ASTRA, AVANT and ASTRA-OCT Navigated Instrument System Instructions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician

DEVICE DESCRIPTION

The SpineCraft Navigation Instrument System is comprised of subsets of instruments intended to be used in conjunction with the StealthStation® Navigation System. The ASTRA, AVANT and ASTRA-OCT Navigated Instruments were tested for compatibility with the Medtronic StealthStation® Navigation System and the Medtronic NavLock® Trackers from the NavLock® Set. The products are supplied clean and "NON-STERILE".

For full instructions on use, please refer to the following manuals and guides:

- ASTRA & AVANT Spine System Navigation Instruments Surgical Technique Manual
- ASTRA-OCT Spine System Navigation Instruments Surgical Technique Manual
- Medtronic's software and user guides

INDICATIONS

ASTRA and AVANT Navigated Reusable Instruments are indicated for preparation and placement of SpineCraft ASTRA Spine system pedicle screws during thoracolumbar sacroiliac spinal surgery to assist surgeon in precisely locating anatomical structures in either open, minimally invasive procedures, or percutaneous, procedures. ASTRA and AVANT Navigated Reusable Instruments are specifically designed for use with Medtronic StealthStation® System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Use of the ASTRA and AVANT Navigated Reusable Instruments is limited to use only with ASTRA Spine System implants.

ASTRA-OCT Navigated Reusable instruments are indicated for preparation and placement of SpineCraft ASTRA-OCT Spine system screws during cervico-thoracic spinal surgery to assist surgeon in precisely locating anatomical structures in open procedures.
ASTRA-OCT Navigated Reusable Instruments are specifically designed for use with Medtronic StealthStation® System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Use of the ASTRA-OCT Navigated Reusable Instruments is limited to use only with ASTRA-OCT Spine System implants.

PRECAUTIONS

The Navigated instruments should only be used by surgeons who are fully experienced in the use of such instruments and the specialized navigated spinal surgery techniques.

CONTRAINDICATIONS

The Navigated Instrument System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device
11. Contraindications under the ASTRA Spine System, ASTRA Extended Tab Screws with the AVANT MIS Instrumentation System, ASTRA-OCT Spine system, Medtronic Navigation StealthStation® System are all applicable to the use of the Navigated Instrument System.
12. ASTRA-OCT navigation instruments are not intended to support occipital screw placement.

POTENTIAL ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Early or late loosening or movement of the implant.
3. Implant migration
4. Metal sensitivity or allergic reaction to a foreign body.
5. Infection, early or late.
6. Nonunion, delayed union.
7. Decrease in bone density due to stress shielding.
8. Pain, discomfort, or abnormal sensations due to the presence of the device.
9. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation in males, paraesthesia, or other types of serious injury.
10. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
11. Pressure on the surrounding tissues or organs.
12. Loss of proper spinal curvature, correction, height, and/or reduction.
13. Bursitis.
14. Paralysis temporary or permanent
15. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
16. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
17. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
18. Damage to lymphatic vessels and/or lymphatic fluid exudation.
19. Spinal cord impingement or damage.
20. Non-union (or pseudoarthrosis)
21. Degenerative changes or instability in segments adjacent to fused vertebral levels.
22. Fracture of bony structures or stress shielding at, above, or below the level of surgery.
23. Discitis, arachnoiditis, and/or other types of inflammation.
24. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
25. Spinal epidural hematoma.
26. Inability to resume activities of normal daily living.
27. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
28. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
29. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
30. Loss of or increase in spinal mobility or function.
31. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
32. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
33. Change in mental status.
34. Cessation of any potential growth of the operated portion of the spine.
35. Death.

