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IMPORTANT INFORMATION FOR INSTRUEMNTS AND CONTAINERS (TOOLS) FROM SYNTROPIQ

The Syntropiq containers are intended to store instruments. Instruments are intended to facilitate implantation of Syntropiq Dynam'X System

DESCRIPTION:

Instruments are designed and manufactured to facilitate insert of implants from Dynam'X System. Only Implants from Dynam'X System shall exclusively be implanted using instruments from Dynam'X System. Any application of any components from Dynam'X System together with any other systems or other manufactures releases Syntropiq for any liabilities. In general Instruments consist of three areas:

1. Working area (can be cutting part, holding part, adjusting part) which interacts with implants of patient anatomy.
2. Gripping area (can be silicone surface, mallet surface, blasted or shaped surface) which allow surgeon to grip and hold instrument
3. Connecting area (can be tube, rod or others) which connects working area with gripping area.

Instruments are mainly made in stainless steel except gripping area which can be cover by silicone. Design and production process should allow surgeons easy and safe implant insertion or space preparation for implant.

MATERIALS:

The tools are made out of medical grade stainless steel or aluminum, some part are made from plastic or silicone. Syntropiq sorely warrants that all devices are manufacture from one of the foregoing material specifications. No other warranties, express or implied, are made.

SHIPPING PACKAGING:

Syntropiq tools is delivered as no sterile.

VALIDATED REPROCESING PROCEDURE

CLEANING:

After use (within a maximum of 2 hours post-operatively) remove gross soil using absorbent paper wipes. Intensive rinsing of the reusable instruments with fluent water or transfer of the medical devices into a bath with an aldehyde-free disinfectant solution is highly recommended. During transportation avoid mechanical damage by ensuring that heavy devices do not get mixed with delicate ones. Pay particular attention to cutting edges, both to avoid personal injury and prevent damage to the reusable instruments. Transport the reusable instruments to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the instruments with a damp cloth to avoid drying of soil.

Totally immerse instruments during the cleaning process in order to prevent aerosolization. Use appropriate-sized, soft nylon brushes - Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Ensure that all surfaces are thoroughly wetted. Use a syringe or pipette to ensure that the cleaning solution reaches all parts of cannulations. Operate articulating devices and those with moving parts. To avoid coagulation of mucus, blood or other body fluids, do not soak instruments in hot water, alcohol, disinfectants or antiseptics. Soak for minimum recommended time by the detergent manufacturer's instructions. Do not exceed two hours soaking in ANY solution. Rinse in running water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the steps above if necessary. Allow to drain on absorbent paper or transfer immediately to cleaning step.

For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level, concentration, and temperature. When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap. Rinse instruments thoroughly with tap water, deionized water or distilled water. Thoroughly rinse all internal lumens, stopcocks and ratchets.

AUTOMATIC CLEANING:

1. Use a soft non-metallic bristle brush (plastic bristles, like nylon) or sponge to thoroughly scrub all traces of blood and debris from all device surfaces for at least one minute.

2. Ensure all channels are thoroughly brushed. Push the brush through the entire length of the channels using a twisting motion to remove debris from both ends for at least one minute.

3. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Ensure all channels are flushed for at least one minute.

4. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and channels can drain freely.

5. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 or to an equivalent standard. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions.

An example of a validated cycle used for cleaning validation included:

Phase	**Recirculation Time (minutes)**	**Water Temp**	**Detergent/Water Type**
Pre-washing in an ultrasonic washing machine	10	< 25°C	0.5% Aniosyme DD1 solution
Proper washing in the washer-disinfector	10	< 55°C	MediClean Forte cleaner/water RO
Thermal disinfection in the washer-disinfector	10	< 90°C	MediKlar washing rinsing/water RO
Drying	20	N/A	N/A

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

DISINFECTION

⚠ **Warning**: **The decontamination process does not sterilize instruments. Refer to and process as outlined in the *STERILISATION* section.**

Select a proper product for high-level disinfection (examples include the glutaraldehyde-family of disinfectant products). Follow the cleaning agent's recommended directions regarding the proper concentration, temperature, contact time and solution re-use. Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection, such as bleach, bi-chloride of mercury. Completely immerse instruments in disinfecting solution - force solution into all areas and cavities.

