Abstract: A cell-based therapy and delivery system is provided to treat pelvic or urological disorders, such as ED, incontinence or prolapse. Embodiments can include a centrifuge having a body portion (14a, 14b) and one or more cell loading arms (16a, 16b). The arms can be pivotably connected to the body portion. A delivery vehicle or device (30), such as a needle tip, injection tool, pellet, plug, bolus or capsule is disposable within the one or more arms such that the centrifuged treatment cells or cellular mixtures (e.g., cells and autologous adipose tissue) are directly loaded into the delivery vehicle for use.
Cell-Based Therapy and Delivery Systems and Methods

RELATED APPLICATION
This application claims priority to and the benefit of U.S. Provisional Application No. 61/243,718, filed September 18, 2009, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION
The present invention relates generally to cellular treatment and delivery systems adapted to treat target tissue, such as the corpora of the male penis, with a cellular therapy or mixture.

BACKGROUND OF THE INVENTION
Erectile dysfunction (ED) is believed to affect more than ninety million men in the United States and Europe, with seventeen million presenting with severe conditions that greatly interfere with the ability to initiate and maintain erections. ED may arise from a number of causes. Age brings on a lack of arterial elasticity in vessels supplying blood to erectile tissues. Damage to nerves necessary for initiating and sustaining erections brought on by chronic conditions (such as diabetes) or by injury can lead to dysfunction. A significant cause of nerve damage comes from injury that occurs during prostate surgeries, especially radical prostatectomies. Although new surgical procedures have been introduced that conserve the nerves in this region, a majority of men who undergo such procedures can still expect some degree of post operative ED.
A number of oral medications for treating ED have entered the marketplace in recent years, including VIAGRA, CIALIS and LEVITRA. These medications all provide significant relief to a large segment of men with ED. However, they each require that the medication be taken in advance of initiation of sexual activity and their effects may be delayed if ingested with food. Further, the effectiveness of such drugs can vary greatly from patient to patient, and is even ineffective in a large cross-section of patients.

Various treatments have also been tried in connection with ED, including administration of Prostaglandin E1 by injection into the cavernosum of the penis, by administration of a suppository into the urethra and by topical administration. These approaches allow for less advance preparation, but are neither consistently effective nor desirable applications across patient populations, especially radical prostatectomy patients.

Surgical interventions are also available for addressing ED, especially where medications are ineffective or contraindicated. Penile implants of many different configurations are used to provide support for an erection. These implants are effective in restoring patient sexual satisfaction. Increasingly, these implants have been engineered to be completely concealed within the patient. However, implants may fail over time and replacement or total removal may be required potentially leaving the patient with no relief at all. In addition, penile implants are an end stage treatment, and it is often desirable to provide treatment earlier in the disease state. Thus, there is a desire to obtain a minimally invasive yet effective and durable solution to treat ED that can be used with minimal to no side effects.

In addition to ED, there is a need for alternative yet effective solutions to treat other damaged or defective tissues within the pelvic region of a patient (man or
woman), including conditions such as male and female fecal and urinary incontinence, bladder pain, vaginal prolapse, and overall urological or gynecological health. Again, such a treatment can include injecting or applying a cellular mixture in or around damaged or defective tissue.

SUMMARY OF THE INVENTION

A cell-based therapy and delivery system is provided herein to solve many of the problems inherent in conventional systems and methods of treating pelvic or urological disorders, such as ED. The systems and methods of the present invention can include various components and elements to facilitate mixing, consolidating, encapsulating, and delivering cellular mixtures, e.g., cells and autologous adipose tissue, into target tissue of a patient to treat ED, urinary and fecal incontinence, bladder pain, vaginal prolapse and other urological or gynecological health issues.

