

Chapter 2

What Kinds of Artificial Hearts Are Available?

2.1 Population of Heart Patients

The patient statistics in Japan is introduced first. 310,000 people died of cerebro-cardiovascular diseases annually. 300,000 patients are saved with physical treatment such as a stent therapy. 40,000 patients are saved with surgical operation using extracorporeal circulation. More than 400 patients are registered for heart transplantation at present and heart donors can be found less than 40 a year. Therefore roughly 260 or more patients should depend on ventricular assist devices. Actually ventricular assist devices are used for 140 patients a year.

2.2 Total-Replacement Artificial Hearts and Ventricular Assist Devices

Variations of the configurations of artificial hearts are shown in Fig. 2.1.

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

The applicable pump mechanisms can be roughly classified into one with valves, one with rotary valves, and one without valves (Fig. 2.2). 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

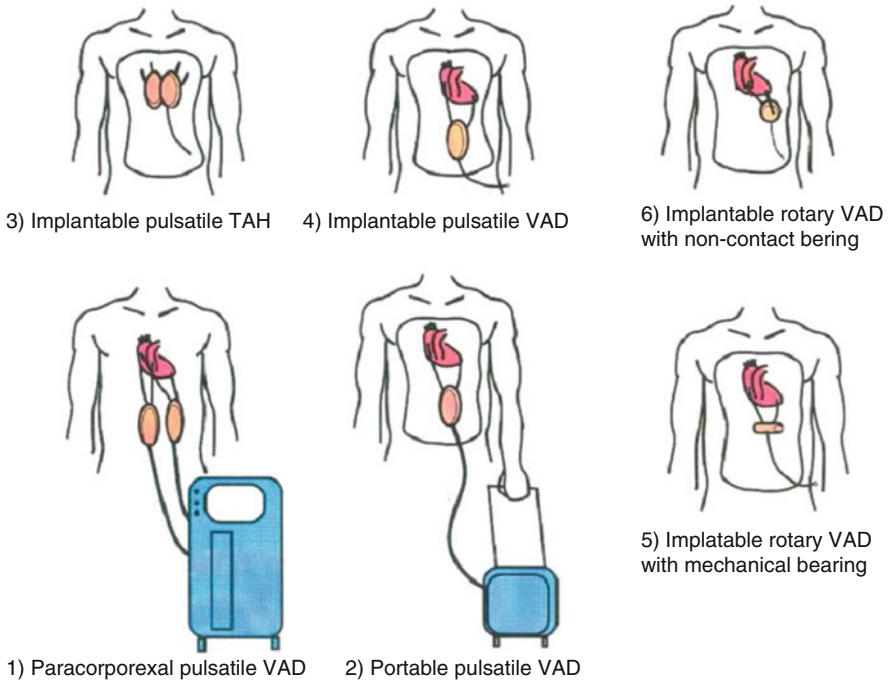


Fig. 2.1 Classifications and configurations of artificial hearts

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 Fig. 2.2. 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.

