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(54) **PERCUTANEOUSLY IMPLANTABLE  
REPLACEMENT HEART VALVE DEVICE  
AND METHOD OF MAKING SAME**

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(57) **ABSTRACT**

The present invention comprises a percutaneously implantable replacement heart valve device and a method of making same. The replacement heart valve device comprises a stent member made of stainless steel or self-expanding nitinol, a biological tissue artificial valve means disposed within the inner space of the stent member. An implantation and delivery system having a central part which consists of a flexible hollow tube catheter that allows a metallic wire guide to be advanced inside it. The endovascular stented-valve is a glutaraldehyde fixed bovine pericardium which has two or three cusps that open distally to permit unidirectional blood flow. The present invention also comprises a novel method of making a replacement heart valve by taking a rectangular fragment of bovine pericardium treating, drying, folding and rehydrating it in such a way that forms a two- or three-leaflet/cusp valve with the leaflets/cusps formed by folding, thereby eliminating the extent of suturing required, providing improved durability and function.

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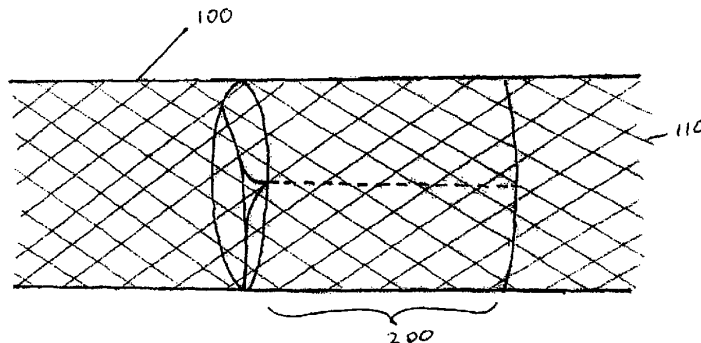
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623/1.26, 900, 2.1-2.19  
See application file for complete search history.

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**17 Claims, 12 Drawing Sheets**



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