

All INDIA INSTITUTE OF MEDICAL SCIENCES  
ANSARI NAGAR, NEW DELHI – 110029  
Department of Surgical Discipline  
(Stores Section)

Ref. No. 27/Surgery/Proprietary/2019-20/St.

Dated: 22.01.2020

Subject: Purchase of DVT Cuff Medium size, Car No. 3040 on proprietary basis rates – reg.

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The request has been received from the Surgeon of Department of Surgical Discipline for purchase of subject item from M/s DJO LLC through their authorized distributors M/s Global Healthcare on proprietary basis. The proposal submitted by M/s Global Healthcare, 409, 2<sup>nd</sup> Floor (Opp. Vasant Vihar Bus Depot) Munirka, New Delhi 110067 India. PAC certifications are attached herewith.

The above document are being uploaded on AIIMS Website for open information to prospective manufactures to submit their objections/comments, (if any) regarding proprietary nature of the equipment/item within 15 days giving reference No. 27/Surgery/Prop./2019-20/St. The comments should be received in the office of Sr. Stores Officer (Surgery), Department of Surgical Disciplines, Center for Medical Education & Technology (CMET), Educational Hall, 1<sup>st</sup> Floor, (Near B.B Dikshit Library), AIIMS, Ansari Nagar, New Delhi-110029 on or before 08/02/2020 up to 04:00 p.m., failing which, it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

  
Sr. Stores Officer (Surgery)

Encl: Related documents enclosed.

1. PAC Certificate enclosed.
2. Specification of equipment.

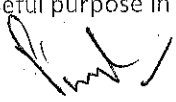
ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
ANSARI NAGAR, NEW DELHI-110029  
DEPARTMENT OF SURGICAL DISCIPLINES


**PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE**

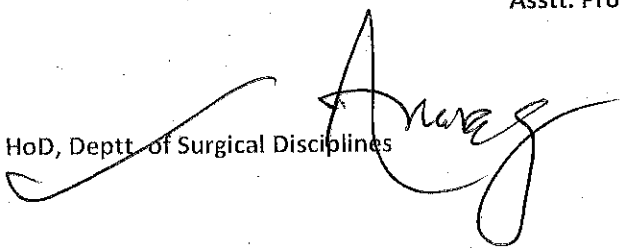
1	Item/Type/Model No. Required along with specification.	Purchase of DVT Cuff Medium size (Cat No. 3040) on proprietary basis – reg.
2	Is the item a spare part attachment or accessory for existing equipment.	Yes – It is accessories of existing DVT Pump.
3	Name of the manufactures/Supplier of the item proposed by the indenter.	M/s DJO LLC 1430 Decision street, vista CA 92081-8553 USA, having manufacture premises at DJO, LLC, 3151 Scott Street, Vista CA 92081
4	Are they sole manufacturers/sold distributors of the item.	Yes
5	Is there any other item with similar/equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding Officer should bring out comparative functional advantage/cost effectiveness of the recommended item from these offered by other.	No other similar DVT Cuff Medium size (Cat No. 3040) available and compatible with existing equipment. It is close system.
6	What were the efforts made to locate alternative source of supply of use other substitutes.	Efforts made on internet to search this on GeM and there is no other alternative source.
7	Why open/limited tender can't be resorted to, for locating alternative source.	This is proprietary Items of M/s DJO LLC 1430 Decision street, vista CA 92081-8553 USA, having manufacturing premises at DJO LLC, 3151 Scott Street, vista CA 92081 USA.
8	Are the proprietary items certifying that the rates are reasonable or not.	Fall Clause declaration submitted by M/s Global Healthcare.
9	Any other justification for procuring item from single source.	M/s Global Health care, authorized distributor of M/s DJO LLC, 1430 Decision street, vista CA 92081-8553 USA, having manufacturing premises at DJO LLC, 3151 Scott Street, vista CA 92081 is only available source of procurement.

The above mentioned information is provided by the firm.

