Flow-NAIL™

Surgical Technique Guide

Patented - www.Flow-Fx.net

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STG-101 Rev C

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Implant OVERVIEW

Cap
Nail Cap

Nail - Trochanteric

125°, 180mm
125°, 220mm
130°, 180mm
130°, 220mm

Screw - Lag
80 - 120mm in 5mm Increments

Screw - Cortical

20 - 60mm in 2mm Increments
60 - 80mm in 5mm Increments

Screw - Anti-Rotation
50 - 100mm in 10mm Increments

Features & BENEFITS

A revolutionary modality for intertrochanteric or subtrochanteric fractures by combining an intramedullary fixation device with precise delivery of bone void filler.

- ***Patented Side-Port Cannula*** delivers the bone void filler where the surgeon needs it through the appropriate fenestrations while protecting the hip joint from unintended intrusion of biologic material.
- Combines the utility and efficacy of the top orthobiologic platforms with the best delivery mechanisms to ensure ***accurate and precise placement of the bone void filler*** to the desired implantation site while using manual low-pressure delivery.
- Flow-Nail is ***available in 125° and 130° neck angles*** with 180 and 220mm lengths to allow for the treatment of the majority of fractures in this area as a stand-alone device.

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Standard INSTRUMENTS

T-Handle

Wrench

Jig Bolt Driver

Nail Reamer Sheath

Slap Hammer Rod

Slap Hammer Slider

Multi-Channel Guide-Wire Guide

Trocar IM Guide-Wire Guide

Guide-Wire

Drive Bolt Loosener

IM Nail Reamer

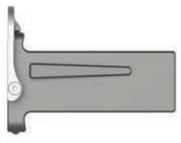
AP Template

Adapter

IM Nail Jig

Cannulated Awl

Lag Screw Sheath

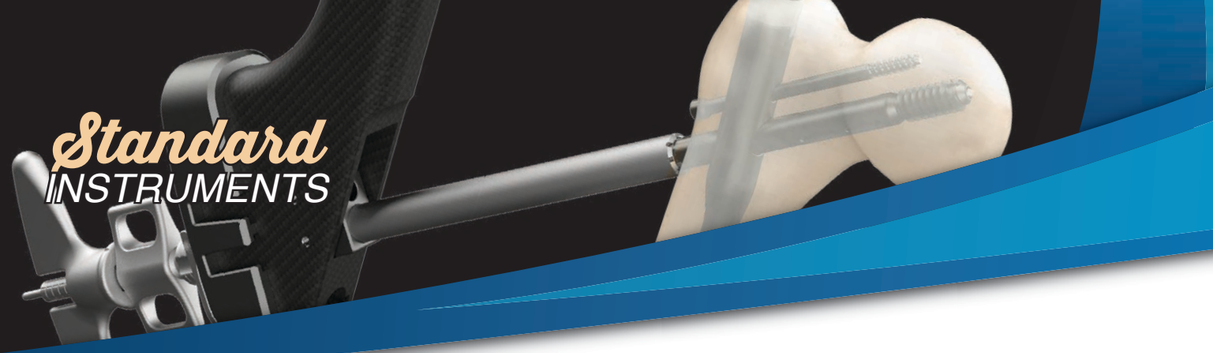


Jig Cartridge

Jig Bolt w/ Integral Lock Washer

Lag Screw Guide-Wire Guide

Trocar Lag Screw Guide-Wire Guide



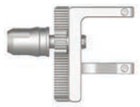
Lag Screw Length Gauge

Lag Screw Drill

Cortical/AR Screw Length Gauge

Lag Screw Driver

Lag Screw Tap



Compression Nut

Lag Screw Driver Fastener

Lag Screw Depth Stop

AR Screw Sheath

Cap Driver Bolt

Cap Driver

AR Screw Drill

AR Screw Shealth Trocar

AR & Cortical Screw Driver

AR & Cortical Screw Driver Bolt

Cortical Screw Sheath

Cortical Screw Sheath Trocar

Cortical Screw Drill

Cortical Screw Rescue Sheath

Side Port Cannula

BVF Gauge

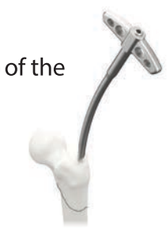
Side Port Cannula Plunger

Position the patient on fracture table with pressure areas well padded. Perform closed reduction under flouroscopy as needed. Sterile prep as per routine. Preoperative antibiotics recommended.

IM Nail Prep

1. Fasten nail to jig using the IM jig bolt with integral lock washer ensuring that the jig splines are aligned correctly and jig bolt is tightened firmly.
    - Determine the incision location. Incise and dissect to the femoral cortical wall.
    - The nail incision will be approximately 3cm long.

