

# ArtAssist® Arterial Pump Technology

a product by **ACI Medical, LLC**

## *Executive Summary*

### **ArtAssist® Arterial Pump description**

- **Controller:** operates on mains voltage. Accommodates bilateral or unilateral limb treatment for the upper and lower extremities.
- **Tubing:** reusable; connects the controller to the cuffs
- **Cuffs:** single patient use; durable enough for at least 6 months of therapy



### **Indications for Use**

The ideal candidate for ArtAssist® Arterial Pump therapy has been diagnosed with peripheral arterial disease (PAD) and may suffer from:

- Intermittent claudication
- Critical limb ischemia
- Rest pain
- Ulceration
- Lower & upper extremities

**Typical prescription:** 1 hour T.I.D. (three times per day) for a minimum of 90 days. This recommended regimen allows time for collaterals to form. For severe cases, the ArtAssist® Arterial Pump can be used 6 or more hours per day.

Accommodations for special cases are also possible:

- If foot compression is intolerable, the patient can undergo calf-only compression for approximately 1 week, or until foot compression is tolerable
- Calf and thigh cuffs are available for non-healing below-knee amputation wounds
- Upper extremity cuffs are available
- Though the lower extremity cuff fits almost all patients, smaller cuffs are available for those of petite stature

### **Contraindications for Use**

- Rapidly deteriorating disease/acute ischemia due to arterial blood clots

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- Uncontrolled infection/during episodes of superficial phlebitis, cellulitis or osteomyelitis
- When increased venous and lymphatic return is undesirable, such as in patients with severe congestive heart failure
- When deep vein thrombosis (DVT) or pulmonary embolism exists or is suspected

## **Has the ArtAssist® Arterial Pump been studied in a clinical setting?**

Yes. In fact, with more than 25 clinical studies already conducted on this machine, ArtAssist® Arterial Pump Technology is the only device of its kind to have been designed and optimized for inducing the necessary physiological effects to treat arterial disease.

In addition, ArtAssist® Arterial Pump Technology has been studied for the treatment of Intermittent Claudication and Critical Limb Ischemia. Investigators have also concluded that this technology promotes Arteriogenesis, the permanent opening of collateral arteries.

## **Where does ArtAssist® therapy take place?**

Typically, patients use the ArtAssist® Arterial Pump in the comfort of their own homes so that the prescribed treatment regimen can easily be maintained.

## **For how long should a patient use the ArtAssist® Arterial Pump?**

A prescription for the ArtAssist® Arterial Pump lasts indefinitely. Therefore, upon the physician's recommendation, a patient may do one of two things:

### **Rent**

It is typically recommended that the ArtAssist® Arterial Pump be rented for a period of at least 90 days to allow collateral formation. If the patient needs additional therapy, the pump can be rented on a month-to-month basis thereafter. All accessories are included with the machine, but replacement and repair fees are at the discretion of the distributor.

At the end of therapy, the pump and its accessories are picked up by FedEx or the distributor.

### **Purchase**

A patient can own the pump by purchasing it outright or renting to own. Again, all accessories are initially included, but the patient (or purchasing agent) is responsible for replacement of cuffs, tubing, etc.

## **How do patients finance use of the ArtAssist® Arterial Pump?**

There are many ways a patient can obtain a pump. Here are some of the most popular ways to finance therapy:

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## **Out-of-Pocket**

Some patients are able to afford renting or purchasing the ArtAssist® Arterial Pump with their own funds.

## **Reimbursement by Private Insurance**

If a patient wishes to be reimbursed, the pump is paid for upfront while the patient discusses coverage with his or her private insurance provider.

## **Reimbursement by Public Health Program**

In some cases, government programs such as Medicare can be billed for usage of the pump. This depends on each health care organization's reimbursement policy.

## **Payment by Military/Veteran's Administration**

In the United States, many veteran's health systems are willing to rent or purchase the ArtAssist® Arterial Pump for their veterans to use. In this case, the pump distributor may be able to bill the association directly.

## **How can one distribute the ArtAssist® Arterial Pump?**

Both inside and outside of the United States, durable medical equipment (DME) dealers can request distribution ability from ACI Medical, LLC. A DME dealer has the option of purchasing pumps at a special dealer's price and/or sharing revenue with ACI Medical on each pump rented out.

The main advantage to sharing revenue is the constant access to ACI Medical's latest and best version of ArtAssist® Arterial Pump Technology.

The ArtAssist® Arterial Pump has U.S. FDA allowance to market under section 510(k).

The ArtAssist® Arterial Pump meets electrical safety regulations and has been issued the CE mark.

The ArtAssist® Arterial Pump is manufactured under ISO 13485 quality system certification and ACI Medical (the manufacturer) is a registered medical device manufacturer with the U.S. FDA.



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