I/We certify that the software license at Sr. No. 1 above is required to be procured on single tender basis as the source supply is definitely known/the specified brand proposed was advantages in meeting our functional requirement and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

  
Dr. Piyush Ranjan  
Associate Prof. of Surgery

  
Dr. Kamal Kataria  
Asstt. Prof. of Surgery

  
HoD, Deptt. of Surgical Disciplines


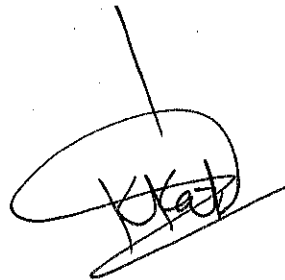
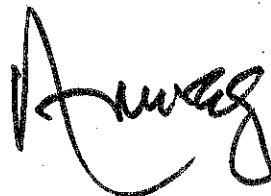
(STORES SECTION)  
DEPARTMENT OF SURGICAL DISCIPLINES  
ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Sub: Procurement for purchase of Cat No. 3040, DVT Cuff Medium size for Surgery.  
Rate reasonability & urgency certificate thereof.

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Certified that the following members of the Technical Committee are jointly and individually satisfied that the goods recommended for purchase are of the requisite specification and quality, priced at the prevailing market rate. The subject items are urgently required in surgery Department.

\*\*\*\*\*

A handwritten signature in black ink, appearing to be 'Raj' or similar, written in a cursive style.A handwritten signature in black ink, with the word 'Khat' written in a bold, stylized font across the middle of the signature.A handwritten signature in black ink, appearing to be 'Anwar', written in a cursive style.

20<sup>th</sup> September 2019

The Director  
All India Institute of Medical Science  
Ansari Nagar  
New Delhi  
110029

Dear Sir

**Sub: Authorisation Letter**

We DJO LLC, with its principal office located at 1430 Decision street, Vista, California 92081-8553, U.S.A. having its Indian Subsidiary office DJO Global India Healthcare Pvt Ltd located at Level 5, The Executive Centre, Tamarai Tech Park, No.16-20A, Inner Ring Road, Guindy, 600 032 (INDIA), who are proven and reputable manufacturers of Aircast, Donjoy, Chattanooga.

We hereby authorize Messrs Global Healthcare of 409, 2<sup>nd</sup> Floor, Munirka, Opp. Vasant Vihar Bus Depot, New Delhi-110067 (India) to quote or submit tenders as our authorized distributor and enter into rate contract for any of your requirement on aforesaid mentioned products and also collect the payment.

This authorization is valid till December 2020

Thanking you

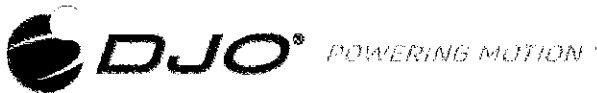
Yours faithfully,  
For DJO Global India Healthcare Pvt. Ltd

  
Edward Arul  
Managing Director  
+91 9677019261









DJO LLC / 1430 Decision Street / Vista, CA 92081 / 609.521.9549 / [djophotob.com](http://djophotob.com)

18<sup>th</sup> September 2019

### Proprietary Article Certificate

To Whomever It May Concern:

This is to certify that the Venaflow<sup>®</sup> Elite System (30BI and 30BI-B) with rapid inflation and the VenaFlow<sup>®</sup> Elite System with S mode (30BI-S and 30BI-SB) with rapid and slow inflation, both offering graduated sequential compression technology are proprietary products of DJO LLC, 1430 Decision Street, Vista CA 92081 USA, having manufacturing premises at DJO, LLC, 3151 Scott Street, Vista, CA 92081 USA.

DJO, LLC is marketing these products under the DJO, LLC brand as the Venaflow<sup>®</sup> Elite System name with the novel feature of therapeutic intermittent compression for reducing risk of deep vein thrombosis.

Technology in the Venaflow Elite System for rapid inflation and graduated sequential compression that work to mimic ambulation and accelerate venous velocity is a technology widely patented by DJO, LLC.

The VenaFlow Elite System will only work when used with the VenaFlow Elite cuffs, incorporating calf cuffs, thigh cuff and foot cuff. These cuffs cannot be used with any other intermittent pneumatic pump.

The above-noted products are marketed by DJO, LLC and are legally based at the address noted above. The product design and specifications are proprietary and owned and controlled by DJO, LLC USA.