2. Drive guide-wire into femoral canal.
    - The entry point is slightly lateral to the tip of the trochanter.
    - Remove the guide-wire guide.
    - Cannulated Awl is provided optionally



Awl

3. Ream proximally for the nail.
    - Ream down to the lesser trochanter.
    - Distal reaming is not required.
    - Remove all instruments when complete.

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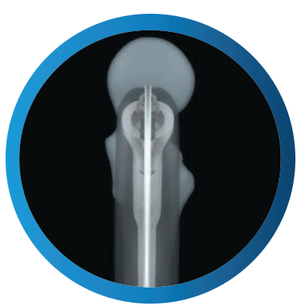
IM Nail Prep Continued

4. Reduce the fracture if open reduction is necessary.
    - No fracture reduction tools are provided with the instrument set.

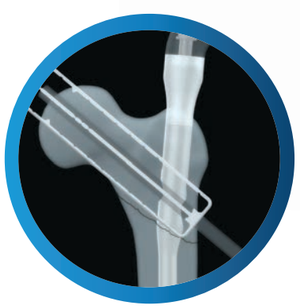
IM Nail Placement

5. Attach the correct angle and length nail to the jig.
    - Fasten the nail to the jig using the IM jig bolt.
    - Insert the Jig Cartridge into the correct slot in the jig.
    - Depending on the angle of the nail to be used, insert the cartridge into the Jig in either the 125˚ or 130˚ position. Orient the cartridge such that the lag screw hole is nearer the distal end of the Jig and ensure the cartridge ejector handle is positioned below the lag screw hole.

6. Insert the nail.
    - Slide the nail into position in the femoral canal, using the AP template and the alignment aids integrated into the jig to determine proper position and orientation.
    - The AP template is attached by sliding its foot into the correct slot (125˚ or 130˚) on the Jig and threading its fastener into the jig.
    - The upper bar of AP template corresponds to AR screw channel in the Flow-Nail



Simulated Lateral X-Ray



Simulated AP X-Ray

Lag Screw Prep

7. Incise for the lag screw.
   - Ensure lag screw is in place prior to AR screw insertion
   - The incision will be approximately 3cm.

8. Install the lag screw sheath into the jig.
   - Run the lag screw sheath into the jig cartridge until bone contact and remove the trocar.

9. Install the lag screw guide-wire with fluoroscopic guidance on AP/Lateral.
   - Drive the guide-wire to within 5mm of the femoral head cortical bone.

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Lag Screw Prep Continued

10. Measure the lag screw length.
    - Measure the distance from the top of the lag screw sheath to the end of the guide-wire after ensuring
    - that lag screw sheath is in firm contact with the bone.

    Remove the guide-wire guide and length gauge when complete. The guide-wire stays in place.

11. Drill for the lag screw with fluoroscopy.
    - Set the stop on the step drill and drill up to the stop.
    - Use caution when passing the drill through the nail.
    - Remove the lag screw step drill.

12. Tap for the lag screw with fluoroscopy.
    - Tap over the guide-wire.
    - Remove the tap.

Lag Screw Placement

13. Install the lag screw.
    - Ensure Lag Screw is placed prior to AR Screw insertion
    - Fasten the correct length and slot configuration lag screw to the lag screw driver.
    - Install the lag screw.
    - Some attention may be needed to the final orientation of the slots on the lag screw so proper connection to the driver is necessary. The slot on the Lag Screw must align with the blue mark on the Lag Screw Driver.

Note: Assembling the lag screw driver.

- Attach the correct length and slot configuration lag screw to the lag screw driver using the lag screw driver bolt. Ensure the Lag Screw Slot aligns with the blue mark on the Lag Screw Driver. Attach the T-handle.
- Drive the lag screw manually over the guide-wire to the desired depth and confirm with fluoroscopy.

14. Compress the fracture.
    - Apply the Compression Device carefully to achieve desired compression. Take caution to prevent pullout in the soft bone wheel forcing the lag screw driver away from the lag screw sheath.
    - Remove the t-handle and guide-wire.

Lag Screw - Delivery of Bone Void Filler

Prior to use of Flow-FX BVF, please inject 3-4 cc of radio-opaque contrast through Side-Port Cannula and Lag Screw to confirm that hip joint has not been compromised. If Hip joint has been penetrated, BVF use is not advised.

16. Prepare the BVF per the manufacturer's instructions.
    - Attach BVF syringe to the Side Port Cannula when complete.

