

Claims

1. An airway management device, comprising:
a body (6) including an external shell moulded from a polypropylene copolymer (PP) blended with a thermoplastic elastomer (TPE) of styrene-ethylene/butylene-styrene (SEBS),
5 the external shell extending from a proximal opening to a distal tip of the body (6), the external shell having a curved portion (35) and a linear portion (37).
2. The airway management device of claim 1, further including an intermediate strip (38) moulded from a polypropylene copolymer (PP) attached to said external shell
10 intermediate to the curved portion (35) and the linear portion (37).
3. The airway management device of claim 1, further including a first over-mould of SEBS comprising a posterior contour (35) and a distal contour (34) on the external shell.
4. The airway management device of claim 3, wherein the first over-mould comprises a
15 distal perimeter (26) defining a first opposed edge of an over-moulded cuff membrane (25) continuing tangentially from said perimeter (26) as a toroidal curve whose end point is in spaced relation and normal to the first opposed edge, the end points defining an open posterior (27) perimeter or second opposed edge and a linear portion (37) over-moulding a proximal end such that said curved portion (35) and the linear portion (37) are joined as a
20 single moulding by planar sealing voids (36) to first and second sides of an intermediate strip (38).
5. The airway management device of claim 4, further including a second over-mould of SEBS closing said open length of membrane (27), forming an inflatable cuff.
6. The airway management device of claim 5, wherein the posterior contour (35) of the
25 body (6) is adapted to be located within a hypopharynx and a distal end (2) is adapted to be located within an upper oesophageal sphincter creating an oesophageal seal, wherein immediately superior to a distal opening (20), and the anterior compound curvature (33) of the external shell is an internal posterior surface of a passage or gastric drain tube (24) reducing the bulk of the distal tip (2).
- 30 7. The airway management device of claim 6, further including a surrounding contour (34) over-moulding said anterior compound curvature (33) of the external shell and which is adapted for locating and pressing against the hypopharynx, the distal to proximal full length

configuration of the external shell providing resistance against displacement of the distal opening (20) superiorly from increasing oesophageal pressure (70).

8. The airway management device of claim 6, wherein the drain tube (24) and a drain tube distal opening (20) are integral with a distal posterior contour (34) and where the said
5 drain tube (24) is not surrounded by an annular volume of said inflatable cuff.

9. The airway management device of claim 6, further including a closed tubular section (30) forming a chamber (32) providing a space for a distal portion of the inflatable cuff with a posterior displacement when inflated.

10. The airway management device of claim 6, wherein through any horizontal cross
10 section of said inflatable cuff, first and second edges (27), for at least the length of the distal portion of the gastric drain tube (31), are maintained parallel to a median plane (10) of the curved portion (35) such that the width between the first and second edges (27) after second over-moulding is equal to an outer diameter of the distal drain tube (31).

11. The airway management device of claim 10, wherein a curvature of the inflatable cuff
15 membrane (25) between said first (26) and second (27) opposed edges is a single contiguous curve of uniform durometer hardness, sealing posteriorly against a hypopharynx and anteriorly against a laryngeal inlet without adhesive joint.

12. A method of forming the airway management device according to claim 1,
20 comprising:
providing a removable connector/adaptor (39) on the linear portion to reduce a length from a proximal opening (42) of the body (6) through to a trachea (68), thereby providing additional depth of insertion of a distal tip (63) of an endotracheal tube.

13. A method of forming the airway management device according to claim 1,
25 comprising:
providing a finger stopper (60) creating a fixed position to rest a thumb during insertion, to grip a proximal end (37) when removing the device after intubation and to act as a depth indicator, with reference to teeth, when the device is in situ.

30 14. A method of forming an airway management device, comprising:
providing a body (6) comprising polypropylene copolymer (PP) and thermoplastic elastomer (TPE) of styrene-ethylene/butylene-styrene (SEBS), including an external shell

moulded from a majority PP copolymer blended with SEBS extending from a proximal opening to a distal tip of the body (6).

15. The method of claim 14, further including the step of:

5 attaching an intermediate strip (38) moulded from polypropylene copolymer to said external shell intermediate to a curved portion (35) and a linear portion (37) of the body (6).

16. The method of claim 15, further including the step of:

10 providing a first over-mould of SEBS comprising an initial posterior contour (35) and distal contour (34) over-moulded onto the external shell, whose distal perimeter (26) defines a first opposed edge of an over-moulded cuff membrane (25) that continues tangentially from said distal perimeter (26) as a toroidal curve whose end point is in spaced relation and normal to the first opposed edge, the end points collectively defining an open posterior (27) perimeter or second opposed edge and a linear portion over-moulding the proximal end (37) 15 such that said curved portion (35) and the linear portion (37) are joined as a single moulding by planar sealing voids (36) to lateral sides of said intermediate strip (38).

17. The method of claim 16, further including the step of:

20 providing a second over-mould of SEBS closing said membrane (25), forming an inflatable cuff and completing the said body (6).

18. A method of forming an object, comprising:

25 injection moulding a first portion of the object over a first core associated with a fixture;
after the injection moulding of the first portion, moving a second core associated with the fixture to a deployed position; and
injection moulding a second portion of the object over the second core and the first portion.

30 19. The method of claim 18, wherein the step of moving the second core associated with the fixture to the deployed position comprises rotating the second core relative to the fixture.

