VolarE Hook Plate for Distal Radius

1. **Manufacturer:**

ASTROLABE – Fabricação de Implantes Médicos, Lda
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CE 2797

2. **All type reference articles us table below:**

Table 1 – Astrolabe VolarE Hook plates.

	VolarE Hook Plates Models
99.06.00.00001	VolarE Hook Plate, Standard
99.06.00.00002	VolarE Hook Plate, Narrow
99.06.02.02075	VolarE Hook Plate, Screw

3. **Intended use**

The VolarE Hook Plate are intended to buttress a volar marginal fragment, fixing with the volare hook screw on the distal part of the family Special Locking Plates Radius VolarE.

4. **Presentation and Clinical Indications**

VolarE Hook Plates and Screw as exemple in figure 1.

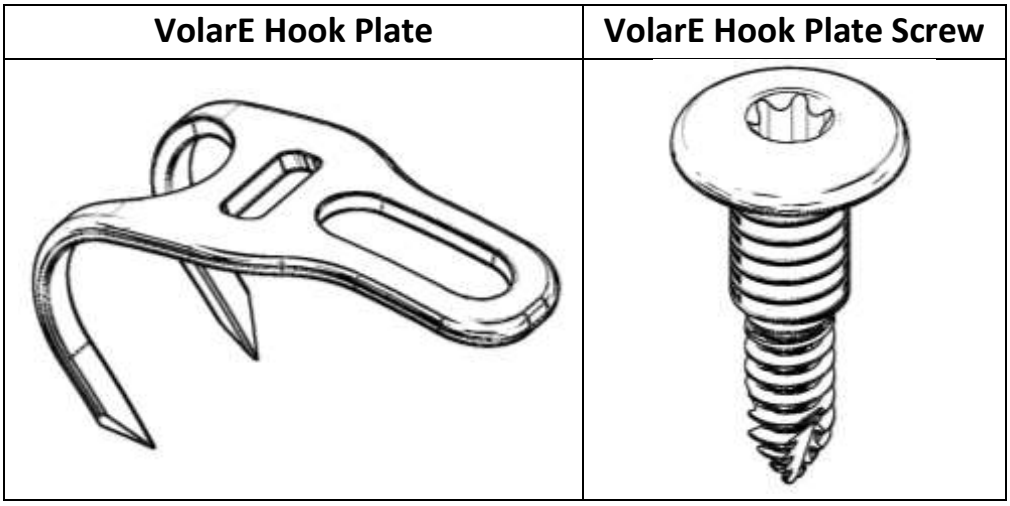


Figure 1 – Astrolabe VolarE Hook Plates and Screw.

The full catalogue of plates produced by Astrolabe - Fabricação de Implantes Médicos is available on our website https://www.astrolabe-medical.com/pt/.

These VolarE Hook Plates are implantable devices made of ASTM F136 titanium alloy, with two different sizes (standard and Narrow) an oblong hole for fixation and two spikes grab the bone fragment, to best adapt to the specific size of volar fragment of the distal radius.

The VolarE Hook Plate Screw are implantable devices made of ASTM F136 titanium alloy, single size for fixation of the VolarE Hook Plates into the distal part of the family Special Locking Plates Radius VolarE.

If the removal of the implants is necessary, the surgical instruments also manufactured by ASTROLABE should be used.

5. Contraindications

- Patients with an active or suspected infection, or immunocompromised patients.
- Patients with certain metabolic disorders, degenerative diseases, circulatory diseases and/or systemic disorders.
- Patients with a tumour in the treatment area.
- Known or suspected intolerance to the foreign bodies (products) to be applied.
- Patients who would not be capable of performing the required post-operative care, based on their physical or mental condition.
- Instances of severe damage to bone structure as well as degenerative processes which can interfere with the healing process.
- Addiction to drugs, alcohol or medication.
- For patients performing activities involving walking or running or which would otherwise incite excessive muscular strain, the effort produced may cause the implant to fail.

6. Possible Adverse Effects

- Infection
- Pain
- Allergic reaction to the constituent materials of the implants
- Nerve damage, vascular injury and healing disorders
- Restricted movement
- Insufficient and/or delayed bone healing
- Risk of the implant breaking, warping, loosening or migrating in the event of excessive strain and/or weight

7. Warnings and Precautions

- The healthcare professional in charge of the surgical procedure is responsible for the proper assessment of patients and providing them ~~with suitable training and~~ information with respect to selecting and inserting implants, as well as taking the final decision to leave or remove implants post-operation. Implants must be removed following completion of bone consolidation on a case-by-case basis wherever possible.

- The surgeon must be specifically trained, experienced and fully familiar with the use of internally attached rigid devices, surgical procedures and post-operative care. Patients must strictly follow the post-operative instructions given by their surgeon. The patient must be made aware of the limitations of their metallic implants and given guidance on tolerable loads prior to the complete consolidation of the fracture.

