US 20110067471A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2011/0067471 A1

Griswold (43) Pub. Date: Mar. 24, 2011

(54) METHOD AND APPARATUS FOR CREATING FORMED ELEMENTS USED TO MAKE WOUND STENTS

(75) Inventor: Erik Griswold, Penngrove, CA (US)

(73) Assignee: Medtronic Vascular, Inc., Santa Rosa, CA (US)

(21) Appl. No.: 12/693,574

(22) Filed: Jan. 26, 2010

Related U.S. Application Data

(60) Provisional application No. 61/243,578, filed on Sep. 18, 2009, provisional application No. 61/243,581, filed on Sep. 18, 2009, provisional application No. 61/243,582, filed on Sep. 18, 2009, provisional application No. 61/243,592, filed on Sep. 18, 2009, provisional application No. 61/243,597, filed on Sep. 18, 2009, provisional application No. 61/243,600, filed on Sep. 18, 2009.

Publication Classification

(51) Int. Cl.

B21F 3/02 (2006.01)

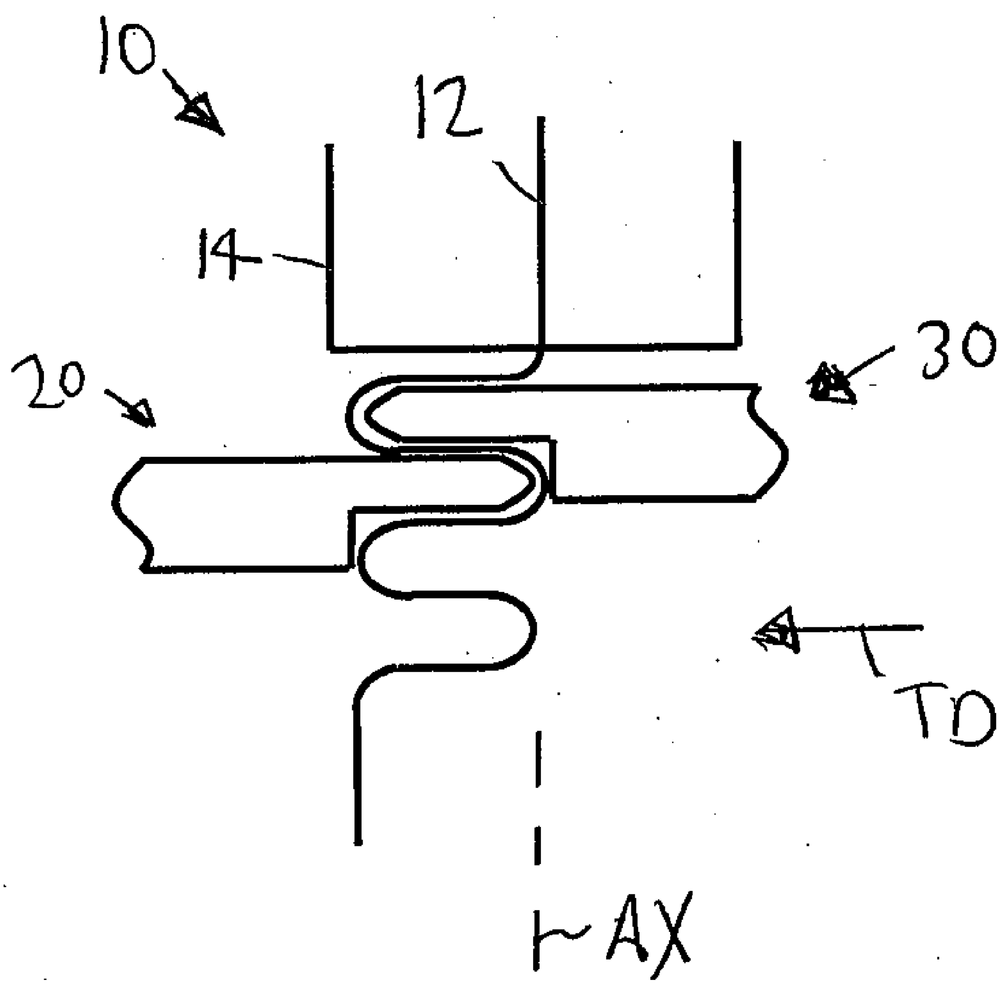
B21F 45/00 (2006.01)

B21F 1/04 (2006.01)

(52) U.S. Cl. 72/135; 72/142; 72/145; 140/92.3; 72/179

(57) ABSTRACT

A method for forming a wave form for a stent includes providing a length of a formable material from a supply of the formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member. The second forming member is positioned closer to the feeder than the first forming member. The length is about the length of a substantially straight portion of the wave form. The method also includes moving the first forming member in a second direction substantially perpendicular to the first direction to a position in contact with the formable material, and moving the second forming member in a third direction substantially opposite the second direction to wrap the formable material about a distal end of the first forming member.



