Instructions for use

Instrument Set for MIS Pedicle Screw System

FIELDS OF APPLICATION:
Instrument set for application of MIS Z-Pedicle Screw System.

GENERAL
The instructions can't replace the training, carefulness and the user's knowledge of the technology. We therefore assume that the respective legal rules, engineer standards and recommendations are known. **Please read these instructions and the surgical technique very carefully, before you prepare and use the product for the first time!**

INDICATIONS:
The instrument set is tuned especially for the use with the MIS Z-Pedicle Screw System. It's used for fixation of single or multiple vertebraes in the lumbar and thoracal spine. The system supports different surgical techniques and it can be used for open as well as for minimally invasive techniques.

The set consists of all necessary instruments for the particular case. Implants are single sterile packaged.

Prior to usage all instruments has to be cleaned and subjected to a sterilization process as they are delivered in a non-sterile condition.

Basic Instruments:
The **Awl** consist of 2 parts: **Awl A06 383 (1.)** and **Awl Inner Part A06 309 (2.)** and is used with the Screw Driver Handle C07 909 (06.). It is used to open the pedicle especially for special bone conditions like sclerotized bone. After opening of the pedicle the awl inner part is removed and the Z-Guide Wire can be inserted through the cannulation.

(3.) Thread Drill A06 380
The thread drill can be used with high bone density / hard bones for pre-drilling and pre-cutting of the Pedicle Screws.

(4.) Screwdriver Pedicle Screw A06 006
Screwdriver for determination of the screw length and application of the pedicle screws.

(5.) Screwdriver Ini A06 005
Screwdriver for insertion and tightening of the Inis. (It is used in combination with the T-handles.)

(6.) Screwdriver Handle C07 909
It is used in combination with the awl or can be used with any other instruments with a 1/4" coupling e.g. Screwdriver Pedicle Screw A06 006, Screw Driver Ini A06 005 etc. Note: For final fixation of the rod the Ini has to be fixed with the T-handle with torque limiter.

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(7.) T-handle with Torque Limiter A06 007
For final fixation of the rod the Ini is fixed with the T-handle with torque limiter. The required torque is preset. When the required torque is reached while fixation of the Ini, a clearly defined “click” is noticeable.

(8.) T-handle with Ratchet A06 374
The ratchet can be switched between right and left via the sliding collar. In the neutral position (middle position) the ratchet is deactivated. The T-handle is cannulated.

(9.) Tulip Breaker A06 370
The instrument is used for breaking off the tulips **after final fixation of the Inis**. Be aware that all Inis are fixed with the required torque. After that the Tulip Breaker has to be inserted into the shaft of the pedicle screw until the Ini is reached. Via clockwise turning (360°) the tulip is cut in the break off area.

(10.) Rodinserter A06 300
The rod inserter is used to hold the rod for insertion. Therefore the rod has to be put into the inserter and fixed by turning the tensioning nut until adequate stability (hand tightening) is reached. Then percutaneous insertion can be performed.
Attention: the ledge of the tensioning nut has to be positioned in the opening in the handle.
Note: The instrument is intended to be disassembled for cleaning. After cleaning the threads are supposed to be lubricated with instrument oil.

(11.) Counter Support A06 373
The **Counter Support** has multiple features. The **“Connection lengthening shaft”** (1*) is used for the final tightening of the Inis to prevent undefined circular motion of the pedicle screw while fixing the Ini. With the help of the **“Coupling Screwdriver”** (2*) the spindle of the Dico can be turned to adjust the required distraction or compression. The side notch of the Counter Support **“Removing guide wire”** (3*) can be used to remove the guide wire after the screw length is measured and the screw inserted half way.
(1-3*) Please see Surgical Technique for further information.

(12.) Distraction- and Compression Instrument (Dico) A06 500
By the use of the Dico the Z-Rod length can be determined. It is also used for the distraction and compression. To get the required distraction or compression turn the spindle with the help of the Counter Support.
Note: The instrument is intended to be disassembled for cleaning. After cleaning the threads are supposed to be lubricated with instrument oil.

(13.) Rodbender A06 381
Instrument for bending of the rods. Through lifting and turning of the turning knob the bending radius can be adjusted (3 positions).

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Revision Instruments

(14.) Screwdriver Revision A06 310

The Screwdriver Revision is used at the time the drive in the screw head is not accessible anymore or worn. Like a rod the instrument can be guided along the tulip and fixed with the Ini.

(15.) Tulipadapter A06 306 and 16. Clamping Tube A06 389

In a revision or extension case the Tulipadapter in combination with the Clamping Tube have the same function as the lengthening shaft. It is attached onto the screw head. The Clamping Tube is sidled over the adapter to avoid a possible separation of the tulip.

17. Revision Instrument Inner Part A06 384

The Revision Instrument Inner Part is used to the ease the adaptation of the Tulipadapter with the Tulip. The tip of the revision instrument inner Part is centered in the screw head and the Tulipadapter is inserted over the instrument.

18. Chuck Rod A06 385

Is used to grab and replace a rod independent of the coupling.

Container

19. Rack A06 508

To comply with actual cleaning- and sterilization requirements, Z-Medical has designed the rack for the instruments as sheet metal part. This ensures minimal areas of support and contact and thus minimizes non-cleaned areas. All instruments are fixed at multiple points or via notches or sinks to be safe against slipping.

