

POSTOPERATIVE RECOVERY

The AEROBIKA® OPEP device is a cost-effective addition to the prevention and treatment of post-operative pulmonary complications (PPCs).

SUMMARY: This retrospective study found a 39% reduction in all-cause rehospitalizations and shorter length of stay for patients using the AEROBIKA® OPEP device. The AEROBIKA® OPEP device cohort had 80% lower costs versus standard of care post-discharge. Higher post-discharge costs for the standard of care cohort was driven by higher readmission rates, longer length of stay (some much longer in the IS group, up to 81 days) and higher overall costs for the readmission.

A Real-World Evidence Study Assessing the Impact of Adding the AEROBIKA® Oscillating Positive Expiratory Pressure Device to Standard of Care Upon Healthcare Resource Utilization and Costs in Post-Operative Patients. Burudpakdee C, *et al.* Pulmonary Therapy 2018;4(1):87-101.



COMPARATIVE STUDY

AEROBIKA® OPEP device users had lower rates of subsequent severe disease exacerbation and all-cause inpatient admission compared to the Acapella+ device.

SUMMARY: A real-world retrospective study of COPD/Chronic Bronchitis patients where the AEROBIKA® OPEP device significantly reduced all-cause inpatient visits and severe disease exacerbations, including 30-day inpatient readmissions and 12-month inpatient visits, compared to Acapella. Combined with previous clinical and real-world data, these findings further support the use of AEROBIKA® OPEP device as an add-on to usual care for the treatment of severe COPD exacerbations and highlights the benefit of the AEROBIKA® OPEP device versus an alternative OPEP device.

Tse J, Wada K, Wang Y, Coppolo D, Kushnarev V, Suggett J. Impact of Oscillating Positive Expiratory Pressure Device Use on Post-Discharge Hospitalizations: A Retrospective Cohort Study Comparing Patients with COPD or Chronic Bronchitis Using the Aerobika® and Acapella+ Devices. International Journal of Chronic Obstructive Pulmonary Disease 2020;15 2527-253.



3 Devices, 7 Therapeutic Options

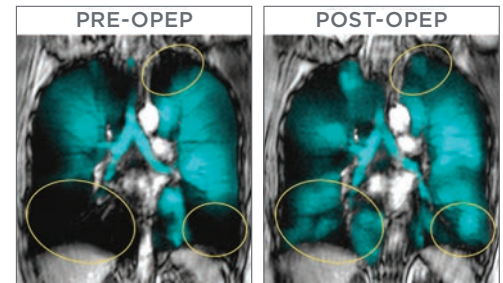
510(k) Cleared to be safe and effective for their intended use.

<p>1</p> <p>AEROECLIPSE® II BAN</p> 	 <p>Combination Therapy</p> <p>2</p>	<p>3</p> <p>Combination Therapy with Manometer Accessory</p> 	 <p>AEROBIKA® OPEP Device with Manometer Accessory</p> <p>4</p>	<p>5</p> <p>AEROBIKA® OPEP Device</p> 	 <p>Tandem Therapy</p> <p>6</p>	<p>7</p> <p>VersaPAP® Positive Airway Pressure Device</p> 
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CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

AEROBIKA® OPEP device provided improvements in lung function, quality of life and ventilation in COPD patients.

SUMMARY: Study evaluating OPEP use in COPD sputum-producers, showed significant improvements in forced vital capacity (FVC), ease-in-bringing-up-sputum, St. George Respiratory Questionnaire (SGRQ), and 6 minute walk distance (6MWD). Increases in gas distribution demonstrated by hyperpolarized ^3He magnetic resonance imaging (MRI). Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. Svenningsen S, *et al.* Journal of COPD 2016;13(1):66-74.



AEROBIKA® OPEP device is a cost-effective addition to COPD disease management.

SUMMARY: A model evaluated the cost-effectiveness of the AEROBIKA® OPEP device versus standard of care (no OPEP/PEP therapy) among post-exacerbation COPD patients. Findings include significant reductions in the number of patients requiring hospitalization and significant reductions in overall direct medical costs per patient. Use of the AEROBIKA® OPEP device after an exacerbation is more effective and less costly compared to standard of care.