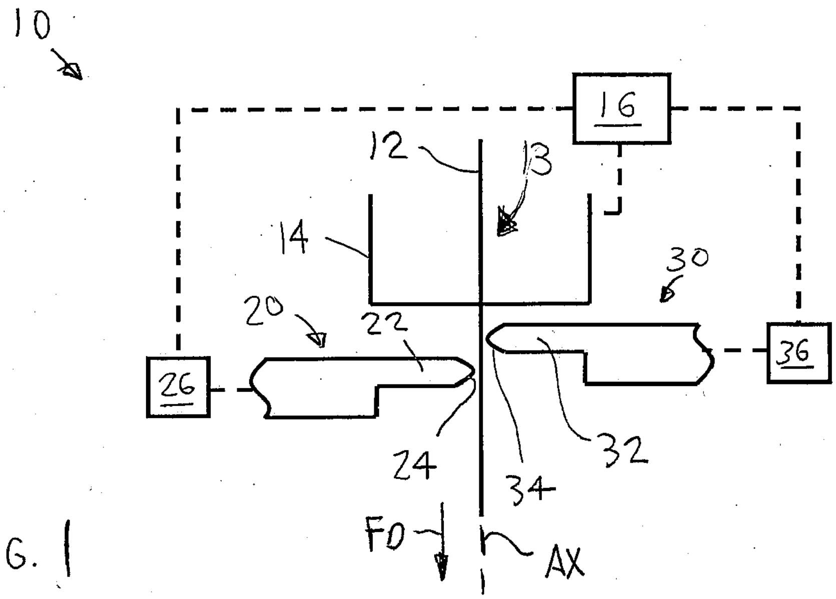


FIG. 1

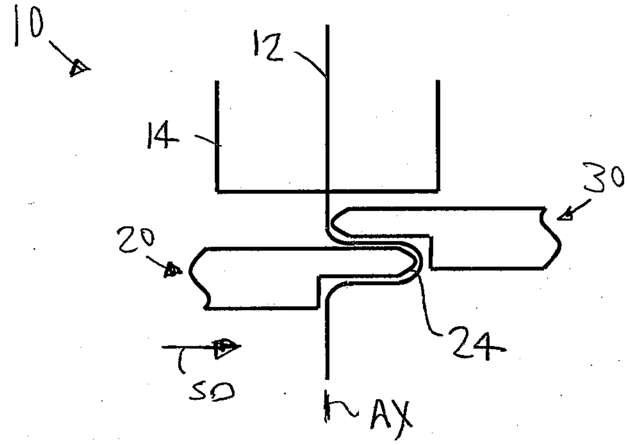


FIG. 2

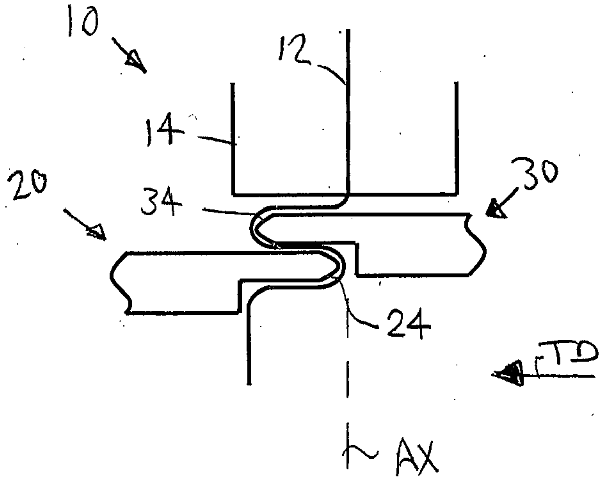


FIG. 3

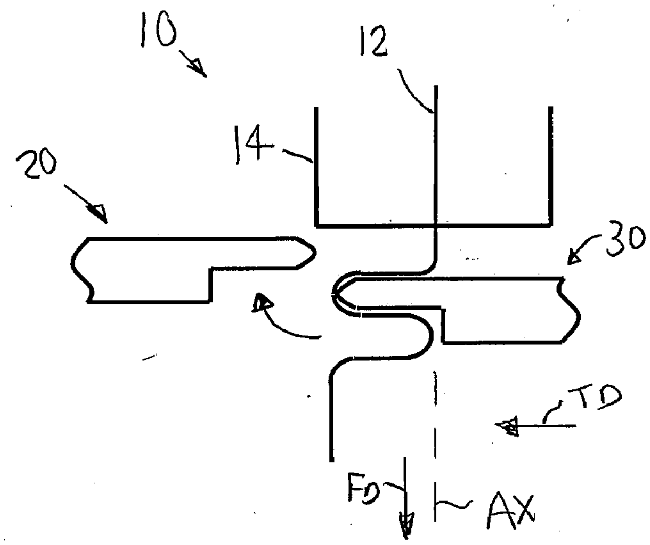


FIG. 4

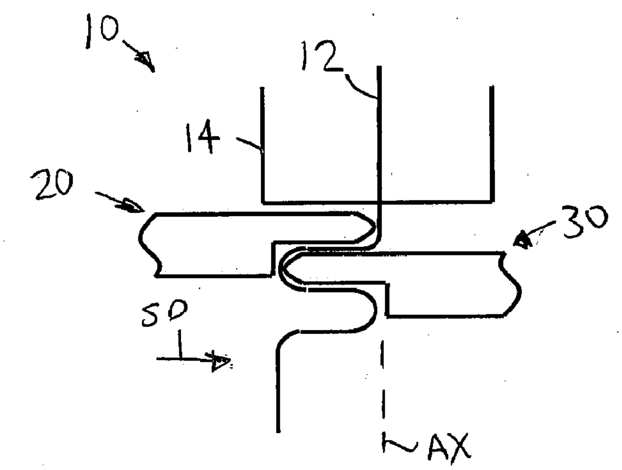


FIG. 5

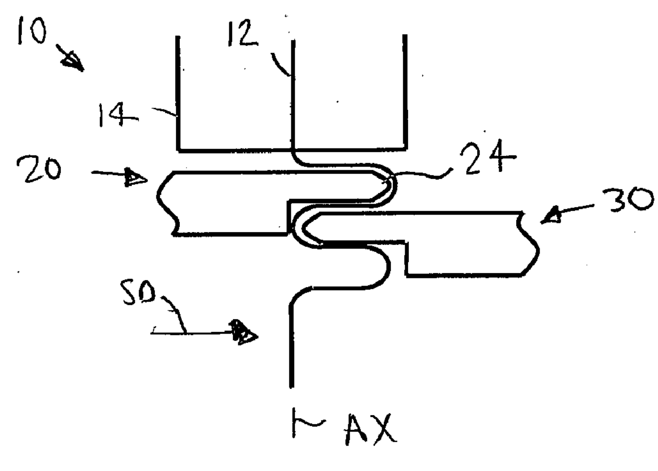


FIG. 6

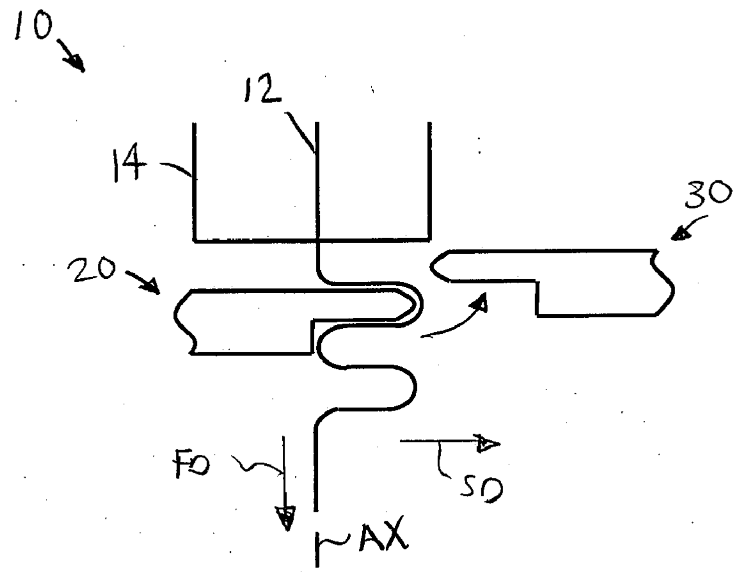


FIG. 7

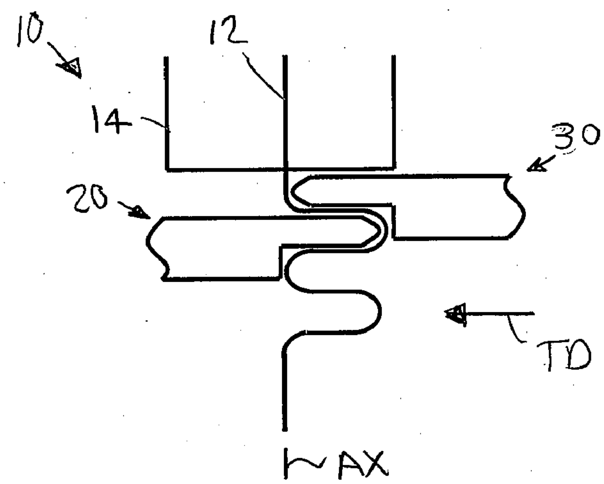


FIG. 8

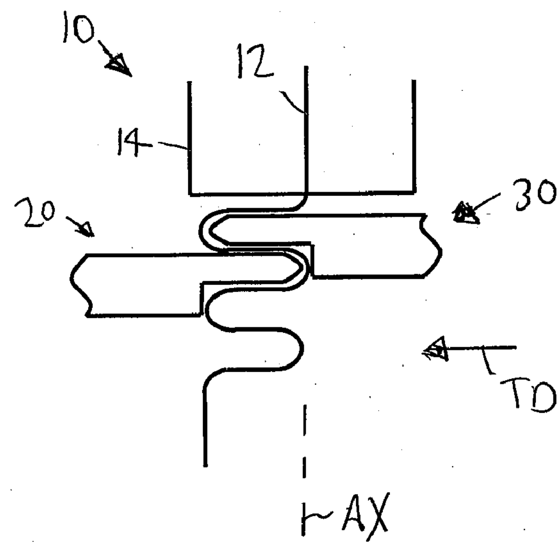


FIG. 9

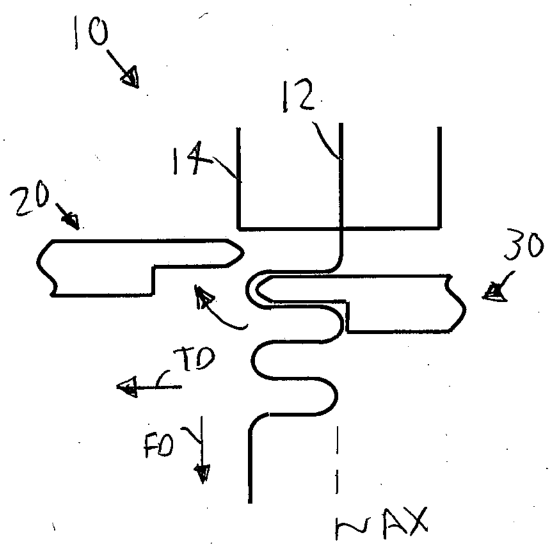


FIG. 10

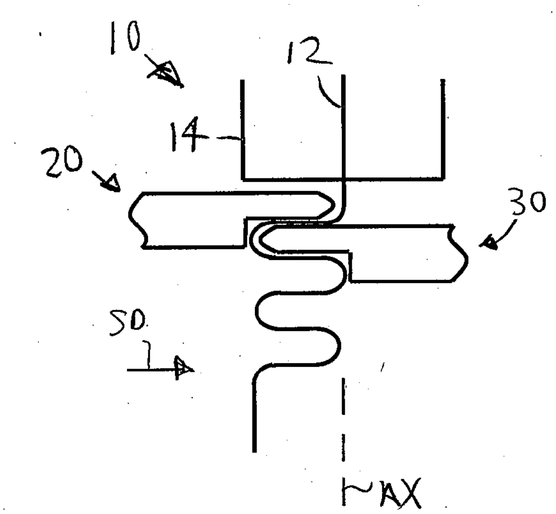


FIG. 11

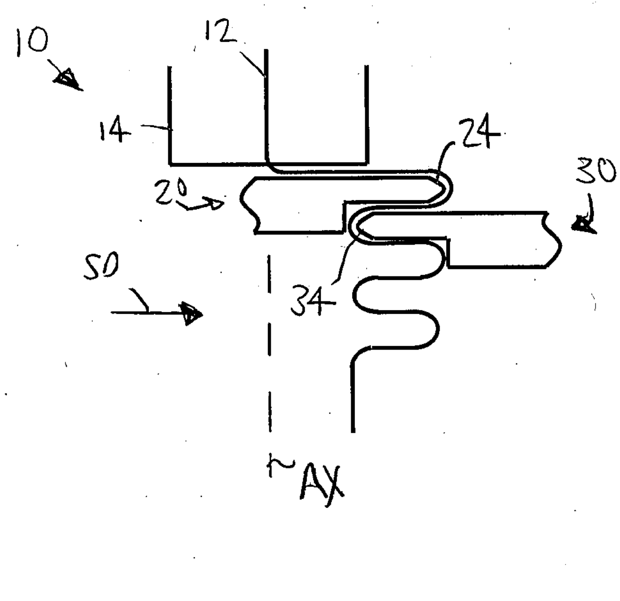


FIG. 12

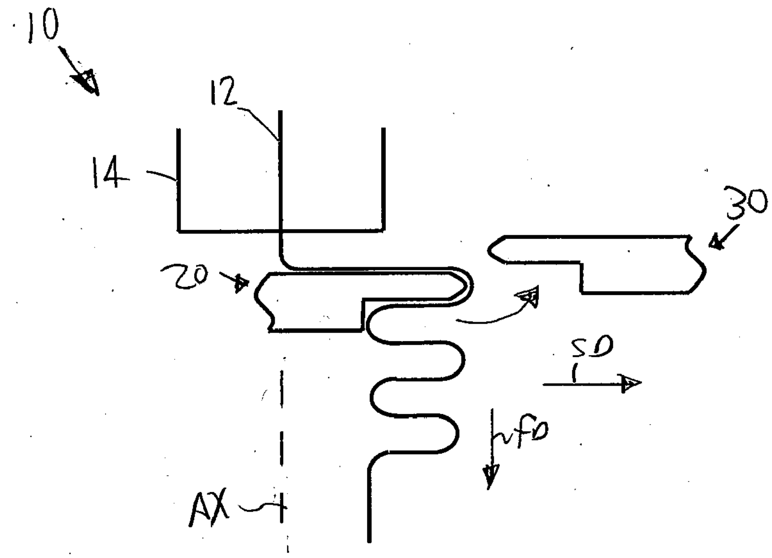


FIG. 13

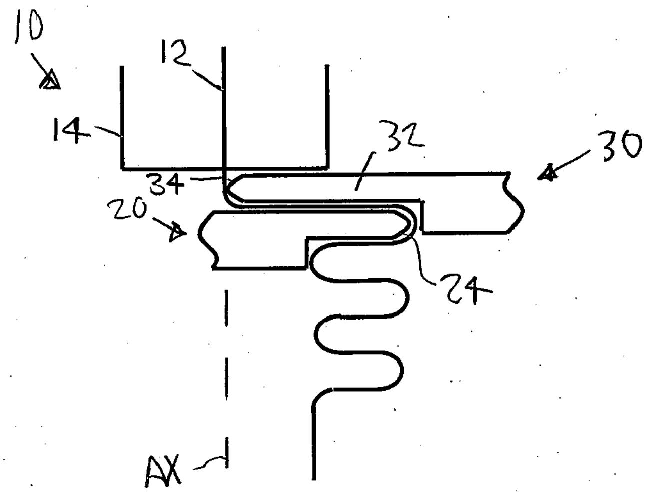


FIG. 14

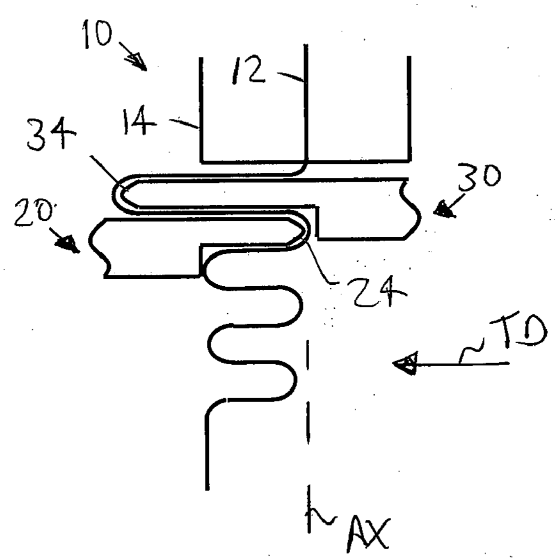


FIG. 15

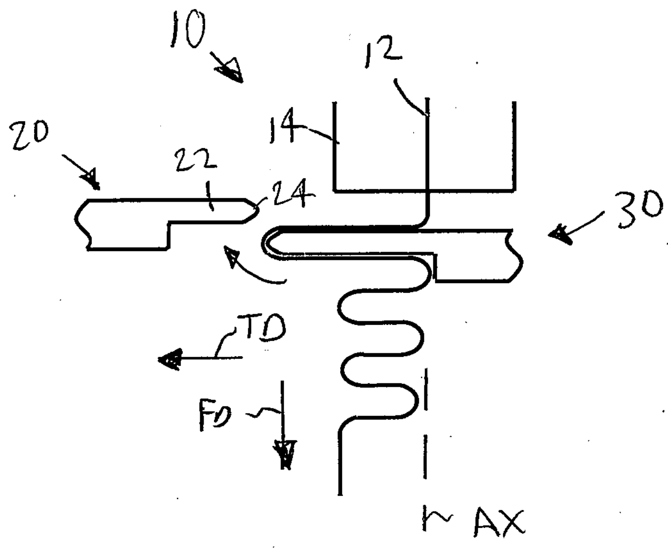


FIG. 16

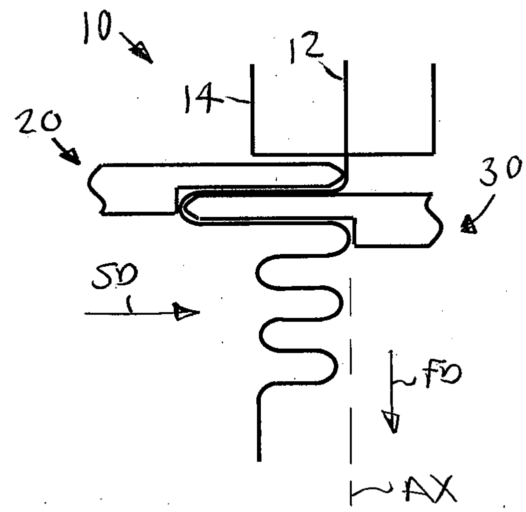


FIG. 17

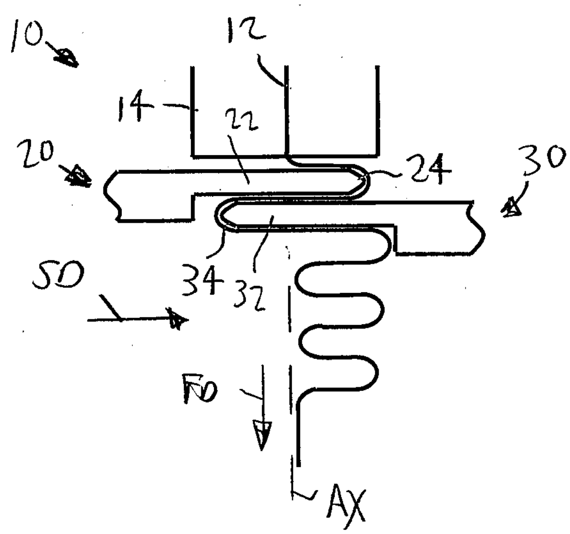


FIG. 18

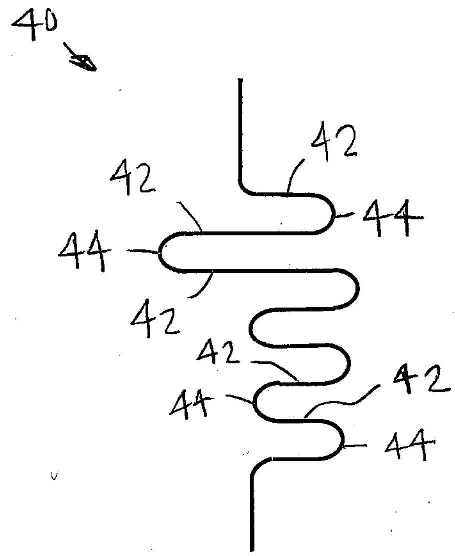


FIG. 19

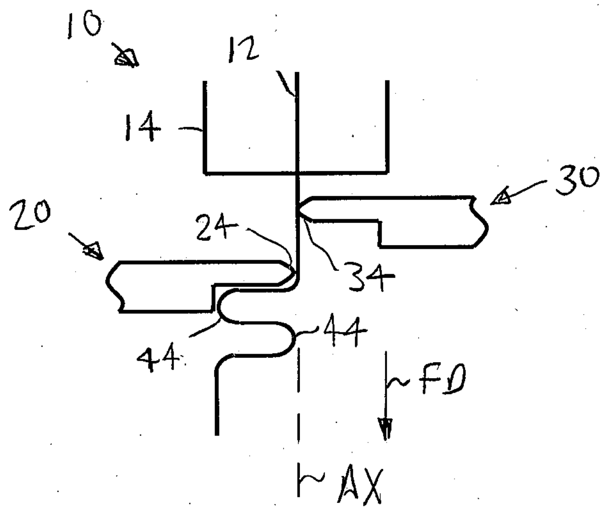


FIG. 20

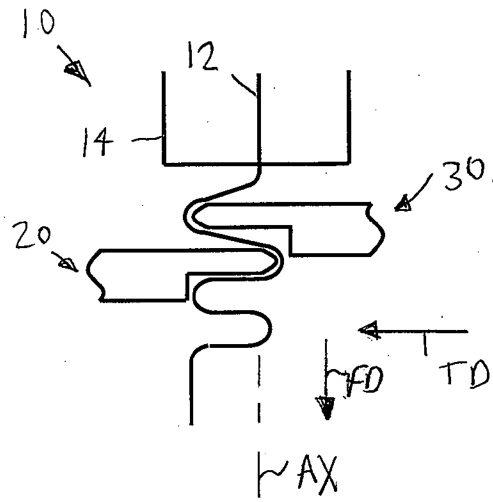


FIG. 21

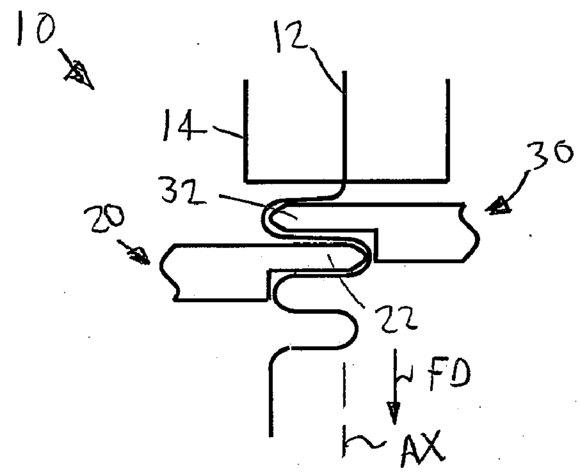


Fig. 22

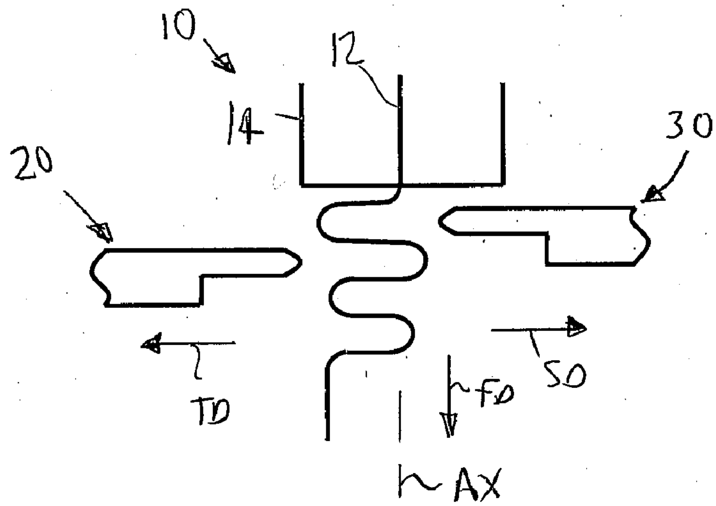


Fig. 23

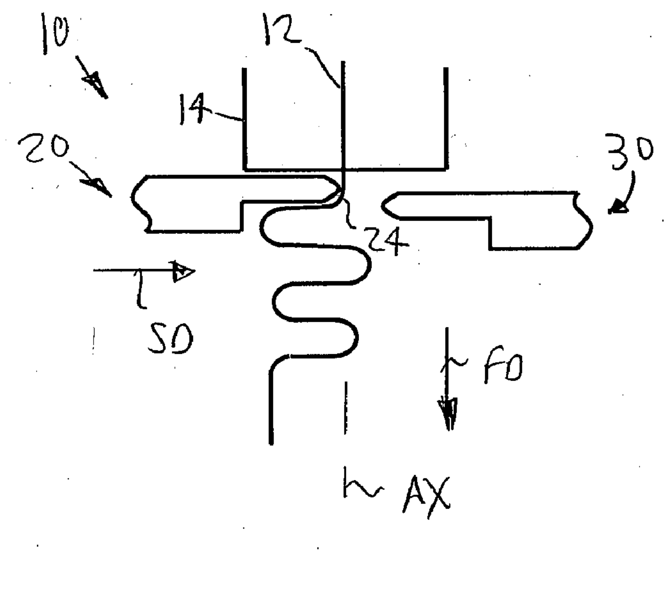


Fig. 24

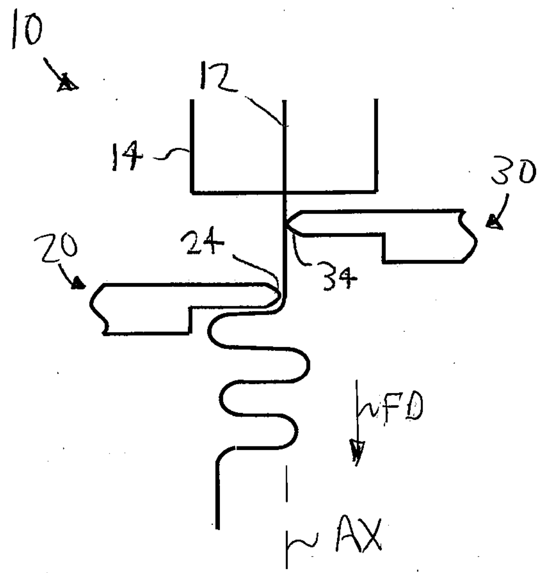


FIG. 25

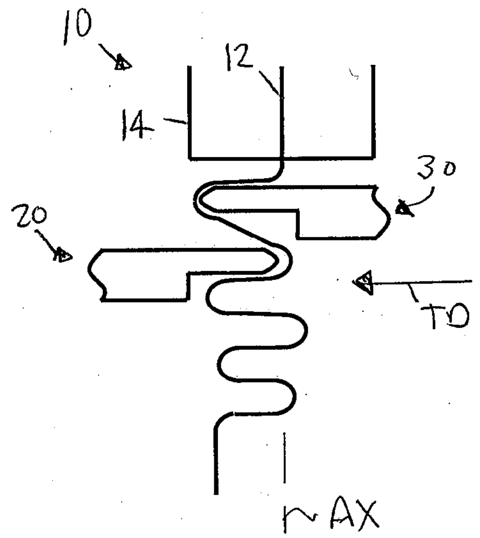


FIG. 26

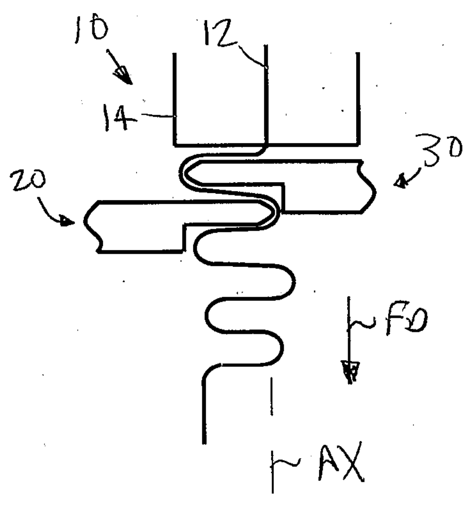


FIG. 27

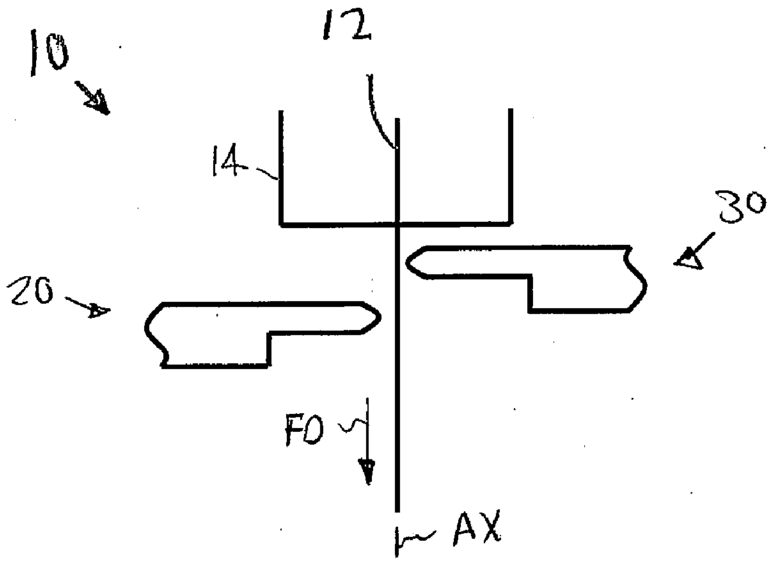


FIG. 28

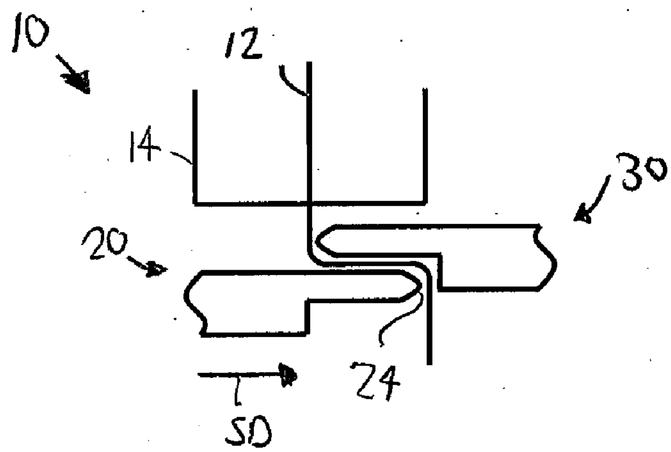


FIG. 29

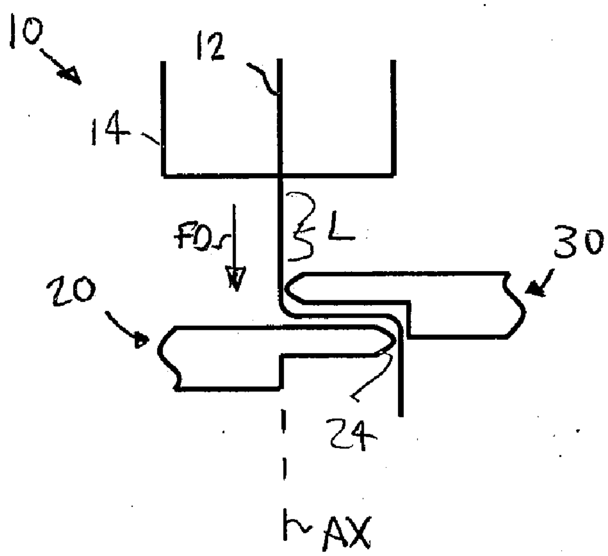


FIG. 30

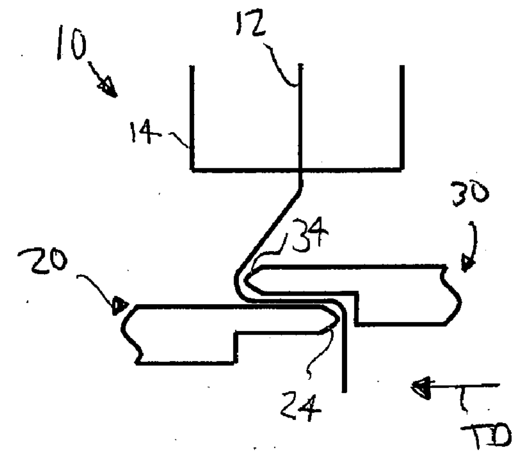


FIG. 31

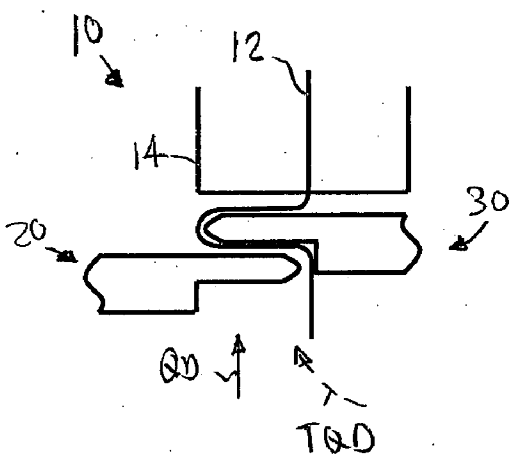


FIG. 32

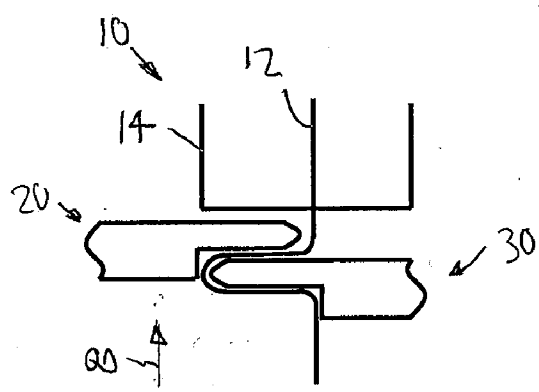


FIG. 33

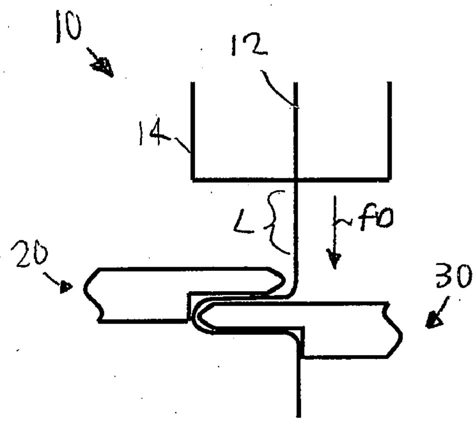


FIG. 34

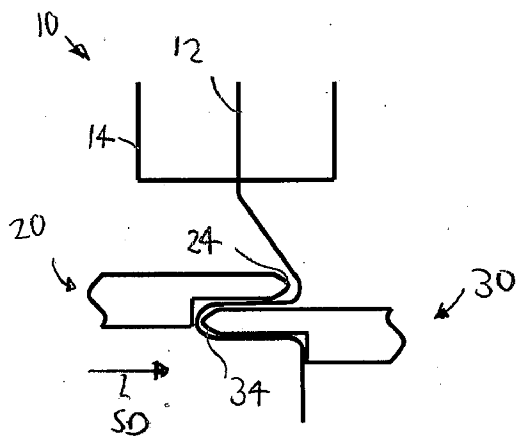


FIG. 35

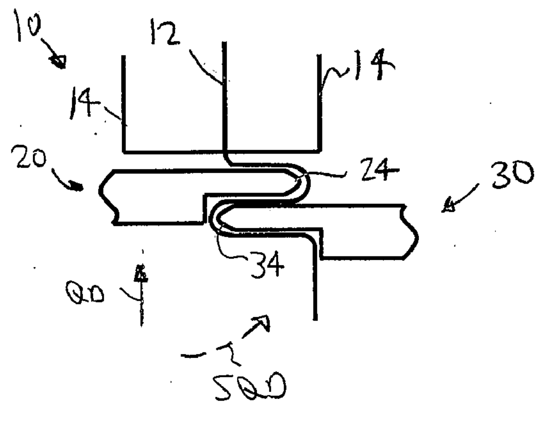


FIG. 36

METHOD AND APPARATUS FOR CREATING FORMED ELEMENTS USED TO MAKE WOUND STENTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority from U.S. Provisional Patent Application Ser. No. 61/243,578, filed on Sep. 18, 2009, the entire content of which is incorporated herein by reference. This application also claims the benefit of priority from U.S. Provisional Patent Application Ser. Nos. 61/243,581, 61/243,582, 61/243,592, 61/243,597, and 61/243,600, all filed on Sep. 18, 2009, the entire contents of all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention is generally related to an apparatus and method for forming a wave form for a stent. More particularly, the present invention is related to an apparatus and method for forming the wave form from a formable material, such as a wire or a strip of material.

[0004] 2. Background of the Invention

