DEVICE FOR THE TREATMENT OF ESOPHAGEAL STENOSIS

Fig. 1

The device (1) for the treatment of oesophageal stenosis comprises at least a body with elongated shape intended to be inserted in the oesophagus of a patient and variable rigidity means (3) associated externally with said body (2).
DEVICE FOR THE TREATMENT OF OESOPHAGEAL STENOSIS

Technical Field
The present invention relates to a device for the treatment of oesophageal stenosis.

Background Art
As is known, oesophageal stenosis can be caused by numerous factors such as, e.g., lesions caused by swallowing caustic substances, cicatricial lesions following oesophageal anastomosis for atresia, post-chemotherapy or radiotherapy or peptic lesions, etc.

To permit the recovery of correct organ function, thus providing the patient with a good quality of life, intervention generally consists in dilating the oesophagus tract affected by the stenosis.

These dilatations must be repeated over time in order to address the inevitable occurrence of relapses.

In order to avoid an excessive number of dilatations, specific devices are used, also called "removable stents".

The devices of known type used to dilate the oesophagus tract affected by the stenosis can be of two types: of the self-expanding type or to be introduced after the dilatation of the stenosis.

The devices of self-expanding type are suitable for compressing the inner walls of the stenotic oesophagus tract, thereby preventing its restenosis and having the characteristic of allowing food to pass inside it.

This type of device does not however allow restoring, once it has been removed, a sufficiently large gauge of the oesophagus and, above all, it does not allow this to recover the elasticity needed to ensure the correct and independent function of the organ.

The second type of known devices described above is suitable, instead, for passing food around the stent, i.e. between its outer wall and the inner wall of the oesophagus. In particular, the use of this type of device aims at forcing the oesophagus to perform a continuous dilatation activity so as to achieve a larger and, above all, more elastic gauge of the oesophagus.

This type of device, however, also has some drawbacks.
In fact, the food which transits between the device and the wall of the oesophagus can both find it hard to transit and inflame or irritate the oesophagus itself due to the little available space and its scarce elasticity. Such drawback, together with the feeling of retrosternal obstruction felt by the patient, can occur above all during periods immediately after the introduction of the device into the oesophagus, following the applied dilatation.

The use of these known devices can therefore prove stressing for the patient and for the oesophagus itself, and worsen a clinical situation already in itself delicate, with consequent suffering for the patient.

Description of the Invention

The main aim of the present invention is to provide a device which allows overcoming the drawbacks of the background art.

In particular, the present invention aims at providing a device which allows passing food between the device itself and the internal walls of the oesophagus and which, at the same time, does not cause any problem for the patient. In particular, the present invention proposes to reduce to the utmost the risk of irritations or lesions affecting the oesophagus due to the presence of the device itself.

Within this aim, one object of the present invention is to provide a device which can be able to adapt to the specific conditions of the patient, so as to best optimise the applied therapy and, at the same time, not represent any further type of problem for the patient, thereby making his/her full recovery easier.

Yet another object of the present invention is to provide a device that can be applied to the patient in an easier way with respect to a device of known type.

Another object of the present invention is to provide a device for the treatment of oesophageal stenosis which allows overcoming the mentioned drawbacks of the state of the art within the ambit of a simple, rational, easy and effective to use as well as low cost solution.

The above objects are achieved by the present device for the treatment of oesophageal stenosis, comprising at least a body with elongated shape intended to be inserted in the oesophagus of a patient and characterised in that it comprises variable rigidity means associated externally with said body.
Brief Description of the Drawings
Other characteristics and advantages of the present invention will become more evident from the description of a preferred, but not sole, embodiment of a device for the treatment of oesophageal stenosis, illustrated purely as an example but not limited to the annexed drawings in which:
Figure 1 is a longitudinal section view of the device according to the invention.

