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Nimbus

Nimbus Arm Set

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1. Product Handling

The Distal Connector, is supplied in a non-sterile condition and must be cleaned and sterilized before each use according to the instructions provided below. The Nimbus Drape is supplied as a sterile kit. All other devices/components are supplied and used non-sterile and should be cleaned before use according to the instructions provided below. Sterile components should always be stored unopened in their respective packs. Prior to use, inspect packaging for damage that may have compromised sterility. Also inspect labeling to verify that expiration date has not passed. If product is damaged or expired, do not use. When removing sterile products from packaging, observe relevant aseptic technique.

High temperatures, moisture and humidity can damage Nimbus products. Protect the product against moisture and humidity. Do not store close to radiators and protect from high radiation. Do not expose the product to large impacts and vibration, the product is not designed for impulse loads.

2. Product Description and Materials

The Nimbus **Arm Set** is mounted to the accessory rail of operating tables and it is used to support a variety of instruments relative to patient's body during orthopedic surgical procedures. The device can be locked in any desired position or orientation using a one-hand operation release trigger at any time.

The Nimbus Arm Set includes the following modular components:

1 x Nimbus Arm (6973335)
1 x Bedrail Clamp (6973336)

The following is a list of the approved accessories for the Nimbus Arm:

- Distal Connector (6973337)
- Nimbus Drape (sterile) (6973339)

Distal Connector (6973337)
The Distal Connector (6973337) is used as intermediate element designed to couple the Nimbus Arm (6973337) to a variety of instruments intended for orthopedic surgical procedures.

Nimbus Drape (sterile) (6973339)
The Nimbus Drape (sterile) (6973339) is used to cover the Nimbus Arm. The kit includes 5 sleeves (nimbus drape).

3. Indications

The Nimbus products and all related components and attachments listed above are indicated for patients undergoing orthopedic surgery.

4. Intended Use

The Nimbus Arm Set is used, in combination with specific accessories, to position a variety of instruments relative to patient's body immediately before, during and after surgical interventions as well as for examination and treatment.

5. Contraindications

Contraindications include but are not limited to: Infection local to the operative site, signs of local inflammation, patients who are unwilling to restrict activities or follow medical advice, patients with physical or medical conditions that would prohibit beneficial surgical outcome, use with components of other systems unless otherwise specified.

6. Precautions and Warnings

Device functionality may be impaired through improper use and/or positioning of Nimbus products. Service and modification to the devices is to be provided by trained personnel only. These devices should be inspected and proper function verified before each use, ensure that this user manual is readily available to all personnel at all times.

- The maximum load capacity for the Nimbus Arm is 20 lbs. (9 Kg).
- Improper use and positioning may lead to injury. Follow all instructions for use of the operating table system and Nimbus Products and maintain observation of patient while product is in use.
- Use only approved accessories with Nimbus products. All accessories must be used in accordance with instructions for use. Accessories made by other providers may be used only with written approval from NuVasive.
- Risk of burns may occur through contact between the Nimbus products and electrical equipment such as computer components and defibrillators. Contact between the patient and metallic surfaces must be avoided.
- The product can be repositioned by opening fastening elements. Prior to initially mounting or repositioning the product, hold the movable segments securely so that they do not fall or move suddenly. Also, be aware that moving the product during initial mounting or repositioning can expose personnel, patient, and other equipment to pinching or shearing. Prior to mounting or repositioning the product, be sure that the patient, all other personnel and equipment are clear of the product so pinching or shearing does not occur.
- Improperly secured products or accessories may result in patient injury. After initial positioning and after every repositioning of the product, check all fastening elements (clamps/handles… etc.) to make sure they are fully closed and secure.
- Do not continue to use the Nimbus products if the products are worn, defective or damaged in any way. Only use the product in full working condition.
- The Nimbus product is to be used only with accessories specifically designed for the product and approved by NuVasive.
- A sterile cover must be used on the Nimbus Arm during surgery to avoid contact with liquids and other substances used in surgery.
- The product is designed to support only the attached instrument. Do not apply any additional loads by leaning or resting on the product.

- Avoid exposing the product to high impacts, vibration, moisture, humidity and radiation.
- A risk of infection exists if the product is stored or used in a non-sterilized environment. If the product is stored or used in a non-sterile environment, clean the product before use using the instructions given in the "Cleaning" section.
- An approved sterile disposable kit is required for proper use of the product. The Nimbus Drape is the only sterile disposable kit approved for use with the Nimbus product.

