

Filed on behalf of: BONUTTI SKELETAL INNOVATIONS LLC Paper _____
Date: May 30, 2014

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW,
INC.

Petitioner,

v.

BONUTTI SKELETAL INNOVATIONS LLC

Patent Owner

Case: IPR2013-00629
Patent 7,806,896

**DECLARATION OF DR. SCOTT D. SCHOIFET, M.D. IN
SUPPORT OF PATENT OWNER RESPONSE**

Exhibit 2004
Smith & Nephew v.
Bonutti Skeletal Innovations LLC
Trial IPR 2013-00629

Introduction

I, Scott D. Schoifet, hereby declare under the penalty of perjury:

1. I reside at 19 Macclesfield Drive, Medford, NJ. 08055.
2. I am a board certified surgeon specializing in Total Joint Replacement and Adult Reconstructive Surgery in the practice of Reconstructive Orthopedics P.A.
3. I have been retained as an expert witness and asked to render opinions regarding certain matters pertaining to the inter partes review (IPR2013-00629) of the Bonutti U.S. Patent No. 7,806,896 (“the '896 patent”). I offer this declaration (“Declaration”) in support of Bonutti Skeletal’s Patent Owner Response.
4. I obtained my Medical Degree from Columbia University College of Physicians and Surgeons, New York, New York in 1983. I completed my General Surgery Residency at St. Vincent’s Hospital, New York, New York, in 1985; and my Orthopedic Residency at the Strong Memorial Hospital, University of Rochester, Rochester, New York in 1988. I completed my Fellowship in Total Joint Replacement and Adult Reconstructive Surgery at the Mayo Clinic in Rochester, Minnesota, in 1989, where I was appointed as an Instructor in Orthopedic Surgery. I obtained my board certification from the American Board of Orthopedic Surgery in 1991.

5. Shortly after completing my Fellowship, I entered private practice in September, 1989. I joined Reconstructive Orthopedics P.A. in May, 1990. I am an instructor for Minimally Invasive Surgery Quad Sparing for Partial and Total Knee Replacements, both nationally and internationally.

6. I have performed over 7,000 total knee and total hip replacements. I performed my first minimally invasive surgery (“MIS”) knee replacement in November of 2003 and have performed over 4,800 MIS total knee replacements since then. I currently average 700 MIS total knee replacements per year.

7. I am a fellow of the American College of Surgeons (FACS), and the American Academy of Orthopaedic Surgeons (FAAOS). I also am a member of the American Association of Hip and Knee Surgeons (AAHKS).

8. A more detailed account of my work experience and qualifications is included in my curriculum vitae, which is attached as Appendix A to this Declaration.

9. In connection with my study of this matter and reaching the opinions stated herein, I have reviewed and considered:

(A) the '896 patent and its prosecution history before the United States Patent and Trademark Office, focusing on claim 1;

(B) Scott L. Delp, et al., “Computer Assisted Knee Replacement,” 354 Clinical Orthopaedics and Related Research (1998) (“Delp”) (Exhibit 1003);

(C) S. David Stulberg, et al., “Computer-Assisted Total Knee Replacement Arthroplasty,” 10(1) Operative Techniques in Orthopaedics (Jan. 2000) (“Stulberg”) (Exhibit 1005);

(D) Roderick H. Turner, et al., “Geometric and Anametric Total Knee Replacement,” in Total Knee Replacement (A.A. Savastano, M.D. ed. 1980) (“Turner”) (Exhibit 1008);

(E) Stryker Howmedica Osteonics, Scorpio Single Axis Total Knee System – Passport Total A.R. Total Knee Instruments – Passport A.R. Surgical Technique (May 2000) (“Scorpio”) (Exhibit 1009);

(F) U.S. Patent 5,871,018 (February 16, 1999) (“Delp ‘018”) (Exhibit 1004);

(G) the Institution Decision in IPR 2013-00629, paper 10 (February 28, 2014)(“Institution Decision”), focusing on the discussion of the instituted grounds of Stulberg in view of Turner or Scorpio, and Delp in view of Turner or Scorpio; and

(H) the Declaration Of Jay D. Mabrey, MD, MBA (Exhibit 1002), focusing on the discussion of Stulberg in view of Turner or Scorpio, and Delp in view of Turner or Scorpio.

10. I also have a Scorpio Anterior Resection Cutting Guide, of the type described in Scorpio, which I examined in preparing this Declaration. What I refer

to as the Anterior Resection Guide includes three parts: the A/R Anterior Skim Cutting Guide bearing Model No. 7650-5003-A, the alignment guide bearing reference number I-K1287AR02, and an intramedullary rod bearing Model No. 7650-1026. Photographs of the Anterior Resection Guide that I examined are included in Exhibit 2005, which I have also reviewed.

11. I understand that the Patent Office has instituted a review of claim 1 of the '896 patent based on the following two grounds: (i) Whether claim 1 would have been obvious to a person of ordinary skill in the art based on the disclosure of Stulberg in view of either Turner or Scorpio; and (ii) Whether claim 1 would have been obvious to a person of ordinary skill in the art based on the disclosure of Delp in view of either Turner or Scorpio.

Priority Date

12. In preparing this Declaration, I have reviewed the '896 patent and considered each document cited herein, in light of the knowledge of a person of ordinary skill in the art in the field of knee arthroplasty, as it stood in the timeframe of 2000-2003.

13. I have been instructed by counsel that the effective filing date of the '896 patent with respect to the subject matter of claim 1 is August 28, 2001. I have also been informed that the Petitioner may assert other effective filing dates, up to and including November 25, 2003. In any event, my opinion would remain

unchanged regardless of the effective filing date chosen within the timeframe of 2000-2003.

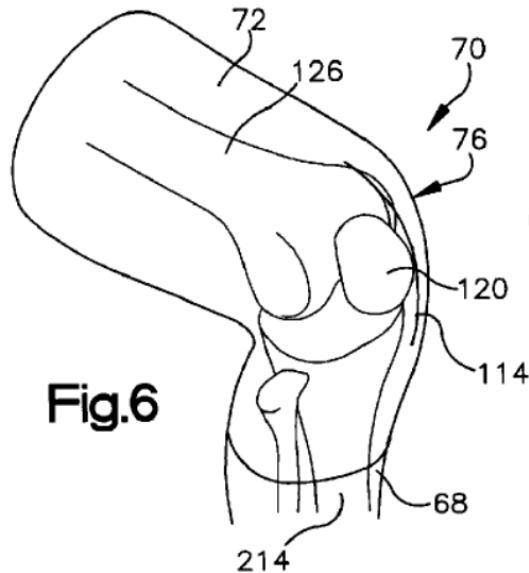
The Person Of Ordinary Skill In The Art

14. Based on my experience, it is my opinion that a person of ordinary skill in the art to which the '896 patent relates in the 2000-2003 timeframe would have an undergraduate degree in mechanical engineering or biomechanical engineering or graduate coursework covering topics relevant to biomechanical devices or orthopedics, or an orthopedic surgeon having experience performing knee arthroplasty or joint replacement procedures. In this Declaration, whenever I refer to a person of ordinary skill in the art, it is to be understood that I refer to a person of that skill in the 2000-2003 timeframe.

General Background Of The '896 Patent

15. The '896 patent in general describes methods and surgical techniques for knee-joint replacement using MIS techniques. Knee replacement surgery is commonly referred to as knee arthroplasty.

16. A portion of a human leg, including a knee joint, is schematically illustrated in Figure 6 of the '896 patent, reproduced below. Generally speaking, the knee is the portion of the leg where the femur 126, tibia 214, and patella 120 meet. In every-day use, the femur is the thigh bone, the tibia is the shin bone, and the patella is the knee cap.



Description of the State of the Art at the Timeframe of 2000-2003

17. Prior to the methods disclosed in the '896 patent, knee replacement surgery was invasive and involved a relatively long incision. To obtain access to the knee joint, the surgeon needed to cut and strip soft tissue from the bone to provide the surgeon with full access to and visualization of the knee joint to permit the surgeon to position surgical instruments relative to the ends of the femur and tibia. To further increase access to and visualization of the femur and tibia, the patella was moved from its normal position and everted. A patella is everted when it is turned over or flipped over so that the inner side of the patella is exposed and facing outward and away from the femur and tibia. Everting the patella was necessary to move the patella sufficiently out of the way so that the instruments, including cutting blocks used to guide cutting instruments for shaping the bones to

receive implants, could be properly positioned on the femur and tibia.

18. The cutting blocks for the timeframe 2000-2003 were large, bulky and invasive, and a person of ordinary skill in the art would not have thought otherwise because making a large incision, splitting the quadriceps, and everting the patella was common practice. Large incisions, such as 12 to 16 inches, were simply accepted whether the procedure involved computer-assisted navigation or not. It was well understood that shortening the width of a guide surface would reduce precision because it would not allow the entire cut of the femur to be guided as precisely. In the timeframe 2000-2003 it was believed that more precise cuts would result in better outcomes.

Claim Construction

19. I understand that the *inter partes* review was instituted with regard to claim 1 which is set forth below:

Claim 1 of the '896 patent

1. A method of replacing at least a portion of a patient's knee, the method comprising the steps of:
 - making an incision in a knee portion of a leg of the patient;
 - determining a position of a cutting guide using references derived independently from an intramedullary device;
 - positioning a cutting guide using the determined position,
 - passing the cutting guide through the incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to

the bone free of an extramedullary or intramedullary alignment rod;
moving a cutting tool through the incision into engagement
with a guide surface on the cutting guide; and
forming at least an initial cut on the femur by moving the
cutting tool along the guide surface;
attaching a replacement portion of the knee to the cut surface,
the replacement portion having a transverse dimension that is larger
than a transverse dimension of the guide surface.

