United States Patent [19]

Reger

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[45] Date of Patent: **Nov. 28, 1995**

[54] **METHOD OF MAKING AN ARTIFICIAL HEART VALVE STENT**

[75] Inventor: **Vincent A. Reger**, Portland, Oreg.

[73] Assignee: **Reger Medical Inc.**, Portland, Oreg.

[21] Appl. No.: **286,162**

[22] Filed: **Aug. 4, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 84,663, Jun. 28, 1993, abandoned, which is a continuation of Ser. No. 834,416, Feb. 12, 1992, Pat. No. 5,258,023.

[51] **Int. Cl.^{6}** **A61B 19/00**; A61F 2/24
[52] **U.S. Cl.** **128/898**; 623/2; 623/66; 623/901
[58] **Field of Search** 623/2, 11, 66, 623/901, 12; 128/898; 112/262.1; 29/890.12, 890.124, 890.126, 890, 128, 890.132

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Primary Examiner—Paul B. Prebilic

Attorney, Agent, or Firm—Foster & Foster; Lynn G. Foster

[57] **ABSTRACT**

A novel, long lasting prosthetic heart valve compatible with implantation in a human natural heart valve annulus. The prosthetic heart valve comprises a trileaflet heart valve apparatus which in form, dimension, and function resembles a human trileaflet heart valve, but which is formed of synthetic resinous material. A seamless supporting frame capable of annular deformation and limited perimetric expansion during each heartbeat is totally enveloped in an essentially biologically inert cylindrical cover to form a cusp supporting stent for the valve leaflet apparatus. The free top and bottom edges of the cylindrical cover are disposed on the exterior of the stent and everted outward to provide at least one sewing ring. Valve embodiments comprise aortic and mitral implantable valves. For the aortic implant, the outwardly everting free sewing ring forming edges are separated by circumferentially disposed compressible and expandable material which provides a pliable, compliant interface between the valve and the natural valve annulus at the implanting site. In one embodiment, the synthetic trileaflet heart valve apparatus is formed by a unicast mold. In another embodiment, the heart valve apparatus is formed from a cylinder of synthetic resinous material. Valve sewing ring covers can be selectively impregnated with antibiotic medicants to substantially eliminate early post implant infection. Use of non-thrombogenic biochemically inert materials in a valve apparatus which mimics operation of a natural heart valve essentially eliminates the need for long term administration of anticoagulants.
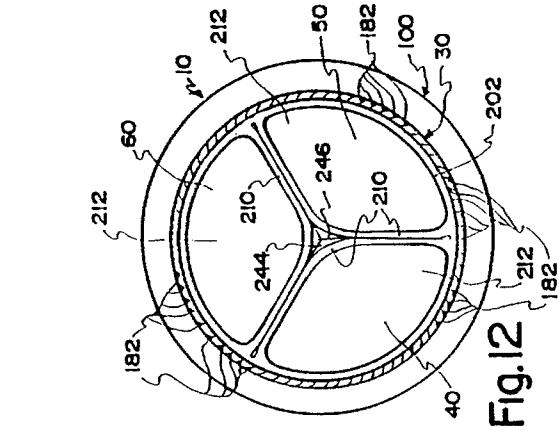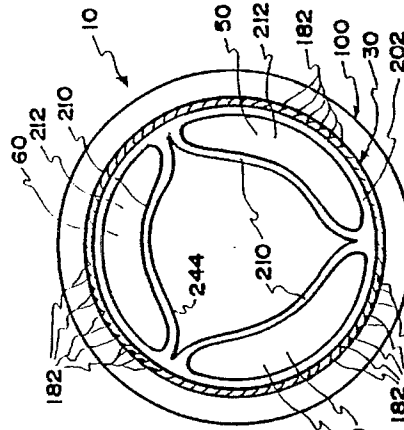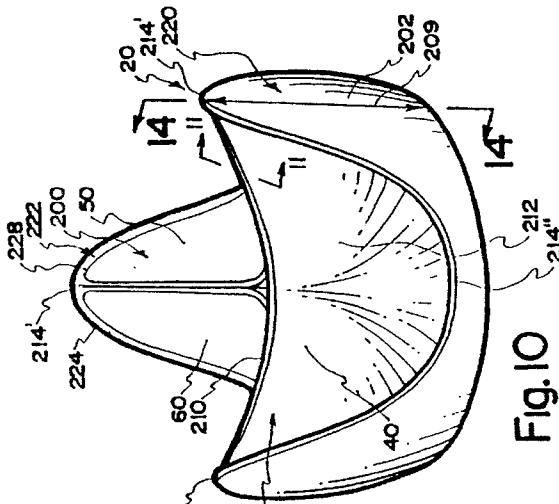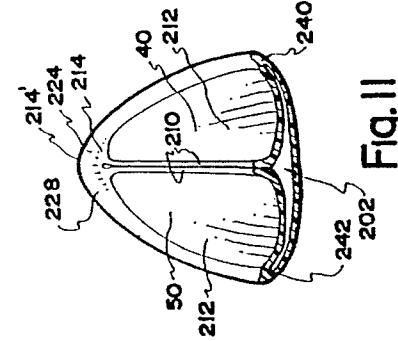
3 Claims, 5 Drawing Sheets

