

[54] **METHOD FOR MAINTAINING THE REDUCTION OF A SLIDING ESOPHAGEAL HIATAL HERNIA**

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[51] Int. Cl. **A61b 19/00; A61f 1/00**

[58] Field of Search **3/1; 128/1 R, 334 R, 325, 128/95, 346, 96, DIG. 23, DIG. 25**

[56] **References Cited**

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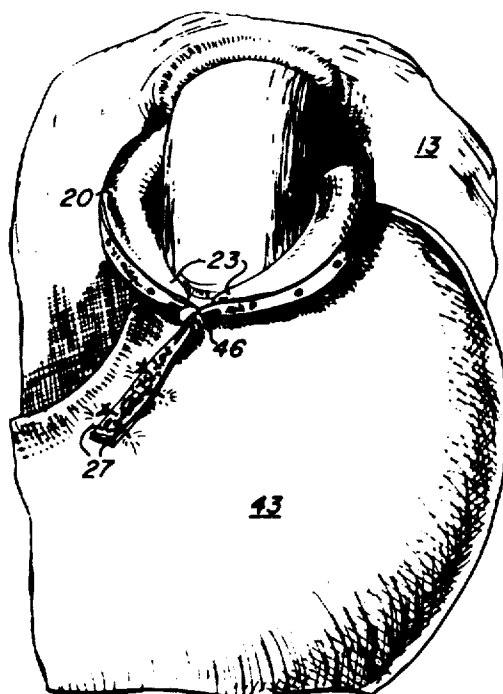
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[57] **ABSTRACT**

A method and prosthesis for use in maintaining the intra-abdominal reduction of a sliding esophageal hiatal hernia. The prosthesis is a generally C-shaped cushion member which is shaped and dimensioned to be placed around the distal esophagus. The overall size of the prosthesis is large enough to prevent extension of the gastric fundus into the thoracic cavity through an enlarged esophageal hiatus. Tie means are provided to maintain the cushion member in operative position. The prosthesis bears radio-opaque indicia to facilitate radiographic determination of its position after placement.

