The *ArmSafe*®

A New Device for Protecting the Upper Extremities during Surgery, Anaesthesia and Transport of Ill or Injured Persons

 A Synopsis

**The Problem: 1. Protection during Surgery and Anaesthesia.**

* During surgery and anaesthetic procedures, injury to body tissues, and nerves in particular, can occur due to excessive pressure and/or tension caused by poor positioning and inadvertent displacement of the arms.
* Peripheral nerve injuries account for approximately 16% of all anaesthesia related claims in the United States[[1]](#footnote-1). The ulnar nerve is the most commonly injured nerve. In the USA, short term, spontaneously resolving ulnar nerve injuries may occur in up to between 60.000 and 90.000 patients per year, and long term, severely debilitating injuries, in at least 5000 patients per year2,3.
* Symptoms usually do not become apparent until more than 24 hours after the surgery when the patient has been discharged. The frequency of these injuries is, therefore, often not appreciated by the attending staff. As a result, many injuries, go undetected, or are not investigated properly until the patient makes a complaint or takes legal action.
* There is a lack of dedicated methods and devices for adequately and safely securing and protecting the arms during surgical procedures and anaesthesia.

**The Solution:**

The *ArmSafe* is a new device designed for positioning and protecting the arms during surgery/anaesthesia and transport of patients. It is made of a fire retardant polyurethane foam material, shaped to form a semi encircling “channel” which surrounds the arm from the armpit to the tip of the fingers.

The arm is secured in the channel with two wide soft straps that attach to the side walls of the device. The height of the side walls increases towards the upper end, to better accommodate the larger volume of the upper arm. In the middle part of the device there is a vertical slot/opening in the side walls to allow electrical leads or tubing to exit. These slots also facilitate folding of the device when being packaged and stored.

Apart from the 2 straps securing the arm in the device, there are 2 additional straps to secure the device to the standard arm board used to position an arm for i.v. access and monitoring equipment. Alternatively, the device can be secured to the arm board with “Velcro” strips. The *ArmSafe* device can equally well be used to protect the arm when it is positioned along the side of the operating table as well as in most other body positions used during surgery.

The device is supplied compressed and vacuum packed ensuring a very small volume (20x150x280mm) and easy storage. Approximate weight is only 230 grams.

A biomechanical study of interface pressures in the elbow region, with the arm supported by a standard arm board setup and the *ArmSafe* device, showed potentially harmful interface pressures (3 to four times above capillary closing pressure), even when the arm was normally positioned (Medical Device Partnering Program, Engineering Department, Flinders University). When the arm was displaced into an abnormal position on a standard arm board, peak pressures registered in the medial elbow region, where the ulnar nerve is located, were up to 10 times as high as the capillary closing pressure. By preventing displacement of the arm, the *ArmSafe* device will prevent these high, potentially injurious pressures occurring.

The *ArmSafe* will also help to prevent those nerve injuries caused by excessive traction secondary to displacement from an originally safe position.

Feedback from operating room nurses in a clinical trial has been very positive. The *ArmSafe* was used on 56 arms, in 35 patients having surgery in the supine position. In 19 cases the nurse had never used the *ArmSafe* before. In all 35 cases the nurse thought the *ArmSafe* was easy to use. In all but one case the nurse thought the *ArmSafe* was better than the standard methods used. Anecdotal evidence from patients has also indicated that the *ArmSafe* is perceived as being an exceptionally comfortable arm support.

**The Problem: 2. Protection during Transport**

* During transport of ill or injured persons, **with** or **without** injuries to the upper extremities, there is a need to safely position, protect and/or splint the arms to minimize bleeding and pain, prevent secondary injuries, or to simply provide a comfortable position for the arms during transport of ill, non-injured patients.
* In the typical “stretcher” found in road ambulances and other emergency transport vehicles for air and sea transport, there is a lack of space with ensuing difficulty to safely position and protect the arms. Inadvertent, sometimes violent, movements by the patient, or by the vehicle, increases the risk of injuries.
* There is thus a risk that the arms or hands can be displaced into potentially harmful positions caused by pressure against the edge of the stretcher or by being wedged in between the stretcher and the walls of the transport vehicle. The risk is compounded by an increasing average body weight and girth in the population.
* Although there are many devices available, there is a lack of dedicated and standardized methods and devices that fulfil the demands of a simple and universally applicable device that is easy to use and comfortably positions and protects the arms during transport.

**The Solution:**

By deleting the straps for securing the “surgical” *ArmSafe* device to an arm board, the same device can equally well be used for securing and protecting the arms during stretcher and ambulance transport.

The device can be used on one or both arms. It can be used together with already commonly used conventional stretcher and ambulance strap/harness arrangements or with a dedicated “Velcro” strap system.

Due to its lack of a rigid shell (such as found in cardboard or plastic splints) the soft and conforming foam of the *ArmSafe* will provide a gentle and wide pressure distribution area as well as protection and splinting of the arm, which will be enough for non injured arms and even for many cases of injured arms.

When more splinting effect for injured arms is desirable a second *ArmSafe* modification can be used which incorporates a plastic semi-rigid strip attached to the underside of the *ArmSafe* channel. A lockable hinge allows the device to be folded and vacuum packed with the same small foot print as the basic *ArmSafe* model.

**Summary of salient features of the *ArmSafe***®**.**

* Safely positions and protects the arms during surgery/anaesthesia and during transportation of ill or injured persons.
* Easy and quick to use.
* Fits all existing equipment.
* Protects and provides easy access to I.V. lines and monitoring equipment.
* Standardized. Same device and application to most situations.
* Single use. No risk of contamination and transmission of pathogens.
* Easy to store. Comes vacuum packed with small foot print (20x150x280mm) and light weight (230gram).
* The total potential surgical/anaesthetic procedure market in the USA and Europe could amount to 100 million plus procedures yearly.
* The markets for transportation use includes civilian and military transports (road, air, sea), as well as initial stretcher transportation after sporting and other recreational injuries.
* Other potential markets include nursing homes, hospital wards and emergency departments in situations where protection, splinting or immobilization of an arm is indicated.
* An international patent application (PCT/AU2009/001411 entitled “Limb Supporting Apparatus” was filed on 28 October 2009 and published on 14 May 2010 (WO2010/051577). A US patent application has also recently been filed (S/N 12/925,204).

Additional information including a video demonstrating the use of the *ArmSafe* during surgery, is available on URL:

<http://www.youtube.com/watch?v=3_h_ePJaxLA>  (short version, 2.5 min)

<http://www.youtube.com/watch?v=hOhz1ItgtEg>   (longer version, 10 min)

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1. Wijayasiri, L., Batas, D. & Quiney, N., Hereditary neuropathy with liability to pressure palsies and anaesthesia: perioperative nerve injury. Anaesthesia, 2006. 61: 1004-1006.

2 Warner, M.A., Warner, M.E. & Martin, J.T., Ulnar Neuropathy. Incidence, Outcome and Risk factors in Sedated or Anesthetized Patients. Anesthesiology, 1994. 81: 1332-1340.

3 Warner, M.A., et al., Ulnar Neuropathy in Surgical Patients. Anesthesiology, 1999. 90: 54-59 [↑](#footnote-ref-1)