CLAIMS

1. An occlusion device for closing an anatomical defect in a tissue comprising a conduit connecting an opening on a first tissue and an opening on a second tissue, the occlusion device comprises a scaffold and a delivering system, the scaffold comprising:

a) a proximal support structure comprising at least two arms;

b) a distal support structure comprising at least two arms, wherein the arms are adapted to provide anchorage for the distal support structure within the conduit; and

c) a waist portion adapted for extending through the opening on the first tissue and connecting the proximal support structure with the distal support structure,

wherein the scaffold consists essentially of a biodegradable polymer, wherein the proximal support structure and the distal support structure comprise or consist of polycaprolactone (PCL), poly-(D,L-lactide-co-caprolactone) (PLC), or a mixture thereof , and

the delivering system comprising:

a) a sheath;

wherein, the occlusion device is configured for delivery to the tissue with the scaffold situated in the sheath, the arms of the proximal support structure being folded at their inner ends in an outward direction away from the waist portion;

characterised in that the distal support structure comprises a threaded interior surface; and in that the delivery system comprises further

b) a rod comprising a threaded exterior surface to engage with the threaded interior surface of the distal support structure for moving the scaffold through the sheath; and

c) a reinforced rod housing which surrounds the rod, and in that the occlusion device is configured for delivery to the tissue with the scaffold situated in the sheath, the arms of the distal support structure being

folded at their inner ends in an inward direction in the direction of the waist portion.

2. The occlusion device according to claim 1, wherein the scaffold further comprises a proximal occlusion film supported by the proximal support structure.

3. The occlusion device according to claim 1 or 2, wherein the at least two arms of the proximal support structure are three or more spokes outwardly extending from the middle of the proximal support structure and connected at their inner end with each other.

4. The occlusion device according to any one of claims 1 to 3, wherein the at least two arms of the distal support structure are three or more spokes outwardly extending from the middle of the distal support structure and connected at their inner end with each other.

5. The occlusion device according to claim 3 or 4, wherein each of the proximal support structure and the distal support structure comprises 2 to 8 of said spokes.

6. The occlusion device according to any one of claims 1 to 5,wherein the arms of the distal support structure are adapted to provide anchorage for the device in the tissue by outwardly extending from the middle of the distal support structure and contacting the conduit wall.

7. The occlusion device according to any one of claims 2 to 6, wherein the proximal occlusion film expands between the arms of the proximal support structure.

8. The occlusion device according to any one of claims 1 to 7, wherein the proximal support structure and/or the distal support structure comprise a

connector adapted for connecting the respective support structure with the waist portion.

9. The occlusion device according to claim 8, wherein the connector is a joint protruding in the middle of the proximal and/or distal support structure in the direction of the waist portion.

10. The occlusion device according to any one of claims 1 to 7, wherein the proximal support structure, the distal support structure and the waist portion are integrally formed.

11. The occlusion device according to any one of claim 1 to 10, wherein the biodegradable polymer is selected from the group consisting of polycaprolactone (PCL), poly-(D,L-lactide-co-caprolactone) (PLC), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polylactic acid (PLA), polycaprolactone-polylactic acid copolymer (PCL-PLA copolymer), polylactide-polyglycolide copolymer (PLGA), poly(trimethylene carbonate) (TMC); copolymers of polycaprolactone (PCL) and poly(trimethylene carbonate) (TMC); triblock copolymers of polylactic acid (PLA), polycaprolactone (PCL) and/or poly(trimethylene carbonate) (TMC); polylactic acid-polyethylene oxide copolymers, polygluconate polyhydroxybutyrate, polyanhydride, polyphosphoester, poly(amino acids), polydioxanone, cellulose, collagen, chitosan, and mixtures thereof.

12. The occlusion device according to any one of claims 1 to 11, wherein the waist portion consists essentially of a biodegradable polymer selected from the group consisting of polycaprolactone (PCL), poly-(D,L-lactide-co-caprolactone) (PLC), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polylactic acid (PLA), polycaprolactone-polylactic acid copolymer (PCL-PLA copolymer), polylactide-polyglycolide copolymer (PLGA), poly(trimethylene carbonate) (TMC); copolymers of polycaprolactone (PCL) and poly(trimethylene carbonate) (TMC); triblock copolymers of polylactic acid

(PLA), polycaprolactone (PCL) and/or poly(trimethylene carbonate) (TMC), and mixtures thereof.

