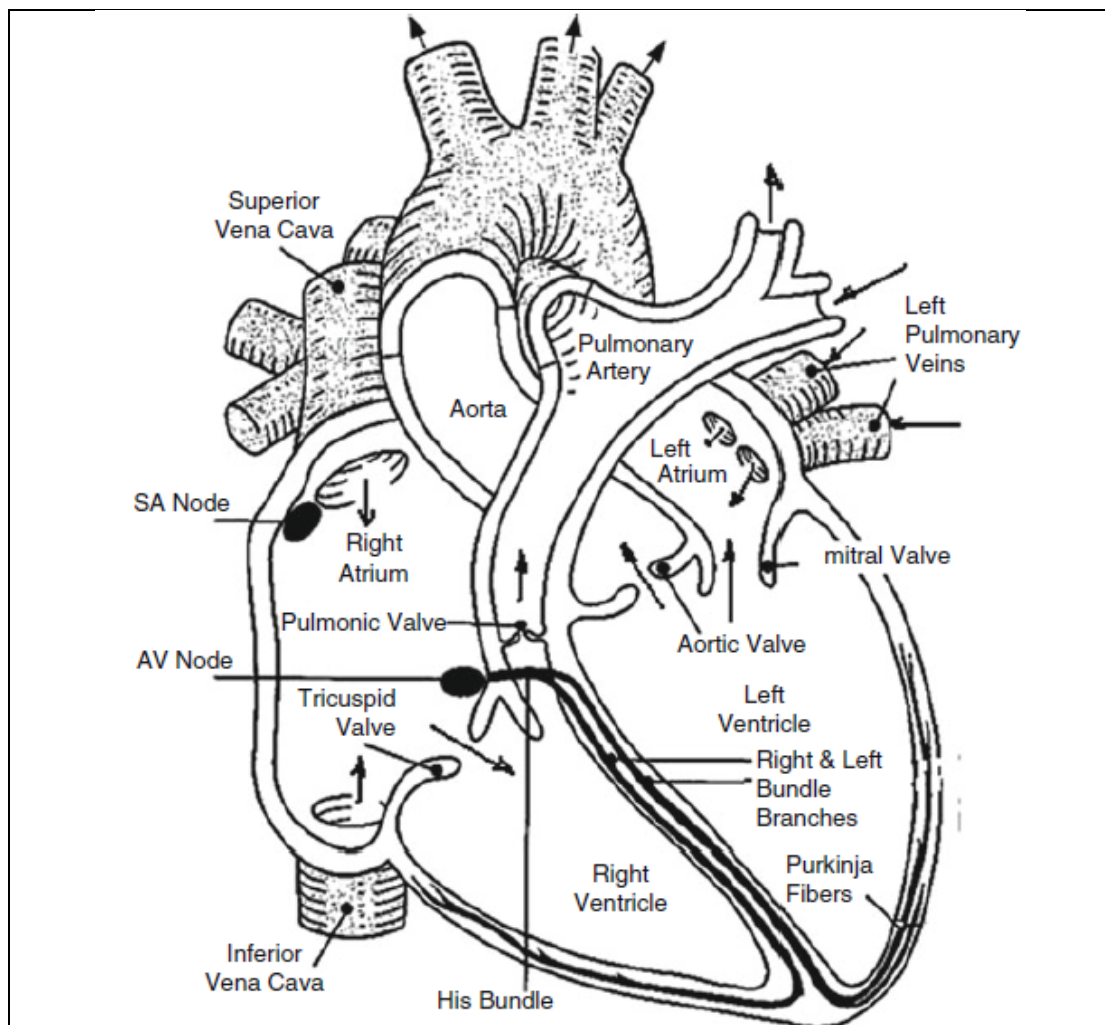


## Lecture # 3

# Design of the Total Artificial Heart

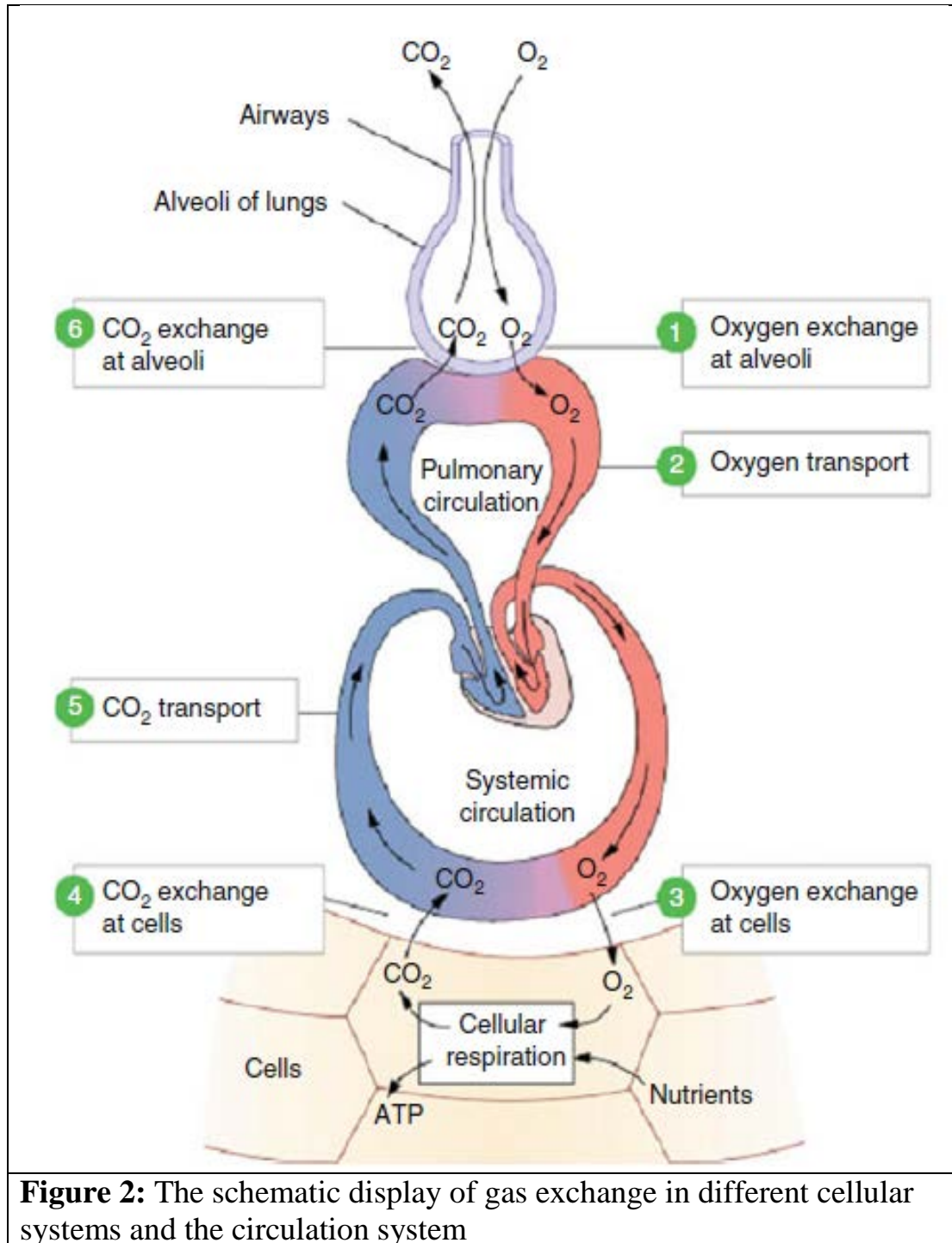
## 1. Introduction

An **artificial heart** is a mechanical device that is implanted into the body to replace the biological heart. The term “artificial heart” has often inaccurately been used to describe ventricular assist devices (VADs), which are pumps that assist the heart but do not replace it. A clean view of the normal heart is shown in Figure 1.



**Figure 1:** A schematic longitudinal sectional view of the human heart

An artificial heart is also distinct from a cardiopulmonary bypass machine (CPB), which is an external device used to provide the functions of both the heart and lungs. CPBs are only used for a few hours at a time, most commonly during open heart surgery (Figure 2).