Fig.1

Fig.2

Fig.3
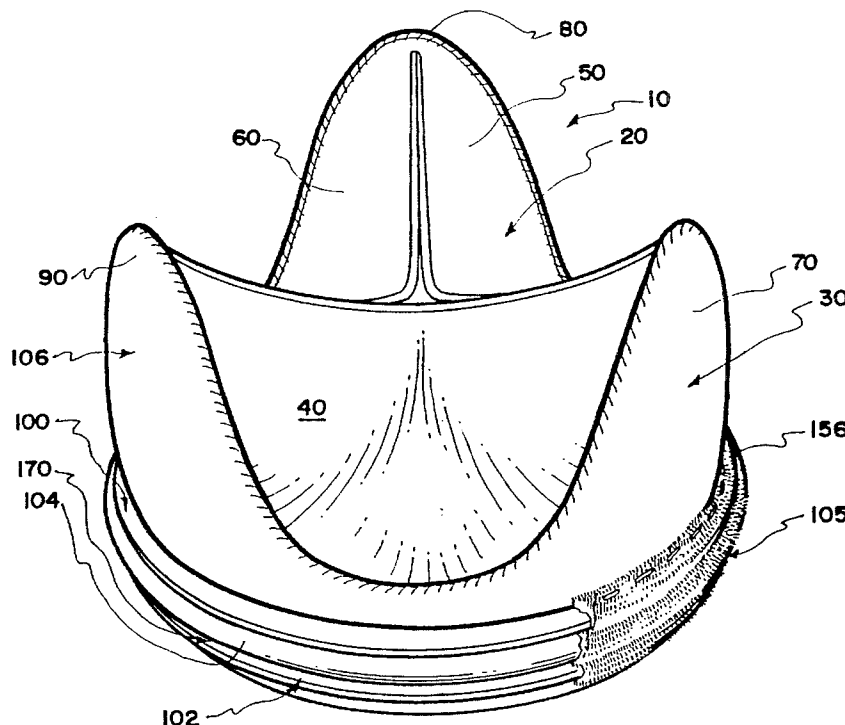