[0005] A stent is typically a hollow, generally cylindrical device that is deployed in a body lumen from a radially contracted configuration into a radially expanded configuration, which allows it to contact and support a vessel wall. A plastically deformable stent can be implanted during an angioplasty procedure by using a balloon catheter bearing a compressed or "crimped" stent, which has been loaded onto the balloon. The stent radially expands as the balloon is inflated, forcing the stent into contact with the body lumen, thereby forming a support for the vessel wall. Deployment is effected after the stent has been introduced percutaneously, transported transluminally, and positioned at a desired location by means of the balloon catheter.

[0006] Stents may be formed from wire(s) or strip(s) of material, may be cut from a tube, or may be cut from a sheet of material and then rolled into a tube-like structure. While some stents may include a plurality of connected rings that are substantially parallel to each other and are oriented substantially perpendicular to a longitudinal axis of the stent, others may include a helical coil that is wrapped or wound around a mandrel aligned with the longitudinal axis at a non-perpendicular angle.

[0007] Stent designs that are comprised of wound materials generally have complex geometries so that the final stents may be precisely formed. The small size and complexity of some stent designs generally makes its formation difficult. Wound stents are formed such that when unsupported, they create the desired stent pattern and vessel support. This process generally involves winding a source material around a supporting structure such as a rod or mandrel and creating a helical or spring-like wrap pattern. To provide greater support, along this wrapped element, geometries are formed into the source material to better support the tissue in between each wrap, usually of sinusoidal nature. A potential down side to a wrapped stent is that the ends of the stent are generally not perpendicular to the longitudinal axis of the stent, but rather terminate at a pitch angle induced by the helical wrapping.

SUMMARY OF THE INVENTION

[0008] Embodiments of the present invention describe an apparatus and method for forming a wave form for a stent that provides formed geometries that can alter a pitch angle such that the wound stent terminates at a substantially perpendicular angle to the longitudinal axis of the stent. More specifically, the apparatus and method according to embodiments of the present invention allow for the amplitude and wavelength of any individual or half element of the wave form to be manipulated to provide the desired interwrap support.

