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(54) APPARATUS AND METHOD TO ACCESS THE BONE MARROW FOR ONCOLOGY AND STEM CELL APPLICATIONS

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Publication Classification

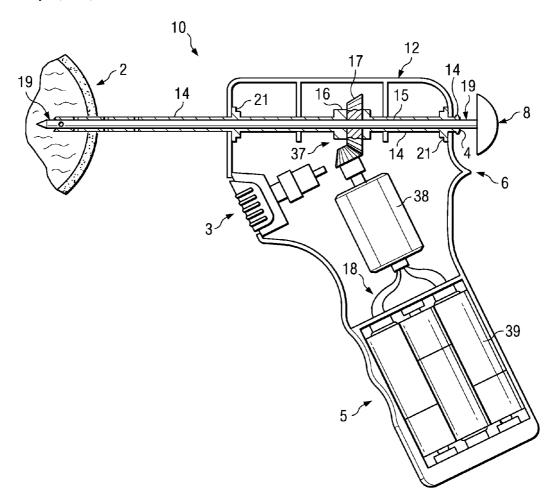
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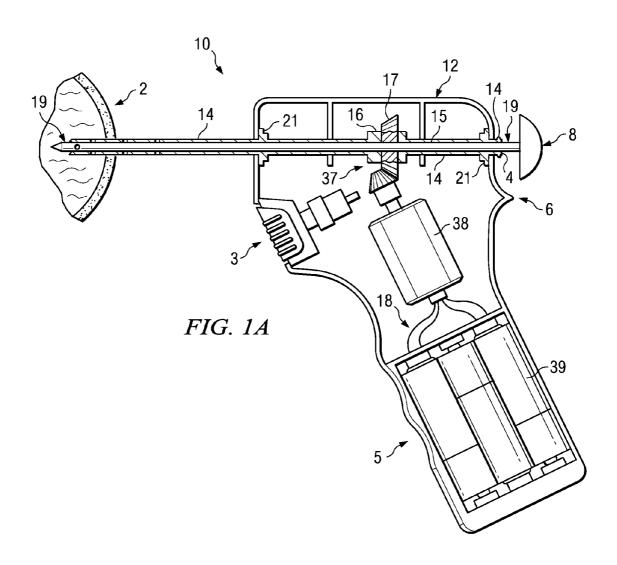
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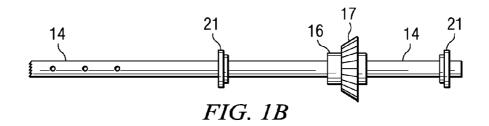
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(57)ABSTRACT

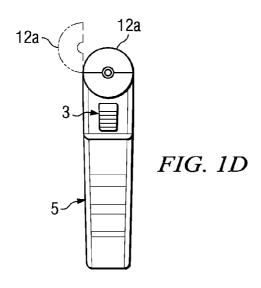
An apparatus for removing portions of bone marrow from a bone is provided. The apparatus includes a housing and a hollow drive shaft operable to engage a gear assembly. The hollow drive shaft includes a first end operable to penetrate the bone and a second end operable to allow retrieval of portions of bone and bone marrow. The apparatus also includes a removable trocar. The removable trocar includes an inner channel operable to convey portions of bone and bone marrow. The gear assembly is able to engage and rotate the hollow drive shaft. A motor operable to drive the hollow drive shaft into the bone marrow by rotation of the hollow drive shaft and a power supply and associated circuitry operable to power the motor are also included.

