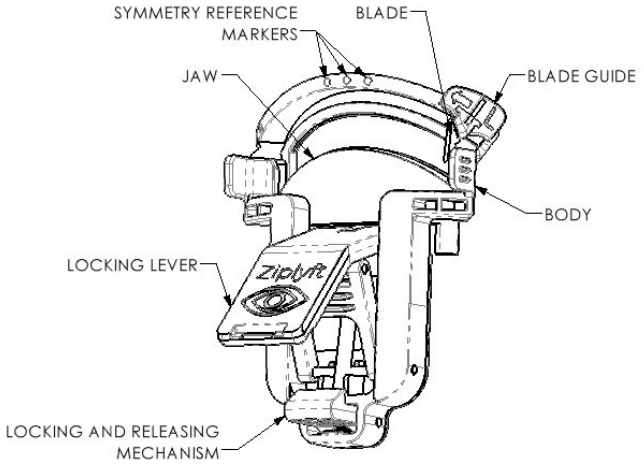
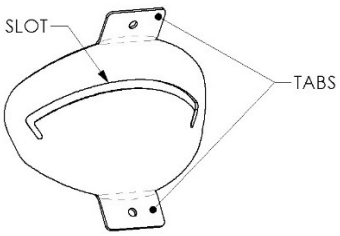
Ziplyft™ Upper Eyelid Lift Kit

Instructions for Use (IFU)





DESCRIPTION

The Osheru Ziplyft Kit consists of a left and right side device designed to facilitate bilateral blepharoplasty, two (2) Ziplyft-Assist devices (only included in model OSH-ZLK**A**-MED), and a pair of ophthalmological forceps.

INDICATIONS/INTENDED USE

Ziplyft is a nonpowered, handheld device intended to facilitate the removal of excess eyelid skin. The Ziplyft-Assist is a non-powered, handheld device intended to capture, enable marking and secure excess eyelid skin intended for removal. They are indicated for use in the treatment of excess/unwanted eyelid skin during blepharoplasty procedures and to treat conditions such as dermatochalasis.

CONTRAINDICATIONS

- Active infection
- Severe dry eyes
- Active inflammatory cicatrizing skin conditions
- Pathologic conditions of the eyelids or orbital structures.

WARNINGS

Do not use if the product, protective packaging, or sterile packaging is damaged, opened unintentionally before use, and/or exposed to environmental conditions outside of those specified in the IFU.

This device was designed and tested for single patient use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing, or resterilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness, or death. Risk of residual contamination and resterilization failure may lead to patient injury, infection, illness, or death.

PRECAUTIONS

- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

COMPLICATIONS

Potential complications associated with the use of the Ziplyft Kit are the same as the potential complications associated with blepharoplasty procedures in general. Potential complications include but are not limited to infection, bleeding, wound dehiscence, asymmetry, insufficient skin removal, excessive skin removal, abnormal lid crease, drooping upper eyelid, scarring, and unsatisfactory results.

HOW SUPPLIED

This kit is supplied sterile (sterilized using irradiation) and for single patient use.

STORAGE AND HANDLING

- Handle with care. Store at room temperature in an area designed to maintain sterile packaged items. Avoid prolonged temperature excursions. Device should be securely stored.
- Breaches of package integrity will not maintain sterility of device.

INSTRUCTIONS FOR USE

- **Patient Prep**
  - Ensure the surgical site has been prepared according to standard clinical practice.
- **Pre-Procedure Device Check**
  - Identify the correct device for each side:
    - The device with the white blade guide, marked “R” is intended for use on the right side.
    - The device with the black blade guide, marked “L” is intended for use on the left side.

- Before patient contact, position the blade guide in the temporal direction:
  - White blade glide positioned on the left side of the device
  - Black blade glide positioned on the right side of the device.

- **Optional Use of Ziplyft-Assist Device**
  - Position the Ziplyft-Assist over the area of tissue intended for engagement.
  - Squeeze the tabs to open the Ziplyft-Assist slot fully.
  - Using the green forceps, grasp the central portion of the tissue to be engaged and guide it through the open slot.
  - Release the tabs to allow the Ziplyft-Assist device to return to its closed position, securing the tissue within the slot.
- **Positioning the Ziplyft Device**
  - Verify that the blade guide is positioned temporally.
  - Open the jaws fully
  - Using the included forceps, gently lift the target tissue and guide it into the open jaws of the device.
  - Ensure that the tissue intended for removal is seated within the jaws before closure. Closing the jaws prematurely may prevent complete tissue engagement.
- **Locking the Device**
  - Confirm that the target tissue is fully enclosed within the jaws.
  - While stabilizing the device with non-dominant hand, gently depress the locking lever until the latch clicks into place.
  - Keep the device locked for the duration required for proper device function.
- **Use on the Opposite Side**
  - Repeat the same steps using the corresponding left or right device.
  - Use the three symmetry reference markers to verify consistent device positioning on both sides.
- **Cutting and Tissue Removal**
  - Stabilize the base of the device body securely with dominant hand,
  - Using the thumb of the opposite hand, advance the blade guide completely across the device to complete the cut.
  - The included forceps may be used to gently support the tissue being excised as the blade advances
- **Maintaining Device Positioning After Cutting**
  - Leave the jaws locked for the duration required for proper device function.
- **Device Removal**
  - Press the lever arm to release the locking mechanism while stabilizing the device body.
  - Remove device carefully to avoid disturbing the treated tissue.
- **Orientation of the Tissue Ridge**
  - Ensure the elevated tissue ridge created by the device is positioned as required for proper adhesive application.
- **Application of Tissue Adhesive**
  - Apply tissue adhesive to the treated areas according to adhesive manufacturer's instructions for use.

Additional Information
A separate surgical technique guide containing procedural considerations related to the Ziplyft device is available upon request from *Osheru*.

SAFE DISPOSAL
The Ziplyft devices should be disposed of in a secure sharps' container due to its guarded blade.
The Ziplyft-Assist and forceps may be disposed of according to normal healthcare facility procedures.

REPORTABLE INCIDENTS
If a serious incident occurs in relation to the device, notify Osheru and the local authority, if applicable or required within the region

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Refer to the electronic symbols glossary at www.ziplyft.com/symbols for explanations of symbols used in device labeling.

To request a copy of this eIFU in paper form please contact contact@osheru.com