

[54] **BONE MARROW BIOPSY INSTRUMENT**

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[22] Filed: **Jan. 9, 1974**

[21] Appl. No.: **432,044**

[52] U.S. Cl. **128/2 B; 128/221; 128/310;**
128/347

[51] Int. Cl. **A61b 10/00; A61b 17/16**

[58] Field of Search **128/2 B, 2 F, 310, 221,**
128/347

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Sullivan and Kurucz

[57] **ABSTRACT**

An improved bone marrow biopsy instrument is disclosed. The instrument comprises an elongate hollow alignment needle having a point which will advantageously penetrate soft tissue and indent bone surfaces. A rotatable bone cutting cannula is insertable within the alignment needle lumen.

In use, the alignment needle is inserted through soft tissue overlying the bone from which a biopsy specimen is to be removed. Upon encountering the bone, linear pressure is exerted to indent the bone surface. The indent serves to hold the aligning needle in position and to provide an initial cutting surface. The bone cutting cannula is then inserted within the lumen of the aligning needle until it reaches the indent area. Rotation of the bone cutting cannula cuts through the bone periosteum and cortex to give access to the medullary cavity of the bone. The bone cutting cannula is then withdrawn and replaced with an appropriate marrow tissue cutting and collecting cannula or marrow blood collection syringe.

