

By purchasing this instrument, you have chosen a high-quality product whose proper use and handling are illustrated in the following. To keep the risks for patients and users to a minimum, we ask you to read and follow the instructions for use carefully. The instruments may only be used, disinfected, cleaned, and sterilized by trained and qualified professionals.

### **1. Purpose**

Bone drills and reamers are used to produce and prepare an osteotomy in the patient's bone that is precisely matched in diameter and depth to the implant to be inserted.

### **2. Indication**

Bone drills and reamers are intended for use in the following indications: non-conservative treatment of fractures and / or degenerative diseases by osteosynthesis procedures:

- Screw osteosynthesis
- Plate osteosynthesis
- Fixator external

### **3. Contraindications**

The products are designed exclusively for the procedures described in the indication in conjunction with the treatment principles of the Arbeitsgemeinschaft für Osteosynthesefragen (AO) and are contraindicated for all other applications.

### **4. Intended user group**

The products are designed only for qualified physicians in the field of bone surgery as well as medical professionals (surgical assistants) with sufficient knowledge regarding the identification, selection, provision and aseptic handling of instruments during surgical procedures.

### **5. Intended patient group**

The products are intended for use in patients with the clinical pictures / pathological conditions mentioned in the indication.

No restrictions on age or etiology. No other patient-specific restrictions or contraindications.

**WARNING: Do not use damaged products!**

### **7. Handling**

**Warning: Do not use damaged products! (see tests / function control)**

The tools are connected to a drive unit via the connection at the proximal end. Activation of this drive unit causes the drill or milling cutter to rotate in a controlled manner. The tool, which is equipped with sharp cutting grooves, gradually removes bone material through rotation until the desired drilling depth or ablation on the bone is achieved.

The drills and reamers may only be used with a drive or hand instrument that matches the connection (e.g., T-handle or drill handle), see section Compatibility. Before use, make sure that the tool is correctly seated in the holder; it must not have any play in the holder.

The instrument must be powered before it is applied to the bone. The lowest possible pressure applied by the drill, a high drilling speed and the use of instruments that are as sharp as possible reduce the risk of overheating and associated thermal necrosis and/or breakage of the drill. Contact with metallic objects must be avoided, as the tools may become blunt. The instruments must not be overstressed by twisting or levering, as this may damage or break instrument parts. The bone drills and reamers do not contain any user-serviceable parts. The bone drills and reamers must not be repaired - this may result in injury to the user or patient.

**Already known residual risks / side effects with intended use**

Phase	Risk	Possible cause
During treatment	Tissue necrosis due to thermal damage of surrounding tissue	Use of worn, unserviceable drills; use of drills unsuitable for the treatment in question; selection of wrong drilling parameters (speed, feed, drilling sequence) Use of drills without simultaneous rinsing
	Soft as well as hard tissue injuries, remaining fragments of the instrument in the patient's body due to fragmentation or breakage of the drill tip / cutting edge	Excessive force applied during the drilling operation, use of worn drills. Non-compliance with treatment principles / good treatment practice
After treatment	Systemic late complications due to tissue damage / necrosis at the treatment site.	Use of worn, unserviceable drills; use of drills unsuitable for the treatment in question; selection of wrong drilling parameters (speed, feed, drilling sequence) Use of drills without simultaneous rinsing

**Materials**

**2 Instructions for reprocessing according to DIN EN ISO 17664-1**

Method: Cleaning, Disinfection, Sterilization hot steam (EN ISO 17665-1)



The instruments are supplied non-sterile and must be cleaned, disinfected and sterilized before initial and subsequent use.

The efficiency and suitability of the procedures specified below for reprocessing the products concerned have been validated by the manufacturer. It is the responsibility of the operator to ensure effective reprocessing by means of appropriate equipment, processing aids and sufficiently qualified personnel. Any deviation from the procedures specified below must be checked by the user / operator for its influence on the safe and effective reprocessing of the products. In the event of deviations from the procedures described below, the manufacturer accepts no responsibility for the effectiveness and compatibility of these procedures. The instruments may only be reprocessed by people who have the necessary expertise and training and who are able to assess any risks that arise with the corresponding effects.

### 3. Restriction of reprocessing



Due to the product design and the materials used, the service life of the products is limited to a maximum of 20 application or reprocessing cycles. Do not use products that have exceeded their service life! The use of products beyond their maximum service life can lead to reduced performance, mechanical damage and consequent risk of injury to the patient!



**Do not use damaged products!**



**Attention:** In case of use of the instruments in patients with Creutzfeldt-Jakob disease or HIV infection, we decline any responsibility for reuse. For the reprocessing of the instruments in case of Creutzfeldt-Jakob disease or HIV infection, special validations and routine monitoring of the procedures by the user are required.

- Contain and transport used instruments in a labeled, closed, puncture proof device per facility procedure.

Transport to processing area as soon as possible.

- Separate heavy instruments from delicate instruments.
- Do not put heavy instruments on top of delicate instruments.
- Keep instruments moist between point of use and decontamination

### 4. Preparations at the place of use

To prevent incrustation of dirt and coagulation of blood residues, visible contamination on the product should be removed immediately after use. Avoid temperatures above 40 °C (104 °F) to prevent fixation of biological residues. The products are to be transferred in a suitable, sealed container, within one hour of reprocessing. Immediately after use, manual disinfection should be performed to reduce the risk of infection for users and hygiene staff. The instruments are placed in disinfectant solution for this purpose. Make sure that the instruments are completely immersed in the disinfectant solution without bubbles forming. Observe the manufacturer's instructions for the disinfectant solution.

