



SALVINO - FLEX LLC
CHEST TUBE INSERTION DEVICE

Fast Facts

- BUSINESS** The Company was been formed for the purpose of developing, marketing and selling a patented hand-held, disposable device for use in connection with the insertion of chest tubes.
- BACKGROUND** The concept was derived by Chris K. Salvino, M.D., as Level I Trauma Center Director for Good Samaritan Hospital in Downers Grove, Illinois.
- TECHNOLOGY** The technology consists of a hand-held disposable device comprising a shaft with an eccentric blade stored in a retracted position below the distal surface. Upon activation by a trigger mechanism, the blade advances and rotates in such a way as to expose approximately 1 mm of its cutting edge. The advance-and-rotate integrated motion (a snap action with rapid advance and sweep of the blade) facilitates an incision (i.e. a slicing action as the blade rotates). Upon release of the activation mechanism, the cutting edge retracts to its initial safe position below the shaft's distal surface. This retracted positioning precludes unwanted exposure to the sharp edge during tissue manipulation and clinician handling.
- The device is a single use, disposable unit. The shaft cross section has an elliptical shape providing the following advantages: (1) The longitudinal access provides added space for a longer cutting edge, (2) When turned horizontally, the shaft provides easier penetration between the ribs with less pain for the patient, and (3) The shaft may be twisted to separate ribs. The sheath is flexible in the cross sectional plane while having longitudinal ribs or stiffeners. This facilitates flexibility to conform to space between the ribs plus still be longitudinally stiff to accommodate insertion. A compliant sheath is positioned over the shaft and is left behind after incision and path generation. The sheath conforms to the shape between the ribs and serves as the introducer for the chest tube.
- The sheath is designed with an annular flange that can contain a tissue adhesive and antibiotics. Applied to the skin, it provides a pneumo-seal to close and seal the wound, facilitating protection against infection, eliminating the need for suturing.
- MARKET** The target audience comprises physicians, surgeons and their patients in the clinical areas of emergency room medicine, ICU management, cardiovascular and thoracic surgery requiring rapid, effective chest tissue incision and tube insertion. This includes some procedures for thoracostomy, and other therapeutic procedures on the respiratory system, and also lobectomy or pneumonectomy, heart valve procedures, coronary artery bypass grafts, and other heart procedures. An additional application area is late stage lung and breast cancer.

The size of the United States market has been estimated at 535,000 procedures per year for trauma & emergency medicine, 1,255,250 annual procedures for cardiovascular and thoracic surgeries, and 43,475 procedures for late stage lung and breast cancer. Procedures that would be performed outside the hospital by paramedics and in the battlefield are not included in this count.

Planned list price per single use unit is \$155. The aggregate market value for the initial three targeted market segments is \$337 million (annual sales). The international market is estimated at 1.15X (\$388 million).

COMPETITION

The primary competitor to the Salvino-Flex device for tube thoracostomy is the current standard open technique: use of a scalpel, finger and/or hemostat (blunt dissection and digital exploration). This method encompasses use of a scalpel blade to make an incision through the skin, probe and dissection of the incision with a finger, dissection through the intercostal muscle with a hemostat, and placement of the chest tube using the hemostat as facilitator. Procedural complications with this technique are significant patient pain, misdirection of the tube during insertion, tube disconnection, or leakage around the tube with resultant subcutaneous emphysema.

Serious complications with the open technique include lung trauma with ensuing lung contusion, pulmonary and diaphragmatic lacerations, intercostal artery bleeding, splenic, hepatic and gastric lacerations, and injury to the heart and great vessels. Physicians report infections around the tube site, keloid formation, and chronic pain. Overall morbidity is 2% to 10%. The practitioner risks scalpel injury, particularly as most of these procedures are done urgently.

The distinguishing characteristics of the Salvino-Flex device are its patented eccentric blade (replacing the sharp trocar), elliptical shaft (easier penetration between ribs), simple gearing mechanism for blade advancement and retraction, tissue adhesive and antibiotic applicator sheath (precludes need for scalpels, needles - except for local anesthesia - or sutures), enhanced safety to both the patient and clinician, and reduced device requirements (no scalpels, sutures, hemostats, and gauze).

FOUNDERS

Chris K. Salvino, MD, MS, MS, MT, FACS, previously Medical Director of the Level I (Major) Trauma Department at Good Samaritan Hospital in Downers Grove, Illinois is President at the Weight Intervention and Surgical Healthcare (WISH) Center. He is board-certified in general surgery. Flex Partners, Inc. is a medical device design, engineering firm, based in Encinitas, California. Martin Kleckner III, PhD, MBA, MA, is Managing Principal of La Costa Group LLC in Carlsbad, California.

MARKET VALUATION

<u>Market Value (\$ Millions)</u>	<u>(Annual Sales)</u>	<u>Price per Unit: \$155</u>
United States	\$337 ML	COGS: \$35.75
International	\$388 ML	Non-U.S. Multiple: 1.15
TOTAL:	\$725 ML	