

CLAIMS

1. A flexible elongate tubular spring structure for a flexible scoring balloon catheter configured for insertion into a vessel within a mammalian cardiovascular system or other fluid or air carrying conduit or duct within a living mammalian body, the scoring balloon catheter comprising an inflatable elongate balloon having a working region spanning a length, an outer surface along its working region, a first internal passage along which a guide wire is insertable, a second internal passage for passage of a pressurized fluid in communication with the interior of the balloon, and a first longitudinal axis centrally aligned with and extending through the first internal passage, wherein the working region of the balloon in a folded, undeployed, or unexpanded state respectively has a folded, undeployed, or unexpanded outer cross sectional area perpendicular to the first longitudinal axis, wherein the working region of the balloon in an expanded or deployed state respectively has an expanded or deployed outer cross sectional area perpendicular to the first longitudinal axis that is greater than the folded outer cross sectional area, the undeployed outer cross sectional area, and the unexpanded cross sectional area, and wherein the tubular spring structure has a distal end, a proximal end, a length therebetween within which a lumen resides, and a second longitudinal axis centrally aligned with its lumen, and wherein the tubular spring structure comprises:

- (i) a plurality of annular ring structures, each annular ring structure having an unexpanded length and providing along its length a lumen having a central axis longitudinally extending therethrough and a relaxed cross sectional area perpendicular to the central axis which in the absence of the balloon is less than the folded, undeployed, or unexpanded outer cross sectional area of the balloon's working region, wherein each annular ring structure is configured for circumferential engagement with the outer surface of the balloon such that the central axis of the annular ring structure is longitudinally aligned with a portion of the first longitudinal axis, wherein each annular ring structure is configured for resilient expansion in radial directions perpendicular to the central axis including outward radial expansion away from the central axis in response to radial forces exerted on the annular ring structure by expansion of the balloon, and wherein each annular ring structure comprises:

- a distal annular spring having a circumference and configured for circumferentially residing around the outer surface of the balloon, wherein the distal annular spring is configured for resilient radial expansion relative to a plane perpendicular to the central axis, and wherein the distal annular spring is configured for exerting an

inward circumferential compressive force toward the central axis in response to outward radial expansion of the distal annular spring away from the central axis beyond the relaxed cross sectional area;

a proximal annular spring longitudinally separated from the distal annular spring, the proximal annular spring having circumference and configured for circumferentially residing around the outer surface of the balloon, wherein the proximal annular spring is configured for resilient radial expansion relative to a plane perpendicular to the central axis, and wherein the proximal annular spring is configured for exerting an inward circumferential compressive force toward the central axis in response to outward radial expansion of the proximal annular spring away from the central axis beyond the relaxed cross sectional area;

a set of spacing elements peripherally disposed around the annular ring structure between the distal annular spring and the proximal annular spring, wherein the set of spacing elements couples the distal annular spring to the proximal annular spring and maintains a longitudinal separation distance between the distal and proximal springs;

and

(ii) a plurality of scoring links, wherein each scoring link has a length and couples a distinct pair of adjacent annular ring structures and spans a longitudinal spatial gap between each annular ring structure within the pair of annular ring structures coupled thereby, wherein each scoring link comprises a set of scoring structures along at least portions of its length, wherein each scoring structure is configured as a traumatic element with respect to contact with tissue within the vessel, conduit, or duct, wherein serially successive scoring links along the length of the tubular spring structure are disposed at or indexed across different radial positions relative to each other about the second longitudinal axis, and wherein the length of each scoring link is greater than the unexpanded length of each annular ring structure within the adjacent pair of annular ring structures coupled thereby.

2. The tubular spring structure of claim 1, wherein each of the distal annular spring and the proximal annular spring has a cross sectional area perpendicular to the central axis which in the absence of the balloon is less than the folded, undeployed, or unexpanded outer cross sectional area of the balloon.