7. Preoperative Planning

Ensure that all sterile components (Distal Connector, Nimbus Drape (sterile)) are available before surgery, and that all non-sterile items have been inspected for proper function and cleaned.

8. Adverse Effects

Chaffing or redness of the patient's skin is possible.

9. Cleaning and Sterilization

Reusable Sterilizable accessories: The Distal Connector is supplied in a non-sterile condition and must be cleaned and sterilized before the first and every use following the guidelines listed below.

Disposable Sterilizable accessories: The Nimbus Drape is supplied as a single-use sterile kit. DO NOT RE-STERILIZE OR REUSE. DISPOSE AFTER USE.

Reusable Non-Sterilizable: All other Nimbus products and accessories are reusable and are to be used in non-sterile condition. Wipe down after each use. DO NOT AUTOCLAVE OR IMMERSE.

Recommendation for the Care and Handling for Reusable Sterilizable Nimbus Products and Accessories

REUSABLE STERILIZABLE ACCESSORIES DESCRIPTION	Nimbus reusable sterilizable accessories are used in surgical procedures. Use of Nimbus accessories should only be performed with Nimbus devices or devices distributed by NuVasive. Nimbus accessories are generally composed of stainless steel and aluminum. Sterilization of reusable sterilizable accessories must occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and detailed below. Sterilizable reusable accessories are provided non-sterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.
WARNINGS	Carefully inspect each instrument to ensure that all visible blood residue and other contaminants have been removed. Do not autoclave or immerse the Nimbus Arm. Do not re-sterilize or re-use any Nimbus single-use disposable kit.
CAUTION	Federal Law (USA) restricts this device to sale by or on the order of a physician.
REPROCESSING LIMITATIONS	Nimbus accessories can be steam sterilized and repeat sterilization will not adversely affect them. If problems related to accessories are identified, please bring it to the attention of NuVasive for investigation. The lifetime of an accessory is typically limited by normal wear and damage due to use.
DISCLAIMER	NuVasive has verified through laboratory testing that our accessories are suitable for the sterilization cycles listed in the sterilization section of the IFU. It is the user's responsibility to verify that equipment is performing as intended, and conditions are achieved.

INSTRUCTIONS FOR USE

POINT OF USE PREPARATION	Keep accessories moist and do not allow blood and/or bodily fluids to dry on the accessories. The decontamination process should begin immediately after the completion of the surgical procedure. If cleaning must be delayed, place accessories in a covered container with pH Neutral enzymatic detergent to delay drying. Accessories should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning. Wash all accessories whether or not they were used or were inadvertently contacted with blood. Disassemble accessories with removable parts; loosen accessories with movable parts, as applicable.
DECONTAMINATION	Decontamination is for the purpose of microbial inactivation. Saturate the surface completely with full strength intermediate disinfectant/cleaner* (e.g., CaviCide) and allow to remain in contact with devices for 5 minutes.

A. MANUAL CLEANING: ALL ACCESSORIES	1. **Pre-Cleaning:** Remove all visible soil by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g., MetriZyme) and disassemble/loosen accessories, if suitable. The majority of the surgical accessories and trial devices are simply constructed and will not require disassembly. However, some of the more complex accessories are made of several components and these should be disassembled into their individual parts prior to decontamination. Scrub with the appropriate soft bristle brush until visibly clean; actuate through the full range of motion. 2. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g., MetriZyme) and sonicate for 10 minutes. Ultrasonic cleaners can be used with hot water per the manufacturers' recommended temperature; however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment. 3. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes three (3) times. * Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Other cleaning/disinfection methods may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.
B. MANUAL CLEANING: ACCESSORIES WITH CANNULAS, LUMENS, OR HOLES	1. **Pre-Cleaning:** Follow the "Pre-Cleaning" and "Washing" steps in Section A. Manual Cleaning – ALL ACCESSORIES. 2. **Washing:** After ultrasonic cleaning, in a fresh enzymatic cleaning bath use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub any cannula, lumen, or hole(s). Push in and out, using a twisting motion to remove debris. Use a syringe filled with enzymatic neutral pH cleaning solution to flush hard to reach internal areas. 3. **Rinsing:** Flush the instrument paying special attention to the cannulations, lumens, and/or holes with deionized or distilled water. For example, a minimum of 2 minutes three (3) times.
C. MANUAL CLEANING: ARTICULATING ACCESSORIES	4. **Pre-Cleaning:** Follow the "Pre-Cleaning" and "Washing" steps in Section A. Manual Cleaning – ALL ACCESSORIES. 5. **Washing:** After ultrasonic cleaning, immerse the instrument in fresh neutral pH enzymatic cleaning solution to avoid aerosol generation. Actuate moveable mechanisms through full range of motion, such as knobs, hinges, box locks, or spring-loaded/retractable features. For accessories with flexible shafts, bend or flex the instrument under the neutral pH cleaning solution while brushing the flexible areas. For accessories with internal cavities, after actuating components in the neutral pH cleaning solution, fully open components and use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the internal cavities. Use a syringe filled with enzymatic neutral pH cleaning solution to flush hard to reach internal areas 6. **Rinsing:** Actuate and/or retract moveable parts while rinsing with deionized or distilled water. For example, a minimum of 2 minutes three (3) times. For accessories with flexible shafts, flex the instrument while rinsing.
DRYING	Ensure device is dry prior to inspection and sterilization preparation. Accessories must be thoroughly dried to remove residual moisture before they are stored. Filtered compressed air may be used prior to air drying if available.

