VSK Medical Limited

# About VSK

VSK Medical Limited is a professional marketing and sales organization specializing in medical devices and other healthcare related products in the worldwide market except for the United States and China. At present, its main focus is the external counterpulsation ( "ECP" ) systems, including the Enhanced External Counterpulsation, or EECP®, therapy system from Vasomedical Inc., the gold standard of external counterpulsation technology.

Created as a joint venture between Vasomedical, Inc. of USA and Chongqing PSK-Health Sci-Tech Development Co., Ltd. of China, VSK Medical combines the strength and resources of both companies to better serve the global healthcare marketplace by offering quality products that are configured and priced appropriately for different regions of the world, thereby meeting various regulatory, clinical and economic demands for medical diagnosis, monitoring and treatment. Taking advantage of many years of technical and clinical developments by Vasomedical and PSK on external counterpulsation technology, VSK Medical is well positioned and fully committed to broadening the reach of this effective therapy so that many more patients around the world can benefit from it to improve the quality of their lives.

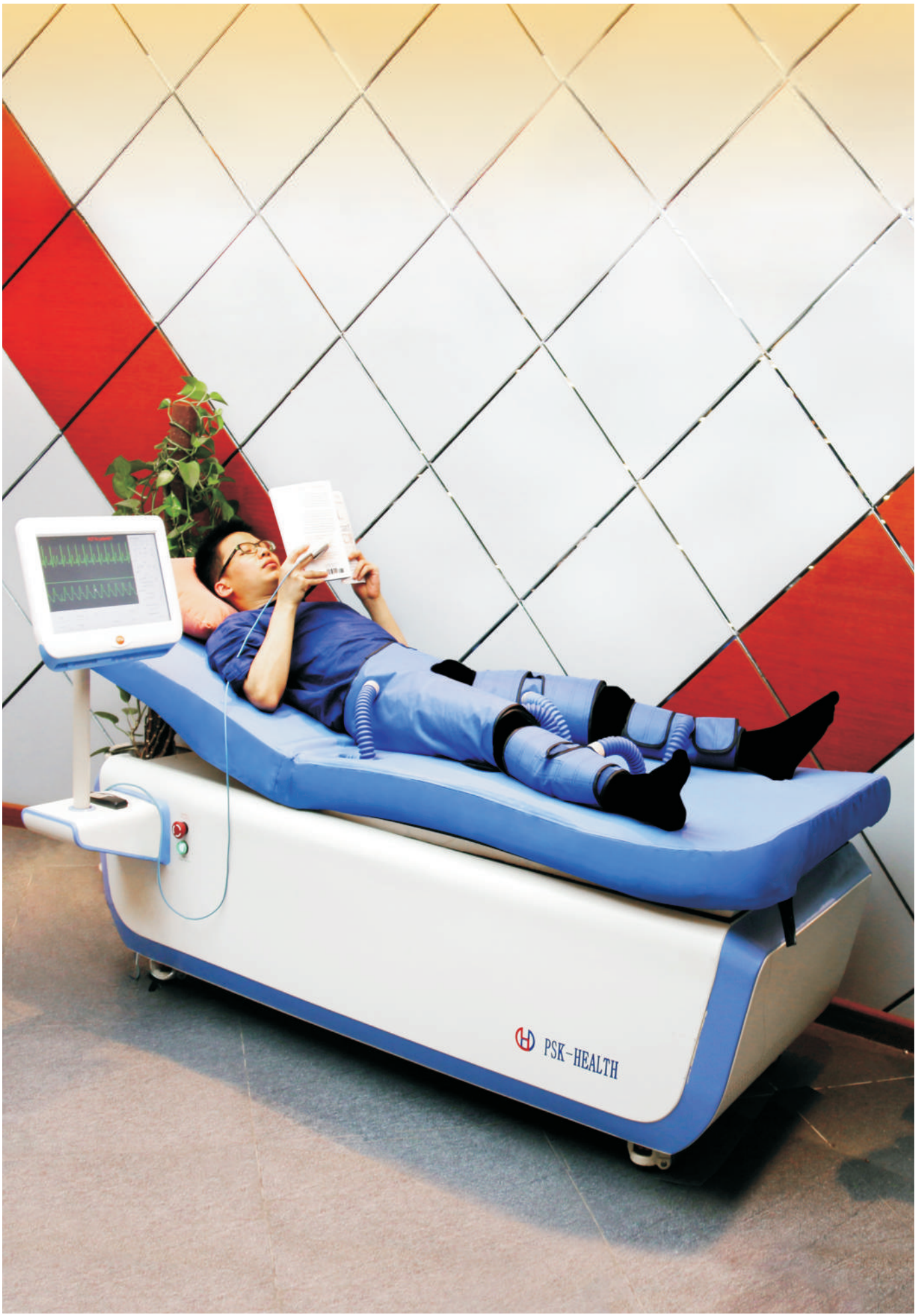
Currently, VSK Medical' s experienced and professional marketing and sales team is based in three locations to serve its customers and distribution partners – Westbury, NY, USA; Chongqing, China; and Bangalore, India – and is working diligently with healthcare professionals all over the world to provide innovative, non-invasive medical devices designed to improve healthcare and enhance the lives of millions of patients around the globe. Stay tuned to see more product offerings in the future.

# AN OVERVIEW OF EECP® AND ECP THERAPY

EECP (Enhanced External Counterpulsation) Therapy and ECP (External Counterpulsation) Therapy are terms which describe the noninvasive, complimentary or alternative treatment prescribed by physicians and cleared for marketing by the U.S. FDA as a Class II device for the treatment of patients with chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularizations. It has also been used and shown to be effective in published clinical studies for patients suffering from the symptoms of ischemic cardiovascular and other circulatory involved diseases such as congestive heart failure, peripheral vascular disease, stroke, diabetes, renal disease, erectile dysfunction, high blood pressure, and other diseases or patient conditions that may benefit from improved circulation and blood flow.

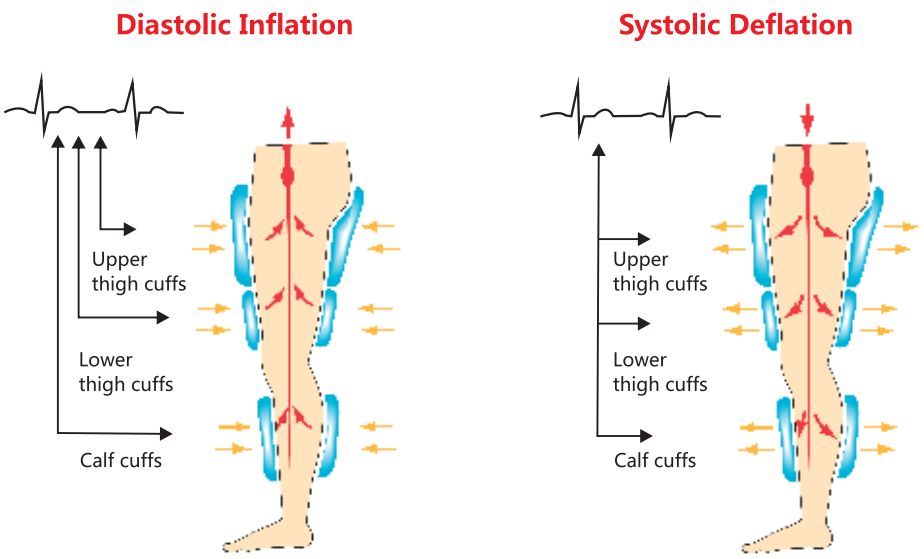
Both EECP Therapy, a name which has been trademarked by Vasomedical Inc., Westbury, NY in the marketing of its treatment method and treatment devices and ECP Therapy, the generic term used to describe all other forms of external counterpulsation (including the ECP systems manufactured by PSK – Chongqing, China) , are based upon the proven hemodynamic principal of counterpulsation, which involves increasing blood flow (volume and pressure) to the heart during diastole (when the heart is at rest) and reducing the workload and oxygen demand the heart uses to pump blood throughout the body in systole.

In addition to the clinically proven hemodynamic principal of counterpulsation, extensive research in clinical studies published in peer-reviewed medical journals have demonstrated the many mechanisms of action that are responsible for the improvement in endothelial function and blood flow produced by the therapy as well as the long term outcomes, which show these initial benefits to last three to five years. While every year a number of clinical articles on EECP and ECP continue to be published in medical journals and textbooks worldwide, some using PSK ECP systems and supported by PSK, most of the over 200 clinical articles published in the literature on EECP and ECP therapy were performed on Vasomedical EECP therapy systems and reported in clinical studies supported by Vasomedical.


