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TREATING BACK PAIN BY RE-ESTABLISHING THE EXCHANGE OF NUTRIENT & WASTE

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FIELD OF INVENTION

This invention relates to methods and devices for transporting nutrients and waste into and out of the intervertebral disc to halt or reverse the degeneration of the intervertebral disc.

BACKGROUND

10 Low back pain is a leading cause of disability and lost productivity. Up to 90% of adults experience back pain at some time during their lives. For frequency of physician visits, back pain is second only to upper respiratory infections. In the United States the economic impact of this malady has been reported to range from \$50-\$100 billion each year, disabling 5.2 million people. Though the sources of low back pain are varied, in many cases the
15 intervertebral disc is thought to play a central role. Degeneration of the disc initiates pain in other tissues by altering spinal mechanics and producing non-physiologic stress in surrounding tissues.

The intervertebral disc **100** absorbs most of the compressive load of the spine, but the facet joints **142**, **143** of the vertebral bodies **159** share approximately 16%. The disc **100**
20 consists of three distinct parts: the nucleus pulposus **128**, the annular layers and the cartilaginous endplates **105**, as shown in Figures 1 and 2. The disc **100** maintains its structural properties largely through its ability to attract and retain water. A normal disc **100** contains 80% water in the nucleus pulposus **128**. The nucleus pulposus **128** within a normal disc **100** is rich in water absorbing sulfated glycosaminoglycans, creating the swelling
25 pressure to provide tensile stress within the collagen fibers of the annulus. The swelling pressure produced by high water content is crucial to supporting the annular layers for sustaining compressive loads, as shown in a longitudinal view in Figure 2.

In adults, the intervertebral disc **100** is avascular. Survival of the disc cells depends on diffusion of nutrients from external blood vessels **112** and capillaries **107** through the cartilage
30 **106** of the endplates **105**, as shown in Figure 2. Diffusion of nutrients also permeates from peripheral blood vessels adjacent to the outer annulus, but these nutrients can only permeate



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up to 1 cm into the annular layers of the disc **100**. An adult disc can be as large as 5 cm in diameter; hence diffusion through the cranial and caudal endplates **105** is crucial for maintaining the health of the nucleus pulposus **128** and inner annular layers of the disc **100**.

Calcium pyrophosphate and hydroxyapatite are commonly found in the endplate **105** and
5 nucleus pulposus **128**. As young as 18 years of age, calcified layers **108** begin to accumulate in the cartilaginous endplate **105**, as shown in Figure 3. The blood vessels **112** and capillaries **107** at the bone-cartilage interface are gradually occluded by the build-up of the calcified layers **108**, which form into bone. Bone formation at the endplate **105** increases with age.

When the endplate **105** is obliterated by bone, diffusion between the nucleus pulposus **128**
10 and blood vessels **112** beyond the endplate **105** is greatly limited. In addition to hindering the diffusion of nutrients, calcified endplates **105** further limit the permeation of oxygen into the disc **100**. Oxygen concentration at the central part of the nucleus **128** is extremely low. Cellularity of the disc **100** is already low compared to most tissues. To obtain necessary nutrients and oxygen, cell activity is restricted to being on or in very close proximity to the
15 cartilaginous endplate **105**. Furthermore, oxygen concentrations are very sensitive to changes in cell density or consumption rate per cell.

The supply of sulfate into the nucleus pulposus **128** for biosynthesizing sulfated glycosaminoglycans is also restricted by the calcified endplates **105**. As a result, the sulfated glycosaminoglycan concentration decreases, leading to lower water content and swelling
20 pressure within the nucleus pulposus **128**. During normal daily compressive loading on the spine, the reduced pressure within the nucleus pulposus **128** can no longer distribute the forces evenly along the circumference of the inner annulus to keep the lamellae bulging outward. As a result, the inner lamellae sag inward, while the outer annulus continues to bulge outward, causing delamination **114** of the annular layers, as shown in Figures 3 and 4.

25 The shear stresses causing annular delamination and bulging are highest at the posteriolateral portions adjacent to the neuroforamen **121**. The nerve **194** is confined within the neuroforamen **142** between the disc and the facet joint **142**, **143**. Hence, the nerve **194** at the neuroforamen **121** is vulnerable to impingement by the bulging disc **100** or bone spurs.

When oxygen concentration in the disc falls below 0.25 kPa (1.9 mm Hg), production of
30 lactic acid dramatically increases with increasing distance from the endplate **105**. The pH within the disc **100** falls as lactic acid concentration increases. Lactic acid diffuses through

micro-tears of annulus irritating the richly innervated posterior longitudinal ligament 195, facet joint and/or nerve root 194. Studies indicate that lumbar pain correlates well with high lactate levels and low pH. The mean pH of symptomatic discs was significantly lower than the mean pH of the normal discs. The acid concentration is three times higher in symptomatic
5 discs than normal discs. In symptomatic discs with pH 6.65, the acid concentration within the disc is 5.6 times the plasma level. In some preoperative symptomatic discs, nerve roots 194 were found to be surrounded by dense fibrous scars and adhesions with remarkably low pH 5.7-6.30. The acid concentration within the disc was 50 times the plasma level.

Approximately 85% of patients with low back pain cannot be given a precise
10 pathoanatomical diagnosis. This type of pain is generally classified under "non-specific pain". Back pain and sciatica can be recapitulated by maneuvers that do not affect the nerve root, such as intradiscal saline injection, discography, and compression of the posterior longitudinal ligaments. It is possible that some of the non-specific pain is caused by lactic acid irritation secreted from the disc. Injection into the disc can flush out the lactic acid. Maneuvering and
15 compression can also drive out the irritating acid to produce non-specific pain. Currently, no intervention other than discectomy can halt the production of lactic acid.

The nucleus pulposus 128 is thought to function as "the air in a tire" to pressurize the disc 100. To support the load, the pressure effectively distributes the forces evenly along the circumference of the inner annulus and keeps the lamellae bulging outward. The process of
20 disc degeneration begins with calcification of the endplates 105, which hinders diffusion of sulfate and oxygen into the nucleus pulposus 128. As a result, production of the water absorbing sulfated glycosaminoglycans is significantly reduced, and the water content within the nucleus decreases. The inner annular lamellae begin to sag inward, and the tension on collagen fibers within the annulus is lost. The degenerated disc 100 exhibits unstable
25 movement, similar to a flat tire. Approximately 20-30% of low-back-pain patients have been diagnosed as having spinal segmental instability. The pain may originate from stress and increased load on the facet joints and/or surrounding ligaments. In addition, pH within the disc 100 becomes acidic from the anaerobic production of lactic acid, which irritates adjacent nerves and tissues.

30 Resilient straightening of a super elastically curved needle within a rigid needle is described in prior art DE 44 40 346 A1 by Andres Melzer filed on November 14, 1994 and FR

2 586 183 - A1 by Olivier Troisier filed on August 19, 1985. The curved needles of these prior art are used to deliver liquid into soft tissue. In order to reach the intervertebral disc without an external incision, the lengths of the curved and rigid needles must be at least six inches (15.2 cm). There are multiple problems when attempting to puncture the calcified endplate as described in the prior art. Shape memory material for making the curved needle usually is elastic. Nickel-titanium alloy has Young's modulus approximately 83 GPa (austenite), 28-41 GPa (martensite). Even if the handles of both the curved and rigid needles are restricted from twisting, the long and elastically curved needle 101 is likely to twist within the lengthy rigid needle 220 during endplate 105 puncturing, as shown in Figures 54 and 55. As a result, direction of puncture is likely to be deflected and endplate 105 puncture would fail.

Furthermore, in the prior art, the sharp tips of their rigid needles are on the concave sides of the curved needles. When puncturing a relatively hard tissue, such as calcified endplates 105, the convex sides of the curved needles are unsupported and vulnerable to bending, resulting in failure to puncture through the calcified endplates 105. To minimize bending or twisting, the sizes of their curved and rigid needles are required to be large. By increasing the sizes of the curved 101 and rigid 220 needles, friction between the curved 101 and rigid 220 needles greatly increases, making deployment and retrieval of the curved needle 101 very difficult. In addition, a large opening created in the disc 100 by the large needles may cause herniation of the nucleus pulposus 128. Similarly, a large opening at the endplate 105 may cause Schmorl's nodes, leakage of nucleus pulposus 128 into the vertebral body 159.

In essence, the support from the distal end of the rigid needle 220 in Figures 62-67 of this invention is relevant to support puncturing of a relatively hard tissue, such as calcified endplate 105 with a small diameter needle 101. Furthermore, the non-round cross-sections of the curved 101 and rigid 220 needles in Figures 56-60 to prevent twisting are also relevant to ensure successful puncturing through the calcified endplate 105.