17. Attach the BVF gauge.
    - Attach the BVF gauge to the lag screw driver.
    - Set the BVF gauge to the correct length lag screw.

Note: The gauge must attach to the driver so that the opening in the gauge is aligned with the blue mark on the driver.

18. Dispense the BVF, confirming location with fluoroscopy.
    - Insert the BVF side-port cannula into the BVF side-port cannula guide.
    - Push the BVF side-port cannula in until the tip of the cannula is at the end of the lag screw (a band on the cannula indicates where the cannula tip is relative to the lag screw tip).
    - Withdraw cannula as needed to localize desired delivery portals.

Note: The band around the SPC in conjunction with the markings on the BVF gauge indicates that the port of the SPC is located at the depth of the first lag screw slot (the fenestrations in the tip of the lag screw are in front of it and the second slot is behind it). The long line down the SPC being centered in the BVF gauge window indicates that the port of the SPC is oriented toward the open slot.

Anti-Rotation Screw Placement

To be performed after Lag Screw placement

20. Determine the incision location and incise.
    - It may be necessary to enlarge the incision proximal to the lag screw sheath.

21. Drill for the anti-rotation screw using fluoroscopy for assistance.
    - Advance the sheath to the femoral lateral cortex and remove the trocar.
    - Replace with the drill.
    - Use caution when passing the drill through the nail and take care not to over-penetrate the medial cortex to avoid vascular injury.
    - Identify the screw length by reading the number on the drill where it passes out of the sheath.
    - Remove the drill.

22. Place the anti-rotation screw.
    - Attach the correct length AR screw to the AR screw driver using the AR screw driver bolt. Attach the T-handle.
    - Drive the AR screw manually through the AR screw sheath to the desired depth and confirm with fluoroscopy.
    - Remove the lag screw driver and bolt when complete.
    - Remove the anti-rotation screw sheath, driver, and bolt as well as the jig cartridge when complete.

Note: AR Screw length can be confirmed with AR Screw Length Guage on reverse of Lag Screw Length Gauge

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Distal Cortical Screw Placement

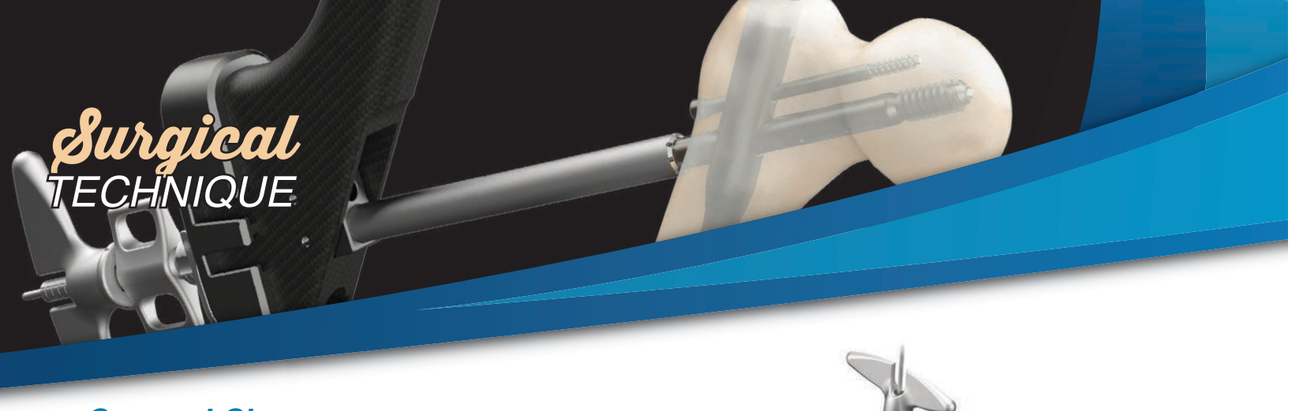
23. Determine the incision location and incise.

24. Install the cortical screw sheath.
    - The cortical screw sheath can be placed in either the static or dynamic position by flipping it 180° to target the upper end of the slot in the nail or the lower end of the slot in the nail.
    - There is a different slot for each nail length, the cortical screw sheath pictured is in the slot for the 180° long nail.
    - Drill hole alignment may be altered with Cortical Screw Rescue Sheath for atypical alignment issues

25. Drill for the cortical screw using flouroscopy as needed.
    - Advance the sheath to the femoral lateral cortex and remove the trocar.
    - Excess pressure on jig with 220mm nail may influence alignment of cortical drill hole. Drill hole alignment may be altered with Cortical Screw Rescue Sheath for atypical alignment issues. Do not plunge with drill but advance 1-2 mm beyond far cortex for best screw purchase.
    - Identify the screw length for bicortical purchase by reading the number on the drill just outside the sheath. Cortical screw length can confirmed with measurement gauge on reverse side of Lag Screw Length Gauge
    - Remove the drill.

