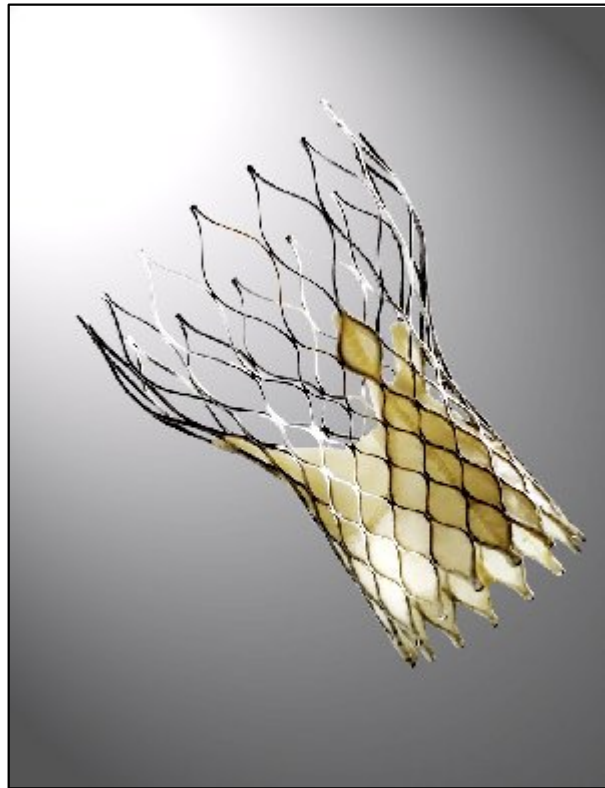


Percutaneous Aortic Valve Replacement

Patient Information Brochure



Mercy Angiography, June 09

The Team of Medical Doctors Involved

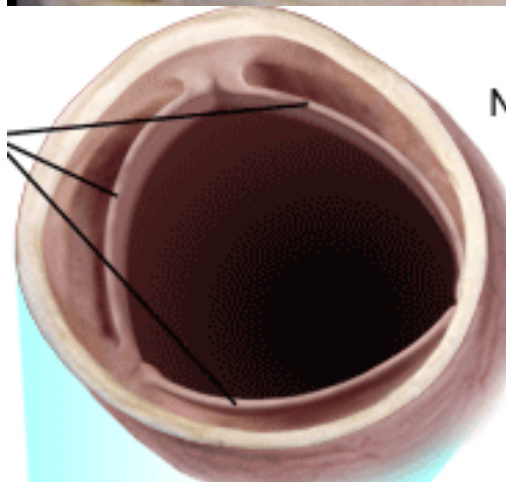
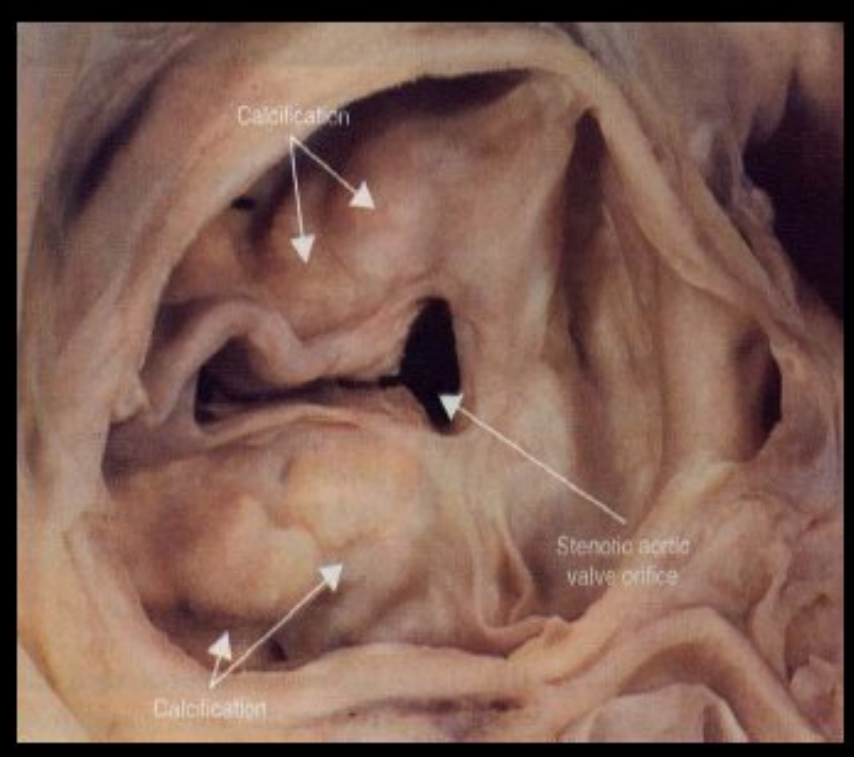
John Ormiston	(Interventional cardiologist)
Peter Raudkivi	(Cardiothoracic Surgeon)
Mark Webster	(Interventional cardiologist)
Jim Stewart	(Interventional cardiologist)
Malcolm Legget	(Cardiologist)
Arthur Coverdale	(Cardiologist)
Neil Middleton	(Cardiac anaesthetist)
Cornelius Kruger	(Cardiac anaesthetist)