20. The method of claim 18, further including the steps of:

35 attaching a pre-formed part to the object;
placing one or more removable cores into the object; and
placing one or more removable cores inside the injection mould prior to moulding a second portion of the object; and

over-moulding a membrane as part of the second portion of the object.

21. The method of claim 20, further including the step of injection moulding a third portion closing and sealing the membrane to form an inflatable portion of the object.

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22. The method of claim 21, further including the step of removing the removable cores from the membrane of the object prior to injection moulding the third portion.

23. The method of claim 21, wherein:

10 the step of injection moulding the first portion is completed in a first mould including the fixture; and

the step of injection moulding the second portion is completed in a second mould including the fixture; and

15 the step of injection moulding the third portion to close and seal the membrane in a third mould including the fixture.

24. The method of claim 18, further including the step of transferring the fixture from a first mould to a second mould between the steps of injection moulding the first portion and second portion of the object.

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25. The method of claim 18, wherein the step of injection moulding the first portion of the object over the first core associated with the fixture comprises forming the external shell of the object.

25 26. The method of claim 18, further including the steps of:
moving the first core to release a proximal end of the object; and
removing the object from the second core of the fixture.

27. The method of claim 18, further including the step of:
30 providing a body comprising polypropylene copolymer (PP) and thermoplastic elastomer (TPE) of styrene-ethylene/butylene-styrene (SEBS), and
wherein the first portion comprises an external shell moulded during the first injection moulding step from a majority PP copolymer blended with SEBS extending from a proximal opening to a distal tip of the body.

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28. The method of any of claims 18-27, wherein the object comprises an airway management device.

29. An apparatus for forming an injection moulded object, comprising:
a reconfigurable fixture including a first movable core over which a first portion of the injection moulded object is formed and a second movable core over which a second portion
5 of the injection moulded object is formed.
30. The apparatus of claim 29, wherein the first movable core is adapted for rotating relative to the fixture.
- 10 31. The apparatus of claim 29 or 30, wherein the second movable core is adapted for rotating relative to the fixture.
32. The apparatus of any of claims 29-31, further including a first removable core adapted for being removably attached to the fixture.
- 15 33. The apparatus of claim 32, wherein the first removable core comprises a connector for connecting to the fixture.
34. The apparatus of claim 32, wherein the first removable core comprises a handle.
- 20 35. The apparatus of claim 31, wherein the fixture comprises a spring for maintaining the second movable core in a deployed position.
36. A method of manufacturing an airway management device, comprising:
25 providing a tubular body having a linear portion and a curved portion, the tubular body including a plurality of supports adjacent to a posterior channel;
providing an intermediate strip in engagement with the plurality of supports and overlying the posterior channel; and
over-moulding material onto the intermediate strip.
- 30 37. The method of claim 36, further comprising the steps of:
injection moulding a first portion of the body of the airway management device over a first core associated with a fixture;
after the injection moulding of the first portion, moving a second core associated with
35 the fixture to a deployed position; and
injection moulding a second portion of the body over the second core and the first portion of the body.

38. The method of claim 37, wherein the step of moving the second core associated with the fixture to the deployed position comprises rotating the second core relative to the fixture.

5 39. The method of claim 37, further including the steps of:
placing one or more removable cores in the tubular body; and
placing one or more removable cores inside the second injection mould; and
over-moulding the removable cores with a membrane as part of the second portion of
the body.

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40. The method of claim 39, further including the steps of:
removing said removable cores from close proximity to the first core and second core
leaving an open membrane; and
over-moulding the second portion with a third portion closing and sealing the
15 membrane to form an inflatable cuff on the tubular body.

41. The method of claim 40, further including the step of moving the first core and
removing the removable cores to release the tubular body.

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42. The method of any of claims 39-41, further including the steps of:
placing a first material in one or more voids adjacent the intermediate strip with a first
material; and
melting a portion of the intermediate strip comprising a second material so as to
diffuse the first material into the second material.

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43. A method of forming an object, comprising:
in a first injection mould, injection moulding a first portion of the object over a first
core associated with a fixture;
placing the fixture in a second injection mould; and
30 injection moulding a second portion of the object.

44. The method of claim 43, wherein the first core is movable relative to the fixture, and
further including the step of moving the first core following the injection moulding of the first
portion or the second portion of the object.

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45. The method of claim 43, wherein the step of injection moulding the second portion of
the object comprises injection moulding over a second core associated with the fixture.

46. The method of claim 45, wherein the second core is movable relative to the fixture, and further including the step of moving the second core to a deployed position after the step of injection moulding the first portion of the object and prior to the injection moulding of the
5 second portion of the object.

47. The method of claim 43, further including the step of placing one or more removable cores inside the second injection mould prior to the step of injection moulding the second portion of the object.
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48. The method of claim 43, wherein the step of injection moulding the second portion of the object comprises over-moulding an open membrane onto the one or more removable cores.
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49. The method of claim 48, wherein the one or more removable cores are removed from the second injection mould together with the fixture.

50. The method of claim 49, wherein the one or more removable cores are removed from the open membrane after injection moulding the second portion and prior to injection
20 moulding the third portion of the object.

51. The method of claim 50, further including the step of closing and sealing the open membrane to form an inflatable portion of the object.

25 52. An airway management device formed by the method of any of claims 36-51.