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Tavori

(54) **DEVICE AND METHOD FOR DELIVERY OF RAPIDLY SEPARATING BODY OF FLUID, FORMING BONE RECONSTRUCTION MEDIUM**

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(57) **ABSTRACT**

Delivery assembly for a liquid solution and granulated flakes of bone material. The device is capable of delivering multi component compound such as trinaric system, a liquid solution, living tissue cells and granulated flakes of bone material, or multi compound, to form a bone reconstruction compound and delivering the same. The delivered body of fluid is subjected to static head and dynamic head unclogging settled components and hold them as a body of fluid. The device includes a reservoir, a delivery tube, a moving member, designed to move and provide force or motion vector to the body of fluid in said tube, said reservoir is connected to said delivery tube with a passage allowing body of fluid to pass either by gravity, dynamic head provided by mixing device, or by static head.

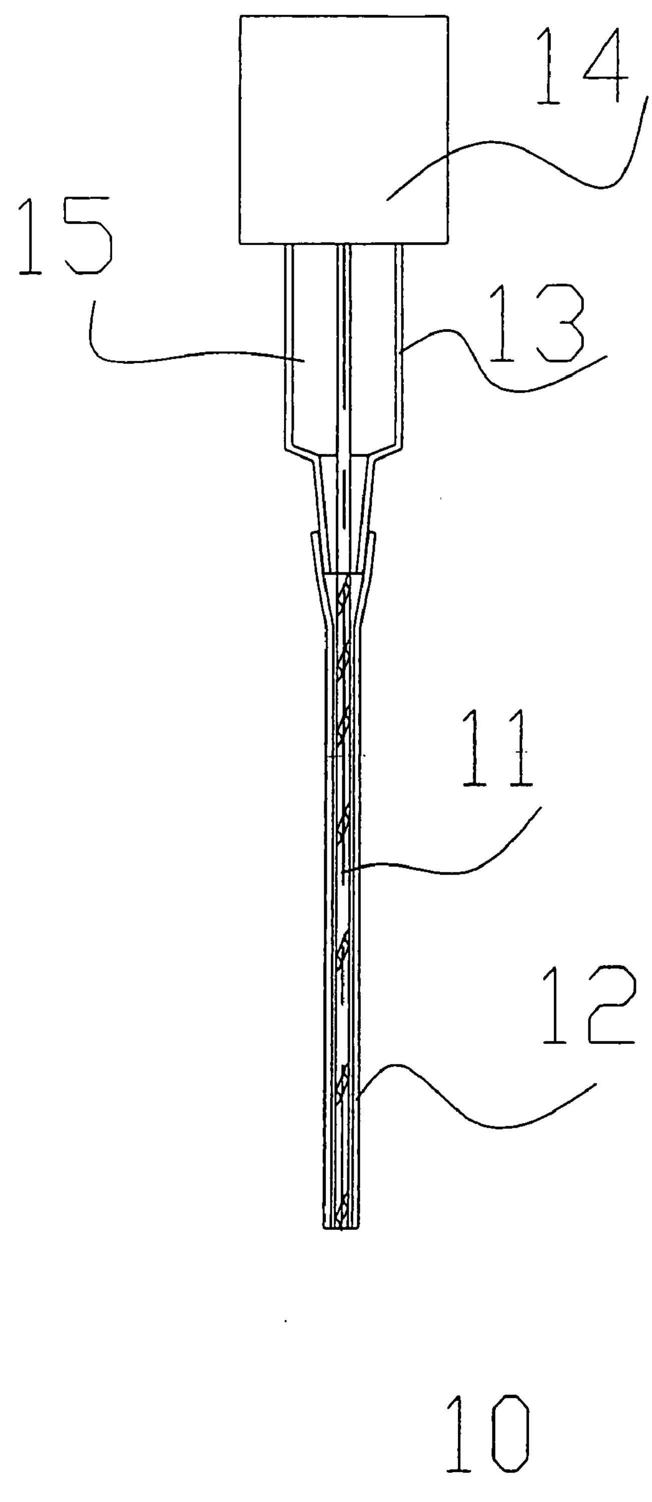

Fig 1

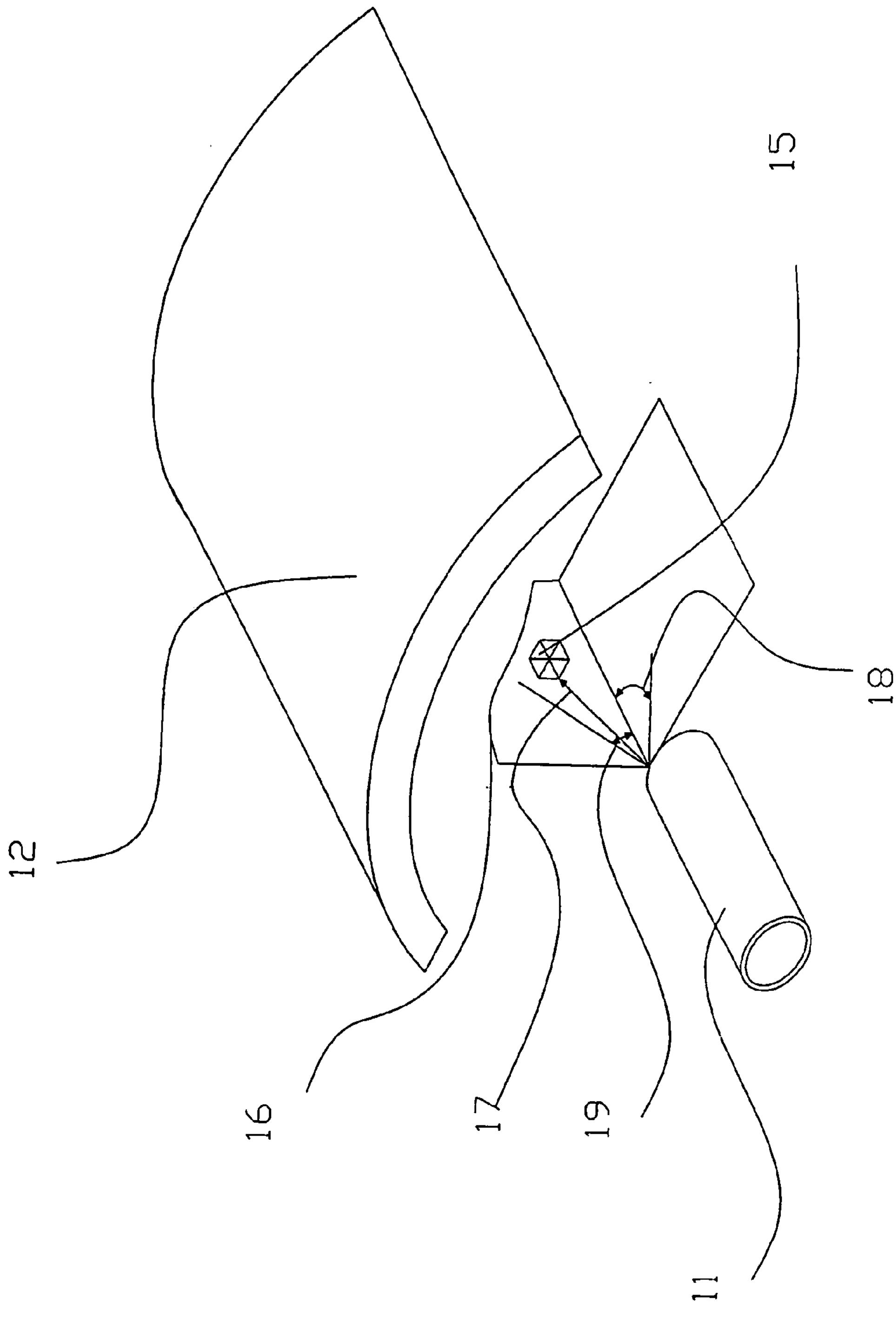

Fig 2

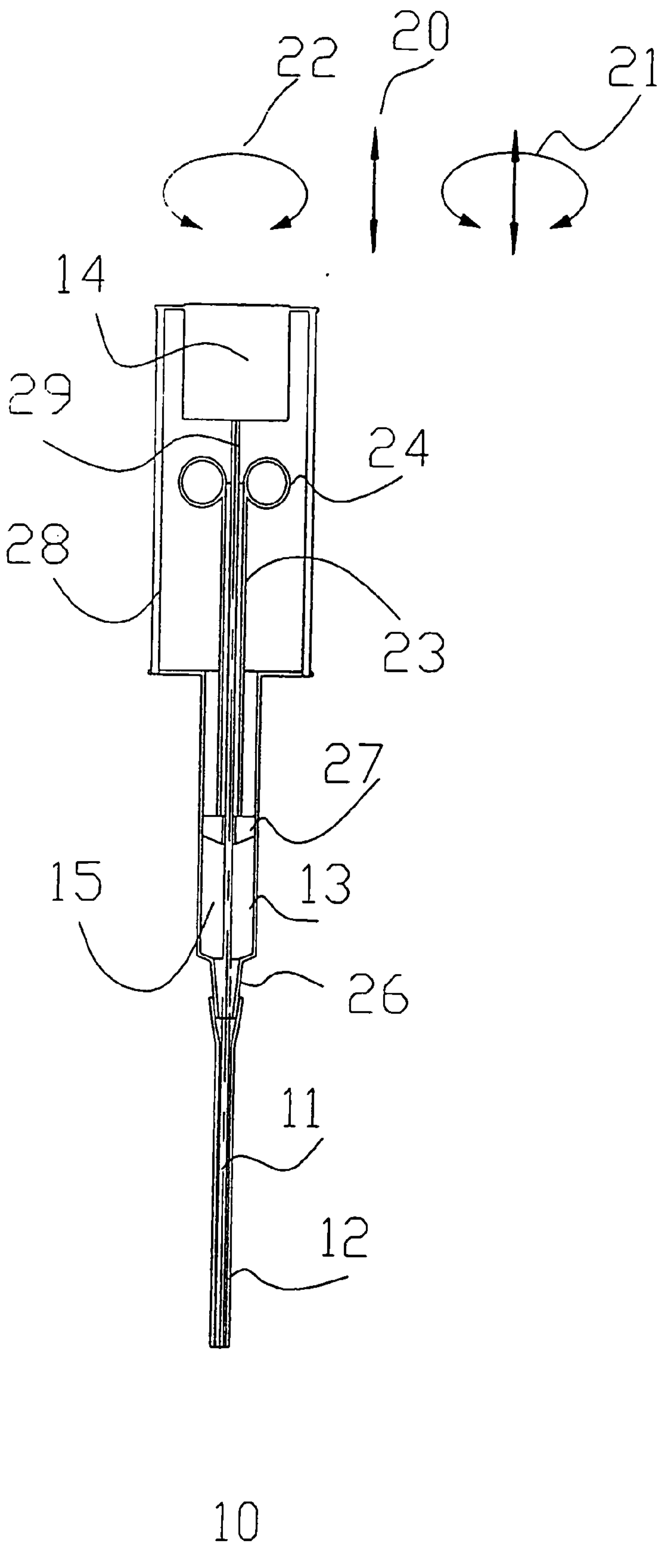

Fig 3

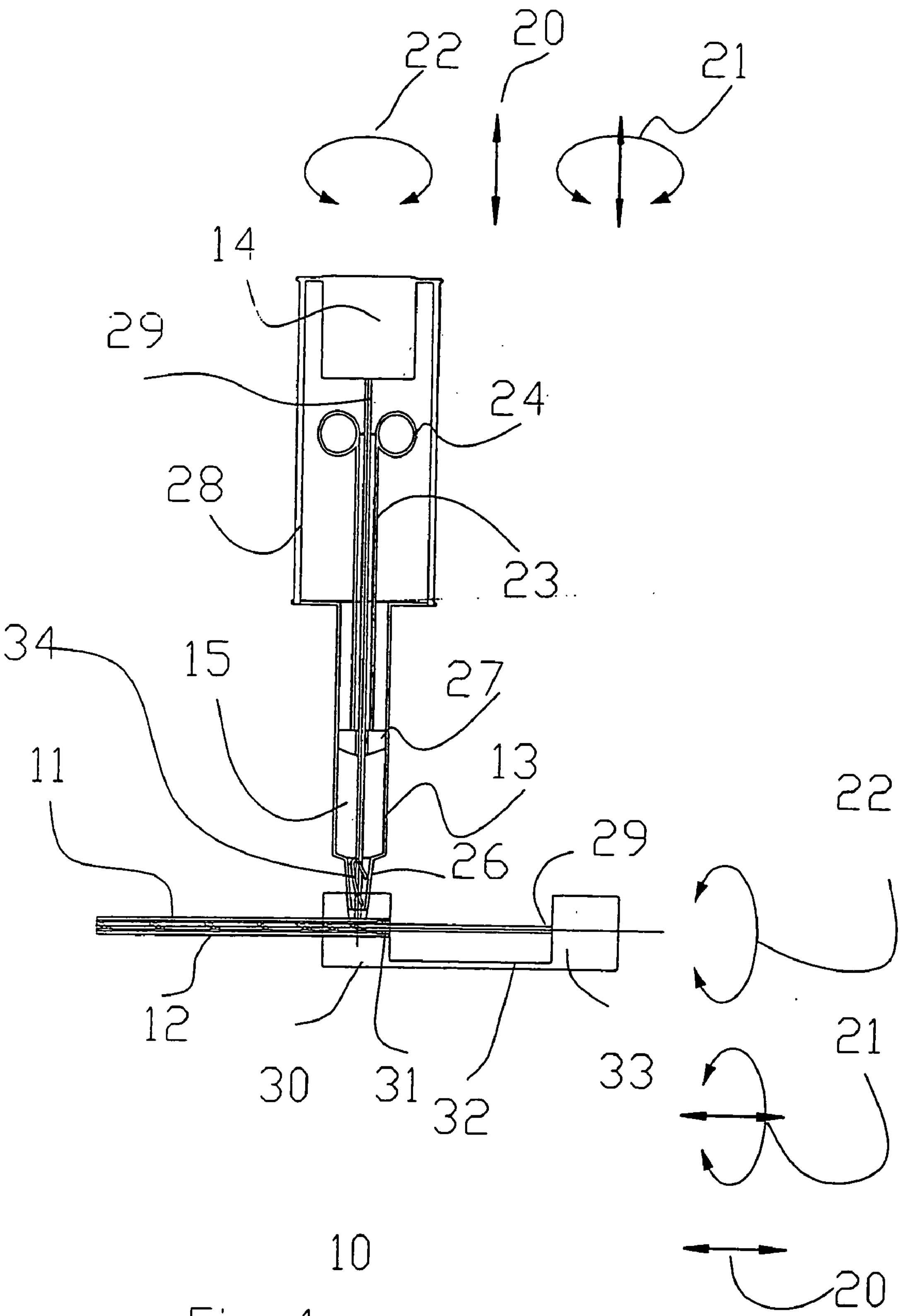

Fig 4

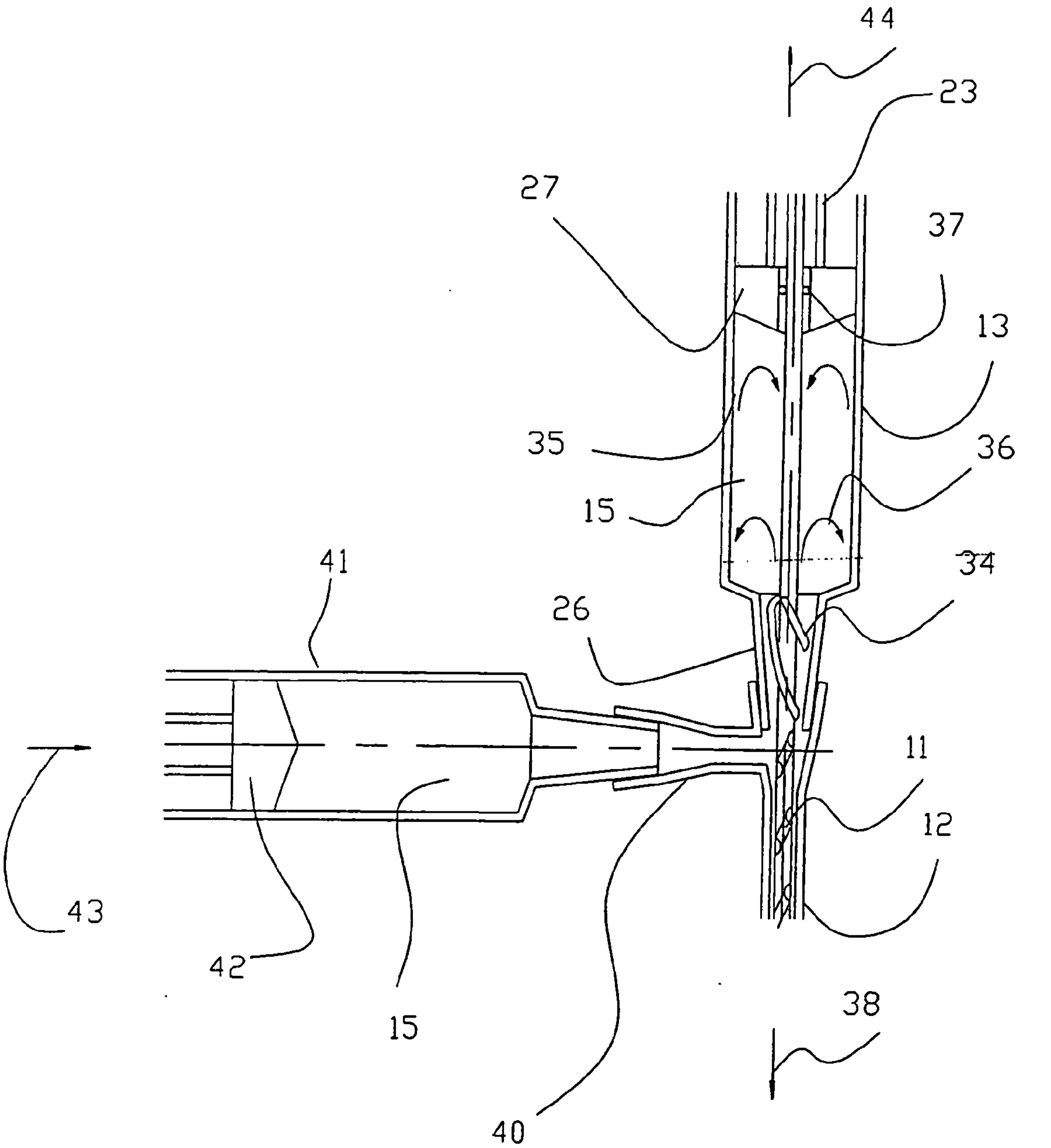

Fig 5

