

DRILL

137182-1

The following languages are included in this packet:

English (en)
Español (es)
Türkçe (tk)

Deutsch (de)
Italiano (it)

Nederlands (nl)
Português (pt)

Français (fr)
中文-Chinese (sch)

Distributed by:

WRIGHT.

Wright Medical Technology, Inc.
5677 Airline Rd. Arlington, TN 38002
Tel: 901-867-9971 www.wmt.com

EC REP

Wright Medical EMEA
Krijgsman 11
1186 DM Amstelveen
The Netherlands

CE 0124

Manufactured by:
aap Implantate AG
Lorenzweg 5
12099 Berlin, Germany
Tel.:+49 (0) 30 750 19 0
Fax:+49 (0) 30 750 19 222
www.aap.de

INSTRUCTIONS FOR USE

EN

DESCRIPTION:

SYSTEM: DRILL

Drill and cannulated drill, also called “drills” in the following.

aap drills are manufactured from materials for surgical instruments in compliance with national and international standards.

Warnings and Precautions

The drills are supplied unsterile by *aap* and must be imperatively prepared prior to use.

aap drills should be used only in the context of their intended function.

In general, prior to the procedure the surgeon must be familiar with the surgical procedure and especially with the surgical technique relevant to the drills used. The correct selection and placement of the drills is extremely important. We recommend pre-operative planning for determining the most appropriate sizes and the final position of the drills. Instructions on the combination of the drills can be found in the respective Surgical Technique. *aap* has not tested combinations using implants and instruments of other manufacturers and any combination is at the risk and hazard of the surgeon.

Drills except cannulated drills are utensils that may be subject to wear through repeated use and lose their functionality. It is imperative that their function be inspected both before and after each preparation. Cannulated drills are intended for single use only. For Small-diameter drills an inspection of the flutes must be carried out, in order to ensure that they are not dull.

Do not reuse the instruments used for guiding the cannulated drill. Kirschner wires supplied by *aap* are authorized as an instrument for single use only.

aap must be promptly informed, as soon as complications occur in connection with the drill used.

In case of premature failure of drills whose cause is suspected to be the geometry, surface quality or mechanical stability, please send them to *aap* in a clean, disinfected and sterile condition. The manufacturer cannot accept any other returns of used drills.

Driven Instruments

- Use instruments only in accordance with this and the instructions on use for surgical motor-driven systems.
- Clamp instruments up to the stop / attachment.
- Before initial start-up, inspect the secure seating of the instrument.
- Avoid rocking and tilting.
- Excessive pressing force must be avoided and ensure adequate cooling
 - in order to prevent premature failure
 - in order to prevent elevated heat development (thermal necrosis)
 - for preventing smearing of instrument blades
 - for longer service life.

Packaging and Sterility

All *aap* drills are supplied unsterile; it is imperative that they be prepared before use.

The manufacturer guarantees the cleanliness of the aforementioned medical devices in their original and undamaged packaging only up to the point in time that they are opened. The surgeon is responsible for maintaining asepsis up to the patient.

Before opening the product packaging, inspect it for any damage. Drills from damaged packaging must not be used.

Preparation of Medical Devices

Handling New Drills

New drills must be cleaned before first-time sterilization or being used for the first time. Protective caps and foils and other transport protection must be removed completely.

Handling Non-sterile Drills

- Prepare drills as quickly as possible.
- Remove surface contamination as soon as possible using a disposable cloth.
- In the case of cannulated drills we recommend the use of a cleaning wire, in order to carry out the first-time cleaning of the bore.
- In machine cleaning, lay the drills on drainage baskets suitable for this cleaning process (avoid rinse shadows).
- Disassemble dismantlable drills into their component parts.
- Disposal is preferably dry.

- When disposing of wet drills use a cleaning-active DGHM-listed disinfectant agent (comply with manufacturer's instructions for drill material and disinfectant). Before machine cleaning and disinfection, thoroughly rinse the drills in clear, running water.
- If necessary, carry out ultrasound cleaning according to the device manufacturer's instructions:
 - as effective mechanical support
 - for pretreatment of drills with dried-on contamination before machine cleaning
 - If at all possible, drills with threaded working ends should not be cleaned in the ultrasound bath but cleaned only manually or by machine. With machine cleaning secure the drills in suitable holders.

Cleaning Accessories

- Detergent: Prepare detergent (i.e. LIQUI-NOX®, Alconox, Inc. 8.5 pH) per manufacturer recommendations.
- Enzymatic Cleaner: Prepare enzymatic cleaner (i.e. ENDOZIME®, Ruhof Corporation 6.0-7.5 pH) per manufacturer recommendations.

Manual Cleaning / Disinfection

- Disassemble all components as per manufacturer instructions (if appropriate).
- Rinse with cold tap water to remove gross contamination.
- Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
- Scrub thoroughly with a soft brush and / or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.

- Rinse with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
- Bathe in a detergent solution prepared per manufacturer directions for 5 minutes.
- Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
- Rinse thoroughly / flush with deionized / reverse osmosis (RO/DI) water.
- Sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
- Rinse thoroughly / flush with RO/DI water.
- Dry with a clean, soft, absorbent, disposable cloth.
- Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Machine Cleaning / Disinfection

- Manual precleaning is mandatory.
- When selecting the cleaning program, take into account the material (e.g. titanium, CoCr, CrNi, stainless instrument quality steel, aluminum, POM, etc.) of the instruments to be cleaned.

Comply with the instructions of the device manufacturer (manufacturer of cleaning machine). We recommend a low sudsing detergent neutral to slightly basic with pH 7.0 to 10.0.

- Place the instruments in the device so that articulations are open and the water can drain out of lumina, blind holes and channels.
- Carry out the final rinse using demineralized water.
- After running the cleaning cycle, inspect the critical points (lumina, blind holes and channels). If there is any visible contamination, repeat the cycle or clean manually.
- Observe an adequate drying phase.
- Remove the instruments from the machine immediately at the end of the program.

Care / Inspection

- Allow the drills to cool to room temperature.
- Lightly lubricate moving parts (e.g. articulations and latches) with a sterilizable, steam-permeable maintenance oil which is cleared by the FDA.
- After every cleaning and disinfection inspect the drills for cleanliness, function and damage such as bent, fragmented, torn, worn and broken parts, for example.
- Segregate and replace damaged and defective drills.

Packing

- Store drills with threaded working ends in suitable holders.

Sterilization

The minimum recommended steam sterilization conditions for Darco Headed Cannulated Screws are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

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

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with with AAMI ST79:2006/A1:2008 & A2:2009 and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

Storage

The user must avoid all effects that could affect the product marking or shelf-life of the drills, the drill surface or the drill geometry such as unnecessary commotion, strains, heat, UV radiation, moisture, etc.

Final Remarks

The aforementioned instructions were validated by *Wright Medical Technology, Inc.* and *aap* as being suitable preparation for the repeat use of the drills, but cannot substitute for a detailed process description, because a detailed description of the variety of preparation procedures used world-wide is not possible. The preparer is responsible for obtaining the desired result in the actual preparation using equipment, materials and personnel in the preparation facility. To achieve this, a validation and routine inspections of the process on site is required. Deviations from the instructions provided by the processor are to be examined for their efficacy and possible adverse consequences and documented.