MONDEAL Medical Systems GmbH
Am Gewerbering 7
78570 Mühlheim a.d. Donau
Germany

Instructions for Use:
MONDEAL Extremity Bone Fixation System

The Symbol Glossary is located on the last page of this IFU.

The following instructions for use provide important information on using the specified products and services. They are a constituent part of the product and must be available to the user at all times. Please read the instructions for use in full before commencing any work.

Device Description

The MONDEAL Extremity Bone Fixation System is a series of bone plates and screws for repairing small bone fractures, facilitating joint fusion, non-union, and reconstruction of the orthopedic extremities for the adult and pediatric populations. The plates are anatomical shaped to fit the placement site. Locking screws that engage the plate is offered in variety of lengths can also be angulated up to 15 degrees relative to the perpendicular plane of the plate. The locking mechanism of the screws to the plate result in a stronger, three-dimensional construct by offsetting load more evenly across the construct. Non-locking, cannulated screws are also offered to either be used with the plates where a non-locking feature is desired or on their own as a lag screw.

Implant Material

Implants are made of pure titanium (ASTM F67, ISO 5832-2) or titanium alloy (ASTM F136, ISO 5832-3).

Indications for Use

The MONDEAL Extremity Bone Fixation System is intended for fixation of fractures, revision procedures, joint fusion, non-unions, and reconstruction of the orthopedic small bone extremities. **This system is not intended for spinal use.**

Contraindications

1. Active infection near the fracture site(s).
2. Skeletally immature patients, osteoporosis, bone resorption and poor bone formation or inadequate bone stock that can lead to non-union.
3. Fractures that cannot be acceptably reduced by traction alone.
4. Foreign body (material) sensitivity.
5. Long delay after injury.
6. Nerve damage as a result of surgical trauma.
7. Increased fibrous tissue response due to unstable comminuted fractures.
8. Patients with mental or neurological conditions who are unwilling or incapable of following post-operative care instructions.

Possible Adverse Effects

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

- Early or late infection
- Delayed union
- Malunion or nonunion of the fracture site resulting from improper alignment
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures
- 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 Precautions

- 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 indications on the use of the product represent a group of standard instructions that can be adjusted to particular needs and situations that may arise according to the ability, experience and diagnosis made by a legally qualified medical user. Responsibility for proper selection of patients, adequate training, experience in the choice and placement of implants and the decision to leave or remove implants postoperatively, rests with the surgeon.
- The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient. Particular attention should be given to postoperative discussion and the necessity for periodic medical follow-up.
- The patient must be instructed on proper postoperative procedure and should be advised to report any unusual changes of the operated site to the surgeon. The patient should be closely monitored if a change at the fixation site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure and discuss with the patient the need for any measures deemed necessary to aid healing. Delayed healing, nonunion or subsequent bone resorption or trauma may lead to excessive stress on the implant(s) and result in loosening, bending, cracking or fracturing.
- 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.

Use of original products

All components of the system have been designed and manufactured for a specific purpose and are therefore finely tuned to one another. 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 thoroughly 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.

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Product Offering

Screws, Standard, Foot System

Module	Diameter	Length	Colour	Screw	Head
1	2.0 mm	6 – 22 mm	Blue	Non-Locking / Locking	
1	2.3 mm	6 – 22 mm	Purple		
2	2.7 mm	8 – 30 mm	Gold		
2	3.0 mm	8 – 60 mm	Grey		
3	3.5 mm	10 – 60 mm	Green		
3	4.0 mm	10 – 60 mm	Blue		

Plates, Foot System

Module	Type	Colour	Plate thickness
1	Fixation and compression plate	Blue	1.0 mm
2		Gold	1.5 mm; 2.0 mm; 3.0 mm
3		Green	1.5 mm; 3.0 mm

