

Exhibit A



US006702821B2

(12) **United States Patent**
Bonutti

(10) **Patent No.:** **US 6,702,821 B2**
(45) **Date of Patent:** **Mar. 9, 2004**

(54) **INSTRUMENTATION FOR MINIMALLY INVASIVE JOINT REPLACEMENT AND METHODS FOR USING SAME**

3,807,393 A 4/1974 McDonald
3,811,449 A 5/1974 Gravlee
3,903,549 A 9/1975 Deyerle
3,911,923 A 10/1975 Yoon
3,920,022 A 11/1975 Pastor

(75) **Inventor:** **Peter M. Bonutti**, Effingham, IL (US)

(List continued on next page.)

(73) **Assignee:** **The Bonutti 2003 Trust A**, Effingham, IL (US)

OTHER PUBLICATIONS

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 144 days.

The M/G Unicompartmental Knee—Minimally Invasive Surgical Technique—Publication date unknown, but before Aug. 1, 2001.

(21) **Appl. No.:** **09/941,185**

Scorpio Single Axis Total Knee System—PassPort Total Knee Instrumentation—PassPort A.R. surgical Technique—Publication date unknown, but before Aug. 1, 2001.

(22) **Filed:** **Aug. 28, 2001**

NexGen Complete Knee Solution—Design Rationale—Publication date unknown, but before Aug. 1, 2001.

(65) **Primary Publication Data**

Insall/Burstein II Modular Knee System—Publication date unknown, but before Aug. 1, 2001.

US 2002/0029045 A1 Mar. 7, 2002

Related U.S. Application Data

(List continued on next page.)

(63) Continuation-in-part of application No. 09/815,405, filed on Mar. 22, 2001, now abandoned, and a continuation-in-part of application No. 09/789,621, filed on Feb. 21, 2001, now Pat. No. 6,635,073, and a continuation-in-part of application No. 09/737,380, filed on Dec. 15, 2000, now Pat. No. 6,503,267, and a continuation-in-part of application No. 09/602,743, filed on Jun. 23, 2000, now Pat. No. 6,361,565, and a continuation-in-part of application No. 09/569,020, filed on May 11, 2000, now Pat. No. 6,423,063, and a continuation-in-part of application No. 09/526,949, filed on Mar. 16, 2000, now Pat. No. 6,620,181, and a continuation-in-part of application No. 09/483,676, filed on Jan. 14, 2000, now Pat. No. 6,468,289.

Primary Examiner—David O. Reip

(74) *Attorney, Agent, or Firm*—Fleit Kain Gibbons Gutman Bongini & Bianco; Paul D. Bianco; Martin Fleit

(51) **Int. Cl.⁷** **A61B 17/56**

(52) **U.S. Cl.** **606/88; 623/20.14**

(58) **Field of Search** 606/79, 80, 82,
606/86, 87, 88, 89; 623/20.14, 20.15, 20.21;
128/898

(57) **ABSTRACT**

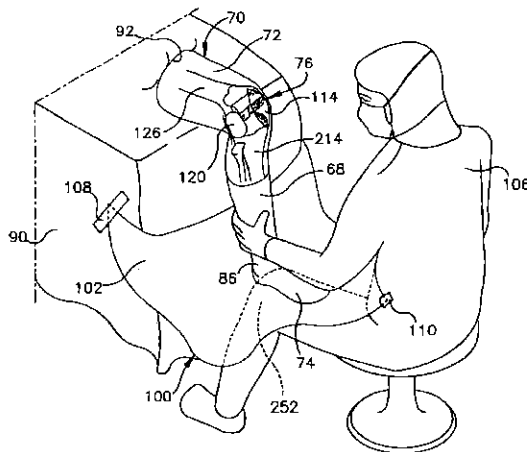
An improved method of performing surgery on a joint in a patient's body, such as a knee, includes making an incision in a knee portion of one leg while a lower portion of the one leg is extending downward from an upper portion of the one leg and while a foot connected with the lower portion of the one leg is below a support surface on which the patient is disposed. The incision is relatively short, for example, between seven and thirteen centimeters. A patella may be offset from its normal position with an inner side of the patella facing inward during cutting of a bone with a cutting tool. During cutting of the bone, one or more guide members having opposite ends which are spaced apart by a distance less than the width of an implant may be utilized to guide movement of a cutting tool.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,229,006 A 1/1966 Nohl
3,624,747 A 11/1971 McKnight

39 Claims, 22 Drawing Sheets



US 6,702,821 B2

Page 2

U.S. PATENT DOCUMENTS

3,967,625 A	7/1976	Yoon	5,322,505 A	6/1994	Krause
3,989,049 A	11/1976	Yoon	5,344,423 A	9/1994	Dietz et al. 606/87
3,991,426 A	11/1976	Flom	5,344,458 A	9/1994	Bonutti 623/18
3,994,287 A	11/1976	Turp	5,348,541 A	9/1994	Lyell
4,053,953 A	10/1977	Flom	5,368,599 A	11/1994	Hirsch
4,085,466 A	4/1978	Goodfellow	5,379,133 A	1/1995	Kirk
4,085,743 A	4/1978	Yoon	5,403,319 A	4/1995	Matsen, III et al. 606/88
4,103,680 A	8/1978	Yoon	D358,647 S	5/1995	Cohen
4,299,224 A	11/1981	Noiles	5,425,355 A	6/1995	Kulick 128/4
4,311,145 A	1/1982	Esty	5,425,745 A	6/1995	Green
4,344,193 A	8/1982	Kenny	5,445,639 A	8/1995	Kuslich
4,373,709 A	2/1983	Whitt	5,454,365 A	10/1995	Bonutti
4,374,523 A	2/1983	Yoon	5,454,815 A	10/1995	Geisser
4,385,404 A	5/1983	Sully	5,456,268 A	10/1995	Bonutti
4,509,518 A	4/1985	McGarry	5,456,720 A	10/1995	Schultz
4,545,375 A	10/1985	Cline	5,472,415 A	12/1995	King
4,565,192 A	1/1986	Shapiro	5,484,095 A	1/1996	Green
4,574,794 A	3/1986	Cooke et al.	5,497,933 A	3/1996	DeFonzo
4,619,391 A	10/1986	Sharkany	5,514,139 A	5/1996	Goldstein
4,624,254 A	11/1986	McGarry	5,514,143 A	5/1996	Bonutti et al. 606/86
4,641,648 A	2/1987	Shapiro	5,514,153 A	5/1996	Bonutti
4,662,372 A	5/1987	Sharkany	5,520,692 A	5/1996	Ferrante 606/80
4,682,598 A	7/1987	Beraha	5,520,694 A	5/1996	Dance et al. 606/86
4,685,460 A	8/1987	Thornton	5,522,897 A	6/1996	King
4,739,751 A	4/1988	Sapega et al.	5,540,695 A	7/1996	Levy
4,817,602 A	4/1989	Beraha	5,549,683 A	8/1996	Bonutti
4,936,852 A	6/1990	Kent	5,554,169 A	9/1996	Green
4,961,954 A	10/1990	Goldberg	5,569,163 A	10/1996	Francis
4,964,865 A	10/1990	Burkhead	5,570,700 A	11/1996	Vogeler
4,979,949 A	12/1990	Malsen, III et al. 606/53	5,578,039 A	11/1996	Vendrely et al. 606/88
4,985,038 A	1/1991	Lyell	5,593,448 A	1/1997	Dong
5,007,912 A	4/1991	Albrektsson et al. 606/87	5,597,379 A	1/1997	Haines
5,032,132 A	7/1991	Matsen	5,609,603 A	3/1997	Linden
5,060,678 A	10/1991	Bauman	5,624,463 A	4/1997	Stone
5,098,437 A	3/1992	Kashuba	5,632,745 A	5/1997	Schwartz
5,099,859 A	3/1992	Bell 128/781	5,643,272 A	7/1997	Haines
5,100,689 A	3/1992	Goldberg	5,649,946 A	7/1997	Bramlet
5,108,441 A	4/1992	McDowell	5,662,710 A	9/1997	Bonutti
5,111,987 A	5/1992	Moeinzadeh	5,667,069 A	9/1997	Williams
5,123,906 A	6/1992	Kelman	5,667,512 A	9/1997	Johnson 606/88
5,152,744 A	10/1992	Krause	5,667,520 A	9/1997	Bonutti
5,152,778 A	10/1992	Bales	5,702,447 A	12/1997	Walch
5,154,717 A	10/1992	Matsen, III et al. 606/53	5,702,475 A	12/1997	Zahedi
5,163,949 A	11/1992	Bonutti	5,707,350 A	1/1998	Krause
5,170,800 A	12/1992	Smith	5,712,543 A	1/1998	Sjostrom
5,171,243 A	12/1992	Kashuba	5,716,360 A	2/1998	Baldwin et al. 606/80
5,171,244 A	12/1992	Caspari et al. 606/88	5,718,708 A	2/1998	Webb
5,174,300 A	12/1992	Bales	5,723,331 A	3/1998	Tubo
5,176,702 A	1/1993	Bales	5,733,292 A	3/1998	Gustilo et al. 606/88
5,178,622 A	1/1993	Lehner	5,749,876 A	5/1998	Duvillier et al. 606/88
5,183,053 A	2/1993	Yeh	5,755,731 A	5/1998	Grinberg
5,183,464 A	2/1993	Dubrul	5,755,791 A	5/1998	Whitson
5,186,178 A	2/1993	Yeh	5,755,803 A	5/1998	Haines
5,197,968 A	3/1993	Clement	5,769,855 A	6/1998	Bertin et al. 606/88
5,197,971 A	3/1993	Bonutti	5,769,899 A	6/1998	Schwartz
5,197,987 A	3/1993	Koch	5,772,594 A	6/1998	Barrick 600/407
5,207,692 A	5/1993	Kraus	5,788,700 A	8/1998	Morawa et al. 606/88
5,217,463 A	6/1993	Mikhail	5,810,827 A	9/1998	Haines
5,228,459 A	7/1993	Caspari	5,817,109 A	10/1998	McGarry
5,234,433 A	8/1993	Bert et al. 606/88	5,842,477 A	12/1998	Naughton et al. 128/898
5,258,004 A	11/1993	Bales	5,846,931 A	12/1998	Hattersley
5,269,785 A	12/1993	Bonutti	5,860,981 A	1/1999	Bertin et al. 606/89
5,273,524 A	12/1993	Fox	5,866,415 A	2/1999	Villeneuve
5,275,166 A	1/1994	Vailekunas	5,871,493 A	2/1999	Sjostrom
5,282,803 A	2/1994	Lackey 606/80	5,879,354 A	3/1999	Haines
5,285,773 A	2/1994	Bonutti	5,888,219 A	3/1999	Bonutti
5,293,878 A	3/1994	Bales	5,899,914 A	5/1999	Zirps
5,295,994 A	3/1994	Bonutti	5,908,424 A	6/1999	Bertin et al. 606/88
5,304,181 A	4/1994	Caspari et al. 606/80	5,911,723 A	6/1999	Ashby et al. 606/88
5,308,349 A	5/1994	Mikhail 606/88	5,913,874 A	6/1999	Berns
			5,921,990 A	7/1999	Webb

US 6,702,821 B2

Page 3

5,961,499 A 10/1999 Bonutti
 5,997,566 A 12/1999 Tobin
 6,012,456 A 1/2000 Schuerch
 6,015,419 A 1/2000 Strome
 6,019,767 A 2/2000 Howell 606/96
 6,022,350 A 2/2000 Ganem
 6,056,754 A 5/2000 Haines
 6,059,817 A 5/2000 Bonutti
 6,063,095 A 5/2000 Wang et al. 606/139
 6,077,287 A 6/2000 Taylor
 6,086,593 A 7/2000 Bonutti
 6,090,122 A 7/2000 Sjoström
 6,099,531 A 8/2000 Bonutti
 6,099,532 A 8/2000 Florea
 6,102,850 A 8/2000 Wang et al. 600/102
 6,118,845 A 9/2000 Simon et al. 378/62
 6,159,246 A 12/2000 Mendes et al. 623/20
 6,171,340 B1 1/2001 McDowell
 6,174,321 B1 1/2001 Webb
 6,185,315 B1 2/2001 Schmucker et al. 382/108
 6,187,023 B1 2/2001 Bonutti
 6,195,168 B1 2/2001 De Lega
 6,197,064 B1 3/2001 Haines
 6,198,794 B1 3/2001 Peshkin et al. 378/42
 6,211,976 B1 4/2001 Popovich et al. 359/15
 6,214,051 B1 4/2001 Badorf
 6,228,121 B1 5/2001 Khalili
 6,258,127 B1 7/2001 Schmotzer
 6,277,136 B1 8/2001 Bonutti
 6,290,703 B1 9/2001 Ganem
 6,325,806 B1 12/2001 Fox
 6,328,572 B1 12/2001 Higashida
 6,338,737 B1 1/2002 Toledano
 6,358,266 B1 3/2002 Bonutti
 6,391,040 B1 5/2002 Christoudias

6,406,495 B1 6/2002 Schoch
 6,409,722 B1 6/2002 Hoey
 6,431,743 B1 8/2002 Mizulani
 D462,767 S 9/2002 Meyer
 6,500,181 B1 12/2002 Portney
 2001/0034554 A1 10/2001 Pappas
 2001/0037155 A1 11/2001 Merchant
 2002/0029038 A1 3/2002 Haines

OTHER PUBLICATIONS

NexGen Complete Knee Solution—Surgical Technique for the LPS-Flex Fixed Bearing Knee—Publication date unknown, but before Aug. 1, 2001.

NexGen Complete Knee Solution—Extramedullary/Intramedullary Tibial Resector Surgical Technique—Publication date unknown, but before Aug. 1, 2001.

NexGen Complete Knee Solution—Multi-Reference™ 4-in-1 Femoral Instrumentation—Anterior Reference Surgical Technique—Publication date unknown, but before Aug. 1, 2001.

NexGen Complete Knee Solution—Intramedullary Instrumentation Surgical Technique—For the NexGen Cruciate Retaining & Legacy® Posterior Stabilized Knee—Publication date unknown, but before Aug. 1, 2001.

Surgical Navigation for Total Knee Arthroplasty—Believed to have been presented at the American Academy of Orthopedic Surgeons in Feb. of 2001.

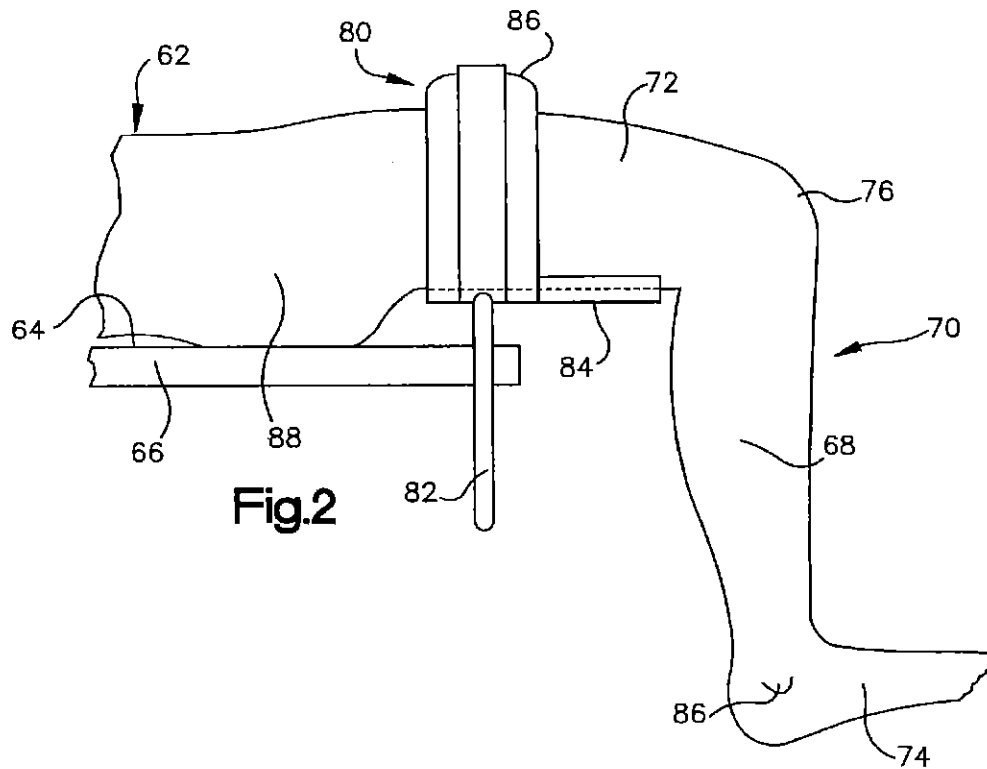
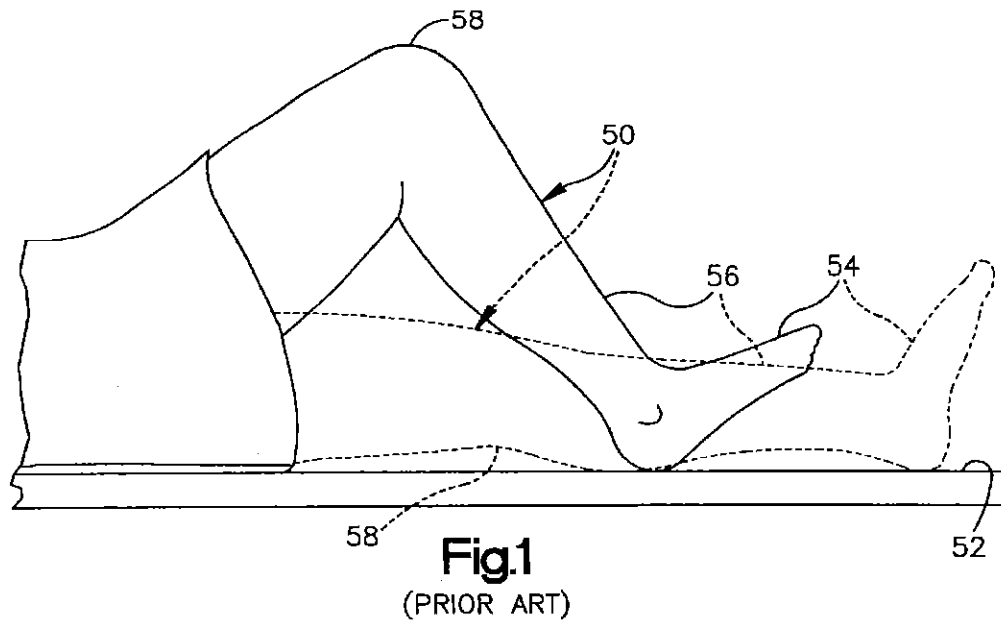
Operative Arthroscopy—John B. McGinty, M.D.—Department of Orthopaedic Surgery, Medical University of South Carolina, Charleston, South Carolina—©1991 by Raven Press, Ltd. p. 9.