**Figure 2:** The schematic display of gas exchange in different cellular systems and the circulation system

## 2. Total-Replacement Artificial Hearts and Ventricular

### Assist Devices

Variations of the configurations of artificial hearts are shown in Figure 3.

- Pneumatic driven pulsatile VAD for hospital use.
- Pneumatic/hydraulic driven pulsatile VAD on a portable carry.
- Electro-hydraulic total-replacement artificial heart (TAH).
- Implantable pulsatile VAD with electro-magnetic driver.
- Implantable rotary VAD with mechanical bearings.
- Implantable rotary VAD with non-contact bearings.

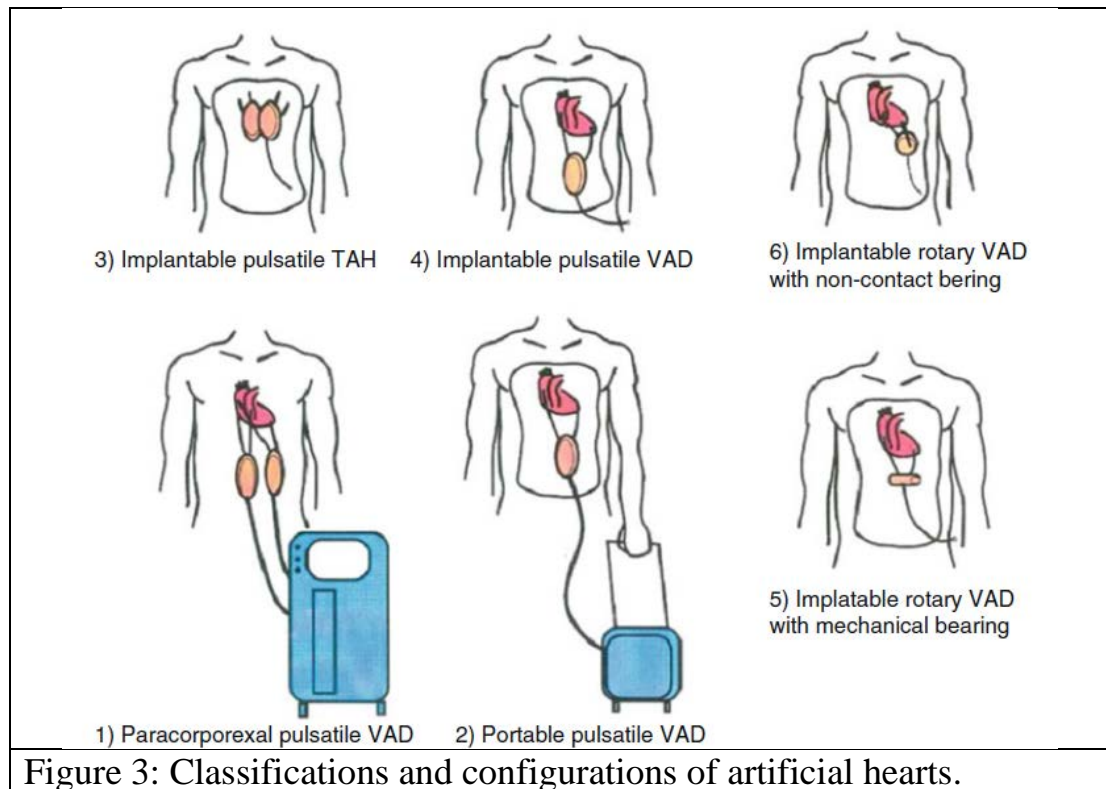


Figure 3: Classifications and configurations of artificial hearts.