Embodiments of the Invention
With particular reference to such figures, globally indicated by 1 is a device for the treatment of oesophageal stenosis.
The device 1 comprises at least a body 2 of elongated shape, intended to be inserted in the oesophagus of a patient in correspondence to the stenotic tract to be treated.
More in particular, in the embodiment shown in the illustration, the body 2 has a substantially circular section.
According to the invention, the device 1 comprises variable rigidity means 3 externally associated with the body 2. The variable rigidity means 3 define at least in part the external surface of the device 1 which comes into contact with the food inside the patient's oesophagus.
Advantageously, the variable rigidity means 3 comprise at least one flexible element 4 associated with the body 2 so as to define an air chamber 5 placed between these and suitable for receiving a work fluid. The work fluid can consist of a gas, of a liquid or of a mixture of gas and liquid.
The flexible element 4, made e.g. of plastic or the like, has a thin thickness and is spaced from the outer surface 2a of the body 2.
Suitably, the device 1 comprises at least a connection element 6 placed between the body 2 and the flexible element 4.
Preferably, the connection element 6 is shaped so as to connect the outer surface 4a of the flexible element 4 to the outer surface 2a of the body 2. More in detail, the connection element 6 defines a link surface 6a substantially inclined with respect to the outer surface 4a of the flexible element 4 and to the outer surface 2a of the body 2. Such link surface 6a is suitable for facilitating the transit of food in the space in between the device 1 and the inner wall of the oesophagus.
In the preferred embodiment shown in figure 1, the flexible element 4 has a substantially tubular shape and is fitted substantially coaxial to the body 2. The air chamber 5 therefore has a substantially annular shape.

In this embodiment, the device 1 comprises at least two connection elements 6 arranged in correspondence to the axial extremities of the flexible element 4. Each of these two connection elements 6, arranged therefore on opposite sides of the flexible element 4, has a respective, substantially conical, link surface 6a. More in particular, in the embodiment shown in figure 1, the link surfaces 6a of the connection elements 6 converge outwards and have an opposite, i.e., specular, inclination the one to the other.

The connection elements 6 axially delimit the air chamber 5 placed between the body 2 and the flexible element 4. Consequently, the air chamber 5 is axially delimited by the connection elements 6, externally by the flexible element 4 and internally by the body 2.

Advantageously, the device 1 comprises at least one channel 7 communicating with the air chamber 5 and suitable for allowing this to be filled with the work fluid. More in particular, the channel 7 is integrally defined in the body 2 and has a gap 7a communicating with the air chamber 5.

Preferably, the channel 7 is connected to a valve device, not represented in figure 1, suitable for regulating the flow of work liquid at the inlet/outlet of the air chamber 5. Through the channel 7, the operator can therefore introduce the required quantity of fluid inside the air chamber 5, consequently regulating the pressure inside this and, therefore, the rigidity of the wall defined by the flexible element 4.

Suitably, the body 2 also defines a pipe 8 separated from the channel 7. More in detail, the channel 7 is defined along the wall which delimits the pipe 8.

In a particular embodiment, the device 1 also comprises a nasogastric tube associated with the body 2. More in particular, such nasogastric tube is fitted inside the pipe 8 of the body 2.

Preferably, the device 1 comprises one or more radiopaque markers suitable for allowing the identification from outside of the exact position of the device itself inside the oesophagus. Such markers can be positioned inside the walls of the
body 2 or, alternatively, inside the connection elements 6 or the walls of the nasogastric tube.

The operation of the device according to the invention is the following.

Before introducing the device 1 inside the patient, the doctor in charge can control, e.g. by introducing sterile water, how the rigidity of the flexible element 4 varies according to the quantity of introduced liquid.

The device 1 is then fitted to the patient by means of a known method which contemplates inserting a guiding wire of the rigid type using the work channel of a previously-used endoscope. After removing the endoscope and performing the dilatations of the tract of stenotic oesophagus using an appropriate technique, the device 1 is made to move along the guiding wire and its position is controlled by means of a suitable radiological instrument. The extremity of the device 1 which comes out of the oral cavity is then made to transit in the retropharynx and made to come out of a nostril.

