LOADING DILATOR WITH A VARIABLE GIRTH IN A LOCALIZED AREA

Abstract: A loading dilator (10) introducing a tracheostomy tube (100) into a stoma (140) formed in an outer body wall of a patient includes a handle (12) and a tubular portion (14) received in a distal opening (61) of the handle. The tubular portion includes a radially outer dilator member (20), and a radially inner actuation member (32) substantially spanning the length of the tubular portion. A radially intermediate segment has a conical member (26) at a tapered distal end of the tubular portion, a compressible member (30) positioned proximal of the conical member, and an elongated tubular member (40) proximal of the compressible member. The conical member is engaged with the inner actuation member such that the conical member and inner actuation member are proximally movable relative to the elongated tubular member, whereby the compressible member is deformable from a smaller diameter to a larger diameter for facilitating entry into the stoma of a medical apparatus. The handle has a trigger (80) operatively engaged with the inner actuation member for effecting proximal movement of the inner actuation member and conical portion.
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Girth IN A LOCALIZED AREA

BACKGROUND

[0001] 1. Technical Field. This application relates to a dilator for dilating an opening in the body of a patient for a medical use, and more particularly, to a loading dilator having a variable girth in a localized area of the dilator for use in placement of a medical device, such as a tracheostomy tube.

[0002] 2. Background Information. The establishment of an adequate air passageway is a critical step in maintaining the ability of a seriously ill or injured patient to breathe, or in performing resuscitation on a patient unable to breathe. Endotracheal intubation (the placement of a tube through the nostrils or mouth and into the trachea itself) is a widely-used method for establishing an air passageway. However, in order to establish an optimal air passageway for endotracheal intubation, the trachea, nostrils and/or mouth must normally be free, or at least substantially free, of obstruction. When an obstruction is present, endotracheal intubation is not generally possible, and an alternative passageway for airflow must be established.

[0003] The most direct way to provide an air passageway under these circumstances is to form a stoma, or opening, in the tracheal wail. Once formed, a tracheostomy tube is inserted through the stoma. Conventional tracheostomy tubes often include an open distal aperture and a circumferential inflatable cuff. The cuff provides a seal between the tracheal wall and the tracheostomy tube at a location proximal to the distal aperture. The seal prevents the intrusion of blood, tissue or foreign matter into the lower trachea, bronchi and lungs, while permitting complete control and monitoring of the airflow established through the tracheostomy tube, including the provision of positive pressure ventilation. The open distal aperture provides a passageway for air into the lungs of the patient.
Several methods and devices are known for forming or enlarging
a stoma in a tracheal wall. In one such method, a small opening is initially
made in the tracheal wall. A needle is inserted through the small opening,
such that the tip of the needle is in the interior space of the trachea. A wire
guide is then passed into the trachea through a bore in the needle, and the
needle is thereafter withdrawn. Sequentially sized dilators may then be
advanced over the wire guide to facilitate gradual dilation of the tracheal
entrance to an appropriate size.

Recently, a single curved dilator, sold by Cook Incorporated of
Bloomington, Indiana, under the name BLUE RHINO®, has been
developed that avoids the necessity to use multiple dilators. The BLUE
RHINO® dilator, so called because its shape resembles the horn of a
rhinoceros, has a distal end portion that is curved in a substantially
continuous manner, wherein an increasingly larger diameter portion of the
dilator may be inserted into the trachea, thereby facilitating clearance of
the posterior tracheal wall. Further description of the BLUE RHINO®
dilator is provided in U.S. Patent No. 6,637,435, incorporated by reference
herein.

Another method for forming or enlarging a stoma in a trachea!
wall for introduction of a tracheostomy tube is described in U.S. Patent No.
5,653,230, incorporated by reference herein. This method employs a
balloon catheter having an inflatable balloon at a distal end of the catheter.
The catheter is inserted over a percutaneously inserted wire guide, and the
catheter is advanced along the wire guide until the balloon lies across the
tracheal wall. The balloon is then inflated to radially dilate a portion of the
tracheal wall, thereby forming a stoma in the wall that corresponds to the
inflated diameter of the balloon.

