DARCO® CANNULATED HEADED SCREWS AND ASSOCIATED INSTRUMENTS

143991-3

℞ ONLY

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Your kit may contain implants and instruments manufactured by Wright or aap*, unless* aap *devices are not licensed in your geography (then only Wright devices are contained in the kit). (*aap *implants and instruments are distributed by Wright.) Wright has tested the compatibility between the devices manufactured by Wright and manufactured by* aap*; the devices may be used interchangeably.*

The system indications for use, manual cleaning & handling, and sterilization instructions for both manufacturers are identical.

aap *implants are not licensed in Canada. Kits distributed in Canada contain only implants manufactured by Wright.*

February 2016

Manufactured by:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
CANNULATED SCREWS

OUTLINE:

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DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number
2	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
Rx ONLY	For prescription use only
	Do not use if packaging is ripped or damaged
STERILE	Sterile
	Non-Sterile
	Do not resterilize
	MR Conditional
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
Al_2O_3	Alumina
ZrO_2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
$CaSO_4$	Calcium Sulfate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
PDLLA	Poly D, L-Lactic Acid
PDMS	Silicone 55D
PEEK	Poly Ether Ether Ketone
Al	Aluminum
DBM	Demineralized Bone Matrix

I. GENERAL PRODUCT INFORMATION

Through the advancement of surgical fusion hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after fusion occurs. The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection.

Surgeons must be familiar with the applicable operative technique and instructions for use for each product. This package insert and immediate package label contain essential warnings and precautions for each surgery. Additionally the surgical technique should be referenced for detailed information about implant selection, relevant product details, proposed surgical instructions, and/or assembly use. The surgeon should contact Wright for the proposed product-specific surgical technique.

In using fusion implants, the surgeon should be aware of the following:

- **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support.

- **In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:**
  1. **Patient's occupation or activity**. If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.

  2. **Condition of senility, mental illness, or alcoholism**. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

  3. **Foreign body sensitivity**. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. PATIENT SELECTION

Use of surgical fusion hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of post-operative therapy
- Cooperative patient

B. INDICATIONS

DARCO® HEADED CANNULATED SCREWS

DESCRIPTION
The DARCO® Headed Cannulated Screws are available in various sizes, thread types, and lengths. The screws contain a hex drive interface and an optional washer is available with the system. The screws and washers are manufactured from titanium alloy.

INDICATIONS
The DARCO® Headed Cannulated Screws are intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. Wright's washers may be used with the screws in cases where the patient has poor bone quality.

- Minimally invasive fracture/ joint reconstruction
- 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 (Apohysis)
- Fractures of small joint bones
  - Malleolar fractures
  - Navicular fractures
- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture and metatarsal V
- Fractures of the tarsal region

C. CONTRAINDICATION

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 that could affect the function of the implant
- 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

D. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:
- 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 *WMT* products but are in principle observed with any implant. Promptly inform *WMT* 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 *WMT* 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.

E. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients. Instructions on combining implants can be found in the corresponding surgical technique. Wright has tested combinations using implants and instruments for the manufacturers Wright and *aap*; any other combination is at the risk and hazard of the surgeon.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

The main goal of surgery with this implant is to establish bony fusion. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.

Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider minimizing the potential for complications:

- Follow guidelines for indications and contraindications
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant

Avoid flawing implant surfaces or excessive bending to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:

- Implant removal
- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

Over time, metallic implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
- 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.
- If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- 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 MRU exam in case of metallic fragments. This may help reduce the possibility of serious injury from the fragment.

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

F. HANDLING AND STERILIZATION

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. WMT is solely responsible for the medical devices and their supply presentation. Any change made to these results in a new medical device for which WMT assumes no responsibility. The required instrument set can be ordered from WMT.

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

IMPLANTS

The implants described in this package insert are provided non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-sterile.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in, but are not limited to, significant degradation in device performance, cross-infection, or contamination which may result in serious patient harm.

