Loaner Program Guidance

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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EN

1. Purpose

This guidance is intended to assist a healthcare facility in developing procedures for the processing of DePuy Synthes Loaners Sets.

2. Scope

This guidance provides information on the following with respect to DePuy Synthes Loaner Sets:

- Pre-surgical handling
- Pre-surgical processing
- Reprocessing after surgical use.
- Healthcare Facility responsibilities

3. Important Information

Loaner sets are provided non-sterile. Loaner Sets are required to be fully cleaned, inspected and steam sterilized prior to surgical use in accordance with the healthcare facility established policies and procedures, and in accordance with DePuy Synthes instructions for use. Instructions for use are available upon request by contacting your local DePuy Synthes Sales Consultant.

Loaner sets provided to a healthcare facility may have been previously used in surgical procedures. While these guidelines are provided to assist healthcare facilities satisfy their respective obligations for use and subsequent transport of the sets the loaner sets must be inspected by the healthcare facility for damage and residual or environmental soils prior to sterilization, and on surgical preparation and use.

Following surgical use, loaner sets must be disassembled, cleaned, thermally disinfected and inspected in accordance with the healthcare facility established policies and procedures and with reference to the DePuy Synthes instructions for use. Documented evidence of decontamination should be provided or made available for inspection prior to shipping.

Please refer to the instructions for use for detailed instructions on disassembling, cleaning, disinfection, inspection and sterilization for each product.

Any Implant that has had direct patient contact should not be processed for reuse and should be discarded in accordance with local procedures.

DePuy Synthes must be notified immediately in writing if the Loaner Set has been used on a patient known or suspected to have a transmissible spongiform encephalopathy (TSE) such as Creutzfeldt-Jakob Disease (CJD). In these cases the loaner set may need to be disposed.

4. Terminology

Cleaning

Removal of contamination from an item to allow for appropriate further processing and subsequent use

Contaminated

Soiled with matter of biologic origin that potentially contains blood-borne pathogens.

Disinfection

Process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use

Instructions for use (IFU)

Information provided by the medical device manufacturer which includes the processing of a medical device that requires cleaning followed by disinfection and/or sterilization to ensure that the device is cleared and supported for its intended use (e.g., safe handling, transportation or invasive surgical use).

Loaner Set

Medical devices compiled and shipped together for use in a particular procedure that are shipped to a health care facility for use in surgical procedures but are not owned by the health care facility.

Processing

Physical and/or chemical means to render a surface or item safe for handling, use or disposal.

Sterilization

Validated process used to render a device free from viable microorganisms.

NOTE: **In a sterilization process, the nature of microbiological inactivation is described by an exponential function. Therefore, the presence of a viable microorganism on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.**

Washer/disinfector

A machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practice.

5. Drop-off locations and procedures

The healthcare facility shall designate the appropriate location for the DePuy Synthes representative to drop off Loaner Sets. The area should be designated for drop-off and verification of receipt at or associated with the device processing department of the facility where Personal Protective Equipment (PPE) is not required.

6. Device Processing and Instructions for Use (IFU)

Healthcare facilities are required to have established policies and procedures regarding the safe processing of reusable medical devices. These policies and procedures should be developed and periodically updated to be compliant with best practices and the most recent versions of standards and guidance published by ISO or other local organizations. Healthcare facilities should also follow the products written instructions for use (IFU) where appropriate during the processing of the loaner set.

7. Care and Handling of loaner sets on receipt and prior to surgical use

Loaner sets are provided non-sterile but have been cleaned and disinfected prior to shipping to the healthcare facility. On receipt, loaner sets should be checked to ensure the correct set is received, all devices are present and devices are not damaged. DePuy Synthes should be notified of any problems identified.

Loaner sets are required to be cleaned, thermal disinfected, inspected, packaged for sterilization and steam sterilized at the healthcare facility prior to surgical use. Please refer to product IFUs for detailed instructions on product processing.

Processing should be performed in a designated processing department in accordance with the healthcare facility established policies and procedures, with reference to the DePuy Synthes instructions for use. Automated equipment such as thermal washer-disinfectors and steam sterilizers should be in compliance with ISO requirements, maintained in accordance with manufacturer's instructions and in reference to best practices. Cleaning or other chemicals should be in labelled for use on medical devices and used in compliance with the manufacturer's instructions. Water quality can have a significant impact in the cleaning, disinfection and steam sterilization of devices, therefore processing facilities should consider best practices (such as those outlined in AAMI/ANSI TIR34 Water for the reprocessing of medical devices (2014) or other similar local requirements).

