



Only valid if attached to label or product



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EN

ENGLISH

Intended Purpose

Incipio Devices instrumentation consists of reusable medical devices and their accessories intended for use in orthopedic surgical procedures. Incipio Devices instruments should only be used by qualified personnel, fully trained in the handling and use of surgical devices and the relevant surgical procedures.

General Safety Notes

- Additional information related to use, assembly and disassembly of Incipio Devices' surgical instrumentation, as well as additional language translations of these Instructions for Use are available on the website (www.incipiodevices.com).
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation.
- It is the duty of the user to ensure that the reprocessing procedures are followed; that resources and materials are available to capable personnel; and that hospital protocols and policies are followed.
- Users should always wear appropriate personal protective equipment when processing devices.
- Incipio Devices' instrument trays are not intended to maintain the sterility of their contents. Appropriate packaging must be used by health care personnel to ensure the sterility of the tray and its contents.
- Any serious incident or malfunction of Incipio Devices surgical instruments that results or could potentially result in serious injury to the patient and/or users must be reported to Incipio Devices and to the national regulatory body of the country in which the user is established, in accordance with applicable regulations.

Warnings

- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instruments and to take into account the risk of infection if a cut appears.
- Incipio Devices instruments are provided non-sterile and must be cleaned and sterilized prior to each use.
- In the event of suspected prion contamination, safely discard the instrument in accordance with applicable laws and regulations. Do not reuse.
- Instruments are provided in a single package, in an envelope or blister. Product identification is given on external label. Do not use if the packaging is damaged.
- Remove all instruments from their packaging prior to cleaning and sterilisation. Any protective caps or foils must also be removed.
- The instruments must not enter in contact with fluoride or chloride-based products nor with fat-based detergents. Instruments which have synthetic (plastic) components must not be in contact with strong acid solutions (pH <4), alkalis, organic or ammonia-based solvents as well as oxidizing chemicals or any other agent which could adversely alter the material.
- Mixing of instruments or components from different manufacturers is not recommended and may cause issues with compatibility, function or performance. Incipio Devices disclaims any liability in case of incompatible instruments or components from different sources being used.

Point of Use Care

- Wipe blood and debris from device throughout surgical procedure to prevent it from drying onto the surface. Flush cannulated instruments once with sterile water to prevent the drying of soil and/or debris to the inside.
- The instruments require pre-cleaning directly after usage (within 2 hours, in order to prevent drying).

Basics of Cleaning and Disinfection

- If possible, the automated cleaning and disinfection procedure should be used for cleaning and disinfection of the instruments. The manual procedure, even in case of application of an ultrasonic bath, should only be used if the automated procedure is not available.
- The decontamination/pre-cleaning steps are to be performed in both cases.

Preparation for Decontamination/Pre-cleaning

- Disassemble instruments with removable parts or open instruments completely prior to cleaning, disinfection, and sterilization. Refer to specific disassembling instructions provided with the instruments when needed.
- All the instruments require manual processing prior to cleaning and disinfection, directly after usage (within 2 hours, in order to prevent drying). Pay special attention to lumens/cannulae of instruments.
- Soak and/or rinse the instruments prior to cleaning to loosen any visible soil or debris. Use a freshly prepared enzymatic cleaning detergent (pH ≤8.5) to soak the instruments. Follow detergent manufacturer's instructions for use regarding concentration, temperature, and soaking time. Assist cleaning by brushing with a soft bristle brush. Do not use steel wool or abrasive cleaners.
- Use cold tap water (<40°C/104°F) for a minimum of 1 minute to rinse the instruments.

Automated Cleaning and Disinfection using a Washer/Disinfector

- Decontamination/pre-cleaning steps shall be followed prior to the automated method listed below.
- Place the disassembled instruments in the Washer/Disinfector in such a way they are not entering in contact with each other.
- Ensure that all the design features of the devices are accessible to cleaning, all the hinges are open and all the cannulations and holes can drain.
- Start the standard instrument washer/disinfector cycle with the following minimal parameters:

Cycle	Exposure Time	Temperature	Detergent
Prewash	2 minutes	Cold tap water (<40°C/104°F)	N/A
Wash	5 minutes	>60°C (140°F)	Neutral pH enzymatic detergent
Neutralization	2 minutes	Cold tap water (<40°C/104°F)	N/A
Rinse	1 minute	Cold tap water (<40°C/104°F)	N/A
Thermal disinfection	5 minutes	>90°C (194°F)	N/A
Drying	7-30 minutes	Hot air 100-120°C (212-248°F)	N/A

- Check instruments for visible soil. Repeat cleaning if soil is visible.
- Follow detergent manufacturer's instructions for use regarding concentration, temperature, and soaking time.
- The washer/disinfector manufacturer's operating instructions and recommended guidelines shall be followed. Use only washer/disinfectors that have been approved according to ISO 15883. The washer/disinfector must be properly installed, maintained and calibrated.

