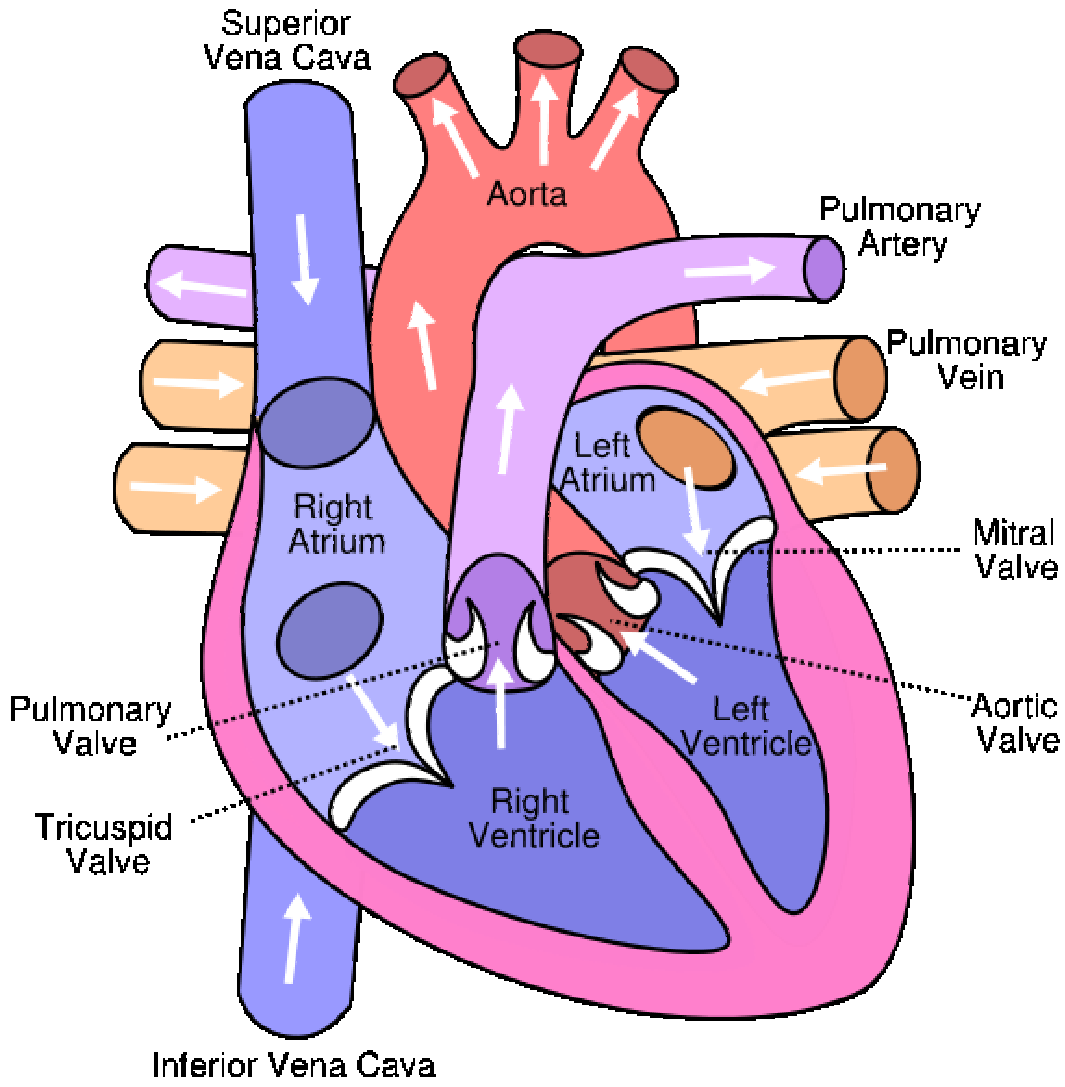
Biocompatible materials 16.01.2012

- Implants for the blood circulatory system
- Wound dressings and suture materials
- Controlled drug delivery systems

