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.
OUTLINE:

I. GENERAL PRODUCT INFORMATION
   A. PATIENT SELECTION
   B. INDICATIONS
   C. CONTRAINDICATIONS
   D. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
   E. PRECAUTIONS
   F. HANDLING & STERILIZATION
   G. STORAGE CONDITIONS

DEFINITIONS

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>B/C</td>
<td>Batch code</td>
</tr>
<tr>
<td>LMT</td>
<td>Catalog number</td>
</tr>
<tr>
<td>D</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>C</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>I</td>
<td>Consult operating instructions</td>
</tr>
<tr>
<td>T</td>
<td>Use by</td>
</tr>
<tr>
<td>L</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>K</td>
<td>Keep dry</td>
</tr>
<tr>
<td>F</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>R</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>DC</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>REP</td>
<td>Authorized EC Representative in the European Community</td>
</tr>
<tr>
<td>SREW</td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td>STERL</td>
<td>Sterilized using radiation</td>
</tr>
<tr>
<td>STERL 4</td>
<td>Sterilized using gas plasma</td>
</tr>
<tr>
<td>STERL 5</td>
<td>Sterilized using aseptic processing techniques</td>
</tr>
<tr>
<td>STERL 8</td>
<td>For prescription use only</td>
</tr>
<tr>
<td>STERL 1</td>
<td>Do not use if packaging is ripped or damaged</td>
</tr>
<tr>
<td>STERL 3</td>
<td>Sterile</td>
</tr>
<tr>
<td>STERL 2</td>
<td>Non-Sterile</td>
</tr>
<tr>
<td>STERL 1</td>
<td>Do not re-sterilize</td>
</tr>
<tr>
<td>MR</td>
<td>MR Conditional</td>
</tr>
</tbody>
</table>

Abbreviation | Material
---|---
Ti | Titanium
Ti6Al4V | Titanium Alloy
CoCr | Cobalt Chrome Alloy
AlO | Alumina
ZrO | Zirconia
SS | Stainless Steel
UHMWP | Ultra High Molecular Weight Polyethylene
CaSO4 | Calcium Sulfate
HA | Hydroxyapatite
PMMA | Polymethylmethacrylate
PDLLA | Polylactide Acid
PDMS | Silicone SSD
PEEK | PolyEther Ether Ketone
Al | Aluminum
DBM | Demineralized Bone Matrix

I. INDICATIONS

PATIENT SELECTION

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 and adequate bone support.

CONTRAINDICATION

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

CONTRAINDICATION

In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, musculoskeletal or neurologic pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteolytic 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
- Coagulopathy
- Tumor
- Fracture or dislocation of the implant

Other medical or surgical preconditions that could compromise the potentially beneficial procedure, such as:

- Presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Pronounced left shift in the differential leukocyte count

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Abnormal positioning of the implant
- Loss of function of the implant
- Migration of the implant
- Fracture of the bone
- Fracture of the implant
- Thrombosis and embolism
- Wound hematomas and delayed wound healing
- Temporary or persistent functional neurovascular perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Complication with localized tissue reactions
- 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 HMF products but are in principle observed with any implant. Promptly inform WMT as soon as complications occur in connection with the implants on 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 exposure, inadequate preparation of the recipient implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

L. 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 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.

Surgery 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 surgeon. Additionally, the surgeon should be familiar with the 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:

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 unreasonable functional expectations.

2. Condition of senility, mental illness, or psychosis. These conditions, among others, may cause the patient to ignore or 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.
E. PRECAUTIONS

Following the instructions for use provided in this 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 and instruments for the manufacturer Wright and 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:

- Uncontrolled stability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncontrolled 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
- Avoid collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant

Avoid flaking 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 unretracted 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. Procedure or treatments that should be avoided such as MRI-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 arthroplasty.

Concerning Magnetic Resonance Imaging

The devices described in this package insert have not been evaluated for safety and compatibility in the MRI 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 packaging. 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 is not limited to, significant degradation in device performance, cross infection, or contamination which may result in serious patient harm.