11 Claims, 12 Drawing Figures

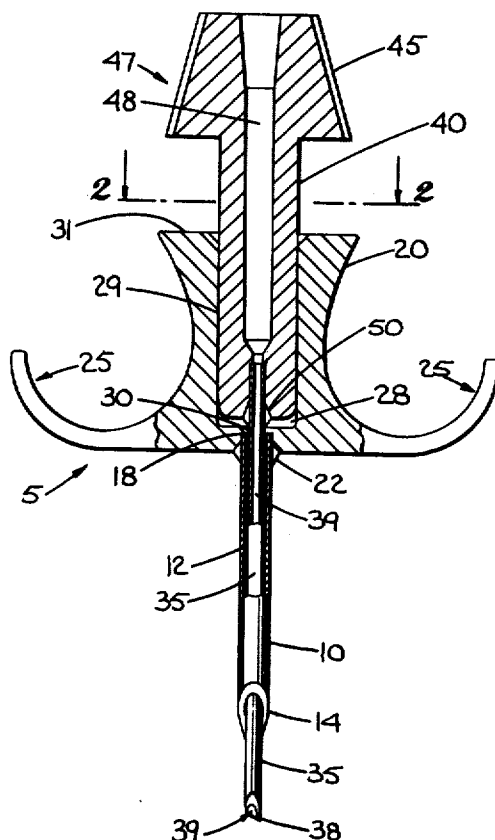


Fig. 1

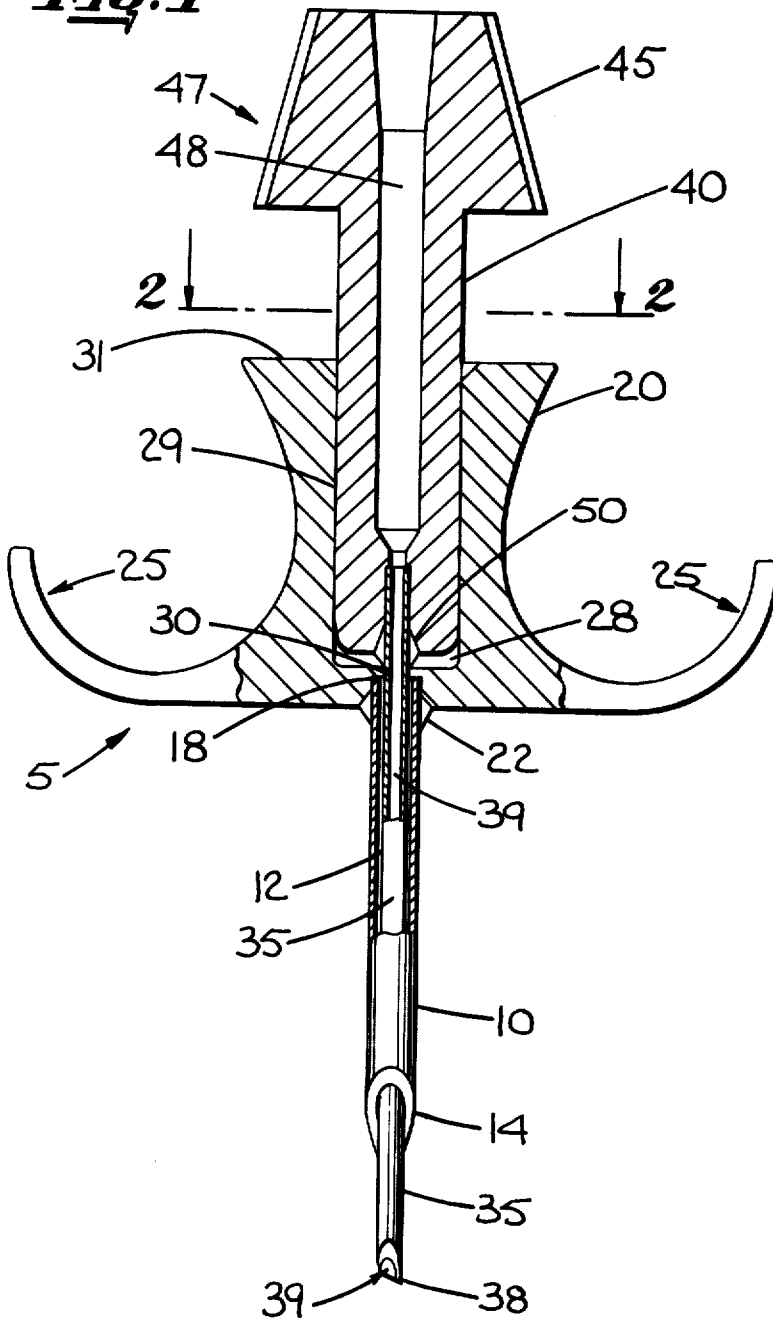


Fig. 2

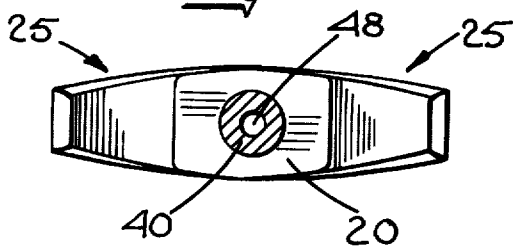


Fig. 3

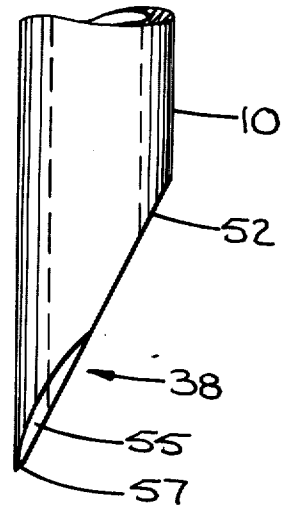


