INSTRUMENTS
137181-1

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Distributed by:

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

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: INSTRUMENTS

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

Warnings and Precautions

The instruments are supplied non-sterile by *aap* and must be imperatively prepared prior to use.
aap instruments 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 instruments used. The correct selection and placement of the instruments is extremely important. We recommend pre-operative planning for determining the most appropriate sizes and the final position of the instruments. Instructions on the combination of the instruments 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.
Instruments 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.
aap must be promptly informed, as soon as complications occur in connection with the instrument used.

In case of premature failure of instruments 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 instruments.

Packaging and Sterility

All *aap* instruments are supplied non-sterile; 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. Instruments from damaged packaging must not be used.

Preparation of Medical Devices

Please follow these preparation instructions, in order to maintain the value of your instruments. The manifold possibilities for preparation are based on the material compatibilities of the respective instruments. Successful preparation is the sole responsibility of the user. When doing this, please comply especially with the instructions and specifications given in the instructions on use and the relevant national statutory regulations and standards.

Handling of New Instruments

New instruments 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 of non-sterile instruments

- Prepare instruments as quickly as possible.
- Remove surface contamination as soon as possible using a disposable cloth.
- In the case of grooved or channeled instruments 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 instruments on drainage baskets suitable for this cleaning process (avoid rinse shadows).
- Dismantle instrument assemblies into their individual parts.
- Disposal is preferably dry.
- When disposing of wet instruments use a cleaning-active DGHM-listed disinfectant agent (comply with manufacturer's instructions for instrument material and disinfectant). Before machine cleaning and disinfection, thoroughly rinse the instruments in clear, running water.
- If necessary, carry out ultrasound cleaning according to the device manufacturer's instructions:
  - as effective mechanical support
  - for pretreatment of instrument with dried-on contamination before machine cleaning
  - If at all possible, instruments with threaded working ends should not be cleaned in the ultrasound bath but cleaned only manually or by machine. With machine cleaning secure the instruments 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 instruments 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 instruments for cleanliness, function and damage such as bent, fragmented, torn, worn and broken parts, for example.
- Segregate and replace damaged and defective instruments.

Packing

- Store instruments with threaded working ends in suitable holders.
- Secure instruments with latches in the first detent.

Sterilization

The minimum recommended steam sterilization conditions for Wright Medical Technology, Inc. reusable instruments 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 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 instruments, the instrument surface or the instrument geometry such as unnecessary commotion, strains, heat, UV radiation, moisture, etc.

Final Remarks

The aforementioned instructions were validated by *WMT* and *aap* as being suitable preparation for the repeat use of the instruments, 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 provides by the processor are to be examined for their efficacy and possible adverse consequences and documented.