The applicable pump mechanisms can be roughly classified into one with valves, one with rotary valves, and one without valves (Figure 3). Using technical terms, they are:

1. Pulsatile flow pump (Reciprocating pump): A type generating pulsatile flow by a reciprocating motion of a diaphragm with the aid of valves. Most of the early VADs were pulsatile flow pumps. Another pulsatile type drives flow through a bucket relay with small



compartments, which is sometimes called a rotary displacement pump. For example, a roller pump or a tube pump is used as a surgical pump.

2. Continuous flow pump (Rotary pump or Turbo pump): A type generating a continuous flow and a constant pressure with a constant rotational speed without valves. Most of the recent VADs are continuous flow pumps.

From a stand of clinical use, naming of pulsatile flow pumps and continuous flow pumps are often used to describe the blood flow characteristics.

Concrete pump configurations are listed in Figure 4. For clinical use only a diaphragm pump, a pusher-plate pump, a roller pump, a centrifugal pump and an axial-flow pump have been applied so far.

A pulsatile flow pump drives a certain amount of blood with a stroke and determines flow rate, namely volume/time. On the other hand, a continuous flow pump generates a certain amount of pressure and the flow rate is determined by the body circulatory resistance, namely the patient's condition.

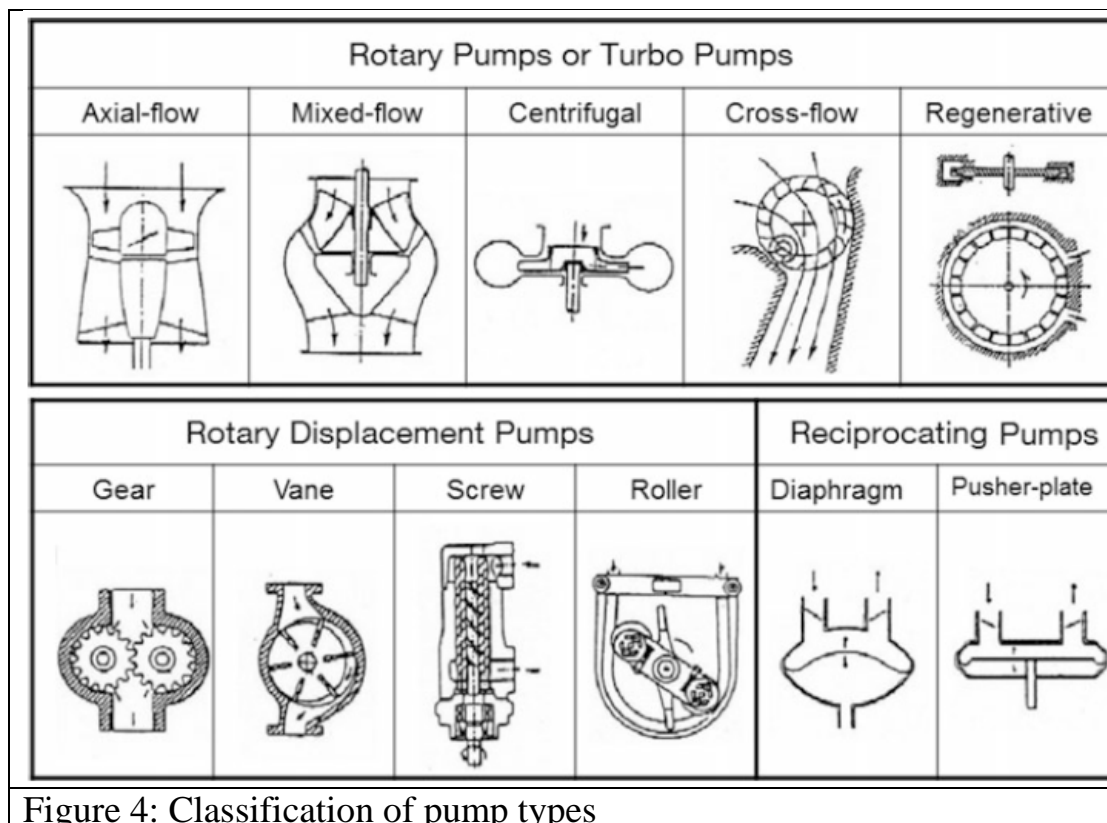
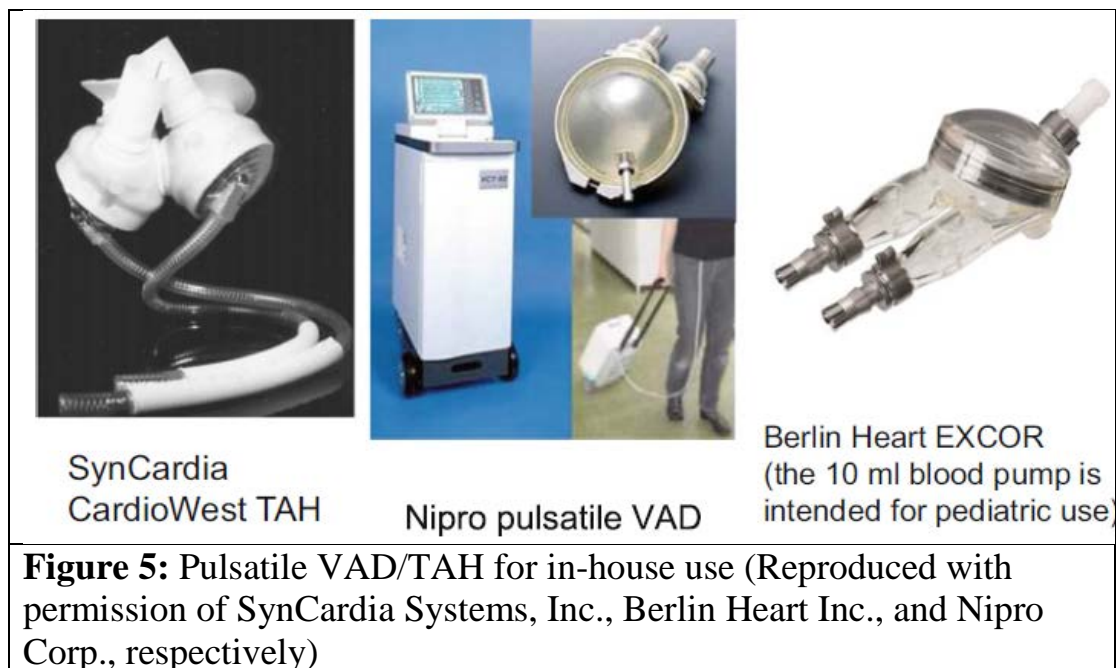