U.S. Patent

Mar. 9, 2004

Sheet 1 of 22

US 6,702,821 B2



U.S. Patent

Mar. 9, 2004

Sheet 2 of 22

US 6,702,821 B2

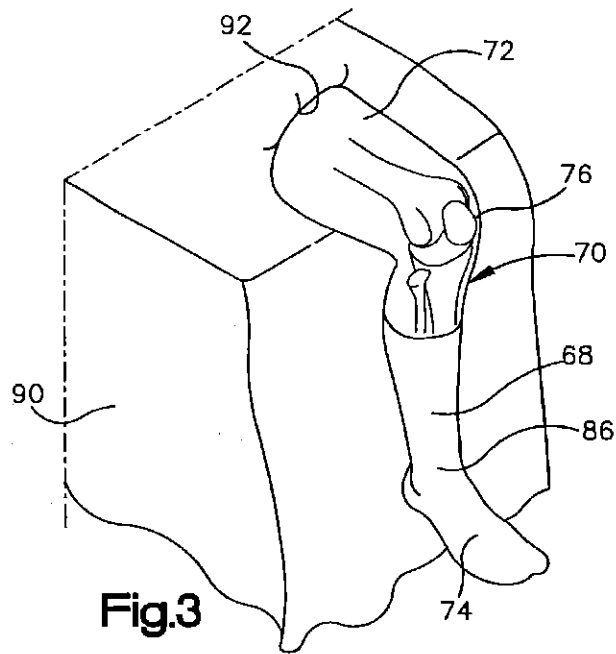


Fig.3

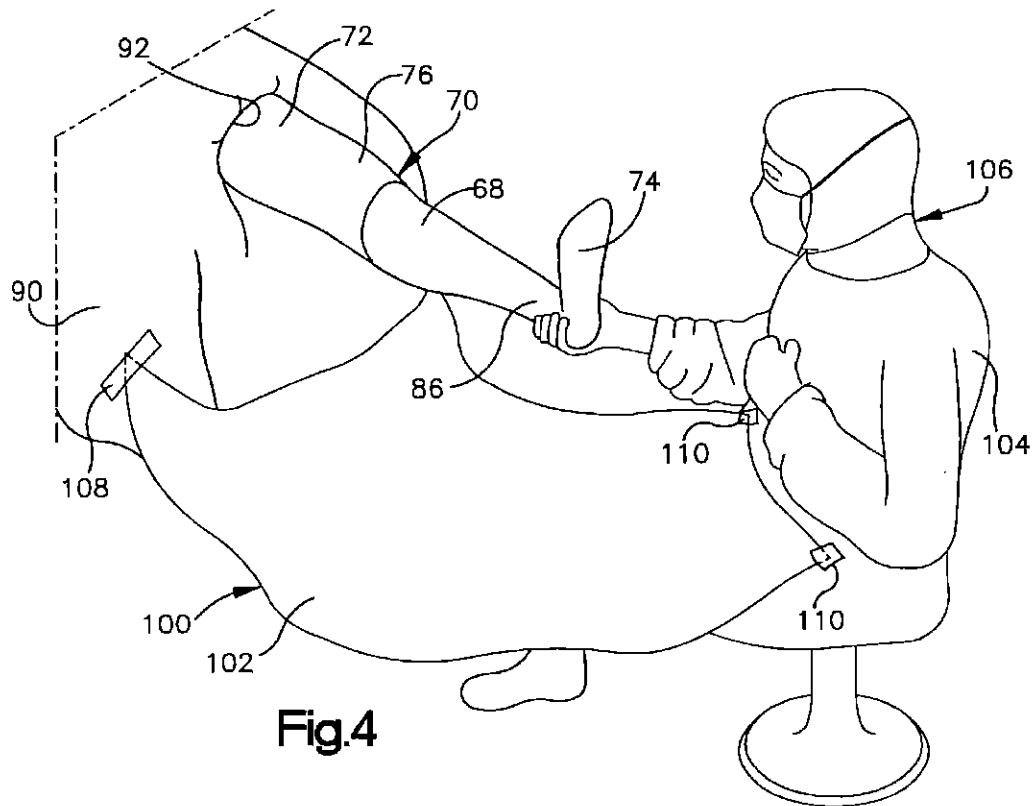


Fig.4

U.S. Patent

Mar. 9, 2004

Sheet 3 of 22

US 6,702,821 B2

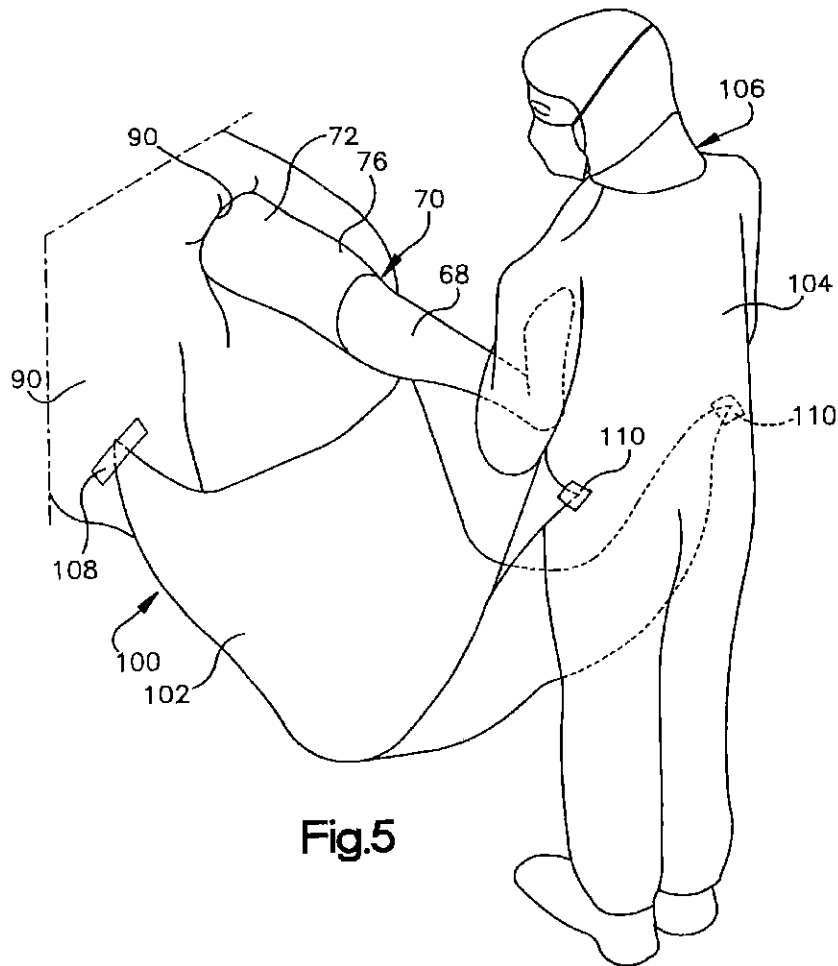


Fig.5

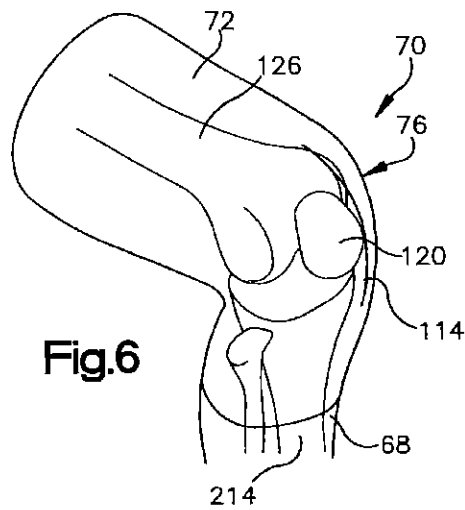


Fig.6

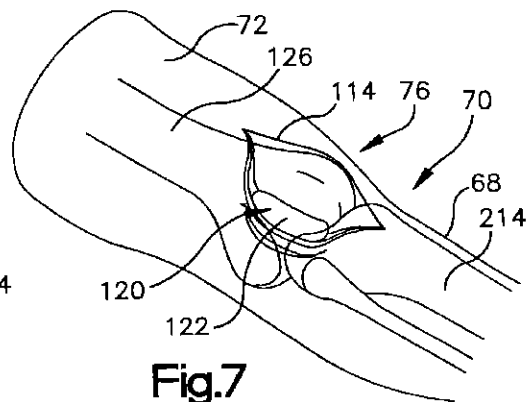


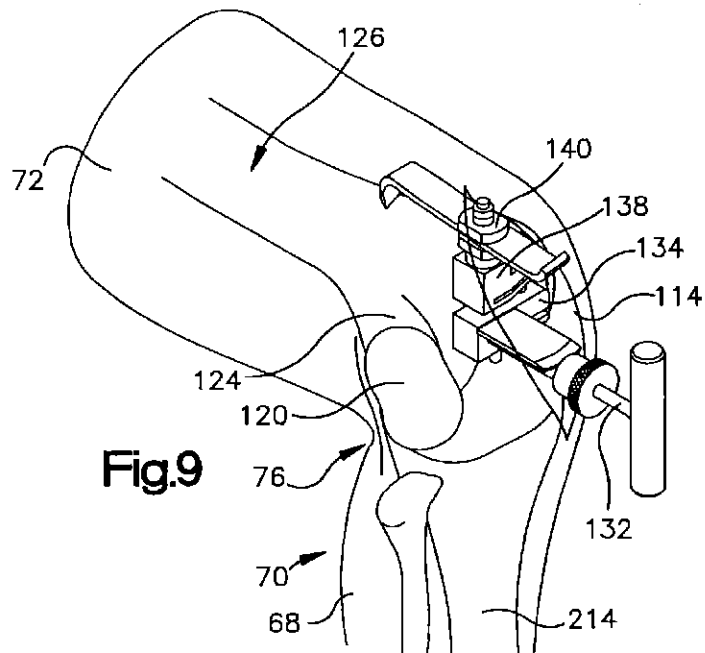
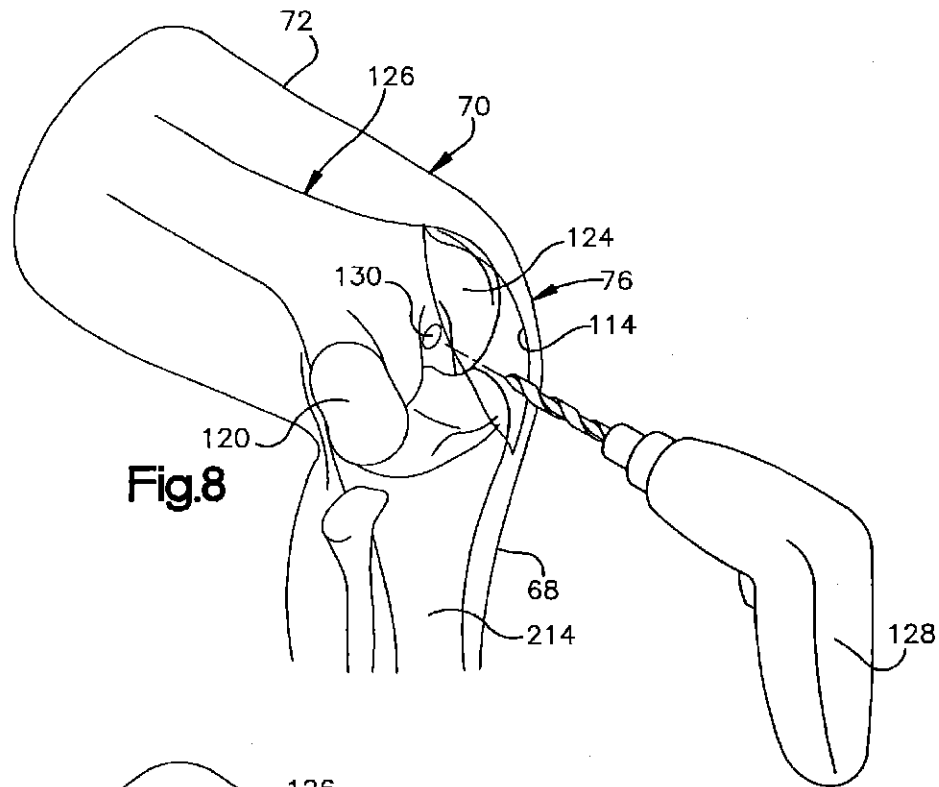
Fig.7

U.S. Patent

Mar. 9, 2004

Sheet 4 of 22

US 6,702,821 B2

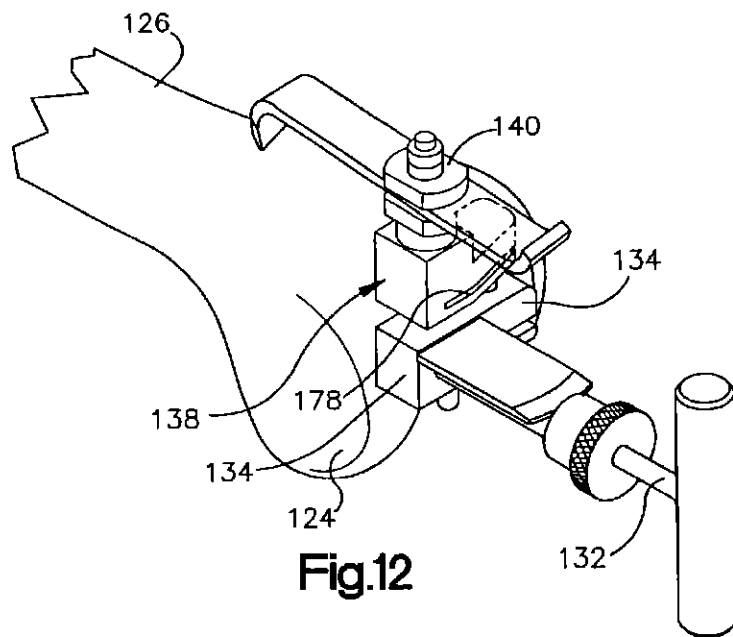
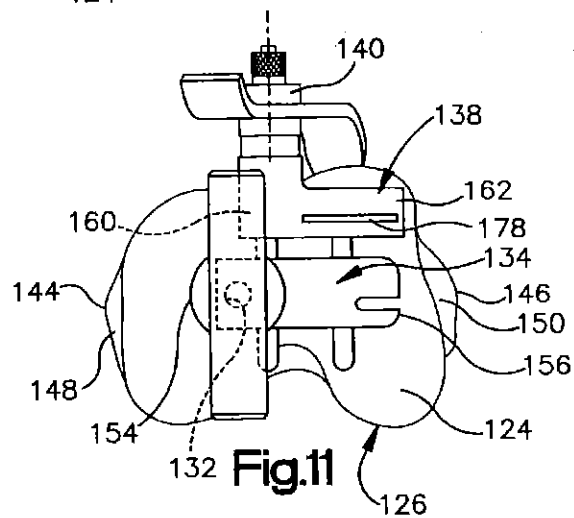
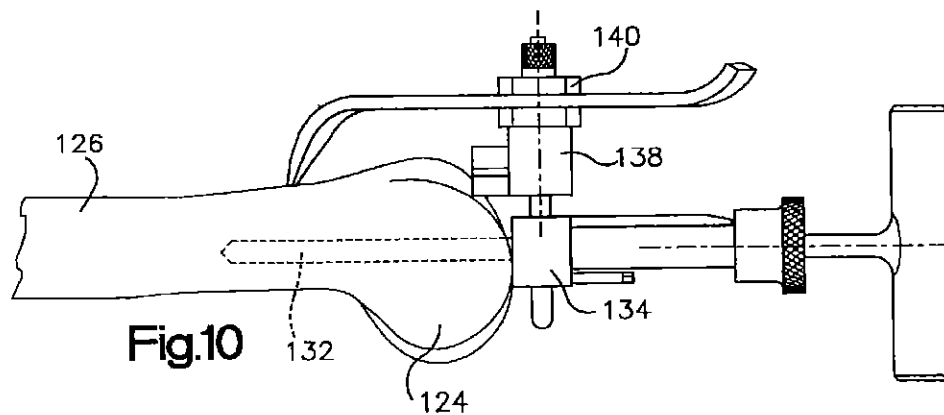


U.S. Patent

Mar. 9, 2004

Sheet 5 of 22

US 6,702,821 B2

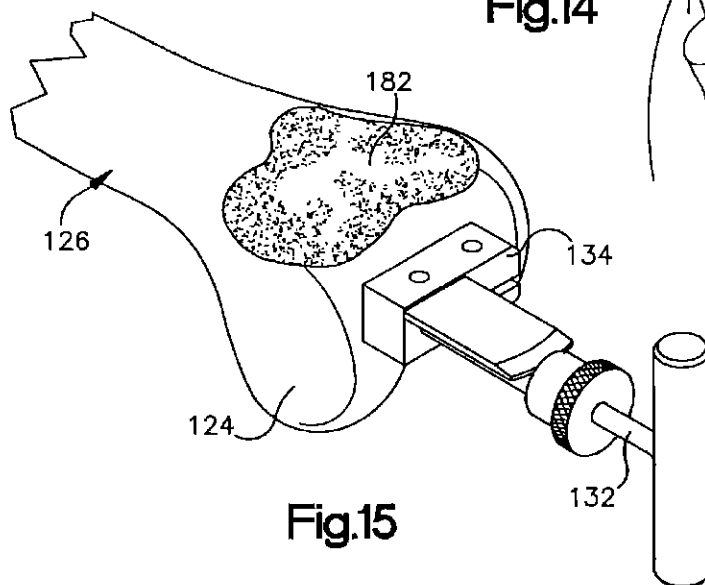
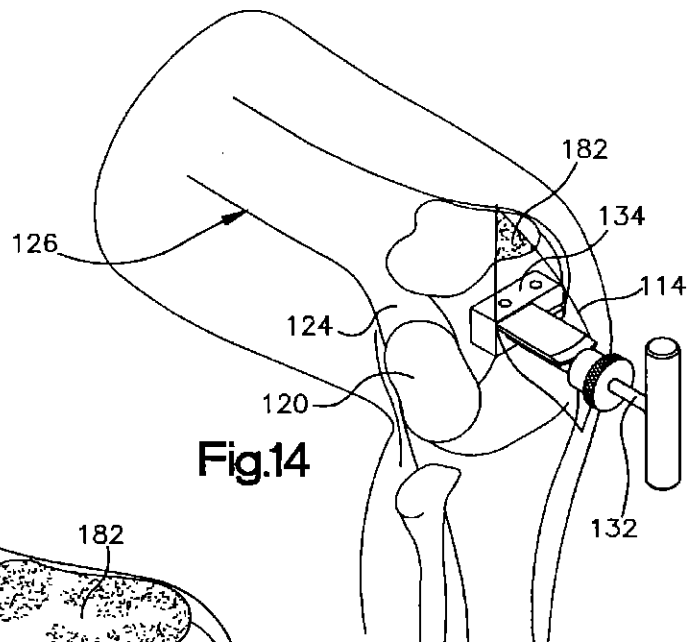
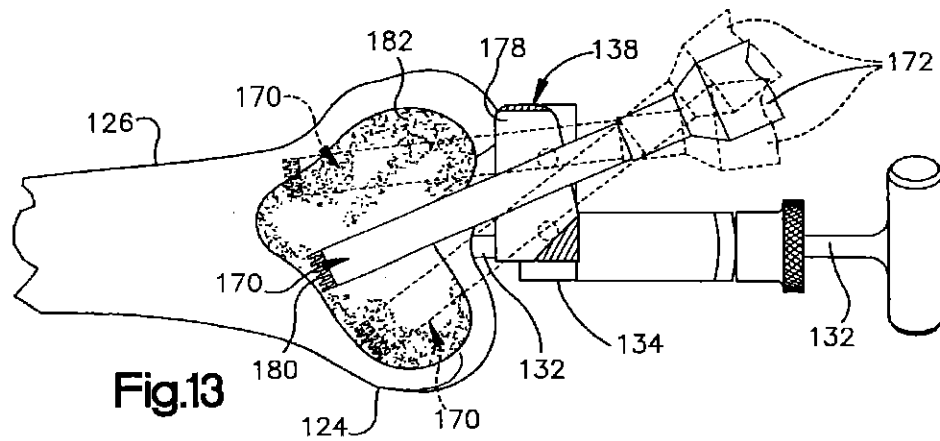


U.S. Patent

Mar. 9, 2004

Sheet 6 of 22

US 6,702,821 B2

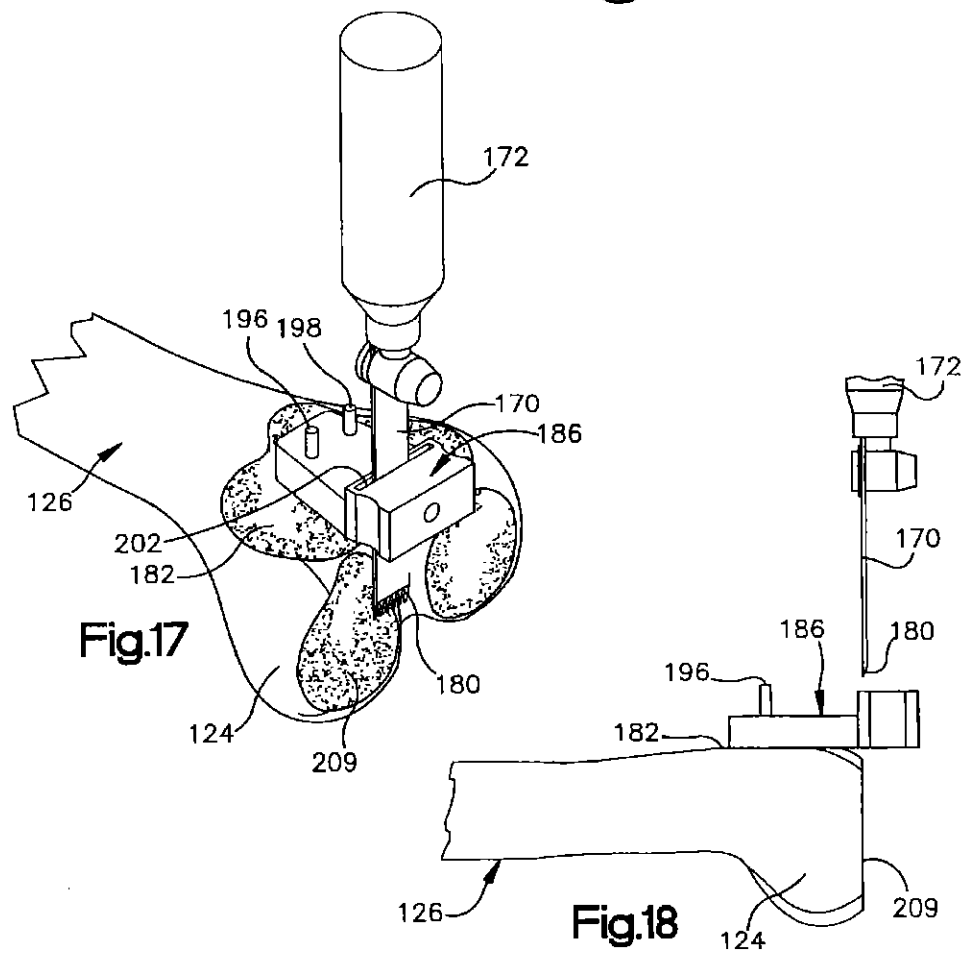
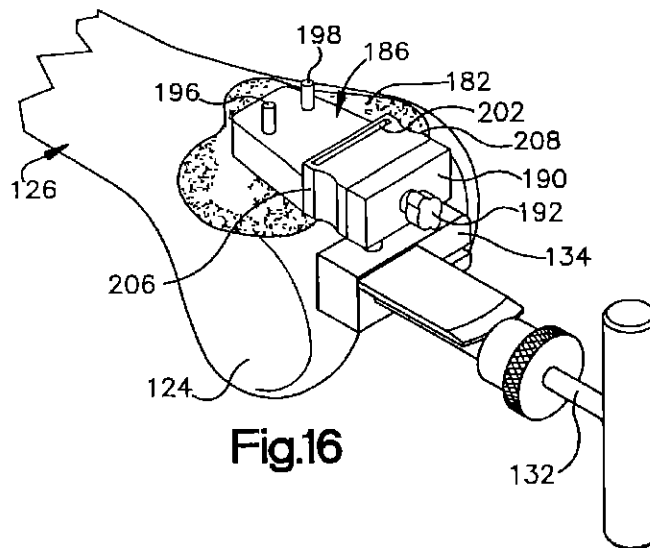


