Claims

1. An occlusion device for closing an anatomical defect in tissue comprising an opening connecting a front side and a back side of a tissue, wherein the occlusion device is adapted to be included into a sheath of a catheter, and the occlusion device comprises:

(i) a scaffold comprising:

- a head tube positioned at an anterior end of the scaffold,
- a tail tube positioned at a posterior end of the scaffold; wherein the head tube and the tail tube are movable along the direction towards and away from each other, and
- an engaging means connected to the head tube and being adapted to be engagable at the tail tube, and

(ii) a foldable section comprising:

- a foldable head portion which is connected at one end to the head tube and being adapted to be disposed together with the head tube at the front side of the anatomical defect,
- a foldable tail portion which is connected to one end of the tail tube and being adapted to be disposed together with the tail tube at the back side of the anatomical defect, and
- a waist portion adapted to extend through the opening of the anatomical defect and being arranged between the foldable head portion and the foldable tail portion,

wherein each of the foldable head portion and the foldable tail portion comprises two arms extending between the head tube and the waist portion and between the tail tube and the waist portion, respectively, wherein each arm consists of at least one sheet-like film having a folding segment at which the arm is foldable such that a part of the arm extending from one side of the folding segment folds over another part of the arm extending from another side of the folding segment,

wherein the two arms of at least one of the foldable head portion and the foldable tail portion are configured such that, in the folded state when deployed for closing the anatomical defect, surfaces of the two arms facing the tissue extend completely around the anatomical defect, and

wherein the folding segment of each arm defines a folding axis and is pre-configured with greater flexibility at the folding axis than said part and said another part of the arm so as to facilitate folding of the arm about the folding axis.

2. The occlusion device according to claim 1, wherein the two arms of the foldable head portion are arranged on each other in a manner that the engaging means is positioned between the two arms.

3. The occlusion device according to claim 1, wherein the two arms of the foldable tail portion are arranged on each other in a manner that the engaging means is positioned between the two arms.

4. The occlusion device according to claim 1, wherein the engaging means is a hollow tube.

5. The occlusion device according to claim 1, wherein the engaging means is integrally provided with the head tube and wherein the engaging means extends from the head tube in the direction of the tail tube and wherein, in the unfolded form of the occlusion device, the engaging means extends over a length in the direction of the tail tube which is half the length between the waist portion and the head tube.

6. The occlusion device according to claim 1, wherein the head tube is hollow and has a threaded interior.

7. The occlusion device according to claim 6, wherein the engaging means is engageable at the tail tube by means of a lock which is a flexible end cap having two crossed slots in its center wherein the end cap is integrally provided at the posterior end of the tail tube.

8. The occlusion device according to claim 1, wherein the foldable head portion is welded to the head tube and/or the foldable tail portion is welded to the tail tube.

9. The occlusion device according to claim 1, wherein the foldable head portion is laminated with the head tube and/or the foldable tail portion is laminated with the tail tube.

10. The occlusion device according to claim 1, wherein the foldable head portion is glued on the head tube and/or the foldable tail portion is glued on the tail tube.

11. The occlusion device according to claim 1, wherein the foldable head portion is sewed to the head tube and/or the foldable tail portion is sewed to the tail tube.

12. The occlusion device according to claim 1, wherein at least one of or all of the head tube, the end tube, the engaging means, or the foldable section are of a polymeric material.

13. The occlusion device according to claim 12, wherein the polymeric material comprises a non-biodegradable or a biodegradable polymer.

14. The occlusion device according to claim 13, wherein the non-biodegradable polymer is selected from the group consisting of polyurethane, poly(ether urethanes), poly(ester urethanes), polyvinylchloride, polyalkylenes, polyethylene terephtalate polyvinylacetate, poly ethylene-co-vinyl acetate and nylon.

15. The occlusion device according to claim 13, wherein the biodegradable polymer is selected from the group consisting of polycaprolactone (PCL), polylactic acid (PLA), polycaprolactone-polylactic acid copolymer (PCL-PLA copolymer), polyglycolide (PLGA), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polygluconate (PGA), polylactide-polygluconate copolymer (PLGA), polylactic acid-polyethylene oxide copolymers, polyhydroxybutyrate, polyanhydride, polyphosphoester, poly(amino acids), polydioxanone, cellulose, collagen and chitosan.

16. The occlusion device according to claim 12, wherein the polymeric material of the foldable section has a modulus range of about 10^4 to about 10^7 Pa at 37 °C.

17. The occlusion device according to claim 1, wherein the entire occlusion device is made of a polymeric material.

18. The occlusion device according to claim 1, wherein the tail tube has a threaded exterior surface.

19. The occlusion device according to claim 1, wherein one or more elements selected from the head tube, the tail tube, the engaging member and the foldable section comprise a therapeutically active agent.