Various embodiments of the system can include a centrifuge having a body portion and one or more arms. The arms can be pivotally connected to the body portion. A delivery vehicle or device, such as a needle tip, injection tool, pellet, bolus or capsule is disposable within the one or more arms such that the centrifuged treatment cells or cellular mixtures are directly loaded into the delivery vehicle. As such, conventional cell harvesting methods of washing, filtering and transferring centrifuged cells to an injection needle are eliminated. Instead, the loaded delivery vehicle can be removed from the arm for direct use (e.g., capsule), or an injection needle can be inserted into the arm to engage and mount the cell loaded needle tip for use with an injection needle or syringe. The cell loadable needle tip and centrifuge arms can include various structures, components and configurations to provide selective attachment and delivery vehicle mounting.
Embodiments of the present invention are directed to delivering treatment cells to target tissue of a patient. Delivery devices can include a catheter device having one or more injectate tines or apertures adapted to deliver the treatment cells to the target tissue. Further, various devices and cell markers can be included to improve visualization and deployment of cellular injections. The delivery devices can be incorporated with the centrifuge systems and methods disclosed herein, or as distinct tools to expel or deliver treatment cells to the target tissue. Various filtering, mixing and grinding devices can be included as well with the delivery devices of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a centrifuge system with cell loading arms in accordance with embodiments of the present invention.

Fig. 2 is a front view of a centrifuge system with cell loading arms in accordance with embodiments of the present invention.

Fig. 3 is an exploded view of mounting fixture and needle components for a centrifuge system in accordance with embodiments of the present invention.

Fig. 4 is a view of a mounting fixture for a centrifuge system in accordance with embodiments of the present invention.

Fig. 5 is a perspective view of a collection fixture for a centrifuge in accordance with embodiments of the present invention.

Fig. 5a is a perspective view of a porous delivery vehicle construct in accordance with embodiments of the present invention.
Fig. 6 is a sectional schematic view of a centrifuge or microfuge, and incorporated delivery needle in accordance with embodiments of the present invention.

Fig. 7 is a schematic view of a tissue grinder and mixer device in accordance with embodiments of the present invention.

Fig. 8 is a schematic view of a filter column for use with a delivery device in accordance with embodiments of the present invention.

Fig. 9 is a schematic view of a catheter injectate delivery device for deployment in the penis in accordance with embodiments of the present invention.

Fig. 10 is a schematic view of a catheter injectate delivery device for deployment in a body lumen in accordance with embodiments of the present invention.

Fig. 11 is a shrouding condom-like delivery device in accordance with embodiments of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring generally to Figs. 1-11, various embodiments of cell-based therapy and delivery systems 10 are shown. The systems 10 can include various components and elements to facilitate mixing, centrifuging, filtering and injecting cellular mixtures, e.g., cells and autologous adipose tissue or scaffolding material, into target tissue of a patient to treat ED, urinary and fecal incontinence, bladder pain, vaginal prolapse and other urological or pelvic health issues. The various components of the systems 10 can be constructed of materials such as polymers, metals, and other like materials compatible for use with such injection or treatment systems and methods.
The systems disclosed herein can be used to treat ED. With such a treatment application, cell and adipose mixtures may be injected into the corpora in a manner that assists in distributing and retaining the cellular mixture within the corpora for a period of time, e.g., minutes. Proper distribution and cell retention is promoted by driving the cellular treatment into the larger sinusoid spaces of the mid-corpora. Before, during or after injection of the cellular treatment in the corpora of the male penis, a vacuum (e.g., vacuum erection device) or other like device can be implemented to further promote the influx of blood into the penis to increase distribution and cellular viability through increased oxygenation of the tissues. Various devices, drugs and known means can be implemented to induce an erection before, during or after the injection to promote blood flow in the penis.


As depicted in the embodiment of Figs. 1-5, the cell-based therapy and delivery system can include a centrifuge having body portions 14a, 14b. The body portions 14a, 14b can be integrally or separately formed to define a unitary body portion having respective extending arms 16a, 16b. Further, the centrifuge can include one or more engagement portions 18 adapted to operably link with a spinning centrifuge motor or shaft mechanism. Those of ordinary skill in the art will
understand various centrifuge motor and drive mechanisms and systems can be incorporated to couple with and spin the centrifuge 12 at high speeds to provide the desired cell isolation and collection techniques implemented with embodiments of the present invention. The centrifuge 12 can take on a variety of shapes, sizes and configurations, including lab centrifuges and microfuges known and used by those of ordinary skill in the art.