Implants for the blood circulatory system

Diagram of the human heart



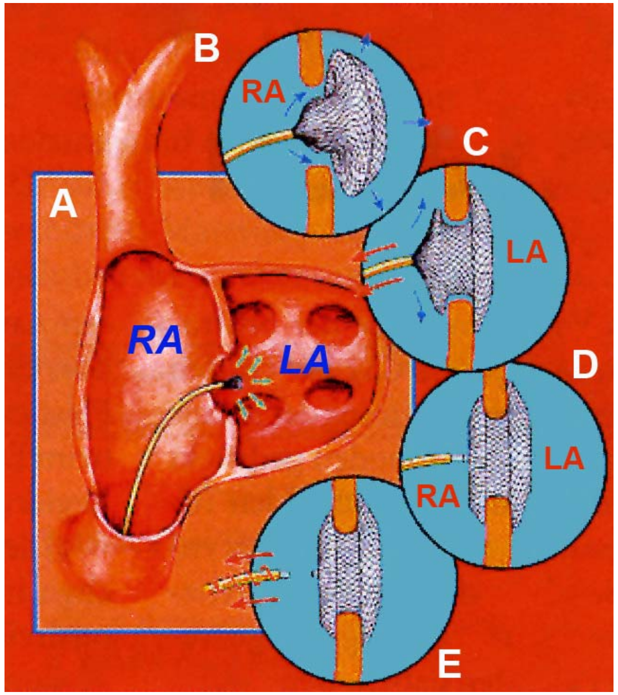
http://en.wikipedia.org/wiki/Image:Diagram_of_the_human_heart_%28cropped%29.svg

Sealing systems for the cardiac septum

- Defects in the cardiac septum shall be sealed minimal invasive during catheter-based cardiac examination („interventional sealing“)
- Thus, a catheter is shifted from the groin to the heart, and through the catheter an implant is inserted (placed) in the defect.

Kunststoffe 2007, 97, pp. 96

A ... Positioning of the catheter at the defect



B/C ... Positioning of the implant at both sides of the defect

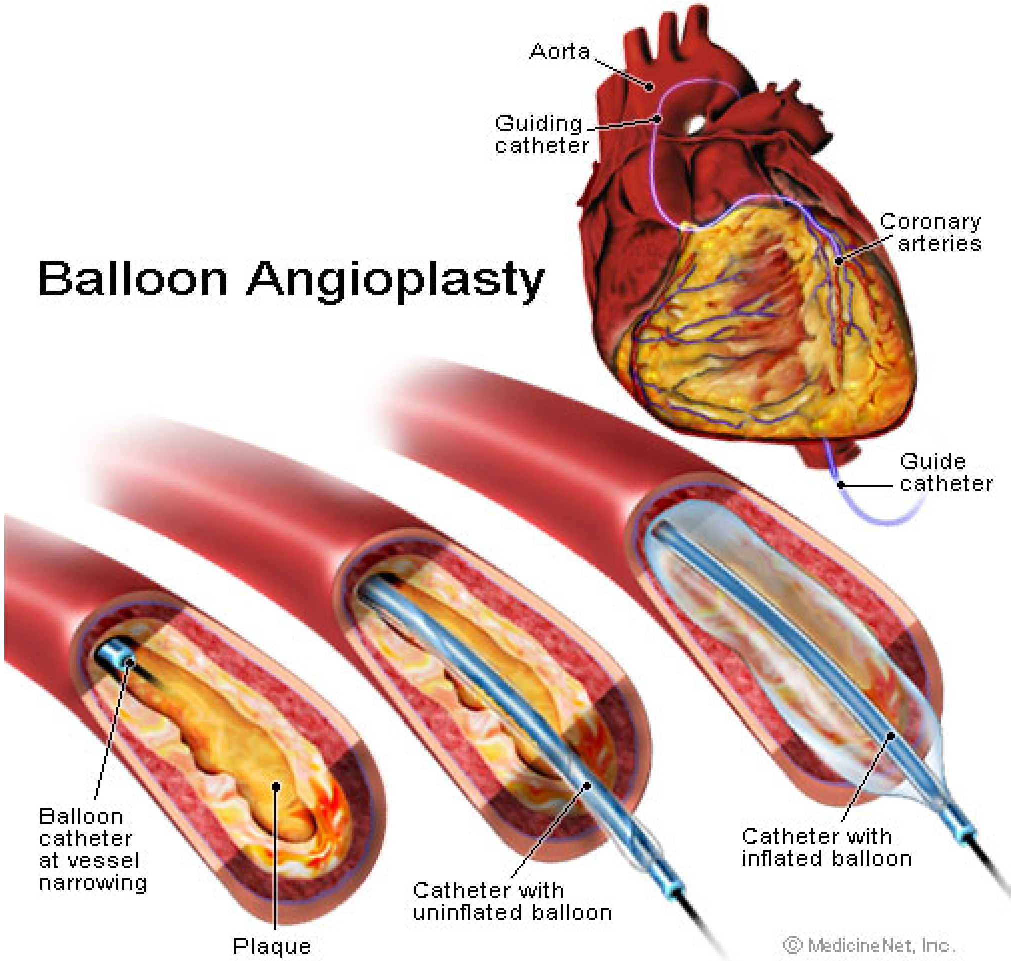
D ... Anchorage (fixation)

