Abstract:

A stoma measuring device (1) comprising a thin plate-shaped flat body inside which a plurality of holes (102) of different size is provided, said plate-shaped flat body (101) being made of a material that can be sterilized several times so that the measuring device can be used several times.
STOMA MEASURING DEVICE

DESCRIPTION

Technical field

The present invention relates to a stoma measuring device.

State of the Art

As it is well known, under certain clinical conditions the patient must be subjected to stoma surgery, i.e. a surgical anastomosis of the bowel or urinary tract. With this procedure, an opening is made on the patient's skin for connecting the intestine or urinary system with the outside environment, thus allowing organic material (urine or feces) to drain. The opening has no sphincter, i.e. the ring of muscle that can close it; stools and urine cannot be therefore retained and go out uncontrollably.

For collecting said organic material, bags or pouches are applied to these openings through wafers in which a hole must be provided to receive the stoma. The size of said hole changes according to the stoma size and therefore from patient to patient; it shall be made by a nurse who cut it in the wafer after having identified the most appropriate diameter among those usually already indicated on the wafer. Once holed, the wafer will adhere to the patient's skin stickily. The bag or pouch for draining the organic material is then associated to said wafer.

In stoma management it is fundamental to identify the correct size of the stoma so as perfectly to insulate the surrounding skin against the effluents. This also allows a lower risk of peristomal skin complications and increases the guarantee that the stoma appliance remains properly in place.

Devices or elements made of paper or plastic are well known for measuring the stoma diameters; they have a plurality of holes of different diameters but have the drawback of not allowing an easy choice of the most appropriate diameter. These devices cannot be sterilized and therefore cannot be used in operating room during stoma surgery. Moreover, they can become impregnated with biological liquids and are poorly manageable due to their lack of consistency, i.e. they tend to bend offering substantially no mechanical resistance.

The known measuring devices are disposable and therefore they cannot be reused.

Due to their poor usefulness and practicality, the known measuring devices are
often not used and the operator chooses the most appropriate diameter at a rough guess.

As specified above, to get good results the hole should be neither too small, as it must receive the stoma, nor too large, as the patient's skin would remain uncovered instead of being adequately insulated for the above mentioned reasons.

Summary of the Invention

The invention provides a stoma measuring device that completely or partially overcomes one or more drawbacks of the known devices.

The object of some embodiments of the invention is to provide an instrument allowing easily and precisely to measure the stoma and to choose the most appropriate diameter for the stoma size, with a direct evaluation in situ, i.e. directly putting the stoma measuring device on the patient's skin.

The stoma measuring device of the invention substantially comprises a plate-shaped flat body made of a material that can be sterilized and reused both in a surgery and in an operating room. The material and the thickness of the stoma measuring device are chosen so that the device has a sufficient stiffness to detect the stoma size on the patient's body without bending, as it occurs in the measuring devices made of paper or plastic sheet, thus making the measurement unreliable or even impossible. The plate-shaped flat body has a plurality of through openings or holes of different sizes. The stoma is measured by comparing the stoma with the holes, with which the stoma measuring devices is provided.

Sterilizable and reusable material generally means a material satisfying adequate mechanical and heat resistance requirements needed repeatedly to use the device, sterilizing it after each use, maintaining the shape and size features sufficient for the device purposes.

In some currently preferred embodiments of the invention, the stoma measuring device is made of sterilizable steel. According to other embodiments, the stoma measuring device is made of a metal or alloy with equivalent features, in terms of size and shape constancy, when repeatedly used and sterilized.

The device may be also made of synthetic materials able to maintain an adequate size and shape constancy.

Thanks to the above mentioned characteristics, the stoma measuring device according to the invention can be easily washed and/or sterilized, easily contained in
the sterilizing bags and kept among the surgical instruments in the operating rooms or on the nurse carts in the hospital departments (surgery, urology, etc.) and wards accessible by ostomates.

The holes or openings in the plate-shaped flat body of the stoma measuring device are preferably round with variable diameter. In other embodiments the holes or openings are elliptical and of variable sizes. In the case of elliptical holes, changes in the minor axis and/or in the major axis of the ellipse can be provided. Several holes can be provided, for instance, with a major axis of constant length and a minor axis of variable length and/or vice versa. Alternatively, a series of holes can be provided, differing from one another in the size of both the minor axis and the major axis. In other embodiments, on the same stoma measuring device elliptical holes can be provided subdivided into groups, in each group one of the two axes (major and minor) remaining constant and the other varying between a minimum and a maximum.

Holes having shapes other than round or elliptical are also possible. However, the latter are the most advantageous and adequate, as the stoma tends to take a round or slightly elliptical shape as a result of the natural behavior of biological tissues.

