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Morales

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(54) **COLLET TYPE CRIMPING TOOL**

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

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(52) **U.S. Cl.** **29/282**; 29/283.5; 606/1; 606/198; 623/1

(58) **Field of Search** 29/283.5, 243.522, 29/234, 235, 243.519, 237, 243.5, 243.518, 515, 282; 279/42; 72/402; 606/1, 108, 198; 623/1

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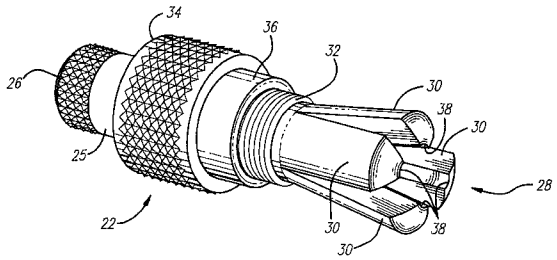
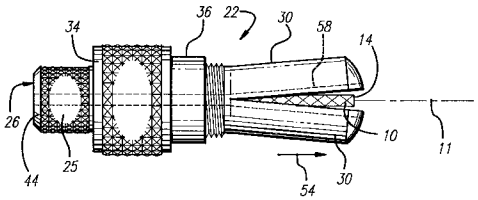
(57) **ABSTRACT**

A sterile tool for crimping a stent onto a balloon catheter is disclosed. The stent crimping tool includes two major components, a cylindrical body having external threads and a rotating collar with internal threads engaging the external threads. The collet end of the cylindrical body is split into segmented jaws that are biased to flare outward in an open state. A stent loaded onto a balloon catheter and situated inside the open segmented jaws can undergo a crimping operation when the collar is rotated and advances toward the flared open segmented jaws. When the collar engages the segmented jaws, the jaws are forced to converge and close onto the stent-catheter assembly thereby crimping the stent onto the balloon catheter.