[0009] According to an aspect of the present invention, there is provided a method for forming a wave form for a stent. The method includes providing a length of a formable material from a supply of formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member. The second forming member is positioned closer to the feeder than the first forming member. The method also includes moving a distal end of the first forming member across the axis in a second direction substantially perpendicular to the first direction to engage and deform the formable material while engaging the formable material with a distal end of the second forming member, moving the distal ends of the first and second forming members across the axis in a third direction that is substantially opposite the second direction to draw and form the formable material over the distal end of the second forming member, and disengaging the first forming member from the forming material. The method also includes moving the first forming member and the second forming member relative to each other so that the first forming member is positioned closer to the feeder than the second forming member, moving the distal end of the first forming member into engagement with the deformable material, and moving the distal ends of the first and second forming members across the axis in the second direction to draw and form the formable material over the distal end of the first forming member.

[0010] According to an aspect of the present invention, there is provided a method for forming a wave form for a stent. The method includes providing a length of a formable material from a supply of formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member. The second forming member is positioned closer to the feeder than the first forming member. The length is about the length of a substantially straight portion of the wave form. The method also includes moving the first forming member in a second direction substantially perpendicular to the first direction to a position in contact with the formable material, and moving the second forming member in a third direction substantially opposite the second direction to wrap the formable material about a distal end of the first forming member.

[0011] According to an aspect of the present invention, there is provided a method for forming a wave form for a stent that includes providing a length of a formable material from a supply of formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member. The second forming member is positioned closer to the feeder than the first forming member. The method includes moving the first forming member into contact with the formable material and across the axis in a second direction substantially perpendicular to the first direction, and folding the formable material over the second forming member by moving the second forming member and the first forming member in a third direction substantially opposite the second direction and moving the second forming member and the first forming member in a fourth direction substantially opposite the first direction.