U.S. Patent

Mar. 9, 2004

Sheet 7 of 22

US 6,702,821 B2

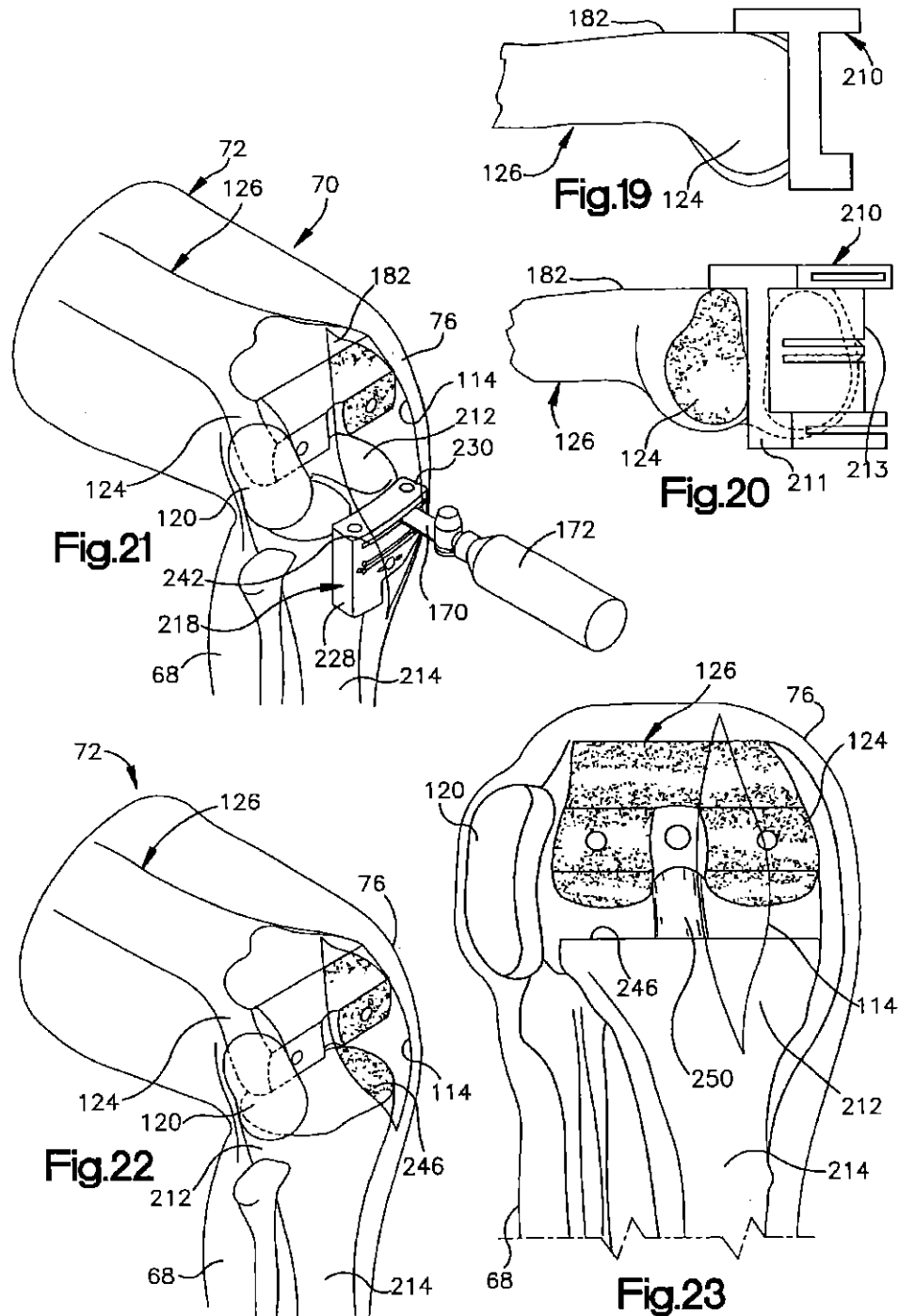


U.S. Patent

Mar. 9, 2004

Sheet 8 of 22

US 6,702,821 B2

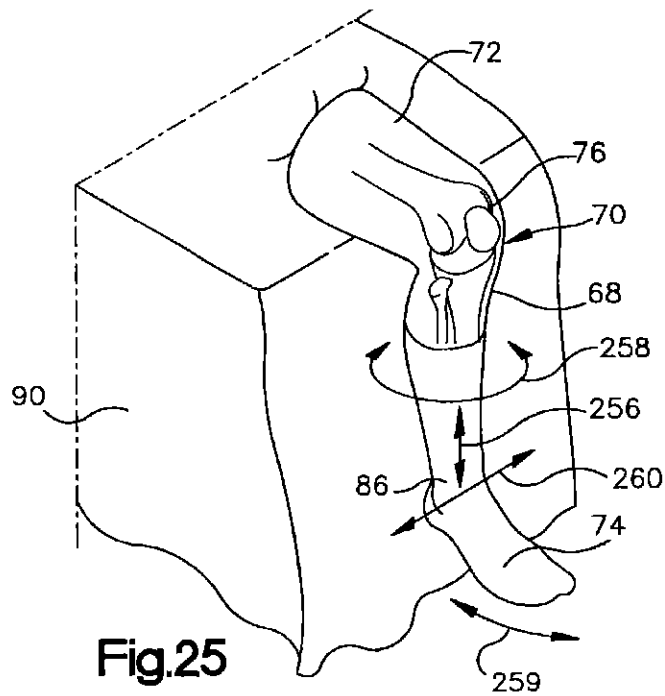
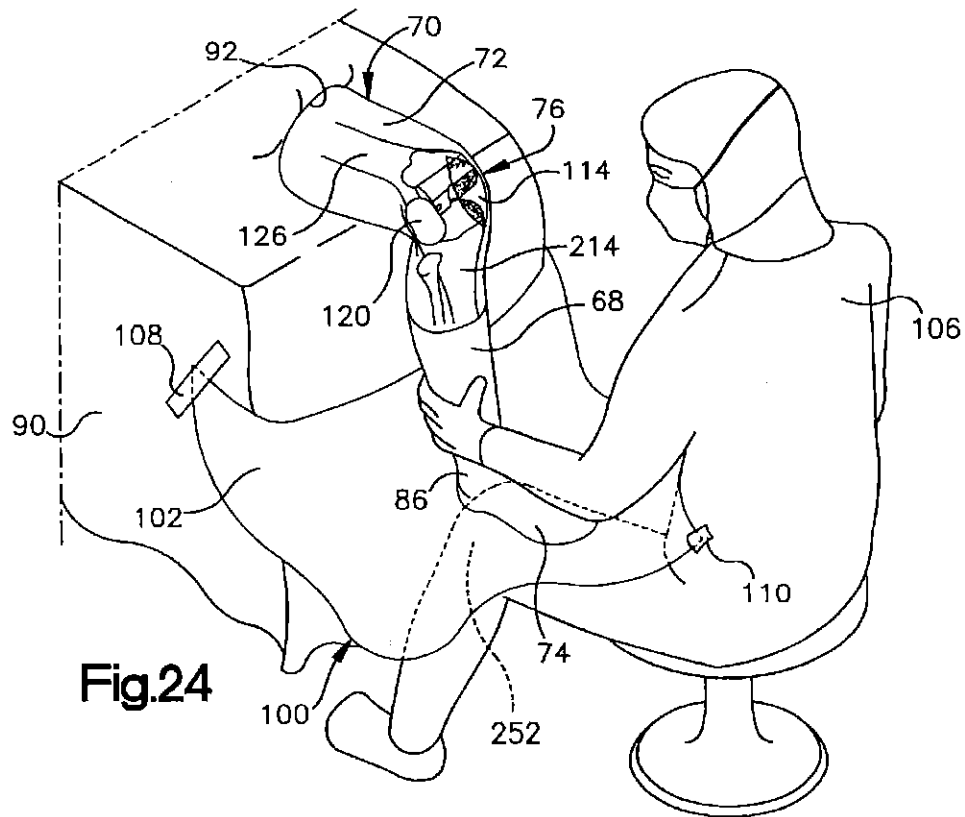


U.S. Patent

Mar. 9, 2004

Sheet 9 of 22

US 6,702,821 B2

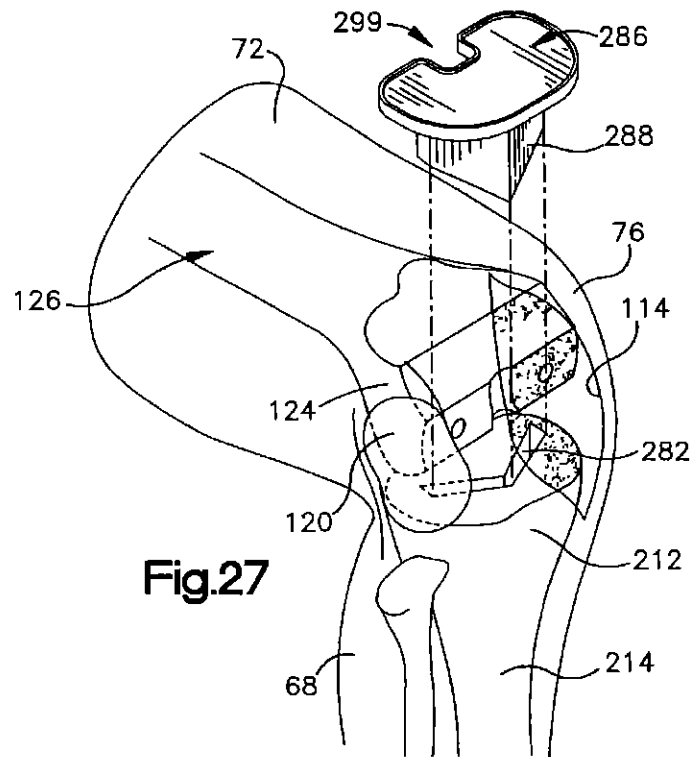
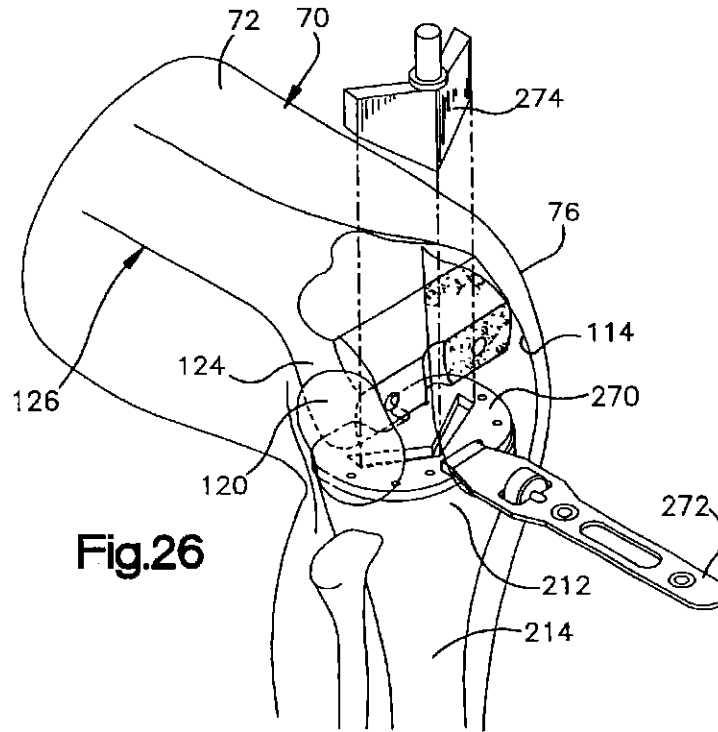


U.S. Patent

Mar. 9, 2004

Sheet 10 of 22

US 6,702,821 B2



U.S. Patent

Mar. 9, 2004

Sheet 11 of 22

US 6,702,821 B2

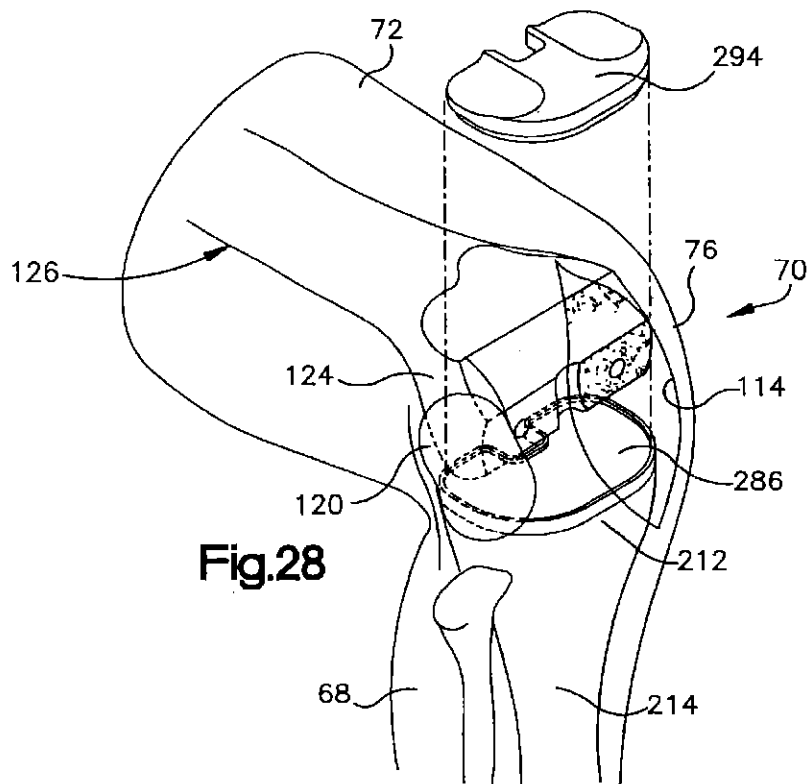


Fig.28

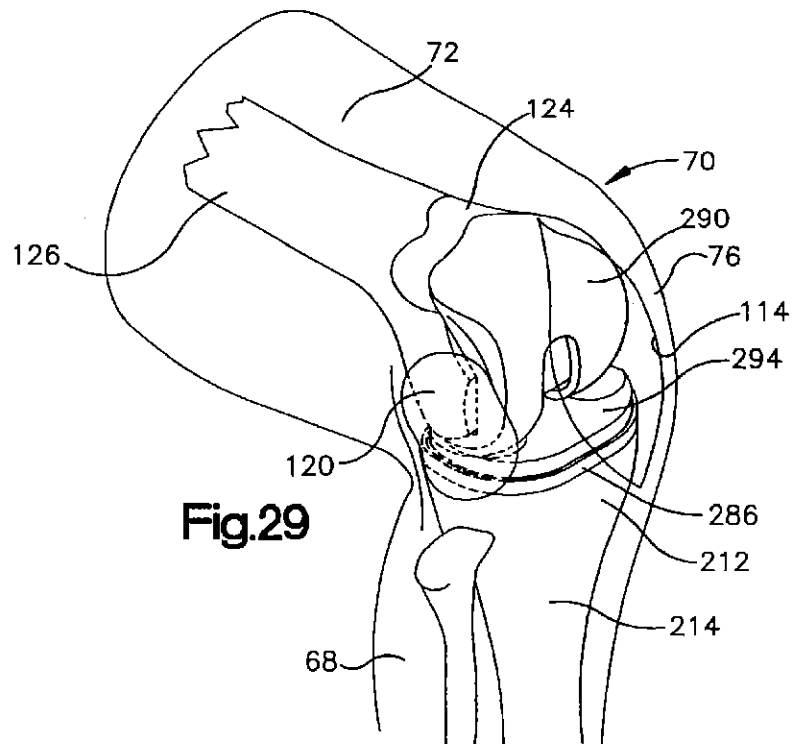


Fig.29

U.S. Patent

Mar. 9, 2004

Sheet 12 of 22

US 6,702,821 B2

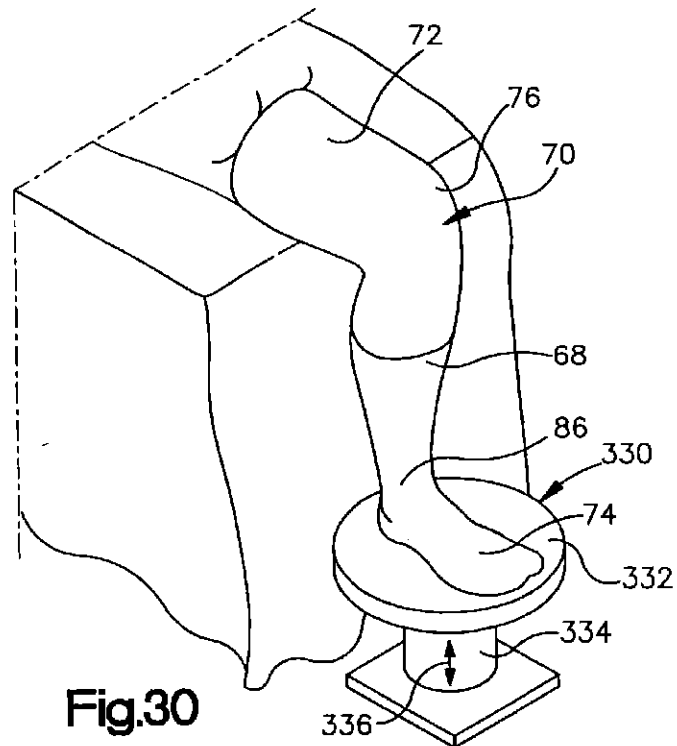


Fig.30

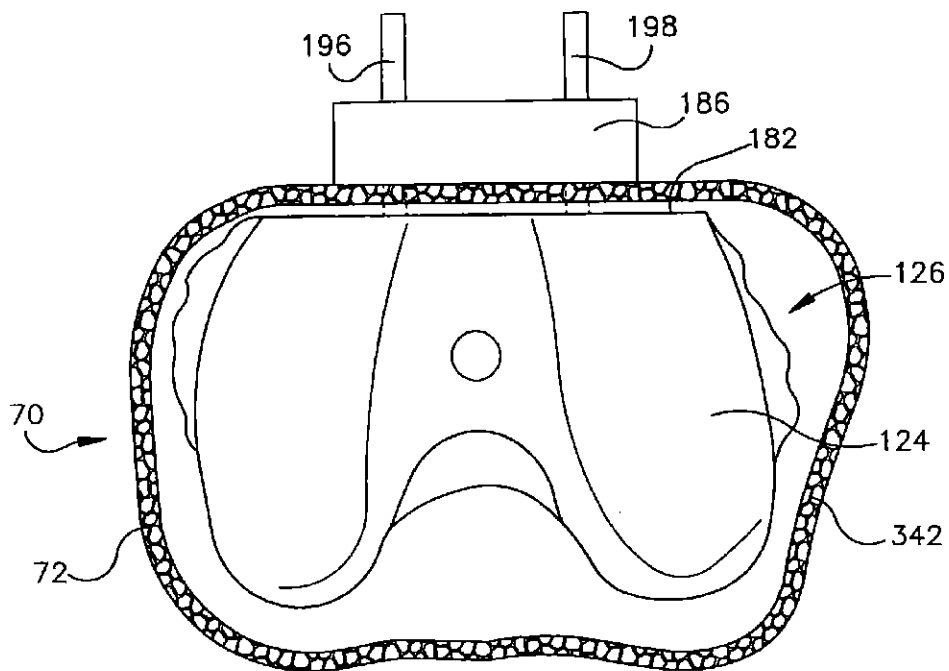


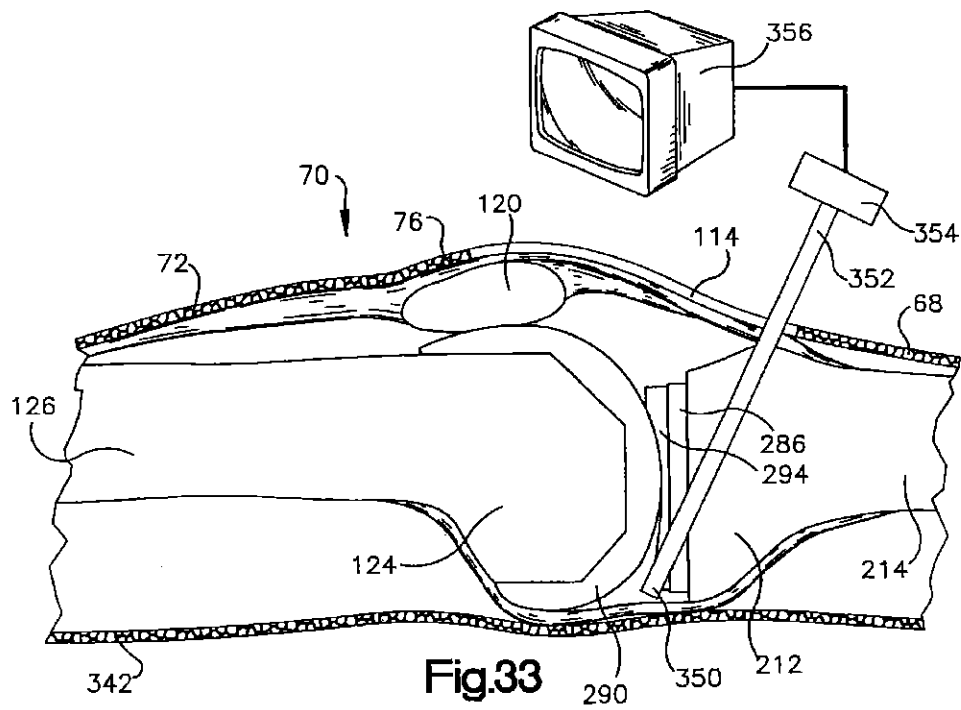
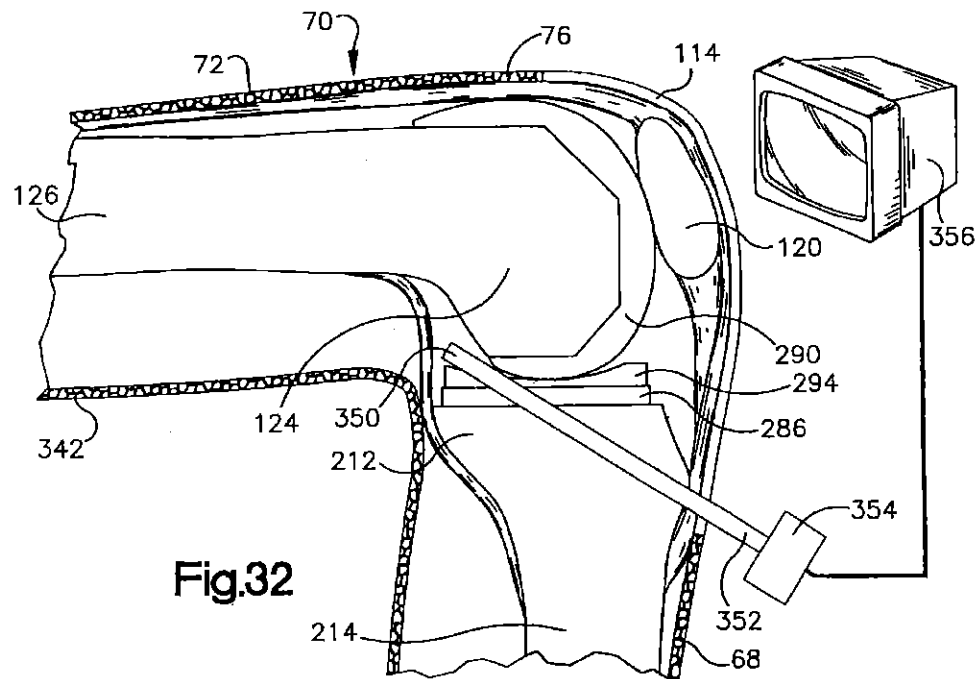
Fig.31