The centrifuge 12 body can be generally bowl or basket shaped, with the arms 16a, 16b extending out from sides of the body to define the region of the centrifuge that will isolate, collect and load cells or cellular mixtures into a delivery vehicle upon completion of the high-speed spinning process. The arms 16a, 16b can be fixed or pivotable. In one embodiment, as shown in Figs. 1-2, the arms 16a, 16b can each include a collection portion 20 and a base portion 22. One or more hinges 24 or like mechanisms can be included to provide selective pivotable disposition of the collection portion 20 with respect to the base portion 22. A locking mechanism can be included to retain the collection portion 20 in alignable engagement with the base portion 22 during use. For instance, the base portion 22 can include a first tab 25a that can be selectively locked to and released from a second tab 25b of the collection portion 20. Other embodiments of the arms 16a, 16b can include ports, channels, or opening panels or elements adapted to provide selective access into the arms for seating and unseating various delivery vehicles or devices. As detailed herein, the delivery vehicles or devices can include a needle tip, capsule, pelleted cells, plugs or like constructs to facilitate use in the centrifuge 12 and direct application at the target treatment site. The base portion 22 can include a mating or sealing mechanism 26 configured to provide secure coupling of the base portion 22 to the collection portion 20 upon pivotable closure of the arms 16a, 16b.
The collection portion 20 can be tapered to include an end dome or cap. The collection portion 20 can further include at least one lumen or aperture 28. The lumen 28 is adapted to receive various devices, fixtures, needles, capsules, bolus constructs, or a myriad of other like cell delivery vehicles such that centrifugation of the cell or cell mixtures within the centrifuge 12 directly loads the cell or cell mixtures within the cell delivery vehicle for use. As such, the isolated and collected cells can be removed from the arms 16a, 16b via the delivery vehicle for use directly at a target tissue site or in a delivery device such as an injection needle. Intermediate washing, filtration and other processes typically required to transfer the centrifuged cells from the system to a delivery device (e.g., needle) are eliminated. The centrifuged cells can be isolated or collected in a pellet, plug or encapsulated form to define the cell delivery vehicle for injection or application within the patient.

In one embodiment, the cell delivery vehicle can include a needle tip or portion 30. The needle tip 30 can include a needle 34, a base 32, and an internal lumen 36 extending from base 32 to the needle 34. The needle tip 30 can be a portion of any needle known by those of ordinary skill in the art for loading and injecting fluid, cells or cellular mixtures into target tissue of a patient. The needle tip 30, or even a complete needle device, can be inserted or mounted directly within one or more of the arms 16a, 16b (e.g., lumen 28 of the collection portion 20) to collect the centrifuged cells or cellular mixture. In a modular embodiment, the needle tip 30 can be placed within a needle mounting fixture 40.

As shown in Figs. 3-4, the needle mounting fixture 40 can include a head portion 42 and a base portion 44. The head and base portions can be separate but connectable components. The head portion 42 can be sized and shaped to fit within the collection portion 20 of the centrifuge arms. For instance, a tapered end of the
head portion 42 can generally match and fit in a like construct of the collection portion 20. The head portion 42 can include a needle lumen 46 adapted to receive the needle 34 of the needle tip 30. The base portion 44 can include a lumen 48 adapted to receive the base 32 of the needle tip 30. The base portion 44 can further include a funnel lumen 50 in communication with the lumen 48. Various apertures, fasteners or other attachment features 52 can be included with the head and base portions 42, 44 to facilitate selective engagement and disengagement of the components for seating and removing the needle tip 30 from the mounting fixture 40. When the needle tip 30 is seated, a path of fluid communication is provided from the interior or cavity of the centrifuge 12, to the funnel lumen 50, through the lumen 48, and into the needle lumen 46 of the needle tip 30. Accordingly, the centrifuged cells or cellular mixture are isolated during the spinning process through the arms 16a, 16b, into and through the funnel lumen 50 and lumen 48, for collection or loading in the needle tip 30 (e.g., internal needle lumen 36). Upon completion of the cellular collection process, the arms 16a, 16b can be pivotably opened to expose the needle tip 30 (e.g., within the fixture 40) having the loaded or collected treatment cells or cellular mixtures therein. The needle tip 30 can then be removed and attached to an injection or syringe needle for use in treating target tissue within the patient.