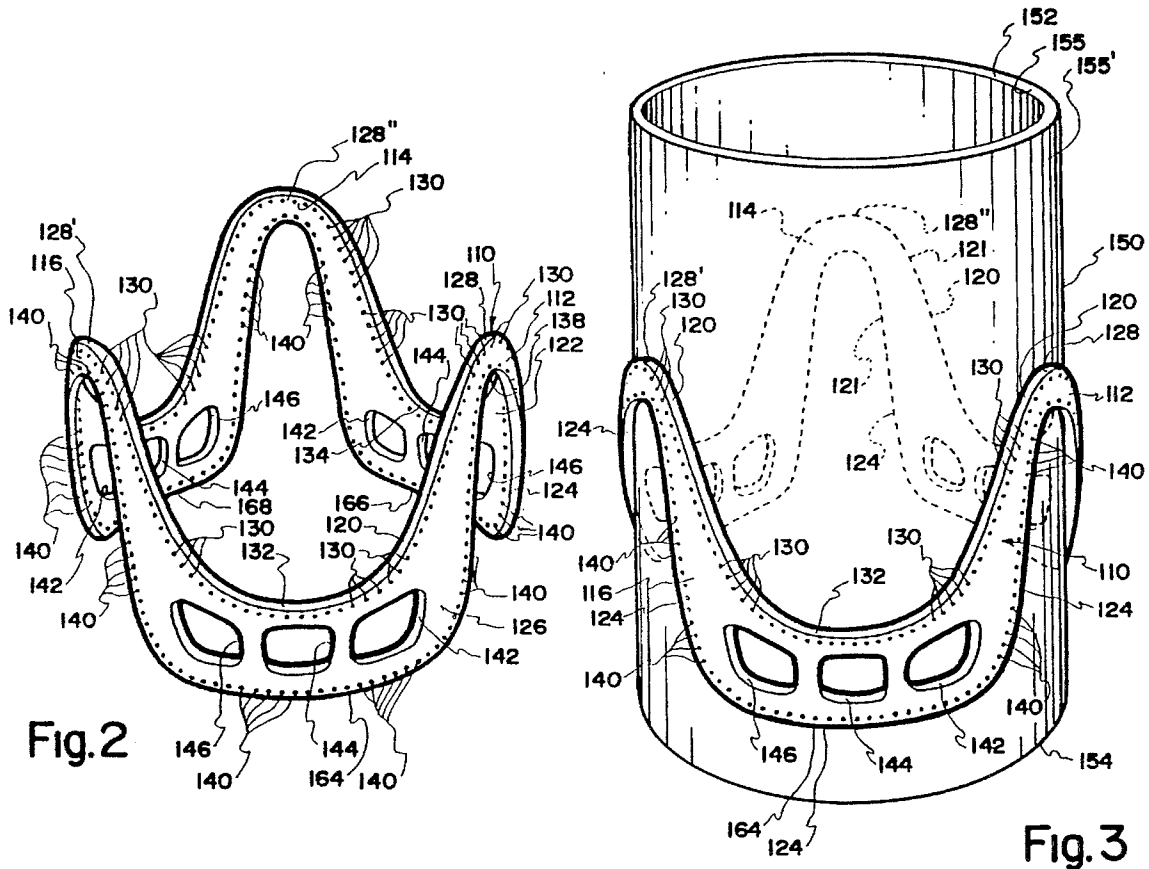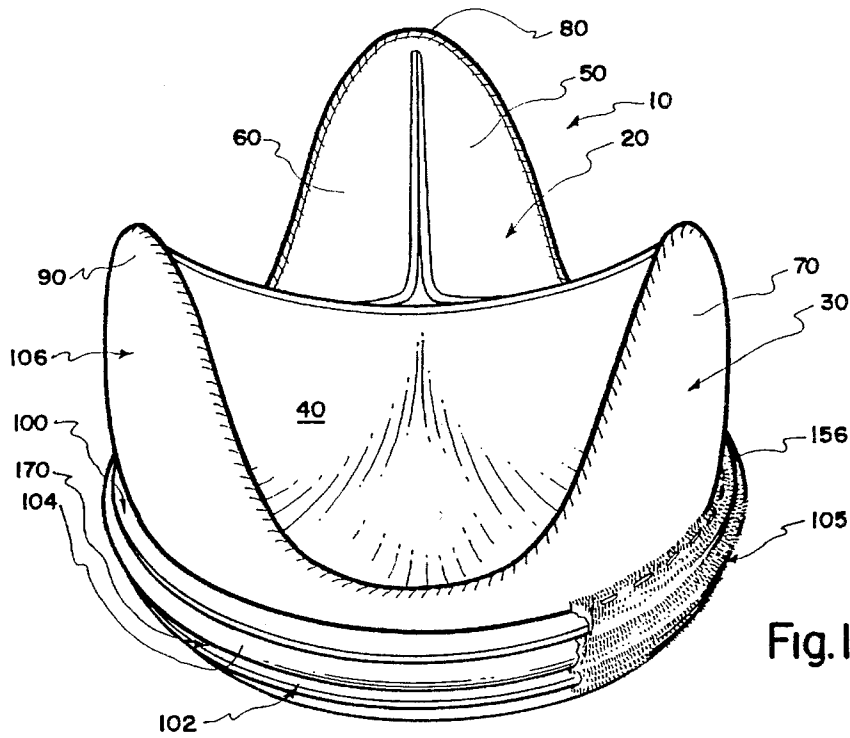
Fig.12

