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SURGICAL HEART VALVES

Mechanical

- ❑ **Durable – valves lasting 20-30 years**
- ❑ Thrombogenic-patients require anticoagulation therapy for life
- ❑ **Preferred in younger patients with >10-15 yrs. of life expectancy**.
- ❑ Preferred in patients who require lifelong anticoagulant therapy

Biological

- ❑ **Limited lifespan – 10% of homografts and 30% of heterograft fail within 10-15 years**.
- ❑ Low thrombogenic potential-lifelong anticoagulation is not required.
- ❑ Preferred in older patients with <10-15 years life expectancy.
- ❑ Preferred in those who cannot (or will not) take lifelong anticoagulation therapy.

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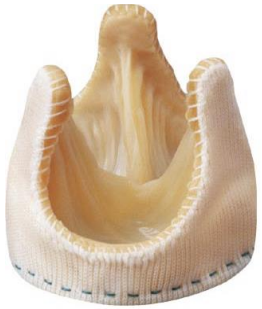
Types of Tissue Valves

- **Stented Tissue Valves**
  - **Intact porcine valves**
    - Medtronic's tissue valves
      - Reduction of muscle shelf bar
    - Some Edwards' porcine tissue valves
  - **Composite porcine valves**
    - St. Jude Medical's stented tissue valves
      - Three separate leaflets – either the left or the non-coronary cusps – triple composite
  - **Pericardial valves**
    - Edwards' valves
      - Pericardial tissue

Stentless Tissue Valves

Subcoronary

- Medtronic
- St. Jude Medical



Full Root

- Edwards
- Medtronic
- St. Jude Medical
- Currently in Europe
  – US and other geographies RELEASE CANCELED