Figure 4: Classification of pump types



### **3. Generation Progress of Implantable Ventricular Assist Devices**

The initial concept of an artificial heart was a total replacement of a natural heart since there was no extra space in the thorax surrounded by breast bones. It was called as a total-replacement artificial heart or a total artificial heart (TAH), which is accompanied by removal of a natural heart. The first application to human was in 1969. The second use was a clinical trial of Jarvik-7TAH in 1981 after the mutuality of biocompatible materials. Though many total-replacement artificial hearts have been developed with pneumatic pulsatile mechanism, covering all of them is not the purpose of the present book. A landmark was thought to be the 'Abiocor' of an electro hydraulic pulsatile pump whose pump and energy transmitting coils were totally implanted. One of the presently available TAHs is SynCardia 'CardioWest', which was formally called 'Jarvik-7', and can now be used as temporary TAH (Figure 5). Recent epoch making research is that two rotary pumps were used as a function of a total-replacement heart.



Then a new application preserving a natural heart and bypassing the left ventricle emerged, which is called a ventricular assist device (VAD). This type became recently a standard care for serious heart patients. Typical Japanese pulsatile VAD in-house use is Nipro VAD and is applied mainly before long-term implantable VADs (Figure 5).



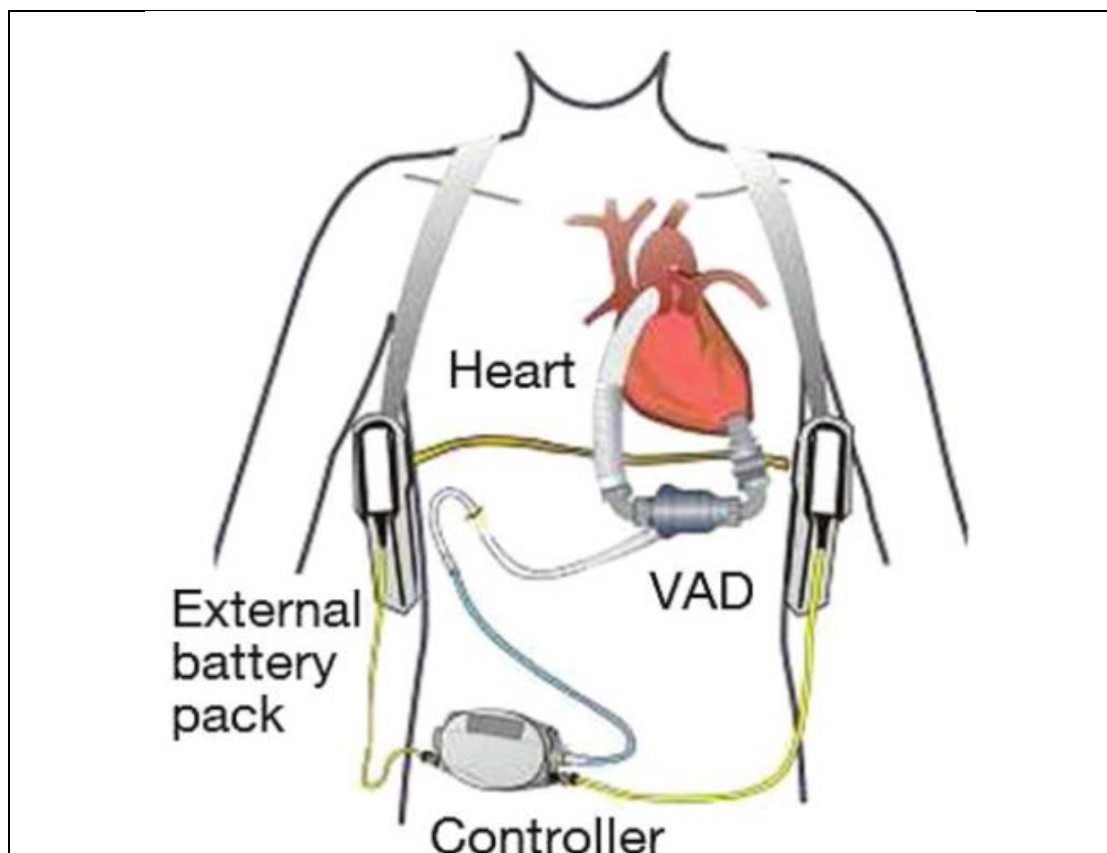
The progress of implantable VADs can be classified into three generations:

**The first generation** of implantable VAD was implantable pulsatile VADs with electro-magnetic driver. Since their weight was more than 1 kg, they were applicable to patients who weigh more than 80 kg.

**The second generation** was brought by the emergence of rotary VADs with mechanical bearings, corresponding item (5). An innovation occurred in size of a blood pump and enabled patients to go out of hospital.

**The third generation** was brought by non-contact bearings. It extended dramatically the durability of VADs and enabled patients to return jobs and to use the VAD permanently.

A typical configuration of presently available VADs is shown in Figure 6. A ventricular assist system is composed mainly of a blood pump, a controller, and external batteries. A patient usually carries two batteries and charges other two batteries. Each battery can supply usually for more than 8 h.