U.S. Patent

Mar. 9, 2004

Sheet 13 of 22

US 6,702,821 B2

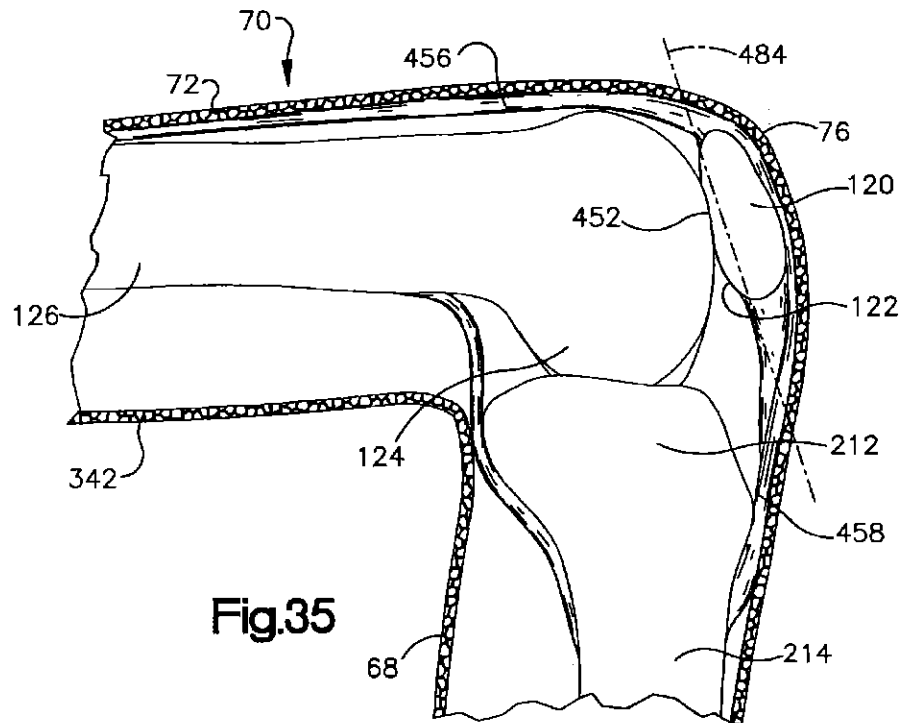
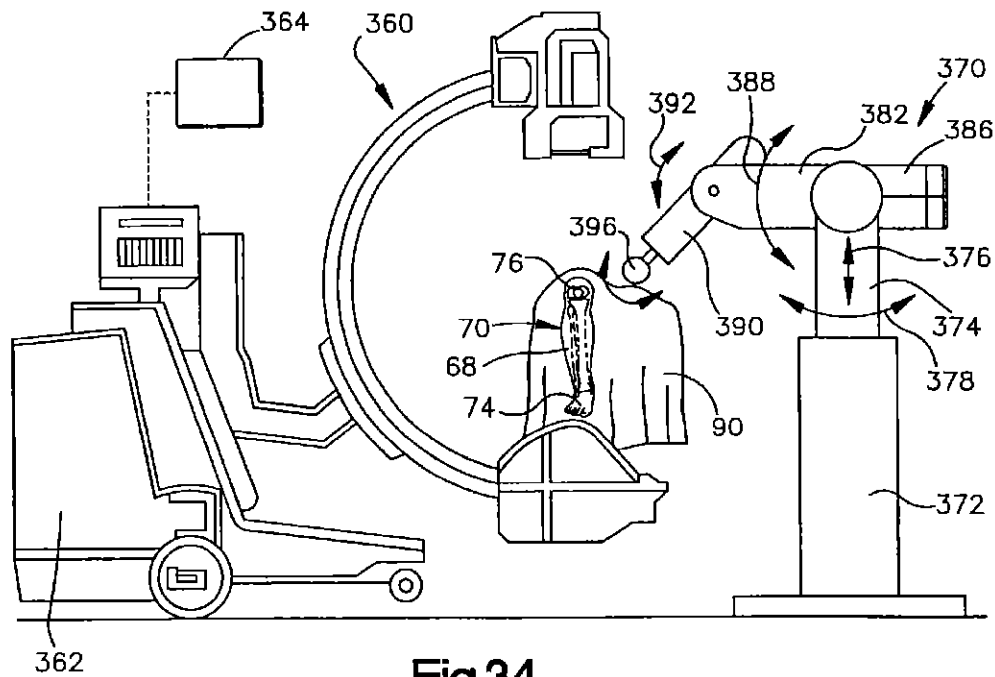


U.S. Patent

Mar. 9, 2004

Sheet 14 of 22

US 6,702,821 B2

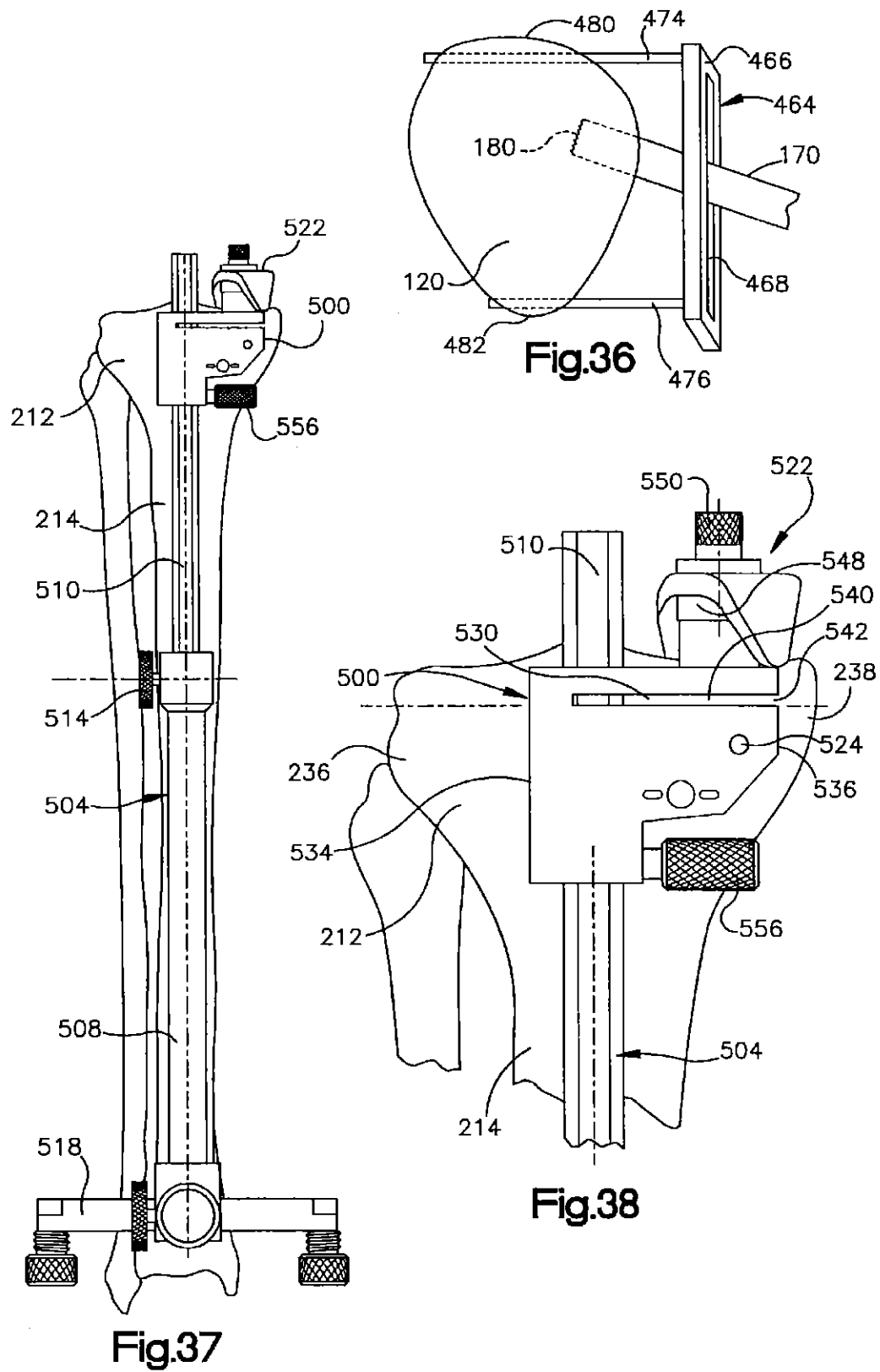


U.S. Patent

Mar. 9, 2004

Sheet 15 of 22

US 6,702,821 B2



U.S. Patent

Mar. 9, 2004

Sheet 16 of 22

US 6,702,821 B2

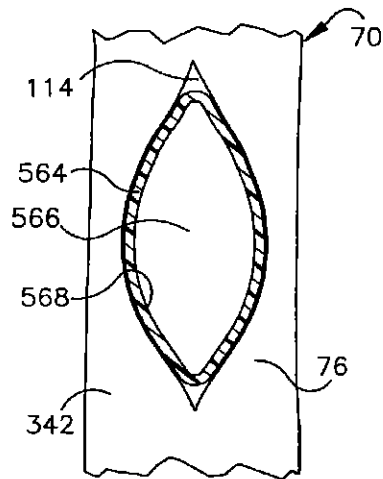


Fig.39

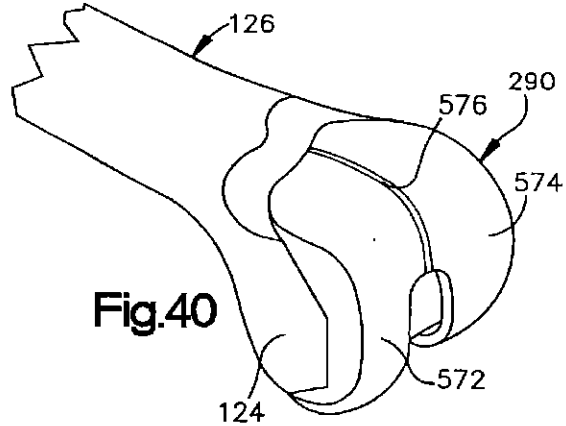


Fig.40

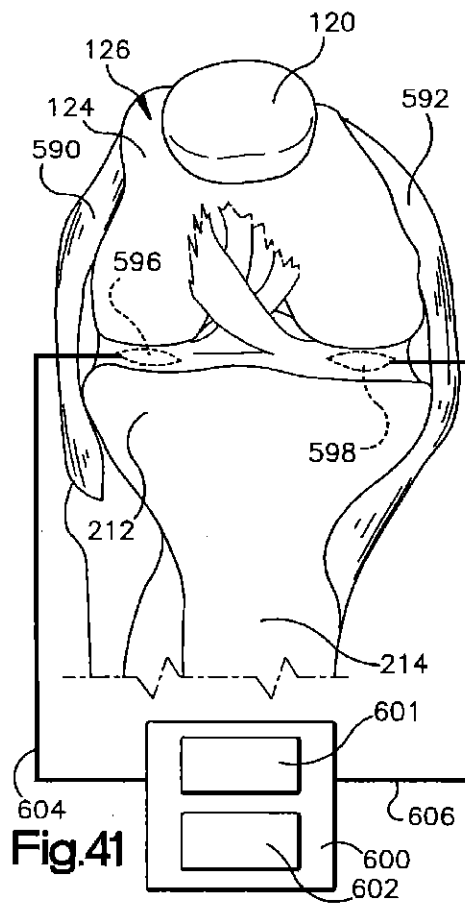


Fig.41

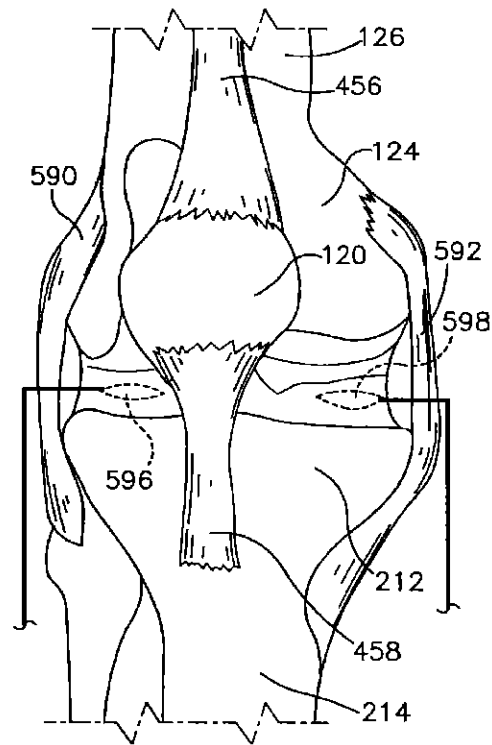


Fig.42

U.S. Patent

Mar. 9, 2004

Sheet 17 of 22

US 6,702,821 B2

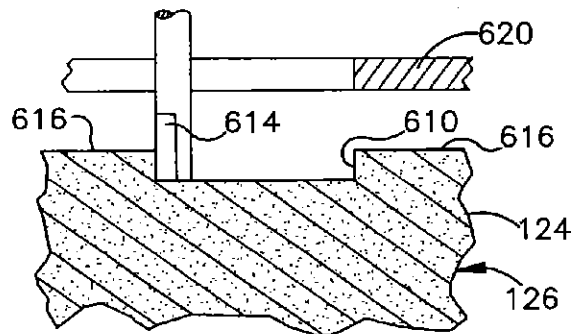
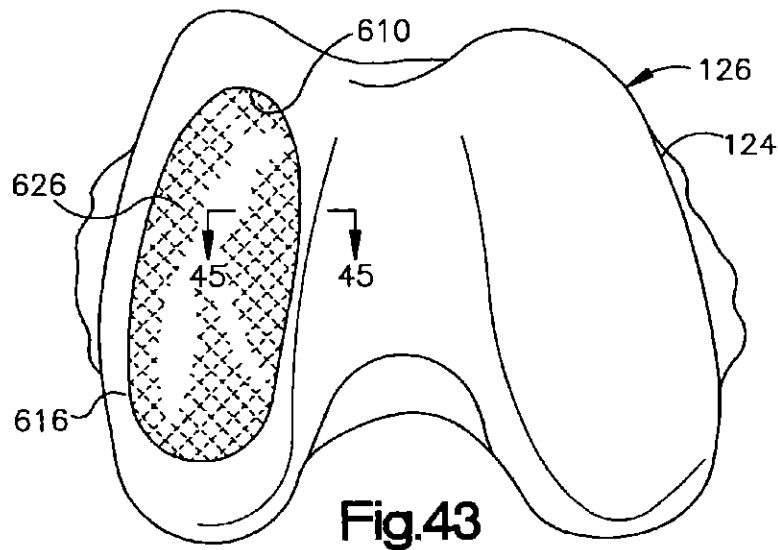


Fig. 44

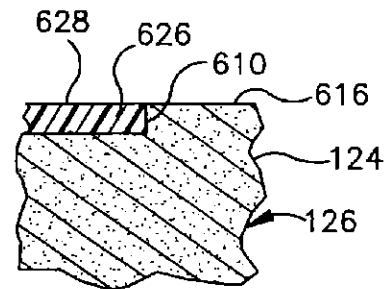


Fig. 45

U.S. Patent

Mar. 9, 2004

Sheet 18 of 22

US 6,702,821 B2

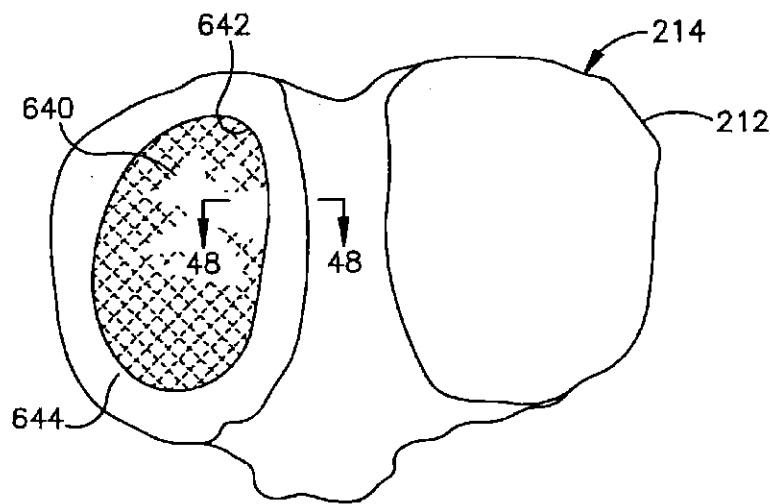


Fig.46

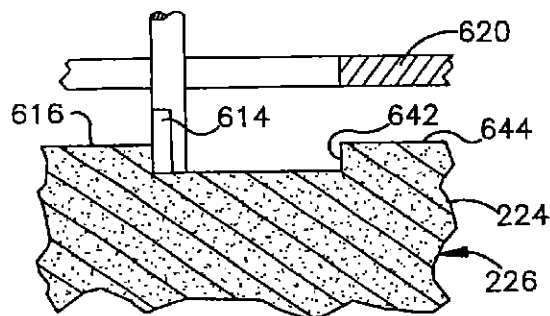


Fig.47

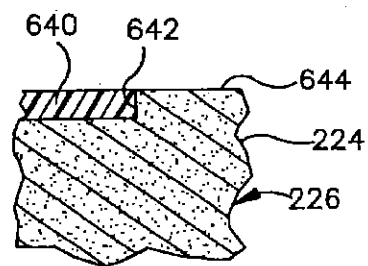


Fig.48

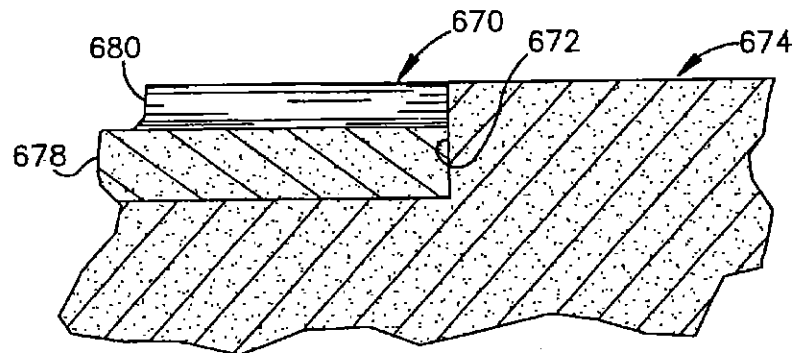


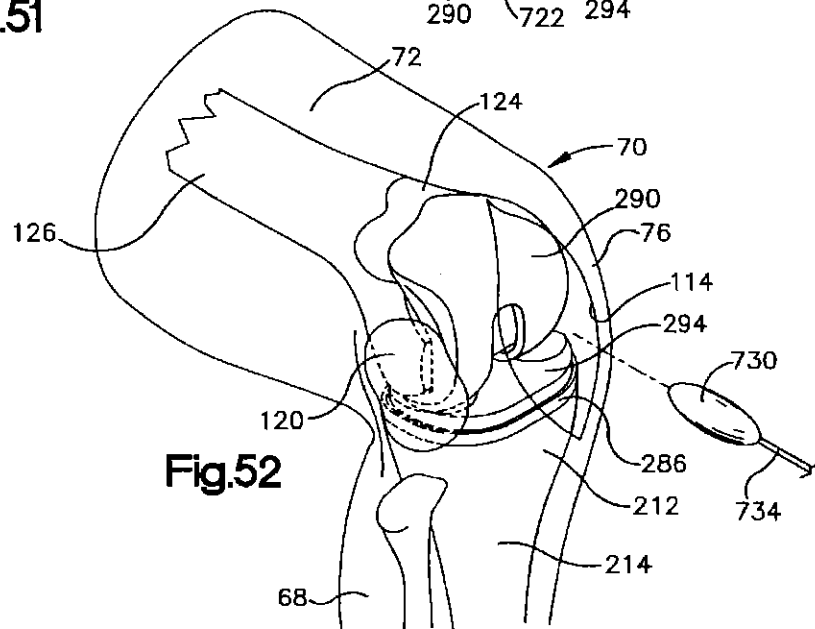
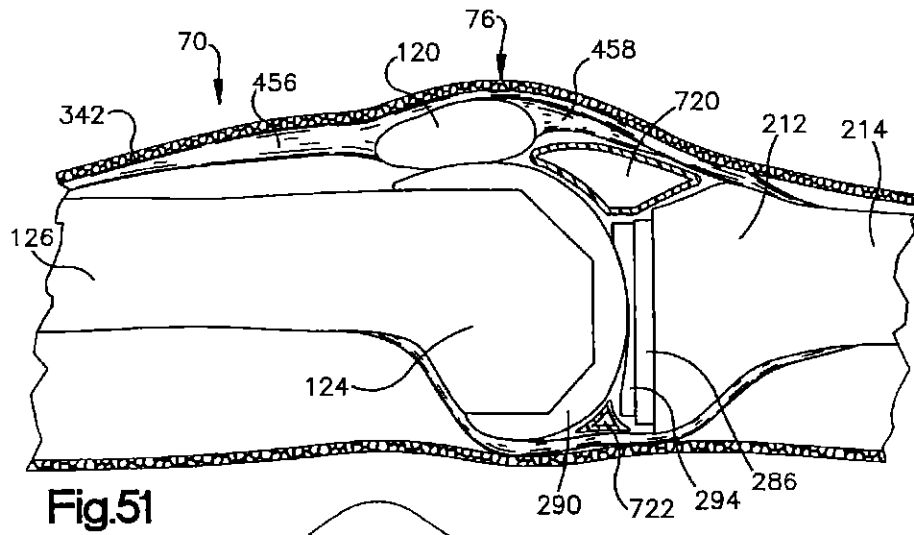
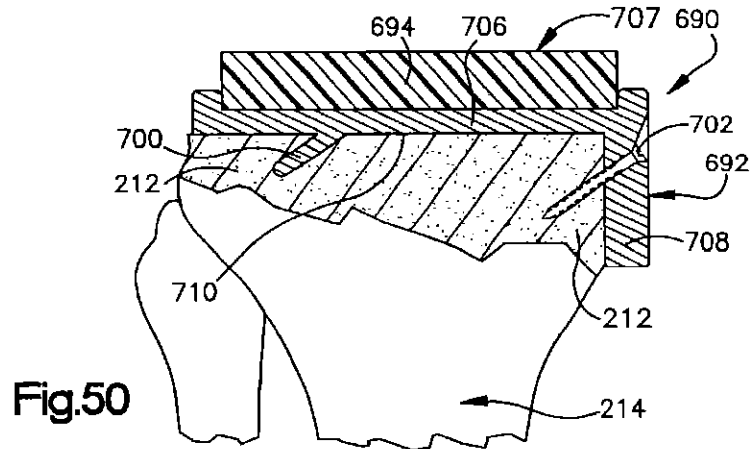
Fig.49