- ❑ A normal heart valve allows blood to flow in one direction only without obstruction
- ❑ A valve that is narrowed is said to have “stenosis”
- ❑ Aortic stenosis (narrowing of the aortic valve that lies between the left ventricle and the aorta) is the most common valve problem
- ❑ Aortic stenosis is usually due calcium building up on the valve leaflets so they become rigid and restrict blood flow

Normal aortic valve with thin flexible leaflets that can open fully



Stenosed (narrowed) aortic valve with calcified leaflets that are rigid and cannot open fully



Open valve does not restrict flow

Aortic stenosis may lead to

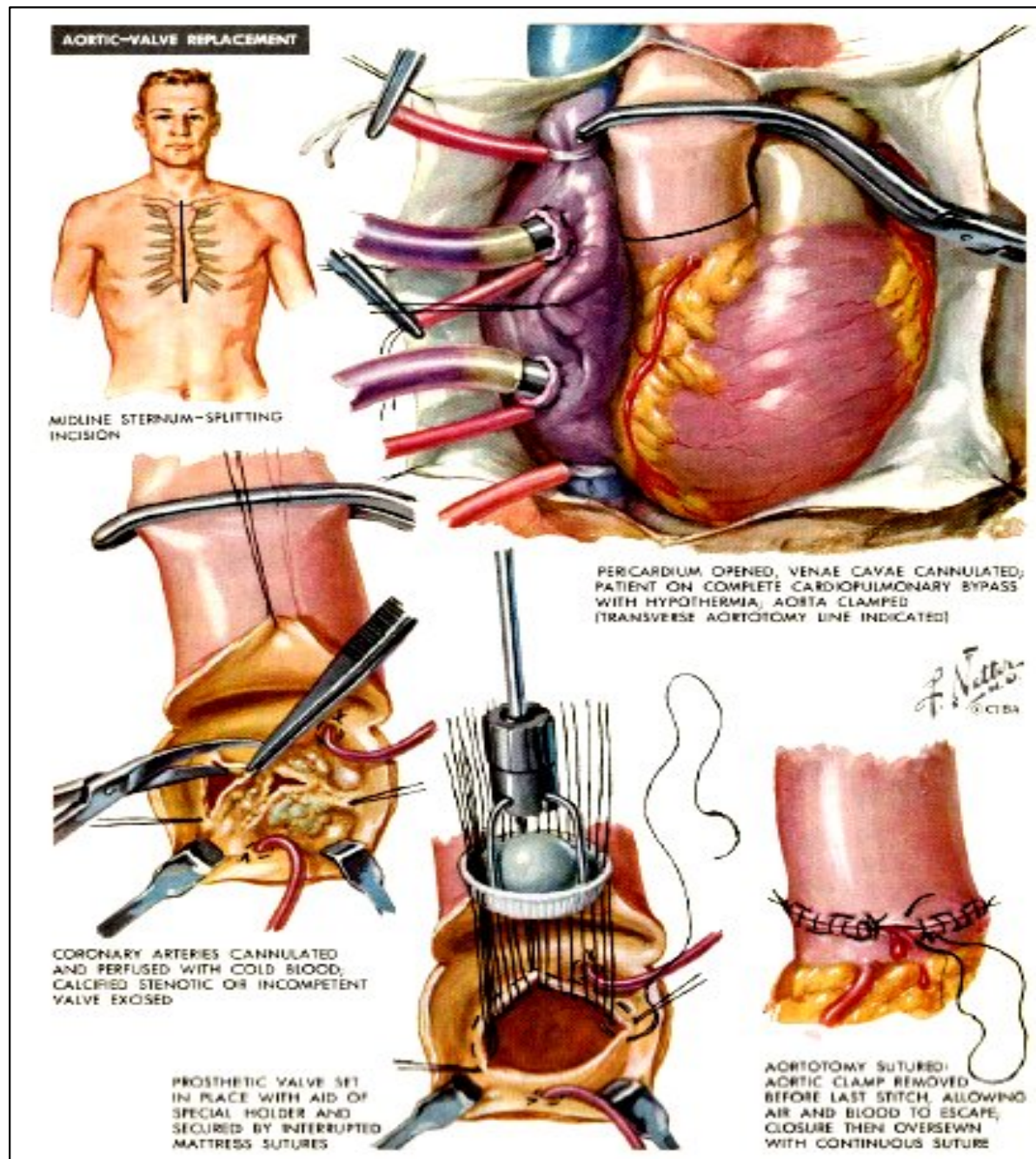
- Shortness of breath due to heart failure with build up of fluid in the lungs
- Angina because of insufficient blood reaching the heart muscle
- Blackouts because of insufficient blood reaching the head
- Sudden death