2.3 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

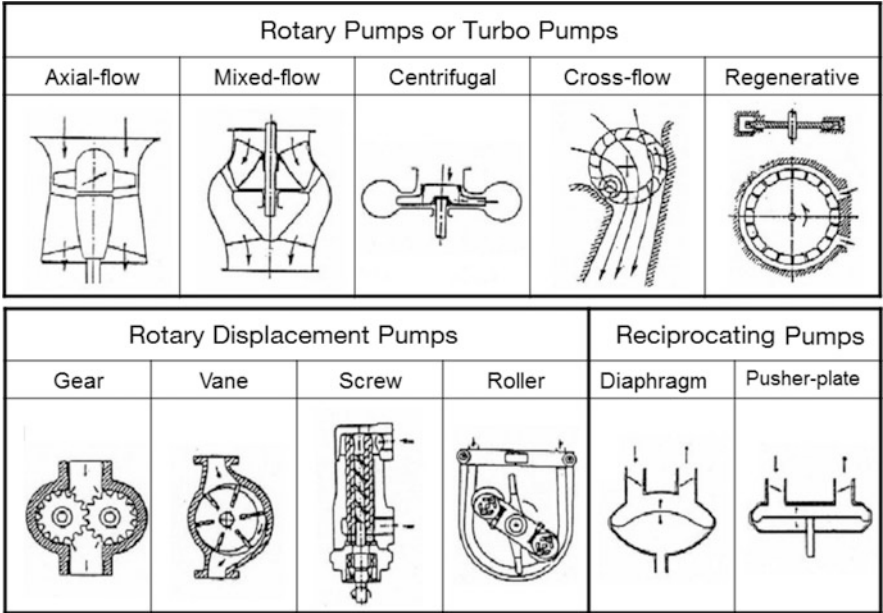


Fig. 2.2 Classification of pump types

accompanied by removal of a natural heart. The first application to human was in 1969. The second use was a clinical trial of Jarvik-7 TAH in 1981 after the maturity 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 ‘Abiomed’ 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 (Fig. 2.3). Recent epoch making research is that two rotary pumps were used as a function of a total-replacement heart.

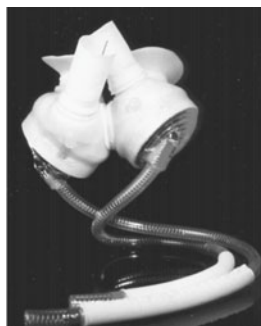
Then a new application preserving a natural heart and bypassing the left ventricle emerged, which is called a ventricular assist device (VAD). This type became recently a standard care for serious heart patients. Typical Japanese pulsatile VAD in-house use is Nipro VAD and is applied mainly before long-term implantable VADs (Fig. 2.3).

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, corresponding above item (4). 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, corresponding item (6). It extended dramatically the durability of VADs and enabled patients to return jobs and to use the VAD permanently.



SynCardia
CardioWest TAH



Nipro pulsatile VAD



Berlin Heart EXCOR
(the 10 ml blood pump is
intended for pediatric use)

Fig. 2.3 Pulsatile VAD/TAH for in-house use (Reproduced with permission of SynCardia Systems, Inc., Berlin Heart Inc., and Nipro Corp., respectively)

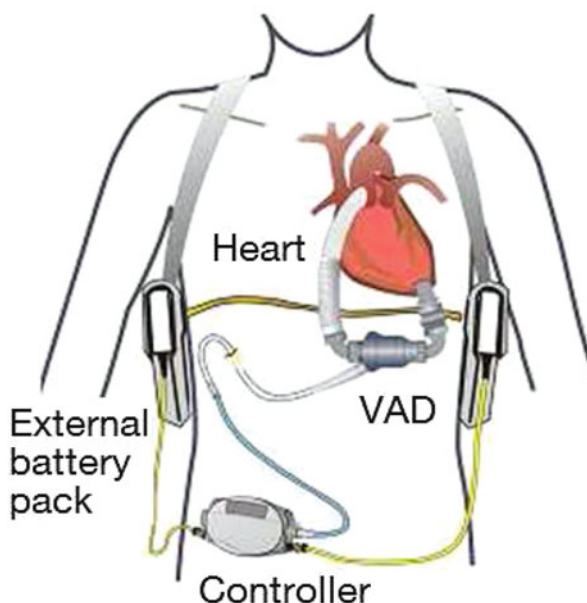


Fig. 2.4 Recent configuration of an implantable VAD, example of HeartMate II (Reproduced with permission of Thoratec Corp.)

A typical configuration of presently available VADs is shown in Fig. 2.4. 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.

2.4 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 BerlinHeart 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 (Fig. 2.5). Novacor was implanted to more than 1800 patients before 2008 and HeartMate XVE 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.

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 (Fig. 2.6).

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 SunMedical ‘EVAHEART’ using hydrodynamic bearing/mechanical seal, and the HeartWare ‘HVAD’ using hydrodynamic bearing (Fig. 2.7). Axial flow pumps have also been developed such as BerlinHeart ‘INCOR’, and ‘NEDO pump’ though being in a development stage (Fig. 2.8).