[0012] According to an aspect of the present invention, there is provided a forming apparatus configured to form a wave form for a stent out of a formable material. The wave form includes a plurality of substantially straight portions and a plurality of curved portions. The apparatus includes a feeder constructed and arranged to receive a supply of the formable material and provide the formable material along an axis, and a first forming member configured to be movable along two orthogonal axes. The first forming member includes a first elongated portion having a first engaging surface at a distal end of the first elongated portion. The first engaging surface is configured to engage a first side of the formable material. The apparatus also includes a second forming member configured to be movable along the two orthogonal axes. The second forming member includes a second elongated portion having a second engaging surface at a distal end of the second elongated portion. The second engaging surface is configured to engage a second side of the formable material that is opposite the first side. The apparatus also includes a controller in communication with the feeder, the first forming member, and the second forming member. The controller is configured to control movement of the first and second forming members to control a length of each substantially straight portion of the wave form and to control a wavelength within the wave form.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying schematic drawings in which corresponding reference symbols indicate corresponding parts, and in which:

[0014] FIG. **1** is a schematic view of an embodiment of a forming apparatus configured to deform a formable material into a desired wave form for a stent, with the formable material being provided in a first direction by a feeder;

[0015] FIG. **2** is a schematic view of the forming apparatus of FIG. **1**, with a first forming member being moved in a second direction substantially perpendicular to the first direction to deform the formable material into a half element of the wave form;

[0016] FIG. **3** is a schematic view of the forming apparatus of FIG. **2**, with a second forming member and the first forming member being moved in a third direction substantially opposite the second direction to deform the formable material into another half element of the wave form;

[0017] FIG. **4** is a schematic view of the forming apparatus of FIG. **3**, with the first forming member moving away from the formable material and towards the feeder;

[0018] FIG. **5** is a schematic view of the forming apparatus of FIG. **4**, with the first forming member being moved towards the formable material in the second direction;

[0019] FIG. **6** is a schematic view of the forming apparatus of FIG. **5**, with the first forming member and the second forming member being moved in the second direction to deform the formable material into another half element of the wave form;