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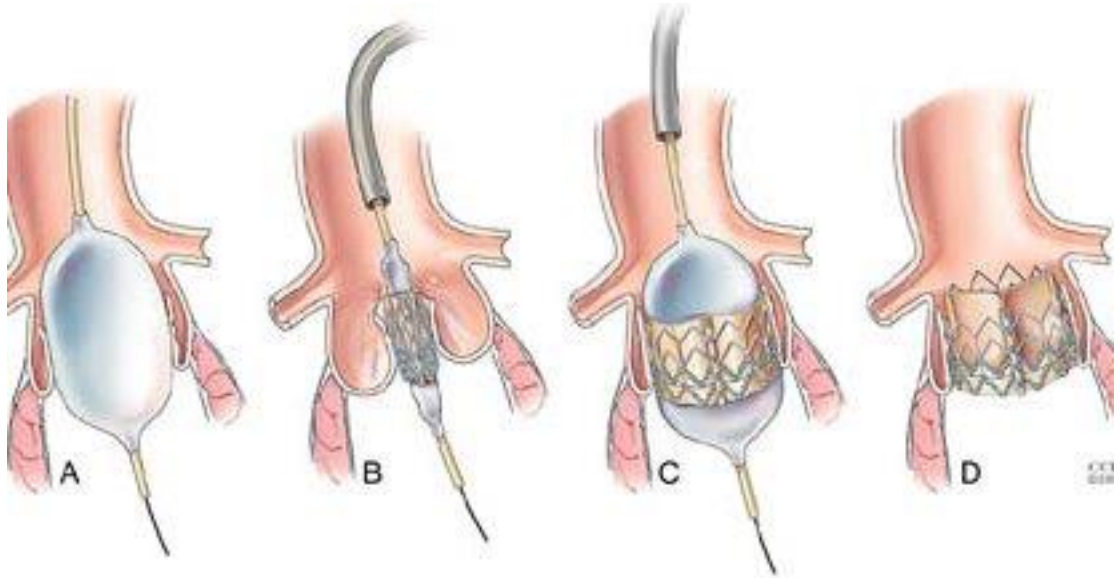
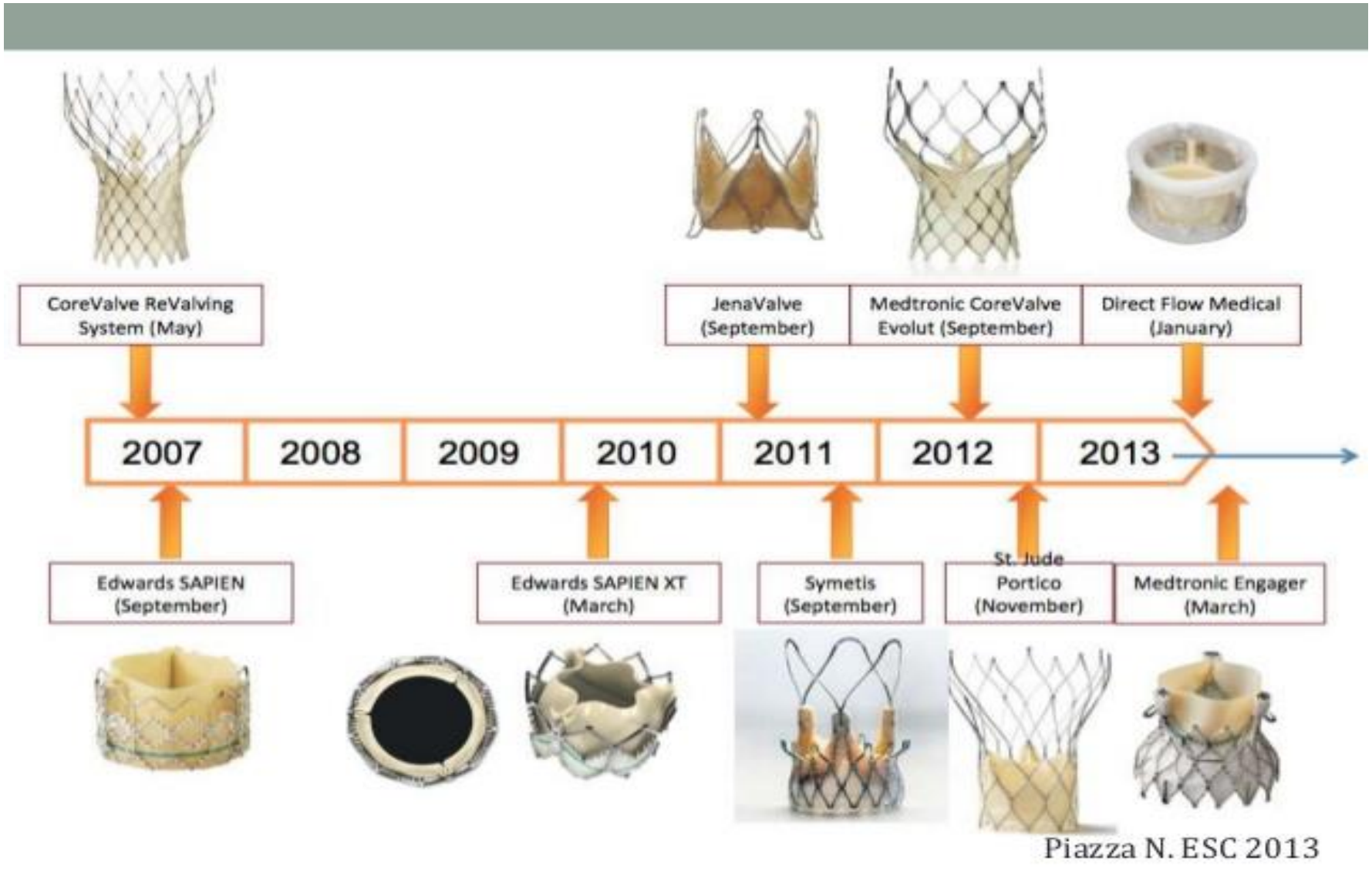
TRANSCATHETER IMPLANTATION



TISSUE IS STILL THE SAME

TAVI /TMVR /TMR etc,etc



Biological tissue valves

Advantages of biological heart valve	Disadvantages of biological heart valve
1. Design of valve are closer to the design of the natural valve. 2. Do not require long term anticoagulant 3. Do not cause damage to blood cells 4. Do not suffer from many of structural problems experienced by the mechanical heart valve	1. Stiffening of the tissue due to the build up calcium. 2. Calcification can cause a restriction of blood flow through the valve (stenosis) or cause tears in the valve leaflets.

