JAZZ SPINAL INSTRUMENTS

INSTRUCTIONS FOR USE
ANCILLARY FOR POSITIONING IMPLANET IMPLANTS
NON STERILE AND REUSABLE

Rx Only Caution: Federal Law restricts this device to sale by or on the order of physician

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LOT Lot Number (Batch Code)

Caution, Consult Accompanying Documents

Manufacturer

NON STERILE Non-sterile

REF Catalog Number

Consult Instructions for Use
www.seaspine.com/eIFU

Prior to using the ancillary supplied by SeaSpine, the operating theatre personnel and the surgeon must read through the recommendations provided in these instructions.

DESCRIPTION

This equipment is delivered clean but not sterile. It must be pre-disinfected, cleaned and sterilized prior to use.
JAZZ ancillaries are intended to be used as reusable surgical instruments in orthopedic or spine surgeries and then in contact with blood, bone, tissue and other body fluids.

MATERIALS

The materials used comply with current regulations. The ancillaries consist of stainless steel, titanium, aluminum, polymer or elastomer type materials: polyacetal (POM), polysulfone (radel), and silicone.

INDICATIONS FOR USE

The surgical instruments are intended to manipulate tissue or for use with other devices in orthopedic and spine surgery

CONTRAINDICATIONS

Refer to the contraindications for specific Spinal Systems and implants that may be used with these surgical instruments. With any surgery, the following contraindications exist:

-Infection in or around the operative site
-Allergy or sensitivity to instrument material
-Use of incompatible materials from other systems
-Any case not described in the indication

WARNINGS AND PRECAUTIONS

Ancillaries manufactured by IMPLANET must be used exclusively for positioning JAZZ implants. They must be used with the application for which they have been designed.
The ancillaries must be used in accordance with the recommendations contained in the labeling instructions for implants and in compliance with traditional, acknowledged surgical techniques. The latest versions of the operating technique brochures are available from customer services and/or on the SeaSpine internet site. JAZZ ancillaries must be used by qualified surgeons trained in the surgical techniques associated with their use; they must have read through these instructions for use and have understood the limitations associated with using ancillaries.
Do not use an implant which has been damaged by an ancillary.
It is important to pay particular attention to vital organs and vessels.
Under no circumstances can JAZZ ancillaries be modified or mounted on components produced by other manufacturers. Structures designed to involve other JAZZ components must be constructed in accordance with the nomenclature instructions.
Prior to any intervention, users are recommended to check that the ancillaries are in good condition, complete and functional in accordance with the nomenclature instructions: presence of all components and all sizes, mechanism in working order, legibility of markings particularly for instruments incorporating a measurement function, assembly with the relevant ancillaries, sharpness of cutting instruments, straightness of instruments (e.g.: reamers, drills) absence of damage (warping, excessive wear, impact, cracks, corrosion, discoloration), and other changes which might affect satisfactory use. Also check that holes and cavities are clean.
The lifetime of an ancillary depends on how often it is used and the care taken when handling, cleaning and storing it.
Any faulty instrument must be returned to SeaSpine prior to use for replacement or repair.
New and used JAZZ reusable ancillaries must be thoroughly cleaned and sterilized after each use. The appropriate reprocessing instructions recommended and validated by IMPLANET and that must be applied by the user are defined in chapter "Reprocessing instructions". It must be noted that failure to properly clean the device can lead to inadequate sterilization. There is a likelihood of microbial transmission and risk of infection if the device is not sterile.
Healthcare personnel must ensure cleaning and sterilization of reusable ancillaries before returning them to SeaSpine. Next user must also inspect the set upon receipt and carry out cleaning and sterilization before use.
Precautions should be observed by healthcare personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges. Personal Protective Equipment should be worn when handling or working with contaminated or potentially contaminated medical devices.

POSSIBLE ADVERSE EFFECTS

Poor maintenance or incorrect use of ancillaries may result in serious injuries for the patient or the medical team. See below a list of the most frequent adverse effects:
Neurological lesions, paralysis, pains, lesions of the soft tissues, organs or joints in the event of incorrect use, slippage, faulty ancillary or breakage of the device.
Injury due to excessive pressure on instruments for tightening, bending or cutting in-situ.
Crack, fracture or accidental perforation of the bone.
Infection particularly in the event of inappropriate cleaning and sterilization.
Cuts in the gloves or epidermis of the medical personnel.
If an ancillary breaks, the fragments must be removed from the patient to avoid damage. In addition, the materials constituting the ancillaries are not necessarily implantable and could also generate post-operative complications of a biological nature.

REPROCESSING INSTRUCTIONS - (PRE-CLEANING, CLEANING AND STERILIZATION)

After the intervention, ancillaries must be pre-cleaned, cleaned and sterilized.
N.B.: comply with national regulatory requirements under all circumstances.
In countries concerned by contamination by NCTA (Non Conventional Transmissible Agent), the specific reprocessing procedures must be applied in accordance with the local regulations.

