AUSTRALIA

CLARIANCE

Spinal instruments and trials

1. INTENDED USE

The reusable manual surgical instruments are intended for scraping, cutting, gripping, holding, removing or manipulating structural tissues, components of spinal devices associated with these instruments. Idys®- ALIF ZP trials are intended to determine the size of implant to be chosen.

2. DESCRIPTION

Instruments and trials are designed to be used in a wide variety of spinal procedures. They are non-powered devices, or devices that are not connected to a power source, which are used manually, are reusable or disposable and are intended for various spinal surgical procedures.

The reusable manual surgical instrument for spinal surgery is made of medical quality stainless steel according to the ASTM F899 standard, or of a titanium alloy according to the ASTM F136 standard, or of a polymer material.

Idys®- ALIF ZP trials are made of medical quality stainless steel according to the ASTM F136 standard. Several trials are anodized in different colors according to their sizes. Their dimensions are similar to implants of their own range.

Choice of the appropriate instrument and trial is the responsibility of the surgical team.

The instruments and trials may be used when preparing and approaching spinal structures and when placing spinal implants. It may be used in combination with other instruments which are specifically dedicated to a CLARIANCE product (e.g. quick-connect removable handle). These manual instruments and trials for spinal surgery may only be used with CLARIANCE products. Please refer to the surgical technique relating to the product for detailed information. Detailed information about the surgical technique for using CLARIANCE products is available on request. Please get in touch with CLARIANCE or its local representative.

3. INDICATIONS

The instruments are intended for scraping, cutting, gripping, holding, removing or manipulating structural tissues, components of spinal devices associated with these instruments. Choice of the appropriate instrument is the responsibility of the surgical team.

4. CONTRA-INDICATIONS

None known.

5. PERFORMANCE.

The performance claims of Idys ALIF ZP 3DTi instruments are same as Idys ALIF ZP 3DTi implants:

- Provide stability of the lumbar column until fusion occurs
- Promote fusion

6. POTENTIAL ADVERSE EVENT.

The following side effects or possible effects may occur during spinal surgery. A list of potential incidents associated with these instruments and trials includes:

- Breakage of the instrument or trial during surgery.
- Damage done to neurological tissues and elements due to poor positioning and placement of implants or instruments or trials.
- Infection.

Comment: Drugs and/or additional surgery may be necessary to correct some of these side effects.

7. STORAGE AND PACKAGING

Packaging for each of the components must be intact on receipt. If using a loan or consignment system, all sets of instruments and trials must be carefully inspected and all components carefully checked to make sure there has been no deterioration before using them. Any products with damaged packaging must not be used and must be returned to CLARIANCE.

Manual spinal surgery instruments and trials must be handled as seldom as possible and always with the greatest possible care. The instruments and trials (in their original packaging) must be carefully stored in a clean, dry place. Do not expose the instruments and trials to extreme temperatures.

In the event of these requirements not being adhered to, the mechanical properties may be reduced and in some cases, this could lead to the implant failing.

8. INSPECTION, CLEANING AND STERILIZATION

All the instruments and trials are delivered non-sterile. They must be cleaned using alkaline cleaning agents and then rinsed in deionized water before sterilization. Please note that it is necessary to disassemble some instruments in order to ensure proper cleaning. Please refer to the 99REPINS document "Manual instruments: Instructions for maintenance, cleaning and sterilization" to get detailed instructions. All products must be sterilized before they are introduced into a sterile surgical site, or (if applicable) when the product is returned to CLARIANCE.

Method	Cycle	Temperature	Exposure time	Drying time[1]
Steam	Dynamic air removal	132°C (270°F)	4 Minutes	20 Minutes
Steam	Gravity	132°C (270°F)	15 Minutes	30 Minutes
Steam	Dynamic air removal	134°C (273°F)	18 Minutes	30 Minutes

[1]The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer’s recommendations.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

9. WARNINGS AND PRECAUTIONS

PREOPERATIVE

- Do not reuse single-use instruments.
- Only sterilize clean instruments and trials; sterilization is only effective on clean instruments and trials.
- All the instruments and trials supplied non-sterile by CLARIANCE must be cleaned and sterilized before use.
- If surgery requires devices that are supplied sterile by CLARIANCE, additional sterile instruments should be available in the event of any unexpected need.
- Given that mechanical parts are involved, the surgeon must be trained in the use of these instruments and trials before employing them and must personally check that all the required components and instruments are present before surgery starts.

INTRAOPERATIVE

- Breakage, slipping or incorrect use of instruments, trials or implants may injure the patient or damage the device.
- Always take care when handling instruments and trials and putting them away.
- Do not drop the instruments and trials, otherwise they may get damaged. Do not use a damaged instrument or trial.

POSTOPERATIVE

- Disassemble the instruments before immersing them in decontamination tanks.
- Avoid any body fluids drying on the instruments and trials, immerse them in decontamination tanks as soon as possible.
- Avoid covering the instruments and trials with a wet field or one soaked with tap water - do not use a saline solution after usage and before decontamination.

10. DISPOSAL.

Disposal of all infectious wastes must be in accordance with applicable national and local regulations and the medical waste protocol of the medical center, and not endanger the security or the health of patient, user, or another person until its complete disposal (including cleaning, decontamination and waste).

11. PRODUCT COMPLAINTS.

Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identification, durability, reliability, safety, effectiveness and/or performance, should notify CLARIANCE. Further, if any of the instruments or trials do not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, CLARIANCE should be notified immediately.

If any CLARIANCE product may have caused or contributed to the death or serious injury of a patient, CLARIANCE and the National Competent Authority where the incident has occurred should be notified as soon as possible by telephone or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from CLARIANCE.

For any information, please contact the Australian Sponsor:

Australian Sponsor
Emergo Australia
Level 20 Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
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FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

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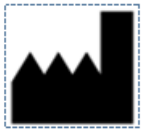
Symbol	Significance	Symbol	Significance
	Manufacturer		Lot number or batch code
	Catalog Number		Do not reuse / Single use only
	Attention: See package insert		Non-sterile
	Manufacturing country		Unique device identifier
	Do not use if packaging is damaged		Consult instructions for use or consult electronic instructions for use

Symbol	Significance	Symbol	Significance
	Sale of this device is restricted by or on the order of a physician		Packaging is sensitive to humidity
	Medical device		

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