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Rx only

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# ONELIF™ INTERVERTEBRAL BODY REPLACEMENTSYSTEM INSTRUCTION FOR USE

## Commonly Used Symbols for Medical Devices

| SYMBOL | DEFINITION |
|---|---|
| | Manufacturer |
| | Date of manufacture |
| | Use by date |
| | Do not re-use |
| | Do not re-sterilize |
| | Do not use if package is damaged |
| Ø | Diameter |
| | Consult instructions for use |
| | Caution: Consult accompanying documents |
| MR | MR conditional |
| | Non-sterile |
| STERILE EO | Sterilized using ethylene oxide |
| STERILE R | Sterilized using irradiation |
| QTY | Quantity per package |
| LOT | Batch code |
| REF | Reference |
| EC REP | Authorized representative in the European Community |
| Rx only | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician |

This package insert covers the OneLIF™ Intervertebral Body Replacement System Instruments that are used for the implantation of this system.

## INDICATIONS

The OneLIF™ Interbody Fusion System is an interbody fusion device system indicated for use in skeletally mature patients at one or more levels of the lumbosacral spine (L2-S1), in patients with the following indications: degenerative disc disease (DDD) defined as back pain with degeneration of the disc confirmed by patient history and radiographic studies, spinal deformity (degenerative scoliosis or kyphosis), spondylolisthesis or retrolisthesis, and failed previous fusion (pseudoarthrosis). Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

The OneLIF™ Interbody Fusion System is intended to be used with or without the screws which accompany the implants. These devices are intended for stand-alone use in patients with DDD or degenerative spondylolisthesis at one or two contiguous levels only when used with at least three screws per implant (including at least one screw in each endplate) and when ≤ 20° lordotic implants are used. When used at more than 2 contiguous levels, or for treatment of conditions other than DDD or degenerative spondylolisthesis, or with fewer than 3 accompanying screws, or when using implants greater than a 20° lordotic angle, the system must be supplemented by posterior fixation (e.g., pedicle screw system) cleared for use in the lumbar spine.

The implants can be placed via a variety of open or minimally invasive approaches. These include anterior and oblique approaches. The implant is designed for use with autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft.

## CONTRAINDICATIONS INCLUDE, BUT ARE NOT LIMITED TO:

1. Patients with known or probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, leuokocytosis, cardiovascular, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative instructions including restrictions on movement especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any patient that has had prior fusion surgery at the level(s) to be treated is a relative contraindication.
7. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
8. Rapid degenerative disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
9. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
10. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
11. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any case not described in the indications for use.
13. Reuse or multiple use of the device.

## WARNINGS

The implantation of the OneLIF Spinal Implant is a technically demanding procedure presenting a risk of serious injury to the patient and should only be performed by experienced spinal surgeons with specific training in the use of this system. In addition, based on the mechanical testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient factors (e.g. smoking, occupation), which may impact the performance of the implants.

1. Implants and instruments are provided non-sterile.

2. Implants may be reprocessed prior to use and must be sterilized before use.
3. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.
4. Instruments must be cleaned and sterilized before use.
5. Instruments are critical devices and must be terminally sterilized by steam sterilization prior to surgical use.
6. Prior to sterilization and promptly following each procedure, thoroughly clean all instruments according to the procedures outlined below. The parameters for sterilization and sterilization processes listed below are only valid for devicesthat have been properly cleaned.
7. All instruments should not be allowed to dry before reprocessing to effectively clean and remove contaminants including blood, body fluids, bone and tissue debris, and other contaminants.
8. Contaminated instruments should not be rinsed with hot water (temperature greater than 110°F (45°C), concentrated alcohol, certain liquid chemical sterilant, or certain disinfectants such as glutaraldehyde or ortho-phthaladldehyde as these may cause protein-based lubricants as these may inhibit sterilization.
9. Do not use silicon or oil-based lubricants as these may inhibit sterilization.
10. Do not use metal cleaning tools such as metal or wire brushes, scouring pads, etc. to clean the instruments as these may damage the surface of the instruments.
11. Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.
12. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.
13. Due to the presence of implants, image artifacts may appear on X-ray, CT, and/or MR imaging.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bonequality and/or nerve paralysis are also poor candidates for spinefusion.

