Annex A: Amended claims of UK Patent

1. A cover for a ~~medical scoping device~~colonoscope shaft, the cover comprising an elongate tubular member and being arranged for application over the ~~medical scoping device~~colonoscope shaft with the cover extending along at least a part of the length of a distal end of the shaft, the tubular member comprising an inner surface at least a part of which grips the shaft and holds the cover in place and an outer surface comprising a plurality of spaced projecting elements having a tip and a base that are moveable between a resting position to a position wherein the tip of the projecting element is substantially parallel to a longitudinal axis of the ~~medical scoping device~~colonoscope and to a position that is at an angle approximately perpendicular to the longitudinal axis of the ~~medical scoping device~~colonoscope shaft so that the said projecting elements are fanned out to contact with and provide support for and to dilate a lumen wall of a ~~body passage~~ colon into which the ~~medical scoping device~~colonoscope has been inserted, wherein the projecting elements are positioned in one or more rings running circumferentially around the cover, and wherein projecting elements in a distal ring are adapted to flare outwards on withdrawal from the colon to keep the instrument tip in the central part of the colon as the instrument moves backwards, and to evert colonic folds enabling their proximal surfaces to be viewed.

2. A cover according to claim 1 wherein the projecting elements are in the form of bristles, spikes, spines, fins, wedges, paddles or cones and are arranged to extend outwardly and away from the outer surface of the elongate tubular member.

3. A cover according to either preceding claim wherein the projecting elements are cylindrical, conical or tapered.

4. A cover according to any preceding claim wherein the projecting elements are formed integrally with the outer surface of the elongate tubular member or are attached or moulded thereto or are moulded to cross members.

5. A cover according to any preceding claim wherein the at least a part of the inner surface of the tubular member which grips the shaft and holds the cover in place is at the proximal and distal end regions of the tubular member.

6. A cover according to any one of claims 1 to 4 wherein the at least a part of the inner surface of the tubular member which grips the shaft and holds the cover in place is over the entire inner surface of the tubular member.

7. A cover according to any preceding claim~~s~~ wherein the elongate tubular member is ~~either~~ a contiguous tubular member.

8. A cover according to any one of claims 1 to 6 wherein the elongate tubular member is provided with slits, ridges or gaps running in a longitudinal direction and parallel with the longitudinal axis of the ~~medical scoping device~~colonoscope.

9. A cover according to ~~any one of~~ claim 8 wherein the number of slits or gaps is directly proportional to the number of projecting elements and wherein the projecting elements ~~being~~ are positioned in the slits or gaps between solid parts of the tubular member.

10. A cover according to any preceding claim wherein the projecting elements are between 2 to 20 mm in length from base to tip.

11. A cover according to claim 10 wherein the projecting elements are between 4 to 14 mm in length from base to tip.

12. A cover according to any preceding claim wherein the length of the projecting elements are marginally shorter at either or both the distal and proximal ends of the cover.

13. A cover according to claim 12 wherein the projecting elements that are of a longer length are more flexible and are constructed of a softer material than projecting elements of a shorter length.

14. A cover according to any preceding claim wherein the projecting elements are in the form of hairs or bristles and the diameter of the projecting element is between 0.5 to 3.0 mm.

15. A cover according to any preceding claim wherein the elongate tubular member and/or the projecting elements are constructed of a biocompatible f~~ee~~lexible material selected from the group comprising polymers, plastics, elastomers, silicon and silicon elastomeric materials and rubbers.

16. A cover according to any preceding claim wherein the projecting elements in a resting position are acutely angled with respect to the central longitudinal axis of the ~~medical scoping device~~colonoscope shaft at an angle of between 35° to 85°.

17. A cover according to claim 16 wherein the angle is about 75°.

18. A cover according to any preceding claim wherein the projecting elements are positioned in rings running circumferentially around the cover and along the length of the cover.

19. A cover according to claim 18 wherein there are between 1 to 20 rings.

20. A cover according to either claim 18 or 19 wherein each ring comprises between 4 to 16 projecting elements.

21. A cover according to any one of claims 18 to 20 wherein the rings of the projecting elements are spaced apart by a distance of between 2.5 cm to 0.5 cm.

22. A cover according to any one of claims 18 to 21 wherein a first or distal ring of projecting elements is positioned between 1 mm to 20 mm from the distal end tip of the cover.

23. A cover according to any one of claims 18 to 22 wherein the last or proximal ring of projecting elements is positioned between 1 cm and 5 cm from the proximal end of the cover.

24. A cover according to any one of claims 1 to 11 and 14 to 23 wherein the projecting elements are all of equal diameter, length, number in ring and evenly spaced apart rows of rings.

25. A cover according to any one of claims 1 to 23 wherein the projecting elements are a mixture of different sizes and number.

26. A cover according to any preceding claim wherein the projecting elements are either straight or curved.

27. A cover according to any preceding claim further comprising an over cuff.

28. A cover according to claim 27 when dependent on claim 8 wherein the over cuff is placed over the cover and is provided with slits or gaps of approximately the same dimensions as that of the cover so that the projecting elements are able to protrude through the aligned slits or gaps.

29. A cover according to either claim 27 or 28 wherein the over cuff is of the same or approximately the same length as the cover.

30. A cover according to any one of claims 27 to 29 wherein the over cuff is constructed of a polycarbonate or a plastics material.

31. A cover according to any one of claims 27 to 30 wherein the projecting elements ~~in~~, on insertion into a body orifice, fall below an outer surface of the over cuff.

32. A cover according to any preceding claim wherein the cover is provided with one or more apertures positioned at the proximal end of the cover.

33. A cover according to any preceding claim further comprising a viewing means at the distal end which is optionally in the form of an open ended transparent plastic or Perspex® cap.