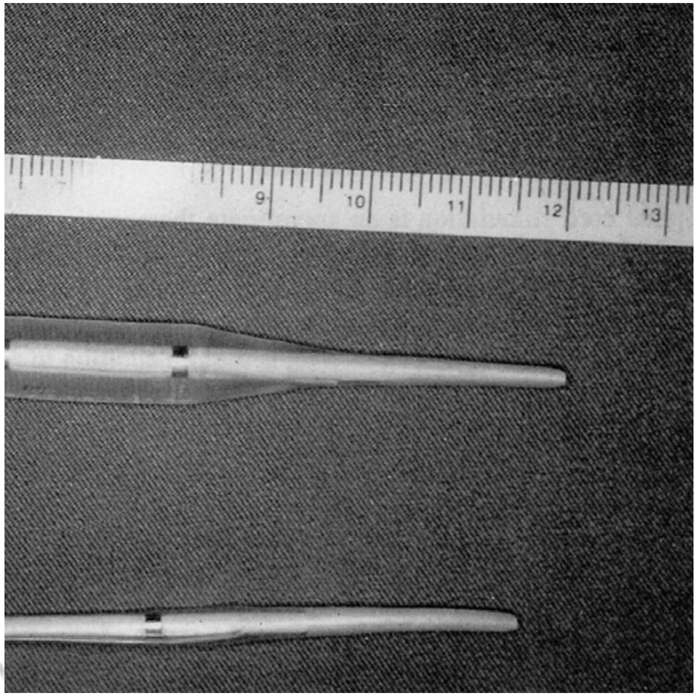
E ... loosening of the catheter

Catheter-based cardiac treatment

RA ... right atrium
LA ... left atrium

Conventional Balloon Catheter



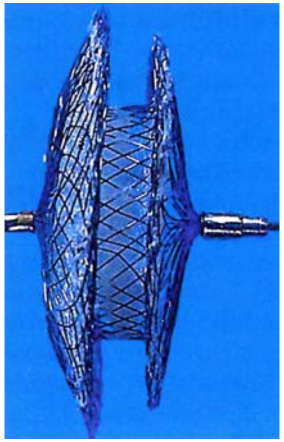


(S. Dumitriu, 1994)

Initial state (below), unfolded state (above)

Sealing systems for the cardiac septum

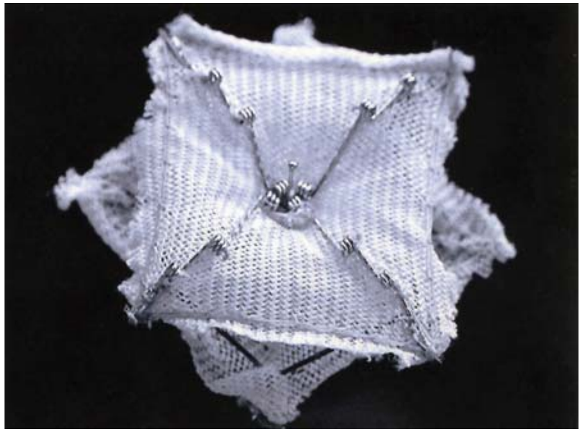
- Common implants are material combinations of metal frames and polymer covering or filling that remain in the body
- *The vision*: After a few month the implant is ingrown, the defect sealing function is transferred to the body-own tissue, i.e. a material should be used that can be totally degraded.