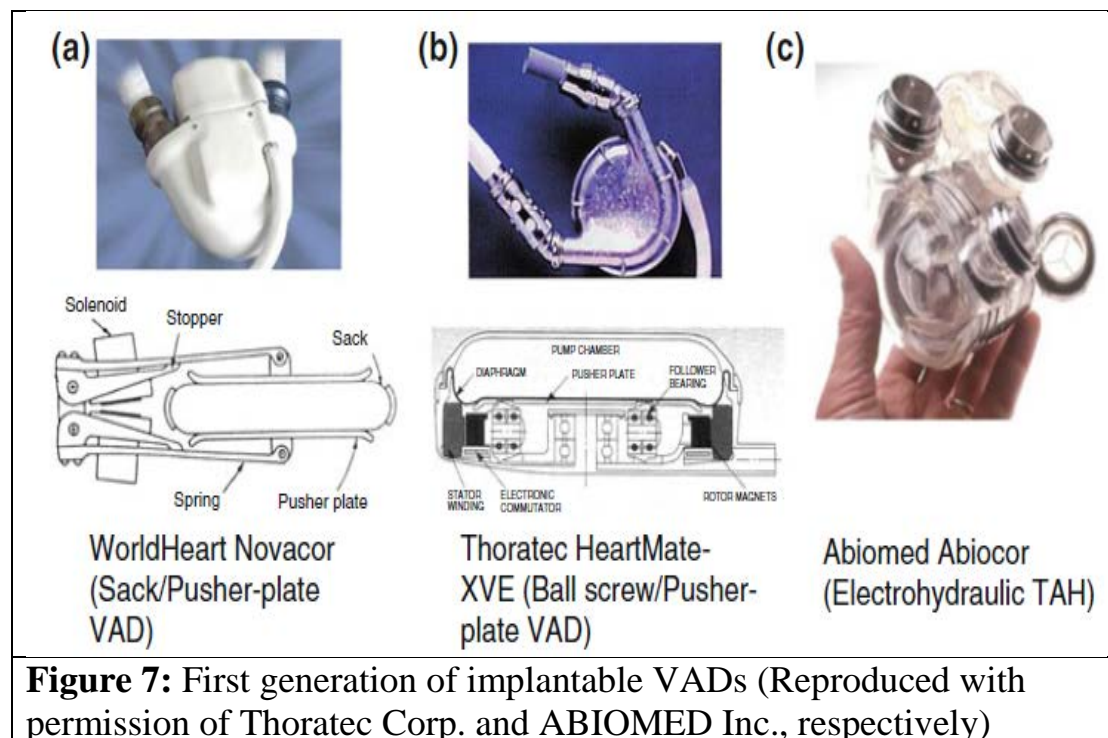


**Figure 6:** Recent configuration of an implantable VAD, example of HeartMate II (Reproduced with permission of Thoratec Corp.)

#### **4. Practical Artificial Hearts: 1st to 3rd Generation**

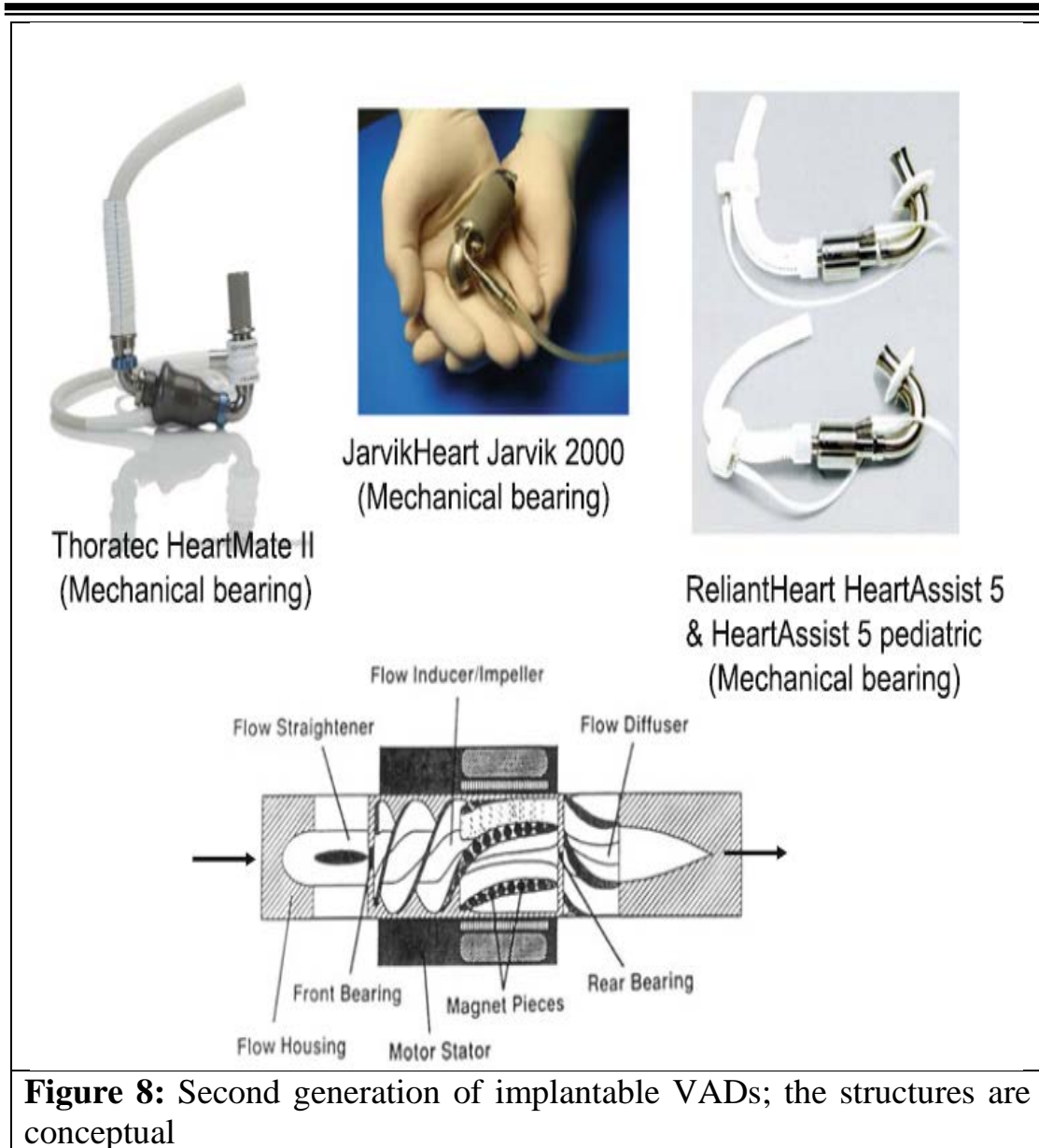
A diaphragm type in hospital use is driven pneumatically and composed of blood pumps, a console, and blood/air tubes. It is driven through a polymer diaphragm by switching compressed air/vacuum. Typical devices are the Nipro VAD, the Abiomed AB5000, and the Berlin Heart EXCOR including pediatric use.