For DJO LLC,

Sincerely,

Tim Allard, Senior Manager Regulatory (Affairs and Compliance)

**AIRCAST**

VenaFlow® Elite



Making DVT Prevention A Priority

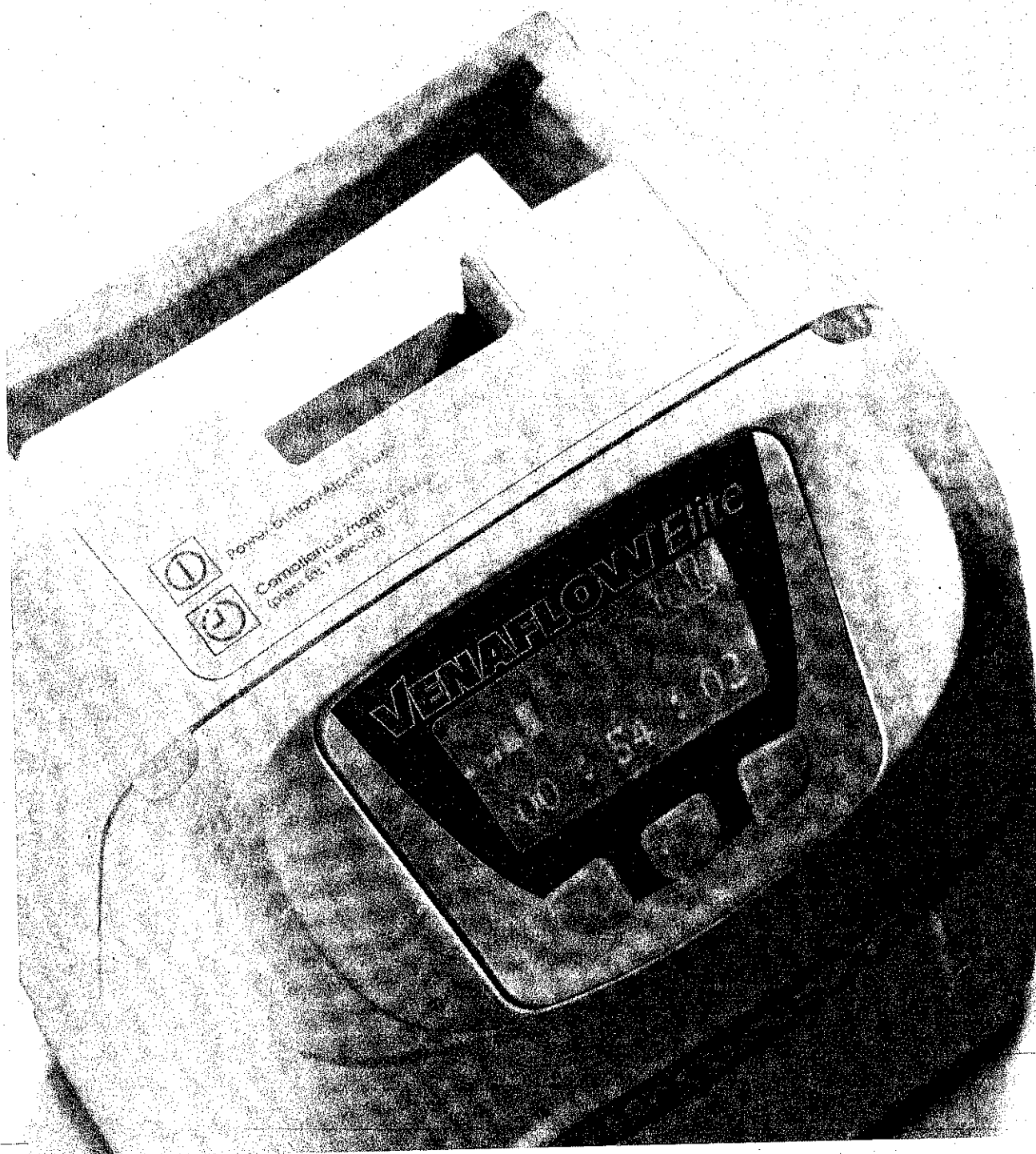


VenaFlow

# AIRCAST®

For more than 30 years, medical professionals worldwide have depended on Aircast® for technological breakthroughs in patient care. Rooted in sound scientific methods, each Aircast product is developed using the concept of "functional management." We have set a new standard of care for sprains and other injuries with our patented technology and use of graduated pneumatic compression.