20. I have been instructed that I should interpret the terms of the claim following a legal standard defined as the “broadest reasonable interpretation consistent with the specification.” I have been informed that under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure.

21. I have also been instructed to interpret certain claim terms in the following manner for purposes of this *inter partes* review:

- (1) “cutting guide” – a “guide that has a guide surface”; and
- (2) “guide surface” – “a surface that guides a cutting instrument.”

Overview Of The '896 Patent

22. The '896 patent describes a number of surgical devices and surgical methods, and discusses the use of reduced size cutting guides in knee replacement surgery. ('896 patent, col. 3, ll. 15-30, col. 17, 47-60, col. 69-71, col. 103-104).

23. The '896 patent explains that the “benefits of having a smaller incision include improved cosmetic results, improved rehab, less dissection of muscle and soft tissue, and preservation of the quadriceps mechanism.” (Id., col. 15, ll. 15-18). It explains that this is achieved by using reduced size cutting guides, “the size of the incision ... can be reduced”, and “reducing the size of the incision ... reduces damage to body tissue of the patient.” (Id., col. 18, ll. 36-38).

24. The '896 patent discloses down sizing of instrumentation to be smaller than the implants positioned in the knee portion of the patient. Specifically, the opposite ends of the instrumentation may be 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. The length of the cutting guide surface is less, in the transverse dimension, than the transverse dimension of replacement part. The cutting surface may be less than the length of the cut to be made on the bone, and the cut on the bone is completed using the previously cut surface as a guide for the cutting tool. (Col. 3, ll. 15-29, Figures 11-13, 53, 54, 94, 95, 96, for example).

25. The '896 patent contrasts its reduced size cutting guides from conventional cutting guides such as the Scorpio cutting guides of Exhibit 1009. The '896 patent explains that the "Scorpio" (TM) Single Axis Total Knee System is a known anterior resection guide and femoral alignment guide with a distance

between opposite ends of the guide being greater than the traverse dimensions of the femoral and tibial implants. (Col. 18, ll. 18-31)

26. The '896 patent describes various reduced size cutting guides such as femoral and tibial cutting guides secured with intramedullary alignment rods (col. 17, ll. 15-17, Figures 9-13), and femoral and tibial cutting guides secured with extramedullary alignment rods (Figures 37-38, col. 44, ll. 20-36, col. 17, ll. 15-17).

27. Also described in the specification are femoral cutting guides that are secured to the bone free of an extramedullary or intramedullary alignment rod (Figures 53, 54, cols. 69-71, Figures 94, 95, cols. 103-104).

28. The '896 patent also discusses the “guide surface” of the aforementioned cutting guides. (Col. 20, ll. 15-21 (Figures 9-13), col. 45, ll. 46-48 (Figure 38), col. 69, ll. 6-34 (Figure 53), col. 70, ll. 27-63 (Figure 54), col. 105, ll. 13-27 (Figure 94)).

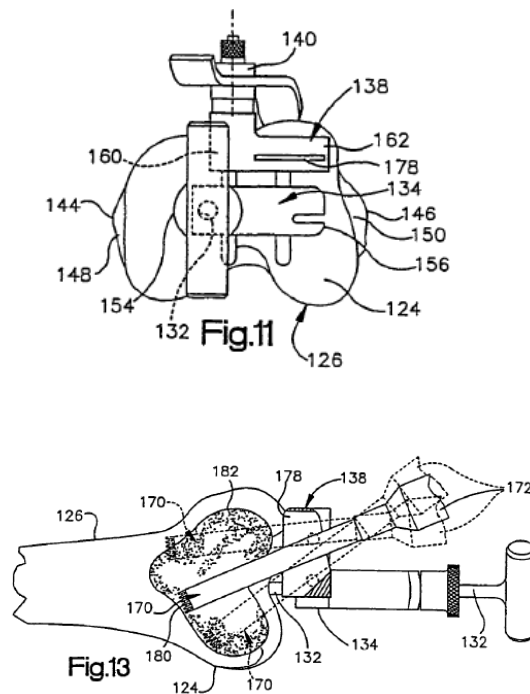
29. The '896 patent explains that the guide surface extends only part way across the femur (or tibia in the case of Figures 37-38). (Col. 20, ll. 18-19 (Figure 13), col. 45, ll. 45-62 (Figure 38), col. 69, ll. 47-49 (Figure 53), col. 71, ll. 9-12, 22-25, 45-49 (Figure 54), col. 105, ll. 17-19 (Figure 94)).

30. The '896 patent explains that an initial cut can be made with the guide surface, and then the remainder of the cut can be made using the initial cut as a guide. (Col. 20, ll. 52-col. 21, ll. 9 (Figure 13), col. 45, ll. 60-67 (Figure 38), col.

69, ll. 51-63 (Figure 53), col. 71, ll. 12-16, 25-29, 45-49 (Figure 54), col. 105, ll. 19-22 (Fig. 94), col. 110, ll. 45-50).

31. The '896 patent explains that the use of shorter cutting surfaces allows for reduced incision sizes (Id., col. 17, ll. 47-50) and, accordingly “improved cosmetic results, improved rehab, less dissection of muscle and soft tissue, and preservation of the quadriceps mechanism.” (Id., col. 15, ll. 15-18, see also col. 18, ll. 34-38, col. 19, ll. 36-42, col. 21, ll. 28-30).

32. With reference to the cutting guide of Figures 10-13 which is secured with an intramedullary alignment rod, the '896 patent describes guide surface 178:



('896 patent, col. 20, ll. 15-46).

33. I note that guide surface 178 is shown as extending substantially across the entire cutting guide 138 notwithstanding the fact that the slot extends

across only about two-thirds of the front face of the cutting guide 138. In particular, the guide surface 178 narrows as it extends from top to bottom of Figure 13 (or right to left from the perspective of Figure 11), but remains continuous on the bone-side¹ of the guide.

34. With regard to the cutting guide of Figure 37-38 which is secured with an extramedullary alignment rod, the '896 patent describes guide surface 530 at column 45, line 45 to column 46, line. 20. This surface also extends to the bone side of the guide.

35. With regard to the cutting guide of Figure 53, the '896 patent describes guide surfaces 762, 764, 770, 780. (col. 69, ll. 1-50). As shown in Figure 53, femoral alignment guide 750 is positioned on the on the distal end of the femur 126 and is secured to the femur 126 by pins 784, 786. (Id. col. 69, ll. 35-41). No intramedullary or extramedullary alignment rod is used. The cutting guide extends only part way across the distal end of the femur. (Id., col. 69, ll. 47-48). As with the guide surface 178 of Figure 13, the guide surfaces of Figure 53 extend to the bone side of the cutting guide.

36. With regard to the cutting guide of Figure 54, the '896 patent describes guide surfaces 806, 812, 816, 820, 824. (Col. 70, ll. 19-62). As shown in Figure 54, the alignment guide 800 is a “side cutting guide” which is positioned on

¹ From the perspective of Figure 13, the bone side is the left side of the guide 138.

a lateral surface 802 of the femur 126 and secured to the femur 126 by pins 830, 832. (Id., col. 70, ll. 19-20, col. 71, ll. 4-5). No intramedullary or extramedullary alignment rod is used. As with the guide surfaces of Figures 13 and 53, the guide surfaces of Figure 54 extend to the bone side of the cutting guide.

37. Cutting guide 1372 shown in Figures 94 and 95 includes a base 1376 and cutting guide surface 1374. Cutting guide 1372 can be secured to the bone free of an extramedullary or intramedullary alignment rod. (Id., col. 104, ll. 49-51 (“If desired, the base 1376 could be pinned directly to the femur in a manner analogous to the cutting guide 800 (FIG. 54)”)). Further, “the guide surface 1374 can be made so that the size of the guided portion of the cuts can be adjusted depending upon the size of the bone and the implant that is to be used;” and “the guide surface 1374 can be made to have a length less than the extent of the cut to be formed on the distal end portion of the femur.” (Id., col. 105, ll. 13-19). The cutting guide 1372 can be “positioned on the femur using a computer navigation system.” (Id., col. 104, ll. 53-54).

Stulberg

38. Stulberg is directed to computer-assisted total knee replacement and is concerned with improving the accuracy of the instrumentation used in total knee replacement procedures. It focuses on using computer-assisted technology to improve the consistency of the location of reference points that guide the

placement of the bone cutting guides. Stulberg reports that “alignment errors of greater than 3° are associated with more rapid failure and less satisfactory results . . .” (Stulberg, p. 25) Stulberg also reports that while “[m]echanical alignment guides have improved . . . accuracy” (*id.*), they are still unsatisfactory in that they have “fundamental limitations that limit their ultimate accuracy.” (*Id.*).