In some embodiments, in the same device holes equal in shape can be provided, or combinations of holes of different shapes, for instance round and elliptical or other shapes.

In some embodiments, to simplify the use of the stoma measuring device, near each hole, or at least near some of them, at least one value corresponding to a hole dimension, for instance the diameter, is indicated in a readable manner on at least one side of the plate-shaped body.

In some advantageous embodiments the plate-shaped body of the device is designed with rounded corners.

In some advantageous embodiments, to simplify the use of the device, the holes are arranged according to a sequence of gradually increasing or decreasing sizes, for instance according to a sequence of progressively increasing diameters, from a minimum diameter to a maximum diameter, or vice versa, with steps that can be constant in value (for example a progressive increment of 5 mm) or variable in value according to the different use requirements.

The number of holes, their diameter or size values, as well as their shapes and arrangements on the plate-shaped body can vary and can be set according to the
different use requirements.

According to some embodiments, the plate-shaped body has an elongated shape, the holes being arranged along the major axis, i.e. along the longitudinal extension of the plate-shaped body of the stoma measuring device.

The plate-shaped flat body can be for instance tapered from one end of maximum width, near which a hole of maximal diameter is arranged, to one end of minimum width, near which a hole of minimal diameter is arranged.

In some embodiments the plate-shaped flat body can have different shapes, for instance elliptical, round, square, rectangular, triangular, etc, the holes being of different sizes and diameters, arranged on at least one portion of the surface of said plate-shaped body according to the different use requirements.

**Brief description of the drawings**

This and further features and advantages of the invention will be more apparent from the detailed description below of some advantageous and various embodiments of the invention, illustrated by way of non-limiting example in the attached tables of drawings, wherein:

figures 1 and 2 show a top view and a perspective view, respectively, of the stoma measuring device, according to a preferred embodiment;

figures 3 and 4 show two enlarged and partial views of the device of figures 1 and 2, respectively towards the end of minimum width and the end of maximum width;

figures 5 to 8 show a top view of some modified embodiments of the invention.

**Detailed description of embodiments**

The detailed description below of preferred embodiments is made with reference to the attached drawings. The same reference numbers in different drawings identify the same or similar elements. Furthermore, the drawings are not necessarily in scale. The detailed description below does not limit the invention. The scope of the invention is defined by the attached claims.

In the description, the reference to "an embodiment" or "the embodiment" or "some embodiments" means that a particular feature, structure or element described with reference to an embodiment is comprised in at least one embodiment of the described subject matter. The phrase "in one embodiment" or "in the embodiment" or
"in some embodiments" in the description do not therefore necessarily refer to the same embodiment or embodiments. The particular features, structures or elements can be furthermore combined in any adequate way in one or more embodiments.

With reference to the figures, the stoma measuring device is indicated as a whole with number 1 and comprises a plate-shaped body 101 made of a sterilizable material, which can be used several times, after sterilization, thanks to the features of mechanical resistance and of stress resistance, for instance thermal stresses during sterilization, of said sterilizable material. In advantageous embodiments the material is metal, and preferably sterilizable steel. The material and the size, in particular the thickness of the plate-shaped body 101, are chosen so that the plate-shaped body does not bend and is not subject to permanent deformations during use, and is preferably substantially rigid. "Substantially rigid" means that the plate-shaped body must be subject to a deformation that is negligible, as far as the measurement purposes are concerned, when applied to the patient's body with a sufficient force to make it adhere to the involved body portion. A plurality of holes 102 are provided on the plate-shaped flat body; said holes are of different size, for instance of different diameters, or (in the case of elliptical holes) with axes of variable dimensions. In practical terms the holes 102 are openings through the thickness of the plate-shaped flat body of the stoma measuring device. Their shapes and sizes are chosen so as to correspond to the most practical cases that can occur in the use of the device. A precise measurement of the stoma can require a great number of measuring holes; it is therefore possible to provide more stoma measuring devices, forming together a set of stoma measuring devices, each of which with a plurality of holes or openings of different sizes and/or shapes.

The plate-shaped flat body 101 is thin, for instance with a thickness of nearly 1.5-2 mm, and is provided with rounded corners.

The holes 102 in the plate-shaped flat body 101 are preferably round, or of other shape, for instance elliptical.

In the same stoma measuring device 1 according to the invention, holes 102 can be provided, all with the same shape, for instance round, as in the embodiment illustrated in figures 1 to 4, or holes 102 of different shapes can be combined together, for instance round and elliptical or other shapes.

For instance, in the embodiments of figures 5, 7, and 8 the combination of
round holes 102 with elliptical holes 102 is shown.