- All implants and instruments may be required for each surgery. The non-use of specific tools for each step of the implantation procedure may compromise the integrity of the implanted device, resulting in premature failure and subsequent injury to the patient. Failed implant devices may require additional surgery and removal.

Moreover, surgical instruments may be damaged or broken if not used adequately during handling, the surgical procedure or reprocessing. Please refer to the VolarE System surgical technique guide to review the surgical approach in each step.

- Do not mix implants made of dissimilar metals within the same structure. Different metals in contact with each other may accelerate the corrosion process owing to galvanic corrosion.
- The use of implants from multiple manufacturers is not recommended owing to possible incompatibilities of the metals, mechanics and the design of the implant.
- Repeated bending can weaken the plate and may lead to its fracture and failure of the implant. If the implant needs to be moulded, this should not be bent at acute angles, bent in the opposite direction, scratched or warped. It can only be moulded once.
- Osteosynthesis devices are recommended for use in patients whose bones are strong enough to sustain the effectiveness and benefits of rigid fixation.
- Implants are designed for temporary use, i.e. until osteosynthesis occurs.
- Only clean and sterilised devices may be implanted or used when applying the products. Cleaning and sterilisation instructions must be carefully followed.
- Personal protective equipment must always be used when handling or working with contaminated or potentially contaminated surgical implants.
- The correct selection of the implant is very important. The successful fixation of the fracture increases with the adequate selection of the shape, size and design of the implant. The shape and size of the human bone and soft tissues place restrictions on implant sizes and resistances. The selection of the wrong product (such as undersized implants in areas with high levels of functional stress) may result in the loosening, warping or breaking of the product, as well as the possibility of a bone fracture.
- Supporting the body's weight is not recommended until bone fusion has occurred.
- Implants must be applied in a sterile environment.
- Implants are for single use only. Reuse entails an increased risk of contamination. This may result in possible cross-infection/contamination risks when used with other devices that have not been sufficiently cleaned and/or sterilised.
- The use, reuse or reprocessing of explanted, contaminated, used or damaged implants (e.g. as a result of scratches) is prohibited. This also applies to contact with bodily fluids. Reusing implants may result in potential mechanical failure and an increased risk of infection. Apparently undamaged implants may present signs of fatigue as a result of unknown previous stress which may result in premature failure or the shortening of the life of the implant.
- Only instruments suitable for inserting ASTROLABE products should be used. Combining our products with other manufacturers' products may entail severe risks for patients, users and third parties.

Exception: The use of our products in combination with motorised or drive systems. However, in this case the instructions of the manufacturer of such equipment for combined use with other products must be strictly followed.

8. Recommendations and Instructions

8.1. Recommendations

- The patient must be duly informed, prior to surgery, of all the risks and side effects arising from use of the products in question as well as the expected outcome of the surgery (such as temporary restrictions on movement). Moreover, doctors must inform patients that medical monitoring and follow-up is crucial for the success of the operation. Doctors must instruct their patients to immediately notify them of any changes in the region where the operation was performed, so that suitable measures may be taken for continuation of the treatment.

- The product and surgical procedure selected should be based on the type of bone defect, anatomical location, indications for surgery and accepted medical standards as well as the patient's weight, physical condition, activity level and co-operation.

- Carefully inspect and verify the implants prior to use.

- Follow standard practice for rigid fixation (i.e. the typical AO procedure) when inserting implants.

- Only trained, experienced medical professionals must handle the devices.

8.2. Instructions for plate-screw systems

The implants are designed to adapt adequately to the bone to be treated. Each system is designed according to the location where it should be used. However, the plates can be adjusted to the bone to fit them perfectly to its anatomy, if necessary.

Careful plate bending is possible, to a limited degree (in line with the anatomy proper of the bone), provided it is done with due care, the appropriate plate has been selected and an appropriate instrument is used. Multiple deformations should be avoided. Multiple bending of the plate without following the indications, as well as bending it to acute angles, bending it backwards and forwards, scratching it or warping it can weaken the plate and lead to fracture or failure of the implant as well as the reduction of its useful life.

Once an implant is moulded it cannot be moulded again to its original shape, as this may cause its fracture and the consequent failure of the system.

In the case of fixed-angle implants, the drill guide must be placed in the hole of the screw nearest to the bending area before bending occurs. This prevents damage to the screw thread.

In the event of **shortening the bone plate**, the cut surfaces must be trimmed with appropriate instruments. The surgeon must ensure that the stability, load capacity and the fixing plate are maintained.

