

English

OWNER'S MANUAL

Straight
handpiece



PRESENTATION OF MANUAL

INSTRUCTIONS FOR USE

Technical Name: Dental Hand Instruments

Trade Name: Dental Hand Instrument for Low Speed

Models:

- PEÇA RETA INTRA 32 PR
- PEÇA RETA INTRA 32 PR SPRAY
- PEÇA RETA INTRA SL 30

Brand: Saevo

Manufacturer/ Distributor:

Alliage S/A Indústrias Médico Odontológica

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ATTENTION

For greater safety:

Read and understand all the instructions contained in these instructions for use before installing or operating this equipment.

Note: These instructions for use must be read by all the operators of this equipment.

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IDENTIFICATION OF EQUIPMENT

Dear Customer

This manual is a general presentation of your product and it will give you important details to help you to solve possible problems.

Please, read it and keep this with you.



Indication of Use

The Alliage handpieces are intended to remove caries, remove restorations and perform tooth sectioning, as an aid in extracting teeth, and they are for exclusive dental use, and must be handled by trained, qualified and regulated health professionals according to local legislation.

Contraindication

None known.

DESCRIPTION OF EQUIPMENT

General Description

Compact handpiece, ergonomic design, body made of metal with surface treatment. Transmission system supported on high precision bearings, providing a low noise level, extremely high durability and work without loss of power. Coupling via the INTRA system and rotation of 360°.

The Alliage handpieces have been planned to offer maximum performance in the most severe clinical procedures. With a design which caters for ergonomics, torque, sensitivity and lightness. Produced with technology (MADE IN BRAZIL) and material of the utmost durability.

Double internal Spray (according to model acquired): directed to the tip of the Bur, the double internal Spray system cools the cutting region of the Bur into any working position. Refrigeration prevents the occurrence of overheating in dental preparations that could lead to damage to the healthy dental structure.

To ensure safe operation of your equipment, use only the mounting assembly (chair, equip, water unit and reflector) provided by Alliage Authorized Reseller Service.

Application specification

Alliage Dental Handpieces are designed to perform most routine dental procedures in intraoral region treatments.

Operation principle

The Straight handpiece is intended to be used with Low Speed Micromotor with Intra connection operated by pneumatic pressure.

Significant physical characteristics

The Straight handpiece promotes Bur rotations of a maximum of 12,400 revolutions/minute, and the transmission of the rotation effect is made from the Micromotor to the Straight handpiece on a 1: 1 scale.

User profile

Alliage Dental Handpieces can be operated and handled by users of both sexes, with the ability to read and understand images, symbols, icons, western Arabic characters (Arial font), alpha numeric characters, knowing how to distinguish intraoral part of the human body, not being able to present a degree of visual imperfection for reading or seeing and an average degree of impairment of recent memory, not being in a clear capacity to perform the activities and functions of the product in a correct manner to the profession.

The user needs to be a qualified health professional and trained with technical competence in the health and dentistry field.

DESCRIPTION OF EQUIPMENT

Models



Attention

The contents of this page are of an informative nature, the equipment being able to differ from that illustrated. So, upon acquiring the product check the technical compatibility between equipment, coupling and accessories.



Internal Spray Irrigation System



01 - Intra Straight Piece 32 PR / SL 30 (external spray)

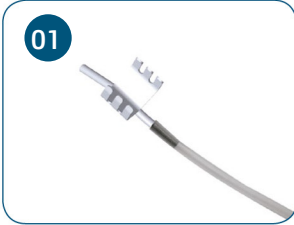
02 - Intra Straight Piece 32 PR Spray (internal spray)

b - Adjustment ring

** Bur sold separately.

DESCRIPTION OF EQUIPMENT

Sets and Parts



Attention

- The use of any part, accessory or material not specified or foreseen in these instructions for use is entirely the user's responsibility.

01 - Cooling kit (external spray adapter)

02 - Adapter for lubrication

*03 - Lubricant Lubs

TECHNICAL SPECIFICATIONS

General features

Transmission

1:1

System

Intra rotary

Maximum rotation

12.400 r/min

Bur fastening system

Ring speed with extreme - simplicity and speed

Bur type

FG Standard

Sterilization

Autoclavable up to 135°C

Coupling type

Type 2

Length X2

Long type - min. 32mm.

Torque

0,350 - 1,000 N.cm.