STEROILIZATION

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. Soak in an enzymatic detergent solution prepared per manufacturer’s directions for 5 minutes.
4. Soak thoroughly with a soft brush and/or pipe cleaner, preferably flush any very narrow lumens with enzymatic detergent solution into the lumen using a syringe.
5. Rinse with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumen until free of debris.
6. Bath in a detergent solution prepared per manufacturer’s directions for 5 minutes.
7. Soak thoroughly with a soft brush and/or pipe cleaner; preferably flush any very narrow lumens with detergent solution using a syringe.
8. Rinse thoroughly/flash with deionized/reverse osmosis (RO)/DI water.
9. Sterilize for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer’s 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-sterile medical grade wrapping material.
2. Autoclave according to the following parameters:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>Cycle Type</td>
<td>Minimum Set Point</td>
</tr>
<tr>
<td>Steam Sterilization</td>
<td>Exposure Temperature</td>
<td>270 °F (132 °C)</td>
</tr>
<tr>
<td></td>
<td>Time Step</td>
<td>4 minutes</td>
</tr>
</tbody>
</table>

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.

DAREO® is a licensed trademark of Wright Medical Technology, Inc.
Instructions for Use

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

Recommendations Regarding Device Fragments

1. Use medical device in accordance with their labeled indications and the manufacturer's instructions for use, especially during implantation and retrieval.
2. Report any clinical or technical problems or complications associated with the equipment used.
3. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.
4. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
5. Bathe in a detergent solution prepared per manufacturer directions for 5 minutes.
6. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
7. Rinse thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
8. Disassemble all components as per manufacturer instructions (if appropriate).
9. Flash the fluid pocket.
10. Irrigate with saline and withdraw.

Contraindications

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

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

- Pregnancy
- Congestive heart failure
- Inactive neoplasms
- Active neoplasms
- Active neoplasms
- Active neoplasms
- Active neoplasms
- Active neoplasms
- Active neoplasms
- Active neoplasms

Possible Complications

- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic
- Acute or chronic infections, local or systemic

Examples of complications include:

- The manufacturer cannot accept any other returns of used implants.
- The surgeon is held liable for complications associated with inadequate anaesthesia, inadequate preparation of the reassembled implant led in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behaviour.
- Packaging and Sterility
- All medical devices are supplied unsterile; it is imperative that they be prepared before use.
- The manufacturer guarantees the sterilization of the aap medical devices in their original and unopened packaging only up to the point in time that they are opened.
- The surgeon is responsible for maintaining asepsis up to the point of use.
- Before opening the product packaging, inspect it for any damage. Medical devices from damaged packaging must not be used.
-warehousing and handling of implants. The products are intended for single use.
- Re-use, including the use of kits etc.
- The aap Cannulated Screw System has been tested for heating or migration in the MR environment.
- The cannulated screws and guide wires are supplied by aap in an unsterile condition and must imperatively be prepared before use.

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 foil 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 with deionized / reverse osmosis (RO/DI) water.
9. Soak for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Rinse thoroughly with RO/DI water.
11. Dry with clean, soft, absorbent, disposable cloth.

These recommendations are consistent with AAMIR 5779:2000/1:2006 & A1:2009 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, cleaning, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

Sterilization

The minimum recommended steam sterilization conditions for Dado 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:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Set Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Sterilization</td>
<td>270 °C (132 °C)</td>
<td>4 minutes</td>
<td>20 minutes</td>
<td>4 minutes</td>
</tr>
</tbody>
</table>

After sterilization, remove the component from its wrapping using accepted sterile techniques 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 AAMIR 5779:2000/1:2006 & A1:2009 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, cleaning, 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 infection.

Dispose and replace damaged and defective medical devices.

Storage

The manufacturer 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 unwarranted compression, strain, heat, UV radiation, moisture, etc.