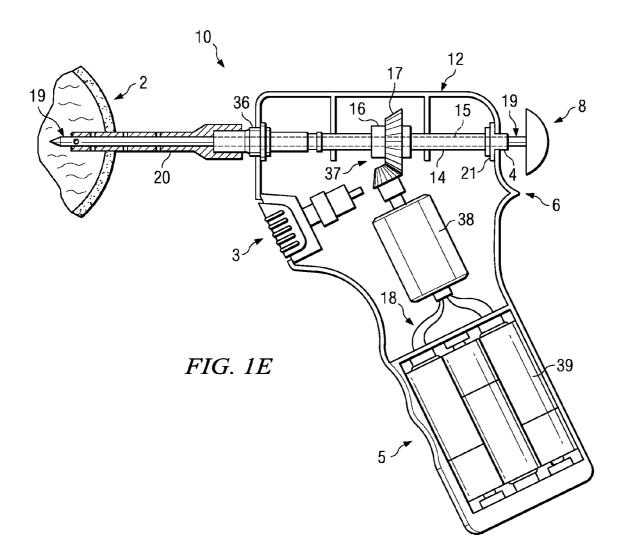


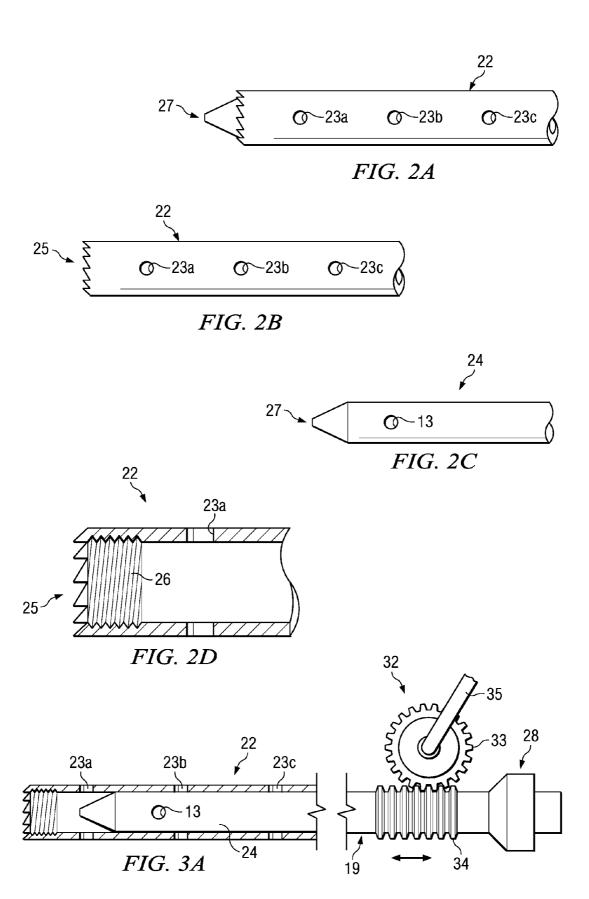


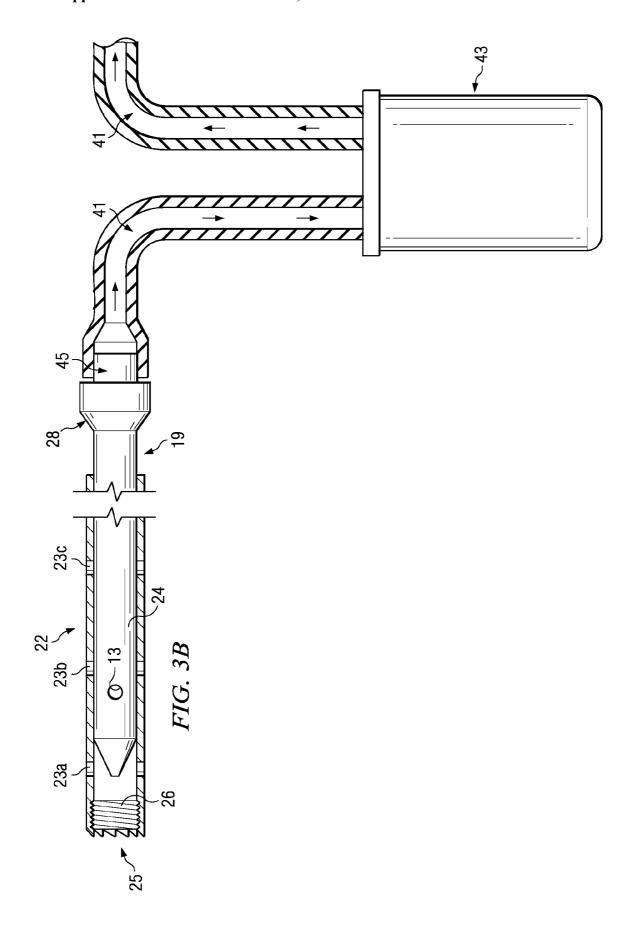


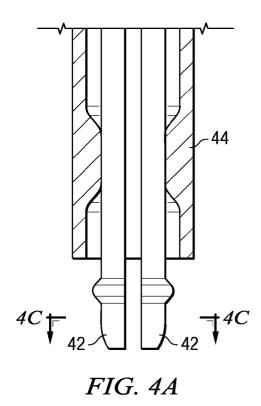












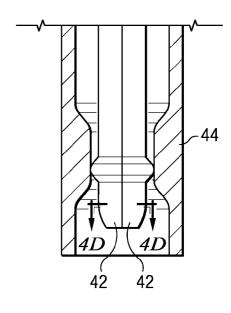


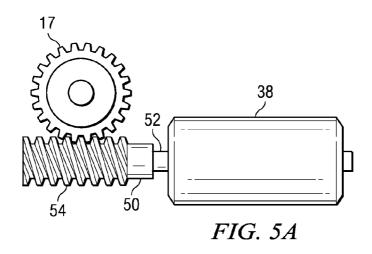
FIG. 4B

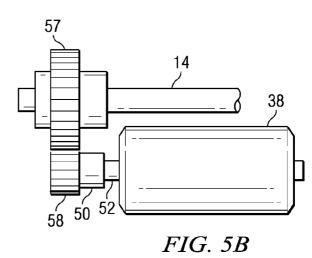


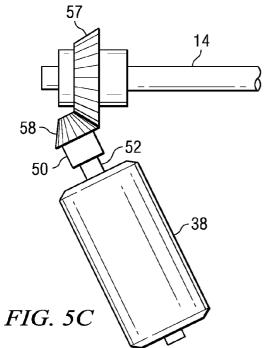




FIG. 4D







APPARATUS AND METHOD TO ACCESS THE BONE MARROW FOR ONCOLOGY AND STEM CELL APPLICATIONS

RELATED APPLICATION

[0001] This application is a divisional of U.S. patent application Ser. No. 11/781,597 filed Jul. 23, 2007, which is a divisional of U.S. patent application Ser. No. 11/389,732 filed on Mar. 27, 2006, which is a divisional of U.S. patent application Ser. No. 10/448,650 filed May 30, 2003, by Larry J. Miller, which claims priority to U.S. Provisional Patent Application Ser. No. 60/384,756 filed May 31, 2002. The contents of these applications are incorporated herein in their entirety by this reference.

TECHNICAL FIELD

[0002] The present invention is related to an apparatus and method for withdrawing specimens from the bone or bone marrow. The apparatus and method can be used to extract stem cells or bone marrow for transplantation or diagnostic purposes.

BACKGROUND OF THE INVENTION

[0003] There are many clinical conditions where it is important to be able to access and retrieve bone marrow. In some cases it may be necessary to treat diseases with a bone marrow or stem cell transplant to restore functioning blood cells in the body after high-dose chemotherapy. Such conditions may include acute leukemias, brain tumors, breast cancer, Hodgkin's disease, multiple myeloma, neuroblastoma, non-Hodgkin's lymphomas, ovarian cancer, sarcoma and testicular cancer. In other cases it is necessary to access the bone marrow to obtain a sample of the marrow for diagnostic testing. These conditions may include cancer of any type and hematologic disease of any origin.

[0004] Current techniques for gaining access to bone marrow can be difficult, traumatic and occasionally dangerous, depending on the site selected for harvest, the operator's expertise and the patient's anatomy. In general, the devices available for gaining access to the medullary cavity of the bone, where the bone marrow is located, include a trocarfitted needle, with handles to facilitate application of pressure and rotation. These types of devices require substantial force to break through the outer cortex of the bone by a fracturing technique. The exertion of high pressure upon the needle causes pain for the patient and often damages the tip of the needle. This is particularly a problem when harvesting from the sternum of a patient because the excess force can cause penetration through the sternum and can damage underlying structures such as the heart and great vessels.

[0005] Another disadvantage of current techniques to access the bone marrow is that frequently more than one penetration site into the bone is required to retrieve enough bone marrow to either perform diagnostic tests or for transplantation purposes. To retrieve an adequate sample of bone marrow for either a bone marrow or stem cell transplant, a physician may need to put the needle into several different parts of the pelvis which may require up to six needle puncture sites or more. This multiple-pass requirement can be extremely painful for a patient and may deter people from donating bone marrow. This technique of using multiple passes can also cause fatigue in smaller operators who may lack strength to complete multiple-pass procedures.