16 Claims, 2 Drawing Sheets





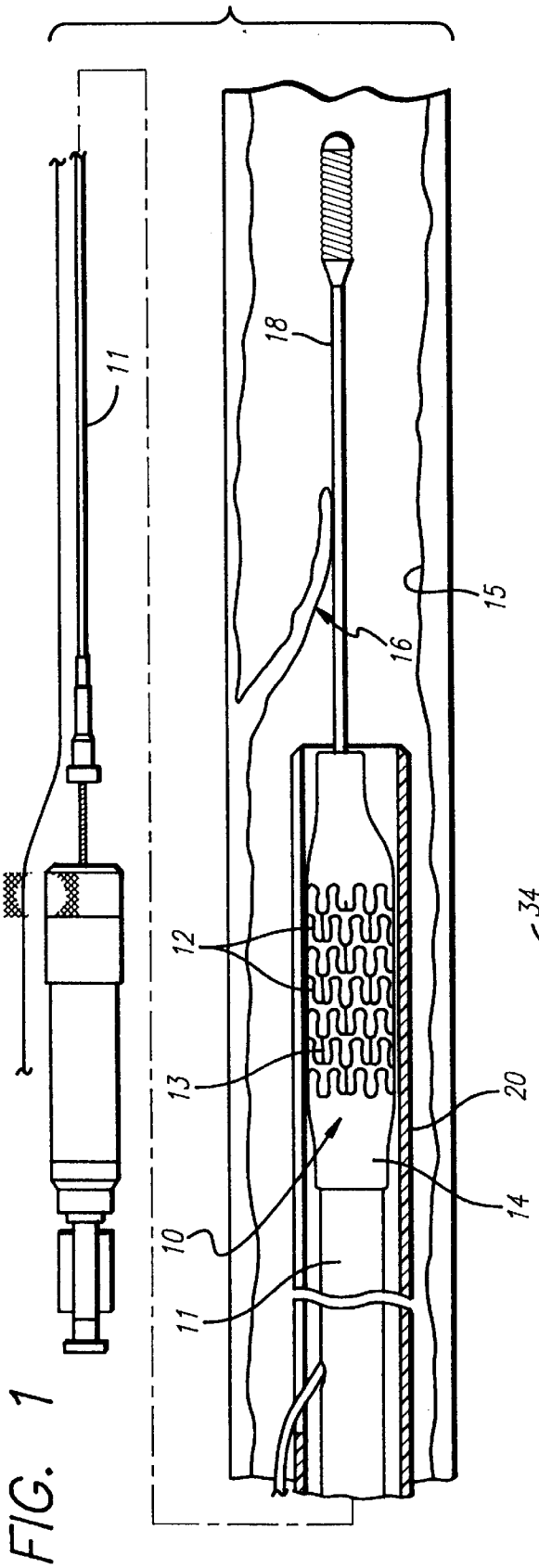


FIG. 1

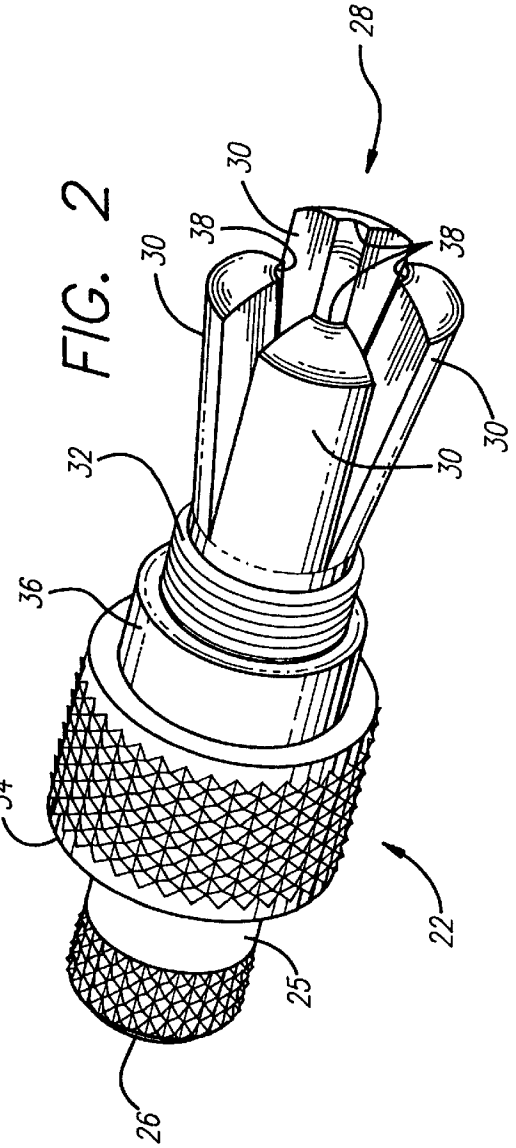


FIG. 2

FIG. 3A

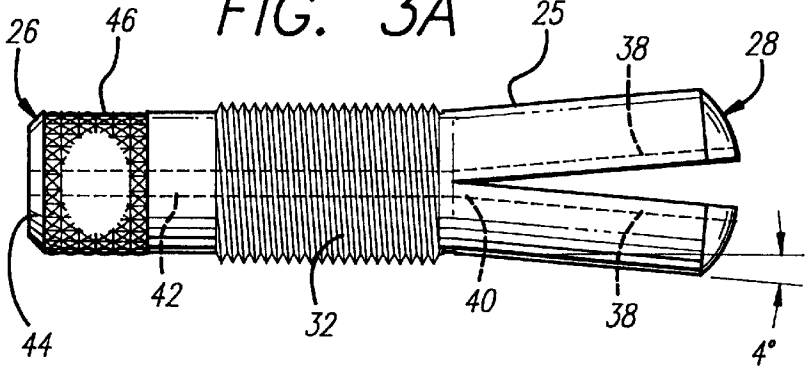


FIG. 3B

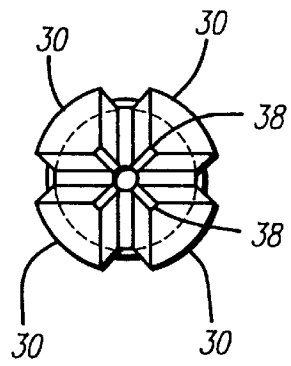


FIG. 4A

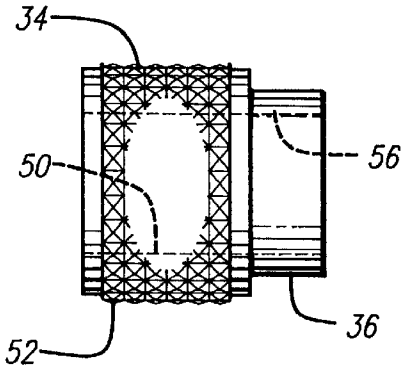
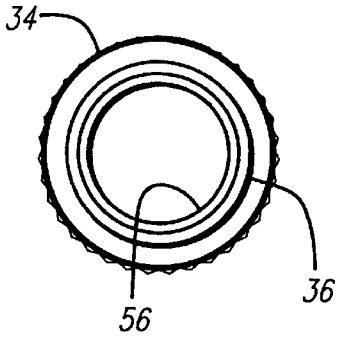