Prior to screw insertion, a drill bit of appropriate size must be used for pre-drilling. The drilling depth is determined by a gauge, in order to establish the length of screw. In relation to fixed-angle uni-directional screws, drilling must be done with the drilling sleeve screwed to the plate.

In general, the use of a tap is not necessary except when the procedure may involve hard bone.

The insertion and removal of the screw with a screwdriver must occur with sufficient pressure and at an angle that is exactly perpendicular to avoid any risk of damage. Some resistance is to be expected at the end of tightening. The screw must be carefully tightened right to its limit, to prevent damage to bone or the products.

The surgeon must carefully insert the bone screws because excessive torque can lead to implant failure.

8.3. Instructions for VolarE Hook Plate

Prior to volare hook plate insertion, a hook plate reduction tool must be used to reduction the fragment guided with the proper k-wires, then the volare hook plate spikes are inserted in the holes left by the k-wires and properly positioned in the Special Locking Plates Radius VolarE with the insertion of volare hook plate screw using the shaft srew driver and locking to the plate.

9. Packaging and Storage

The implants are supplied non-sterile, as stated on the label.

Non-sterile implants must be stored in a cool, dry place in their original packaging with no exposure to light until they are sent off for sterilisation. They must not be exposed to ionising radiation.

So as to keep products from corroding they must be kept away from chemical products.

The implants must not be stored directly on the floor. Storage on shelves at least 10cm above floor level is recommended.

There are no special transport conditions to be considered.

The label on the packaging contains the batch information for the product. It is recommended that the batch data is recorded in the patient's records for traceability purposes.

10. Cleaning and Sterilisation

All non-sterile products must be cleaned and sterilised prior to use in the operating theatre. The user is responsible for ensuring the correct performance and validation of these processes. Only trained, experienced professionals capable of assessing potential risks and subsequent effects must handle the devices.

The following cleaning and sterilisation instructions should be incorporated into the validated procedures in place in the institution. National standards, regulations and/or restrictions must also be included in this process.

The use of demineralised water helps keep stains from appearing on medical devices and also prevents corrosion. Use cleaning solutions and detergents with low foaming action.

10.1.1. Cleaning

ASTROLABE products must be washed with alkaline or enzymatic cleaning agents. Only chemical and cleaning agents approved by the manufacturer for surgical products made of titanium/titanium alloys must be used. Highly alkaline cleaning solutions may stain surfaces.

The instructions provided by the manufacturer of the cleaning agent with respect to operations and loads, water temperature, concentration of the solution, application time, rinsing and drying should be complied with.

10.1.2. Manual Cleaning

The automatic mechanical washing of devices is preferred to manual washing as a standard process is achieved. This procedure should only be performed as a last resort when an automatic washer is not available.

When carrying out wholly manual washing procedures the methodology set out by the hospital should be complied with, particularly with respect to immersion in cleaning solution, the washing support materials and recommended products. The cleaning solution must be prepared in accordance with the manufacturer's recommendations.

Non-fibrous sponges with soft bristles and nylon brushes are recommended for manual cleaning procedures so as not to damage implant surfaces and coating.

Water temperature cannot be higher than room temperature as this facilitates the detachment of organic and chemical residues.

To keep contaminants from spreading the instruments must be scrubbed with a brush when fully immersed in the cleaning solution.

Rinse thoroughly to ensure there is no detergent residue left and dry using medical air or disposable absorbent wipes that do not shed fibres.

10.1.3. Ultrasonic Cleaning

Use an ultrasonic cleaning device suitable for medical applications. The manufacturer's instructions must be followed.

Implants that are cleaned in ultrasonic equipment must first be washed with the specific auxiliary means available, prior to immersion in the cleaning solution.

The level of cleaning solution must never exceed the maximum limit indicated inside the tank. Temperatures must not exceed 40ºC.

The basket of the ultrasonic device must be large enough to ensure that all the instruments are completely submerged in the cleaning solution.

Only implants made out of the same metallic alloy should be placed in each load to prevent corrosion.

The devices are rinsed with running, preferably demineralised, water so no detergent residue is left and then dried using disposable absorbent wipes that do not shed fibres, or with medical air.

10.1.4. Automatic Cleaning

In the case of mechanical cleaning, the implants must be arranged in the washing baskets in a manner that does not cause damage.

Washing baskets should not be overloaded so that all the materials are exposed to the action of the water jets.

Only implants made from the same metallic alloy should be placed in each washing load, to prevent corrosion.

The instructions provided by the manufacturer of the washing machine or cleaning agent regarding the respective operation and loads, water temperature, disinfectants or solution concentration, application time, rinsing and drying phases and times must be complied with for optimal cleaning results and to prevent damage to materials.

Use indicators where possible, which allow cleaning action efficiency to be monitored.

Implants must be dried following washing.