- ❑ Of patients with severe aortic stenosis who have symptoms, and who do not have valve replacement, between 50 and 80% will be dead in two years

- ❑ The standard of care for severe symptomatic aortic stenosis has been surgical valve replacement

- ❑ There are many patients who are not suitable or are very high risk for surgical replacement because of one or more of the following –advanced age, conditions such as kidney problems, chest problems, problems with blood supply to the brain, weak heart muscle, or previous heart surgery

Surgical aortic valve replacement is a major operation

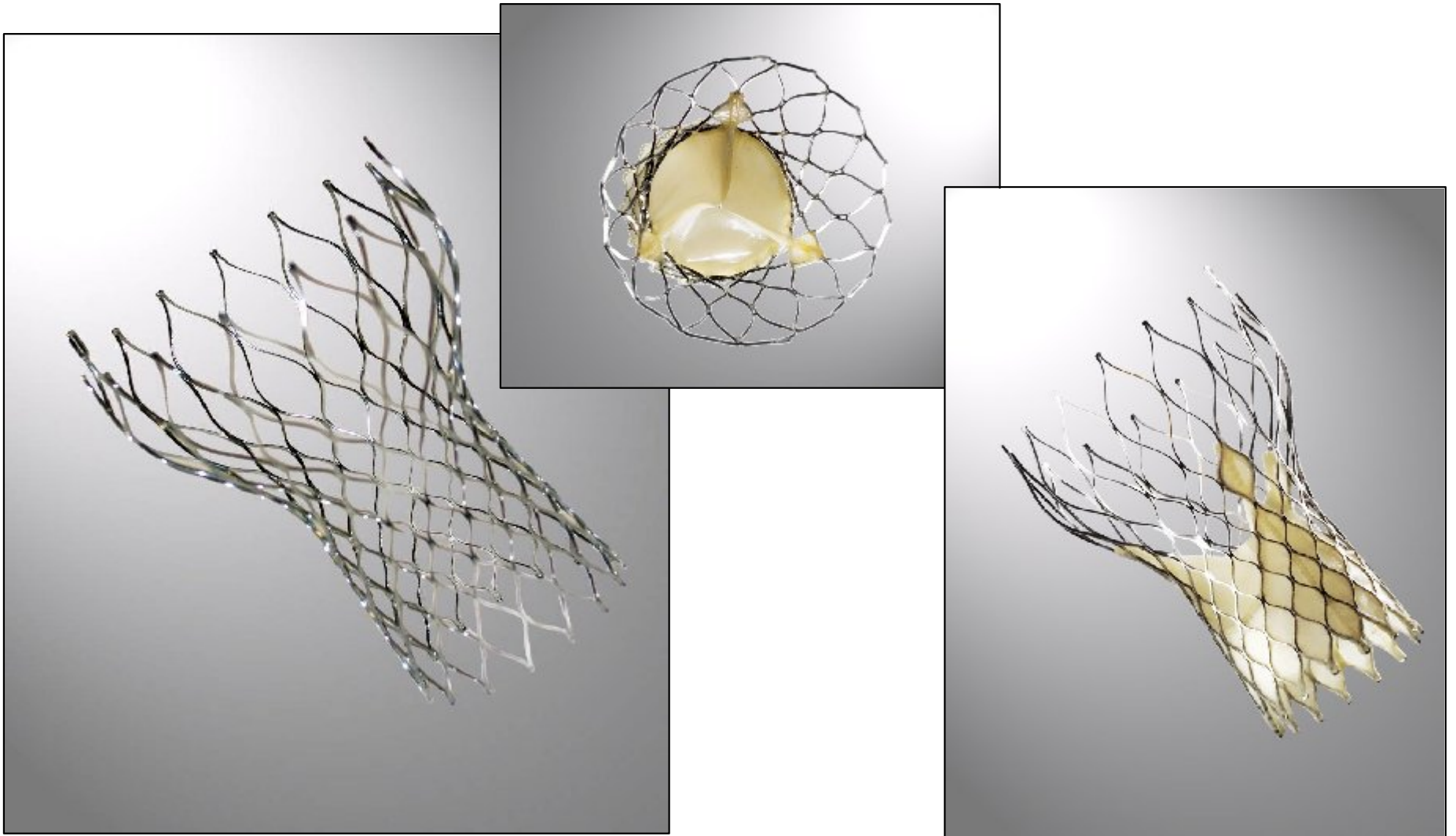


- ❑ There is an important breakthrough for replacing the aortic valve called Percutaneous Aortic Valve Replacement
- ❑ The diseased valve is pushed aside by inflation of a balloon
- ❑ The new valve is advanced into position from a small hole made in the groin or a small incision in the chest
- ❑ Sometimes general anaesthesia is used
- ❑ There is no major incision in the chest and a heart lung machine is not used
- ❑ Recovery is quicker
- ❑ Many patients who have previously been turned down for surgery or are very high risk may now be treated