Aircast is a brand of DJO Global. DJO is a leading global developer, manufacturer and distributor of high-quality medical devices that provide solutions for musculoskeletal health, vascular health and pain management. The company's brands address the continuum of patient care from injury prevention to rehabilitation after surgery, injury or degenerative disease.



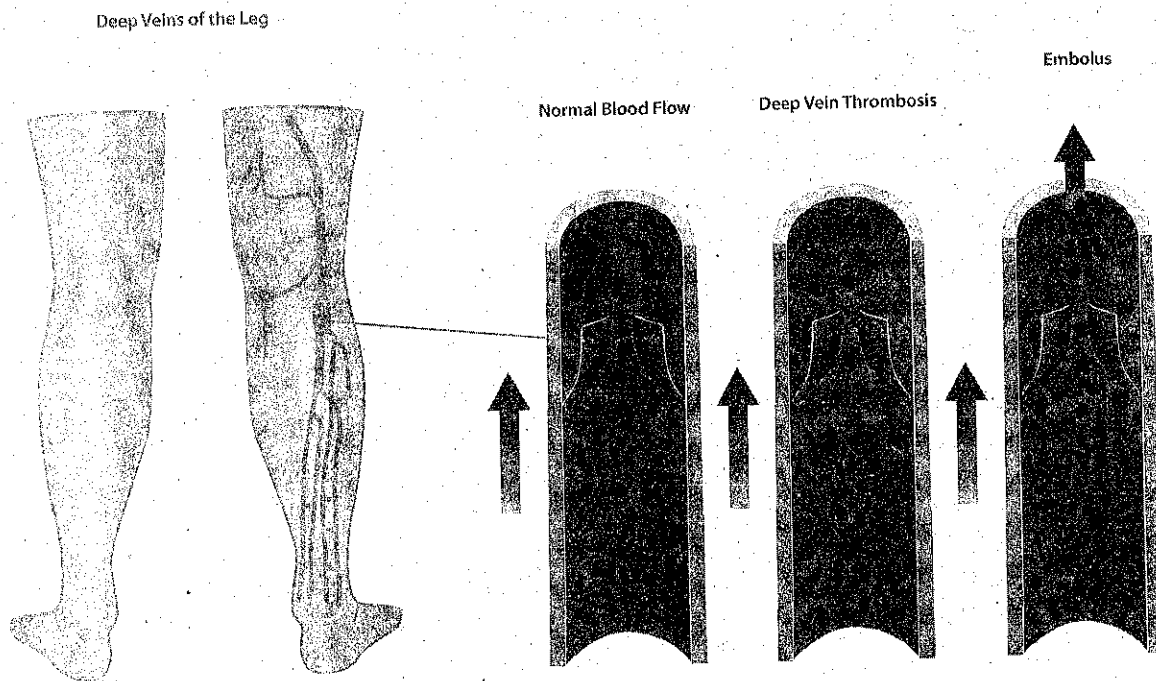
## Deep Vein Thrombosis (DVT) and Pulmonary Embolism

Hundreds of thousands of deaths occur annually as a result of blood clot diseases, such as Deep Vein Thrombosis or Pulmonary Embolism (close to 200,000 in the United States alone). Considered to be one of the primary causes of unexpected hospital deaths (according to Samuel Z. Goldhaber of Harvard Medical School), this incredibly high and dangerous incidence of DVT incurs significantly high costs for the healthcare facilities who have to deal with the complications or fatalities associated with this condition.

There are few DVT prevention modalities available: anti-coagulant drugs or intermittent pneumatic compression devices (IPC) are the most common solutions. Clinical research shows that the most effective DVT prevention is the multimodal approach, combining both of the above methods.<sup>10</sup>

In recent years, there has been an increased awareness and focus on the importance of DVT prevention. Not only to try and reduce the occurrences of clot diseases, but also to counter the financial impact of DVT related conditions on healthcare facilities. The high incidence of hospital acquired DVT (especially prominent in patients who have undergone surgical procedures) incurs unexpected costs such as un-scheduled hospital bed occupancy, re-admissions costs, etc.<sup>7</sup>

In this context, more and more protocols are recommending a multimodal DVT prevention approach for surgeries lasting 30-60 minutes or more, national health services are establishing DVT prevention guidelines, hospitals are setting up committees dedicated to DVT prevention.<sup>11</sup> The prevention of DVT is fast becoming a priority in the healthcare sphere, and the new Aircast VenaFlow Elite is the perfect device to achieve that aim.