Patients with previous spinal surgery at, or adjacent to, the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

## MAGNETIC RESONANCE ENVIRONMENT

The OneLIF™ Interbody Fusion System has not been evaluated for safety in the MR environment. It has not been tested for heating, or unwanted movement in the MR environment. The safety of the OneLIF™ Interbody Fusion System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

## SOME POSSIBLE COMPLICATIONS AND ADVERSE REACTIONS AND/OR EFFECTS

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any, or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, acute or persistent CSF leakage, meningitis.
8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss due to surgical trauma or other reasons.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
10. Loss of bladder control or other types of urological system compromise.
11. Reproductive system compromise or loss of function.
12. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
13. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
14. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.
15. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
16. Non-union (pseudo-arthrosis), delayed union, mal-union which may require further surgery.
17. Cessation of any potential growth of the operated portion of the spine.
18. Loss of or increase in spinal mobility or function.
19. Inability to perform the activities of daily living.
20. Misalignment of anatomical structures, including loss of proper spine curvature, correction, reduction and/or height.
21. Pain or discomfort.
22. Hemorrhage of blood vessels and/or hematomas.
23. Re-operation.
24. Death.

Additional surgery may be necessary to correct the occurrenceof some of these possible adverse events.

## PREOPERATIVE MANAGEMENT

A Successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Failure rates in spinal fusion procedures are published, and spinal fusion failure is an accepted risk of the procedure. Preoperative planning and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant are critical considerations in achieving a successful result.

The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The devices must be handled and stored carefully and protected from damage.

All patients contemplating implantation of this device should be apprised of the risks associated with the procedure, as well as the limitations regarding activities following surgery. Only patients that meet the criteria described in the Indications should be selected. Patient conditions and/or predispositions, such as those mentioned in the Contraindications, should be avoided.

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to NovApproach Spine.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.

## INTRAOPERATIVE MANAGEMENT

The surgeon should follow established practices and specific instructions for implantation of the devices. Bone graft must be placed in the area to be fused. The device is not intended, or expected, to be the only mechanism of support of the spine. Regardless of the etiology of the spine pathology fore which the implantation of this device was chosen, it is the expectation and requirement that adequate anterior column support exists, either by virtue of existing anatomy, or by means of a spinal fusion or arthrodesis. Without solid biological anterior column support, the device cannot be expected to support the spine indefinitely and will fail in any of several modes. The modes may include bone-implant interface failure, implant failure, or bone failure.

1. Caution should be taken in handling and positioning the implants to avoid excessive forces that could cause deformation or fracture of the device or injury to the surrounding tissue. Damage to the implants may affect their ability to interface properly and/or perform in the manner intended.
2. Extreme caution and protection should be used around neural elements. Damage to the nerves will cause loss of neurological functions.
3. Extreme caution and protection should be used around blood vessels. Damage to the vessels will cause blood loss that could end in death.
4. Implant size selection should be done carefully to ensure injury to surrounding tissues is avoided. Improperly sized implants may compromise performance.
5. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
6. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
7. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
8. Screws should be attached to the mating driver so that they are fully seated on the driver and this fit is maintained throughout the implantation or assembly step. Bone screws must be fully seated in the interbody device prior to the assembly of the Retention Plate.
9. Insufficient torque application of the Retention Plate screw during assembly to the interbody device could result in disassembly of one or more of the components of the implant construct which could lead to patient harm including, but not limited to: instability, lack of fusion, vascular injury and/or death.
10. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery and confirm the intended assembly and location of the implants.
11. Implants should not be reused under any circumstances.
12. Different manufacturers use different materials, varying tolerances, and design configurations. The OneLIF spinal implants must not be used with components from any other system or manufacturer since dimensional compatibility cannot be assured.

## POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices. If partial weight-bearing is recommended or required prior to forming bony union, the patient must be warned that loosening or breakage of the implant is a complication which can occur as a result of excessive or early weight-bearing or excessive muscular activity. It is important that immobilization of the surgical site be maintained until bony union consolidates and been confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
2. Postoperative patients should be instructed to limit activity (e.g. lifting, sports, twisting motions, smoking, consuming alcohol) as determined by their surgeon to avoid, among other things, non-union, implant loosening, or disassembly.
3. If a non-union develops, or the implants loosen or disassemble, bend and/or break, the device(s) should be

revised and removed immediately before serious injury occurs. The device is not intended, or expected to be, the only mechanism of support of the spine. No implant can be expected to withstand the unsupported stresses of full weight bearing indefinitely. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant and can cause eventual bending, loosening or breakage of the device(s).

4. Any decision to remove the implants should take into consideration the risk to the patient of additional surgeries, as well as the difficulty of removal and associated harm.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
6. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

## SINGLE USE

Implants are intended for single use only. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death.

Titanium implants may be processed by automated means prior to sterilization. Implants that have directly come in contact with the patient or bio-contaminants must be discarded.

## GENERAL INFORMATION

NovApproach Spines' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments.
Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions fromthe manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.
Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

## CLEANING INSTRUCTIONS

- Instruments must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. The mechanical inspection should include, but not be limited to, the following:
  1. Confirm that all mechanisms operate properly (i.e. Inserter handle and shaft rotate, Screwdriver Handle actuates, Screwdriver blade articulates freely, etc.).
  2. Awls appear to be sharp.
  3. There are no apparent bends or cracks in instrumentation.
  4. If any of these situations exist please return instrument to NovApproach Spine and arrange for a replacement.
- Compliance is required with the equipment manufacture's user instructions and recommendations for chemical detergents.
- It is the responsibility of the facility/user to qualify any deviations from the recommended method of processing.
- **NovApproach Spine, LLC** recommends the following cleaningand sterilization instructions for instrumentation:
  1. Disassemble the retention plate guide into separate components, including (See Appendix A – Disassembly Instructions):
     a. Separate the Retention Plate Driver from the Torque Limiter.
     b. Separate the Torque Limiter from the Handle.
  2. Disassemble the Fixed Angle Screwdriver Assembly into separate components, including (See Appendix B – Disassembly Instructions, Step 1-2):
     a. Rotate the "Knob" until it is fully disengaged from the "tube".
     b. Pull out inner "shaft" to remove from "tube".
  3. Rinse all instruments in cool tap water for a minimum of three (3) minutes for each disassembled component. Actuate all buttons and levers while rinsing to facilitate debris removal.
  4. Rinse instruments in cold tap water for an additional three (3) minutes each. During the rinsing, brush devices and flush with a 50mL volume of tap water 5X (Instruments should be free of visible debris)..
  5. Enzymatic Soak/Brush/Flush
     a. Completely submerge instruments in pH Neutral enzymatic cleaner (US: e.g. Steris Prolystica 2X) prepared according to the manufacture's instructions, using warm (110° F Min) tap water.
     b. Rotate the instruments below the surface of the cleaner and actuate all buttons and levers while submerged to facilitate debris removal and to eliminate any trapped air bubbles.
     c. Ensure there is no contact between the instruments and allow instruments to soak in enzymatic cleaner for a minimum of 20 minutes.
     d. Following the soak, and while still submerged, brush each instrument component for a minimum of three (3) minutes. Pay special attention to orifices, cracks, crevices, and all lumens of the instruments. Use soft nylon bristle brushes while flushing with enzymatic cleaner (Flush each instrument 5X with the cleaning solution). Actuate all buttons and levers a minimum of 4 times while submerged.
  6. Fresh Enzymatic Cleaner Flush
     a. Prepare a fresh cleaning solution per Step 4a. Use a 60 mL syringe to jet flush all joints/cracks and gaps in the instruments with the cleaning solution a minimum of 5 times. Actuate all buttons and levers three (3) times while flushing
  7. Ultrasonic Clean
     a. Place instruments in ultrasonic cleaner ensuring that all instruments are disassembled and submerged with a freshly prepared solution of pH Neutral enzymatic cleaner (prepared per step 4a). Ensure there is no contact between the instruments and rotate the instruments below the surface of the cleaner and actuate all buttons and levers four (4) times while submerged to facilitate debris removal and to eliminate any trapped air bubbles.
     b. Allow instruments to soak in the solution while sonicating for a minimum of 20 Minutes
  8. Rinse in hot water
     a. Rinse instruments under hot (110°F minimum) running water and rinse for a minimum of three (3) minutes
     b. Actuate all buttons and levers three (3) times while rinsing, and ensure water penetrates all cracks, crevices, lumens, and

