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CE 1639

# A7080. 0.2g and A7082. 0.4g Malhotra Platinum Segments

***Weight tolerances +/-0.05g.***

***EU Edition.***

***Caution: This device is only to be used by a suitably trained and qualified physician under normal operating room conditions. Contact Altomed for further details.***

**Unique Device Identifiers (UDI):**
A7080 - 0.2g Segment: 05055505140305
A7082 - 0.4g Segment: 05055505140312

**Symbols Used to BS EN ISO 15223-1 and ASTM F 2503:**


Single Use Device


Keep away from direct sunlight and keep dry

Sterilized in Ethylene


Instructions for Use


Do not use if pack is damaged

CE 1639 Meets EU CE Mark Requirements


Use By Date

Lot Number

Catalogue Number


Fragile. Handle with care


Caution. Consult instructions for use.


Manufactured by

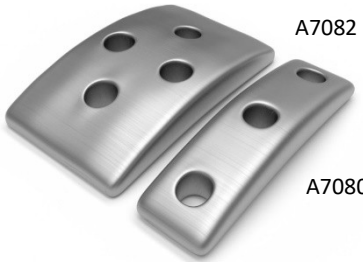
MRI safe under the specified conditions

## Intended Use

Malhotra Platinum Segments® are eyelid implants used in Lagophthalmos to weigh down the upper eye lid to aid closure.

## Device Description

The Malhotra Platinum Segments® have been developed with Raman Malhotra FRCOphth in order to provide gravity assisted treatment for lagophthalmos. The sutured format also allows the chain to be flexible and mould to the contour of the patient's eye. The surgeon selects the quantity and sizes of weight to be used for each individual patient. The weights are made from an alloy of Platinum and Iridium and are available from Altomed Limited (sales@altomed.com). Weights can be removed or added by the Surgeon if deemed necessary.



A7082 Malhotra Platinum Segment® 0.4g 6.00mm x 4.00mm x 1.00mm

A7080 Malhotra Platinum Segment® 0.2g 6.00mm x 2.30mm x 1.00mm

## Contra-Indications

These devices should not be used on patients with known allergies to platinum, iridium or nickel. They should also not be used when there is inflammation or signs of infection of the upper eyelid.

## Precautions

In immunocompromised patients, those with wound-healing disorders, or those receiving cytotoxic drugs or radiotherapy, additional immediate post-operative prophylactic systemic antibiotic therapy is recommended to reduce the risk of early infection. If it is necessary to advise the patient to complete upper eyelid stretching, they should be shown how to do this correctly to prevent damage by the implant.

## Adverse Reactions

Possible adverse reactions include: migration, extrusion, infection, inflammation, ptosis/blepharoptosis, astigmatism or worsening of an existing condition, allergic reaction, residual lagophthalmos, and formation of granulation tissue, bleeding, irritation of the eyelid, poor cosmesis (e.g. bulging), dryness, redness, soreness and secretions after sleep.

## Guidelines for Implantation

See ***"Malhotra Platinum Segments: New platinum chain for adjustable upper eyelid loading in facial palsy"*** video on YouTube[GB] http://youtu.be/jZTavNOxh8U and ***"Platinum segments: a new platinum chain for adjustable upper eyelid loading"*** by Raman Malhotra, Kimia Ziahosseini, Cornelia Poitelea, Andre Litwin, Suresh Sagilial. British Journal of Ophthalmology. 2015 Dec;99(12):1680-5.



Form ALT I031 – Issue 08/0221

The Surgeon should consider implantation of the device when other treatments for lagophthalmos have failed. The information below is for guidance only and is not intended to replace the Surgeons existing technical knowledge. The surgeon will have been trained in the implantation procedure, if not then additional training must be carried out prior to use. It is recommended to use a corneal eye-shield to prevent accidental damage to the cornea.

As for any eyelid implant, the surgeon should determine the suitability of each patient taking into account any "special needs groups" (i.e. individuals incapable of undertaking the post-operative care as required such as not rubbing or otherwise interfering with the device, or individuals lacking the capacity to give consent such as patients with dementia, severe mentally impaired etc.) and assess against the risks involved in not treating the condition.

**1.** Determine the weight required. This weight should be selected by using a Lid Sizing Set that has been developed and is marketed for this purpose. Follow the instructions for use provided with the sizing set selected. It is recommended to use the minimum quantity of Malhotra Platinum Segments® to obtain the desired weight. Maximum recommended total weight is 2.0g.