CoreValve Components

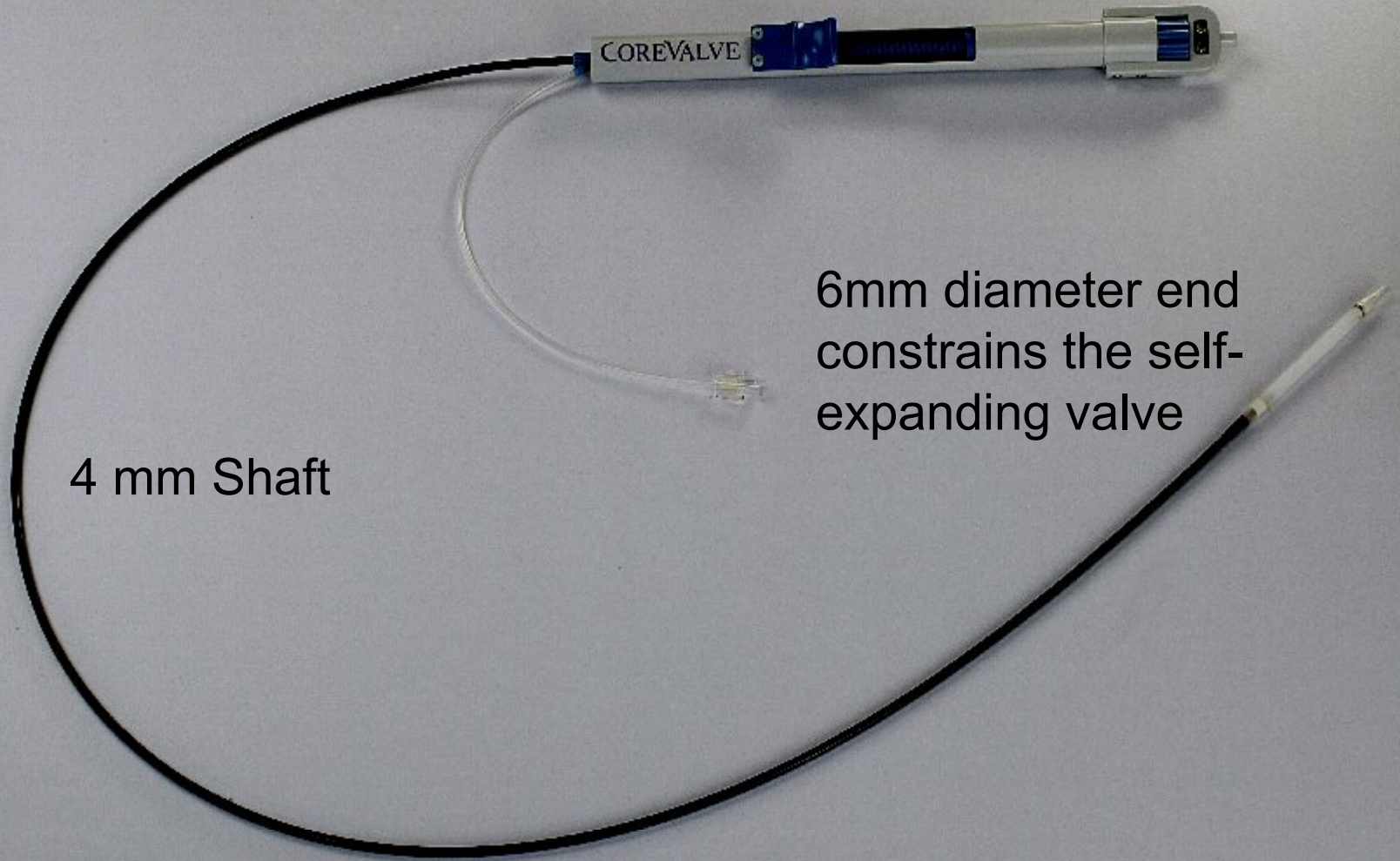
A self-expanding metal (Nitinol) frame

The leaflets are made from porcine pericardium (pericardium is a thin sack in which the heart lies)



