ANTON HIPP
Instruments & Implants

Drilling Instruments

Instruction for Use

ENGLISH

IMPORTANT PRODUCTINFORMATION!
PLEASE READ CAREFULLY BEFORE EACH CLINICAL APPLICATION!

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Dear customer!
With your purchase, you will receive a high-quality product, the proper use of which is described in the following. In order to minimize hazards for patients and users, we ask you tu carefully read an oberve the instruction für use.
Anton Hipp GmbH also offers user training for our systems and products. Please contact your direct distributor or contact us.

DESCRIPTION
The drilling instruments are used for predrilling implants (osteosynthesis) when using bone screws without self-drilling function. The drilling instruments are color-coded to show the user which drills to use for which screw system. The choice of the respective drill and thus also of the respective screw is made by the treating surgeon.

MATERIALS
Stainless steel according to DIN EN ISO 7153-1

INTENDED USE / INDICATION
Drilling instruments for predrilling when using bone screws in the following areas:
- MKG (Oral and Maxillofacial Surgery)
- Hand surgery
- Foot surgery

for fixation of bone screws and bone substitutes during reconstruction or osteosynthesis as well as for stabilization and rigid fixation in fractures.

CONTRAINDICATION
The products are contraindicated for all other uses except for the techniques mentioned in the intended purpose / indication(s).

COMPLICATIONS / SIDE EFFECTS
After contact with the drilling instrument, hypersensitivity reactions can be triggered in a patient with material intolerance to stainless steel. In the event of such a reaction, the procedure must be discontinued immediately and the necessary steps taken.
In the course of market monitoring, further potential complications / side effects such as breakage of the drill instrument and swallowing of components could be identified.

GENERAL WARNINGS
- Depending on the use of the screw system, select the corresponding color-coded drill bit.
- The drilling depth for the selection of the appropriate screw length is to be determined.
- Hooking of the drilling instrument can cause the contra-angle handpiece head to strike or even break the bearing.
- If an unbalance occurs, the drilling process must be stopped immediately. The defective drilling instrument must be replaced.
- Excessive application of force or axial forces can lead to excessive loading as a result of which the drilling instruments can be damaged or break.
- When using bone drills, ensure appropriate cooling to avoid heat damage and necrosis formation on the bone.
- Improper sterilization as well as non-sterile handling can lead to serious health risks for the patient.
- Defective, blunt or otherwise non-functional tools must be disposed of and must not be used.

The identification of the screws and drills is done by color coding, which the system displays.

ACCESSORIES / COMBINATION PRODUCTS
Depending on the connection, the drilling instruments are to be operated with the corresponding drilling machines or commercially available motor systems. The compatibility does not depend on the machine type but on the instrument receptacles.

Drilling instruments / drilling aids
Always use the shortest possible drill bit to ensure the best possible concentricity. It should be checked whether the drill connection and the drill are compatible. Basically, only work with drill sleeve or similar and at speeds of <= 1000 rpm. When drilling, ensure sufficient cooling with NACl to minimize the heat load on the bone. This is the only way to minimize the risk of bone demineralization.

Depth gauge
Measurement of the screw length with the plate/mesh after drilling has been completed. The value displayed on the depth gauge corresponds to the screw length as indicated on the packaging.

APPLICATION AND SAFETY INSTRUCTIONS

The products must be checked for defects, cracks, nicks or other damage before use. Damaged products must be sorted out.

The products are delivered in a non-sterile condition and must be completely cleaned, disinfected and sterilized by the user before first use.

STORAGE NOTICE
Drilling instruments must be stored before use in an environment that maintains their packaging and cleanliness. Dry atmosphere, no extreme temperatures, no exposure to sunlight, ionized radiation and contaminated particles. To avoid corrosion, pay special attention to the absence of chemicals in the immediate vicinity.

EXCLUSION OF REUSABILITY
Drilling instruments that have been used once must not be reused. The products are intended for single use only. If drilling instruments are not used clinically and are not contaminated in the operating room, they may be used after reprocessing and sterilization.

CLEANING / DISINFECTION
Basics
If possible, a mechanical process (washer-disinfector) should be used for cleaning and disinfection. A manual process - also using an ultrasonic bath - should only be used if a mechanical process is not available or in accordance with country-specific requirements (e.g. in Germany, a mechanical process is mandatory for critical B products) due to the significantly lower effectiveness and reproducibility.
Pretreatment must be carried out in both cases.

Pretreatment
Pretreatment is not required, as drills that have already been in contact with a patient or have become contaminated must not be reused under any circumstances.