orifices.

c. Use a 60mL syringe filed with hot water (110°F minimum) to jet flush all joints/cracks and gaps in the instruments two (2) times. Actuate all buttons and levers while flushing

9. Final Rinse
   a. Rinse all instruments using AAMI TIR37 compliant rinse water for four (4) minutes.
10. Dry
   a. Dry instruments with a soft, lint-free cloth
   b. Dry the instruments with filtered pressurized air
   c. Optional: Heated dry in a 90-120°F instrument dryer
11. Lubrication
   a. Hinged, rotating, sliding, or articulating instruments should be lubricated with water-soluble product (e.g. Instrument milk or equivalent).
12. Assemble the Fixed Angle Screwdriver Assembly into separate components, including (See Appendix B – Disassembly Instructions, Step 3-4):
   a. Push out inner "shaft" into "tube".
   b. Rotate the "Knob" until it is fully engaged and finger tight with the "tube".

## STERILIZATION

The instruments and implants are supplied NON-STERILE and must be sterilized prior to use. Recommended sterilizationmethods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify
that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle has been validated to a sterility assurance level (SAL) of 10-6.

| Method | Cycle | Temperature | Exposure Time | Dry Time |
|---|---|---|---|---|
| Steam | Pre-Vacuum | 132°C (270°F) | 4 Minutes | 60 Minutes |

**For additional information regarding any of NovApproach Spines' devices, please contact NovApproach Spine, LLC Customer Service at inquiry@novapproachspine.com**

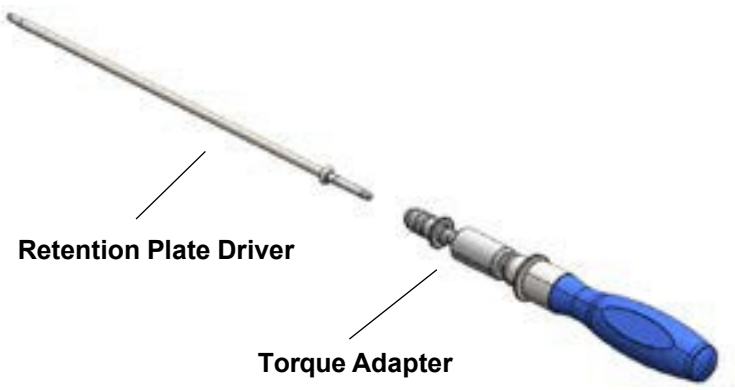
**CAUTION**
**Federal law restricts this device to sale by, or on the order of, a physician.**

**PATENT**
**Covered by one or more patents. See www.novapproachspine.com/patents for details**
**OTHER**
**Some components may not be currently available. Please contact your NovApproach Spine representative for additional information.**