3. The tubular spring structure of claim 1 or claim 2, wherein each scoring link has a length greater than 200% of the unexpanded length of a shortest annular ring structure within the pair of adjacent annular ring structures coupled thereby.
4. The tubular spring structure of any one of claims 1 – 3, wherein for each pair of adjacent annular ring structures, the spatial gap between the annular ring structures thereof is at least 0.3mm.
5. The tubular spring structure of any one of claims 1 – 4, wherein each pair of adjacent annular ring structures is longitudinally organized as a first annular ring structure disposed distal to a second annular ring structure, wherein the proximal annular spring of the first annular ring structure is closest to the distal annular spring of the second annular ring structure, and wherein the scoring link that couples the first annular ring structure to the second annular ring structure extends from the distal annular spring of the first annular ring structure to the proximal annular spring of the second annular ring structure.
6. The tubular spring structure of any one of claims 1 – 5, wherein each spacing element is configured as a generally atraumatic element with respect to contact with tissue within the vessel.
7. The tubular spring structure of any one of claims 1 – 6, wherein each spacing element has a width that is between 50% to 500% of the width of each scoring link and/or a scoring element carried thereby.
8. The tubular spring structure of any one of claims 1 – 7, wherein for each annular ring structure the set of spacing elements includes a plurality of distinct spacing elements longitudinally aligned with the central axis, wherein the tubular spring structure has a total of N scoring links and $(N+1)$ annular ring structures.
9. The tubular spring structure of claim 8, wherein an angular separation between serially successive scoring links around the second longitudinal axis is $(360 / Y)$ degrees, where Y is a number between 3 and 5.

10. The tubular spring structure of any one of claims 1 – 9, wherein the distal annular spring comprises a plurality of spring members that are coupled together around the circumference of the distal annular spring.
11. The tubular spring structure of any one of claims 1 – 10, wherein the proximal annular spring comprises a plurality of spring members that are coupled together around the circumference of the proximal annular spring.
12. The tubular spring structure of claim 10 or claim 11, wherein each spring member includes a first end segment, a second end segment, and an apex therebetween, and wherein each end segment of each spring member is coupled to one of a spacing element and a scoring link.
13. The tubular spring structure of claim 10 or claim 11, wherein each spring member includes a first end segment, a second end segment, and an apex therebetween, and wherein each end segment of each spring member is coupled by a spacing element.
14. The tubular spring structure of any one of claims 10 – 13, wherein each spring member includes or is in the form of a geometric shape resembling, approximating, or essentially identical to a “v” or a “c”.
15. The tubular spring structure of any one of claims 1 – 14, wherein the second longitudinal axis adopts a curvilinear or curved shape in response to flexure of the tubular spring structure, and wherein each scoring link has a geometric shape that is essentially identical to the geometric shape of a segment along or of the second longitudinal axis to which it most closely resides in response to flexure of the tubular spring structure.
16. The tubular spring structure of any one of claims 1 – 15, wherein each scoring structure within the set of scoring structures is elongate and is longitudinally aligned with the second longitudinal axis.
17. The tubular spring structure of any one of claims 1 – 16, wherein each scoring link has a scoring structure integrally formed thereon, or integrally forms a scoring structure.

18. The tubular spring structure of any one of claims 1 – 17, wherein each scoring structure has a rectangular, trapezoidal, or raised blade cross-sectional shape perpendicular to the second longitudinal axis.
19. The tubular spring structure of any one of claims 1 – 18, wherein each spacing element within each annular ring structure of a pair of adjacent annular ring structures is elongate and is longitudinally aligned with the central axis, and each spacing element within each annular ring structure of the pair of adjacent annular ring structures has a length that is at least 40% of the length of the scoring link that couples the adjacent pair of annular ring structures.
20. The tubular spring structure of any one of claims 1 – 19, wherein each annular ring structure comprises a metal mesh.
21. The tubular spring structure of any one of claims 1 – 20, wherein the tubular spring structure is formed of at least one metal.
22. The tubular spring structure of any one of claims 1 – 21, wherein the tubular spring structure is integrally formed from a metal tube.
23. The tubular spring structure of any one of claims 1 – 22, wherein at least portions of at least some of the plurality of scoring links of the tubular spring structure and/or one or more other portions of the tubular spring structure carry a therapeutic substance.
24. A scoring balloon catheter structure comprising:
an elongate angioplasty balloon having a first length, a circumference, and a working region along the first length; and
an elongate expandable tubular mesh structure mounted on the angioplasty balloon and having a second length, wherein the second length is parallel to the first length when the angioplasty balloon and the expandable tubular mesh structure are in a straight configuration, wherein the expandable tubular mesh structure includes a plurality of ring structures that circumferentially surround the angioplasty balloon along its working region, wherein each ring structure has a third length and comprises a pair of distinct resiliently expandable rings lengthwise coupled by a set of spacing elements, wherein each ring structure is configured for elastic expansion and deformation in response to expansion of

the angioplasty balloon while remaining below its plastic deformation limit, wherein each ring structure is separated from an adjacent ring structure along the second length by a nonzero first separation distance, wherein each distinct pair of adjacent ring structures is coupled by a single distinct scoring element having a fourth length that is greater than the third length and which comprises a traumatic structure configured for scoring or cutting tissue within a mammalian vessel, conduit, or duct.

