Packaging Insert

IMPORTANT INFORMATION

Reprocessing of Surgical Instruments

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CE 2797 UKCA 0086

Only valid if attached to label or product

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NON STERILE

EN ***ENGLISH***

General
Incipio Devices instrumentation consists of reusable surgical instruments and their accessories intended for use in orthopedic surgical procedures. The reusable instruments and accessories are delivered non-sterile and must be cleaned and sterilized before each use following the processes indicated in this document. Incipio Devices' instruments are intended for use by qualified health care personnel, fully trained in the handling and use of surgical devices and the relevant surgical procedures.

Incipio Devices' instrumentation is purchased by Implant Manufacturers for use in their surgical procedure kits. Refer to the Implant Manufacturer's surgical technique for information related to the surgical approach and technique recommended for the relevant implant system.

This document should be carefully read and understood prior to using Incipio Devices' instrumentation.

Intended Use and Clinical Benefits
Bone Reaming Instruments are intended to ream the acetabulum and prepare the bone for the insertion of the cup implant during either primary or revision hip arthroplasty. Bone Reaming Instruments include:
- Acetabular Reamers, available in sizes from 36mm to 80mm in 1mm increments, used to ream a hemispherical cavity for the acetabular implant.
- Reamer Handles, available in straight, offset and angled configurations to accommodate conventional or tissue sparing surgical approaches. Reamer handles are equipped with commonly used power drill connections. The type of connection is described in the product description on the label.

Impaction Instruments are intended to position and place acetabular cup implants into the prepared acetabulum during hip arthroplasty surgeries. They comprise
- Cup Impactors, which attach to the acetabular cup implant by way of a mating thread and maintain the cup secure during the impaction process. Cup impactors are designed to connect to a 3rd party cup implant in accordance with their specifications. The thread gage compatibility is laser marked on the product and noted in the product description on the label.
- Orientable Alignment Guides are accessory devices intended to aid the surgeon in the alignment and orientation of the acetabular up prior to impaction. They may be used in combination with Incipio Devices Offset Cup Impactors.

Instrument Trays are rigid containers, intended to enclose, protect and organize Incipio Devices surgical instruments and associated components during transport, sterilization and storage.

Intended Users and Patient Population
Use of reusable surgical instruments shall be limited to fully trained and qualified medical professionals competent in the relevant orthopedic surgical procedures and the use of associated instrumentation. The decision to use a surgical instrument for a patient procedure is left to the discretion and professional judgement of the surgeon.

General Safety Notes
- Electronic copies of these instructions for use are available on the website (www.incipiodevices.ch/ifu).
- Incipio Devices has validated the processes provided in these instructions to be capable of being effective. Alternative methods of processing outside of the scope of this document may be suitable for reprocessing; however, these must be validated by the end user.
- It is the duty of the user to ensure that the reprocessing procedures are followed, that resources and materials are available to trained and competent personnel, and that hospital protocols and policies are followed.
- 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.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation.
- Users should always wear appropriate personal protective equipment when processing devices.
- Where an Incipio Devices surgical instrument is intended to connect to a 3rd party device (i.e., power drills, cup implant) the type of connection (power coupling, thread gage) is identified in the product description on the label. Thread gauge compatibility is etched on the product, where appropriate.
- 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.
- Where applicable, Incipio Devices instrumentation has been designed and tested to work effectively in combination. Use of Incipio Devices instrumentation with devices, instruments and accessories from any other manufacturer is not recommended. Where instruments from other manufacturers are used, the new combination must be duly tested to ensure the devices can perform safely and effectively together.

Limitations
Repeated reprocessing that includes decontamination, cleaning and sterilization has minimal effects on these instruments. Product lifetime is determined by wear and damage due to use and handling. Surgical instruments must be carefully inspected prior to each use to ensure they are functional. Scratches, dents, cracks and other damage can result in instrument breakage or tissue injury. Instruments that show signs of excessive wear (pitting, corrosion, cracks, illegible markings) should not be used. Frequently used instruments must be replaced regularly.

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. For devices with detachable components, the devices must be disassembled prior to cleaning as shown in appendices 1-4.
- 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.
- All reusable instruments are subject to repeated stresses related to bone contact, high torque, impaction, or reprocessing cycles. Instruments should be carefully inspected before each use to ensure that they are fully functional. Dull cutting edges, scratches, wear, nicks, abnormal play, and/or corrosion can result in loss of function, instrument breakage and patient/user injuries. If instruments are visibly damaged or degraded, discontinue use and dispose of the instruments in accordance with applicable regulations.
- Ensure that no instruments, parts, or fragments are left in the surgical site prior to closure as patient injury may result. Metal instruments or their fragments can be located by means of an external imaging device (e.g. X-ray, CT scan).
- When using Incipio Devices offset or angled reamer handles, do not apply axial load to the reamer handle before activating the power drill. Start the power drill at half the normal reaming speed and increase the axial load progressively. Reamer handles should not be operated with an input torque exceeding 21Nm, or at a speed above 250rpm. Such misuse may result in accelerated wear, damage or breakage of the universal joints.