PSK-HEALTH

## HOW IS EECP/ECP THERAPY DELIVERED?

The EECP/ECP system consists of three sets of inflatable pressure cuffs wrapped around the calves and the lower and upper thighs, including the buttocks, as the patient lies down on the table. In synchronization with each cardiac cycle, obtained with an integrated 3 electrode single channel ECG, the cuffs are sequentially inflated from the calves to the buttocks during diastole to produce an arterial retrograde flow towards the aortic root to increase coronary blood flow. EEC/ECP simultaneously increases venous return to raise cardiac output. The cuffs are deflated simultaneously before the onset of systole to provide an empty vascular space reducing systemic vascular resistance in the lower extremities to receive blood ejecting from the heart, significantly reducing the workload and oxygen demand of the heart.




## PATIENT SELECTION

EECP/ECP therapy is primarily used as a non-pharmacologic outpatient treatment for patients with chronic stable angina experiencing chest pain, atypical pain, shortness of breath, fatigue or cough. Published clinical studies have demonstrated EECP/ECP provides a derived benefit for patients with severe, diffuse coronary atherosclerosis and persistent angina, or significant silent ischemia burden, such as elderly patients and those with diabetes, challenging coronary anatomies, or debilitating heart failure, renal failure, or pulmonary disease. EECP/ECP therapy has also been shown to be effective in relieving angina symptoms in patients with Cardiac Syndrome X. Benefits of EECP/ECP have also been determined in the management of angina in the elderly, angina patients with left main disease, and in patients with mild refractory angina (CCS Class II). EECP/ECP therapy is equally effective in reducing angina symptoms in patients with or without diabetes, and in patients with all ranges of body mass index.

## U.S. FDA INDICATION FOR THE USE OF EXTERNAL COUNTERPULSATION AS A CLASS II DEVICE

Chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularizations.

## CONTRAINDICATIONS

EECP/ECP therapy should not be used for the treatment of patients with:

- Arrhythmias that interfere with machine triggering,
- Bleeding diathesis,
- Active thrombophlebitis,
- Severe lower extremity vaso-occlusive disease,
- Presence of a documented aortic aneurysm requiring surgical repair,
- Pregnancy.

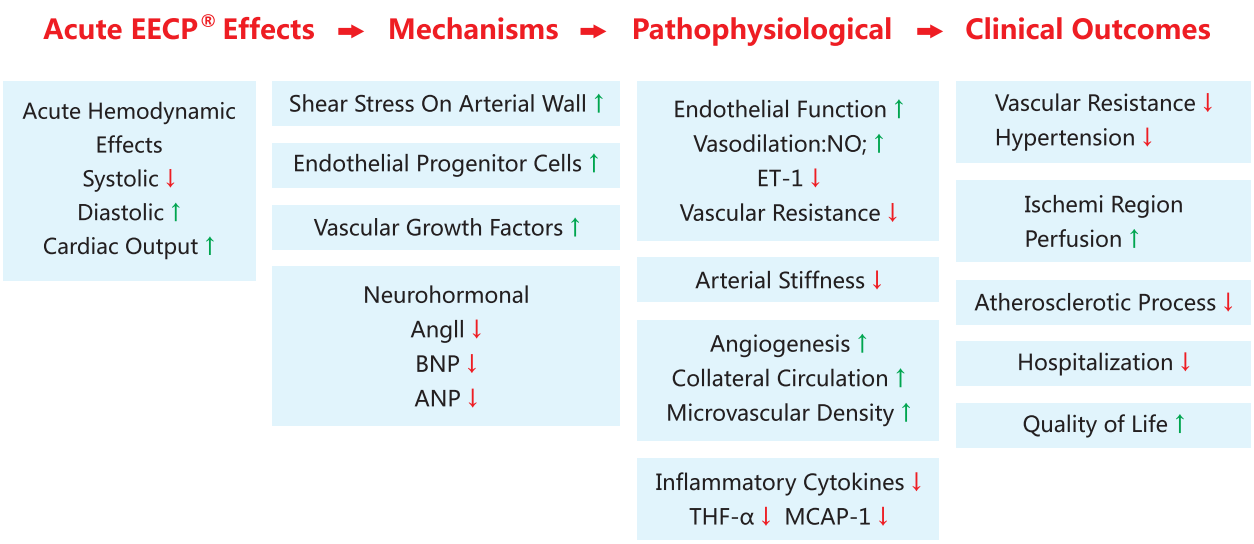
## PRECAUTIONS

- Patients with blood pressure higher than 180/110 mmHg should be controlled prior to treatment.
- Patients with a heart rate of more than 120 bpm should be controlled prior to treatment.

- Patients at high risk of complications from increased venous return should be carefully chosen and monitored during treatment. Decreasing cardiac afterload by optimizing cuff inflation and deflation timing may help minimize increased cardiac filling pressures and the possibility of pulmonary congestion due to increased venous return.
- Patients with clinically significant valvular disease should be carefully chosen and monitored during treatment with EECP/ECP. Certain valve conditions, such as significant aortic insufficiency or severe mitral or aortic stenosis, may prevent the patient from obtaining benefit from diastolic augmentation and reduced cardiac afterload in the presence of increased venous return.

## MECHANISMS OF ACTION

There is evidence demonstrating improved endothelial function via the hemodynamic effects by the increased shear stress acting on the arterial wall, reducing arterial stiffness and providing protective effects against inflammation, inhibiting intimal hyperplasia and the atherosclerotic process.




There is also evidence that EECP® Therapy triggers a neurohormonal response that includes the production of growth and vasodilataon factors, which together with the increased pressure gradient created across the occlusive site during EECP® Therapy, promotes recruitment of new arteries, while dilating and normalizing the function of existing blood vessels. The collaterals bypass stenoses and increase blood flow to ischemic areas of the heart, leading to improved clinical outcomes.

**2012 EECP® Therapy is listed in the ACCF/AHA 2012 Clinical Guidelines for SIHD with a IIb Level of Recommendation**
**2013 EECP® Therapy is added to the 2013 European Society of Cardiology (ESC) Guidelines on the Management of Stable Coronary Artery Disease (SCAD), with a IIa Level of Recommendation**

## OTHER POSSIBLE USES DEMONSTRATED EFFECTIVE IN PUBLISHED CLINICAL STUDIES

*Left Ventricular Dysfunction and Heart Failure*

*Enhanced external counterpulsation improves exercise tolerance in patients with chronic heart failure.*
*Feldman AM1, Silver MA, Francis GS, Abbottsmith CW, Fleishman BL, Soran O, de Lame PA, Varricchione T; PEECH Investigators.*
*Journal of the American College of Cardiology.2006 Sep 19.48(6):1199-1206.Epub 2006 Aug 25.*

*Enhanced External Counterpulsation Improves Exercise Duration and Peak Oxygen Consumption in Older Patients With Heart Failure: A Subgroup Analysis of the PEECH Trial*

*Charles W. Abbottsmith MD, Eugene S. Chung MD, Thomas Varricchione MBA, RRT, Thomas Varricchione MBA, RRT, Paul-Andre de Lame MD, Marc A. Silver MD, Gary S. Francis MD, Arthur M. Feldman MD, PhD and for the Prospective Evaluation of EECP in Congestive Heart Failure (PEECH) Investigators*
*Congestive Heart Failure.2006 Nov-Dec:12(6):307-311*

*Stroke and Cerebrovascular Disease*

***Does external counterpulsation augment mean cerebral blood flow in the healthy brain? Effects of external counterpulsation on middle cerebral artery flow velocity and cerebrovascular regulatory response in healthy subjects.***
***Jungehuelsing GJ1, Liman TG, Brunecker P, Ebel A, Endres M, Buschmann I, Pagonas N, Buschmann EE; Arteriogenesis Network; Center for Stroke Research Berlin.***
***Cerebrovascular Disease 2010.30.612-617***
***Role of external counterpulsation in the Treatment of Ischemic Stroke***
***Han JH, Leung, WH, Wong, KS***
***Journal of Geriatric Cardiology June 2010 Vol 7,No.2.88-92***

*Diabetes*

***Anti-inflammatory effects of enhanced external counterpulsation in subjects with abnormal glucose tolerance.***
***Martin JS1, Braith RW. Appl Physiology Nutrition Metabolism. 2012 Dec;37(6):1251-5. doi: 10.1139/h2012-112. Epub 2012 Oct 11.***
***Enhanced external counterpulsation improves peripheral artery function and glucose tolerance in subjects with abnormal glucose tolerance.***
***Martin JS. Beck DT, Aranda JR.JM.Braith RW***
***First published December 22.2011.doi:10.1152/jappiphysiol.01336.2011***
***Jappl Physiol 2012;112;868-876***