According to not illustrated embodiments, other combinations of holes 102 of different shapes may be provided.

Said holes 102 have different sizes or diameters, from a minimum diameter to a maximum diameter, so as to meet the various use requirements, i.e. to identify the most adequate diameter according to the size of the patient’s stoma.

In the embodiment of figures 1 to 4, near each hole 102 the respective values 103 of the diameters or sizes of the holes are indicated in a readable manner on at least one side of the plate-shaped flat body 101.

The holes 102 are preferably arranged in a sequence of progressively increasing diameters or sizes, from a minimum diameter to a maximum diameter, with increments that can be constant in value or variable in value according to different use requirements. The value of the size increment from one hole to the other contributes to measurement accuracy. The smaller this increment, the greater the measurement accuracy, as the difference in size between two holes substantially represents the measurement definition degree. This incremental value will be chosen also taking into account the fact that the lower this value, the greater the number of holes required to perform the measurement, and therefore the larger the size of the device, or the number of devices in a set. In some embodiments the difference in size between consecutive holes may decrease as the absolute size of the holes decreases.

In the embodiment illustrated in figures 1 to 4, eight holes 102 are provided, with a progressive diameter increment of 5 mm, but different numbers of holes 102 and different increments may be provided in not illustrated embodiments, depending upon different use requirements.

The stoma measuring device 1 may be provided in different types, wherein the number of holes 102, the respective values 103 of the different diameters or sizes, as well as the shapes of the holes 102 and their arrangements on the plate-shaped body 101 may be different according to the various use requirements.

According to the preferred embodiment of figures 1 to 4, the plate-shaped body 101 has an elongated shape, the holes 102 being arranged aligned along the major axis.

In this preferred embodiment, the plate-shaped flat body 101 can be for instance tapered from one end of maximum width (figure 4), near which a hole 102 of
maximal diameter is provided, to one end of minimum width, near which a hole 102 of minimal diameter is provided.

With the described device, the stoma is measured identifying the hole 102, the diameter of which is most similar to the stoma size (the stoma is not illustrated). The substantial stiffness of the stoma measuring device 1 allows to perform this operation precisely and easily and the evaluation directly in situ, i.e. directly putting the device 1 on the patient's skin, wherein said device is sterile, manageable and reusable.

The diameter of the hole 102, identified as the most similar to the stoma size, allows identifying precisely and easily the most adequate diameter of the hole to be made in the appliance wafer by the nurses by cutting said wafer. The diameter to be cut may be identified among a plurality of hole diameters already indicated on the wafer, comparing these pre-marked diameters on the wafer with the diameter on the measuring device identified as the most similar to the stoma actual diameter.

The wafer, onto which the hole of the correct diameter has been cut, is then made adhere to the patient's skin by means of an adequate adhesive. A bag can be associated with said wafer for collecting the organic material, as above specified. Instead of identifying a pre-marked cut diameter on the wafer, it is possible to make a hole with a diameter exactly corresponding to the diameter identified on the measuring device 1, practically using this latter as a cutting template.

The stoma measuring device 1 described above has a wide range of uses:

- in the surgery sets for abdominal surgery involving a bowel or urinary stoma surgery (for identifying the diameter, in order to cut the post-operative appliance);
- in the stoma-care nurses, for identifying the correct diameter to cut the wafer of the appliance;
- in the out-patient departments and urologic surgeries, that often manage ostomates;
- in the surgeries for stoma management;
- in training courses for stoma management.

The stoma measuring device or instrument according to the invention can be easily washed and/or sterilized (by cleansing, sanitization) and easily contained in the sterilizing bags and kept among the usual surgical instruments in the operating rooms or on the nurse carts in the hospital departments (surgery, urology, etc.) and wards.
accessible by ostomates.

In particular, the elongated shape of the stoma measuring device 1 illustrated in the embodiment of figures 1 to 4 can be easily grasped on the right, on the left and in the middle thereof, allowing easily and fluently to put and move the measuring device on the abdomen of a patient lying on a bed, on an operating table, on a stretcher etc..

The plate-shaped flat body 101 of the stoma measuring device 1 may be also provided with shapes other than that illustrated in figures 1 to 4, for instance elliptical, rectangular, round, triangular, square, polygonal, etc, the holes 102 being different in sizes and diameters and provided on at least one portion of the surface of said plate-shaped body 101 according to the different use requirements.

Some of these embodiments are illustrated in figures 5 to 8, wherein:

in figure 5, the plate-shaped body 101 is elliptical and has six holes 102, partially round and partially elliptical;

in figure 6 the plate-shaped body 101 is rectangular and has seven round holes 102;

in figures 7 and 8 the plate-shaped bodies 101 are illustrated, respectively round and triangular in shape, with seven holes 102, partially round and partially elliptical.