The loaner set shall be inspected for visual cleanliness and physical damage prior to preparation for sterilization. Guidance on inspection of cleanliness and damage provided in the section on **Care of loaner sets at the point of surgical use** can be utilized in the steps in preparation for surgery as well. Inspections may also include the use of residual soil detection methods such as protein, hemoglobin or ATP swab methods. Detection methods should not be used that require chemicals to be applied to a device, unless a method is provided for the removal of such chemicals to render the device for any subsequent processing and patient use (e.g., rinsing with a critical water source). Devices that fail cleanliness inspections should be subjected to additional cleaning in compliance with the processing department's policies and procedures.

Packaging materials and procedures, as well as the requirements for steam sterilization should be in compliance to the requirements of ISO (such as the most recent versions of ISO 11607-1 Packaging for terminally sterilized medical devices) and with reference to the loaner set instructions for use.

Sterile packaged loaner sets should be stored and transported to the point of surgical use in compliance to healthcare facility established policies and procedures, packaging materials manufacturers' instructions and local requirements. They should be protected from extremes of temperature, moisture, dust and other environmental risks.

8. Care of loaner sets at the point of and following surgical use

Loaner sets should be checked and verified to be ready for patient use in accordance with healthcare facility established policies and procedures. The healthcare facility processing department should be notified of any problems identified.

All loaner sets are considered biohazardous following surgical use, even if devices appear to be unused, and should be cleaned and thermally disinfected to render them safe for handling. Cleaning and disinfection is required to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the loaner sets are rendered safe for handling, including shipping.

Cleaning and disinfection must be performed in accordance with the healthcare facility established policies and procedures, with reference to the DePuy Synthes instructions for use (to include cleanliness, damage, function and any missing devices).

Loaner sets shall be transported in their designated sets/containers to a defined processing facility for decontamination in accordance with the healthcare facility established policies and procedures.

The loaner sets shall be cleaned, thermal disinfected and inspected in accordance with the healthcare facility established policies and procedures, with reference to the products' instructions for use prior to shipping.

At a minimum, the loaner set shall be inspected for visual cleanliness and physical damage. Close inspection is particularly important for devices with the following feature:

- Lumens and cannulas
- Parts that can be disassembled for inspection
- Device articulations
- Device or device-tray junctions
- Crevices

Devices that fail cleanliness inspections should be subjected to additional cleaning in compliance with the central service/sterile processing department's policies and procedures.

Physical damage or functional inspection tests include but are not limited to any evidence of:

- Breakage
- Distortion
- Wear
- Misalignment
- Surface defect, including wear, corrosion, chips, nicks, burrs, or loss of finish
- Worn or loose screws or other fastening mechanisms
- Chipped or missing teeth on serrations or points
- Clogged lumens or cannulations
- Cracks
- Defects on cutting edges, such as chips or roughness
- Damage to threads on screws and other threaded mechanisms
- Scoring
- Ratchet function
- Sharpness of cutting edges
- Smooth actuation of articulating mechanisms
- Smooth action of hinges and joints
- Staining
- Corrosion
- Legibility of identifying markings, such as product code numbers, color coding and/or descriptions

Any facility-specific labels must be removed from all tray levels prior to return.

DePuy Synthes should be notified of any missing or damaged devices on loaner set return.

Documented evidence of decontamination should be provided or made available for inspection prior to shipping.

The Loaner Set may be shipped directly to a designated DePuy Synthes site or made available for pickup by a representative of DePuy Synthes in an area of the healthcare facility where Personal Protective Equipment is not required.

9. Healthcare facility responsibilities for DePuy Synthes Loaner Sets

- Loaner Sets must be fully cleaned, disinfected, inspected, and terminally sterilized upon receipt and prior to use in a surgical procedure.
- After a surgical procedure, Loaner sets must be fully cleaned, disinfected, and inspected in a manner that renders the devices safe for handling. The Loaner Sets will be made available in designated areas of the facility where Personal Protective Equipment is not required by hospital policy.
- Notify your DePuy Synthes representative of any difficulties with the Loaner Set including missing, damaged, non-functional or soiled devices.
- The Instructions for use for the products have been validated by DePuy Synthes to adequately prepare the loaner sets for surgical use. It is the responsibility of the healthcare facility to ensure that the processing steps used at the facility are adequate and that facility employees are appropriately trained. All equipment should be compliant to and routinely monitored for effectiveness consistent with ISO or other local standards and guidelines.

10. DePuy Synthes Contact information

For all inquiries regarding loaner programs or DePuy Synthes products contact your local DePuy Synthes Sales Consultant or visit www.DePuySynthes.com.

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