Following formation of the stoma by any of the known methods,
an introducer/loading dilator is pre-loaded with a tracheostomy tube, and
the distal end of the combined apparatus is passed through the stoma over
the previously-inserted wire guide. It is desirable to provide a
dilator/tracheostomy tube combination that has a generally smooth transition from dilator to tube, thereby facilitating the smooth entry of the distal, or leading, portion of the tube through the stoma. However, since there are a number of different sizes and manufacturers of tracheostomy tubes, there is a possibility that a significantly-sized lip (resulting from the respective differences in diameter between the loading dilator and the tracheostomy tube), may be present at the transition between the loading dilator and the distal (i.e., leading) end of the tracheostomy tube. The presence of a lip at a junction between a smaller diameter loading dilator and a larger diameter tracheostomy tube can hinder insertion of the tracheostomy tube through the stoma, and can increase the trauma experienced by the patient upon insertion of the tube.

It would be desirable to provide a loading dilator that is sized to accommodate tracheostomy tubes having a range of diameters, and that is structured to minimize the transition between the loading dilator and the tracheostomy tube upon insertion of a dilator/tracheostomy tube assembly.

BRIEF SUMMARY

The problems of the prior art are addressed by the features of the present invention. In one form thereof, the invention comprises a loading dilator for introducing a medical apparatus, such as a tracheostomy tube, into a stoma in a patient. The loading dilator comprises a tubular portion having a proximal end and a distal end. The tubular portion includes a radially outer dilator member substantially spanning a length of the tubular portion, wherein the radially outer dilator member has a tapered distal end portion. A radially intermediate segment comprises a conical member at the tapered distal end portion, a compressible member positioned proximal of the conical member, and an elongated tubular member proximal of the compressible member. A radially inner actuation member spans a length of the tubular portion. The conical member is engaged with the inner actuation member such that the
conical member and inner actuation member are proximally movable relative to the elongated tubular member. The compressible member is deformable from a smaller diameter condition to a larger diameter condition upon the proximal movement. A handle of the loading dilator has a proximal end and a distal end, and an opening formed at the distal end for receiving the tubular portion proximal end. The handle further has a trigger mechanism operatively engaged with the inner actuation member for effecting the proximal movement of the inner actuation member and the conical portion upon an activation of the trigger mechanism.

[0010] In another form thereof, the invention comprises a method for positioning a medical apparatus, such as a tracheostomy tube, across a stoma formed in an outer body wall of a patient. Initially, a dilator is provided, wherein the dilator comprises a handle and a tubular portion extending from the handle. The tubular portion comprises a radially outer dilator member substantially spanning a length of the tubular portion, and having a tapered distal end portion. A radially intermediate segment comprises a conical member at the tapered distal end portion, a compressible member positioned proximal of the conical member, and an elongated tubular member proximal of the compressible member. A radially inner actuation member spans a length of the tubular portion. The conical member is engaged with the inner actuation member such that the conical member and inner actuation member are proximally movable relative to the compressible member and the elongated tubular member, wherein the compressible member is deformable from a smaller diameter condition to a larger diameter compressed condition upon the proximal movement. The handle has a trigger mechanism operatively engaged with the inner actuation member for effecting the proximal movement of the inner actuation member and conical portion upon an activation of the trigger mechanism. The medical apparatus is loaded onto the radially outer dilator member, and positioned such that a distal end of the medical apparatus is disposed proximal to the compressible member on the radially
outer dilator member. The trigger mechanism is activated to effect the proximal movement of the inner actuation member and conical portion, thereby deforming the compressible member from the smaller diameter condition to the larger diameter condition, wherein the compressible member and the distal end of the medical apparatus define a transition from the radially outer dilator member to the distal end of the medical apparatus. The tapered distal end portion of the radially outer dilator member is inserted into the stoma, and the dilator is advanced such that a portion of the medical apparatus lies across the stoma. Once the medical apparatus is positioned across the stoma, the compression on the compressible member may be released, and the dilator may be removed from the interior of the tracheostomy tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Fig. 1 is a sectional side view of a dilator according to an embodiment of the present invention in a resting position;

