EXHIBIT B

(12) EX PARTE REEXAMINATION CERTIFICATE (7911th)

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Sheldon et al.

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(54) ACETABULAR CUP ASSEMBLY WITH SELECTED BEARING

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(2006.01)

(52) **U.S. Cl.** **623/22.28**; 623/22.21

Field of Classification Search None See application file for complete search history.

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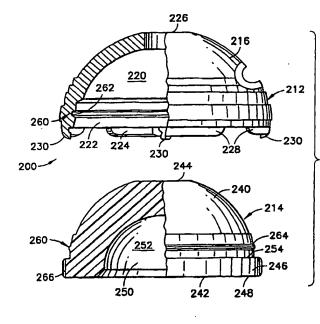
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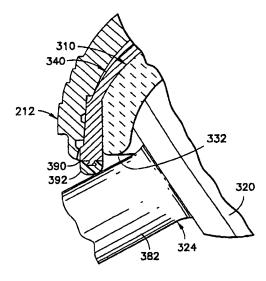
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(57)**ABSTRACT**

An acetabular cup assembly allows pre-operative or interoperative selection and securement of a bearing member within a shell member of the acetabular cup assembly, the bearing member being selected from a plurality of bearing members having different characteristics, including bearing characteristics, securement characteristics, position characteristics and orientation characteristics, so as to enable a surgeon to select those characteristics most appropriate to a particular patient, as determined by a pre-operative assessment or by an evaluation of conditions encountered at an implant site during the implant procedure, and to incorporate the desired characteristics into the acetabular cup assembly with ease and economy.





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1 **EX PARTE** REEXAMINATION CERTIFICATE **ISSUED UNDER 35 U.S.C. 307**

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made 10 to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims 21-24, 26, 33 and 34 are cancelled.

Claims 20 and 25 are determined to be patentable as amended.

New claims 35-55 are added and determined to be patent-

Claims 1-19 and 27-32 were not reexamined.

acetabular cup assembly having] and an internal bearing member for selective securement within the shell member interoperatively, the internal bearing member being selected from a plurality of bearing members having different characteristics, including different securement characteristics, such that the acetabular cup assembly selectively is provided with characteristics corresponding to the characteristics of the selected internal bearing member, the shell member comprising:

an internal cavity;

- a first securing element within the cavity of the shell member, the first securing element having a first securing structure compatible with the securement characteristics of at least one of the plurality of internal bearing 40 members; and
- a second securing element within the cavity of the shell member, the second securing element having a second securing structure compatible with the securement characteristics of at least another of the plurality of 45 internal bearing members;
- the first and second securing structures being juxtaposed with one another and placed at relative locations such that the effectiveness of each of the first and second securing elements is maintained while in the presence 50 of the other of the first and second securing elements, whereby the one and the another of the internal bearing members each is selectable for effective selective securement within the shell member to complete the acetabular cup assembly interoperatively;
- wherein the shell member includes a lower end and an upper end, the cavity extends from the lower end toward the upper end of the shell member, and the first and second securing elements are located adjacent the lower end of the shell member;
- wherein the bearing member includes an external securing surface, and the second securing element includes an internal securing surface, the external securing surface and the internal securing surface having complementary tapered configurations for interlocking in 65 response to seating engagement of the complementary tapered configurations; and

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- wherein the bearing member includes a rib projecting from the bearing member, and the first securing element includes a recess in the shell member for receiving the rib of the bearing member, the tapered configuration of the internal securing surface extends between an upper end and a lower end.
- 25. The invention of claim [24] 20 wherein the recess is located essentially midway between the upper and lower ends of the internal securing surface.
- 35. The assembly of claim 20, further comprising at least one anti-rotation element configured to engage a complementary anti-rotation element of the bearing member.
- 36. The assembly of claim 20, wherein the different characteristics of the internal bearing members include different
- 37. The assembly of claim 36, wherein the material of the at least one of the plurality of internal bearing members includes at least one of ceramic, metal, and plastic.
- 38. The assembly of claim 37, wherein the at least one of 20 the plurality of internal bearing members comprises a projection extending from the bearing member, and the first securing element includes a recess in the shell member for receiving the projection of the bearing member.
- 39. The assembly of claim 20, wherein the bearing mem-20. [A] An assembly having a shell member [for use in an 25 ber includes a lower end and an upper end, and the lower attached a state of the basis o end of the bearing member extends beyond the lower end of the shell member when the bearing member is assembled in the shell member.
 - 40. The assembly of claim 20, wherein the recess is located intermediate the upper end and the lower end of the tapered configuration of the internal securing surface to establish an upper internal securing surface segment and a lower internal securing surface segment, with each of the upper and lower internal securing surface segments having 35 a length between the upper and lower ends of the internal securing surface sufficient to maintain securing effectiveness throughout the internal securing surface.
 - 41. An acetabular cup system, comprising:
 - a plurality of internal bearing members, each comprising: an inner bearing surface for receiving a head member; an outer surface; and
 - a central bearing member axis defined by the outer surface;
 - the internal bearing members having different characteristics, including different axial securement characteristics and different material characteristics, wherein (i) at least one first internal bearing member of the plurality comprises a polyethylene bearing surface and a securement projection on the outer surface, and (ii) at least one second internal bearing member of the plurality comprises a metal or ceramic bearing surface and an outer securement taper extending axially; and
 - a shell member, comprising:

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- an external surface, an internal surface, a central shell axis which coincides with the central bearing member axis when assembled, the external surface having an apex at one end and a peripheral end surface at the opposite end which is the outermost axial extent of the shell member at that opposite end, the internal surface defining an internal cavity;
- at least one securement recess in the internal surface within the cavity of the shell member and spaced axially from the peripheral end surface and not extending to the external surface, the securement recess being compatible with the securement projection of the at least one first internal bearing member of the plurality of internal bearing members to axi-

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ally secure the first internal bearing member within the shell member; and

an internal securement taper on the internal surface within the cavity of the shell member, the internal securement taper extending axially and being compatible with the outer securement taper of the at least one second internal bearing member of the plurality of internal bearing members to axially secure the second internal bearing member within the shell member;

the securement recess and the internal securement 10 taper being juxtaposed with one another and placed at relative locations such that the effectiveness of each of the securement recess and the internal securement taper is maintained while in the presence of the other of the securement recess and the internal $^{\,15}$ securement taper, whereby the first and the second of the internal bearing members each is selectable for effective selective axial securement within the cavity of the shell member to complete the acetabular cup assembly intraoperatively.

42. The system of claim 41, wherein the different characteristics of the plurality of bearing members include different orientations of a bearing socket relative to the cavity of the shell member when the bearing member and the shell member are in seated engagement.

43. The system of claim 41, wherein the different characteristics of the plurality of bearing members include different locations of a bearing socket relative to the cavity of the shell member when the bearing member and the shell member are in seated engagement.

44. The system of claim 41, wherein the securement recess and the securement taper are located adjacent the peripheral end surface of the shell member.

45. The system of claim 41, the bearing member further including at least one bearing anti-rotation element and the 35 shell member further including at least one shell antirotation element compatible with the bearing anti-rotation element to rotationally fix the bearing member within the cavity of the shell member.

46. The system of claim 45, wherein the bearing antirotation element is on the outer surface of the bearing member and the shell anti-rotation element is a recess that extends into the peripheral end surface of the shell member.

47. The system of claim 41, wherein the bearing member extends beyond the peripheral end surface of the shell member when the bearing member is assembled in the shell member.

48. The system of claim 41, wherein the recess extends circumferentially about the cavity of the shell member.

49. An acetabular cup assembly, comprising:

a first internal bearing member, comprising: an inner surface for receiving a head member; an outer surface;

wherein the internal bearing is selected from a plurality of bearing members having different characteristics, 55 including different securement characteristics and different material characteristics, such that the acetabular cup assembly is provided with characteristics corresponding to the characteristics of the selected internal bearing member; and

a shell member, comprising:

an internal cavity;

a first securing element within the cavity of the shell member, the first securing element having a first characteristics of at least one of the plurality of internal bearing members; and

a second securing element within the cavity of the shell member, the second securing element having a second securing structure compatible with the securement characteristics of at least another of the plurality of internal bearing members;

the first and second securing structures being juxtaposed with one another and placed at relative locations such that the effectiveness of each of the first and second securing elements is maintained while in the presence of the other of the first and second securing elements, whereby the one and the another of the internal bearing members each is selectable for effective selective securement within the shell member to complete the acetabular cup assembly interoperatively;

wherein the material of the selected bearing member includes at least one of ceramic, metal, and plastic; and wherein the outer surface of the selected bearing member includes a metal material and the inner surface of the selected bearing member includes ceramic.