**The first generation of implantable VADs** consists of pulsatile pumps. A pusher plate type squeezes and expands a polymer sack with hard plates. WorldHeart ‘Novacor’ used a pusher plate with an electromagnet and Thoratec ‘HeartMate XVE’ with a ball screw (Figure 7). Novacor was implanted to more than 1800 patients before 2008 and HearMateXVE to more than 4600 patients over the world. As a total replacement heart (TAH), the Abiomed ‘Abiocor’ obtained FDA humanitarian device exemption (HDE) approval in 2006, which push/pulls blood through a polymer diaphragm using silicone oil, which is called an electrohydraulic type.



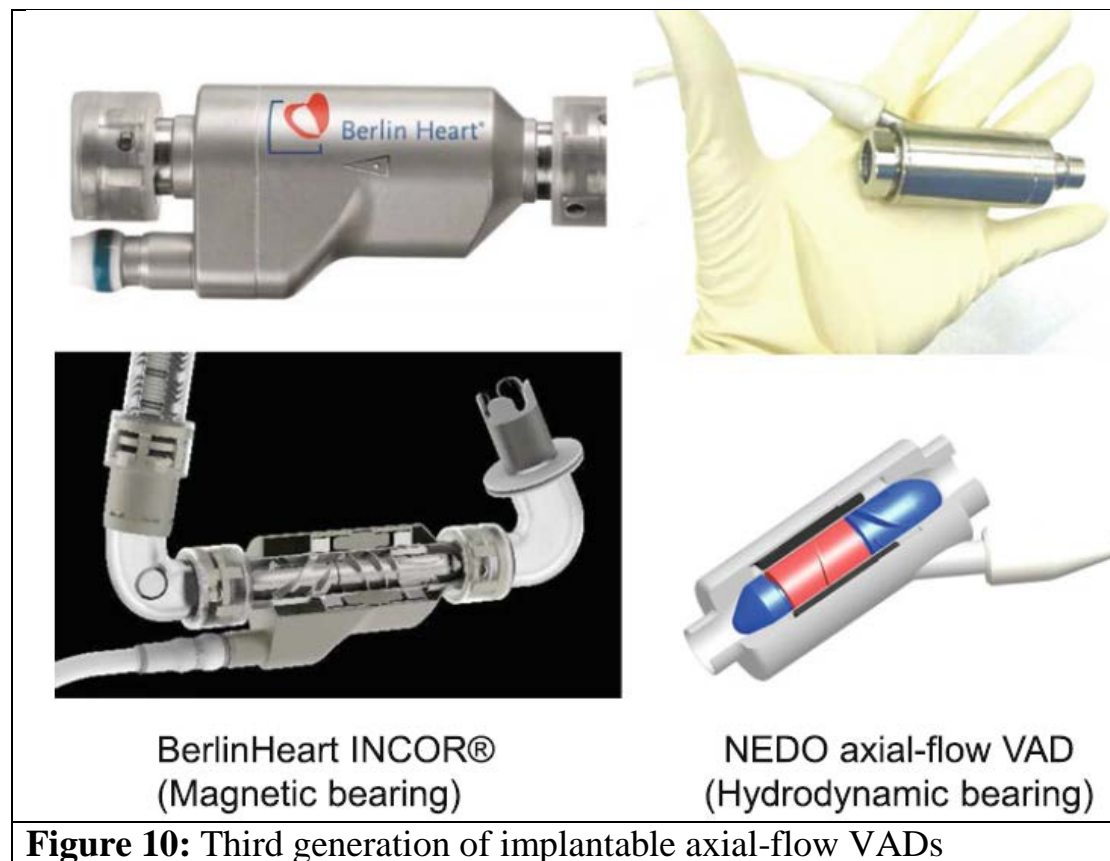
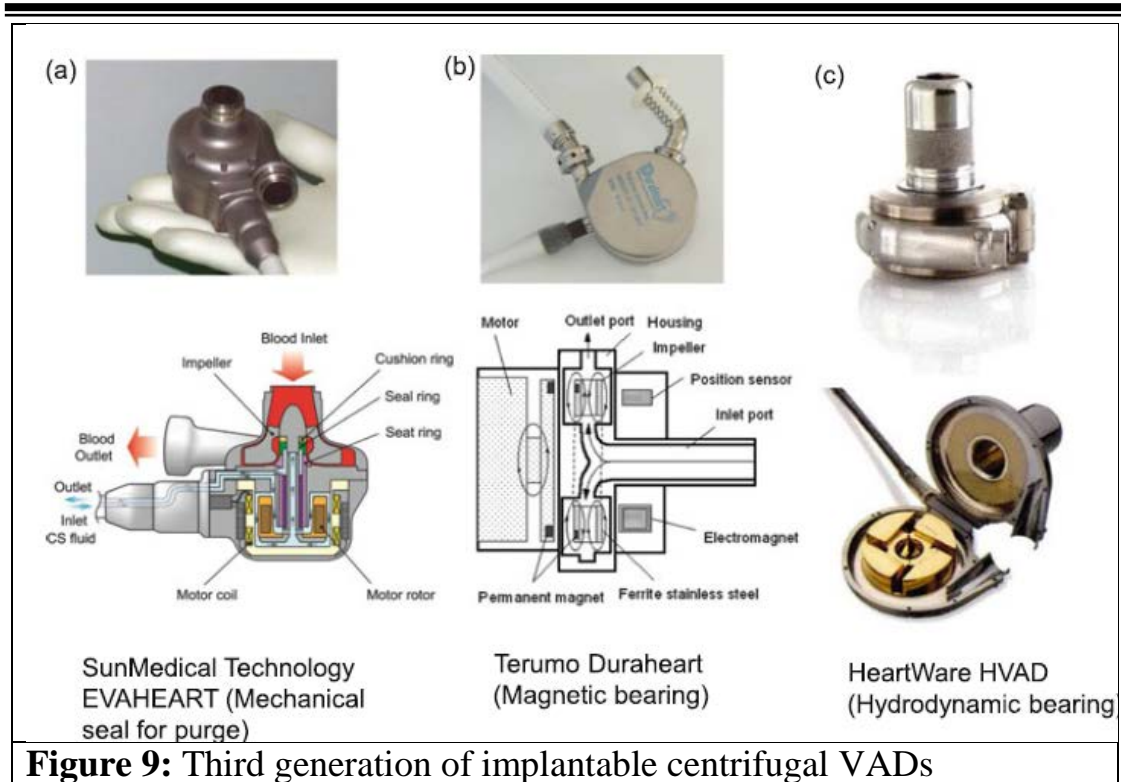
**Figure 7:** First generation of implantable VADs (Reproduced with permission of Thoratec Corp. and ABIOMED Inc., respectively)

