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Kuslich

(54) **SEMI-BIOLOGICAL INTERVERTEBRAL DISC REPLACEMENT SYSTEM**

(76) Inventor: **Stephen D. Kuslich**, Grant Township, MN (US); **Patricia K. Kuslich**, legal representative, (US)

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(57) **ABSTRACT**

Disclosed is a system and method for a partially biological disc replacement that stimulates natural fibrous, cartilaginous or other tissue growth in the DDD cavity, resulting in a partial biological disc replacement. Multiplicities of fibronous pieces of fibro-cartilaginous tissue promoting material are inserted into the DDD cavity inducing tissue growth. The fibro-cartilaginous tissue

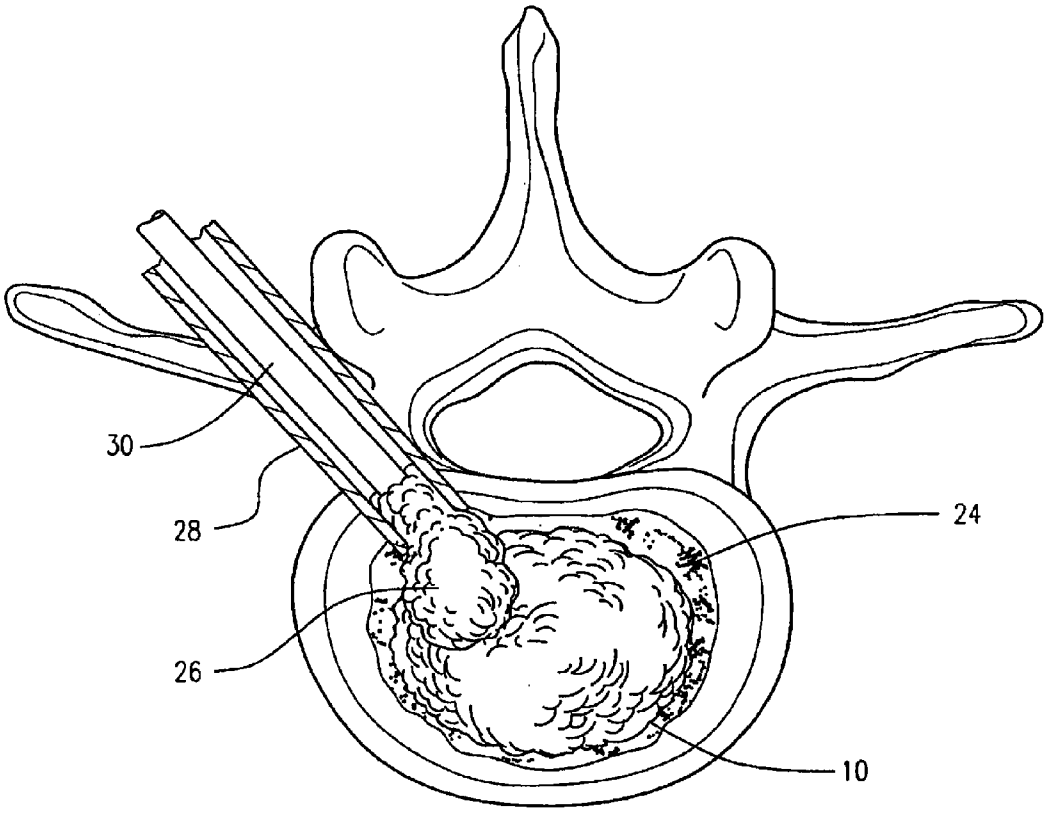


FIG. 1

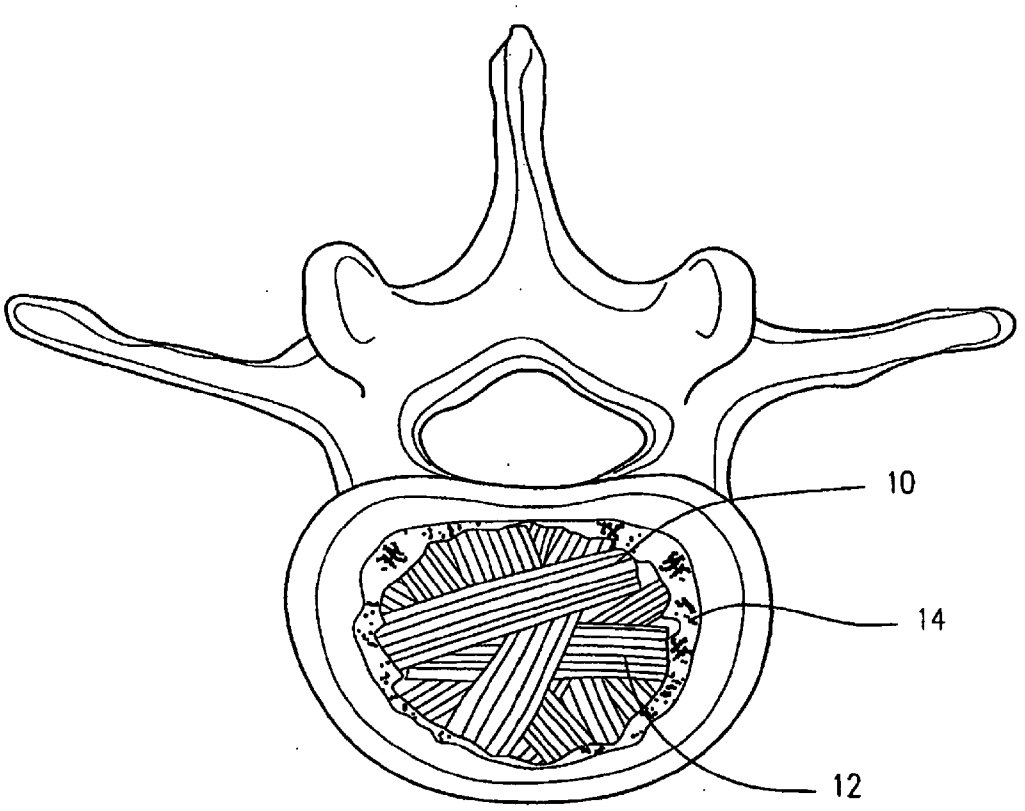


FIG. 2

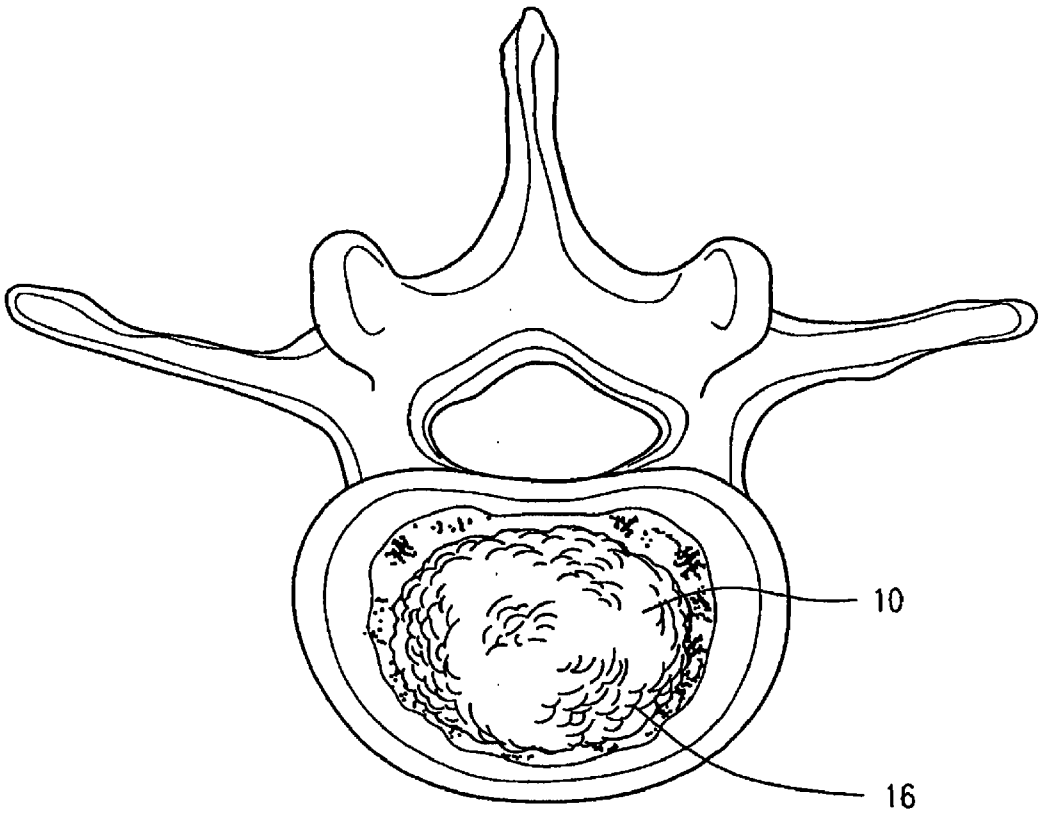


FIG. 3

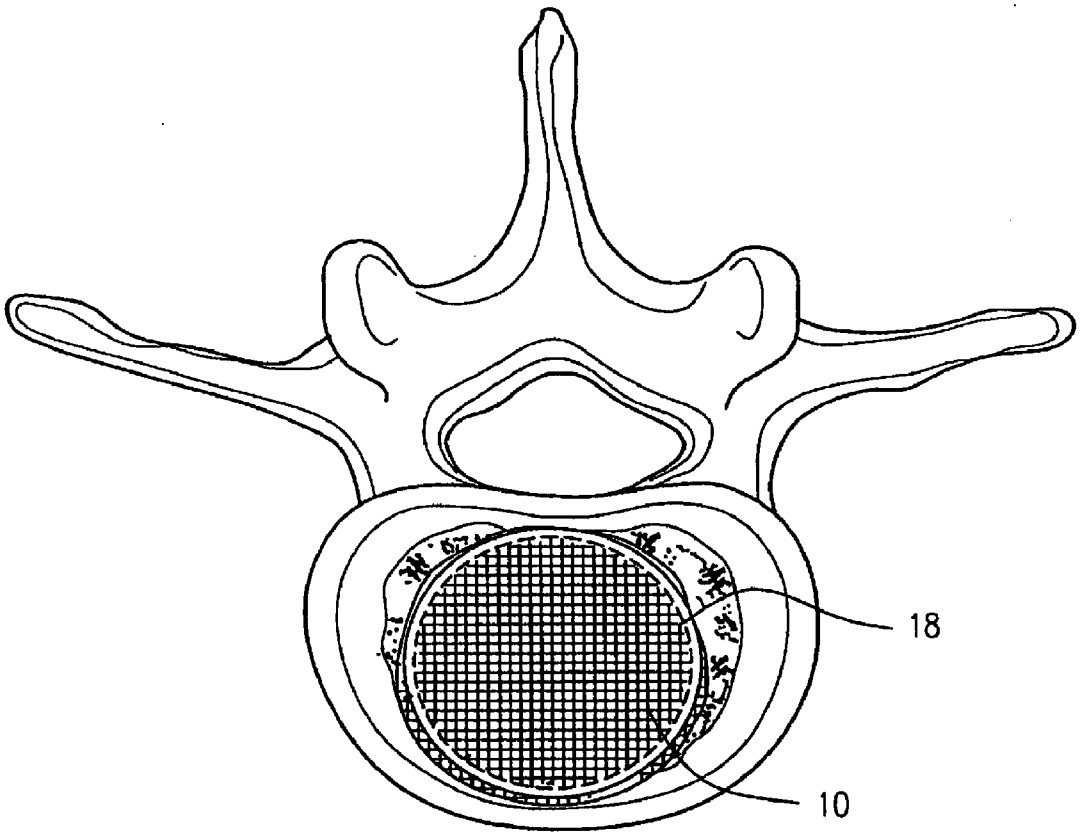


FIG. 4

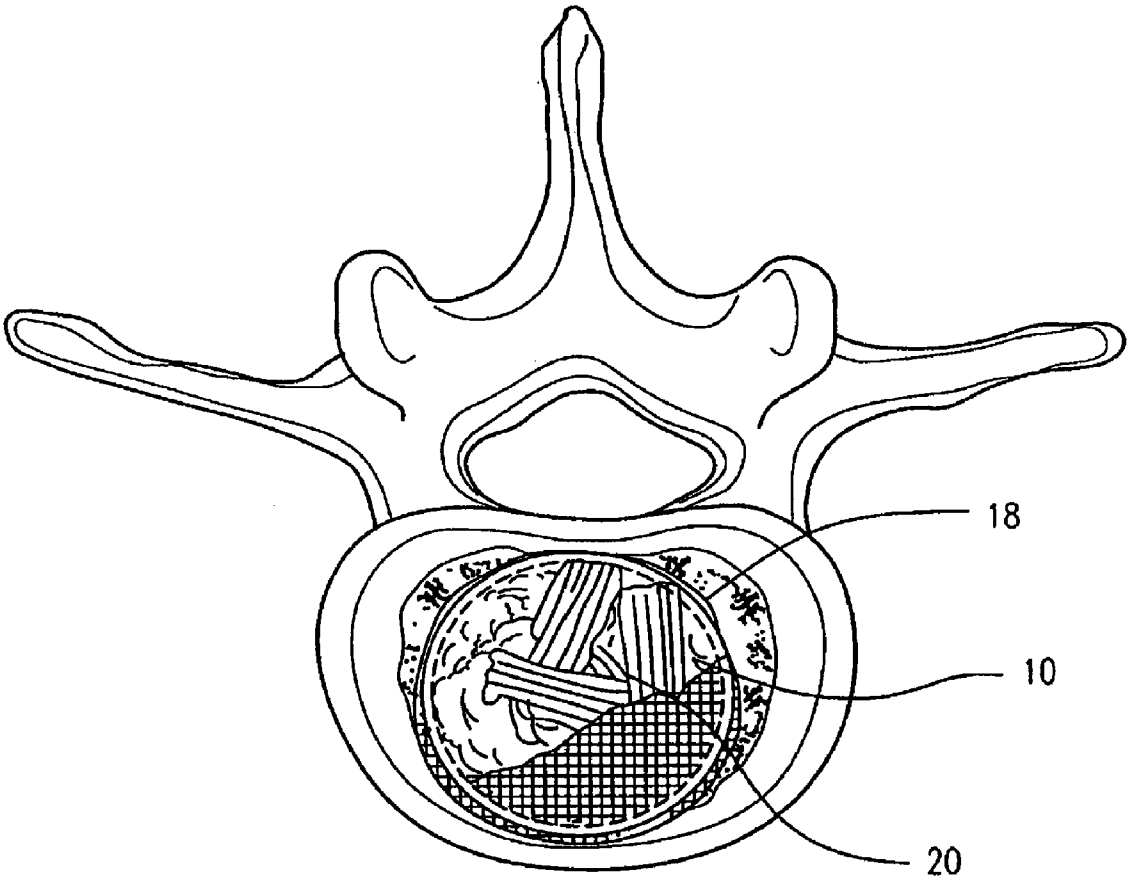


FIG. 5

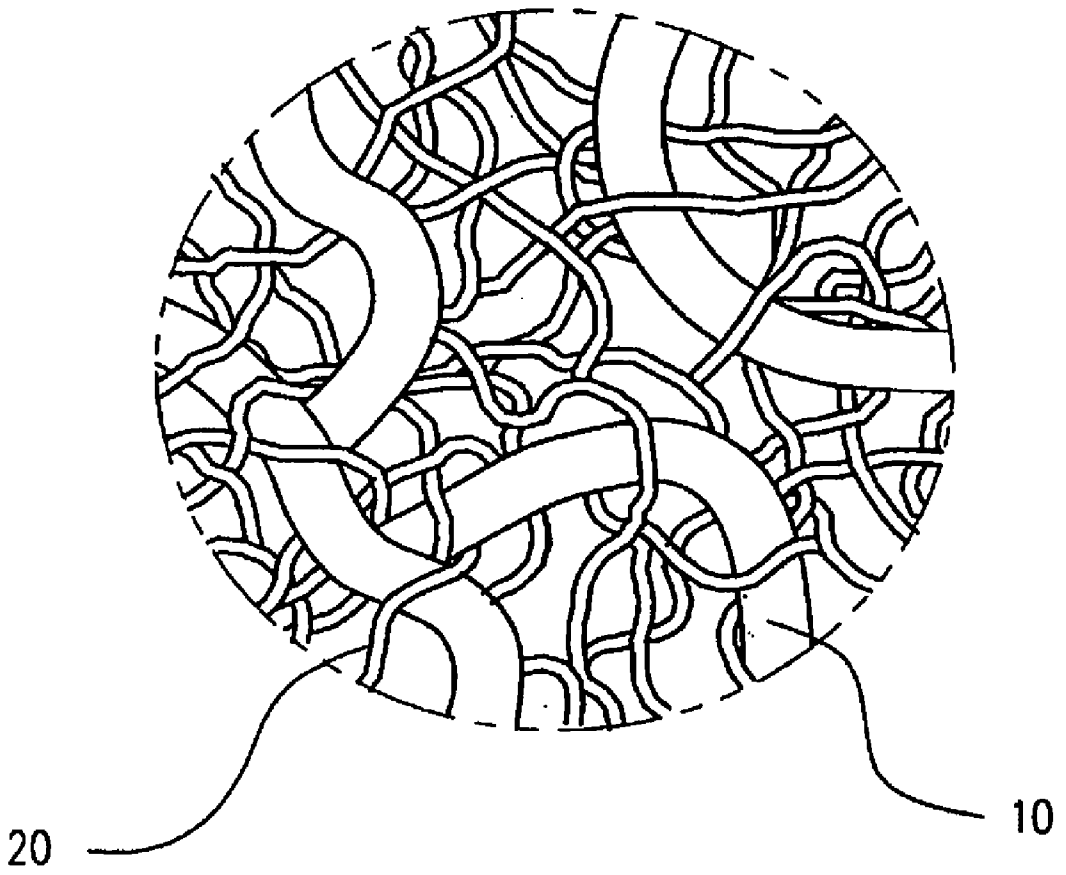


FIG. 6

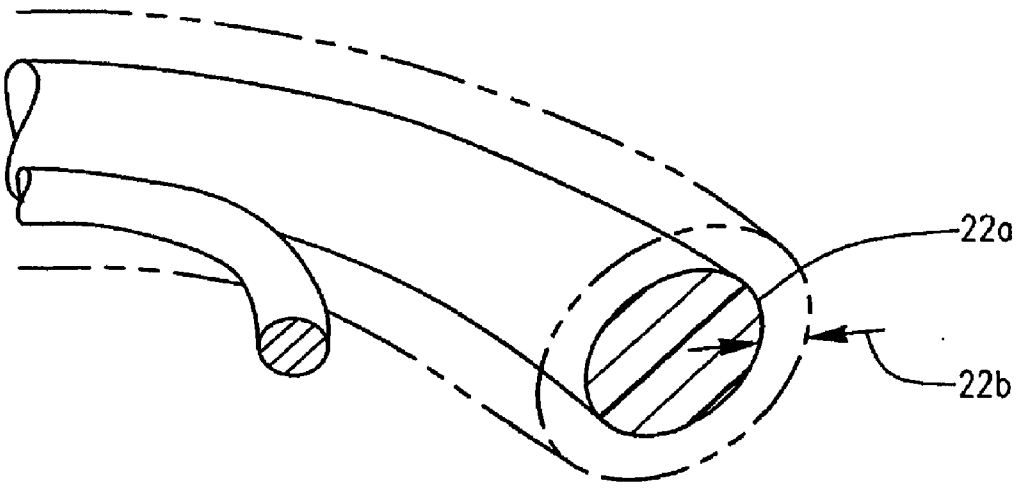


FIG. 7

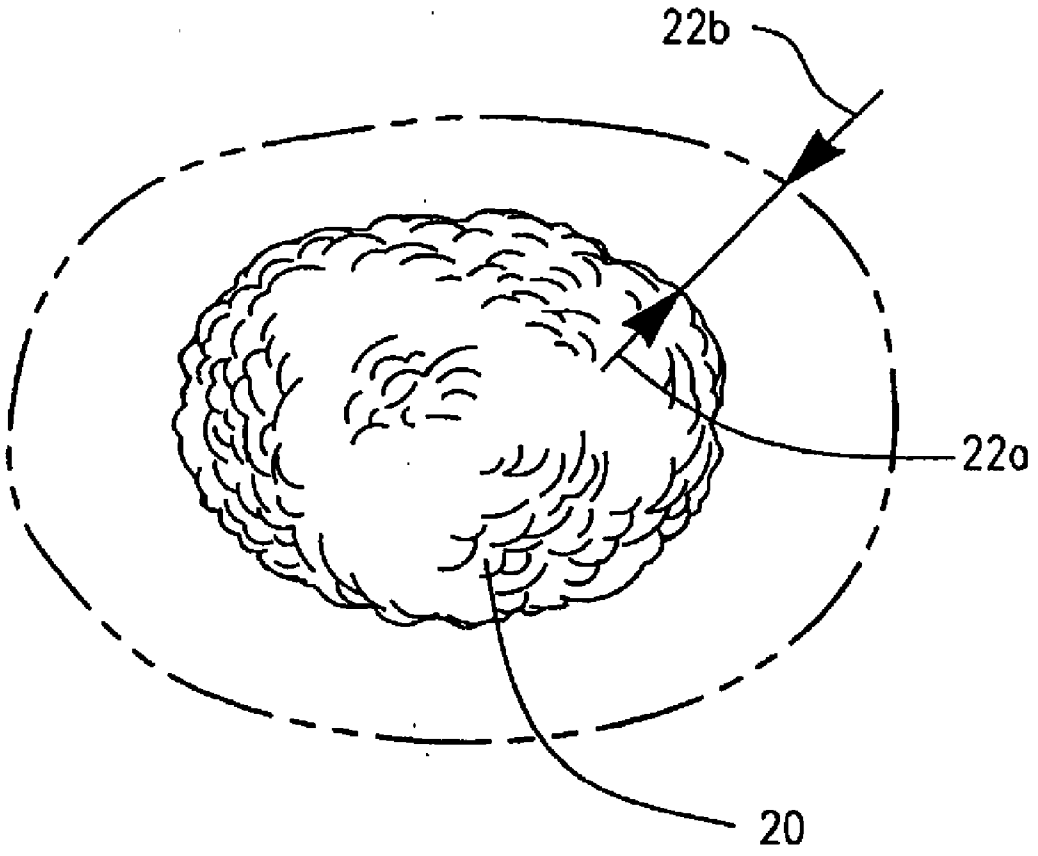


FIG. 8

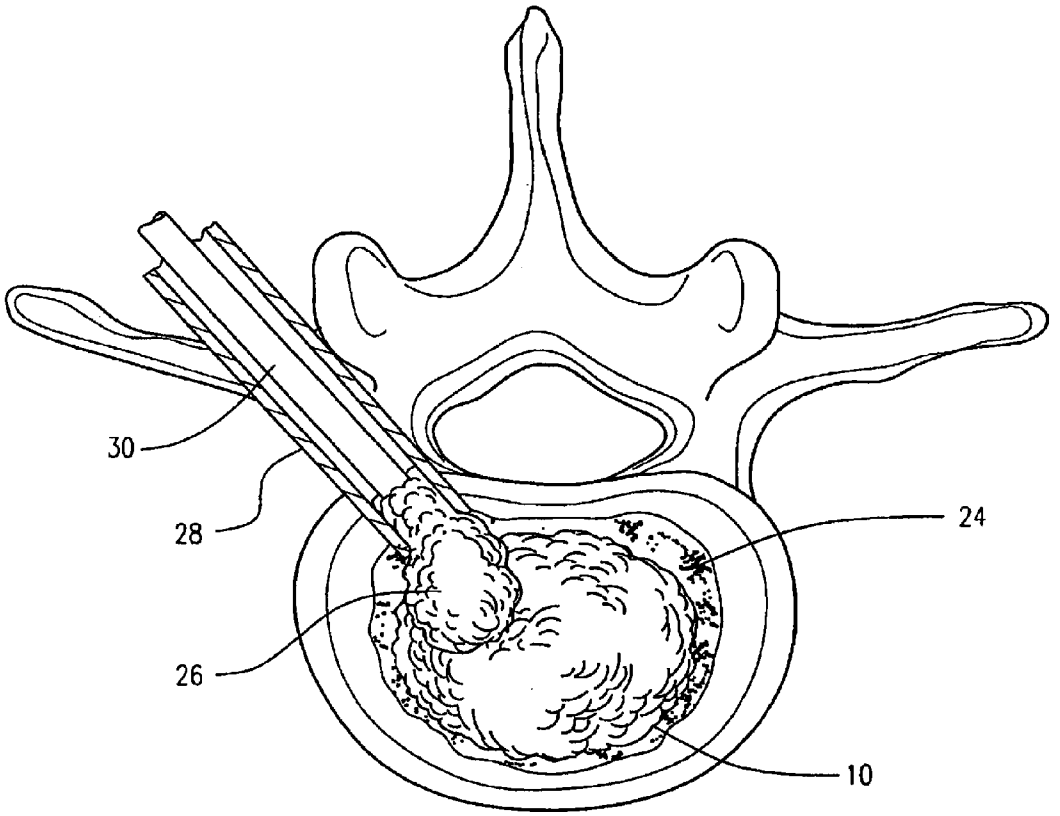


