marked copy of amended claims, 080814

Claims

1. An ostomy device ~~characterised in that it comprises~~comprising:

an implant arranged, in use, to be located inside the body of a person near the site of a stoma,

discharge device~~means~~ having a tubular member and at least one of an annular disc and a flange member, and

the tubular member has a first end and a second end with a respective opening at each end, the first end is insertable into the intestine of the person via the stoma such that ~~arranged, in use, to provide means~~the tubular member is positionable in the intestine of the person ~~for~~to discharge fluid and materials from inside the intestine, from the opening at the first end of the tubular member to the opening at the second end of the tubular member~~to exit~~, to the exterior of the body of the person, the intestine used to form the stoma, and

the at least one of the annular disc and the flange member is provided at the second end of the tubular member such that the tubular member extends from the at least one of the annular disc and the flange member on a first side of the at least one of the annular disc and the flange member, and the at least one of the annular disc and the flange member is arranged to bear against the exterior of the body of the person near the site of the stoma when the tubular member is positioned in the intestine of the person,

a retention member~~means~~ which, in use, is~~to be~~ operatively associated with the implant, the implant and the retention member being magnetically attracted such that the discharge device is removably retained ~~the discharge means~~ at the site of the stoma by magnetic force, and

a user-operable discharge control valve ~~means~~ to open and close to thereby control the discharge of the fluid and materials to the exterior of the body of the person such that fluid and material are dischargeable from the tubular member to the exterior of the body of the person when the user-operable discharge control valve is in an open condition and fluid and material are not dischargeable from the tubular member to the exterior of the body of the person when the user-operable discharge control valve is in a closed condition,

wherein the at least one of the annular disc and the flange member is provided with a recess at the first side of the at least one of the annular disc and the flange member and adjacent to the second end of the tubular member such that the recess extends around

the second end of the tubular member in a circular manner and is aligned over the stoma when the tubular member is positioned in the intestine of the person, and

wherein an annular inflatable bladder is positioned in the recess adjacent to the second end of the tubular member to closely contact the stoma and to shield the stoma and seal around the site of the stoma at the exterior of the body of the person when the tubular member is positioned in the intestine of the person, and

wherein the user-operable discharge control valve is located adjacent to the second end of the tubular member to discharge fluid and material from the opening at the second end of the tubular member and through the user-operable discharge control valve when the user-operable discharge control valve is in the open condition, to exit the ostomy device to the exterior of the body of the person when the tubular member is positioned in the intestine of the person.

~~2. An ostomy device characterised in that it comprises~~

~~discharge means arranged, in use, to provide means for fluid and materials to exit to the exterior of the body of the person,~~

~~means, in use, to removably retain the discharge means at the site of a stoma, and~~

~~valve means to control the discharge of the fluid and materials to the exterior of the body of the person.~~

~~3. An ostomy device according to claim 2, characterised in that it further comprises an implant arranged, in use, to be located inside the body of a person near the site of a stoma,~~

~~4. An ostomy device according to any one of the preceding claims, characterised in that, in use, the discharge means is removably retained at the site of the stoma by magnetic force.~~

~~5. An ostomy device according to any one of the preceding claims, characterised in that the means, in use, to be operatively associated with the implant and removably retain the discharge means at the site of the stoma comprises retention means.~~

~~6. An ostomy device according to claim 5, characterised in that the implant and the retention means are magnetically attracted.~~

~~7. An ostomy device according to claim 5 or 6, characterised in that the retention means comprises a retention member.~~

8. An ostomy device according to claim 7, characterised in that the retention member is substantially in the form of a ring or an annular disc.

9. An ostomy device according to any one of claims 5 to 8, characterised in that the retention means comprises at least a portion of the discharge means.

10. An ostomy device according to claim 9, characterised in that the portion of the discharge means is an annular disc or flange member.

211. An ostomy device according to any one of the preceding claims 1, whereincharacterised in that the implant is flexible.

12. An ostomy device according to any one of the preceding claims, characterised in that the implant is substantially in the form of an annular disc.