**The second generation of VADs** consists of implantable rotary pumps with mechanical bearings. Most of them are axial-flow-pumps such as the JarvikHeart ‘Jarvik-2000’, the Thoratec ‘HeartMate-II’, and the ReliantHeart ‘HeartAssist 5’ which was originally developed by NASA and Baylor College of Medicine (Figure 8).

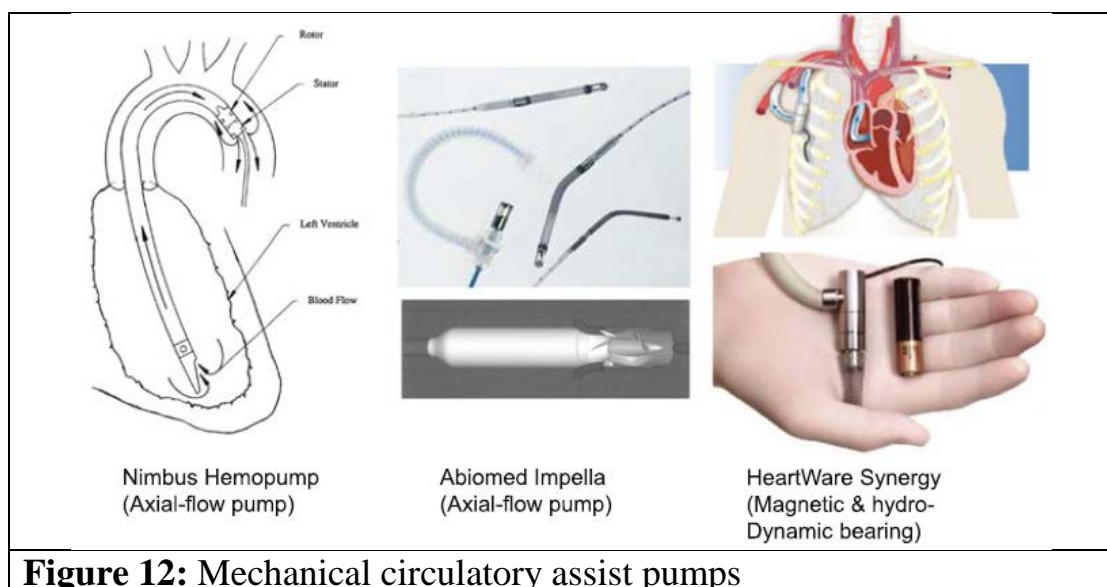
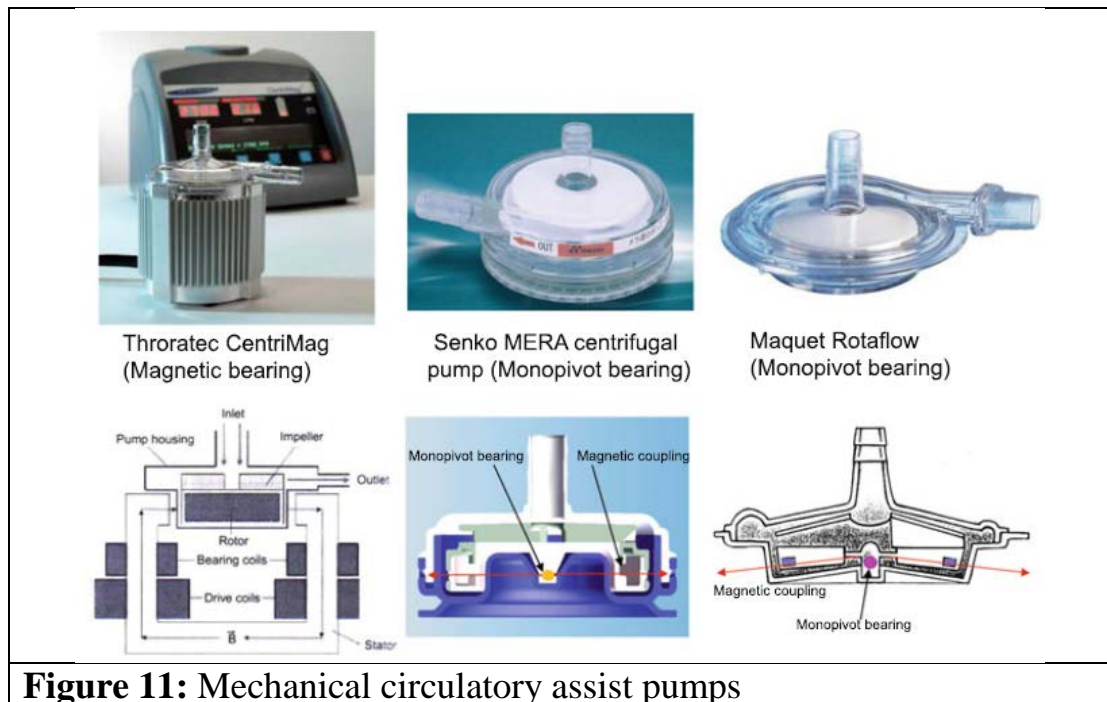