Referring generally to Fig. 5, the arms 16a, 16b are adapted to receive a collection fixture 60. The collection fixture 60 can include a funnel lumen 62 and a cylindrical lumen 64. The collection fixture 60 can be sized and shaped for seating within the collection portion 20. Like the needle fixture 40, the collection fixture 60 is adapted to collect and load centrifuged cells or cellular mixtures during the centrifuge spinning process. However, rather than inserting a needle tip 30 within the fixture, other delivery vehicle constructs 66 can be mounted or inserted within the
fixture 60 (e.g., lumen 64) for loading of the centrifuged cells. For instance, a capsule, a pellet, a plug, a bolus element, or other like constructs can be placed within the fixture 60 to collect the centrifuged cells. The loaded constructs can be constructed of various materials, shapes and configurations to provide the desired cell delivery vehicle. Various embodiments of the vehicle delivery construct 66 can be shaped and sized to generally match or correspond to anatomical features (e.g., bladder neck, urethra, penis, etc.) to promote placement, deployment and therapeutic application of the cells or cellular mixtures at the target treatment site.

In one embodiment, the delivery vehicle construct 66 is a capsule 70. The capsule 70 can be constructed of resorbable or biocompatible materials. Further, the capsule 70 can be constructed of a material adapted for time release during use within the patient. Centrifuged cells or cellular mixtures traverse the funnel lumen 62 and into the uncapped capsule 70 for use. The capsule can be constructed of various known materials, including Torpac or Gelatin. Upon completion of the centrifugation process, the capsule can be removed and capped such that the cells or cellular mixtures are encapsulated within an advantageous delivery vehicle for use. The capsule 70 can include a translucent or transparent window to facilitate visualization of the capsule contents, or to provide a bioabsorbable portion of the capsule. Additional drugs, saline or like components can be injected into the capsule prior to delivery to the target tissue. After a short time, the bioabsorbable window dissolves to allow the cells to migrate. The entire capsule can also dissolve to leave no trace of the capsule after treatment. Other embodiments of the capsule can include slots or channels, such as laser cut slots, to facilitate controlled release of the loaded cells within the capsule. Introducer or insertion tools can be included to facilitate deployment of the capsule to the treatment site. The tool can include features to
protect the capsule during deployment and facilitate proper placement at the target site.

In various embodiments, the delivery vehicle construct 66 can simply be a concentrated pellet of the centrifuged cells formed in the one or more arms 16a or 16b for later application delivery within a syringe, capsule or other device. Alternatively, the delivery vehicle construct 66 can include a porous (e.g., sponge-like or absorbent) or bolus structure or device adapted to receive the centrifuged cells within the fixture 60 for later delivery at or within the target tissue site.

Various cells or cell mixtures are envisioned for use with the present invention, including those loaded in the delivery vehicle as a result of the centrifugation process. Cells or mixtures initially placed or loaded into the centrifuge for isolation and concentration can include adipose (i.e., fat) tissue, stem cells, and other desirable cell types. It is noted that adipose includes or yields a high number of cell types, including stem cells. The adipose tissue can come from anywhere in the body. In one embodiment, the adipose tissue is obtained from the abdominal area of the patient. Other common areas may include the thigh and back area of the patient. Adipose-derived autologous cells can result from the centrifugation process to provide a heterogeneous cell mixture used in the described tissue treatment procedures. The various cells that can be derived from adipose can include endothelial cells, endothelial precursors and progenitors, mesenchymal stem cells, vascular smooth muscle cells, fibroblasts, pericytes, macrophages, and the like. Collagen can be added to cells and mixed with adipose cells to get a desired injectable product or injectate. Further, Fibrin™, Fibronogen thrombin, inflammatory agents, elastin or denatured proteins can be added to create the desired injectate to promote local retention and scaffolding. In certain embodiments, cells or cellular mixtures can be mixed with
InteXen™ graft materials to promote or increase the desired healing response at the treatment area.