39. Stulberg states that the computer-assisted techniques it describes use “conventional incision and exposure.” (*Id.* p. 27). Stulberg does not indicate that a smaller incision size is necessary, and does not in any way indicate that the size of the alignment guides or cutting guides is of interest. Nothing in Stulberg suggests that the size of conventional mechanical alignment guides or cutting guides is problematic. My review of Stulberg shows that it does not object to extramedullary or intramedullary alignment guides *per se*, but rather is concerned with more *accurate placement* of the cutting and alignment guides. This is indicated, for example, in its computer-assisted tibial procedure, an extramedullary alignment guide is used (Figure 12), and the computer technique is used to more finely tune the position of the cutting guide. (*Id.* p. 29, right column, final two paras.).

40. To elaborate, as shown in Figures 16B and 17, the guide surface of the cutting guide is larger than the replacement component. It can be seen that the guide surface extends beyond the femur. The replacement component (Figure 20)

clearly has a transverse dimension that is smaller than the transverse dimension of the guide surface. There is no indication whatsoever that this is disadvantageous and in fact no indication anywhere that the relative sizes of the guide surface and the replacement portion are of interest. Rather, Stulberg is concerned with accurate placement of the cutting guides so that a more precise cut can be made. (Id. at p. 25 (Abst.), p. 25, left. col., first par., p. 25, right col., second par.)

Delp

41. Delp is concerned with the accurate and consistent alignment of knee implants for total knee replacement using various computer-assisted techniques. Its focus is on the *accuracy* of mechanical alignment systems: “[a]lthough mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations of this technology that will inhibit additional improvements.” (Delp, p. 49, left col.).

42. Like Stulberg, Delp does not express any concern for the size of conventional incisions, or the size of conventional alignment devices or cutting guides. Rather, it is the *accuracy* of the alignment and cutting guides that is of concern. (Id., p. 49, left col., p. 50, left col.).

43. Delp discusses three distinct technologies: (i) computer integrated instruments, (id., pp. 50-51); (ii) image guided knee replacement, (id., pp. 51-53); and (iii) robot assisted knee replacement, (id., pp. 53-54).

44. The first is computer integrated instruments - According to Delp, this technique uses an optical localizer to determine the mechanical axes of the femur and tibia, and then uses a computer workstation to display the position of the cutting block relative to its desired position. Once the cutting block is “oriented properly it is secured in position and the cuts are made with a standard oscillating saw.” (Id., p. 51, left col.). As reported at page 55, this technique uses “standard cutting guides.” (emphasis added). Accordingly, although Delp does not specifically discuss how the cutting guide is secured, it follows that since a “standard cutting guide” is used, it is to be secured in the standard way.

45. The second is image guided knee replacement – In this technique, according to Delp, three dimensional computer models of the patient’s femur and tibia are constructed using computer tomographic data. (Id., p. 51, last par.). An intraoperative system is used to “determine the position and orientation of the patient’s femur and tibia and to guide the surgeon in the placement of the cutting jigs.” (Id., p. 52, last two pars.) According to Delp, the intraoperative system includes a graphics workstation, a coordinate measurement probe, and “a set of cutting blocks that have been modified to attach to the measurement probe.” There is no suggestion that the cutting blocks/cutting jigs are in any other way different than standard cutting blocks/jigs. There is no indication that they are not secured to the femur/tibia in a conventional manner.

46. The third is robot assisted knee replacement – Three robot assisted techniques are described: Kienzle et al - In this technique, a robotic procedure is used to more accurately “drill the alignment holes for conventional cutting blocks for femoral and tibial implants.” (Id., p. 54, 1st par.); Fadda et al- In this technique, “a sophisticated pre-operative planning system [is linked] to a standard industrial robot to allow placement of cutting blocks and machining of bone.” (Id., p. 54, 2nd par.); and Davies et al.- In this technique, an active constraint robot (ACROBOT) to cut the femur without the use of cutting guides. (Id., p. 54 (“virtual cutting block”)).

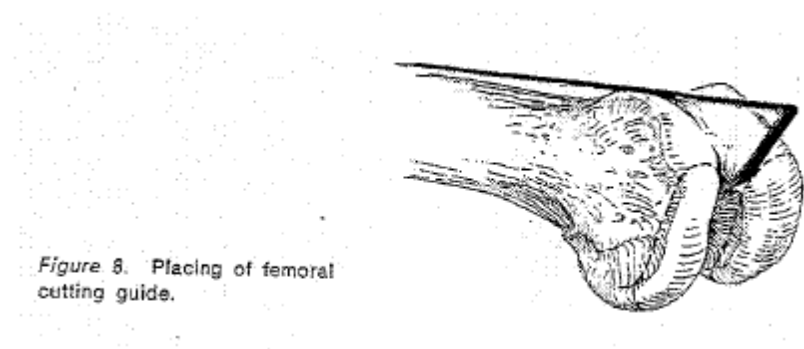
47. The computer integrated technique, the image guided technique and the first two robot assisted techniques use standard cutting blocks, presumably secured in their standard way, and the last uses no cutting block at all. However, in each technique, Delp is concerned with the accuracy of the placement of the cuts, not the size of the cutting surfaces (Id., p.49, Abs., p. 50, left col., first and second pars.)

Turner

48. The Turner article is published in 1980, 18 years prior to Delp, and 20 years prior to Stulberg. The subject matter of Turner is directed to geometric and anametric total knee replacement (“TKR”) techniques. The cutting guide that is relied upon by Dr. Mabrey (Figure 8) is employed in the geometric technique.

The geometric TKR was a primitive design that had been abandoned as a failure by 1990, long before Delp or Stulberg. In particular, it was found that while the theory of the geometric TKR was that “(4) although stability in flexion [as the knee flexes] may be sacrificed somewhat with spherical surfaces, the requirements for stability in flexion are no nearly as significant functionally as are the requirements for stability at or near full extension,” (Turner, p. 174), the opposite was in fact true because flexion instability is one of the primary causes of total knee pain and failure, not extension instability. By 1988, the geometric TKR was known to have a 10 year survivability of only 69%.

49. In the technique described in Turner, the femoral cutting guide is mounted with an extramedullary alignment rod, as illustrated in Figure 8:



50. A person of ordinary skill in the art at the timeframe 2000-2003 would recognize the above figure as an extramedullary alignment rod which terminates with a cutting guide. A person of ordinary skill in the art at the timeframe 2000-2003 would also recognize that this cutting guide, whose extramedullary alignment is achieved by inserting “[t]he femoral cutting guide ...

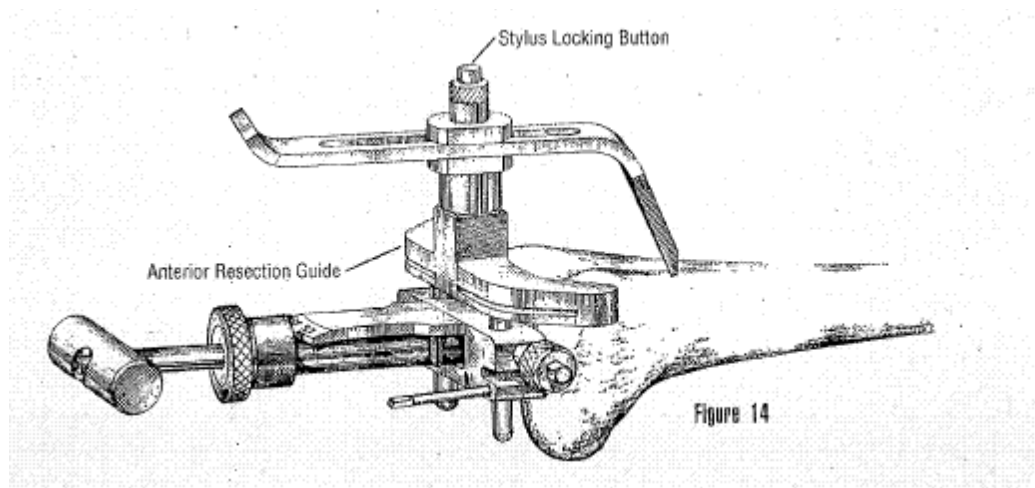
in the midline, deep to the suprapatellar pouch,” and which is thereafter used to cut the femur “with a power or hand saw parallel with the guide that is approximately 30 degrees to the long axis of the femur” would provide a far more imprecise cut than the techniques criticized in Delp and Stulberg. In the timeframe of 2000-2003, a person of ordinary skill in the art would not consider using the femoral cutting guide of Figure 8 in a knee replacement surgery.

51. There is no discussion of limiting incision sizes in Turner, and no indication that the relative size of the cutting surface of the cutting guide and the replacement component is of any interest.

Scorpio

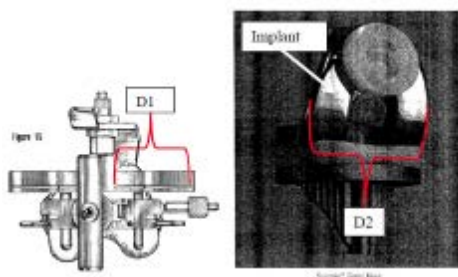
52. Scorpio is a publication describing the Scorpio Single Axis Total Knee System and various instruments for use in total knee replacement surgery. In particular, Scorpio discusses Osteonics Passport A/R Instrumentation designed for anteriorly based femoral resections. I am familiar with the Scorpio Single Axis Total Knee System, and used much of the instrumentation described in this publication, including the anterior resection guide, at least as early as 2003.