Prepare a bath with disinfection solution at the concentration and temperature specified in the detergent manufacturer's instructions. Immerse the device completely for at least the time specified in the detergent manufacturer's instructions. Rinse cannulations at least three times with a syringe. Rinse for at least 1 min in running water of the specified quality until all traces of disinfectant solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts, using a syringe, if needed. Dry the reusable instrument using filtered, compressed air or clean, lint-free wipes. If additional drying is required, arrange instruments in a clean area or heat in an oven below 110°C. Visually inspect and repeat complete manual cleaning and disinfection if required.

INSPECTION

Before preparing for sterilization, all reusable instruments should be inspected. Generally un-magnified visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:
• Soil "traps" such as mating surfaces, hinges, shafts, rotating gears, and lumens;
• Recessed features (Holes, Textured surfaces, and cannulations);
• Features where soil may be impacted into the device, such as drill flutes adjacent to the cutting tip and sides of teeth on broaches and rasps;
• Cutting edges should be checked for sharpness and damage.
Mating devices should be checked for proper assembly. Instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required). Rotating instruments, such as multiple use drill bits, and reamers, should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface. "Flexible" instruments should be checked for damage to the spiral element.

⚠ **Warning**: Syntropiq does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on many factors, including the method and duration of each use and the handling between uses. For devices that are impacted during the surgical procedure, check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

PACKAGING FOR STERILIZATION:

For Blue Wrap

Syntropiq case/tray configurations should be double wrapped according to individual Hospital's Central Sterilization Room technique. The packaging for terminally sterilized reusable instruments should be suitable for steam sterilization and the appropriate grade for the weight of the instruments. Additionally, the blue wrap should be compliant to the following requirements:

• AAMI ST79
• ISO 11607
• CE mark
• FDA 510(k) clearance for specified sterilization parameters

STERILISATION:

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Only sterile products should be placed in the operative field.

Remove all packaging materials prior to sterilization. Products delivered as unsterile are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	EXPOSURE TIME
STEAM PRE-VACUM 132 °C	4 MINUTES
STEAM GRAVITY 121°C	40 MINUTES
STEAM GRAVITY 134°C	30 MINUTES
EtO 52°C - 54°C	Pre-vac: 25in.Hg-635mmHg (min) Humidity: 40-60% RH Gas Concentration: 600mg/L (min) EO gas mixture may vary (i.e., 10/90% HCFC by weight or 100%) Exposure Time: 120 minutes Post-vac: 20in.Hg-508mmHg (min) Aeration: 8 hours (min)

Syntropiq has validated the above sterilization cycles and has records in file. The validation has been performed in Syntropiq containers for sterilization and storage of its products.

Other sterilization cycles may be also suitable, as long as hospital or any other medical center is using validated technique for the sterilization of the reusable orthopedics instruments.

STORAGE

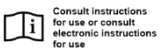
The components of Dynam'X Spinal System should be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions, and handling. A maximum shelf life for sterilized reusable instruments should be defined by each health care facility based on the recommendations of the wrap or container manufacturer.

WARRANTY AND PRODUCT COMPLAINTS:

Every spinal product from Syntropiq is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any implant or instrument delivered from Syntropiq proving to be defective will be replaced or repaired, at Syntropiq discretion, with no any charge.

Any customer or user, who has any complaint or who has experienced any dissatisfaction in the product quality, durability, safety, reliability should inform Syntropiq or its Distributor. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the description of the complaint. Please provide the report directly to Syntropiq or to its Distributor.

SYMBOLS USED



CUSTOMER SERVICE

Additional information about the Dynam'X System or any other Spinal Systems is available from Syntropiq. You may also want to contact your local Syntropiq Sales Representative.

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