13. The occlusion device according to any one of claims 1 to 12, wherein the proximal support structure is more flexible than the remainder of the scaffold.

14. The occlusion device according to any one of claims 1 to 13, wherein the proximal support structure has shape memory.

15. The occlusion device according to claim 14, wherein the proximal support structure elastically deforms in response to an applied force, and returns to more than 50 % of its original shape upon release of the applied force.

16. The occlusion device according to any one of claims 2 to 15, wherein one or more elements selected from the proximal support structure, the proximal occlusion film, the distal support structure, and the waist portion comprise a therapeutically active agent.

17. The occlusion device according to claim 16, wherein the therapeutically active agent is present as a coating on the proximal occlusion film.

18. The occlusion device according to claim 16 or 17, 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-hypertensive agent.

19. The occlusion device according to claim 18, wherein the therapeutically active agent comprises a drug, a protein, a growth factor, or combinations thereof.

20. The occlusion device according to claim 19, wherein the protein is selected from the group consisting of elastin, collagen, fibronectin, laminin, and mixtures thereof.

21. The occlusion device according to claim 19, wherein the growth factor is basic fibroblast growth factor, platelet-derived growth factor, or a mixture thereof.

22. The occlusion device according to any one of claims 1 to 21, wherein one or more elements selected from the group of the proximal support structure, the proximal occlusion film, the distal support structure, and the waist portion comprise a radiopacifier deposited at its surface and/or blended in the material the elements comprise.

23. The occlusion device according to claim 22, wherein the proximal support structure and the distal support structure comprise a radiopacifier.

24. The occlusion device according to claim 22 or 23, wherein the radiopacifier comprises or consists of barium sulfate.

25. The occlusion device according to any one of claims 22 to 24, wherein the amount of radiopacifier comprised in either of, or both, the proximal occlusion film and waist portion ranges from about 0 wt % to about 40 wt %.

26. The occlusion device according to any one of claims 22 to 25, wherein the amount of radiopacifier comprised in either of, or both, the proximal support structure and the distal support structure ranges from about 1 wt % to about 40 wt %.

27. The occlusion device according to any one of claims 1 to 26 provided in a sterilized package.

28. An in-vitro method of closing an anatomical defect in a tissue comprising a conduit connecting an opening on a first tissue and an opening on a second tissue, the method comprising:

a) providing an occlusion device comprising a scaffold and a delivering system, the scaffold comprising:

i) a proximal support structure comprising at least two arms;

ii) a distal support structure comprising a threaded interior surface and at least two arms, wherein the arms are adapted to provide anchorage for the distal support structure within the conduit; and

iii) a waist portion adapted for extending through the opening on the first tissue and connecting the proximal support structure with the distal support structure,

wherein the scaffold consists essentially of a biodegradable polymer, wherein the proximal support structure and the distal support structure comprise or consist of polycaprolactone (PCL), poly-(D,L-lactide-co-caprolactone) (PLC), or a mixture thereof, and the delivering system comprising:

i) a sheath;

ii) a rod comprising a threaded exterior surface to engage with the threaded interior surface of the distal support structure for moving the scaffold through the sheath; and

iii) a reinforced rod housing which surrounds the rod,

wherein the occlusion device is configured for delivery to the tissue sample with the scaffold situated in the sheath, the arms of the proximal support structure being folded at their inner ends in an outward direction away from the waist portion, and the arms of the distal support structure being folded at their inner ends in an inward direction in the direction of the waist portion,

b) moving the sheath containing the scaffold through the opening on the second tissue, the conduit, and the opening on the first tissue,

c) moving the proximal support structure of the scaffold out of the sheath through the opening on the first tissue by using the rod,

d) deploying the proximal support structure at the front side of the first tissue to close the defect from the front side,

e) withdrawing the sheath to release a portion of the waist portion of the scaffold in the opening and to release the distal support portion and the remaining portion of the waist portion within the conduit, and

f) deploying the distal support structure of the scaffold within the conduit to anchor the device.

29. The method according to claim 28, further comprising disconnecting the rod and moving the rod out of the conduit.

30. Use of an occlusion device according to any one of claims 1 to 27 or a method according to any one of claims 28 or 29 for in-vitro closing of a septal defect or shunt in a heart.

31. The use according to claim 30, wherein the septal defect is selected from the group consisting of atrial septal defects, ventricular septal defects, patent ductus arteriosus, and patent foramen ovale.