313. An ostomy device according to any one of the preceding claims1 or 2, whereincharacterised in that the discharge means comprises a tubular member the at least one of the annular disc and the flange member has an annular plate portion that surrounds the recess and is arranged, in use, to bear against the exterior of the body of the person near the site of the stoma when the tubular member is positioned in the intestine of the person, and a portion of the tubular member is arranged, in use, to be located in the intestine that is used to form the stoma.

14. An ostomy device according to any one of the preceding claims, characterised in that the discharge means comprises an annular disc, or flange member, at substantially one end of the tubular member and is arranged, in use, to bear against the body of the person near the site of the stoma when the tubular member is located in the intestine of the person.

15. An ostomy device according to any one of the preceding claims, characterised in that the valve means is user operable such that a user is able to open and close the valve means.

416. An ostomy device according to any one of the preceding claims 15, whereincharacterised in that the discharge devicemeans comprises a first portion and a second portion detachably connected together, the first portion having the tubular member and the second portion having the user-operable discharge control valve means.

517. An ostomy device according to any one of the preceding claims 15 or 16, whereincharacterised in that the user-operable discharge control valve means comprises

a housing,

a sealing member mounted in the housing and movable from a first, closed position, in which the user-operable discharge control valve ~~means~~ is in a closed condition and does not allow fluid and material to pass through the user-operable discharge control valve, to a second, open position in which the user-operable discharge control valve ~~means~~ is in an open condition to allow fluid and material to pass through the discharge device, and

a handle~~means~~ operable to move the sealing member between the first and second positions to open and close the user-operable discharge control valve ~~means~~,

wherein the ~~means to move the sealing member~~handle is operable to open and close the user-operable discharge control valve ~~means~~, in use, to control the discharge of the fluid and materials to the exterior of the body of the person.

~~18. An ostomy device according to claim 17, characterised in that the housing of the valve means is arranged to be in fluid communication with the tubular member.~~

619. An ostomy device according to claim 5~~17 or 18~~, ~~characterised in that the~~wherein the user-operable discharge control valve ~~means~~ further comprises a valve seat and the sealing member has a ~~substantially~~ convex surface and a ~~substantially~~ concave surface on respective opposed faces thereof, wherein the convex surface is in contact with the valve seat in the closed condition of the user-operable discharge control valve ~~means~~ and the convex surface is positioned adjacent an inner surface of the housing and is no longer in contact with the valve seat in the open condition of the user-operable discharge control valve ~~means~~.

~~20. An ostomy device according to claim 19, characterised in that the convex surface is provided at the upstream side of the direction of fluid flow through the discharge means.~~

~~21. An ostomy device according to any one of claims 17 to 20, characterised in that the sealing member is rotatably mounted in the housing via a shaft extending from the sealing member such that the sealing member is moveable between the first and second positions to open and close the valve means.~~

722. An ostomy device according to ~~any one of~~ claims 5 or 6~~17 to 21~~, ~~wherein~~characterised in that the housing is provided with a neck having a diameter less than the diameter of the portion of the housing that accommodates the sealing member and the valve seat is provided between the neck and the portion of the housing that accommodates the sealing member.

~~23. An ostomy device according to any one of claims 17 to 22, characterised in that the means to move the sealing member comprises a handle which is operable by a user to open and close the valve means.~~

824. An ostomy device according to any one of the preceding claims ~~17 to 23~~, ~~characterised in that it~~ further comprisinges a pressure relief valve ~~provided~~ to release gas pressure from inside the tubular member ~~at the upstream side of the direction of fluid flow through the discharge means~~, as required, when the user-operable discharge control valve ~~means~~ is in the closed condition, and vent the gas from the pressure relief valve.

925. An ostomy device according to claim 824, ~~characterised in that~~wherein the pressure relief valve comprises a tube and a closable hole is provided in the sealing member such that a tip of the tube is moveable through the closable hole in the sealing member to allow gas from inside the tubular member to exit and vent through the tube, and the tube is moveable to retract the tip and close the closable hole to return the pressure relief valve to the closed condition.

1026. An ostomy device according to claim 925, ~~wherein~~characterised in that the pressure relief valve further comprises a spring to bias the tube such that the tip is retracted in the closed condition of the pressure relief valve.