Fig. 4

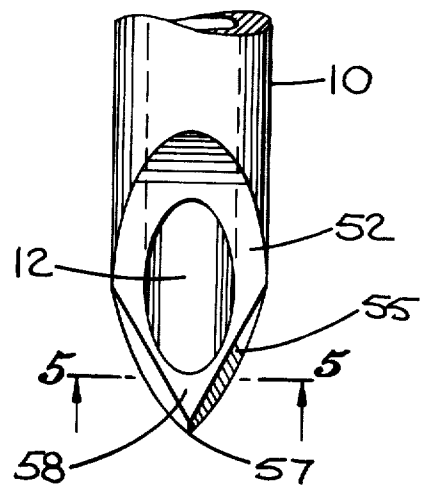


Fig. 5

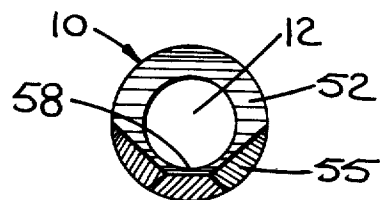


Fig. 6

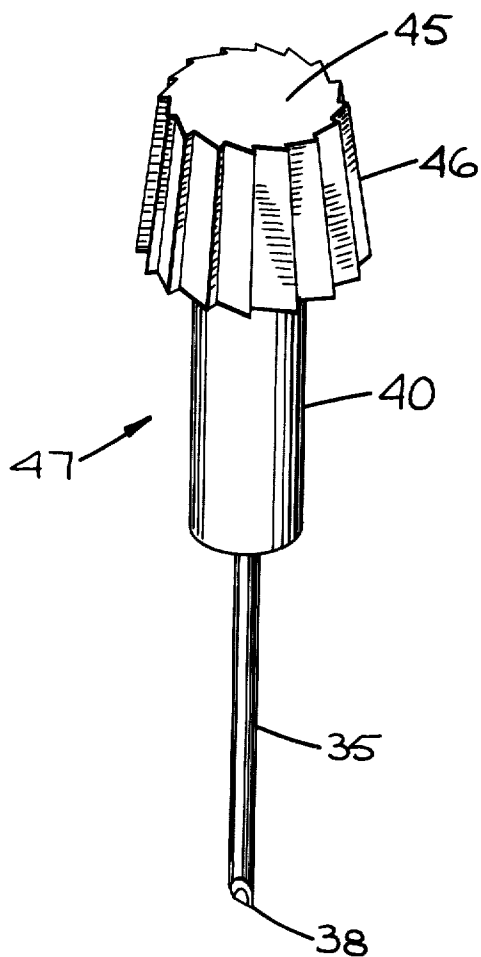


Fig. 7

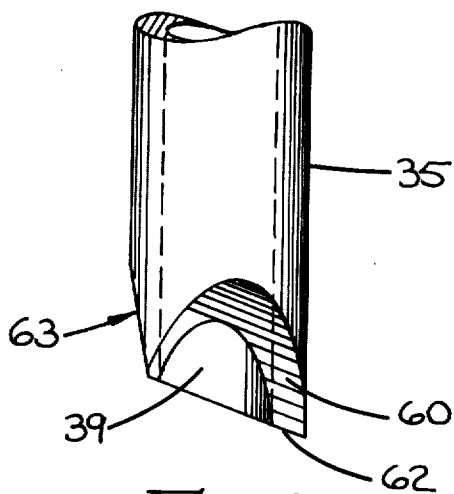


Fig. 8

