

# ArtAssist<sup>®</sup>

THE ARTERIAL ASSIST DEVICE<sup>®</sup>

with *endo/shear*<sup>™</sup>  
for arteriogenesis



**ArtAssist<sup>®</sup>**  
THE ARTERIAL ASSIST DEVICE<sup>®</sup>  
Model AA-1000

Latest evolution targets non-surgical revascularization with EndoShear<sup>™</sup> technology

Home-use therapy

Still the only device optimized for arterial disease

Applies a unique form of intermittent pneumatic compression (IPC)

Still the only device of its kind supported by randomized controlled trials

*endo/shear*<sup>™</sup>  
for arteriogenesis

## CLINICAL STUDIES DEMONSTRATE

- ▶ **86-94%** limb salvage rates on non-reconstructable limbs<sup>44, 45, 59</sup>
- ▶ Promotes **healing** of ischemic foot ulcers (including diabetic)<sup>44, 45</sup>
- ▶ **Resolves** rest pain in 82% of patients within 3 months<sup>27, 45, 59</sup>
- ▶ **Walk Farther<sup>®</sup>**: Doubles and triples walking distance in claudicants<sup>39, 40, 41, 63, 65</sup>
- ▶ Promotes **healing** in amputation sites<sup>11</sup>
- ▶ Increases toe pressure and ABI's through **arteriogenesis**<sup>32, 48</sup>
- ▶ **Positive results** after failed bypass surgeries & endovascular procedures<sup>26, 32</sup>

All references available at:  
[acimedical.com/artassist/clinical-studies](http://acimedical.com/artassist/clinical-studies)

## The ArtAssist® device Re-ordering Parts

### ▶ Controller

AA-1000

### ▶ Tubing Set

# 02-0101--202

### ▶ Cuff Sets

- Standard Leg.....#02-0105-216
- Upper Extremity.....#02-0105-416
- Small Leg.....#02-0105-516
- BKA Thigh & Calf
  - Long.....#02-0105-616
  - Short.....#02-0105-716

### ▶ Power Cord

# 09-0120-001

If ordering from outside of the USA,  
please specify configuration.

**For a more efficient ordering  
process, please have your  
device's serial number ready  
when you call.**

**The serial number is located to  
the left of the power cord input  
and starts with "AD3".**



## Improve blood flow to ischemic limbs with ArtAssist®...The Arterial Assist Device®

**Understanding the underlying physiology of increasing  
arterial flow**

**Designing a device based on this understanding**

**Determining the long-term clinical benefit to patients with  
critical limb ischemia**

With these goals in mind, ACI Medical developed ArtAssist®...The Arterial Assist Device®: revolutionary technology that significantly increases blood flow in the major arteries and at the tissue level.

**The ArtAssist® device applies rapid, high-pressure pneumatic compression to the foot, ankle & calf to increase arterial blood flow**

It is indicated for:

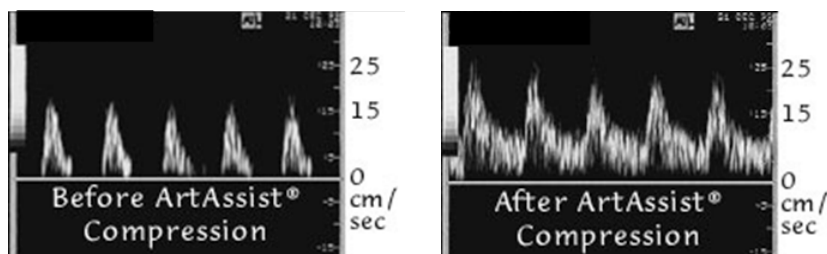
- patients with peripheral arterial disease (PAD) including non-surgical candidates,
- diabetic and non-diabetic arteriopathic foot and leg ulcers,
- after bypass surgery,
- intermittent claudication and rest pain (critical or subcritical ischemia).

There are no known adverse reactions.

**The ArtAssist® device is the first and only external pneumatic compression device optimized for increasing arterial blood flow**

Clinical studies have determined the optimal parameters (timing, pressure, intervals, bladder size and placement, patient position) to maximize blood flow. Arterial blood flow improvements are observed using duplex ultrasonic imaging and at the tissue level in the foot using laser Doppler fluximetry.

### Blood flow increased 3.1 times



**Fig. 1** Doppler imaging in the popliteal artery shows pre-compression and post-compression velocities on a patient with Fem-pop disease.

## The ArtAssist® device improves blood flow by at least **three physiological mechanisms**

1. By compressing all the tissues below the knee, a large volume of venous blood is emptied with the venous pressure dropping close to zero. Arterial pressure is unchanged by compression; therefore, the increased arterial-venous pressure gradient results in greater arterial inflow.

### **Flow = Pressure Gradient / Resistance**

The increase pressure gradient alone does not account for the large blood flow increases; especially the end-diastolic flow shown in **Fig. 1**.

2. A second mechanism for action involves the endothelium. This structure plays an important role in controlling peripheral resistance. Endothelial release of NO causes vasodilation.
3. Perhaps the most important mechanism is arteriogenesis, the opening of collaterals, which have been shown angiographically, with improved ABI's, PVR's and tissue biopsies.

