

CLAIMS

What is claimed is:

1. A vascular occlusion device, comprising:
 - a. A handle having a slider;
 - b. An inner shaft coupled to the handle;
 - c. An outer shaft over the inner shaft and coupled to the slider;
 - d. A scaffold structure having a distal end, a scaffold transition zone and a proximal end having a plurality of legs wherein each leg of the plurality legs is coupled to a distal portion of the inner shaft, wherein the scaffold structure moves from a stowed configuration when the outer shaft is extended over the scaffold structure and a deployed configuration when the outer shaft is retracted from covering the scaffold structure; and
 - e. A scaffold covering over at least a portion of the scaffold structure, the multiple layer scaffold covering having a distal scaffold attachment zone where a portion of the scaffold covering is attached to a distal portion of the scaffold, a proximal scaffold attachment zone where a portion of the scaffold covering is attached to a proximal portion of the scaffold and an unattached zone between the distal attachment zone and the proximal attachment zone wherein the scaffold covering is unattached to an adjacent portion of the scaffold.
2. The vascular occlusion device of claim 1 wherein the plurality of legs is two legs or three legs.
3. The vascular occlusion device of claim 2 wherein the scaffold covering extends from the distal end of the scaffold structure to each of the two legs or the three legs.
4. The vascular occlusion device of claim 1 wherein the scaffold covering extends from the distal end of the scaffold structure proximally to cover approximately 20%, 50%, 80% or 100% of the overall length of the scaffold structure.
5. The vascular occlusion device of claim 1 wherein the scaffold covering extends completely circumferentially about the scaffold structure from the distal attachment zone to the proximal attachment zone.

6. The vascular occlusion device of claim 1 wherein the scaffold covering extends partially circumferentially about the scaffold structure from the distal attachment zone to the proximal attachment zone with an uncovered scaffold structure.
7. The vascular occlusion device of claim 6 wherein the scaffold covering extends partially circumferentially about 270 degrees of the scaffold structure from the distal attachment zone to the proximal attachment zone.
8. The vascular occlusion device of claim 6 wherein a first scaffold covering extends partially circumferentially about 45 degrees of the scaffold structure from the distal attachment zone to the proximal attachment zone and a second scaffold covering extends partially circumferentially about 45 degrees of the scaffold structure from the distal attachment zone to the proximal attachment zone, wherein the first scaffold covering and the second scaffold covering are on opposite sides of the longitudinal axis of the scaffold structure.
9. The vascular occlusion device of claim 1 wherein the multiple layer scaffold covering is attached to the scaffold in the distal scaffold attachment zone and in the proximal scaffold attachment zone by encapsulating a portion of the scaffold, by folding over a portion of the multiple layer scaffold covering and encapsulating a portion of the scaffold, by stitching the multiple layer scaffold covering to a portion of the scaffold, or by electrospinning the multiple layer scaffold to a portion of the scaffold.
10. The vascular occlusion device of claim 1 wherein the scaffold structure is formed from slots cut into a tube.
11. The vascular occlusion device of claim 1 wherein the covering is applied to nearly all, 80%, 70%, 60%, 50%, 30% or 20% of the scaffold structure.
12. The vascular occlusion device of claim 1 wherein scaffold covering is formed from multiple layers.
13. The vascular occlusion device of claim 12 wherein the layers of the multiple layer scaffold covering are selected from ePTFE, PTFE, FEP, polyurethane or silicone.

