OMNIBotics System BalanceBot Instrumentation

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Symbols used in labelling:

SYMBOL	SIGNIFICANCE	SYMBOL	SIGNIFICANCE
LOT	**BATCH CODE**	REF	CATALOGUE REFERENCE
NON-STERILE	NON-STERILE DEVICE		WARNING, SEE INSTRUCTIONS FOR USE
	MANUFACTURER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

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

CONTENTS

BalanceBot surgical instruments are supplied by OMNIlife science specifically to prepare the affected joint for the Apex Knee™ and Unity Knee™ System implants using computer-assisted surgery.

MATERIAL

BalanceBot surgical instruments are manufactured from medical grade stainless steels, aluminum and plastics. All instruments are user sterilized and are re-usable unless specified otherwise.

INTENDED USE

The instrumentation has been designed to facilitate bone preparation and implantation of the Apex Knee™ and Unity Knee™ Systems. A Surgical Technique can be obtained from Corin-OMNI.

DECONTAMINATION, CLEANING AND STERILIZATION

Surgical instruments are supplied non-sterile and must be cleaned and sterilized before initial use. Remove instruments from all packaging, decontaminate, clean and place in the appropriate location in the instrument pan provided by OMNI prior to sterilization. The instruments must be decontaminated, cleaned and sterilized before and after each patient use to prevent the transmission of infection from patient to patient.

Autoclave sterilization is recommended. The autoclave must be validated by the hospital and regularly checked to assure the recommended sterilization temperatures are reached for the entire exposure time. Other sterilization methods are possible but must be validated by the user. Individuals responsible for handling and use of the instruments should familiarize themselves with all decontamination, cleaning, packaging, and sterilization instructions before conducting any of these procedures.

EXAMINE PRIOR TO USE

All instruments should be visually inspected for any signs of deterioration prior to conducting a surgical procedure. Physical signs of deterioration include pitting or corrosion of the metallic components and cracking, crazing, swelling, or excessive softening or brittleness of the polymeric external pieces. Any instruments that have physically or functionally deteriorated should be removed from service. The cleaning and sterilization processes may cause discoloration of the metallic components but should not affect the function of the instrument.

The following process is recommended:

Point of Use	Prompt, initial treatment to remove and/or prevent drying of soil and contaminants is recommended to facilitate subsequent cleaning steps after each use.
Pre-Clean	-Disassemble any instrumentation that requires disassembly per manufacturer's instructions -Rinse BalanceBot under flowing, warm (20-25 °C) water for a minimum of 2 minutes, using a soft-bristled nylon brush (such as an appropriately sized cannula brush), low-lint wipes, and/or gloved hands to aid in the removal of visible gross soil. - Manually extend the two bellows of the BalanceBot main body into the fully extended position to facilitate cleaning within the crevices (See pictured instructions below). Ensure bellows remain open for the remainder of the pre-cleaning and cleaning steps. -Clean all instruments before sterilization. -Prepare a neutral enzymatic cleaning solution sufficient to fully submerge the Spacer, and allow the submerged device to soak for a minimum of 1 minute -Scrub entire surface area of Spacer for a minimum of 2 minutes using a soft nylon instrument brush and low-lint wipes; give special attention to challenging areas using an appropriately sized channel brush. Scrub device below water line to prevent aerosolization of contaminants -Following scrub, inspect Spacer for visible soil residue. If visible soil residue is observed on the device, repeat operation until there is no visible soil residue. -Rinse in warm (38-49ºC) water for 1 minute. Thoroughly flush all lumens & other difficult to reach areas. Actuate while rinsing.
Cleaning (manual)	-Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent per manufacturer's instructions. -Rinse with final rinse water quality of reverse osmosis or distilled water, actuating any moving parts while rinsing for 1 minute. Repeat rinse twice. -Dry Spacer using compressed air and a dry lint-free cloth until the device exterior surfaces are visually dry;
Cleaning (automated)	Execute the cycle using a pH neutral enzymatic detergent according to the following parameters: Step 1: Pre-Wash: Minimum Temperature: Cold Tap Water Minimum cycle time: 2 minutes Step 2: Enzyme Wash: Minimum Temperature: Hot Tap Water Minimum cycle time: 4 minutes Step 3: Wash (Detergent % according to manufacturer specification): Minimum Temperature: 65.5 °C (149.9°F) Minimum cycle time: 2 minutes Step 4: Neutralization: Minimum Temperature: Hot Tap Water Minimum cycle time: 2 minutes Step 5: Rinse: Minimum Temperature: Hot Tap Water Minimum cycle time: 15 seconds Step 6: Thermal Rinse (A0 = 3000): Minimum Temperature: 82.2 °C (180.0°F) with Lubricant (% Lubricant according to manufacturer specification) Minimum cycle time: 1 minute Step 7: Hot Air Dry: Minimum Temperature: HIGH Minimum cycle time: 6 minutes
Inspection	-Inspect instruments for any damage or remaining contaminants. -Contact OMNI life science if instruments are damaged. -Repeat cleaning if contamination remains. - The instruments must be cleaned, disinfected, and dried prior to sterilization.
Sterilization Preparation	-Place instruments in the correct location in the instrument pan. - Ensure the BalanceBot bellows are in the fully extended position prior to placing the unit in the instrument pan - Do not stack pans for sterilization -Wrap the pan in a double layer of FDA cleared CSR wrap. OR -Place instruments into a SterilContainer