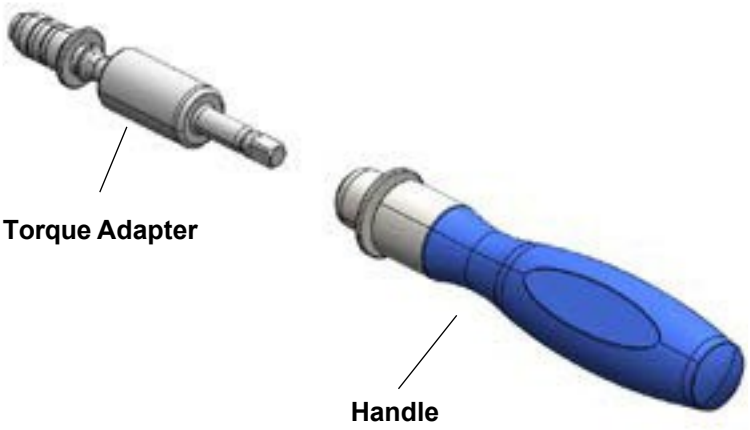


## APPENDIX A
**Instrument Disassembly instructions – Retention Plate Guide Screwdriver**

1. Separate the Retention Plate Driver from the Torque Limiter.

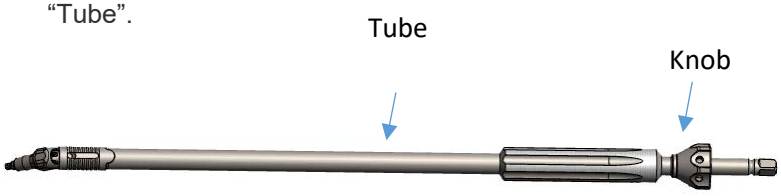



2. Separate the Torque Limiter from the Handle

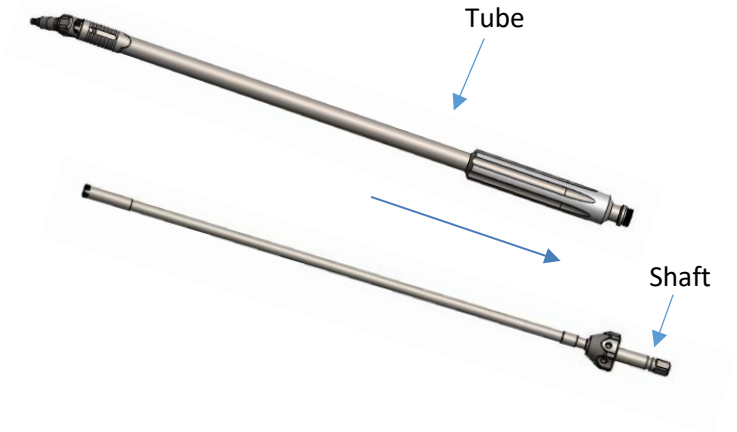


**APPENDIX B**
**Instrument Disassembly instructions – Fixed Angled Screwdriver Assembly**

1. Rotate the “Knob” until it is fully disengaged from the “Tube”.

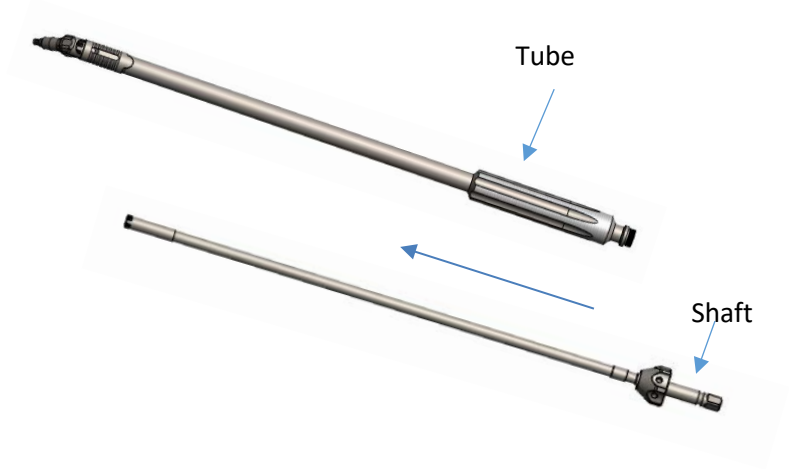



2. Pull out inner “Shaft” to remove from “Tube”.




**Instrument Assembly instructions, Post Cleaning – Fixed Angled Screwdriver Assembly**

3. Push out inner “Shaft” into “Tube”.




4. Rotate the “Knob” until it is fully engaged and finger tight with the “Tube”.