1 Claim, 6 Drawing Figures



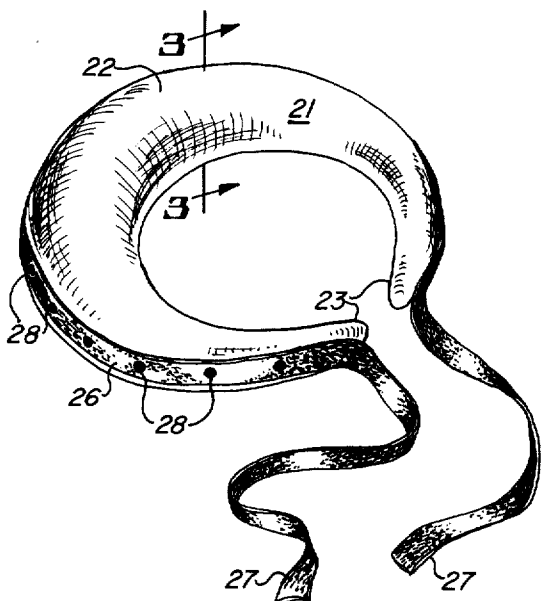


FIG. 2

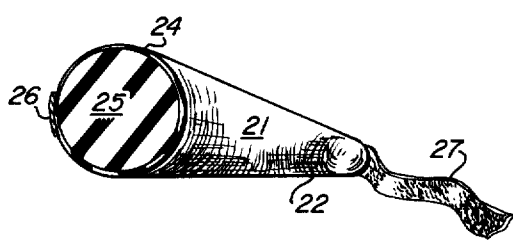


FIG. 3

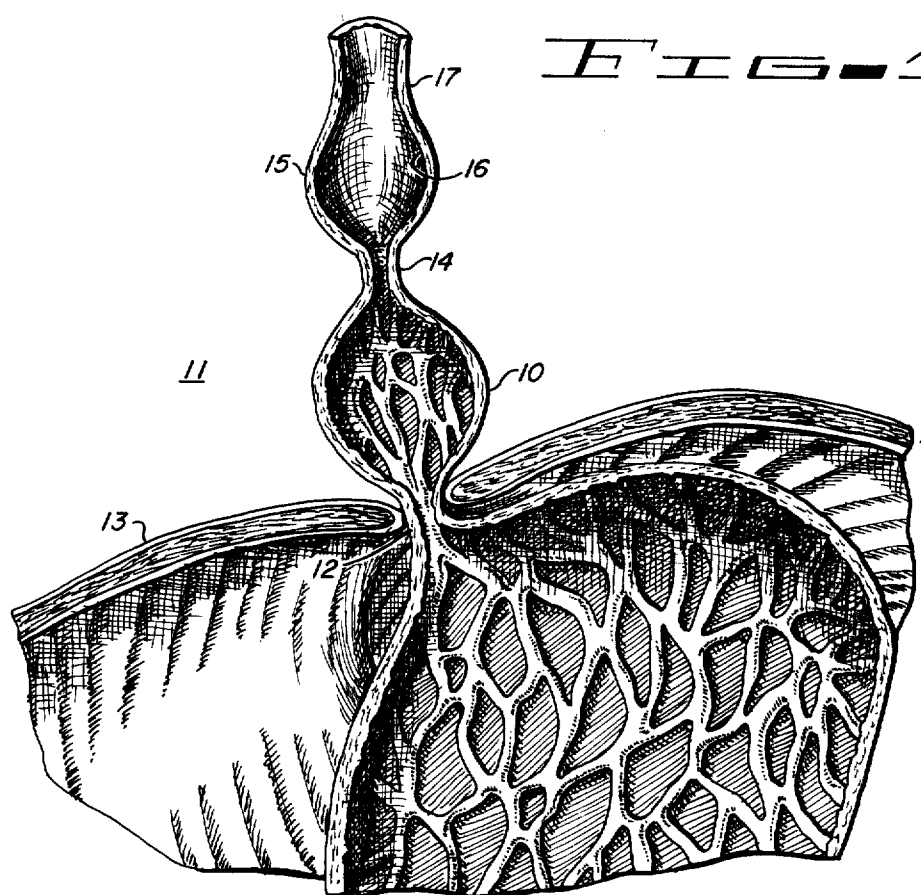


FIG. 1

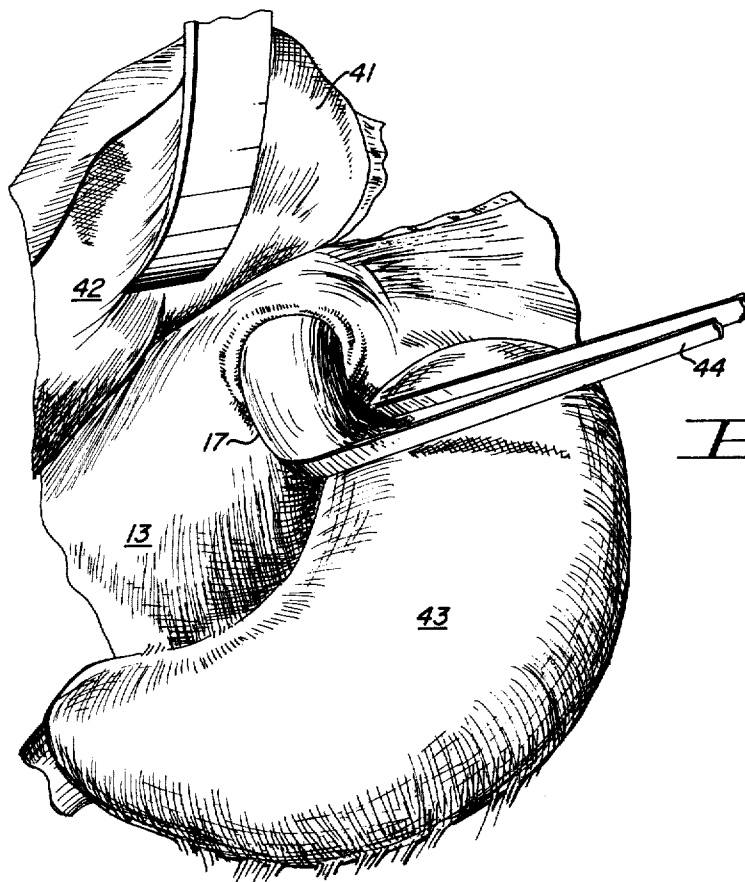


FIG. 4

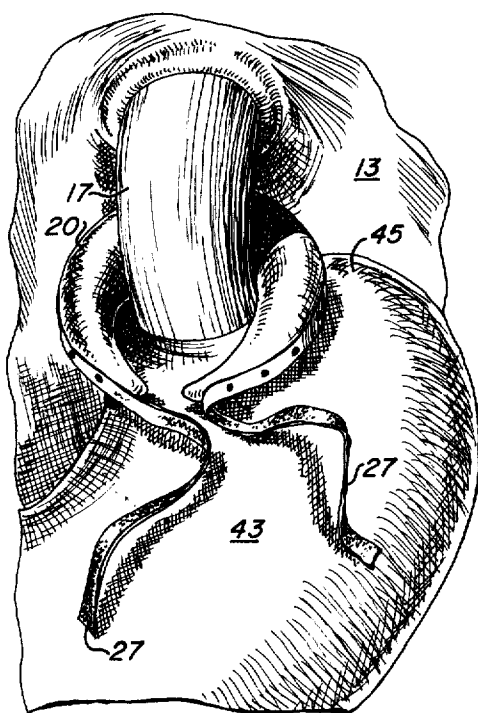


FIG. 5

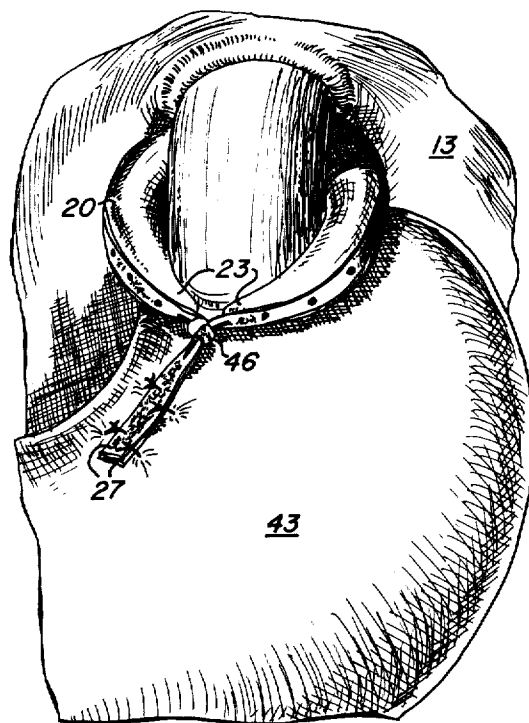


FIG. 6

METHOD FOR MAINTAINING THE REDUCTION OF A SLIDING ESOPHAGEAL HIATAL HERNIA

This invention relates to a surgical prosthesis.

More particularly, the invention concerns a prosthesis for use in maintaining the intra-abdominal reduction of a sliding esophageal hiatal hernia.

In another and more specific respect, the invention relates to a prosthesis of the character described which bears radio-opaque indicia to facilitate radiographic determination of the position of the prosthesis after placement thereof.

When the esophageal hiatus of the diaphragm muscle becomes enlarged, a portion of the stomach immediately below the gastro esophageal junction (the gastric fundus) may actually slide upwardly through the esophageal hiatus into the chest or thoracic cavity. This anatomic condition, known as a "sliding esophageal hernia" frequently causes gastro esophageal reflux in which stomach acids and foods are regurgitated into the esophagus. The characteristic symptoms of gastro esophageal reflux consist of substernal burning, regurgitation and frequent eructations. These symptoms are accentuated by recumbency, tight garments and physical activity, particularly bending at the waist. Long-term gastro esophageal reflux leads to complications, namely dysphagia from an esophageal stricture.

Various procedures have been devised for the repair of sliding esophageal hernias. Crural repair almost invariably fails since it is almost impossible to effectively suture the constantly moving diaphragm. Therefore, other procedures to prevent the stomach from sliding through the enlarged esophageal hiatus were devised. According to the "posterior gastropexy" procedure of Hill, the crura is closed behind the esophagus and the stomach is sutured to the arcuate ligament over the aorta to hold the stomach within the abdominal cavity. According to the "Niessen II" procedure, the gastric fundus is formed into a ring around the distal esophagus. The added bulk of this ring around the esophagus forms a valve preventing regurgitation and, at the same time, preventing the stomach from sliding through the enlarged esophageal hiatus.