20. The occlusion device according to claim 19, wherein the therapeutically active agent is selected from the group consisting of a drug, an antibiotic, an anti-inflammatory agent, an anti-clotting factor, a hormone, a nucleic acid, a peptide, a cellular factor, a growth factor, a ligand for a cell surface receptor, an anti-proliferation agent, an anti-thrombotic agent, an antimicrobial agent, an anti-viral agent, a chemotherapeutic agent, and an anti-hyertensive agent.

21. The occlusion device according to claim 1, wherein one or more elements selected from the group of the head tube, the tail tube, the engaging means and the foldable section comprise a radiopacifier deposited at its surface and/or blended in the material the elements comprise.

22. A delivering system for an occlusion device of claim 1 adapted to be included into a sheath of a catheter, comprising:

at least one first delivering means adapted to push the occlusion device through a sheath and to guide the head portion of the foldable section in a position at the front side of a tissue defect, and

at least one second delivering means adapted to move the tail tube into the direction of the head tube to allow the tail tube to be moved against the back side of the tissue.

23. The delivering system according to claim 22, wherein the at least one first delivering means is a delivering rod extending through the tail tube towards the head tube of the occlusion device and being removably connected to the head tube.

24. The delivering system according to claim 23, wherein the delivering rod is made of a shape memory metal such as a Ni-Ti alloy like nitinol, Cu-Zn alloy, Fe-Ni-Al alloy or shape memory polymer.

25. The delivering system according to claim 23, wherein the delivering rod has a threaded exterior surface at the end of the delivering rod facing the tail tube wherein the end of the delivering rod is threaded to engage a threaded interior surface of the head tube.

26. The delivering system according to claim 22, wherein the at least one second delivering means is a cylindrical hollow deployment tube.

27. The delivering system of claim 26, wherein the deployment tube is made of a polymeric material.

28. The delivering system according to claim 26, wherein the deployment tube has a thread at the inner surface of its tip which is adapted to be engaged into the thread of the tail tube.

29. The delivering system according to claim 22, further comprising a sheath adapted to cover at least the occlusion device and the first and second delivering means.

30. A kit comprising an occlusion device of claim 1 and a delivering system for the occlusion device, the delivering system comprising:

at least one first delivering means adapted to push the occlusion device through the sheath and to guide the head portion of the foldable section in a position at the front side of a tissue defect, and

at least one second delivering means adapted to move the tail tube into the direction of the head tube to allow the tail tube to be moved against the back side of the tissue.

31. The kit according to claim 30 provided in a sterilized package.

32. A method of closing an anatomical defect in a tissue comprising an opening connecting a front side and a back side of a tissue, comprising the steps of:

- providing a sheath into which an occlusion device according to claim 1 and a delivering system have been inserted, the delivery comprising:
  - at least one first delivering means adapted to push the occlusion device through the sheath and to guide the head portion of the foldable section in a position at the front side of a tissue defect, and

- at least one second delivering means adapted to move the tail tube into the direction of the head tube to allow the tail tube to be moved against the back side of the tissue,

- pushing the occlusion device through the sheath to the site of the anatomical defect by using a first delivering means of the delivering system,
- pushing a head tube of a scaffold and a foldable head portion of the foldable section of the occlusion device out of the sheath through the defect to the front side of the tissue,
- folding the foldable head portion by moving the head tube of the occlusion device in the direction of the front side of the tissue by means of the first delivering means to close the defect from the front side,
- withdrawing the sheath to release the waist portion and the tail portion of the foldable section of the occlusion device in the opening and at the back side of the tissue, respectively, and
- moving the tail tube of the occlusion device against the back side of the tissue by means of the second delivering means of the delivering system to fold the foldable tail portion of the foldable section of the occlusion device and locking the occlusion device at the anatomical defect from the back side of the tissue.

33. The method according to claim 32, wherein the sheath goes through the opening while the foldable head portion and the head tube are pushed out of the sheath.

34. The method according to claim 32, wherein the sheath is at the front side of the defect while the foldable head portion and the head tube are pushed out of the sheath.

35. The method according to claim 32, further comprising the step of retrieving the delivering system out of the sheath of the catheter.

36. The method according to claim 35, wherein the step of retrieving the delivering system comprises the steps of withdrawing the first delivering means removably connected to the head tube of the occlusion device and removing the second delivering means by withdrawing it out of the catheter.

37. The method according to claim 32, further comprising a re-anchoring step, wherein the sheath is held in position, the first delivering means is moved forward to unfold the

folded head portion and then performing re-anchoring by folding the foldable head portion of the foldable section of the occlusion device.

38. The method according to claim 32, further comprising a correction step of the sealing procedure, wherein the first delivering means is held in position and the second delivering means is moved to unfold the entire occlusion device and to move back the foldable tail portion of the occlusion device into the sheath again and repeating the folding procedure.

39. The method according to claim 32, wherein the anatomical defect in a tissue is a septal defect or shunt in the heart or the vascular system.

40. The method of claim 39, wherein the septal defect is an atrial septal defect, ventricular septal defect, patent ductus arteriosus, or patent foramen ovale.