## VenaFlow Elite - Walk Away From Risk

As part of its commitment to providing global healthcare solutions, preventing Deep Vein Thrombosis (DVT), is one of DJO's priorities.

In this context, DJO is launching the New Aircast VenaFlow Elite System.

Based on the clinically proven VenaFlow platform technology, the new VenaFlow Elite unit is a state-of-the-art device, now encased in an up-to-date, low profile and light-weight design.<sup>1,2</sup>



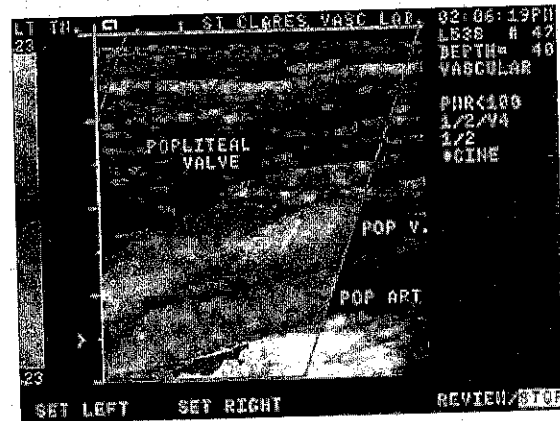
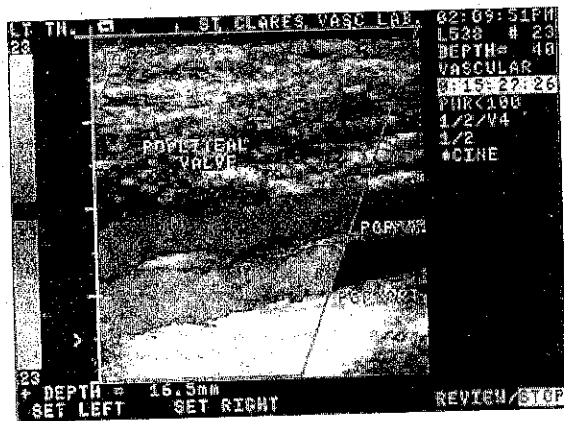
## How does VenaFlow Elite prevent DVT?

Blood clots often form behind venous valves.

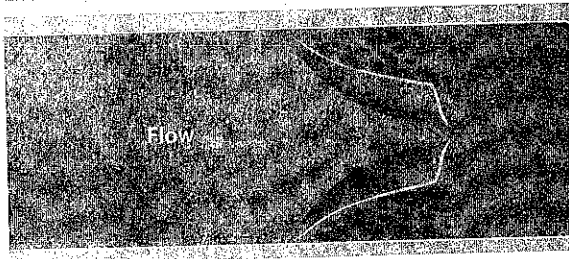
An intermittent pneumatic inflation device such as VenaFlow Elite, which combines normal inflation and graduated sequential compression accelerates venous velocity, which in turn creates turbulence to prevent clot formation.

### Colour scale:

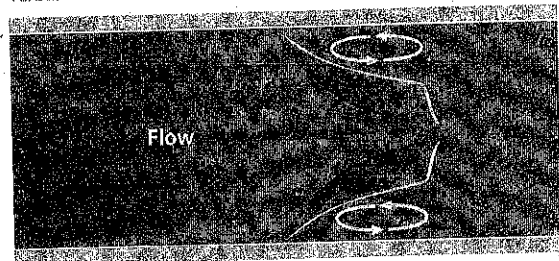
Black - No flow; Blue/Green - toward the heart; Red/Yellow - away from the heart\*