According to another feature of the invention, thanks to the consistency of the stoma measuring device 1 resulting from the material it is made of (for instance sterilizable steel), the device may be used by the nurses to trace, with a pencil or the like, the most adequate diameter on the wafer to cut, if this diameter is not already indicated on the same wafer.

The embodiments described above and illustrated in the drawings have been explained in detail as examples of embodiments of the invention. It will be clearly apparent to those skilled in the art that modifications, variants, additions and omissions are possible, without however departing from the principles, the scope of the concept and the teachings of the present invention as defined in the attached claims. The scope of the invention shall be therefore determined exclusively based upon the widest interpretation of the attached claims, comprising in this scope these modifications, variants, additions and omissions. The terms "comprising" and its derivatives do not exclude the presence of further elements or steps in addition to
those specifically indicated in a given claim. The term "a" or "an" before an element, means or feature of a claim does not exclude the presence of a plurality of these elements, means or features. If a device claim claims a plurality of "means", some or all of these "means" can be embodied as a single component, member or structure.

The enunciation of given elements, features or means in distinct dependent claims does not exclude the possibility of combining said elements, features or means together. When a method claim lists a sequence of steps, the sequence with which these steps are listed is not binding and can be changed, if the particular sequence is not indicated as binding. Any reference numbers in the appended claims are provided to facilitate reading of the claims with reference to the description and to the drawing, and do not limit the scope of protection represented by the claims.
CLAIMS

1. A stoma measuring device (1) comprising a thin plate-shaped flat body inside which a plurality of holes (102) of variable size are provided, said plate-shaped flat body (101) being made of a material that can be sterilized several times so that the measuring device can be used several times.

2. Device according to claim 1, wherein said plate-shaped flat body is made of sterilizable steel.

3. Device according to claim 1 or 2, wherein said plate-shaped flat body (101) has a stiffness sufficient to substantially maintain its shape when applied to the patient's body with a sufficient contact pressure to measure the stoma.

4. Stoma measuring device (1) according to one or more of the previous claims, wherein said holes (102) have a round and/or elliptical shape.

5. Stoma measuring device (1) according to one or more of the previous claims, comprising holes (102) that are all equal in shape and of variable dimensions.

6. Stoma measuring device (1) according to one or more of the previous claims, comprising holes that are different in shape.

7. Stoma measuring device (1) according to one or more of the previous claims, comprising round holes with variable diameter and/or elliptical holes with axes of variable dimensions.

8. Stoma measuring device (1) according to one or more of the previous claims, wherein near at least some of said holes, and preferably near each of said holes (102), respective readable values (103) of the holes diameters or dimensions are indicated on at least one side of the plate-shaped flat body (101).

9. Stoma measuring device (1) according to one or more of the previous claims, wherein said plate-shaped flat body (101) has rounded corners.

10. Stoma measuring device (1) according to one or more of the previous claims, wherein said plate-shaped flat body (101) has an elongated shape and wherein said holes (102) are aligned along the longitudinal extension of said plate-shaped flat body.

11. Stoma measuring device (1) according to claim 10, wherein said plate-shaped flat body (101) is tapered from one end of maximum width, near which a hole (102) of maximal dimension is arranged, to one end of minimum width, near which a hole (102) of minimal dimension is arranged.
12. A set of measuring devices according to one or more of the previous claims.

13. Set according to claim 12, wherein said measuring devices have holes (102) that are at least partially different in shape and/or dimensions from one device to the other, to give an overall number of measuring holes, different from one another, greater than the number of holes available on a single device.

14. A stoma measuring method using a stoma measuring device according to one or more of the previous claims, comprising the steps of:

- placing a sterilized stoma measuring device on a patient's body portion in which a stoma has been made;
- from the holes of said stoma measuring device, choosing the hole that is as similar as possible in dimension and/or shape to the stoma dimension and/or shape;
- using the dimension and/or the shape of the chosen hole as a stoma measure.

15. Method according to claim 14, comprising the step of sterilizing the stoma measuring device once again after having performed the measurement.

16. Method according to claim 14 or 15, comprising the step of making a hole or aperture in a wafer to be applied to a stoma, based upon the performed stoma measurement.
INTERNATIONAL SEARCH REPORT

PCT/EP2012/067996

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/107 A61F5/445 G01B3/34

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G01B A61F

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

Electronic data base consulted during the international search (name of database and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>us 4 517 747 A (MORIN J DONALD [CA]) 21 May 1985 (1985-05-21) column 1, line 1 - line 42; figures 1-2</td>
<td>1, 4, 7-9, 12-15</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

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