[0012] Fig. 2 is sectional side view of the dilator of Fig. 1 at a first half of a trigger pull;

[0013] Fig. 3 is a sectional side view of the dilator of Fig. 1 at a second half of a trigger pull;

[0014] Fig. 4 is a sectional side view of the dilator of Fig. 1 at maximum bulge of the compressible member;

[0015] Fig. 5 is a sectional side view of the dilator of Fig. 1 with the locking member disengaged, thereby allowing return to a small diameter;

[0016] Fig. 6 is an enlarged sectional side view of the dilator handle;

[0017] Fig. 7 is a side view of the distal end portion of the dilator having a tracheostomy tube loaded thereon, and showing the bulge formed by the compressible member;

[0018] Fig. 8 is a side view of the distal end portion of the dilator having a tracheostomy tube loaded thereon as shown in Fig. 7, prior to formation of the bulge; and
Fig. 9 is a view illustrating the use of the loading dilator in placing the tracheostomy tube across a stoma in the tracheal wall.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It should nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

In the following discussion, the terms "proximal" and "distal" will be used to describe the axial ends of the device of the present invention, as well as the axial ends of various component features. The "proximal" end is used in conventional manner to refer to the end of the device (or component) that is closest to the operator during use of the assembly. The "distal" end is used in conventional manner to refer to the end of the device (or component) that is initially inserted into the patient, or that is closest to the patient.

Figs. 1-6 illustrate side sectional views of a dilator 10, according to a preferred embodiment of the present invention. As shown in the figures, dilator 10 includes a handle 12, and a tubular portion 14 received in an opening 61 at a distal end of handle 12. Handle 12 and tubular portion 14 are manipulatable in a manner to be described, such that a compressible member 30 positioned at the distal end of tubular portion 14 may be selectively compressed, or deformed, to form a bulge 31, as shown in Figs. 3 and 4. The components may be structured to provide a bulge of virtually any desired diameter. Preferably, the bulge will range from having an outer diameter just slightly larger than the outer diameter of
the surrounding surface, up to about 150% of the original outer diameter. When a tracheostomy tube 100 is loaded on dilator 10, the presence of bulge 31 provides a generally smooth, gradual transition from the outer surface of dilator 10 to the distal end portion 102 of tracheostomy tube 100, as shown in Fig. 7. In contrast, Fig. 8 illustrates the "lip" formed between the outer surface of dilator 10 and the distal end portion 102 of tracheostomy tube 100 prior to formation of the bulge.

[0023] The features of the embodiment of dilator 10 illustrated in Figs. 1-6 will now be described in greater detail. Tubular portion 14 includes an outer dilator member 20. Outer dilator member 20 comprises a thin-walled tube formed of a material having sufficient elasticity to enable it to bend to a curved orientation as the dilator is positioned in a curved tracheostomy tube, and to conform to the bulging of the compressible member 30. In one form thereof, outer dilator member 20 is formed of polyurethane having a wall thickness of about 0.020 inch (0.51 mm) and an outer diameter of about 0.25 to 0.375 inch (6.35 to 9.53 mm). Proximal end 21 of outer dilator member 20 is securely received in opening 61 in handle 12. Distal end 22 of outer dilator member 20 tapers to an end point 23. End point 23 is open to permit passage of a wire guide 110 therethrough (shown in phantom in Fig. 1).

[0024] Interior of outer tubular member 20 is a conical member 26, a compressible member 30, and an elongated tubular member 40. Conical member 26 is formed from a rigid composition, preferably a rigid polymer such as an acetal polymer. As with the other corresponding elements described herein, conical member 26 also has a central opening, or bore, extending therethrough.