Final Remarks

The presented technical and instrumental instructions were validated by aap and aap are 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 worldwide is not possible. The prepare is responsible for obtaining the desired result in the actual preparation with equipment, materials and personal in the preparation facility. To achieve this, a validation and routine inspection of the process is not required. Deviations from the instructions provided by the processor are to be examined for their efficacy and possible adverse consequences and documented.

REF.: WM 7022-00 (137183-1)
REV.: 5 / 05 2010
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 Practices**

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 affect their use.
- 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.
- Adhere to the current guidelines and safety of unrelated devices included in the following:
  - The material composition of the fragment (if known).
  - The size of the fragment (if known).
  - The size and shape of the fragment.
  - The potential mechanisms for injury, e.g. migration, infection.
  - The presence of any treatments or treatments that should be avoided such as an MRI exam in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

**CLEANING AND HANDLING OF WRIGHT INSTRUMENTS**

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 either ethylene oxide (ETO) or other validated sterilization processes.

Limitations and Rigidities 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. Renewal 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 many instruments use extreme caution to avoid injury, consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of user contact.
- Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
- Inspect the instrument case and instruments for damage when received and after each use and cleaning. Incompletely clean, decontaminated and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination, but may also contribute to increased dwell times in sterilization equipment.

Preparation for Cleaning processes

1. Disassemble. If components as per manufacturer instructions (if appropriate).
2. Rinse with cold tap water for a minimum of 1 minute; use a spaygun to remove gross contamination.
3. Scrub thoroughly with a soft brush and/or pipe cleaner, repeated flush any very narrow lumens with enzymatic detergent solution using a syringe.
4. Rinse with cold tap water for a minimum of 1 minute; use a spaygun to remove all remaining debris.
5. Bathe in a detergent solution prepared per manufacturer directions for 5 minutes.
6. Scrub thoroughly with a soft brush and/or pipe cleaner, repeated flush any very narrow lumens with enzymatic detergent solution using a syringe.
7. Rinse with cold tap water for a minimum of 1 minute; use a spaygun to remove all remaining debris.
8. Scrub thoroughly with a soft brush and/or pipe cleaner, repeated flush any very narrow lumens with enzymatic detergent solution using a syringe.
9. Rinse with cold tap water for a minimum of 1 minute; use a spaygun to remove all remaining debris.
10. Dry with a clean, soft, absorbent, disposable cloth.
11. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visibly dry. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) must not be used for cleaning medical lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

An automatic cleaning process may involve a washer-sterilizer, a washer-sanitizer/disinfector, ultrasonic cleaner or related other types machine that clean and decontaminate items. There are many different types of ultrasonic machines, each with its own unique indications, 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 proper detergent may also provide a drying function for non-ultrasonic cleaning. 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 manufacturers’ recommendation temperature (usually 90-140°F or 32-60°C) and specially formulated detergents. Follow manufacturers’ recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading pattern, instrument cavities, 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 cavities depends on instrument construction, exposure time, pressure of delivered solution, and pH of the decontaminant 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.

Steam Sterilization

Steam sterilization is the minimum recommended steam sterilization conditions for Wright reusable instruments as follows:

1. Double wrap the component in a FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:
   - **Cycle Type:** 270°F (132°C)
   - **Temperature:** 270°F (132°C)
   - **Minimum Set Point:** 15 minutes
   - **Exposure Time:** 4 minutes
   - **Repetitions:** 1
3. Allow the component from its wrapping using accepted sterile technique with powder-free gloves. Inspect 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 and methods. It is important to recognize that the effectiveness of the sterilization processes depend on the environment in which the equipment was used. It is important to ensure that the equipment and the environment conform to the requirements of the sterilization process. The equipment and the environment must be validated to ensure that the equipment and the environment conform to the requirements of the sterilization process.

**ETO Sterilization**

ETO sterilization is defined as the sterilization of medical devices that cannot be steam sterilized. Wright instruments manufactured of stainless steel may be ETO sterilized. Those instruments manufactured of UHMWPE cannot be ETO sterilized. Wright instruments manufactured of stainless steel may be steam sterilized with no detrimental effects. Those instruments containing UHMWPE cannot be steam sterilized. ETO sterilization is a non-thermal process that uses ethylene oxide gas to sterilize medical devices. Wright instruments manufactured of stainless steel may be ETO sterilized with no detrimental effects. Those instruments manufactured of UHMWPE cannot be ETO sterilized.