## **Protocol**

Patients rent the ArtAssist® device for home use because it is easy to use and there is no need for a clinician to operate the device. Patients need only turn on one switch (all timing and pressures are preset). The device alarms when therapy is completed. The recommended therapy is one hour, three times a day for at least 90 days to allow time for collateral vessels to form.

## **Clinical Trials**

Randomized controlled trials showed tripling and doubling of pain free walking distances in claudicants. Clinical trials showed 86% to 94% limb salvage rates in non-surgical patients with critical limb ischemia. Visit [acimedical.com/artassist](http://acimedical.com/artassist) for the latest research.

## **Contraindications**

1. During episodes of superficial phlebitis, cellulitis or osteomyelitis
2. When increased venous and lymphatic return is undesirable, such as in patients with severe congestive heart failure
3. When deep vein thrombosis or pulmonary embolism exists or is suspected
4. Acute ischemia due to arterial blood clots

## **Prescription**

- 1 hour, 3 times/day for 90 days (collaterals take 3+ months to open)
- Give Rx to patient with toll free number:  
**888 4 LEG FLO (888 453-4356)**

## **ACI Medical takes care of the rest!**

We work directly with your patients for shipping, billing, proper usage, and answering any questions they may have.

## **Real Life Successes** ▶

“I expect to be walking a golf course again this year. **One year ago, I thought that was a pipe dream!**”

- Don S., Ontario, Canada

“I am very lucky to have found something that has helped me so much, and **I still have my limbs.**”

- Lorraine K., Fargo, ND

“I found, to my relief, that I was able to walk further without pain. It felt good having that sensation pumping and knowing that I was getting more blood to the area and going down to the mailbox to get the mail. After using the ArtAssist® for a period of approximately a week, **I was able to walk up the hill without stopping.**”

- Dr. Fred C., San Diego, CA

“The ArtAssist® device has incorporated the important elements and the **optimization of the hemodynamics**. Namely, the high-pressure inflation, the rapid inflation, the sequence in between foot and calf, and then the repetition at three times each minute.”

- Anthony Comerota, MD, Vascular Surgeon

“[With the ArtAssist® device] we have a double-mechanism that produces such a major increase in the arterial flow...if you have an increase in the arterial flow, the endothelium is stimulated, it produces nitric oxide and **on the long-term, we get a fantastic collateral circulation...** that explains why people, after 2 or 3 months of using it, can double and triple their claudication distance.”

- Andrew N. Nicolaidis, MS, FRCS, Professor of Vascular Surgery

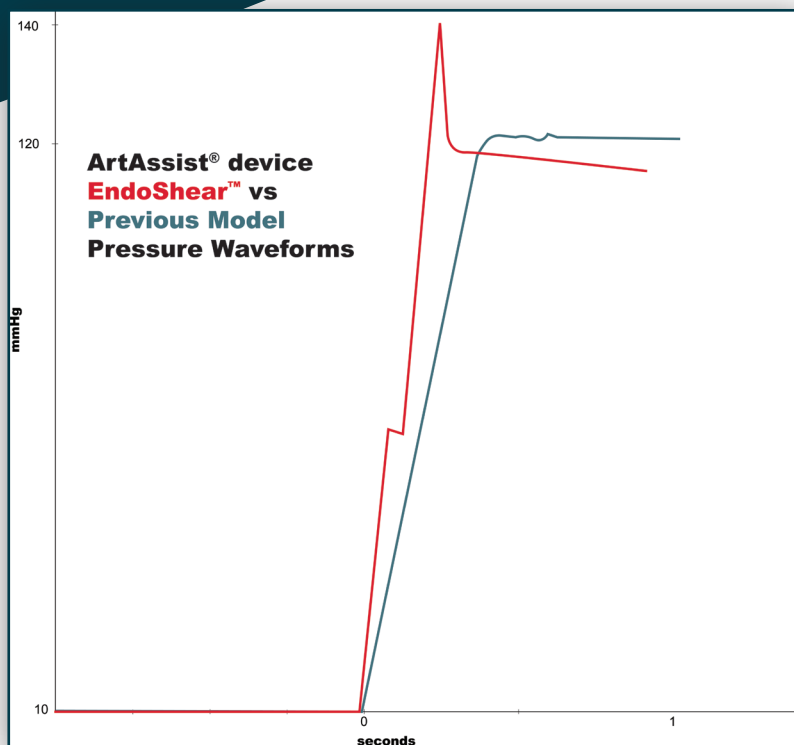
# What is EndoShear™ for Arteriogenesis? ▶

## Functionality

- Optimized for collateral artery growth
- Higher endothelial shear stress means higher chance of long-term benefits
- Multiple compression sequence delivers compression & decompression in well under 300 milliseconds
- New adaptive technology senses how much air should inflate cuffs, providing consistent therapy
- FDA 510(k) compliant & patent pending

## Ease of use

- 7 lbs. lighter than previous model
- Readily available for patients.  
See contact information below



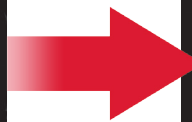
## Arteriogenesis has arrived.™

### Collateralization Case Report: Angiographic Evidence

van Bemmelen, et al.  
*Ann Vasc Surg* 2003



Before



After 4 months'  
treatment with the  
ArtAssist® device



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