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Location: Belo Horizonte, MG

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New Manufacturing Facility, 2018, Belo Horizonte

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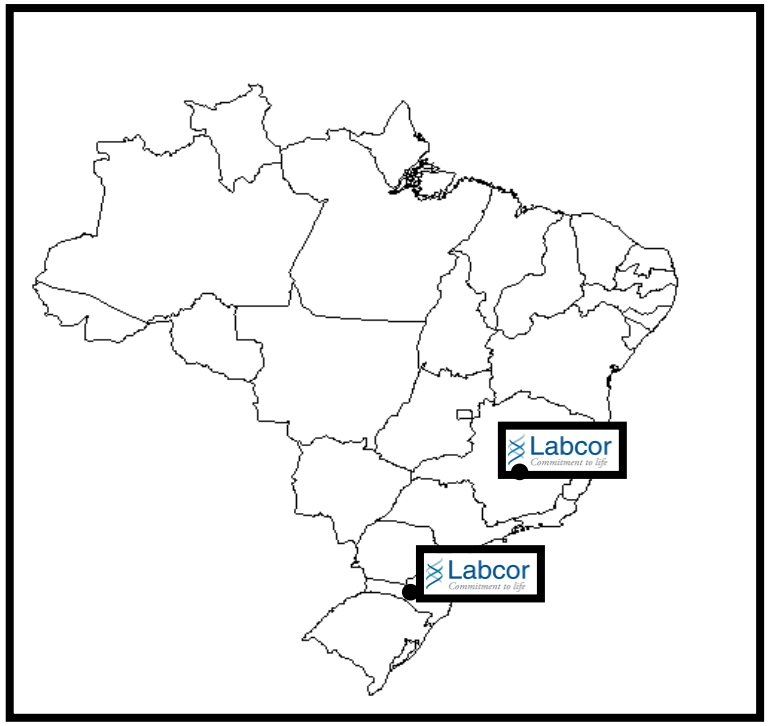
Research Center

Chapecó Facility

TISSUE PROCESSING TECHNOLOGY



Certifications

-GMP - ANVISA

- ISO 13485:2003 / 9001:2008 – DNV

- CE Mark for Different Products

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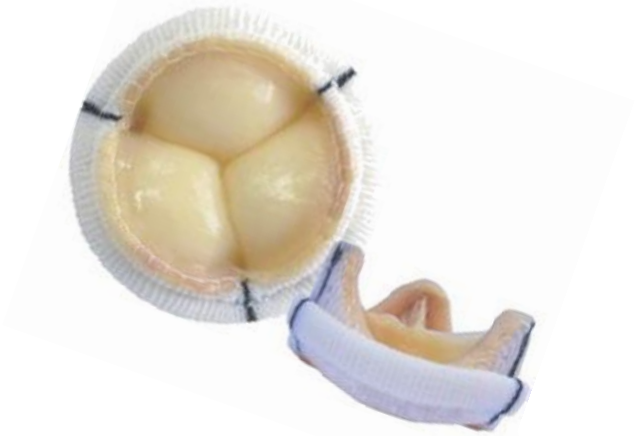
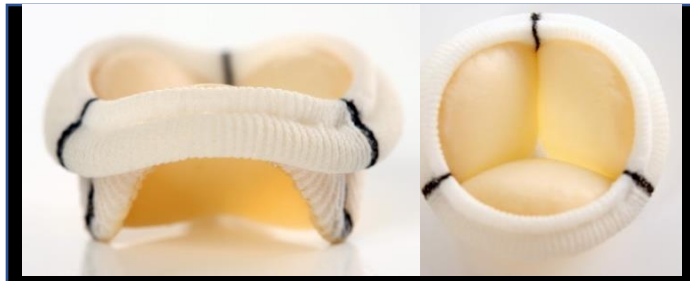
Glutaraldehyde Technology

It may be used to sterilize heat-sensitive articles that cannot undergo sterilization by physical processes such as: acrylic grafts, catheters, drains and polystyrene tubes. Glutaraldehyde has been often used to disinfect certain equipment such as endoscopes, respirator connections, respiratory therapy equipment, dialysis equipment, spirometry tubes, among others.