Fig.13

Fig.10

Fig.11

Fig.4

Fig.5

Fig. 6

Fig. 7

Fig. 8

Fig. 9
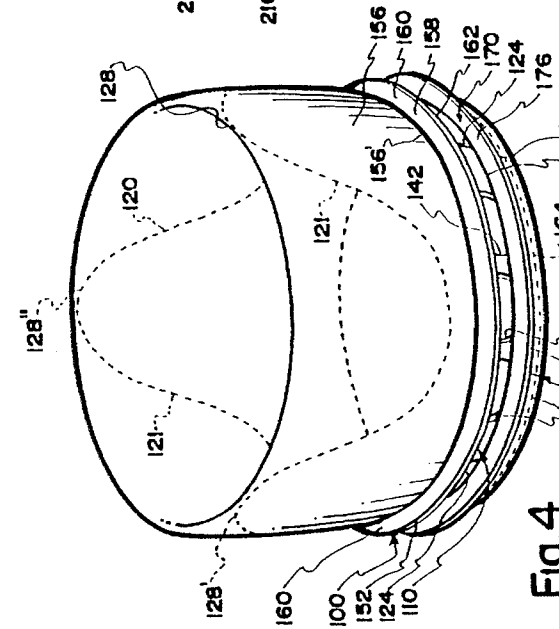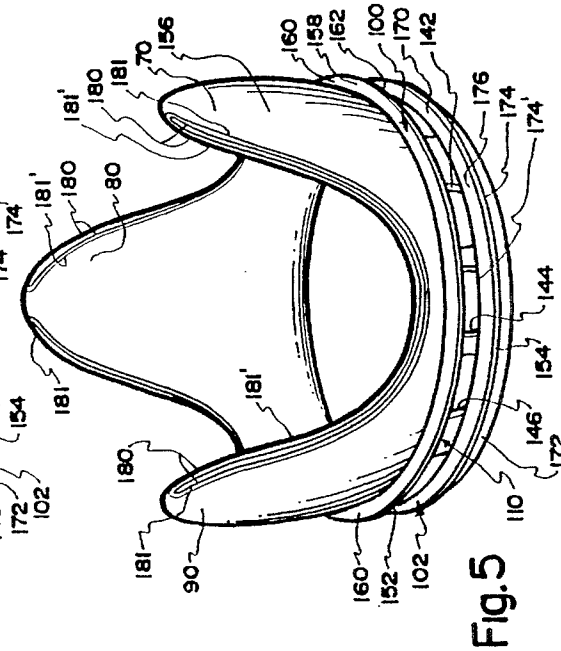