Note: Additional surgery may be required to correct some of these potential adverse events

WARNINGS

The following are warnings for this device.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only.
6. AN IMPLANT SHOULD NEVER BE RE-USED. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
7. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
8. To facilitate fusion, a sufficient quantity of autograft bone should be used.
9. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
10. The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient
11. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
12. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
13. The components of this system should not be used with components of any other system or manufacturer.
14. Titanium components should not be used with stainless steel components within the same system.
15. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
16. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
17. SpineCraft does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
18. The use of the Navigated Instrument System should only be used with the indicated pedicle screw systems.
19. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
20. Users must ensure that surgical accuracy be assessed before the procedure and repeatedly throughout the procedure by positioning the tip of each navigated instrument on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. When verifying the accuracy of the Navigated Drivers, the accuracy test must include the Screw (of which diameter and length are selected/entered in the software) assembled securely onto the driver. The screw tip will be placed on an identifiable anatomical landmark and compared to the tip location as displayed on the screen.
21. In the event of a registration failure or suspected inaccuracy, the Navigated Instruments should not be used with the Navigation System and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. The implant components should be handled and stored carefully, protected from any damage, including corrosive environments.
4. Correct selection of the implant is very important.
5. An adequate inventory of implant sizes should be available at the time of surgery.

All implants and instruments must be unpacked, inspected for damage, cleaned and sterilized prior to use in the operative field. Instruments requiring sharp tips and/or edges to function should be inspected prior to use. If such instruments have dulled and will not function optimally, they should be returned to SpineCraft for replacement.

INTRAOPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae.
2. Adequate exposure bony preparation and grafting is essential to achieving this result.
3. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting the screws.
4. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
5. The implants must be handled and contoured carefully to avoid notching or scratching the surface.
6. Before closing the soft tissues, all of the locking cap screws should be tightened firmly according to the operative technique.
    - Ex-planted implants must never be reused.
    - The placement of screws should be checked radiographically prior to assembly of the rod construct.
    - During construct assembly do not cross thread locking cap screws. Rotate locking cap screws counter clockwise for 1 to 2 revolutions in screw head before attempting to thread locking cap screw into screw head.

POSTOPERATIVE

1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation devices.
2. Surgical implants must be never reused. Any retrieved devices should never be

reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.

3. **Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.**

MAGNETIC RESONANCE ENVIRONMENT

The ASTRA and ASTRA-OCT implants used with The ASTRA, AVANT and ASTRA-OCT navigated instruments system have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of The ASTRA and ASTRA-OCT implants used with The ASTRA, AVANT and ASTRA-OCT navigated instruments 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.

PROCESSING

All instruments must be cleaned, disinfected and sterilized before each use; this applies especially to the first-time use after delivery because all instruments are shipped in non-sterile condition (clean and disinfect after removing the transport packaging and sterilize after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization. When using instruments, please make sure to keep dirty instruments separate and do not place them back into the instrument tray in order to prevent serious contamination of the equipped instrument tray. Clean/disinfect the dirty instruments, sort them and place them back in the instrument tray, then sterilize the entire equipped instrument tray.

Within the scope of your responsibility for instrument sterility, please ensure that only cleaning/disinfection and sterilization processes which have been appropriately validated in a device-specific and product-specific manner are used, that the employed devices (disinfecting machine, sterilizer) undergo regular maintenance and inspections and that the validated parameters are complied with during each cycle. In addition, please follow all applicable laws in your country as well as the hygiene regulations of the medical practice or hospital in question. This applies especially to the various requirements regarding effective prion inactivation.

INSTRUMENTS CARE AND HANDLING:

1. Failure to follow the instructions provided in this insert may result in instrument breakage and potential adverse effects on user or patient.
2. Use only instruments specifically designed for use with their associated instruments.
3. Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. The following instructions should be followed to minimize damage:
   - Inspect the instruments and instrument case for damage when purchased and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside for repair service or return to SpineCraft.
   - Thoroughly clean and dry instruments, whether or not they were used or were inadvertently contacted with blood or saline, to reduce corrosion and potential cross-contamination.
   - Care should be taken to limit navigational instrument bending or damage during handling, which can influence navigational accuracy and/or registration.
4. Health care personnel should conduct testing in the health care facility to assure that the conditions essential to sterilization can be achieved and that specific configuration of the contents is acceptable for the sterilization process and for the requirements at the point of use.
5. AORN and ANSI/AAMI standards, practices and guidelines should be consulted for detailed guidelines for related to proper care, maintenance and handling of surgical instruments and container systems.

