MONDEAL
MEDICAL SYSTEMS GMBH

Instructions for use for the **MONDEAL LOMAS / MONDEFIT System**

Basic information

Basic instructions for using mini anchor screws and orthodontic accessories from MONDEAL Medical Systems GmbH (hereinafter referred to as MONDEAL) It is imperative that all designs and instructions in this manual are observed and complied with.
The implant may only be inserted by orthodontists, dentists, oral surgeons and physicians specialising in oral and maxillofacial surgery.
If you are unsure, or have any questions, please contact us.

Information and symbols on labels

REF	Item number
QTY	Packaging quantity
LOT	LOT number
NON STERILE	Non-sterile
	Do not re-use
	Manufacturer
	Manufacturing date
	Warning
	Consult instructions for use
CE 0297	Marking for medical devices in risk class IIa and IIb
CE	Marking for medical devices in risk class I

Products

These instructions for use cover implantable screws (miniscrews) intended for single use on the patient. All components are placed on the market as **NON-STERILE** and must undergo a suitable preparation process before the first use.

LOMAS screws

Image	Head shape	Diameter	Length	Colour
	Standard	1.5 mm	7-11 mm	Gold
		2.0 mm	7-11 mm	Grey
		2.3 mm	9 mm	Grey
	Hook	1.5 mm	7-11 mm	Gold
		2.0 mm	7-11 mm	Grey
		2.3 mm	9 mm	Grey
	Quad (horizontal, 0.018x0.025")	1.5 mm	7-11 mm	Gold
		2.0 mm	7-11 mm	Grey
		2.3 mm	9 mm	Grey
	Quad (horizontal, 0.022x0.028")	1.5 mm	7-11 mm	Green
		2.0 mm	7-11 mm	Blue
		2.3 mm	9 mm	Blue
	Quad (vertical, 0.018x0.025")	2 mm	7-11 mm	Grey
		2.3 mm	9 mm	Grey
	Quad (vertical, 0.022x0.028")	2 mm	7-11 mm	Blue
		2.3 mm	9 mm	Blue

MONDEFIT screws

Image	Diameter	Length	Colour
	1.5 mm	7-11 mm	Gold
	2.0 mm	7-11 mm	Grey
	2.3 mm	9 mm	Blue

All MONDEAL implants consist of a titanium alloy Ti6Al4V ELI (according to ASTM F136, ISO 5832-3). All titanium materials used are biocompatible, corrosion resistant and non-toxic in the biological environment. Titanium is completely non-magnetic.

Accessories
The LOMAS and MONDEFIT screws can be combined with conventional orthodontic accessories such as rubbers/elastics, springs, wires, etc.
When using the MONDEFIT system, make sure that only specific MONDEAL MONDEFIT accessories, such as abutments, MONDEplates, wires, fixing screws, hook locks and mobilizers, are used (see product catalogue):

The specific MONDEFIT accessory is made of special stainless implant steel (1.4441) in accordance with ISO 7153-1. This steel is characterised by its high corrosion resistance, biocompatibility and antimagnetic behaviour.

The impression cap used in the laboratory and the laboratory/manipulation implant are made of stainless steel 1.4305.

Intended use

The implant is used for temporary anchorage in bone to fix orthodontic appliances and aids for treating tooth misalignments.

Indication

Indications for the LOMAS/MONDEFIT system may include:

- Molar distal and mesial movement
- Molar anchorage, front anchorage
- Intrusion and extrusion
- Alignment of retained teeth
- Straightening molars
- Palatal expansion
- Temporary dentures for molars
- Changing the tooth position as part of pre-prosthetic treatment

Clinical procedure

LOMAS/MONDEFIT screws

- Selection of the insertion site, screw length and diameter with the aid of imaging techniques (measurement of bone and mucosal thickness).
- Local anaesthesia. Possibly only surface anaesthesia.
- Possibly pilot hole (12-12625 or 10-67517, depending on the screw length). Mandibular and as perforation of the compact bone, palatal. Manually, using a suitable screwdriver, or with a motor system. 500-800 rpm, with constant rinsing with chilled, physiological saline solution.
- A separate drill must be used for each patient.
- Insertion using motor system: 10-20Ncm recommended.
- The mini anchor screw is screwed in through the gingiva into the bone. Palatal: 90° to the occlusal plane is possible, median and paramedian. Approximately 5-6mm distance when using two mini anchor screws median. Paramedian: always 3mm to the midline on an imaginary transverse line between the palatal cuspids of the first premolars. Orientation: third palatal ridge.
- Immediate weight-bearing is possible.
- Removal of the mini anchor screw is performed in the reverse order. When unscrewing the screw, no anaesthesia is necessary.

Did you know:
Screws with a gingiva collar/partial thread can be found in the category LOMAS VEGAS.

MONDEFIT plates

- The MONDEFIT system used as a tandem screw (2 screws blocked with a MONDEPLATE) is exclusively for the palate.
- The plates can be placed both median and para-median.
- The MONDEFIT accessory is contoured and affixed after the MONDEFIT screw is inserted, either directly on the patient or in a laboratory using an impression cap (A33-VX1-0001) and a laboratory/manipulation implant (A33-VX1-0002) by taking an impression.
- During the bending process, make sure that the wire and the plate are held firmly and that the wire is not bent at the welding point, otherwise it may break!