[0006] Retrieving bone samples for diagnostic purposes is likewise difficult. Occasionally the core sample of bone is not retrieved because it is not extracted successfully with a standard biopsy needle. Thus, multiple attempts may be necessary to obtain a satisfactory bone or bone marrow biopsy.

[0007] Current techniques require that biopsy needles be forced by manual pressure into bone. These techniques may have undesirable side effects such as damaging a needle tip or having the needle slide off the proposed bone target and into organs or soft tissues.

SUMMARY OF THE INVENTION

[0008] There is a need for an apparatus and method to access the bone marrow that is minimally traumatic to the patient and that allows a sufficient amount of bone marrow to be removed the first time the bone is penetrated. In accordance with teachings of the present invention, an apparatus and method for the removal of portions of bone marrow from a bone are provided.

[0009] In one embodiment the apparatus includes a housing and a hollow drive shaft operable to engage a gear assembly. The hollow drive shaft includes a first end operable to penetrate the bone and a second end operable to allow retrieval of portions of bone and bone marrow. The hollow drive shaft also includes an inner channel operable to convey portions of bone and bone marrow. The apparatus also includes a removable trocar with a first end operable to penetrate the bone and a second end. The removable trocar includes an inner channel operable to convey portions of bone and bone marrow. The gear assembly is able to engage and rotate the hollow drive shaft. A motor operable to engage the gear assembly and drive the hollow drive shaft into the bone marrow by rotation of the hollow drive shaft and a power supply and associated circuitry operable to power the motor are also included.

[0010] In another embodiment, an apparatus for removing portions of bone and bone marrow from a bone for diagnostic or therapeutic purposes is provided that includes a housing and a hollow drive shaft operable to engage a gear assembly. The hollow drive shaft includes a first end operable to attach to a penetrator and a second end operable to allow retrieval of portions of bone marrow. The hollow drive shaft also includes an inner channel operable to convey portions of bone marrow to an operator. The detachable penetrator is able to penetrate the bone marrow and collect specimens of bone marrow. Also included is a trocar having a first end operable to penetrate the bone marrow and a second end. The trocar can be removably inserted into the inner channel of the hollow drive shaft. A connector operable to releasably attach the penetrator to a hollow drive shaft is also included. A gear assembly operable to engage and rotate the hollow drive shaft is provided. A motor operable to engage the reduction gear assembly and drive the penetrator into the bone marrow by rotation of the hollow drive shaft and a power supply and associated circuitry operable to power the motor are also provided.

[0011] In a further embodiment of the invention a hollow drive shaft assembly operable to remove bone or tissue from a bone marrow is provided. An outer hollow drive shaft and a removable inner trocar operable to penetrate the bone marrow are included. The outer hollow drive shaft is removably coupled to a gear assembly and the outer hollow drive shaft includes an inner channel operable to convey portions of bone and bone marrow.

[0012] In a further embodiment of the invention a method for performing a bone marrow biopsy is provided that

includes inserting a hollow drive shaft and trocar into the bone marrow by means of a powered apparatus. The trocar may be removed from the hollow drive shaft and suction may be applied to an inner channel of the hollow drive shaft so that portions of bone and bone marrow may be retrieved from the inner channel of the hollow drive shaft.

[0013] An alternative method of performing a bone marrow biopsy is provided that includes attaching a penetrator to a hollow drive shaft and inserting an inner trocar into the hollow drive shaft and penetrator. The penetrator is then inserted into the bone marrow by a powered apparatus. The inner trocar is removed from the hollow drive shaft and penetrator, and suction may be applied to the inner channel of the hollow drive shaft to retrieve portions of bone marrow. In a particular embodiment of the invention the site of bone marrow biopsy is controlled by a second end of the trocar comprising a ratcheted gear operable to control the depth of sampling from the bone marrow.

[0014] In a further embodiment of the invention, a method of harvesting bone marrow for transplantation is provided that includes inserting a hollow drive shaft and inner trocar into the bone marrow by means of a powered apparatus coupled with the hollow drive shaft. The inner trocar is removed from the hollow drive shaft. A suction is then applied to the inner channel of the hollow drive shaft to retrieve portions of bone marrow. The inner trocar may be replaced into the hollow drive shaft. The steps of removing the inner trocar from the hollow drive shaft and applying suction to the inner channel of the hollow drive shaft to retrieve portions of bone marrow may be repeated until a sufficient quantity of bone marrow has been harvested for bone marrow transplantation.

