EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 28.07.2004 Bulletin 2004/31

(21) Application number: 00306919.2

(22) Date of filing: 14.08.2000

(51) Int Cl.7: A61J 15/00

(54) Shim device for enteral feeding system
Ausgleichsstück für ein enterales Ernährungssystem
Cale pour système d’alimentation entéral

(84) Designated Contracting States: DE FR GB IT

(30) Priority: 17.08.1999 US 375925

(43) Date of publication of application: 21.02.2001 Bulletin 2001/08

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Description

1. Field of the Invention

[0001] The present invention relates to a device for use with gastrointestinal tubes, and more particularly to a support arrangement for use with low profile gastrointestinal feeding systems. More specifically, the present invention relates to a step up shim for supporting a portion of the low profile gastrointestinal feeding system on the outer surface of a patient.

2. Prior Art

[0002] It is known from US4861334 to provide a gastrostomy tube which is retained in place without the use of any stitching. The tube is held in place through the use of a balloon inside the stomach and a collar pressing against the abdominal wall of the patient. A trocar is employed to elongate and implant the gastrostomy tube.

[0003] It is further known from US3961632 to provide a trans-abdominal stomach catheter placement system involving an external nasogastric intubation device. A modified Foley catheter is inserted through the abdomen wall into the stomach and secured therein, in order to effectively dispose the stomach for ready and reliably located penetration by a trocar or the like. The device has a mobile distal end and uses a magnetic intubation device and technique to distend or advance the forward portion of the stomach wall into relatively close proximity to the exterior abdomen wall, and in doing so laterally displacing intestinal or other members which might lie therebetween, whereby damage to or cutting of such members is avoided in implanting the catheter.

[0004] Low profile gastrointestinal feeding systems are frequently used for long term tube fed patients who are ambulatory and/or in a combative state and require some type of gastrostomy device to provide nutrition to a patient unable to take nutrition orally. These gastrointestinal system comprise a feeding set attached to a source of nutrition at one end and a low profile gastrostomy tube at the other end. The low profile gastrostomy tube is normally inserted through a stoma formed in the patient's abdominal wall utilising an internal retention member designed to pass through a stoma formed in a wall of the abdomen and stomach or other visceras of a patient in order to secure the low profile gastrostomy tube within the organ of choice. The method of using this type of obturatable internal retention member consists of insertiing an obturator rod into the lumen of the low profile gastrostomy tube until the rod abuts or engages the distal end of the internal retention member. The internal retention member comprises a plurality of flexible retaining arms attached to the hollow tubular member that mechanically elongate and thereby slendrize the silicone, latex or polyurethane retaining arms to a size about that of the diameter or the tubular member when the obturator rod is pushed axially toward the patient. Such slenderization of the retaining arms allows safe insertion or removal of the tubular member and internal retention member into or from an established, matured stoma of a patient. Such obturatable internal retention members are currently the most common means used to insert, anchor and secure the low profile gastrostomy tube in a matured stoma of a patient.

After the internal retention member has been inserted inside the stomach, the obturator rod is withdrawn through the tubular member which allows the flexible retaining arms of the internal retention member to assume its preset enlarged shape, thereby retaining the internal retention member inside the stomach so that it cannot be withdrawn back through the stoma. Once the internal retention member assumes its preset enlarged shape, the feeding tube with a connection member at one end is attached to the external retention member of the low profile gastrostomy tube in order to establish fluid flow communication between the source of nutrition and the patient's stomach. In this way, nutrition is provided to the patient through the low profile gastrostomy tube. Unfortunately, the external retention member is required to be seated on the patient's stomach for long periods of time while the patient is being fed through the low profile gastrostomy tube. This long term, continuous contact between the legs of the external retention member and the patient's stomach can cause pressure necrosis of the skin area.