More than
150,000 implants

Glutaraldehyde Products



Dokimos Plus ®

Aortic and Mitral Bovine Pericardium Heart Valve with Reducer® Treatment

Instar®

Inorganic valved conduit biosynthetic With Dokimos Plus® Valve

TIV ®

Inorganic Aortic Valved Conduit

TLPB

Stented Aortic and Mitral Porcine Heart Valve

Supra-G

Porcine Aortic Valve Conduit

Magis

Annuloplasty Ring

T07 EAIS

Porcine Pulmonary Conduit Tricomposite valve with bovine pericardium tube

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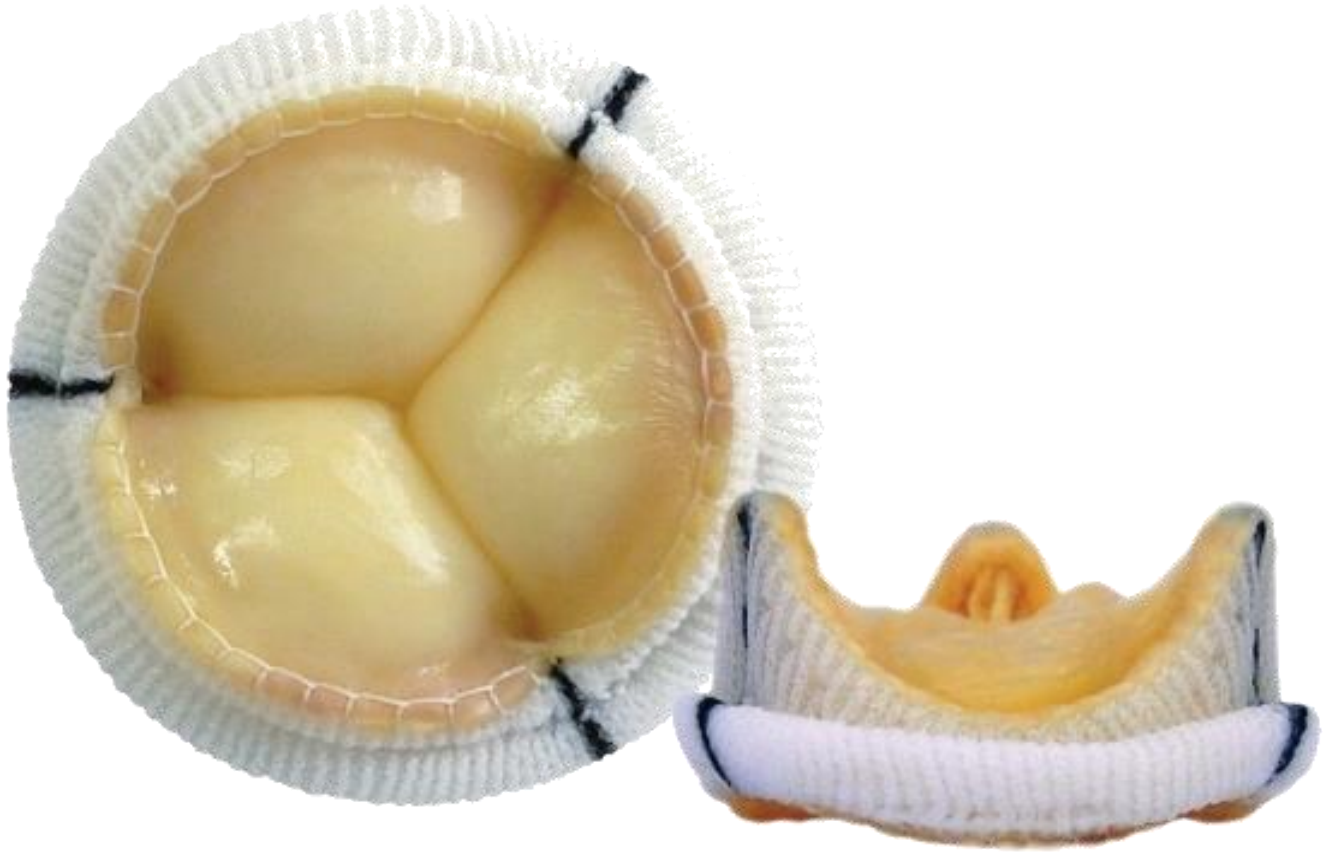