[0015] In a particular embodiment of the invention, the site of harvest within the bone marrow may be changed by a ratcheted gear attached to the second end of the trocar. The gear may be used to change the depth of sampling from the bone marrow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] A more complete and thorough understanding of the present embodiments and advantages thereof may be acquired by referring to the following description taken in conjunction with the accompanying drawings, in which like reference numbers indicate like features, and wherein:

[0017] FIG. 1A illustrates an embodiment of an apparatus for removing a bone marrow sample shown in longitudinal cross section.

[0018] FIG. 1B illustrates an embodiment of a hollow drive shaft of the current invention.

[0019] FIG. 1C illustrates an embodiment of a trocar of the current invention.

[0020] FIG. 1D illustrates an embodiment of an apparatus of the current invention.

[0021] FIG. 1E illustrates an embodiment of an apparatus for removing a bone marrow sample shown in longitudinal cross section.

[0022] FIG. 2A illustrates an example of a hollow drive shaft or penetrator of the current invention.

[0023] FIG. 2B illustrates an example of a hollow drive shaft or penetrator of the current invention.

[0024] FIG. 2C illustrates an example of an inner trocar of the current invention.

[0025] FIG. 2D illustrates an example of a hollow drive shaft or penetrator of the current invention.

[0026] FIG. 3A illustrates an example of an attachment of the current invention.

[0027] FIG. 3B is an illustration of an attachment of the current invention.

[0028] FIG. 4A is an illustration of a hollow drive shaft and trocar of the current invention.

[0029] FIG. 4B is an illustration of a hollow drive shaft and trocar of the current invention.

[0030] FIG. 4C is an illustration of a hollow drive shaft and trocar of the current invention in cross section.

[0031] FIG. 4D is an illustration of a hollow drive shaft and trocar of the current invention in cross section.

[0032] FIG. 5A-C illustrates example gear assemblies of the current invention.

DETAILED DESCRIPTION OF THE INVENTION

[0033] Preferred embodiments of the invention and its advantages are best understood by reference to FIGS. 1A-5C herein like numbers refer to same and like parts.

[0034] FIG. 1A illustrates an example of an apparatus for removing bone marrow from a bone. Apparatus 10 may be used to obtain a sample of bone marrow from any suitable bone in the body such as the iliac crest or the sternum. In one embodiment, apparatus 10 includes housing 12, a hollow drive shaft 14, removable trocar 19, gear assembly 37, motor 38 and power supply 39. Housing 12 may include on/off switch 3, handle 5 and guard 6. Handle 5 may be angled downward to allow ease of operation and also to allow end of hollow drive shaft 14 to turn without obstruction from a hand. Housing 12 encompasses power source 39, motor 38 and associated circuitry 18, hollow drive shaft 14 and gear assembly 37. Hollow drive shaft 14 includes inner channel 15 and collar 16. Gear 17 of gear assembly 37 engages collar 16 of hollow drill shaft 14 and thereby rotates hollow drive shaft 14. [0035] Removable trocar 19 may be inserted into inner channel 15 of hollow drive shaft 14. Trocar 19 is hollow and has an inner channel operable to convey bone and bone marrow samples. Trocar 19 may have a handle 8 that can be used to tighten trocar 19 in place or to remove it from inner channel 15 of hollow drive shaft 14. Hollow drive shaft 14 may include luer lock connector 4 at the point where it exits housing 12. A luer lock connector may allow hollow drive shaft to connect to a suction apparatus such as a tubing or syringe or to any other suitable apparatus that would assist in obtaining a bone or bone marrow biopsy specimen. An access port, such as a suction port may also releasably attach to an end of hollow drive shaft where it exits housing 12, for example to a luer lock connector. Such an attachment may be a plug, a port, a suction apparatus, swivel port or other adapter.

[0036] FIG. 1B shows hollow drive shaft 14 removed from apparatus 10. In one embodiment, hollow drive shaft 14 may include one or more thrust bearings 21. Thrust bearings may absorb pressure from the thrust of a drive shaft into bone during drilling. Also included in hollow drive shaft are side ports shown in further detail in FIG. 2. FIG. 1C illustrates removable trocar 19 which includes handle 8. Handle 8 may be formed into a shape that is easily grasped and turned during the process of obtaining a biopsy. Removable trocar 19 may include one or more side ports operable to access a bone marrow specimen shown in greater detail in FIG. 2.

