Biocomposites®

SYNICEM
HIP SPACER TRIALS

DIRECTIONS FOR USE, INDICATIONS, WARNINGS, PRECAUTIONS
AND ADVERSE REACTIONS.

INTRODUCTION:

This document 'Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of products', includes information about:

- The reprocessing (cleaning, disinfection and sterilisation) of products from Biocomposites
- The inspection and maintenance of the instruments
- The identifying features relating to wear/tear and loss of usability
- The reprocessing of the products (cleaning, disinfection and sterilisation) which is described in this document was tested and validated by Biocomposites.
- In the following text, the term 'Trial Spacers Set' refers to trials and trays/Case.

DESCRIPTION:

These trial spacers are reusable devices /accessories for momentary use. They permit to select the correct definitive spacer without having to manipulate it. They are made of stainless steel and their size and shape reproduce those of the corresponding definitive spacers. They are supplied non-sterile, inside a multiperforated tray/case suitable for their sterilization.

INTENDED USE:

The Hip Trial Spacer Set allows for the selection of the correct spacer to avoid manipulation prior to implantation during a two-step revision hip arthroplasty. They reproduce the shape and size of the corresponding spacers.

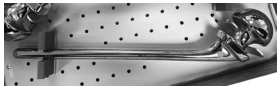
TRIAL SPACER LOCATION IN THE CASE

The location where the trial spacers should be placed on the tray inside the box is shown below.

CONTENT:

DESCRIPTION	PART NUMBER	UDI-DI
Synicem Hip Spacer Trial Tray Regular	882022	15060155712106
Synicem 40C Hip Trial	885410	15060155712243
Synicem 48C Hip Trial	885411	15060155712250
Synicem 48M Hip Trial	885412	15060155712267
Synicem 56C Hip Trial	885413	15060155712274
Synicem 56M Hip Trial	885414	15060155712281

DESCRIPTION	PART NUMBER	UDI-DI
Synicem Hip Spacer Trial Tray XL	882023	15060155712113
Synicem Hip 40CXL	885415	15060155712298
Synicem Hip 48CXL	885416	15060155712304
Synicem Hip 56CXL	885417	15060155712311

	LOCATION OF THE DIFFERENT MEASUREMENTS WITHIN THE TRAY.	LOCATION OF TRIALS COMPONENTS.
Hip		
Hip XL		

WARNINGS AND PRECAUTIONS:

- The instructions provided are given as a guide for processing the Trial Spacer Set and have been validated by the manufacturer. It is the responsibility of the healthcare institution to ensure that the processing is performed using the equipment, materials, and competent personnel at a designated processing area. This will include the handling of devices during transportation, processing, and storage prior to use.
- Those using these instructions should be qualified with documented expertise, competence, and training in accordance with procedures, guidelines, and local standards.
- Before, during, and after the processing Trial Spacers Set, the person must

comply with personal hygiene and safety regulations, as well as make use of the appropriate protective elements and equipment.

- Used Trial Spacers is considered a biohazard, so healthcare institutions must ensure that transport and handling procedures comply with regulations and local guidelines.
- Trial Spacers Set must be cleaned, inspected and sterilized before clinical use.
- Trial Spacers Set should be carefully inspected before each use to ensure that they are functional. During the inspection process, when there is evidence of changes in the mechanical, physical, or chemical characteristics of the device, do not use it; as repeated conditions of use, cleaning, and re-sterilization may compromise the integrity of the design or material and reduce safety, efficacy or compliance with relevant specifications.
- The cleaning agent must be intended for manual cleaning and ultrasonic cleaning and must not differ from the concentration and temperature specified by the cleaning agent manufacturer. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials.
- The manufacturer used in its validation activities an FDA-approved enzyme active detergent with a maximum pH of 9.
- Never use metal brushes or steel wool for cleaning.
- Trial Spacer must be cleaned separately from the tray / case for proper cleaning results. The tray / case was designed as an organizational tool in preparation for sterilization, storage and surgical use. It is not designed for cleaning in their fully assembled state.

LIMITATION OF PROCESSING:

Trial Spacers Set does not have an indefinite functional life. Repeated processing cycles in compliance with these instructions have minimum effects on device life and function. End of Life is determined by wear and damage due to surgical use and handling. Evidence of damage and wear on the device may include but is not limited to corrosion, discoloration, deformation, excessive scratches, cracks, and wear.

TRIAL SPACERS CLEANING INFORMATION

PROCESSING STEPS:

STEP 1: POINT OF USE CARE

After use (within a maximum of 2 hours postoperatively) remove excess soil with a damp, lint-free cloth.

STEP 2: CONTAINMENT AND TRANSPORTATION

Transport the Trial Spacer inside the multi-perforated tray provided for this purpose, to the point where cleaning will be performed. If transport to the processing area is

likely to be delayed, keep the Trial Spacer moist at all times to avoid drying of soil.

STEP 3: CLEANING

Preparation before cleaning

Remove visible soil by rinsing with utility water* for 5 to 10 minutes. Intensive rinsing of the Trial Spacer is recommended.

*NOTE: AAMI TIR 34.

Manual Cleaning

Prepare a cleaning solution at the concentration and temperature specified by the enzymatic detergent manufacturer using utility water*.
Completely immerse the trial spacer in the prepared solution.
Clean the Trial Spacer by brushing with a soft bristle brush for 2 to 5 minutes with utility water*.
Rinse the Trial Spacer with critical water* for 1 minute and dry with a lint-free cloth.
If, after completing the manual cleaning step, visual inspection reveals the presence of any remaining soil on the device, repeat the cleaning steps described above.