*Erectile Dysfunction*

***Enhanced External Counterpulsation as a New Treatment Modality for Patients with Erectile Dysfunction***
***Froschemaier SE, Werner D, Leike S, Scheneider M, Waltenberger J, Daniel WG, Wirth MP, Urologia Internationalis,1998;61(3):168-171.***
***Enhanced External Counterpulsation in Patients with Coronary Artery Disease-Associated Erectile Dysfunction. Part II: Impact of Disease Duration and Treatment***
***EI-Sakka Al. Morsy AM, Faglh BI.***
***The Journal of Sexual Medicine.2007 Jul 18;(5)448-1453[Epub ahead of print***

## SUGGESTED TREATMENT PROTOCOL

The treatment protocol for angina and the studies that demonstrated effectiveness when used to relieve patient symptoms of other ischemic diseases is administered to patients on an outpatient basis, usually in daily one-hour sessions, five days per week over seven weeks for a total of 35 treatments. EECP® is equally effective if it is given twice daily, each with one-hour session separated by a minimum of 30-minutes break for a total of three and a half weeks. The procedure is well tolerated and under this suggested protocol, approximately 75% of patients experience relief of symptoms caused by their coronary artery disease following the course of treatment.

## CLINICAL BENEFITS

Clinical evaluation of EECP/ECP in patients with angina pectoris and congestive heart failure has been performed in multi-center, single center and registry-based clinical investigations. Results of these investigations have demonstrated clinical benefit and safety in:

- Time to ST-depression during stress test
- Peak oxygen consumption
- Exercise duration
- Angina episodes
- Nitroglycerin usage
- Quality of life
- Functional ability measures MUST-EECP (Multicenter Study of Enhanced External Counter- pulsation): Effect of EECP® on Exercise

## MUST-EECP (Multicenter Study of Enhanced External Counter – pulsation): Effect of EECP® on Exercise Induced Myocardial Ischemia and Angina Episodes

Arora, et al., J Am Coll Cardiol 1999;33:1833-40

## GOAL

- Assess safety and efficacy of EECP®

## ENDPOINTS

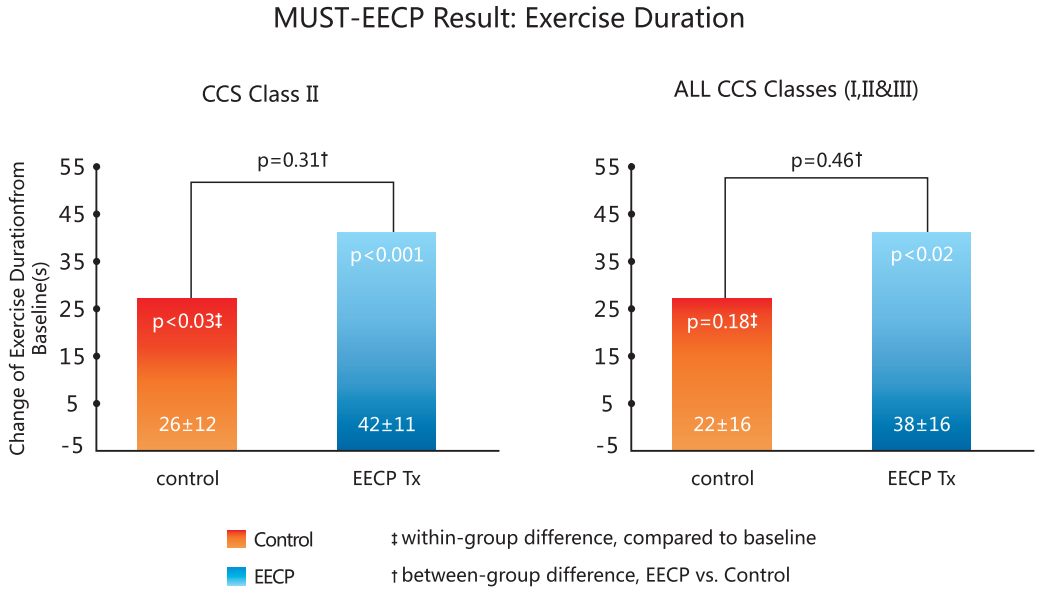
- Exercise duration
- Time to ≥1-mm ST-segment depression
- Angina episodes
- Nitroglycerin usage

## STUDY DESIGN

- A multicenter, prospective, randomized, blinded, sham- controlled trial conducted in 7 university hospitals with-139 angina outpatients randomized to the active EECP® group (n=72) using 300 mmHg pressure applied to the cuffs versus the inactive EECP® group (Control, n=67) with up to 75 mmHg pressure to the treatment cuffs
- Patients with documented angiographic stenosis >70% in at least one major coronary artery, history of-myocardial infarction (MI), or positive nuclear exercise stress test for infarction (MI), or positive nuclear exercise stress test for MI or ischemia
- Exercise treadmill test (ETT) using a standard or a modified Bruce protocol at baseline and within 1 week after completion of EECP® treatment
- 35 1-hour EECP® treatment sessions were delivered once or twice per day to both the active and the inactive group with appropriate cuff pressure.

## RESULTS

- Significant increase in exercise time post-EECP® from baseline in the active EECP® group (426±20 to470±20 s, p<0.001) versus inactive (432±22 to 464±22s, p<0.03). However, there was no statistically significant difference between the groups in change in exercise duration from baseline to post-EECP® (active 42±11 vs inactive 26±12 s, p>0.3).
- EECP® significantly improved time to ≥1-mm ST- segment depression in the active group (337±18 to379±18 s, p<0.002) compared with the inactive group (326±21 to 330±20 s, p<0.74). There was a significant difference between the groups in the change in time to exercise-induced ischemia from baseline to post-EECP® in the active group (37±11 s) versus the inactive group (-4 ±12 s), p=0.01.




Arora RR, Chou TM, Jain D, Fleishman B, Crawford L, McKiernan T, Nesto R.The Journal of the American College of Cardiology.1999 Jun; 33(7):1833-1840.

## CONCLUSION

- MUST-EECP® demonstrates that EECP® Therapy can reduce angina and extend the time to ischemia and increase exercise tolerance in patients with symptomatic CAD.

## PEECH (Prospective Evaluation of Enhanced External Counterpulsation in Congestive Heart Failure): EECP® Improves Exercise Tolerance in Patients with Chronic Heart Failure.

Feldman, et al., J Am Coll Cardiol 2006;48:1198-205

## GOAL

- Assess the benefits of EECP® in the treatment of patients with mild to moderate heart failure

## ENDPOINTS

**Primary:**

- Percentage of subjects with ≥ 60 s increase in exercise duration at 6 months after EECP® treatmentor
- Percentage of subjects with ≥ 1.25 ml/min/kg increase in peak volume of oxygen uptake (pVO2) at 6 months after completion of EECP® Therapy

**Secondary:**

- Exercise duration
- Peak Vo2
- NYHA functional classification
- Quality of life using the Minnesota Living with Heart Failure (MLWHF) instrument

## STUDY DESIGN

- A prospective, randomized, controlled trial conducted in 29 centers with NYHA functional class II and III heart failure patients (n=187*) having a left ventricular ejection fraction (LVEF)≤ 35%, randomized in a 1:1 ratio to EECP® (n=93) versus control with protocol-defined pharmacologic therapy (PT, n=94)

* Intent to treat

- Exercise treadmill test (ETT) and peak oxygen uptake using a standard modified Naughton protocol at baseline, 1 week after EECP® treatment completion and at 3-month and 6-month follow-up
- 35 1-hour EECP® treatment sessions were delivered once or twice per day to the EECP® group.

## RESULTS

- Exercise duration increased by ≥ 60 s in 35.4% in theEECP® group compared with 25.3% in the PT group at the 6-month follow-up visit (p=0.016).
- Peak VO2 increase by ≥ 1.25 ml/kg/min did not differ between the two groups (22.8% vs 24.1%).
- EECP® was associated with a significant increase in exercise duration versus PT at 1-week follow-up (26.4±12.2 vs -5.5±11.7 s, p<0.01), at 3-month follow- up (34.5±13.9 vs -7.0±12.7 s, p=0.014) and at 6-month follow-up (24.7±15.2 vs -9.9±13.2 s, p=0.013) after treatment.
- EECP® significantly improved ≥ 1 NYHA functional class with 33.3% of patients vs 11.4% in the PT group 1 week after completion of EECP® treatment, and 31.6% vs 12.2% at 3 month, 31.3% vs 14.3% at 6-month follow-up.
- Quality of Life (QoL), assessed by a Minnesota Living with Heart Failure instrument, also improved significantly in the EECP® group when compared with the PT group at the 1-week and 3-month follow-up. However, there was no difference in QoL at the 6-month follow-up.