## 5. Manual pre-cleaning

1. Remove coarse surface contamination under running, cold tap water using a suitable brush or cloth.
2. Immerse the products for 10–30 minutes in an enzymatic cleaning solution (0.5–2%) prepared with tap water (< 30 °C / < 86 °F). (drinking water quality). Ensure that all surfaces and cavities are completely wetted. Then clean the surfaces, channels, lumens, and cavities of the instrument under cold running water (< 30 °C / < 86 °F, drinking water quality) using a suitable brush (not a steel brush). Flush crevices, slots, and cavities for approximately 10 seconds using a water pressure gun.
3. Place the instruments in a suitable ultrasonic cleaning bath. Ensure the instruments are completely immersed in a 0.5–2% enzymatic instrument detergent solution prepared with deionized water.
4. Use appropriate instrument trays or wire baskets and do not overload them. Ensure the cleaning solution reaches all surfaces, channels, and cavities.
5. Renew the ultrasonic bath solution before each use.
6. Clean instruments for 10 minutes at room temperature using a frequency of at least 35 kHz.
7. Rinse the entire instrument with deionized water for at least 1 minute. This step can be omitted if automatic cleaning is continued immediately.
8. Each instrument must be completely dry inside and out after pre-cleaning to prevent rusting or malfunction. Dry the liquid with soft cloths / swabs. Hollow parts or inner channel can be dried using a compressed air system.  
This step can be omitted if automatic cleaning is continued immediately.

## 6. Mechanical cleaning and disinfection



For cleaning and disinfection, a mechanical process should be used wherever possible in a suitable washer-disinfector (WD) that meets the requirements of the EN ISO 15883 series of standards. A manual process - also using an ultrasonic bath - should only be used if a mechanical process is not available due to the significantly lower effectiveness and reproducibility and requires specific development and validation under the sole responsibility of the user.

Only validated automated cleaning and disinfection procedures may be used. The following points must be particularly observed during machine reprocessing:

- A prerequisite for effective machine reprocessing is the correct loading of wire baskets, inserts, holders, etc. in accordance with rinsing requirements.
- The wire baskets must not be overloaded so that the instruments are well rinsed.
- Large-volume instruments must be placed on the wire baskets in such a way that water accesses every corner and they do not obstruct the cleaning of other instruments.
- Cannulations of instruments must be rinsed completely.
- The instruments must be placed or stored according to their mechanical sensitivity in such a way that damage is excluded: Sharp cutting edges must be exposed.
- The instruments must be removed from the machine immediately after the end of the program, as corrosion can occur due to residual moisture if they remain in the closed machine.

The reprocessing procedure described below was validated using a washer-disinfector compliant with EN ISO 15883 and an enzymatic medical instrument detergent.

1. Pre-rinse for 1 minute with cold tap water (< 30 °C / < 86 °F, drinking water quality).
2. Drain water
3. 3 minutes pre-rinse with cold tap water
4. Drain water
5. Clean using an enzymatic detergent in deionized water at 55 °C ± 1 °C (131 °F ± 2 °F) for at least 10 minutes.
6. Drain water
7. 3 minutes rinse with cold tap water
8. Drain water
9. 2 minutes of rinsing with demineralized water
10. Thermal disinfection at 92 °C ± 2 °C (198 °F ± 4 °F) for ≥ 5 minutes



Thermal disinfection is not a final process that puts the product into a ready-to-use state. The disinfection step serves exclusively to improve protection against infection between cleaning and sterilization. Subsequent sterilization is always necessary.

## 7. Drying

Dry the instruments using the drying cycle of the washer-disinfector at 100 °C (212 °F) for 30 minutes. If necessary, additional manual drying may be performed using a lint-free cloth.

drying can be achieved using a lint-free cloth. Dry cannulations of instruments with sterile compressed air.

## 8. Tests / Functional check

After cleaning, the products must be visually checked for cleanliness and integrity. Unclean products must be cleaned again; damaged products must be sorted out and disposed of.

Identify the instruments. The instruments must be checked for proper functioning before each use and may only be used in sterile conditions.

Damage to the surface, such as scratches, cracks, nicks, notches, etc., as well as bent parts, means that they must not be used. The products must then be disposed of in accordance with hospital practice.

## 9. Packaging

The products must be packaged for sterilization using sterilization packaging suitable for moist heat sterilization in accordance with EN ISO 11607-1.

The packaging must:

- withstand temperatures of at least 137 °C (279 °F)
- be appropriately sized so that the seal is not under tension when the product is packaged
- allow adequate steam penetration and drying

The validated sterilization procedure was performed using double sterilization pouches.

**10. Sterilization**

Steam sterilization (moist heat) is the recommended method for sterilizing these instruments.

The following steam sterilization parameters are consistent with commonly accepted hospital sterilization practices.

**Steam Sterilization Cycle (Pre-Vacuum)**

Parameter	Specification
Pre-vacuum pulses	3 fractionated vacuum phases
Temperature	134 °C (273 °F)
Exposure Time	5 minutes
Minimum Dry Time	≥ 20 minutes

**11. Storage**

Store sterilized instruments in sterile packaging in a closed cabinet, protected from dust, moisture and temperature fluctuations.

**12. Disposal**

Products that are no longer usable must not be reused and must be disposed of in accordance with the clinic’s guidelines and regulations.

**13. Warranty**

The products are made of high-quality materials and are subjected to quality control before delivery. Should faults nevertheless occur, please contact our service department. Hayden Medical assumes no liability if it can be proven that these instructions for use have been violated. Defective products must have gone through the entire reprocessing process before being returned.

All serious incidents related to the device shall be reported to the manufacturer and to the competent authority of the Member State where the user and/or the patient is established.