The third generation devices consist of implantable rotary VADs with non-contact bearings. Most of them are centrifugal-pumps such as the Terumo ‘DuraHeart’ using a magnetic bearing, the Sun Medical ‘EVAHEART’ using hydrodynamic bearing/mechanical seal, and the Heart Ware ‘HVAD’ using hydrodynamic bearing (Figure 9). Axial flow pumps have also been developed such as BerlinHeart ‘INCOR’, and ‘NEDO pump’ though being in a development stage (Figure 10).



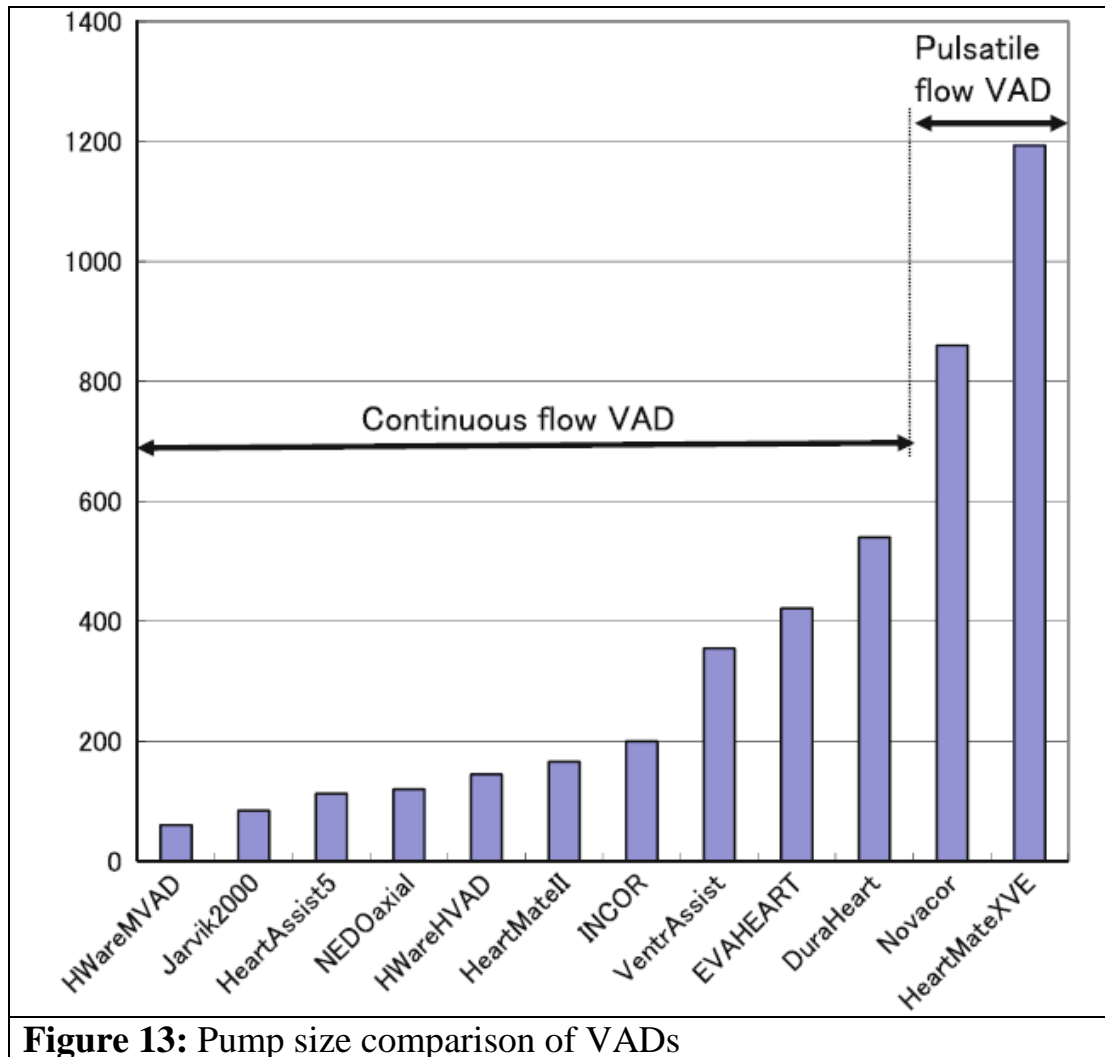


Recently mechanical circulatory assist pumps have also become necessary for the term before VAD implantation. Thoratec ‘CentriMag’ conducted clinical trial as a short term VAD. Other candidates are emerging such as Maquet ‘Rotaflow’ or SenkoMedical ‘MERA centrifugal pump’ (Figure 11). Recently, a small implantable pump are developed for a partial circulatory assist such as HeartWare ‘Synergy’. For emergency use, Abiomed ‘Impella’, a small axial flow pump, has been used like a balloon pump (Figure 12).





A pump size comparison of VADs is shown in Figure 13. It can be understood that recent implantable VADs weigh around 100 g though the early implantable VADs weigh more than 1000 g.



**Figure 13:** Pump size comparison of VADs

Clinical application of pulsatile flow and continuous flow VADs in the USA is shown in Figure 14. In almost all cases, continuous flow VADs have been applied after 2010. They are used as bridge to transplantation (BTT) and bridge to candidacy (BTC), which means that an unqualified patient used VADs to improve his/her condition to qualification.