2. It is recommended to suture Malhotra Platinum Segments® together to form the chain (**A**) with the knots on the anterior surface. Use non-absorbable sutures such as 6/0 Nylon (e.g. Ethilon) with a needle that will freely pass (**B**) though the 0.9mm suture hole. If unsure on the suitability of the needle, check before use.

3. Create the pretarsal pocket ensuring the levator aponeurosis is not damaged. The Malhotra Platinum Segments® are placed in a supratarsal location, opening the orbital septum and sutured to distal levator aponeurosis following levator recession. This technique requires a stepped skin crease incision, preserving as much pretarsal orbicularis as possible, the superior 2-3mm of tarsal plate is exposed, avoiding further excessive undermining of pre-tarsal orbicularis. The orbital septum is incised, levator aponeurosis exposed and carefully dissected and separated from Müller's muscle to recess the levator palpebrae superioris (a levator recession is not carried out for cases of blink-lagophthalmos only). At least two segments are fixed to the superior tarsal border edge (at minimum, medial and lateral segments) using 6/0 ethilon non-absorbable sutures (**B** and **C**). Segments are placed to overlie the cornea. The thin aponeurosis edge is draped over the superior segment holes and sutured with 6/0 ethilon (**D**). Orbicularis oculi is closed with continuous 6-0 vicryl or 6/0 ethilon and the skin sutured with a continuous subcuticular 6-0 prolene suture (e.g. Ethicon, UK. W8870T, P6 8mm 3/8c needle) (**E**). Steristrips 6.4mm (1/4in) (3M, USA A1842) are placed over the incision line for 5 days.

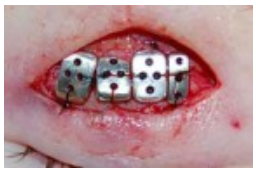
4. The patient should be told to refrain from manipulating the implant either by rubbing or touching for at least 2 weeks.

5. Post-operation monitoring is recommended at 1-2 weeks, 3 months, and 6 months. Additional monitoring may be required based upon an individual patient's clinical condition and situation.

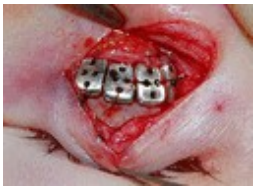
**A**

**B**

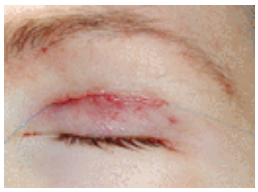
**C**



**D**



**E**



**Please report any adverse events, complications, or other side effects to the Quality Department at Altomed.**

This package contains a patient implant card and patient stickers. Please attach the stickers of the implants used to the patient card and to your own patient record. Please present the Patient Card to the patient after the operation and advise them of its MRI compatibility. This person is implanted with a Malhotra Platinum Eyelid Weight and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury. See **MRI Safety Information** below.

**Disposal**

If removed after use, the implants must be disposed of in accordance with hospital approved procedures for contaminated waste. They must not be reused as this is not in the best interest of the patient. Reuse and/or reprocessing may result in changes to the structure of the device, microbial contamination, exposure to processing residues and other undetermined factors which will add unnecessary risk and potential harm to the patient. This will increase the risk of migration and extrusion. If reused, the "User" becomes the manufacturer in accordance with Medical Device Regulations, Altomed will not accept any responsibility or liability for the reuse of these devices.

**Biocompatibility**

The Malhotra Platinum Segments® are made from an alloy of platinum and iridium, materials which are biocompatible for surgical implantation. The devices do not contain latex or phthalates.

**MRI Safety Information**


Non-clinical testing has demonstrated the **Malhotra Platinum Segment® configurations up to a total weight of 2.0g are MR Conditional**. Non-clinical testing demonstrated that the entire family of the Malhotra Platinum Segment® is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla
- Maximum spatial field gradient of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg in the Normal Operating Mode

Under the scan conditions defined, the Malhotra Platinum Segment® is expected to produce a maximum temperature rise of 2°C after 15-minutes of continuous scanning. In non-clinical testing, the image artefact caused by the Malhotra Platinum Segment® extends approximately 10-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. The Malhotra Platinum Eyelid Weight and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury.

Contact **quality@altomed.com** or ***Resources*** **at www.altomed.com** for further queries regarding MRI safety information.