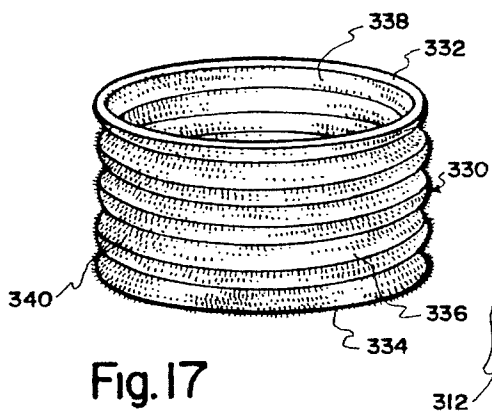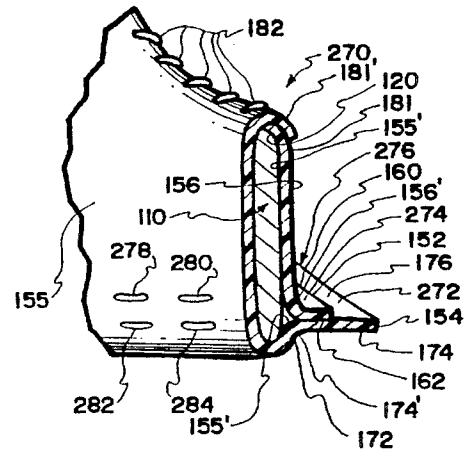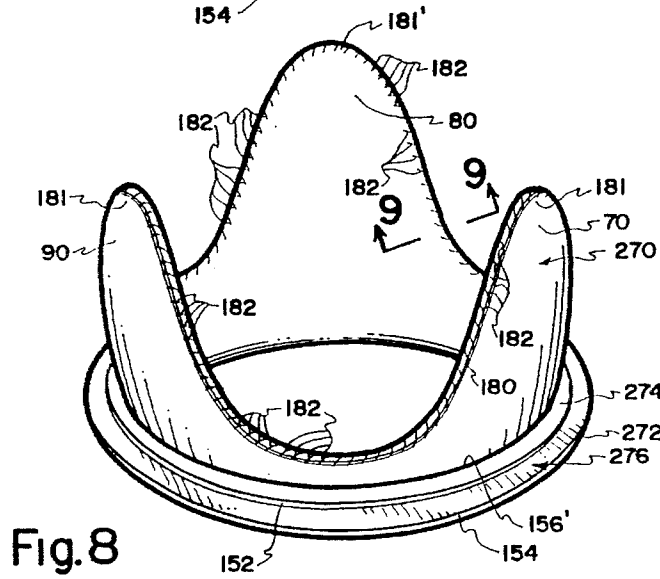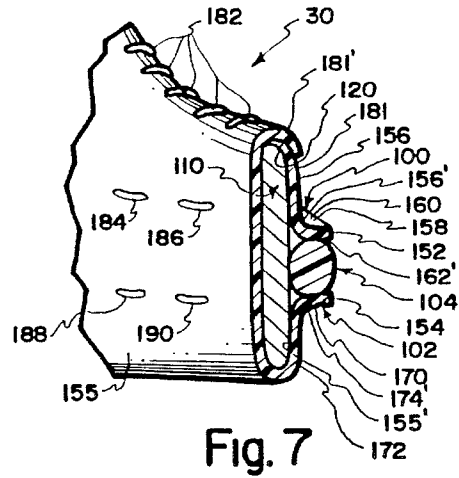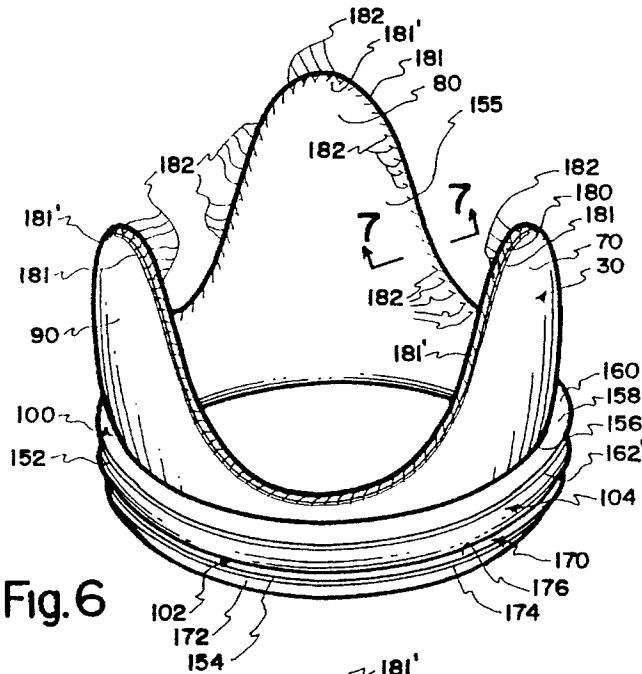