SUMMARY OF INVENTION

In this invention, conduits are delivered through the calcified endplates to re-establish the exchange of nutrients and waste between the disc and vertebral bodies. The conduit is delivered within an elastically curved needle. The curved needle is resiliently straightened within a rigid needle. The rigid needle punctures into a degenerating disc with calcified

endplates. The elastically curved needle carrying the conduit is then deployed from the rigid needle to resume the curved configuration and puncture through the calcified endplate. By retrieving the curved needle back into the rigid needle while holding a plunger behind the conduit stationary, the conduit is deployed across the endplate to transport nutrients and waste
5 between the disc and vertebra.

The puncturing device in this invention is designed to minimize twisting and friction between the curved and rigid needles. The device also provides support to the elastically curved needle to minimize bending during endplate puncturing. In addition, the device is designed to deliver at least one conduit at the endplate to bridge between the avascular
10 intervertebral disc and the vertebral body for exchange of nutrients, oxygen, carbon dioxide, lactate and waste.

Nutrients and oxygen are abundantly supplied by peripheral blood vessels near the outer annulus. Conduits can also be deployed transverse the degenerating disc to draw nutrients from the outer annulus into the nucleus pulposus to halt disc degeneration.

After nutrient and waste exchange is re-established by the semi-permeable conduits, stem cells, growth factor or gene therapeutic agents can be injected into the disc to promote regeneration. In addition, the disc with semi-permeable conduits is still immunoisolated. Donor cells injected into the disc can be nourished by nutrients through the semi-permeable conduits without triggering an immune response. These cells are selected for their capability
20 to biosynthesize therapeutic agents, such as insulin and neurotransmitters. The therapeutic agents are transported through the semi-permeable conduits into body circulation to treat a disease.

REFERENCE NUMBER

100	Intervertebral disc	108	Blockade or calcified layers
25 101	Needle	109	Plunger
102	Bevel or tapering	110	Monofilament
103	Trocar	112	Blood vessels
104	Lumen or channel of conduit	113	Tissue gripping flange
105	Endplate	114	Annular delamination
30 106	Hyaline cartilage	115	Epiphysis
107	Capillaries	116	Penetration marker

121	Neuroforamen	160	Tissue ingrowth indentation
122	Braided multi-filament	161	Knot
123	Spinal cord	162	Protrusion or ring
124	Porous conduit	163	Coating
5 125	Tube	184	Impingement
126	Conduit	193	Psoas muscle
127	Electronic cutter or laser	194	Nerve root
128	Nucleus pulposus	195	Posterior longitudinal ligament
129	Facet joint	121	Neuroforamen
10 130	Handle of curve needle	217	Screw entry
131	Guide rail of curve needle handle	220	Rigid sleeve or needle
132	Handle of rigid sleeve	224	Puncture
133	Track of rigid sleeve handle	230	Dilator
134	Electronic cutting device	268	Lumen of rigid sleeve
15 135	Electric cord	269	Lumen of rigid needle
140	Sacrum	270	Window of rigid sleeve
142	Superior articular process	271	Shape memory extension
143	Inferior articular process	272	Ramp in lumen of rigid needle
153	Label indicating curved direction	276	Syringe
20 159	Vertebral body	277	Donor cells

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts a healthy disc **100** with normal swelling pressure within the nucleus pulposus **128** to support the layers of annulus during compressive loading.

Figure 2 shows a longitudinal view of a spine segment, displaying outward bulging of annular layers during compression of a healthy disc **100** between cartilaginous **106** endplates **105**.

Figure 3 shows that the calcified layers **108** of the endplates **105** hinder diffusion of nutrients between the inner disc **100** and the vertebral bodies **159**, leading to inward bulging and annular delamination **114**.

Figure 4 depicts a degenerated and flattened disc with reduced swelling pressure within the nucleus pulposus **128** and annular delamination.

Figure 5 depicts trocar **103** insertion into the disc **100** using the guiding technique similar to that used in discography.

Figure 6 shows insertion of a dilator **230** over the trocar **103**.

Figure 7 depicts withdrawal of the trocar **103**. The dilator **230** acts as a passage leading
5 into the disc **100**.

Figure 8 shows a longitudinal view of the degenerated spinal segment with insertion of the dilator **230**.

Figure 9 depicts an elastically curved needle **101**.

Figure 10 shows the elastic needle **101** being resiliently straightened within a rigid sleeve
10 **220**.

Figure 11 shows a round cross-section of the needle **101** within the rigid sleeve **220**.

Figure 12 depicts insertion of the resiliently straightened needle **101** within the rigid sleeve **220** into the dilator **230** leading into the disc **100**.

Figure 13 shows a longitudinal view of the needle **101** and sleeve **220** assembly inserted
15 into the dilator **230** leading into the disc **100**.

Figure 14 depicts upward puncturing of the needle **101** into the endplate **105** (not shown) by deploying the resiliently straightened needle **101** from the rigid sleeve **220**.

Figure 15 shows endplate **105** puncturing through the calcified layers **108** by deploying the curved needle **101** from the rigid sleeve **220**.

Figure 16 depicts permeation of water, nutrients and metabolites through the puncture
20 sites **224** of the superior and inferior endplates **105**.

Figure 17 depicts re-establishment of swelling pressure by the renewed biosynthesis of glycosaminoglycan within the nucleus pulposus **128**.

Figure 18 depicts an electronic device **134** empowering a cutter **127** to puncture, drill,
25 abrade or cauterize through the calcified endplate **105**.

Figure 19 depicts a conduit **126** in the form of an elastic tube **125** with tissue-holding flanges **113** and longitudinal opening **104**.

Figure 20 shows insertion of the elastic tube **125** onto the elastically curved needle **101** with a sliding plunger **109** abutting the tube **125**.

Figure 21 depicts the needle **101** carrying the elastic tube **125** being resiliently
30 straightened within the rigid sleeve **220**.

Figure 22 shows insertion of the needle **101**, elastic tube **125**, sleeve **220** and plunger **109** into the dilator **230**.

Figure 23 depicts deployment of the needle **101** delivering the tube **125** through the calcified layer **108** of the endplate **105**.

5 Figure 24 shows withdrawal of the needle **101** while holding the plunger **109** stationary to dislodge the tube **125** from the needle **101**.

Figure 25 shows the lower portion of the tube **125** dislodged within the nucleus pulposus **128** and the top portion deployed within the cranial vertebral body **159** (not shown) through the endplate **105** (also not shown).

10 Figure 26 depicts stacking of a square handle **130** of the curved needle **101** within a handle **132** of the rigid sleeve **220** to avoid rotation between the needle **101** and sleeve **220**.

Figure 27 depicts a handle **130** of the elastically curved needle **101**, containing guide rails **131** and an orientation line **153** to show the direction of the curvature.

15 Figure 28 shows tracks **133** on a handle **132** of the rigid sleeve **220** with orientation line **153** and penetration markers **116**.

Figure 29 depicts the assembly with the rails **131** in the tracks **133** to avoid rotation between the needle **101** and the sleeve **220**.

Figure 30 shows resumption of the curvature as the elastically curved needle **101** is deployed from the rigid sleeve **220**.

20 Figure 31 shows oval cross-sections of the needle **101** and the rigid sleeve **220** to prevent rotation between the needle **101** and sleeve **220**.

Figure 32 indicates square cross-sections of the needle **101** within the sleeve **220**.

Figure 33 depicts rectangular cross-sections of the needle **101** within the sleeve **220**.

Figure 34 shows triangular cross-sections of the needle **101** within the sleeve **220**.

25 Figure 35 depicts a conduit **126** made as a small tube **125** with a longitudinal channel **104**.

Figure 36 indicates a conduit **126** made as a braided tube **125** with a longitudinal channel **104**.

Figure 37 shows a conduit **126** made with porous material in a tubular form **125**.

Figure 38 depicts a conduit **126** made as a braided suture **122** or braided thread **122**.

30 Figure 39 indicates a conduit **126** made with a flexible porous or spongy fiber **124**.

Figure 40 shows a conduit **126** abutting against a plunger **109** within a lumen **269** of an elastically curved needle **101**.

Figure 41 shows a bevel **102** at the distal end of the lumen **268** of the rigid sleeve **220** to minimize friction during deployment and retrieval of the curved needle **101**.

5 Figure 42 depicts the elastically curved needle **101** with the conduit **126** being resiliently straightened within a rigid sleeve **220**.

Figure 43 indicates insertion of the assembly containing the needle **101**, conduit **126**, plunger **109** and sleeve **220** into a dilator **230**.

Figure 44 shows deployment of the curved needle **101** through the calcified endplate **105**.

10 Figure 45 depicts dislodgement of the conduit **126** by withdrawing the needle **101** while holding the plunger **109** stationary.

Figure 46 depicts insertion of the needle **101**, conduit **126**, plunger **109** and sleeve **220** assembly into the dilator **230** leading into disc **100**.

Figure 47 shows deployment of the curved needle **101** through the calcified endplate **105**.

15 Figure 48 depicts withdrawal of the needle **101** while the plunger **109** is held stationary to dislodge the conduit **126** through the calcified endplate **105**.

Figure 49 shows a portion of the conduit **126** within the nucleus pulposus **128** and the remaining portion within the vertebral body through the endplate (not shown).