FIG. 4B



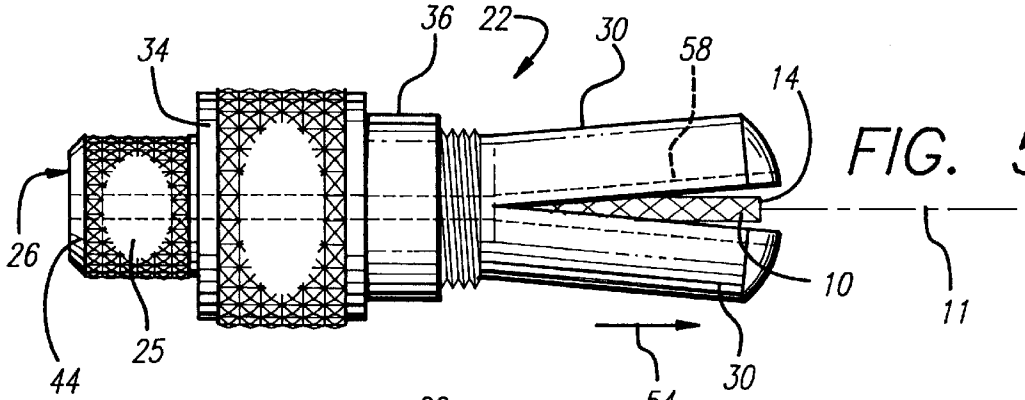


FIG. 5

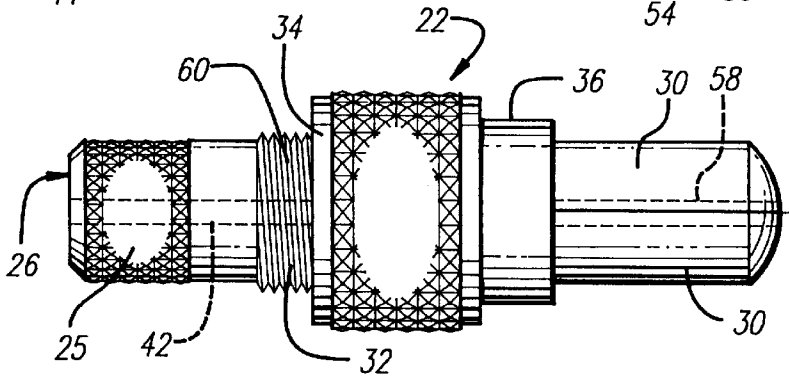


FIG. 6

COLLET TYPE CRIMPING TOOL

BACKGROUND OF THE INVENTION

The present invention relates to an apparatus for loading a tubular graft, such as a stent, onto the distal end of a catheter assembly of the kind used, for example, in percutaneous transluminal coronary angioplasty (PTCA) procedures, in percutaneous transluminal angioplasty (PTA) procedures, atherectomies, and the like.

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient, through the brachial or femoral arteries and advanced through the vasculature until the distal end of the guiding catheter is in the ostium of the aorta leading to the coronary arteries. A guide wire and a dilatation catheter having a balloon on the distal end are introduced through the guiding catheter with the guide wire sliding within the dilatation catheter. The guide wire is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guide wire until the dilatation balloon is properly positioned across the arterial lesion. Once in position across the lesion, a flexible and expandable balloon is inflated to a predetermined size with a radiopaque liquid at relatively high pressures to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile so that the dilatation catheter can be withdrawn from the patient's vasculature and the blood flow resumed through the dilated artery. As should be appreciated by those skilled in the art, while the above-described procedure is typical, it is not the only method used in angioplasty.

In angioplasty procedures of the kind referenced above, restenosis of the artery may develop at or near the treatment area, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the development of restenosis and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a stent, inside the artery at the treated area. The stent is transported in its delivery diameter through the patient's vasculature. At the deployment site, the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter. The stent also may be of the self-expanding type.

Since the catheter and stent travel through the patient's vasculature, and typically through the coronary arteries, the stent must have a small delivery diameter and must be firmly attached to the catheter until the physician is ready to implant it. Thus, the stent must be loaded onto the catheter so that it does not interfere with delivery, and it must not come off the catheter until it is implanted.