TLPB BIOPROSTHESIS

8-year experience with the LABCOR bioprosthesis in the Aortic position

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Klinik für Herz-Thoraxchirurgie,
Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil Bochum

Background:

Between 2004 and 2010 330 patients with a mean age of 75,8±7,2 years and mean logistic EuroSCORE of 8,5% underwent AVR with the LABCOR TLPB-A Supra porcine bioprosthesis in our institution. This paper presents clinical results against the background following a trend towards bovine devices through the last decade.

Patients and Methods:

Patients diagnosed with aortic valve stenosis requiring isolated aortic valve replacement, as well as patients with the additional need of concomitant bypass surgery were included in this follow up study. Between 09/2004 and 10/2010 a total of 330 patients received biological AVR using the LABCOR porcine bioprostheses. Concomitant bypass surgery was performed in 130 cases. Preoperatively, 69 patients (21%) were in NYHA class II, 214 (65%) in class III and 47 (14%) in class IV.

Surgical technique:

Patients were operated using standard cardiopulmonary bypass as well as standard cristalloid cardioplegia (Bretschneider). The porcine valves were implanted in a supraanular fashion using felt-armed u-stitches.

Follow-up:

Data were obtained during a 6 month interval period through telephone interviews with patients and referring physicians. Giudelines for reporting mortality and morbidity were followed in these Interviews

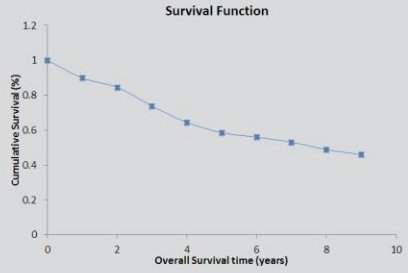
Statistical Analysis:

Statistical Analysis was performed using SPSS 20.0 statistical software. The patient population data, operative and follow up clincal data was characterized through descriptive statistics. For continuous variables, the number of patients, mean (+- SD), minimum and maximum were provided. For categorical variables, the number and percentage of patients were provided. Survival Analysis was performed using the Kaplan-Meier survival Method. Early event rates were calculated as the number of patients having the event divided by the total number of patients, expressed as a percentage. Late events were summarized using linear rates (% per pt-year), and calculated by dividing the number of late events by the sum of patient years.

Results:

The follow up rate was 98%. The 30 day mortality rate amounted 4,8% (n=16). There was no evidence of valve failure during this period. Mean follow up was 5,6 patient years. Total follow up 1441patient years.
5 year survival amounted 60% (±1,4), 8 year survival 49% (± 1,6). 50% (n=89) of the contacted patients were NYHA Class I 39% (n=69) in NYHA Class II 10% (n=18) and 0,6% (n=1) in NYHA class IV.

Out of 136 late deaths 9 were valve related (0,6%/ pt-year) with 1 case of paravalvular leakage, 6 cases of endocarditis, one stroke and one patient who suffered from cerebral hemorrhage. 26 late deaths were cardiac (1,8%/pt-year), 49 were noncardiac (3,4%/pt-year) and 56 were unexplained (3,9%/pt-year)



Adverse events:

Frequency of adverse events and actuarial freedom from valve related adverse events 5 years and 8 years after aortic valve replacement.

