



US005961549A

United States Patent [19]
Nguyen et al.

[11] **Patent Number:** **5,961,549**
[45] **Date of Patent:** **Oct. 5, 1999**

[54] **MULTI-LEAFLET BIOPROSTHETIC HEART VALVE**

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[21] Appl. No.: **08/833,176**

[22] Filed: **Apr. 3, 1997**

[51] **Int. Cl.**⁶ **A61F 2/24**

[52] **U.S. Cl.** **623/2; 623/900**

[58] **Field of Search** **623/1, 2, 11, 12, 623/66, 13, 900**

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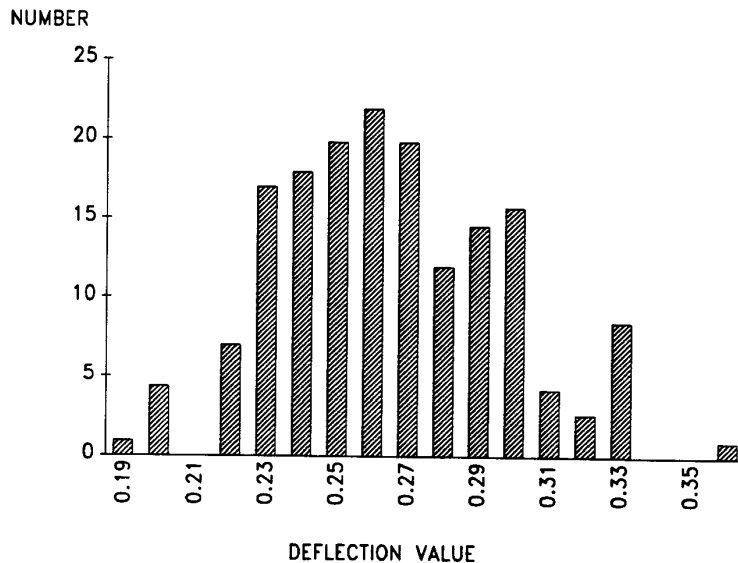
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[57] **ABSTRACT**

Heart valve leaflet selection methods and apparatuses which subject individual leaflets to loads and measure the resulting deflection to more reliably group leaflets of similar physical characteristics for later assembly in prosthetic heart valves. The deflection testing may be accomplished using a variety of test set ups which are designed to impart a load on the leaflet which simulates the actual loading within a heart valve. The results from a number of deflection tests are used to categorize individual leaflets, which data can be combined with other data regarding the characteristics of the leaflet to better select leaflets for assembly into a multi-leaflet heart valve. In one embodiment, the deflection test is combined with an intrinsic load test, and leaflets having similar deflection and intrinsic load values used in the same heart valve. One apparatus for testing the leaflets includes a frame for securing the arcuate cusp of the leaflet while the straight coapting edge remains free, to simulate the actual leaflet mounting configuration within the heart valve prosthesis. The frame may include a lower portion having a recess for the leaflet and plurality of receptor holes around the peripheral edge of the recess, and an upper portion having a plurality of needles which extend downward through the leaflet and into the receptor holes and secure the edges of the leaflet.