Sealing systems for Catheter-based cardiac treatment

above: Amplatzer

below: CardioSeal, material polyester covered steel)



Kunststoffe 2007, 97, pp. 96

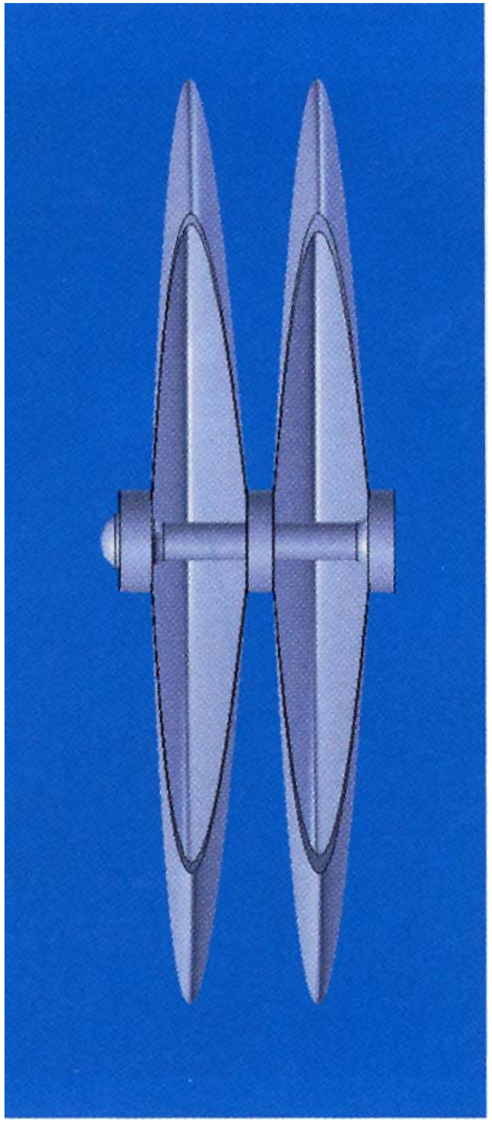
Sealing systems for the cardiac septum

- Requirements
  - The implant has to be guided through the catheter with a diameter of 3–5 mm
  - Defect dimension $\leq$ 40 mm
  - Portable in folded or packed state and able to completely unfold or unpack for the sealing
  - No shift, break or loosening!
- Materials
  - Poly-l-lactide (PLLA) Resomer L207®
  - Poly-l-lactide-co-trimethylcarbonate (70:30) (PLLA-co-TMC) Resomer LT706®

Source: Kunststoffe 2007, 97, pp. 96

Sealing systems for the cardiac septum

- Prototype
  - In packed state the implant is similar a tube that can be placed at the defect through the catheter
  - In the defect two discs are stretched (left and right arterial) and fixed by snapping a connection



- Current status
  - Functionality tests
  - preparation of in vivo animal experiments (sheep model)