Adverse event	Late events		Actuarial freedom from event (% +/-SD)	
	N	%/pt-year	5 years	8 years
Thromboembolism	8	0,6	96,3 ± 1,7	92,9 ± 1,7
-Permanent neurological deficit	3	0,2	98,7 ± 1,0	98,7 ± 1,0
-TIA	3	0,2	99,2 ± 0,6	98,3 ± 1,1
-Acute myocardial infarction	2	0,1	99,4 ± 0,5	98,7 ± 0,9
-Valve Thrombosis	0	0	100 ± 0,0	100 ± 0,0
-Peripheral embolic event	1	0,1	99,3 ± 0,6	99,3 ± 0,6
Structural valve deterioration	3	0,2	99,2 ± 0,7	96,9 ± 1,4
Endocarditis	9	0,6	96,8 ± 1,4	96,8 ± 1,4
Paravalvular leak	3	0,2	99,3 ± 0,5	97,5 ± 1,5
Major hemorrhage	7	0,5	97,3 ± 1,3	95,7 ± 1,4
Reoperation	15	1,0	96,0 ± 1,8	87,3 ± 2,7
Explant	15	1,0	96,0 ± 1,8	87,3 ± 2,7

Conclusion:

In this middle follow-up term of 8 years of clinical experience in a single center, the LABCOR porcine bioprosthesis shows reliable and satisfying results comparable to other commercial porcine heart valves in a patient group with a medium risk profile. Nevertheless, further long-term assessment and echocardiographic examination is needed.

Aortic valve replacement with the composite Labcor porcine

Bioprosthesis in the elderly.

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Abstract

BACKGROUND:

This paper presents the analysis of clinical results of the composite porcine Labcor bioprosthesis in the replacement of aortic valves in the elderly

METHODS:

This retrospective study was carried out in the Thoracic and Cardiovascular Surgical Department, La Pitié-Salpétrière Hospital, Paris, for replacement of calcified, stenosed aortic valves between 1988 and 1995. It involved a series of 100 patients aged 70 and over (mean: 80+/-5 years ranging from 70 to 90). There were 63 female and 37 male patients. Preoperatively, five patients were in NYHA Class I, 23 in Class II, 65 in Class III and 7 in Class IV.

RESULTS:

Fifteen patients died in the early postoperative stage and 13 during the follow-up period. There was no evidence of valve failure. The average follow-up was 32 months and the actuarial survival rate at 5 years was 74+/-5%. Complications due to bleeding occurred in 3 patients taking anticoagulant treatment. There were neither valvular thrombosis nor embolism. Two patients presented with prosthetic endocarditis. Two patients received a reoperation because of leakage (1 septic). The five-year follow-up showed that 96% of patients did not require further surgery. When this study was completed, 83% of patients were in Class I or II versus 71% in Class III or IV prior to surgery.

CONCLUSIONS:

In the early/middle follow-up term, the results obtained when replacing the aortic valve with the composite Labcor bioprosthesis in the

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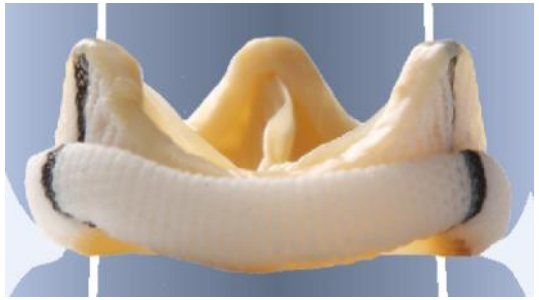
Biocor & Epic



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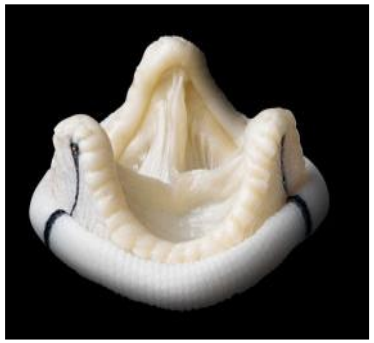