Bur Specifications

As per ISO 1797.1:2017 and made of steel or hard metal

Standard Burs

Type

Type 2 rod

Dimensions of the bur

Working diameter: 2,34mm \pm 0,01

Minimum rod fitting length: Mínima 30mm

Bur length: Maximum 44,5mm

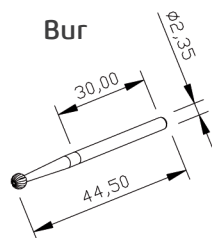
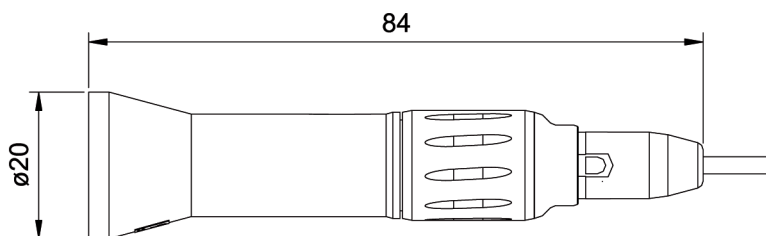
Weights

Model	Net Weight	Gross Weight
32 PR / 32 PR Spray	48g	113g
32 SL 30	50g	115g

TECHNICAL SPECIFICATIONS

Dimensions (mm)

32 SL 30 / 32 PR / 32 PR Spray



TECHNICAL SPECIFICATIONS

Packing symbols



Stacking limit by number



Keep dry



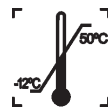
This side Up



Keep out of sunlight



Fragile, handle with care



Temperature limitation

Product symbols



Sterilizable in a steam sterilizer (autoclave) at the specified temperature



Recyclable



General warning



Indicates that the product must be taken to a special waste collection site at the end of its useful life.



Attention



Instructions for use



Serial number



Model number



Manufacturing date



Manufacturer



To indicate a reference to spraying liquid



Close



Open



Model



Lot

ABBREVIATIONS

PR - Straight handpiece
S - Spray

OPERATION OF EQUIPMENT



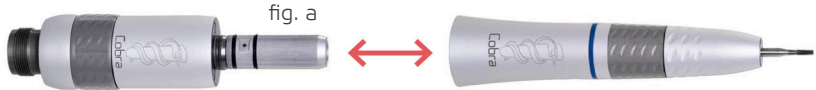
Warning

Handpieces must be used at a height of up to 1 meter from the ground.

Coupling to the micromotor

Ensure that the connection of the instrument is compatible with that of the equipment. In order to couple it, press the instrument on the coupling of the micromotor until it is fastened (fig. a). To uncouple, by means of pressure, pull out the Handpiece.

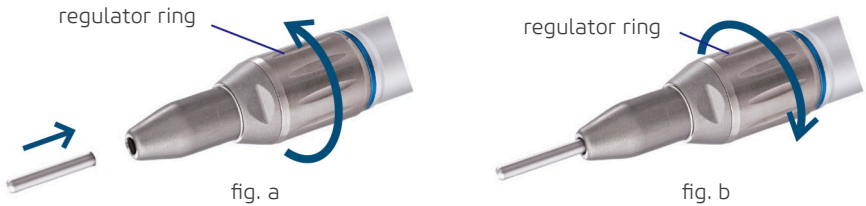
Before putting it into operation for the first time, follow lubrication procedures (see page 16).



Warning

Never place or remove the instrument when the micromotor is functioning.

Fixing the Bur



To insert the bur, turn the ring counter-clockwise until the end of stroke (fig. a).

Insert the bur into the hole until the end of the limiter and return the ring to the starting position (fig. b).



Warning

Make sure that the bur is docked to the bottom for correct fixation (fig. b).

Use good quality and standard burs.

Burs with very long stems can produce excessive vibration by decreasing the lifetime of the bearings.

External refrigeration system



Fit the refrigeration kit into the Straight handpiece (fig. a).

Position the refrigeration kit's rip in the straight tip guide as (fig. b).

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Recommendations for preserving the equipment

Your equipment has been designed and developed according to the standards of modern technology. Similarly to other kinds of equipment, it requires special care, which is many times neglected due to several reasons and circumstances. Therefore, here are some important reminders for your daily routine. Try to follow these simple rules, which will save you a lot of time and will avoid unnecessary expenses once they start making part of your working procedure.