15 Claims, 9 Drawing Sheets



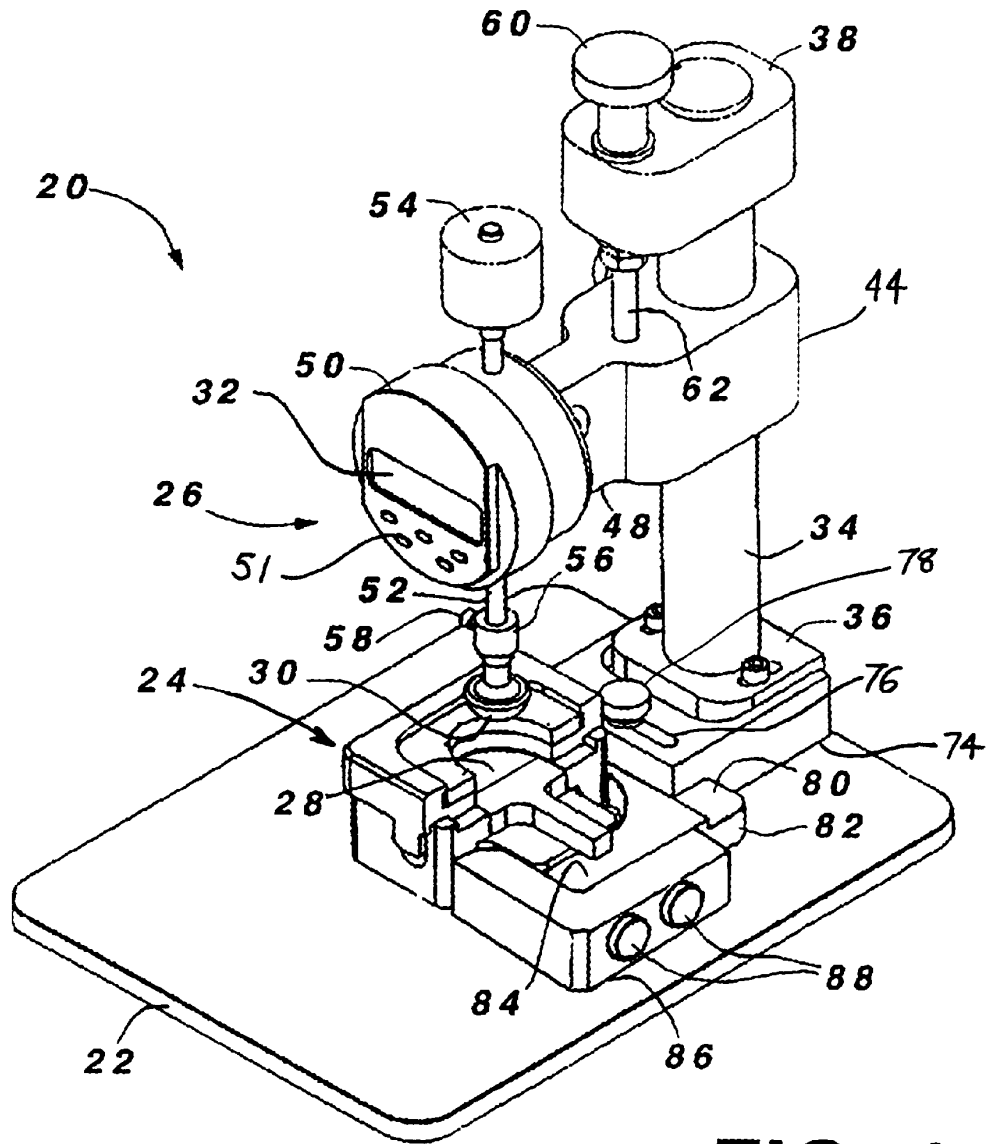


FIG. 1

FIG. 3

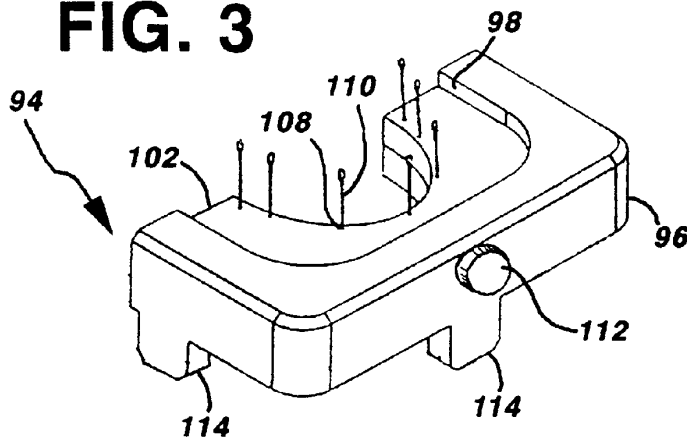


FIG. 4

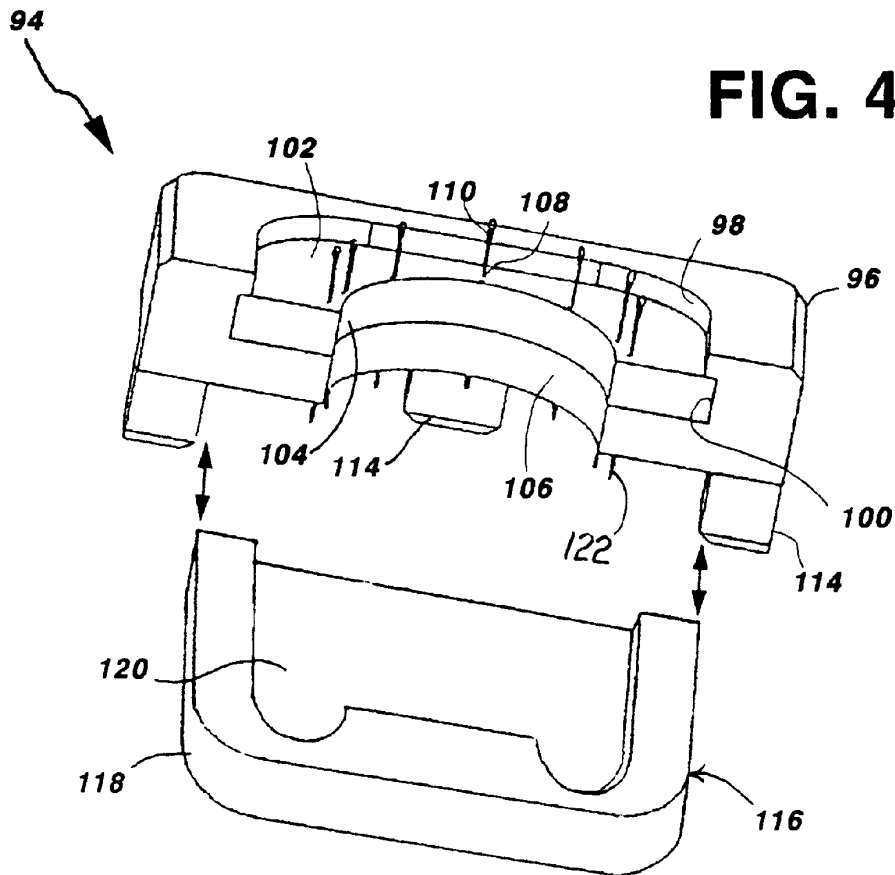