Note: 220mm nail distal alignment can be influenced by pressure applied to jig and cause misaligned drill hole

26. Place the cortical screw.
    - Attach the correct length cortical screw to the AR/cortical screw driver.
    - The cortical screw will not require threading until it
    - passes through the nail. Confirm screw placement with fluoroscopy. Jig cartridge removal enables a shoot through lateral view
    - Remove the cortical screw sheath and driver when complete.



Cap and Close

27. Remove jig.

- Drop a guide-wire through the nail jig bolt.
- Unfasten the jig bolt from the nail, but it should remain captive to the jig.

28. Install the cap.

- Attach a cap to the cap driver using the cap driver fastener.
- Follow the guide-wire to the nail and install the cap.
- Unfasten the cap driver bolt.
- Remove the cap driver and the guide-wire.

29. Nail Removal

- Remove Lag Screw, AR Screw and Cortical screw through stab incisions , using fluoroscopy as needed.
- Incise buttock scar and develop dissection plane.
- Remove Nail Cap and attach assembled slap hammer using Reamer Sheath for soft tissue retraction if needed.
- Guide Wire inserted into ail may make slaphammer attachment easier.

29. Close

Flow-Nail ™

Trochanteric Nail

Instructions for Use

DESCRIPTION

The Flow-FX Flow-Nail is designed as a trochanteric nail system for fixation of stable and unstable proximal fractures of the femur and is composed of an intramedullary nail, sliding, fenestrated lag screw, anti-rotation screw, cortical screws and accompanying instruments.

The Flow-Nail can also be used for the delivery of bone void fillers capable of being delivered via a 16-gauge needle.

INDICATIONS

The Flow-Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures. The Flow-Nail can also be used for the delivery of injectable bone void fillers capable of being delivered via a 16-gauge needle.

MATERIALS

The Flow-Nail implant components are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

CONTRAINDICATIONS

- Insufficient quantity or quality of bone, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply or obliteration of the medullary canal or femoral neck and head.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Material sensitivity documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Use of contrast media in patients with a known contraindication to contrast.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS

- For professional use only.
- Do not use this system without fully reading the instructions for use.
- The surgeon should be familiar with the general principles and technique of intramedullary nails to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures and the Flow-Nail System.
- The surgeon should be familiar with the general principles and technique of delivering bone void filler using the Flow-Nail System.
- Surgeons should follow the surgical technique.
- Selection of the correct Nail and Lag Screw length is very important. Determination of the alignment of the femoral neck and head should be performed using fluoroscopy and/or designated gauges.
- If delivery of a bone void filler is required in an area adjacent to a joint, injection of 4cc of radiopaque contrast through the side port cannula is recommended to confirm the integrity of the articular surface. If the articular surface is not intact, delivery of bone void filler in that area is not recommended.
- Patients should be cautioned against significant load bearing prior to good callus formation. Patients who are either noncompliant or predisposed to delayed union or non-union, must have auxiliary support.
- Periodic x-rays are recommended for at least six months to detect any changes in position, nonunion, loosening, bending or cracking of components.
- Patients should be cautioned that even after complete healing there is a higher risk for re-fractures while the Nail is in position.
- Postoperative care and physical therapy should be structured to prevent excessive loading of the operated extremity.
- The implant system has not been evaluated for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
- All implants and all instruments, with the exception of some Side Port Cannulas, are provided non-sterile. All non-sterile implants and instruments must be sterilized prior to surgery in accordance with the Sterilization Section.
- Screws and hardware from other device manufacturers should not be combined with the Flow-Nail System.
- Flow-Nail implants should only be used for delivery of bone void fillers that have been validated for use with the device.

PRECAUTIONS / INSPECTION

- The Flow-Nail implants, the Trocar-Tipped Guide-wire, and the Side Port Cannula for the application of bone void filler are one-time use. The Side Port Cannula and Trocar-Tipped guide-wire will be disposed of in accordance with local requirements. The implants are intended to remain in the patient.
- The Flow-Nail Instrument set, with exception of the Side Port Cannula and Trocar-Tipped Guide-Wire, is intended to be reusable and will be cleaned and sterilized in accordance with the Sterilization Section.
- The Side Port Cannula has been demonstrated to survive 5 steam sterilization cycles but should be examined for structural integrity before use. Gamma sterilized Side Port Cannulas shall not be re-sterilized.
- Proper handling and storage of the system components is mandatory. Damage or alterations may produce stresses and cause defects, which could become the focal point for failure.
- All implants and instruments must be inspected prior to use for any damage. Do not use if damage exceeds normal standards for

implants and instruments.