FIG. 9

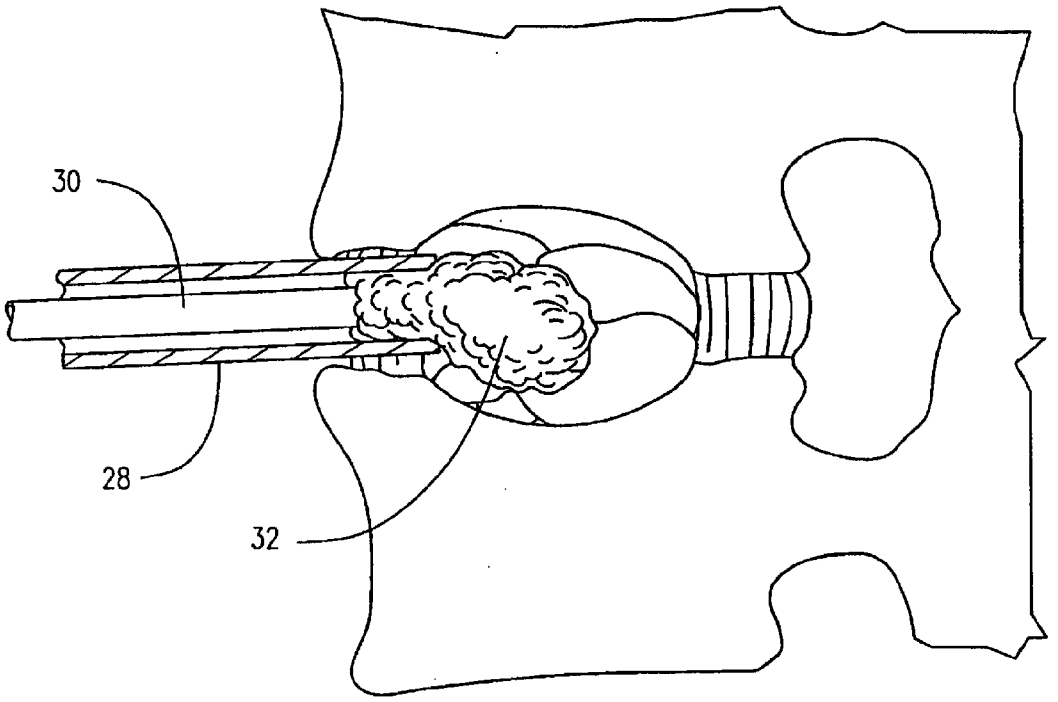
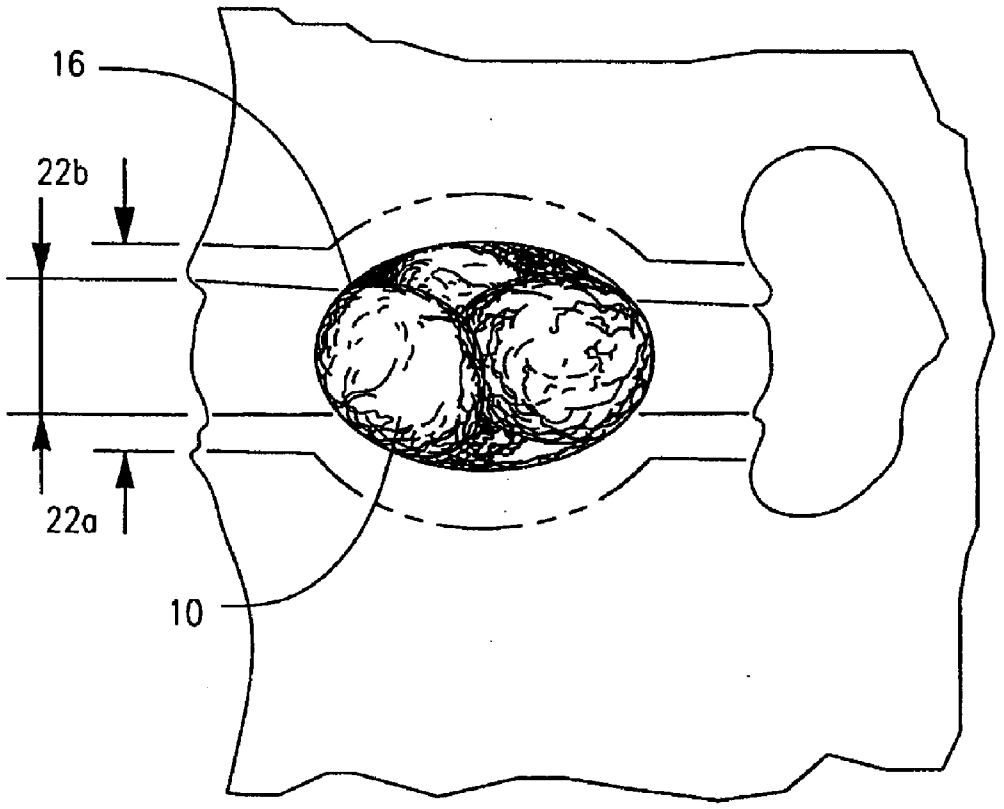


FIG. 10



SEMI-BIOLOGICAL INTERVERTEBRAL DISC REPLACEMENT SYSTEM

PRIORITY

[0001] This application is a divisional of U.S. application Ser. No. 12/247,760, filed Oct. 8, 2008, now U.S. Pat. No. 8,012,211, which is a divisional of U.S. application Ser. No. 10/702,096, filed Nov. 5, 2003, abandoned, which claims the benefit of U.S. Provisional Application No. 60/423,900 filed Nov. 5, 2002, the disclosures of each of which are hereby fully incorporated herein by reference in their entirety.

FIELD

[0002] The present invention relates generally to the field of systems adapted to replacing or assisting bone of a natural vertebral column of a living body. More specifically, the present invention relates to a system and method that surgeons can use to construct a semi-biological nuclear replacement that will replace the diseased nucleus and ultimately function in a manner similar to a natural disc nucleus.

BACKGROUND

[0003] Low back pain is a condition affecting millions of humans. This syndrome causes great personal, economic and social hardship. Resultant consequences to family members, co-workers and the community are significant.

[0004] Scientific evidence indicates that the symptoms of low back pain are most commonly caused by degenerative pathology in the spinal motion segment. The spinal motion segment consists of a unit of spinal anatomy bounded by two vertebral bodies that includes the two vertebral bodies and the interposed intervertebral disc, as well as the attached ligaments, muscles and the facet joints. Degenerative pathology in the spinal motion segment is primarily related to intervertebral disc degeneration.