[0037] In one embodiment, shown in FIG. 1D, housing 12 may include a releasable hatch or door 12a that may be opened to allow hollow drive shaft and attached gear 17 to be

removed after use of apparatus 10. This may be desirable where apparatus 10 is reusable and hollow drill shaft 14 and removable trocar 19 are disposable. A releasable hatch or door may also be desirable to clean the inside of apparatus 10. [0038] In another embodiment of the current invention, shown in FIG. 1E, detachable penetrator 20 may be attached to hollow drive shaft 14 by means of connector 36 and drilled into bone 2. In this embodiment, removable trocar 19 may be inserted into inner channel 15 of hollow drive shaft 14 and into the hollow channel of penetrator 20. Penetrator 20 may include side ports to permit access to bone and bone marrow samples during a biopsy or bone marrow harvest procedure. One advantage of an embodiment that includes a detachable penetrator is it allows penetrators of various sizes and configurations to be attached to hollow drive shaft 14. In this embodiment, connector 36 includes an inner channel operable to allow retrieval of bone and bone marrow specimens. [0039] FIGS. 2A-D show an end 22 of either a hollow drive shaft or a penetrator that is suitable to penetrate a bone. FIG. 2A, illustrates hollow drive shaft or penetrator end 22 which may include multiple sampling ports 23 through which bone marrow or other biopsy material may be aspirated. Sampling ports 23a, 23b and 23c are each operable to retrieve a portion of bone marrow. When removable trocar end 24 is in position within inner channel of hollow drive shaft end 22 sampling port 13 of removable trocar end 24 may align with sampling port 23a, 23b, or 23c. An operator may determine the level in the bone marrow where a specimen is taken or which sampling port (23a, 23b or 23c) to align with trocar sampling port 13. Hollow drive shaft or penetrator end 22 may include serrated tip 25 as shown in FIG. 2B or any other suitable configuration for sampling bone or bone marrow.

[0040] FIG. 2C shows removable trocar end 24 having a sampling port 13 near tip 27 through which a sample of bone or bone marrow can be retrieved as well as through a sampling port 23a, 23b or 23c. When sampling port 23a, 23b or 23c of hollow drive shaft or penetrator 22 is aligned with sampling port 13 of removable trocar 24, a portion of bone marrow may be suctioned out of the bone. Removable trocar 24 may be removed allowing bone marrow to be suctioned through one or more sampling ports 23 of hollow drive shaft or penetrator 22 at different sites in a bone marrow cavity sequentially. FIG. 2D shows another example of tip 25 of hollow drive shaft or penetrator end 22 having internal threads 26 that are able to engage a specimen of bone and core it out as hollow drive shaft or penetrator 22 is drilled into bone. Threads 26 may engage and adhere to a portion of bone or to a semisolid substance such as bone marrow and maintain contact with the specimen so it may be successfully retrieved.

[0041] FIG. 3A shows operating mechanism 32 that may be included in some embodiments of the invention and may be attached to hollow drive shaft 14 and manipulated to change the depth in a bone marrow where sampling occurs. Operating mechanism 32 includes handle 35 and gear 33. Gear 33 engages gear 34 attached to trocar 19. Suction port 28, shown attached to trocar 19, may be used to retrieve portions of bone marrow from inner channel 15 of hollow drive shaft 14.

[0042] FIG. 3B shows an example suction port 28 that may be connected to trocar 19 where it exits housing 12. In one embodiment of the invention a suction port or suction swivel apparatus may also be connected to the hollow drive shaft 14. This feature allows a suction apparatus of the type well known to one skilled in the art to be used to obtain bone marrow samples. Suction port 28 may also be configured to attach

directly to a penetrator for example in an embodiment of the invention where the penetrator is detached from the housing before it is accessed for bone marrow retrieval. Also shown in FIG. 3B is a suction swivel apparatus 45 that allows a suction tube 41 to attach to suction port 28. Suction swivel apparatus 45 allows suction port 28 to remain attached to suction tube 41 while an attached drilling apparatus is drilling into bone marrow without kinking or twisting suction tube 41. Also shown in FIG. 3B is receptacle 43 that is interposed between suction tube 41 and a source of suction such that a bone marrow specimen may be successfully retrieved into receptacle 43 and not lost into a suction machine.