34. A cover according to any preceding claim wherein the outer surface of the cover is coated with a lubricating agent selected from the group comprising a hydrogel polymer, poly(2-hydoxyethyl methacrylate) (PHEMA), ComfortCoat®, silicone, glycerine, olive oil, castor oil, chlorotrifluoroethylene (CTFE oil) and polyphenyl ethers or a mixture thereof, optionally wherein the cover is coated only at its distal most part and on an outer surface of the projecting elements of the distal most part.

35. A cover according to any preceding claim wherein the cover is detachable or removable from the ~~medical scoping device~~colonoscope.

36. A cover according to any preceding claim wherein the projecting elements are moveable beyond the angle approximately perpendicular to the longitudinal axis of the ~~medical scoping device~~colonoscope shaft and flick over at a critical point of maximum inflexion so that the tips point towards the distal end of the ~~scoping medical device~~colonoscope.

37. A cover according to any one of claims 1 to 36 further including a projecting elements closure means which can be drawn from a distal to a proximal end to cover and flatten the projecting elements from a position that is approximately perpendicular to the longitudinal axis of the ~~medical scoping device~~colonoscope shaft to a position wherein the projecting elements are approximately parallel to the said axis.

38. A ~~medical scoping device~~colonoscope comprising the cover according to any one of claims 1 to 37 releasably attached thereto and covering at least a part of its shaft at its distal end.

39. ~~A medical scoping device according to claim 38 wherein the device is an endoscope or an enteroscope~~A colonoscope comprising the cover according to any one of claims 1 to 37 releasably attached thereto and covering at least a part of its shaft at its distal end for improving endoscopic visualisation, wherein when advancing the covered colonoscope into the patient's bowel or small intestine and the distal end encounters a bend or loop in the patient's bowel or small intestine, the colonoscope is withdrawn towards its proximal end causing the projecting elements to splay or fan out and to dilate the lumen of the colon whilst holding the colonoscope in position, wherein the projecting elements open a lumen and evert thereby flattening colonic folds for inspection during withdrawal whereby visualisation is further enhanced as colonic folds revert to their normal anatomical position permitting light from the colonoscope to play across the mucosa, thus enabling careful visualisation of the surface of the mucosa that was hitherto hidden or difficult to view.

40. Use of a cover according to any one of claims 1 to 37 or a ~~medical scoping device~~colonoscope according to either claim 38 or 39, in locating the presence of abnormal tissue or confirming the presence of normal tissue in a body cavity.

41. Use according to claim 40 wherein the body cavity is the gastro-intestinal tract.

42. A kit comprising at least one cover according to any one of claims 1 to 37 and optionally further comprising a ~~medical scoping device~~colonoscope.

43. Use of a ~~medical scoping device~~colonoscope according to ~~either~~ claim 38 ~~or 39~~ in avoiding looping during inspection of an individual's ~~bowel or small intestine~~colon, wherein when advancing the covered ~~medical scoping device~~colonoscope into the patient's ~~bowel or small intestine~~colon and the distal end encounters a bend or loop in the patient's ~~bowel or small intestine~~colon, the ~~medical scoping device~~colonoscope is withdrawn towards its

proximal end causing the projecting elements to splay or fan out and to dilate the lumen of the ~~bowel or small intestine~~colon whilst holding the ~~medical scoping device~~colonoscope in position, if necessary air is then drawn out causing the ~~body passage~~colon walls to collapse around and about the projecting elements thereby drawing the ~~body passage~~colon wall into spaces between the projecting elements so said projecting elements engage with and grip the ~~body passage~~colon wall, the ~~medical scoping device~~colonoscope is then further withdrawn towards the proximal end causing it to straighten and the ~~body passage~~colon wall to concertina along the shaft of the colonoscope proximal to the bend or loop whilst the lumen ahead of the distal end opens up, the ~~medical scoping device~~colonoscope is then advanced towards its distal end and the bend or loop is navigated.

44. Use of a ~~medical scoping device~~colonoscope according to ~~either~~ claim 38 ~~or 39~~ in improving endoscopic visulaisation, wherein when advancing the covered ~~medical scoping device~~colonoscope into the patient's ~~bowel or small intestine~~colon and the distal end encounters a bend or loop in the patient's ~~bowel or small intestine~~colon, the ~~medical scoping device~~colonoscope is withdrawn towards its proximal end causing the projecting elements to splay or fan out and to dilate the lumen of the ~~bowel or small intestine~~colon whilst holding the ~~medical scoping device~~colonoscope in position, wherein the projecting elements open a lumen and evert thereby flattening colonic folds for inspection during withdrawal whereby visualisation is further enhanced as colonic folds revert to their normal anatomical position permitting light from the ~~medical scoping device~~colonoscope to play across the mucosa, thus enabling careful visualisation of the surface of the mucosa that was hitherto hidden or difficult to view.

45. Use of a ~~medical scoping device~~colonoscope according to ~~either~~ claim 38 ~~or 39~~ in improving and maintaining tip position during a medical scoping procedure, wherein when advancing the ~~medical scoping device~~colonoscope into the patient's ~~bowel or small intestine~~colon and the distal end encounters a bend or loop in the patient's ~~bowel or small intestine~~colon, the ~~medical scoping device~~colonoscope is withdrawn towards its proximal end causing the projecting elements to splay or fan out and to dilate the lumen of the ~~bowel or small intestine~~colon whilst holding the ~~medical scoping device~~colonoscope in position, wherein the projecting elements maintain the ~~medical scoping device~~colonoscope tip in a central part of the ~~bowel~~ colon lumen as the device moves in a proximal direction thereby holding the mucosa to prevent the tip from flipping backwards so as to maintain position during scoping and thus maintaining tip position.