14. The vascular occlusion device of any of claims 1-13 wherein the scaffold covering or the more than one layers of a multiple layer scaffold covering is applied to a scaffold structure external surface, to a scaffold structure internal surface, to encapsulate the distal scaffold attachment zone and the proximal scaffold attachment zone, as a series of spray coats, dip coats or electron spin coatings to the scaffold structure.
15. The vascular occlusion device of any of claims 1-13 wherein the multiple layer scaffold covering has a thickness of 5 – 100 microns.
16. The vascular occlusion device of any of claims 1-13 wherein the multiple layer scaffold covering has a thickness of about 0.001 inches in an unattached zone and a thickness of about 0.002 inches in an attached zone.
17. The vascular occlusion device of claim 1 further comprising a double gear pinion within the handle that couples the outer shaft to the slider.
18. A method of providing selective occlusion with distal perfusion using a vascular occlusion device, comprising:
- advancing the vascular occlusion device in a stowed condition along a blood vessel to a position adjacent to one or more peripheral blood vessels in the portion of the vasculature of the patient selected for occlusion while the vascular occlusion device is tethered to a handle outside of the patient;
 - transitioning the vascular occlusion device from the stowed condition to a deployed condition using the handle wherein the vascular occlusion device at least partially occludes blood flow into the one or more peripheral blood vessels selected for occlusion wherein the position of the vascular occlusion device engages with a superior aspect of the vasculature to direct blood flow into and along a lumen defined by a covered scaffold structure of the vascular occlusion device;
 - deflecting a portion of an unattached zone of the covered scaffold in response to the blood flow through the lumen of the covered scaffold into an adjacent opening of the one or more peripheral blood vessels in the portion of the vasculature of the patient selected for occlusion;
 - transitioning the vascular occlusion device from the deployed condition to the stowed condition using the handle; and
 - withdrawing the vascular occlusion device in the stowed condition from the patient.

19. The method of claim 18 wherein the one or more peripheral blood vessels in the portion of the vasculature of the patient selected for occlusion is selected from the group consisting of a hepatic artery, a gastric artery, a celiac trunk, a splenic artery, an adrenal artery, a renal artery, a superior mesenteric artery, an ileocolic artery, a gonadal artery and an inferior mesenteric artery.
20. The method of claim 18 the covered scaffold unattached zone further comprising a position of a portion of the unattached zone to deflect into a portion of at least one of a hepatic artery, a gastric artery, a celiac trunk, a splenic artery, an adrenal artery, a renal artery, a superior mesenteric artery, an ileocolic artery, a gonadal artery and an inferior mesenteric artery when the vascular occlusion device is positioned within a portion of the aorta.
21. A method of temporarily occluding a blood vessel, comprising:
- a. Advancing a vascular occlusion device in a stowed condition along a blood vessel to a position adjacent to one or more peripheral blood vessels selected for temporary occlusion;
 - b. Transitioning the vascular occlusion device from the stowed condition to a deployed condition wherein the vascular occlusion at least partially occludes blood flow into the one or more peripheral blood vessels selected for temporary occlusion while directing the blood flow through and along a lumen of a covered scaffold of the vascular occlusion device; and
 - c. Transitioning the vascular occlusion device out of the deployed condition to restore blood flow into the one or more peripheral blood vessels selected for temporary occlusion when a period of temporary occlusion is elapsed.
22. The method of claim 21 wherein directing the blood flow through and along the lumen of the vascular occlusion device maintains blood flow to components and vessels distal to the vascular occlusion device while at least partially occluding the blood flow to the one or more peripheral blood vessels.
23. The method of claim 21 or claim 22 wherein the one or more peripheral blood vessels are the vasculature of a liver, a kidney, a stomach, a spleen, an intestine, a stomach, an esophagus, or a gonad.

24. The method of claim 21 or claim 22 wherein the blood vessel is an aorta and the peripheral blood vessels are one or more or a combination of: a hepatic artery, a gastric artery, a celiac trunk, a splenic artery, an adrenal artery, a renal artery, a superior mesenteric artery, an ileocolic artery, a gonadal artery and an inferior mesenteric artery.
25. A method of reversibly and temporarily occluding a blood vessel, comprising:
- a. Advancing an at least partially covered scaffold structure of a tethered vascular occlusion device to a portion of an aorta to be occluded; and
 - b. Using a handle of the vascular occlusion device to deploy the at least partially covered scaffold structure within the aorta to occlude partially or completely one or more or a combination of: a hepatic artery, a gastric artery, a celiac trunk, a splenic artery, an adrenal artery, a renal artery, a superior mesenteric artery, an ileocolic artery, a gonadal artery and an inferior mesenteric artery using a portion of a multiple layer scaffold covering while simultaneously allowing perfusion flow through a lumen of the at least partially covered scaffold structure to distal vessels and structures.
26. The method of any of claims 21-22 and 25 wherein the insertion of the vascular occlusion device or of the at least partially covered scaffold device to a blood vessel which is the aorta is introduced by transfemoral artery approach or by trans-brachial artery approach or by trans-radial artery approach.
27. The method of any of claims 21-22 and 25 further comprising: advancing the vascular occlusion device over a guidewire into a position adjacent to a landmark of the skeletal anatomy.
28. The method of any of claims 21-22 and 25 wherein a portion of an unattached zone of a multiple layer scaffold covering distends in response to blood flow along a lumen of the scaffold of the vascular occlusion device to occlude an opening of any of a hepatic artery, a gastric artery, a celiac trunk, a splenic artery, an adrenal artery, a renal artery, a superior mesenteric artery, an ileocolic artery, a gonadal artery and an inferior mesenteric artery.
29. A vascular occlusion device, comprising:
- a. A handle having a slider knob;
 - b. An inner shaft coupled to the handle;
 - c. An outer shaft over the inner shaft and coupled within the handle to the slider knob;