Manual Cleaning and Disinfection

- Rinse the pre-cleaned instruments intensively under running cold tap water (<40°C/104°F) for a minimum of 2 minutes by application of jet pistol.
- Submerge the instruments in a freshly prepared enzymatic cleaning detergent (pH ≤8.5) solution. Follow detergent manufacturer's instructions regarding concentration, temperature, and soaking time as well as post-rinsing. Pay attention on complete soaking of lumens by swaying. Use soft bristle brush to assist cleaning (complete brushing of all inner and outer surfaces). For cleaning the cannulation of cannulated instruments, the nylon brush has to be moved in a rotating way through the cannulation. Do not use steel wool or abrasive cleaners. Activate joints, handles and other moveable device features to expose all areas to the detergent solution.
- In case of taps or other instruments with deep grooves or complex geometries, assist cleaning by ultrasonic treatment at a frequency of 35 kHz for the same time again, as used for initial soaking.
- Remove the instruments of the cleaning solution and rinse the instruments thoroughly with deionised or purified water at least three times for a minimum of 1 minute. Pay attention on complete soaking and swaying of lumens, cannulae or other hard to reach areas. Activate joints, handles and other moveable device features in order to rinse thoroughly.
- Submerge the instruments in a freshly prepared enzymatic disinfectant solution. Follow detergent manufacturer's instructions regarding concentration, temperature, and soaking time as well as post-rinsing. Pay attention to completely soak lumens by swaying. Activate joints, handles and other moveable device features to expose all areas to the disinfectant solution.
- Remove the instruments of the disinfectant solution and rinse the instruments thoroughly with deionised or purified water at least five times for a minimum of 1 minute. Pay attention on complete soaking and swaying of lumens, cannulae or other hard to reach areas. Activate joints, handles and other moveable device features in order to rinse thoroughly.
- Visually inspect the instruments and repeat the cleaning process if needed until no visible soil remains on the instruments. Recesses and hidden areas should be carefully inspected to ensure that entrapped or other residual materials are completely removed.
- Dry the instruments using a fresh, clean, soft, lint-free cloth. To avoid water residues, insufflate cavities of instruments by using clean, oil and particle free compressed air.

Inspection

- Incipio Devices instruments should be inspected after processing, prior to sterilization.
- Carefully inspect each instrument to ensure that all visible blood and soil has been removed.
- Visually inspect instruments for damage, wear and/or rust. If damage, wear and/or rust that may compromise the function of the instrument are noted, do not use the instrument and notify the appropriate person.
- Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Instruments with welded joints that are subject to mechanical stress or vibrations during use may weaken over time. Care should be taken to thoroughly inspect welded joints for fractures prior to use.
- Cutting instruments may lose efficiency with repeated use. Care should be taken to inspect cutting edges for damage (nicks, fracture, corrosion) or visible signs of wear. Dull cutting edges require greater amount of force to achieve a desired cut and may cause patient injury.
- Instruments and devices incorporating polymer components should be inspected for extensive surface damage (e.g. cracks, delamination, crazing), distortion or warping.
- Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

Maintenance

- Repeated reprocessing that includes decontamination, cleaning and sterilization has minimal effects on instruments. Product lifetime is determined by wear and damage due to use. Frequently used instruments have to be replaced regularly.
- Torque limiting devices, torque wrenches or similar instruments may require specific inspection for accuracy and/or recalibration. Refer to the instructions indicated in the surgical technique or from the distributor.
- Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant to reduce friction and wear. Follow lubricant manufacturer's instructions. Instrument oils or grease shall not be used.

Packaging

- The cleaned and disinfected instruments must be packaged in its still disassembled state.
- When packaging individual instruments, use medical grade single-use steam sterilization pouches of appropriate size to double pack single instruments.
- When packaging the instruments in instrument trays with lid, use medical grade steam sterilization wrap using the double wrap method. Instrument trays with lid may also be placed in an approved sterilization container with a gasket lid for sterilization.
- Packaging and wrap shall be conforming to EN ISO 11607, as well as suitable for steam sterilization (temperature resistance up to at least 138°C (280°F), with sufficient steam permeability).

Sterilization

- Incipio Devices instruments are intended to be sterilized by the steam autoclaving procedure (pre-vacuum - at least three vacuum cycles/fractionated vacuum procedure) regularly used in the hospital (according to EN 285/EN 13060, validated according to EN ISO 17665-1).

Cycle	Exposure Time	Temperature
Pre-vacuum	4 to 18 minutes	132/134°C (270/273°F)

- ETO sterilisation, cold sterilisation and flash sterilization techniques must not be used. Incipio Devices disclaims any liability for any problem further to the use of these sterilisation methods.
- The current recommended dry times for Incipio Devices cases can range from a standard 20 minutes to an extended 60 minutes. Dry times may be highly variable due to difference in sterile barrier system and weight of complete load. The user should employ verifiable methods (e.g. visual inspection) to confirm adequate drying.
- Make sure that the sterilization indicator inside the basket confirms that the content has been sterilized.
- Do not use the instruments if still hot. Let the instruments cool down to room temperature before starting the surgery.
- The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained and calibrated. Only approved sterilization equipments and wrap/pouches should be used by the end-user. It is the sole responsibility of the end-user to ensure the clean and sterile conditions of the instruments. The statutory requirements and hygienic provisions of each country must be absolutely observed.

Storage and Handling

- Surgical instruments are sensitive to damage. Even small surface scratches can increase wear and the risk of corrosion. Instruments should be handled with care at all times.
- Storage zones for surgical instruments should be away from areas of humidity to avoid excessive corrosion. This recommendation is equally valid for the transport and packaging of surgical instruments.
- Store sterilized instruments in a dry, clean and dust free environment at temperatures between 5°C to 40°C (41°F to 104°F).

Disposal

Worn and damaged instruments should be thoroughly cleaned and disinfected prior to disposal in accordance with the operating procedures of the healthcare facility and in conformance with local regulations.

Important statement

It is strictly prohibited to carry out any modification whatsoever on Incipio Devices instrument. Only Incipio Devices has the competence to carry out such work. If this recommendation is not followed, Incipio Devices disclaims any liability for any subsequent consequences.

Symbols

	Catalogue number		Non-sterile
	Lot number		Authorized representative
	Keep dry		Caution
	Manufacturer		Consult instruction for use
	Date of manufacture		For use only by a licensed physician