[0043] FIG. 4A-D shows an example hollow drive shaft end or penetrator end 44 and inner trocar 42 having a split-needle configuration. An inner trocar 42 is inserted into a hollow drive shaft or penetrator end 44. Inner trocar 42 shown in the open position in FIG. 4A is advanced past the end of hollow drive shaft end or penetrator end 44 where it may be opened and inserted into bone, bone marrow or other tissue. Inner trocar 42 may be closed, shown in FIG. 4B, so that a specimen is retained in its grasp as it is withdrawn from the body. FIG. 4C shows a cross section of the split-needle inner trocar 42 where the tip of the inner trocar 42 is in the open position. FIG. 4D shows a cross section of the trocar 42 is shown in the closed position.

[0044] The apparatus may or may not include a reduction gear assembly. A reduction gear assembly may include a worm gear assembly shown in more detail in FIG. 5A and may include first connector 50 that connects shaft 52 of motor 38 to worm gear 54. A reduction gear assembly may be used to decrease the RPMs between the motor and penetrator assembly to provide an optimum RPM at the point of insertion of penetrator assembly into bone. FIG. 5B illustrates a further embodiment of a reduction gear assembly wherein a first spur gear 57 engages a second spur gear 58. FIG. 5C illustrates an alternate embodiment of a reduction gear assembly wherein spur gear 58 is offset forty-five degrees relative to hollow drive shaft 14 which may be preferable in some embodiments of the present invention. In this embodiment spur gear 58 may be offset at any angle and is not limited to forty-five degrees. Other gears may be used in a reduction gear assembly, for example a planetary gear (not expressly shown) may be used alone or in combination with a worm gear or a spur gear.

[0045] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alternations can be made herein without departing from the spirit and scope of the invention as defined by the following claims.

What is claimed is:

1. A hollow drive shaft assembly operable to remove bone marrow specimens from a bone for diagnostic or therapeutic purposes comprising:

an outer hollow drive shaft operable to penetrate the bone and associated bone marrow;

the outer hollow drive shaft having an inner channel operable to convey bone marrow specimens therethrough for diagnostic or therapeutic purposes;

the outer hollow drive shaft having one end operable to penetrate the bone in response to rotation of the hollow drive shaft; and

a removable trocar disposed within the outer hollow drive shaft with a first end of the removable trocar operable to penetrate the bone and associated bone marrow.

- 2. The hollow drive shaft assembly of claim 1 wherein the first end of the removable trocar further comprises a tip with a cutting edge disposed thereon.
- 3. The hollow drive shaft assembly of claim 1 wherein the outer hollow drive shaft further comprises a body having at least one side port operable to obtain specimens of the associated bone marrow.
- **4**. The hollow drive shaft assembly of claim **1** wherein the removable trocar further comprises:
 - an inner channel operable to convey bone marrow specimens therethrough for diagnostic or therapeutic purposes; and
 - at least one side port operable to obtain specimens of the associated bone marrow.
- 5. The hollow drive shaft assembly of claim 1 wherein the one end of the hollow drive shaft further comprises serrated teeth operable to penetrate the bone and associated bone marrow.
- 6. The hollow drive shaft assembly of claim 1 wherein the outer hollow drive shaft further comprises:
 - internal threads disposed proximate the first end of the outer hollow drive shaft; and
 - the internal threads operable to maintain contact with a specimen of bone or bone marrow during retrieval.
- 7. A hollow drive shaft assembly operable to penetrate a bone and remove bone marrow from the bone for transplantation purposes comprising:
 - an outer hollow drive shaft having a first end operable to penetrate the bone and associated bone marrow;
 - the outer hollow drive shaft having a second end operable to allow retrieval of bone marrow for transplantation purposes;
 - a gear attached to the outer hollow drive shaft;
 - the outer hollow drive shaft and attached gear operable to be disposed within a housing and rotated by a motor disposed within the housing;
 - the outer hollow drive shaft having an inner channel extending from the first end of the outer hollow drive shaft through the second end of the outer hollow drive shaft:
 - the inner channel operable to convey bone marrow from the first end of the outer hollow drive shaft through the second end of the outer hollow drive shaft for transplantation purposes after inserting the hollow drive shaft into the bone and associated bone marrow by the motor coupled with the outer hollow drive shaft;
 - a leur lock connector disposed on the second end of the outer hollow drive shaft; and
 - the leur lock connector operable to connect a suction apparatus to assist in obtaining bone marrow through the inner channel of the outer hollow drive shaft; and
 - the outer hollow drive shaft having sampling ports operable to obtain portions of the associated bone marrow.
- **8**. The hollow drive shaft assembly of claim **7** further comprising a removable trocar having a tip with a cutting edge.
 - a removable trocar with at least one sampling port operable to obtain specimens of the bone marrow.
- 9. The hollow drive shaft assembly of claim 7 further comprising:
 - a movable trocar:
 - an inner channel disposed within the removable trocar; and