U.S. Patent

Mar. 9, 2004

Sheet 19 of 22

US 6,702,821 B2



U.S. Patent

Mar. 9, 2004

Sheet 20 of 22

US 6,702,821 B2

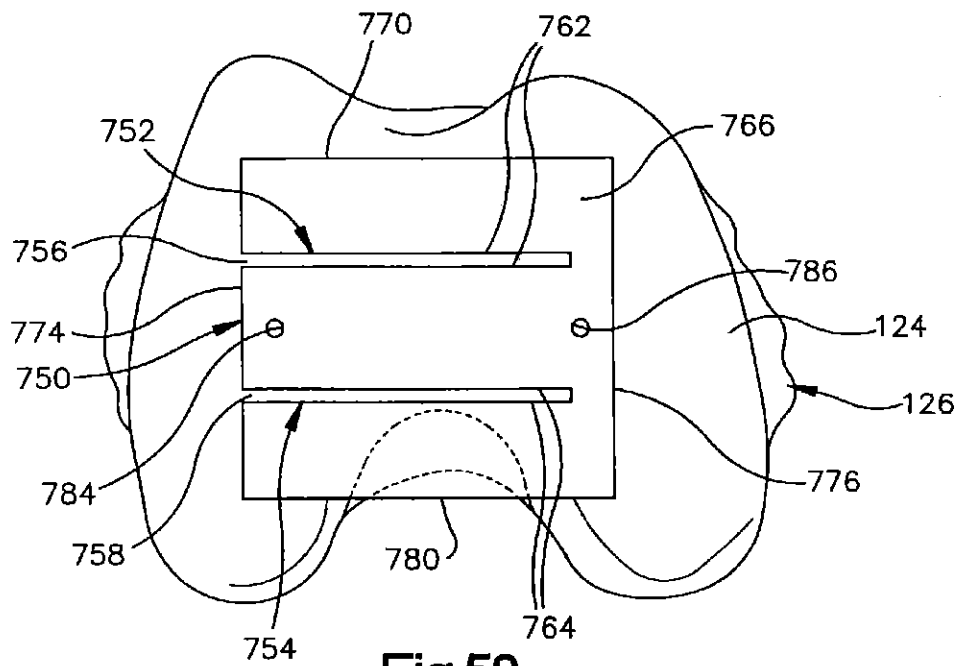


Fig. 53

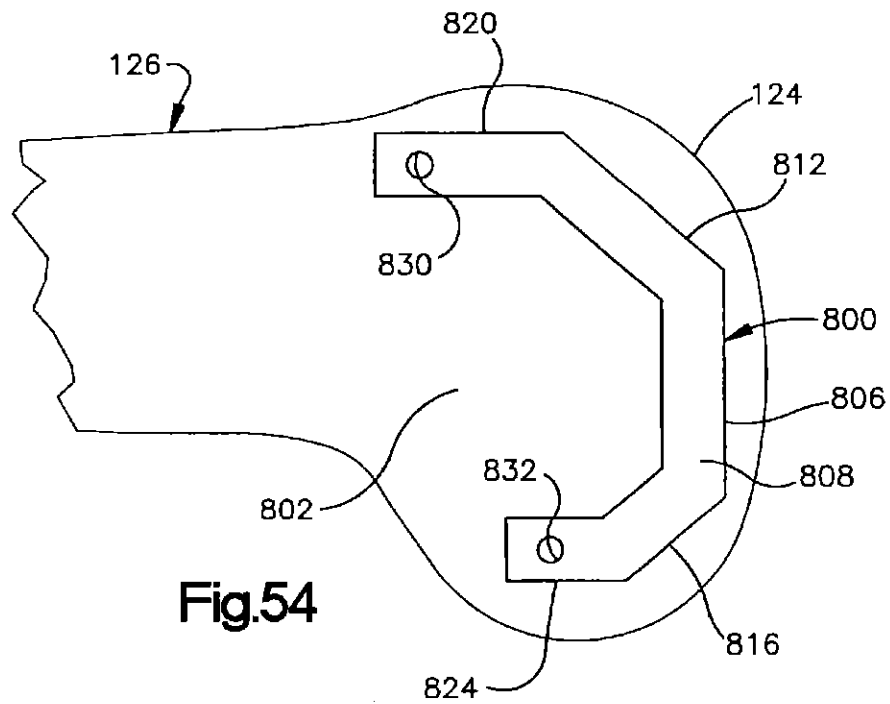


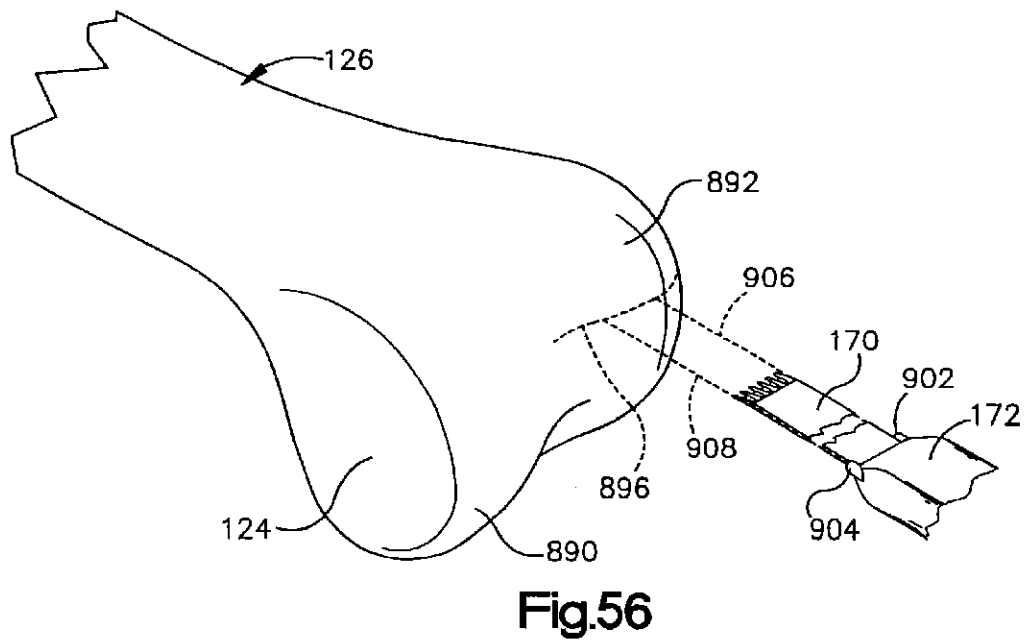
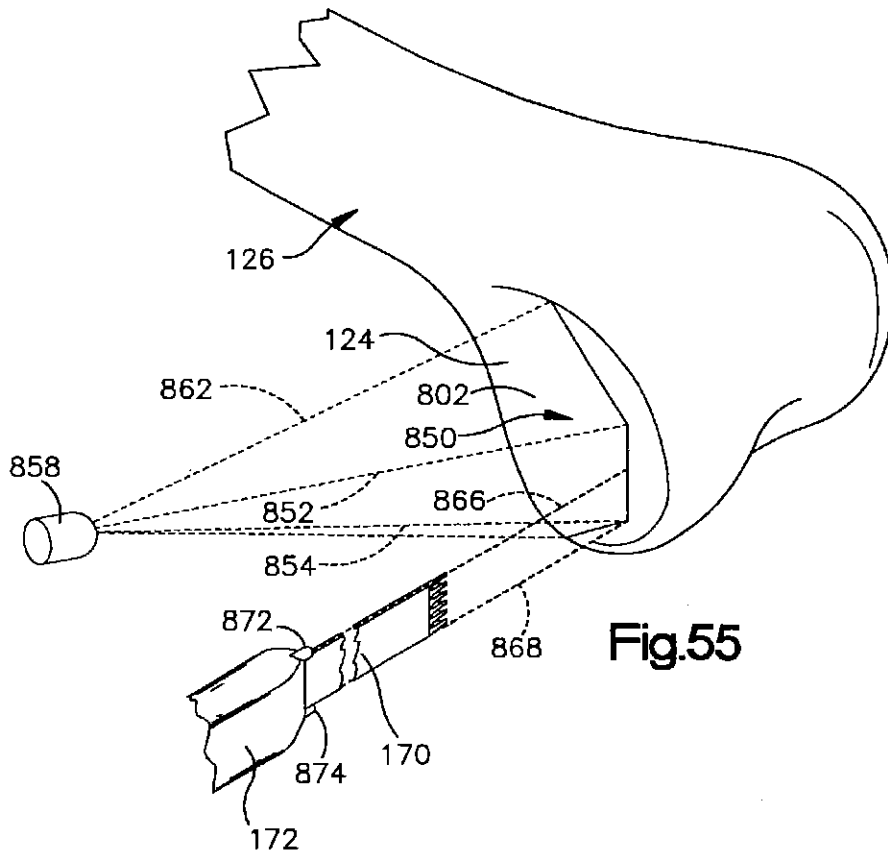
Fig. 54

U.S. Patent

Mar. 9, 2004

Sheet 21 of 22

US 6,702,821 B2



U.S. Patent

Mar. 9, 2004

Sheet 22 of 22

US 6,702,821 B2

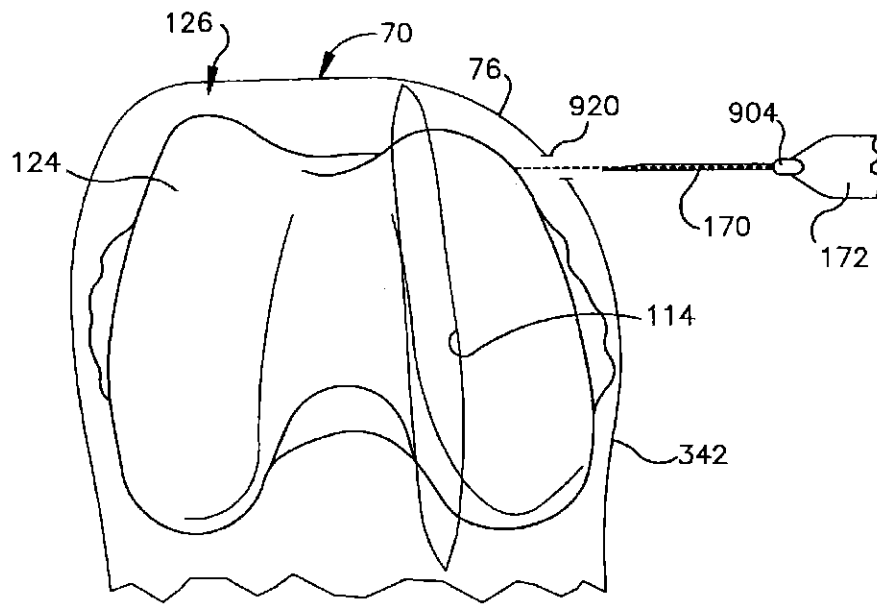


Fig.57

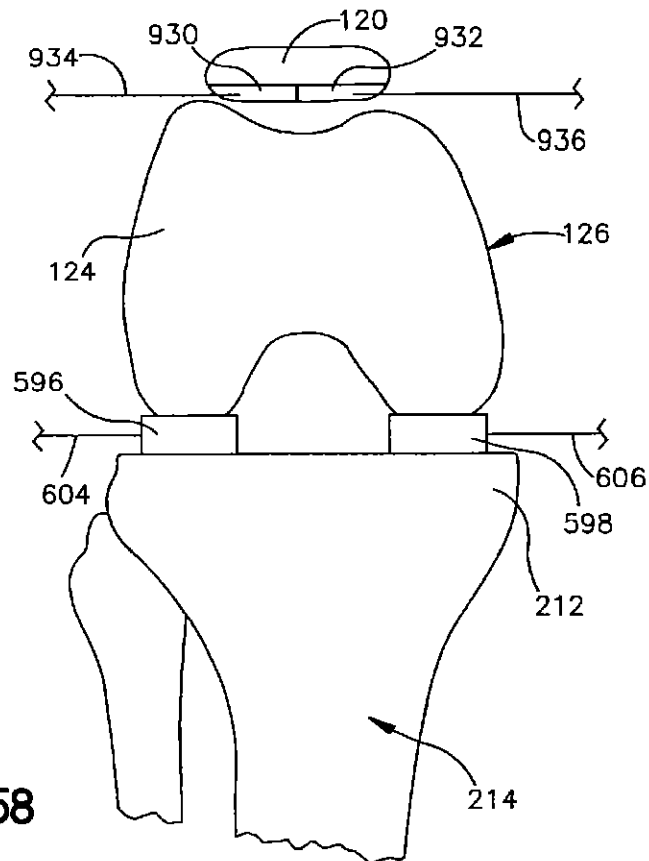


Fig.58

US 6,702,821 B2

1

INSTRUMENTATION FOR MINIMALLY INVASIVE JOINT REPLACEMENT AND METHODS FOR USING SAME

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 09/737,380 filed Dec. 15, 2000, now U.S. Pat. No. 6,503,267. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/815,405 filed Mar. 22, 2001, now abandoned. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/569,020 filed May 11, 2000, now U.S. Pat. No. 6,432,063. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/483,676 filed Jan. 14, 2000, now U.S. Pat. No. 6,468,289. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/602,743 filed Jun. 23, 2000, now U.S. Pat. No. 6,361,565. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/526,949 filed on Mar. 16, 2000, now U.S. Pat. No. 6,620,181. This application is also a continuation-in-part of U.S. patent application Ser. No. 09/789,621 filed Feb. 21, 2001, now U.S. Pat. No. 6,635,073.

BACKGROUND OF THE INVENTION

The present invention relates to a new and improved method of performing surgery. The surgery may be of any desired type. The surgery may be performed on joints in a patient's body. The surgery may be performed on any desired joint in a patient's body. Regardless of the type of surgery to be performed, a limited incision may advantageously be utilized.

This specification relates to limited incision partial or total knee joint replacements and revisions and is the result of a continuation of work which was previously performed in conjunction with the subject matter of U.S. Pat. No. 5,514,143. This specification also contains subject matter which relates to U.S. Pat. Nos. 5,163,949; 5,269,785; 5,549,683; 5,662,710; 5,667,520; 5,961,499; 6,059,817; and 6,099,531. Although this specification refers to knee joints, it should be understood that the subject matter of this application is also applicable to joints in many different portions of a patient's body, for example a shoulder, spine, arm, hand, hip or foot of a patient.

During a total or partial knee replacement or revision, an incision is made in a knee portion of a leg of the patient to obtain access to the knee joint. The incision is relatively long to enable instrumentation, such as a femoral alignment guide, anterior resection guide, distal resection guide, femoral cutting guide, and femoral anterior, posterior and chamber resection guide to be positioned relative to a distal end portion of the femur. In addition, the incision must be relatively large to enable a tibial resection guide to be positioned relative to the proximal end portion of the tibia.

With known procedures of total or partial knee replacement, the incision in the knee portion of the patient is made with the leg of the patient extended (straight) while the patient is lying on his or her back. At this time, the extended leg of the patient is disposed along and rests on a patient support surface. After the incision has been made in the knee portion of the leg of the patient, the leg is flexed and a foot connected with the leg moves along the patient support surface. The knee portion of the flexed leg of the patient is disposed above the patient support surface. This results in the soft tissue in the knee being compressed against the back of the knee joint. This makes it very difficult

2

to access posterior or soft tissue to remove bone spurs (ostified), meniscus, posterior capsule, ligaments in the back of the joint, and/or any residual soft tissue or connective tissue that is blocking further flexion.

After the incision has been made and while the leg is flexed with the foot above the patient support surface, the surgeon can not view arteries, nerves and veins which are sitting just posterior to the knee capsule. Therefore, a surgeon may be very reluctant, or at least very careful, of inserting instruments into the back of the knee joint to remove tissue. This may result in osteophytes, bone spurs and similar types of posterior soft tissue being left in place.

With known techniques, the patella is commonly everted from its normal position. When the patella is everted, the inner side of the patella is exposed and faces outward away from end portions of the femur and tibia. The outer side of the everted patella faces inward toward the end portions of the femur and the tibia. Moving the everted patella to one side of end portions of the femur and tibia tends to increase the size of the incision which must be made in the knee portion of the patient's leg.

After implants have been positioned in the knee portion of the patient's leg, it is common to check for flexion and extension balancing of ligaments by flexing and extending the knee portion with the foot above the support surface. If the ligaments are too tight medially or laterally, they can be released to obtain the desired tension. However, the checking of ligament balance by flexing and extending the leg of the patient, ignores rotational balancing of ligaments. Since the femoral implant is movable relative to the tibial implant, the stability of the knee joint is dependent upon balancing of the ligaments in flexion, extension, and rotation.

SUMMARY OF THE INVENTION

The present invention relates to a new and improved method and apparatus for use in performing any desired type of surgery on a joint in a patient's body. The joint may advantageously be a knee joint. However, the method and apparatus may be used in association with surgery on other joints in a patient's body. There are many different features of the present invention which may used either together or separately in association with many different types of surgery. Although features of the present invention may be used with many different surgical procedures, the invention is described herein in conjunction with surgery on a joint in a patient's body.

One of the features of the present invention relates to the making of a limited incision. The limited incision may be in any desired portion of a patient's body. For example, the limited incision may be in a knee portion of a leg of a patient. The limited incision may be made while a lower portion of the leg of the patient is extending downward from the upper portion of the leg of the patient. At this time, a foot connected with the lower portion of the leg of the patient may be below a surface on which the patient is supported. The limited incision may be made while the lower portion of the leg of the patient is suspended from the upper portion of the leg or while the lower portion of the leg and/or the foot of the patient are held by a support device. After the incision has been made, any one of many surgical procedures may be undertaken.

It is believed that in certain circumstances, it may be desired to have a main incision of limited length and a secondary incision of even smaller length. The secondary incision may be a portal or stab wound. A cutting tool may be moved through the secondary incision. An implant may be moved through the main incision.

US 6,702,821 B2

3

Once the incision has been made, a patella in a knee portion of the patient may be offset to one side of its normal position. When the patella is offset, an inner side of the patella faces inward toward the end portions of a femur and tibia.

Although any one of many known surgical procedures may be undertaken through the limited incision, down sized instrumentation for use in the making of cuts in a femur and/or tibia may be moved through or part way through the incision. The down sized instrumentation may be smaller than implants to be positioned in the knee portion of the patient. The down sized instrumentation may have opposite ends which are spaced apart by a distance which is less than the distance between lateral and medial epicondyles on a femur or tibia in the leg of the patient.

It is contemplated that the down sized instrumentation may have cutting tool guide surfaces of reduced length. The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool.

It is contemplated that at least some, if not all, cuts on a bone may be made using light directed onto the bone as a guide. The light directed onto the bone may be in the form of a three dimensional image. The light directed onto the bone may be a beam along which a cutting tool is moved into engagement with the bone.

There are several different orders in which cuts may be made on bones in the knee portion of the leg of the patient. It is believed that it may be advantageous to make the patellar and tibial cuts before making the femoral cuts.

There are many different reasons to check ligament balancing in a knee portion of the leg of a patient. Ligament balancing may be checked while the knee portion of the leg of the patient is flexed and the foot of the patient is below the support surface on which the patient is disposed. Flexion and extension balancing of ligaments may be checked by varying the extent of flexion of the knee portion of the leg of the patient. In addition, rotational stability of the ligaments may be checked by rotating the lower portion of the leg of the patient about its central axis. Balancing of ligaments may also be checked by moving the foot of the patient sideways, rotating the lower portion of the leg of the patient, and/or moving the foot anteriorly or posteriorly.

It is believed that it may be advantageous to utilize an endoscope or a similar apparatus to examine portions of the patient's body which are spaced from the incision. It is also contemplated that images of the knee portion of the patient's leg may be obtained by using any one of many known image generating devices other than an endoscope. The images may be obtained while the patient's leg is stationary or in motion. The images may be obtained to assist a surgeon in conducting any desired type of surgery.

Balancing of the ligaments in the knee portion of a patient's leg may be facilitated by the positioning of one or more transducers between tendons, ligaments, and/or bones in the knee portion. One transducer may be positioned relative to a medial side of a knee joint. Another transducer may be positioned relative to a lateral side of the knee joint. During bending of the knee joint, the output from the transducers will vary as a function of variations in tension forces in the ligaments. This enables the tension forces in ligaments in opposite sides of the knee portion to be compared to facilitate balancing of the ligaments.

Patellar tracking may be checked by the positioning of one or more transducers between the patella and the distal

4

end portion of the femur. If desired, one transducer may be placed between a medial portion of the patella and the distal end portion of the femur. A second transducer may be placed between a lateral portion of the patella and the distal end portion of the femur. Output signals from a transducer will vary as a function of variations in force transmitted between the patella and femur during bending of the leg.

The articular surface on the patella may be repaired. The defective original articular surface on the patella may be removed by cutting the patella while an inner side of the patella faces toward a distal end portion of a femur. The step of cutting the patella may be performed while the patella is disposed in situ and is urged toward the distal end portion of the femur by connective tissue. An implant may then be positioned on the patella.

It is contemplated that the size of the incision in the knee or other portion of the patient may be minimized by conducting surgery through a cannula. The cannula may be expandable. To facilitate moving of an implant through the cannula, the implant may be formed in two or more portions. The portions of the implant may be interconnected when the portions of the implant have been positioned in the patient's body. Although the implants disclosed herein are associated with a patient's knee, it should be understood that the implants may be positioned at any desired location in a patient's body.

An implant may be positioned in a recess formed in a bone in a patient. The implant may contain biological resurfacing and/or bone growth promoting materials. The implant may contain mesenchymal cells and/or tissue inductive factors. Alternatively, the implant may be formed of one or more materials which do not enable bone to grow into the implant.

In accordance with one of the features of the present invention, body tissue may be moved or stretched by a device which is expandable. The expandable device may be biodegradable so that it can be left in a patient's body. The expandable device may be expanded to move and/or stretch body tissue and increase a range of motion of a joint. The expandable device may be used to stretch body tissue in which an incision is to be made.

An improved drape system is provided to maintain a sterile field between a surgeon and a patient during movement of the surgeon relative to the patient. The improved drape system includes a drape which extends between the surgeon and a drape for the patient. During surgery on a knee portion of a leg of a patient, the drape system extends beneath a foot portion of the leg of a patient. It is contemplated that the drape system will be utilized during many different types of operations other than surgery on a leg of a patient.