To prevent the product, check that there is no leakage in the handpiece, according to the method below:

Attach the handpiece to the appropriate hose, connect it with the activated spray. Check for a leak in the connection between the handpiece and the coupler.

Transportation, storage and operation

This equipment must be transported and stored observing the following directions:

- Avoid falls and impacts;
- Keep it dry, do not expose it to rain, water drops or wet floor;
- Keep it away from water and direct sunlight, and in its original wrapping;
- Don't move it over irregular surfaces, protect it from rain and observe the maximum stack quantity specified in the packaging;

Environmental condition for transportation or storage:

- Room temperature range for transportation or storage -12°C a $+50^{\circ}\text{C}$.

Environmental operation condition:

- Room temperature range for functioning $+10^{\circ}\text{C}$ to $+40^{\circ}\text{C}$.
- Recommended room temperature range $+21^{\circ}\text{C}$ to $+26^{\circ}\text{C}$.
- Relative humidity range for functioning 30% to 75%.
- Atmospheric pressure range 700 hPa to 1060 hPa (525 mmHg to 795 mmHg).
- Operation altitude: $\leq 2000\text{m}$.



Attention

The Equipment maintains its condition of safety and efficacy, provided that it is maintained (stored) as mentioned in this instruction of use. Thus, the equipment will not lose or alter its physical and dimensional features.

Sensibility to predictable environmental conditions in regular use conditions

- The equipment has been planned not to be sensitive to interference such as magnetic fields, external electrical factors, electrostatic discharge, pressure or variance of pressure, provided that the equipment is installed, maintained, clean, preserved, transported and operated as per this instruction for use.

Precautions and warnings "during the use" of equipment

- The equipment should only be operated by duly enabled and trained technicians (Dental Surgeons, Capacitated Professionals).
- Before the first use and/or after long interruptions from work such as vacations, clean and disinfect the equipment.
- If any maintenance should be required, only use services of the Alliage Authorized Technical Assistance.
- Owing to its delicate components, this handpiece must not be dropped or undergo impacts.
- Although this equipment has been planned in accordance with the standards of electromagnetic compatibility, it can, in very extreme conditions, cause interference with other equipment.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Do not use this equipment together with other devices very sensitive to interference or with devices which create high electromagnetic disturbance.

- Do not expose the plastic parts to contact with chemical substances, use in the routines of dental treatment, such as: acids, mercury, acrylic liquids, amalgams, etc.
- The use of pneumatic or electric tools to perform any type of recording on handpieces, could lead to damage to the surface treatment of the product, causing the loss of warranty.

Manufacturer shall not be responsible for:

- Use of the equipment differing from that for which it is intended.
- Damages caused to the equipment, the professional and/or the patient by the incorrect installation and erroneous procedures of maintenance, differing from those described in these Instructions for use which come with the equipment or by the incorrect operation of it.

Precautions and warnings “after” the use of equipment

- Always maintain the equipment clean for the next operation.
- Do not modify any part of the equipment. Do not disconnect the cable or other connections without need.
- After using the equipment, clean and disinfect all the parts which may be in contact with the patient.

Precautions in case of alteration in the functioning of equipment



Warning

Do not use the equipment in conditions unsuitable for use.

- If the equipment has any abnormality, check if the problem is related to any item listed in the topic of unforeseen events (failures, causes and solutions). If it is not possible to resolve the problem, contact your representative (Alliage).

Precautions to be adopted against foreseeable or uncommon risks, related to the deactivation and abandoning of equipment

In order to avoid environmental contamination or undue use of the Equipment after it has become useless, it should be discarded in the suitable place (as per the local legislation of the country).

- Pay attention to the local legislation of the country for the conditions of installation and disposal of residue.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Precautions for the Reduction of the Environment Impact

Alliage S/A aims to achieve an environmental policy that encourages the environmentally conscious supply of medical products that continuously minimize environmental impact and are more environmentally friendly and human health friendly.

To keep a minimum impact on the environment, observe the following recommendations:

- After installation, forward the recyclable materials for the recycling process.
- During the life circle of the equipment, turn it off when it is not being used.

The biomedical waste comprises nonhigh material susceptible to cause disease or house pathogenic organisms that must be stored in a yellow bag properly labeled with the symbol of biological hazard, or stored in a container resistant to perforation, tight and even collection and incineration.