Screws, cannulated, foot system

Module	Diameter	Length	Colour	Thread	Head
1	2.0 mm	8 – 24 mm	Blue	Full thread	
1	2.3 mm	8 – 26 mm	Purple	Full thread / Partial thread	
2	2.7 mm	8 – 30 mm	Gold	Fully threaded	
2	3.0 mm	8 – 60 mm	Grey	Full thread / Partial thread	
3	3.5 mm	16 – 60 mm	Green	Fully threaded	
3	4.0 mm	16 – 60 mm	Blue	Partial thread	
3	4.5 mm	16 – 70 mm	Grey	Full thread / Partial thread	
4	6.5 mm	25 – 120 mm	Grey	Partial thread	
4	7.5 mm	55 – 140 mm	Blue	Partial thread	

DTS Screws (Double Threaded Screws)

Screw	Diameter	Length	Colour	Type	Head
Standard	2.5 / 3.0 mm	14 – 28 mm	Grey	Cannulated	
Mini	3.0 / 3.5 mm	14 – 28 mm	Gold	Cannulated	

Clinical Procedure

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

Self-drilling screws are not recommended for very small and thin parts of bone, as they can be displaced by the axial pressure during insertion. 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.

Plates Used in Conjunction with Screws:

1. Prepare the patient with a general or reginal anesthetic to the affected small limb and use a pneumatic (tourniquet) for partial deprivation of the blood supply.
2. During the procedure, observe (using intra-operative x-ray fluoroscopy) the fractured bone segment area(s). X-ray fluoroscopy observation is required during the entire procedure to ensure proper plate placement, proper bone screw position and depth, and adequate fracture alignment by the bone plate device.
3. Make the proper incision to the limb subchondral bone fracture site. Proceed with transection of musculature if possible along the course of muscle fibers. Reduce and align fracture segments using bone holding forceps.
4. Place the appropriate size (straight plate, Y-plate, H-plate) bone plate across the fracture site. Slight bending of the plate is permissible to appropriately fit on the limb bone fracture site.
5. Using the drill guide and drill instruments, drill the appropriate size hole at up to a $\pm 15^{\circ}$ angulation through each plate hole for maximum position and purchase in the near and opposite cortex of the limb subchondral bone.
6. Using the screw depth gauge inserted in the drill hole, measure for the length of the bone screw that will penetrate and lock into both the near and opposite limb cortex again for maximum purchase of subchondral bone.
7. Place proper bone screw within the appropriate pre-prepared drill hole in the plate. All bone screws are self-tapping. Firmly seat the threaded head of each bone screw within the hole of the plate for a secure tight fit and angle stable locking of the bone screw within the plate.
8. A standard non-locking, self-tapping, bone screw is also available for use if locking of the screw to the plate is not designed. A countersink tool is available to allow seating of the non-locking cortical screw against bone within the plate hole.
9. Prepare a final check (using intra-operative x-ray fluoroscopy) of the fracture reduction, alignment, and plate/screw positioning before closing. Placement of recon drainage before skin closure for 12-24 hours can be useful to prevent postoperative haematoma in some cases and is recommended. Postoperative treatment entails a proper bandage dressing for 2 weeks (until the wound heals), physiotherapy for 5-7 weeks for minor stress loading of the limb to promote bone healing and limb rehabilitation, and subsequent full loading of the limb upon the consult discretion of the patient with the doctor. Only consider removal of the implant after 1 year of service when necessary.

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Cannulated Screw System:

1. Prepare the patient with a general or regional anesthetic to the affected limb and use a pneumatic (tourniquet) for partial deprivation of the blood supply.
2. During the procedure, observe (using x-ray fluoroscopy) the fractured bone segment area(s). X-ray fluoroscopy observation is required during the entire procedure to ensure proper guide pin placement, proper bone screw depth, and adequate fracture impaction by the bone screw device.
3. Following fracture reduction under image fluoroscopy control, insert the required size calibrated guide pin across the fracture site engaging the subchondral bone. If additional fixation is necessary across the fracture site, insert additional calibrated guide pins. Place the multiple guide pins parallel in direction to each other and in such a manner to avoid interference contact.
4. Place the calibrated Depth Gauge over the calibrated guide pin and read the actual depth of the pin in the bone. The surgeon may elect to use the appropriate screw 5-10 mm less than the Depth Gauge reading depending on screw penetration (i.e., so as not to penetrate the opposite cortex).
5. Using the Gauge Cannulated Screwdriver, drive and sent the self-drilling and self-tapping screw over the guide pin and check the screw depth and fracture impaction with fluoroscopic x-ray.
6. Remove the calibrated guide pin.
7. Repeat steps 4-6 for additional screw fixation across the fracture site and close.

