

Issue Date:10th November 2021

SAFETY ALERT NOTICE.

Drug / Product / Device : LUCAS Chest Compression System



Identified Issue / Concern / Problem/ Evidence of harm.

Pathology reports indicated in 3 instances that there was significant injury to patients where CPR and Mechanical CPR had been deployed. There is no evidence as to whether the injuries occurred in manual or mechanical phase however it was observed that in at least one case the stabilisation strap was not used which could lead to poor device positioning. If you are unsure as to strap use please consult user manual and your ECAO now.

Actions Required / Risk Treatment strategy

Always apply the stabilisation strap as soon as is practicable in keeping with the manufacturer's guidance. Please also regularly check back plate and suction cup position.

5.5 Apply the Stabilisation Strap

The LUCAS Stabilisation Strap helps secure the correct position during operation. Apply it while the LUCAS device is active to keep interruptions to a minimum.

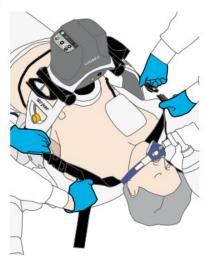
Caution - Stabilisation Strap application Delay the application of the LUCAS Stabilisation Strap if this prevents or delays any medical treatment of the patient.

- Remove the neck strap, which is a part of the Stabilisation Strap, from the Carrying Case (the support legs strap of the Stabilisation Strap should already be attached to the support legs).
- Extend the neck strap fully at the buckles.
- Carefully lift the patient's head and put the cushion behind the patient's neck. Position the cushion as near the patient's shoulders as possible.
- Connect the buckles on the support leg straps with the buckles on the neck strap. Make sure that the straps are not twisted.

- Hold the LUCAS support legs stable and tighten the neck strap tightly.
- Make sure that the position of the Suction Cup is correct on the patient's chest.

If it is not, adjust the position:

- a. Push ADJUST.
- B. Release the neck strap from the support leg straps.
- c. Adjust the Suction Cup position (as described in the section 5.4.2).
- d. When the Suction Cup is in the correct position, push ACTIVE (continuous) or ACTIVE (30:2) to start the compressions again.
- e. Attach the neck strap again. Refer to the steps 2 to 5 above.



Issued by: Quality & Patient Safety Team



