

UNCONDITIONAL AMENDMENT A – EP(UK) 1,624,810

CLAIMS:

- 5 1. A fixation device for engaging tissue comprising:
a pair of fixation elements (18) each having a first end, a free end opposite the first
end, and an engagement surface (50) therebetween for engaging the tissue, the first ends
being movably coupled together such that the fixation elements (18) are moveable between
1) a closed position wherein the engagement surfaces (50) face each other, and 2) an
10 inverted position wherein the engagement surfaces (50) face away from each other; and
an actuation mechanism (58) ~~adapted for coupling~~ to the fixation elements
adapted to move the fixation elements (18) between the closed position and the inverted
position, further comprising a pair of gripping elements (16), each gripping element (16)
moveable with respect to one of the fixation elements (18) and being disposed in
15 opposition to one of the engagement surfaces (50) so as to capture tissue therebetween,
wherein the gripping elements (16) are movable from an undeployed configuration in which
each gripping element (16) is separated from an opposing engagement surface (50), to a
deployed configuration in which the gripping element (16) is adjacent to the opposing
engagement surface (50) and wherein each fixation element (18) is at least partially
20 concave and each gripping element (16) is at least partially recessed within the fixation
element (18) in the deployed configuration or wherein the gripping elements (16) are
approximately parallel to each other in the undeployed configuration.
2. A fixation device as in claim 1, wherein the fixation elements (18) are further
25 moveable to an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement
surface (50) of one fixation element (18) forms an angle of more than about 5° and less
than about 90° with the engagement surface (50) of the other fixation element (18), or
30 wherein in the open position the engagement surface (50) of one fixation element (18)
forms an angle of more than about 90° and less than about 180° with the engagement
surface (50) of the other fixation element (18).

4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward

the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

5 12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

10 13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

15 14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

20 15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member
25 has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

30 16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

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19. A fixation device as in any one of the preceding claims, wherein the free ends of the fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

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20. A system comprising:

a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and

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a fixation device as in any one of the preceding claims.

FIRST AUXILIARY REQUEST

CLAIMS:

- 5 1. A fixation device for engaging tissue for the repair of a valve of the heart, the fixation device comprising:
- a pair of fixation elements (18) each having a first end, a free end opposite the first end, and an engagement surface (50) therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements (18) are moveable between
- 10 1) a closed position wherein the engagement surfaces (50) face each other, and 2) an inverted position wherein the engagement surfaces (50) face away from each other; and
- an actuation mechanism (58) coupled to the fixation elements adapted to move the fixation elements (18) between the closed position and the inverted position, further
- 15 comprising a pair of gripping elements (16), each gripping element (16) moveable with respect to one of the fixation elements (18) and being disposed in opposition to one of the engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping elements (16) are movable from an undeployed configuration in which each gripping element (16) is separated from an opposing engagement surface (50), to a deployed configuration in which the gripping element (16) is adjacent to the opposing engagement
- 20 surface (50) and wherein each fixation element (18) is at least partially concave and each gripping element (16) is at least partially recessed within the fixation element (18) in the deployed configuration or wherein the gripping elements (16) are approximately parallel to each other in the undeployed configuration.
- 25 2. A fixation device as in claim 1, wherein the fixation elements (18) are further moveable to an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 5° and less
- 30 than about 90° with the engagement surface (50) of the other fixation element (18), or wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 90° and less than about 180° with the engagement surface (50) of the other fixation element (18).

4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward

the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

5 12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

10 13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

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14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

20 15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member
25 has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

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17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

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19. A fixation device as in any one of the preceding claims, wherein the free ends of the fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

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20. A system comprising:

a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and

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a fixation device as in any one of the preceding claims.

SECOND AUXILIARY REQUEST

CLAIMS:

- 5 | 1. A fixation device for engaging tissue for the repair of a valve of the heart, the
| fixation device comprising:
| a pair of fixation elements (18) each having a first end, a free end opposite the first
| end, and an engagement surface (50) therebetween for engaging the tissue, the first ends
| being movably coupled together such that the fixation elements (18) are moveable between
10 | 1) a closed position wherein the engagement surfaces (50) face each other, and 2) an
| inverted position wherein the engagement surfaces (50) face away from each other; and
| an actuation mechanism (58) coupled to the fixation elements adapted to move the
| fixation elements (18) repositionably between the closed position and the inverted position,
| further comprising a pair of gripping elements (16), each gripping element (16) moveable
15 | with respect to one of the fixation elements (18) and being disposed in opposition to one of
| the engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping
| elements (16) are movable from an undeployed configuration in which each gripping
| element (16) is separated from an opposing engagement surface (50), to a deployed
| configuration in which the gripping element (16) is adjacent to the opposing engagement
20 | surface (50) and wherein each fixation element (18) is at least partially concave and each
| gripping element (16) is at least partially recessed within the fixation element (18) in the
| deployed configuration or wherein the gripping elements (16) are approximately parallel to
| each other in the undeployed configuration.
- 25 | 2. A fixation device as in claim 1, wherein the fixation elements (18) are further
| moveable to an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement
| surface (50) of one fixation element (18) forms an angle of more than about 5° and less
30 | than about 90° with the engagement surface (50) of the other fixation element (18), or
| wherein in the open position the engagement surface (50) of one fixation element (18)
| forms an angle of more than about 90° and less than about 180° with the engagement
| surface (50) of the other fixation element (18).

4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward

the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

5 12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

10 13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

15 14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

20 15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member
25 has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

30 17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

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19. A fixation device as in any one of the preceding claims, wherein the free ends of the fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

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20. A system comprising:

a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and

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a fixation device as in any one of the preceding claims.

THIRD AUXILIARY REQUEST

CLAIMS:

- 5 | 1. A fixation device for engaging tissue for the repair of a valve of the heart, the
| fixation device comprising:
- 10 | a pair of fixation elements (18) each having a first end, a free end opposite the first
| end, and an engagement surface (50) therebetween for engaging the tissue, the first ends
| being movably coupled together such that the fixation elements (18) are moveable between
| 1) a closed position wherein the engagement surfaces (50) face each other, and 2) an
| inverted position wherein the engagement surfaces (50) face away from each other,
| wherein the fixation elements (18) are further moveable between a first position for
| capturing the tissue and a second position for fixing the tissue, wherein the engagement
| surfaces (50) are spaced apart in the first position and are closer together and generally
15 | face toward each other in the second position; and
- 20 | an actuation mechanism (58) coupled to the fixation elements adapted to move the
| fixation elements (18) repositionably between the closed position and the inverted position,
| further comprising a pair of gripping elements (16), each gripping element (16) moveable
| with respect to one of the fixation elements (18) and being disposed in opposition to one of
25 | the engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping
| elements (16) are movable from an undeployed configuration in which each gripping
| element (16) is separated from an opposing engagement surface (50), to a deployed
| configuration in which the gripping element (16) is adjacent to the opposing engagement
| surface (50) and wherein each fixation element (18) is at least partially concave and each
25 | gripping element (16) is at least partially recessed within the fixation element (18) in the
| deployed configuration or wherein the gripping elements (16) are approximately parallel to
| each other in the undeployed configuration.
- 30 | 2. A fixation device as in claim 1, wherein the first position is~~fixation elements (18) are~~
| ~~further moveable to~~ an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement
surface (50) of one fixation element (18) forms an angle of more than about 5° and less
than about 90° with the engagement surface (50) of the other fixation element (18), or

wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 90° and less than about 180° with the engagement surface (50) of the other fixation element (18).

5 4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

10 5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

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7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

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8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

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9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

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11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation
5 elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

19. A fixation device as in any one of the preceding claims, wherein the free ends of the
10 fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

20. A system comprising:
15 a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and
a fixation device as in any one of the preceding claims.

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FOURTH AUXILIARY REQUEST

CLAIMS:

- 5 | 1. A fixation device for engaging tissue for the repair of a valve of the heart, the fixation device comprising:
- a pair of fixation elements (18) each having a first end, a free end opposite the first end, and an engagement surface (50) therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements (18) are moveable between
- 10 | 1) a closed position wherein the engagement surfaces (50) face each other, and 2) an inverted position wherein the engagement surfaces (50) face away from each other, wherein in the inverted position the engagement surfaces (50) provide an atraumatic surface to deflect tissue, wherein the fixation elements (18) are further moveable between a first position for capturing the tissue and a second position for fixing the tissue, wherein
- 15 | the engagement surfaces (50) are spaced apart in the first position and are closer together and generally face toward each other in the second position; and
- an actuation mechanism (58) coupled to the fixation elements adapted to move the fixation elements (18) repositionably between the closed position and the inverted position, further comprising a pair of gripping elements (16), each gripping element (16) moveable
- 20 | with respect to one of the fixation elements (18) and being disposed in opposition to one of the engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping elements (16) are movable from an undeployed configuration in which each gripping element (16) is separated from an opposing engagement surface (50), to a deployed configuration in which the gripping element (16) is adjacent to the opposing engagement
- 25 | surface (50) and wherein each fixation element (18) is at least partially concave and each gripping element (16) is at least partially recessed within the fixation element (18) in the deployed configuration or wherein the gripping elements (16) are approximately parallel to each other in the undeployed configuration.
- 30 | 2. A fixation device as in claim 1, wherein the first position is ~~fixation elements (18) are further moveable to~~ an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 5° and less