There are many different features to the present invention. It is contemplated that these features may be used together or separately. It is also contemplated that the features may be utilized in association with joints in a patient's body other than a knee joint. For example, features of the present invention may be used in association with surgery on vertebral joints or glenoid joints. However, it is believed that many of the features may be advantageously utilized together during the performance of surgery on a patient's knee. However, the invention should not be limited to any particular combination of features or to surgery on any particular joint in a patient's body. It is contemplated that features of the present invention will be used in association with surgery which is not performed on a joint in a patient's body.

US 6,702,821 B2

5

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the invention will become more apparent upon a consideration of the following description taken in connection with the accompanying drawings wherein:

FIG. 1 is a schematic illustration depicting extended and flexed positions of a patient's leg during performance of knee surgery in a known manner;

FIG. 2 is a schematic illustration depicting the manner in which a leg support is used to support an upper portion of a leg of a patient above a support surface on which the patient is disposed in a supine orientation during performance of knee surgery;

FIG. 3 is a schematic illustration depicting the patient's leg after a portion of a drape system has been positioned over the patient, the leg being shown in a flexed condition with the foot below the patient support surface and with an upper portion of the leg supported by the leg support of FIG. 2;

FIG. 4 is a schematic illustration of the patient's leg of FIGS. 2 and 3 in an extended condition and of the drape system which extends between a surgeon and the patient;

FIG. 5 is a schematic illustration depicting the manner in which the drape system of FIG. 4 maintains a sterile field during movement of the surgeon relative to the patient;

FIG. 6 is a schematic illustration depicting the manner in which an incision is made in the knee portion of the leg of the patient when the leg is in the position illustrated in FIGS. 2 and 3;

FIG. 7 is a schematic illustration depicting the manner in which the incision is expanded and a patella is everted with the leg of the patient extended;

FIG. 8 is a schematic illustration depicting the manner in which a drill is utilized to form a passage in a femur in the upper portion of the leg of the patient with the leg in the position illustrated in FIGS. 2 and 3 and the patella offset from its normal position;

FIG. 9 is a schematic illustration of the positioning of a femoral alignment guide in the hole formed by the drill of FIG. 8 with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 10 is a schematic illustration depicting the position of an anterior resection guide and a stylus relative to the femoral alignment guide of FIG. 9 before an anterior femur cut has been made with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 11 is a schematic illustration, taken generally along the line 11-11 of FIG. 10, further illustrating the relationship of the anterior resection guide and stylus to the distal end portion of the femur;

FIG. 12 is a schematic illustration further illustrating the relationship of the anterior resection guide and stylus to the distal end portion of the femur;

FIG. 13 is a schematic illustration depicting the manner in which a cutting tool is moved along a guide surface on the anterior resection guide during making of an anterior femur cut with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 14 is a schematic illustration depicting the relationship of the femoral alignment guide to the femur after making of the anterior femur cut of FIG. 13, the anterior resection guide and stylus being removed from the femoral alignment guide, and the leg of the patient being in the position illustrated in FIGS. 2 and 3;

6

FIG. 15 is a schematic illustration of the anterior femur cut and femoral alignment guide of FIG. 14;

FIG. 16 is a schematic illustration depicting the manner in which the femoral alignment guide is utilized to position a distal resection guide relative to the distal end portion of the femur after making of the anterior femur cut and with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 17 is a schematic illustration depicting the manner in which a distal femur cut is made with a cutting tool after the femoral alignment guide has been removed, the leg of the patient being in the position illustrated in FIGS. 2 and 3;

FIG. 18 is a schematic illustration depicting the relationship of the cutting tool and distal resection guide of FIG. 17 to the femur;

FIG. 19 is a schematic illustration depicting the manner in which a femoral cutting guide is positioned on the distal end portion of the femur with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 20 is a schematic illustration further depicting the relationship of the femoral cutting guide to the distal end portion of the femur;

FIG. 21 is a schematic illustration depicting the relationship of a tibial resection guide to the proximal end portion of a tibia in the lower portion of the patient's leg after making the femoral cuts and with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 22 is a schematic illustration of the distal end portion of the femur and the proximal end portion of the tibia after making the femoral and tibial cuts with the leg of the patient in the position illustrated in FIGS. 2 and 3 and the patella offset to one side of the incision;

FIG. 23 is a schematic illustration further depicting the femoral and tibial cuts of FIG. 22;

FIG. 24 is a schematic illustration depicting the manner in which force is applied against the bottom of the patient's foot by a surgeon's knee with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 25 is a schematic illustration depicting the various directions in which the lower portion of the patient's leg can be moved relative to the upper portion of the patient's leg to expose portions of the bone at the incision in the knee portion of the patient's leg and to check ligament balancing;

FIG. 26 is a schematic illustration depicting the manner in which a tibial punch is positioned relative to a tibial base plate with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 27 is a schematic illustration depicting completed preparation of the tibia for a tibial tray implant with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 28 is a schematic illustration depicting positioning of a tibial bearing insert in the tibial tray of FIG. 27 with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 29 is a schematic illustration depicting femoral and tibial implants with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 30 is a schematic illustration of an apparatus which may be utilized to move the lower portion of a patient's leg relative to the upper portion of a patient's leg when the patient's leg is in the position illustrated in FIGS. 2 and 3;

FIG. 31 is a schematic illustration depicting the manner in which a distal resection guide is connected with a patient's femur by pins which extend through the guide and through skin in the upper portion of the patient's leg into the femur with the leg of the patient in the position illustrated in FIGS. 2 and 3;

US 6,702,821 B2

7

FIG. 32 is a schematic illustration depicting the manner in which an endoscope may be inserted through an incision in a patient's knee to inspect portions of the patient's knee which are remote from the incision with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 33 is a schematic illustration similar to FIG. 32, depicting the manner in which the endoscope may be inserted through the incision in the patient's knee with the leg of the patient extended;

FIG. 34 is a schematic illustration depicting the manner in which an imaging apparatus may be utilized to generate images of a portion of the patient's leg and the manner in which a robot may be utilized to position cutting tools or other devices relative to the patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 35 is a schematic illustration depicting the relationship of a cut line to a patella in a knee of the leg of the patient with the leg in the position illustrated in FIGS. 2 and 3 and with the patella in the normal position;

FIG. 36 is a schematic illustration depicting the manner in which a cutting tool is moved relative to a guide member to cut the patella of FIG. 35 while the patella is disposed in situ;

FIG. 37 is a schematic illustration depicting the manner in which a tibial alignment shaft and a tibial resection guide are positioned relative to a tibia in a lower portion of a leg of the patient with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 38 is an enlarged fragmentary view of a portion of FIG. 37 and illustrating the construction of the tibial resection guide;

FIG. 39 is a schematic illustration depicting the relationship between an expandable cannula and an incision in the knee portion of one leg of the patient with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 40 is a schematic illustration depicting the relationship between two separate portions of an implant which are interconnected within the patient's body;

FIG. 41 is a schematic illustration depicting the relationship of transducers to a flexed knee joint of a patient when the leg of the patient is in the position illustrated in FIGS. 2 and 3;

FIG. 42 is a schematic illustration, generally similar to FIG. 41, illustrating the relationship of the transducers to the knee joint when the leg of the patient is extended;

FIG. 43 is a schematic illustration of a distal end portion of a femur in a leg of a patient with the leg in the position illustrated in FIGS. 2 and 3 and illustrating the relationship of an implant to a recess in the end portion of the femur;

FIG. 44 is a schematic sectional view depicting the manner in which a cutting tool is used to form a recess in the end portion of the femur of FIG. 43 with the leg of the patient in the position illustrated in FIGS. 2 and 3;

FIG. 45 is a schematic sectional view, taken generally along the line 45—45 of FIG. 43 further illustrating the relationship of the implant to the recess;

FIG. 46 is a schematic end view of a proximal end portion of a tibia in a leg of a patient, with the leg in the position illustrated in FIGS. 2 and 3, illustrating the relationship of an implant to a recess in the end portion of the tibia;

FIG. 47 is a schematic sectional view depicting the manner in which a cutting tool is used to form the recess in the end portion of the tibia of FIG. 46;

FIG. 48 is a schematic sectional view, taken generally along the line 48—48 of FIG. 46, further illustrating the relationship of the implant to the recess;

8

FIG. 49 is a schematic sectional view illustrating the relationship of another implant to a recess in a bone in a patient's body;

FIG. 50 is a schematic illustration depicting the relationship between a tibial implant and a tibia in the leg of the patient;

FIG. 51 is a schematic illustration depicting the relationship of expandable devices to the knee portion of a patient's leg;

FIG. 52 is a schematic illustration depicting the manner in which an expandable device may be positioned relative to a knee portion of a patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 53 is a schematic illustration depicting the manner in which a femoral cutting guide may be mounted on a distal end of a femur in a patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 54 is a schematic illustration of the manner in which a femoral cutting guide may be mounted on a side surface of a femur in a patient's leg with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 55 is a schematic illustration depicting the manner in which light is directed onto a distal end portion of a femur with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 56 is a schematic illustration depicting the manner in which light is used to guide movement of a cutting tool relative to a distal end portion of a femur with the patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 57 is a schematic illustration depicting the manner in which a cutting tool is moved relative to a secondary incision with a knee portion of a patient's leg in the position illustrated in FIGS. 2 and 3;

FIG. 58 is schematic illustration depicting the relationship of transducers to a patella and distal end portion of a femur with the patient's leg in the position illustrated in FIGS. 2 and 3.

DESCRIPTION OF SPECIFIC PREFERRED EMBODIMENTS OF THE INVENTION

Known Method of Performing Surgery on a Patient's Knee

During the performance of surgery using known methods, a patient is supported on an operating table or other support surface 52 (FIG. 1). When a leg 50 of the patient is in the extended position illustrated in dashed lines in FIG. 1, a foot 54 connected with a lower portion 56 of the leg 50 is disposed above the support surface 52. During an operation on a knee portion 58 of the leg 50, the knee portion is raised and lowered relative to the support surface as the leg 50 is flexed and extended. However, the foot 54 is always disposed above the support surface 54 and may be supported by the support surface throughout the operation.

During this known operating procedure, an incision is made in the knee portion 58 of the leg 50 when the leg is in the extended position illustrated in dashed lines in FIG. 1. At this time, the foot 54 of the patient may rest on the support surface 52 or be disposed in a foot support located above the support surface. Once an incision has been formed in the knee portion 58, the leg 50 may be flexed or bent to the position illustrated in solid lines in FIG. 1.

As the knee portion 58 is bent, the leg 50 is flexed and compresses the soft tissue of the knee portion 58 against the back of the knee joint. This makes it very difficult to access the posterior of the knee portion 58 to remove bone spurs (ostified), the meniscus, the posterior capsule, and/or any residual soft tissue or bone that is blocking further flexion.

US 6,702,821 B2

9

The catching or pinching of soft tissue in the posterior aspect of the knee portion 58 may prevent further flexion and limits the range of motion. In addition, arteries, nerves and veins are sitting just posterior of the knee joint.

Due to the lack of access to the posterior of the knee portion 58, a surgeon may be very reluctant or, at least, very careful about inserting instruments blindly into the back of the knee joint to remove tissue. This may result in osteophytes, bone spurs and similar types of posterior soft tissue will be left in place.

Cuts are made on a femur and tibia with the leg 50 in the bent or flexed condition, illustrated in FIG. 1. This results in the distal end portion of the femur and the proximal end portion of the tibia in the leg 50 being pressed together adjacent to the cuts. This interferes with ligament balancing. The relatively large incision which is necessary to accommodate known instrumentation systems increases time required for the patient to recover from the operation.

Preparation for Operation

It is contemplated that various features and/or combinations of features of the present invention will be utilized during surgery on different portions of a patient's body, such as a head, trunk or limbs of a patient. Although at least some of the features of the present invention are believed particularly advantageous when utilized in association with surgery on any one of the many joints in a patient's body, it is believed that the various features and/or combination of the features of the present invention are particularly advantageous when utilized in conjunction with surgery on a knee portion of a leg of a patient. It should be understood that the various features of the present invention may be use separately or in any desired combination of features.

Surgery on the knee portion of the patient may relate to any one of many different aspects of the knee portion, such as ligaments, tendons, articular surfaces, and/or total or partial knee replacements or revisions. Although the disclosure herein frequently refers to one particular type of knee operation, that is, a total knee replacement, features of the invention may be utilized with any desired type of surgery. It is believed that it will be apparent to a person having a knowledge of knee surgery how various features of the invention may be utilized with either a full or partial knee replacement. Therefore, there has been only minimal mention herein of how the features of the invention are applicable to partial knee replacements.

When knee surgery is to be performed in accordance with one of the features of the present invention, the patient 62 (FIG. 2) is disposed on a support surface 64 of an operating table 66. If desired, a patient support surface 64 other than an operating table could be used to support the patient. A lower portion 68 of a leg 70 extends downward from an upper portion 72 of the leg 70. A foot 74 connected with the lower portion 68 of the leg 70 is disposed below the support surface 64. The leg 70 is flexed so that a knee portion 76 of the leg is bent.

In accordance with another of the features of the present invention, the upper portion 72 of the leg 70 is supported above the support surface 64 by a leg support 80 (FIG. 2). The leg support 80 includes a stand or base section 82 which is connected with the operating table 66. The leg support 80 includes a base 84 which is connected with an upper end portion of the stand 82. The base 84 is engaged by and supports the upper portion 72 of the leg 70.

A generally annular thigh holder 86 extends around the upper portion 72 of the leg 70 of the patient and is connected with the base 84 and stand 82. The base 84 has a portion which extends along the posterior side of the upper portion

10

72 of the leg 70 of the patient. The base 84 supports the upper portion 72 of the leg 70 above and spaced from the support surface 64. However, the upper portion 72 of the leg 70 could be disposed in engagement with the support surface 64 if desired.

The leg support 80 supports the leg 70 of the patient with a hip 88 of the patient hyperflexed at an angle of twenty to thirty degrees throughout the operation on the knee portion 76. The leg support 80 may have a known commercial construction or may have a construction similar to that disclosed in U.S. Pat. No. 4,373,709 or U.S. Pat. No. 6,012,456. If desired, a tourniquet may be combined with the leg support 80 in a manner similar to that provided in known leg supports or in a manner similar to that disclosed in U.S. Pat. No. 4,457,302.

In accordance with another feature of the invention, the lower portion 68 (FIG. 3) of the leg 70 is suspended from the upper portion 72 of the leg. This enables the foot 74 and ankle portion 86 of the leg 70 of the patient to be freely moved in any direction or a combination of directions. Thus, the foot 74 and ankle portion 86 of the leg 70 of the patient can be moved anteriorly or upward (as viewed in FIG. 3) to decrease the extent of flexion of the knee portion 72 or even to extend or straighten the leg 70.

Alternatively, the foot 74 and ankle portion 86 may be moved posteriorly toward the operating table 66, from the position illustrated in FIG. 3, to hyperflex the knee portion 72 of the leg of a patient. The foot 74 may be moved sidewardly, that is in either a lateral or medial direction. In addition, the foot 74 may be rotated about the longitudinal central axis of the lower portion 68 of the leg 70.

It is contemplated that the foot 74 and ankle portion 86 may be simultaneously moved in a plurality of the directions previously mentioned. If desired, the upper portion 72 of the leg 70 of the patient may be supported on a separate section of the operating table 66, in a manner similar to the disclosure in U.S. Pat. No. 5,007,912.

After a drape 90 has been positioned over the patient 62 and the operating table 66, in the manner illustrated in FIG. 3, the leg 70 extends out of the drape. The drape 90 may be connected with the leg support 80 and have an opening 92 (FIGS. 3 and 4) through which the leg of the patient extends. This enables the leg 70 of a patient to be moved between the extended position illustrated in FIG. 4 and a hyperflexed position in which the foot 74 is disposed posteriorly from the position illustrated in FIG. 3.

When the leg 70 is in a hyperflexed condition, the included angle between the upper and lower portions 72 and 68 of the leg 70 is less than ninety degrees. The leg 70 may be flexed from the extended position of FIG. 4 to a hyperflexed position by manually moving the foot 74 and an ankle portion 96 of the leg 70 relative to the operating table 66 (FIG. 2) while the upper portion 72 of the leg is held by the leg support 80. When the leg 70 is hyperflexed, a portion of the foot 74 may be disposed beneath the operating table 66 (FIG. 2).

An improved drapery system 100 (FIG. 4) includes the drape 90 and a drape 102 connected with a gown 104 on a surgeon 106. The illustrated drape 102 is formed separately from the drape 90 and gown 104. However, the drape 102 may be integrally formed as one piece with the drape 90. Alternatively, the drape 102 may be integrally formed as one piece with the gown 104.

In the embodiment illustrated in FIG. 4, the drape 102 is formed separately from the gown 104 and the drape 90. The drape 102 is connected to the drape 90 by suitable clamps 108. The drape 102 is connected with the waist of the

US 6,702,821 B2

11

surgeon 106 by clamps 110 to the gown 104. Rather than utilizing clamps 108 to interconnect the drapes 90 and 102, the drapes could be interconnected by Velcro, ties, or other known devices. Of course, similar devices could be utilized to connect the drape 102 with the gown 104 of the surgeon 106.

The improved drapery system 100 maintains a sterile field between the leg 70 and the surgeon 106 during movement of the surgeon relative to the patient 62. Thus, when the surgeon is in a seated position (FIG. 4) the drapery system 100 provides a sterile field which extends from the surgeon to the space beneath and adjacent to the leg 70. When the surgeon stands (FIG. 5) the drapery system 100 continues to maintain a sterile field between the surgeon and the patient. This enables the surgeon 106 to move the leg 70 of a patient during an operation without contaminating the sterile field. The draping system 100 enables the sterile field to be maintained when the patient's leg is moved between the extended position of FIGS. 4 and 5 and a hyperflexed position in which the foot 74 of the patient is disposed beneath the operating table 66.

During movement of the surgeon 106 relative to the patient, for example, between the seated position of FIG. 4 and the standing position of FIG. 5, the drape 102 moves with the surgeon and maintains a sterile field. Thus, when the surgeon 106 moves toward and away from the patient, the end portion of the drape 102 connected with the surgeon also moves toward and away from the patient. As the surgeon moves toward the patient, a portion of the drape 102 between the surgeon 106 and patient is lowered. As the surgeon moves away from the patient, the portion of the drape 102 between the surgeon and patient is raised. The foot 74 connected with the leg 70 of the patient is always above the drape 102 during movement of the surgeon 106.

Although the drapery system 100 has been illustrated in FIGS. 3-5 in association with a patient's leg 70, the drapery system may be used in association with surgery on any desired portion of a patient's body. For example, the drapery system 100 could be used to maintain a sterile field between a surgeon and patient during surgery on a trunk portion of a patient's body. Alternatively, the drapery system 100 could be used to maintain a sterile field during surgery on a head or arm portion of a patient's body.

Incision

In accordance with another feature of the present invention, a limited incision 114 (FIG. 6) is formed in the knee portion 76 of the leg 70. The incision 114 is made just medial to the patella 120. However, the incision 114 could be disposed laterally of the patella 120. Although the length of the incision 114 may vary depending upon the circumstances, the incision 114 will usually have a length of between about seven (7) and about thirteen (13) centimeters. However, even smaller incisions may be made when circumstances permit.

The incision is made when the knee portion 76 of the leg is flexed and the lower portion 68 of the leg extends downward from the upper portion 72 of the leg in the manner illustrated in FIGS. 2 and 3. At this time, the upper portion 72 of the leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2). The lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg (FIGS. 2 and 3).

When the knee portion 76 of the leg 70 is flexed so that the lower portion 68 of the leg is suspended at an angle of approximately ninety degrees relative to the upper portion 72 (FIGS. 2 and 3), the incision 114 (FIG. 6) may have a length of approximately ten (10) centimeters. When the leg

12

70 is straightened from the flexed condition of FIGS. 2 and 3 to the extended condition of FIGS. 4 and 5, the length of the incision 114 may decrease by between ten and thirty percent. Thus, in one specific instance, an incision 114 had a length of approximately eleven (11) centimeters when the leg 70 was in the flexed condition of FIGS. 2, 3 and 6 and a length of slightly less than ten (10) centimeters when the leg was in the extended condition of FIG. 5. By making the incision 114 with the leg in a flexed condition (FIGS. 2, 3, and 6) and operating on the leg 70 with the leg in a flexed condition, the overall length of the incision can be reduced from the length of incisions which have previously been made in the leg when it is in the extended condition.

It is preferred to have the incision 114 located adjacent to the medial edge of the patella 120, in the manner illustrated schematically in FIG. 6. However, the incision 114 could be located adjacent to the lateral edge of the patella 120 if desired. Alternatively, the incision 114 could be disposed midway between lateral and medial edges of the patella 120.

Although it is desired to minimize the length of the incision 114, it is contemplated that the incision may have a length of approximately twice the length of the patella. It may be desired to have the incision 114 extend from a proximal end of the tibia in the leg 70 to the epicondylar notch on the distal end portion of the femur in the leg 70. The length and location of the incision 114 may vary depending on the size of the implants to be positioned in the knee portion 76 and the location at which the implants are to be positioned. It is believed that it may be desired to have the incision 114 be smaller than the implants even though the implants must move through the incision. The viscoelastic nature of the body tissue and mobility of the incision 114 enables the implants to be larger than the incision and still move through the incision.

A straight incision 114 has been illustrated in FIG. 6. However, the incision 114 could have a different configuration if desired. For example, the incision 114 could have an L-shaped configuration. The incision 114 could be skewed at an acute angle to a longitudinal central axis of the patella 120. If desired, the incision 114 could have a configuration matching the configuration of either the lateral or medial edge of the patella 120.

Immediately after the incision 114 is formed, the leg 70 may be moved from the flexed condition of FIGS. 2 and 3 to the extended condition of FIG. 5. While the leg 70 is in the extended condition, the incision 114 (FIG. 7) is elastically expanded using suitable retractors. The retractors apply force against the viscoelastic body tissue of the knee portion 76. The retractors have a construction similar to that disclosed in U.S. Pat. No. 5,308,349. Alternatively, a pneumatic retractor, such as is disclosed in U.S. patent application Ser. No. 09/526,949 filed on Mar. 16, 2000 by Peter M. Bonutti may be utilized to expand the incision.