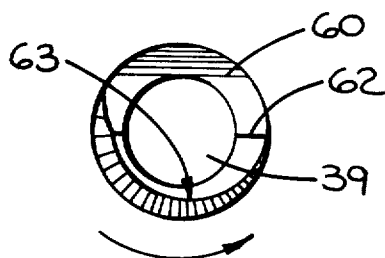


Fig. 9

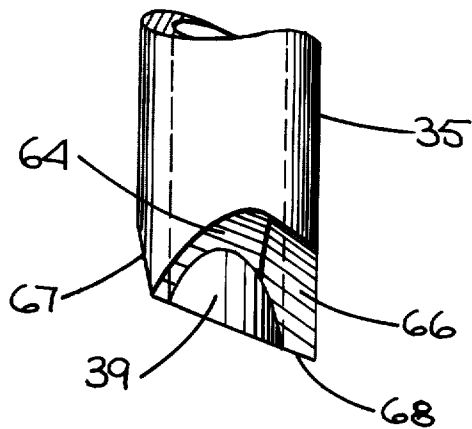


Fig. 10

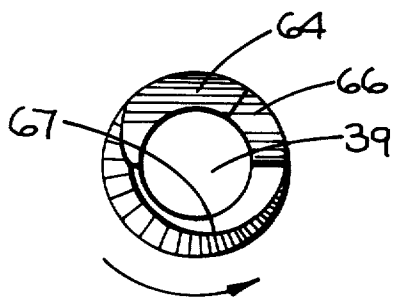


Fig. 11

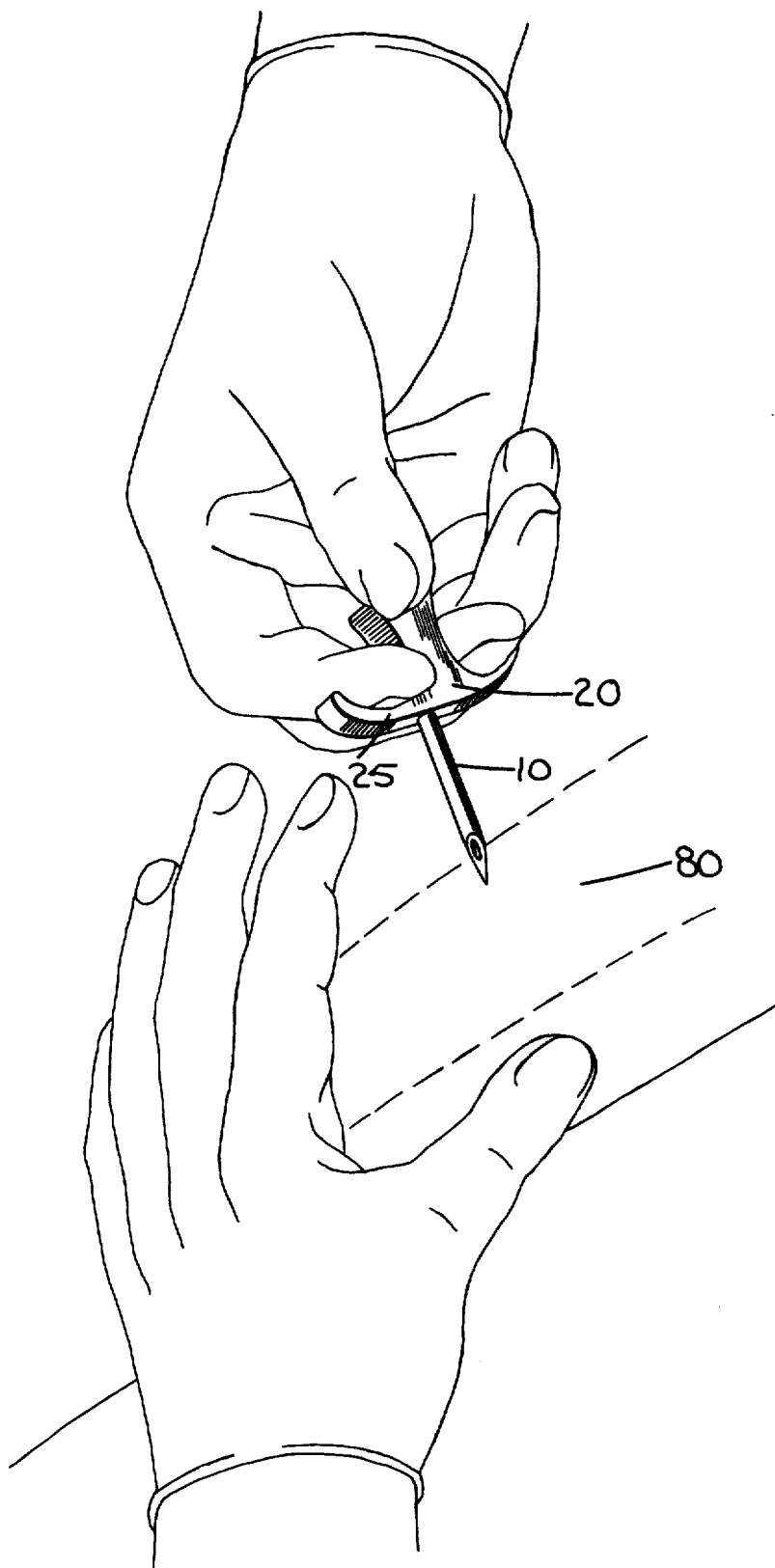
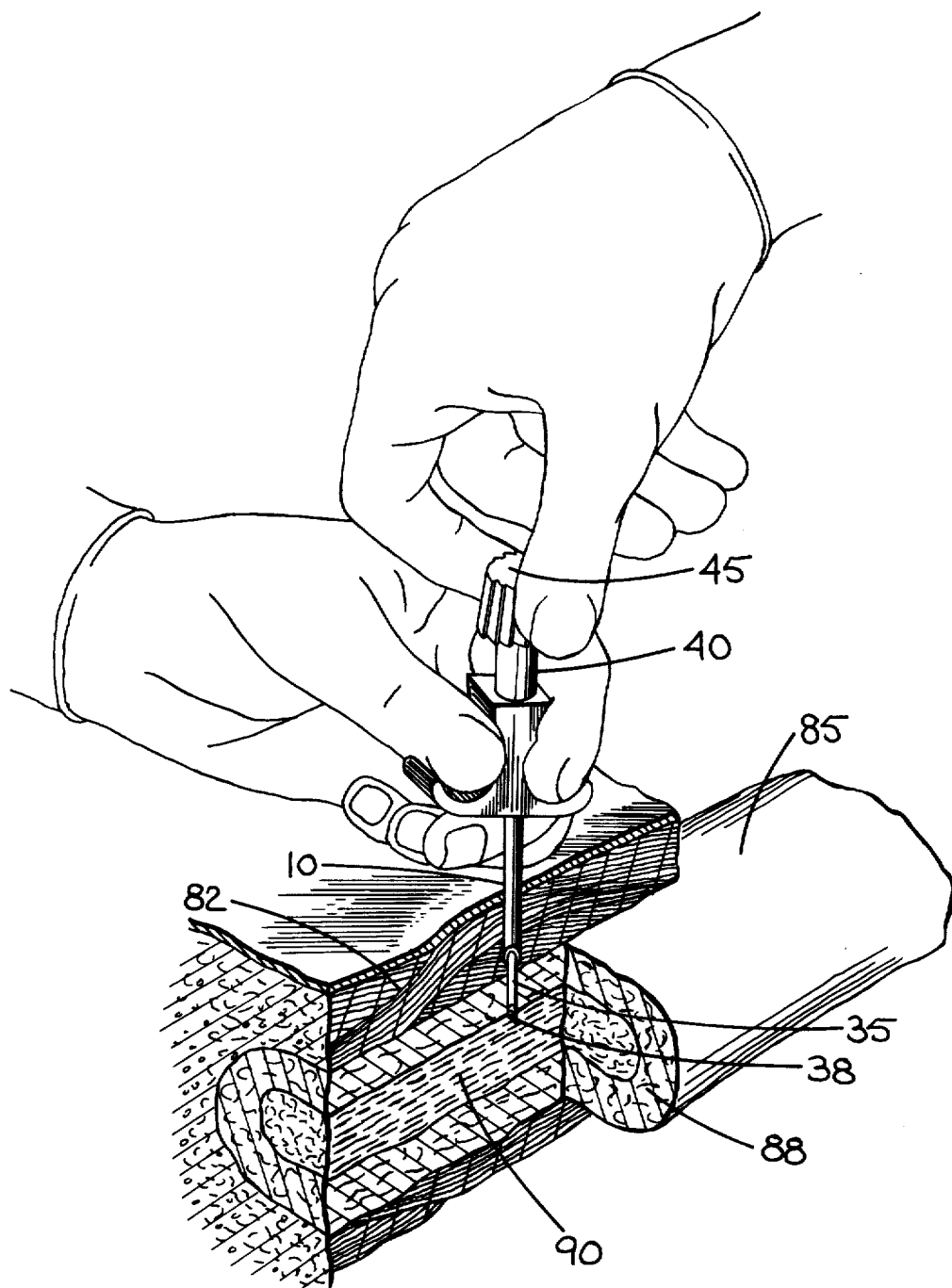