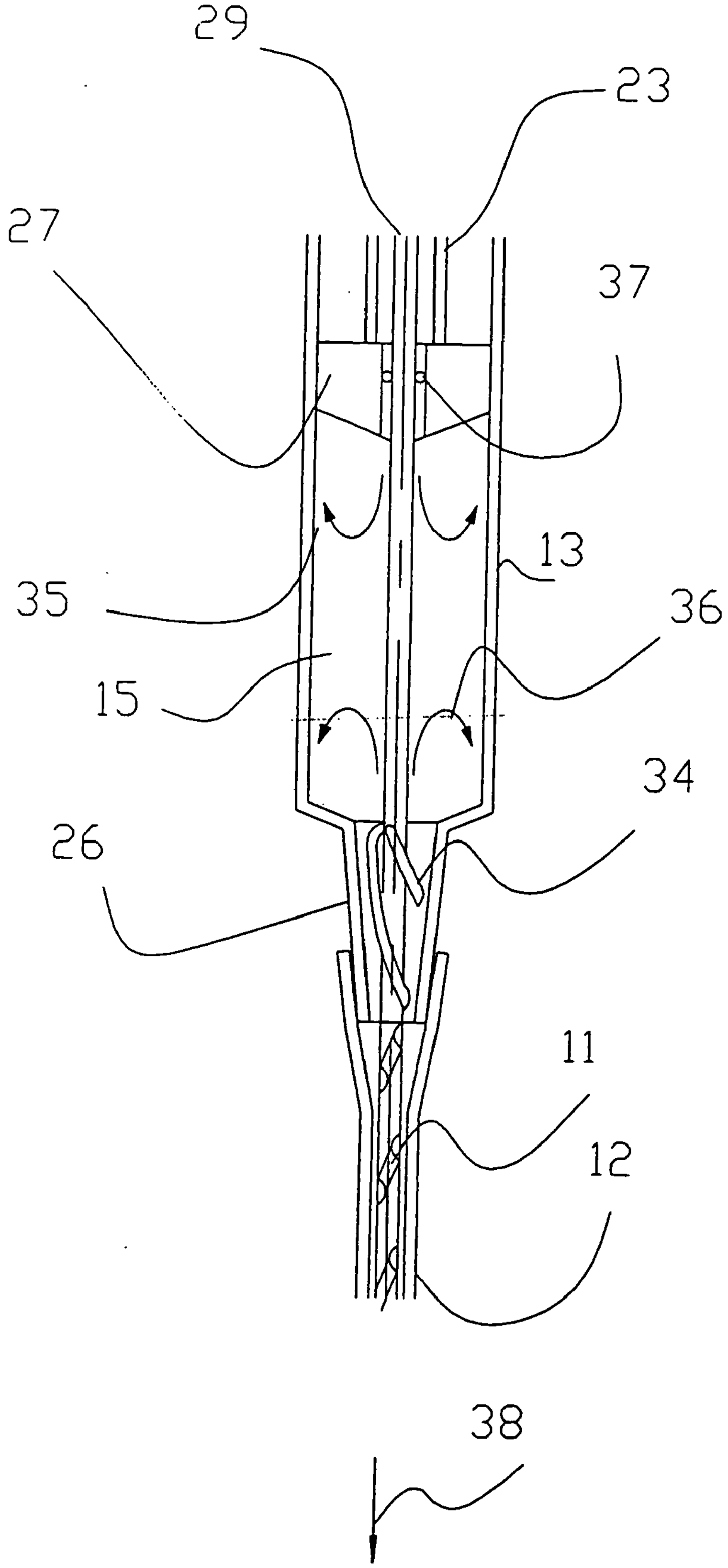

Fig 6

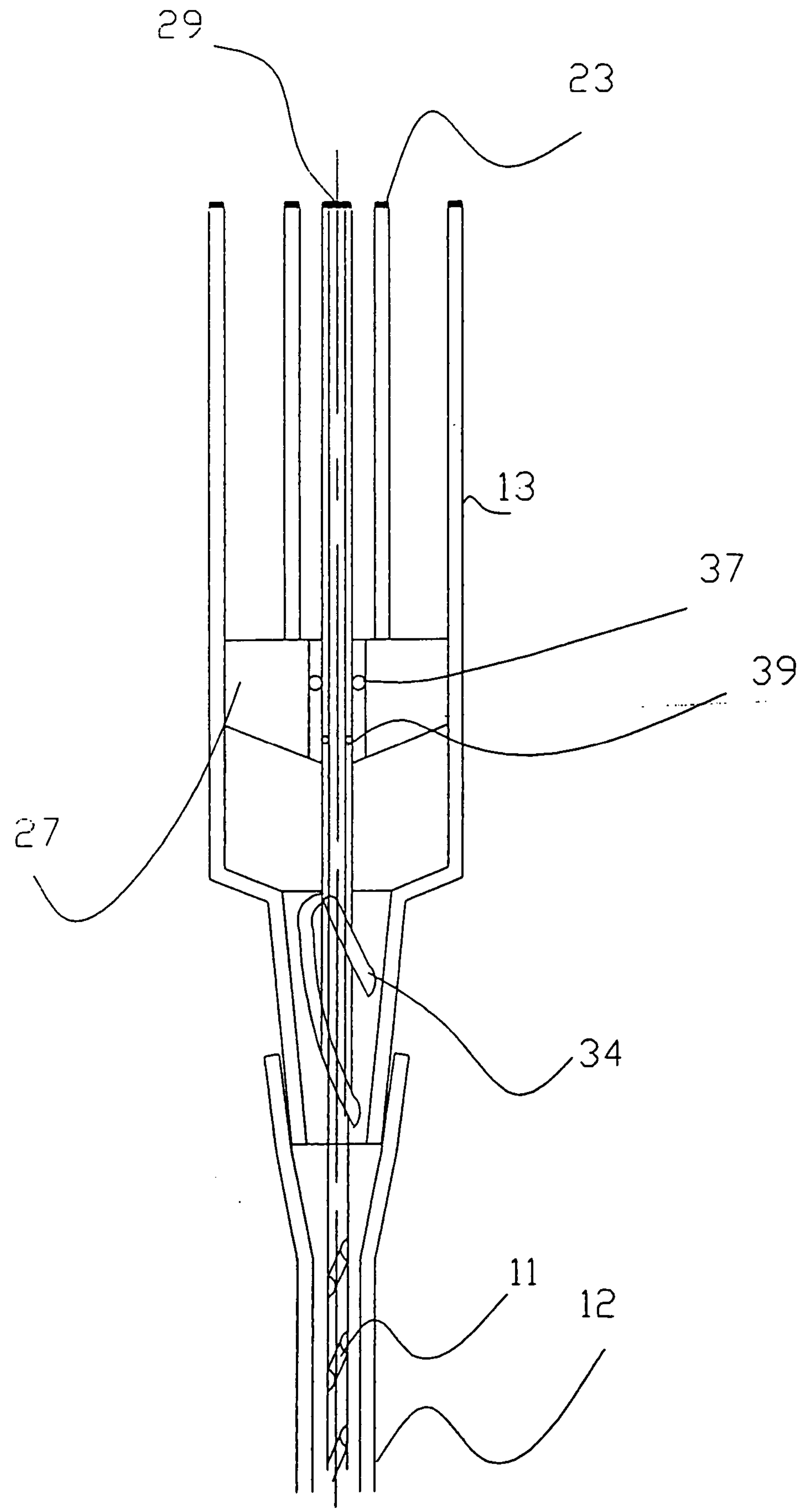

Fig 7

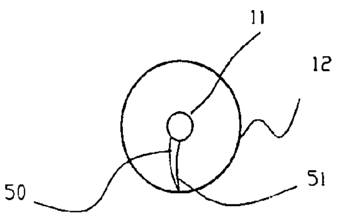

Fig 8d

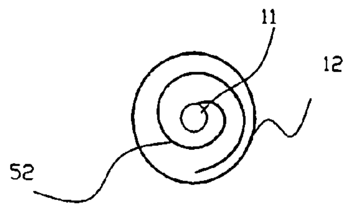

Fig 8e

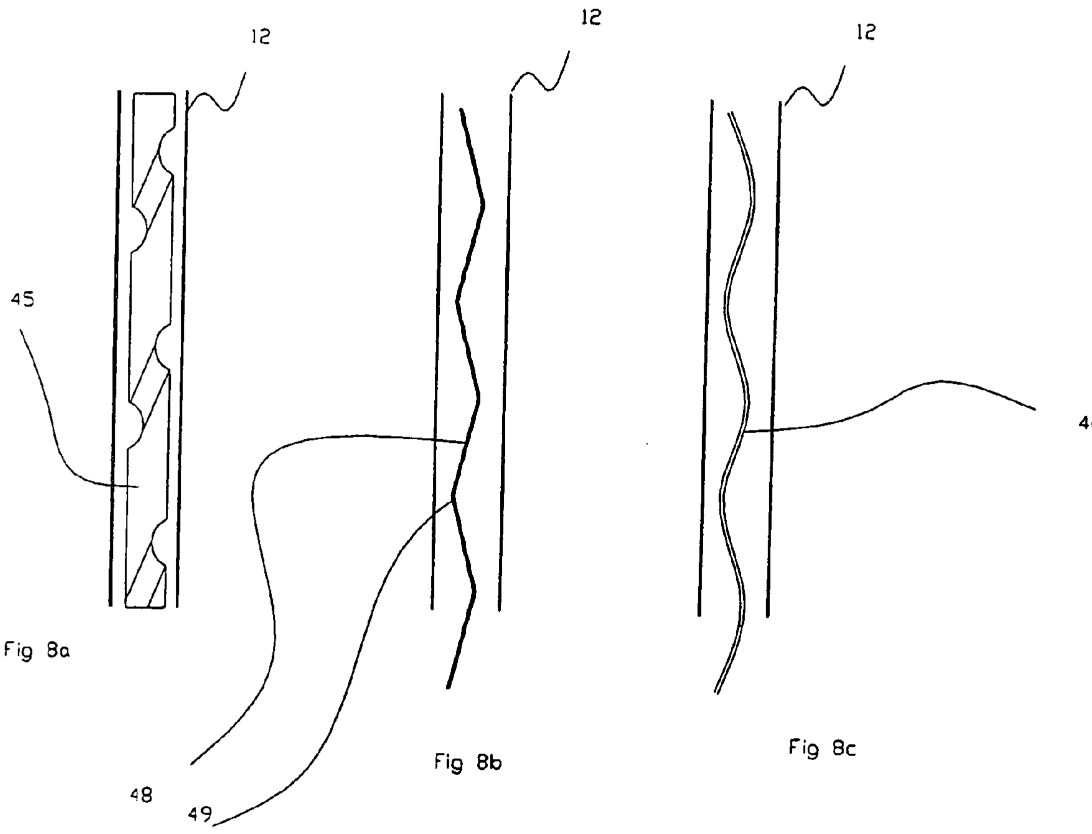

Fig 8a

Fig 8b

Fig 8c

11

Fig 8

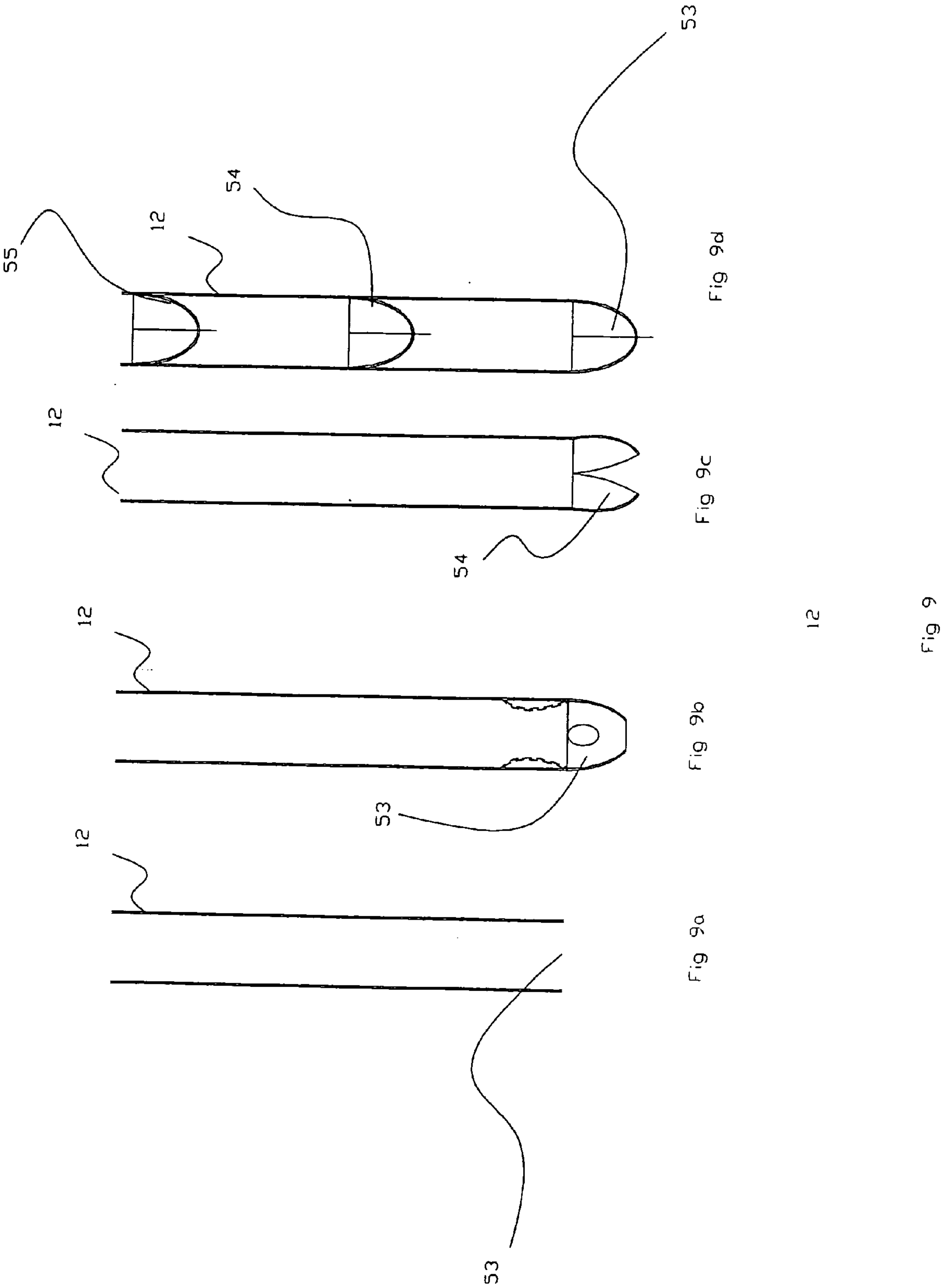
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Fig 9d
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Fig 9c
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Fig 9b
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Fig 9a
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Fig 9

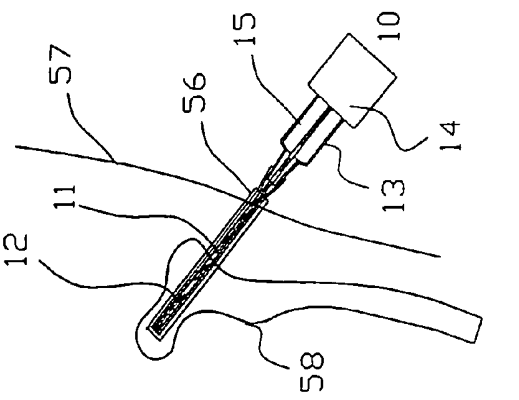