53. In Scorpio, the initial femoral cut is made using the anterior resection guide shown below:

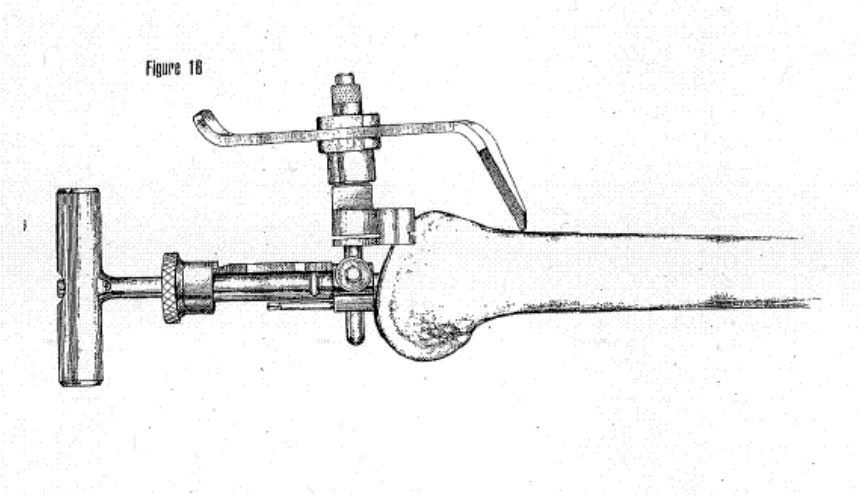
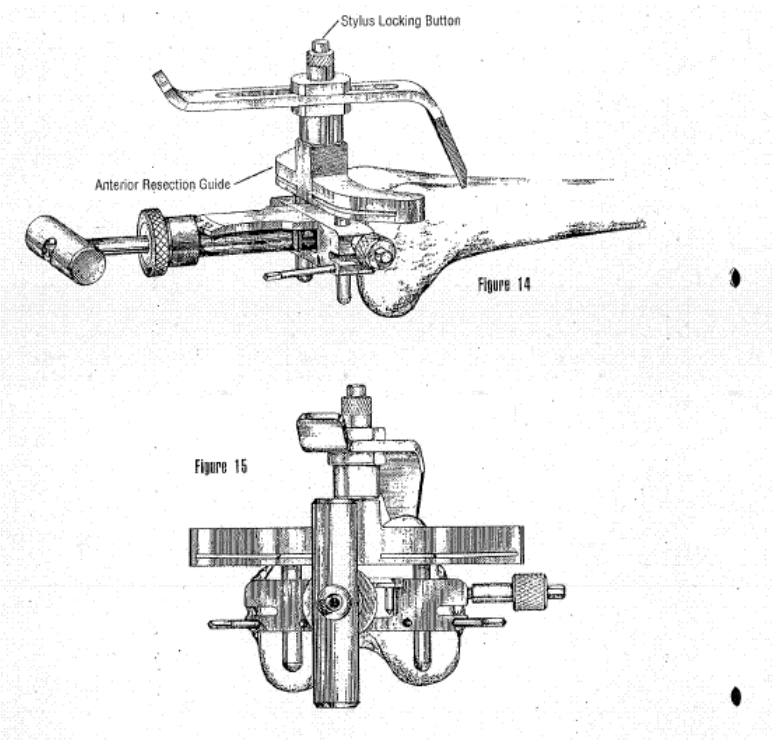


54. The anterior resection guide is mounted to the femur with an intramedullary alignment rod, as shown in Figure 9 and in Figure 12. (*Id.*, pp. 6-7).

55. In his Declaration, and at paragraph 70 in particular, Dr. Mabrey alleges that the Anterior Resection Guide is composed of two guide surfaces, of which he alleges surface D1 (below) is less than the transverse dimension of the replacement portion (implant D2):



56. I disagree for a number of reasons which I will discuss later in this declaration. However, to begin with, Scorpio only illustrates the cutting guide from the perspective of the physician:

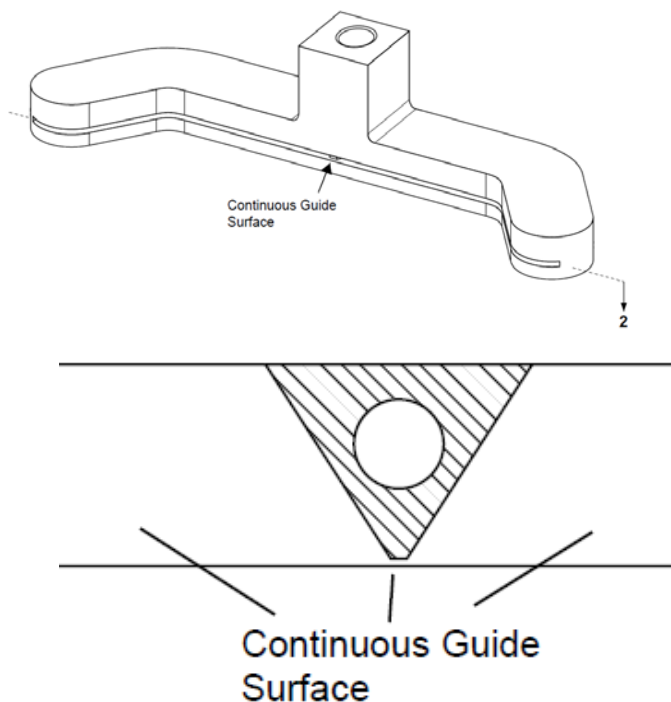


57. There is no illustration in Scorpio that shows the cutting guide from the opposite (i.e. bone-side) perspective from Figure 15.

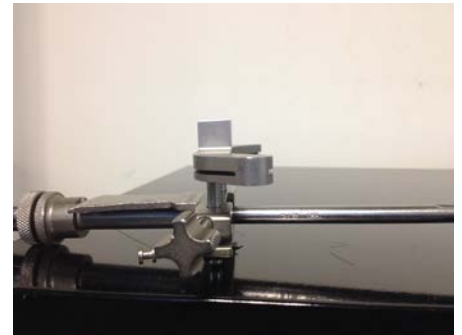
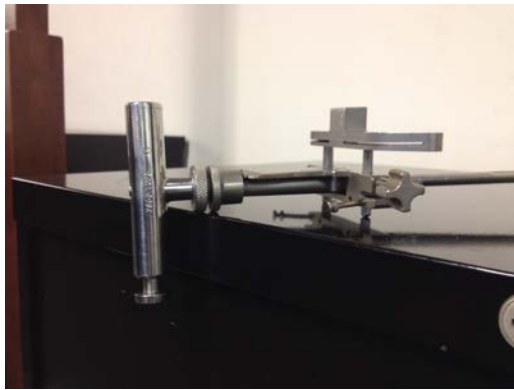
58. A person of ordinary skill in the art considering Scorpio at the timeframe 2000-2003 would understand that in order to create the anterior cut on the femur, the guide surface on the bone side of the anterior resection guide would

have to extend continuously between the lateral and medial sides of the cutting guide (i.e. from the right side to the left side of the guide when viewed from the perspective of Figure 15).

59. In fact, the Scorpio Anterior Resection Guide that I used in 2003 had a single continuous guide surface that extends across the entire cutting guide. The guide surface narrowed and widened from one side of the cutting guide to the other, but it extended as a single continuous surface throughout. This continuous surface can be seen in the photos of the Anterior Resection Guide in Exhibit 2005, and I have included two drawings illustrating the guide from the bone-side as Exhibit 2007:



(Exh. 2007)



(Exh. 2005, Photos from the perspective of Scorpio Figures 14, 15, and 16)



(Exh. 2005, Photos from the bone side of the device of Scorpio)

60. There is no discussion of limiting incision sizes in Scorpio, and no indication that the relative size of the cutting surface of the cutting guide and the replacement component is of any interest.

Stulberg in view of Turner**Stulberg**

61. Stulberg is concerned with providing improved accuracy in positioning cutting guides by using computer-assisted techniques to more accurately position the cutting guide on the femur. A person of ordinary skill in the art at the 2000-2003 timeframe would understand that Stulberg is principally concerned with increasing the precision of the cuts made using the cutting guides. This was typical at the timeframe 2000-2003 as it was believed that more precise cuts would result in better outcomes. That turned out not to be true in practice. Accuracy is repeatedly stressed in Stulberg. (Stulberg, Abst., and first three pars. on p. 25; p. 27 (“The goal of the computer-assisted system is to increase the accuracy and reproducibility...”); and p. 33).

62. A person of ordinary skill in the art would also understand that the cutting tools and blocks in Stulberg are very large and invasive without sparing the quadriceps and thus not concerned with minimally invasive procedures. A person of ordinary skill in the art in 2000-2003 familiar with Stulburg would also recognize that Stulberg is not at all concerned with performing a minimally invasive procedure, and thus, not concerned with the size of cutting guide surface nor concerned with shortening the cutting guide surface length. This is typical of

the thinking at the time. The same is true of Delp² (Delp, pp. 49, 50).

63. Stulberg is concerned about improving accuracy and no person of ordinary skill in the art in 2000-2003 concerned with accuracy would consider shortening the cutting guide surface length. Shortening the guide surface would have been expected to reduce precision, and not allow the entire anterior cut of the femur to be guided as precisely because the physician would have to freehand the cut beyond the end of the guide surface.