Clots can form behind valve cusps



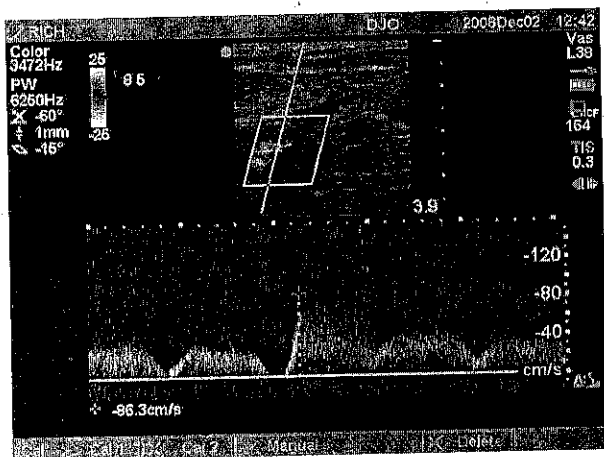
Turbulence reduces clot formation



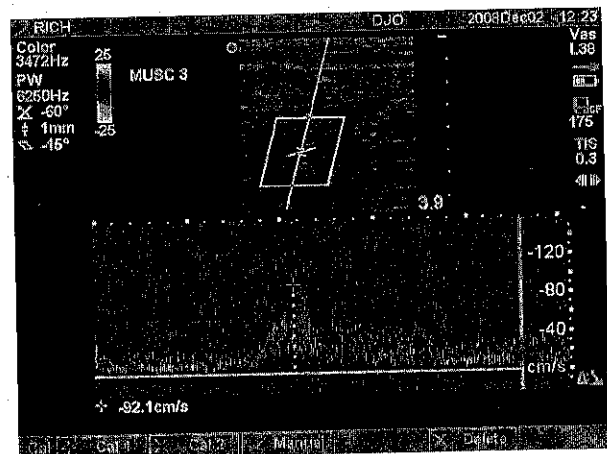
## VenaFlow Elite Mimics Ambulation

The VenaFlow platform technology provides proven performance, simulating peak venous velocities produced through ambulation. The Dopplers below exhibit the blood velocity achieved under the following conditions: ambulation, with VenaFlow Elite and with two competitive slow inflation devices.<sup>2</sup>

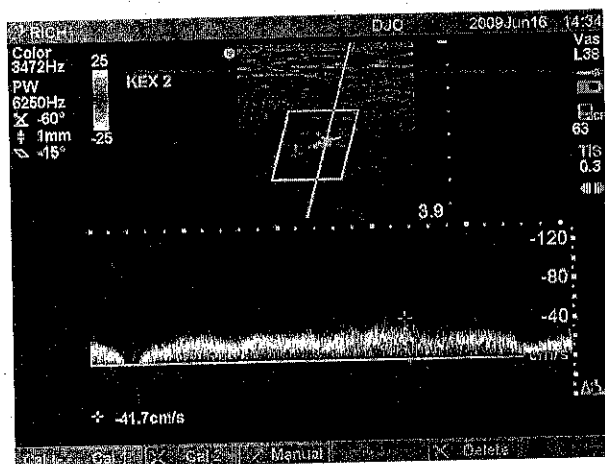
Dopplers measured at Femoral vein.



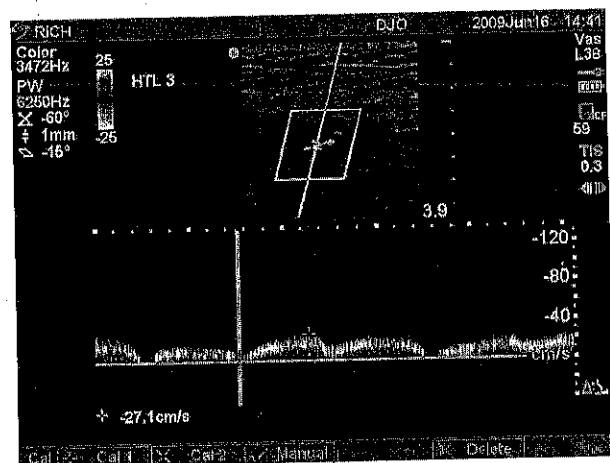
Plantar/dorsiflexion  
111% increase in venous velocity



