OMNI ART™ AND OMNIBot™ SYSTEM 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
OMNI ART™ and OMNIBot Instrumentation is supplied for computer-assisted surgery with the OMNIBotics System and ART Application, specifically to prepare the affected joint for OMNI Apex Knee™ and Corin Unity™ System implants. Please refer to the OMNI ART Knee Application and OMNIBot Instructions For Use.

Material
OMNI ART and OMNIBot surgical instruments are manufactured from medical grade stainless steel, titanium 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 Corin Unity™ System. A Surgical Technique can be obtained from OMNI.

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) 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.
c) Soft tissue: percutaneous pin insertion may damage fatty, muscular or fascial tissue.
d) The OMNI ART and OMNIBot Instrumentation Pan must only be used with ART and OMNIBot Instrumentation and instruments must be placed in their proper locations as indicated on the trays.
e) These validated cleaning and sterilization instructions are only applicable to OMNI ART and OMNIBot™ trays that include devices manufactured and/or distributed by OMNI.
f) Read the Instructions for Use specific to the manufacturer's implants or procedure being performed for the list of required instruments.
g) Read the specific instructions for use delivered with the instruments and any components of the OMNIBotics or ART Application Instructions for Use.
h) Do not clean or disinfect the instruments within the Sterilization Tray as this may result in insufficient cleaning or disinfection.
i) Protective gloves and eyewear should be worn throughout the cleaning procedure to protect against splattered infectious materials and decontaminating and cleaning agents.
j) 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.
k) 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.
l) Strong acids, solvents of ethylene dichloride, phenolic solutions, and aniline solvents are incompatible with the instruments and may cause damage.
m) Do not use metallic brushes or pads during the cleaning and sterilization procedures to avoid damaging the instruments.
n) The maintenance of instrument sterility is the responsibility of the health care institutions.
o) 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.
p) Certain parts such as the cables, seals, and enclosure are fragile. They must be handled with care.
q) OMNI assumes no responsibility in the event of incorrect use of the instruments and accessories.
r) The parts on the enclosure and the cover must not be dismantled. If the central locking screw of the enclosure axes become dismantled, check the presence and integrity of the seal in the groove of the axes (oval shaped metallic part) before reassembling them prior to sterilization.
s) Check the presence and integrity of the clear O-ring seal on the edge of the cover before sterilization and use.
t) If there is any doubt in the integrity of any component the instrument must be sent back to 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.

The following process is recommended:

Pre-Clean	• Clean all instruments before sterilization. • Submerge instruments in enzymatic detergent & soak for 10 minutes. • Scrub submerged articles with a soft sponge & agitate. • Use a pipe cleaner or brush in any lumens and crevices. • Actuate any moving parts to loosen trapped contaminants. • Rinse in warm (38-49°C) water for 1 minute. Thoroughly flush all lumens & other difficult to reach areas. Actuate while rinsing. • Following the initial rinse of the OMNIBot enclosure top, the inside of the connector lumens is rinsed again with clean pressurized water from a sprayer, syringe or other pressurized clean water source for a minimum of 1 minute.
Cleaning (manual)	• Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent. • Rinse with clean water, actuating any moving parts while rinsing for 1 minute. Repeat rinse twice. • Dry instruments thoroughly with a clean, lint free cloth.
Cleaning	Execute the cycle using a pH neutral enzymatic

(automated)	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. • 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
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.

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.

Lifespan

The OMNIBOT® Enclosure Body (4144-7000 & NS-41000) and the OMNIBOT® Enclosure Cover (4144-4000 & NS-42000) are designed to resist 100 sterilization cycles. Once 100 sterilization cycles have been reached for these two parts they must be sent back to OMNI. The table on the other side of this page is provided to facilitate tracking of the number of uses of these components in your facility.

Specific maintenance is compulsory for OMNI systems. This maintenance must be carried out every 12 months by a service engineer qualified by OMNI.

	Date of Cycle (MM/DD/YY)	
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	Date of Cycle (MM/DD/YY)	
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