












Instructions for use for the MONDEAL Rotating Instruments (cutting and non-cutting)

Basic information

 Basic instructions for the use of MONDEAL Medical Systems GmbH (hereinafter referred to as MONDEAL) instruments in the fields of orthopedics and osteosynthesis. It is imperative that all explanations and instructions in this manual are observed and complied with.


Information and symbols on labels

	Item number
	Quantity
	Batch code
	Non-Sterile
	Do not re-use
	Manufacturer
	Date of manufacture
	Caution
	Consult instructions for use
	CE mark of conformity




Products

These instructions for use are valid for all rotating Instruments for all Screws and Plate Systems of MONDEAL. The rotating instruments are available in different diameters, lengths, working depths and connection types.




The rotating instruments are made of instrument steel according to ISO 7153-1, EN 10088 and ASTM F899.

 All components are placed on the market **NON-STERILE** and must undergo a suitable preparation process before the first use.

Rotating cutting instruments – Not reusable:



	core hole and sliding hole drill
	Thread cutter
	Headroom Countersink

Connection types - cutting instruments – Not reusable:





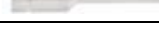

	Dental - Connection
	Stryker - Connection
	AO - Connection

Color coding - Cutting instruments – Not reusable:





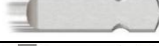

The rotating instruments are provided with colored rings that represent the appropriate screw diameter and Modul. The width of the color ring serves to distinguish between core and sliding hole drills.

Color coding	Drill-Type
	Sliding hole drill
	Core hole drill

Rotating non-cutting instruments – reusable:


		CF-Klingen (Cross-Fit)
		MCD-Klinge (Mondeal Contour Drive)
		LOMAS/MONDEFIT

Connection types – non-cutting instruments – reusable:

	Dental - Connection
	Connection 1200-System
	Connection 1700-System
	Connection 2000-System
	AO - Connection
	Angle handpiece

Intended use

Rotating cutting instruments – Not reusable:

 The rotating cutting instruments, such as drills, taps and countersinks are used to open or widen hard tissues or bones and soft tissues. The instruments are designed for use with active instruments. The rotating cutting instruments are designed for **single use** and not for reuse.

Rotating non-cutting instruments – reusable:

Rotating non-cutting instruments, such as screwdriver blades, are used to insert or remove orthopedic screws into or from a patient's body. The instruments are designed for use with active instruments. The rotating **non-cutting** instruments are designed for **multiple use**.

Indication

Rotating cutting instruments – Not reusable:

Rotating cutting instruments are used to pretreat bones and tissues for the insertion of orthopedic screws, during traumatology, hand, foot, maxillofacial and orthodontic procedures.

Rotating non-cutting instruments – reusable:

Rotating non-cutting instruments are used as a fixation instrument for orthopedic screws during traumatology, hand, foot, maxillofacial and orthodontic procedures.



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.
- History of other illnesses known to the user that negatively influence the healing process.
- Ulcers in the area surrounding where the material is to be placed.
- 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 instruments themselves. These include, among others:

- Hypersensitivities to metals or other allergic reactions
- Injured nerves and tendons
- Irritation to soft tissue
- Superficial and deep infections
- Breakage of the instrument
- Pain and swelling

Taking into consideration the patient's clinical status and medical history, the attending physician must determine that the use of instruments 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.
- Products damaged by transport, handling in the clinic or other causes may not be used under any circumstances!
- All rotating cutting Instruments are intended for one-time use and must under no circumstances be reused.
- Use the necessary care when using and storing the products.
- Activate the rotating instruments only when the field of view is within your field of vision and the desired contact is made. Do not activate the product when it is out of the field of application. There is a risk of injury!
- In order to avoid overheating and bone damage, in addition to adequate cooling, it may be necessary to stop drilling every 5 seconds for 10 seconds.
- Increased torque during bone drilling may cause drill-bit breakage.

Compatibility

- A safety-related safety in combinations of medical devices is only given if
- these are designated as such in the respective instructions for use, or
 - the purpose and interface specification, which allows for the combination of products.

When selecting the receptacle, attention must be paid to the correct connection system as well as to a secure locking or firm seat / fixation.

Clinical procedure

- To assist and prevent soft tissue injury, drills should generally be used using drilling guides or other suitable instruments.
- The user must check the compatibility of the drill connection with the insert handpiece. Additional periodic inspections and maintenance of the handpiece help prevent damage to the drill.
- Use a drilling speed of 500-800 rpm to avoid overheating and bone necrosis. When using a high-speed drilling system, the user must ensure a configuration with the manufacturer of the device that has a rotational speed of at most 800 rpm.
- When using rotary cutting instruments, sufficient cooling must be ensured by flushing with physiological saline solution (NaCl) to keep thermal damage to the bone tissue as low as possible. The combination of cooling and low rotational speed (<800 rpm) significantly reduces the risk of screw loosening due to bone demineralization.
- Axial guidance of the instrument significantly reduces the risk of breakage or fatigue.
- The shortest possible drills should be used for the respective clinical indication. Longer drills are inherently susceptible to eccentric rotation, especially when there is no physical resistance.

Use of original products

All system components 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.

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 instrument 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
- Practical exercises in handling the system, the operational procedure from a technical point of view and postoperative after-care

Special notes on single-use products

Rotating cutting instruments – Not reusable:

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 instrument can significantly impair the stability of the product and its resistance to wear.

Rotating cutting instruments must be disposed of in line with local requirements.

MONDEAL does not accept any liability in the case of non-compliance.



Special notes on reusable products



Rotating non-cutting instruments – reusable:

Rotating non-cutting instruments, such as screwdriver blades, can be reused after reprocessing.

For reprocessing, the instruction

"Preparation instructions, cleaning, disinfection and sterilization" must be observed.

Storage

The instruments should be stored dry and protected from dust at room temperature. There are no special requirements for the storage of the product.

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.

Guarantee

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
- Improper preparation and sterilization
- Not observing the instructions for use



Notes on 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).

If possible, a machine method should be used for cleaning and disinfection.



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

"Preparation instructions, cleaning, disinfection and sterilization"

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 the information on the Internet at www.mondeal.de.



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