

FDA INVESTIGATION

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1. General Information:

Device Generic Name: Patient-activated support harness Device

Trade name: HEART HUGGER - Sternum Support Harness

Manufacturer: General Cardiac Technology, Inc..  
147 S. River Street, St. 232

Santa Cruz, CA 95060

2. Indications for Use:

For use in supporting the sternum against percussive expansion during respiratory therapy, coughing and deep-breathing following open-heart surgery.

Device Description:

A cloth band partly around the torso, suspended from shoulder straps, with handles provided to allow on demand support to the sternum.

4. Alternative Practices and Procedures:

Alternate practice is to hug a pillow, folded sheet or stuffed animal.

5. Adverse Effects of the Device on Health:

No adverse effects were reported during clinical investigation.

6. Summary of Investigation:

Site A: PROVIDENCE MEDICAL CENTER  
Seattle, Washington

Investigator: CARDIOVASCULAR GROUP, INC.  
Seattle, Washington Ms.  
Linda Leitzinger, RN

Site B: MEMORIAL MEDICAL CENTER OF JACKSONVILLE  
Jacksonville, Florida

Investigator: NORTH FLORIDA CARDIOVASCULAR  
Jacksonville, Florida Mr. J.  
Theodore Wingard, MD

Site C: ASHVILLE VETERANS ADMIN. MEDICAL CENTER  
Ashville, North Carolina

Investigator: ASHVILLE VETERANS ADMIN. MEDICAL CENTER  
Ashville, North Carolina Ms. Zelda Curtis,  
RN

a. Subject selection and criteria:

All subjects were adult open-heart surgery patients who had no surgical or recuperative complications.

b. Study population:

30 patients.  
Patients were 27 to 74 years old  
(average 60.2 years).

c. Materials and Methods:

Each subject was given a HEART HUGGER and instructed on its use and function. Each subject filled out a questionnaire daily until released from the hospital. Additionally, the investigator filled out a questionnaire for each subject. The questionnaires elicit subjective responses to specific questions. The collected responses to all questionnaires represent the data collected in these investigations.

d. Adverse reactions:

No adverse effects were reported.

e. Device failures and replacements:

None

f. Statistical Analysis of clinical investigation:

Subjects:

1. 27 of 30 patients (97%) reported that the device was easy to use.
2. 26 of 30 patients (87%) reported that use of the device proved effective in reducing the pain experienced during respiratory therapy, coughing and sneezing.
3. 26 of 30 patients (87%) reported no restriction to normal movement or that the device assisted normal movement by providing sternum support.
4. 27 of 30 patients (90%) recommended that other patients experiencing similar conditions use the device for sternum support.
5. 26 of 30 patients (87%) reported that the device would continue to be beneficial during recuperation at home following release from the recovery ward.

Investigators:

1. In 28 of 30 patients (93%), the device appeared to reduce patient pain.
2. Use of the device reduced patient complaints regarding pain in 26 of 30 patients (87%).
3. In 27 of 30 subjects (90%), the device appeared to reduce anxiety about the need to cough during respiratory therapy.
4. In 30 of 30 subjects (100%), the device did not interfere with the function of drainage tubes or monitoring equipment.

Conclusions Drawn from the Investigation:

HEART HUGGER is indicated for support of the sternum following open-heart surgery and other thoracic surgery procedures.

The following conclusions address the information requested by the FDA:

1. HEART HUGGER is effective in providing support to the sternum against percussive expansion during respiratory therapy, coughing and deep-breathing following open-heart surgery.
2. Therapeutic medical binders, to which HEART HUGGER is substantially equivalent, have no established performance standards.
3. HEART HUGGER does not interfere with the function of chest tubes or monitoring equipment.

a. Discussion of data on safety and effectiveness:

There is a need for a therapeutic medical binder that provides support to the sternum during respiratory rehabilitation following open-heart surgery. Respiratory rehabilitation is important in reducing the risk of complications of pulmonary edema, e.g. a collapsed lung, infection or pneumonia.

Patients are required to facilitate their respiratory rehabilitation by executing deep breathing exercises and frequent coughing to expel fluid from their lungs. During this coughing, or when sneezing, the patient's thorax is violently expanded by the action of the lungs and associated muscles. This percussive expansion causes extreme strain to the sternum incision which is only beginning the process of healing ... resulting in excruciating pain. This debilitating pain is experienced by most patients and is often cited as "the worst part of the recovery." This pain causes great energy loss and its' anticipation causes high anxiety, therefore, the patients go to great lengths to avoid any activity which might result in coughing or sneezing.

Conventional therapeutic medical binders are contraindicated due to their application of constant restraining pressure. Such constant pressure introduces the risk of pulmonary atelectasis and failure to expand the lungs due to pulmonary restriction.

The normally accepted and hospital suggested solution to this painful problem is to hug a pillow or stuffed animal in order to splint or support the sternum. This solution, while providing an inward pressure to the sternum, provides no support against the violent expansion of the sternum incision. It is generally recognized by the patients to be totally ineffective. Another solution sometimes suggested is to place a strip of cloth or toweling around the chest with the ends crossed in front. The patient may then pull on the crossed ends to apply restraining pressure.

Neither of these methods is effective for the following reasons: 1. A pillow does not apply support in the appropriate manner or direction. 2. The crossed strap" method must be applied by muscles which were severely weakened by the surgical procedure. 3. Neither of these methods is readily available when the patient needs them suddenly. 4. Neither of these methods will stay in proper position during the walking required of ambulatory patients.

HEART HUGGER was invented by an open-heart surgery patient as a result of his own experiences in coping with the pain of respiratory therapy, coughing and deep-breathing. It satisfies the post-operative recovery requirements of pulmonary function, accessibility, and ease of use.

HEART HUGGER reduces the patients' anxiety about the necessity of coughing during respiratory rehabilitation. (One subject exclaimed, "Now I can cough intentionally!") Investigators reported that in 26 of 30 subjects (87%), complaints regarding pain were reduced and 27 of 30 subjects (90%), subjects appeared to be less anxious about the necessity to cough during respiratory rehabilitation.

Unanticipated benefits reported were the ability to support the sternum incision when changing positions in bed, when getting into or out of bed and when straining during bowel movements.

HEART HUGGER was designed to be worn loosely at all times. The handles are kept in place through the use of the

restraining cord. This cord is designed to slip during normal use of the device, allowing the handles to remain in place without restricting pulmonary function.

HEART HUGGER presents no restriction to normal movement of the patient and in fact was reported to be beneficial to the patient by supporting the sternum while getting in and out of bed and in changing positions in bed.

In 26 of 30 subjects (8i%), study subjects reported that HEART HUGGER's use would be beneficial after release from the recovery ward and during recuperation at home.

b. Risk/benefit analysis:

HEART HUGGER presents no inherent risk to the recovering open-heart surgery patient. It provides the benefit of reduced risk of complications due to pulmonary edema without introducing the risk of pulmonary atelectasis and failure to expand the lungs due to pulmonary restriction.