The position of the body 2 inside the oesophagus can, e.g., be blocked by fitting a nasogastric tube to the patient.

During the fitting of the device 1, the air chamber 5 is suitably empty, so as to allow an easier adaptation of the flexible element 4 to the shape of the patient's oesophagus.

Once the device 1 has been fitted to the patient, the doctor can introduce the work fluid along the channel 7 so as to gradually fill the air chamber 5 until the required rigidity of the flexible element 4 has been achieved.

This way, the doctor can regulate the rigidity of the flexible element 4 and, therefore, the resistance exercised during the transit of the food through the oesophagus, according to the conditions of the patient and the progress of the rehabilitation therapy.

To remove the device 1 from the patient, it is best to empty the air chamber 5 again so as to reduce the rigidity of the flexible element 4 as much as possible and thus make its removal easier.

It has in practice been ascertained how the described invention achieves the proposed objects and in particular the fact is underlined that the present device for the treatment of oesophageal stenosis, thanks to the presence of the air
chamber, allows performing an effective action for the whole time it is fitted to the patient, at the same time reducing the pain suffered by the patient him/herself.

In fact, by correcting the pressure inside the air chamber of the device according to the invention on the basis of the patient's condition, the resistance exercised upon the transit of the food can be adjusted.

Furthermore, the device according to the invention is also easier to fit compared to devices of known type.
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CLAIMS

1) Device (1) for the treatment of oesophageal stenosis, comprising at least a body (2) with elongated shape intended to be inserted in the oesophagus of a patient and characterised in that it comprises variable rigidity means (3) associated externally with said body (2).

2) Device (1) according to claim 1, characterised in that said variable rigidity means (3) comprise at least a flexible element (4) associated with said body (2) so as to define at least an air chamber (5) placed in between them and which can be filled with a work fluid.

3) Device (1) according to claim 2, characterised in that said flexible element (4) has a substantially tubular shape.

4) Device (1) according to one or more of the preceding claims, characterised in that said body (2) has a substantially circular section and that said flexible element (4) is fitted substantially coaxially to said body (2).

5) Device (1) according to one or more of the claims from 2 to 4, characterised in that it comprises at least a connection element (6) of said flexible element (4) to said body (2).

6) Device (1) according to one or more of the preceding claims, characterised in that it comprises at least two of said connection elements (6) associated with the axial extremities of said flexible element (4) and shaped so as to taper the outer surface (4a) of said flexible element (4) to the outer surface (2a) of said body (2).

7) Device (1) according to one or more of the preceding claims, characterised in that each of said connection elements (6) defines a respective link surface (6a) inclined with respect to the outer surface (4a) of said flexible element (4) and to the outer surface (2a) of said body (2).

8) Device (1) according to one or more of the preceding claims, characterised in that said connection elements (6) delimit axially said air chamber (5).

9) Device (1) according to one or more of the preceding claims, characterised in that said body (2) comprises at least a channel (7) communicating with said air chamber (5) suitable for allowing its filling with a work fluid.

10) Device (1) according to one or more of the preceding claims, characterised
in that it comprises valve means associated with said channel (7) and suitable for adjusting the inlet flow of the work fluid in said air chamber (5).

11) Device (1) according to one or more of the preceding claims, characterised in that said body (2) comprises at least a pipe (8) separated from said channel (7).

12) Device (1) according to one or more of the preceding claims, characterised in that it comprises at least a nasogastric tube associated with said body (2).

13) Device (1) according to claim 12, characterised in that said nasogastric tube is associated with said body (2) through said pipe (8).
**INTERNATIONAL SEARCH REPORT**

**International application No**
PCT/IB2012/000287

### A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M29/00 A61B1/32

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

### B. FIELDS 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 data base and, where practicable, search terms used)
EPO-Internal, WPI Data

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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* Further documents are listed in the continuation of Box C.  
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