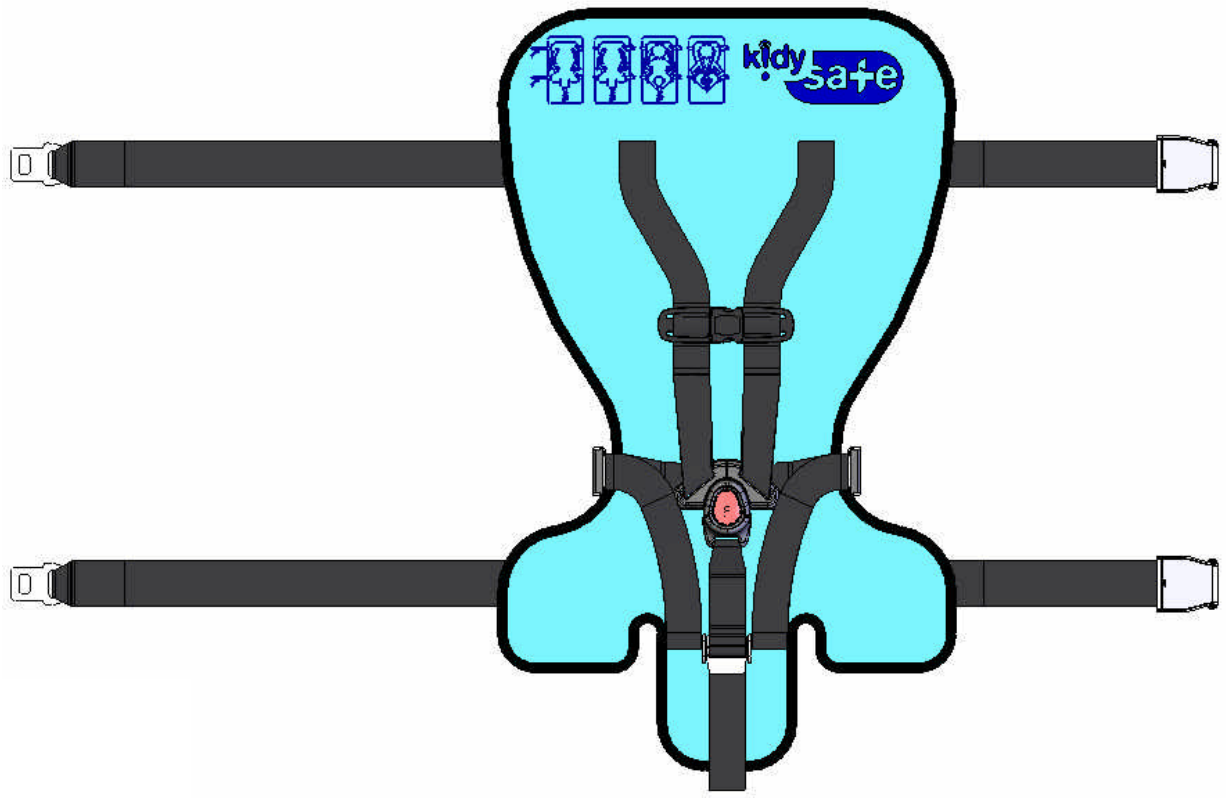
PEDIATRIC RESTRAINT SYSTEM FOR AMBULANCE STRETCHERS



DESCRIPTION OF THE DEVICE

Kidysafe is a pediatric restraint system for ambulance stretchers used to hold children during their transportation by ambulance.

The device consists of a body canvas with a protective vinyl coating developed to provide a resistant efficient barrier versus germs, abrasion and stains. The canves is provided with straps to fasten the device to the ambulance stretcher. The length of the straps can be adjusted to various stretcher sizes.

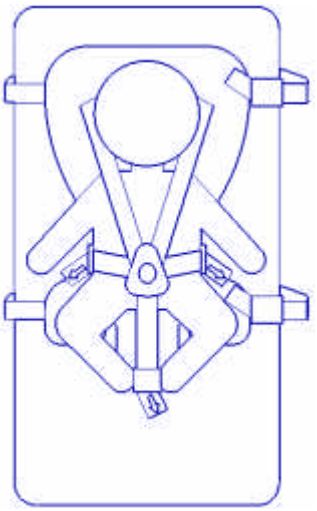
In addition to the straps that fasten the device to the stretcher, it is also equipped with straps to hold the child to the device. These straps have a five-point centralised buckling system located over the abdominal area of the patient. This system allows the release of the child as quickly as possible by simply releasing the buckling mechanism mentioned above

As a result, the device can be adjusted to any size of ambulance stretcher, is safe and extremely simple and easy to use.