Fig 10b

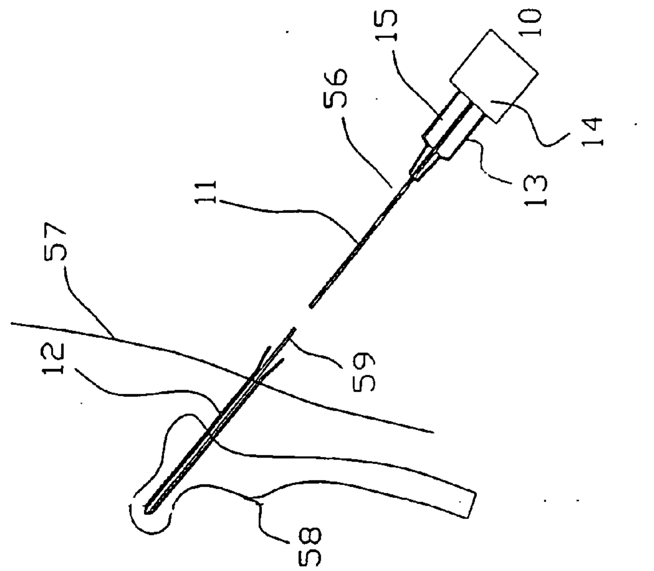

Fig 10a

Fig 10

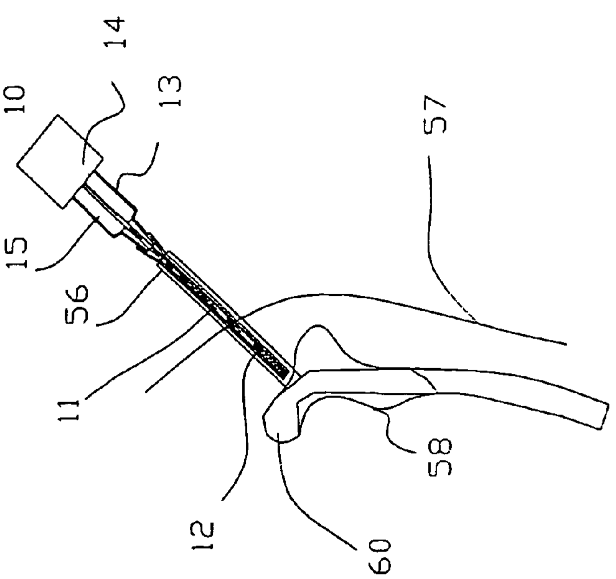

Fig 10c

DEVICE AND METHOD FOR DELIVERY OF RAPIDLY SEPARATING BODY OF FLUID, FORMING BONE RECONSTRUCTION MEDIUM

FIELD OF THE INVENTION

[0001] The present invention relates generally to a delivery assembly, one that is particularly suited for delivering rapidly separated body of fluid composed of a liquid solution, living tissue cells and granulated flakes of bone, or simulated bone material to form a bone reconstruction medium and delivering a bone reconstruction medium with a minimal invasive surgery.