1127. An ostomy device according to any one of claims ~~24~~8 to ~~26~~10, ~~characterised in that~~further comprising a removable cap ~~is provided~~ to close an end of the housing and ~~the cap~~ accommodates the pressure relief valve.

~~28. An ostomy device according to claim 27, characterised in that the cap is removable.~~

~~29. An ostomy device according to any one of the preceding claims, characterised in that it further comprises securing means, in use, to secure the discharge means at the site of the stoma.~~

1230. An ostomy device according to any one of claims 4 to 1129 ~~when appended to claim 16~~, ~~characterised in that~~further comprising securing means, in use, to secure the discharge device at the site of the stoma, and the securing means comprises a case ~~means~~ arranged, in use, to be provided between the retention membermeans and the site of the stoma ~~substantially~~and the case covers the second portion of the discharge ~~means~~device.

1331. An ostomy device according to claim 1230, ~~characterised in that~~wherein the retention membermeans is arranged to be removably mounted to the case ~~means~~.

1432. A fluid flow control valve for a medical device, ~~characterised in that it~~ comprisinges

a housing,

a sealing member mounted in the housing and rotatable~~movable~~ from a first, closed position, in which the fluid flow control valve is in a closed condition, to a second, open

position in which the fluid flow control valve is in an open condition to allow fluid and material to pass through the fluid flow control valve, and

a handlemeans operable to rotatemove the sealing member between the first and second positions to close and open and close the fluid flow control valve, and

a pressure relief valve to release gas pressure in the closed condition of the fluid flow control valve and vent the gas from the pressure relief valve,

wherein the pressure relief valve comprises a tube and a closable hole is provided in the sealing member such that a tip of the tube is moveable through the closable hole in the sealing member to allow gas to exit and vent through the tube, and the tube is moveable to retract the tip and close the closable hole to return the pressure relief valve to the closed condition, and

wherein the fluid flow control valve is arranged to be provided in a medical device and the handlemeans to move the sealing member is operable to rotate the sealing member to open and close the fluid flow control valve to control the passageflow of fluid and materials through the medical device fluid flow control valve when the medical device is in use with the body of a person.

~~33. A fluid flow control valve according to claim 32, characterised in that the housing of the fluid flow control valve is arranged to be in fluid communication with a tubular member of the medical device.~~

1534. A fluid flow control valve according to claim 1432 or 33, ~~characterised in that it~~ further comprisinges a valve seat and the sealing member has a ~~substantially~~ convex surface and a ~~substantially~~ concave surface on respective opposed faces thereof, wherein the convex surface is in contact with the valve seat in the closed condition of the fluid flow control valve and the convex surface is positioned adjacent an inner surface of the housing and is no longer in contact with the valve seat in the open condition of the fluid flow control valve.

1635. A fluid flow control valve according to claim 1534, whereincharacterised in that the convex surface is provided at the upstreamone side of the sealing member adjacent an openingthe direction of fluid flow through the medical device.

~~36. A fluid flow control valve according to any one of claims 32 to 35, characterised in that the sealing member is rotatably mounted in the housing via a shaft extending from the sealing member such that the sealing member is moveable between the first and second positions to open and close the fluid flow control valve.~~

1737. A fluid flow control valve according to ~~any one of~~ claims 15 or 1632 to ~~36~~, whereincharacterised ~~in that~~ the housing is provided with a neck having a diameter less than the diameter of the portion of the housing that accommodates the sealing member and the valve seat is provided between the neck and the portion of the housing that accommodates the sealing member.

~~38. A fluid flow control valve according to any one of claims 32 to 37, characterised in that the means to move the sealing member comprises a handle which is operable by a user to open and close the fluid flow control valve.~~

~~39. A fluid flow control valve according to any one of claims 32 to 38, characterised in that a pressure relief valve is provided to release gas pressure at the upstream side of the direction of fluid and materials flow through the medical device, as required, when the fluid flow control valve is in the closed condition.~~

~~40. A fluid flow control valve according to claim 39, characterised in that the pressure relief valve comprises a tube and a closable hole is provided in the sealing member such that a tip of the tube is moveable through the closable hole in the sealing member to allow gas to exit through the tube and the tube is moveable to retract the tip and close the closable hole.~~

1841. A fluid flow control valve according to any one of claims 14 to 1740, whereincharacterised ~~in that~~ the pressure relief valve further comprises a spring to bias the tube such that the tip is retracted in the closed condition of the pressure relief valve.