Figure 50 depicts two conduits **126** within the lumen **269** of the needle **101**.

20 Figure 51 shows deployment of two conduits **126** through superior and inferior calcified endplates **105**.

Figure 52 indicates disc **100** height restoration from regained swelling pressure within the nucleus pulposus **128** following the re-establishment of nutrient and waste exchange.

25 Figure 53 depicts two conduits **126** extending from the nucleus pulposus **128** into superior and inferior vertebral bodies **159** through the calcified endplates **105** (not shown).

Figure 54 depicts twisting of the curved needle **101** within the rigid sleeve **220** during endplate **105** puncturing. The cross-section is shown in Figure 62.

Figure 55 shows the cross-sectional view of Figure 61. The elastic needle **101** twists or rotates within the rigid sleeve **220**.

30 Figure 56 depicts prevention of twisting by using a needle **101** and sleeve **220** with elliptical cross-sections.

Figure 57 shows a cross-sectional view of the elliptical needle **101** within the elliptical sleeve **220**, depicted in Figure 63, to limit rotational movement.

Figure 58 indicates a square cross-section of the needle **101** and sleeve **220**.

Figure 59 indicates a rectangular cross-section of the needle **101** and sleeve **220**.

5 Figure 60 indicates a triangular cross-section of the needle **101** and sleeve **220**.

Figure 61 depicts bending or drooping of the curved needle **101** during endplate **105** puncturing.

Figure 62 shows a sharpened end or tip of the rigid needle **220** providing support beneath the convex side of the curved needle **101** to reduce bending or drooping during puncturing.

10 Figure 63 depicts an extended distal end of the rigid needle **220** to lengthen the support beneath the convex side of the curved needle **101** during endplate **105** puncturing.

Figure 64 shows a window **270** near the distal end of a sleeve **220** with an elliptical cross-section. The distal portion of the window **270** is slanted or sloped to conform to the curved needle **101**.

15 Figure 65 depicts the sharp tip of the elastically curved needle **101** located on the concave side of the curvature for ease of protrusion through the window **270**.

Figure 66 shows support of the convex side of the curved needle **101** by the distal pocket of the window **270** to strengthen the needle **101** to puncture endplate **105**.

Figure 67 shows a rigid needle **220** with the window **270**.

20 Figure 68 depicts the elastically curved needle **101** within a curved shape memory extension **271**. Both curved needle **101** and extension **271** are housed within a rigid sleeve **220**.

Figure 69 shows resilient straightening of the shape memory extension **271** within the rigid sleeve **220**.

25 Figure 70 shows endplate **105** puncturing by the fortified curved needle **101** without increasing the size of the endplate **105** puncture.

Figure 71 shows a sharpened shape memory extension **271** to support endplate **105** puncturing.

30 Figure 72 shows a longitudinal cross section of a curved needle **101** with non-uniform outer diameter, supported by a ramp **272** within the lumen **268** of the rigid needle **220**.

Figure 73 depicts a conduit **126** containing a multi-filament **122** section and a tubular **125** section.

Figure 74 shows a multi-filament **122** with a tube **125** at the mid-portion to prevent mineralization or clotting, especially around the endplate **105**.

5 Figure 75 depicts a monofilament **110** within the multi-filament **122** to assist deployment.

Figure 76 shows degradable tubes (shaded) **125** covering both ends of a multi-filament **122** to prevent bunching during deployment from the curved needle **101**.

Figure 77 shows the needle **101** carrying the conduit **126** transverse the degenerating disc **100**.

10 Figure 78 depicts a longitudinal view of Figure 84 to deliver a conduit **126** transverse a degenerating disc **100**.

Figure 79 depicts withdrawal of the needle **101** while holding the plunger **109** stationary to deploy or dislodge the conduit **126** within the degenerating disc **100**.

15 Figure 80 depicts drawing of nutrients from the outer annulus into the nucleus pulposus **128** through capillary action or convection flow within the conduit **126**.

Figure 81 depicts a radiopaque, echogenic or magnetic coating **163** on the needle **101** to indicate the location of the conduit **126** within the needle **101**.

Figure 82 shows two conduits **126** inserted through the disc **100** to exchange nutrients and waste between the outer annulus and the nucleus pulposus **128**.

20 Figure 83 depicts the distal tip of the needle **101** penetrating beyond the intervertebral disc **100**.

Figure 84 shows the length of the conduit **126** extending beyond the disc **100** to maximize exchange of nutrients and waste.

25 Figure 85 depicts restoration of swelling pressure within the nucleus pulposus **128** enabling it to sustain compressive loading.

Figure 86 shows a conduit **126** extending into the Psoas major muscle **193** for nutrient and waste exchange to nourish and/or regenerate the disc **100**.

Figure 87 depicts two conduits **126** extending into both Psoas major muscles **193** to expedite nutrient and waste exchange to nourish and/or regenerate the disc **100**.

30 Figure 88 depicts a series of knots **161** tied on a multi-filament **122** to prevent or minimize conduit **126** migration with time.

Figure 89 shows rings **162** or protrusions on the conduit **126** to prevent or minimize migration with time.

Figure 90 shows indentations **160** to promote tissue ingrowth and prevent or minimize conduit **126** migration with time.

5 Figure 91 shows injection of donor cells **277** through a syringe **276** into a disc **100** containing conduits **126** through cranial and caudal endplates **105**.

Figure 92 shows injection of donor cells **277** through a syringe **276** into a disc **100** with conduits **126** transverse the disc **100** and extending into muscles **193**.

DETAILED DESCRIPTION OF THE EMBODIMENTS

10 Since diffusion from the endplate **105** is crucial for maintaining the intervertebral disc, effort is made to re-establish nutrient and waste exchange between the nucleus pulposus and circulation within the vertebral body. Guided by anteroposterior and lateral views from fluoroscopes, a trocar **103** enters posteriolaterally, 45° from mid-line into the disc **100**, as shown in Figure 5. This guiding technique is similar to the one used in diagnostic injection of
15 radiopaque dye for discography or chymopapain injection for nucleus pulposus digestion. A dilator **230** is inserted over the trocar **103**, as shown in Figure 6. The trocar **103** is then withdrawn. The dilator **230** remains as a passage leading into the disc **100**, as shown in Figure 7. Figure 8 shows the distal end of the dilator **230** near the nucleus pulposus **128** of the degenerating disc **100**.

20 An elastically curved needle **101**, as shown in Figure 9, is resiliently straightened in a rigid sleeve **220** indicated in Figure 10. The round cross section of the straightened needle **101** and sleeve **220** is shown in Figure 11. The resiliently straightened needle **101** within the rigid sleeve **220** is inserted into the dilator **230** and the disc **100**, as shown in Figure 12. A longitudinal view of the needle **101** insertion into the degenerating disc **100** is indicated in
25 Figure 13. The elastically curved needle **101** is deployed by holding the rigid sleeve **220** stationary while pushing the needle **101** inward. The needle **101** resumes the curved configuration as it exits the distal opening of the sleeve **220**, puncturing upward as shown in Figure 14, through the cartilage **106** and calcified layers **108** into the vertebral body **159**, as indicated in Figure 15.

30 Multiple endplate **105** punctures **224** can be accomplished to re-establish the exchange of nutrients and waste between the disc **100** and bodily circulation. After retrieving the

elastically curved needle **101** into the sleeve **220**, the assembly of needle **101** and sleeve **220** can be further advanced into or slightly withdrawn from the disc **100** to puncture more holes **224** through the calcified cranial endplate **105**. By turning the assembly of needle **101** and sleeve **220** 180° , the caudal endplate **105** can also be punctured, as shown in Figure 16, to re-establish the exchange of nutrients, oxygen and waste through the superior and inferior endplates **105**. Figure 17 indicates restoration of swelling pressure within the nucleus pulposus **128** enabling the disc **100** to sustain compressive loads. With the presence of oxygen within the disc **100**, production of lactic acid may also decrease and ease chemical irritation and pain.

Endplate **105** puncturing can also be accomplished by electronic devices **134**, such as a laser, cutting or abrading device. Figure 18 depicts an electronic device **134** powering a cutter **127** to puncture, drill, abrade or cauterize the endplate **105** to re-establish the exchange of nutrients and waste. The electronic device **134** can be a cautery, laser, or drill.

Re-establishing the exchange of nutrients and waste through the calcified endplate **105** can also be accomplished using a conduit **126**. A conduit **126** can be an elastic tube **125** with a lumen or channel **104** and tissue-holding flanges **113** at both ends, as shown in Figure 19. The orientations of the flanges **113** located at both ends of the conduit **126** are counter gripping to anchor onto the endplate **105**. The tube **125** is inserted over the elastically curved needle **101** and abutting a sliding plunger **109**, as shown in Figure 20. The needle **101** carrying the elastic tube **125** is resiliently straightened within the rigid sleeve **220**, as depicted in Figure 21. The assembly of the straightened needle **101**, tube **125**, sleeve **220** and plunger **109** is inserted into the dilator **230**, as shown in Figure 22, and into the disc **100**. As the resilient needle **101** carrying the tube **125** is deployed from the rigid sleeve **220**, the curvature of the needle **101** resumes and punctures through the calcified endplate **105**, as shown in Figure 23. The needle **101** is withdrawn while the plunger **109** is held stationary to dislodge the tube **125** from the needle **101** into the endplate **105**, as shown in Figure 24. The lumen **104** of the tube **125** acts as a passage for exchanging nutrients, gases and waste between the vertebral body **159** and the inner disc **100**. A portion of the tube **125** is in the nucleus pulposus **128** or inner disc **100**, while the remaining portion is within the vertebral body (not shown) in Figure 25.