BACKGROUND OF THE INVENTION

[0002] In many surgical procedures, particularly orthopedic procedures, it is common practice to deliver body of fluid composed of liquid part and solid fraction. Most common practice is to deliver bone cement. In special cases, a trinaric body of fluid, composed of a liquid solution, living tissue cells and granulated flakes of bone material is required to be delivered. By a non-limiting example, in a femur bone open major surgery, required to remove bone parts, or bone marrow, the healing process is relatively long and traumatic to the patient. It is required to deliver the body of fluid with minimally invasive procedure. When introducing a prosthetic device, enhanced growth of bone around and into the prothesis is advisable to allow minimal healing and recovery time.

[0003] Other uses of such a delivery system include but not limited to, repairing or mending bone fractures or shattered bone, during face reconstruction after major trauma, during dental surgery. Moreover, delivered compound may be used together with as a drug delivery long term release system, whereby the body of fluid includes desired drugs and applied to a specific surgical site. Another application may be used together with body temperature or UV cured foundation, used to secure and hold bone and delivered compounds in a specific surgical site. As a non-limiting example, such foundation compound may be designed to be absorbed by the body over time. Because of the necessity for a fairly quick surgical procedure, a surgical assistant almost universally prepares the delivered body of fluid during the course of the operation in the sterile operating room.

[0004] Currently, delivered components forming body of fluid are mixed in a mixing bowl and, once fully mixed, the body of fluid is manually transferred from the mixing bowl to a dispensing reservoir of a dispensing device. Typically, devices similar to large diameter injection syringe or caulking guns are employed for dispensing the fully mixed body of fluid to the desired location in the surgical site. These devices relay on static head or hydrostatic pressure, to force the body of fluid threw an orifice transferring potential energy into a kinetic one.

[0005] Such device is disclosed in U.S. Pat. No. 5,551,778 to Hauke et al, another devices are disclosed in U.S. Pat. No. 5,876,116 to Barker et al, U.S. Pat. No. 5,893,488 Hoag et al. U.S. Pat. No. 6,019,765 Thornhill et al. U.S. Pat. No. 6,045,555 Smith et al. U.S. Pat. No. 6,048,346 Reiley et al. U.S. Pat. No. 6,083,229 Constantz et al. U.S. Pat. No. 6,086,594 Brown U.S. Pat. No. 6,149,655 Constantz et al. U.S. Pat. No. 5,553,754 Dentler, do not address the basic requirements and constrains of delivered body of fluid, composed of a liquid solution, living tissue cells and granulated flakes of bone material. The body of fluid is characterized by several constrains, as compound tend to rapidly separate into its components, the solid fracture tend to plug the delivery tube, high pressure, high velocity delivery is not advisable with living tissue components, coagulation may occur, non even delivery of body of fluid may occur as solid fracture tend to separate during delivery in the delivery tube, and delivered compound may be lean in one or more of its components. The higher the shear rates, the suspension dilates and enters the grain-inertia regime, where the shear stress increases quadratically with the shear rate.

[0006] In long flow, especially in small lumen diameters, or when L/D is above 10, the shear stress increased with increasing normal force. In such a quasistatic regime, the particles interlock. The quasistatic regime is dominated by short-range frictional contacts between the particles. It occurs at low strain rates under the application of compressive stress, and the stresses show strain rate independence. Successful models for the quasistatic regime have been based on Coulomb friction interactions, which are relatively insensitive to shear rate. In the suspension literature, wall slip is usually attributed to particle migration and the formation of wall slip behavior, created in unsteady flow, which is frequently referred to as "stick-slip" behavior. Stick slip is observed at low interstitial fluid viscosities, small ratios of lumen size to particle size, low shear rates, and high suspension concentration that can cause of plug flow. The flow regime turns into quasistatic regime where the particles interlock.

SUMMARY OF THE INVENTION

[0007] The present invention provides a body of fluid delivery assembly for a liquid solution, living tissue cells and granulated flakes of bone material to form a bone reconstruction compound and delivering the same. The delivered body of fluid is subjected to static head as gravity or hydrostatic pressure, and dynamic head designed to provide movement to compound of body of fluid, unclog settled components and hold them as a body of fluid. The device includes a reservoir, said reservoir may further include a mixing device, said reservoir may include a static head device, a delivery tube, said delivery tube includes a moving member, designed to move and provide force or motion vector to the body of fluid in said tube, said reservoir is connected to said delivery tube with a passage allowing body of fluid to pass either by gravity, dynamic head provided by mixing device, or by static head.

[0008] Accordingly, the present invention provides a method comprising the steps of providing minimal cut threw the flesh, providing access surgical site possibly by a small diameter hole in the bone to the surgical site, inserting delivery tube into surgical site, filling reservoir with body of fluid, operating the delivery system, delivering the body of fluid to surgical site, retracting delivery tube outwardly from the surgical site while maintaining delivery until out of the bone, removing device from patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] **FIG. 1** is describing simplified device in accordance of the first embodiment of the present invention;

[0010] FIG. 2 describing simplified physical behavior of a component of body of fluid in accordance of the first embodiment of the present invention;

[0011] FIG. 3 describing simplified device in accordance of the second embodiment of the present invention.

[0012] FIG. 4 describing simplified device in accordance of the third embodiment of the present invention.

[0013] FIG. 5 describing simplified device in accordance of the fourth embodiment of the present invention.

[0014] FIG. 6 describing simplified device with as operated.

[0015] FIG. 7 describing simplified device in accordance of the fifth embodiment of the present invention.

[0016] FIG. 8 describing is describing shapes of dynamic head provider.

[0017] FIG. 9 describing is describing delivery tube.

[0018] FIG. 10 is describing the usage of device 10.

DETAILED DESCRIPTION

[0019] FIG. 1 is describing device 10. Device 10 having a delivery tube 12, dynamic head provider 11, reservoir 13 and power generating ability 14.

[0020] Reservoir 13 is designed to hold body of fluid 15, required to be delivered.

[0021] Additionally, Reservoir 13 is designed to provide body of fluid 15 static head or hydrostatic pressure. Static head can also be produced due to gravity. Reservoir 13 can be realized as a standard component. As a non-limiting example, a glass or flexible Erlenmeyer bottle, or with reduced volume capability, such as common syringe. Special design of reservoir 13 may include flexibility to provide static head by a simple fmger squeeze, thus reducing reservoir 13 volume. Dynamic head provider 11 is designed to have relative movement, either rotary, reciprocating or oscillating, to body of fluid 15 to pass threw the delivery tube 12. By having such movement, Dynamic head provider 11 add another component of force or motion to the flow in which body of fluid 15 is exposed to. This component is used to break settling of body of fluid 15, when passing via delivery tube 12, or present in reservoir 13. Dynamic head provider 11, may be realized integrally with delivery tube 12, or reservoir 13 thus reducing components required to realize device 10. Power generating ability 14 is used to provide agitation or other movement to hold components of body of fluid 15, dispersed and not settled. Power generating ability 14 is also used to provide relative movement between delivery tube 12, and dynamic head provider 11. Power generating ability 14, can be realized by manually tilting device 10 by hand, or by squeezing reservoir 13 by hand, or by connecting to other power source. Such a power source can be an electric, hydraulic, spring operated or pneumatic motor, capable of delivering any of rotary or reciprocating or oscillating motion. Power generating ability 14 may also be realized by subjecting delivery tube 12, or dynamic head provider 11 or complete device 10 to electromagnetic or ultrasonic fields. Numerous power source devices are present, and in operating room environment, Hall drill, available from Zimmer U.S.A, can provide rotary motion, and a Sternum saw, available from Zimmer U.S.A, or De Soutter Medical, which can provide oscillating or reciprocating motion. Moreover Power-generating ability 14 may be designed to produce oscillations between delivery tube 12, and dynamic head provider 11 due to out of phase inertial motion of the body of fluid 15, and dynamic head provider 11 system.

[0022] FIG. 2 is describing a part of body of fluid 15, inside device 10, and physical relationship as to forces of flow. The body of fluid 15 can not be considered as a single phase fluid, as it is composed of a liquid solution, living tissue cells and bone flakes. Moreover, the liquid solution, living tissue cells combination forms a non-Newtonian compound, with low characteristics of fluidity behavior. Such a part may be composed of either component of a body of fluid 15, and may be a liquid, gas, Living tissue cells, such as blood, stem cells, bone marrow cells and the like, Bone flacks, said bone flacks may be coated with drug compound, or with a gelling agent providing affinity to living tissue cells, or drug compound and the like, to adhere to the bone flacks, thus posing a semi solid fraction in body of fluid 15. Parts of device 10, dynamic head provider 11 and delivery tube 12 are also shown.

[0023] The shape of a part of body of fluid 15 is of irregular shape, both simple 3-D shapes such as sphere, cube and the like, and flakes as coming out of the mill, without and ordered structural shape.