than about 90° with the engagement surface (50) of the other fixation element (18), or wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 90° and less than about 180° with the engagement surface (50) of the other fixation element (18).

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4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable
10 independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation
15 mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further
comprises a coupling member (19) and a stud (74) slidably coupled to the coupling
member, the first ends being coupled to one of either the coupling member (19) or the stud
20 (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one
of either the coupling member (19) or the stud (74) by a hinge wherein the link members
25 are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking
mechanism (106) adapted to lock the fixation elements (18) in a desired position.

30 10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation
5 elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

19. A fixation device as in any one of the preceding claims, wherein the free ends of the
10 fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

20. A system comprising:
15 a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and
a fixation device as in any one of the preceding claims.

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FIFTH AUXILIARY REQUEST

CLAIMS:

- 5 | 1. A fixation device for engaging tissue for the repair of a valve of the heart, the fixation device comprising:
- a pair of fixation elements (18) each having a first end, a free end opposite the first end, and an engagement surface (50) therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements (18) are moveable between
- 10 | 1) a closed position wherein the engagement surfaces (50) face each other, and 2) an inverted position wherein the engagement surfaces (50) face away from each other, wherein in the inverted position the engagement surfaces (50) provide an atraumatic surface to deflect tissue, wherein the fixation elements (18) are further moveable between a first position for capturing the tissue and a second position for fixing the tissue, wherein
- 15 | the engagement surfaces (50) are spaced apart in the first position and are closer together and generally face toward each other in the second position; and
- an actuation mechanism (58) coupled to the fixation elements adapted to move the fixation elements (18) repositionably between the closed position and the inverted position, further comprising a pair of gripping elements (16), each gripping element (16) moveable
- 20 | with respect to one of the fixation elements (18) and being disposed in opposition to one of the engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping elements (16) are movable from an undeployed configuration in which each gripping element (16) is separated from an opposing engagement surface (50), to a deployed configuration in which the gripping element (16) is adjacent to the opposing engagement
- 25 | surface (50) and wherein each fixation element (18) is at least partially concave and each gripping element (16) is at least partially recessed within the fixation element (18) in the deployed configuration ~~or wherein the gripping elements (16) are approximately parallel to each other in the undeployed configuration.~~
- 30 | 2. A fixation device as in claim 1, wherein the first position is ~~fixation elements (18) are further moveable to~~ an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 5° and less

than about 90° with the engagement surface (50) of the other fixation element (18), or wherein in the open position the engagement surface (50) of one fixation element (18) forms an angle of more than about 90° and less than about 180° with the engagement surface (50) of the other fixation element (18).

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4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable
10 independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation
15 mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further
20 comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one
25 of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking
mechanism (106) adapted to lock the fixation elements (18) in a desired position.

30 10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward
5 the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with
10 the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an
15 unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

20 14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling
25 member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member has a mating surface for engagement with the delivery device, the mating surface having a
30 sigmoid shape.

16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation
5 elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

19. A fixation device as in any one of the preceding claims, wherein the free ends of the
10 fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

20. A system comprising:
15 a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and
a fixation device as in any one of the preceding claims.

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SIXTH AUXILIARY REQUEST

CLAIMS:

- 5 1. A fixation device for engaging tissue comprising:
a pair of fixation elements (18) each having a first end, a free end opposite the first
end, and an engagement surface (50) therebetween for engaging the tissue, the first ends
being movably coupled together such that the fixation elements (18) are moveable between
1) a closed position wherein the engagement surfaces (50) face each other, and 2) an
10 inverted position wherein the engagement surfaces (50) face away from each other; and
an actuation mechanism (58) coupled to the fixation elements adapted to move the
fixation elements (18) between the closed position and the inverted position, further
comprising a pair of gripping elements (16), each gripping element (16) moveable with
respect to one of the fixation elements (18) and being disposed in opposition to one of the
15 engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping
elements (16) are movable from an undeployed configuration in which each gripping
element (16) is separated from an opposing engagement surface (50), to a deployed
configuration in which the gripping element (16) is adjacent to the opposing engagement
surface (50) and wherein each fixation element (18) is at least partially concave and each
20 gripping element (16) is at least partially recessed within the fixation element (18) in the
deployed configuration or wherein the gripping elements (16) are approximately parallel to
each other in the undeployed configuration.
2. A fixation device as in claim 1, wherein the fixation elements (18) are further
25 moveable to an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement
surface (50) of one fixation element (18) forms an angle of more than about 5° and less
than about 90° with the engagement surface (50) of the other fixation element (18), or
30 wherein in the open position the engagement surface (50) of one fixation element (18)
forms an angle of more than about 90° and less than about 180° with the engagement
surface (50) of the other fixation element (18).

4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward

the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

5 12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

10 13. The fixation device of ~~any one of claims 9, 10,~~ 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

15 14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

20 15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member
25 has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

30 16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

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19. A fixation device as in any one of the preceding claims, wherein the free ends of the fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

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20. A system comprising:

a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and

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a fixation device as in any one of the preceding claims.

SEVENTH AUXILIARY REQUEST

CLAIMS:

- 5 1. A fixation device for engaging tissue comprising:
a pair of fixation elements (18) each having a first end, a free end opposite the first
end, and an engagement surface (50) therebetween for engaging the tissue, the first ends
being movably coupled together such that the fixation elements (18) are moveable between
1) a closed position wherein the engagement surfaces (50) face each other, and 2) an
10 inverted position wherein the engagement surfaces (50) face away from each other; and
an actuation mechanism (58) coupled to the fixation elements adapted to move the
fixation elements (18) between the closed position and the inverted position, further
comprising a pair of gripping elements (16), each gripping element (16) moveable with
respect to one of the fixation elements (18) and being disposed in opposition to one of the
15 engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping
elements (16) are movable from an undeployed configuration in which each gripping
element (16) is separated from an opposing engagement surface (50), to a deployed
configuration in which the gripping element (16) is adjacent to the opposing engagement
surface (50) and wherein each fixation element (18) is at least partially concave and each
20 gripping element (16) is at least partially recessed within the fixation element (18) in the
deployed configuration or wherein the gripping elements (16) are approximately parallel to
each other in the undeployed configuration.
2. A fixation device as in claim 1, wherein the fixation elements (18) are further
25 moveable to an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement
surface (50) of one fixation element (18) forms an angle of more than about 5° and less
than about 90° with the engagement surface (50) of the other fixation element (18), or
30 wherein in the open position the engagement surface (50) of one fixation element (18)
forms an angle of more than about 90° and less than about 180° with the engagement
surface (50) of the other fixation element (18).

4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward

the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

5 12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

10 13. The fixation device of ~~any one of claims 9, 10, 11 or 12~~, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

15 14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

20 15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member
25 has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

30 16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

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19. A fixation device as in any one of the preceding claims, wherein the free ends of the fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

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20. A system comprising:

a catheter (86, 300) having a proximal end and a distal end, the catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and

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a fixation device as in any one of the preceding claims.

EIGHTH AUXILIARY REQUEST

CLAIMS:

- 5 1. A fixation device for engaging tissue comprising:
a pair of fixation elements (18) each having a first end, a free end opposite the first
end, and an engagement surface (50) therebetween for engaging the tissue, the first ends
being movably coupled together such that the fixation elements (18) are moveable between
1) a closed position wherein the engagement surfaces (50) face each other, and 2) an
10 inverted position wherein the engagement surfaces (50) face away from each other; and
an actuation mechanism (58) coupled to the fixation elements adapted to move the
fixation elements (18) between the closed position and the inverted position, further
comprising a pair of gripping elements (16), each gripping element (16) moveable with
respect to one of the fixation elements (18) and being disposed in opposition to one of the
15 engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping
elements (16) are movable from an undeployed configuration in which each gripping
element (16) is separated from an opposing engagement surface (50), to a deployed
configuration in which the gripping element (16) is adjacent to the opposing engagement
surface (50) and wherein each fixation element (18) is at least partially concave and each
20 gripping element (16) is at least partially recessed within the fixation element (18) in the
deployed configuration or wherein the gripping elements (16) are approximately parallel to
each other in the undeployed configuration.
2. A fixation device as in claim 1, wherein the fixation elements (18) are further
25 moveable to an open position between the closed position and the inverted position.
3. A fixation device as in claim 1, wherein in the open position the engagement
surface (50) of one fixation element (18) forms an angle of more than about 5° and less
than about 90° with the engagement surface (50) of the other fixation element (18), or
30 wherein in the open position the engagement surface (50) of one fixation element (18)
forms an angle of more than about 90° and less than about 180° with the engagement
surface (50) of the other fixation element (18).