In procedures where the stent is placed over the balloon portion of the catheter, it is necessary to crimp the stent onto the balloon portion to reduce its diameter and to prevent it from sliding off the catheter when the catheter is advanced through the patient's vasculature. Non-uniform crimping can result in sharp edges being formed along the now uneven surface of the crimped stent. Furthermore, non-uniform stent crimping may not achieve the desired minimal profile for the stent and catheter assembly. Where the stent is not reliably crimped onto the catheter, the stent may slide off the catheter and into the patient's vasculature prematurely as a loose foreign body, possibly causing blood clots in the vasculature, including thrombosis. Therefore, it is important

to ensure the proper crimping of a stent onto a catheter in a uniform and reliable manner.

This crimping is often done by hand, which can be unsatisfactory due to the uneven application of force resulting in non-uniform crimps. In addition, it is difficult to visually judge when a uniform and reliable crimp has been applied.

Some self-expanding stents are difficult to load by hand onto a delivery device such as a catheter. Furthermore, the more the stent is handled the higher the likelihood of human error, which would be antithetical to a properly crimped stent. Accordingly, there is a need in the art for a device for reliably crimping a stent onto a catheter.

There have been attempts at devising a tool for crimping a stent onto a balloon delivery catheter. An example of such a tool comprises a series of plates having substantially flat and parallel surfaces that move in a rectilinear fashion with respect to each other. A stent carrying catheter is disposed between these surfaces, which surfaces crimp the stent onto the outside of the catheter by their relative motion and applied pressure. The plates have multiple degrees of freedom and may have force-indicating transducers to measure and indicate the force applied to the catheter during crimping of the stent.

Another stent loading tool design is comprised of a tubular member housing a bladder. The tubular member and bladder are constructed to hold a stent that is to be crimped onto a balloon catheter assembly. Upon placement of the stent over the balloon portion of the catheter, a valve in the loading tool is activated to inflate the bladder. The bladder compresses the stent radially inward to a reduced diameter onto the balloon portion of the catheter to achieve a snug fit. In this way, the stent is crimped onto the distal end of a balloon catheter with a minimum of human handling. The foregoing stent crimping tools are disclosed in, for example, commonly owned and assigned U.S. Pat. Nos. 5,437,083 and 5,546,646 to Williams et al.

Yet another stent crimping tool is known in the art as the BARD XT, which is actually a stent loader. It is constructed of a tubular body with a ball at one end connected to a plurality of long, thin strips passing through the rigid tubular body. An uncrimped stent is placed over the plurality of long, thin strips, which hold the stent in an expanded state. The balloon portion of a catheter is inserted into the cylindrical space formed by the plurality of strips. When the user pulls on the ball while holding the tubular body against the stent, the strips are slid from beneath the stent and the stent is transferred onto the balloon portion.

Still another conventional stent crimping tool is manufactured by JOHNSON & JOHNSON and appears similar to a hinged nutcracker. Specifically, the tool is comprised of two hand operated levers hinged at one end and gripped in the palm of the hand at the opposite end. A cylindrical opening holding a crimping tube is provided through the mid-portion of the tool to receive therein a stent loaded onto a balloon catheter. The crimping operation is performed by the user squeezing the handle thereby pressing the crimping tube which in turn pinches the stent onto the balloon catheter.

While the prior art devices are suitable for crimping stents onto balloon catheters, they suffer from problems such as non-uniform crimping forces, resulting in non-uniform crimps, and they are unsuitable for use by physicians in a cath lab who desire to crimp the stent onto the balloon catheter.

SUMMARY OF THE INVENTION

The present invention is directed to a method and apparatus for crimping an intravascular stent onto the distal end

of a catheter. The apparatus is comprised of a cylindrical body having a gripping end and a collet end, wherein the cylindrical body at the collet end transitions into a plurality of segmented jaws that are flared outward. Threads are disposed on the cylindrical body in between the collet end and the gripping end. A collar is rotatably mounted on the cylindrical body and has an internal threaded opening engaging the threads on the body and a front inside diameter of the internal threaded opening that engages the plurality of segmented jaws, wherein advancing the collar along the threads translates the front inside diameter over the flared segmented jaws to converge the jaws into a closed state.

In a preferred embodiment, a groove is formed along a length of each jaw so that when the plurality of segmented jaws are in the closed state, the grooves collectively form a cylindrical cavity leading to an opening at the collet end of the cylindrical body. Thus, closing the segmented jaws onto the stent mounted to the balloon portion of the catheter when the stent and catheter are situated within the cavity crimps the stent onto the catheter.