# EECP® IMPROVES EXERCISE DURATION AND PEAK OXYGEN CONSUMPTION IN OLDER PATIENTS WITH HEART FAILURE

Abbottsmith, et al., CHF 2006;12:307-311

## GOAL

- Assess whether the effects of EECP® Therapy in the overall PEECH population could be observed in patients 65 years and older

## ENDPOINTS

- Percentage of subjects with ≥ 60 s increase in exercise duration at 6 months after completion of EECP® Therapy or
- Percentage of subjects with ≥ 1.25 ml/min/kg increase in peak volume of oxygen uptake (pVO2) at 6 months after completion of EECP® therapy

## STUDY DESIGN

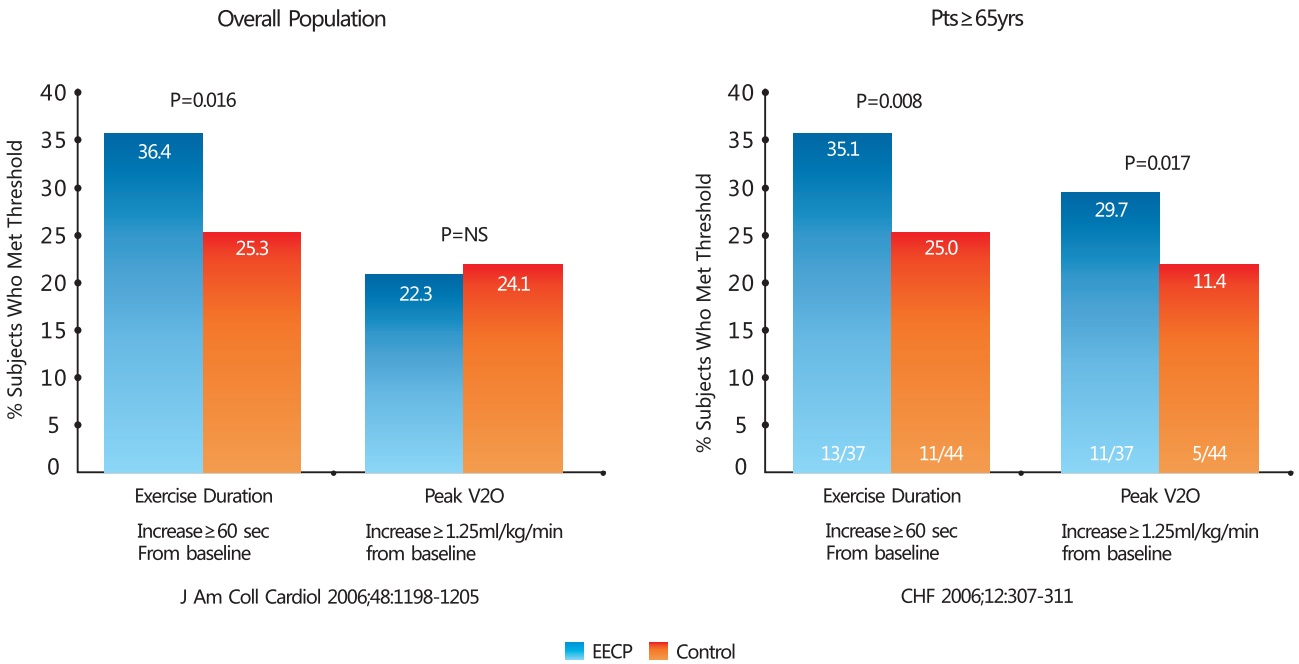
- A prespecified subgroup of elderly patients ≥ 65 years enrolled in the PEECH trial were randomized to the EECP® group (n=41) versus the control with protocol- defined pharmacologic therapy (PT, n=44) group

## RESULTS

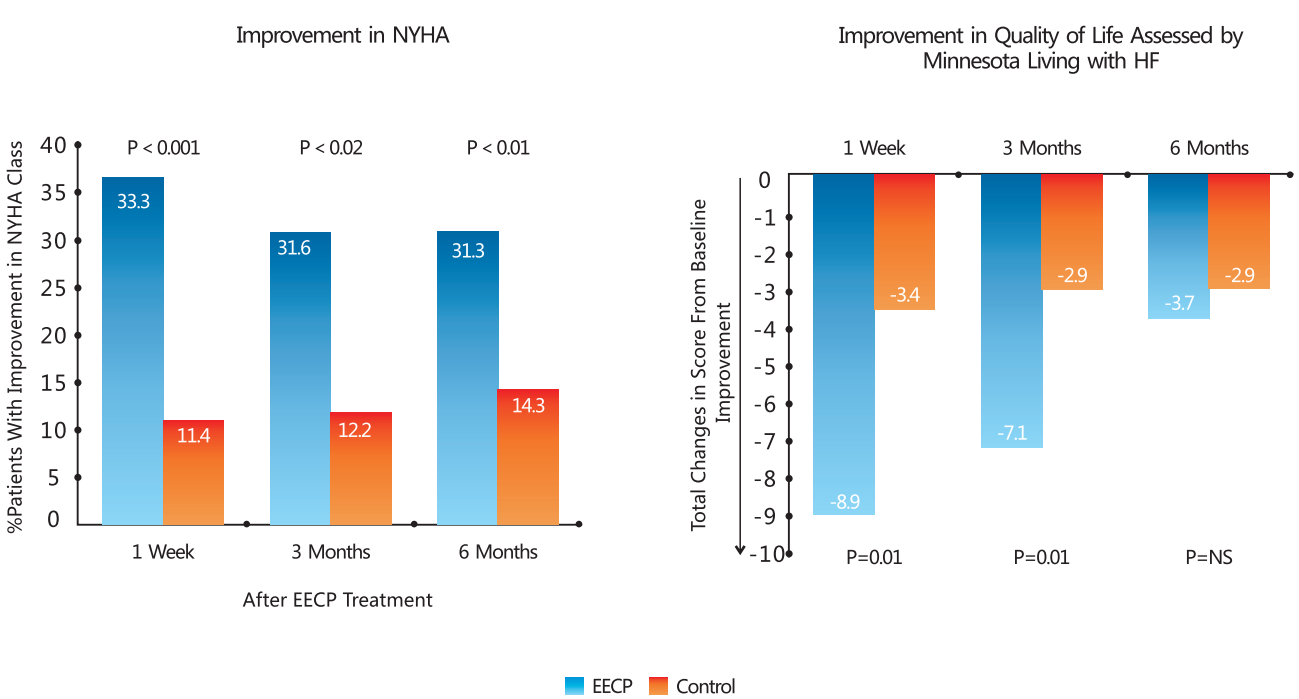
- In contrast to the overall population in the PEECH trial, the major findings of this subgroup analysis demonstrated a significantly higher responder rate in pVO2 in the EECP® group at the 6-month follow-up when compared with the control PT group (29.7% vs 11.4%, p=0.017).

## PEECH Co-Primary Endpoint Analysis

% Responders at 6 Months Follow-Up Exercise Duration and Peak Vo2




## PEECH: Secondary Endpoints



## Coronary Collateral Growth by External Counterpulsation: A Randomized Controlled Trial

Gloekler, et. al, Heart 2010;96:202-207

### GOAL

- To test the hypothesis that EECP® treatment augments coronary collateral development

### ENDPOINTS

**Primary:**

- Coronary collateral flow index (CFI)

**Secondary:**

- Coronary collateral conductance (CCC)
- Brachial artery flow-mediated dilatation (FMD)

### STUDY DESIGN

- 20 sessions of EECP® Therapy over 4 weeks, each session lasting 90 minutes, were performed in 20 chronic stable coronary artery disease patients randomly assigned to the EECP® group (n=10) with 300 mmHg cuff inflation pressure versus the sham control group (n=10) with 80 mmHg inflation pressure.
- CFI was determined by invasive coronary catheterization pressure measurements and calculated by dividing the mean distal coronary pressure during balloon occlusion by the mean aortic pressure after subtracting out the central venous pressure (CVP) from both.
- CCC was determined by the ratio of myocardial blood flow to the difference of aortic pressure to distal coronary pressure during balloon occlusion.
- FMD was determined using 2-dimensional vascular ultrasound imaging.

