EC REP

Authorised Representative in the European Community
Advena Ltd. Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta

Intended Use	Malhotra Platinum Segments are eyelid implants used in Lagophthalmos to weigh down the upper eye lid to aid closure.
Indication(s)	Bell's (facial) palsy / paralysis resulting in lagophthalmos, unilateral or bilateral paralysis. They can also be used in: Acoustic neuroma, Benign facial nerve tumour, Brain tumour, Congenital, Iatrogenic activities, Idiopathic, Malignant and benign parotid tumour Birth, facial, nerve or other trauma, Carcinoid tumour, Cholesteatoma, Chronic otitis media, Cerebellopontine angle epidermoid tumour, Muscular dystrophy, Postpolio, Vestibular schwannoma, Surgery to the middle ear, Apoplexy, Nonparalytic lagophthalmos on blink, Incomplete blink and reduced frequency of blink Aesthetic or functional deficits, Thyroid ophthalmology, Ramsey Hunt syndrome, Squamous cell carcinoma, Stroke, Treatment on patients with existing implants, Prominent implants, poor eyelid contour, dropped or flattened eyelids, extrusion, persistent erythema, allergic reaction, exchange for platinum chain, repositioning and removal (e.g., exchange, return of nerve function, extrusion).
Sterility	Single use devices supplied sterile (Ethylene Oxide). They should not be re-sterilized or re-processed or reused as the device may degrade or cause physical harm or infection to 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.
Intended Patient Group(s)	Determined by qualified surgeon, as is the most suitable total weight for the implant. The surgeon will be aware of the individual patients needs and their specific anatomy and will determine the best method of implantation according to their training.
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel.
Clinical Benefits & Performance Characteristics	Made from biocompatible materials for surgical implantation. Do not contain latex or phthalates.
Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water. The devices are implanted into the upper eyelid either singularly or in multiples of one at the recommendation of the surgeon. Implants provide the additional weight needed to close the upper eyelid when the orbital musculature is compromised by facial paralysis. Segment implants are surgically inserted and sutured together and into place. Surgically reversible.
Contraindications	These devices should not be used on patients with known allergies to platinum, iridium or nickel.

Manufactured by:
Altomed Ltd, 2 Witney Way, Boldon Business Park, Tyne & Wear, NE35 9PE, UK
Tel: +44 (0) 191 519 0111, Fax: +44 (0) 191 519 0283, E--mail: admin@altomed.com

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Warnings & Precautions	Not to be used when there is inflammation or signs of infection of the upper eyelid. 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.
Residual Risks & Undesirable Side-Effects	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.
Additional Safety Information	Surgeon must take 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. Non-clinical testing has demonstrated the 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 device is expected to produce a maximum temperature rise of 2°C after 15-minutes of continuous scanning. In non-clinical testing, the image artefact extends approximately 10-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. May be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury. The 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.
Disposal Considerations	If removed after use, the implants must be disposed of in accordance with hospital approved procedures for contaminated waste.
In the event of an incident or defective device	If any serious incident has occurred in relation to the device, the user and/or patient should be report it to the manufacturer at the contact details below, and the competent authority of the Member State in which the user and/or patient is established (refer to https://ec.europa.eu/health/md_sector/contact_en)

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Links to Further Information	See “Malhotra Platinum Segments: New platinum chain for adjustable upper eyelid loading in facial palsy” video on YouTubeGB 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.

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