The Hill procedure described above is very difficult to perform on obese patients and it appears that the sutures from the lesser curvature of the stomach to the arcuate ligament are of a transient nature. According to the Niessen II procedure, it is necessary to suture the stomach to itself and to the esophagus. However, according to the procedure which I have devised, utilizing the prosthetic device described herein, it is unnecessary to suture the stomach to itself or to any other anatomic structure and it is not even necessary to close the crura.

Accordingly, it is a principal object of the present invention to provide a surgical prosthetic device.

Another object of the invention is to provide a prosthesis specially adapted for use in the correction of a sliding esophageal hiatal hernia.

Still another object of the invention is to provide a prosthesis of the type described which is utilized in a procedure for repair of a sliding esophageal hiatal hernia which does not require suturing the stomach to itself or to other anatomic structures.

Still another object of the invention is to provide a prosthesis which can be readily located by radiograph

examination to determine whether it remains in its proper operative position.

Yet another object of the invention is to provide a prosthesis which acts as a mechanical valve to prevent gastroesophageal reflex.

These and other further and more specific objects and advantages of the invention will be apparent to those skilled in the art from the following detailed description thereof, taken in conjunction with the drawings, in which:

FIG. 1 is a cross-sectional view of the stomach, diaphragm and esophagus illustrating a typical sliding esophageal hiatal hernia;

FIG. 2 is a perspective view of the preferred embodiment of the prosthesis which I have invented for use in accordance with my procedure for repairing a sliding esophageal hiatal hernia;

FIG. 3 is a sectional perspective view of the prosthesis of FIG. 2 taken at section line 3—3 thereof;

FIG. 4 is a perspective anatomical drawing illustrating the step according to my procedure of reduction of the hiatal hernia;

FIG. 5 is a perspective anatomical drawing illustrating the initial steps in the implantation of the prosthesis of FIGS. 1-2; and

FIG. 6 is a perspective anatomical drawing illustrating the prosthesis of FIGS. 1-2 located in its proper operative position to prevent recurrence of the hiatal hernia.

Briefly, in accordance with my invention, I provide a prosthesis for use in maintaining the intra-abdominal reduction of a sliding esophageal hiatal hernia. The prosthesis prevents extension of the gastric fundus into the thoracic cavity through the enlarged esophageal hiatus. The prosthesis comprises a generally C-shaped cushion member, the inside dimensions of which generally correspond to the normal outside dimensions of the distal esophagus and the outside dimensions of the cushion member are somewhat larger than the enlarged esophageal hiatus. The C-shaped member is deformable to permit adjustment of the spacing of the free ends thereof at a distance selected to permit normal expansion of the esophagus during swallowing. Means are provided for maintaining the cushion member in operative position around the distal esophagus between the gastric fundus and the diaphragm and for maintaining the selected spacing of the free ends of the C-shaped prosthesis.

According to the preferred embodiment of the invention, the prosthesis bears radio-opaque indicia which facilitates radiograph determination of the position of the prosthesis after placement thereof around the distal esophagus. The means for maintaining the cushion member in its operative position preferably comprise an elongate tape member secured around the periphery of the cushion member. The free ends of the tape extend substantially beyond the free ends of the C-shaped cushion member, i.e., a distance sufficient to allow the ends of the tape member to be tied together and sutured to the gastric fundus.

Turning now to the drawings, FIG. 1 depicts a typical sliding esophageal hiatal hernia and shows the gastric fundus 10 extending into the thoracic cavity 11 through the enlarged esophageal hiatus 12 of the diaphragm 13. In this position, the lesser sphincter 14 of the esophagus 15, being transposed into the chest from its normal position just below the esophageal hiatus 12, operates less

effectively. This permits gastro esophageal reflex of stomach acids and foods which are not evacuated by esophageal peristalsis and which remain in the lower esophagus for prolonged periods causing irritation and damage to the lower esophageal mucosa 16.