The handle **130** of the curved needle **101** and the handle **132** of the rigid sleeve **229** are used to maintain the direction of needle **101** deployment. The square handle **130** of the curved needle **101** is stacked within the handle **132** of the rigid sleeve **220**, as shown in Figure 26, to avoid rotation between the needle **101** and sleeve **220**. The handle **130** of the needle

5 **101** can also contain guide rails **131**, as shown in Figure 27. The guide rails **131** are sized and configured to fit within the sunken tracks **133** on the handle **132** of the rigid sleeve **220**, as indicated in Figure 28. Direction of the needle's curvature is indicated by the orientation lines **153** on the handle **130** of the needle **101**, as shown in Figure 27, and on the rigid sleeve **220** as shown in Figure 28. To indicate depth of insertion into the body, penetration markers **116** are

10 labeled on the sleeve **220**, as shown in Figure 28. The guide rails **131** within the tracks **133** keep the handles **130**, **132** from rotating around each other, as shown in Figure 29. As the resiliently straightened needle **101** advances and protrudes from the rigid sleeve **220**, the curvature of the needle **101** resumes, as shown in Figure 30. Since the handle **130** of the needle **101** and the handle **132** of the sleeve **220** are guided by the rails **131** in tracks **133**, the

15 direction of needle **101** puncturing is established and predictable for the operator or surgeon.

Non-circular cross-sections of the needle **101** and rigid sleeve **220** can also prevent rotation. Figure 31 shows a needle **101** and a sleeve **220** with oval cross-section. Figure 32 indicates a square cross-section. Figure 33 depicts a rectangular cross-section. Figure 34 shows a triangular cross-section.

20 Conduits **126** can also be made small enough to fit within the lumen of the elastically curved needle **101**. A conduit **126** can be a small tube **125** with a longitudinal channel **104**, as shown in Figure 35, for transporting nutrients, oxygen and waste dissolved in fluid. The tubular conduit **126** with a lumen **104** can be braided or weaved with filaments, as shown in Figure 36. The fluid can be transported through the lumen **104** as well as permeated through

25 the braided filaments of the tube **125**. The tubular conduit **126** can also be molded or extruded with porous or spongy material, as shown in Figure 37, to transport nutrients, oxygen and waste dissolved in fluid through the lumen **104** as well as through the pores.

Nutrients, oxygen, lactate, metabolites, carbon dioxide and waste can also be transported in fluid through capillary action of multi-filaments or braided filaments **122**, as shown in

30 Figure 38. A conduit **126** may not require the longitudinal lumen **104** as mentioned. A strand of braided filaments **122** can be a suture with channels formed among weavings of the

filaments, capable of transporting fluid with nutrients, gases and waste. The braided filaments 122 can be coated with a stiffening agent, such as starch, to aid deployment using the plunger 109. Similar to the channels formed by the braided filaments 122, a conduit 126 made as a spongy thread 124, as shown in Figure 39, can also transport fluid with nutrients, gases and wastes through the pores and channels formed within the porous structure.

A conduit 126 is inserted into a longitudinal opening 269 of an elastically curved needle 101 abutting a plunger 109, as shown in Figure 40. To minimize friction between the curved needle 101 and the rigid sleeve 220, the distal end of the lumen 268 of the sleeve 220 is angled or tapered with a bevel 102 or an indentation, conforming to the concave curvature of the needle 101, as shown in Figure 41. A lubricant or coating to lower friction can also be applied on the surface of the elastically curved needle 101 and/or within the lumen 268 of the rigid sleeve 220. The elastically curved needle 101 carrying the conduit 126 is resiliently straightened within a rigid sleeve 220, as shown in Figure 42. The assembly is then inserted into a dilator 230, as indicated in Figure 43, which leads into the disc 100. As the resiliently straightened needle 101 is deployed from the sleeve 220, the needle 101 carrying the conduit 126 resumes the curved configuration and punctures into the cartilaginous endplate 105 through the calcified layers 108, as shown in Figure 44. The elastically curved needle 101 is then retrieved into the sleeve 220 while the plunger 109 is held stationary to deploy the conduit 126 at the calcified endplate 105, as shown in Figure 45.

Figure 46 depicts insertion of the needle 101, conduit 126, plunger 109, sleeve 220 and dilator 230 into the disc 100. The resiliently straightened needle 101 carrying the conduit 126 is deployed from the sleeve 220, resumes the curvature and punctures through the endplate 105 and calcified layers 108, as shown in Figure 47. While the plunger 109 behind the conduit 126 is held stationary, the elastically curved needle 101 is withdrawn from the calcified endplate 105 and retrieved into the sleeve 220 to deploy, expel or dislodge the conduit 126 at the calcified endplate 105, as shown in Figure 48. The conduit 126 acts as a channel or a passage, bridging between the bone marrow of the vertebral body 159 and the disc 100 to re-establish the exchange of fluid, nutrients, gases and wastes. Figure 49 shows the general location of the conduit 126 between the disc 100 and the vertebral body through the calcified endplate (both not shown).

Multiple conduits **126** can be loaded in series into the curved needle **101**, as shown in Figure 50. Each conduit **126** is deployed sequentially at the calcified endplate **105** by retrieving the curved needle **101** and holding the plunger **109** stationary. In essence, the plunger **109** is advanced toward the distal end of the needle **101** one conduit-length at a time.

5 After deploying the first conduit **126** at the cranial endplate **105**, the rigid sleeve **220** is rotated 180° to deploy the second conduit **126** into the caudal endplate **105**, as shown in Figure 51. Multiple conduits **126** within the elastically curved needle **101** allow surgeons to implant multiple conduits through calcified endplates **105** without having to withdraw the needle **101** assembly, reload additional conduits **126** and re-insert the assembly into the disc **100**.

10 In the supine position, disc pressure is low. During sleep, fluid is drawn in by the water absorbing glycosaminoglycans within the nucleus pulposus **128**. By bridging the calcified endplate **105**, the glycosaminoglycans draw fluid with sulfate, oxygen and other nutrients through the conduits **126** into the nucleus pulposus **128** during sleep by (1) capillary action, and (2) imbibing pull of the water-absorbing glycosaminoglycans. The flow of sulfate,
15 oxygen and nutrients is channeled within the conduit **126** unidirectionally toward the nucleus pulposus **128**, rather than via the dispersion mechanism in diffusion.

It is generally accepted that disc **100** degeneration is largely related to nutritional and oxygen deficiency. By re-establishing the exchange, a renewed and sustained supply of sulfate may significantly increase the production of sulfated glycosaminoglycans and restore
20 swelling pressure. Restoration of swelling pressure within the nucleus pulposus **128** reinstates the tensile stresses within the collagen fibers of the annulus, thus reducing the inner bulging and shear stresses between the layers of annulus, as shown in Figure 52. Similar to a re-inflated tire, disc **100** bulging is reduced and nerve impingement is minimized. Thus, the load on the facet joints **129** is also reduced to ease pain, the motion segment is stabilized, and disc
25 **100** space narrowing may cease. The progression of spinal stenosis is halted and/or reversed, as shown in Figure 53 to ease pain.

In daily activities, such as walking and lifting, pressure within the disc **100** greatly increases. Direction of the convective flow then reverses within the conduit **126**, flowing from high pressure within the disc **100** to low pressure within vertebral bodies **159**. The lactic
30 acid and carbon dioxide dissolved in the fluid within the nucleus pulposus **128** is slowly

expelled through the conduit 126 into the vertebral bodies 159, then to bodily circulation. As a result, the lactic acid concentration decreases, and pH within the disc 100 is normalized.

Furthermore, due to the abundance of oxygen in the disc 100 supplied through the conduit 126, lactic acid normally produced under anaerobic conditions may drastically decrease.

5 Hence, the pain caused by acidic irritation at tissues, such as the posterior longitudinal ligament 195, superior 142 and inferior 143 articular processes of the facet joint, shown in Figure 53, is anticipated to quickly dissipate. Buffering agents, such as bicarbonate, carbonate or others, can be loaded or coated on the conduits 126 to neutralize the lactic acid upon contact and spontaneously ease the pain.

10 The elasticity of the curved needle 101 still can twist within the rigid sleeve 220 during endplate 105 puncturing, as shown in Figure 54. The likelihood of twisting increases with the length of the elastic needle 101. The twisting is depicted in a cross-sectional view of the sleeve 220, needle 101 and conduit 126 in Figure 55. The elastic twisting between the shafts of the needle 101 and sleeve 220 allows directional shift at the tip of the needle 101 during
15 contact with the calcified endplate 105. As a result, puncturing of the endplate 105 may fail.