Child restraint system:

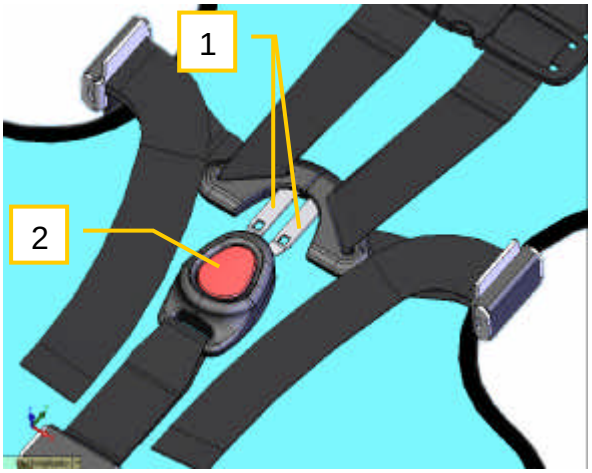
The child-fastening system consists of a centralised buckling system located over the abdominal area of the patient. This system allows the release of the child as quickly as possible by simply releasing the buckling mechanism. There is also a strap-fastening system located over the chest of the child. The child-fastening system includes elements for quick adjustment of the strap length that can adapt to a variety of child anthropometrics for which the product was designed.

Straps:



The child restraint harness consists of five straps. Two straps hold the child by the shoulders, another two hold the pelvic area and the last strap holds the inguinal region, preventing the child from slipping out of the device.

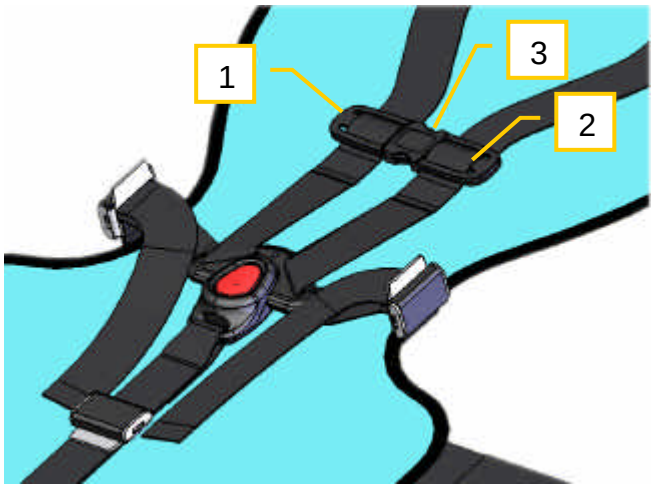
5 points locking buckle:



The system is fastened and locked at a single centralised point located over the abdominal region of the patient and clearly visible, so that, in the event of an accident, the child release manouver can be carried out very quickly by simply pushing the red release button (2). The force required on this button to release the child is 5 kg, which prevents young children from releaseing themselves accidentally.

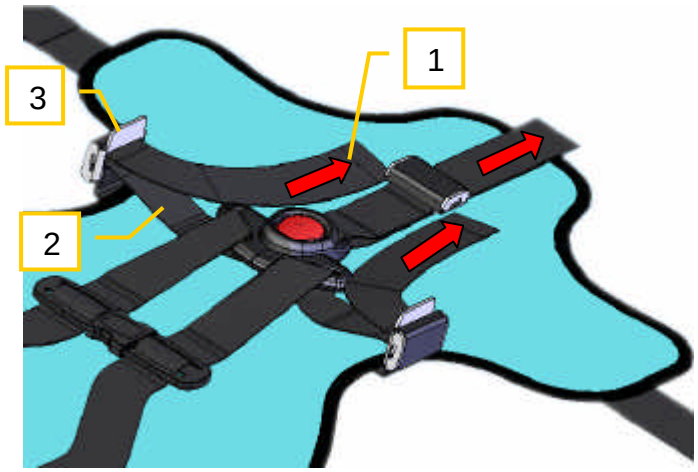
The buckle design is such that it can only be assembled in the correct manner. The closing mechanism only locks if the two parts (1) are inserted in in the main body (2). The closing mechanism is designed to withstand loads over 1000 kg.