FIG. 2 depicts the prosthetic device which I have invented consisting of a generally C-shaped cushion member 21, the inside dimensions of which generally correspond to the normal outside dimensions of the distal esophagus (reference character 17, FIG. 1). In a typical prosthesis constructed in accordance with the invention, the inside dimensions will equal about 3.75 × 2.5 centimeters, although prosthetic devices having somewhat larger and somewhat smaller inside dimensions should be provided to the surgeon for use where the patient may have an esophagus somewhat larger or somewhat smaller than normal.

The outside dimensions of the prosthesis are sized to be substantially larger than the enlarged esophageal hiatus (reference character 12, FIG. 1), and in a typical prosthesis constructed in accordance with the invention, the outside dimensions will equal about 6.25 × 5.25 centimeters. Obviously, these outside dimensions are also variable in accordance with the size of the enlarged esophageal hiatus of a particular patient.

In accordance with the preferred embodiment of the invention as shown in FIGS. 2-3, the cushion member has a generally circular cross-section and is tapered from the central portion 22 toward the free ends thereof 23. The prosthesis is preferably constructed by filling an outer flexible integument 24 with a gel liquid 25 such that the entire cushion member 21 is deformable to permit adjustment of the spacing of the free ends 23 at a selected distance which will permit normal expansion of the esophagus during swallowing. The precise materials of construction of the integument 24 and filler 25 of the C-shaped cushion member 21 are not highly critical so long as they are compatible with body tissues, i.e. do not induce rejection or cause other bodily reaction. In the presently preferred embodiment of the invention, I employ medical grade silicone elastomers and gels manufactured by the Dow Chemical Company and sold under the trade name "Silastic". These silicones are used to manufacture prosthetic devices for breast implants, the Kauffman procedure for urethral surgery for incontinence, and other prosthetic devices used for penile implants, etc. A tape 26, preferably silicone-coated Dacron, is secured to the C-shaped cushion member 21 around the outer periphery thereof and the free ends 27 of the tape extend substantially beyond the free ends 23 of the C-shaped cushion member 21, to a distance sufficient to allow the extending ends 27 of the tape 26 to be tied together and sutured to the

gastric fundus, as will be explained below. In the preferred embodiment of the invention, spaced dots 28 of a radio-opaque dye are provided on the tape 26 such that after implantation of the prosthesis, radiographic examination will reveal whether the prosthesis is in its proper operation position.

The procedures which I have developed and the method of use of the prosthesis of FIGS. 2-3 are illustrated in FIGS. 4-6. My procedure consists of opening the abdominal cavity and retracting the left lobe 41 of the liver 42 medially. The peritoneum and the sac of the hiatal hernia are then incised and the hernia is reduced by retracting the stomach 43 intra-abdominally, for example, by the use of an encircling Penrose drain 44 to expose the distal esophagus 17 below the diaphragm 13. As shown in FIG. 5, the prosthesis 20 of FIGS. 2-3 is then placed around the distal esophagus 17 immediately above the gastric fundus 45. The free ends 27 of the tape 26 are tied at 46 to locate the free ends 23 of the prosthesis 20 at the proper spacing and the free ends 27 are then sutured to the stomach to maintain the prosthesis 20 in its proper operative position around the distal esophagus 17 and between the gastric fundus 45 and the diaphragm 13.

Having now described my invention and the use thereof in such clear, concise and exact terms as to enable those skilled in the art to understand the invention and practice it, and having identified the presently preferred embodiments of the invention, I claim:

1. A method for maintaining the intra-abdominal reduction of a sliding esophageal hiatal hernia whereby extension of the gastric fundus into the thoracic cavity through an enlarged esophageal hiatus is prevented, said method comprising:

- a. positioning a generally C-shaped cushion prosthesis around the distal esophagus, the inside diameter of said prosthesis generally corresponding to the normal outside diameter of the distal esophagus and the outside diameter thereof being larger than said enlarged esophageal hiatus, said C-shaped member being deformable to permit adjustment of the spacing of the free ends thereof at a selected distance;
- b. adjusting said free ends of said prosthesis at a spacing to permit normal expansion of the esophagus during swallowing; and
- c. fixing said free ends of said prosthesis in said adjusted position to maintain said C-shaped cushion prosthesis in operative position around the distal esophagus between the gastric fundus and the diaphragm and to maintain said adjusted spacing of said free ends.

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