To avoid twisting, the cross-sections of the needle 101 and sleeve 220 can be made non-round, such as oval in Figure 56 with a cross-sectional view in Figure 57. A square cross-section is shown in Figure 58. A rectangular cross-section is shown in Figure 59. A triangular cross-section is in Figure 60.

20 The elastic property of the curved needle 101 may bend and fail to penetrate through the calcified endplate 105, as shown in Figure 61. The direction of the bend or droop is at the convex side of the curvature of the needle 101. To minimize the droop, the distal end of the rigid sleeve 220 is cut at an angle, providing an extension to support the convex side of the curved needle 101 during endplate 105 puncturing, as shown in Figure 62. The angled cut of
25 the rigid sleeve 220 functions as a rigid needle 220 with a sharp tip supporting the convex side of the curved needle 101, as shown in Figure 62. The supporting structure can be further extended by cutting an indentation near the distal end of the rigid needle 220, as shown in Figure 63, to increase support of the convex side of the curved needle 101 during endplate 105 puncturing.

30 To further support the elastically curved needle 101, a window 270 may be located near the distal end of the rigid sleeve 220 with an oval cross-section, as shown in Figure 64. The

distal side of the window 270 is open slanted at an angle. The slant can also be formed with multiple angles into a semi-circular-like pocket, sized and configured to fit the convex side of the elastically curved needle 101. Figure 65 shows protrusion of the elastically curved needle 101 from the window 270 of the rigid sleeve 220. The sharp tip of the curved needle 101 is located on the concave side of the curvature to avoid scraping or snagging on the distal portion of the window 270 during deployment. Figure 66 shows deployment of the elastically curved needle 101 from the window 270 of the rigid sleeve 220. The semi-circular pocket of the distal window 270 supports and brackets around the base of the convex curvature to minimize bending, twisting and/or deflection of the curved needle 101 during endplate 105 puncturing. In essence, the slanted portion of the window 270 provides a protruded pocket to direct and support the curved needle 101. The distal end of the rigid sleeve 220 can be sharpened to function as a rigid needle 220 with the window 270, as shown in Figure 67.

When a substantial amount of bone is formed, puncturing through the bony endplate 105 with a small curved needle 101 can be challenging. Increasing the size of the needle 101 and creating a large hole 224 at the endplate 105 may cause leakage of nucleus pulposus 128 into the vertebral bodies 159. To support a small curved needle 101, a shape memory extension 271 containing a curvature similar to the curved needle 101 is added to strengthen and support the elastically curved needle 101, as shown in Figure 68. The shape memory extension 271 can be indented, as shown in Figure 68, or tubular at the distal end. The curved needle 101 and shape memory extension 271 are capable of sliding independently within the rigid sleeve or needle 220. Figure 69 shows resiliently straightening of both the curved needle 101 and shape memory extension 271 within the rigid sleeve 220. Both the curved needle 101 and shape memory extension 271 apply stresses on the rigid sleeve 220. To minimize potential bending of the rigid sleeve 220, the stresses are distributed over a larger area by positioning the tip of the needle 101 proximal to the curvature of the shape memory extension 271, as shown in Figures 68-69. Spreading of the stresses also helps to ease the deployment and retrieval of both the needle 101 and shape memory extension 271.

For tissue puncturing, the shape-memory extension 271 is deployed from the rigid sleeve 220, as shown in Figure 68, followed by the curved needle 101 gliding along the curvature of the shape-memory extension 271 and puncturing into the calcified endplate 105, as shown in Figure 70. The shape memory extension 271 provides support to the needle 101 to minimize

bending and twisting during puncturing without increasing the size of the puncture. The shape memory extension 271 can also be non-indented and sharpened to facilitate tissue piercing, as shown in Figure 71. To dislodge the conduit 126 at the endplate 105, the plunger 109 behind the conduit 126 is held stationary, while the curved needle 101 is retrieved into the shape memory extension 271. The shape memory extension 271 is then withdrawn into the rigid sleeve 220.

The outer diameter of the curved needle 101 can be made non-uniform, being small at the distal end for creating a small opening, as shown in Figure 72. The adjoining curved portion of the needle 101 contains a thick wall and a larger outer diameter to support and strengthen the process of endplate 105 puncturing. The transition between the small and large outer diameters is gradual, as shown in Figure 72, or in steps. The curved needle 101 with varying outer diameters can be made by grinding, machining or injection molding.

The lumen 268 of the rigid needle 220 may have a bevel 102 and a double-sided ramp 272, as shown in Figure 72. The bevel 102 or tapering at the distal end of the lumen 268 minimizes friction against the concave side of the curved needle 101 during deployment and retrieval. The double-sided ramp 272 is protruded at the side opposite to the bevel 102 with the distal side in continuation with the sharp tip or extended end of the rigid needle 101. The proximal side of the ramp 272 or protrusion can be shaped to conform to and support the convex side of the curved needle 101 during endplate 105 puncturing. The ramp 272 can be made with epoxy, solder or other hardened material, then shaped by machining. The ramp 272 can also be created during a molten process to seal the lumen 268 at the distal end. The sealed end is then cut, the ramp 272 and bevel 102 are shaped, and the lumen 268 is re-opened by machining.

Sections of the conduit 126 are made to optimize the exchange of nutrients and waste. Figure 73 shows a conduit 126 with braided filaments 122 connected to a porous tube 125 with a lumen 104. The tubular 125 portion acts as a funnel, collecting nutrients from capillaries within the vertebral body 159 and funneling the nutrients into braided filaments 122 within the nucleus pulposus 128.

Especially at the endplate 105, mineralization within the pores or channels of the conduit 126 may occlude or block the exchange of nutrients and waste between the vertebral body 159 and disc 100. Figure 74 shows a tube 125 covering or wrapped around the mid-section of the

conduit 126 to prevent ingrowth of minerals or tissue into the pores or channels. The material for making the tube 125 can also have swelling, expanding or sealing characteristics to seal the puncture at the endplate 105 and prevent formation of Schmorl's node. The swelling, expanding or sealing material can be polyethylene glycol, polyurethane, silicon or others. An anti-ingrowth film or coating at the mid-section of the conduit 126 may also discourage mineralization or occlusion within the channels or pores to ensure long lasting exchange of nutrients and waste.

Especially within the vertebral body 159 or outer annulus, formation of fibrous tissue over the conduit 126 may occur, hindering the exchange of nutrient and waste. A portion of the conduit 126 can be coated, grafted, covalently bonded or ionic bonded with a drug to minimize fibrous formation. The drug can be actinomycin-D, paclitaxel, sirolimus, cell-growth inhibitor or fibrous tissue inhibitor.

Due to the soft or pliable characteristic, conduits 126 made with braided filaments 122 are difficult to deploy with the retrieving needle 101 and stationary plunger 109. A conduit 126 made with braided filament can be stiffened with water soluble agents, such as starch, collagen, hyaluronate, chondroitin, keratan or other biocompatible agents. After deployment, the soluble stiffening agent dissolves within the body, exposing the filaments to transport nutrients, oxygen and waste. Figure 75 shows a monofilament 110 used as a stiff core within the braided conduit 126 to assist deployment. The monofilament 110 can be made with degradable material to maximize transport area after deployment of the conduit 126.

Degradable tubes 125, indicated in the shaded area of Figure 76, can also be used to wrap and stiffen the braided filaments 122. The degradable tube 125 or the degradable monofilament 110 can be made with poly-lactide, poly-glycolide, poly-lactide-co-glycolide or others.

Since nutrients are relatively abundant within the peripheral 1 cm of the disc 100, the conduit 126 can also draw nutrients from the outer annulus through capillary action into the nucleus pulposus 128. A needle 101 carrying the starch-stiffened conduit 126 (not shown) and a plunger 109 is punctured into a disc 100 with calcified endplates 105, as shown in Figure 77. The needle 101 guiding technique is similar to the one used in diagnostic injection of radiopaque dye for discography or chymopapain injection for nucleus pulposus 128 digestion to treat herniated discs 100. Guided by anteroposterior & lateral views from fluoroscopes, the needle 101 enters posteriolaterally, 45° from mid-line into the disc 100. A

longitudinal view of the needle **101** carrying the stiffened conduit **126** puncturing through the disc **100** with calcified endplates **108** is shown in Figure 78.

By holding the plunger **109** stationary while the needle **101** is being withdrawn, the conduit **126** is dislodged from the lumen of the needle **101** and deployed across the disc **100**, as shown in Figures 79-80. At least one end of the conduit **126** is placed less than 1 cm from the periphery of the disc **100** to draw nutrients and drain lactic acid. To enhance imaging, the section of the needle **101** containing the conduit **126** can be coated with a radiopaque, echogenic or magnetic coating **163**, as shown in Figure 81. Multiple conduits **126** can be safely and accurately deployed into different areas of a degenerating disc **100**. Figure 82 shows two conduits **126** deployed across a degenerating disc **100**, exchanging nutrients and waste between the inner and outer disc **100**.