[0025] Compressible member 30, positioned proximal of conical member 26, is a short, generally tubular structure that is formed from a composition capable of bulging under compressive forces in the manner shown in Figs. 3 and 4. One non-limiting example of a suitable composition is an elastomer, such as silicone rubber. Compressible
member 30 is sized to bulge to the desired diameter when compressed a specific distance along its longitudinal axis. Preferably, compressible member 30 and the distal portion of outer dilator member 20 are the only portions of dilator 20 that are capable of significant deformation as the girth of the distal portion of dilator 10 is increased, in a manner to be described.

[0026] Elongated tubular member 40 is a thick-walled (e.g., 0.071 inch, (1.8 mm)) tubular structure formed of a composition that is only minimally deformable, but has favorable flexural characteristics. One non-limiting example of a suitable composition for elongated tubular member 40 is PVC (polyvinyl chloride). The flexural characteristics enable the tubular member to bend to a curved orientation as the dilator is positioned in a curved tracheostomy tube, and then return to its "straight" orientation as shown in the figures as it is withdrawn from the tracheostomy tube.

[0027] Conical member 26, compressible member 30 and elongated tubular member 40 are aligned along the length of tubular portion 14 in the manner shown in Fig. 1. These aligned members have a wire guide bore extending therethrough. An inner actuation member 32 extends interiorly of members 26, 30 and 40 along this bore from the distal tip of dilator 10, to the proximal portion of the dilator that is received in handle 12. Inner actuation member 32 is preferably formed from a polymer tube having high tensile strength, such as PEEK (polyetheretherketone).

[0028] Distal end 34 of inner actuation member 32 is adhered or otherwise bonded to conical member 26. Compressible member 30 and elongated member 40 are not bonded to inner actuation member 32. As a result, axial movement of inner actuation member 32 causes a corresponding movement of conical member 26.

[0029] Preferably, proximal portion 33 of inner actuation member 32 is flared, as best illustrated in Fig. 6. A length of small bore tubing, such as hypotube 36, is provided over a proximal portion of inner actuation member 32. Small bore tubes formed of relatively rigid compositions are well known in the medical arts, and those skilled in the art can readily
select an appropriate tube for use in the inventive device. Metals and metal alloys, such as stainless steel and nitinol, are particularly common compositions, and may be utilized to form the small bore hypotube 36 utilized herein. In the embodiment shown, hypotube 36 spans a proximal portion of inner actuation member 32 located within handle 12. Preferably, hypotube 36 also includes a flared proximal end 37. Flared end 37 envelopes flared proximal end 33 of the inner actuation member, as best shown in the enlarged view of Fig. 6.

[0030] Handle 12 is preferably formed from tubular portions of a rigid composition, such as chlorinated polyvinyl chloride. In the embodiment shown herein, handle 12 comprises tubular segments 60, 64, 68. Tubular segments 60, 64, 68 may be adhered, threaded, or otherwise bonded together into the position shown. Alternatively, the handle segments may be integrally formed by known means.

[0031] Handle tubular segment 60 is the distal-most segment of handle 12. Handle segment 60 includes a distal opening 61 sized to securely receive the proximal end of tubular portion 14, e.g., via a friction fit. Opening 61 terminates at handle wall 44. When the device is assembled as shown, the distal end of tubular portion 14 abuts against wall 44, thereby limiting proximal movement of tubular portion 14.