CoreValve for percutaneous aortic valve delivery system

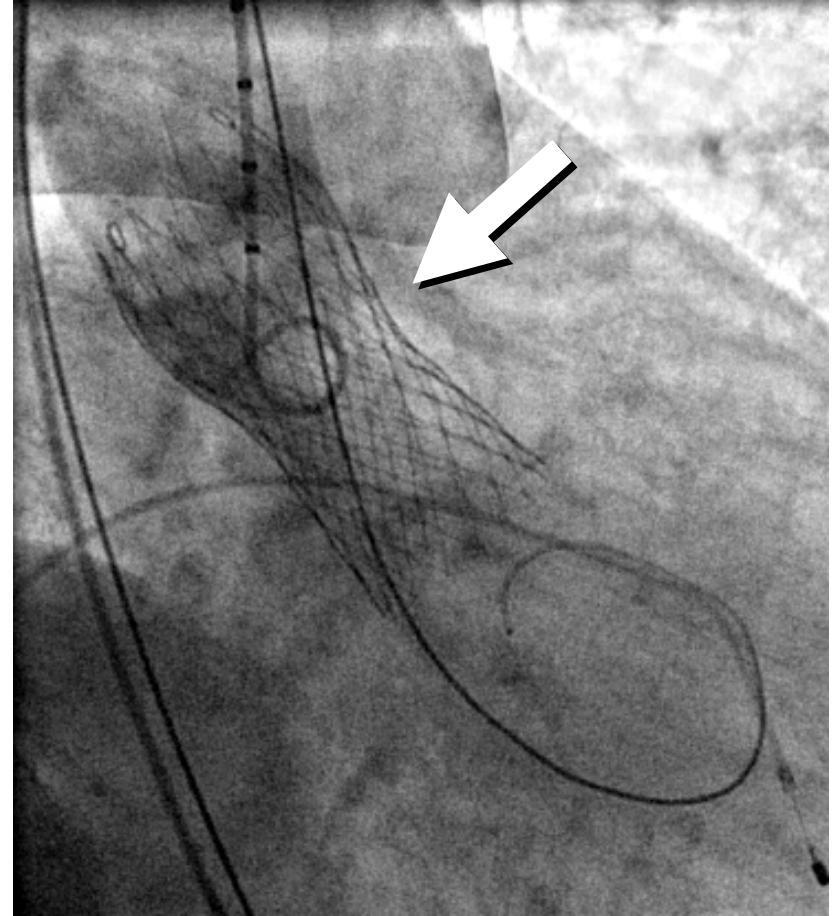
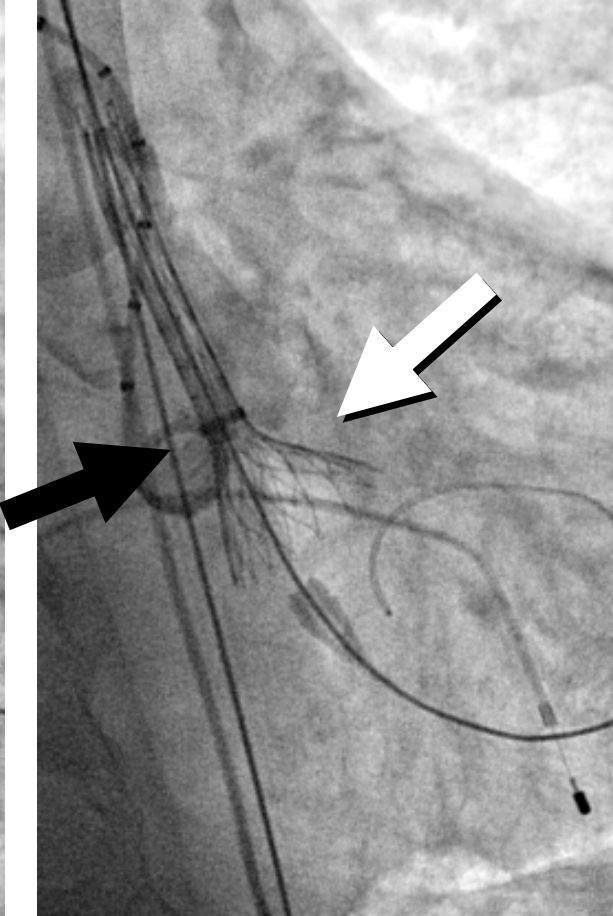
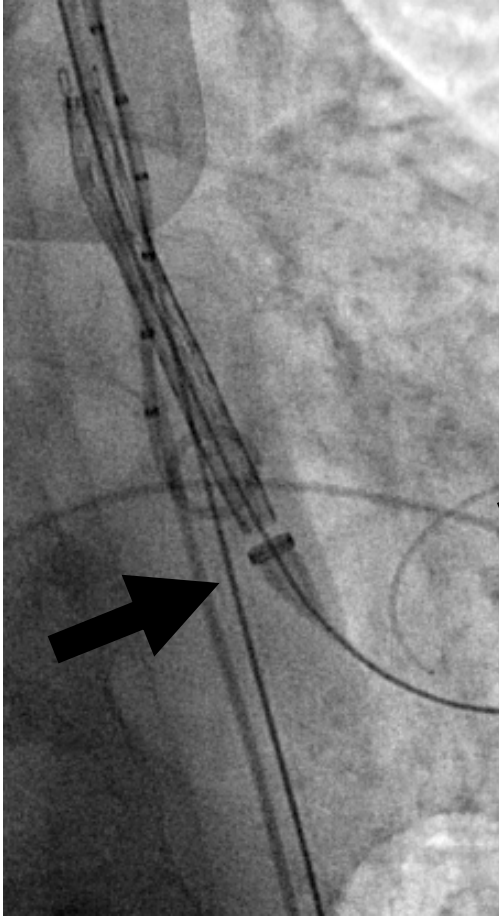
Release Handle