### RESULTS

- CFI changed from 0.125±0.073 at baseline to 0.174±0.104 at follow-up in the EECP® group (p=0.006), and from 0.129±0.122 to 0.111±0.125 at follow-up in the sham group (p=0.14). The absolute change in CFI from baseline to follow-up amounted to 0.069±0.128 in the EECP® group and -0.017±0.049 in the sham group
- Resting CCC obtained during vessel occlusion changed from 0.365±0.268 at baseline to 0.568±0.585 ml/ min/100 mmHg at follow-up in the EECP® group (p=0.072), and from 0.229±0.212 at baseline to 0.305±0.422 ml/min/100 mmHg at follow-up in the sham group (p=0.45).
- FMD changed from 4.3±1.5 % at baseline to 6.9±3.5 % at follow-up in the EECP® group (p=0.018), and from 6.0±3.0 % at baseline to 7.6±3.5 % at follow-up in the sham group (p=0.10). The absolute change in FMD from baseline to follow-up amounted to 1.75±2.8 % in the EECP® group and 0.50±1.0 % in the sham group (p=0.07).

### ADVERSE EVENTS

- No MACE was reported.

### CONCLUSION

- EECP® Therapy appears to be effective in promoting collateral growth. The extent of collateral function improvement is related to the amount of improvement in systemic endothelial function.

## ART.NET.-2 TRIAL: IMPROVEMENT OF FRACTIONAL FLOW RESERVE AND COLLATERAL FLOW BY TREATMENT WITH EECP®

E. E. Buschmann, et al., Eur J Clin Invest 2009;39 (10):866-875

### GOAL

- To investigate the effect of EECP® on coronary collateral artery growth

### ENDPOINTS

- Primary: Invasive pressure derived collateral flow index (CFIp) and fractional flow reserve (FFR)
- Secondary: Symptom-limited bicycle ergometric test
- Canadian Cardiovascular Society (CCS) and New York Heart Association (NYHA) classification

## STUDY DESIGN

- 23 patients with angiographic narrowing of >70% in at least one coronary artery assessed by FFR<0.8 were randomized in a 2:1 manner to 35 hours, 1 hour daily, 5 hours per week for 7 weeks active EECP® treatment (n=16) or to the control group (n=7) with 7 weeks, 5 times per week walk-in appointment for non-therapy related diagnostics, nutrition-counseling.
- Cardiac catheterization with hemodynamic measurements of aortic pressure (Pa), central venous pressure (Pv) , mean distal coronary pressure (Pd) and coronary wedge pressure (Pw) were measured with a balloon occlusion proximal to the coronary stenosis.
- A symptom-limited bicycle ergometric test was performed at baseline and at the 8th week starting with 25 or 50 Watts and continued with an increase of 25 Watts every 2 minutes.
- CCS and NYHA were evaluated before the invasive procedure at baseline and at the 8th week.

## RESULTS

- CFIp defined to be the ratio of (Pw-Pv) to (Pa-Pv) increased from 0.08±0.01 to 0.15±0.02 ($p<0.001$) in the EECP® group while there was no significant change in the control group (0.15±0.03 to 0.14±0.02 ($p=0.7$).
- The FFR changed from 0.68±0.03 at baseline to 0.79±0.03 at follow-up in the EECP® group ($p=0.001$), with no change in the control group from 0.68±0.06 to 0.7±0.05 ($p=0.4$) at follow-up.
- A significant reduction in CCS classification was achieved after EECP® treatment ($p=0.008$) whereas in the control group no change was observed ($p=0.25$).
- The severity of dyspnea as measured by NYHA classification was reduced after EECP® ($p<0.001$) but not within the control group ($p=0.28$) .
- At the end of therapy, 81% of the EECP® group were free of angina pectoris compared to 56% at baseline, and in the control group, only 14% improved after 7 weeks.

## ADVERSE EVENTS

- No MACE occurred during the study.

## CONCLUSION

- This study provides direct functional evidence for the stimulation of coronary angiogenesis via EECP® in patients with stable CAD.

# INTERNATIONAL EECP® PATIENT REGISTRY I AND II (IEPR I AND II)

## GOAL

- IEPR I and II were organized to document the patterns of use, patient characteristics, safety and efficacy of EECP® during the treatment period and long term follow-up for a period of 3 years post treatment.

## STUDY DESIGN

- IEPR-I: 5,056 patients from Jan 1998 to July 2001 in 119 U.S. and 21 International sites with a 3 year follow-up
- IEPR-II: 2,917 consecutive patients from Jan 2002 to Oct 2004 in 95 U.S. sites with a 2 year follow-up
- IEPR data was collected by the Epidemiology Data Center of the University of Pittsburgh.
- Entry criteria: consecutive patients gave consent and underwent at least 1 hour of EECP® treatment.

## DATA COLLECTION

- IEPR- Phase 1
- Patients' demographics
- Medical history
- CAD status, quality of life
- CCS Classification, medication
- Angina frequency
- Adverse clinical events before EECP®,post EECP®, and during follow-up period
- IEPR-Phase 2
- NYHA class
- Number of hospitalizations for heart failure patients
- Duke Activity Status Index

## RESULTS

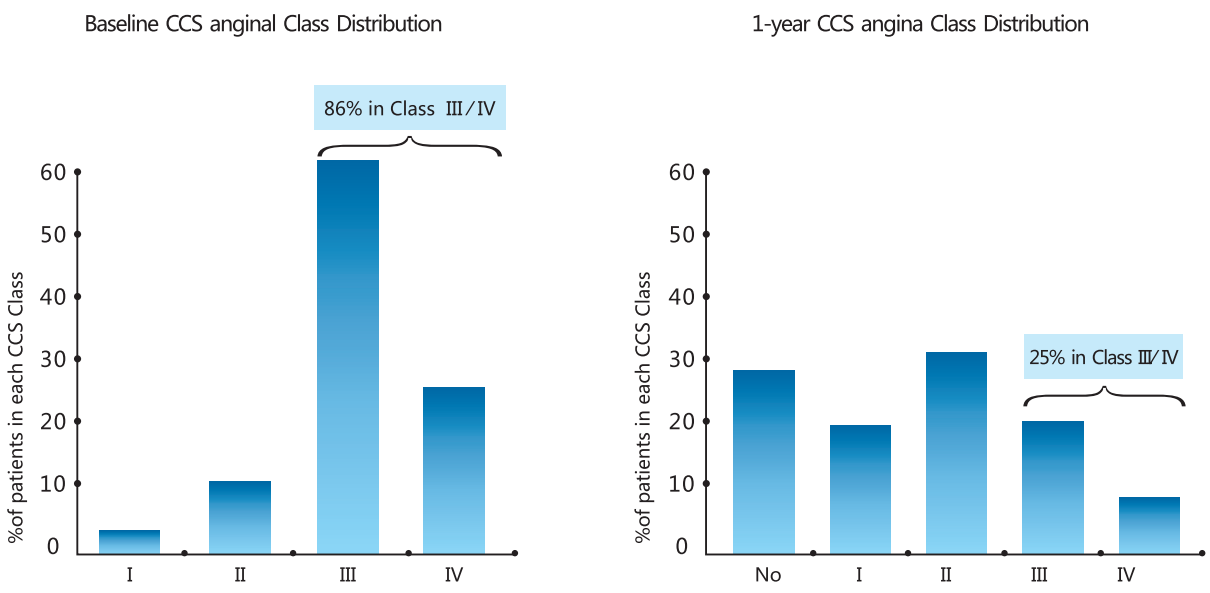
(Selected results from more than 66 published papers)

## PRIMER: PRACTICAL APPROACH TO THE SELECTION OF PATIENTS FOR AND APPLICATION OF EECP®

Michaels, et al., Nat Clin Pract Cardiovascular Med 2006;3(11):623-632

- At baseline, 86% of the 7,973 CAD patients were in Canadian Cardiovascular Society (CCS) angina class III and IV. At the 6-month follow-up after EECP®, 25% of the 4,565 patients were in CCS class III and IV. 76% of patients improved their CCS angina status by at least 1 class.