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

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 Wright 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 Table 5 guidelines and have been developed and tested using specific equipment to achieve a Sterility Assurance Level (SAL) of 10^{-6}. 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.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

G. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

Instructions for Use

WRIGHT

Distributed by:
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CE 0124

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EC REP

Wright Medical UK Ltd
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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
  - o Fractures of the head of the humerus
  - o Fractures of the head of the tibia
  - o Cooper fractures of the tibia
  - o 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 (Apohysis)
- Fractures of small joint bones
  - o Malleolar fractures
  - o Navicular fractures
- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture and metatarsl V
- 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 require 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*.
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 (132.2 °C)	Exposure Temperature	270 °F (132.2 °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.*
- Inspect 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.

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REV.: 5 / 05.12.2010

WRIGHT

EC REP

CE 0086*

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL TECHNOLOGY, INC.
CLEANING AND HANDLING OF WRIGHT INSTRUMENTS

Surgical instruments are supplied non-sterile and must be cleaned and sterilized before use. After use, these instruments must be, at minimum, properly decontaminated, cleaned, and stored. The following information outlines the proper steps for reprocessing Wright surgical instruments to help assure their long life.

Intra-Operative Precautions

Use medical devices in accordance with their labeled indications and Wright's instructions for use, especially during insertion and removal.

- 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.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- 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.

Cleaning Accessories

Water	Cold deionized or reverse osmosis water should be used, as temperatures above 140°F (60°C) will coagulate proteins, rendering them difficult to remove from contaminated items.
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 Accessories	Brushes and/or Pipe Cleaners, Syringes, Gloves, Absorbent Disposable Cloth (i.e. KIMWIPE®, Kimtech Science)
Ultrasonic Cleaner	Ultrasonic Cleaners should be monitored routinely to ensure they are working properly.

Limitations and Restrictions of Reprocessing

Surgical instruments are designed for their durability and ability for reuse. Wright's reusable instruments are typically manufactured from stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments. End of functional life is normally determined by wear and damage due to use.
Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Cleaning/ Disinfection

Warnings	When handling sharp instruments use extreme caution to avoid injury: consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
	Always double-wrap the components in an FDA-cleared CSR wrap or similar type non-woven, medical grade wrapping material. Flash-autoclaving of individual instruments should be avoided, whenever possible. Unwrapped components DO NOT maintain sterility.

Clean instruments as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with cold water or an appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently contacted with blood or saline solution.

Preparation for Cleaning	• The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by instrument design. The cleaning process should include an individual properly gowned with appropriate glove and personal protective equipment. • This may require opening all hinged items or the disassembly of those items with multiple or removable parts. • Those items with mating surfaces, i.e. ratchets, hinges, serrations, lumens, blind holes, etc. must be carefully cleaned to remove all visible debris from the items. • Additional assembly/disassembly instructions may be found in the product specific surgical technique.
Manual 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.
Automated Cleaning/ Disinfection	An automatic cleaning process may involve a washer- sterilizer, a washer-sanitizer/disinfector, ultrasonic cleaner or other related type machines that clean and decontaminate items. There are many different types of automatic washer systems, each with their own unique instructions that must be followed. These machines typically perform an initial cold water rinse followed by a cleaning cycle using a low sudsing detergent (neutral to slightly basic pH, 7.0 to 10.0). The detergent is thoroughly rinsed off, followed by a final rinse in deionized or reverse osmosis water. The process cycle may also provide a drying function for the cleaned items. The automatic cleaning machine may also contain a decontamination cycle, which is discussed in the next section. • Ultrasonic cleaners can be used with hot water per manufacturer's recommended temperature (usually 90-140ºF or 32-60ºC) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment. • Washer- Decontamination Equipment will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment.

Inspection, Maintenance, and Testing

Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their exacting performance. To minimize damage, the following should be done: • Inspect the instrument case and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside for repair service or return to Wright. • After cleaning, the disassembled instruments should be reassembled and placed in their proper locations in the instrument cases where appropriate. • Only use an instrument for its intended purpose. • For devices with hinged/mating surfaces or moving components, a biocompatible, surgical-grade lubricant intended for heat sterilized medical instruments should be used per the manufacturer's guidelines.
Wright does not accept responsibility or liability of this instrument nor any of the component parts upon which repairs and/or modifications have been made or attempted except as performed by Wright.