[0020] FIG. **7** is a schematic view of the forming apparatus of FIG. **6**, with the second forming member moving away from the formable material and towards the feeder;

[0021] FIG. **8** is a schematic view of the forming apparatus of FIG. **7**, with the second forming member being moved towards the formable material in the third direction;

[0022] FIG. **9** is a schematic view of the forming apparatus of FIG. **8**, with the first forming member and the second forming member being moved in the third direction to deform the formable material into another half element of the wave form;

[0023] FIG. **10** is a schematic view of the forming apparatus of FIG. **9**, with the first forming member moving away from the formable material and towards the feeder;

[0024] FIG. **11** is a schematic view of the forming apparatus of FIG. **10**, with the first forming member being moved towards the formable material in the second direction;

[0025] FIG. **12** is a schematic view of the forming apparatus of FIG. **11**, with the first forming member and the second forming member being moved in the second direction to deform the formable material into another half element of the wave form;

[0026] FIG. **13** is a schematic view of the forming apparatus of FIG. **12**, with the second forming member moving away from the formable material and towards the feeder;

[0027] FIG. **14** is a schematic view of the forming apparatus of FIG. **13**, with the second forming member being moved towards the formable material in the third direction;

[0028] FIG. **15** is a schematic view of the forming apparatus of FIG. **14**, with the first forming member and the second forming member being moved in the third direction to deform the formable material into another half element of the wave form;

[0029] FIG. **16** is a schematic view of the forming apparatus of FIG. **15**, with the first forming member moving away from the formable material and towards the feeder;

[0030] FIG. **17** is a schematic view of the forming apparatus of FIG. **16**, with the first forming member being moved towards the formable material in the second direction;

[0031] FIG. **18** is a schematic view of the forming apparatus of FIG. **17**, with the first forming member and the second forming member being moved in the second direction to deform the formable material into another half element of the wave form;

[0032] FIG. **19** illustrates an embodiment of a wave form generated by the forming apparatus of FIGS. **1-17**;

[0033] FIG. **20** is a schematic view of the forming apparatus of FIG. **1** according to an embodiment of the present invention, with the formable material being drawn from the feeder and the first forming member being moved in the first direction;

[0034] FIG. **21** is a schematic view of the forming apparatus of FIG. **20**, with the second forming member being moved in the third direction to deform the formable material;

[0035] FIG. **22** is a schematic view of the forming apparatus of FIG. **21**, with the first and second forming members being moved towards the feeder to continue to deform the formable material into a whole element of the wave form;

[0036] FIG. **23** is a schematic view of the forming apparatus of FIG. **22**, with the first and second forming members being moved away from the formable material;

[0037] FIG. **24** is a schematic view of the forming apparatus of FIG. **23**, with the first forming member being moved in the second direction towards the formable material, after the first forming member has been moved towards the feeder;

[0038] FIG. **25** is a schematic view of the forming apparatus of FIG. **24**, with the formable material being drawn from the feeder and the first forming member being moved in the first direction;

[0039] FIG. **26** is a schematic view of the forming apparatus of FIG. **25**, with the second forming member being moved in the third direction to deform the formable material;

[0040] FIG. **27** is a schematic view of the forming apparatus of FIG. **26**, with the first and second forming members being moved towards the feeder to continue to deform the formable material into another whole element of the wave form;

[0041] FIG. **28** is a schematic view of an embodiment of the forming apparatus of FIG. **1**, with the formable material being provided in the first direction;

[0042] FIG. **29** is a schematic view of the forming apparatus of FIG. **28**, with the first forming member being moved in the second direction to deform the formable material;

[0043] FIG. **30** is a schematic view of the forming apparatus of FIG. **29**, with the formable material being drawn from the feeder in the first direction by movement of the first forming member and the second forming member;

[0044] FIG. **31** is a schematic view of the forming apparatus of FIG. **30**, with the first forming member and the second forming member being moved in the third direction;

[0045] FIG. **32** is a schematic view of the forming apparatus of FIG. **31**, with the first forming member and the second forming member being moved in a fourth direction, which is opposite the first direction;

[0046] FIG. **33** is a schematic view of the forming apparatus of FIG. **32**, after the first forming member has been moved to a position in between the feeder and the second forming member;

[0047] FIG. **34** is a schematic view of the forming apparatus of FIG. **33**, with the formable material being drawn in the first direction by movement of the first forming member and the second forming member;

[0048] FIG. **35** is a schematic view of the forming apparatus of FIG. **34**, with the first forming member and the second forming member being moved in the second direction; and

[0049] FIG. **36** is a schematic view of the forming apparatus of FIG. **35**, with the first forming member and the second forming member being moved in the fourth direction.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0050] The following detailed description is merely exemplary in nature and is not intended to limit the invention or the application and use of the invention. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

[0051] FIG. **1** schematically illustrates an embodiment of a forming apparatus **10** that is configured to deform a formable material **12** into a desired shape, i.e. wave form, as discussed in further detail below. The forming apparatus **10** includes a feeder **14** that is constructed and arranged to receive a supply of the formable material **13** and to provide the formable material **12** substantially along an axis AX in a first direction FD. The feeder **14** may be configured to actively feed the formable material **12** along the axis AX in the first direction, or may be configured to passively feed the formable material by allowing the formable material **12** to be drawn from the feeder **14**, as discussed in further detail below. The forming apparatus **10** also includes a controller **16** that is configured to communicate with the feeder **14**. The controller **16** may be programmed to provide signals to the feeder **14** so that the feeder **14** feeds the formable material **12** at a desired rate or velocity, and also stops feeding the formable material **12** when desired.

[0052] The forming apparatus **10** also includes a first forming member **20** and a second forming member **30**. The first forming member **20** includes an elongated, or finger-like, portion **22** that has an engaging surface **24** at a distal end thereof. The engaging surface **24** is configured to engage the formable material **12** on one side thereof and deform the formable material **12** into a desired shape, as discussed in further detail below.

[0053] Similar to the first forming member **20**, the second forming member **30** includes an elongated, or finger-like, portion **32** that has an engaging surface **34** at a distal end thereof. The engaging surface **34** is configured to engage the formable material **12** on a side that is opposite the side of the formable material **12** that is engaged by the engaging surface **24** of the first forming member **20**. As illustrated in FIG. **1**, the first forming member **20** and the second forming member **30** are positioned so that the engaging surface **24** of the first forming member **20** and the engaging surface **34** of the second forming member **30** face each other on opposite sides of the formable material **12**.

[0054] The first forming member **20** and the second forming member **30** may be moved relative to the feeder **14** by actuators **26**, **36**, respectively, that are schematically illustrated in FIG. **1**. Each of the actuators **26**, **36** is in communication with the controller **16** so that the controller **16** may send signals to the actuators **26**, **36** to control movement of the first and second forming members **20**, **30**, respectively. In addition, the feeder **14** may be connected to an actuator (not shown) that is in communication with the controller **16** so that the controller may control movement of the feeder **14** relative to the first and second forming members **20**, **30**.

[0055] In operation, the first forming member **20** is initially positioned on one side of the axis AX, and the second forming member **30** is initially positioned on the opposite side of the axis AX relative to the first forming member **20** such that the engaging surface **24** of the first forming member **20** and the engaging surface **34** of the second forming member **30** face each other, as illustrated in FIG. **1**. In an embodiment, the controller **16** sends a signal to the feeder **14** to advance the formable material **12** by a predetermined amount or length in the first direction FD substantially along the axis AX. In an embodiment, the feeder **14** does not actively advance the formable material **12**, but instead allows the formable material **12** to be drawn by the first forming member **20** and/or the second forming member **30**, as understood by one of ordinary skill in the art.

[0056] As illustrated in FIG. **2**, the first forming member **20** is moved in a second direction SD that is substantially perpendicular to the first direction FD and the axis AX so that the engaging surface **24** engages the formable material **12** and deforms the formable material **12** as the engaging surface **24** passes over the axis AX. The second forming member **30** may hold its position relative to the axis AX until the first forming member **20** has completed its movement in the first direction FD.

[0057] FIG. **3** illustrates the second forming member **30** engaging the formable material **12** with the engaging surface **34** and moving in a third direction TD that is substantially opposite the second direction SD and substantially perpendicular to the axis AX. At the same time or at about the same time, the first forming member **20** also moves with the second forming member **30** in the third direction TD while still engaging the formable material **12**, and the feeder **14** feeds an additional amount of formable material **12** in the first direction FD or the feeder **14** allows the additional amount of formable material **12** to be drawn in the first direction FD. Due to the movement of the first and second forming members **20**, **30**, the formable material **12** folds over the top of the elongated portion **32** of the second forming member **30**, as illustrated in FIG. **3**, to form a half element (i.e., half wavelength) of the wave form.

[0058] As illustrated in FIG. **4**, the first forming member **20** then disengages from the formable material **12** and moves away from the formable material **12** in the third direction TD. In addition, the first forming member **20** moves towards the feeder **14** in a direction that is substantially opposite the first direction **20**. At the same time, or about the same time, the second forming member **30** moves in the first direction FD as the feeder **14** provides a small amount of formable material **12** in the first direction, desirably at about the same rate that the second forming member **30** moves in the first direction FD, to make room for the first forming member **20** in between the feeder **14** and the second forming member **30**. The formable material **12** may be drawn from the feeder **14** or the feeder **14** may actively feed the formable material **12**.

[0059] The first forming member **20** then moves in the second direction SD towards the formable material **12**, engages the formable material **12** with the engaging surface **24**, as illustrated in FIG. **5**, and continues to move in the second direction SD, as illustrated in FIG. **6**. At the same time, or about the same time, that the engaging surface **24** of the first forming member **20** moves across the axis AX and to the position illustrated in FIG. **6**, an additional length of the formable material **12** is provided to accommodate for the distance traveled by the engaging surface **24** relative to the axis AX, and the second forming member **30** moves at substantially the same speed as the first forming member **20**, in the second direction SD. The additional length may be drawn from the feeder **14** or may be fed by the feeder **14**, as discussed above.