4. A fixation device as in claim 1, wherein the gripping elements (16) have frictional features (60) configured to enhance grip on tissue engaged thereby.

5. A fixation device as in claim 1, wherein the gripping elements (16) are movable independently of the fixation elements (18) or wherein the gripping elements (16) are biased toward the engagement surfaces (50).

6. A fixation device as in any one of the preceding claims, wherein the actuation mechanism (58) comprises a pair of link members (68) coupled to the fixation elements (18) whereby moving the link members (68) moves the fixation elements (18).

7. A fixation device as in claim 6, wherein the actuation mechanism (58) further comprises a coupling member (19) and a stud (74) slidably coupled to the coupling member, the first ends being coupled to one of either the coupling member (19) or the stud (74), and the link members (68) being coupled to the other of either the coupling member (19) or the stud (74).

8. A fixation device as in claim 7, wherein the link members (68) are connected to one of either the coupling member (19) or the stud (74) by a hinge wherein the link members are connected to the fixation elements (18) by a hinge.

9. A fixation device as in any one of the preceding claims, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position.

10. A fixation device as in any one of claims 1 to 6, further comprising a locking mechanism (106) adapted to lock the fixation elements (18) in a desired position, wherein the actuation mechanism (68) comprises a movable stud (74) coupled to the fixation elements (18), the locking mechanism (106) being configured to frictionally engage the stud to prevent movement thereof.

11. A fixation device as in claim 10, wherein the locking mechanism comprises a wedging element (110) for frictionally engaging the stud (74), further comprising a coupling member (19) having a pair of sidewalls (116), at least one of the sidewalls sloping toward

the other sidewall, the stud (74) being slideable between the sidewalls (116), the wedging element (110) being movably disposed between the stud and at least one sidewall.

5 12. A fixation device as in claim 11, wherein the wedging element comprises a rolling element (110) configured to roll along the at least one sidewall (116) in engagement with the stud wherein the rolling element comprises a barbell (110) having a pair of generally cylindrical caps and a shaft therebetween, the shaft being configured to engage the stud between the caps.

10 13. The fixation device of any one of claims 9, 10, 11 or 12, further comprising an unlocking mechanism adapted to unlock the fixation elements (18) so as to be movable from the desired position, the unlocking mechanism comprising a harness (108) coupled to the wedging element (110), the harness adapted to move the wedging element to reduce frictional engagement of the stud (74).

15 14. The fixation device of any one of the preceding claims, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device.

20 15. The fixation device of any of claims 1 to 6, further comprising a coupling member (19) for detachably coupling the fixation device to a delivery device, wherein the coupling member (19) comprises an outer member having an axial channel, the outer member being coupled to one of either the fixation elements (18) or the actuation mechanism (58), and an inner member extending slidably through the axial channel and coupled to the other of either the fixation elements (18) or the actuation mechanism (58), wherein outer member
25 has a mating surface for engagement with the delivery device, the mating surface having a sigmoid shape.

30 16. The fixation device of any one of the preceding claims, further comprising a covering (100) on the fixation elements (18) adapted for promoting tissue growth.

17. The fixation device of any one of the preceding claims, further comprising a coating on the fixation elements (18) adapted for delivering a therapeutic agent.

18. A fixation device as in any one of the preceding claims, wherein the fixation elements (18) have longitudinal edges between the first end and the free end, the longitudinal edges being curved about a longitudinal axis away from the engagement surfaces.

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19. A fixation device as in any one of the preceding claims, wherein the free ends of the fixation elements (18) curve away from the engagement surfaces about a transverse axis generally parallel to the engagement surface (50), wherein the free ends of the fixation elements (18) are curved about a second axis not parallel to the transverse axis.

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20. A system comprising:

an endovascular delivery device comprising a flexible delivery catheter (86, 300), the delivery catheter comprising a shaft having a proximal end and a distal end, the delivery catheter configured to pass from remote vasculature of a patient to a location within the patient's body near a tissue; and

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a fixation device as in any one of the preceding claims, the fixation device being releasably attached to the distal end of the delivery catheter.

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