Turner

64. First, I note that a person of ordinary skill in the art in 2000-2003 would recognize that the procedure in Turner results in a very large incision of approximately 12-16 inches along the quadriceps that was the standard at the time of publication and timeframe 2000-2003. (Turner, Fig. 8, p. 181) At the time of the Turner publication and in the 2000-2003 timeframe, a person of ordinary skill in the art would not think otherwise to making a big incision, split the quadriceps, and evert the patella because it was common practice. This is also evident, for example, from the devices and procedures in Stulberg and Scorpio. (Stulberg, Figs. 2, 6, 16, pp. 26, 29, 35) (Scorpio, Figs. 1, 2, 3, 14, pp. 3, 9).

² Although this section of my Declaration is concerned with the combination of Stulberg in view of Turner or Scorpio, to avoid later redundancy, I have also noted where the same would be true of Delp in view of Turner or Scorpio.

65. I have known for decades of the geometric total knee replacement procedure discussed in Turner, and the femoral cutting guide shown in Figure 8 of Turner (hereinafter “Turner Cutting Guide”) which is used in the geometric knee procedure. The geometric total knee replacement procedure was a primitive design with poor outcomes when compared to modern knees (post 1990). A person of ordinary skill in the art in 2000-2003 would not consider using either the Turner Cutting Guide, or the geometric total knee replacement procedure described in Turner.

66. The Turner Cutting Guide is a handheld cutting guide that is positioned by laying and running the long arm of the guide along the top of the femur bone inserted in the midline, deep to the suprapatellar pouch. (Turner, p. 181) The combination extramedullary rod and cutting guide that makes up Turner simply sits in between the condyles and extends up the center of the femur bone so that it generally aligns with the medullary canal of the femur. It is known as an extramedullary alignment rod because it is an alignment rod that is not located inside the medullary canal of the femur. The cutting guide is used to cut the femur with a saw parallel with the guide that is approximately 30 degrees to the long axis of the femur.

67. As reported in Turner, an underlying theory of the geometric TKR was that “(4) although stability in flexion [as the knee flexes] may be sacrificed

somewhat with spherical surfaces, the requirements for stability in flexion are no nearly as significant functionally as are the requirements for stability at or near full extension.” (Turner, p. 174). It turned out that the opposite was in fact true because flexion instability is one of the primary causes of total knee pain and failure, not extension stability. A person of ordinary skill in the art at the timeframe 2000-2003 would recognize this and not consider using the teachings of the Turner Cutting Guide in combination with Stulberg (or, for that matter, with Delp).

68. In 2000-2003, a person of ordinary skill in the art would find no motivation to combine the teachings of Turner with a computer-assisted technique, such as Stulberg’s (or Delp’s), because Turner is such a primitive design and because there would be no improvement in accuracy by using computer-assisted procedures, such as the procedures in Stulberg (and Delp) to position the primitive Turner Cutting Guide. A person of ordinary skill in the art would not consider Turner to be a reference for any type of knee replacement from the year 1990 on. I started practice in 1990 and this device was long gone and rejected because of its failure rate. For example, the implant is designed to achieve only 90 degrees of flexion, far less than a modern knee (125-150). In the July 1988 issue of CORR (Clinical Orthopaedics and Related Research), Coventry reviewed a 10 year follow-up of 129 patients with geometric total knee, and found there was a revision

rate of 20% and a surgical complication rate of 12 %, and the predicted implant survival at 10 years was 69% (Exhibit 2006). A person of ordinary skill in the art in 2000-2003 would find no motivation to combine the teachings of Turner with a computer-assisted technique, such as Stulberg's (or Delp's).

Stulberg and Turner are Not Combinable

69. A person of ordinary skill in the art reviewing Turner in 2000-2003 would recognize that the Turner Cutting Guide is a very crude extramedullary alignment guide that would not be suitable for use as a femoral cutting guide in knee replacement surgery in the 2000-2003 timeframe. The Turner Cutting Guide is nothing more than a handheld rod with a cutting guide edge that is so small that a cutting blade would pivot about the guide surface during a cut, even by an experienced physician. (Turner, Fig. 8, p. 181) Cuts like this are called freehand cuts or eyeball cuts. Guides like Turner are also known as approximate cutting guides because the cut, for all practical purposes, is made freehand resulting in an approximate cut.

70. Cuts made with the Turner Cutting Guide can be referred to as "eyeball cuts" because they are guided by the eye and not a cutting jig or guide. A person of ordinary skill in the art would understand that the eyeball cut in Turner is very imprecise because the cut relies primarily on the physician free-handing the cut with little to no guidance from the cutting guide. (Turner, Fig. 8, p. 181) This

eyeball cut is far more imprecise, for example, than the techniques criticized in Stulberg and Delp. A person of ordinary skill in the art in the 2000-2003 timeframe would recognize this imprecision and not consider using the teachings of the Turner Cutting Guide in combination with either Stulberg or Delp because it would result in a far less accurate surgical outcome.

71. Another reason that a person of ordinary skill in art in 2000-2003 would not combine the teachings of the femoral cutting guide of Turner with the distal femoral cutting block of Stulberg, or modify Stulberg based on the teachings of the Turner Cutting Guide, is because the femoral cutting guide of Figure 8 of Turner (Turner, p. 181) serves a different function than the distal femoral cutting block of Figure 16 of Stulberg. (Stulberg, p. 35) The femoral cutting guide of Turner is designed for use in a different surgical procedure (geometric knee replacement) to make an entirely different cut in the femur than the distal cutting guide of Stulberg. In particular, I note that the Turner Cutting Guide makes a distal cut which is not perpendicular to the mechanical axis of the femur. This can be seen in Figure 9 of Turner. In contrast, the technique described in Stulberg, and all other techniques that I am aware of that were in use in the 2000-2003 timeframe require a distal cut that is perpendicular to the mechanical axis of the femur.

72. I disagree with Dr. Mabrey's statement that "a person of ordinary skill in the art would want to combine the teachings of Stulberg with ... Turner ...

to yield the predictable improvement of a more accurate surgical outcome” and the statement that “[t]his combination is no more than the predictable use of prior art technology according to its established function to achieve a predictable result.” (Mabrey Decl. para. 92).

73. A person of ordinary skill in the art in 2000-2003 would recognize that the proposed combination of Stulberg and Turner (or Delp and Turner) does not result in a more accurate surgical outcome. Turner is nothing more than a handheld rod with a cutting guide edge that is so small that a cutting blade would pivot about the guide surface during a cut, even by an experienced physician. (Turner, fig. 8, p. 181) The proposed combination of the teachings of Stulberg and Turner (or Delp and Turner) yields a less accurate surgical instrument, and thus, a less accurate surgical outcome. Using computer-assisted navigation to make an eyeball cut is not going to make the procedure any better.

74. Another reason a person of ordinary skill in the art in 2000-2003 would not consider combining the teachings of Stulberg (or Delp) with Turner is that a person of ordinary skill in the art would have had difficulties performing computer-assisted navigation resection with the Turner Cutting Guide because it is so small and unstable, even with the extramedullary rod, and the result would undoubtedly been less accurate than what Stulberg (or Delp) offers. This would be contrary to what Stulberg (and Delp) is trying to achieve, namely accuracy: “The

goal of the computer-assisted system is to increase the accuracy and reproducibility...”. (Stulberg, p. 27, see also Stulberg, p. 25 (Abst. and first three pars), and Stulberg, p. 33; Delp, pp. 49, 50)

**Even if For Some Reason Combined
Stulberg and Turner Would Not Create the Claimed Invention**

75. Turner is a combination extramedullary rod and cutting guide that sits in between the condyles and extends up the center of the femur bone so that it generally aligns with the canal of the femur. Even if the teachings of Stulberg and Turner (or Delp and Turner) were for some reason combined, a person of ordinary skill in the art in 2000-2003 would recognize that Turner, without the extramedullary rod, is nothing more than a cutting guide edge, and thus, would not abandon the extramedullary rod portion. A person of ordinary skill in the art would understand that the resulting combination would need to include the extramedullary rod portion because there would be no apparent way to position the cutting surface of the femoral cutting guide. (Turner, Fig. 8, p. 181)

Stulberg in view of Scorpio

Scorpio

76. I am very familiar with the anterior resection guide shown in Figures 14-16 of Scorpio. As I mentioned previously, I used the system described in Scorpio in 2003. At that time period the bone side of the anterior resection guide that I used had a cutting guide surface that was continuous between the lateral and

medial side of the cutting guide. In fact, as mentioned above, I have a Scorpio anterior resection guide and femoral alignment guide and when I inspected the bone side of the Scorpio guide I saw that the cutting guide surface between the lateral and medial side of the cutting guide is continuous. As noted above, Exhibit 2005 contains true and correct copies of photographs of that anterior resection guide. A person of ordinary skill in the art in 2000-2003 looking at this device would recognize that Scorpio has a single continuous guide surface that extends across the cutting guide.