For various embodiments, a desirable size for the adipose particles or cellular mixtures can be approximately 1 mm or smaller, for those treatments directed to injecting or applying the cellular mixture into the mid-corpora of the penis where the sinusoid spaces are generally the largest. It is understood that venous outflow originates in tiny venules leading from the peripheral sinusoids immediately beneath the tunica. Accordingly, the adipose particles can be sized so that they remain in the larger mid-corpora, generally preventing the particles from travelling to the smaller peripheral sinusoids of the penis and reducing the risk of a fat embolism. Other particular dimensions, as well as grinding and filtering parameters can be employed depending on the particular treatment site and needs. In one embodiment, the centrifuge 12 can include a mixing arm or mechanism to blend collagenase and cells to speed up the separation process.

In certain embodiments, the centrifuge 12 can be incorporated with a tissue grinder, mixer and/or syringe or like delivery system to combine the benefits of cellular consolidation with delivery to the target treatment or tissue site. For instance, the above-disclosed centrifuge, or known centrifuge devices, can be provided in a handheld configuration including a centrifuge and needle or syringe device 13 to facilitate collection and injection and cell delivery therapy in a single system, as shown if Fig. 6. The syringe itself can be adapted to spin, or can be mounted within a spinning centrifuge, such that the needle or syringe isolates or collects the cells or cellular mixture for applying to target tissue. To provide the desired scalability and functionality desired for various embodiments, the centrifuge devices described herein can be replaced or combined with a microfuge device 15. Various microfuge devices
are known to those of ordinary skill in the art. Further, the centrifuge 12 or other components described or incorporated herein can be combined with placement mechanisms such as straps, clamps or shrouding devices. These placement mechanisms can be particularly useful in coupling the cell delivery systems and components onto or around the penis for treating ED.

Various delivery devices are provided for delivering a cellular treatment or the centrifuged cellular treatment to the target tissue site of the patient. The delivery devices can be used to treat various diseases and disorders, such as ED, urinary incontinence, vaginal wall prolapse, and other urological or gynecological conditions.

Embodiments of the present invention can include a tissue grinder and mixer device 90, as shown in Fig. 7. The device 90 can be incorporated with or in lieu of a conventional syringe. The device 90 can include a mixing chamber 94. The mixing chamber 94 can include a plurality of cell injection apertures 96 defined by an injection manifold 98. One or more plunger devices 100 can be manually operated or motorized to push the tissue through the mixing chamber 94 for controlled injection out the injection apertures 96. One or more screens or like devices 102 can be included to filter the tissue traversing through the mixing chamber 94. Various embodiments of the device 90 can operate as a fat or tissue extruder in preparation for treatment injections.

Various filters or other output control devices can be included with embodiments of the present invention to limit or control the quantity of desired cells or cellular mixture going into the syringe for treatment applications. In one embodiment, a treatment syringe, for use with the disclosed embodiments or other known treatment syringes such as those disclosed in the incorporated references, can include a columned §1 region having one or more filters 82, as shown in Fig. 8. The
filters 82 can be configured to have various porous dimensions and constructs to promote selective or layered cell separation. A wash of compatible flow material or cells can be applied over the bulk tissue. Large filter configurations can serve to block mass bulk, medium filter configurations can serve to block adipose tissue, and smaller or dense filter configurations can serve to allow only stem or like cells through.