25. The scoring balloon catheter structure of claim 24, wherein each ring structure is slightly expanded beyond a ring structure resting state diameter when mounted on the angioplasty balloon and the angioplasty balloon is in a folded, undeployed, or unexpanded state.

26. The scoring balloon catheter structure of claim 24 or claim 25, wherein each scoring element exhibits one of a square, a trapezoidal, and a raised blade cross sectional profile.

27. The scoring balloon catheter structure of any one of claims 24 – 26, further comprising a therapeutic substance coating disposed on at least a portion of the tubular mesh structure.

28. The scoring balloon catheter structure of claim 27, wherein the therapeutic substance coating is disposed on each scoring element.

29. The scoring balloon catheter structure of any one of claims 24 – 28, wherein the tubular mesh structure includes at least four ring structures, and at least three scoring elements that are circumferentially separated from each other at indexed positions about the periphery of the angioplasty balloon.

30. The scoring balloon catheter structure of any one of claims 24 – 29, wherein each ring structure comprises a pair of annular spring structures that are coupled together by a plurality of spacing elements that establish a nonzero second separation distance between the pair of annular spring structures.

31. The scoring balloon catheter structure of claim 30, wherein the set of spacing elements is atraumatic relative to each scoring element with respect to tissue within the vessel, conduit, or duct.

32. A scoring balloon catheter structure comprising:
an elongate angioplasty balloon having a first length, a circumference, and a working region along the first length; and
an elongate expandable tubular mesh structure having a second length and mounted on the angioplasty balloon, wherein the expandable tubular mesh structure comprises:
a plurality of ring structures that circumferentially surround the angioplasty balloon along its working region, wherein each ring structure is configured for elastic expansion and deformation in response to expansion of the angioplasty balloon while remaining below its plastic deformation limit, and wherein each ring structure is separated from an adjacent ring structure along the second length by a nonzero first separation distance; and
a plurality of scoring elements that longitudinally couple the plurality of ring structures, wherein each scoring element comprises a structural element configured for scoring or cutting vascular tissue; and
a therapeutic substance disposed on only the scoring elements,
wherein each distinct pair of directly adjacent ring structures is coupled by a single scoring element.

33. A flexible scoring balloon catheter, comprising:
an inflatable elongate balloon having a distal end, a proximal end, and a working region therebetween configured for dilation within a vessel of a mammalian cardiovascular system vessel or other fluid or air carrying conduit or duct within a mammalian body, the balloon having a length along its working region, an outer surface along its working region, an internal passage along which a guide wire is insertable, and a first longitudinal axis centrally aligned with and extending through the internal passage, wherein the working region of the balloon in a folded or undeployed state respectively has a folded or undeployed outer cross sectional area perpendicular to the first longitudinal axis, and wherein the working region of the balloon in an expanded or deployed state respectively has an expanded or deployed outer cross sectional area perpendicular to the first longitudinal axis that is greater than the folded outer cross sectional area and the undeployed outer cross sectional area;
a catheter having a distal portion and a proximal portion, wherein the balloon is mounted on the catheter distal portion, and wherein the catheter comprises an inflation lumen extending therethrough in fluid communication with an interior region of the balloon; and

a flexible elongate tubular spring structure of any one of claims 1 – 23, surrounding portions of the working region of the balloon along the catheter distal portion.

34. The flexible scoring balloon catheter of claim 33, further comprising at least one of:
a tether structure configured for tethering or anchoring the tubular spring structure to at least one of a portion of the catheter and a portion of the balloon;
a proximal adhesive bond coupling a proximal end of the tubular spring structure to at least one of a proximal zone of the catheter distal portion and an unexpandable proximal segment of the balloon; and
a distal adhesive bond coupling a distal end of the tubular spring structure to at least one of a distal zone of the catheter distal portion and an unexpandable distal segment of the balloon.

35. The flexible scoring balloon catheter of claim 34, wherein the tether structure comprises:
a tubular collar carried by a shaft of the catheter proximal to the balloon; and
at least one elongate tether link coupled to each of the tubular collar and the tubular spring structure.

36. The flexible scoring balloon catheter of claim 34, wherein the flexible scoring balloon catheter includes each of the proximal adhesive bond and the distal adhesive bond, wherein the distal adhesive bond is intentionally formed weaker than the proximal adhesive bond.

37. The flexible scoring balloon catheter of any one of claims 33 – 36, wherein the flexible scoring balloon catheter excludes protective elements configured to limit or shield contact between the plurality of scoring links and tissue within the vessel prior to inflation of the balloon from the folded, undeployed, or unexpanded state to the expanded or deployed state.