[0024] A part of body of fluid 15, is subjected to a flow field, most commonly described by the following formula:

$$\rho\frac{D\vec{V}}{Dt} = \rho\vec{B} - \nabla p + \mu\nabla^2\vec{V}$$

[0025] This equation is known as the Navier-Stokes equation, for Newtonian fluids. The term on the left side of the equation represents the total derivative consisting of the temporal and convective acceleration terms, of which the convective acceleration are non-linear. The terms on the right side of the equation represent the body acting forces, the pressure gradient, and the forces due to the viscosity of the fluid. The body acting forces are proportional to the wetting behavior between the particles, surface and shape and liquidic part of the body of fluid. The velocity field is proportional to the pressure drop field and can be described as graph 16, where curve proximae is upstream, and curve distalia is downstream. Of coarse, graph 16 may oscillate, and create average downstream flow, intermittent flow or upstream flow. When considering a reservoir 13 and a delivery tube 12, such a body of fluid 15 poses higher delivery phenomena. It is known from prior art that according to Bernoulli's equation, when a fluid flows steadily through a long, narrow, horizontal pipe of constant cross section, the pressure along the pipe will be constant. In practice, however, we observe a pressure drop as we move along the direction of the flow. Body of fluid 15 composed of a liquid solution, living tissue cells and bone flakes, has rapid separation characteristics, and at the far flow field, solid or semi solid particles will separate from the body of fluid 15 and will be subjected to external forces generated by dynamic head provider 11, and delivery tube 12. Moreover, flow in long constrictions with a small lumen diameter, or flow separation regions, or turbulent energy losses in cases of severe stenosis, reduce the energy content of the fluid.

[0026] When the proportion of the delivery tube **12** length and lumen diameter are above **10**, the settled particles will form a plug flow, which will end as clogging delivery tube **12**.

[0027] In this invention, additional vector **17** is used to bring particles from body of fluid **15**, settled on delivery tube **12**, back into the body of fluid **15** hence unclogging the plug formed. The vector **17** is adding another component of force or motion, to the body acting forces, coming from external source. Vector **17** is characterized by value, position, and angle of attack. The angle of attack is represented as polar coordinates **18**, as θand **19** as ϕ. Polar coordinates are between 0 to 2 ¶ and can be subjected to a rotary or reciprocating field or any other combination regime, hence providing vector **17** to apply force or motion to body of fluid **15**. Although vector **17** is shown coming from dynamic head provider **11** it also may be coming from delivery tube **12**, as a result of electromagnetic or ultrasonic field, thermal energy or impact between particles. Forces generated from slip stick phenomena, from delivery tube **12**, or from particles interaction are not shown. Vector **17** is adding components to the basic Navier-Stokes equation, results a modified Navier-Stokes equation:

$$\rho\frac{D\vec{V}}{Dt} = \rho\vec{B} - \nabla p + \mu\nabla^2\vec{V} + \vec{F}\delta(x, y, z, \varphi, \theta, t, S)$$

[0028] Where the added component is dependant in value F, in position (x,y,z), in direction (Θ,ϕ), in time (t), and value S, resembling shape. The importance of S, relates to volume, surface area of from body of fluid **15**, moment of inertia, gyration radii and other dynamic functions, generated by travel of particle of body of fluid **15** in medium. The term time (t) may be substitute with frequency (1/t). Of coarse, δ(x,y,z,ϕ,θ,t,S), may be a function, independent or dependant of any of its components.

[0029] Expanding this formula,

$$\rho\frac{\partial\vec{V}}{\partial t} + \rho\vec{V}\cdot\nabla\vec{V} = -\nabla p + \rho\vec{g} + \mu\nabla^2\vec{V} + \vec{F}\delta(x, y, z, \varphi, \theta, t, S)$$

[0030] Looking into the formula,

$$\rho\frac{\partial\vec{V}}{\partial t}$$

[0031] is the local acceleration, $\rho\vec{V}\cdot\nabla\vec{V}$is the convective acceleration, $-\nabla p$ is the pressure force per unit volume, $\rho\vec{g}$ is the body force per unit volume, $\mu\nabla^2\vec{V}$ is the viscous forces per unit volume and $\vec{F}\delta$(x,y,z,ϕ,θ,t,S) Is externally added component of force per unit of shape, Examination of the above equation shows that each term has units of force per unit volume, or, F/L3. Therefore, Added component $\vec{F}\delta$(x,y,z,ϕ,θ,t,S) satisfy basic equation, as if we divide each term by a constant having those same units (F/L3), we would obtain a dimensionless equation. Furthermore, the viscosity and specific gravity values are also changing, when Vector **17** is not pure mechanical, activated by electromagnetic ultrasonic fields or pneumatic or hydraulic dissipation or impact, when heat is applied or generated. As a non limiting example, such a phenomena is present when dynamic head provider **11** is realized as a stream of a component of body of fluid **15**, the local flow regime is a combination of regimes, creating a vector **17**.

[0032] **FIG. 3** is describing device **10**, further including a ram **27**, designed to apply pressure and push body of fluid **15** threw fimnel **26** via delivery tube **12**. Funnel **26**, may be angled or parallel, constitutes continuous integral part of reservoir **3**. Ram **27** may be realized as standard syringe ram, or any other piston arrangement. Pusher **23** and handle **24** activate Ram **27** in reservoir **13**. Pusher **23** and handle **24** are drawn schematically as can be realized as hand operated equipment, power operated include leverage as caulk guns, and equipped with metering or motorized capability. Pusher **23** may include a passage between power generating ability **14**, and dynamic head provider **11**. Power generating ability **14**, is connected to dynamic head provider **11** via a coupling **29**, capable of delivering power generated, such as rotary movement, **22**, linear movement **20**, or combination movement **21**. Rotary movement, **22** may be either continuous or reciprocating, vibration or frequency oscillating. Linear movement **20** may be either continuous or reciprocating, vibration or frequency oscillating, either small short stroke, or full length stroke, as the length of delivery tube **12**, allowing small portions of body of fluid **15** to be rammed all the way out of delivery tube **12**, Combination of movement **21**, both rotary and linear, in required operating regime, as independently operated, or timed linear and than timed rotary, capable of rotating and than pushing. Coupling **29** is further including capability to couple electromagnetic, ultrasonic fields, or pneumatic or hydraulic dissipation or impact. Frame **28** is described schematically, and designed to hold together components of device **10**, however frame **28** may be designed integrally, thus frame **28** is imbedded into device **10**.

[0033] **FIG. 4** is describing device **10** in an angle position. In this arrangement, hydraulic Tee joint, **30** is mounted over funnel **26**, and delivery tube **12** dynamic head provider **11**. Reservoir **13** is further including a mixer **34**, integrated inside funnel **26**, and connected to power generating ability **14** via passage in pusher **23** and coupling **29**. Mixer **34** may be designed for minimum or maximum free volume inside funnel **26**. moreover, mixer **34** may be designed as a syringe and a needle system, operating as to motion **20**. creating oscillating motion in body of fluid **15**. In such an arrangement, delivery tube **12** and dynamic head provider **11** is in an angle to reservoir **13**, handle **24**, pusher **23**, ram **27** frame **28** coupling **29** and power generating ability **14**. Hydraulic Tee joint **30**, also including a seal **31**, capable of transferring movement generated by power generating ability **33**, and sealing body of fluid **15** from dripping proximally, outside of the distal surgical site. This angled arrangement allows linear movement **20**, rotary movement, **22**, combination of movement **21**, to be separately introduced to dynamic head provider **11**, and body of fluid **15** or other components.

Frame **32**, connecting hydraulic Tee joint, **30**, and power generating ability **33**, is described schematically, however frame **33** may be designed integrally, thus frame **33** is imbedded into device **10**.

[0034] **FIG. 5** is describing part of device **10** having a delivery tube **12**, dynamic head provider **11**, reservoir **13** and power generating ability **14**. Mixer **34**, connected to coupling **29** via pusher **23** inside funnel **26**, can generate opposite direction flow regime **36**, further mixing components of body of fluid **15**, or in-direction flow regime **35**, capable of dynamically powering body of fluid **15** into fimel **26** and to delivery tube **12** as to required direction **38**. Moreover, Mixer **34** and dynamic head provider **11**, can be realized integrally as a secondary syringe and a needle system, capable of being integrated inside ram **27** or pusher **23**, creating additional flow regime when subjected to movement **20**. Ram **27** further including seal **37** allowing passage of movements **20**,**21**,**22** (not shown) and sealing body of fluid **15** inside reservoir **13** and ram **27** system. Mixer **34** may be extended into reservoir **13**, and can be made of flexible material such as flexible plastic or Nitinol, capable of collapsing into small volume, at the bottom of reservoir **13** or funnel **26**.

[0035] **FIG. 6** is describing part of device **10**, having ram **27** driven by pusher **23**, minimizing reservoir **13** volume. Ram **27** includes seal **37**, allowing passage of movements **20**,**21**,**22** (not shown) and sealing body of fluid **15** inside reservoir **13** and ram **27** system, via coupling **29**. Inside coupling **29**, seal **39** is holding, allowing passage of movements **20**,**21**,**22** (not shown) and sealing body of fluid **15** inside reservoir **13** and ram **27** system. This arrangement allow passage of independent movements **20**,**21**,**22**, (not shown) between power generating ability **14**, dynamic head provider **11**, and mixer **34**. As a non-limiting example, rotary movement can be transferred to mixer **34**, and mechanical, oscillating electromagnetic or US field to dynamic head provider **11**. Movements can be pure mechanical, activated by electromagnetic ultrasonic fields or pneumatic or hydraulic dissipation or impact, and can be achieved via seal **39**.