Fig. 17
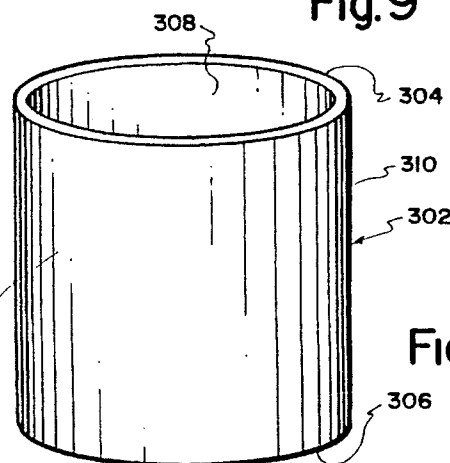
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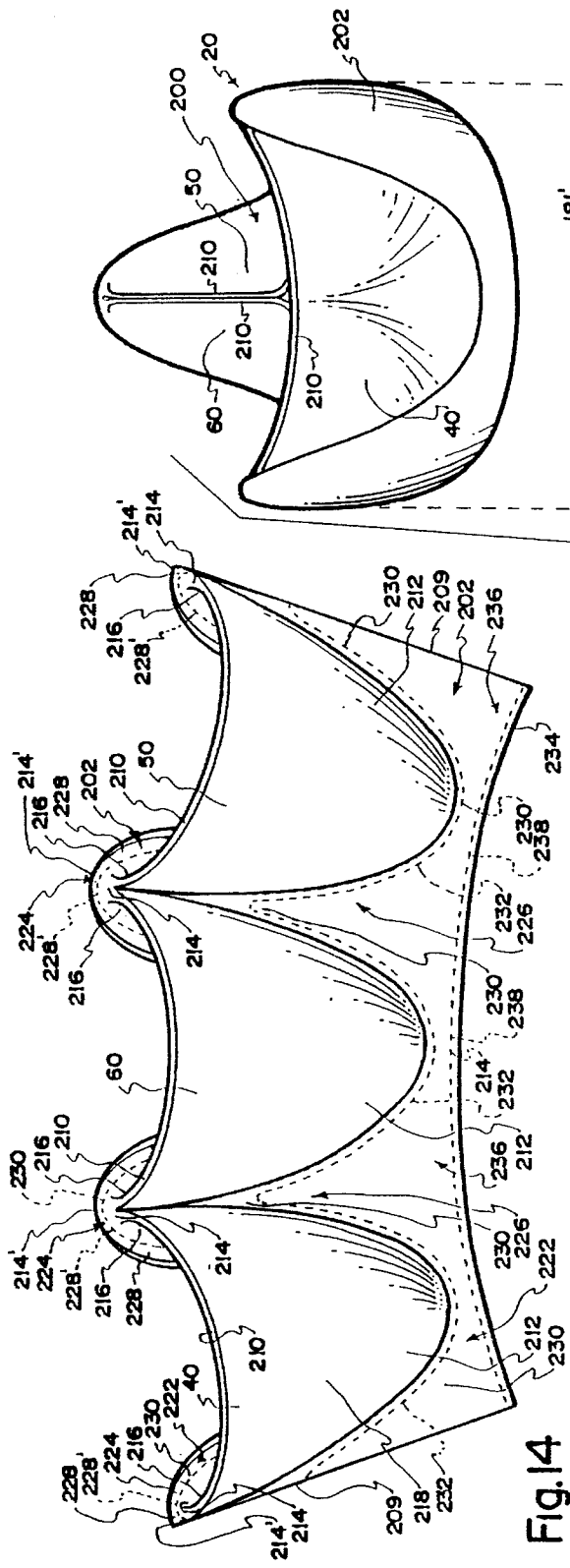
Fig. 14

