

INFORMED CONSENT RELEASE
for
"The Empathy Lungs"™ C.O.P.D. Simulator

Based on the results of extensive field testing, "The Empathy Lungs"™ C.O.P.D. Simulator (U.S. and Foreign Patents Pending) has been found to be a highly effective, beneficial and safe teaching aid when handled or worn by individuals who are in reasonably good health, and who behave in a correct and careful manner while handling or wearing this teaching aid. Since you (or your child) are being offered the educational opportunity to use The Empathy Lungs™, you are hereby provided with full information regarding this product's intended and potential effects, benefits, avoidable risk factors, and reasonable precautions to be maintained while handling or wearing this product. **As a prerequisite to handling or wearing the Empathy Lungs™, carefully read and complete this form.**

"The Empathy Lungs"™ C.O.P.D. Simulator is a unique and powerful tool for smoking prevention and cessation.

Intended for use only as serious teaching aid, it is comprised of a custom designed Torso Constrictor (a truss-like garment) that is strategically weighted -- and worn around the wearer's torso - along with a customized Airway Mask which, when worn together will temporarily simulate the pronounced "shortness of breath" or "breathlessness" that characterizes Chronic Obstructive Pulmonary Disease (which is comprised primarily of Emphysema and/or Chronic Bronchitis), as well as that of Asthma, and Lung Cancer. This unique, hands-on simulator has been engineered for one-time, short term use of just fifteen to thirty minutes, during which time it will safely enable the wearer to physically experience COPD's typically strenuous, labored, shallow, "upper-chest breathing only", as well as the subsequent fatigue, irritability and emotional distress that inevitably results from the feeling of "not getting enough air". Wearing The Empathy Lungs™ also measurably reduces the wearer's lung capacity, as evidenced by the "before and after" measurements of their Peak Expiratory Flow rates; these **PEF** rates are quickly measured by an easy-to-use Peak Flow Meter (included). Such an experience invariably impacts the wearer with a realistic "sneak preview" of the eventual, debilitating effects of smoking, which is the primary cause of COPD -- currently affecting over 45 million patients as of 2005. COPD is the 1th leading cause of death in the U.S., and is projected to become the 3^m leading cause of death by 2020. Since The Empathy Lungs™ simulator can be worn by both males and females, ranging in age from 12 to 82, it finally gives teachers and medical professionals a hands-on, uniquely effective approach to motivate adolescents to never begin smoking, and to help current smokers gain an emotional "gut-level" determination to quit smoking for good. Furthermore, in many instances, wearing this simulator will motivate a smoker to finally go to their family physician for simple Spirometer testing that reveals their current lung function, and learn what practical changes they can make to preserve their remaining lung health. Handling or wearing The Empathy Lungs™ is to be done on a strictly voluntary basis, and will be done only while under the careful supervision of a trained and authorized instructor. Recommended wearing time is 15 to 30 minutes.

Individuals who weigh less than 100 pounds, or more than 300 pounds, should NOT use this device. Handling or wearing The Empathy Lungs might put individuals with certain medical conditions or pre-existing injuries at risk™. The following checklist is intended to help identify such individuals who might be put at risk, and who should therefore **NOT** use this device. If you (or your child) desire to handle or wear The Empathy Lungs™, **indicate here if you (or your child) currently have any of the following medical conditions or health impairments: (Check either YES or NO)**