Contraindications

- Insufficient quantity or quality of bone mass/substance, which prevents stable fixation of the device at or in the vicinity of the implant site.
- Lack of vascularisation.
- Lack of oral hygiene.
- History of other illnesses known to the user that negatively influence the healing process.
- Known allergies and/or hypersensitivities to the implant materials.
- General contraindications.
- Previous infections.
- Ulcers in the area surrounding where the material is to be placed.
- Exposure to radioactive radiation or chemotherapy.
- Mental, physical, or neurological conditions that impair the patient's ability to heal after the operation.
- Patients who are unable and/or unwilling to cooperate during the treatment phase.

Possible complications

In most cases, possible complications are caused due to patients' individual constitutions and general circumstances than due to the implant itself. These include, among others:

- Hypersensitivities to metals or other allergic reactions.
- Osteonecrosis, osteoporosis.
- Insufficient revascularisation.
- Injured nerves and tendons.
- Irritation to soft tissue.
- Superficial and deep infections.
- Loosening of the implant and implant loss.
- Pain and swelling.

Taking into consideration the patient's clinical status and medical history, the attending physician must determine that the use of implants is appropriate for the individual case in question, after weighing up the risk/benefit assessment for the specific patient.

Warnings and precautionary measures

- As the manufacturing company, MONDEAL recommends the user read all available documents thoroughly before the first use in practice, and contact users who already have experience with this type of treatment method.
- The products mentioned may only be used by specialist medical staff with the appropriate training.
- The product must be handled and stored with care. Damage to or scratches on the implant can significantly impair the stability of the product and its resistance to wear.
- The products are shipped as non-sterile and must be cleaned and sterilised by the user before use.
- All implant components are intended for one-time use and must under no circumstances be reused.
- In order to avoid the implant coming loose or being lost, it must be pointed out to the patient that they should under no circumstances manipulate the implant with their tongue. It is strongly recommended that the orthodontic device be applied to the patient as soon as possible after implant placement to avoid manipulation of the implant with the tongue and resulting loosening of the implant.
- The patient must be briefed as to postoperative hygiene.

MRT environment

The LOMAS and MONDEIFT implants and the corresponding accessories have not been tested for safety and compatibility in a computer tomography (CT) or magnetic resonance imaging (MRI) environment. For this reason, such use is to be refrained from. The contraindicated use is the responsibility of the treating physician. The possible dangers include

- Possible misinterpretation of the examination due to disturbing image artefacts.
- Heating or migration of the implant due to a reaction to the magnetic field.

Use of original products

All components of the system have been designed and manufactured for a specific purpose and are therefore finely tuned to each other. No component may be modified by the user or replaced by any instrument or product from a third-party manufacturer, even if this resembles or even exactly matches the size or shape of the original product.

Using products from other manufacturers in conjunction with MONDEAL products may result in incalculable risks and/or contamination of the material; or the implant and instrument do not fit together, which can endanger the patient, user or third parties.

Special notes on single-use products

Depending on the product type, the first use in line with the intended purpose may lead to the following on the product, among others

- Contamination of the product that can no longer be safely controlled
- Material fatigue and change to the material
- Damage that is not obvious, e.g., in the form of micro-cracks
- Damage to or scratches on the implant can significantly impair the stability of the product and its resistance to wear.

Notes on appropriate product selection

MONDEAL, as manufacturer, does not recommend any particular surgical procedures for specific patients. The surgeon performing the operation is himself/herself responsible for choosing the appropriate implant in the case he/she is presented with.
The attending physician should have made himself/herself familiar with the procedure, e.g. through:

- Meticulously studying all product documentation
- Meticulously studying the current specialist literature
- Consultation with colleagues who have experience using this system
- Practical exercises in handling the system, the operational procedure from a technical point of view, and postoperative after-care

In the case of complications, it may be necessary to remove the implant. The screwdriver intended for this purpose should be used when removing it. It is important to ensure that the screwdriver/screw head connection is aligned exactly axially.

Re-use

Implants that have been inserted and removed again must be disposed of in line with local requirements. They may not be re-processed. Re-using single-use products can impair the structural integrity of the implants and increases the risk of functional failure, which can lead to injuries to the patient. Re-using single-use products also creates a contamination risk, e.g., due to transmission of germs from patient to patient. This can result in injury to and/or illness in the patient and/or user.
Instruments may be re-used – if they are used with appropriate care and so long as they are not damaged or dirty.
MONDEAL does not accept any liability in the case of non-compliance.

Returns

Any product return shipments may only be sent back to us after disinfection/sterilisation has been performed which is clearly evident (appropriate packaging with sterility indicators, decontamination certificate, etc.) The relevant ordinance on hygiene and commercial premises must be adhered to.

Warranty

MONDEAL delivers only tested and fault-free products to its customers. All our products are designed and manufactured to meet the highest quality standards. MONDEAL, as the manufacturer of the products, excludes all warranty claims, and assumes no liability for direct or consequential damages, resulting from:

- Unintended use.
- Improper use, application or handling.
- Lack of training.
- Improper preparation and sterilisation.
- Substitution of a MONDEAL product by a third-party product.
- Not observing the instructions for use.

Notes on cleaning, disinfection and sterilisation

All implants, instruments, containers and accessories of MONDEAL systems are delivered as **NON-STERILE** and must be cleaned, disinfected and sterilised before each use; this also applies to the first use after delivery (after removal of the protective packaging for transport).

A mechanical method should be used for cleaning and disinfection if possible. Manual procedures – even using an ultrasonic bath – should not be used as these are significantly less effective and may cause damage.

For a description of the validated procedure for cleaning, disinfection and sterilisation, see the

"Preparation instructions, cleaning, disinfection and sterilisation".

Additional Information

You can request further information on the products (e.g., surgical techniques, care, cleaning, disinfection and sterilisation) from your contact person. In addition, you will find all information on the Internet at www.mondeal.de.

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