AVALIGN OSTEOTOMY SET INSTRUMENTATION INSTRUCTIONS FOR USE

DESCRIPTION / MATERIAL COMPOSITION

Surgical instruments within the Osteotomy Set are manual medical tools designed solely for use in surgical procedures outlined by the Avalign Osteotomy Set Surgical Technique. Instruments are made from different materials including stainless steels and medical grade silicone that comply with the standards applicable to them. These materials are not implantable. Avalign instruments do not contain any Latex components.

USE

Instruments contained within the Osteotomy Set must be used in the manner prescribed in the Osteotomy Set Surgical Technique provided by Avalign. Prior to using the instruments, the surgeon shall give full consideration to all aspects of the surgical intervention as well as to the limits of the instrumentation. Recommendations for use are provided in the Osteotomy Set Surgical Technique provided by Avalign.

POTENTIAL ADVERSE EFFECTS

Incorrect maintenance, cleaning, or handling may render the instruments unsuitable for their intended use, cause corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff. As a result of the mechanical features required, the instruments contained in the Osteotomy Set are made from NON-IMPLANTABLE materials. In the event an instrument breaks, no fragment must remain in the patient as this could cause post-operative complications and require further intervention.

Below is a list, albeit not exhaustive, of potential complications:

- Neurological lesion, paralysis, pain, lesion of the soft tissues, the visceral organs or the joints, in the event of incorrect use or breakage of the instruments.
- Infection, if the instruments are not properly cleaned and sterilized.
- Dural leaks, compression of vessels, damage to nerves or nearby organs as a result of slippage or poor positioning of a faulty instrument.
- Damage caused by the involuntary releasing of the springs of certain instruments.
- Damage caused by the instruments used to bend or cut in-situ due to excessive forces occurring when they are used.
- Cutting the gloves or the skin of surgical staff.
- Tissue lesions on the patient or surgical staff and/or an increase in operating time as a result of having to dissemble the instruments during surgery.
- Crack, fracture or involuntary perforation of the bone.

PRE-OPERATIVE PRECAUTIONS

Anyone using the Osteotomy Set can obtain a Surgical Technique by requesting one from a Avalign representative or distributor. Those using brochures published more than two years before the surgical intervention are advised to request an updated version from Avalign directly. Do not use any instrument in a manner that it was not designed or intended for as described in the accompanying Surgical Technique. Misuse of instruments could have an adverse effect on the patient or staff.

The devices may only be used by doctors who are fully familiar with the surgical technique required. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by the implant manufacturer. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Any electrosurgical devices have the potential for providing an ignition source. Do not use in the presence of flammable substances.

Ensure that any product intended for reuse is properly cleaned and sterilized to avoid any detrimental effects to the patient or staff.

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CAUTION
Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

PACKAGING
Instruments contained in the Osteotomy Set are supplied NON-STERILE in an instrument container or individually packaged. The containers and the packaging of the instruments must be intact when received. The packaging materials must be completely removed prior to cleaning and sterilization.

INSTRUCTION PRIOR TO USE
The life of the instruments depends on the number of times they are used as well as precautions taken in handling, cleaning, and storage. A high level of care must be used to ensure the instruments remain in good working order.

All instruments should be examined for signs of wear damage by doctors and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection of the working surfaces, articulation points, and springs. It should also include verifying all welded connections, that all components are present, and the cleanliness of the orifices and cavities, as well as the absence of any cracks, distortion, impact, corrosion or other change. For instruments with articulations, lubrication may be necessary. Instruments within the set that perform a measuring function must be inspected of wear and the clear visibility of any surface markings.

AVALIGN shall not be responsible in the event of the use of instruments that are damaged, incomplete, show signs of excessive wear and tear, or that have been repaired or sharpened outside the control of AVALIGN. Any faulty instruments must be replaced prior to any surgical intervention.

INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS
Instruments are provided NON-STERILE.

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Furthermore, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps outlined in the following sections.