FIG. 5

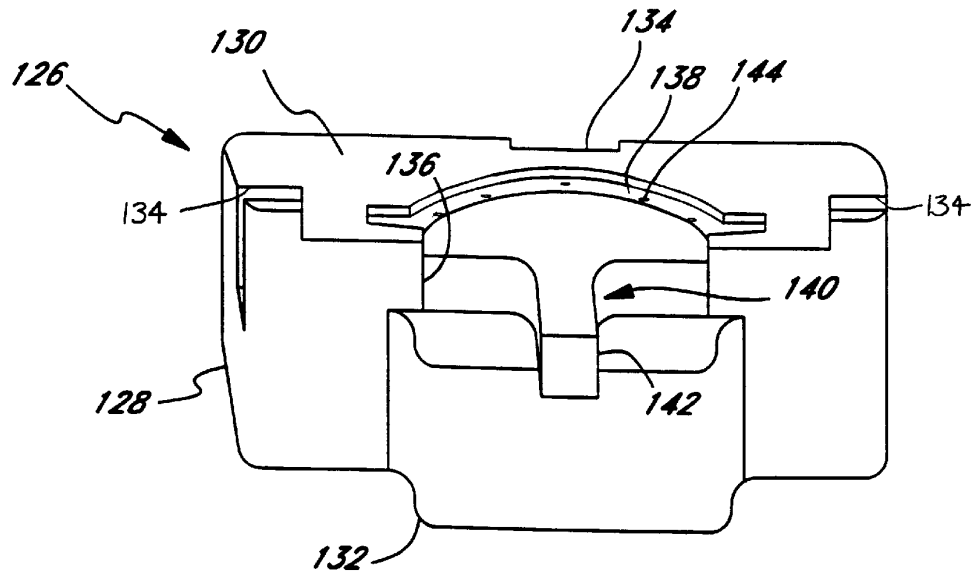
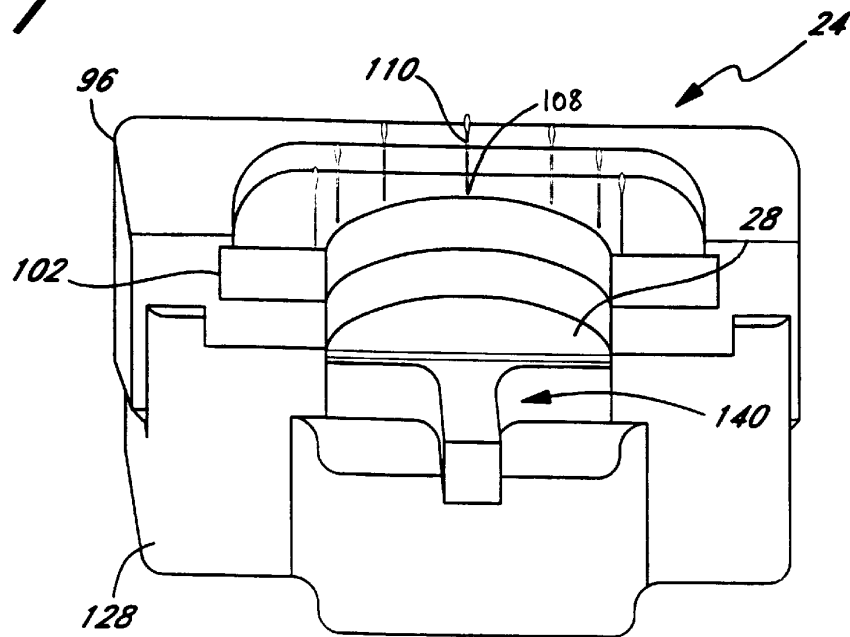


FIG. 7



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