<table>
<tr><td>MAINTENANCE INSPECTION AND TESTING</td><td>After cleaning, the accessories (disassembled, if applicable) should be visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts (e.g., hinges) to verify that each instrument functions throughout its intended range of motion. Place accessories into appropriate configuration within instrument case and wrap with protective FDA cleared sterilization wrap according to AAMI / AORN guidelines.

Surgical accessories and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:
1. Inspect instrument cases and accessories for damage when received and after each use and cleaning. Incompletely cleaned accessories should be re-cleaned, and those that need repair returned for servicing.
2. Only use an instrument for its intended purpose.
3. When handling sharp accessories use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.
4. If accessories appear to be damaged in such a way that may compromise the performance of the instrument, contact your NuVasive representative for a replacement.
5. Visually inspect the instrument and check for damage and wear, moveable parts should have smooth movement, locking mechanisms should fasten securely</td></tr>
<tr><td>TRANSPORT</td><td>Compliance with the general precautionary measures for handling contaminated/biologically hazardous materials is required.</td></tr>
<tr><td>STERILIZATION</td><td>Accessories supplied by NuVasive have been thoroughly cleaned, inspected, and tested for proper function prior to shipment. Unless otherwise indicated, these accessories are NOT STERILE and must be sterilized prior to use. Accessories provided outside of instrument sets should be fully loosened/disassembled and wrapped in FDA cleared sterilization wrap per AAMI ST:79/AORN Guidelines. Flash (immediate use) steam sterilization by exposure at 132°C / 270°F should only be used as an emergency procedure. Accessories must be cleaned and disassembled prior to processing.

The following are minimum cycles required for steam sterilization that has been validated by NuVasive under laboratory conditions to achieve a SAL of 10^{-6} with components loosened or disassembled. NuVasive has data on file.

Sterilization with a Pre-Vacuum Sterilizer (HI-VAC):
270° F (132° C), 4-minute exposure time</td></tr>
<tr><td>DRY TIME</td><td>The following are minimum dry time requirements for the indicated steam sterilization cycles.
<table>
<tr><th>Name/Part Number</th><th>Dry Time Requirements (minutes)
Pre-Vacuum Sterilizer
270° F (132°C), 4-minute</th></tr>
<tr><td>NIMBUS DISTAL CONNECTOR (6973337)</td><td>20</td></tr>
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<tr><td>STORAGE/ACCESSORY CARE</td><td>Accessories must be thoroughly dried to remove residual moisture before they are stored. Accessories that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped accessories or instrument cases to prevent damage to the barrier. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling. If necessary, hinged, rotating, or articulating accessories can be lubricated with a neutral pH instrument lubricant specifically designed for compatibility with steam sterilization that has been listed with the FDA. Instrument lubricants containing mineral oil, silicone oil, or other oil bases should NOT be used.</td></tr>
<tr><td>CONTACT INFORMATION</td><td>NuVasive, Inc.
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It remains the responsibility of the user to ensure that the reprocessing is performed using appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained to achieve the desired result. This normally requires validation and routine monitoring of the process.

WARNING! Do not autoclave or immerse the Nimbus Arm.

WARNING! Do not re-sterilize or re-use any Nimbus single-use disposable kit.