Packaging

Wright instrument cases are intended to protect instrumentation during shipping. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Wright does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Wright that should have been cleaned and sterilized by the end user.

Sterilization

Wright instruments manufactured of stainless steel may be steam sterilized with no detrimental effects. **Those instruments containing UHMWPE (Ultra high molecular weight polyethylene) cannot be steam sterilized, as heat is detrimental to the plastic.** These instruments should be sterilized by ethylene oxide (ETO) or other validated sterilization method. All items to be sterilized must be thoroughly cleaned and packaged appropriately for the type of sterilization. The package must permit contact of the sterilant with the item, while also serving as a barrier to microorganisms, during any storage period. Users should wear non-linting gloves, i.e. Latex or Nitrile, when handling reusable instruments, to minimize bioburden and particulates. Inspect the product packaging for tears, holes, moisture or other defects. If these concerns are present, segregate these items and reprocess them.

Steam Sterilization

The minimum recommended steam sterilization conditions for Wright 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 Table 5 guidelines and have been developed and validated 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.

ETO Sterilization

Instrumentation to be ETO sterilized must be cleaned and packaged appropriately. The packaging for items ETO sterilized varies somewhat from steam sterilization, in that paper to paper, paper or polyethylene film to Tyvek®, synthetic nonwovens, textiles and rigid container systems suitable for ETO sterilization may be used. Use only a FDA-cleared sterilization wrap, pouch, or other device that is designed to allow sterilant penetration and to maintain sterility. The uniqueness of a hospital ETO sterilizer as compared to an industrial ETO sterilizer precludes Wright listing any processing parameters. The number of different variables involved in an ETO sterilization process, such as the ETO concentration and exposure time, relative humidity or temperature may vary significantly in a hospital unit as compared to an industrial sterilizer. The recommendations of the sterilizer manufacturer must be followed when sterilizing with ETO gas. Wright surgical instruments can be processed at temperatures of 55°C (131°F).

Storage

Surgical instruments that will not be utilized within a short time and will not be immediately returned to Wright, should be stored clean, decontaminated and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination of the item. Those items in a sealed paper or polyethylene Tyvek® pouch may be stored in a sealed polyethylene bag, and sterilized at a later date. All instruments returned to Wright must be cleaned and decontaminated before shipping. The four main types of packaging for steam sterilization consist of textiles, nonwovens, pouch packaging and rigid container systems. These packaging types offer various levels of protection from contamination, which must be consistent with the final intent of the item.

References

ISO 17664:2004(E) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices. ISO 17665 (2006) Sterilization of Health Care Product – Moist heat ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers. AAMI TIR 30:2003 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices Adherence to ISO 17664, ISO 17665, AAMI TIR 12 and AAMI TIR 30 is noted within sterility validation procedure L114-0015. Validations are conducted to AAMI ST79 as applicable and are noted as such.

Instructions for Use

CE

WRIGHT

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EC REP

Wright Medical UK Ltd
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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 the secure the instruments in suitable holders.

Cleaning Accessories

- Detergent: Prepare detergent (i.e. LIQUI-NOX , Alconox, Inc. 8.5pH) 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 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.

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Instructions for Use

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EC REP

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www.aap.de

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
  - o in order to prevent premature failure
  - o in order to prevent elevated heat development (thermal necrosis)
  - o for preventing smearing of instrument blades
  - o 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 dismantleable 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:
  - o as effective mechanical support
  - o for pretreatment of drills with dried-on contamination before machine cleaning
  - o 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 the secure the drills in suitable holders.

Cleaning Accessories

- Detergent: Prepare detergent (i.e. LIQUI-NOX , Alconox, Inc. 8.5pH) 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 *WMT 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 provides by the processor are to be examined for their efficacy and possible adverse consequences and documented.

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