Figs. 9-11 show various delivery devices 110 that can be used to deliver the treatment cells or cellular mixtures to the treatment site - e.g., corpora of the male penis for ED treatment, or urethral or pelvic tissue sites in male and female patients. Certain embodiments can include a catheter device 112 having one or more extending tines 114 in fluid communication with a lumen of the catheter. As such, the treatment cells or mixture can be advanced by various known means through the catheter lumen and out the extending tines 114 for contact on or in target treatment tissue. The level of injectate pressure applied to advance the treatment cells out of the tines can vary depending on the level of treatment penetration desired. For instance, a high pressure can be utilized to facilitate penetration at least to some extent into the treatment tissue. Lower pressure can be employed to provide a surface treatment or layering to the target tissue. In various embodiments, the catheter can include one or more apertures in communication with the internal lumen of the catheter to facilitate delivery of the treatment injectate from the catheter to the treatment site. Various injectate or needless device structures, components, methods and techniques described and depicted in U.S. Patent Publication No. 2006/0129125 and International Publication No. WO2007/079152 are envisioned for use, alone or in combination, with embodiments of the present invention. As such, the entire disclosures of the above-referenced publications are incorporated herein by reference. Different concentrations
of treatment cells can be employed for injection through the tines or apertures to better control of cell distribution and treatment. Further, various cool down stages can be employed to modify and improve the makeup and deliverability of the injectate.

Embodiments of the catheter device 112 can be inserted in through the meatus of the penis such that the injectate tines 114 or apertures are adjacent the target treatment site. Further, markers 116 or other indicia can be included along any portion of the catheter to facilitate deployment and positioning of the catheter during insertion and use. The markers 116 can include various known marking techniques for surgical tools. Moreover, nano-dot or other nano-marking elements can be included on or with the treatment cells themselves. Such nano-marking in the cells can also provide indication of flow rate and location during use and injection. For instance, marked cells can be tracked and followed to ensure the marked injectate is penetrating or reaching the target tissue structure - e.g., corpora of the penis, or pelvic tissue. Various dyes, magnetic particles and other known indicia or additives can be employed for use in tracking the cells with known surgical visualization tools, monitors and equipment.

In the embodiment of Fig. 10, the catheter 112 is adapted to traverse the urethra U or other pelvic body lumen to reach and treat a target tissue site. The catheter 112 of this and other embodiments can include a balloon 120 or like expansion device adapted to position and anchor the injectate tines 114 or apertures in place within the body lumen. Once in place, the treatment injectate can be expelled from the catheter. The balloon device 120 can be deflated or otherwise contracted to allow for removal of the catheter 112 from the body lumen.
Other embodiments of the delivery device 110 can include a small guidewire adapted to traverse through a cystoscope to expel cellular treatment injectate through tines or apertures in the guidewire, much like the catheter devices 112 disclosed herein. Still other embodiments can employ a guidewire or catheter device as disclosed herein for use with known DaVinci robot components, arms, and systems to provide cellular injectate treatment.

Fig. 11 depicts an embodiment of the delivery device 110 having a thin-walled shrouding element 124 or condom-like device. The element 124 is adapted to fit over at least a portion of the male penis, and can include at least one port 126. Various cell injection devices can be coupled with the port 126, wherein the treatment injectate is expelled from the injection device, through the port 126 and into the interior of the shrouding element 124 for retention during treatment. When the shrouding element 124 is placed on the penis and injected with treatment cells or cellular mixtures, treatment occurs transdermally.

The needle or syringe devices adapted to deliver the treatment cells to the target tissue site (e.g., corpora) in the present invention can include one or more needles to provide selective or spatial distribution of the treatment cells to the tissue. Further, the needle lengths can be predefined or adjustable to control the depth of penetration into the target tissue. Various stops and other devices can be included to prevent the needles from penetrating beyond an acceptable or predefined depth. Further, various protrusions, abrasive surfaces, and like features can be included with the delivery devices 110, or their components, to promote localized injury or trauma at or proximate the tissue treatment site. Such trauma can allow for an increase in healing efficacy and retention of the treatment cells at the target tissue site.
A variety of materials may be used to form portions or components of the present invention, including nitinol, polymers, elastomers, thermoplastic elastomers, metals, ceramics, springs, wires, plastic tubing, and the like.

All patents, patent applications, and publications cited herein are hereby incorporated by reference in their entirety as if individually incorporated, and include those references incorporated within the identified patents, patent applications and publications.

Obviously, numerous modifications and variations of the present invention are possible in light of the teachings herein. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein.
CLAIMS

1. A cell therapy centrifuge system, comprising:
   a main body portion;
   one or more loading arms extending out from the main body portion, the one or more loading arms including a lumen defined therein; and
   a cell collection fixture adapted to at least partially fit within the lumen of the one or more loading arms, wherein the cell collection fixture is adapted to collect cells in a cell delivery vehicle during spinning of the main body portion such that the cell delivery vehicle is removable from the one or more loading arms for use in treating target tissue of a patient.

