Drill bits, countersinks, positioning pins, reamers, pulling devices and reduction devices

1. Manufacturer

ASTROLABE – Fabricação de Implantes Médicos
R. José Gomes Ferreira, 2 – Armazém 1
2660-517 São Julião do Tojal
Portugal

CE 0086

2. Raw Material

The raw material of the drill bits, countersinks, reamers, pulling devices and reduction devices is stainless steel according to the specifications of the ASTM F899 or ISO 7153-1 standards.

The raw material of the positioning pins is stainless steel according to the specifications of the ISO 5832-1 or ASTM F138 standards.

3. Presentation and Clinical Indications

This brochure includes the drill bits, countersinks, positioning pins, reamers, pulling devices and reduction devices sold by Astrolabe – Fabricação de Implantes Médicos, Lda, namely:

Table 1 – Models of Astrolabe Drill Bits, Countersinks, Positioning Pins, Reamers, Pulling Devices and Reduction Devices.

INSTRUMENT	MODEL
Drill Bits	AO Coupling (AO)
	Stryker Coupling (Stryker)
	Dental Coupling (Dental)
	Cannulated - SZ Coupling (SZ)
	Cannulated - AO Coupling (AO)
	Cannulated - Round Shaft
	Graduated - AO Coupling (AO) - Drill Stop
Countersinks	AO Coupling
	Cannulated - AO Coupling (AO)
	Cannulated - SZ Coupling (SZ)
	Cannulated - Round Shaft
Positioning Pins	Positioning Pin
Reamers	DHS/DCS
	DCS
	DHS
	DCS Complete
	DHS Complete
Pulling Device	w/o Nut
	Pulling Device
Reduction Device	Push-Pull

The full catalogue of reusable surgical instruments produced by Astrolabe - Fabricação de Implantes Médicos, Lda. is available on our website http://www.astrolabe-medical.com/.

The drills, countersinks and positioning pins are designed to facilitate the insertion of osteosynthesis devices at the upper and lower ends of bones:

- Countersinks (cannulated and non-cannulated) are used to prepare a cavity in cortical bone where the screw head will sit, thereby enabling it to be aligned with the bone surface or be embedded below the surface.

- Positioning Pins sit directly in a specific hole of the plate, pressing down and holding its position while the screws are inserted.

- Drill Bits (cannulated and non-cannulated) are used to create a pilot hole to accommodate a screw or other threaded device for rigid fixation.

Reamers, pulling devices and reduction devices are intended to facilitate the insertion of osteosynthesis devices into upper or lower limbs:

-Reamers are intended to effect resection (remove a part of the bone) and to accurately turn a specific area of bone to accept the prosthetic implant.

- Pulling Devices allow a temporary reduction of the fracture during surgery, since they pull the bone in the direction of the plates to be applied.

- Reduction devices temporarily hold the plate in the bone, through a hole of the same plate.

4. Contraindications

These products have no contraindications. The devices may be damaged or broken if the instruments are used incorrectly during handling, the surgical procedure or reprocessing.

5. Possible Adverse Effects

The bone may overheat during drilling, which can result in irreversible local osteonecrosis. The irrigation of the site during drilling is recommended.

6. Warnings and Precautions

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 motor or drive systems. In this case the instructions of the manufacturer of the equipment for combined use with other products must be strictly followed.

Surgeons should be specifically trained, experienced and be fully familiar with the use of surgical instruments and surgical techniques.

All instruments that form part of an Astrolabe system 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.

Cleaning and sterilisation instructions must be carefully followed.

Due care must be taken when handling devices with sharp points or edges.

Personal protective equipment must always be used when handling or working with contaminated or potentially contaminated surgical instruments.

Do not exert stress on instruments by twisting or using them as leverage, since this can damage or break the instrument.

7. Recommendations

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 instruments prior to use. They must be inspected after each procedure to ensure they are in good working order. All cutting edges must be uninterrupted and flawless. Defective or damaged instruments and/or those with suspected defects or damage, must not be used. These instruments should be replaced.

Note: Instruments returned to ASTROLABE must be duly decontaminated and sterilised, and sent with relevant proof that such processes have been performed.

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. Packaging and Storage

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

Non-sterile instruments 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 instruments 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.

9. 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.

9.1. Preparation for decontamination - Maintenance during surgery

All ASTROLABE medical devices must only be used for the specific purpose for which they were designed.