Fig. 15

Fig. 16

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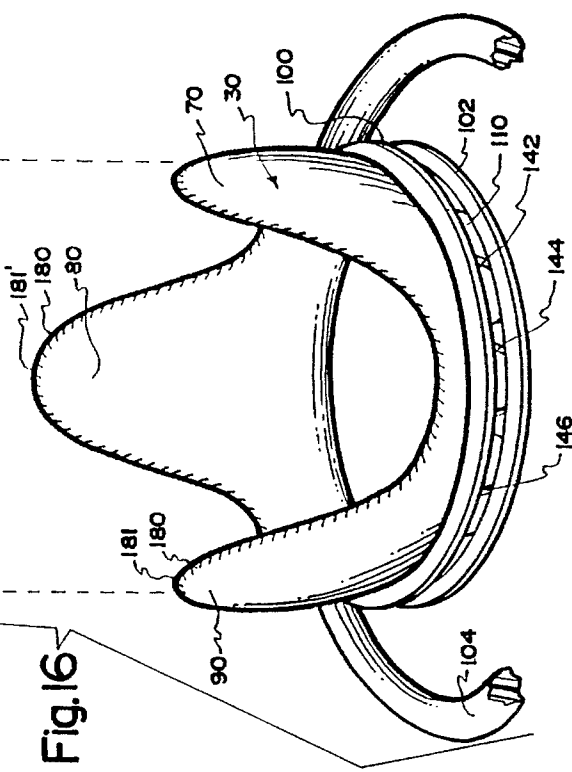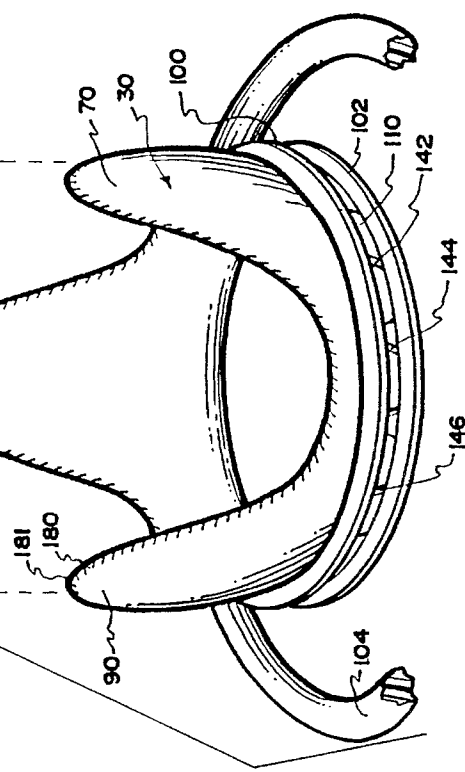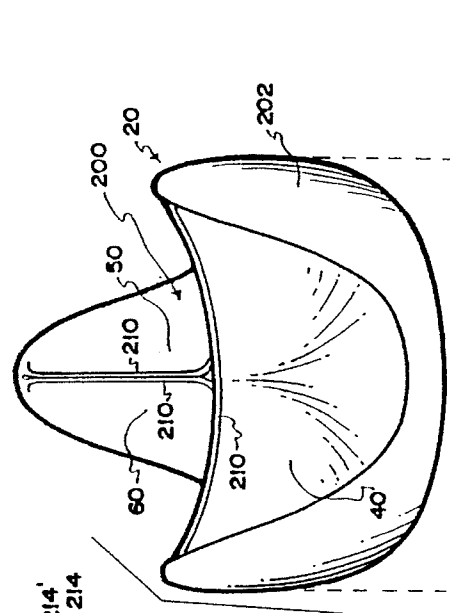Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

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