[0060] Similar to the movement of the first forming member **20** that is represented in FIG. **4**, the second forming member **30** then moves away from the formable material **12** and away from the axis AX in the second direction SD, and also moves towards the feeder **14** in a direction substantially opposite the first direction, as illustrated in FIG. **7**. At the same time, or about the same time, the first forming member **20** moves substantially in the first direction FD as a small amount of formable material is provided in the first direction along the axis AX so as to make room for at least the elongated portion **32** of the second forming member **30** in between the feeder **14** and the first forming member **20**.

[0061] The second forming member **30** then moves in the third direction TD towards the formable material **12**, as illustrated in FIG. **8**, engages the formable material **12** with the engaging surface **34**, and continues to move in the third direction TD, as illustrated in FIG. **9**. At the same time, or about the same time, that the engaging surface **34** of the first forming member **30** moves across the axis AX and to the position illustrated in FIG. **9**, a suitable length of the formable material **12** is provided (i.e. drawn or fed) to accommodate for the distance traveled by the engaging surface **34** relative to the axis AX.

[0062] Similar to the movement of the first forming member **20** illustrated in FIG. **4**, the first forming member **20** then disengages from the formable material **12** and moves away from the formable material in the third direction TD, as illustrated in FIG. **10**. In addition, the first forming member **20** moves towards the feeder **14** in a direction that is substantially opposite the first direction FD. At the same time, or about the same time, the second forming member **30** moves in the first direction FD as a small amount of formable material **12** is provided in the first direction, desirably at about the same rate that the second forming member **30** moves in the first direction FD, to make room for the first forming member **20** in between the feeder **14** and the second forming member **30**.

[0063] The first forming member **20** then moves in the second direction SD towards the formable material **12**, as illustrated in FIG. **11**, engages the formable material **12** with the engaging surface **24**, and continues to move in the second direction SD, as illustrated in FIG. **12**. At the same time, or about the same time, that the engaging surface **24** of the first forming member **20** moves across the axis AX and to the position illustrated in FIG. **12**, a suitable length of the formable material **12** is provided to accommodate for the distance traveled by the engaging surface **24** relative to the axis AX. FIG. **12** illustrates that the first and second forming members **20**, **30** may move away from the axis AX by a greater distance than previously illustrated. In fact, the distances travelled by the first and second forming members **20**, **30** relative to the axis AX in the second direction and/or third direction may be different each time the engaging surfaces **24**, **34** move across the axis AX. The controller **16** is configured to control the movement of the first and second forming members **20**, **30** and may be configured to control the rate at which the formable material **12** comes out of the feeder **14**.

[0064] Similar to the movement of the second forming member **30** that is represented in FIG. **7**, the second forming member **30** then moves away from the formable material **12** and away from the axis AX in the second direction SD, and also moves towards the feeder **14** in a direction substantially opposite the first direction, as illustrated in FIG. **13**. At the same time, or about the same time, the first forming member **20** moves substantially in the first direction FD and a small amount of formable material is provided in the first direction along the axis AX so as to make room for at least the elongated portion **32** of the second forming member **30** in between the feeder **14** and the first forming member **20**.

[0065] The second forming member **30** then moves in the third direction TD towards the formable material **12**, as illustrated in FIG. **14**, engages the formable material **12** with the engaging surface **34**, and continues to move in the third direction TD, as illustrated in FIG. **15**. At the same time, or about the same time, that the engaging surface **34** of the first forming member **30** moves across the axis AX and to the position illustrated in FIG. **14**, the feeder **14** feeds a suitable length of the formable material **12** to accommodate for the distance traveled by the engaging surface **34** relative to the axis AX.

[0066] The method continues to repeat itself, as illustrated by FIGS. **16-18** until the formable member **12** is formed into a desired shape, such as the shape containing a wave form **40** illustrated in FIG. **19**. The wave form **40** includes a plurality of substantially straight portions **42** that are connected by curved portions **44**, as illustrated in FIG. **19**. Different amplitudes, i.e., lengths of the substantially straight portions **42**, and different wave lengths between the curved portions **44** may be generated by varying the distance traveled by the engaging surfaces **24**, **34** and the amount of formable material **12** that is provided by the feeder **14** when the first and second forming members **20**, **30** move. A desired wave form may be programmed into the controller **16** so that the controller **16** signals the actuators **26**, **36** and the feeder **14** in a manner that yields the desired wave form. As illustrated in FIG. **19**, the amplitudes of the wave form need not be centered on a central feed location in the first direction FD. In an embodiment, the amplitudes of the wave form may be formed to progress in the first direction FD and additionally in the second direction SD and in the third direction TD similar to a stair case or wave. The illustrated embodiment is not intended to be limiting in any way.

[0067] FIGS. **20-27** illustrate a method for forming the wave form **40** in accordance with another embodiment of the present invention, after a couple of curved portions **44** of the wave form **40** have been formed, for example by the method described above with respect to FIGS. **1-5**, or with the method discussed below with respect to FIGS. **28-36**. As illustrated in FIG. **20**, the formable material **12** is provided (i.e., drawn or fed) in the first direction FD by the feeder **14** as the first forming member **20** is moved in the first direction FD at substantially the same rate as the formable material **12**, and the second forming member **30** is positioned closer to the feeder **14** than the first forming member **20**.

[0068] As illustrated in FIG. **21**, the second forming member **30** is moved in the third direction TD to engage the formable material **12** and deform the formable material **12**. The first forming member **20** may remain stationary while the second forming member **30** moves in the third direction, or the first forming member **20** may move towards the feeder **14** in a direction that is opposite the first direction FD. As illustrated in FIG. **22**, the first and second forming members **20**, **30** are moved towards one another, either by movement of one or both of the first and second forming members **20**, **30** so as to "squeeze" the formable material **12** in between the elongate portions **22**, **32** and form a full element (i.e. one wavelength) of the wave form. In addition, the feeder **14** may be moved towards the second forming member **30** or the first and second forming members **20**, **30** may be moved towards the feeder **14** so that the feeder **14**, the first forming member **20**, and the second forming member **30** are generally positioned as shown in FIG. **22**.

[0069] FIG. **23** illustrates the first forming member **20** being moved in the third direction TD and away from the formable material **12** and the second forming member **30** being moved in the second direction SD and away from the formable material **12**. The first forming member **20** may then be moved towards the feeder **14** and in a direction that is opposite the first direction, and then moved in the second direction SD so that the engaging surface **24** engages the formable material **12**, as illustrated in FIG. **24**.

[0070] Next, the formable material **12** is provided (i.e., drawn or fed) in the first direction FD by the feeder **14** as the first forming member **20** is moved in the first direction FD at substantially the same rate that the formable material **12** is being provided, and the second forming member **30** is positioned closer to the feeder **14** than the first forming member **20**, as illustrated in FIG. **25**. As shown in FIG. **26**, the second forming member **30** is moved in the third direction TD to engage the formable material **12** and deform the formable material **12**. The first forming member **20** may remain stationary while the second forming member **30** moves in the third direction, or the first forming member **20** may move towards the feeder **14** in a direction that is opposite the first direction FD.

[0071] As illustrated in FIG. **27**, the first and second forming members **20**, **30** are moved towards one another, either by movement of one or both of the first and second forming members **20**, **30** so as to wrap the formable material **12** around the elongated portion **22** of the first forming member **20** and to essentially "fold" the formable material **12** in between the elongated portions **22**, **32** and form another full element of the wave form. In addition, the feeder **14** may be moved towards the second forming member **30** or the first and second forming members **20**, **30** may be moved towards the feeder **14** so that the feeder **14**, the first forming member **20**, and the second forming member **30** are generally positioned as shown in FIG. **27**. The steps of the method illustrated in FIGS. **20-27** may be repeated until the desired wave form is generated by the forming apparatus **10**.

[0072] Although the illustrated embodiment shows the wave form being generated on one side of the axis AX, in another embodiment, the positioning of the first and second forming members **20**, **30** may be adjusted so that the first and second forming members **20**, **30** alternate as to which member is located the closest to the feeder **14** when the formable material **12** is being deformed.

[0073] FIGS. **28-36** illustrate another embodiment of a method of forming a wave form in accordance with another embodiment of the present invention. As illustrated in FIG. **28**, the method starts with providing a length of the formable material **12** in between the first forming member **20** and the second forming member **30** in the first direction FD. FIG. **29** illustrates the first forming member **20** being moved in the second direction SD so that the engaging surface **24** engages the formable material **12** and deforms the formable material **12** while the second forming member **30** remains stationary.

[0074] As illustrated in FIG. **30**, the first forming member **20** and the second forming member **30** are moved in the first direction so that a length L of the formable material may be drawn out of the feeder **14**. The length L should be greater than or equal to the desired length of next strut of the wave form. As illustrated in FIG. **31**, the first forming member **20** and the second forming member **30** are moved in the third direction as the engaging surfaces **24**, **34** engage the formable material **12**. The first forming member **20** and the second forming member **30** are also moved in a fourth direction QD that is opposite the first direction, as illustrated in FIG. **32**. In an embodiment, rather than the first forming member **20** and the second forming member **30** being moved in the second direction SD and the fourth direction QD sequentially, the first forming member **20** and the second forming member **30** may be moved along an arc or trajectory, as indicated by the dashed line TQD in FIG. **32**.