**Storage**

Wright instruments that are not used within a short time and will not be immediately returned by Wright, should be stored clean, decontaminated and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination, but may also contribute to increased dwell times in sterilization equipment. The instruments should be stored in a dry, clean, and well-ventilated area. The instruments should be stored in a dry, clean, and well-ventilated area.

**References**

Description: The instruments are supplied non-sterile by aap and must be imperatively prepared prior to use. The 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 equipment. When selecting the instruments, the surgeon is responsible for maintaining asepsis up to the patient.

Warnings and Precautions
The instruments are supplied non-sterile by aap and must be imperatively prepared prior to use. The 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 equipment. When selecting the instruments, the surgeon is responsible for maintaining asepsis up to the patient.

Warnings and Precautions
The instruments are supplied non-sterile by aap and must be imperatively prepared prior to use. The 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 equipment. When selecting the instruments, the surgeon is responsible for maintaining asepsis up to the patient.

Handling of New Instruments
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 compatibility of the respective instrument. 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 purpose.
- 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 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. When machine cleaning, secure the instruments in suitable holders.

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

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 sterile, steam-permeable maintenance oil which is cleared by the FDA.
- After every cleaning and disinfection inspect the instruments for cleanliness, functionality and damage such as bent, fragmented, torn, worn and broken parts, for example.
- Segregate and replace damaged and defective instruments.

Packaging
- 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:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Temperature</td>
<td>270 °F (132 °C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>20 minutes</td>
</tr>
</tbody>
</table>

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 process parameters 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 provided by the processor are to be examined for their efficacy and possible adverse consequences and documented.
Instructions for Use

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 sterile by aap and must be imperatively prepared prior to use. aap drills should be used only in the context of their intended function.

It is 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 silent that may be subject to wear through repeated use and lose their functionality. It is imperative that their function be inspected 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. Anm 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, disinfectant- and sterile condition. The manufacturer cannot accept any other remains 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 startup, 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 sterilized. 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 foil 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 set, 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 mine shafts).
- Disassemble cannulated drills into their component parts.
- Do not touch or clean any of the drill heads.
- If at all possible, drills with threaded working ends should not be cleaned in the ultrasonic 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. 8.5pH) per manufacturer recommendations.
- Enzymatic Cleaner: Prepare enzymatic cleaner (i.e. ENDOZIME, Ruhof Corporation 6.0-7.5 pH) per manufacturer recommendations.
- Rinse with cold tap water to remove gross contamination. 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 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 with detergent solution using a syringe.
- Rinse thoroughly /flush with RO/DI water.
- 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

- 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 subduing detergent neutral to slightly basic with pH 7 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.
- Remove and disinfect the syringes.
- 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.

Packaging

Store drills with threaded working ends in suitable holders.

Sterilization

The minimum recommended steam sterilization conditions for Draco Headed Cannulated Screws are as follows:
1. Double wrap the component in an FDA cleared CV wrap or similar type non-sterile medical grade wrapping material.
2. Autoclave according to the following parameters:

<table>
<thead>
<tr>
<th>Steam Sterilization</th>
<th>Temperature</th>
<th>Time</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>132°C</td>
<td>10 minutes</td>
<td>270°C</td>
</tr>
<tr>
<td>Class 2</td>
<td>132°C</td>
<td>10 minutes</td>
<td>270°C</td>
</tr>
<tr>
<td>Class 3</td>
<td>132°C</td>
<td>10 minutes</td>
<td>270°C</td>
</tr>
</tbody>
</table>

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 a EAR 1712, and in 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 observe all effects that could affect the product marking or shelf-life of the drills, the drill surface or the drill geometry such as unnecessary creasing, stains, 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 worldwide is not possible. The provider 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 evaluated for their efficiency and possible adverse consequences and documented.

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