- the sampling port of the removable trocar operable to be aligned with the sampling ports of the outer hollow drive shaft to retrieve a sample of bone marrow.
- 10. A hollow drive shaft and a trocar operable to penetrate a bone and bone marrow comprising:
 - a first gear attached to the hollow drive shaft;
 - the first gear operable to be engaged with a second gear attached to a motor to rotate the hollow drive shaft;
 - the hollow drive shaft having a first end operable to penetrate the bone and associated bone marrow;
 - the hollow drive shaft having a second end operable to retrieve specimens of bone and the bone marrow;
 - an inner channel formed in the hollow drive shaft;
 - the inner channel of the hollow drive shaft operable to convey specimens of bone and associated bone marrow therethrough;
 - a plurality of sampling ports formed in the hollow drive shaft spaced from the first end;
 - the sampling ports operable to provide access to the associated bone marrow;
 - the trocar operable to be removably inserted the inner channel of the outer hollow drive shaft;
 - a sampling port formed in the trocar spaced from a first end of the trocar; and
 - the sampling port of the trocar operable to be aligned with respective sampling ports of the outer hollow drive shaft to convey portions of the bone marrow to an inner channel disposed within the trocar.
- 11. A hollow drive shaft operable to penetrate a bone and to remove a semisolid substance such as a bone marrow specimen from the bone comprising:
 - an outer hollow drive shaft having a first end operable to penetrate the bone and associated bone marrow;
 - the outer hollow drive shaft operable to be rotated by a
 - the outer hollow drive shaft having a first end operable to penetrate the bone and associated bone marrow;
 - a threaded portion formed adjacent to the first end of the outer hollow drive shaft; and
 - the threaded portion operable to retrieve a bone marrow specimen.
- 12. The hollow drive shaft assembly of claim 11 wherein the first end further comprises serrated teeth.
- **13**. A hollow drive shaft assembly operable to remove bone or bone marrow from a bone for diagnostic or therapeutic purposes comprising:
 - an outer hollow drive shaft and a removable inner trocar operable to penetrate the bone marrow;
 - the outer hollow drive shaft removably coupled to a gear assembly; and
 - the outer hollow drive shaft further comprising an inner channel operable to convey portions of bone and bone marrow characterized by the removable trocar having an inner channel operable to convey portions of bone and bone marrow therethrough.
- **14**. The hollow drive shaft assembly of claim **13** further comprising internal threads operable to engage a portion of bone or bone marrow.
- 15. The hollow drive shaft assembly of claim 13 wherein the hollow drive shaft comprises a body with at least one side port operable to obtain portions of bone marrow.
- 16. The hollow drive shaft of claim 13 wherein the inner trocar comprises a tip with a cutting edge and further com-

prises a body with at least one side port operable to obtain bone marrow tissue from the bone marrow.

17. A hollow drive shaft assembly operable to remove bone or bone marrow from a bone for diagnostic or therapeutic purposes comprising:

an outer hollow drive shaft and a removable inner trocar operable to penetrate the bone marrow;

the outer hollow drive shaft having an inner channel operable to convey portions of bone or bone marrow therethrough;

the outer hollow drive shaft removably coupled to a gear assembly;

the outer hollow drive shaft further comprising an inner channel operable to convey portions of bone or bone marrow; and

a connector operable to releasably attach a penetrator to the hollow drive shaft.

18. The hollow drive shaft assembly of claim 18 wherein the inner trocar comprises a tip with a cutting edge and further comprises at least one side port operable to obtain bone marrow tissue from the bone marrow.

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