[0005] A typical internal retention member is disclosed in U.S. Patent No. 5,248,302 to Patrick et al. entitled "Percutaneous Obturatable Internal Anchoring Device" which describes a deformable obturatable internal retention member designed to pass through a stoma formed in a wall of the abdomen and stomach or other visceras of a patient in order to secure the low profile gastrostomy tube within the organ of choice. The method of using this type of obturatable internal retention member consists of inserting an obturator rod into the lumen of the low profile gastrostomy tube until the rod abuts or engages the distal end of the internal retention member. The internal retention member comprises a plurality of flexible retaining arms attached to the hollow tubular member that mechanically elongate and thereby slendrize the silicone, latex or polyurethane retaining arms to a size about that of the diameter or the tubular member when the obturator rod is pushed axially toward the patient. Such slenderization of the retaining arms allows safe insertion or removal of the tubular member and internal retention member into or from an established, matured stoma of a patient. Such obturatable internal retention members are currently the most common means used to insert, anchor and secure the low profile gastrostomy tube in a matured stoma of a patient.

Therefore, there appears a need in the art for a device for supporting an external retention member of a low profile gastrostomy tube in order to more evenly distribute the pressure applied by the legs of the external retention member over a wider area of the patient's skin.

OBJECTS AND SUMMARY OF THE INVENTION

[0006] In brief summary, the present invention overcomes and substantially alleviates the deficiencies in the prior art by providing a shim device according to
According to the invention, there is provided a shim device for supporting and evenly distributing the weight of a portion of a gastrointestinal feeding system. The invention is to provide a shim device having a dual height feature which allows the user to spread apart both parts of the leaf portion in order to slide the axial opening around the center portion with one large pad located between each respective leaf portion. A pair of apertures are formed between two opposing ends of the axial opening adjacent each large pad. Finally, a radial slit is formed along one of the four leaf portions between the outer edge of the leaf portion and the axial opening which allows the user to spread apart both parts of the leaf portion in order to slide the axial opening around the bottom portion of the external retention member in order to engage the shim to the low profile gastrointestinal feeding system.

**0008** Accordingly, the primary object of the present invention is to provide a shim device for supporting and evenly distributing the weight of a portion of a gastrointestinal feeding system;

**0009** Another object of the present invention is to provide a shim device having a dual height feature which permits alternatively supporting a portion of a feeding system at two different heights depending on which side of the shim device is used.

**0010** A further object of the present invention is to provide a shim device made of a flexible, resilient material.

**0011** According to the invention, there is provided a shim device for use with gastrointestinal tubes comprising:

- a shim body having opposed sides, said shim body including an inner portion having an axial opening and a plurality of apertures therethrough, said shim body further including at least one outer portion defining an outer edge radially extending outwardly from said inner portion, said at least one outer portion having a radial slit formed therethrough; whereby a first plurality of support pads is formed on one of said opposed sides and extends a first height; and a second plurality of support pads is formed on the other of said opposed sides and extends a second height therefrom, wherein either one of said first or second plurality of support pads provides a base and the other of said first or second plurality of support pads provides a support surface.

**0012** Preferably said at least one outer portion comprises four outer portions.

**0013** In a preferred embodiment said first height is approximately about 2.5 millimeters, and wherein said second height is approximately about 4.0 millimeters.

**0014** Said shim body may further comprise at least one aperture.

**0015** Preferably said at least one aperture comprises two apertures oppositely disposed about said axial opening.

**0016** In a preferred embodiment said radial slit extends between said axial opening and said outer edge.

**0017** Said first plurality and said second plurality of support pads may each include a plurality of outer pads proximate said outer edge, and wherein said first plurality and said second plurality of support pads each include a plurality of inner pads disposed on said inner portion proximate said axial opening.

**0018** In an alternative arrangement said first plurality and said second plurality of support pads may each include a plurality of outer pads proximate said outer edge, and wherein said first plurality and said second plurality of support pads each include a plurality of inner pads disposed proximate said axial opening.