Mechanical cleaning/disinfection (WD)
When selecting the WD, it is important to ensure that,
- that the WD basically has a tested effectiveness (e.g. DGHM or FDA approval/ clearance/ registration or CE marking according to DIN EN ISO 15883),
- that, if possible, a tested program for thermal disinfection (A0 value > 3000 or - in the case of older devices - at least 5 min at 90 °C/194 °F) is used (in the case of chemical disinfection, there is a risk of disinfectant residues on the products),
- that the program used is suitable for the products and contains sufficient rinsing cycles (at least three depleting steps after cleaning (or neutralization, if applied) or conductivity control recommended to effectively prevent detergent residues),
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,
- that the air used for drying is filtered (oil-free, low in germs and particles) and
- that the WD is regularly maintained, checked and calibrated.

When selecting the cleaning agent system to be used, the following points must be observed,
- that this is basically suitable for cleaning invasive medical devices made of metals and plastics,
- that, if thermal disinfection is not used, a suitable disinfectant with tested efficacy (e.g. VAH / DGHM or FDA / EPA approval / clearance / registration or CE marking) is also used and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the products.

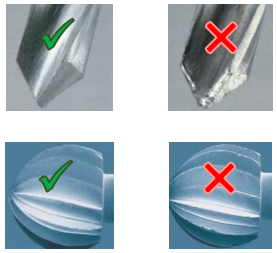
The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, the disinfectant, as well as the specifications for post-rinsing, must be strictly observed.
Procedure:
1. Place the products in the washer-disinfector. Make sure that the products do not touch each other.
2. Start the program.
3. Remove the products from the WD at the end of the program.
4. Check and pack the products as soon as possible after removal.

Proof of the basic suitability of the products for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognized (§ 19 MPDG) test laboratory using the pre-cleaning and cleaning agent Cidezyme / Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.

FUNCTIONAL TESTING AND PACKAGING
The products must be checked for cleanliness and functionality after reprocessing and before sterilization. If necessary, the reprocessing process must be repeated until the product is visually clean.

Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) that meet the following requirements (material/process):
- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA-Clearance)
- suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F) sufficient steam permeability)
- Sufficient protection of the products or sterilization packaging against mechanical damage
- Regular maintenance in accordance with the manufacturer's specifications (sterilization container)
- A maximum weight of 10 kg per package/content of the sterilization container must not be exceeded.

The drilling instruments must be checked for flawless surfaces, correct assembly and functionality. Do not use severely damaged instruments, instruments with unrecognizable markings (color marks), signs of corrosion or blunt cutting edges. Blunt cutting instruments must not be reground.



After reprocessing and sterilization, check the color markings!

STERILIZATION
Only the sterilization methods listed below may be used for sterilization; other sterilization methods are not permitted.

Steam sterilization
- fractionated vacuum process (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA-Clearance)
- validated according to DIN EN ISO 17665 (valid IQ/OQ (picking) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)

Sterilization time (exposure time at the sterilization temperature):

Germany
minimum 5 minutes at 134 °C (273 °F)
USA
minimum 4 minutes at 132 °C (270 °F), drying time minimum 20 minutes
France
minimum 5 minutes at 134 °C (273 °F) if required for prion inactivation Sterilization time 18 minutes
Other Countries
minimum 5 minutes at 132 °C (270 °F) / 134 °C (273 °F)

PRODUCT LIFE
- Anton Hipp recommends using new drilling instruments for every procedure. To protect against heat necrosis, always rinse cutting tools with cooling liquid.
- Wear, use-related wear or accidental cutting in metal (e.g. in tissue protection sleeves or metal forceps) shorten the service life of the drilling instruments. A binding statement on the expected service life of drilling instruments can therefore not be made.
- Reuse of blunt or defective instruments may cause necrosis due to excessive heat generation. Drilling, milling with a defective drilling instrument may be inaccurate and the osteosynthesis correspondingly unsatisfactory. Always carefully check the functionality of the instruments after cleaning. If necessary, replace instruments that are not in perfect working order.
- Blunt drilling instruments must not be reground.

DISPOSAL
Disposal of medical devices unless otherwise specified, devices must be disposed of as medical devices in accordance with facility procedures.

INTERACTION WITH DRUGS
Interactions with drugs are not known.

DISCLAIMERS / WARRANTY
The products are made of high quality materials and are subjected to quality control before delivery. However, should any defects occur, please contact our service department. However, we cannot guarantee that the products are suitable for the respective operation. This must be determined by the user himself. We cannot accept any liability for accidental or resulting damage.
Any product liability expires,
- In case of damage due to improper storage, handling, cleaning and / or sterilization
- in case of faulty cleaning and sterilization
- in case of non-observance of these instructions for use

SYMBOLIC

Manufacturer

Date of manifacture

Non-steril

Do not reuse

Batch designation

Catalog number

Serial number

Store dry

Protect from sunlight

Prescription

Attention

Observe instruction for use

CE marking with number of the Notified Body

Medical product

IFU_200_V_03 - Revision 03 - EN
Basis UDI-DI
Drills 4066591PG02XY