Chest buckle:



The Kidysafe is equipped with a strap-fastening system located over the chest region of the patient. This clip type buckle sistem allows quick fastening and release of the mechnism. To fasten it, just insert part (1) into part (2) until a click is heard. To release, just apply pressure to the tabs (3).

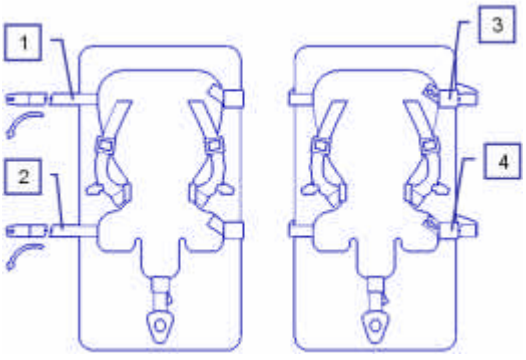
Strap length adjusting system.

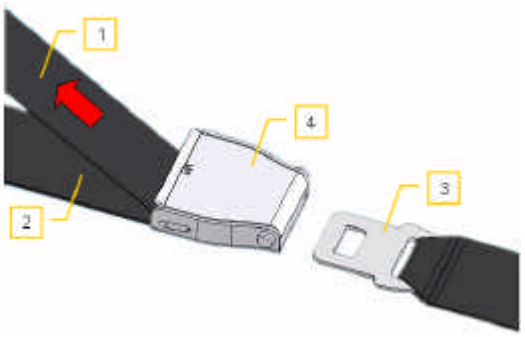


The strap length adjusting systems are located at the free ends of the straps. Their purpose is to adjust the straps to a variety of child anthropometric sizes for the mass group for which the product is designed. Once the child is placed on the device and the straps are fastened, these can be adjusted by simply pulling the free ends (1) of the straps. If, on the contrary, we wish to loosen the straps, all that is required is to hold the adjuster (3) and simultanenously pull the other end (2) of the strap.

Kidysafe fastening system:

The device consists of a body canvas provided with straps to fasten the device to the ambulance stretcher. The length of the straps can be adjusted to various stretcher sizes.The straps that fasten the device to the stretcher are fastened at two points. Straps (1 and 2) wrap around the mattress of the stretcher and part of the frame and are then fastened by the anchoring system (3 and 4).





The strap fixing and length adjusting buckles are located at the free ends of the straps. These allow the straps to be fastened to the stretcher and adapt to the various sizes of ambulance stretchers for which the product has been designed. The buckles are the same as those used for plane safety belts. To fasten the strap, insert the tab (3) into the buckle (4). Once the strap is fastened, the length is adjusted by pulling the free end (1) of the strap. If, on the contrary, we wish to loosen the straps, all that is required is to pull the other end (2) of the strap.

APPLIED STANDARDS AND IMPLEMENTED SOLUTIONS

1.1 List of standards applied

The standards and regulations applied in the development of the product are listed below:

REGULATION 93/42/CEE	Medical devices.
BS EN 1865-2000	Specifications for stretchers and other patient handling equipment used in road ambulances
BS EN 1789-2000	Medical vehicles and their equipment. Road ambulances.
BS EN 1021-1	Assessment of the ignitability of upholstered furniture.
BS EN 980	Graphical symbols for use in the labelling of medical devices
CR 14060	Medical device traceability

1.2 Implemented solutions.

- The materials used in the manufacture of the Kidysafe are resistant to bacteria, fungi, stains and putrefaction. In addition, they are washable, waterproof and gasoline/oil resistant.

- The Kidysafe is not affected by disinfectants (bleach, soapy water,alcohol, hidrogen peroxide and other possible liquid disinfectants)

- The Kidysafe cushion is anti-slip.

- The straps tensile strength is over 7.2 KN
- The Kidysafe complies with the inflamability requeriments of the European standard EN 1021-1.
- Storage temperature range between -30ºC and -70ºC
- Operational temperature range between -5ºC and 50ºC.
- The Kidysafe is resistant to the vivrations transmitted by the ambulance.
- The materials used in the manufacture are compatible with biological tissues, cells and body fluids, bearing in mind the purpose of the product.
- The design is apt for easy handling and minimises product contamination by the patient or vice-versa during use.
- The packaging bag preserves the product and prevents it from deterioration.

STORAGE

Allways keep the Kidysafe in its storage bag when not in use. This will protect the product from deterioration and maintain the required conditions of cleanliness.

Storage bag dimensions: 5x20x48 cm