

CANNULATED SCREW SYSTEM

137183-1

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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



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: CANNULATED SCREW SYSTEM

Materials:

- CrNi alloy in accordance with ISO 5832-1 and ASTM F 138 / ASTM F 139
- Titanium alloy in accordance with ISO 5832-3 and ASTM F 136

Warnings and Precautions

The cannulated screws and guide wires are supplied by *aap* in an unsterile condition and must imperatively be prepared before use. These products are intended for single use. Re-use, including the use of Kirschner wires as guide wires for cannulated screws is prohibited by *aap*. Implants 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 implants used. The correct choice and placement of the implant is extremely important. We recommend pre-operative planning for determining the most appropriate size and the final position of the implant. Instructions on combining implants can be found in the corresponding 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.

The *aap* Cannulated Screw System has not been evaluated for safety and compatibility in the MR environment. The *aap* Cannulated Screw System has not been tested for heating or migration in the MR environment.

Recommendations Regarding Device Fragments

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
3. Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;

- e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Indications

In principle, the indication for surgical osteosynthesis must be made only when it is apparent that other conservative methods can no longer be expected to yield success.

Cannulated Screws

The *aap* Cannulated Screws are intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. *aap*'s washers may be used with the screws in certain applications.

- Minimally invasive fracture / joint reconstructions
- Multiple- fragment joint fractures
- Simple metaphyseal fractures
- Simple epiphyseal fractures
 - Fractures of the head of the humerus
 - Fractures of the head of the tibia
 - Cooper fractures of the tibia
 - Fractures of the radius
- Fractures of the wrist, ankle, elbow and shoulder
- Scaphoid fractures and other fractures of the hand
- Metatarsal fractures and other fractures of the foot

- Ligament fixation of the proximal humerus
- Ligament avulsion injuries (Apophysis)
- Fractures of small joint bones
 - Malleolar fractures
 - Navicular fractures
- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture of metatarsa IV
- Fractures of the tarsal region

Wire products

- Guide wire in cannulated screw osteosynthesis

Contraindications

Inflammation, sepsis and osteomyelitis are absolute contraindications.

All applications that are not defined by the indications are contraindicated.

In addition, surgical success can be adversely affected by:

- acute or chronic infections, local or systemic
- vascular, muscular or neurological pathologies that compromise the concerned extremity
- all concomitant pathologies that could affect the function of the implant

- osteopathies with reduced bone substance such as severe osteoporosis
- any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- known or suspected sensitivity to metal
- corpulence: an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- whenever the use of the implant comes into conflict with the anatomical structures of physiological status.

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- the presence of tumors
- congenital abnormalities
- immunosuppressive pathologies
- increased sedimentation rates that cannot be explained by other pathologies
- increased leukocyte (WBC) count
- pronounced left shift in the differential leukocyte count.

Patient Information

Patients who smoke or use other products containing nicotine frequently present a higher risk of pseudoarthroses. The patient must be informed of the limitations of loading of the implant, particularly

of the foreseeable effects on the surgical results in the event of non-compliance with the post-operative instructions of the surgeon. In addition, the patient must be informed that the foreseeable lifetime of the implants used depends on his / her weight and level of physical activity and the load bearing capacity of an implant is not comparable to that of healthy bone.

Tissue damage in the immediate region of the implant cannot be ruled out in the event of occupational exposure to strong electromagnetic alternating fields and requires future caution and provisions by the patient.

All information provided to the patient must be documented.

Possible Complications

- loosening, deformation or fracture of the implant
- acute post-operative wound infections and late infections with possible sepsis
- migration, subluxation of the implant with resulting reduction in range of movement
- fractures resulting from unilateral joint loading
- thrombosis and embolism
- wound hematoma and delayed wound healing
- temporary and protracted functional neurological perturbation
- tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- corrosion with localized tissue reaction and pain
- pain, a feeling of malaise or abnormal sensations due to the implant used
- bone loss due to stress shielding

All possible complications listed here are not typical of *aap* products but are in principle observed with any implant.

Promptly inform *aap* as soon as complications occur in connection with the implants or surgical instruments used.

In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide *aap* with the explant(s) in a cleaned, disinfected and sterile condition.

The manufacturer cannot accept any other returns of used implants.

The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

Packaging and Sterility

All *aap* medical devices 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. Medical devices from damaged packaging must not be used.

Handling

When removing the medical devices from the packaging, inspect the integrity of the medical devices and the correspondence of the device type and size with the labeling. Damaged medical devices must not

be used. *aap* is solely responsible for the medical devices and their supply presentation. Any change made to these results in a new medical device for which *aap* assumes no responsibility. The required instrument set can be ordered from Wright Medical Technology, Inc.

Please see the Surgical Technique for further details on implantation of the components and on the instrument set.

Preparation of Medical Devices

Please follow these preparation instructions, in order to maintain the value of your medical devices. The manifold possibilities for preparation are based on the material compatibilities of the respective medical devices. 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 Medical Devices

It is prohibited to reprocess used implants or implants that came in contact with body fluids.

Nevertheless all devices must be cleaned prior to sterilization and use. Protective caps and foils and other transport protection must be removed completely.

Cleaning

1. Disassemble all components as per manufacturer instructions (if appropriate).
2. Rinse with cold tap water to remove gross contamination.
3. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.

4. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. Rinse with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. Bathe in a detergent solution prepared per manufacturer directions for 5 minutes.
7. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. Rinse thoroughly/flush with deionized/reverse osmosis (RO/DI) water.
9. Sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Rinse thoroughly/flush with RO/DI water.
11. Dry with a clean, soft, absorbent, disposable cloth.
12. 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.

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 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.

Care / Inspection

- Allow the medical devices to cool to room temperature.
- Implants that came in contact with body fluids should never be reused. Please ensure that they will be sent back according to a validated protocol that they are in no transmission of infectious diseases.
- Segregate and replace damaged and defective medical devices.

Storage

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

Final Remarks

The aforementioned instructions were validated by *Wright* and *aap* as being suitable preparation for the use of the medical devices 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.