[0075] After the portion of the wave form has been formed, as illustrated in FIG. **32**, the first forming member **20** is moved in the fourth direction QD to a position that is in between the second forming member **30** and the feeder **14**, as illustrated in FIG. **33**. With the first forming member **20** in this position, the first forming member **20** and the second forming member **30** may be moved in the first direction FD so that the formable material **12** may be drawn in the first direction by a length L, as illustrated in FIG. **34**. As before, the length L is greater than or equal to the desired length of the next strut of the wave form.

[0076] FIG. **35** illustrates the first forming member **20** engaging the formable material **12** with the engaging surface **24** as the first forming member **20** and the second forming member **30** are moved in the second direction SD. At the same time, or after the first forming member **20** and the second forming member **30** have been moved in the second direction SD, the first forming member **20** and the second forming member **30** are moved in the fourth direction QD, as illustrated in FIG. **36**. FIG. **36** also illustrates an arc or trajectory, represented by the line SQD that the first forming member **20** and the second forming member **30** may take instead of the sequential linear movements in the second direction SD and the fourth direction QD. The second forming member **30** may be moved in the fourth direction QD to a position in between the first forming member **20** and the feeder **14**, and the method depicted by FIGS. **30-36** may be repeated until the desired wave form is formed.

[0077] It has been found that the method of creating the wave form that is illustrated in FIGS. **28-36** forms struts that may be perfectly straight, or very close to being perfectly straight, and the struts may be formed without being drawn over one of the engaging surfaces **24**, **34**. Drawing the formable material over one of the engaging surfaces **24**, **34** may create struts in the wave form that may be slightly curved.

[0078] The steps illustrated in the embodiment of FIGS. **1-18** may be mixed in with the steps illustrated in the embodiment of FIGS. **20-27**, and/or the embodiment of FIGS. **28-36**, as appropriate, in order to achieve the desired wave form.

[0079] For example, the controller **16** may be programmed with the desired wave form and corresponding signals may be communicated to the feeder **14** and the actuators **26**, **36** that move the first and second forming members **20**, **30**, so that the first and second forming members **20**, **30** are moved relative to the feeder **14** and the formable member **12** accordingly. The forming apparatus **10** uses multi-axis motions to deform the formable material **12** and create a specific wave form or stent pattern that creates a stent having substantially perpendicular ends when wound about mandrel or other suitable structure. In an embodiment, the forming apparatus uses a multi-slide to create the multi-axis motions, but it is not necessary to use a multi-slide to create such motions. Other arrangements are contemplated to be within the scope of the invention.

[0080] The formable material **12** may be a wire or strip material that plastically deforms when deformed by the first and second forming members **20**, **30** so that the wave form generally holds its shape after being formed. By adjusting the shape and size of the first and second forming members **20**, **30**, the relative motions of the first and second forming members **20**, **30** in relation to each other, the formable material **12**, and the feed rate or draw rate and/or movement of the feeder **14**, various amplitudes, periods, and shapes may be created within the wave form to form the overall desired shape for the stent.

[0081] Embodiments of the stents made using the method and apparatus discussed above may be formed from a wire or a strip of suitable material. In certain embodiments, the stents may be formed, i.e., etched or cut, from a thin tube of suitable material, or from a thin plate of suitable material and rolled into a tube. Suitable materials for the stent include but are not limited to stainless steel, iridium, platinum, gold, tungsten, tantalum, palladium, silver, niobium, zirconium, aluminum, copper, indium, ruthenium, molybdenum, niobium, tin, cobalt, nickel, zinc, iron, gallium, manganese, chromium, titanium, aluminum, vanadium, and carbon, as well as combinations, alloys, and/or laminations thereof. For example, the stent may be formed from a cobalt alloy, such as L605 or MP35N®, Nitinol (nickel-titanium shape memory alloy), ABI (palladium-silver alloy), Elgiloy® (cobalt-chromium-nickel alloy), etc. It is also contemplated that the stent may be formed from two or more materials that are laminated together, such as tantalum that is laminated with MP35N®. The stents may also be formed from wires having concentric layers of different metals, alloys, or other materials. Embodiments of the stent may also be formed from hollow tubes, or tubes that have been filled with other materials. The aforementioned materials and laminations are intended to be examples and are not intended to be limiting in any way.

[0082] While at least one exemplary embodiment has been presented in the foregoing detailed description of the invention, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or exemplary embodiments are only examples, and are not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient roadmap for implementing an exemplary embodiment of the invention, it being understood that various changes may be made in the function and arrangement of members described in an exemplary embodiment without departing from the scope of the invention as set forth in the appended claims.

What is claimed is:

1. A method for forming a wave form for a stent, the method comprising:

providing a length of a formable material from a supply of the formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member, the second forming member being positioned closer to the feeder than the first forming member;

moving a distal end of the first forming member across the axis in a second direction substantially perpendicular to the first direction to engage and deform the formable material while engaging the formable material with a distal end of the second forming member;

moving the distal ends of the first and second forming members across the axis in a third direction that is substantially opposite the second direction to draw and form the formable material over the distal end of the second forming member;

disengaging the first forming member from the forming material;

moving the first forming member and the second forming member relative to each other so that the first forming member is positioned closer to the feeder than the second forming member;

moving the distal end of the first forming member into engagement with the deformable material; and

moving the distal ends of the first and second forming members across the axis in the second direction to draw and form the formable material over the distal end of the first forming member.

2. The method according to claim **1**, wherein the distal ends of the first and second forming members each comprise an engaging surface for engaging the formable member, and wherein each engaging surface is shaped to form a curved portion between two substantially straight portions in the wave form.

3. The method according to claim **1**, wherein an amount of movement of the distal ends of the first and second forming members relative to the axis substantially determines a length of a substantially straight portion of the wave form.

4. The method according to claim **1**, further comprising

disengaging the second forming member from the forming material;

moving the first forming member and the second forming member relative to each other so that the second forming member is positioned closer to the feeder than the first forming member;

moving the distal end of the second forming member into engagement with the deformable material; and

moving the distal ends of the first and second forming members across the axis in the third direction to draw and form the formable material over the distal end of the second forming member.

5. The method according to claim **1**, wherein the providing comprises drawing a length of the formable material with the first forming member and/or the second forming member.

6. A method for forming a wave form for a stent, the method comprising:

providing a length of a formable material from a supply of the formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member, the second forming member being positioned closer to the feeder than the first forming member, the length being about the length of a substantially straight portion of the wave form;

moving the first forming member in a second direction substantially perpendicular to the first direction to a position in contact with the formable material; and

moving the second forming member in a third direction substantially opposite the second direction to wrap the formable material about a distal end of the first forming member.

7. The method according to claim **6**, further comprising moving the first forming member and/or the second forming member to adjust a wavelength of a portion of the wave form.

8. The method according to claim **7**, wherein the first forming member and the second forming member are moved closer to one another to shorten the wavelength of the portion of the wave form.

9. The method of claim **6**, further comprising

moving the first forming member in the third direction and the second forming members in the second direction to disengage the first and second forming members from the formable material;

moving the first forming member in a direction opposite the first direction and towards the feeder so that the first forming member is positioned closer to the feeder than the second forming member;

moving the distal end of the first forming member into engagement with the deformable material;

providing a second length of the formable material along the axis in the first direction while moving the first forming member in the first direction; and

moving the second forming member in the third direction to wrap the formable material about the distal end of the first forming member.

10. The method according to claim **9**, wherein the length and the second length are substantially the same.

11. The method according to claim **9**, wherein the length and the second length are different.

12. The method according to claim **9**, wherein the providing the second length of the formable material comprises drawing the formable material with the first forming member and/or the second forming member.

13. A method for forming a wave form for a stent, the method comprising:

providing a length of a formable material from a supply of the formable material in a feeder along an axis in a first direction in between a first forming member and a second forming member, the second forming member being positioned closer to the feeder than the first forming member;

moving the first forming member into contact with the formable material and across the axis in a second direction substantially perpendicular to the first direction; and

folding the formable material over the second forming member by moving the second forming member and the first forming member in a third direction substantially opposite the second direction and moving the second forming member and the first forming member in a fourth direction substantially opposite the first direction.

14. The method according to claim **13**, further comprising

moving the first forming member so that the first forming member is positioned closer to the feeder than the second forming member;

drawing a length of the formable member from the feeder with the first forming member and the second forming member; and

folding the formable material over the first forming member by moving the first forming member and the second forming member in the second direction and moving the first forming member and the second forming member in the fourth direction.

15. The method according to claim **13**, wherein the second forming member and the first forming member are moved in the third direction and then are moved in the fourth direction sequentially.

16. The method according to claim **13**, wherein the second forming member and the first forming member are moved in the third direction and in the fourth direction simultaneously.

17. A forming apparatus configured to form a wave form for a stent out of a formable material, the wave form comprising a plurality of substantially straight portions and a plurality of curved portions, the apparatus comprising:

a feeder constructed and arranged to receive a supply of the formable material and to provide the formable material along an axis;

a first forming member configured to be movable along two orthogonal axes, the first forming member comprising a first elongated portion having a first engaging surface at a distal end of the first elongated portion, the first engaging surface being configured to engage a first side of the formable material;

a second forming member configured to be movable along the two orthogonal axes, the second forming member comprising a second elongated portion having a second engaging surface at a distal end of the second elongated portion, the second engaging surface being configured to engage a second side of the formable material that is opposite the first side; and

a controller in communication with the feeder, the first forming member, and the second forming member, the controller being configured to control movement of the first and second forming members to control a length of each substantially straight portion of the wave form and to control a wavelength within the wave form.

18. The forming apparatus according to claim **17**, further comprising a first actuator in communication with the controller and configured to move the first forming member, and a second actuator in communication with the controller and configured to move the second forming member.

19. The forming apparatus according to claim **17**, wherein the formable material is a wire.

20. The forming apparatus according to claim **17**, wherein the formable material is a strip of material.

* * * * *