Loaner Programme Guidance

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Table of Contents

GB

1. Purpose

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

2. Scope

This guidance provides information on the following topics in respect of DePuy Synthes Loaner Sets:

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

3. Important Information

Loaner sets are supplied non-sterile. Loaner Sets are required to be fully cleaned, inspected and steam sterilised before surgical use, in accordance with policies and procedures established by the healthcare facility and with DePuy Synthes instructions for use. Instructions for use are available on request: contact your local DePuy Synthes Sales Consultant.

Loaner sets supplied to a healthcare facility may have previously been used in surgical procedures. While these guidelines are provided to help healthcare facilities fulfil their respective obligations for the use and subsequent transport of the sets, the loaner sets must be inspected by the healthcare facility for damage and residual or environmental soiling before sterilisation, and on surgical preparation and use.

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

Please refer to the instructions for use for detailed instructions on disassembling, cleaning, disinfection, inspection and sterilisation 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 form of transmissible spongiform encephalopathy (TSE), such as Creutzfeldt-Jakob Disease (CJD). In these cases the loaner set may need to be disposed of.

4. Terminology

Cleaning

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

Contaminated

Soiled with matter of biological 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 manufacturer of the medical device, including processing of a medical device that requires cleaning followed by disinfection and/or sterilisation 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 assembled and dispatched together for use in a particular procedure; these devices are sent to a healthcare facility for use in surgical procedures but are not owned by the facility.

Processing

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

Sterilisation

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

NOTE: **In a sterilisation 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 with regard to the safe processing of reusable medical devices. These policies and procedures should be developed and periodically updated to comply with best practices and the most recent versions of standards and guidance published by ISO or other local organisations. Healthcare facilities should also follow the product's written instructions for use (IFU) where appropriate during the processing of the loaner set.

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

Loaner sets are supplied non-sterile but have been cleaned and disinfected before dispatch 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, thermally disinfected, inspected, packaged for sterilisation, and steam sterilised at the healthcare facility before 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 policies and procedures established by the healthcare facility and with DePuy Synthes instructions for use. Automated equipment, such as thermal washer-disinfectors and steam sterilisers, should comply with ISO requirements, and be maintained in accordance with the manufacturer's instructions and with best practices. Cleaning or other chemicals should be labelled for use on medical devices and used in compliance with the manufacturer's instructions. Water quality can have a significant impact on cleaning, disinfection and steam sterilisation of devices. Hence, 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 before preparation for sterilisation. Guidance on inspection for cleanliness and damage provided in the section on **Care of loaner sets at the point of surgical use** can be used during the preparation phases for surgery as well. Inspections may also include the use of methods for detecting residual contamination, such as protein, haemoglobin 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 prepare 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 requirements for steam sterilisation, should comply with ISO standards (such as the most recent versions of ISO 11607-1 Packaging for terminally sterilised medical devices) and with the loaner set's instructions for use.

Sterile packaged loaner sets should be stored and transported to the point of surgical use in compliance with policies and procedures established by the healthcare facility, and with manufacturers' instructions and local requirements regarding packaging materials. They should be protected from extreme temperatures, 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 policies and procedures established by the healthcare facility. The healthcare facility's 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 dispatch.

Cleaning and disinfection must be performed in accordance with policies and procedures established by the healthcare facility and with 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 policies and procedures established by the healthcare facility.

The loaner sets shall be cleaned, thermally disinfected and inspected before dispatch, in accordance with policies and procedures established by the healthcare facility and with the product's instructions for use.

The minimum procedure required is for the loaner set to be inspected for visual cleanliness and physical damage. Close inspection is particularly important for devices presenting the following features:

- 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 cannulas
- 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 identification markings, such as product code numbers, colour coding and/or descriptions

Any facility-specific labels must be removed from all tray levels before they are returned.

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 before dispatch.

The Loaner Set may be sent 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 sterilised on receipt and before 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 comply with and be routinely monitored for effectiveness consistent with ISO or other local standards and guidelines.

10. DePuy Synthes Contact information

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

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