**0019** Preferably said outer pads comprise two outer pads disposed on said at least one outer portion.

**0020** Preferably said inner pads comprise four pads disposed on said inner portion and aligned approximately between each of said four outer portions.

**0021** These and other objects of the present invention are realised in the preferred embodiment of the present invention, described by way of example and not by way of limitation, which provides for a shim device for supporting and evenly distributing the weight of a gastrointestinal feeding system.

**0022** Additional objects, advantages and novel features of the invention will be set forth in the description which follows, and will become apparent to those skilled in the art upon examination of the following more detailed description and drawings in which like elements of the invention are similarly numbered throughout.
BRIEF DESCRIPTION OF THE DRAWINGS

[0023]

Fig. 1a is a planar view of the shim device according to the present invention;
Fig. 1b is a planar view of the shim device showing the slit spread open according to the present invention;
Fig. 2 is a side view of the shim device according to the present invention;
FIGS. 3a-3d are isometric views of the engagement sequence showing the shim device being engaged to an external retention member according to the present invention; and
FIG. 4 is a planar view of the external retention member engaged to the shim device according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0024] Referring to the drawings, the preferred embodiment of the shim device of the present invention is illustrated and generally indicated as 10 in FIG. 1a. The shim device 10 comprises a shim body 12 which forms four substantially identical outer portions 24 that surround an inner portion 26. Inner portion 26 forms an axial opening 22 through shim body 12 with a slit 20 that extends from opening 22 to outer edge 40 through one of the outer portions 24. As shall be discussed in greater detail later, slit 20 is adapted to be spread apart, as shown in FIGS. 1b and 4, so that the tubular member 36 of the low profile gastrointestinal feeding system may be slipped through slit 20 and engaged around axial opening 22. Preferably, slit 20 is located so that one of the outer portions 24 is split evenly in half, although slit 20 may also be located along one portion of the shim body 12 as long as tubular member 36 can be slipped through slit 20 and engaged with axial opening 22.

[0025] Two apertures are located on either side of axial opening 22 and are formed through shim body 12 for providing air flow to the patient's skin layer when the low profile gastrointestinal feeding system is attached to the patient.

[0026] It should be understood from the foregoing that, while particular embodiments of the invention have been illustrated and described, various modifications can be made thereto.

Claims

1. A shim device (10) for use with gastrointestinal tubes comprising:
   a shim body (12) having opposed sides (28,30), said shim body (12) including an inner portion (26) having an axial opening (22) formed there-through, said shim body (12) further including at least one outer portion (24) defining an outer edge (40) radially extending outwardly from said inner portion (26), said at least one outer portion (24) having a radial slit (20) formed therethrough characterised in that a first plurality of support pads (14) formed on one of said opposed sides (28,30) and extending a first height; and a second plurality of support pads (14) formed on the other of said opposed sides (28,30) and extending a second height therefrom, wherein either one of said first or second plurality of support pads provides a base and the other of said first or second plurality of support pads provides a support surface.

2. A shim device (10) according to claim 1, wherein said at least one outer portion (24) comprises four outer portions (15).

3. A shim device (10) according to claim 1, wherein said first height is approximately about 2.5 millimeters, and wherein said second height is approximately about 4.0 millimeters.

4. A shim device (10) according to claim 1, wherein said shim body (12) further comprises at least one aperture (18).

5. A shim device (10) according to claim 4, wherein said at least one aperture (18) comprises two apertures (18) oppositely disposed about said axial opening (22).

6. A shim device (10) according to claim 1, wherein said radial slit (20) extends between said axial opening (22) and said outer edge (40).

7. A shim device (10) according to claim 1, wherein said first plurality and said second plurality of support pads (14) each include a plurality of outer pads (15) proximate said outer edge (40), and wherein said second plurality of support pads (14) each include a plurality of inner pads (16) disposed on said inner portion (26) proximate said axial opening (22).