6mm diameter end
constrains the self-
expanding valve

4 mm Shaft

With the device across the diseased valve, the sheath is withdrawn (black arrow) so that the self-expanding frame is no longer constrained and can open up (white arrow)



Outcomes with CoreValve aortic valve replacement

- Delivery abolishes the aortic valve narrowing
- Important valve leakage is rare
- There is a 90% chance of achieving this without death or stroke
- Almost all patients have improvement in symptoms
- Tissue heart valves deteriorate with time but so far this has not been observed with the CoreValve but only a few patients have had the valve for more than 3 years

Outcomes from the CoreValve Registry in very high risk patients

Procedural

Number of patients =1243

Procedural death	1.7%
Blood collection around and compressing on the heart	1.4%
Vascular access complications	2.3%
Conversion to surgery	0.6%

30 day outcomes

Number of patients=646

Death	6.7%	(cardiac 3.9%)
Permanent pacemaker	12.2%	
MI	0.7%	
Stroke	1.4%	

There is a 92% chance of successful implantation without death or stroke

- ❑ Implantation problems with the CoreValve are rare and, in the unlikely event that they occur, it will not be possible to convert to conventional heart surgery
- ❑ In the unlikely event that we might wish to transfer a patient to Cardiovascular Intensive Care at Auckland City Hospital, a bed may not be available

After the procedure

- Patients will go to an intensive care ward
- They will have a urinary catheter (until they are mobile), an IV line, a temporary pacemaker in a neck vein, and may need a mask or nasal prongs for oxygen.
- Patients are usually their feet the same day or the next day
- After intensive care, patients will go to a less intensive monitoring situation. They will have chest ECG leads and two small boxes to carry around (one to transmit ECG signals to a central station and another to pace the heart if necessary)
- There may be bruising in the groin
- There will be a consultation on rehabilitation
- Hospital stay may be about 5-6 days after the procedure

- ❑ The CoreValve has been shown to be a safe and effective percutaneous procedure in patients considered unsuitable or very high risk for surgical valve replacement
- ❑ The ongoing registry will determine durability