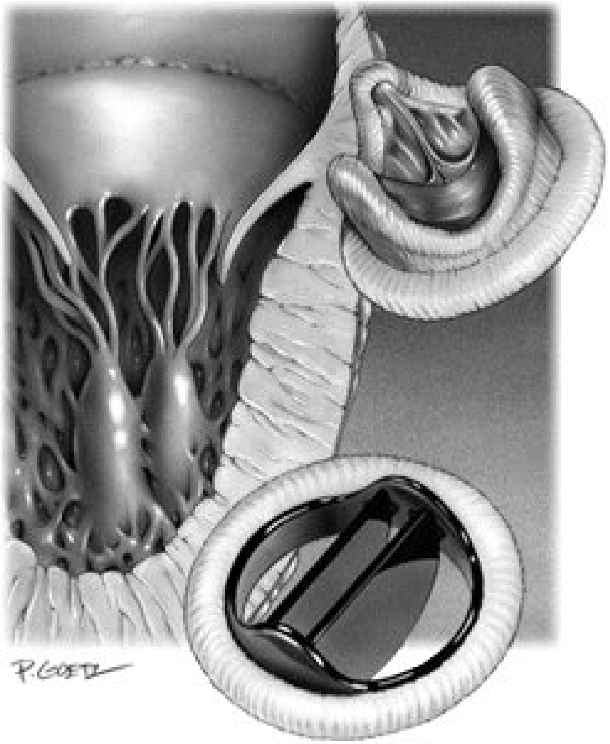
Kunststoffe 2007, 97, pp. 96

Heart valves

Henry Gray's Anatomy of the Human Body

Prosthetic heart valves

- First used in humans in 1960
- Replace the natural heart valves (mitral, tricuspid, aortic and pulmonic)
  when these no longer perform their normal functions
- Mechanical heart valves and tissue heart valves



http://cape.uwaterloo.ca/che100projects/heart/files/testing.htm

Mechanical heart valves

- Materials:
  - Silicone elastomer
  - PTFE
  - Polyester (sewing ring)
  - CoCr-alloys
  - Mo-alloys
  - Stainless steel
  - Titanium
  - Pyrolytic carbon

- Types:
  - Caged ball
  - Tilting disc
  - Bileaflet

Mechanical heart valves
Caged ball

The caged ball design is one of the early mechanical heart valves, that uses a small ball that is held in place by a welded metal cage.

The ball in cage design was modeled after ball valves used in industry to limit the flow of fluids to a single direction.

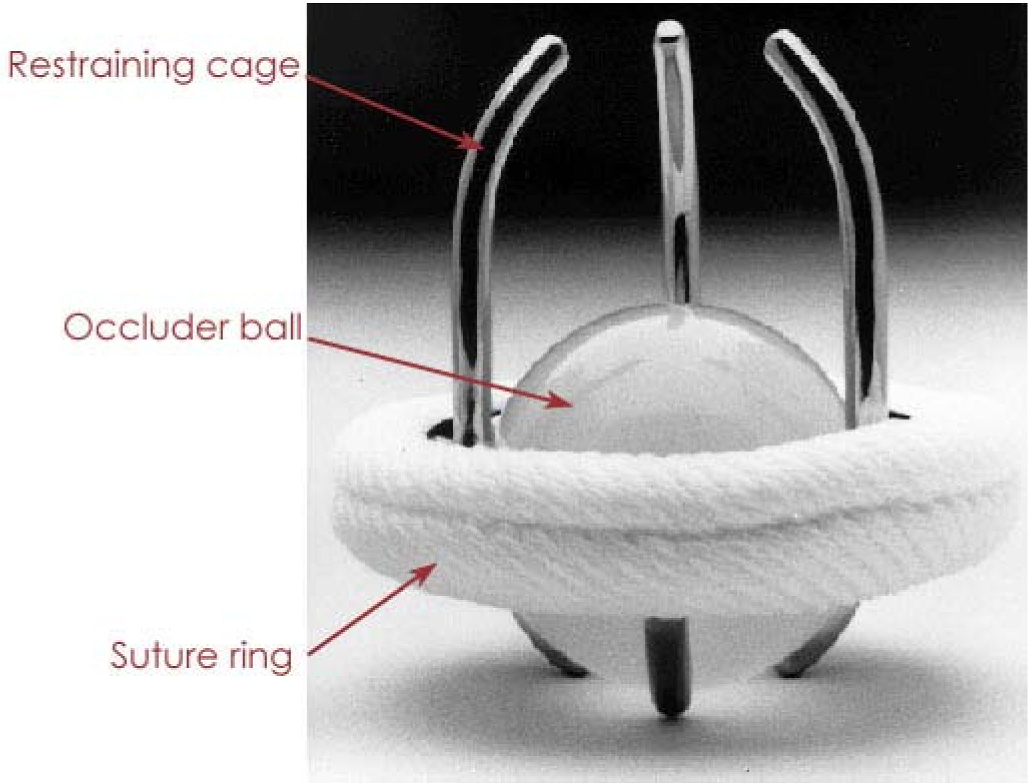
Natural heart valves allow blood to flow straight through the center of the valve. This property is known as central flow, which keeps the amount of work done by the heart to a minimum.

With non-central flow, the heart must work harder to compensate for the momentum lost to the change of direction of the fluid.