VenaFlow Elite  
112% increase in venous velocity



Slow inflation device  
50% increase in venous velocity



Slow inflation,  
uniform compression device  
33% increase in venous velocity

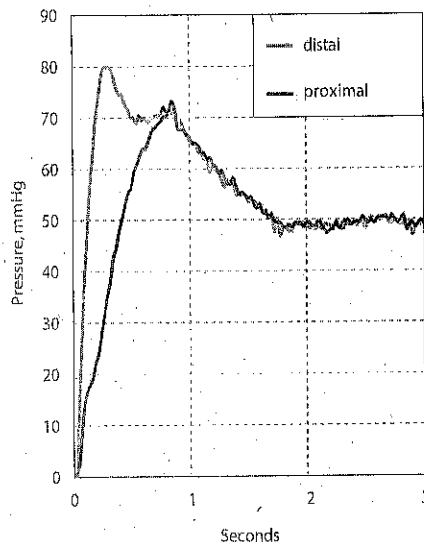
## 3 STEPS TO WALK AWAY FROM RISK

"VenaFlow Elite is the only DVT compression device that combines normal inflation and graduated, sequential compression."

This unique technology combination makes it the only device proven to mimic physiologic blood flows achieved through ambulation.<sup>1</sup>

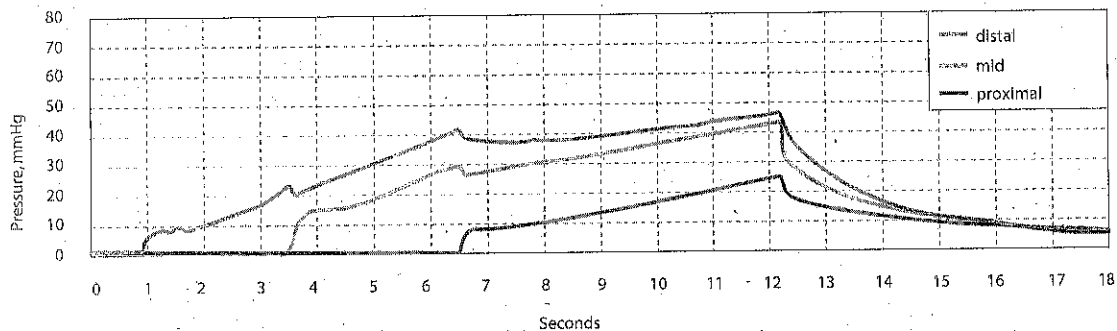
### Normal Inflation vs Slow Inflation

VenaFlow Elite pressure curve



The VenaFlow Elite System inflates in less than a 1/2 second, thus providing the shear stress needed to advance fibrinolysis and prevent clots from forming behind the valve cusps. Slow inflation devices reach settle pressures in approximately 4 to 12 seconds depending on the device<sup>2</sup>.

Slow inflation device pressure curve



### Normal inflation is proven to be more efficient than slow inflation:

- "Intermittent pneumatic compression with a faster inflation rate dramatically increases blood flow, generates greater shear stress on the vascular wall, stimulates greater nitric oxide release, and consequently results in stronger responses of vasodilatation when compared with intermittent pneumatic compression with a slower inflation rate." (Kang Liu et al)<sup>2</sup>
- "[Slow inflation devices] do not mimic normal physiologic venous pump action. They may be ineffective in preventing the more dangerous proximal deep venous thrombosis." (Gardner and Fox)<sup>3</sup>
- Roberts et al established that "devices with a greater rate of inflation produced improved flow augmentation as compared with those with a slower rate of inflation. ... [VenaFlow] produced the greatest increase in peak venous velocity compared with all the other devices." (Westrich, 1998)<sup>4</sup>

## ② Graduated Sequential Compression

The VenaFlow Elite provides graduated sequential compression via the new Integrated Graduated Sequential Flow (IGSF) system, which increases venous velocity by inflating the distal aircell first, and then the proximal second, thus mimicking the blood circuit during ambulation.

The IGSF is comprised of a single tube that connects to the Duplex™ aircells in the cuff (2 overlapping & seamless aircells). When in use, the distal aircell inflates first within a ½ second, then, during the distal pressure inflation, the air flows into the proximal aircell. After 6 seconds, the cuff deflates.