[0032] The distal end of handle tubular segment 64 is affixed to the proximal end of handle segment 60, e.g., via a threaded connection. Handle segment 64 includes a first radial opening 65 for passage of first lever 74 therethrough, and a second radial opening 66 for passage of second lever 80. Levers 74, 80 are held in the tubular segment in any conventional manner, such as by passing a respective pin 78, 84 from one side of handle segment 64 to the other, and through an opening in a base portion of the lever. Handle tubular segment 64 also includes a crevice 77 for receiving spring 76. Spring 76 is maintained in position under compression.
The distal end of handle tubular segment 68 is affixed to the proximal end of handle segment 64. Handle segment 68 includes a bore 67 extending therethrough. A flare-fitting 52 and flare nut 54 are received in bore 67. As shown in the enlarged view of Fig. 6, flared ends 33, 37 of the respective inner actuation member 32 and hypotube 36 fit over the distal portion of flare-fitting 52, and are captured by flare nut 54. Preferably, flare fitting 52 includes an inner threaded portion 53 that is threadably received in complementary outer threaded portion 55 of flare nut 54 for capturing flared ends 33, 37. The respective flared ends of inner actuation member 32 and hypotube 36 are clamped between flare-fitting 52 and flare nut 54, such that proximal movement of hypotube 36 translates to corresponding movement of the underlying inner actuation member 32.

First lever 74 includes legs 74A and 74B. A first aperture 75 extends through leg 74B. Preferably, first lever 74 is formed such that the boundary surrounding all or part of first aperture 75 has a sharpened inwardly-directed surface, preferably, a sharpened inside corner. As best shown in Fig. 6, hypotube 36 passes through first aperture 75, First aperture 75 is sized relative to the outer diameter of hypotube 36 in a manner such that hypotube 36 is movable through aperture 75 when leg 74B is moved to a substantially vertical orientation (Fig. 5), but that hypotube is substantially prevented from moving in a distal direction when the lever is spring-loaded in the clamped position, as shown, e.g., in Fig. 6.

Second lever 80 includes legs 80A and 80B. A second aperture 81 extends through leg 80B. As shown in the figures, hypotube 36 also passes through second aperture 81. However, the diameter of second aperture 81 is much larger than that of first aperture 75. Thus, hypotube 36 is freely movable through second aperture 81, regardless of the orientation of second lever 80.

In the embodiment shown, handle 12 also includes disks 88, 89 positioned substantially in the axial center of handle 12. Preferably, disks
88, 89 pass over the outer surface of hypotube 36, and are biased apart by spring 82. Disks 88, 89 are provided with respective center apertures 90, 91. Apertures 90, 91 are sized to permit passage of hypotube 36 therethrough with little clearance, and are generally similar in diameter to aperture 75. Disk 88 acts to create tension on hypotube 36, in a manner to be described. Disk 89 acts as a journal to keep hypotube 36 substantially centered within the handle, and yet permit longitudinal movement of the hypotube therethrough.

[0037] Figs. 7 and 8 illustrate side views of the distal end portion of dilator 10, wherein a conventional tracheostomy tube 100 is loaded on the outer surface of the dilator in well-known fashion. Tracheostomy tube 100 has an open distal, or leading, end 102 and a circumferential inflatable cuff 104 positioned near open distal end 102. Upon inflation, the cuff provides a seal between the tracheal wall and the tracheostomy tube in well known fashion, for preventing the intrusion of blood, tissue and other foreign matter into the lower trachea, bronchi and lungs. When the tracheostomy tube is properly positioned in the trachea, the open distal end 102 provides a passageway for air into the lungs of the patient. A conventional flange 108 may be provided at the proximal end of the tracheostomy tube for abutment against the skin of the patient when tracheostomy tube 100 is inserted through the stoma.

[0038] Tracheostomy tubes are well known in the art, and tracheostomy tube 100 is merely one example of a suitable tracheostomy tube that can be utilized in connection with the inventive loading dilator. As shown herein, the curvature of tracheostomy tube 100 imparts a corresponding curve in the distal portion of dilator 10.

[0039] In Fig. 7, the compressible member 30 of dilator 10 is shown in its deformed condition. See, e.g., Figs. 3 and 4. In contrast, in Fig. 8 compressible member 30 is shown in the at rest, or undeformed, condition. See, e.g., Figs. 1, 2 and 5. As shown in Fig. 8, when compressible member 30 is not deformed, a significant lip may be present at the
transition between the dilator body and the distal end 102 of tracheostomy tube 100. The presence of the lip is prone to cause difficulty when inserting the tracheostomy tube through the stoma, thereby resulting in additional trauma to the patient. To the contrary, when the compressible member 30 is deformed to form the bulge 31 as shown, a substantially non-traumatic diametrical transition is created between loading dilator 10 and distal end 102 of tracheostomy tube 100. As stated above, the respective components of dilator 10 may be structured to provide a bulge of virtually any desired diameter and contour. Thus, the amount of taper may be adjusted to virtually any amount desired to ease entry of the dilator and tracheostomy tube into the stoma.