2. The system of claim 1, wherein the one or more loading arms includes two opposing loading arms.

3. The system of claim 1, wherein the one or more loading arms include a base portion and a collection portion pivotably connected to facilitate seating and removal of the cell delivery vehicle.

4. The system of claim 1, wherein the cell delivery vehicle is an injection-needle portion.

5. The system of claim 1, wherein the cell delivery vehicle is a capsule.

6. The system of claim 1, wherein the cell delivery vehicle is a porous construct.
7. The system of claim 4, wherein the needle portion is adapted to attach to an injection syringe for injection of the collected cells.

8. The system of claim 1, wherein the cell delivery vehicle is a time-released capsule.

9. The system of claim 1, wherein the collection fixture includes a lumen at least partially tunneled to facilitate cell collection.

10. A cell-based therapy centrifuge system, comprising:
   a main body portion;
   two cell loading arms extending out from the main body portion, the cell loading arms each including an internal bore in fluid communication with an interior of the main body portion, wherein the cell loading arms further include a base portion pivotably coupled to a collection portion; and
   a cell collection fixture adapted to at least partially fit within the interior bore of the collection portion, wherein the cell collection fixture is adapted to collect treatment cells in a cell delivery vehicle during spinning of the main body portion for use in treating a target tissue site.

11. The system of claim 10, wherein the cell delivery vehicle is an injection needle tip.

12. The system of claim 11, wherein the needle tip is adapted to attach to an injection syringe for injection of the collected cells into the target tissue site.
13. The system of claim 10, wherein the

14. The system of claim 13, wherein the capsule is a time-released capsule.

15. The system of claim 10, wherein the cell delivery vehicle is a porous construct.

16. The system of claim 10, wherein the base portion and the collection portion of the cell loading arms include an engagement mechanism.

17. The system of claim 16, wherein the engagement mechanism is a tab engagement mechanism.

18. A method of treating a target tissue site in a patient with treatment cells, comprising:

   providing a centrifuge system including a body portion and at least one pivotable loading arm, wherein the at least one pivotable arm includes a collection fixture having an internal lumen adapted to selectively receive a cell delivery vehicle;

   inserting the cell delivery vehicle into the collection fixture of the at least one pivotable arm;

   actuating the centrifuge system to spin at a high speed such that treatment cells are collected and loaded in the cell delivery vehicle;

   removing the cell delivery vehicle from the collection fixture; and

   using the cell delivery vehicle to directly treat a target tissue site of a patient.
19. The method of claim 18, wherein the method of claim 18, wherein the
and using the cell delivery vehicle includes inserting the needle portion into an
injection syringe.

20. The method of claim 18, wherein the cell delivery vehicle is a capsule and
using the cell delivery vehicle includes placing the capsule at the target tissue site of
the patient.
**INTERNATIONAL SEARCH REPORT**  
**International application No**  
PCT/US2010/049515

A. **CLASSIFICATION OF SUBJECT MATTER**

**INV.** B04B5/04  B04B7/08

ADD.

According to International Patent Classification (IPC) into both national classification and IPC

B. **FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

B04B  A61K  C12M  C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. **DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>US 2005/084961 A1 (HEDRICK MARC H [US] ET AL) HEDRICK MARC H [US] ET AL</td>
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<td>paragraph [0173] ; figures 7,8, 13</td>
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Further documents are listed in the continuation of Box C.  
[ ] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another document or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"S" document member of the same patent family

Date of the actual completion of the international search

21 January 2011

Date of mailing of the international search report

01/02/2011

Name and mailing address of the ISA

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Fax. (+31-70) 340-3016

Authorized officer

Lei Tner, Josef
INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 18-20
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. **□** Claims Nos:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **□** Claims Nos:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. **□** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **□** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. **□** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos:

4. **□** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

- No protest accompanied the payment of additional search fees.
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