



LEG & ARM LIFT ELECTRICAL, MODEL 2009-01



INSTRUCTIONS FOR USE (IFU)

NOT A STERILE DEVICE





Explanation of symbols on labels and packs



Manufacturer



Date of production



Serial number



Catalogue Article Number



For single use



Read the user instructions



Read the directions



Declaration of conformity, Class I
(MDR)



Latex-free product



Unique Device Identification



Medical Device

Manufacturer:

Opitek International
Gøngehusvej 252
DK-2950 Vedbæk
Denmark

Phone: +45 39 66 16 44
Email: info@opitek.dk

For ordering components and accessories:

www.opitek-international.dk info@opitek.dk shop.opitek.dk



Description and indication(s):

Prevent injuries when lifting patients' legs and arms in the operating theatre.

The preparation of a surgical site on either the arms or legs of a patient often requires lifting, holding, and lowering procedures. This job is normally undertaken by theatre staff and can be physically demanding.

This unique electrical lift uses a hand control to lift the patient's leg or arm into the correct position. The limb can also be lowered using the hand control to ensure a smooth and safe process.

Scan, see and read our flyer and videos with many examples of use in many clinical lifting situations and the handling of the different strap types:

**Precautionary measures:**

- When using the equipment, care must be taken to avoid overexertion of the patient's extremities.
- Be careful to place the lift's longest pair of legs under the patient/operating table to prevent the lift from tilting.
- Make sure that all loose parts are securely mounted or are placed in the designated holders on the equipment (see photos below).
- Please ensure that no lifting arms remain fitted to the equipment when it is "parked" for charging or after use. This is to avoid personnel walking into the equipment and sustaining injuries due to equipment/lifting arms protruding beyond the base of the lift.
- If disposable straps are used, it is important that they are not re-used to avoid cross-contamination.
- During use, care should be taken to ensure that there is no risk of crushing for the operator or patient between fixed and movable parts.

Side effects:

No side effects have been reported with the use of the equipment

Photos may differ from the delivered model.

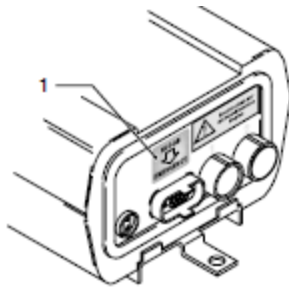
Charging:

The equipment should be regularly charged, e.g. overnight, or once a week, with the supplied adapter, or when the indicator light flashes “empty”. The battery is fully charged when the green indicator light comes on.

The safety cut-off (**the red button - EMERGENCY STOP**) is triggered when the button is pressed. To restore full functionality, turn the knob in the direction of the arrow.

Safety lowering:

Lowering in the event of power loss is always possible by pressing the button labelled “emergency down” located under the control box (the box with the emergency stop – marked “1” in the drawing below).

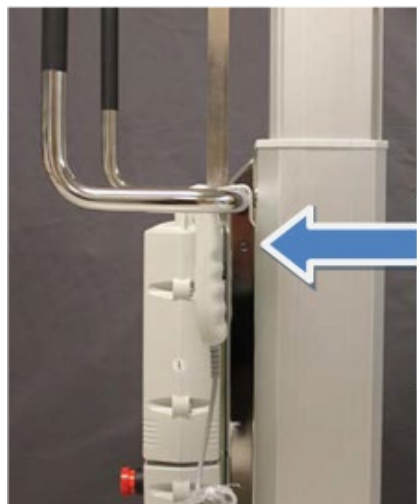


Unlike EMERGENCY STOP, the “emergency down” option is intended for use in the event of a failure. A defective control can be bypassed by pressing “emergency down”. This means that electric lowering (withdrawal) of the drive is possible. The “emergency down” only applies to the drive on channel 1.

Press “Emergency Down” on the yellow button (↖fig., pos. 1)



**EMERGENCY
STOP**



Indgangen til laderen er på højre side af benløfteren.

Accessories and storage holder included:



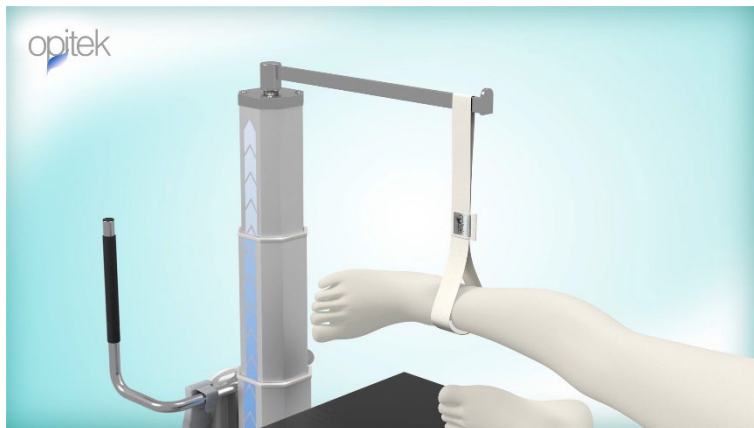
The following accessories are included as standard:

- 1) Lifting arm, 50 cm
- 2) Elevation part, 40 cm
- 3) Lifting arm for bilateral lifting

Accessories that can be purchased:

- 1) Lifting arm, extended, 72 cm (article no: 200115)

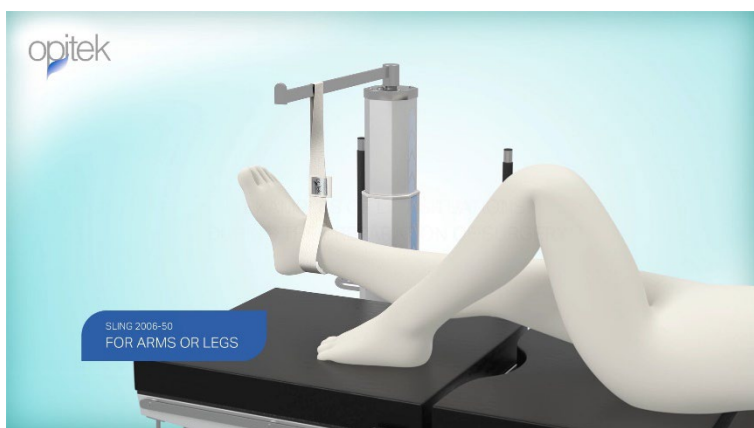
Use of the leg and arm lift:



When lifting one of the patient's legs, the lifting strap with article no. **2006-50** is frequently used.