8. A shim device (10) according to claim 2, wherein said first plurality and said second plurality of support pads (14) each include a plurality of outer pads (15) proximate said outer edge (40), and wherein said first plurality and said second plurality of support pads (14) each include a plurality of inner pads (16) disposed proximate said axial opening (22).

9. A shim device (10) according to claim 8, wherein said outer pads (15) comprise two outer pads (15)
Revendications

1. Dispositif de cale (10) destiné à être utilisé avec des tubes d'alimentation gastro-intestinaux, comprenant :

   un corps de cale (12) comportant des côtés opposés (28, 30), ce corps de cale (12) comprenant une partie intérieure (26) percée d'une ouverture axiale (22), ainsi qu'au moins une partie externe (24) définissant un bord externe (40) partant radialement vers l'extérieur de la partie intérieure (26), cette partie externe au moins unique (24) comportant une fente radiale (20) formée à travers celle-ci,

caractérisé en ce qu'

   une première pluralité de patins de support (14) est formée sur l'un des côtés opposés (28, 30) et s'étend sur une première hauteur ; et

   une seconde pluralité de patins de support (14) est formée sur l'autre des côtés opposés (28, 30) et s'étend sur une seconde hauteur à partir de celui-ci ;

   l'une ou l'autre des première et seconde pluralités de patins de support fournissant une base tandis que l'autre des première et seconde pluralités de patins de support fournit une surface de support.

2. Dispositif de cale (10) selon la revendication 1, dans lequel
   la partie externe au moins unique (24) comprend quatre parties extérieures (15).

3. Dispositif de cale (10) selon la revendication 1, dans lequel
   la première hauteur est approximativement de 2,5 millimètres et la seconde hauteur est approximativement de 4,0 millimètres.

4. Dispositif de cale (10) selon la revendication 1, dans lequel
   le corps de cale (12) comprend en outre au moins une ouverture (18).

5. Dispositif de cale (10) selon la revendication 4, dans lequel
   l'ouverture au moins unique (18) consiste en deux ouvertures (18) disposées de part et d'autre de l'ouverture axiale (22).

6. Dispositif de cale (10) selon la revendication 1, dans lequel
   la fente radiale (20) s'étend entre l'ouverture axiale (22) et les bords extérieurs (40).

7. Dispositif de cale (10) selon la revendication 1, dans lequel
   la première pluralité et la seconde pluralité de patins de support (14) comprennent chacune un certain nombre de patins extérieurs (15) à proximité du bord externe (40) ; et

   la première pluralité et la seconde pluralité de patins de support (14) comprennent chacune un certain nombre de patins intérieurs (16) disposés sur la partie intérieure (26) à proximité de l'ouverture axiale (22).

8. Dispositif de cale (10) selon la revendication 2, dans lequel
   la première pluralité et la seconde pluralité de patins de support (14) comprennent chacune un certain nombre de patins extérieurs (15) à proximité du bord externe (40) ; et

   la première pluralité et la seconde pluralité de patins de support (14) comprennent chacune un certain nombre de patins intérieurs (16) disposés à proximité de l'ouverture axiale (22).

9. Dispositif de cale (10) selon la revendication 8, dans lequel
   les patins extérieurs (15) comprennent deux patins extérieurs (15) disposés sur la partie extérieure au moins unique (24).

10. Dispositif de cale (10) selon la revendication 8, dans lequel
    les patins intérieurs (16) comprennent quatre patins disposés sur la partie intérieure (26) et alignés approximativement entre chacune des quatre parties extérieures (24).

11. Dispositif de cale (10) selon la revendication 1, dans lequel
    ce dispositif de cale (10) est réalisé dans un matériau élastique flexible.