1-year cumulative clinical outcomes from IEPR-1




| MACE | N=4565 |
|---|---|
| Death(%) | 5.0 |
| MI(%) | 4.8 |
| PCI(%) | 7.5 |
| CABG(%) | 3.1 |
| Heart Failure exacerbation(%) | 6.5 |
| Hospitalization for a cardiac cause(%) | 26.7 |

**Angina**

76% of patients with at least 1CCS class reduction post-EECP maintained their improvement at 1-year

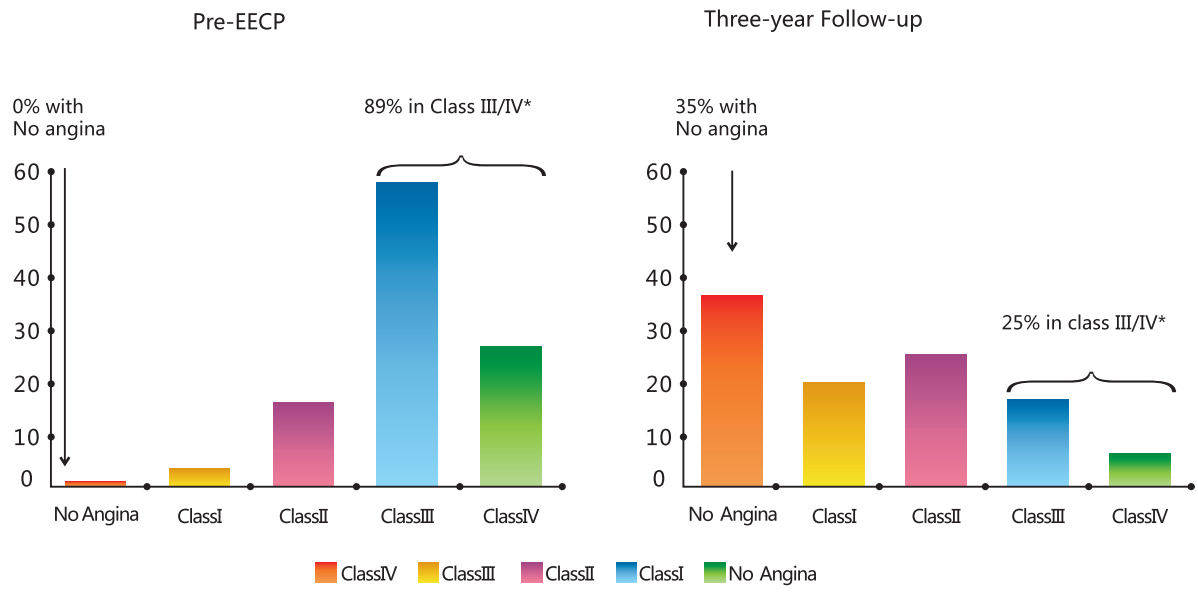
Mean#of angina episodes/week at 1-yr 4±7
Nat Clin Pract Cardiovasc Med 2006;3(11):623-32

## Enhanced External Counterpulsation in the Treatment of Chronic Refractory Angina: A Long-term Follow-up Outcome from the International Enhanced External Counterpulsation Patient Registry

Loh, et al., Clin Cardiol. 2008;31,4:159-164

At 3 years follow-up, there was a reduction in CCS Class of at least 1 class in 78% of the patients, and by at least 2 classes in 38%. This was sustained in 74% of the patients during follow-up.

## 3-Year Follow-up from IEPR-1



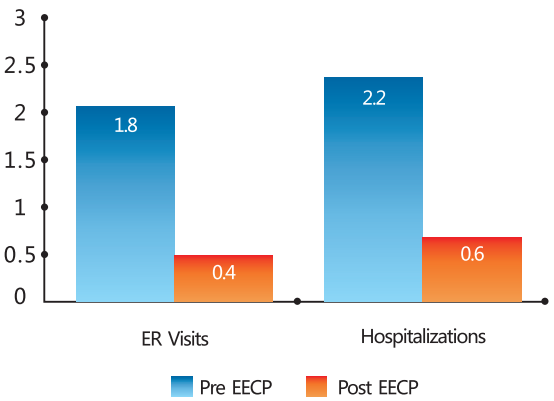

## Impact of EECP® on Emergency Department Visits and Hospitalizations in Refractory Angina Patients with Left Ventricular Dysfunction

Soran, et al., CHF 2007;13:36-40

- There were 2,917 patients enrolled in IEPR-II. 450 had refractory angina with LV dysfunction (LVEF≤40%) and complete data on emergency department (ED) visits and hospitalizations 6 months before EECP® treatment. 93% were in CCS class III and IV, 50% had history of heart failure (HF), mean LVEF was 30±8%.
- After completion of EECP® treatment, angina class decreased by at least 1 CCS class in 72% of the patients, 19% reported no angina and 2% had an increase in angina class. Mean angina frequency decreased by 7±14 episodes per week from 11.4±16.9 to 3.8±10.9 (p<0.001).

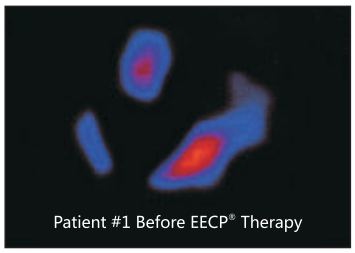
N=1,427 from 36 centers,1,061(74.4%)completed ted 3-year follow-up, 220(15.4%) had died 146(10.2%) failed to complete their 3-year follow-up (median 15.8 months), they were Included in post-treatment outcome and follow-up events*p<0.001 comparing Class III/IV pre-EECP to 3-year follow-up Improvement was sustained in 74% of patients during 3-year follow-up
Clinical Cardiology 2008;31,4:159-164

## EECP reduced ER Visits & Hospitalizations in Patients with LVD

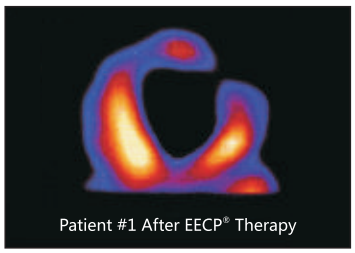



Cost effectiveness / 1,000 patients

| | Cost ER* | Cost Hospital | Iotal ER+Hospital | Iotal Cost to HealthcareSystem |
|---|---|---|---|---|
| EECP | 2,770 | 39,789 | $42,599 | $42,559,200 |
| EECP | 616 | 10,852 | $11,468 | $11,467,600 |
| Reduction hospitalization costs after treated with EECP | | | | $31,019,600 |
| Cost to treat with EECP | | | | $3,640,000 |
| Annual saving healthcare / 1,000HF patients | | | | $27.451,600 |



Patient #1 Before EECP® Therapy



Patient #1 After EECP® Therapy

## CASE STUDIES

### Case study 1

Elderly male patient, two previous myocardial infarctions, previous bypass surgery

### Evaluation

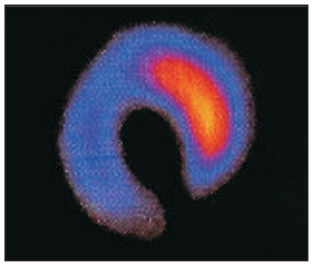
Ischemic cardiomyopathy
Progressive angina with minimal exertion
100% occlusion of proximal portions of all three native coronary arteries
Maintained on medical therapy

### Outcome

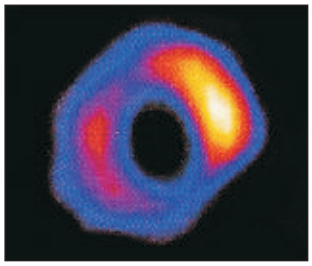
Following 35 one-hour sessions of EECP
left ventricular ejection fraction(LVEF)
Increased by 80% from baseline
functional status and chest pain improved markedly
posttreatment stress test showed improved cardiac perfusion and function

## EECP produces visible improvements in the treatment of angina

Pre-EECP

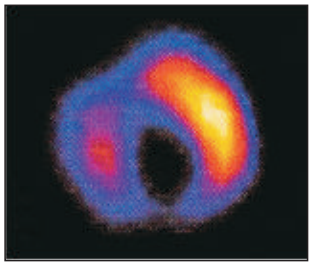


Post-EECP

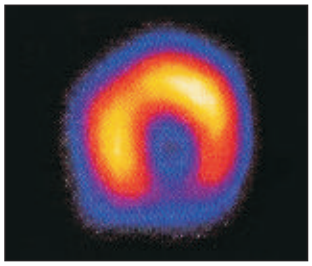


Markedly improved anteroseptal and inferior wall perfusion in post-EECP stress scintigram

Pre-EECP



Post-EECP



Markedly improved anteroseptal and inferior wall perfusion in post-EECP stress scintigram