[0036] **FIG. 7** is describing part of device **10**, having a delivery tube **12**, dynamic head provider **11**, reservoir **13** and power generating ability **14**. Mixer **34**, connected to coupling **29** via pusher **23** inside funnel **26**. Hydraulic Tee joint, **40**, is mounted over funnel **26**, further including possibility to connect at least a single additional reservoir **41**, capable of holding body of fluid **15**. When ram **42** is pushed in direction **43** and ram **27** is pulled in direction **52**, body of fluid **15** is transferred from reservoir **41** to reservoir **13**, providing easy loading tool and procedure. In this procedure, delivery tube **12** is temporarily plugged by an external device (not shown), or mixer **34** may be operated to draw body of fluid **15**, into reservoir **13**. The system of reservoir **41** and reservoir **13**, allow added hydraulic movement regime, as ram **42** and ram **27** may be operated respectively, with directions **43**, **52**, and against directions **43**, **52**. Ram **42** and ram **27** are subjected to power, generated either by hand or other device, allowing reciprocating movement of body of fluid **15** in such a system. Moreover, part of body of fluid **15** may be in reservoir **13** and another part in reservoir **41**, allowing "mixing when delivered" capability. Reservoir **13**, with installed components, may substitute additional reservoir **41**. Reservoirs **13**,**41** may be incorporated with metering capability, showing amount delivered. Hydraulic Tee joint, **40**, may be provided with capability to hold plurality of reservoir **41**, and stopcocks, (not shown), allowing removal of reservoir **41**, when not required.

[0037] **FIG. 8** is describing shapes of dynamic head provider **11**. Dynamic head provider **11**, may be in a shape of a rod, a cylinder, or any other shape. It may constitute a part of other components of device **10** (not shown), it may be made of relatively stiff material, such as stainless steel, or flexible material such as polymer or Nitinol, capable of rotating, oscillating or moving along a curved axis line, or partly curved axis line. Distal tip of dynamic head provider **11** is designed not to harm the tissue at surgical site. Distal tip of dynamic head provider **11**, may be enclosed inside delivery tube **12**, may be of soft material, when protrude distally from delivery tube **12**, maybe round in shape. All arrangements of dynamic head provider **11** may be hollow, allowing passage of body of fluid **15** or a component of body of fluid **15**. In **FIG. 8***a*, Dynamic head provider **11** may be realized as a lead screw, implementing Archimedes screw principal **45**. When rotated, inside delivery tube **12**, body of fluid **15** (not shown), is transferred along the longitudinal axis. This arrangement is capable of delivering high pressure. The lead angle may be constant or a progressing type, capable of accelerating body of fluid **15** (not shown), when rotated at constant speed. In **FIG. 8***b*, another arrangement is present as taking only a thread from a lead screw, **46**, much like a common coil spring. This arrangement is designed to further give movement to body of fluid **15** (not shown), and breaking the plug flow. The lead angle may be of a progressing type, capable of accelerating body of fluid **15** (not shown), when rotated at constant speed. This arrangement allows minimal dimensions of the dynamic head provider **11**, and delivery tube **12** system.

[0038] In **FIG. 8***c*, another arrangement is present in collapsible form **47**, composed of linear segments **48** and collapsible joints **49**. When subjected to linear movement **20** (not shown) it collapses along the longitudinal axis. Balancing forces and stress in collapsible joint **49**, yields spontaneous release of stress, and amplified movement. This arrangement allows ramming of body of fluid **15** by dynamic head provider **11** out of delivery tube **12**. Arrangement **45**,**46**,**47**, may be hollow inside, allowing additional seepage of another component, either pneumatic or hydraulic, of body of fluid **15** (not shown).

[0039] In **FIG. 8***d*, a side view of dynamic head provider **11** is shown. The shape of a blade is holding inside delivery tube **12**. Such an arrangement can be realized, as a non-limiting example, as a shape of a common spiral drill bit. Front edge **50**, and trailing edge **51**, constitutes a blade, which may be of various shapes. Of coarse, plurality of front edge **50**, and trailing edge **51**, may be used. Front edge **50**, and trailing edge **51**, may touch delivery tube **12**, or be distant, allowing backwash flow, hence providing additional flow regime, breaking the plug flow, holding components inside body of fluid **15**.

[0040] In **FIG. 8***e*, a side view of dynamic head provider **11** is shown. In this arrangement, a dynamic head provider **11** is in a form of rotating spiral **52**. Such a rotating spiral **52**, when collapsing in the longitudinal axis, provides additional movement to body of fluid **15** components.

[0041] **FIG. 9** is describing delivery tube **12**. Delivery tube **12** can be realized as intra-vascular catheter, available from Cordis, U.S.A, a venous cannula, available from Medtronic, U.S.A., A simple tube, made out of any body compatible material of construction, either metal or polymer, of relatively stiff material, such as stainless steel, or flexible material such as polymer or Nitinol, capable of rotating, oscillating or moving along a curved axis line, or partly curved axis line.

[0042] **FIG.** 9*a*, describe the distal tip **53** of delivery tube **12**, designed to allow easy insertion of delivery tube **12** threw the flesh and into surgical site. Distal tip **53** of delivery tube **12** is designed not to harm the tissue at surgical site. Distal tip **53** of delivery tube **12**, may be flat, in any angle relative to longitudinal axis of delivery tube **12**.

[0043] **FIG.** 9*b* further describing the distal tip **53** of delivery tube **12**. Distal tip **53** of delivery tube **12**, may be round or oval in shape, including orifice or plurality of orifice, much like present in venous cannula, available from Medtronic, allowing delivery of body of fluid **15**, and insertion over the pin used in Intra medullary set. Distal tip **53** of delivery tube **12** may be of soft material, easily collapsible inside delivery tube **12**, (shown with dashed line) when forced by external force (not shown).

[0044] **FIG.** 9*c* further describing the distal tip **53** of delivery tube **12**. In this arrangement, several cuts are made to distal tip **53**, to form a one-way valve **54** capable of releasing body of fluid **15** coming from inside delivery tube **12**, into surgical site. When pressure at surgical site is higher than pressure generated by dynamic head provider **11** and ram **27** system, one way valve **54** is closing, holding delivered body of fluid **15** at surgical site.

[0045] **FIG.** 9*d* further introducing one-way valve **55**, inside delivery tube **12**. In this arrangement, reciprocating movement of body of fluid **15**, is governed by one way valves **54**,**55**, creating "peristaltic" distal advance of body of fluid **15** in portions, resulting intermittent movement. Of coarse, plurality of one-way valve **55** may be incorporated inside delivery tube **12**.

[0046] **FIG. 10** is describing the usage of device **10**. The following paragraph is describing usage of device **10** by a non-limiting example relating to Femur bone orthopedic surgery. Of coarse, other procedures may be performed. Described tools are included as Intra medullary set, for orthopedic surgery.

[0047] A small cut is made threw the skin and the Tensor fasciae latae muscle, all the way until the bone line **57** is schematically representing the contour of skin and flesh. The bone is prepared for puncturing. Using Hall drill, or other device, the bone **58**, is drilled with small diameter drill bit, larger than delivery tube **12**. Described procedures may be performed under any available imaging system, Radio, US, CT and the like. Delivery tube **12**, and or dynamic head provider **11**, may be integrated with radio opaque capability, allowing procedure under fluoroscopy. Materials of construction of device **10** can be made of any material suitable for use as surgical device. These materials including, but not limited to, metals, titanium, Nitinol Stainless steel, and polymer materials as pebax, PU. PE, PP, PET, PTFE PVC, or any other body compatible material. Providing delivery tube **12**, and or dynamic head provider **11** of flexible material, allow delivery tube **12**, and or dynamic head provider **11** to bend over and follow channel provided in the bone, as it may be in an arc shape, and the Intra medullary set, does not necessarily providing straight, round, parallel hole.

[0048] **FIG. 10***a*, is showing status when the drill is removed leaving guiding device **59**, usually in a form of a pin, distally at the surgical site, proximal end protruding out from the flesh **57**. Delivery tube **12**, is disassembled from device **10**, and inserted over the guiding device **59**. Body of fluid **15**, is loaded into reservoir **13**. Guiding device **59** is removed from delivery tube **12**, and device **10** is assembled with Delivery tube **12**, and dynamic head provider **11**. Power generating ability **14**, is activated and body of fluid **15** is passing into surgical site, either by gravity and dynamic head or by other methods of static head and dynamic head. Device **10** is moved distally and proximally, to provide cavity for body of fluid **15** to accumulate. Such a movement also used to pack and fill cavity, and such movement is progressing out of the bone, coming proximally. When required volume is delivered, device **10** is removed. **FIG. 10***b* is describing fully assembled device **10**. Device **10** can be use fully assembled and loaded. In such a procedure, a cannula **56** with diameter larger than delivery tube **12** is slide over the guiding device **59**. The guiding device **59** is removed and fully loaded and assembled device **10** is inserted and operated. When moved distally and proximally, to provide cavity for body of fluid **15** to accumulate, the cannula **56** is retracted together with device **10**.