77. I have read Dr. Mabrey's deposition testimony where he states that a person of ordinary skill in the art would assume from the figures of Scorpio that the metal piece dividing the front of the guide surface would extend all the way through to the bone side of the guide, and that it would have been obvious and make more sense from a manufacturing and structural basis to construct the guide so that the metal divider piece extends completely through the guide to the bone side. (Mabrey Tr., 89-91). I disagree. A person of ordinary skill in the art in 2000-2003 would clearly recognize from the figures that Scorpio would not function as an anterior resection guide if the center metal piece in front of the guide surface extended all of the way to the bone side of the guide surface. The metal piece cannot extend all of the way to the bone side of the cutting guide because if it did a physician would not be able to cut the entire condyle portion of the bone. A person

of ordinary skill in the art would recognize from Figures 15 and 18 of Scorpio (showing a front view of the cutting guide) and Figure 20 (showing the cut made by the cutting guide), that a cutting blade moving toward the trochlear groove would be blocked from cutting the entire condyle if the dividing metal piece extended all the way to the bone side of the cutting guide. A person of ordinary skill in the art in 2000-2003 would understand from Scorpio that the dividing piece could not extend all the way to the bone side and that the guide surface would have to be a continuous surface from the lateral to the medial ends of the cutting guide surface. A person of ordinary skill in the art would also recognize that even if the physician angled the cutting blade between the outer most portion of the cutting guide surface and the dividing metal piece, the cutting blade would be blocked by the dividing metal piece from reaching and thus cutting the entire condyle if the dividing metal piece extended all the way to the bone side of the guide surface. This would be true even if the surgeon accessed the bone through the left and right physician side openings.

78. Even though a person of ordinary skill in the art in 2000-2003 looking at the Scorpio publication would understand that the dividing metal piece could not pass all the way to the bone side of the cutting guide, thus leaving a continuous guide surface from the lateral to medial end, I can shed some light on what the bone side view of Figures 15 and 18 look like because, as I mentioned

previously, I have a Scorpio device and have used such a guide in surgery. The dividing piece depicted in figures 15 and 18 does extend towards the bone side of the cutting guide surface, but it does not pass all the way to the bone side of the cutting guide surface. A space is left on the cutting guide surface between the end of the dividing metal piece and the bone side of the cutting guide surface, leaving a continuous guide surface from the lateral side to the medial side of the cutting guide surface. This is illustrated above at paragraph 59. This space is necessary to allow the cutting blade to be angled enough to cut an entire condyle, i.e., to the trochlear groove side of the condyle. With this space, if a physician starts a cutting saw blade on one side he can run it right through to the other side of the bone. Further, because of the need to angle the cutting blade, the dividing piece extends towards the bone side in the shape of a truncated triangle with the space between the flat apex of the truncated triangular dividing metal piece and the bone side of the guide surface, leaving a continuous cutting guide surface:



(Exh. 2005)

79. I note for completeness that the square block on top of the resection

guide in Scorpio holds the depth gauge rod that can be raised and lowered. A person of ordinary skill in the art in 2000-2003 would understand from looking at figures 14, 15, 17 and 18 that the depth gauge rod may or may not pass through the square block to the cutting guide surface. A person of ordinary skill in the art would also understand that there is no reason or need for the square block and rod to pass through to the guide surface because the square block itself, on top of the resection guide, would provide enough support for the depth gauge because the depth gauge requires little force when in use or set. If one was to conclude that the block and rod or simply only the rod did pass through to the cutting guide surface, one of ordinary skill in the art would understand that the rod would be centered on the block and the block would not extend flush to the bone side of the cutting guide, because if the guide surface did not extend across the center of the cutting guide, the cutting guide could not make the required anterior cut for reasons set forth above in paragraphs 77 and 78. Further, as mentioned above, the guide surface of the Scorpio anterior resection guide does, in fact, extend continuously from the lateral side to the medial side of the cutting guide, despite the fact that the bore extends through the guide (Exhibit 2007).

80. A person of ordinary skill in the art in 2000-2003 familiar with Scorpio would understand that the cutting tools and blocks in Scorpio are very large and invasive without sparing the quadriceps, and thus, not concerned with

minimally invasive procedures. (Scorpio, Figs. 1, 2, 3, 14, pp. 3, 9). A person of ordinary skill in the art familiar with Scorpio would recognize that Scorpio is not at all concerned with performing a minimally invasive procedure, and thus, not concerned with of the size of cutting guide surface nor concerned with shortening the cutting guide surface length.

Stulberg and Scorpio are Not Combinable

81. A person of ordinary skill in the art in 2000-2003 would not consider combining the teachings of Stulberg (or Delp) with Scorpio. A person of ordinary skill in the art would have had difficulties performing computer-assisted navigation resection with the Scorpio guide because the guide is so large and would be unstable without the positioning and mounting assistance of the intramedullary rod of Scorpio. A person of ordinary skill in art would recognize that Scorpio is an anterior referencing guide, and not a 4 in 1 cutting block (like the cutting block shown in Figures 16 and 17 of Stulberg), and therefore does not allow the adjustments required by Stulberg or Delp to position it properly with computer-assisted navigation. As designed, there is no way to use computer navigation to properly position the Scorpio anterior referencing guide. When the Scorpio anterior referencing guide is properly located, it only rests only on the non-eroded condyle. The intramedullary rod allows proper placement perpendicular to the mechanical axis. If Scorpio were pinned to the femur, it would need to be pinned

to both condyles, and then it would no longer be perpendicular to the mechanical axis. The size and shape of Scorpio requires that it be mounted by an intramedullary alignment rod. If Stulberg (or Delp) were, for some reason, to have been combined with Scorpio, the resulting combination would undoubtedly be a computer-navigated placement of the intramedullary rod of Scorpio. However, this would be contrary to one aspect of what computer-assisted navigation is trying to achieve – to eliminate the intramedullary rods and the bleeding and potential extravasation of marrow into the bloodstream associated with these rods. Accordingly, a person of ordinary skill in the art in the 2000-2003 timeframe would not consider using the teachings of Scorpio with the computer-assisted techniques discussed in Stulberg (or Delp).

82. I disagree with Dr. Mabrey's statement that the combined teachings of Stulberg and Scorpio would "yield the predictable improvement of a more accurate surgical outcome" and the statement that "[t]his combination is no more than the predictable use of prior art technology according to its established function to achieve a predictable result." (Mabrey Decl., par. 92) Scorpio is an anterior referencing guide and not a 4 in 1 cutting block, and therefore does not allow the adjustments required by Stulberg position it properly with computer-assisted navigation. Further, Scorpio is mounted with an intramedullary alignment rod and a person of ordinary skill in the art would know that intramedullary rods

produce bleeding and can cause extravasation of marrow into the bloodstream and would find the cutting guide of Stulberg to be superior, and thus, would not modify Stulberg with the teachings of Scorpio.

**Even if Somehow Combined, Stulberg and Scorpio
Would Not Create the Claimed Invention**

83. If a person of ordinary skill in the art in 2000-2003 were to combine the teachings of the Stulberg with Scorpio, the result would not be a method in which “the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface” because a person of ordinary skill in the art would understand that Scorpio discloses a continuous guide surface larger than the replacement portion. (See paragraphs 76-79 above).

84. In fact, a person of ordinary skill in the art in 2000-2003 considering the teachings of Stulberg (or Delp) with Scorpio would be discouraged from reducing the size of the cutting surface, so that it is less than transverse dimension of the femoral component, because to do so would reduce precision by not allowing the entire anterior cut of the femur to be guided as precisely.

85. If a person of ordinary skill in the art in 2000-2003 were to combine the teachings Scorpio with Stulberg (or Delp), he would recognize that Scorpio is too far too large, heavy and bulky to be supported in place against the femur by pins or by a pin, such as that used in Stulberg. A person of ordinary skill in the art

would understand that to prevent shifting and moving during a procedure (a requirement for accuracy) that an intramedullary rod would be needed.

Accordingly, if Scorpio were to be combined with Stulberg (or Delp), the combination would include the intramedullary rod of Scorpio. However, as I stated previously, knowing that intramedullary rods produce bleeding and potential extravasation of marrow into the bloodstream, a person of ordinary skill in the art would likely choose not to use Scorpio at all.

Delp in view of Turner or Scorpio

Delp

86. Delp, like Stulberg, discusses computer-assisted techniques. (Delp, Abst., p. 49, right col, p. 50, left col., p. 55, left col.) A person of ordinary skill in the art in the 2000-2003 timeframe would understand that Delp, like Stulberg, is principally concerned with increasing the precision of the cuts made using the cutting guides. (Delp, Abst., p. 50 bottom left and right cols.) This was typical at the timeframe 2000-2003 as it was believed that more precise cuts would result in better outcomes. That turned out not to be true in practice. Although the above discussion focuses on Stulberg in combination with Turner or Scorpio, the same would apply to Delp in combination with Turner or Scorpio.

87. Delp is concerned about improving accuracy and a person of ordinary skilled in the art in 2000-2003 concerned with accuracy would not consider shortening the cutting guide surface length. Shortening the guide surface

would have been expected to reduce precision, and not allow the entire anterior cut of the femur to be guided as precisely because the physician would have to freehand the cut beyond the end of the guide surface.

88. A person of ordinary skill in the art in 2000-2003 familiar with Delp would also recognize that Delp is not concerned with minimally invasive procedures and is not concerned with the size of the cutting guide surface. This is typical of the thinking at the time. In fact, Delp provides considerably less detail regarding its techniques than the later published Stulberg.