In locations lacking any major blood vessel and organ, the tip of the needle **101** can be guided beyond the disc **100**, as shown in Figure 83, to deploy the conduit **126** beyond the disc **100**, as shown in Figure 84. The extended conduit **126** may draw significantly more nutrients into the disc **100**. In addition, the extended conduit **126** may be more effective in disposing the waste generated within the disc **100** and expediting the repair and/or regeneration of the disc **100**, as shown in Figure 85.

Psoas major muscles **193** are located adjacent to the lumbar segment of the spine. The needle **101** carrying the conduit **126** can puncture beyond the disc **100** into the muscle **193**. As a result, the conduit **126** can draw nutrients from the muscle **193** into the disc **100**, as shown in Figure 86. Muscles **193** are well supplied with nutrients and oxygen, and muscles **193** dissipate lactic acid well. By extending into the muscles **193**, the conduits **126** can draw an abundant amount of nutrients and safely deposit the waste from the inner disc **100** to repair or regenerate the degenerating disc **100**, as shown in Figure 87. The supple and tensionless conduits **126** are expected to be free from interfering with the functions of the disc **100** and muscles **193**.

Methods and devices for conduit **126** deployments can also be in various combinations. The conduits **126** can be delivered into the endplates **105**, as shown in Figure 53, and transverse the annulus, as shown in Figures 82 or 87.

An accelerated disc degeneration model was developed using rat tails. A tail section involving three discs was twisted or rotated 45° and held for 2 weeks. The section was then

compressed by coil springs and held for an additional period of time. All discs within the section degenerated. Discs that had received additional nucleus pulposus from donor discs by injection experienced a delay in degeneration. Furthermore, insertions of the additional nucleus pulposus prior to the destructive loads provided the longest delay against disc
5 degeneration.

After lumbar fusion procedures, the intervertebral discs **100** of adjacent free motion segments degenerate quickly. The degenerative process leads to more pain and possibly more surgery; following each new fusion is a new vulnerable segment adjacent to it. Accelerated degeneration of segments adjacent to a lumbar fusion may be the result of additional post-
10 fusion stress and load. In the rat model, the added volume within the nucleus pulposus had a protective function against the destructive load. In conjunction with spinal fusion procedures, implanting conduits **126** within discs **100** adjacent to the fused segment may provide adequate swelling pressure contributed by an abundant supply of sulfate and oxygen to delay and hopefully prevent adjacent disc **100** degeneration.

15 Device migration with time is always a concern. The average age of patients undergoing back surgery is 40-45 years old. The conduit **126** is expected to remain in place within the patients for fifty or more years. Migration of the tensionless conduits **126** may result in loss of effectiveness, but it is not likely to be detrimental to nerves, ligaments, muscles or organs. To minimize migration, knots **161** can be tied on the braided conduit **126**, as shown in Figure
20 **88**, to anchor within the annulus, endplate **105** and/or muscle **193**. Similar to knots **161**, rings **162** or protruded components **162** can be crimped on the conduit **126**, as shown in Figure **89**. Both the knots **161** and the protrusions **162** are small enough to fit within the needle **101**. Tissue ingrowth can also limit or prevent device migration. Indentations **160** or tissue ingrowth holes **160** can be created on the conduit **126**, as shown in Figure **90**, to discourage
25 migration with time.

The conduit **126** can also be used as a delivery vehicle to introduce healing elements for maintaining or regenerating the disc **100**. The conduit **126** can be coated or seeded with growth factor, stem cells, donor cells, nutrients, buffering agent or minerals. Cells sensitive to sterilization can be loaded aseptically. Installations of conduits **126** can be in multiple stages,
30 separated by days, weeks, months or even years. Initial conduit **126** deployment prepares the

biological conditions, including pH, electrolytic balance and nutrients, to favor cell proliferation. Subsequent deployments may contain seeded cells within the conduit 126.

Since cellularity within the inner disc 100 is low, cell migration from the outer annulus or vertebral bodies 159 can be helpful in regenerating the degenerating disc 100. Cells can be
5 transported along the convective flow within the conduit 126 into the nucleus pulposus 123. The channels or pores within the conduit 126 need to be sufficiently large, about 50 to 200 microns. For minerals, nutrients, lactic acid and gas exchange alone, the channels or pore size can be much smaller. Hence, the useful range of the channel or pore size of the conduit 126 is about 200 microns to 10 nanometers.

10 Potentially useful coating for the conduit 126 include antibiotic, anti-occlusive coating, lubricant, growth factor, nutrient, sulfate, mineral, buffering agent, sodium carbonate, sodium bicarbonate, alkaline, collagen, hydroxyapatite, analgesic, sealant, humectant, hyaluronate, proteoglycan, chondroitin sulfate, keratan sulfate, glycosamino-glycans, heparin, starch, stiffening agent, radiopaque coating, echogenic coating, cells or stem cells.

15 The tube 125 for preventing occlusion from mineralization or tissue ingrowth can be made with a biocompatible polymer, such as polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate or polyethylene glycol. Similar material can be used to coat or partially coat the conduit 126 to prevent blockage of nutrient and waste transport. The coating should be
20 able to withstand sterilization by gamma, electron beam, autoclave, ETO, plasma or UV light to prevent infection.

Especially for investigative purposes, a biodegradable conduit 126 may provide evidence within weeks or months. Since the conduit 126 degrades within months, any unforeseen adverse outcome would be dissipated. If the investigative-degradable conduit 126 shows
25 promise, a permanent conduit 126 can then be installed to provide continuous benefits. The biodegradable conduit 126 can be made with polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate, silk, catgut, collagen, poly-p-dioxanone or combinations of these materials. Other degradable polymers, such as polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-
30 gama-ethyl-glutamate, poly-DTH-iminocarbonate, poly-bisphenol-A-iminocarbonate, poly-

ortho-ester, polycyanoacrylate or polyphosphazene can also be used. Similar biodegradable material can be used to make the biodegradable monofilament **110** in Figure 75.

A wide range of non-degradable materials can be used to fabricate the conduit **126**. Biocompatible polymers, such as polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, silk, cotton, or linen are possible candidates. Fiberglass can also be a part of the conduit **126** to provide capillarity for transporting nutrients and waste. Conduits **126** can also be made with metal, such as nickel-titanium alloy or stainless steel. Both non-degradable and degradable conduits **126** can be formed by molding, extruding, braiding, weaving, coiling, spiraling or machining. The conduits **126** can have a longitudinal lumen **104**, pores and/or channels for fluid exchange. The conduit **126** can be a suture with a proven safety record. The conduit **126** can also be called or classified as a shunt, wick, tube, braided suture, braided filaments, thread or sponge. The disc **100** with the conduits **126** installed can be called the shunted disc **100**.

The rigid needle **101**, trocar **103**, dilator **230** and plunger **109** can be made with stainless steel or other metal or alloy. The elastically curved needle **101**, shape memory extension **271** and plunger **109** can be formed with nickel-titanium alloy. The needle **101**, rigid needle **220**, dilator **230**, shape memory extension **271** and plunger **109** can be coated with lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and/or echogenic agents.

Since nutrients and oxygen are extremely low particularly in degenerating discs **100**, cell death is common, and healthy cells capable of producing glycosaminoglycans are few. Healthy cells **277** can be drawn from another disc **100** within the patient to inject with a syringe **276** into the degenerated disc **100**, as shown in Figure 91. Exchange of nutrients and waste is re-established through the newly installed conduits **126** through the cranial and caudal endplates **105** to nourish both the donor cells **277** and the remaining cells within the degenerating disc **100**. Similarly, donor cells **277** can also be injected into the disc **100** with transverse conduits **126** to revitalize the disc **100**, as shown in Figure 92. Since cellularity within the degenerative disc **100** is low, introduction of donor cells **277** may expedite the process of halting or reversing disc degeneration.

The avascular disc **100** is well sealed. Even small ions, such as sulfate, and small molecules, such as proline, are greatly limited from diffusing into the nucleus pulposus **128**.

The well sealed disc **100** may be able to encapsulate donor cells **277** from a disc **100** of another person, cadaver or animal without triggering an immune response. For disc **100** regeneration, the donor cells **277** can also be stem cells **277**, notochord **277** or chondrocytes **277**. The semi-permeable conduits **126** are permeable to nutrients and waste but impermeable to cells, proteins, glycoproteins and/or cytokines responsible for triggering an immune reaction. The cells of the immune system include giant cells, macrophages, mononuclear phagocytes, T-cells, B-cells, lymphocytes, Null cells, K cells, NK cells and/or mask cells. The proteins and glycoproteins of the immune system include immunoglobulins, IgM, IgD, IgG, IgE, other antibodies, interleukins, cytokines, lymphokines, monokines and/or interferons.