After the incision 114 has been elastically expanded, a patella 120 and tissue on the lateral side of the incision may be everted in a manner illustrated in FIG. 7. Thus, the patella 120 is moved from the normal orientation of FIG. 6 to the everted or flipped orientation of FIG. 7 while the leg 70 of the patient is in the extended orientation of FIG. 7. At this time, the inner side 122 of the patella 120 is facing outward away from other bones in the knee portion 76. The outer side of the everted patella 120 is facing inward toward other bones in the knee portion 76. This enables the inner side 122 of the patella 120 to be examined.

In order to enable a relatively small incision 114 to be used for operating on bones in the knee portion 76 of the leg 70 of the patient, the patella 120 is returned back to its

US 6,702,821 B2

13

normal position with the inner side 122 of the patella facing inward and the outer side of the patella facing outward. As this occurs, the opening at the incision 114 contracts. The retractors are then utilized to apply force against opposite sides of the incision 114. As this occurs, the viscoelastic body tissue is extended, the opening at the incision 114 is again expanded, and the patella 120 is pushed to the lateral side of the knee portion 76. This moves the patella 120 to a location offset to one side of the incision 114 in a manner illustrated in FIG. 8. The leg 70 is then flexed to the orientation shown in FIGS. 2 and 3.

If desired, the foregoing step of inverting the patella 120 may be omitted. The patella 120 may be left in orientations in which the inner side 122 of the patella faces inward throughout the operation. If this is done, the inner side 122 of the patella 120 may be inspected by tilting the patella from its normal orientation and/or using viewing devices, such as an endoscope. Regardless of how the inner side 122 of the patella 120 is inspected, moving the patella to the offset position of FIG. 8, with the inner side 122 facing inward, facilitates utilization of an incision 114 having a limited length. It is contemplated that many different surgical procedures could be conducted on the knee portion 76 with the patella 120 in the offset position of FIG. 8.

Femoral Procedure

Expansion of the incision 114 with the known retractors exposes a distal end portion 124 (FIG. 8) of a femur 126 in the upper portion 72 of the leg 70. The incision 114 is movable relative to the distal end portion 124 of the femur 126 to maximize exposure of the femur through the limited length of the incision. The femur 126 is then cut to receive an implant. Although either intramedullary or extramedullary instrumentation can be utilized, intramedullary instrumentation is used during cutting of the femur 126. Therefore, a drill 128 is utilized to access the intramedullary canal or marrow cavity in the femur 126.

The drill 128 is utilized to form a hole 130 in the center of the intercondylar notch in the distal end portion 124 of the femur 126 in a known manner. The drill 128 is used to form the hole 130 while the leg 70 is in the orientation illustrated in FIGS. 2 and 3. The patella 120 is in the offset position illustrated in FIG. 8. At this time, the inner side 122 (FIG. 7) of the patella faces toward the femur 126.

An epicondylar reference guide (not shown) engages the hole in the distal end portion 124 of the femur 126 to enable a line parallel to an epicondylar axis peaks of the medial and lateral condyles to be inscribed on the distal end portion 124 of the femur 126. At this time, the leg 70 is in the orientation illustrated in FIGS. 2, 3, 8 and 9. A shaft 132 (FIGS. 9, 10, 11 and 12) of a femoral alignment guide 134 is then inserted into the intermedullary opening 130.

The femoral alignment guide 134 is then aligned with the epicondylar line which extends parallel to the epicondylar axis through the peaks of the lateral and medial condyles on the distal end portion 124 of the femur 126. The femoral alignment guide 134 is utilized to support an anterior resection guide 138 and stylus 140 (FIGS. 10, 11 and 12) on the distal end portion 124 of the femur 126 in the upper portion 72 of the leg 70 of the patient. Although only the femur 126 is illustrated in FIGS. 10, 11 and 12, it should be understood that the leg 70 is in the orientation illustrated in FIGS. 2 and 3. The upper portion 72 of the leg 70 is supported by the leg support 80.

In accordance with one of the features of the present invention, the instrumentation is down sized to enable the size of the incision 114 (FIG. 9) to be minimized. The downsized instrumentation has a transverse dimension

14

which is smaller than a transverse dimension of an implant to be placed in the knee portion 76 (FIG. 9). Thus, the femoral alignment guide 134 and anterior resection guide 138 have transverse dimensions, perpendicular to a longitudinal central axis of the femur 126, which are smaller than transverse dimensions of a femoral implant 290, tibial bearing insert 294, and a tibial tray 286 (FIG. 29) in a direction perpendicular to the longitudinal central axis of the femur 126 (FIG. 9).

The instrumentation extends from a center portion of the femur 126 toward one side of the femur (FIG. 11). In the particular operation illustrated schematically in FIGS. 7-12, the incision 114 is offset to the medial side of the patella 120. Therefore, the instrumentation is offset to the medial side of the femur 126. However, if the incision 114 is offset to the lateral side of the patella 120, the instrumentation would be offset to the lateral side of the femur 126. If the incision 114 was centrally disposed relative to the femur 126, the instrumentation would be centrally disposed relative to the femur. Thus, the instrumentation is in general alignment with the incision 114 and extends only part way across the distal end portion 124 of the femur 126.

The femoral alignment guide 134 (FIGS. 10, 11 and 12) and anterior resection guide 138 have opposite ends which are spaced apart by distance which is less than a distance between epicondyles 148 and 150 on the distal end portion 124 of the femur 126. The distance between opposite ends 154 and 156 of the femoral alignment guide 134 is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 of the lateral and medial epicondyles 148 and 150. Similarly, a distance between an end 160 and an opposite end 162 of the anterior resection guide 138 is less than two thirds ($\frac{2}{3}$) of the distance between the tips 144 and 146 of the lateral and medial epicondyles 148 and 150.

The distance between opposite ends of a known femoral alignment guide and the distance between opposite ends of a known anterior resection guide are approximately the same as or greater than the distance between the tips 144 and 146 of the lateral and medial condyles 148 and 150. The distance between opposite ends of the known femoral alignment guide and the distance between opposite ends of the known anterior resection guide are greater than the transverse dimensions of the femoral and tibial implants 286, 290 and 294 (FIG. 29). This known anterior resection guide and femoral alignment guide are commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. under the designation "Scorpio" (trademark) Single Axis Total Knee System.

The incision 114 must be large enough to enable the femoral alignment guide 134 and the anterior resection guide 138 to pass through the incision. By reducing the size of the femoral alignment guide 134 and anterior resection guide 138, the size of the incision 114 can be reduced. Of course, reducing the size of the incision 114 reduces damage to body tissue of the patient 62. The femoral alignment guide 134 and the anterior resection guide 138 may be larger than the incision 114. This is because the incision 114 can be resiliently stretched and/or moved relative to the femur 126 to enable the femoral alignment guide 134 and anterior resection guide 138 to move through the incision.

The distance between opposite ends 154 and 156 of the femoral alignment guide 134 is less than the distance which a femoral implant extends across the distal end portion 124 of the femur 126. Similarly, the distance between opposite ends 160 and 162 of the anterior resection guide 138 is less than the distance which the femoral implant extends across the distal end portion 124 of the femur 126. The femoral

US 6,702,821 B2

15

alignment guide 134 and the anterior resection guide 138 both extend medially from a center portion of the femur 126. However, if the incision 114 was offset laterally of the patella 120, the femoral alignment guide 134 and the anterior resection guide 138 would extend laterally from the center portion of the femur 126. Similarly, if the incision 114 was centered relative to the patella 120, the femoral alignment guide 134 and anterior resection guide 138 would be centered relative to the femur 126.

Positioning of the femoral alignment guide 134 and anterior resection guide 138 on the distal end portion 124 of the femur 126 is facilitated by distracting the knee joint under the influence of the weight of the lower portion 68 of the patient's leg and the foot 74. Thus, when the femoral alignment guide 134 and anterior resection guide 138 are positioned on the distal end portion 124 of the femur 126, the lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg. At this time, the foot 74 is below the level of the support surface 64 (FIG. 2) on which the patient is disposed in a supine orientation. The upper portion 72 of the patient's leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2).

By distracting the knee joint under the influence of the weight of the lower portion 68 of the leg of the patient, the distal end portion 124 of the femur 126 is exposed through the relatively small incision 114 (FIG. 9). Exposure of the distal end portion 124 of the femur 126 at the limited incision 114 is promoted by moving the lower portion 68 of the leg 70 and the incision relative to the femur. In addition, exposure of the distal end portion 124 of the femur 126 is promoted by having the patella 120 offset to the lateral side of its normal position. The inner side 122 of the patella 120 faces inward toward the distal end portion 124 of the femur 126 so that the skin on the knee portion 76 is not excessively stretched by everting the patella.

In accordance with another feature of the present invention, the instrumentation is at least partially positioned between the distal end portion 124 of the femur 126 and body tissue of the knee portion 76 (FIG. 9). To enable the size of the incision 114 to be minimized, the instrumentation is moved laterally of the incision so that a portion of the instrumentation moves between the knee capsule and the end portion 124 of the femur 126. This results in a portion of the instrumentation being exposed at the incision 114 and a laterally extending portion of the instrumentation being concealed by body tissue. For example, the end 154 (FIG. 11) of the femoral alignment guide 134 and/or the end 160 of the anterior resection guide 138 are overlaid by body tissue adjacent to the lateral edge portion of the incision 114. The body tissue which overlies portions of the instrumentation may include skin, the knee capsule, and connective and soft tissues.

When the femoral alignment guide 134 and anterior resection guide 138 are connected with the femur 126, central axis of the femoral alignment guide and anterior resection guide are medially offset from the central axis of the femur. Thus, the central axis of the femur 126 extends through a lateral portion, that is, left portion as viewed in FIG. 11, of the femoral alignment guide 134. The anterior resection guide 138 is almost entirely offset to the right (as viewed in FIG. 11) of the central axis of the femur 126. The incision 114 is disposed along a medial edge, that is, a right edge as viewed in FIG. 6, of the patella 120 when the patella is in its normal or initial position.

By having both the incision 114 and the instrumentation medially offset relative to the femur 126, the central portion of the instrumentation is exposed at the incision. Thus, the

16

medial edge of the incision overlaps the medial end 156 of the femoral alignment guide 134 and the medial end 162 of the anterior resection guide 138. Similarly, the lateral edge of the incision 114 overlaps the lateral end 154 of the femoral alignment guide 134 and the lateral end 160 of the anterior resection guide 138.

In view of the foregoing, it can be seen that the leg 70 (FIG. 3) of the patient 62 (FIG. 2) is maintained in the position illustrated in FIGS. 2 and 3 with the foot 74 of the patient below the support surface 64 upon which the patient is supported in a supine position during forming of the incision 114 in the knee portion 76 of the leg 70. The upper portion 72 of the patient's leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2). In addition, the leg of the patient is maintained in the position illustrated in FIGS. 2 and 3 during connection of the femoral alignment guide 134 and anterior resection guide 138 with the distal end portion 124 of the femur 126.

Once the femoral alignment guide 134 and anterior resection guide 138 have been mounted on the distal end portion 124 of the femur 126, an anterior cut is made in the manner illustrated in FIG. 13. During the anterior cut, a blade 170 of a saw 172 is utilized to make a cut across anterior portions of the lateral and medial condyles. The saw blade 170 is moved along guide surface 178 (FIGS. 11 and 12) on the anterior resection guide 138.

The guide surface 178 extends only part way across of the end portion 124 of the femur 126 (FIGS. 11 and 13). The guide surface 178 does not extend across the lateral portion of the end portion 124 of the femur 126. This at least partially results from the fact that the incision 114 (FIG. 6) is offset in a medial direction from the center of the knee portion 76. The incision 114 extends along the medial edge portion of the patella 120 when the patella is in its normal, that is, initial, position. In addition, the large majority of the anterior resection guide 138 extends medially from the central axis of the shaft 132 of the femoral alignment guide 134 (FIG. 11). By having the anterior resection guide disposed in an overlying relationship with the medial portion of the end portion 124 of the femur 126 (FIGS. 11 and 13), the size of the incision 114 can be reduced.

When anterior portions of the lateral and medial condyles 148 and 150 (FIGS. 10, 11 and 12) on the distal end portion 124 of the femur 126 are to be cut with the saw 172, the blade 170 is pivoted sideways (FIG. 13) so that the cutting end of the blade has an arcuate component of movement. The cutting end of the blade 170 will move along a straight path during part of the movement of the blade along the guide surface 178. However, when the blade 170 reaches the ends of the guide surface 178, the saw 172 is pivoted to pivot the blade and move the cutting end of the blade along a path having an arcuate configuration. This results in a generally fan shaped cut which extends only part way across the anterior side of the lateral and medial condyles on the end portion 124 of the femur.

The saw blade may have teeth along opposite longitudinally extending edges. The saw blade 170 and saw 172 are of the oscillating type. However, a reciprocating type saw and blade may be utilized if desired.

Due to the limited length of the anterior resection guide 138, the saw blade 170 is moved along the guide surface 178 to only partially complete the anterior skim cut on the end portion 124 of the femur 126. The guide surface 178 is offset to the medial side of the central axis of femur 126 (FIG. 11). Therefore, the saw blade can only partially form the lateral portion of the anterior skim cut while the saw blade engages the guide surface 178. The anterior resection guide 138 is

US 6,702,821 B2

17

then disconnected from the femoral alignment guide 134 (FIGS. 14 and 15) and the anterior femur cut is completed.

During completion of the anterior femur (skim) cut, previously cut surfaces on the end portion 124 of the femur 126 are used to guide the saw blade 170 (FIG. 13). Thus, an initial portion of the anterior skim cut is made on the distal end portion 124 of the femur 126 while the saw blade 170 is moved along one or more guide surfaces on the anterior resection guide 138. After the anterior resection guide 138 has been disconnected from the femoral alignment guide 134, the saw blade 170 is positioned in engagement with the cut surfaces on the distal end portion 124 of the femur 126. This is accomplished by inserting the saw blade 170 into a slot or saw kerf formed in the distal end portion 124 of the femur during the initial portion of the anterior skim cut.

The saw blade 170 is then moved along the previously cut surfaces on the distal end portion of the femur 126 to guide the saw blade during completion of the anterior skim cut. Utilizing cut surfaces formed during an initial portion of the anterior skim cut to guide the saw blade 170 enables the size of the anterior resection guide 138 to be minimized. Although the illustrated saw blade 170 has teeth 180 at only one end, the saw blade could also have teeth along opposite longitudinally extending edges.

By utilizing the anterior resection guide 138 to guide movement of the saw blade 170 during only an initial portion of forming the anterior skim cut on the distal end portion 124 of the femur 126, the overall length of the anterior resection guide, that is, the distance between the ends 160 and 162 (FIG. 11) of the anterior resection guide can be limited to a distance which is less than the distance between the epicondyles 148 and 150. Specifically, the distance between the ends 160 and 162 of the anterior resection guide 138 is less than two thirds ($\frac{2}{3}$) of the distance between the tips 144 and 146 of lateral and medial epicondyles 148 and 150 on the distal end portion 124 of the femur 126. By limiting the length of the anterior resection guide 138, the size of the incision 114 can be minimized.

It is contemplated that the initial portion of the anterior skim cut could be made with a first cutting tool and the anterior skim cut completed with a second cutting tool. The initial portion of the anterior skim cut may be made with relatively small oscillating saw blade. The final portion of the anterior skim cut may be made with a larger reciprocating saw blade. Alternatively, a small milling cutter could be used to make the initial portion of the anterior skim cut. The final portion of the skim cut could be made with a relatively long milling cutter or saw blade. It may be desired to make the initial portion of the anterior skim cut with a chisel and to complete the anterior skim cut with either a saw blade or a milling cutter.

The illustrated anterior resection guide 138 has a slot which forms the guide surface 178. This results in the saw blade 170 being captured so that the saw blade is restrained against both up and down movement (as viewed in FIG. 11) relative to the anterior resection guide 138. However, in order to reduce the size of the anterior resection guide 138, the slot could be eliminated and the saw blade 170 moved along a flat outer side of the anterior resection guide.

During making of the anterior skim cut, with and without the anterior resection guide 138, body tissue (FIG. 9) overlies at least portions of the lateral and medial condyles being cut. This is due to the relatively short extent of the incision 114. Thus, the saw blade 170 and the portion of the femur 126 being cut by the saw blade are both at least partially enclosed by body tissue overlying the femur during making of the anterior skim cut. During making of the

18

anterior skim cut, the incision 114 is moved relative to the femur 126 to provide clearance for the saw blade.

After the anterior portion of the lateral and medial epicondyles have been cut away and the anterior resection guide 138 removed, a flat anterior cut surface 182 (FIGS. 14 and 15) is disposed on the distal end portion 124 of the femur 126. The anterior skim cut is made on the distal end portion 124 of the femur 126 with the patella 120 offset to one side of the incision 118 (FIG. 14). The inner side of the patella 120 faces toward the distal end portion 124 of the femur 126 when the patella is in the offset position of FIGS. 9 and 14.

The flat anterior cut surface 182 (FIG. 15) extends parallel to the epicondylar axis. The maximum width of the anterior cut surface 182, as measured parallel to the epicondylar axis, is greater than the distance between opposite ends 154 and 156 (FIG. 11) of the femoral alignment guide 134. Similarly, the maximum width of the anterior cut surface 182 (FIG. 15), as measured parallel to the epicondylar axis, is greater than the distance between opposite ends 160 and 162 (FIG. 11) of the anterior resection guide 138. The anterior cut surface 182 is at least partially covered by body tissue which encloses the distal end portion of the femur 126 (FIG. 14).

During making of the anterior skim cut, the patient 62 (FIG. 2) is supported in a supine position on the support surface 64. The upper portion 72 of the leg 70 is disposed above the support surface on the leg support 80. The lower portion 68 of the leg 70 extends downward from the support surface 64. The foot 74 (FIG. 3) of the patient is disposed below the support surface.

Throughout the making of the anterior skim cut and the formation of the flat anterior cut surface 182 (FIGS. 14 and 15) on the distal end portion 124 of the femur 126, the lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg in the manner illustrated in FIG. 3. This results in the knee portion 76 of the leg 70 being distracted by the combined weight of the lower portion 68 of the leg and the foot 74. At this time, the lower portion 68 of the leg 70 dangles from the upper portion 72 of the leg. If desired, a holder could be provided to engage either the foot 74 and/or the lower portion 68 of the leg 70 to maintain the foot 74 and lower portion 68 of the leg in a desired position relative to the support surface 64.

Once the anterior skim cut has been completed, a distal resection guide 186 is positioned relative to the flat anterior skim cut surface 182 (FIG. 16). To position the distal resection guide 186 relative to the cut surface 182, a resection guide stand 190 is mounted on the femoral alignment guide 134 in the manner illustrated in FIG. 16. The distal resection guide 186 is connected with the resection guide stand 190 by rotating a locking knob 192. The distal resection guide 186 and resection guide stand 190 may be magnetized to assure correct assembly. Since the femoral alignment guide 134 is medially offset relative to the distal end portion 124 of the femur 126, the distal resection guide 186 is also medially offset relative to the distal end portion of the femur.

When the distal resection guide 186 is to be connected with the resection guide stand 190, the distal resection guide is moved between the anterior skim cut surface 182 and body tissue overlying the anterior skim cut surface (FIG. 14). Thus, due to the limited extent of the incision 114, skin and other body tissues are disposed over the anterior skim cut surface 182. The distal resection guide 186 slides between the anterior skim cut surface 182 and the body tissue overlying the anterior skim cut surface. A lower (as viewed in FIGS. 16, 17 and 18) major side of the distal resection guide 186 engages the anterior skim cut surface

US 6,702,821 B2

19

182. The opposite or upper (as viewed in FIGS. 16, 17 and 18) major side of the distal resection guide 186 is engaged by the body tissue overlying the anterior skim cut surface 182 (FIG. 14). The surgeon moves the incision 114 and/or the lower portion 68 of the leg 70 relative to the distal end portion of the femur 126 to facilitate movement of the distal resection guide 186 onto the anterior skim cut surface 182.

Once the distal resection guide 186 has been positioned in the desired location on the flat anterior cut surface 182, the distal resection guide 186 is secured in place with pins 196 and 198 (FIG. 16). At this time, body tissue overlies the portion of the distal resection guide 186 spaced from the distal end of the femur. The distal resection guide 186 is medially offset from a central portion of the femur 126 and is aligned with the incision 114. The incision 114 (FIG. 14) is moved relative to the distal end portion 124 of the femur 216 to enable the pins 196 and 198 to be forced into the distal end portion of the femur.

The femoral alignment guide 134 and resection guide stand 190 are then separated from the distal end portion 124 of the femur 126 (FIGS. 17 and 18). As this is done, the resection guide stand 190 (FIG. 16) is separated from the distal resection guide 186. Separation of the resection guide stand 190 from the distal resection guide 186 is accomplished by rotating the knob 192 and moving the resection guide stand 190 upward (as viewed in FIG. 16) to disconnect the guide stand 190 from the femoral alignment guide 134. The intramedullary rod 132 and femoral alignment guide 134 are then removed from the femur 126. The distance between opposite ends 206 and 208 of the distal resection guide 186 is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 (FIG. 11) of the lateral and medial epicondyles 148 and 150.

The distal resection guide 186, like the anterior resection guide 138, is down sized to enable the distal resection guide to move into the knee portion 76 of the patient's leg 70 through a relatively small incision 114. To enable the distal resection guide 186 to move into the incision through a relatively small incision 114, opposite ends 206 and 208 (FIG. 16) of the distal resection guide 186 are spaced apart by a distance which is less than the distance between the lateral and medial epicondyles 148 and 150 (FIG. 11) on the distal end portion 124 of the femur 126. The distance between opposite ends 206 and 208 of the distal resection guide 186 is less than the distance which a femoral implant extends across the distal end portion 124 of the femur 126.

The distal resection guide 186 is offset medially relative to the distal end portion 124 of the femur 126. The incision 114 is also medially offset relative to the distal end portion 124 of the femur 126. This results in the central portion of the guide surface 202 being exposed through the incision 114. The lateral and medial edges of the incision 114 overlap opposite ends 206 and 208 of the distal resection guide 186. The incision 114 also overlaps the anterior side, that is, the upper side as viewed in FIG. 16, of the distal resection guide. During cutting with the saw blade 170 (FIGS. 17 and 18), the incision 114 is elastically expanded with suitable retractors.