89. I disagree with Dr. Mabrey's statement, referencing Figures 2 and 3 of Delp, that "a person of ordinary skill in the art would understand that the Delp Article discloses a replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface." (Delp, Figs. 2, 3, pp. 53-54) (Mabrey Decl., par. 67) I agree with the Patent Trial and Appeal Board that Figures 2 and 3 are "too blurry to discern any meaningful size relationships, a none are discussed in the written portions of the article." (Institution Decision, p. 21) A person of ordinary skill in the art in 2000-2003 would see that Figures 2 and 3 are unclear and that Figure 2 is of a computer-generated oblique image of a cutting block. Figure 2 is so blurry that it is unclear whether a metal divider piece even exists in the center of the guide surface of the block depicted in Figure 2. If Figure 2 was a photograph of a cutting block, one might speculate that there is a metal

divider piece because without a metal divider piece it appears that the top and bottom portions of the cutting block would not be connected. However, this is a computer-generated image of a cutting block, not a photograph. This computer-generated image lacks many mechanical details of a cutting block. For example, no structure whatsoever is shown in Figure 2 for securing the cutting block to the femur. The computer-generated image appears to be intended to illustrate something other than the mechanical details of the cutting block, which is consistent with the lack of mounting hardware illustrated in the figure – the image may be illustrated to show location or what one can do with computer imaging. Even if one was to assume that the computer-generated image was intended to reflect a metal dividing piece, the image is at an oblique angle and too blurry to determine whether it spans the entire cutting guide surface from the front side to the bone side. Further, a person of ordinary skill in the art in the 2000-2003 timeframe would in any case conclude that any such dividing piece does not extend to the bone side of the device. Rather, such a person would understand that if the metal dividing piece did extend all the way to the bone side of the cutting guide surface a physician could not make the cut, just as in the case with Scorpio.

Delp and Turner are Not Combinable

90. For the same reasons I discussed above regarding Stulberg and Turner, a person of ordinary skill in the art in the 2000-2003 timeframe would

never consider using the Turner Cutting Guide in the computer-assisted techniques discussed in Delp. (See paragraphs 69, 70, 73, 74 above). There is no reason to combine the teachings of Delp and Turner. Even a person of ordinary skill in the art would have had difficulties performing computer-assisted navigation resection with the primitive Turner Cutting Guide because it is so small and unstable, even with the extramedullary rod, and the result would undoubtedly been less accurate which is contrary to what Delp is trying to achieve, namely accuracy. (Delp, pp. 49, 50) Further, the combined teachings of Delp and Turner do not result in a more accurate surgical outcome. Turner is nothing more than a handheld rod with a cutting guide edge that is so small that a cutting blade would pivot about the guide surface during a cut, even by an experienced physician. (Turner, Fig. 8, p. 181) The proposed combination of the teachings of Delp and Turner yields a less accurate surgical instrument, and thus, a less accurate surgical outcome. Using computer-assisted navigation to make an eyeball cut is not going to make the procedure any better.

**Even if Somehow Combined Delp and Turner Would Not Create the
Claimed Invention**

91. Even if a person of ordinary skill in the art were for some reason to combine the teachings of Delp with Turner, the result would not be a method in which “the cutting guide secured to the bone free of an intramedullary or extramedullary alignment rod” because a person of ordinary skill in the art would

understand that Turner includes an extramedullary alignment device, and that there would be no apparent reason to abandon this method of alignment. A person of ordinary skill in the art would recognize that Turner, without the extramedullary rod, is nothing more than a cutting guide edge, and thus, would not abandon the extramedullary rod portion. A person of ordinary skill in the art would understand that the resulting combination would need to include the extramedullary rod portion because there would be no other way to position the cutting surface of the femoral cutting guide. (Turner, Fig. 8, p. 181)

Delp and Scorpio are Not Combinable

92. For the same reasons I discussed above regarding Stulberg, a person of ordinary skill in the art in the 2000-2003 timeframe would never consider using Scorpio in the computer-assisted techniques discussed in Delp. (See paragraph 81 above). There is no reason to combine the teachings of Delp and Scorpio. A person of ordinary skill in the art in 2000-2003 would not consider combining the teachings of Delp with Scorpio. Rather, a person of ordinary skill in the art would have understood that it would be extremely difficult, if not impossible, to effectively perform computer-assisted navigation resection with the Scorpio guide because the guide is so large and would be unstable without the positioning and mounting assistance of the intramedullary rod of Scorpio. A person of ordinary skill in art would recognize that Scorpio is an anterior referencing guide, and not a

4 in 1 cutting block, and therefore does not allow the adjustments required by Delp to position it properly with computer-assisted navigation. As designed, there is no way to use computer navigation to properly position the Scorpio anterior referencing guide. As I explained previously, when the anterior referencing guide is properly located, it only rests only on the non-eroded condyle. The intramedullary rod allows proper placement perpendicular to the mechanical axis. If Scorpio were pinned to the femur, it would need to be pinned to both condyles, and then it would no longer be perpendicular to the mechanical axis. For this reason, a person of ordinary skill in the art would have concluded that if Scorpio is to be used with Delp at all, it would be through computer-navigated placement of the intramedullary rod of Scorpio. However, in my opinion, knowing that intramedullary rods produce bleeding and can cause extravasation of marrow into the bloodstream, a person of ordinary skill in the art would not use Scorpio in the computer-assisted technique of Delp at all.

**Even if Somehow Combined Delp and Scorpio Would Not Create the
Claimed Invention**

93. Even if a person of ordinary skill in the art in 2000-2003 were for some reason to combine the teachings of the Delp Article with Scorpio, the result would not be a method in which “the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface” because a person of ordinary skill in the art would understand that Scorpio discloses a

continuous guide surface larger than the replacement portion. (See paragraphs 76-79 above).

94. Further, for the same reasons set forth above in paragraph 85 with regard to Stulberg, if a person of ordinary skill in the art in 2000-2003 were to combine the Delp Article with Scorpio, they would have been motivated to secure Scorpio with an intramedullary rod, and therefore the result would not be a method in which “the cutting guide secured to the bone free of an intramedullary or extramedullary alignment rod.” A person of ordinary skill in the art would have used an intramedullary rod to support the cutting guide, and have used preoperative imaging and measurement probes to more accurately position the cutting guide on the femur.

95. I have read Delp and Scorpio and disagree with Dr. Mabrey’s statement that “it would have been obvious to reduce the length of the guide surface in this manner [the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface] so that the guide could fit through a smaller incision, because doing so was a known solution for reducing trauma.” (Mabrey Decl. par. 70) Delp and Scorpio are not at all concerned about reducing the trauma caused by incision size. The same is true of Stulberg. Rather Delp and Stulberg are concerned about improving accuracy and a person of ordinary skilled in the art concerned with accuracy in 2000-2003 would not

consider shortening the cutting guide surface, because shortening the surface would have been expected to reduce precision, and not allow the entire anterior cut of the femur to be guided as precisely. Further, the large size of Scorpio cutting guides were widely accepted and considered standard for their time. Back in the 2000-2003 timeframe, no cutting block was too large and a person of ordinary skill in the art would have not thought twice about making a 15-inch incision. Large incisions were simply accepted. A person of ordinary skill in the art would also have known that it was also widely accepted to have large cutting block designs because they provided stability when attached to the bone resulting in a clean accurate cut. At the time of the invention computer-assisted navigation involved large incisions, 12-16 inches. A person of ordinary skill in the art would recognize that the procedure in Delp, Stulberg and Scorpio result in a very large incision of approximately 16 inches along the quadriceps that was the standard at the timeframe 2000-2003.

96. I also disagree with Dr. Mabrey's statement that "the sizes of cutting guides and guide surfaces vary according to the preferences of surgeons, and modifying the length of a guide surface is a matter of routine practice." (Mabrey Decl. par. 70) This statement is entirely without support in Stulberg, Delp or Scorpio. In fact, in my experience, the cutting surfaces of cutting guides in the 2000-2003 timeframe were fixed in length. They were not something that a

surgeon could modify ad hoc. A person of ordinary skill in the art, at that time, would have known that the cutting guides are typically in kits that are made to work with a given manufacturer's replacement knee. In other words, if you were implanting a Stryker knee, you would use a specific set of Stryker cutting guides, etc. It is not something that a physician would modify ad hoc.

97. I also disagree with Dr. Mabrey's citation to column 22, lines 45-50 Delp '018 for teaching that a "known benefit of using 'smaller jigs' is to allow 'a smaller incision to be made,' which 'will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints.'" Neither the cited passage nor any other passage of Delp '018 suggests that reducing the cutting surface of a cutting guide is advantageous. This is consistent with the knowledge of a person of ordinary skill in the art in the timeframe 2000-2003 who would have understood that shortening the guide surface would have been expected to reduce precision, and not allow the entire cut to be guided as precisely because the physician would have to freehand the cut beyond the end of the guide surface. The statement referenced in Delp '018 refers to eliminating mechanical alignment systems so that the overall size of the "cutting jig" can be reduced: "Mechanical instrumentation systems in use today rely on cutting jigs that align cuts using discrete metrics and visual means, which can introduce alignment errors. . . . The instrumentation is large because it needs to

cover certain anatomical landmarks to align the cutting jigs.” Col. 22, ll. 35-41; “The computer replaces large complicated mechanical alignment systems allowing smaller cutting jigs to be used, and thus a smaller incision to be made.” Col. 22, ll. 45-48. Delp ‘018 is discussing the fact that eliminating the mechanical alignment systems allows for a reduction in the size of the cutting jigs. It does not at all suggest reducing the size of the cutting surface..

98. This is not surprising, because a person of ordinary skill in the art in 2000-2003 would also understand that shortening the width of a guide surface, so that it is less than the transverse dimension of the femoral knee component, would reduce precision because it would not allow the entire anterior cut of the femur to be guided as precisely.

99. I am being compensated at my normal consulting rate for my work. My compensation is not dependent on and in no way affects the substance of my statements in this declaration.

100. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross

examination.

