

Claims

1. A balloon for expanding an orifice, the balloon comprising:
 - a hollow body having a head, the body being closed at a distal end and open at a proximal end, the head extending from the distal end;
 - 5 a hollow neck positioned between the open proximal end and the distal end of the body;
 - wherein a wall thickness of the neck is greater than a wall thickness of the head.
- 10 2. A balloon as claimed in claim 1, wherein a wall thickness of the head at the distal end is greater than the wall thickness of a remainder of the head.
3. A balloon as claimed in claim 1 or 2, wherein a first end of the neck extends from the proximal end of the body to a second remote end of the neck.
- 15 4. A balloon as claimed in claim 3, wherein the first end of the neck comprises a peripheral lip that protrudes outwardly therefrom.
5. A balloon as claimed in any claim 3 or 4, wherein the neck comprises a waist intermediate its first and second ends.
- 20 6. A balloon as claimed in claim 5, wherein a wall thickness of the waist is less than a wall thickness of a remainder of the neck.
- 25 7. A balloon as claimed in claim 5 or 6, wherein the waist is formed as a progressive narrowing of the wall thickness of a section of the neck.
8. A balloon as claimed in any one of claims 1 to 7, wherein an external diameter of the neck is substantially constant for a length of the neck.
- 30 9. A balloon as claimed in claim 8, wherein the external diameter of the neck ranges from about 5 mm to about 15 mm.
10. A balloon as claimed in any one of claims 1 to 9, wherein the head has a diameter ranging from about 6 mm to about 18 mm in a deflated state.
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11. A balloon as claimed in any one of claims 1 to 10, where the opening at the proximal end has a diameter ranging from about 5 mm to about 10 mm, such as 8 mm.
12. A balloon for expanding an orifice, comprising:
5 a hollow body having a head, the body being closed at a distal end and open at a proximal end with a longitudinal axis extending therebetween, the head extending from the distal end;
wherein the balloon is configured such that when the balloon is inflated the head expands in a radial direction greater than in the longitudinal direction and a
10 diameter of the body remains approximately constant during inflation.
13. A balloon as claimed in claim 12, wherein a length of the balloon extending along the longitudinal direction remains approximately constant during inflation.
- 15 14. A balloon as claimed in claim 12 or 13, wherein the body defines a neck positioned between the head and the proximal end, wherein a diameter of the neck remains substantially unchanged during inflation.
- 20 15. A balloon as claimed in any one of claims 12 to 14 as otherwise defined in any one of claims 1 to 11.
16. A balloon as claimed in any one of claims 1 to 15, wherein the balloon is formed from silicone.
- 25 17. A balloon as claimed in any one of claims 1 to 16, wherein the body and head are unitary with one another.
18. A balloon as claimed in any one of claims 1 to 17, being self-supporting such that in a deflated state the balloon does not collapse in on itself.
- 30 19. A system for expanding an orifice, comprising:
the balloon as claimed in any one of claims 1-18; and
an inflation device for inflating the balloon.
- 35 20. A system as claimed in claim 19, further comprising a flow regulator to regulate the flow of fluid into and out of the balloon, wherein the flow regulator is used to maintain the balloon in an inflated state.

21. A system as claimed in claim 19 or 20, further comprising a connector used to connect the balloon to the inflation device.
- 5 22. A kit for expanding an orifice comprising:
the system of any one of claims 19 to 21; and
a container housing the system.
- 10 23. A mould for forming a balloon that is used to expand an orifice, the balloon comprising a hollow body having a head, the body being closed at a distal end and open at a proximal end with the head extending from the distal end, and a hollow neck extending from the open proximal end of the body, the mould comprising:
a spigot having a first region for forming the body and a second region for forming the head,
15 the first region having a first diameter and the second region having a second diameter, the first diameter being less than the second diameter.
- 20 24. A mould as claimed in claim 23, wherein the spigot further comprises a third region for forming a waist in the neck, the third region having a third diameter that is less than the first diameter.
- 25 25. A mould as claimed in claim 23 or 24, further comprising a female section for receiving the spigot, the female section having a bore that has an internal diameter that is approximately constant.
26. A mould as claimed in any one of claims 23 to 25, wherein the balloon is as otherwise defined according to any one of claims 1 to 18.
- 30 27. A method of forming a balloon, the balloon being used to expand an orifice, the method comprising:
providing the mould as claimed in any one of claims 23 to 26,
applying a balloon precursor to the mould; and
curing the balloon precursor to form the balloon.
- 35 28. A method as claimed in claim 27, wherein the balloon precursor is a silicone precursor material that is cured to form a silicone-based balloon.

29. A method as claimed in claim 27 or 28, further comprising a post-curing step to further cure the balloon.
30. A method as claimed in any one of claims 27 to 29, wherein the balloon is as
5 otherwise defined in any one of claims 1 to 18.