During making of the distal femoral cut, the saw blade 170 moves along the guide surface 202 (FIG. 17) on the distal resection guide 186. The guide surface 202 on the down sized distal resection guide 186 has a length which is less than a transverse dimension of a cut to be made in the distal end portion 124 of the femur 126. The saw 172 may be pivoted, in a manner illustrated schematically in FIG. 13, adjacent to opposite ends of the guide surface 202. This moves the cutting end of the saw blade 170 along an arcuate

20

path to form a generally fan shaped distal femoral cut. The saw 172 may be either a reciprocating or oscillating saw.

Due to the reduced size of the distal resection guide 186, the saw blade 170 (FIGS. 17 and 18) is ineffective to complete the distal femoral cut while the saw blade is in engagement with the guide surface 202 (FIGS. 16 and 17). Therefore, after an initial portion of the distal cut has been made by moving the saw blade 170 along the guide surface 202, the distal resection guide 186 is disconnected from the distal end portion 124 of the femur 126 and the distal femoral cut is completed.

During completion of the distal femoral cut, surfaces formed during the initial portion of the distal femoral cut are effective to guide the saw blade 170. The saw blade 170 (FIGS. 17 and 18) is moved into the saw kerf or slot formed during the initial portion of the distal femoral cut. As the saw blade 170 extends the initial portion of the distal femoral cut, the saw blade slides along cut surfaces formed during the initial portion of the distal femoral cut. Thus, cut surfaces formed during movement of the saw blade 170 along the guide surface 202 are utilized to guide movement of the saw blade during completion of the distal femoral cut.

The initial portion of the distal femoral cut may be made with a first cutting tool and the final portion of the distal femoral cut may be made with a second cutting tool. For example, the initial portion of the distal femoral cut may be made with a relatively small oscillating saw blade which can be readily inserted through the incision 114 into engagement with the distal resection guide 186. The final portion of the distal femoral cut may be made with a larger saw blade which may be of the reciprocating type. It is contemplated that the initial and/or final portion of the distal femoral cut may be made with a milling cutter. It is also contemplated that a chisel may be used to make the initial and/or final portion of the distal femoral cut.

When the distal femoral cut is completed, a flat distal end surface 209 extends across the distal end of the femur 126 (FIG. 17). The distal end surface 209 extends perpendicular to the anterior cut surface 182. The maximum width of the distal end surface 209, as measured parallel to the anterior cut surface 182 and epicondylar axis, is greater than the distance between opposite ends 206 and 208 of the distal resection guide 186. The trochlear groove of the femur extends through the distal end surface 209.

The distal femoral cut is formed with the patella 120 (FIG. 14) offset to one side of the incision 114 and with the inner side 122 of the patella facing toward the distal end portion 124 of the femur 126. In addition, the leg 70 of the patient is in the orientation illustrated in FIGS. 2 and 3 with the foot 74 and lower portion 68 of the leg suspended from the upper portion 72 of the leg. The upper portion 72 of the leg is supported above the support surface 64 by the leg support 80.

A femoral cutting guide 210 (FIGS. 19 and 20) is then positioned on the distal end portion 124 of the femur 126 and utilized to make femoral anterior, posterior and chamfer cuts in a known manner. The femoral cutting guide 210 is connected with the distal end portion 124 of the femur 126 by two pins (not shown) in a known manner. The femoral cutting guide 210 is down sized so that it has opposite ends which are spaced apart by distance which is less than a distance between the lateral and medial epicondyles 148 and 150 (FIG. 11) on the distal end portion 124 of the femur 126. The femoral cutting guide 210 is offset in a medial direction from the center of the femur 126 (FIG. 20). The medially offset position of the femoral cutting guide 210 is the result of the medially offset position of the incision 114 (FIG. 6).

US 6,702,821 B2

21

The initial portion of the femoral anterior, posterior and chamfer cuts are made by moving the saw blade 170 or other cutting tool along guide surfaces on the femoral cutting guide. Due to the relatively small size of the femoral cutting guide, the cuts cannot be completed while moving the saw blade 170 or other cutting tool along guide surfaces on the femoral cutting guide. Therefore, the femoral cutting guide 210 is separated from the distal end portion 124 of the femur 126 and the cuts are completed while guiding movement of the saw blade 170 or other cutting tool with cut surfaces formed during the making of the initial portions of the femoral anterior, posterior and chamfer cuts. When the femoral anterior, posterior and chamfer cuts are completed, the distal end portion 124 of the femur 126 will have the known configuration illustrated in FIGS. 22 and 23.

The femoral cutting guide 210 (FIGS. 19 and 20) may have the same construction as a femoral cutting guide which is commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. The femoral cutting guide may have the construction disclosed in U.S. Pat. Nos. 5,282,803 or 5,749,876. However, it is preferred to down size the known femoral cutting guides to have a distance between opposite ends which is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 (FIG. 11) of medial and lateral condyles 148 and 150 on the distal end portion 124 of the femur 126. This enables the femoral cutting guide 210 to move through the incision 114.

Since the femoral cutting guide 210 is down sized, initial portions of the femoral anterior, posterior and chamfer cuts are made while guiding a saw blade or other cutting tool with the femoral cutting guide. These cuts are subsequently completed utilizing previously cut surfaces to guide the saw blade 170. To complete a cut in this manner, the saw blade 170 or other cutting tool is moved along the previously cut surfaces to guide the saw blade as the cuts are extended.

During the making of the initial portions of the anterior, posterior and chamfer cuts with the femoral cutting guide 210 and the subsequent completion of the cuts without the femoral cutting guide, the knee portion 76 of the leg 70 of the patient is distracted by the weight of the lower portion 68 and foot 74 of the leg. Thus, the lower portion 68 and foot 74 of the leg 70 are suspended from the upper portion 72 of the leg in a manner illustrated in FIGS. 2 and 3 during the making of the femoral anterior, posterior and chamfer resections. The upper portion 72 of the patient's leg 70 is supported above the support surface 64 by the leg support 80 (FIG. 2).

By distracting the knee joint during the making of the femoral anterior, posterior and chamfer cuts, access to the distal end portion 124 of the femur 126 is promoted and the making of the cuts is facilitated. Access to the distal end portion 124 of the femur 126 is also promoted by moving the suspended lower portion 68 of the leg 70 relative to the distal end portion of the femur. The incision 114 may be moved relative to the distal end portion 124 of the femur 126 by applying force to body tissue adjacent to the incision.

Tibial Procedure

Since the knee portion 76 of the leg 70 is distracted, a proximal end portion 212 (FIG. 21) of a tibia 214 is separated from the distal end portion 124 of the femur 126. The foot 74 (FIG. 3) may be moved posteriorly to hyperflex the knee portion 76. This facilitates viewing of the proximal end portion 212 of the tibia 214 through the relatively small incision 114.

When the knee portion 76 (FIG. 2) is hyperflexed, the angle between the upper portion 72 and the lower portion 68 of the patient's leg 70 is less than ninety (90) degrees. At this

22

time, the foot 74 is disposed posteriorly of the position illustrated in FIG. 2. This results in the proximal end portion 212 (FIG. 21) of the tibia 214 being moved anteriorly relative to the distal end portion 124 of the femur 126. The distal end portion 212 of the tibia 214 can then be viewed through limited incision 114. Even though the incision 114 has a relatively short length, it is possible to move the incision relative to the proximal end portion 212 of the tibia 214. Therefore, the entire or at least almost the entire, proximal end surface of the tibia 214 can be viewed through the incision 214.

It is contemplated that an external tibial alignment guide (not shown) will be utilized to align a tibial resection guide 218 (FIG. 21) with the proximal end portion 212 of the tibia 214. The tibial alignment guide has a known construction and may be the same as is commercially available from Howmedica Osteonics of 359 Veterans Boulevard, Rutherford, N.J. Alternatively, the tibial alignment guide may have the construction disclosed in U.S. Pat. Nos. 5,578,039; or 5,282,803.

Once the tibial resection guide 218 (FIG. 21) has been aligned with and secured to the proximal end portion 212 of the tibia 214, the external tibial alignment guide (not shown) is disconnected from the tibial resection guide 218. The tibial resection guide 218 is secured to the proximal end portion 212 of the tibia 214 by suitable pins.

In accordance with one of the features of the present invention, the tibial resection guide 218 is relatively small so that it can be moved through a relatively small incision 114 into engagement with the proximal end portion 212 of the tibia 214. To facilitate moving of the tibial resection guide 218 through a relatively small incision 114, the tibial resection guide 218 is smaller than implants 286 (FIG. 27) and 294 (FIG. 28) to be positioned on the proximal end portion 212 of the tibia 214. The tibial resection guide 218 has a distance between opposite ends 228 and 230 (FIG. 21) which is less than two thirds ($\frac{2}{3}$) of the distance between tips of lateral and medial epicondyles on the tibia 214. Similarly, the distance between the ends 228 and 230 of the tibial resection guide 218 is less than two thirds ($\frac{2}{3}$) of the distance between tips 144 and 146 (FIG. 11) of the lateral and medial condyles 148 and 150 on the femur 126.

During positioning of the external tibial alignment guide and the tibial resection guide 218 (FIG. 21) relative to the tibia 214 in the leg 70 of the patient, the leg 70 is supported in the manner illustrated in FIGS. 2 and 3. Thus, the upper portion 72 (FIG. 2) of the leg 70 is supported above the support surface 64 by the leg support 80. The lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg. The foot 74 (FIG. 3) connected with the lower portion 68 of the leg 70 is disposed below to support surface 64 (FIG. 2).

During positioning of the tibial resection guide 218 on the proximal end portion 212 of the tibia 214, the tibial resection guide is moved between the proximal end portion of the tibia and body tissue overlying the proximal end portion of the tibia. The tibial resection guide 218 is positioned relative to the proximal end portion 212 of the tibia 214 while the incision 114 is resiliently expanded. The incision 114 is expanded by applying force against opposite sides of the incision with suitable retractors. The retractors may have a construction similar to the construction disclosed in U.S. Pat. No. 5,308,349. Alternatively, a pneumatic retractor, such as is disclosed in U.S. patent application Ser. No. 09/526,949 filed Mar. 16, 2000 by Peter M. Bonutti may be used to expand the incision 114.

The tibial resection guide 218 is slid inferiorly, that is, downward (as viewed in FIG. 21) between the proximal end

US 6,702,821 B2

23

portion 212 of the tibia 214 and body tissue adjacent to the proximal end of the tibia. The tibial resection guide 218 is then connected to the proximal end portion 212 of the tibia 214 with suitable pins. Once the resection guide 218 has been connected with the tibia 214, the force applied against opposite sides of the incision 114 by retractors is interrupted and the incision contracts. As this occurs, the body tissue moves over the lower (as viewed in FIG. 21) portion of the tibial resection guide 218 to further enclose the tibial resection guide.

The tibial resection guide 218 is medially offset relative to the proximal end portion 212 of the tibia 214. This is because the incision 114 is medially offset relative to the proximal end portion 212 of the tibia 214. The incision 114 extends from the proximal end portion 212 of the tibia 214 to the superior portion of the trochlear groove in the distal end portion 124 of the femur 126. As was previously mentioned, the incision 114 and the instrumentation may be laterally offset relative to the femur 126 and the tibia 214. Once the tibial resection guide 218 (FIG. 21) has been mounted on a proximal end portion 212 of the tibia 214, a proximal tibial cut is made. The proximal tibial cut is made by moving the blade 170 of the saw 172 along a guide surface 242 on the tibial resection guide 218 (FIG. 21). When the saw blade reaches an end portion of the tibial guide surface 242, the saw 172 is pivoted to move the saw blade 170 in the manner illustrated schematically in FIG. 16. This pivotal movement results in the cutting end portion of the saw blade 170 having an arcuate component of movement. This results in a generally fan shaped cut being formed in the proximal end portion 212 of the tibia 214.

Due to the reduced size of the tibial resection guide 218 to facilitate movement of the tibial resection guide through the incision 114, the saw 172 can only form an initial portion of the proximal tibial cut as the saw blade 170 moves along the guide surface 242 of the tibial resection guide 218. To complete the proximal tibial resection cut, the tibial resection guide 218 is disconnected from the tibia 214.

Once the tibial resection guide 218 has been separated from the tibia 214, the saw blade 170 is inserted into the slit or kerf made by the saw blade during the initial portion of the proximal tibial cut. The cut surfaces which were formed during an initial portion of making the proximal tibial cut on the tibia 214 are then used to guide the saw blade 170 during completion of the proximal tibial cut. Thus, the saw blade 170 is moved along surfaces formed during the making of the initial portion of the proximal tibial cut to guide movement of the saw blade during completion of the proximal tibial cut.

It is contemplated that different cutting tools may be utilized to make the initial and final portions of the proximal tibial cut. Thus, the saw blade 170 used to make the initial portion of the tibial cut may be a relatively small oscillating blade and the saw blade used to make the final portion of the tibial cut may be a relatively long reciprocating blade. Alternatively, the initial and/or final portion of the tibial cut may be made with a milling cutter. If desired, a chisel could be utilized to make the initial portion of the tibial cut. The incision 114 may be expanded with suitable retractors during making of the tibial cut. The retractors may have any desired construction, including the construction disclosed in U.S. Pat. No. 5,308,349. Ligaments and other body tissue adjacent to the proximal end portion 212 of the tibia 214 may be shielded with suitable surgical instruments during making of the tibial cut.

Upon completion of the proximal tibial cut on the proximal end portion 212 of the tibia 214, a flat proximal tibial cut

24

surface 246 (FIG. 22) is exposed on the proximal end portion 212 of the tibia 214 through the incision 114. The flat cut surface 246 has a maximum width, as measured along an axis extending parallel to an axis extending through central axes of the collateral ligaments, which is greater than the distance between opposite ends 228 and 230 of the tibial resection guide 218. The distal end portion 124 of the femur 126 is also exposed through the incision 118.

In order to increase exposure of the proximal end portion 212 of the tibia 214 at the incision 218, the foot 74 and lower portion 68 of the leg 70 (FIG. 24) are moved posteriorly toward the operating table 66 (FIG. 2) to hyperflex the knee portion 76 of the patient's leg 70 during the making of the proximal tibial cut. When the knee portion 76 of the leg 70 is hyperflexed, the ankle 86 is moved from a position either extending through or anterior of a vertical plane extending perpendicular to a longitudinal central axis of the upper portion 72 of the patient's leg 70 to a position disposed posteriorly of the vertical plane. Thus, as viewed in FIGS. 2 and 24, the ankle 86 is moved toward the left. As this occurs, an angle between a longitudinal central axis of the upper portion 72 of the patient's leg and the longitudinal central axis of the lower portion 68 of the patient's leg is decreased to an angle of less than ninety degrees.

Hyperflexing the patient's leg 70 moves the proximal end portion 212 (FIGS. 22 and 23) of the tibia 214 anteriorly away from the distal end portion 124 of the femur 126. At this time, the knee portion 76 of the patient's leg is distracted under the influence of the weight of the lower portion 68 of the patient's leg and the foot 74 connected with the lower portion of the patient's leg. If desired, a force pulling the lower portion of the patient's leg downward (as viewed in FIG. 3) may be applied to the patient's leg to further increase the distraction of the knee portion 76 of the leg and the extent of exposure of the proximal end portion 212 of the tibia 214.

By hyperflexing the knee portion 76 of the patient's leg 70 and applying a downward (as viewed in FIG. 3) force against the lower portion 68 of the patient's leg, the proximal end portion 212 of the tibia 214 is delivered anteriorly that is, toward the surgeon 106 (FIG. 24). Application of a downward force against the lower portion 68 of the patient's leg is effective to open the space between the proximal end portion 212 of the tibia 214 and the distal end portion 124 of the femur 126 to the maximum extent permitted by the tendons and ligaments, that is, fibrous connective tissue, interconnecting the femur and tibia.

This enables the posterior cruciate ligament 250 (FIG. 23) to be checked. In addition, access is provided to the posterior side of the knee portion 76 of the leg 70. The surgeon 106 (FIG. 24) can manually feel the posterior portion of the knee joint. There is sufficient space between the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214 to enable the surgeon 106 to visually and tactilely check the posterior of the knee portion 76 of the patient's leg 70.

Access to the posterior portion of the knee enables osteophytes, bone spurs and similar types of posterior soft tissue to be removed. This enables tissue which could block further flexion of the knee portion 76 to be removed. In addition, it is possible to check the collateral ligaments and other fibrous connective tissue associated with the knee.

At this time, the lower portion 68 of the leg 70 (FIGS. 23 and 24) is suspended from the upper portion 72 of the leg. Therefore, the lower portion 68 of the leg 70 hangs from the upper portion 72. The foot 74 may be supported on the surgeon's knee 252 (FIG. 24). The foot 74 is free to move

US 6,702,821 B2

25

in any direction relative to the knee portion 76. By raising or lowering his or her knee 252, the surgeon 106 can move the tibia 214 relative to the femur 126 and vary the space between the distal end of the femur and the proximal end of the tibia.

By varying force indicated by arrows 256 (FIG. 25), the vertical extent of space between the proximal end portion 212 of the tibia 214 and the distal end portion 124 of the femur 126 (FIGS. 22 and 23) can be either increased or decreased. The force 256 is varied by raising and lowering the surgeon's knee 252. Increasing the space between the proximal end portion 212 of the tibia 214 and the distal end portion 124 of the femur 126 maximizes access to the posterior of the knee portion 76.

By moving the lower portion 68 of the leg 70 upward, the ligaments and other connective tissue between the tibia 214 and femur 126 are relaxed. This enables the lower portion 68 of the leg 70 to be rotated about its longitudinal central axis, in a manner indicated by arrows 258 in FIG. 25. Rotational movement of the lower portion 68 of the leg 70 about its central axis enables the surgeon to check the collateral ligaments and the resistance encountered to rotation of the lower portion 68 of the leg relative to the upper portion 72.

In addition, the foot 74 can be pivoted in a clockwise direction (as viewed in FIG. 25) about the knee portion 76, in the manner indicated by arrow 259 in FIG. 25, to increase the extent of flexion of the knee portion 76. Alternatively, the foot 74 can be pivoted in a counterclockwise direction about the knee portion 76 to decrease the extent of flexion of the leg 70.

The lower portion 68 of the leg 70 can also be moved sidewise, in the manner indicated by the arrow 260 in FIG. 25. When the lower portion 68 of the leg 70 is moved in the manner indicated by the arrow 260, the lower portion of the leg is moved along a path extending through lateral and medial surfaces of the foot 74 and the lower portion 68 of the leg 70. This enables the ligaments and other fibrous connective tissue in the leg to be checked for a range of movement. Although the incision 114 has not been shown in FIG. 25, it should be understood that the lower portion 68 of the leg 70 can be moved in the directions indicated by the arrows in FIG. 25 when the knee portion 76 is in the condition illustrated in FIGS. 22 and 23.

The illustrated instrumentation is formed of a metal which enables the instrumentation to be sterilized and reused. For example, the instrumentation could be formed of stainless steel. However, known metal instruments are relatively heavy and bulky. This substantially increases transportation expense.

It is contemplated that it may be desired to use the instrumentation once and then dispose of the instrumentation. If this is done, the instrumentation may be partially or entirely formed of relatively inexpensive polymeric materials. Thus, the femoral resection guide 134, anterior resection guide 138, distal resection guide 186, femoral cutting guide 210, and/or tibial resection guide 218 could be formed of inexpensive polymeric materials. If this was done, the guides could be used once and disposed of without being sterilized. In addition, the polymeric guides would weigh substantially less than metal guides.

Implants

After the distal end portion 124 of the femur 126 has been prepared and the proximal end portion 212 of the tibia 214 is prepared to receive implants (FIGS. 22 and 23) and prior to insertion of the implants, any necessary work on the patella 120 may be undertaken. During work on the patella, the leg 70 of the patient may be extended and the patella 120

26

is everted or flipped to the position illustrated in FIG. 7. The inner side or articular surface 122 of the patella 120 faces outward and is exposed. Known surgical techniques are then utilized to cut the patella 120 and position an implant on the patella in a known manner. This may be accomplished utilizing any one of many known devices and procedures, such as the devices and procedures disclosed in U.S. Pat. Nos. 4,565,192; 5,520,692; 5,667,512; 5,716,360; and/or 6,159,246. If desired any necessary work on the patella 120 may be undertaken after the femoral and tibial implants have been installed.

Once the femoral and tibial cuts have been made and the patella repaired, femoral and tibial implants are installed in the knee portion of the leg 70. Prior to permanently mounting of the implants in the knee portion 76 of the leg 70, trials are conducted, in a known manner, with provisional femoral and tibial implants. The provisional femoral and tibial implants are releasably positioned relative to the distal end portion 124 of the femur 126 and the proximal end portion 212 of the tibia 214.

The provisional implants are intended to aid the surgeon 106 in assessment of the function and balance of the various ligaments. The trials enable the surgeon 106 to observe the relationship of the provisional femoral and tibial implants relative to each other during flexion and extension of the knee portion 76 of the leg 70. The lower portion 68 of the leg 70 is suspended from the upper portion 72 of the leg (FIGS. 2 and 3) during the trials with the provisional implants. Therefore, the lower portion of the leg 68 can be freely moved relative to the upper portion of the leg to check ligament balancing with the provisional implants. Since the lower portion of the leg 68 is suspended, it is possible to check for flexion and extension balancing of the ligaments and to check for rotational stability and rotational balancing of the ligaments during the trials with provisional implants. The lower portion 68 of the leg 70 can be moved with a combination of flexion or extension, rotation and sidewise movement.

The trials also enable the surgeon to check the manner in which the provisional implants interact with each other during flexion, extension, rotation, and sidewise movement. The manner in which the provisional femoral and tibial implants move relative to each other during combined bending and rotational movement of a patient's leg 70 enables a surgeon to check for the occurrence of excessive space or other undesirable situations between the provisional implants. During trials with provisional implants, the range of motion of the knee joint can be checked in both flexion/extension and rotation.

Utilizing known surgical techniques, it is very difficult, if not impossible, to check for both flexion/extension balancing, rotational balancing, and sidewise balancing during trials with provisional implants. With rotational balancing, the ligaments are balanced through multiple planes. When both flexion/extension and rotation are being checked, the surgeon can locate defects and improve the stability of the knee joint. The surgeon can assess the posterior cruciate ligament, collateral ligament balancing, and posterior capsule balancing. The surgeon can proceed with flexion/extension balancing of ligaments and rotational balancing of the ligaments. This enables the leg 70 to be examined throughout its range of motion during trials with provisional implants.

During an operation on the patient's leg 70, the surgeon can apply upward force against the foot of the patient by resting the foot 74 on the surgeon's knee 252 (FIG. 23) and raising the knee of the surgeon. Of course, when the foot 74