Fig. 12



BONE MARROW BIOPSY INSTRUMENT**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The invention concerns medical-surgical diagnostic instruments and more particularly concerns a novel bone marrow biopsy instrument.

2. Description of the Prior Art

Currently available surgical techniques for gaining access to bone marrow is at best a difficult, traumatic and sometimes hazardous procedure for the individual subjected to this diagnostic procedure. In general, the prior art devices for gaining access to the medullary cavity comprise a short stylet fitted penetration needle, fitted with handles to facilitate application of pressure and rotary motion. Piercing bone with a puncture or penetration point is difficult because bone cortex is too hard and inelastic for deformation. Such penetration needles provide entry to the medullary cavity when, under pressure and rotational forces, a small area of bone surface fractures. This is, of course, traumatic to the patient. The exertion of high pressures upon the needle causes pain and psychological shock for the patient. It also often damages the needle point. Applying pressure on a smooth bone surface with a penetration point also makes it difficult for the operator to maintain directional control of the needle point. The lack of control employing penetration point bone entry instruments can be disastrous (see Bakir, *Dis. Chest*, Vol. 44, (1963), Pg. 435 reporting a death when the needle passed through the sternum and into the heart).

Furthermore, some long bones simply cannot be penetrated by direct linear forces. In such instances, the operator is tempted to rock or rotate the biopsy needle. Often, this type of action forms a hook at the needle point making further penetration even more difficult. Rotating the penetration point results in an eccentric motion at the point which fractures or abrades away bone tissue. Rocking motions give a similar result. For the hazards involved in rocking or rotating penetration points on bone surfaces, see for example Cooper, *Ward Procedures and Techniques*, Butterworth, London, (1967), Pps. 62-4.

It has been previously suggested that the bone surface can be readily penetrated with a drill bit inserted through a needle cannula (Cramer, *Surgery, Gynecology and Obstetrics*, (June 1964), Pg. 1,253). This procedure is not entirely satisfactory for gaining entry into the medullary cavity because a drill is not efficient for low speed cutting of bone. Drills require high pressure to cut and the drill bit of small diameter is generally a brittle metal structure which breaks easily under flexural stress. It is also possible for a rotating drill bit to scrape metal off the enclosing needle cannula and deposit the scrapings within the patient. This is, of course, undesirable.

Another type of bone marrow biopsy instrument employed heretofore is the sternal bone marrow infusion needle of the Trephine type. This needle assembly employs a bone cutting element which is a Trephine cannula having a multiple saw tooth design. In use, the cortical bone fragments tend to pack in the tooth spaces. This inhibits further penetration. To overcome the reduction in penetration, the operator often tends to apply excessive pressure. This results in deformation of the teeth and ultimately can result in an abortive procedure. Further, the Trephine type of cutting needle acts,

in part, by a rubbing action to displace bone, rather than cutting. This limitation affects the use of this instrument because of the added time required to penetrate bone. This is often not tolerated by children or anxious adults.

The apparatus of my invention as hereinafter described permits a well controlled bone marrow biopsy procedure to be carried out with reduced trauma to the patient and a higher degree of safety.

SUMMARY OF THE INVENTION

The invention comprises a bone marrow biopsy apparatus which comprises; (a) an elongate hollow alignment needle which comprises (1) a handle defining a central bore open at both ends of said handle, (2) a cannula having an open distal end defining a soft tissue penetration and bone indenting point and an open proximal end joined to said handle so that said bore and lumen of said cannula form an axial passage traversing the alignment needle; (b) a bone cutting assembly which comprises (1) a handle for rotation; attached to a first end of (2) a cylindrical shank having (a) a diameter such that said shank mates with and bears upon the enclosing surface of the aforementioned central bore when inserted therein; (b) a second end affixed to the proximal end of; (3) a cannula having (a) an open distal end defining a bone cutting point; (b) a diameter less than the diameter of the lumen of the alignment needle cannula; and (c) a length exceeding the length of said alignment needle cannula; the shank and cannula portions of said bone cutting assembly being insertable in and withdrawable from the axial passage of said alignment needle.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view-in-part of the apparatus of the invention.

