

Bovine Pericardium Organic Biological Valvular Prosthesis



Experience
Quality
Performance

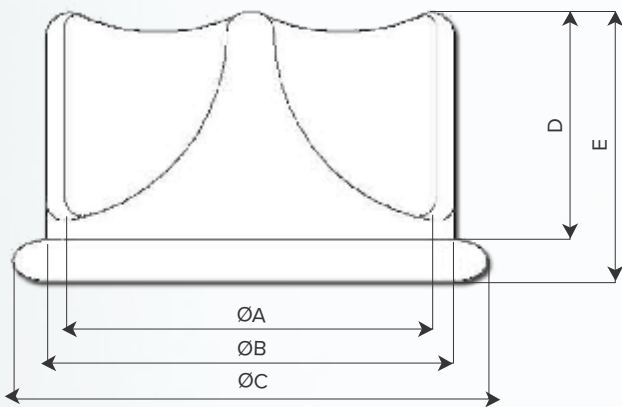
BRAILE
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Description:

The Bovine Pericardium Organic Biological Valvular Prosthesis is made with bovine pericardium treated with glutaraldehyde and preserved in formaldehyde 4%. This treatment gives it proper characteristics of resistance, flexibility and lack of antigenicity. The bioprosthesis is made on a polyacetal support coated with bovine pericardium, over which are assembled the cusps. A special stainless steel wire, inserted externally on the support ring, reinforces the ring base consistency and enables identifying the bioprosthesis position in the patient with a simple radiology exam.

Indication:

The Bovine Pericardium Organic Biological Valvular Prosthesis is indicated for the replacement of the aortic and mitral valves.



Technical Specifications							
Size	ØA ± 0,5mm	ØB ± 0,5mm	ØC ± 1,0mm	D ± 0,5mm	E ± 0,5mm	Aortic Code	Mitral Code
19	14	19	23	7	10	8316	-
21	16	21	25	8	11	8329	-
23	18	23	27	9	12	8332	-
25	20	25	29	10	13	8358	101347
27	22	27	31	11	14	8361	101356
29	24	29	33	12	15	8374	101392
31	26	31	35	13	16	-	8387
33	28	33	37	13	16	-	8390
35	30	35	39	14	17	-	8402

Effective Orifice Area

Results for EOA (Effective Orifice Area) of Organic Prostheses of Bovine Pericardium.

Effective Orifice Area (EOA)*			
Aortic		Mitral	
Diameter	Results (cm ²)	Diameter	Results (cm ²)
19 mm	1.68 ± 0.04	25 mm	2.07 ± 0.05
21 mm	1.93 ± 0.05	27 mm	2.40 ± 0.01
23 mm	2.28 ± 0.04	29 mm	2.66 ± 0.03
25 mm	2.51 ± 0.02	31 mm	3.14 ± 0.01
27 mm	2.69 ± 0.02	33 mm	3.47 ± 0.02
29 mm	2.88 ± 0.02	35 mm	3.89 ± 0.02

* In Vitro Pulsatile Hydrodynamic Performance measurements carried out according to parameters and procedures defined in ISO 5840-2:2021 (beat rate of 70 bpm, cardiac output of 5.0 ± 0.2 l/min and MAP of 100 ± 10 mmHg).

Pressure Gradient

Results for ΔP (Pressure Gradient) of PB Biological Prostheses.

Pressure Gradient (ΔP)*			
Aortic		Mitral	
Diameter	Results (mmHg)	Diameter	Results (mmHg)
19 mm	17.30 ± 7.06	25 mm	3.81 ± 1.82
21 mm	12.96 ± 5.32	27 mm	2.79 ± 0.72
23 mm	10.13 ± 3.16	29 mm	2.54 ± 1.45
25 mm	9.46 ± 1.80	31 mm	2.25 ± 0.57
27 mm	8.96 ± 1.26	33 mm	1.84 ± 0.40
29 mm	8.01 ± 1.28	35 mm	1.63 ± 0.34

* In Vitro Pulsatile Hydrodynamic Performance measurements carried out according to parameters and procedures defined in ISO 5840-2:2021 (beat rate of 70 bpm, cardiac output of 2.0 to 7.0 ± 0.2 l/min and MAP of 100 ± 10 mmHg).