[0005] The fundamental causes of intervertebral disc degeneration are incompletely understood. However, scientific studies substantiate the following general conclusions about the sequential development of degenerative spinal pathology: The nucleus (the central cushion of the disc) loses nutritional support, dehydrates, and fragments. The loss in nutritional support causes nuclear tissue necrosis, the cells die. As the nuclear tissue dies, the pH in the nuclear region decreases and highly irritative chemicals form in the disc. Consequently, as the nucleus can no longer support compression loads, the annulus (the fibrous rim of the disc, surrounding the nucleus) is subjected to loading forces, in the form of compression and shear, that the annulus is poorly designed to handle.

[0006] Nociceptive nerve elements, i.e., pain generating, nerve ending afferents in the outer annulus, are stimulated by a combination of chemical and mechanical forces (leakage of irritative chemicals and compression and shear force on the annulus and spinal motion segment). These pain-detecting nerve elements propagate signals in the central and autonomic nervous system pathways, leading to the activation of central pain-modulating and pain-appreciating centers in the spinal cord and brain. The conscious portions of the brain interpret the resultant excitement of certain nerve centers in the spinal cord and brain as somatic and visceral pain.

[0007] The inventor and his team performed experimental studies directed to the tissue origin of spinal pain. The results of the inventor's observations, recorded during operations on humans undergoing spinal surgery under local anesthesia, conclusively demonstrated that the symptoms of mechanical low back pain originate when the outer portion of the degenerative intervertebral disc (and to a lesser extent, the capsule of the facet joint) is/are stimulated by mechanical forces. Kuslich, Stephen D., Ulstrom, Cynthia L.; "The Origin of Low Back Pain and Sciatica: A Microsurgical Investigation"; *Orthop Clin North Am* 1991 April; 22(2): 181-7.

[0008] For reasons that are not perfectly clear many, if not most, humans develop the aforementioned pathologic changes in the disc nucleus as they approach middle age. Breakdown products of the disc and facet joints stimulate sensitive nerve endings in and around the disc and facet capsule, producing low back pain, and sometimes, sciatica. This pathologic phenomenon is commonly referred to as Degenerative Disc Disease ("DDD"). Degenerative Disc Disease is the primary cause of low back pain. The DDD tissue consists of the dead and/or dying fibrocartilogenous remains of the disc nucleus and inner portions of the annulus. Various toxic chemicals—such as Substance P—have been detected in DDD discs. Other investigators have described low pH (acidity) of fluids in DDD tissue. These chemicals and fluids leak out through fissures and tears in the annulus and irritate and stimulate the nociceptive nerve endings causing back pain.

[0009] Although, effective means to prevent DDD do not exist, some relatively effective treatments for DDD do exist. A number of medical and surgical strategies are known to ameliorate symptoms. These include: pain medications that block or modulate pain afferents, or suppress central pain-recognition centers, exercises that promote tissue nutrition, flexibility and muscle strength (exercises also stimulate the release of endorphin, an endogenous morphine-like chemical), braces that restrict motion and reduce forces on tender spinal tissues, anti-inflammatory oral and injectable medications, and surgical procedures designed to remove tissues pressing on nerves, stabilize spinal motion segments and/or replace pathological tissues.

[0010] Most surgical procedures designed to relieve low back pain and sciatica involves removal of a portion of the intervertebral disc. Unfortunately, removing disc tissue leaves a void in the intervertebral space. The patient's pain following partial or complete disc removal may be more severe than the pain preceding the operation. Therefore, surgeons often perform additional operations that are intended to restabilize the spinal motion segment.

[0011] Strategies for restabilization are many and include: heating the annular region in an effort to destroy nerve endings and "strengthen" or "heal" the annulus, "fusing" the motion segment by applying bone graft on the sides of the motion segment, or within the disc space, applying rigid or semi-rigid support members on the sides of the motion segment or within the disc space, removing and replacing the entire disc with a non-flexible, articulating artificial device and removing and replacing the nucleus.

[0012] A number of artificial disc replacements have been developed. The currently available devices fall into two general categories: total disc replacements and nuclear replacements. The first category consists of total disc replacements that are made of rigid, inert substances such as metal and plastic. Examples of such devices are the Fernstrom "ball-bearing" and the LINK® and PRODISC® devices.

[0013] These types of artificial discs have five main disadvantages. First, is that the devices are relatively large and

non-compressible, so they require relatively large surgical exposures, thereby increasing the chance of morbidity, including infection and hemorrhage. Second, because the devices are constructed from rigid inert metal and plastic materials, they can cause serious damage if they were to displace into positions normally occupied by local nervous or vascular tissues. Third, the device implantation requires the removal of a large portion of the annulus. Such removal greatly reduces the inherent stability of the motion segment, at least early on, before healing occurs around the implant. Fourth, these inert, rigid-component disc replacements do not reproduce natural disc mechanics. Finally, unless these devices become and remain firmly attached to the vertebral endplates, relative motion between the implant and the vertebral bone will cause erosion of the vertebral endplates, possibly leading to subsidence, instability and/or neurological or vascular damage.

[0014] A second class of disc replacement is the nuclear replacement, a form of partial disc replacement. Examples include: the Ray implant (U.S. Pat. No. 4,772,287), the Bao implant (U.S. Pat. No. 5,192,326), and the Sulzer spiral implant (U.S. Pat. No. 5,919,235).

[0015] These devices are also inert, somewhat flexible, non-biological disc replacements. They involve removal of the nucleus and replacement of the nucleus with a non-biological plastic material that may be flexible and malleable. When these devices are placed in the excavated DDD cavity, they rub against living end-plate cartilage and bone. This rubbing may cause healthy living tissue to erode. This erosion may weaken the living cartilage and bone, resulting in subsidence of the device, fragmentation of the device and perhaps, further vertebral instability. Complete displacement and dislocation of the Ray implant has been reported.

[0016] This second category of disc replacements is intended to more closely mimic natural disc mechanics. To accomplish this, some nuclear replacements utilize the water-containing properties of hydrogel. One embodiment of the Ray implant as described in U. S. Pat. Nos. 4,772,287 and 4,904,260 consists of a block of hydrogel in combination with inert jacket such as a plastic fabric casing. The Bao implant as described in U.S. Pat. No. 5,192,326 consists of hydrogel beads enclosed by a fabric shell.

[0017] Devices using large blocks of hydrogel and other inert substances have three main problems. First, there is a 10 to 50 percent extrusion rate of the prosthetic disc beyond the DDD cavity during the post-operative period. Second, because physiologic loads and movements continue after operation, this prosthetic device can erode into the intervertebral bone, increasing instability. Third, inserting the device requires a moderate sized surgical exposure.