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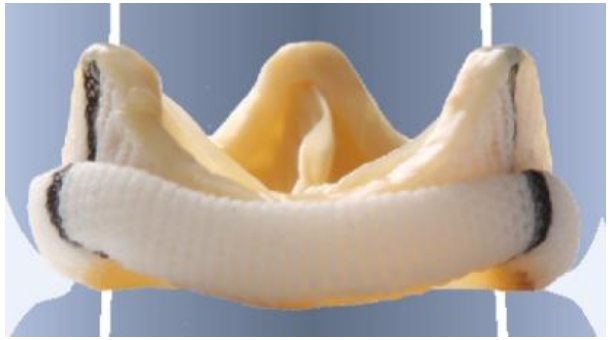
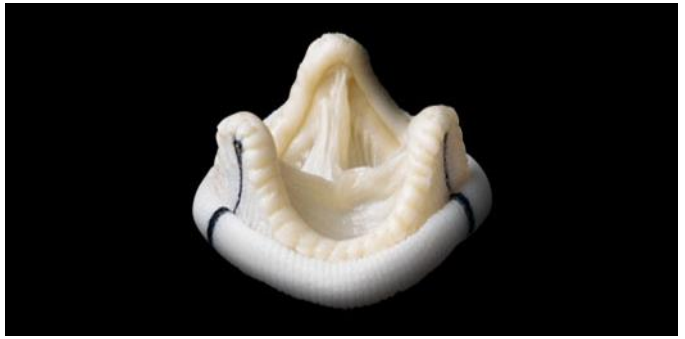
VS.

SJM/ABBOTT

[1]Myken PS, Bech-Hansen, O. A 20-Year Experience with 1,712 Patients with the Biocor Porcine Bioprosthesis. *J Thorac and Cardiovasc Surg*, 2009.137:76-81.
[2]Eichinger WB. Twenty-year experience with the St. Jude Medical Biocor bioprosthesis in the aortic position. *Ann Thor Surg*;2008 Oct 86(4):1204-11





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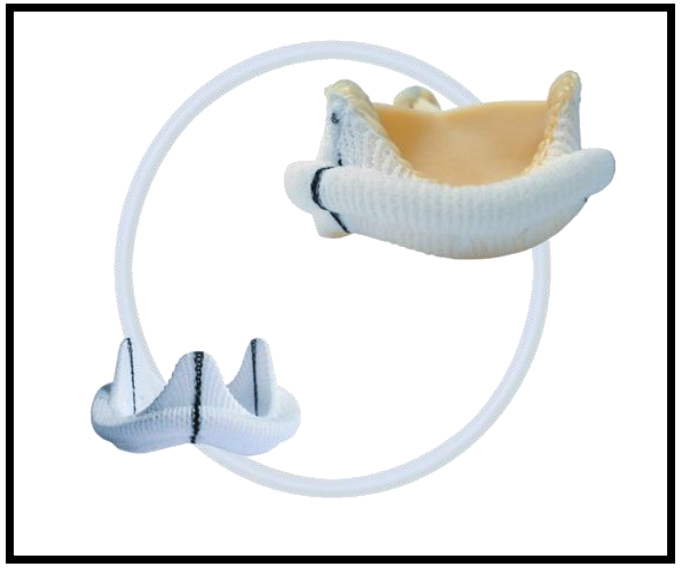
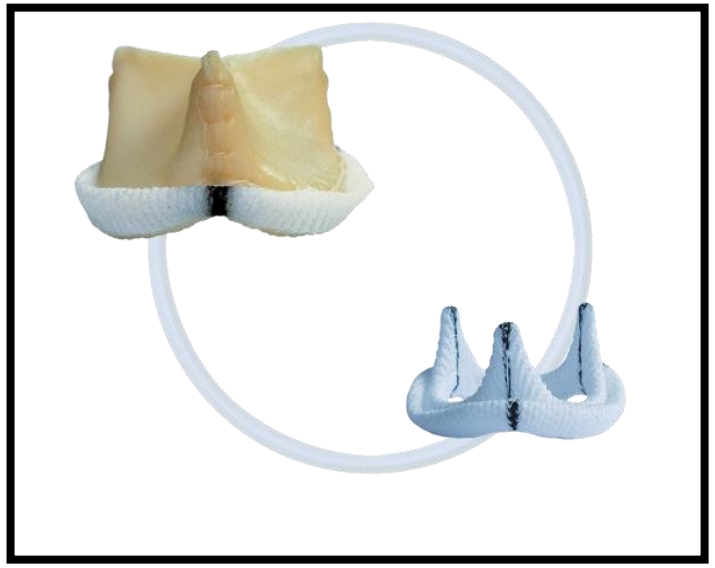
Dokimos™ Plus Aortic and Mitral Bovine Pericardium - Reducer®