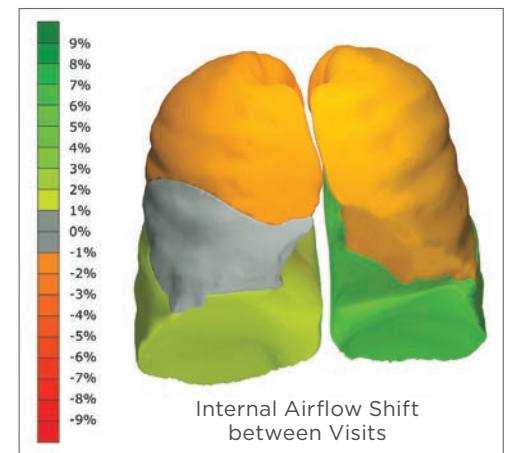
Cost-Effectiveness of the AEROBIKA® Oscillating Positive Expiratory Pressure Device in the Management of COPD Exacerbations. Khoudigian-Sinani S, *et al.* International Journal of COPD 2017;12:3065-3073.

AEROBIKA® OPEP device enables airflow redistribution and influences drug deposition patterns

SUMMARY: Functional respiratory imaging (FRI) evaluated change in airflow correlating with a change in drug deposition after 15 ± 3 days use of the AEROBIKA® OPEP device by 10 COPD patients. When the airflow was redistributed towards the lower lobes there was an increase in FEV₁ (forced expiratory volume in one second) values. These findings are based on the findings of a pilot study which showed the AEROBIKA® OPEP device enables airflow redistribution and influences drug deposition patterns, which may be a contributing factor to the previously reported improved clinical outcomes.

The Use of Functional Respiratory Imaging to Investigate the Impact of an Oscillating Positive Expiratory Pressure Device on Lung Dynamics and Drug Deposition. Kushnarev V, *et al.* Eur Respir J 2018;52:PA3885.

The Effect of the AEROBIKA® Oscillating PEP (OPEP) Device on Airway Structure, Function and Drug Deposition in Patients with COPD. Mussche C, *et al.* Am J Respir Crit Care Med 2018;197:A2408.



Use of the AEROBIKA® OPEP device significantly improves quality of life in COPD.

SUMMARY: An evaluation of the impact of AEROBIKA® OPEP device use on Quality of Life in patients with COPD and chronic bronchitis, showed a responder rate analysis for improvements greater than the Minimum Clinically Important Difference (MCID) showed 64% improvement in SGRQ (MCID \geq 4) and 62% improvement in COPD Assessment Test (CAT) (MCID \geq 2).

Quality of Life (QOL) Responder Rate Analysis Following Use of an Oscillating Positive Expiratory Pressure (OPEP) Device for Chronic Obstructive Pulmonary Disease (COPD): SGRQV CAT Assessments. Stockley RA. Chronic Obstr Pulm Dis. 2017;4(3):225-246.

Survey responses demonstrate a high degree of patient satisfaction with the AEROBIKA® OPEP device.

SUMMARY: 812 survey responses were collected. 90% of patients had COPD, 8% had bronchiectasis, 2% had cystic fibrosis. Compliance to therapy was high with 97% indicating they would continue to use the device. Patient satisfaction was 94% for the device overall, with 96% finding it easy to use.

Survey of Patients Using an Oscillating Positive Expiratory Pressure Device Indicates Improvement in Well-Being and Compliance to Therapy. Harkness H, *et al.* Presented at CRC 2015.

OPEP devices are not the same.

SUMMARY: An *in vitro* investigation assessed the waveforms of OPEP devices and linked pressure pulse amplitude and frequency in order to compare potential effectiveness. TPPI_f values showed the AEROBIKA® OPEP device to be the most effective. Oscillations were high and consistent during each exhalation and covered frequency that support cilia movement.

Assessing the Waveforms of Different Oscillating Positive Expiratory Pressure Devices: A Clinically Relevant Pressure Pulse Laboratory Study. Suggett JA, *et al.* Pediatric Pulmonology 2018;53(S2):343.

For a comprehensive overview of published studies refer to the AEROBIKA® OPEP device Study Summary.