ADVERSE EFFECTS

The adverse events include but are not limited to:

- Implants may migrate, cause pain or stress shield bone even after a fracture has healed.
- Pain, discomfort, nerve or soft tissue damage etc.
- Metal sensitivity or allergies.
- Trauma.
- A pulmonary embolism may result from using this hardware with an injectable bone void filler.

STERILITY *Implants*

The Flow-FX implants are provided non-sterile.

Instruments

The Flow-FX instruments, with exception of the Side Port Cannula, are provided non-sterile. In the case of the Side Port Cannula, the packaging will indicate whether the SPC is sterile or non-sterile. In the case of non-sterile SPCs, clean and sterilize in accordance with the cleaning and sterilization procedure below. Some SPCs are gamma sterilized and individually packaged.

Scope

These cleaning instructions apply to the reusable manual orthopedic surgical instruments used to prepare the bone, and implant the Flow-Nail Trochanteric Nail implant set.

The Side Port Cannula and the Trocar-Tipped Guide-Wires are single use instruments and should be discarded after each use.

WARNINGS AND LIMITATIONS

Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

Repeated processing, according to these instructions, has minimal effect on Flow-Nail reusable manual instruments. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS AT POINT OF USE

Separate any nested instruments and disassemble any instruments that can be disassembled without using tools. Please refer to the surgical tray graphics for the expected state of disassembly.

In addition, the BVF Gauge (101-71) shall be separated into two parts for cleaning and reassembled for sterilization. The separation is accomplished by completing the following procedure.

1. Extend the collar until the set screw is adjacent the 90 notch position.
2. Rotate the collar further clockwise (to the left when viewed from the notch position) until the set screw engages the collar release slot and is unable to rotate further.
3. Slide the collar out of the device.
4. Re-assembly is accomplished by reversing the removal process.

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth or submerge in a basin of sterile water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.

CONTAINMENT / TRANSPORTATION

Universal precautions for handling contaminated/ bio-hazardous materials should be observed.

Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

MANUAL CLEANING PROCEDURE

1. Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (paying close attention to all threads, crevices and other hard-to-clean areas) until all visible soil has been removed. Any instruments with lumens or cannulas should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). The enzyme solution should be changed when it becomes grossly contaminated.
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat steps 5 and 6 with freshly prepared cleaning solution until the instruments are thoroughly clean.
8. Dry instrument with a clean, disposable, absorbent, non-shedding wipe.

AUTOMATED CLEANING PROCEDURE

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

Automated washer/disinfector systems are recommended for cleaning the Flow-Nail implants. For effective automated cleaning of the implant tray, remove the tray cover, remove the removable tray and place it in a covered wire basket and expose the bottom layer of the tray.

DISINFECTION

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.

INSPECTION / FUNCTION TESTING

1. Carefully inspect each instrument to ensure that there is no visible contamination and that all visible blood and soil has been removed. If visible contamination is evident, repeat the Manual Cleaning Procedure above.
2. Visually inspect for damage and/or wear, corrosion, pitting, discoloration or separation of parts. If there is any evidence of damage, do not use the instrument.
3. Check the action of moving parts (such as hinges and box-locks) to ensure smooth operation throughout the intended range of motion.
4. Check instruments with long slender features (particularly rotating instruments) for distortion.
5. When instruments form part of a larger assembly, check that the devices assemble readily with mating components.

INSPECTION / FUNCTION TESTING FAILURE If an instrument fails inspection or a functional test due to improper cleaning, repeat the cleaning procedure. If the instrument continues to fail after repeated cleanings, discard the instrument.

If an instrument fails inspection or a functional test due to wear or damage, discard the instrument.

MAINTENANCE

Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear.

PACKAGING

1. Individually – a standard polyethylene/Tyvek (or equivalent) sterilization pouch of the appropriate size may be used for single instruments. Ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging.
2. In Sets – sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI wrap method (ANSI/AAMI ST79-2010).

STERILIZATION

The following steam sterilization method should be performed:

PROCEDURE	FRACTIONATED VACUUM PROCEDURE
Exposure Time	4 minutes
Temperature	132°C
Drying Time (Implant Tray)	30 minutes
Drying Time (Instrument Tray)	45 minutes

STORAGE

1. Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature and humidity extremes.
2. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

STORAGE INSTRUCTIONS

Implants should be stored at room temperature.

CAUTION

Federal law restricts this device to sale by or on order of a physician.

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