WARNINGS AND PRECAUTIONS:

Following are specific warnings, precautions, and adverse effects. These warnings do not include all adverse effects, which can occur with surgery in general; common surgical risks should be explained to the patient prior to surgery.

1. Instruments must be thoroughly cleaned prior to sterilization. Instruments that are not clean may not be effectively sterilized.
2. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
3. When handling sharp instruments, use extreme caution to avoid injury.
4. Unless otherwise indicated, instrument sets are provided non-sterile and must be sterilized prior to use.
5. Do not reuse instruments labeled for single use only. Reuse may adversely affect performance of the instrument.
6. Flash autoclaving is not permissible.
7. Instruments should never be flash-autoclaved in an instrument case.
8. Follow the instructions and warnings issued by the suppliers of any cleaning and equipment used.
9. Do not use heated air or radiation sterilization.
10. All instruments, instrument trays and sterilization containers must not be exposed to temperatures of 140°C (284°F) during reprocessing steps.
11. Avoid exposure to saline and hypochlorite solutions, as these will promote corrosion.
12. Remove excessive soil with a disposable wipe.

CLEANING:

Limitations and Restrictions

- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning SpineCraft instruments. Alkaline agents with pH≤12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob disease (CJD) are a concern.
- Automated cleaning using a washer/disinfector alone may not be effective for Spinal and Biologics Devices. A thorough, manual or combination manual/automated washer cleaning/disinfection process is recommended. It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from instruments.
- Instruments must be removed from metal or polymer trays for manual or automated cleaning procedures. Instrument trays, cases, and lids must be cleaned separately. Non-sterile, single-use plate and screw implants are an exception to this rule. Plates and screws may remain in the tray or caddy for reprocessing.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.

Manual Cleaning/Disinfection Procedure

Equipment: ultrasonic cleaner, enzymatic cleaner or detergent solution, clean, soft, lint-free single-use cloth or medical grade compressed air. Follow the instructions for use of enzymatic cleaner or detergent solution. Use the following steps:

Step 1	Use a soft nylon-bristled brush to gently scrub the instrument until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush.
Step 2	Rinse/flush instrument and internal components with an enzyme solution (cleaning solution) while actuating instrument (if applicable). (Validation was performed using Enzol as a cleaner)
Step 3	Scrub instrument with soft bristle brush until visibly clean.
Step 4	Immerse the instrument in cleaning solution.
Step 5	Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas with fresh cleaning solution while actuating instrument (if applicable). Flush lumens with cleaning solution using a syringe in order to remove air bubbles from the instruments lumen.
Step 6	Soak in cleaning solution while sonicating for 15 minutes at 40– 50kHz.
Step 7	Rinse instrument in purified water for at least 1 minute or until there is no sign of blood or soil on the instrument or in the rinse stream. Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas.
Step 8	Place prepared disinfecting agents in a sonication unit. Completely submerge instrument in disinfection solution. (Validation was performed using 75% Isopropanol for 10 minutes holding time)
Step 9	Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas with prepared disinfecting agent while actuating instrument (if applicable). Flush lumens with cleaning solution using a syringe in order to remove air bubbles from the instruments lumen.
Step 10	Sonicate for 10 minutes at 40-50kHz submersed in the disinfection solution.
Step 11	Rinse instrument in purified water for at least 1 minute.
Step 12	Remove excess moisture from the instrument with a clean, absorbent, and non-shedding wipe or with medical grade compressed air.