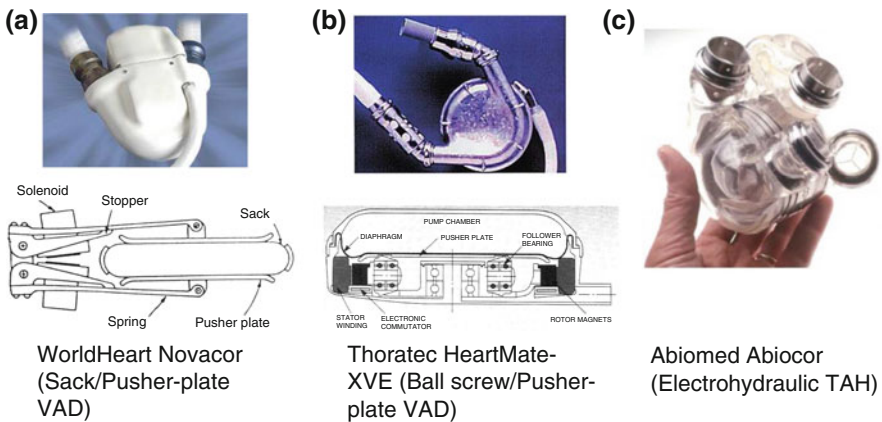


Fig. 2.5 First generation of implantable VADs (Reproduced with permission of Thoratec Corp. and ABIOMED Inc., respectively)



Thoratec HeartMate II
(Mechanical bearing)



JarvikHeart Jarvik 2000
(Mechanical bearing)



ReliantHeart HeartAssist 5
& HeartAssist 5 pediatric
(Mechanical bearing)

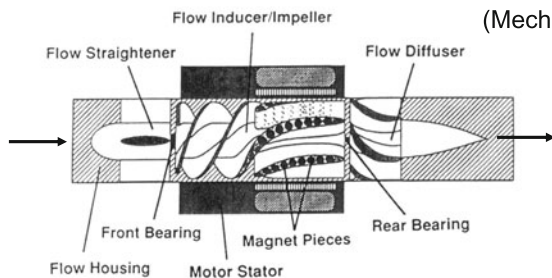
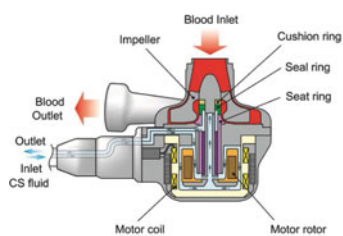
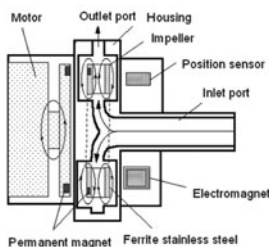
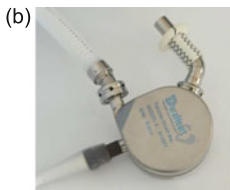


Fig. 2.6 Second generation of implantable VADs; the structures are conceptual (Reproduced with permission of Wiley [1], Thoratec Corp., Jarvik Heart, Inc., and ReliantHeart Inc., respectively)



SunMedical Technology
EVAHEART (Mechanical
seal for purge)



Terumo Duraheart
(Magnetic bearing)



HeartWare HVAD
(Hydrodynamic bearing)

Fig. 2.7 Third generation of implantable centrifugal VADs; the structures are conceptual (Reproduced with permission of Sun Medical Technology Research Corp., Tokyo Women's Medical University, Terumo Corp., and HearWare Inc., respectively)