[0040] Operation of the loading dilator 10 will now be described in connection with its preferred use, namely, positioning a tracheostomy tube in a stoma 140 formed in the tracheal wall 142 of a patient. This is illustrated in Fig. 9. Initially, a wire guide 110 is percutaneously inserted through the tracheal wall in well-known fashion, such as through the interior of a previously-inserted hollow needle (not shown). Following removal of the needle, the wire guide remains in place across the tracheal wall. The opening is then dilated using, e.g., a dilator such as the curved BLUE RHINO® dilator described in the incorporated by reference U.S. Patent No. 6,637,435, or the balloon dilator as described in the incorporated by reference U.S. Patent No. 5,653,230.

[0041] The tracheostomy tube 100 is then loaded onto the outer surface of loading dilator 10, in a manner such that tracheostomy tube distal end 102 is just proximal to the compressible portion of dilator 10. Dilator 10 is "at rest", as shown in Figs. 1 and 8, and first lever 74 is biased to a slightly off center position by spring 76. The position of handle 12 in this view is as shown in the enlarged view of Fig. 6. In this position, compressible member 30 is in its undeformed state. Leg 80B of lever 80 is in a substantially vertical orientation.
Second lever 80, acting in the nature of a trigger, is withdrawn proximally a first distance, as shown in Fig. 2. In this position, lever 80 bears against disk 88, thereby causing disk 88 to tilt. This action creates tension on hypotube 36, thereby causing the sharp inside corners of aperture 90 to "bite", into the outer surface of hypotube 36. As shown in Fig. 3, further withdrawal, or "squeezing", of second lever 80 causes disk 88 to move in a proximal direction. Since aperture 90 bites into the outer surface of hypotube 36, this squeezing action forces hypotube 36 to withdraw slightly in the proximal direction. The spring bias of lever 74 and aperture 75 holds the tube 36 in this position. This action results simultaneously in a corresponding proximal movement of linear actuating member 32, as well as the conical member 26 bonded thereto. The proximal end 42 of elongated tubular member 40 abuts against wall 44 of handle 12, thus preventing appreciable proximal movement of elongated member 40. See, Fig. 6.

Thus, proximal movement of conical member 26 relative to compressible member 30 causes compressible member 30 to deform between movable conical member 26 and substantially stationary tubular member 40. This compression deforms the compressible member 30 to form bulge 31, as shown, e.g., in Fig. 3. This action may be repeated until the desired bulge diameter is achieved. As stated, the presence of the bulge increases the girth of this portion of the loading dilator, thereby providing a relatively smooth transition between the dilator and the tracheostomy tube. As a result, the tracheostomy tube may be inserted through the stoma and into the trachea in a manner that reduces the trauma otherwise present when the lip described above is present. Although this action describes two separate movements of second lever 80 to accomplish deformation of member 30, in actuality these movements may be part of a continuous squeezing action of lever 80.

Proximal movement of hypotube 36 causes a partial release of tension on leg 74B, so that the hypotube may pass proximally (but not
Thus, the sharpened borders of first aperture 75 hold the tension on hypotube 36. Second (ever 80 may then be released, such that it returns to the at rest position by action of spring 82, as shown in Fig. 4. At this time, first lever 74 maintains tension on hypotube 36, thereby maintaining the compressed condition, and resulting in compressible member 30 deforming in a manner such that the bulged configuration shown in this figure is established and maintained.