10.1.5. Visual Inspection

The visual inspection must be performed after cleaning (manual or automatic).

Implants must be verified with respect to cleaning, operation and integrity. All traces of detergent used must have been removed during cleaning. If any contamination is found, the cleaning cycle must be repeated.

The products must be inspected for mechanical damage (breakage, deformation, corrosion, etc.) and fault-free operation. Products which are damaged or are not fully functional may never be used in patients. They must be sent off for repair by a qualified agent or, where necessary, disposed of and replaced.

10.2. Sterilisation

Sterilisation should be carried out according to a validated steam sterilisation process, e.g. , sterilisation in accordance with EN 285:2009 and validated in accordance with ISO 17665-1: 2006.

Recommended sterilization methods are moist steam fractionated, fully demineralized or distilled feed water must be used for steam formation (cf. EN 285) at a temperature of 132 ° C for 5 min and 10 min drying or moist steam fractionated at a temperature of 134 ° C for 5 min and 10 min drying. Astrolabe recommends using bags for sterilization – BOP, is a standard range of peelable see-through pouches and reels made of paper and intrafilm printed film, with steam indicator or similar ~~wrap based on non-woven SMS 100% polypropylene~~ with several characteristic to maintain the sterilization:

- Ability to prevent microbial penetration and maintain sterility and prevents penetration of liquids (i.e., repellent);
- Allows steam to penetrate;
- Easy to use by personnel;
- Conforms to equipment pack contours smoothly and closely;
- Enough sizes to accommodate any sized or shaped item;
- Resists punctures;
- Resists tears;
- Non-toxic;
- No odor;
- Adheres to local and state solid waste disposal rules.

NOTE: The trays of Astrolabe are design so that containers are not needed for effective sterilization

Warnings

Sterilisation must be carried out before using ASTROLABE products. Only completely clean and dry products can be sterilised. Products should be placed in suitable storage systems for sterilisation: Baskets, trays, and implant cases.

The sterilisation package will vary based on the method used. The products must be packaged in accordance with current applicable guidelines and the requirements in place for the chosen sterilisation method.

Contact with other objects which may damage implants or scrape their surface finish should be avoided.

The sterilisation processes for the various load and packaging settings as well as storage time must be established by the professional in charge of the sterilisation process.

Multiple medical devices may be sterilised in an autoclave during one cycle, although it is recommended that the maximum load indicated by the manufacturers is not exceeded. Heavier items should be placed at the bottom of the load.

Since the trays of Astrolabe are design to be sterile without the containers the condensation is avoided and prevents the chances of subsequent corrosion and/or contamination.

Following sterilisation, the packages must be inspected for signs of damage. The sterilisation indicators must also be checked.

Any sterile product packages found to be damaged or damp when removed from the sterilisation chamber should be deemed non-sterile and cannot be used. Sterilised packages must not show any signs of damage which could affect their functioning, so they must undergo regular visual checks. Defective sterilisation trays must be taken out of service and may not be used for sterilisation and/or the storage of sterilised products.

11. Warranty

ASTROLABE products are manufactured using the highest quality materials and are subject to quality assurance controls prior to delivery.

The user is under obligation to inspect the product prior to application, to ensure its adequacy and use for the intended purpose.

As a product manufacturer, ASTROLABE may not be held liable for any direct or indirect damage arising from failure to follow the above-stated instructions, misuse, incorrect handling or preparation, sterilisation, care and maintenance. The repair of the products by companies or individuals who have not been authorised for such by ASTROLABE shall void all claims made under the warranty.

For any queries, please contact us on **+351 219672298.**

12. Product disposal

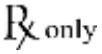
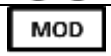
Medical devices must be delivered to a professional company specialised in the disposal of this type of waste or to a recycling system once their useful life has ended.

Used implants must be destroyed. They must be shredded or deformed, at a suitable location where possible, to avoid contaminating humans or the environment. In this way, the implant is clearly made inappropriate for use. It is recommended that the legal requirements regarding potentially contaminating products apply.

Implants are single-use products and must not be reused.

13. Packaging symbols

Table 2 – Product labelling symbols.

Symbol	Description	Symbol	Description
	Catalogue number		Batch number
	CE Marking of Class IIb Implants.		Do not reuse
	Manufacture date (YYYY-MM-DD)		Manufacturer
	Avoid contact with water		Avoid direct exposure to sunlight
	Prescription-only		Do not use if packaging has been opened or is damaged.
	See Instructions for Use		Fragile
	Product's Model		Non-Sterile
	MRI Conditional		

14. Emergency Contact

To report incidents with our products that require immediate resolution, please use the following email: incidents@astrolabe-medical.com;

Always indicate the company name, address, direct contact and detailed description of the incident, including the reference and lot(s) of the affected product(s).