- d. A scaffold structure having at least two legs and a multiple layer scaffold covering, the at least two legs of the scaffold structure attached to an inner shaft coupler in a distal portion of the inner shaft;
 - e. The multiple layer scaffold covering positioned over at least a portion of the scaffold structure, wherein the scaffold structure moves from a stowed condition when the outer shaft is extended over the scaffold structure and a deployed condition when the outer shaft is retracted from covering the scaffold structure.
30. The vascular occlusion device of claim 29 wherein the scaffold structure is formed from slots cut into a tube.
31. The vascular occlusion device of claim 29 wherein the covering is applied to nearly all, 80%, 70%, 60%, 50%, 30% or 20% of the scaffold structure.
32. The vascular occlusion device of claim 29 wherein the multiple layer scaffold covering is made of ePTFE, PTFE, polyurethane, FEP or silicone.
33. The vascular occlusion device of any of claim 29-32 wherein the multiple layer scaffold covering is folded over a proximal portion and a distal portion of the scaffold.
34. The vascular occlusion device of any of claims 29-32 wherein after the multiple layer scaffold covering is attached to the scaffold, the scaffold further comprises a distal attachment zone, a proximal attachment zone and an unattached zone.
35. The vascular occlusion device of any of claims 29-32 wherein the multiple layer scaffold covering further comprises a proximal attachment zone, a distal attachment zone and an unattached zone wherein a thickness of the multiple layer covering in the proximal attachment zone and the distal attachment zone is greater than the thickness of the multiple layer scaffold covering in the unattached zone.
36. The vascular occlusion device of claim 35 wherein the multiple layer scaffold covering on the scaffold structure has a thickness of 5 – 100 microns.

37. The vascular occlusion device of any of claims 29-32 wherein scaffold structure has a cylindrical portion and a conical portion wherein the terminal ends of the conical portion are coupled to the inner shaft.
38. The vascular occlusion device of any of claims 29-32 wherein the inner shaft further comprises one or more spiral cut sections to increase flexibility of the inner shaft.
39. The vascular occlusion device of claim 38 wherein the one or more spiral cut sections are positioned proximally or distally or both proximal and distal to an inner shaft coupler where the scaffold structure is attached to the inner shaft.
40. The vascular occlusion device of any of claims 29-32 the scaffold structure further comprising two or more legs wherein each of the two or more legs terminates with a connection tab that is joined to a corresponding key feature on an inner shaft coupler.
41. The vascular occlusion device of any of claims 29-32 wherein the multiple layer scaffold covering includes one or more or a pattern of apertures that are shaped, sized or positioned relative to the scaffold structure to modify the amount of distal perfusion provided by the vascular occlusion device in use within the vasculature.
42. The vascular occlusion device of any of claims 29-32 wherein the multiple layer scaffold covering includes one or more regular or irregular geometric shapes arranged in a continuous or discontinuous pattern which is selected to adapt the distal perfusion flow profile of the vascular occlusion device in use within the vasculature.
43. The vascular occlusion device of any of claims 1-13, 17, and 29-32 wherein when in a stowed configuration within the outer shaft the overall diameter is between 0.100 inches and 0.104 inches and when in a deployed configuration the covered scaffold has an outer diameter from 19 to 35 mm.
44. The vascular occlusion device of any of claims 1-13, 17, and 29-32 wherein the covered scaffold has an occlusive length of 40 mm to 100 mm measured from a distal end of the scaffold to a scaffold transition zone.