[0045] The loading dilator/tracheostomy tube combination is then manually advanced and inserted through the stoma 140 to the desired placement, and the tracheostomy tube cuff 104 may then be inflated to position the tracheostomy tube within the trachea. When it is desired to release the compression on member 30 (and thereby eliminate the bulge 31), the first lever 74 may simply be tripped, e.g. by finger pressure. This action allows the components to spring back to the at rest configuration of Fig. 1. The loading dilator 10 is then withdrawn. Further details relating to a tracheostomy tube insertion procedure not specific to the features of the present invention are discussed in the incorporated by reference patents.

[0046] It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention.
CLAIMS:

1. A loading dilator for introducing a medical apparatus into a stoma in a patient, comprising:
   a tubular-portion having a proximal end and a distal end, said tubular portion including a radially outer dilator member substantially spanning a length of said tubular portion, said radially outer dilator member having a tapered distal end portion; a radially intermediate segment comprising a conical member at said tapered distal end portion, a compressible member positioned proximal of said conical member, and an elongated tubular member proximal of said compressible member; and a radially inner actuation member, said radially inner actuation member spanning a length of said tubular portion, said conical member engaged with said inner actuation member such that said conical member and inner actuation member are proximally movable relative to said elongated tubular member, said compressible member being deformable from a smaller diameter condition to a larger diameter condition upon said proximal movement; and a handle having a proximal end and a distal end, said handle having an opening formed at said distal end for receiving said tubular portion proximal end, said handle further having a trigger mechanism, said trigger mechanism operatively engaged with said inner actuation member for effecting said proximal movement of said inner actuation member and said conical portion upon an activation of said trigger mechanism.

2. The loading dilator of claim 1, wherein said trigger mechanism comprises a lever, said lever selectively movable for causing said proximal movement of said inner actuation member and said conical member.

3. The loading dilator of claim 1, further comprising a small bore tubular member enveloping a proximal end of said inner actuation member and extending into an interior portion of said handle, said tubular member structured and arranged such that activation of said trigger mechanism causes a portion of said handle to engage said tubular member such that
said handle portion and said tubular member are urged proximally in response to said trigger mechanism activation, thereby resulting in said proximal movement of said inner actuation member and said conical member.

4. The loading dilator of claim 3, wherein said handle comprises a member having an aperture therethrough, said aperture sized for receiving said tubular member therethrough in closely spaced relationship, said apertured member being tiltably responsive to activation of said trigger mechanism such that an edge portion of said aperture grippingly engages said tubular member, wherein proximal movement of said apertured member causes a corresponding proximal movement of said tubular member.

5. The loading dilator of claim 4, wherein said edge of said apertured member has a sharpened surface for effecting said gripping engagement.

6. The loading dilator of claim 5, wherein said apertured member comprises a first lever and said trigger mechanism comprises a second lever, wherein said first lever aperture comprises a first aperture, and said second lever has a second aperture, said second aperture sized for receiving said tubular member therethrough, said second aperture having a larger diameter than said first aperture, such that said tubular member is freely movable through said second aperture upon tilting of said first lever.

7. The loading dilator of claim 6, further comprising a disk member operably engaged with said second lever, said disk member having an aperture therethrough, said disk aperture sized for receiving said tubular member therethrough in closely spaced relationship, said disk member being tiltably responsive to movement of said second lever such that an edge portion of said disk aperture grippingly engages said tubular member.

8. The loading dilator of claim 3, wherein said inner actuation member and said small bore tubular member include respective flared
proximal ends, said flared end of said small bore tubular member 
enveloping said flared end of said inner actuation member.

9. The loading dilator of claim 8, wherein said handle further 
comprises a flare fitting and flare nut for receiving said respective flared 
ends.

10. The loading dilator of claim 1, wherein said compressible 
member comprises an elastomer.

11. The loading dilator of claim 10, wherein said elastomer 
comprises silicone rubber.

12. The loading dilator of claim 10, wherein said compressible 
member is deformable to a larger diameter up to about 150% of the 
smaller diameter.