FIG. 2 is a cross-sectional view along lines 2-2 of FIG. 1.

FIG. 3 is an enlarged side view of a preferred penetration point for the alignment needle shown in FIG. 1.

FIG. 4 is a front view of the penetration point shown in FIG. 3.

FIG. 5 is a cross-sectional view along lines 5-5 of FIG. 4.

FIG. 6 is an isometric view of the cutting needle component of the apparatus shown in FIG. 1.

FIG. 7 is an enlarged side view of a preferred cutting point for the cutting needle shown in FIG. 6.

FIG. 8 is an end view of the cutting point shown in FIG. 7.

FIG. 9 is an enlarged side view of an alternate embodiment cutting point of the cutting needle shown in FIG. 6.

FIG. 10 is an end view of the cutting point shown in FIG. 9.

FIG. 11 shows the alignment needle component held by an operator preparatory to insertion over a bone site.

FIG. 12 shows the alignment needle component of the apparatus of the invention emplaced upon a bone surface after having penetrated overlying soft tissues and the cutting needle component entering a bone medulla.

DETAILED DESCRIPTION OF THE INVENTION

The apparatus of the invention may be fabricated

from standard materials commonly and conventionally employed in the manufacture of surgical instruments. For example, the apparatus of the invention may be fabricated from stainless steel or similar alloys commonly used to fabricate surgical instruments. Alternatively, the cutting and penetration points may be fabricated from surgical steels while the remainder of the apparatus is fashioned from polymeric materials such as, for example, polymethacrylate, polyurethane, polyethylene, polystyrene, polycarbonate and like polymeric materials. The latter materials are well known for fabricating disposable surgical instruments, which is a preferred form of the apparatus of the invention.

The apparatus of the invention will now be further described and exemplified by reference to the various specific embodiments set forth in the drawings.

FIG. 1 is an overall cross-section-in-part view of a bone marrow biopsy apparatus within the scope of the invention. As shown, there is an alignment needle 5 having a cannula body 10 defining a lumen 12 and a soft tissue penetrating and bone indenting point 14. Cannula 10 is preferably of from 14 to 18 gauge tubular stock and has a length just sufficient to reach the surface of the bone. A needle which is unnecessarily long does not contribute to operating stability. As an example, the preferred length of cannula for a sternal biopsy would be about 12 mm. The end of the alignment needle distal to the penetration point 14 is an open end 18 and is attached to a handle 20. The cannula 10 is conveniently integrated with the handle 20 by an epoxy cement joint 22, however, any convenient method of attachment can be employed. The handle 20 has finger grips 25—25 which assist in stabilizing the operator's hold, and help the operator to apply the slight lineal pressure required to indent the bone surface as hereinafter discussed. Handle 20 also defines a bore or guidance hole 28 having a bearing surface 29. There is a conduit 30 joining lumen 12 and bore 28 so that there is an axial passage traversing the alignment needle 5 from penetration point 14 to the proximal end 31 of handle 20. As shown in FIG. 1 bone cutting assembly 47 is employed within the axial passage 12, 28 of alignment needle 5 so that bone cutting cannula 35 is movable linearly and axially in lumen 12 and extends from bore 28 beyond the penetration point 14 of alignment needle 5. The length of cannula 35 exceeds the length of cannula 10 a distance sufficient to penetrate the average bone cortex. For a sternum, this would be about 6 mm. Cannula 35 has a bone cutting point 38 and a lumen 39. Cannula 35 is attached by an epoxy joint 50 to shank 40. Any other conventional method of attachment can be used. Shank 40 fits snugly into the bore 28 of handle 20 and bears on surface 29 of bore 28. A silicone lubricant is advantageously used to reduce the friction between shank 40 and bearing surface 29. As shown, preferably shank 40 and base 28 have substantially larger diameters than lumen 12. This provides a stop for cutting cannula 35 and also provides a large surface area between shank 40 and bearing surface 29. This serves to stabilize the cutting action and to absorb flexural stresses during cutting of the bone cortex. By substantially larger, I mean a diameter of about 6 to about 8 times the diameter of the lumen 12. The proximal end of shank 40 has a handle 45 adapted for rotating component 47.

Shown also in FIG. 1 is an optional feature in conduit 48 which passes through shank 40 and handle 45 to link

with lumen 39 thereby giving a continuous passage traversing the entire bone cutting component 47. This optional feature is useful when the apparatus of the invention is non-disposable. In this latter instance, conduit 48 provides a means of passing a stylet to clear out bone chips which accumulate in lumen 39 during use. Of course, in a disposable unit such an optional feature serves no purpose and may be eliminated.