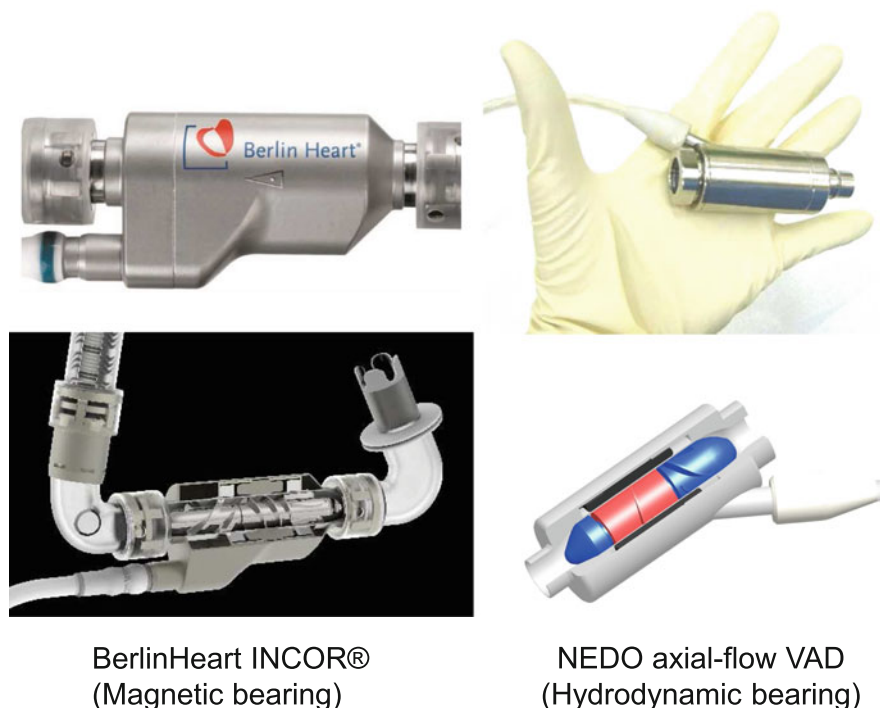


Fig. 2.8 Third generation of implantable axial-flow VADs; the structures are conceptual (Reproduced with permission of Berlin Heart Inc. and NEDO, respectively)

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’ (Fig. 2.9). 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 (Fig. 2.10).

A pump size comparison of VADs is shown in Fig. 2.11. It can be understand that recent implantable VADs weigh around 100 g though the early implantable VADs weigh more than 1000 g.

Clinical application of pulsatile flow and continuous flow VADs in the USA is shown in Fig. 2.12. 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.

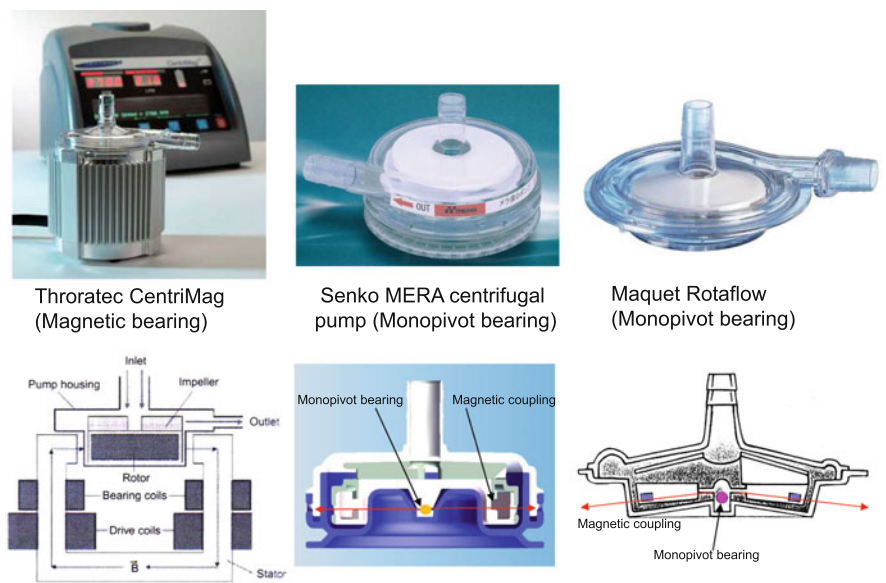


Fig. 2.9 Mechanical circulatory assist pumps (Reproduced with permission of Thoratec Inc., Senko Medical Instrument Mfg. Co., Ltd., and Maquet Gettinge Group, respectively)

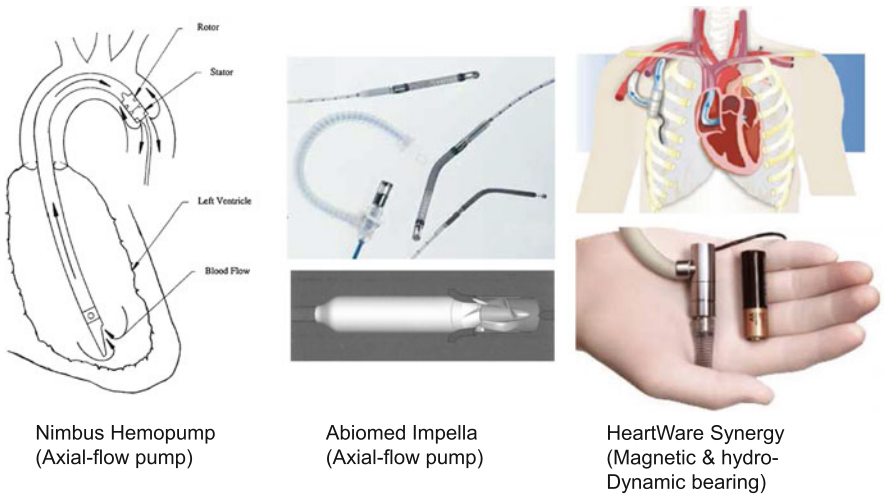


Fig. 2.10 Mechanical circulatory assist pumps [2] (Reproduced with permission of ASAIO/ Walters Kluwer Health Inc., ABIOMED Inc., and HearWare Inc., respectively)