50. An acetabular cup assembly, comprising:

a first internal bearing member, comprising: an inner surface for receiving a head member; an outer surface;

wherein the internal bearing is selected from a plurality of bearing members having different characteristics, including different securement characteristics and different material characteristics, such that the acetabular cup assembly is provided with characteristics corresponding to the characteristics of the selected internal bearing member; and

a shell member, comprising:

an internal cavity;

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a first securing element within the cavity of the shell member, the first securing element having a first securing structure compatible with the securement characteristics of at least one of the plurality of internal bearing members; and

a second securing element within the cavity of the shell member, the second securing element having a second securing structure compatible with the securement characteristics of at least another of the plurality of internal bearing members;

the first and second securing structures being juxtaposed with one another and placed at relative locations such that the effectiveness of each of the first and second securing elements is maintained while in the presence of the other of the first and second securing elements, whereby the one and the another of the internal bearing members each is selectable for effective selective securement within the shell member to complete the acetabular cup assembly interoperatively;

wherein the material of the selected bearing member includes at least one of ceramic, metal, and plastic; and wherein the selected bearing member includes a ceramic bearing surface and a metal securing sleeve, wherein the securing sleeve includes a securement characteristic which is compatible with the first or second securing element of the shell member.

51. An assembly having a shell member and an internal 60 bearing member for selective securement within the shell member interoperatively, the internal bearing member being selected from a plurality of bearing members having different characteristics, including different securement characteristics, such that the acetabular cup assembly selecsecuring structure compatible with the securement 65 tively is provided with characteristics corresponding to the characteristics of the selected internal bearing member, the shell member comprising:

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an internal cavity;

a first securing element within the cavity of the shell member, the first securing element having a first securing structure compatible with the securement characteristics of at least one of the plurality of internal bearing members; and

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- a second securing element within the cavity of the shell member, the second securing element having a second securing structure compatible with the securement characteristics of at least another of the plurality of internal bearing members;
- the first and second securing structures being juxtaposed with one another and placed at relative locations such that the effectiveness of each of the first and second securing elements is maintained while in the presence of the other of the first and second securing elements, whereby the one and the another of the internal bearing members each is selectable for effective selective securement within the shell member to complete the acetabular cup assembly interoperatively;
- wherein the different characteristics of the internal bearing members include different materials;
- wherein the bearing member includes an external securing surface, and the second securing element includes 25
 an internal securing surface, the external securing surface and the internal securing surface having complementary tapered configurations for interlocking in
 response to seating engagement of the complementary
 tapered configurations; and 30
- wherein the bearing member includes a ceramic bearing surface and a metal securing sleeve, wherein the securing sleeve includes the tapered configuration complementary with the internal securing surface of the shell member.
- 52. The shell member of claim 51, wherein the first securing element includes a recess in the internal cavity of the shell member and a first bearing member is polyethylene and further includes a projection extending from the outer surface for reception within the recess.
- 53. A method for implanting an acetabular cup, comprising the steps of:
 - providing an external shell member with an internal cavity and a central shell axis, the shell member having at least one securement recess within the cavity of the shell member and an internal securement taper within the cavity of the shell member and extending axially, wherein the securement recess and the internal securement taper are in juxtaposition with one another and

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placed at relative locations such that the effectiveness of each of the securement recess and the internal securement taper is maintained while in the presence of the other of the securement recess and the internal securement taper;

providing an internal bearing member for axial securement within the cavity intraoperatively and having a central bearing axis, the central shell axis coinciding with the central bearing axis when the shell member and bearing member are assembled, the internal bearing member being selected from a plurality of bearing members having different characteristics, including different material characteristics and axial securement characteristics, wherein (i) at least one first internal bearing member of the plurality comprises a polyethylene bearing surface and a securement projection on the outer surface, and (ii) at least one second internal bearing member of the plurality comprises a metal or ceramic bearing surface and an outer securement taper extending axially, wherein the securement recess is compatible with the securement projection of the first internal bearing member of the plurality of internal bearing members to axially secure the first internal bearing member within the shell member, and the internal securement taper is compatible with the outer securement taper of the second internal bearing member of the plurality of internal bearing members to axially secure the second internal bearing member with the shell;

selecting the first internal bearing member or the second internal bearing member; and

securing the selected internal bearing member within the shell member by engaging the selected internal bearing member with the corresponding securement recess or securement taper for axial securement of the selected bearing member within the shell member and completion of the acetabular cup assembly intraoperatively.

54. The method in claim 53, wherein at least one bearing members among the plurality of bearing members further includes at least one bearing anti-rotation element and the shell member further includes at least one shell anti-rotation element configured to engage the bearing anti-rotation element of a bearing member to rotationally fix the bearing member within the cavity of the shell member.

55. The method of claim 54, wherein the at least one bearing anti-rotation element includes a protrusion, and the shell anti-rotation element includes a recess.

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