CLEANING
Refer to the table below for specific pre-cleaning and cleaning cycle information for manual and automatic cleaning methods. Prepare an enzymatic cleaning solution per the manufacturer's instructions. Soak soiled instrument in the cleaning solution. Use a soft bristle brush to remove all traces of blood and debris, paying close attention to threads, crevices, seams, and any hard to reach areas. If the instrument has sliding mechanisms, hinged joints or flexible areas, actuate the area to free any trapped blood and debris. Rinse the instrument(s) thoroughly with warm tap water. Rinse all lumens, internal areas, sliding mechanisms, and hinged joints, actuating sliding mechanisms and crevices while rinsing. Ultrasonically clean instrument using an enzymatic solution, prepared in accordance with the manufacturer's instructions. Rinse the instrument thoroughly with warm water. Rinse all lumens, internal areas, sliding mechanisms, and hinged joints. Actuate sliding mechanisms and hinged joints while rinsing. Dry immediately after final rinse. Dry any internal areas with filtered, compressed air if available. Check for visible soil, if any soil is present, repeat the cleaning procedure. For instruments with moving parts, lubrication with a medical grade water-soluble lubricant may be necessary where applicable.

	MANUAL CYCLE INFORMATION	AUTOMATIC CYCLE INFORMATION
PRE-CLEANING	• Alcohol wipe • Soak in cleaning solution • 15 minutes, 40°C (104°F) • Use non-metallic brush • Rinse thoroughly in running water	• Soak in Ultrasonic bath • 15 minutes • Use non-metallic brush • Rinse thoroughly in running water
CLEANING	• Soak in Ultrasonic bath • 15 minutes, 40°C (104°F) • Use non-metallic brush • Rinse thoroughly in demineralized water • Dry	• Wash • 93°C (200°F) minimum • 10 minutes • Rinse • Dry

A facility may choose to use different cleaning cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate cleaning to facilitate sterilization.

Inspect all instruments prior to sterilization or storage to ensure instruments are suitable for use. Any instruments showing signs of damage should be set aside and sent for service or repair.

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STERILIZATION

Sterilize with steam sterilization. The following steam sterilization cycle is suggested based upon validation of a single, wrapped, instrument case, within a properly maintained autoclave. It is critical that process parameters be validated for each facility's individual type of sterilization equipment and product load configuration.

CYCLE TYPE	TEMPERATURE	Pulses	EXPOSURE TIME	DRYING TIME
Prevacuum	132 + 3°C (270°F)	4	4 minutes	30 minutes

A facility may choose to use different steam sterilization cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate steam penetration and contact with the instrument case for sterilization.

For further information related to the use of this instrument, please contact your AVALIGN representative or distributor.

STORAGE

The instruments are packaged in individual packages or in containers. After they are used they must be stored in a clean, dry and temperate place.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, should notify Avalign or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, Avalign or its representative must be advised immediately. If a Avalign product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Avalign must be informed as soon as possible by telephone, fax or in writing. For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and a detailed description of the event to help Avalign understand the causes of the complaint.

For further information or complaints, please contact:

Avalign
626 Cooper Ct.
Schaumburg, IL 60173
1-877-289-1096
product.questions@avalign.com

WARRANTY

AVALIGN does not and will not warranty any repairs made to the product by a source not approved by AVALIGN.
AVALIGN will not be responsible for any product failure with unauthorized repairs.
For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

MANUFACTURED BY:

Avalign Technologies
8727 Clinton Park Drive
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1-877-289-1096
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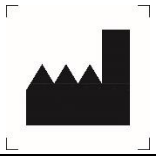
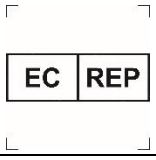
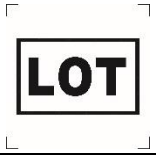
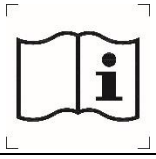
customerservice@seaspine.com

Label Glossary

Symbol	Title and Translations
	Manufacturer
	Authorized Representative in the European Community
	Lot Number / Batch Code
	Catalogue Number
	Consult Instructions for Use
	Caution
	Federal Law (USA) restricts this device to sale by or on the order of a physician