Patentansprüche

1. Ein Ausgleichsstück (10) zur Verwendung mit gastrointestinalen Röhren, mit:

   einem Ausgleichskörper (12) mit einander ge-
genüberliegenden Seiten (28, 30), wobei der Ausgleichskörper (12) einen inneren Abschnitt (26) mit einer axialen Öffnung (22) beinhaltet, welche hierdurch ausgebildet ist, wobei der Ausgleichskörper (12) weiterhin wenigstens einen äußeren Abschnitt (24) beinhaltet, der eine äußere Kante (40) definiert, welche sich radial nach außen von dem inneren Abschnitt (26) aus erstreckt, wobei der wenigstens eine äußere Abschnitt (24) einen durch ihn durch gehenden radialen Schlitz (20) aufweist, dadurch gekennzeichnet, daß eine erste Mehrzahl von Stützkissen (14) an einer der gegenüberliegenden Seiten (28, 30) ausgebildet ist und sich in eine erste Höhe erstreckt; und eine zweite Mehrzahl von Stützkissen (14) einer anderen der gegenüberliegenden Seiten (28, 30) ausgebildet ist und sich hiervon in eine zweite Höhe erstreckt, wobei eine der ersten oder zweiten Mehrzahl von Stützkissen eine Basis schafft und die andere der ersten oder zweiten Mehrzahl von Stützkissen eine Stützoberfläche schafft.

2. Ein Ausgleichsstück (10) nach Anspruch 1, wobei der wenigstens eine äußere Abschnitt (24) vier äußere Abschnitte (15) aufweist.

3. Ein Ausgleichsstück (10) nach Anspruch 1, wobei die erste Höhe annähernd ungefähr 2,5 mm beträgt und wobei die zweite Höhe annähernd ungefähr 4,0 mm beträgt.

4. Ein Ausgleichsstück (10) nach Anspruch 1, wobei der Ausgleichskörper (12) weiterhin wenigstens eine Öffnung (18) aufweist.

5. Ein Ausgleichsstück (10) nach Anspruch 4, wobei die wenigstens eine Öffnung (18) zwei Öffnungen (18) aufweist, welche um die axiale Öffnung (22) herum einander gegenüberliegend angeordnet sind.

6. Ein Ausgleichsstück (10) nach Anspruch 1, wobei der radiale Schlitz (20) sich zwischen der axialen Öffnung (22) und der äußeren Kante (40) erstreckt.

7. Ein Ausgleichsstück (10) nach Anspruch 1, wobei die erste Mehrzahl und die zweite Mehrzahl von Stützkissen (14) jeweils eine Mehrzahl von äußeren Kissen (15) benachbart der äußeren Kante (40) beinhalten und wobei die erste Mehrzahl und die zweite Mehrzahl von Stützkissen (14) jeweils eine Mehrzahl von inneren Kissen (16) beinhalten, welche benachbart der axialen Öffnung (22) angeordnet sind.

8. Ein Ausgleichsstück (10) nach Anspruch 2, wobei die erste Mehrzahl und die zweite Mehrzahl von Stützkissen (14) jeweils eine Mehrzahl von äußeren Kissen (15) beinhalten, wobei die erste Mehrzahl und die zweite Mehrzahl von Stützkissen (14) jeweils eine Mehrzahl von inneren Kissen (16) beinhalten, welche be- nachbart der axialen Öffnung (22) angeordnet sind.

9. Ein Ausgleichsstück (10) nach Anspruch 8, wobei die äußeren Kissen (15) zwei äußere Kissen (15) aufweisen, welche an dem wenigstens einen äußeren Abschnitt (24) angeordnet sind.

10. Ein Ausgleichsstück (10) nach Anspruch 8, wobei die inneren Kissen (16) vier Kissen aufweisen, die an dem inneren Abschnitt (26) angeordnet sind und annähernd in Fluchtung zwischen jedem der vier äußeren Abschnitte (24) sind.

11. Ein Ausgleichsstück (10) nach Anspruch 1, wobei das Ausgleichsstück (10) aus einem flexiblen elastischen Material gefertigt ist.