### Case study 2

- 27-year-old male patient, family history of hyperlipidemia

### Evaluation

- Presented with evectional angina pectoris
- Evaluation revealed:
  - -1.5-2.0mm horizontal ST segment depression on exercise treadmill rest
  - -100% occlusion of mid-right coronary artery
  - -100% occlusion of mid-left anterior descending coronary artery
  - -95% blockages in both proximal mid-right coronary artery and small branch of left circumflex coronary artery
  - -patient considered not suitable for interventional therapy

### Outcome

- Following 35 one-hour session of EECP
  - -angina completely eliminated at normal levels of exertion
  - -posttreatment radionuclide stress testing showed marked improvement in myocardial perfusion

### Case study 3

- 272 year-old male patient, history of, diabetes, gout, hypertension, triple-vessel coronary artery disease (CAD)

### Evaluation

- Presented with stable angina
- Previously declined bypass, maintained on medication
- Stree test suggested progression of CAD
- Severe hypo perfusion of inferior wall and apex with stress perfusion

### Outcome

- Following 45 one-hour sessions of EECP
  - -posttreatment stress testing revealed marked improvement in myocardial perfusion
  - -patient showed increased exercise ability Chest pain symptoms were eliminated
  - -patient no longer required nitroglycerin

## ABOUT PSK-HEALTH

**Chongqing PSK-Health Sci-tech Development Co., Ltd** is a high-tech enterprise specialized in R&D, manufacturing and sales of External Counterpulsation systems for more than 10 years.

PSK-Health owns three factories which are located in Jiangsu, Guangzhou and Chongqing with more than 200 staffs. All the producing process strictly follows the ISO9001 and ISO13485 quality standards. Currently PSK-Health has obtained the approval of SFDA, CE, ISO13485 and US FDA.

In recent years, PSK already became the leader in the field of ECP therapy and technology, PSK diligently reached the target to serve the global healthcare marketplace by offering quality products and best service for the world.

PSK ECP devices have been exported to over 20 countries based on an extensive sales network and professional advantages, such as India, Bangladesh, Turkey, Philippine, Indonesia, Malaysia, New Zealand, Iran, Lebanon, Guatemala, South Africa, Germany, United States and so on.

# PSK P-ECP/TI WITH TOUCH SCREEN


PSK ECP/TI is an All-In-One system which integrates an ergonomically designed patient bed with a high tech electro-mechanical system providing patient comfort and ease of use. It is designed to incorporate special features that assist in noise reduction and heat dissipation. The bed design, based on human engineering, enables patients to enjoy greater comfort during treatment. The modern design of the system provides an appearance of luxury.

## Product Features

- All-in-One design saves floor space
- Uses the latest computer, modern control technique and software control system
- Designed to reduce noise and heat buildup
- Uses German air compressor
- Ergonomic design for patient comfort

## Regulatory and Quality Certifications

- U.S. Federal Drug Administration (FDA) cleared
- EC Certificate of Conformity (CE)
- ISO 13485: 2003/ISO 13485: 2012
- KFDA cleared/Korea
- GOST R cleared/Russia
- ARTGC(TGA) cleared/Australia
- INVIMA registered/Colombia

## Dimension and Weight

L×W×H 2070mm×1120mm×1100mm
Net weight 204kg

## Operating environment:

Temperature 10℃ to 30℃
Relative humidity <70%
Atmospheric pressure 86kPa to 106 kPa
Atmospheric free of corrosive gas

## Power Requirements

AC Single Phase: 220V 50Hz/60Hz
Maximum Power: 2.6KVA

## Noise ≤60db

## Pressure range

0 ~ 440 mmHg or 0 ~ 59 kPa

## ECG Amplifier

Input impedance: >2 MΩ
Common mode rejection ratio: >80db

## Treatment Session Time

Measured in minutes
Adjustable treatment time: 1 min to 60 min (Max.)
System automatically stops when set time expires

## Triggering Method

External trigger: R-wave of patient ECG
External trigger ratio: 1:1 or 1:2
ECG triggers range: 35~125 ±2 bpm for adults

## Cuffs

6 sizes fit all patients' types: XS, S, M, L, XL, XXL
Calf, lower thigh, upper thigh, buttocks are integrated

## Backrest

Remote, 0-45 degrees adjustable backrest
Safe working load: 150KG
Remote control adjustable

## Safety protection function

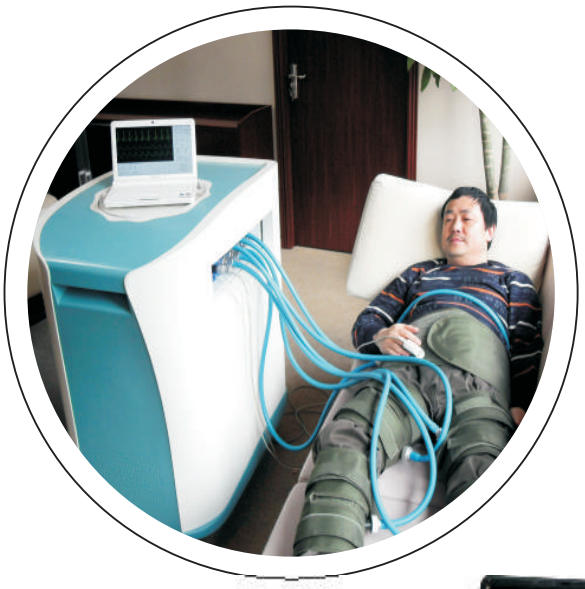
- ECG applied part≥4000V of high-voltage isolation
- finger pulse probe≥2500V of high-voltage isolation
- Heart rate automatically stops counterpulsation in the following conditions: (Max.: 165bpm)
  a) Adults: <35 bpm, >125bpm
  b) Children (under the age of ten): <35bpm, >165bpm
- Automatic exhaust protection while premature beat
- Hand-operated emergency button to stop counterpulsation
- System protection function
- ON/OFF switch on the machine is fused
- Air/Vacuum Pump relay is overload protected

## Patient Protection

- Automatic vacuum deflation of cuffs on early/extra systole
- Automatic high-pressure limit <450 mmHg
- Automatic treatment stop if heart rate goes out of range ( 35—125 bpm)
- Emergency Stop button, easy to reach by patients
- Automatic recognition of the R wave of ECG, machine stops when it detects poor ECG signal
- 2 steps inflation is available for the patients with piles, hip joint surgery, back ache or vertebral column injuries

# P-ECP/TM

TM model is a mobile device that can wheeled to the patient at on a treatment table, hospital bed or reclining chair. It can be shared between rooms and multiple locations in a medical facility, clinic or hospital



## Dimension and Weight

L×W×H 790mm×520mm×1010mm
Net weight 133kg

## Key features

- Uses the latest computer, modern control technique and software control system
- Designed to minimize noise and heat buildup
- Uses efficient pneumatic system with vacuum pump to assist deflation
- Designed for patient comfort and ease of use

# P-ECP/TC

## Key features

- Paediatric Type for children
- Bladder design specifically for Children to prevent from all kinds of circuit malfunction
- Design of air compressor and treatment bed separately

# VSK TOTAL PRODUCT OFFERING

The VSK total product offering provides our customers with the VSK Advantage™, a full complement of customer support services designed to ensure the clinical and economic success of the customer's EECP/ECP therapy programs. In addition to the highest quality, scientifically proven EECP/ECP therapy systems, the VSK Advantage™ includes four customer support programs. These programs were developed over a span of 20 years in cooperation with the companies' customers, who have shared their experience and best practices in achieving clinical and economic success.

## Logistics and Technical Support Program

- Installation by authorized and factory trained service engineers
- Warranty includes telephone and online support
- Post Warranty service programs include preventive maintenance inspections and accessory and supplies discount

## Clinical Support Program

- On-site training by authorized and specially trained instructors
  - -Theory of Operation
  - -Patient Assessment
  - -Inflation and Deflation Timing
  - -Hands on training with your patients when available
- Educational clinical slide presentations
- Clinical Hotline to assist in patient selection and management issues

## Patient Recruiting and Marketing Support Program

- Patient Recruitment support which includes the latest and most effective tools to promote EECP/ECP to patients within the practice, hospital network and medical community
- Marketing materials including files to print patient brochures, posters, videos, newsletters, etc.
- Web site support and links to our web sites
- iPhone Application designed for patients, physicians and therapists
- EECP Forum and other web sites to support the discussion of EECP amongst physicians, patients and therapists.