*NOTE: AAMI TIR 34.

Mechanical Cleaning with Ultrasound:

- Prepare a validated ultrasonic bath (equipment with a frequency greater than or equal to 38 KHz is recommended), with a cleaning solution to the concentration and temperature specified by the enzymatic detergent manufacturer and with utility water*.
- Immerse the Trial Spacer in the ultrasound equipment.
- Clean the Trial Spacer for an estimated time of 5 to 10 minutes.
- Rinse the Trial Spacer with critical water* for 1 minute and dry with a lint-free cloth.
- If, after completing the ultrasonic cleaning step, visual inspection reveals the presence of any remaining soil on the device, repeat the cleaning steps described above.

*NOTE: AAMI TIR 34.

STEP 4: INSPECTION

- Before preparing Trial Spacer for sterilization, it is necessary to inspect them in their entirety for cleanliness and integrity.
- In general, a visual inspection without magnification under good lighting conditions is sufficient.
- All Trial Spacer Sets must be inspected for soil, corrosion (rust, pitting), color alteration, deformation, excessive scratching, cracks and wear.

STEP 5: PACKAGING

- Place the clean and dry products in their proper place within the tray inside their clean multi-perforated case for safekeeping.
- Wrap the case with two layers of wrapping material individually, using the envelope folding, sequential wrapping technique.

NOTE: WRAPS MUST COMPLY WITH A STERILE BARRIER SYSTEM CONFORMING TO ANSI/AAMI ST79 AND BE FDA APPROVED.

STEP 6: STERILIZATION

Nonsterile Trial spacers must be sterilized prior to use, according to the following recommended sterilization parameters. Steam autoclave (moist heat) sterilization using a pre-vacuum cycle (forced air removal) is recommended.

STEAM STERILIZATION CYCLE:

EXPOSURE TIME*	TEMPERATURE	MINIMUM DRYING TIME**
4 minutes	132°C	30 minutes

*EXPOSURE TIME: PERIOD FOR WHICH THE LOAD AND ENTIRE CHAMBER IS MAINTAINED AT THE STERILIZATION TEMPERATURE.

**MINIMUM DRYING TIME: MINIMUM PERIOD DURING WHICH STEAM IS REMOVED FROM THE CHAMBER AND THE CHAMBER PRESSURE IS REDUCED TO PERMIT THE EVAPORATION OF CONDENSATE FROM THE LOAD EITHER BY PROLONGED EVACUATION OR BY THE INJECTION AND EXTRACTION OF HOT AIR OR OTHER GASES. THE DRYING TIME VARIES DUE TO LOAD CONFIGURATION, WRAPPING METHOD AND MATERIAL.

ONCE USED, THE TRIAL SPACERS MUST BE CLEANED AND STERILIZED PRIOR TO SUBSEQUENT USE.

STEP 7: STORAGE

Sterilized products must be kept in a controlled environment i.e. dry and clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

After sterilization, the reusable Trial Spacer Set must be stored in sterilization wraps in a dry, dust-free place. The storage time will depend on the validated sterility assurance process i.e. sterile barrier used, the form of storage, environmental conditions, and handling.

REFERENCES

THE LATEST EDITION OF THE FOLLOWING STANDARDS IS REFERENCED IN THIS DOCUMENT:

- AAMI TIR34: WATER FOR THE REPROCESSING OF MEDICAL DEVICES.
- ANSI/AAMI ST79: COMPREHENSIVE GUIDE TO STEAM STERILIZATION AND STERILITY ASSURANCE IN HEALTH CARE FACILITIES.
- ANSI/AAMI ST98: CLEANING VALIDATION OF HEALTH CARE PRODUCTS-REQUIREMENTS FOR DEVELOPMENT AND VALIDATION OF A CLEANING PROCESS FOR MEDICAL DEVICES.
- ASTM-F3321: METHODS OF EXTRACTION OF TEST SOILS FOR THE VALIDATION OF CLEANING METHODS FOR REUSABLE MEDICAL DEVICES.
- EN 285=2015 A1=2021: STERILIZATION STEAM STERILIZERS - LARGE STERILIZERS.
- ISO 17664-1: PROCESSING OF HEALTH CARE PRODUCTS - INFORMATION TO BE PROVIDED BY THE MEDICAL DEVICE MANUFACTURER FOR THE PROCESSING OF MEDICAL DEVICES - PART 1: CRITICAL AND SEMI CRITICAL MEDICAL DEVICES.
- ISO 17665-1: STERILIZATION OF HEALTH CARE PRODUCTS- MOIST HEAT- PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.
- FOOD AND DRUG ADMINISTRATION, 2015 "REPROCESSING MEDICAL DEVICES IN HEALTH CARE SETTINGS: VALIDATION METHODS AND LABELING"

SYMBOLS

REF CATALOGUE NUMBER*	CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE*	
UDI UNIQUE DEVICE IDENTIFIER (UDI)*	LOT BATCH CODE*	MANUFACTURER*
# MODEL NUMBER*	MD MEDICAL DEVICE*	

℞only FEDERAL LAW RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION, AND USE BY OR ON THE ORDER OF A PHYSICIAN

THE LATEST EDITION OF THE FOLLOWING STANDARDS IS REFERENCED IN THIS DOCUMENT:
* ISO 15223-1: MEDICAL DEVICES — SYMBOLS TO BE USED WITH INFORMATION TO BE SUPPLIED BY THE MANUFACTURER — PART 1: GENERAL REQUIREMENTS

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