The molecular weights of nutrients and waste are usually much smaller than the immuno-responsive cells, proteins and glycoproteins. The transport selectivity can be regulated or limited by the size of the pores or channels within the semi-permeable conduit **126**. The upper molecular weight cut-off of the conduit **126** can be 3000 or lower to allow the passage of nutrients and waste but exclude the immuno-responsive cells, proteins, immunoglobulins and glycoproteins. The semi-permeable conduit **126** may also contain ionic or affinity surfaces to attract nutrients and waste. The surfaces of the semi-permeable conduit **126** can be selected or modified to repel, exclude or reject immuno-responsive components.

In recent years, cell transplants from cadavers or live donors have been successful in providing therapeutic benefits. For example, islet cells from a donor pancreas are injected into a type I diabetic patient's portal vein, leading into the liver. The islets begin to function as they normally do in the pancreas by producing insulin to regulate blood sugar. However, to keep the donor cells alive, the diabetic patient requires a lifetime supply of anti-rejection medication, such as cyclosporin A. In addition to the cost of anti-rejection medication, the long-term side effects of these immuno-suppressive drugs are uncertain. The benefit of cell transplant may not out weigh the potential side effects.

The intervertebral disc **100** with semi-permeable conduits **126** can be used as a semi-permeable capsule to encapsulate therapeutic donor cells **277** or agents, as shown in Figures 91 and 92, and evade the immune response; hence no life-long immuno-suppressive drug would be required. A variety of donor cells **277** or agent can be harvested and/or cultured from the pituitary gland (anterior, intermediate lobe or posterior), hypothalamus, adrenal gland, adrenal medulla, fat cells, thyroid, parathyroid, pancreas, testes, ovary, pineal gland,

adrenal cortex, liver, renal cortex, kidney, thalamus, parathyroid gland, ovary, corpus luteum, placenta, small intestine, skin cells, stem cells, gene therapy, tissue engineering, cell culture, other gland or tissue. The donor cells 277 are immunoisolated within the discs 100, the largest avascular organs in the body, maintained by nutrients and waste transport through the semi-permeable conduits 126. The donor cells 277 can be from human, animal or cell culture. In the supine sleeping position, nutrients and oxygen are supplied through the conduits 126 to the donor cells 277. During waking hours while the pressure within the disc 100 is high, products biosynthesized by these cells 277 are expelled through the conduit 126 into the vertebral bodies 159, outer annulus or muscle 193, then into the veins, bodily circulation and target sites.

The product biosynthesized by the cells 277 within the shunted disc 100 can be adrenaline, adrenocorticotrophic hormone, aldosterone, androgens, angiotensinogen (angiotensin I and II), antidiuretic hormone, atrial-natriuretic peptide, calcitonin, calciferol, cholecalciferol, calcitriol, cholecystokinin, corticotropin-releasing hormone, cortisol, dehydroepiandrosterone, dopamine, endorphin, enkephalin, ergocalciferol, erythropoietin, follicle stimulating hormone, γ -aminobutyrate, gastrin, ghrelin, glucagon, glucocorticoids, gonadotropin-releasing hormone, growth hormone-releasing hormone, human chorionic gonadotrophin, human growth hormone, insulin, insulin-like growth factor, leptin, lipotropin, luteinizing hormone, melanocyte-stimulating hormone, melatonin, mineralocorticoids, neuropeptide Y, neurotransmitter, noradrenaline, oestrogens, oxytocin, parathyroid hormone, peptide, pregnenolone, progesterone, prolactin, pro-opiomelanocortin, PYY-336, renin, secretin, somatostatin, testosterone, thrombopoietin, thyroid-stimulating hormone, thyrotropin-releasing hormone, thyroxine, triiodothyronine, trophic hormone, serotonin, vasopressin, or other therapeutic products.

The products (hormones, peptides, neurotransmitter, enzymes, catalysis or substrates) generated within the shunted disc 100 may be able to regulate bodily functions including blood pressure, energy, neuro-activity, metabolism, activation and suppression of gland activities. Some hormones and enzymes govern, influence or control eating habits and utilization of fat or carbohydrates. These hormones or enzymes may provide weight loss or gain benefits. Producing neurotransmitters, such as dopamine, adrenaline, noradrenaline, serotonin or γ -aminobutyrate, from the donor cells 277 within the shunted disc 100 can treat

depression, Parkinson's disease, learning disability, memory loss, attention deficit, behavior problems, mental or neuro-related disease.

Release of the products biosynthesized by the donor cells 277 within the shunted disc 100 is synchronized with body activity. During activities of daily living, the pressure within the shunted disc 100 is mostly high to expel the products biosynthesized by the donor cells 277 into circulation to meet the demands of the body. In the supine position, the flow within the shunts 126 is reversed, bringing nutrients and oxygen into the disc 100 to nourish the cells 277. Using islets of Langerhans from the donor's pancreas as an example, production of insulin is induced in the shunted disc 100 during sleeping hours when glucose enters into the disc 100. During waking hours when disc pressure is high, insulin is expelled through the conduits 126 into circulation to draw sugars into cell membranes for energy production. At night, the insulin released from the shunted disc 100 is minimal to prevent the hypoglycemia. In essence, products biosynthesized by the donor cells 277 are released concurrent with physical activity to meet the demands of the body.

Some biosynthesized products from the donor cells 277 are appropriately deposited through the vertebral body 159, as shown in Figure 91, then into bodily circulation. Other products may be more effectively transported through the outer annulus, as in Figure 82, and diffused through the abdomen into bodily circulation. Some other products may be far more effective by entering into the muscles 193, as shown in Figure 92.

Growth factors, buffering agents, hormones, gene therapeutic agents, nutrients, minerals, analgesics, antibiotics or other therapeutic agents can also be injected into the shunted discs 100, similar to Figures 91-92.

It is to be understood that the present invention is by no means limited to the particular constructions disclosed herein and/or shown in the drawings, but also includes any other modification, changes or equivalents within the scope of the claims. Many features have been listed with particular configurations, curvatures, options, and embodiments. Any one or more of the features described may be added to or combined with any of the other embodiments or other standard devices to create alternate combinations and embodiments. The conduit 126 can also have a gate to regulate rate and/or flow direction of nutrient, gas and waste exchange.

It is also possible to connect a pump to the conduit 126 to assist the exchange between the

disc **100** and the bodily fluid. A pH electrode may be exposed near the tip of the rigid needle **220** to detect the acidity within the disc **100**.

5 It should be clear to one skilled in the art that the current embodiments, materials, constructions, methods, tissues or incision sites are not the only uses for which the invention may be used. Different materials, constructions, methods or designs for the conduit **126** can be substituted and used. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims. For clarification in claims, sheath is a rigid tubular member. The elastically curved needle **101** can be called the elastic needle.

10

Claims:

1. A deployment device for deploying a conduit into an intervertebral disc, the deployment device comprising:

a sheath,

5 a conduit sized and configured to fit at least partially within said sheath, and
a plunger to deploy said conduit.

2. The deployment device of claim 1, wherein said sheath has a beveled tip.

10 3. The deployment device of claim 1, further comprising a needle located at least partially within said sheath.

4. The deployment device of claim 3, wherein said conduit is located at least partially within said needle.

15 5. The deployment device of claim 3, wherein said conduit is located at least partially around said needle.

6. The deployment device of claim 1, further comprising a coating on said tubular sheath.

20 7. The deployment device of claim 6, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.

25 8. The deployment device of claim 1, wherein said conduit is a tube formed of a biocompatible material.

9. The deployment device of claim 1, wherein said conduit is a multi-filament formed of a biocompatible material.

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10. The deployment device of claim 1, wherein said conduit is a sponge formed of a biocompatible material.
- 5 11. The deployment device of claim 1, wherein said conduit has a plurality of protrusions extending therefrom.
12. The deployment device of claim 11, wherein said protrusions are chosen from the group consisting of flanges, knots and rings.
- 10 13. The deployment device of claim 1, wherein said conduit is formed of a multi-filament portion and a mono-filament portion.
14. The deployment device of claim 1, wherein said conduit is formed of a biodegradable material.
- 15 15. The deployment device of claim 1, wherein said conduit is formed of a non-degradable material.
16. The deployment device of claim 1, wherein said conduit is formed of a non-degradable material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, silk, cotton, linen, fiberglass, nickel-titanium alloy and stainless steel.
- 20 17. The deployment device of claim 1, wherein said conduit is formed of a degradable material chosen from the group of materials consisting of polylactate, polyglycolic, polylactide-co-glycolide, polycaprolactone, trimethylene carbonate, silk, catgut, collagen, poly-p-dioxanone, polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly-DTH-iminocarbonate, poly-bisphenol-
- 25 A-iminocarbonate, poly-ortho-ester, polycyanoacrylate and polyphosphazene.
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18. The deployment device of claim 1, wherein said conduit has a coating chosen from the group of coatings consisting of antibiotic, anti-occlusive coating, lubricant, growth factor, nutrient, sulfate, mineral, buffering agent, sodium carbonate, sodium bicarbonate, alkaline, collagen, hydroxyapatite, analgesic, sealant, humectant, hyaluronate, proteoglycan, chondroitin sulfate, keratan sulfate, glycosamino-glycans, heparin, starch, stiffening agent, radiopaque coating, echogenic coating, gene, cells and stem cells.