Place the leg lift at the operating table with the longest pair of legs under the table.

Using the lifter hand control, raise the leg to the required level and lock the rear pair of wheels of the lift to secure the position.



When lifting a patient in the lateral position (e.g. for hip surgery), pay particular attention to the patient's knee so that it is not subject to unwanted flexion. This can be done by rotating the foot / leg slightly upwards.

When lifting a single arm, the strap with article no. **2006-50** can be used.

Place the lift with the longest pair of legs under the operating table, and raise the arm to the required height.

Lock the rear pair of wheels of the lift to secure the position.

If the patient is seated (e.g. in a “beach chair”), the **elevation kit** (see the illustration on the right) can be used to achieve the desired height for arm/shoulder disinfection. The elevation kit is placed in the same position as the usual lifting arm, which is then placed on top of the attachment. This increases the maximum lifting height by approx. 40 cm.



Lifting the arm with article no. **2006-60**

In this situation, if the arm has to be lifted almost vertically upwards, it is advantageous to use article 2006-60, which has a Velcro® fastening, as opposed to article 2006-50, which is a more “passive” strap type





For forefoot lifting of one of the patient's legs, a lifting strap with article no. **2006-60** is used.

Place the leg lift by the operating table with the longest pair of legs under the table.

Using the hand control, raise the leg to the required level and lock the rear pair of wheels of the lift to secure the position.

The strap is secured with Velcro® Coins (article no. **2006-65**) so that the lifting strap does not slip off the foot.



For bilateral lifting of both of the patient's legs, use the supplied crossbar which is placed on the lifting arm without the use of tools.

Then use strap type **2006-50** or **2006-60** (possibly with Velcro® Coins **2006-65**).

Place the leg lift by the operating table with the longest pair of legs under the table.

Using the hand control, raise the legs to the required level and lock the lift's rear pair of wheels to secure the position.





For lifting in the abdominal/pelvic and lateral positions, the supplied crossbar may be used as a supplement. This is placed on the lifting arm without the use of tools.

Place the leg lift by the long side of the operating table (on the operating side) with the longest pair of legs under the operating table.

Use the strap set with article no. **2006-70**. The wide strap is placed proximal to the knee/thigh and the smaller strap is placed in the arch or around the ankle.

The wide strap is also available on its own as article no. **2006-70-1** (illustration)

Certificates, standards and details for lifting straps:

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
2176-354 DTI



Tested for harmful substances.
www.oeko-tex.com/standard100



2006-50



2006-60 + 2006-65



2006-70-1



2006-70

Cleaning and disinfection:

- To clean the leg lift, use a soft lint-free cloth with a mild detergent.
- Then, if required, wipe the surfaces with a disinfectant.
- The department’s regular disinfectants can be used for surface disinfection of equipment in the operating theatre
- Lifting straps and Velcro® Coins cannot be cleaned or disinfected
- Cleaning and disinfection instructions can be found here:



Product	Article number
Lifting strap (Min. order 50 pcs.) ⊗	2006-50
Lifting strap w/Velcro® (Min. order 50 pcs.) ⊗	2006-60
Velcro® Coin (for strap 2006-60), Bag of 50 pcs. ⊗	2006-65
Lifting strap, set (1 wide strap and 1 narrow strap with Velcro®) (Min. order 10 pcs.) ⊗	2006-70
Lifting strap, wide only (Min. order 10 pcs.) ⊗	2006-70-1
Charger, 230V/28V, for EU plug	0132841
Hand control	EHA11-11B10N-000
Battery, 24V	ZBA-142211

Technical specifications:

Expected battery life approx. 3 years.

Max lifting capacity of the leg lift: 250 kg – 100 kg (0 cm – 50 cm from the centre).

Tensile strength test lifting straps 2006-50: max. 1262 N (approx. 125 kg)

Tensile strength test lifting straps 2006-60: max. 323N (approx. 30 kg)



Declaration of Conformity

We, the manufacturer

Opitek International ApS, Gøngehusvej 252, 2950 Vedbæk, Denmark
(Org. number: 30554582 - SRN: DK-MF-000001594)

declare that the following product(s):

Name of product / article	Article number	UDI-DI
Electrical Leg & Arm Lift	2009-01	5714834000161
Lift String, upholstered	2006-50	5714834000130
Lift String, with Velcro lock	2006-60	5714834000123
Velcro pad for 2006-60	2006-65	5714834000116
String set: 1 pcs 2006-70-1 + 1 pcs. 2006-60	2006-70	5714834000147
Lift String, wide upholstered	2006-70-1	5714834000154

Is (are) in conformity with the provisions of the following:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

**Classification according to Annex VIII, Chapter III, 4.1
Medical Device Class I: Non-invasive devices**

Certification according to and in compliance with Annex I, II and IV

Issued under the sole responsibility of the manufacturer

Place: Vedbæk, **Date:** December 20, 2021

Peter Christensen
CEO, Managing Director
Opitek International ApS



Version: 0.3





opitek

