Flow-Screw™
Cannulated Screw System

Instructions for Use

DESCRIPTION

The Flow-FX Flow-Screw is designed as a Cannulated Screw system for the fixation of a variety of fractures and is composed of a cortical screw and accompanying instruments. The Flow-Screw can also be used for the delivery of injectable bone void fillers capable of being delivered via a 16-gauge needle. The Flow-Screw is not designed to be coupled to other metal implants.

INDICATIONS

The Flow-Screw is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the Flow-Screw can also be used to deliver injectable bone void fillers to a surgical site to treat fractures throughout the skeletal anatomy as deemed appropriate by the surgeon.

MATERIALS

The Flow-Screw implant components are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or stainless steel conforming to ASTM F138 or ASTM F2229.

CONTRAINDICATIONS

- Insufficient quantity or quality of bone, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply.
- 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.
- 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.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.
- Spinal fracture fixation.
- Use with Polymethyl methacrylate (PMMA).

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 treating fractures using cannulated screws.
- The surgeon should be familiar with the general principles and technique of delivering bone void filler using the Flow-Screw system. The bone void filler must be used within the timeframe designated in its labeling.
- Surgeons should follow the surgical technique.
- Selection of the correct screw diameter and length is very important. Determination of the alignment of the fractured bones should be done using fluoroscopy and/or designated gauges.
- Use of contrast media in patients with a known contraindication to contrast.
- 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.
- Using the Flow-Screw drill for BVF delivery is best performed after tapping. Plunging the drill with guide-wire and placing screw without guide-wire is recommended to avoid wire migration.
- 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 screw 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.

- .Most parts, excepting specially packaged disposable kits, are delivered non-sterile. These must be sterilized prior to surgery in accordance with the Sterilization Section.
- Flow-Screw is not indicated for fixation or attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Flow-Screw implants should only be used for delivery of bone void fillers that have been validated for use with the device.

PRECAUTIONS / INSPECTION

- The Flow-Screw™ implants, the guide-wire, Flow-Screw™ drill, Intraosseous Adapters and Side Port Cannula for the application of bone void filler are one-time use. The Side Port Cannula, Flow-Screw drill and Guide-Wire will be disposed of in accordance with local requirements. The implants are intended to remain in the patient.
- The Flow-Screw Instrument set, with exception of the Side Port Cannula, Drill, Trocar-Tipped Guide-Wire and IO adapter, is intended to be reusable and will be cleaned and sterilized in accordance with the Sterilization Section.
- Any Cannulated device placed over a guide-wire should be checked repeatedly to ensure guide-wire is not migrating.
- The Side Port Cannula has been demonstrated to survive 5 steam sterilization cycles but should be examined for structural integrity before use.
- 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.
- If using the Flow-Screw™ drill as a BVF delivery device:
    - It may be used for single-use (patient) delivery of flowable biologic materials and bone void fillers after appropriate placement over a guide-wire and guide-wire removal.
    - The drill is a single patient, single-use instrument intended for disposal after use.
    - Guide-wire should not be replaced after BVF is injected due to risk of guide-wire migration during screw placement. Screw should be placed without guide-wire before BVF hardens.
    - Delivering flowable biologics or bone void fillers in a pressurized manner may lead to alterations in homeostasis and/or embolism. Using slow, smooth delivery at normal tactile pressures is preferred method. Any alteration in blood pressure, heart rate or oxygen saturation should raise concern of embolus.
    - Delivering large amounts of flowable biologics or bone void fillers into a closed myofascial space or compartment may lead to compartment syndrome and require surgical decompression. Frequent neurovascular checks after surgery will minimize likelihood of significant tissue damage from compartment syndrome.
    - Delivering flowable biologics or bone void fillers without fluoroscopic localization may result in inaccurate, unacceptable placement. Fluoroscopy should be used in all cases where precise delivery of material is desired
    - When used to drill more than one hole or deliver biologics to more than one site, appropriate care should be taken to ensure that all biologic material has been satisfactorily removed from the Flow-Screw drill cannulation prior to drilling another hole. Any remaining material that may cause the guide-wire to bind in the drill indicates the need to use a new Flow-Screw drill.
    - When used to drill more than one hole, ensure that the drill has not been bent prior to drilling additional holes. A bent drill will cause the guide-wire to bind and advance past the desired location.
    - Any biologic or bone void filler delivery should be performed in low pressure conditions where flow is enabled by normal tactile pressure. Significant pressure may increase the risk of pulmonary embolus.
    - Flow-Screw drill works well with materials that can be delivered through a 16-gauge needle. If materials of increased viscosity are used, flow through the drill, as well as using the guide-wire as a plunger, will become more difficult. For best results, prior validation of material flow characteristics by Flow-FX or the operating surgeon is recommended.
    - Delivering flowable biologics or bone void fillers in a pressurized manner may lead to alterations in homeostasis and/or embolism.
    - Aseptic technique is necessary even if potential wound contamination is present.
    - Fluoroscopic guidance is strongly recommended for most effective use.
    - Any sign of instrument defect or breakage should lead to immediate discard and replacement.

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 implant with an injectable bone void filler.

STERILITY

The Side Port Cannula, the Trocar-Tipped Guide-Wires, Flow-Screw drill and intraosseous adapters are single use instruments and should be discarded after each use.

Cleaning

Scope

These cleaning instructions apply to the orthopedic surgical implants and instruments used to prepare the bone and implant the Flow-Screw Cannulated Screw implant set. The Side Port Cannula, the Trocar-Tipped Guide-Wires, Flow-Screw drills and the IO adapters are single use instruments and should be discarded after each use.

Both the Implants and the Instruments are contained in the same case/tray. The Implants are further contained within the case in a screw caddy. The intent is to clean the implants within their caddy separately from the instruments. Implant cleaning may be automated. Instruments are recommended to be cleaned manually.

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-Screw 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. There are no instruments that will require disassembly using tools. Please refer to the surgical tray graphics for the expected state of disassembly.

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 and implants 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-Screw implants within their screw caddy. For effective automated cleaning of the screw caddy, remove the tray cover, remove the removable screw caddies.

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 and implant 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 or implant.
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

Scope

Both the implants within their caddies and the instruments are intended to be sterilized together in their case/tray.

The following steam sterilization method should be performed:

PROCEDURE	FRACTIONATED VACUUM PROCEDURE
Exposure Time	4 minutes
Temperature	132°C
Drying Time	30 minutes

STORAGE INSTRUCTIONS

1. Implants and instruments should be stored at room temperature.
2. 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.
3. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

These instructions have been validated by Flow-FX, LLC as being capable of preparing manual orthopaedic surgical instruments for re-use. It is the responsibility of the reprocessor to ensure that reprocessing is performed using the appropriate equipment and materials, and those personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Any deviation by the reprocessor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

CAUTION

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

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