Sterilization	-Pre-vacuum cycle -Temperature: 132°C (270°F) to 137°C (279°F) -Exposure time: 4 minutes to 18 minutes -Dry time: 30 minutes **! Do not use the BalanceBot Motor Unit if the housing has not reached room temperature!**
Storage	-Store wrapped or in SterilContainer prior to immediate use. -Instruments must be stored in a clean, dry and temperate place. -Store instruments in the corresponding instrument system pans.

WARNINGS

a) This document is intended for anyone who has been trained by OMNI. It primarily concerns the user surgeon, the Operating Room staff and individuals performing cleaning and sterilization of the instruments.

b) The surgeon must take care not to exert inappropriate stress on the device and must comply with the operating procedure described in the surgical technique.

c) Prior to using the instrument system, the surgeon should give careful consideration to all aspects of the surgical intervention as well as the limitations of the implant and instruments.

d) Bone quality: Poor bone quality may not provide adequate fixation rigidity, causing the device to move and potentially damage critical structures such as bone, blood vessels or nerves, depending on the insertion site. Using a fixator of an inappropriate size or design may result in bone weakening or fracture. The risk is elevated in osteoporotic bone.

e) Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.

f) The BalanceBot Knee Instrumentation must only be used with the OMNIBotics Knee System and instruments must be placed in their proper locations as indicated on the tray.

g) Do not use the BalanceBot Motor Unit if the housing has not reached room temperature.

h) The BalanceBot has not been validated for use with flash sterilization methods. OMNI does not recommend the use of flash sterilization.

i) Improper use may result in breakage of the instrumentation during operation.

j) Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.

k) Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

l) Protective gloves and eyewear should be worn throughout the cleaning procedure to protect against splattered infectious materials and decontaminating and cleaning agents.

m) All instruments should be decontaminated immediately following use in a surgical procedure in accordance with the procedures described in this section to prevent tissue debris and bodily fluids from drying on the instruments.

n) Read the safety information provided by the manufacturer of the decontaminant bath before beginning the cleaning and procedure for instructions regarding the safe handling and use of these solutions.

o) Strong acids, solvents of ethylene dichloride, phenolic solutions, and aniline solvents are incompatible with the instruments and may cause damage.

p) Do not use metallic brushes or pads during the cleaning and sterilization procedures to avoid damaging the instruments.

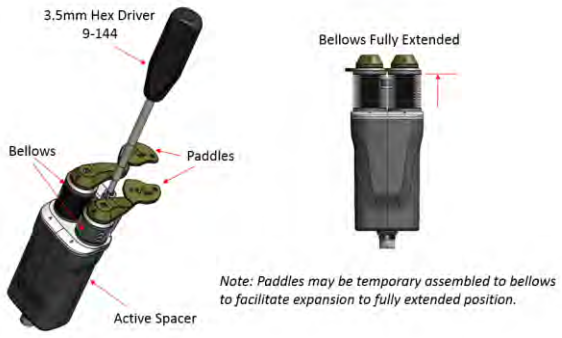
q) The maintenance of instrument sterility is the responsibility of the healthcare institutions.

r) If the instrument is dropped, bumped, or subjected to shock, a visual inspection must be performed. If there is any doubt as to the integrity of the instrument, the instrument must be sent back to OMNI. OMNI assumes no responsibility in the event of incorrect use of the instruments and accessories.

s) If there is any doubt in the integrity of any component the instrument must be sent back to OMNI.

Additional information may be obtained from OMNIlife science, Inc.

BALANCEBOT BELLOWS EXTENSION



LIFESPAN

Specific maintenance is compulsory for the OMNIBotics BalanceBot system. This maintenance must be carried out every 100 Sterilization cycles by a service engineer qualified by OMNI.

BalanceBot NS-52000 or NS-52900 Serial No.: _____			
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