[0018] Kotani, et al. at Hokkaido University in Japan are developing an artificial disc made of a preformed fabric matrix (*Spine* 2001; 26:1562-1569). The fabric matrix is intended to mimic the mechanics of a natural disc. However, this technology also has shortcomings. First, the device's insertion requires a large exposure with a loss of vertebral stabilizers, i.e., the relatively large area of annulus removed during implantation. Second, the device requires that a complex weaving procedure be undertaken during manufacture. Third, many different sizes will be required for different patients and procedures. Fourth, the device must be pre-sized to fit the cavity in the disc. Fifth, since its components contain no water-imbibing component, it cannot re-hydrate itself when local ambient pressures decrease. Thus, it cannot remain hydrated in response to diurnal rhythms and function as a natural disc would function.

[0019] Devices attempting to mimic the mechanics of a natural disc also include such devices as taught in U.S. Pat. No. 6,240,926 to Chin Gan et al. This patent uses a hybrid of cultured intervertebral disc cells and a biodegradable substrate as a nuclear replacement. The device attempts to induce intervertebral disc reformation by regenerating natural disc tissue via the introduction of cultured intervertebral disc cells. Technology such as this is in an early stage of development. Compared to the wide experience with biocompatible materials such as plastics and metals, purely biological replacements may or may not prove to be practical.

[0020] While numerous techniques and devices have been developed to stabilize a spinal motion segment in an effort to ameliorate the consequences of DDD, there is a continuing need for improvements in this field.

SUMMARY

[0021] The present invention is a system for a partially biological disc replacement that stimulates natural fibrous, cartilaginous or other tissue growth in the DDD cavity, resulting in a partial biological disc replacement. Multiplicities of fibronous pieces of fibro-cartilaginous tissue promoting material are inserted into the DDD cavity inducing tissue growth. The fibro-cartilaginous tissue promoting material may be combined with hydrogel or other suitable water-imbibing material.

[0022] The present invention improves upon current techniques by creating a biological disc replacement that induces living, natural fibrous tissue growth into the DDD cavity. It is believed that living, natural fibrous tissue is preferable to dead and/or dying DDD tissue. First, living natural fibrous tissue does not exhibit acidic properties nor leak chemicals that may cause nerve inflammation and back pain. Second, living natural fibrous tissue offers more support and stability than decaying tissue.

[0023] Living natural fibrous tissue is also preferable to inert disc replacements. Living natural fibrous tissue will not erode adjacent cartilage or bone. Furthermore, there is less danger to surrounding tissues or nerves should the replaced material extrude from its intended position. Finally, living natural fibrous or fibro-cartilaginous tissue is more likely to mimic the biomechanical and morphologic characteristics of a natural disc.

[0024] The present invention replaces the dead and/or dying fibro-cartilage of a DDD disc by stimulating living natural fibrous tissue growth with a multiplicity of fibronous pieces, this living natural fibrous tissue fuses with the living tissue of the DDD cavity, forming a partial biological disc replacing the removed DDD tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIG. **1** is a perspective view of bands of fibro-cartilaginous tissue promoting material placed in a disc cavity.

[0026] FIG. **2** is a perspective view of fibro-cartilaginous tissue promoting material placed in a disc cavity.

[0027] FIG. **3** is a perspective view of an OPTIMESH™ filled with fibro-cartilaginous tissue promoting material in a disc cavity.

[0028] FIG. **4** is a cross-sectional view of an OPTIMESH™ filled with fibro-cartilaginous tissue promoting material in a disc cavity.

[0029] FIG. **5** is a perspective view of a mixture of cotton and hydrogel fibers.

[0030] FIG. **6** is a cross-sectional depiction of the expansion of the hydrogel as the hydrogel absorbs fluid.

[0031] FIG. **7** is a perspective of the expansion of the mixture of fibro-cartilaginous tissue promoting material and hydrogel as the hydrogel absorbs fluid.

[0032] FIG. **8** depicts aliquots of the fibro-cartilaginous tissue promoting material and hydrogel being inserted by a piston through a small diameter tube into the disc cavity.

[0033] FIG. **9** is a cross-sectional view of the fibro-cartilaginous tissue promoting material and hydrogel being inserted by a piston through a small diameter tube into the disc cavity.

[0034] FIG. **10** is a cross-sectional view of the bundles of fibro-cartilaginous tissue promoting material and hydrogel expanding as the hydrogel absorbs water.

DETAILED DESCRIPTION

[0035] The present invention mimics the biomechanics of a natural disc nucleus by inducing natural fibrous tissue growth. FIG. **1** depicts the device **10** of the present invention embodied in a preparation of multilayered bands of suitable fibrous tissue promoting material piled in a circular configuration **12** formed to fit securely in the DDD cavity **14**. The suitable fibrous tissue promoting material may include, but is not limited to, autograft, allograft or xenograft of fascia lata and/or throraco-lumbar fascia; natural and/or manmade polymeric fiber; fibrous tissue inducers such as: talc, pharmaceuticals and/or minerals; fibrous tissue morphogenic protein produced by recombinant DNA technology and/or notochord cells from stem cell technology and/or any combination thereof.

[0036] FIG. **2** depicts another embodiment of the device **10** as a tangled knot of suitable fibrous tissue promoting fibers **16**. In yet another embodiment, the device is multiple fabric bands made of suitable fibrous tissue promoting material. In another embodiment, the device is any combination of fibers, string, multilayered bands and/or fabric bands made of suitable fibrous tissue promoting material.

[0037] Finally, as depicted in FIGS. **4** and **5**, another embodiment of the device is a preparation of suitable fibrous tissue promoting material in combination with hydrogel chunks and/or fibers **20**. This embodiment has many advantages. The hydrogel provides water-imbibing qualities similar to a natural disc. The hydrogel thus provides a source of hydration for the device. As the hydrogel absorbs water, the hydrogel and thus the device expands. FIGS. **6** and **7** show the fluid expansion as arrows **22***a* and **22***b*. The suitable fibrous tissue promoting material induces living, natural fibrous tissue growth. The living, natural fibrous tissue gives stability and cushion to the DDD cavity. The combination of stability, cushioning and hydration allows the device of the present invention to closely mimic the characteristics of a natural disc.

[0038] FIG. **8** depicts an important feature differentiating the present invention from all of its predecessors; the device is preferably constructed within the nuclear space **24**, in a piecemeal fashion, by pushing small aliquots **26** of the filaments that make up the ultimate device, through a small diameter hollow injection tube **28**. This feature allows the nuclear replacement device **10** to be introduced through a very small portal, with very little damage or removal of the stabilizing annulus.