Returns

Any product return shipments may only be sent back to us after disinfection/sterilization 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 orhandling.
- Improper preparation andsterilization.
- Not observing the instructions foruse.

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.

Cleaning, Disinfection and Sterilization

All implants, instruments and containers of MONDEAL systems are delivered **NON-STERILE** and 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). Effective cleaning and disinfection are essential requirements for effective sterilization.

The processing instructions for implants and instruments are provided in the next section.

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Processing Non-Sterile MONDEAL Implants

These recommendations are for processing non-sterile MONDEAL implants that are sold in the United States. The information provided applies to unused and non-contaminated MONDEAL implants only. Explanted MONDEAL implants must never be reprocessed and must be handled according to hospital protocol upon removal. Any implant that has not been used, but has become contaminated, must be handled according to hospital protocol. MONDEAL does not recommend the reprocessing of contaminated implants. These recommendations are to be followed unless otherwise noted on specific product inserts.

Please follow the validated hospital processing procedure (handling, cleaning, disinfecting, sterilization) for MONDEAL implants.

PROCESSING INSTRUCTIONS

<table>
<tr><td>Caution</td><td>

Any implant that has not been used, but has become contaminated should be handled according to hospital protocol. MONDEAL does not recommend the reprocessing of contaminated implants.
MONDEAL implants should not be lubricated.
Do not use a MONDEAL implant if the surface is damaged or if other implant properties are impaired.
Do not use steel wool or abrasive cleaners on MONDEAL implants.
MONDEAL implants must not be processed or transported with any type of contaminated materials.
In accordance with AAMI guidelines, MONDEAL does not recommend or support the Immediate Use sterilization method for implants.
MONDEAL implants are critical devices and must be terminally sterilized prior to use.
The sterilization parameters are only valid for devices that are adequately cleaned.
The following parameters are only valid for properly installed, maintained, calibrated, and compliant reprocessing equipment.

</td></tr>
<tr><td>Limits On Reprocessing</td><td>

Repeated processing cycles (ultrasonic, mechanical washing, and sterilization) have minimal effect on MONDEAL implants.
MONDEAL implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration, or residue. Damaged implants must not be implanted.

</td></tr>
<tr><td>Point of Use Care</td><td>

Implants should remain covered until needed to avoid contamination. Only those intended to be implanted should be handled.
Handling prior to implantation should be kept minimal to prevent damage to the surface.

</td></tr>
<tr><td>Containment and Transportation</td><td>

Implants should not come in contact with contaminated devices and/or equipment.
To avoid contamination, implants should be transported separate from soiled devices.
During transportation, ensure that no material or abrasion will be transferred to the implant.

</td></tr>
<tr><td>Preparation for Processing</td><td>Any implant contaminated with blood, tissue, and or bodily fluids/matter must be discarded using appropriate measures. MONDEAL does not recommend the reprocessing of contaminated implants.</td></tr>
<tr><td>Cleaning-Manual Method</td><td>We do not recommend the use of manual cleaning methods.</td></tr>
<tr><td>Cleaning-Mechanical Method</td><td>
Equipment: ultrasonic cleaner, FDA-cleared washer, sterile syringes/pipettes, and/or water jet, enzymatic cleaner & neutral detergent, clean lint-free cloths.

Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

The following cycles, times, temperatures, and detergents are for reference only due to the differences in manufacturer’s equipment. The parameters must be in accordance with the hospitals validated procedure for the equipment used.
<table>
<tr><th>Phase</th><th>Minimum Time (Minutes)</th><th>Minimum Temperature / water</th><th>Detergent Type and Concentration</th></tr>
<tr><td>Pre-rinsing</td><td>01:00</td><td>Cold tap water</td><td>N/A</td></tr>
<tr><td>Cleaning</td><td>10:00</td><td>55°C</td><td>Neodisher MediClean Forte 0.40 %</td></tr>
<tr><td>Post-rinsing</td><td>02:00</td><td>Cold deionized water</td><td>N/A</td></tr>
<tr><td>Thermal disinfection</td><td>05:00</td><td>93°C</td><td>N/A</td></tr>
<tr><td>Drying</td><td>20:00</td><td>100°C</td><td>N/A</td></tr>
</table>
</td></tr>
<tr><td>Detergents / Cleaning Agents Used</td><td>Neodisher MediClean Forte was the cleaning agent used to validate the parameters in these instructions.
MONDEAL does not recommend any specific detergent or cleaning agent.</td></tr>
</table>

<table>
<tr><td>Inspection</td><td>MONDEAL implants must be inspected after processing, prior to sterilization. Any implant with corrosion, discoloration, scratches, flaws, residue, or debris should be discarded</td></tr>
<tr><td>Packaging</td><td>The devices must be packed in a sterilization packaging material which has been cleared by the FDA and meets the requirements of ISO 11607.</td></tr>
<tr><td>Steam Sterilization</td><td>Sterilization must be performed using a validated steam sterilization process according to relevant AAMI/ASTM/ISO standards. Validation was performed in accordance with ISO 17665-1:2006 and ISO 17665-2:2009 to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method.
The following recommendations are for the sterilization of MONDEAL implants:
<table>
<tr><th>Cycle Type</th><th>Configuration</th><th>Temperature</th><th>Exposure Time (in minutes)</th></tr>
<tr><td>Pre-vacuum</td><td>Wrapped</td><td>270°F to 275°F (132°C to 135°C)</td><td>04:00</td></tr>
<tr><td>Gravity displacement</td><td>Wrapped</td><td>250°F to 254°F (121°C to 123°C)</td><td>15:00 to 30:00</td></tr>
</table>
Only FDA-cleared wraps are permissible.

*Dry times may be highly variable due to the differences in packaging materials (e.g. non-woven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.</td></tr>
<tr><td>Additional Information</td><td>The cleaning and sterilization information is provided in accordance with ANSI/AAMI ST81:2004/(R2010), ISO 17664:2004, AAMI TIR30:2011, AAMI TIR12:2010, and ANSI/AAMI ST79:2017.
• The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile MONDEAL implant. It remains the responsibility of the processor and/or hospital to ensure that the processing is actually performed, when using equipment, materials and personnel in the processing facility, in order to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor and/or hospital from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.
• All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.
• Users must wear appropriate protective equipment (PPE) when processing implants.</td></tr>
<tr><td>Manufacturer Contact</td><td>For further information, contact the MONDEAL Customer Service Department.
Phone: 0049 7463 99307 0 Fax: 0049 7463 99307 33 Email: mail@mondeal.de</td></tr>
</table>

SYMBOL GLOSSARY

ISO 15223-1: 2017 **Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied.** **Part 1: General Requirements**			
SYMBOL	**Symbol REF. No.**	**SYMBOL TITLE**	**EXPLANATORY TEXT**
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	N/A	Quantity	Packaging quantity
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	5.4.4	Caution	Indicates the need for the user to review the instructions for use for important safety-related information, such as warnings and precautions, which for a variety of reasons cannot be applied to the medical device itself.
	5.1.1	Manufacturer	Indicates the manufacturer of the medical device.
	5.13	Manufacturing date	Indicates the date on which the medical device was manufactured.

OTHER SYMBOL(S)				
SYMBOL	**REFERENCE**	**TITLE**	**SYMBOL TITLE**	**EXPLANATORY TEXT**
Rx ONLY	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.	Prescription only	Requires prescription in the United States.
	21 CFR 801.109(b)(1)	Labeling-Prescription devices.		
CE 0XXX	MDD 93/42/ECC Article 17 (2)	CE marking	CE Mark with identification number of notified body	Marking for medical devices in risk class IIa and IIb for EU
CE	MDD 93/42/ECC Article 17 (1)		CE Mark	Marking for medical devices in risk class I for EU

Additional Information

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

Manufactured by:	**Distributed by:**
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