All blood and other waste must be removed immediately so that it does not dry on the instruments.

9.2. Preparation for decontamination - Maintenance after surgery

Instruments with more than one component must be dismantled for proper cleaning.

Cannulated instruments must be rinsed immediately after use.

Surgical instruments with dried blood, debris or bodily fluids are more difficult to clean. These devices must be immediately reprocessed after use due to the risk of infection and corrosion.

Externally clean the tools after use with a suitable soft cloth, sponge or soft brush (preferably nylon) disinfected in a cleaning solution.

Instruments with a damaged surface must be separated and cleaned separately.

9.3. Cleaning

ASTROLABE products can be washed with alkaline or enzymatic cleaning agents. Only chemical and cleaning agents approved by the manufacturer for surgical products made of stainless steel must be used. Highly alkaline cleaning solutions may stain surfaces and lead to loss of elasticity, in the case of silicone parts.

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.

9.3.1. 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 instrument surfaces and coating.

All product components must be separated prior to cleaning.

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

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

Special attention must be paid to the joints, tubular elements and cutting edges. Rinse instruments with channels and cavities.

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

9.3.2. Ultrasonic Cleaning

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

Tubular instruments with joints or recesses that are cleaned in ultrasonic equipment must first be washed with the specific auxiliary means available, prior to immersion in the cleaning solution. The instruments constructed of more than one part must be disassembled, if possible, and checked for integrity.

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. All the channels and hollow spaces must be filled with the cleaning solution, free of air bubbles.

Only instruments made of the same metallic alloy should be placed in each load to prevent the risk of 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. At the end of cleaning, all channels should be blown with medical air to remove any remaining liquid.

9.3.3. Automatic Washing

If the facility has an automated washing/disinfection system, that form of washing is preferable to manual cleaning since a standardised process is achieved.

For mechanical cleaning, the products must be positioned so that the channels and hollow spaces may be completely and thoroughly washed.

In the case of reprocessing, all the instruments are thoroughly cleaned with a mild detergent, soft brush and warm water before mechanical washing. Dried blood, bone chips and other deposits must be removed from the instruments and the sterilisation tray. Carefully wash all the instruments and the sterilisation tray with water. Arrange all the instruments in the sterilisation box and ensure that the cover is in place and fully closed.

Washing baskets should not be overloaded so that all the materials are exposed to the action of the water jets. The heavier instruments must be placed at the bottom of the containers.

Only instruments 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.

The instruments must be dried following washing.

9.3.4. Visual and Functional Inspection

The visual and functional inspection must be performed following (manual or automatic) cleaning, after assembly of the product components.

The instruments removed from the cleaning units should be verified with respect to cleaning, functionality and integrity. All traces of the detergent used, as well as blood, pus and secretions, must have been removed during washing. If any contamination is found during a visual check, the cleaning cycle must be repeated.

The cutting edges and threads showing signs of wear must be separated out. The products should 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.

The action of the moving parts must be checked to ensure smooth operation over the desired range of motion (for example, connecting hinges, sliding parts, etc.). If necessary, lubricate with a water-soluble product designed for surgical instruments which have to be sterilised.

9.4. Sterilisation

The recommended sterilisation method is by fractionated steam (≥ 132°C; ≥ 3 bar, ≥ 5 min) followed by drying (≥ 10 min).

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.

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.

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 instruments 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.

Condensation should be avoided to reduce 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 containers must be taken out of service and may not be used for sterilisation and/or the storage of sterilised products.

Protective parts must be placed on the sharp or potentially dangerous areas of the instruments.

10. Reprocessing Limit

The end of the useful life of the instruments is normally determined by wear and damage due to surgical use. The functioning of all devices must be inspected prior to sterilisation. If not operational, they should be disposed of in accordance with internal procedures.

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.

The instruments must be shredded or deformed, at a suitable location where possible, to avoid contaminating humans or the environment.

13. Labelling Symbols

Table 2 – Labelling symbols.

Symbol	Description	Symbol	Description
	Catalogue number		Batch
	Fragile		Marking of Class IIa Instruments.
	Manufacture date		Manufacturer
	Avoid contact with water		Avoid direct exposure to sunlight
	Temperature limit		Do not use if packaging has been opened or is damaged.
	See Instructions for Use		Product Model