## Regulatory and Reimbursement Guidance and Support Materials

- Assistance with documentation required for local registration, licensing, etc.
- Shared experience with government and private payers
- Effective samples of pre-authorization, appeal letters and letters of medical necessity
- Shared experience and guidance in pursuing coverage and appeals

# EXTERNAL COUNTER PULSATION IMPORTANT EVENTS

In 1994, ECP was approved by FDA and CE.

In 2002, it was included in ACC/AHA(American Heart Association) Coronary Heart Disease and Angina Guideline.

In 2006, it was included in ESC(European Society of Cardiology) Coronary Heart Disease and Angina Guideline.

In 2006, it was included in CMA(Chinese Medical Association) Coronary Heart Disease and Angina Guideline.

In 2009, the ECP ACCOCIATION CHINA(EAC) was established.

In 2011, the book of Expert Consensus on China External Counterpulsation Clinical Application was published by the People's Medical Publishing House.
In October 2012, the book of Theory and Practice of Enhanced External Counterpulsation was published by the People's Medical Publishing House.

In 2013, ECP was listed in Expert Consensus on cerebral arterial thrombosis collateral circulation and Intervention in China , and it was published in Chinese Journal of Stroke Volume in April, 2013.

In 2013, the Third External Counterpulsation International Symposium was held during the 24th Great Wall Conference.

In 2013, the IEECPS (International EECP Society) was established.

In 2013, International Expert Consensus Symposium of External Counterpulsation Prescription of Cardiovascular Rehabilitation was held in Beijing.

In July 2014, International Expert Consensus Symposium of Enhanced External Counterpulsation Prescription of Cardiovascular Rehabilitation was published in Chinese Journal of Internal Medicine.

In April 2015, External Counterpulsation branch of Chinese Society of Biomedical Engineering was established.

In 2015, Inaugural Meeting of External Counterpulsation of Chinese Society of Biomedical Engineering and it is as the first Annual Meeting held in Shenzhen.

External Counterpulsation therapy efficacy was confirmed by many research centers of USA, Europe, China and other countries.

External Counterpulsation was positively reported many times by International Top Magazines such as Circulation, Time, Cardiovascular New.

External Counterpulsation was included in Medicare in USA and China.

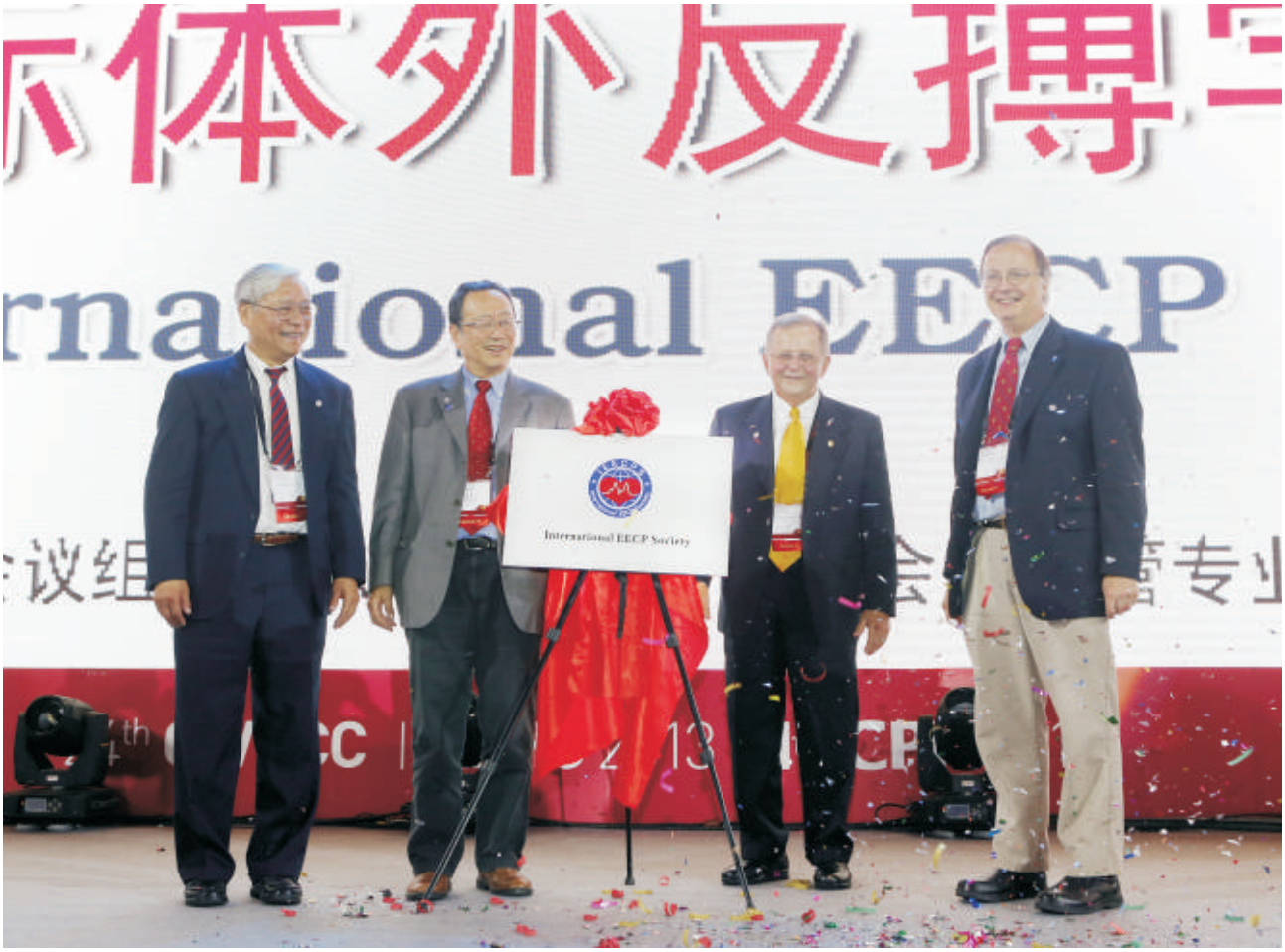

EECP centers were widely developed in more than 30 countries such as USA, German, UK, Japan, Indonesia, India, Malaysia, and Saudi Arabia.

# THE INTERNATIANAL EECP® THERAPY SOCIETY

The International EECP Society (IEECPS) was created in October 2013 as an association of physicians and clinicians involved in the study, research, application and provision of Enhanced External Counterpulsation (EECP) Therapy. Enhanced External Counterpulsation (EECP)Therapy, is an FDA-cleared, non-invasive, treatment for the symptoms of cardiovascular diseases stable ischemic heart disease, angina and congestive heart failure and other. Clinical studies in over 160 published medical and scientific journal articles on the safety and efficacy of EECP therapy have demonstrated that EECP therapy eliminates or significantly reduces symptoms while also improving the quality of life for these patients. Follow up studies have shown these initial benefits to be maintained for 3-5 years. EECP therapy is covered by Medicare and most third-party payers in the U.S. and many countries globally.

The mission of the IEECPS is to promote excellence in the noninvasive treatment of cardiovascular diseases through physician education, research, increased patient awareness, representation, and the advancement of quality patient care with EECP therapy.

The Offical International Website for IEECPS: www.ieecps.org



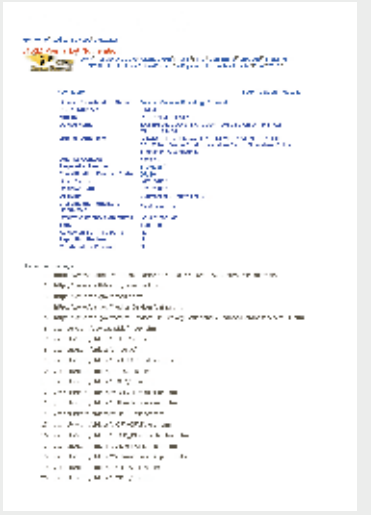

International EECP Society Officially Launched at the Third International EECP Symposium

# QUALIFICATION

PSK-Health operate Quality Management Systems for the Design and Development, Manufacture, Installation, Service and Distribution of ECP Therapy Systems under the highest international standards.

## PSK – Health Regulatory Clearances and Certifications

▼ U.S. FDA Cleared



▼ CE Marked


▼ ISO 13485:2003


▼ ISO 13485:2012


▼ SFDA


▼ Certificate for Exportation

**www.vskmedical.com**
Information about EECP/ECP Therapy systems that are offered by VSK Medical
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**www.EECP.com**
EECP/ECP Therapy clinical information for patients and medical professionals


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