[0039] FIG. **9** depicts an embodiment of the invention where the tissue promoting material **32** is at least one strand with a cross-sectional diameter smaller than the diameter of the injection tube **28**. The invention is really a system, therefore, that allows the surgeon to construct a nuclear replacement using minimally invasive techniques. The system consists of a hollow injection tube **28**, a piston **30**, the filaments **26** (cotton or other fibrous tissue stimulating agents with or without hydrogel) and, in at least one embodiment, a fabric or other porous shell **18** that surrounds and contains the filamentous elements.

[0040] The method of the present invention involves boring a small entrance hole into the DDD cavity **14**. This step can be accomplished using any of several approaches: posterior laminotomy, transforaminal, or any of the anterior or anterior-lateral approaches, including endoscopic approaches. The surgeon then reams the cavity **14** to remove the DDD nucleus and perhaps some of the endplate cartilage and portions of the inner annulus. The cavity **14** is thereby prepared for the optiplasty device insertion.

[0041] The cavity **14** may be prepared by coating its surface with talc, a pharmaceutical or other suitable fibrous tissue promoting material. The multiplicity of fibronous pieces of fibro-cartilaginous tissue promoting material are then inserted using a piston **30** through a small diameter tube **28** and may or may not be secured within an Optimesh™, of U.S. Pat. No. 5,571,189 to the applicant, or any other suitable porous bag.

What is claimed is:

1. A method of constructing a semi-biologic nuclear replacement for a degenerated disc of a spine of a mammalian body comprising:

boring a small entrance hole having a first cross-sectional diameter into the degenerated disc;

creating a cavity having a maximum second cross-sectional diameter that is larger than the first diameter by reaming the degenerated disc and at least partially removing a degenerated disc nucleus via the small entrance hole;

inserting a porous container into the cavity; and

inserting a plurality of pieces of tissue promoting material into the container to create the semi-biologic nuclear replacement for the degenerated disc by stimulating the tissue forming response in the mammalian body to the tissue promoting material.

2. The method of claim **1** wherein the tissue promoting material is selected from a group consisting of fibrous tissue promoting material, cartilaginous promoting material and any combination thereof.

3. The method of claim **1** wherein endplate cartilage is partially removed.

4. The method of claim **1** wherein endplate cartilage is retained.

5. The method of claim **22** wherein portions of an outer annulus are removed.

6. The method of claim **1** wherein portions of an outer annulus are retained.

7. The method of claim **1** wherein the tissue promoting material is selected from a group comprising: autograft, allograft, or xenograft of fascia, manmade polymeric fiber, talc, tissue promoting pharmaceuticals, tissue promoting minerals, tissue morphogenic protein, notochord cells and any combination thereof.

8. The method of claim **1** wherein the disc cavity surface is coated with a tissue promoting material.

9. The method of claim **1** wherein the tissue promoting material is combined with hydrogel.

10. A method of constructing a semi-biologic nuclear replacement for a degenerated disc of a spine of a mammalian body comprising:

boring a small entrance hole into the degenerated disc;

creating a cavity by reaming the degenerated disc and at least partially removing a degenerated disc nucleus via the small entrance hole; and

inserting at least one strand of pliable tissue promoting material into the cavity such that a length of the at least one strand is folded within the cavity to create the semi-biologic nuclear replacement for the degenerated disc by stimulating the tissue forming response in the mammalian body to the tissue promoting material.

11. The method of claim **10** wherein the tissue promoting material is selected from a group consisting of fibrous tissue promoting material, cartilaginous promoting material and any combination thereof.

12. The method of claim **10** wherein endplate cartilage is partially removed.

13. The method of claim **10** wherein the endplate cartilage is retained.

14. The method of claim **10** wherein portions of an outer annulus are removed.

15. The method of claim **10** wherein an outer annulus is retained.

16. The method of claim **10** wherein the tissue promoting material is selected from a group consisting of: autograft, allograft, or xenograft of fascia lata, autograft, manmade polymeric fiber, talc, tissue promoting pharmaceuticals, tissue promoting minerals, tissue morphogenic protein, notochord cells, and any combination thereof.

17. The method of claim **10** wherein the disc cavity surface is coated with a tissue promoting material.

18. The method of claim **10** wherein the tissue promoting material is combined with hydrogel.

19. The method of claim **10** further comprising: inserting a porous container into the disc cavity; said porous container adapted for tissue promoting material insertion therein.

20. A method of constructing a semi-biologic nuclear replacement for a degenerated disc of a spine of a mammalian body comprising:

boring a small entrance hole into the degenerated disc;

creating a cavity by reaming the degenerated disc and at least partially removing a degenerated disc nucleus via the small entrance hole; and

inserting a plurality of pieces of tissue promoting material combined with a plurality of pieces of hydrogel into the cavity to create the semi-biologic nuclear replacement for the degenerated disc by stimulating the tissue forming response in the mammalian body to the tissue promoting material and hydrogel.

21. The nuclear replacement of claim **20** wherein the tissue promoting material is selected from a group consisting of fibrous tissue promoting material, cartilaginous promoting material and any combination thereof.

22. The method of claim **20** wherein endplate cartilage is partially removed.

23. The method of claim **20** wherein the endplate cartilage is retained.

24. The method of claim **20** wherein portions of an outer annulus are removed.

25. The method of claim **20** wherein an outer annulus is retained.

26. The method of claim **20** wherein the tissue promoting material is selected from a group consisting of: autograft, allograft, or xenograft of fascia lata, autograft, manmade polymeric fiber, talc, tissue promoting pharmaceuticals, tissue promoting minerals, tissue morphogenic protein, notochord cells, and any combination thereof.

27. The method of claim **20** wherein the disc cavity surface is coated with a tissue promoting material.

28. The method of claim **20** further comprising:

inserting a porous container into the disc cavity;

said porous container adapted for tissue promoting material insertion therein.

29. A method of constructing a semi-biologic nuclear replacement for a degenerated disc of a spine of a mammalian body comprising:

providing a porous container adapted for placement in the disc;

providing a plurality if pieces of strands of tissue promoting material; and

providing instructions for constructing a semi-biologic nuclear replacement of the degenerated disc, including:

boring a small entrance hole having a first cross-sectional diameter into the degenerated disc;

creating a cavity having a maximum second cross-sectional diameter that is larger than the first diameter by reaming the degenerated disc and at least partially removing a degenerated disc nucleus via the small entrance hole;

inserting the container into the cavity; and

inserting a plurality of pieces of strands tissue promoting material into the container to create the semi-biologic nuclear replacement for the degenerated disc by stimulating the tissue forming response in the mammalian body to the tissue promoting material.

* * * * *