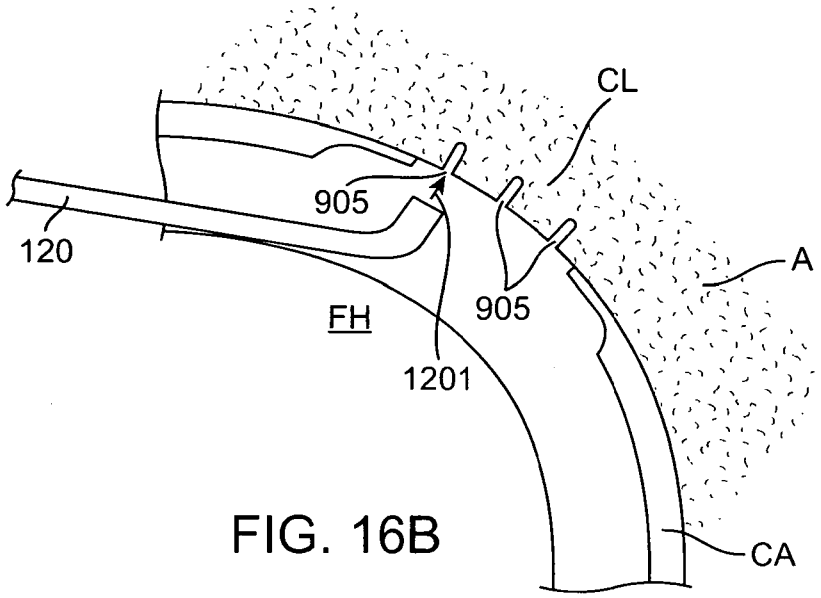

FIG. 16B

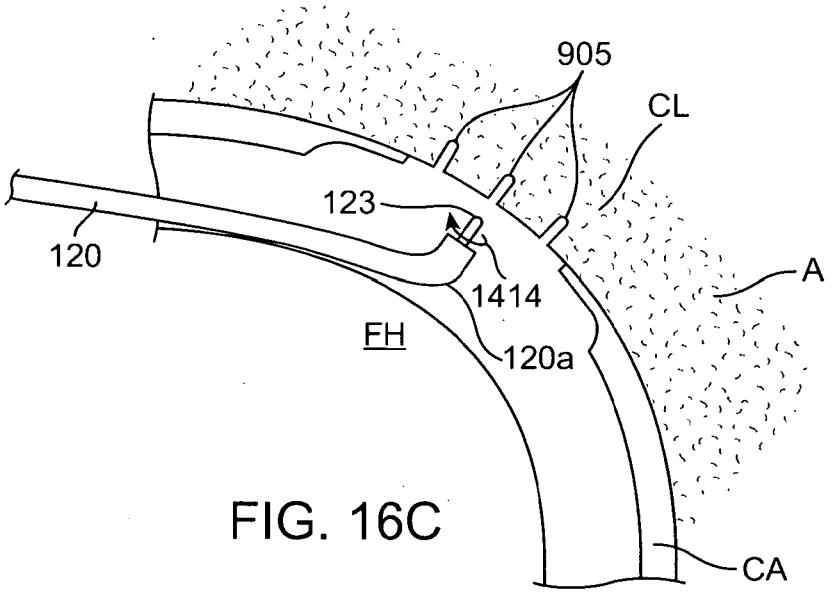

FIG. 16C

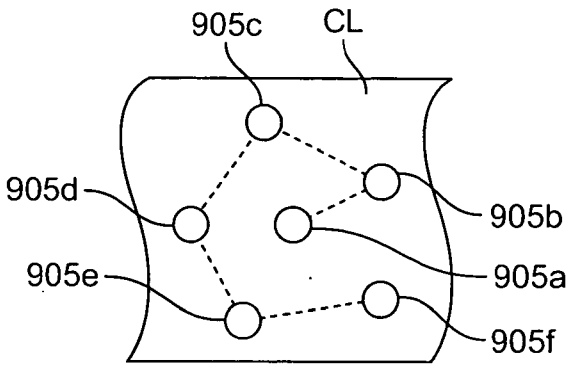

FIG. 16D

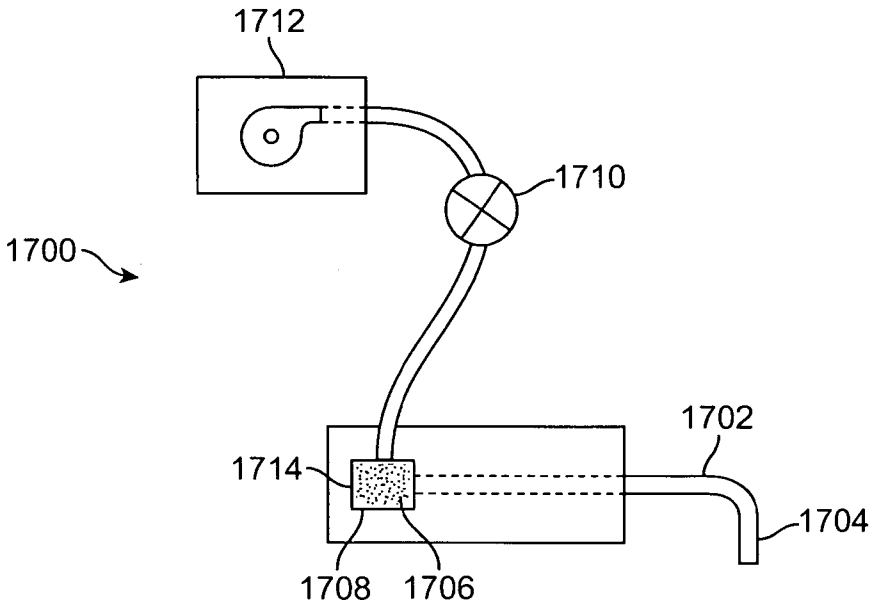

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No
PCT/US201 0/038875

A CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61 B 17/3203 (2010.01)
USPC - 604/151
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(8) - A61B 17/16, 17/32, 17/3203, 18/20 (2010 01)
USPC - 604/151, 606/79, 167, 607/89

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 practicable, search terms used)
MineSoft PatBase

C DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X -- Y	**US 2009/0105792 A1 (KUCKLICK) 23 April 2009 (23 04 2009) entire document**	1, 2, 15, 16, 24 --- 3-14, 17-23, 33
X -- Y	**US 2004/0073223 A1 (BURKINSHAW) 15 April 2004 (15 04 2004) entire document**	25, 26 --- 10, 11, 27-35, 65-71
X -- Y	WO **2003/096871 A2 (PAZ) 27 November 2003 (27 11 2003) entire document**	36, 37, 40-45, 54, 55, 59 --- 7, 21-23, 35, 38, 39, 46-53, 56-58, 60-71
Y	**US 2002/004581 1 A1 (KITTRELL et al) 18 April 2002 (18 04 2002) entire document**	3-6, 47-52
Y	**US 2007/0123894 A1** (CLAYPOOL **et al) 31 May 2007 (31 05 2007) entire document**	8-14, 20, 29-34,69, 70, 71
Y	**US 2006/0195106 A1** (JONES **et al) 31 August 2006 (31 08 2006) entire document**	17
Y	**US 2007/0015102 A1** (VERCELLOTTI **et al) 18 January 2007 (18 01 2007) entire document**	18, 19
Y	**US 2005/0216007 A1** (WOLL **et al) 29 September 2005 (29 09 2005) entire document**	27, 28, 66-68

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"A" document defining the general state of the art which is not considered to be of particular relevance	**"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention**
"E" earlier application or patent but published on or after the international filing date	**"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone**
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	**"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art**
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	**"&" document member of the same patent family**

Date of the actual completion of the international search
28 July 2010

Date of mailing of the international search report
01 SEP 20J⊖

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INTERNATIONAL SEARCH REPORT

International application No.
PCTΛJS2010/038875

C (Continuation). DOCUMENTS CONSIDERED TO **BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0100908 A1 (GRUMBERG et al) 29 May 2003 (29.05.2003) entire document	**30, 32, 70, 71**
Y	US 2002/0111579 A1 (MOUTAFIS et al) 15 August 2002 (15.08.2002) entire document	**39**
Y	US 5,944,686 A (PATTERSON et al) 31 August 1999 (31.08.1999) entire document	**38, 53**
Y	US 5,788,667 A (STOLLER) 04 August 1998 (04.08.1998) entire document	**46, 56-58, 60-64**
Y	US 5,871,462 A (YODER et al) 16 February 1999 (16.02.1999) entire document	**62-64**