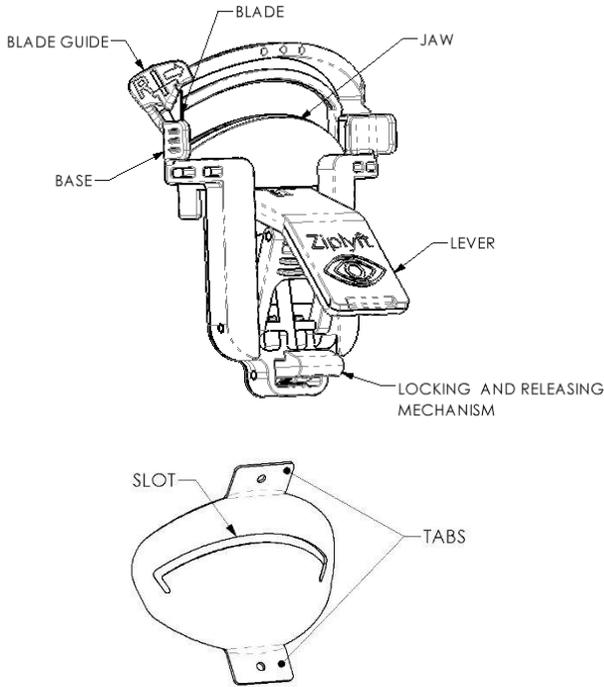


Ziptyft™ Upper Eyelid Lift Kit

Instructions for Use (IFU)



DESCRIPTION

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

INDICATIONS/INTENDED USE

Ziptyft is a nonpowered, handheld device intended to facilitate the removal of excess eyelid skin. The Ziptyft-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 Ziptyft 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**
 - Mark for upper blepharoplasty
- **Pre-Procedure Device Check**
 - The device with the white blade guide, marked with "R" is for the right eyelid; the device with the black blade guide, marked with "L" is for the left eyelid.
 - Prior to placement on the patient, position the blade temporarily: the white blade glide

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- should be on the left side of the device, and the black blade glide should be on the right side of the device.
- With the blade positioned far temporally, open and close the device, and gently and slowly push lever to lock jaw in place, to ensure the surgeon is comfortable with the locking and releasing mechanism. Confirm that the jaws lock securely and release smoothly.
- If the jaws do not function correctly, dispose of the device and open a new one.
- **Ziptyft-Assist Placement (Optional)**
 - Position the Ziptyft-Assist over the marked skin with the slot following the curve of the natural lid crease.
 - Squeeze the tabs together to open the Ziptyft-Assist slot.
 - Using the green forceps, grasp the centrally marked skin and pull all of the marked skin targeted for excision through the slot of the device.
 - Release the Ziptyft-Assist and confirm that all marked skin has been fully pulled through and securely clamped.
- **Positioning the Ziptyft Device**
 - Verify that the blade is positioned temporally before placing the device on the upper eyelid while the eye is closed.
 - Align lower jaw of device with the natural lid crease or lower aspect of the marked skin.
 - Apply gentle pressure to the upper lid with the device to allow lid tissue to come forward through the jaws.
 - Lift the marked excess skin, ensuring all marked skin is enclosed within the device's jaws.
- **Locking the Device**
 - Confirm that the marked skin is fully enclosed within the jaws.
 - While holding in position with non-dominant hand, gently and slowly push lever to lock jaw in place and leave locked for 2 minutes.
- **Repeat and Confirm Symmetry**
 - Perform the same steps on the other eyelid.
 - Use device markings located on the front top of the device body and patient brow markings to ensure symmetric alignment between both eyelids and that the correct amount of tissue is enclosed in the jaws on both right and left sides.
- **Skin Cutting and Removal**
 - While holding the base securely with dominant hand, use thumb with non-dominant hand to push blades across completely to excise the skin. Use forceps to

pull skin against sharp end of blade to remove excess skin.

- Leave the jaws locked for an additional 2 minutes to maintain hemostasis.
- **Device Removal**
 - Unlock the device by pressing the release button with your dominant hand while holding the top of the device with your non-dominant hand.
 - Gently remove device.
- **Drying and Positioning**
 - Gently dry the elevated "zipper-locked" ridge with a Q-tip. Compress, don't rub when drying adjacent to the ridge. Be careful not to unseal the skin.
 - Ensure the elevated ridge is oriented at a 90-degree angle to the incision before applying the adhesive.
- **Application of Tissue Adhesive**
 - Apply tissue adhesive to both right and left incisions according to manufacturers instructions

The surgical technique guide contains further information on the Ziptyft device and may be obtained by contacting *Osheru*.

SAFE DISPOSAL

The Ziptyft devices should be disposed of in a secure sharps' container due to its guarded blade. The Ziptyft-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.ziptyft.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