Caged-ball valves completely block central flow, therefore the blood requires more energy to flow around the central ball.

In addition, the ball is notorious for causing damage to blood cells due to collisions. Damaged blood cells release blood clotting ingredients, hence the patients are required to take lifelong prescriptions of anticoagulants.

Mechanical heart valves
Caged ball



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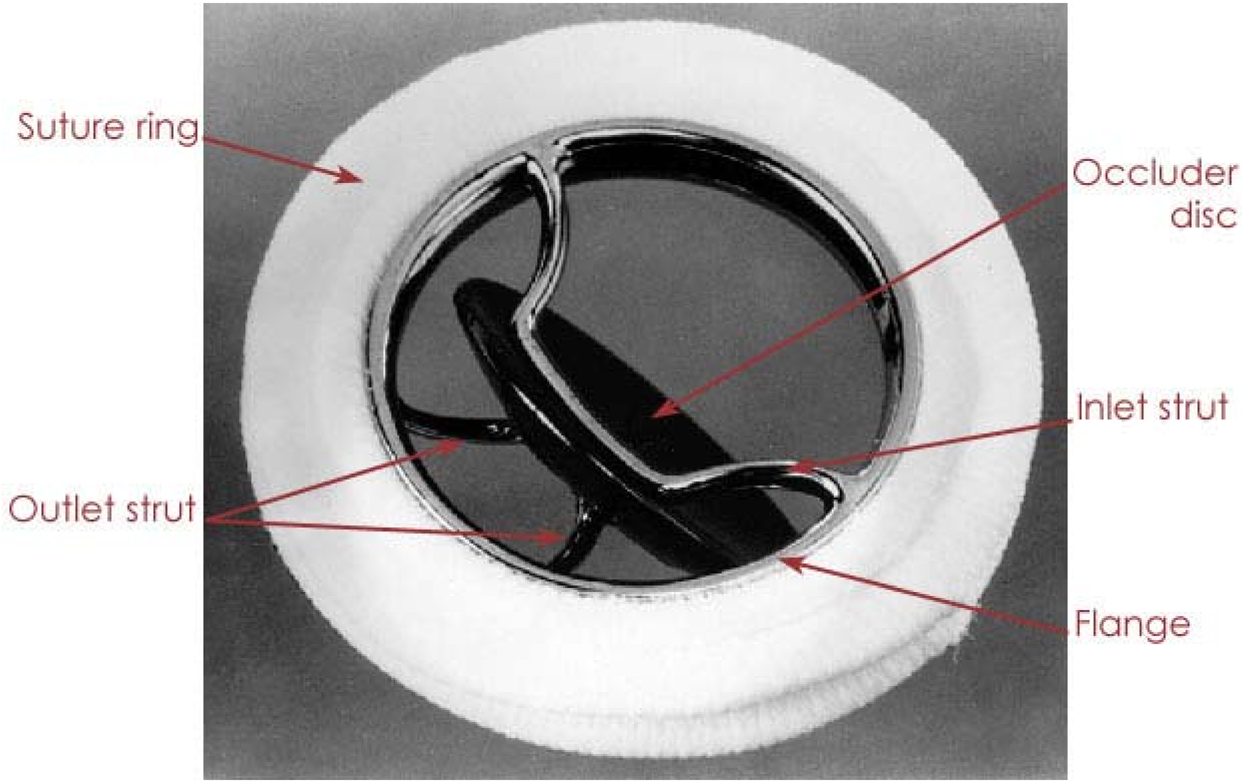
Mechanical heart valves
Tilting disc

For a decade and a half, the caged ball valve remained the best design. In the mid-1960s, a new class of prosthetic valves were designed that used a tilting disc to better mimic the natural patterns of blood flow.
The tilting-disc valves have a polymer disc held in place by two welded struts. The disc floats between the two struts in such a way, as to close when the blood begins to travel backward and then reopens when blood begins to travel forward again.
The tilting-disc valves are vastly superior to the ball-cage design. The titling-disc valves open at an angle of 60° and close shut completely at a rate of 70 times/minute.
This tilting pattern provides improved central flow while still preventing backflow. The tilting-disc valves reduce mechanical damage to blood cells. This improved flow pattern reduced blood clotting and infection. However, the only problem with this design is its tendency for the outlet struts to fracture as a result of fatigue from the repeated ramming of the struts by the disc.