[0049] **FIG. 10***c* is describing procedure for enhancing growth around a prosthesis **60**. This procedure can be used in case surgical site is near the skin, or in case of bone fracture Aa cut is made to expose the surgical site and fully assembled device **10** is used to deliver Body of fluid **15**.

[0050] Described procedures may be performed under any available imaging system, radio, US, CT and the like. Delivery tube **12**, and or dynamic head provider **11**, may be integrated with radio opaque capability, allowing procedure under fluoroscopy. Materials of construction of device **10** can be made of any material suitable for use as surgical device. These materials including, but not limited to, metals, titanium, Nitinol Stainless steel, and polymer materials as pebax, PU. PE, PP, PET, PTFE PVC, or any other body compatible material. Providing delivery tube **12**, and or dynamic head provider **11** of flexible material, allow delivery tube **12**, and or dynamic head provider **11** to bend over and follow channel provided in the bone, as it may be in an arc shape, and the Intra medullary set, does not necessarily providing straight, round, parallel hole.

What is claimed is:

1. Device for delivery body of fluid composed of a liquid solution, and bone flakes comprising Newtonian and Non-Newtonian body of fluid;

device further including means for delivering motion vector to body of fluid;

wherein

said motion vector is holding components of body of fluid in suspension and eliminating plug flow.

2. Device according to claim 1,

wherein

said body of fluid further includes bone marrow.

3. Device according to claim 1,

wherein

said body of fluid further includes stem cells.

4. Device according to claim 1, Said bone flacks compound comprising body of fluid further includes coating with gelling agent,

wherein

said bone flacks gelling agent is holding live tissue cells coating over bone flacks.

5. Device according to claim 1,

wherein

said body of fluid further includes long term drug delivery system.

6. Device according to claim 1, providing motion vector

wherein

said motion vector is described in modified Navier-Stokes equation,

$$\rho\frac{D\vec{V}}{Dt}=\rho\vec{B}-\nabla p+\mu\nabla^2\vec{V}+\vec{F}\delta(x, y, z, \varphi, \theta, t, S).$$

7. Device according to claim 1,

wherein

materials of construction are selected any of a group:

titanium,

Nitinol,

stainless steel,

pebax,

PU. PE, PP,

PET,

PTFE.

8. Device for delivery body of fluid composed of a liquid solution, living tissue cells and bone flakes;

device including reservoir for holding body of fluid, said device further including provision for static head, provision for dynamic head, provisions for power generating ability, and a delivery tube,

and

means for delivering motion vector to body of fluid;

wherein

applying static head makes body of fluid run inside delivery tube

and

means for delivering motion vector to body of fluid is braking the

plug flow, holding components of body of fluid in suspension flow.

9. Device as to claim 8

wherein

static head produced due to gravity.

10. Device as to claim 8

wherein

means for delivering motion vector to body of fluid is selected any of a group:

mechanically moving member,

ultrasound oscillations,

electromagnetic fields,

hydraulic bleeding,

hydraulic impact,

pneumatic seepage.

11. Device as to claim 8

wherein

delivering motion vector to body of fluid is selected any of a group:

Archimedes lead screw principle, with or without provision for backwash,

a thread, in a form of a coil spring

a thread, in a form of a spiral,

a ram, capable of ramming small portions of body of fluid all the way out of delivery tube,

a collapsible ram,

hollow member,

integrally with delivery tube,

integrally with reservoir,

integrally with device.

12. Device as to claim 8, further including a mixer.

13. Device as to claim 8, including power generating ability

wherein

movements are any selected from a group:

linear movement,

rotary movement,

linear and rotary movement,

timed linear and then timed rotary,

thus producing required flow regime for body of fluid, braking the plug flow, holding components of body of fluid in suspension flow.

14. Device according to claim 8, further include pusher, couplings and seals

wherein

coupling and seals may extend via pusher, or may be in an angle to each other, providing capability of transferring movements either separately or together, while seals keep body of fluid inside the device.

15. Device according to claim 8,

wherein

delivery tube includes at least a single one way valve.

16. Device as to claim 8, further including plurality of reservoir.

17. Device as to claim 16,

wherein

any of plurality reservoir is used to maintain flow of body of fluid between reservoirs,

delivering motion vector to body of fluid, braking the plug flow, holding components of body of fluid in suspension flow.

18. Device as to claim 16,

wherein

any of plurality reservoir is used to add another component to body of fluid,

providing mixing when delivered capability.

19. Device for delivery body of fluid composed of a liquid solution, living tissue cells and bone flakes;

device including reservoir for holding body of fluid, said reservoir further including provision for static head, provision for dynamic head,

provisions for power generating ability, and a delivery tube,

device is further including means for delivering motion vector to body of fluid,

said means for delivering motion vector to body of fluid is braking the plug flow, holding components of body of fluid in suspension flow,

wherein

said means for delivering motion vector to body of fluid, and said delivery tube are of flexible material, capable of operating when longitudinal axis is curved.

20. A method for minimally invasive surgery, said surgery providing delivery body of fluid composed of a liquid solution, living tissue cells and bone flakes susceptible of fast settling and plug flow, and, a delivery device, said device including reservoir for holding body of fluid, said device further including provision for static head, provision for dynamic head, provisions for power generating ability, and a delivery tube,

wherein

loading reservoir of said device with body of fluid compound,

providing minimal cut threw the skin and flesh,

preparing the bone for delivery of said body of fluid,

inserting delivery tube of said delivery device threw the flesh into the surgical site operating said power generating ability,

providing static head,

providing dynamic head, said dynamic head having means for delivering motion vector to body of fluid is braking the plug flow, and holding components of body of fluid in suspension flow,

delivering body of fluid to surgical site,

advancing said delivery device around surgical site,

advancing said delivery device out of surgical site while maintaining delivery, until all required amount of said body of fluid is delivered,

removing said delivery device out of the flesh and skin.

21. A method according to claim 11, further including preparing the bone for delivery of said body of fluid,

providing an opening into the bone, larger than said delivery tube,

inserting a cannula larger than said delivery tube,

inserting said delivery device threw said cannula into surgical site,

operating said power generating ability,

providing static head,

providing dynamic head, said dynamic head having means for delivering motion vector to body of fluid is braking the plug flow, and

holding components of body of fluid in suspension flow,

delivering body of fluid to surgical site advancing said delivery device around surgical site advancing said delivery device out of surgical site while maintaining delivery, until all required amount of said body of fluid is delivered,

removing said delivery device out of the flesh and skin.

22. A method according to claim 11, further including preparing the bone for delivery of said body of fluid,

providing an opening into the bone, larger than said delivery tube,

inserting a guiding device smaller than said delivery tube,

inserting said delivery tube separate from said delivery device over the guiding device into surgical site,

removing the guiding device,

assembling said deliver device over said delivery tube comprising complete delivery device,

operating said power generating ability,

providing static head,

providing dynamic head, said dynamic head having means for delivering motion,

vector to body of fluid is braking the plug flow,

holding components of body of fluid in suspension flow,

delivering body of fluid to surgical site,

advancing said delivery device around surgical site,

advancing said delivery device out of surgical site while maintaining delivery, until all required amount of said body of fluid is delivered,

removing said delivery device out of the flesh and skin.

* * * * *

patsnap

专利名称(译)	用于输送快速分离的流体体的装置和方法，形成骨重建介质
公开(公告)号	US20050013805A1
公开(公告)日	2005-01-20
申请号	US10/890169
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[标]申请(专利权)人(译)	TAVORI伊扎克
申请(专利权)人(译)	TAVORI伊扎克
当前申请(专利权)人(译)	TAVORI伊扎克
[标]发明人	TAVORI ITZHAK
发明人	TAVORI, ITZHAK
IPC分类号	A61B A61B17/00 A61F2/28 A61F2/36 A61F2/46 A61K45/00 A61M31/00 B01F11/00 B01F13/00
CPC分类号	A61B17/00234 A61F2/36 A61F2/4601 B01F13/0023 A61F2002/4636 B01F11/0071 B01F13/002 A61F2002/2835 A61F2002/4635
优先权	156945 2003-07-15 IL
外部链接	Espacenet USPTO

摘要(译)

用于液体溶液和骨料颗粒状薄片的输送组件。该装置能够递送多组分化合物，例如三维系统，液体溶液，活组织细胞和骨质颗粒状薄片，或多种化合物，以形成骨重建化合物并递送它。输送的流体体经受静压头和动态头部疏通沉降组分并将它们保持为流体体。该装置包括储存器，输送管，移动构件，设计成移动并向所述管中的流体提供力或运动矢量，所述储存器连接到所述输送管，通道允许流体体通过通过重力，由混合装置或静压头提供的动态头。

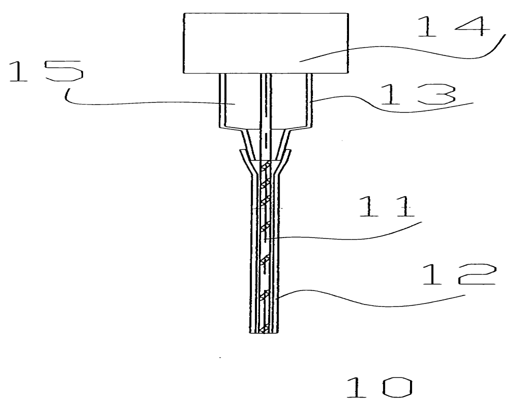

Fig 1