FIG. 2 is a cross-sectional view taken along lines 2—2 of FIG. 1 and clearly shows the positional relationships of handle 20, shank 40 and finger grips 25—25 when the alignment needle and bone cutting component are assembled together.

FIG. 3 is an enlarged section showing a preferred penetration and bone indenting point 38 for alignment needle 5. The penetration and indenting point has a short primary grind 52 and low rotation side bevels 55 which do not intersect the lumen but meet at point 57. The short bevels 55 prevent deep penetration into the bone surface. Preferably, the primary grind is at an angle of from about 18° to about 22° from the cannula 10 axis and lateral side bevels are at angles of from about 34° to about 36° from the cannula axis. The preferred angles keep the alignment needle in position on the bone when employed according to the method of the invention.

FIG. 4 illustrates the penetration and indenting point as shown in FIG. 3 viewed from the front and shows surface 58 at point 57. This surface acts as a scoop to lift a small amount of bone tissue into the lumen 12 when the bone is indented. This small portion of lifted bone gives the bone cutter 47 a surface for initial engagement.

FIG. 5 is a cross-sectional view of FIG. 4 taken along lines 5—5 and further illustrates the preferred point 38.

FIG. 6 is an overall view of the bone cutting component 47 of the apparatus of the invention shown apart from the alignment needle component 5 and illustrates bone cutting point 38, cannula 35, cylindrical shank 40 which mates with bore 28 of handle 20 as shown in FIG. 1 and a handle for rotation 45. Preferred for the handle 45 is a frustrum shape, tapered to a narrow top to enable the operator's fingers to apply slight linear pressure without slipping. The periphery of the handle is preferably designed with ratchet type splines 46 running at an angle to the cannula of between about 15° to about 20° so that the handle 45 is conveniently rotated in one direction only. It is preferred that the cutting edge of the cutting cannula rotate in a direction such that the bone tissue is forced against the surface projected by the indenting point. Rotation in one direction will produce this action. The handle 45 shown in FIG. 6 is for rotation in a clockwise direction which is preferred.

In FIG. 7, there is an enlarged view of a preferred bone cutting point 38 having a top rake primary grind angle 60, cutting edge 62 and peripheral relief 63. The top rake grind is preferably at an angle of from about 18° to about 20° to the cannula axis. The cutting edge is preferably at an angle of from about 25° to about 30° from a line perpendicular to the cannula axis and the peripheral relief covers about 50 percent of the periphery. When viewed from the end as in FIG. 8, one can see the relationship of cutting edge 62 and how it presents a single radial cutting edge equal to the thickness of the tube wall and relieved diametrically and peripherally so that when rotated clockwise it cuts smoothly

and continuously, removing bone chips and directing them into the lumen 39 of the bone cutting point 38.

FIG. 9 shows an alternate embodiment bone cutting point having a primary grind 64, a zero degree secondary grind top rake 66, side rake 68 and peripheral relief 67. When viewed from the end, as shown in FIG. 10, it is seen that this particular point embodiment also functions by a clockwise rotary motion to continuously cut and remove bone chips by directing them into the cannula 39 of bone cutting cannula 10. The illustrated points and their like give the operator total control of the cutting procedure. A minimum of axial pressure is required with smooth rotary action to cut and remove bone cortex with such points.

Referring now to FIG. 11 we can see how the method of the invention is carried out. The alignment needle 5 is held in the hands of an operator, without the bone cutting cannula component 47. Site 80 bordered by the broken lines portrays a site of soft tissue overlying a bone structure such as the sternum. The function of the alignment needle 5 is to establish a secure position on the surface of the bone. Another vital function of the alignment needle 5 is to aid in beginning the cutting operation by presenting a dislodged solid at the lumen 12 entrance, upon which the bone cutting cannula component 47 can engage and further establish entry. These objects are obtained by passing the alignment needle cannula 10 through the dermis, epidermis, subcutaneous tissue, muscle and periosteum overlying the bone to be biopsied. The cannula 10 is inserted as any other hypodermic needle, generally at an angle of from about 45° to about 90° with the bone surface. Once the surface of the bone is reached, the bone is penetrated slightly or "indented" with the point 14 by using the finger positioning handle 20 to apply precise and accurate linear pressure. The finger grips 25 serve to assist in exerting linear pressure and also to stabilize the instrument during the remainder of the biopsy procedure. The "indent" also stabilizes the alignment needle by presenting a surface upon which it catches.