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.
- Surgical instruments should be disassembled as shown in appendices 1-4 of this document.
- 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 (validated with neodisher® MediZym).
- 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

- 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, in tap water at room temperature (<40°C/104°F), for a minimum of 5 minutes. Follow detergent manufacturer's instructions regarding concentration, temperature, and soaking time as well as post-rinsing (validated with Prolystica® 2X concentrate enzymatic preasoak and cleaner at 0.2% from STERIS). 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 for a minimum of 1 minute. Do not use steel wool or abrasive cleaners. Activate joints, handles and other moveable device features to expose all areas to the detergent solution for a minimum of 1 minute.
- Remove the instruments and submerge them in an ultrasonic bath of freshly prepared enzymatic cleaning detergent (pH ≤8.5) solution (same conditions as before), in tap water at room temperature (<40°C/104°F), for a minimum of 10 minutes, at a recommended frequency of 35 kHz. Flush all lumens and articulate joints, handles and other moveable device features with the cleaning solution to minimize the formation of air pockets or bubbles. Follow the instructions of the ultrasonic bath equipment manufacturer.
- Remove the instruments of the cleaning solution and rinse the instruments thoroughly with deionised or purified water at least three times, at room temperature (<40°C/104°F), for a minimum of 1 minute at each time. 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.
- Incipio Devices does not recommend chemical disinfection of the instruments. The devices are designed to withstand a thermal disinfection cycle.

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 must be replaced regularly.
- Prior to sterilization, 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 their 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 encountered due 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 contents have 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 equipment 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.

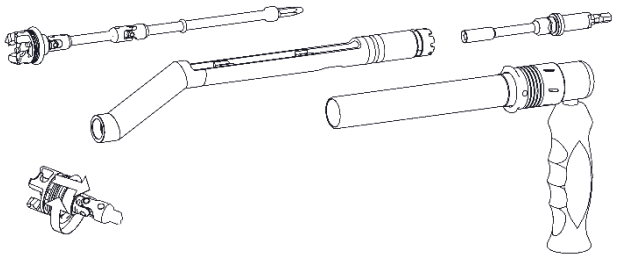
Important statement

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

REF	Catalogue number	NON STERILE	Non-sterile
LOT	Lot number	CC	Country of manufacture
	Keep dry		Do not use if package is damaged
	Manufacturer		Consult instruction for use or consult electronic instruction for use
	Date of manufacture	Rx only	For use only by a licensed physician
	Cleaning according to the instruction for use	134°C	Sterilization according to the instruction for use
EU REP	Authorized representative in the European Community	MD	Medical device
UK REP	Authorized representative in the United Kingdom		Distributor
	Importer (EU / UK)	UDI	Unique Device Identifier

A-1



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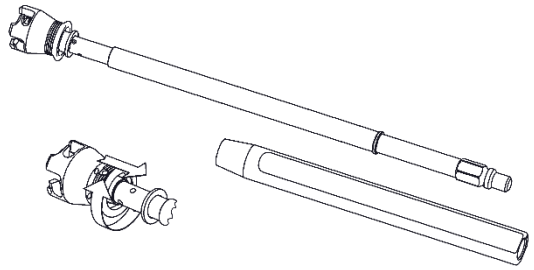

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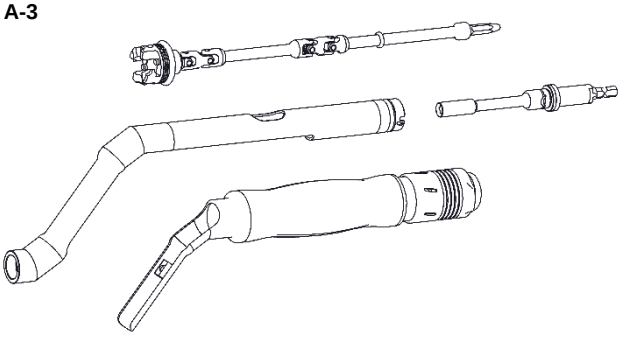

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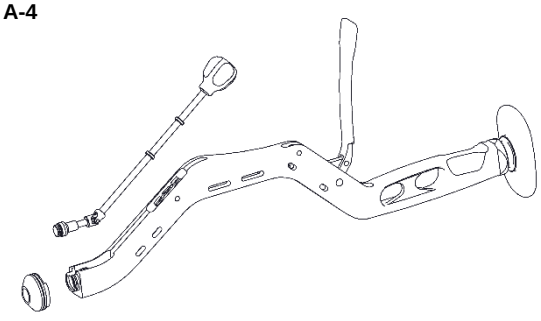

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