Combination Manual/Automated Washer Cleaning/Disinfection Procedure

Equipment: Washer/disinfector (SpineCraft recommends the use of an EN ISO 15883-1 and -2 compliant cleaning / disinfection device in combination with a suitable load carrier. Follow the instructions for use of the device manufacturer of the processing machine), enzymatic cleaner or detergent solution. Use the following cycle parameters:

Step 1	Use a soft nylon-bristled brush to gently scrub the instrument until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush
Step 2	Rinse/flush instrument and internal components with an enzyme solution (cleaning solution) while actuating instrument (if applicable). (Validation was performed using Enzol as a cleaner).
Step 3	Scrub instrument with soft bristle brush until visibly clean.
Step 4	Immerse the instrument in cleaning solution.
Step 5	Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas with fresh cleaning solution while actuating instrument (if applicable). Flush lumens with cleaning solution using a syringe in order to remove air bubbles from the instruments lumen.
Step 6	Soak in cleaning solution while sonicating for 15 minutes at 40– 50kHz.
Step 7	Rinse instrument in purified water for at least 1 minute or until there is no sign of blood or soil on the instrument or in the rinse stream. Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas.
Step 8	Connect the lumens of the instruments to the washing drains using Luer Locks and suitable load carriers, such as MIS trolleys. Instruments without lumens can be reprocessed in instrument baskets.
Step 9	Pre-cleaning using cold tap water for 2min.
Step 10	Cleaning with 0.5% cleaner at 55 °C for 5min with demineralized water
Step 11	Rinsing with demineralized water for 1min.
Step 12	Thermo-disinfection with demineralized water at least 90 °C for 5 min in the washer/disinfector.
Step 13	Hot Air Dry: (95-100°C / 203°F - 212°F): 10 minutes.
Step 14	If instruments were not fully dry after the automated process, remove excess moisture from instruments with a clean, absorbent, and non-shedding wipe or with medical grade compressed air.

Material stability

When choosing the cleaning agent and disinfectant, make sure that they do not contain the following components:

- Anticorrosive/corrosion inhibitors (triethanolamines are particularly problematic)
- Strong organic, mineral and oxidizing acids
- Relatively strong bases (pH must not exceed 12 for instruments made of metal and 10.5 for aluminum/ferrozell ones; neutral or weakly alkaline cleaning agents are recommended)
- Solvents (such as alcohols and acetone) and gasoline
- Oxidizing agents
- Ammonia
- Chlorine and iodine

NOTE: **Certain solutions, such as those that are alkaline-based or contain bleach, glutaraldehyde, or formalin may damage some instruments, particularly soft metal instruments. These solutions should not be used on aluminum or anodized aluminum.**

PREPARATION FOR DECONTAMINATION:

The ASTRA, AVANT and ASTRA-OCT Navigated Instruments cannot be disassembled. Cleaning and Decontamination of these instruments is achieved in the assembled state.

LIMITATIONS ON REPROCESSING

1. Repeated processing has minimal effects on instrument life and function.
2. End of useful life is generally determined by wear or damage due to surgical use.

Carefully inspect instruments between uses to verify proper functioning.

Send damaged instruments to a supplier of authorized repair or refurbishment services.

CLEANING INSPECTION

1. Carefully inspect each instrument before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes, and moveable parts, such as push-buttons/release buttons or hinges.
2. If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse instruments for a minimum of 1 minute with warm, 85°F - 104°F (30°C - 40°C), tap water after using hydrogen peroxide solution.
3. Instruments that are still dirty must be cleaned and disinfected again.

STERILIZATION

ASTM F565 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated FDA cleared steam sterilizer effective sterilization may be achieved using the following parameters:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Reusable Rigid Sterilization Containers:

In order to ensure proper sterilization of SpineCraft Navigation Instruments when using the Aesculap reusable rigid sterilization containers, the following FDA-cleared Aesculap reusable rigid container configuration shall be used in a pre-vacuum steam sterilization cycle using the above listed sterilization parameters.

Aesculap JN443 and JN445 rigid containers (with corresponding JK490 lid and Aesculap single use filters US751 or US994

Ensure that the supplied reusable rigid sterilization container is clean and in proper working order prior to sterilization according to the manufacturer's Instructions for Use.