- | | <u>YES</u> | <u>NO</u> |
|--|------------|-----------|
| 1. Confirmed pregnancy, or the possibility of pregnancy | | |
| 2. Chronic back pain, or disorders of your back, spine, neck or pelvis including, but not limited to, scoliosis, sciatica, slipped or ruptured discs, etc..... | | |
| 3. Any fractured or broken bones, especially of the ribcage, spinal vertebra, or pelvis..... | | |
| 4. Any serious strains (muscle-tendon damage) or serious sprains (ligament damage) of torso... | | |
| 5. Serious weakness or brittleness (e.g. osteoporosis) of your ribcage, neck, pelvis or spine.... | | |
| 6. Dizziness, fainting, vertigo, or uncontrolled hypertension (high blood pressure)..... | | |
| 7. Uncontrolled symptoms of asthma, bronchitis, emphysema, lung cancer, or difficulty breathing. | | |
| 8. History of heart problems or disease including, but not limited to, heart attack, stroke, angina... | | |
| 9. Uncontrolled epilepsy or history of convulsions..... | | |
| 10. Urinary tract or bladder disorders, weakness or infection..... | | |
| 11. Any serious skin bruises, wounds, or recent scars on the front or back torso, or abdomen... | | |
| 12. Any serious weakness or disorder of your abdomen's internal organs, including, but not limited to, hernia, enlargement of liver or spleen, colon disease, or serious abdominal infections..... | | |
| 13. Any other medical condition for which your physician has advised you to avoid strenuous activity | | |

(Continued)

WARNING: Handling or wearing of this product in the presence of any of the above conditions may cause them to get much worse or may cause injury. If you have answered YES to ANY of the above questions, or if you (or your child) have any other abnormal health condition that you believe might put you (or your child) at risk, then YOU (OR YOUR CHILD) ABSOLUTELY SHOULD NOT HANDLE OR WEAR The Empathy Lungs™ COPD Simulator.

The respiratory changes common in COPD (and in the simulation of COPD) naturally impose significant physical demands on the human body. While experiencing any strenuous activity, especially those involving the handling or wearing of weighted components, there is always the possibility of a strain-sprain injury, particularly if an individual does not behave cautiously. MISUSE of The Empathy Lungs™ could cause serious, permanent damage. Therefore, to minimize any risk of injury while wearing The Empathy Lungs™, **the wearer should understand and maintain the following precautions:**

1. **DO NOT wear any component of The Empathy Lungs for more than 15 to 30 minutes.**
2. **DO NOT** simultaneously twist side to side while bending over.
3. **DO NOT** make any abrupt, jerky or swift movement in any direction.
4. **DO NOT** bend over without bending knees (use squatting position).
5. **DO NOT** bounce, jump or run.
6. **DO NOT** act recklessly or frivolously.
7. **DO NOT** engage in any strenuous activity or over-exertion (standing and slow pacing are recommended).
8. **HANDLE CAREFULLY** all weighted components of this device at all times.
9. **IMMEDIATELY DISCONTINUE WEARING THIS DEVICE** (by using the device's release zipper) if you feel any sudden pain, dizziness, panic response, or other adverse effect. Consult a physician if necessary.

I have studied and understand all of the teacher training materials provided by the manufacturer concerning the correct, effective and safe usage of the teaching aid, "The Empathy Lungs"™ COPD Simulator. I have been specifically authorized as a qualified instructor to handle and demonstrate this device. I agree to follow all instructions and precautions of the manufacturer. I agree to carefully supervise the below named individual at all times while he/she is wearing The Empathy Lungs™.

Supervising Instructor's Printed Name Signature Date

I have read and understand the above description of "The Empathy Lungs"™ COPD Simulator, its intended and potential effects, benefits, avoidable risk factors, and the reasonable precautions to be maintained while wearing this teaching aid. I voluntarily agree (or permit my child) to wear The Empathy Lungs™ for purposes of my (or my child's) own benefit. I (or my child) agree to follow the instructions and precautions stated above. I assume all risk and liability for any injury or damage to me (or my child) that might arise out of my (or my child's) handling or wearing of The Empathy Lungs™. I hereby release and forever discharge the manufacturer of The Empathy Lungs, the purchaser and the instructor, from all claims of injuries or suits of any kind arising from my (or my child's) use of The Empathy Lungs™.

Wearer's Printed Name Signature Date
(Or if Minor, Signature of Parent/Legal Guardian)