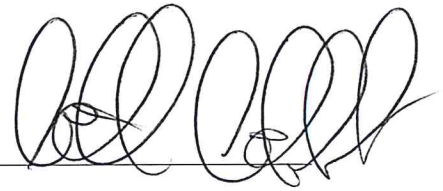
101. I reserve the right to supplement my opinions in the future to respond to any arguments that Petitioner raises and to take into account new information as it becomes available to me.

102. All of the statements made in this declaration of my own knowledge are true. All statements made based on information and belief are believed to be true. Further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject patent.

Date:

5/30/14

Signature: _____

A handwritten signature in black ink, consisting of stylized, overlapping loops and flourishes, positioned above a horizontal line.

Scott D. Schoifet

APPENDIX A

CURRICULUM VITAE

Scott David Schoifet, M.D.

Personal Data:

Date of Birth: 01/21/1958
Place of Birth: Highland Park, New Jersey
Married: 3 Children
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Education:

Highland Park High School Highland Park, New Jersey	Diploma	1975
Cornell University New York State	BA Chemistry	1975 - 1979
Columbia University College of Physicians and Surgeons New York, New York	Honors in General Surgery	1979 - 1983

Post Graduate Training:

Residency, General Surgery	St. Vincents Hospital and Medical Center New York City, New York	1983 - 1985
Residency, Orthopedic Surgery	University of Rochester Strong Memorial Hospital Rochester, New York	1985 – 1988
Fellowship, Adult Reconstructive Surgery	Mayo Clinic Rochester, Minnesota	1988 - 1989

Educational Honors – Awards:

Honors General Surgery Clerkship
Honors Orthopaedic Clerkship
Appointed Instructor in Orthopedics at the Mayo Clinic
Phi Beta Kappa Honor Society – Junior Year, Cornell University

Licenses:

License to practice Medicine and Surgery in State of New Jersey

Board Certification:

American Board of Orthopedic Surgery Re-Certification	July 12, 1991 2021
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Employment History:

Elizabeth Orthopedic Group Reconstructive Orthopedics, P.A.	July, 1989 through April, 1990 May, 1990 through Present
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Faculty Appointments:

Teaching Assistant, Chemistry & Biochemistry
Instructor in Orthopaedic Surgery

Cornell University, New York
Mayo Clinic, Rochester, New York

Hospital and Administrative Appointments:

Attending Physician - Virtua Health System	September 2003 to present
Medical Director – Joint Replacement Institute , Virtua Health System, Voorhees NJ	October 2003 to Present
Instructor, Consultant, Trainer –National MIS Knee Program – Stryker Orthopaedics	April 2004 to Present

Membership – Professional Organizations:

American Academy of Orthopedic Surgery
American College of Surgeons – Fellow
Burlington County Medical Society
New Jersey State Medical Society
American Association of Hip and Knee Surgeons

Research/Publications:

“Treatment of Infection after Total Knee Arthroplasty by Debridement with Retention of Components”
Schoifet, S.D., Morrey, B. F., Journal of Bone and Joint Surgery, 72-A. 1383-1390, October, 1990.

“Long Term Results of Various Treatment Options for Infected TKA’s”
Morrey, B. F., Westholm, F., Schoifet, S. D., Rand, J.A., Bryan, R. S.

“Persistent Infection after Successful Arthrodesis for Infected Total Knee Replacement: A Report of Two Cases”
Schoifet, S. D., Morrey, B. F. Submitted to the Journal of Arthroplasty.

“Hip Arthroplasty in Special Cases: Proximal Femoral Fractures”
Schoifet, S. D., Sim, F. H., Cabanela, M. E. Chapter 49 in Joint Replacement Arthroplasty. Edited by
Bernard F. Morrey, New York, Churchill Livingstone, 1991

“Comparative Safety and Resource Utilization of Total Knee Arthroplasty in Inpatient and Outpatient Settings”
Schoifet, S.D., Journal of Managed Care Medicine, Vol. 14, No.3, pg 27-32, September 2011

Instructor – Clinical Cadaver MIS-TKA Labs – Stryker

Chicago, Illinois	June 15 & 16, 2004
Memphis, Tennessee	September 24 & 25, 2004
Newark, New Jersey	November 2 & 3, 2004
New Brunswick, New Jersey	June 5 & 6, 2005
Memphis, Tennessee	June 23 & 24, 2005
New Brunswick, New Jersey	August 28 & 29, 2005
New Brunswick, New Jersey	November 29 & 30, 2005
New Brunswick, New Jersey	March 26 & 27, 2006
New Brunswick, New Jersey	July 30 & 31, 2006
New Brunswick, New Jersey	October 13, 2006
New Brunswick, New Jersey	October 29 & 30, 2006
New Brunswick, New Jersey	April 1&2, 2007
Mahwah, New Jersey	July 8 & 9, 2007
Mahwah, New Jersey	October 14 & 15, 2007
Mahwah, New Jersey	September 20 & 21, 2008

Presentations:

Acromioclavicular Dislocation: Current Concepts and Controversy City Wide Grand Rounds	January 10, 1987 Rochester, New York
Salvage of Infected Total Knee Replacements Adult Reconstructive Conference,	October 4, 1988 Rochester, Minnesota
Controversies in Bipolar Arthroplasty Adult Reconstruction Conference,	March 7, 1989 Rochester, Minnesota
Long Term Follow up of Infected TKA's Treated by Debridement and Retention of Components. Schoifet, S. D., Morrey, B. F. American Academy of Orthopedic Surgeons,.	February 13, 1990
MIS Knee Surgery - Experience & Techniques	October 21, 2004 York, PA
Advances in Surgical Technology Bioskills Lab	December 2, 2004 New York City, NY
MIS-TKR – Current Techniques Japan: Tokyo, Osaka, Fukuoka and Toyama	March, 2005 Japan
MIS-TKR– Mid-Vastus Approach Annual Meeting of the American Osteopathic Academy of Orthopedic Surgeons	May 13, 2005 Washington, D.C.
MIS-TKR – Bioskills Lecture and Presentation National Orthopaedic Residents Seminar	September, 2005 Boston, MA
“Why Not Evert the Patella” Advances in Surgical Technology Bioskills Lab Current Clinical National Observation Site for Stryker Orthopedic	December, 2005 New York City, NY
“Why Not Evert the Patella” Advances in Surgical Technology, Bioskills Lab Current Clinical National Observation Site for Stryker Orthopedic	December, 2005 New York City, NY
“Why Not Evert the Patella” Advances in Surgical Technology Bioskills Lab Current Clinical National Observation Site for Stryker Orthopedic	December, 2005 New York City, NY
MIS-TKA with a Mini Midvastus Approach 55 th Annual Meeting of the Eastern Japan Association of Orthopedics and Traumatology	September, 2006 Japan
MIS-TKA – Anterior Resurfacing Triathlon Champion's Symposium	October 21, 2006 Dallas, TX
MIS-TKA Current Concepts UMDNJ – Stratford	December, 2006 Stratford, NJ

Long Term Quadriceps Strength Retention in Mini Midvastus Approach Presentation at the Annual Meeting of the American Academy of Orthopedic Surgeons	February 16, 2007 San Diego, CA
Long Term Quadriceps Strength Retention in Mini Midvastus Approach Presentation at EFFORT	May 15, 2007 Florence, Italy
MIS-TKA Current Concepts UMDNJ – Stratford	September, 2007 Stratford, NJ
“Is it time for a knee replacement” Women’s Health Symposium 2007	October, 2007 Mt. Laurel, NJ
Triathalon Partial Knee Replacement Product Skills Training Homer Stryker Center	October, 2008 Mahwah, NJ
“New Outlook on Minimally Invasive Partial vs. Total Knee Replacement in Active Patients” Sixth Annual Sports Medicine Symposium	January, 2009 Voorhees, NJ
“Outpatient Total Knee Arthroplasty” Triathalon Champions Symposium	May, 2009 New Orleans, LA
Triathalon Partial Knee Arthroplasty Product Skills Training Homer Stryker Center	July, 2009 Mahwah, NJ
“Current Trends in Managing the Aging Athlete’s Knee” Homer Stryker Center	March, 2010 Mahwah, NJ
“Current Trends in Managing the Aging Athlete’s Knee” Homer Stryker Center	August, 2010 Mahwah, NJ
Triathalon Partial Knee Arthroplasty Product Skills Training Triathalon PKR Roadshow Innsbruck	June, 2010 Germany/Austria
Triathalon Partial Knee Arthroplasty Product Skills Training Frontiers of Orthopedic Hip & Knee Symposium	November, 2010 Williamsburg, VA
Triathalon Partial Knee Arthroplasty Product Skills Training	March, 2011 Las Vegas, NV
AHIP -Summit on Shared Accountability Episodes of Care: Using Bundled Payments to Improve Quality Outcomes and Reduce Overall Costs	October 8, 2011 Washington, DC
Triathlon Primary Knee and Triathlon Custom Fit Knee Featuring Shapematch Technology Homer Stryker Center	November, 2011 Mahwah, NJ
Strike the Right Balance with Triathlon Get Around Knee Surgical Training Program Homer Stryker Center	April, 2013 Mahwah, NJ
Strike the Right Balance with Triathlon Get Around Knee Surgical Training Program Oquendo Center	May, 2013 Las Vegas, NV
Triathalon Knee Surgical Training Program Oquendo Center	January, 2014 Las Vegas, NV