In the preferred embodiment, the present invention crimping apparatus has four segmented jaws and each segmented jaw includes a generally quarter-circle, cross-sectional shape. The segmented jaws may be modified with a liner, various coatings, foam plates, or a floating head. Such modifications are aimed at gripping and holding the stent without damaging the part. Moreover, when the converged segmented jaws in the closed state are lined, the lining material ensures a constant diameter crimp. The diameter can be adjusted by changing the thicknesses or shapes of the lining material.

In the preferred embodiment of the present invention, the tool is designed to be used in a cath lab to crimp intravascular stents onto balloon catheters by forcing the stent to compress from four points around its circumference onto the exterior diameter of the balloon. The balloon with the uncrimped stent mounted in the correct position thereon is placed inside the flared collet end of the cylindrical body with the collar threaded thereon half way toward the flared collet end.

The balloon and stent are held in position by a third party, a table, or other support. While the balloon and stent are supported, another person can twist the collar to advance it along the length of the threads thereby forcing the segmented jaws at the collet end to converge and close down on to the stent. This closing action crimps the stent onto the balloon.

As mentioned earlier, grooves are formed along the length of each jaw so that in their closed state, the grooves collectively form a cylindrical cavity the dimensions and shape of which match the crimped stent and contain the crimped stent and the catheter balloon when the segmented jaws have fully converged. The grooves may be profiled to vary the diameter and contours along the length of the crimped stent. Some resistance should be encountered, but is normal to the compression process. The stent and catheter balloon can be released from the tool by unscrewing the collar from the cylindrical body thereby releasing the external pressure on the converged segmented jaws allowing the jaws to open.

If the crimping process is not satisfactory, the process can be repeated for as many times as the user would wish. The tool and the operation thereof are extremely simple and repeatable. Indeed, with the rotating motion of the collar along the cylindrical body, it is possible to mark the tool for the precise distance the collar is advanced along the threads of the cylindrical body for accurate crimping of the stent by the converging segmented jaws.

The present invention thus provides the end user with a precise and repeatable method of crimping a stent onto a balloon catheter. To achieve precision, the present invention may be modified with an optional micrometer, strain gauges, or the like for tight control. In contrast, many conventional processes are unreliable and achieve inconsistent and non-uniform crimps. Furthermore, the present invention crimping tool can be used with any stent that is released without a delivery system. The crimping tool may also be sold alone. Finally, the present invention tool solves a common problem with conventional tools of not being able to crimp down to any exact diameter. These and other advantages of the present invention will become more apparent from the following detailed description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view, partially in section, depicting an intravascular stent that is mounted on a delivery balloon catheter and disposed within a vessel.

FIG. **2** is a perspective view of a preferred embodiment of the present invention crimping tool showing the segmented jaws in the open state.

FIGS. **3**A and **3**B show a side elevational and a front view, respectively, of a preferred embodiment cylindrical body having a gripping end and a flared collet end with the segmented jaws in the flared open state.

FIGS. **4**A and **4**B depict a side elevational and a front view, respectively, of a preferred embodiment collar having internal threads, a leading edge, and a knurled exterior.

FIG. **5** is a side elevational view of the present invention wherein a catheter-stent assembly has been loaded into the collet end just prior to the crimping operation.

FIG. **6** is a side elevational view of the present invention crimping tool shown in FIG. **5**, wherein the crimping operation has occurred and the segmented jaws have converged onto the stent-catheter assembly due to advancement of the collar along the cylindrical body of the crimping tool.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates intravascular stent **10** which is mounted onto delivery catheter **11**. Stent **10** generally comprises a plurality of radially expandable cylindrical elements **12** disposed generally coaxially and interconnected by members **13** disposed between adjacent cylindrical elements **12**. Delivery catheter **11** has an expandable portion or balloon **14** for expanding stent **10** within artery **15** or other vessel. Artery **15**, as shown in FIG. **1**, has dissected lining **16** which has occluded a portion of the arterial passageway.

Delivery catheter **11**, onto which stent **10** is mounted, can be essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. Balloon **14** may be formed of suitable materials such as polyethylene, polyvinyl chloride, polyethylene terephthalate and other like polymers. In order for stent **10** to remain in place on balloon **14** during delivery to the site of the damage within artery **15**, stent **10** is compressed onto balloon **14**. This compressing step is known as crimping.

An optional retractable protective delivery sleeve or sheath **20** may be provided to further ensure that stent **10** stays in place on balloon **14** of delivery catheter **11** and to prevent abrasion of the body lumen by the open surface of

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