Dokimos Mitral



Dokimos Aortic



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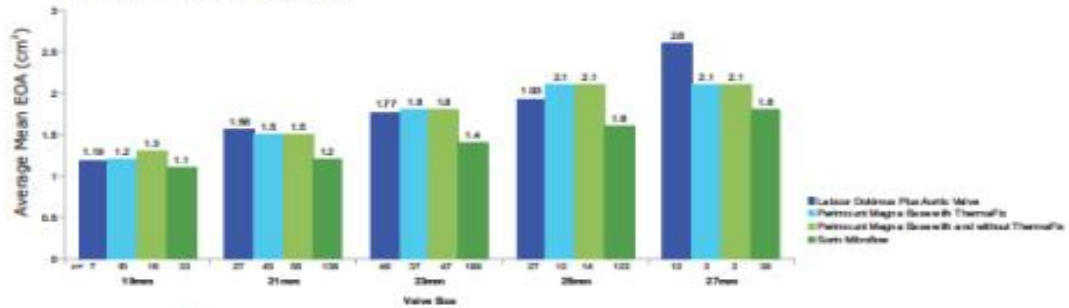
Dokimos Plus Aortic Valve

Comparative Hemodynamics

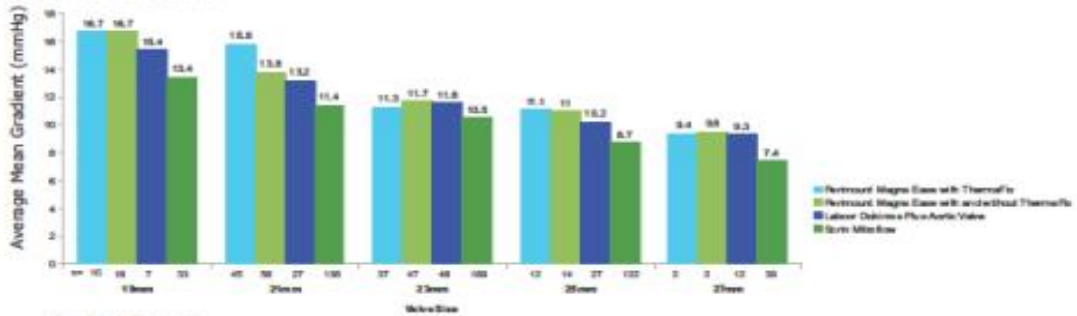
Sorin Mitroflow, Edwards Perimount Magna and Edwards Perimount Magna Ease

Hemodynamic data obtained from multicenter study from 6 clinical sites. Data analyzed by independent echocardiography laboratory.

Effective Orifice Area (EOA)



Mean Gradient



Implant data

Patients implanted valve from Jan/2009 to Nov/2011. Echo performed after 6 months.
Total of Patients: 121 Mean age: 63 +/- 13 years
Male: 57% / Female: 43%
Average Mean EOA: 1.80 cm²
Average Mean Gradient: 11,74mmHg / Average Max Gradient: 22.06mmHg
EOA Index: ≥0.85cm²/m² total:76% / <0.85cm²/m² total:24%

References:

- Edwards Lifesciences Corporation, Carpentier-Edwards Magna Ease Pericardial Aortic Bioprosthesis Model 3300TFX, Instructions for use, 2009. Echo follow-up at one year.
- CarboMedics, Inc., A Sorin Group Company. Mitroflow Aortic Pericardial Heart Valve, Pre-Market Approval Application Summary of Safety and Effectiveness Data, P060038, 2007. Echo follow-up at one year.
- Conte J. Weissman N, Dearani JA, etal. A North American, prospective, multicenter assessment of Mitroflow aortic pericardial prosthesis. Ann Thorac. Surg. 2010;90(1)144-152.e1-3