After the intervention, ancillaries must be pre-cleaned, cleaned and sterilized. The instructions recommended by IMPLANET are described below:

1/ Pre-cleaning (or pre-processing handling at the point of use)

- Disassemble detachable parts and open hinged ancillaries according to the nomenclature instructions or disassembling/reassembling instructions below
- Avoid impacts or scratches which encourage corrosion, avoid contact with other ancillaries
- Immediately after the intervention carry out pre-cleaning of ancillaries in order to facilitate subsequent cleaning, to prevent drying of the device surface, to lower the level of contamination and to protect the personnel and the environment
- Bath the soiled devices for 15 minutes in the cleaning solution at 30°C (to 40°C) prepared with an enzymatic detergent according to the detergent manufacturer's instructions*
- After this step, brush the instrument (but do not use metallic brush) during 2 to 4 minutes. Clean device under cleaning solution.
- Rinse the device in a bath with warm (≥40°C) potable water for at least 3 minutes. Use a large volume, sufficient to completely immerse the device. During this step, move as well as the mobile parts and aggressively flush lumens, holes and other difficult-to-reach areas. Do not reuse the water for rinsing or any other purpose.

2a/ Thorough Automated Cleaning in washer-disinfector (cleaning and heat disinfection using a washer-disinfector are recommended by IMPLANET)

- Position the ancillaries so that all contact is avoided, leaving the joints open and allowing cannulations or holes to be cleaned.
- pre-cleaning with cold running water, 2 minutes
- cleaning at 55 °C during 5 minutes (to 10 minutes) at 0.5% (to 1%) according manufacturer's instructions (cleaning agent: Neodisher Mediclean)
- Neutralization with cold running water, 2 minutes
- Rinsing with cold running water, 2 minutes
- Final rinsing and thermal disinfection: 5 minutes at 90°C and deionized water
- Hot air dry at least 22 minutes (temperature ≥ 75°C)

2b/ Thorough Manual cleaning

- Ultrasound bath for 10 minutes in the cleaning solution at 30°C (to 40°C) prepared with an enzymatic detergent according to the detergent manufacturer's instructions*
- After this step, brush the instrument (but do not use metallic brush) during 2 to 4 minutes. Clean device under cleaning solution. During this step, flush lumens, holes and other difficult-to-reach areas.
- Rinse 2 times in a bath with warm (≥40°C) potable water for at least 1:30 minute. Use a large volume, sufficient to completely immerse the device.
- Ultrasound bath for 15 minutes in a disinfecting solution prepared according to the disinfectant manufacturer's instructions**
- Rinse in a bath of warm (≥40°C) deionized water for at least 1.30 minute. Use a large volume, sufficient to completely immerse the device and thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas with not less than 100 ml. Do not reuse the water for rinsing or any other purpose.
- Repeat the rinsing procedure 4 additional times for a total of 5 rinses with large volumes of deionized water.
- Thoroughly and completely dry the device using a clean absorbent and non-shedding wipe (lint free).

Visual inspection

In order to verify that the soil has been removed and the device has not been damaged, visually inspect all instrument surfaces and verify the functionality after reassembly as required in the nomenclature instructions.
Repeat a thorough cleaning if necessary.

Disassembling/reassembling instructions

Range	Reference	Designation	Description
JAZZ	550295	Braid Tensioner	Before cleaning, remove the detachable handle and the detachable stem by using the locking/unlocking button. Remove the mobile capstan from the rail by pushing on its button then remove the winch from the mobile capstan. After cleaning, clip again the winch in the mobile capstan and engage again the mobile capstan on the rail (placing the capstan on top and on front)

*recommendation based on the validation: Cidezyme (Enzol) enzymatic detergent with a concentration at 0.8%.
**recommendation based on the validation: Cidex OPA (0.3% minimum concentration)

The methods and equipment for cleaning-disinfecting and sterilization used by health facilities must be approved and must be subjected to routine checks in accordance with current regulations and standards.
These processes must be carried out by specialist personnel in compliance with the hygiene rules and procedures normally applicable within the facility.
During the reprocessing steps, avoid contact with other ancillaries, do not use metal brushes or abrasive products but suitable brushes or swabs. Take particular care with cannulations or areas which retain specks of dirt. The final cleaning rinse must be carried out with deionized water prior to drying the ancillaries.

The detergent and disinfectant solutions used must be specific to this type of equipment; the manufacturer's recommendations and parameters must be respected.
It is preferable to use neutral or slightly alkaline agents. Ancillaries containing aluminum can be damaged by strong alkaline products.
Do not use chlorinated products which may lead to the corrosion of stainless steel ancillaries.
Generally speaking, a check must be carried out to ensure the neutrality of the treatment prior to use.

Prior to sterilization, inspect the ancillaries in accordance with the recommendations defined in the chapter entitled "precautions". For mobile or hinged devices, a lubricant for medical use, water soluble and suitable for sterilization may be used.

After cleaning step, ancillaries, placed in their associated trays, must be sterilized in accordance with the recommended parameters below to provide a 10^{-6} Sterility Assurance Level:

Method (wrapped)	Exposure Temperature	Exposure Time	Drying Time	Accessory
Gravity-Displacement Steam sterilization cycle	132°C	15 minutes	30 minutes *(15 minutes*)*	Use a FDA-cleared wrap (or other FDA-cleared accessory) validated to maintain sterility after processing
Pre-vacuum steam sterilization cycle	132°C	4 minutes	20 minutes *(10 minutes*)*	
Pre-vacuum steam sterilization cycle (recommended)	134°C	18 minutes	20 minutes *(10 minutes*)*	This prevacuum sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. Use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature)

* Minimal recommended drying time based on sterilization validation activities

PACKAGING - STORAGE
Ancillaries are packed in individual packaging or in boxes. After use, they must be stored in their box to avoid any damage, in a clean, dry and cool place.

COMPLAINTS
Immediately notify SeaSpine by phone, fax or email regarding complaints, malfunctions or adverse events associated with this product. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service.