With the alignment needle 5 in place and being held firmly by the operator, the bone cutting cannula component 47 is passed through the cannula 10 and handle 20 of the alignment needle component 5. Upon reaching the bone surface with the bone cutting cannula 35 the operator applies a slight linear pressure and a smooth clockwise rotary force in much the same way as a machine screw is started in a threaded hole. No machine or other device is required to prepare the entry hole. Because the cutting motion is rotational, with only slight linear pressure, control of the operation is easily and conveniently maintained by the operator. While cutting, bone tissue is removed in the form of small particles which collect in the bore 39 of the cutting cannula 35. Penetration of the compact bone cortex is easily detected by a relaxation of resistance to cutting. FIG. 12 shows the apparatus of the invention following penetration of soft tissue 82 by alignment needle cannula 10, positioning on bone surface 85 and penetration of bone cortex 88 into medullary cavity 90 by cutting point 38 of bone cutting cannula 35.

Having established access to the bone medullary cavity, one of several procedures may then be followed to remove the desired biopsy specimen required, depending on the nature of the material to be removed. First, the bone cutting apparatus component 47 is withdrawn from the alignment needle 5, axial passage 12, 28,

while leaving alignment needle 5 in place. If the specimen desired is a sample of marrow blood, a conventional hypodermic needle is inserted into the medullary cavity by passage through the axial passage 12, 28 of alignment needle 5. The syringe is filled and withdrawn. If the specimen desired is a sample of marrow tissue, a blunt point cannula, a tissue cutting cannula or a Silverman type inner cannula (Becton-Dickinson, Rutherford, N.J., Catalogue No. 1420) of appropriate size may be inserted in place of the hypodermic syringe to remove a specimen of marrow tissue. Upon obtaining the desired biopsy specimen, the alignment needle 5 is withdrawn and an aseptic dressing applied to the wound.

What is claimed is:

1. A bone cutting component of a bone marrow biopsy apparatus including an alignment needle, which comprises;

a bone cutting assembly which comprises;

- i. a handle for rotation; attached to a first end of
- ii. a cylindrical shank having one end attached to said handle and the second end affixed to the proximal end of
- iii. a cannula having an open distal end defining a bone cutting point which comprises a top rake primary grind of from about 18° to about 20° to the longitudinal axis of said cannula, a cutting edge at an angle of from about 25° to about 30° to a line perpendicular with the longitudinal axis of said cannula, said cutting edge being peripherally relieved; said shank and said cannula being adapted to be received within the bore of said alignment needle of the bone marrow biopsy apparatus.

2. The apparatus of claim 1 wherein the handle for rotation is in the shape of a frustum, tapering toward the top.

3. The apparatus of claim 2 wherein the handle for rotation has splines around the periphery which run at an angle to the longitudinal axis of the cannula portion of from about 15° to about 20°.

4. The apparatus of claim 1 having a secondary grind top rake of 0° to the longitudinal axis of said cannula.

5. A bone marrow biopsy apparatus which comprises:
A. an elongate hollow alignment needle which comprises:

- i. a handle defining a central bore open at both ends of said handle;
- ii. a cannula having an open distal end defining a soft tissue penetration and bone indenting point and an open proximal end joined to said handle so that said bore and the lumen of said cannula form an axial passage traversing the alignment needle;

B. a bone cutting assembly which comprises:

- i. a handle for rotation; attached to a first end of
- ii. a cylindrical shank having
 - a. a diameter such that said shank mates with and bears upon the enclosing surface of the aforementioned central bore when inserted therein;
 - b. a second end; affixed to the proximal end of
- iii. a cannula having
 - a. an open distal end defining a bone cutting point which comprises a top rake primary grind of from about 18° to about 20° to the longitudinal axis of the cannula, a cutting edge at an angle of from about 25° to about 30° to a line

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perpendicular with the cannula longitudinal axis, said cutting edge being peripherally relieved;

- b. a diameter less than the diameter of the lumen of the alignment needle cannula;
- c. a length exceeding the length of said alignment needle cannula; and
- d. an open proximal end attached to the second end of said shank; the shank and cannula portions of said bone cutting assembly being withdrawably mounted in the axial passage of said alignment needle.

6. The apparatus of claim 1 wherein said cylindrical shank has a diameter substantially larger than the diameter of said lumen.

7. The apparatus of claim 1 wherein the penetration and bone indenting point comprises a primary grind at

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an angle of about 18° to about 22° from the cannula longitudinal axis; and lateral side bevels at an angle of about 34° to about 36° from the cannula axis, intersecting at the point.

8. The apparatus of claim 1 wherein the handle (A) (i) has finger grips.

9. The apparatus of claim 1 wherein the handle for rotation (B) (i) is in the shape of a frustum, tapering towards the top.

10. The apparatus of claim 9 wherein the handle for rotation (B) (i) has splines around the periphery which run at an angle to the longitudinal axis of the cannula portion (B) (iii) of from about 15° to about 20°.

11. The apparatus of claim 1 having a secondary grind top rake of 0° to the longitudinal axis of the cannula.

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