13. A method for positioning a medical apparatus across a stoma 
formed in an outer body wall of a patient, comprising:

   providing a dilator comprising a handle and a tubular portion 
extending from said handle, said tubular portion comprising a radially outer 
dilator member substantially spanning a length of said tubular portion and 
having a tapered distal end portion; a radially intermediate segment 
comprising a conical member at said tapered distal end portion, a 
compressible member positioned proximal of said conical member, and an 
elongated tubular member proximal of said compressible member; and a 
radially inner actuation member, said radially inner actuation member 
spanning a length of said tubular portion, said conical member engaged 
with said inner actuation member such that said conical member and inner 
actuation member are proximally movable relative to said compressible 
member and said elongated tubular member, said compressible member 
being deformable from a smaller diameter condition to a larger diameter 
compressed condition upon said proximal movement; said handle having a 
trigger mechanism operatively engaged with said inner actuation member 
for effecting said proximal movement of said inner actuation member and 
said conical portion upon an activation of said trigger mechanism;
loading said medical apparatus onto said radially outer dilator member, and positioning said medical apparatus such that a distal end of said apparatus is disposed proximal to said compressible member on said radially outer dilator member;

activating said trigger mechanism to effect said proximal movement of said inner actuation member and said conical portion, thereby deforming said compressible member from said smaller diameter condition to said larger diameter condition, wherein said compressible member and said distal end of said medical apparatus define a transition from said radially outer dilator member to said distal end of said medical apparatus;

inserting said tapered distal end portion of said radially outer dilator member into said stoma; and

advancing said dilator such that a portion of said medical apparatus lies across said stoma.

14. The method of claim 13, wherein said medical apparatus comprises a tracheostomy tube.

15. The method of claim 14, wherein said compressible member is deformed to an outer diameter substantially as large as a diameter of said distal end of said tracheostomy tube.

16. The method of claim 15, wherein said trigger mechanism comprises a lever, said lever operatively engaged with said inner actuation member.

17. The method of claim 14, further comprising the step of releasing the compression on the compressible member, and removing the dilator from the interior of the tracheostomy tube.

18. The method of claim 13, wherein said larger diameter comprises a first diameter, further comprising the steps of releasing the compression on the compressible member, and reactivating the trigger mechanism to compress said compressible member to a second diameter different from said first diameter.
19. The method of claim 13, wherein said larger diameter condition is up to about 150% of said smaller diameter condition.

20. The method of claim 13, wherein said trigger mechanism comprises a lever, said lever selectively movable for causing said proximal movement of said inner actuation member and said conical member.
INTERNATIONAL SEARCH REPORT

PCT/US2008/051264

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M16/04 A61B17/34

According to International Patent Classification (IPC) and/or both national classification and IPC

B. RELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of database and where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Relevant to claim No.</th>
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<td>A</td>
<td>WO 97/38749 A (LASERSURGE INC [US]) 23 October 1997 (1997-10-23) abstract; figures</td>
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<td>&quot;WO 2006/087512 A (SMITHS GROUP PLC [GB]; TEBBUTT ADAM [NZ]) 24 August 2006 (2006-08-24) abstract; figures</td>
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X Further documents are listed in the continuation of Box C. X See patent family annex.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
  "E" earlier document not published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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* document member of the same patent family

Date of the actual completion of the international search: 28 April 2008
Date of mailing of the international search report: 13/05/2008

Name and mailing address of the ISA/Authorized officer
European Patent Office, P B 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340 2040, Tx. 31651 epo nl, Fax: (+31-70) 340-3016
Azaïza, Mourad

Form PCT/ISA/210 (second sheet) (April 2005)
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**Box No. II**  Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.: 13-20
   - Because the invention is not required to be searched by this Authority, namely:
     - Rule 39. 1 (i) PCT - Method for treatment of the human or animal body by surgery

2. ☐ Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III**  Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ○ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ○ As only some of the required additional search fees were timely paid by the applicant, this international search report covers:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicants protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.
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