20. Perforated Container A06 488

The Perforated Container is used to carry the rack equipped with all instruments. It consists of 2 parts: Perforated Container bottom A06 477_1 and Perforated Container lid A06 488_2

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CONTRAINDICATIONS:

— Infection
— Known allergic reaction to materials the instrument is manufactured of
— Physiologically or psychologically inadequate patient
— Insufficient skin, bone or neurovascular condition
— Possibility of a conservative treatment
— Blood supply limitations and previous infections, which may retard healing
— All non-listed indications

ADVERSE EFFECTS:

— Deep and superficial infections
— Allergies or other reactions to implant materials

⚠ **PRECAUTIONS:**

— It is mandatory that the user, surgeon and surgery personnel are acquainted with the respective surgical technique and implants used.
— Surgical instruments and implants may only be used for surgeries, for which the designated application of the instrument and implant is explicitly necessary and defined.
— The trained expert staff is obligated to examine the surgical implant and its sterile packaging for damages prior to each application i.e. use. In case of the implant or its packaging being damaged or deformed, it is not to be used!
— Only and exclusively Z-Medical's specially manufactured instruments and implants (contained in the respective set) are to be used! If using other instruments and implants, function, warranty and liability are omitted.
— After the shaft is broken off, it must be removed and properly disposed.

⚠ **WARNINGS:**

— Surgical instruments and implants by Z-Medical might possibly have tips and sharp cutting edges, which can perforate skin!
— This product may only be used with accessories from the respective Z-Medical set. Application and use of other instruments or implants is not permitted.
— After having fixed the Ini with torque, releasing of the Ini and repositioning of the rod is not allowed. As a deformation of the rod and therefore a weakening can't be ruled out.
— Cutting edges, blades, tips etc. can be very sensitive to false handling. Thus, these instruments must be handled with care.
— The Z-Pedicle screws and rods have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.
— Do not use the implants if the sterile packaging is damaged or defect.
— The safety and effectiveness of the Z-Pedicle screws and rods has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g. osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

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MATERIAL PROPERTIES:
The components of this set are manufactured from stainless steel according to ASTM F899 and / or ISO 7153-1. Refer to package label for details of materials used.

DELIVERY FORM:
Non-sterile.

CLEANING AND HANDLING:
Surgical instruments are supplied non-sterile and must be cleaned and sterilized before use. After use, these instruments must be, at minimum, properly decontaminated, cleaned, and stored. They should be disinfected and cleaned immediately after use.

To enable efficient cleaning and defection, take apart instruments consisting of multiple parts as far as possible according the products specific instructions as well as guidelines. Lubricate threads with instrument oil prior to sterilization, we recommend Sterilit® i lubricant.

It is always preferable to use machines (washer-disinfectors) for instrument cleaning and disinfection because, unlike manual procedures, machine process can be easily standardized.

Instruments must totally taken part before cleaning.

Manual Cleaning:
Please abide strictly by the manufacturer's references regarding concentration, temperature and application time when using the detergents to be applied. Lukewarm water and detergent solutions (at temperatures optimally in the range of 27℃ to 44℃ [80℉ to 110℉], but not to exceed 60℃ [140℉]).

Automatic Cleaning:
Strictly abide by the manufacturer's specifications for the chemical cleaning products regarding concentration, temperature and application time. Also check the water's chloride concentration in order to prevent pitting. Please also abide strictly to the unit manufacturer's operation instructions.

Afterwards, rinse thoroughly with distilled water.

Improper sterilization and non-sterile handling of the instruments can lead to serious health hazards for patients. Sterilization must be carried out according to a validated steam sterilization process, for example in a sterilizer satisfying AAMI ST 79.

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Prior to sterilization, the instruments must be adequately packaged. The packaging method used must comply with the relevant standards. Check the instruments for cleanness and integrity. Clean and disinfect the instruments and rinse them with distilled water, then dry them carefully.

The minimum recommended steam sterilization conditions for reusable instruments as follows: Exposure time of 4 minutes at 132℃ (270℉).

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 132℃ (270℉)	Exposure Temperature	132℃ (270℉)
	Exposure Time	4 minutes
	Dry Time	20 minutes

Maximal temperature of sterilization 134℃ (273℉).

The Product Decontamination Certificate has to be filled out and signed and sent back to GlobalMed Logistix. If it is not sent with the shipment the decontamination and cleaning will be invoiced to the user.

STORAGE:
Keep in a cool, dry place. Keep away from direct sunlight. Follow package reference.

Before use check all instruments for corrosion, damaged surfaces, chips and contamination, and discard damaged instruments.

INFORMATION:
For further information or product demonstration, please contact the authorized Z-Medical® product specialist.

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Description of used symbols

	Symbol for **"Consult instructions for use"** Indicates the need for the user to consult the instruction for use.
LOT	Symbol for **"Batch Code"** Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Symbol for **"Catalogue number"** Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Symbol for **"Caution"** Indicates the need for the user to consult the instructions for use for important Cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Symbol for **"Manufacturer"** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
CE	Symbol for medical products class I
NON STERILE	Symbol for **"Non sterile"** Indicates a medical device that has not been subjected to a sterilization process.
	Symbol for **"Keep away from sunlight"** Indicates a medical device that needs protection from light sources.
	Symbol for **"Do not use if package is damaged"** Indicates a medical device that should not be used if the package has been damaged or opened.
	Symbol for **"Keep dry"** Indicates a medical device that needs to be protected from moisture.
RxOnly	Symbol for prescription only. U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

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