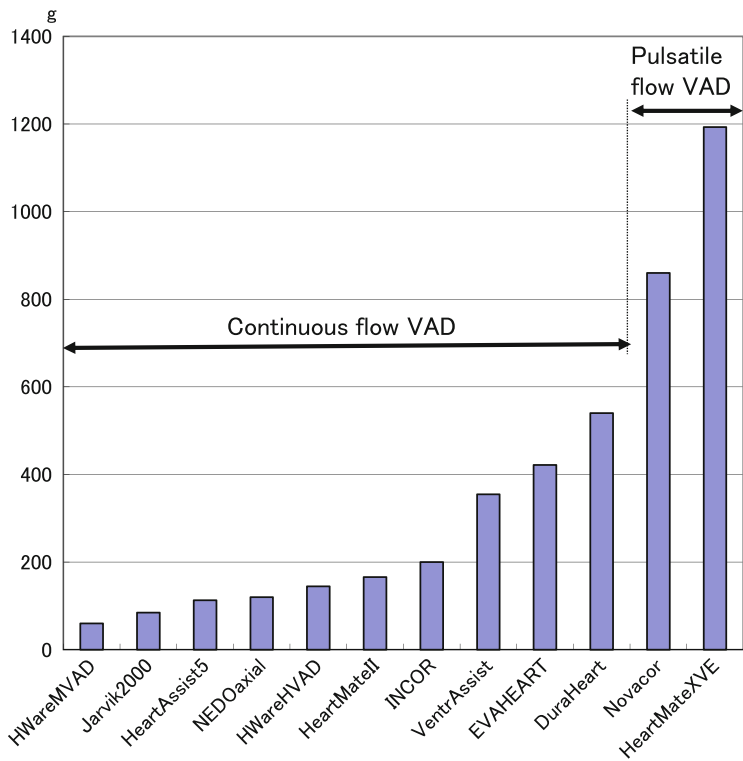


Fig. 2.11 Pump size comparison of VADs

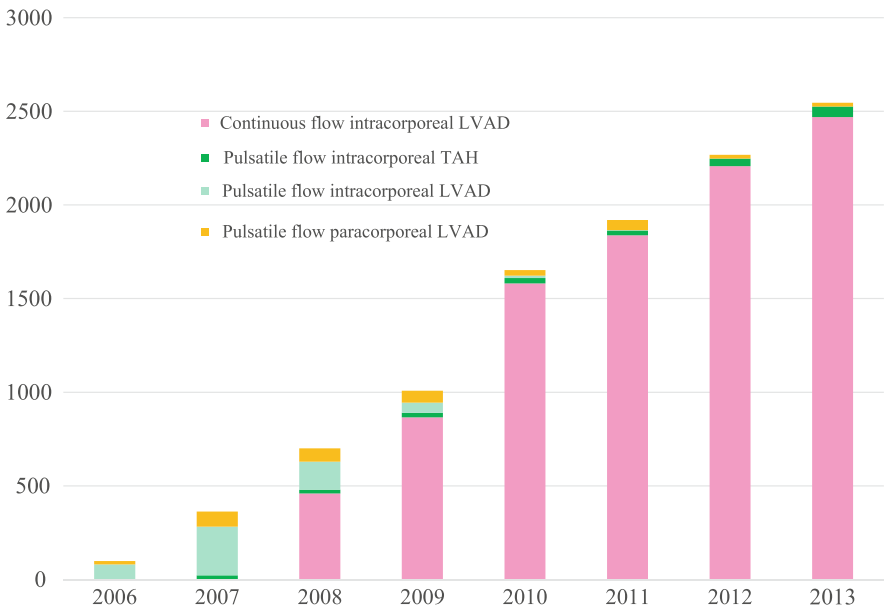


Fig. 2.12 Tendency of clinical application of pulsatile-flow and continuous-flow VADs [3] (Implants data of INTERMACS 2006–2013, N = 10542)

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