1942. A fluid flow control valve according to any one of claims 3914 to 4118, ~~characterised in that~~wherein a removable cap is provided to close an end of the housing and the removable cap accommodates the pressure relief valve.

~~43. A fluid flow control valve according to claim 42, characterised in that the cap is removable.~~

~~44. A fluid flow control valve according to any one of claims 32 to 43, characterised in that the medical device is an ostomy device.~~

~~45. A medical device characterised in that it is provided with a fluid flow control device according to any one of claims 32 to 44.~~

2046. An ostomy insertion device comprising

a tubular member having a first end and a second end with a respective opening at each said end, the first end arranged, in use, to be inserted ~~the tubular member~~ into the body of a person to position the tubular member in the body of the person to discharge fluid

and material from inside the body of the person, from the opening at the first end of the tubular member to the opening at the second end of the tubular member, to the exterior of the body of a person,

at least one of an annular disc and a flange membermeans is provided at the region of a second end of the tubular member spaced from the first end of the tubular membersuch that the tubular member extends from the at least one of the annular disc and the flange member on a first side of the at least one of the annular disc and the flange member, and the at least one of the annular disc and the flange member is arranged to bear against the exterior of the body of the person when the tubular member is positioned in the body of the person,

the at least one of the annular disc and the flange membermeans is provided with a recess and an annular plate portion provided around the recess, thereinthe recess is located at the first side of the at least one of the annular disc and the flange member and adjacent to the second end of the tubular member such that the recess extends around the second end of the tubular member in a circular manner, and an annular plate portion adjacent the recess,

the recess having an annular inflatable bladder provided therein, adjacent to the second end of the tubular member,

wherein, in use, the recess is located substantiallysuch that it is aligned over a stoma of the person when the tubular member is positioned in the body of the person, and the annular plate portion bears against the body of the person around the site of the stoma, and the annular inflatable bladder being inflatable such that inflating the annular inflatable bladder closely contacts the annular inflatable bladder with the stoma to shield the stoma and creates a seal around the site of the stoma at the exterior of the body of the person when the tubular member is positioned in the body of the person.

47. An ostomy insertion device according to claim 2346, characterised in that it further comprises a bladder provided in the recess such that, in use, the bladder is inflatable to seal around the site of the stoma.

2148. An ostomy insertion device according to claim 2446, characterised in thatwherein an inlet is provided in the at least one of the annular disc and the flange membermeans, in use, for injecting air into the annular inflatable bladder to suitably inflate the annular inflatable bladder.

~~49. An ostomy insertion device according to any one of claims 46 to 48, characterised in that the tubular member is provided with stiffening means to provide the tubular member with a degree of rigidity.~~

22. An ostomy device according to any one of claims 1 to 13, wherein the retention member comprises a ring or annular disc.

23. An ostomy device according to any one of claims 1 to 13, or claim 22, wherein the magnetic force between the implant and the retention member is adjustable by the user by adjusting the distance between the implant and the retention member.

24. An ostomy device according to claim 23, further comprising one or more spacers to adjust the distance between the implant and the retention member.

25. An ostomy device according to any one of claims 1 to 13, or claims 22 to 24, wherein an inlet is provided in at least one of the annular disc and the flange member, in use, for injecting air into the annular inflatable bladder to inflate the annular inflatable bladder.

26. An ostomy device according to any one of claims 1 to 13, or claims 22 to 25, wherein the retention member includes the at least one of the annular disc and the flange member of the discharge device.

27. An ostomy device according to any one of claims 1 to 13, or claims 22 to 26, wherein the user-operable discharge control valve is operable without engaging the tubular member.

28. An ostomy device according to any one of claims 1 to 13, or claims 22 to 27, wherein the user-operable discharge control valve is operable independently of the operative association of the retention member and the implant.