Aesculap rigid containers JN443 and JN445 have been validated ONLY with Aesculap single use filters US751 or US994. For the appropriate use of the proposed Aesculap SterilContainer System Extra Long Size, please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THESE INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

Instruments should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all implant and instrument kits used in surgery as well as any unused kits that were in the surgical suite. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters provided in this insert.

INSPECTION / FUNCTIONAL TESTING:

1. Inspect all the instruments after cleaning or cleaning/disinfecting for corrosion, damaged surfaces, chips and impurities and separate out all damaged instruments.
2. Visually inspect instruments and instrument cases for damage and / or wear.
3. Check instruments with long slender features (particularly rotating instruments) for distortion.
4. For cutting features, check edges for distortion/large nicks. Edges should be continuous.
5. Articular surfaces for Trials should be smooth and free of cracks and deep nicks.
6. Check action of moving parts to ensure proper operation.
7. For Hinged Instruments, check for smooth movement of hinge without excessive "play."
8. Check locking mechanisms for action.
9. Ensure dissembled instruments (if applicable) readily assembled with mating components and ensure that mating parts fit together without complications.
10. Check instruments with driving or cutting tip to make sure that they are still in good condition. Inspect ends for distortion, cracks and large nicks.
11. Screwdrivers tips should be carefully inspected before and after every surgery. SpineCraft recommends that screwdrivers should be replaced at the following maximum intervals:
    - T15 & T22 Drivers should be replaced every 6 months
    - Polyaxial Screwdrivers should be replaced every 6 months
12. Inspect for bent or otherwise damaged navigated instruments, which can affect navigational accuracy and/or successful registration.

NOTES:

- **If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact SpineCraft's customer service or your distributor immediately for a replacement.**
- **If corrosion is noted, do not use and contact SpineCraft's customer service or your distributor for a replacement.**
- **SpineCraft cannot be responsible for performance of instruments if the above recommended timeframes are not adhered to.**

MAINTENANCE:

- Reassemble all disassembled instruments (if applicable). Subject all instruments to a functional test.
- Apply surgical-grade lubricant to instruments with hinged/mating surfaces while in the open position.
- Apply surgical-grade lubricant to all moveable parts such as push-buttons, sliding sleeves, closures on tongs, latches, threaded spindles, etc.
- Surgical-grade lubricant should not be used other than for the above purpose whenever possible. Only surgical-grade lubricant (white oil) should be used which – taking into consideration the maximum applied sterilization temperature – are approved for steam sterilization and feature proven biocompatibility.

NOTE: As a rule, no surgical-grade lubricant may be applied to silicone parts.

PACKAGING:

It's recommended to use instrument trays to contain instruments that are provided in sets. Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in the current revision of ANSI/AAMI ST79.

CONTAINMENT AND TRANSPORTATION:

1. Reprocess instruments as soon as is reasonably possible after use.
2. Follow hospital protocols when handling contaminated and bio-hazardous materials.
3. Instruments should be cleaned within 30 minutes after use to minimize the potential of staining, damage, and drying.
4. If cleaning must be delayed, immerse instruments in a compatible detergent solution, spray with an instrument pre-soak solution, or cover instruments with a towel moistened with purified water to prevent drying and encrustation of surgical soil.
5. Place the device in its respective position within the instrument tray.
6. The image of the device is marked in its intended position within the tray.

STORAGE:

Store sterile packaged devices in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

LIMITED WARRANTY:

SpineCraft's non-sterile instruments are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact SpineCraft for current information.

Instructions for the ASTRA, AVANT and ASTRA-OCT non-navigated instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company.

For product information or questions pertaining to service or any non-conformities, please contact your local distributor or SpineCraft customer service by calling 1 877-731-SPINE (877-731-7746) or 630-920-7300.

Symbols:

Catalog Number

Medical Device

Lot Number


Consult instructions for use

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