http://cape.uwaterloo.ca/che100projects/heart/files/testing.htm

Mechanical heart valves
Tilting disc



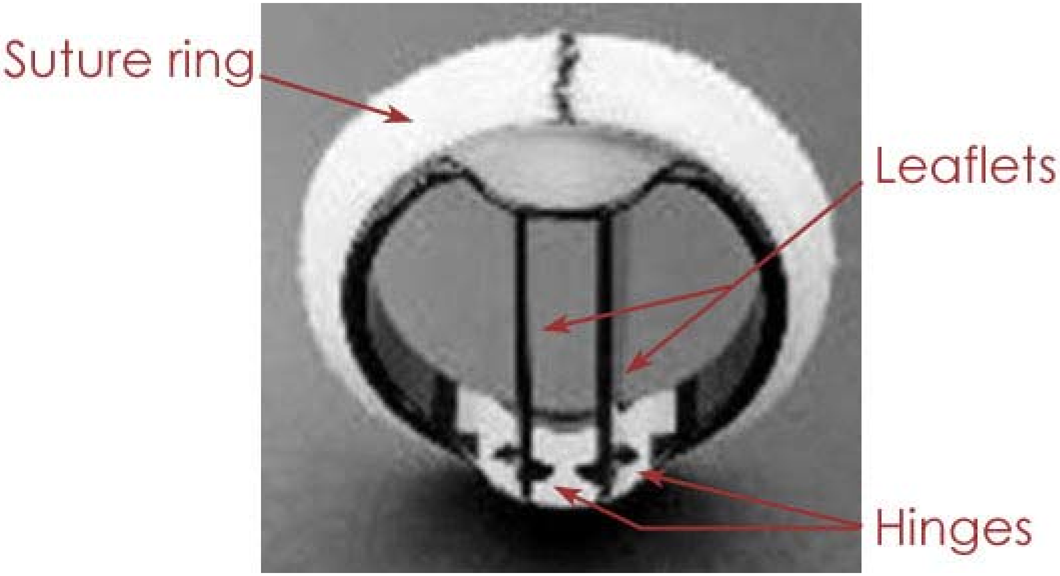
http://cape.uwaterloo.ca/che100projects/heart/files/testing.htm

Mechanical heart valves
Bileaflet valves

In 1979, a new mechanical heart valve was introduced. These valves were known as bileaflet valves, and consisted of two semicircular leaflets that pivot on hinges. The carbon leaflets exhibit high strength and excellent biocompatibility. The leaflets swing open completely, parallel to the direction of the blood flow. They do not close completely, which allows some backflow. Since backflow is one of the properties of defective valves, the bileaflet valves are still not ideal valves. The bileaflet valve constitutes the majority of modern valve designs. These valves are distinguished mainly for providing the closest approximation to central flow achieved in a natural heart valve.

http://cape.uwaterloo.ca/che100projects/heart/files/testing.htm

Mechanical heart valves
Bileaflet valves



http://cape.uwaterloo.ca/che100projects/heart/files/testing.htm

Mechanical heart valves

Advantages:

- High durability: mechanical heart valves are placed in young patients because they typically last for the lifetime of the patient.
- Mechanical valves are suitable for people who do not want additional valve replacement surgery in the future.
- Reproducible manufacturing

Mechanical heart valves

Disadvantages:

- Increased risk of blood clotting: mechanical valve recipients must take anti-coagulant drugs (sodium warfarin) chronically, which effectively makes them borderline hemophiliacs.
- The anti-coagulant used causes birth defects in the first trimester of fetal development, rendering mechanical valves unsuitable for women of child-bearing age.

http://cape.uwaterloo.ca/che100projects/heart/files/testing.htm

Tissue heart valves (Bioprosthetic heart valves)

- Types:
  - Human tissue valves
    - homografts are transplanted from another human being (e.g. cadaver)
    - allografts are valves that are transplanted from one position to another within the same person
  - Animal tissue valves (heterografts or xenografts)

Tissue heart valves (Bioprosthetic heart valves)

