MONDEAL
MEDICAL SYSTEMS GMBH

Instructions for use for the **MONDEAL Cranio-Maxillo-Facial System**

Basic information

Basic instructions for the use of MONDEAL Medical Systems GmbH (hereinafter referred to as MONDEAL) implants and instruments in the fields of orthopaedics and osteosynthesis.

It is imperative that all designs and instructions in this manual are observed and complied with.

Information and symbols on labels

REF	Item number
QTY	Quantity
LOT	Batch coder
NON STERILE	Non-sterile
	Do not re-use
	Manufacturer
	Date of manufacture
	Caution
	Consult instructions for use
CE 0297	CE mark of conformity

Intended use

The Mondeal CMF implant system is intended for the alignment, reconstruction and stabilization of bone, bone fragments or bone transplants in the area of the face and cranium.

Indication

MONDE | neuro

- Fractures,
- Craniotomies,
- Reconstructive procedures,
- Bone defects

in the cranio-facial area.

MONDE | face

- Fractures (eg. Le Fort I, II, III),
- Osteotomies (orthognatic surgery),
- Reconstructive procedures,
- Bone defects,
- Dysgnathies

of the cranial area, naso-orbital area, infra-orbital area, external wall of maxillary sinus, frontal sinus, midface and mandible.

MONDE | mandible

- Fractures,
- Osteotomies,
- Reconstructive procedures,
- Bone defects

of the mandible.

MONDE | imf

- Performing an intermaxillary fixation.

Implant materials

All MONDEAL implants are made of pure titanium (ASTM F67, ISO 5832-2) or titanium alloy (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.

The implants are designed for single use and not for re-use. All components are placed on the market **NON-STERILE** and must undergo a suitable preparation process before the first use.

Clinical procedure

Selection of the place of insertion and the screw size with the aid of imaging techniques. Local anaesthesia, if necessary, a pilot hole for perforation of the compact bone. The screw is lifted out of the container with the aid of the appropriate blade and screwed into the bone through the corresponding plate holes.
The screwing into the bone (insertion) is performed manually with the accessories intended for this purpose using the most even rotational movements possible until the screw head has just been countersunk in the plate. After surgery, the surgical site is to be protected.

Bone plates

Bone plates can be easily, quickly and precisely adapted to any surface with the help of bending instruments. Due to the cold forming that occurs during the bending process, the hardness of titanium increases and its bending ability decreases. It is therefore crucial that the desired shape of the implant is achieved with as few bending manoeuvres as possible. Excessive bending can cause the plate to break after surgery. One should avoid extreme angles and small bending radii coming together, as there is a risk of microscopically visible damage occurring on the implant after surgery (cracks, deformed screw holes, etc.). In such cases, the implant must be replaced by a new, more carefully bent implant.
Deformed screw holes not only increase the risk of the implant fracturing in this area, but also make precise placement of the screw head in the plate more difficult.

Bone screws

It is necessary to ensure that the screwdriver/screw head connection is aligned exactly in the axial direction; otherwise, there is an increased risk of damage for implants and screwdrivers due to mechanical action.
When inserting the bone screw, the screwdriver must be guided over the screw head with sufficient axial pressure to ensure that axial alignment and good contact between the screwdriver and screw are achieved.

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.
- 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.
- Growth plates must not be bridged with plates or screws.

Possible complications

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

- Hypersensitivities to metals or other allergic reactions.
- Osteonecrosis, osteoporosis.
- Insufficient revascularisation.
- Bone resorption/poor bone formation.
- CRPS syndrome.
- Injuries to nerves and tendons.
- Irritation of the soft tissue.
- Superficial and deep infections.
- Reflex dystrophy.
- Loosening and breakage of the implant.
- Pain and swelling.
- Loss of reduction, refracture and revision.
- Complications during implant removal due to an insufficiently dissected implant.

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.
- Damage to or scratches on the implant can significantly impair the stability of the product and its resistance to wear.
- Products damaged by transport, handling in the clinic or other causes may not be used under any circumstances!
- All implant components are intended for one-time use and must under no circumstances be reused.
- Use the necessary care when using and storing the products.
- The system containers and implant modules may not be shaken vigorously or overturned as the implants or instruments may otherwise be damaged or fall out.
- Instruments are re-usable when single use it is not expressly stated.

MRT environment

The CMF system implants 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.

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 other things:

- 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.

Note on angular stability

The MONDEAL locking screws provide a polyaxial locking technique.

In the case of the fixed-angle screw, it is important to ensure that, during pre-drilling, a drill sleeve is inserted into the thread of the plate, which later specifies the drilling direction and thus also the desired position of the screw in the bone. This position is secured by screwing the external thread on the screw head together with the internal thread of the plate hole – the basis of a fixed-angle system.

The surface of the screw terminates with the plate, giving it a shape not found with this level of stability in conventional non-locking screw and plate combinations. A positive result of this method is also the transmission of force through the reduced contact surface between plate and bone, since the plates are not pressed onto the bone, but rather only rest upon it. The actual fixing of the screw takes place in the internal thread of the plate already. This method is less suitable, however, when the screw is to be used as a compression screw to pull a bone fragment up to the plate. In this case, you can then resort to our system's non-fixed-angle screws.

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 decision as to whether to later leave or remove the implant, and the after-care treatment, are the responsibility of the user.
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.

Implants are generally designed to remain in place temporarily and to be removed again after the bone has sufficiently healed. Implants are not intended as long-term replacements for intact bone material. The usual duration of use of implants for mechanical support of osteosynthesis is between 30 days and 6 months.

Adequate postoperative relief that allows for immediate adaptation or mobilisation must be ensured (e.g. splinting and/or immobilisation), taking into account the fracture conditions and the willingness of the patient to cooperate. The fixation achieved by MONDEAL implants is to be treated gently after the operation until healing is complete. The after-care instructions given by the doctor must be strictly adhered to in order to avoid detrimental strain to the implant. Early weight-bearing can lead to loosening, bending or breakage of the implant.

In the case of complications, it may be necessary to remove the implant. The screwdriver intended for this purpose should be used for removing the implant. 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 and 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. As the manufacturer of the products, MONDEAL excludes all warranty claims and assumes no liability for direct or consequential damages resulting from:

- Unintended use.
- Improper use, application or handling.
- Improper preparation and sterilisation.
- Not observing the instructions for use.

Notes on cleaning, disinfection and sterilisation

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

A mechanical process must be used for cleaning and disinfection.

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

"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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