19. The deployment device of claim 1, wherein said conduit has a pore size of 200 microns to 10 nanometers.

20. The deployment device of claim 1, wherein said conduit has channels therethrough, said channels having a diameter of 200 microns to 10 nanometers.

21. The deployment device of claim 1, further comprising a tube located around a central portion of said conduit.

22. The deployment device of claim 21, wherein said tube is formed of a material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate and polyethylene glycol.

23. The deployment device of claim 1, wherein at least a portion of said conduit is coated with fibrous tissue inhibitor.

24. A deployment device for deploying a conduit into an intervertebral disc, the deployment device comprising:

a tubular sheath,

a first elastic needle having a straightened position and a curved position, said

straightened position being elastically straightened within said tubular sheath, and

said curved position being elastically curved and located at least partially outside said tubular sheath,

an actuator to moved said first elastic needle between said straightened position and said curved position, and
a conduit sized and configured to fit at least partially within said tubular sheath.

5 25. The deployment device of claim 24, wherein said first elastic needle has a beveled tip.

26. The deployment device of claim 25, wherein a point of said beveled tip is located on a concave side of said first elastic needle, when said first elastic needle is in said curved position.

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27. The deployment device of claim 24, wherein said tubular sheath has a sharp tip.

28. The deployment device of claim 27, wherein said sharp tip is oriented on a convex side of said first elastic needle, when said first elastic needle is in said curved position.

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29. The deployment device of claim 24, wherein said tubular sheath and said first elastic needle have non-round cross sections.

30. The deployment device of claim 29, wherein said tubular sheath and said first elastic needle have similar cross-sectional shapes.

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31. The deployment device of claim 24, wherein said tubular sheath and said first elastic needle have oval cross sections.

25 32. The deployment device of claim 24, further comprising a second elastic needle, said second elastic needle located at least partially around said first elastic needle.

33. The deployment device of claim 32, wherein said first and second elastic needles have similar curvatures and said curvatures are oriented in similar directions.

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34. The deployment device of claim 24, further comprising an opening extending through a wall of said tubular sheath proximate a distal end thereof.

5 35. The deployment device of claim 24, wherein said tubular sheath has a ramp located therein.

36. The deployment device of claim 35, wherein said ramp is located proximate a distal end of said tubular sheath and located proximate a convex side of said first elastic needle.

10 37. The deployment device of claim 24, wherein said first elastic needle is formed of nickel-titanium alloy.

38. The deployment device of claim 24, wherein said first elastic needle has a non-uniform cross-section.

15 39. The deployment device of claim 38, wherein said first elastic needle has a distal end and a proximal end, said distal end being smaller than said proximal end.

20 40. The deployment device of claim 24, further comprising a plunger for deploying said conduit.

41. The deployment device of claim 24, further comprising a coating on said tubular sheath.

25 42. The deployment device of claim 41, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.

30 43. The deployment device of claim 24, further comprising a coating on said first elastic needle.

44. The deployment device of claim 43, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.

5 45. The deployment device of claim 24, wherein said conduit is a tube formed of a biocompatible material.

46. The deployment device of claim 24, wherein said conduit is a multi-filament formed of a biocompatible material.

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47. The deployment device of claim 24, wherein said conduit is a sponge formed of a biocompatible material.

15 48. The deployment device of claim 24, wherein said conduit has a plurality of protrusions extending therefrom.

49. The deployment device of claim 24, wherein said conduit is formed of a multi-filament portion and a mono-filament portion.

20 50. The deployment device of claim 24, wherein said conduit is located within said first elastic needle.

51. The deployment device of claim 24, wherein said conduit is located at least partially around said first elastic needle.

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52. The deployment device of claim 24, wherein said conduit has a coating chosen from the group of coatings consisting of antibiotic, anti-occlusive coating, lubricant, growth factor, nutrient, sulfate, mineral, buffering agent, sodium carbonate, sodium bicarbonate, alkaline, collagen, hydroxyapatite, analgesic, sealant, humectant, hyaluronate, proteoglycan,
30 chondroitin sulfate, keratan sulfate, glycosamino-glycans, heparin, starch, stiffening agent, radiopaque coating, echogenic coating, gene, cells and stem cells.

53. The deployment device of claim 24, wherein said conduit has a pore size of 200 microns to 10 nanometers.

54. The deployment device of claim 24, wherein said conduit has channels therethrough, said channels having a diameter of 200 microns to 10 nanometers.

55. The deployment device of claim 24, further comprising a tube located around a central portion of said conduit.

56. A conduit for re-establishing exchange of nutrients and waste between an intervertebral disc and bodily circulation, the conduit comprising:

an elongated member formed of a biocompatible material, said elongated member being locatable such that a first portion of said elongated member is within a patient's nucleus pulposus within the intervertebral disc.

57. The conduit of claim 56, wherein a second portion of said elongated member is locatable such that said second portion extends through an endplate and into a vertebra.

58. The conduit of claim 56, wherein said elongated member has a second portion and a central portion, wherein said elongated member is locatable such that said central portion extends through a periphery of the intervertebral disc and said second portion extends outside the intervertebral disc.

59. The conduit of claim 56, wherein a second portion of said elongated member is locatable such that said second portion extends to an outer annulus of the intervertebral disc.

60. The conduit of claim 56, wherein said conduit is a tube formed of a biocompatible material.

61. The conduit of claim 56, wherein said conduit is a multi-filament formed of a biocompatible material.

62. The conduit of claim 61, wherein said multi-filament is braided.

63. The conduit of claim 56, wherein said conduit is a sponge formed of a biocompatible material.

64. The conduit of claim 56, wherein said conduit has a plurality of protrusions extending therefrom.

65. The conduit of claim 56, wherein said conduit is formed of a multi-filament portion and a mono-filament portion.

66. The conduit of claim 56, wherein said conduit is formed of a biodegradable material.

67. The conduit of claim 56, wherein said conduit is formed of a non-degradable material.

68. The conduit of claim 56, wherein said conduit is porous and has a pore size of 200 microns to 10 nanometers.

69. The conduit of claim 56, wherein said conduit has channels therethrough, said channels each having a diameter of 200 microns to 10 nanometers.

70. The conduit of claim 56, further comprising a tube located around a central portion of said conduit.

71. The conduit of claim 70, wherein said tube is formed of a material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate and polyethylene glycol.

72. The conduit of claim 56, wherein at least a portion of said conduit is coated with fibrous tissue inhibitor.

5 73. A treatment kit used to provide immunoisolated retention of donor cells within a patient's intervertebral disc:

the conduit of claim 56,
and donor cells injectable into the intervertebral disc.

10 74. The treatment kit of claim 73, wherein the donor cells are from a gland.

75. The treatment kit of claim 73, wherein the donor cells are from tissue.

15 76. The treatment kit of claim 73, wherein the donor cells have an origin chosen from the group of origins consisting of the pituitary gland, hypothalamus, adrenal gland, adrenal medulla, fat cells, thyroid, parathyroid, pancreas, testes, ovary, pineal gland, adrenal cortex, liver, renal cortex, kidney, thalamus, parathyroid gland, ovary, corpus luteum, placenta, small intestine, skin cells, stem cells, gene therapy, tissue engineering and cell culture.

20 77. The treatment kit of claim 73, further comprising growth factor injectable into the intervertebral disc.

78. The treatment kit of claim 73, wherein the donor cells are capable of creating a therapeutic product.

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79. The treatment kit of claim 73, wherein the donor cells are capable of creating a product chosen from the group of biosynthesized products consisting of adrenaline, adrenocorticotrophic hormone, aldosterone, androgens, angiotensinogen (angiotensin I and II), antidiuretic hormone, atrial-natriuretic peptide, calcitonin, calciferol, cholecalciferol, calcitriol, cholecystokinin, corticotropin-releasing hormone, cortisol, dehydroepiandrosterone, dopamine, endorphin, enkephalin, ergocalciferol, erythropoietin, follicle stimulating hormone,

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γ -aminobutyrate, gastrin, ghrelin, glucagon, glucocorticoids, gonadotropin-releasing hormone, growth hormone-releasing hormone, human chorionic gonadotrophin, human growth hormone, insulin, insulin-like growth factor, leptin, lipotropin, luteinizing hormone, melanocyte-stimulating hormone, melatonin, mineralocorticoids, neuropeptide Y, 5 neurotransmitter, noradrenaline, oestrogens, oxytocin, parathyroid hormone, peptide, pregnenolone, progesterone, prolactin, pro-opiomelanocortin, PYY-336, renin, secretin, somatostatin, testosterone, thrombopoietin, thyroid-stimulating hormone, thyrotropin-releasing hormone, thyroxine, triiodothyronine, trophic hormone, serotonin, and vasopressin.