These valves are most often heart tissues recovered from animals at the time of commercial meat processing. The leaflet valve tissue of the animals is inspected, and the highest quality leaflet tissues are then preserved. They are then stiffened by a tanning solution, most often glutaraldehyde. The most commonly used animal tissues are: porcine, which is valve tissue from a pig, and bovine pericardial tissue, which is from a cow.
The most common cause of bioprosthesis failure is stiffening of the tissue due to the build up calcium. Calcification can cause a restriction of blood flow through the valve (stenosis) or cause tears in the valve leaflets.
Since younger patients have a greater calcium metabolism, bioprostheses tend to last best in senior citizens.
Once a bioprosthesis is implanted, the valve itself does not require any type of anti-coagulant drugs. Its degeneration is simply a gradual process, as it grows with the body.

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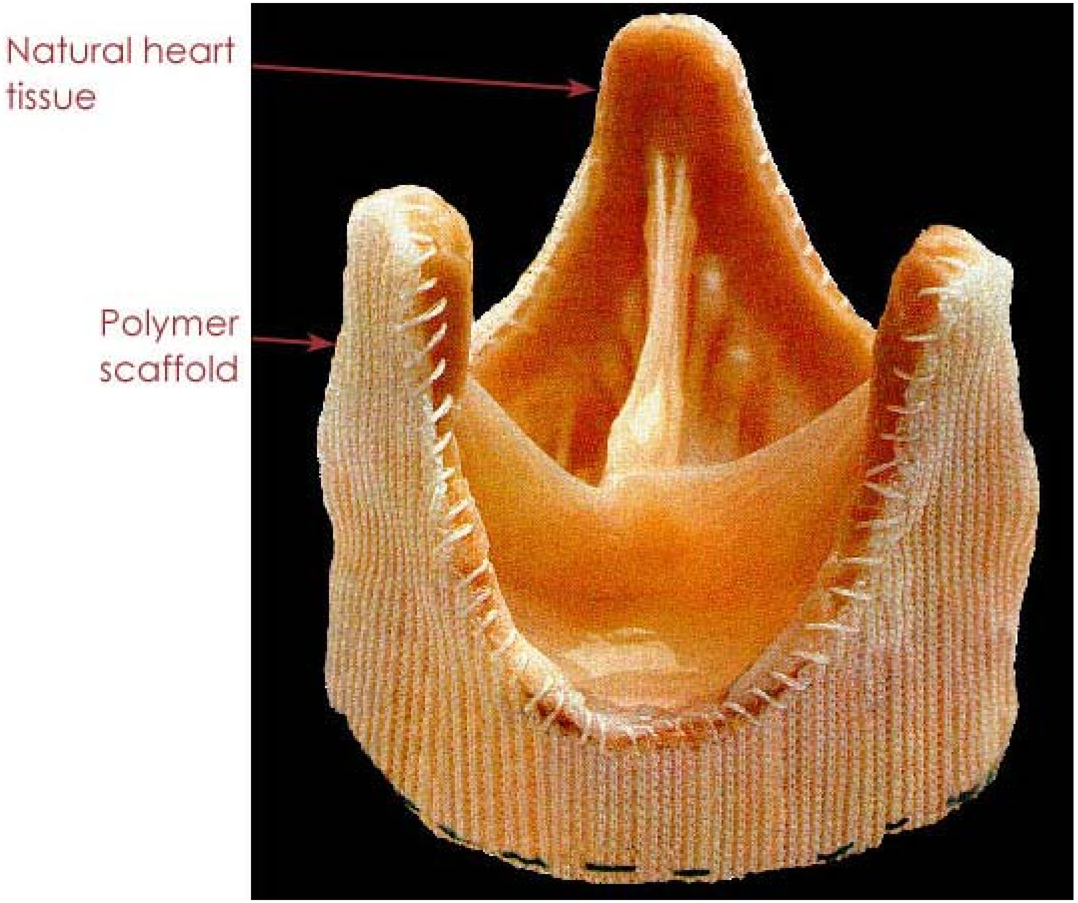
Tissue heart valves (Bioprosthetic heart valves)

Animal tissue valves (heterografts or xenografts)



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