### Sequential compression devices are proven to be more effective than non-sequential devices

Research shows that graduated, sequential compression devices are more effective than a non-sequential device in clearing blood from the soleal, tibial and femoral veins and therefore is more effective at preventing deep venous thrombosis proximal to the calf. (Nicolaidis)<sup>5</sup>

— "The use of elliptical, sequential and rapid-filling compression of the leg with overlapping aircells produces significant hemodynamic changes in the common femoral vein, which are superior to other sequential slow or rapid filling IPC devices." (Labropoulos)<sup>6</sup>

### VenaFlow Elite emulates blood flow during ambulation

The sequence of blood flow during ambulation begins by emptying the distal calf first, then the foot and finally the proximal calf. This is the mechanism of VenaFlow's graduated, sequential compression which squeezes the distal portion of the calf, then the proximal for a simulation of ambulation.<sup>3</sup>

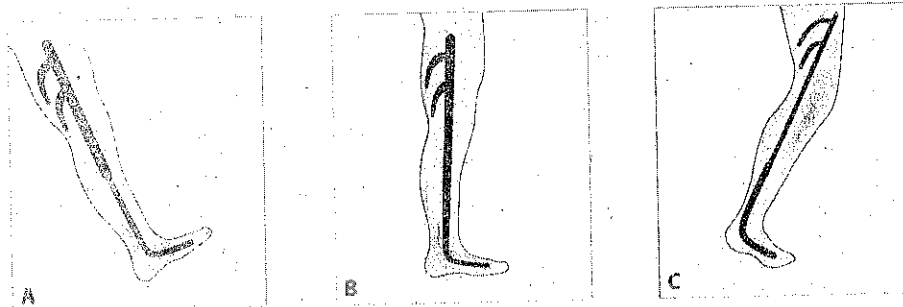


Fig. A, B & C: Sequence of venous pump action during ambulation. Note that the physiological sequence is distal calf pump, foot pump then proximal calf pump.

## ③ Asymmetric Compression

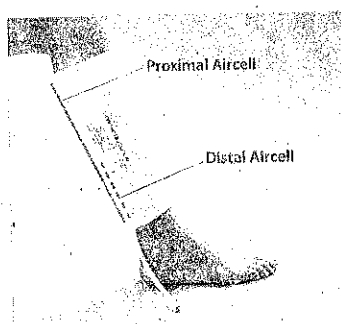
VenaFlow Elite's cuffs, featuring Aircast's exclusive Duplex aircell system (2 overlapping and seamless aircells) apply focused compression to the deep veins and sinuses, maximizing peak blood velocity and total flow.

The cuffs' design, with the distal aircell overlapping the proximal one, generates the increased venous velocity by applying a higher pressure to the distal portion of the calf. Circumferential compression is not as efficient in achieving superior venous velocity, as it addresses the superficial veins and requires more pressure to reach the deeper veins.

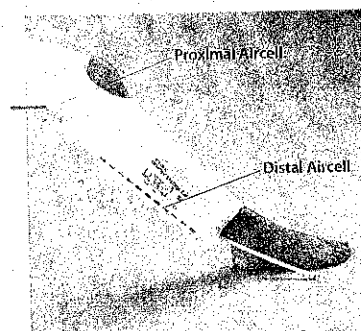
### Asymmetric compression is proven to be superior to circumferential compression in emptying veins

The VenaFlow Elite's duplex aircells apply focused compression to the anterior and posterior portion of the calf to effectively empty the veins and augment peak venous velocity.<sup>4</sup>

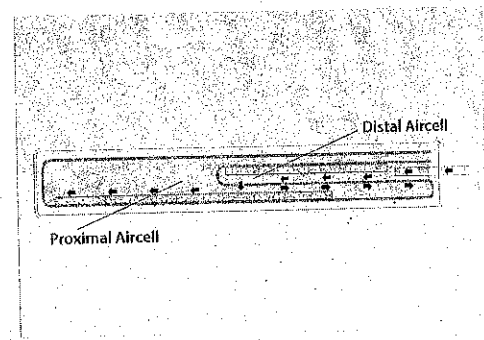
— Research shows that the distal aircell accounts for most of the velocity of venous return, and the proximal aircell "supplements and extends the action of" the distal aircell. (Labropoulos)<sup>6</sup>



Overlapping distal aircell increases venous velocity



Distal aircell inflates first, proximal aircell follows



VenaFlow Elite Cuffs Airflow Sequence