The packaging consists of cardboard, plastic and expanded polystyrene (EPS) which are 100% recyclable materials.

Dimensions:

Main unit: 0,170 X 0,071 X 0,030 / MASS: About: 0,128 Kg.

EQUIPMENT REUSE



Handpieces may only be serviced in the field at the points described in the user manual. If they need to be disassembled, they must be taken to the manufacturer.

Additional procedures for reuse

The equipment can be reused in undetermined, i.e. unlimited, quantities, only needing to be cleaned, disinfected and Sterilization.

Cleaning and Disinfection

These processes should be used in the handpieces.

Uncouple the piece from the INTRA fit terminal.

Remove the diamond tip or bur.

Do not use microabrasive material or steel wool when cleaning, or employ organic solvents or detergents which contain solvents such as ether, stain remover, etc.



For your protection, during the equipment cleaning and disinfection process, use PPE such as disposable gloves and goggles.

The cleaning and disinfection process must be performed at each patient change.

When starting the process, check for visible dirt, such as blood or saliva.

For cleaning use a clean, soft cloth moistened with mild soap and then dry with a clean, soft cloth or paper towel.

For the disinfection process of the Handpiece, use disinfectant detergent foam without alcohol that has active components based on didecyldimethylammonium chloride.

Apply the disinfectant detergent foam on the surface or on a clean cloth and spread it on the surface to be treated. Respect the antimicrobial contact time specified by the manufacturer.



Warning

Never submerge the instrument in a disinfection bath.

Never use product peracetic acid for cleaning, since it is corrosive.

Sterilization

Follow the appliance manufacturer's instructions.

They must be sterilized, handpieces and bur remover.

Sterilize only clean and lubricated Handpieces.

Clean, lubricate and remove excess oil from the instrument as indicated above, place it in surgical-grade paper packaging (not supplied with the product) and sterilize in a steam autoclave for one cycle.



Sterilization time minimum 30 minutes at 121 °C or minimum 3 minutes at 135 °C, and equivalent temperature and time parameters may be used within this range. Maximum sterilization temperature 135 °C.



Warning

Sterilize before 1st use, product do not provided sterilized.

Not valid or recommend to the sterilization by ethylene oxyde.

Do not sterilize in an oven.

Before sterilization, connect it to the delivery unit and activate it for a few seconds to eliminate the excess of oil.

If the excess of oil is not eliminated, it may cause burnt residue in the bearing.

EQUIPMENT REUSE

Spray lubrication

To carry out the lubrication of your equipment, we recommend the use of the Lubs product. Lubrication must be carried out by the posterior hole of the Straight handpiece. Insert the adapter into the hole as illustrated in fig. (a).

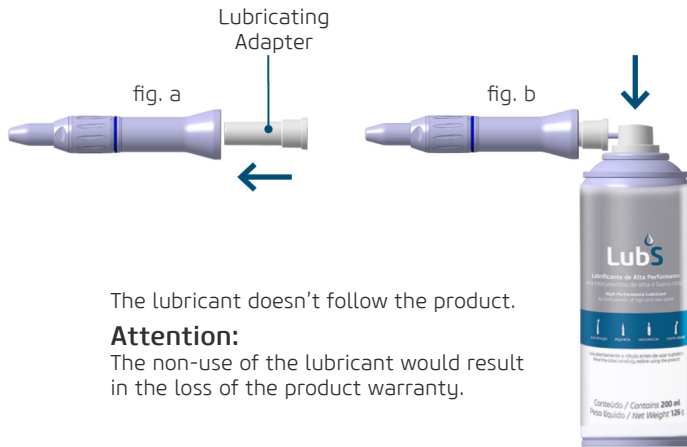
Firmly fit the oil applicator nozzle into the adapter hole (b) and apply the spray for 1 or 2 seconds, by observing the lubrication into the instrument head.

Cover the piece with absorbent paper to remove the excess of oil.



Warning

Before lubricating the handpieces, remove the bur.



The lubricant doesn't follow the product.

Attention:

The non-use of the lubricant would result in the loss of the product warranty.



Attention

Handpieces not subjected to sterilization process should be lubricated at least twice a day.

INSPECTION AND MAINTENANCE

Periodic Inspection

It is imperative that this equipment is regularly inspected to ensure operational safety and functional reliability.

The manufacturer is exempt from responsibility that the standard results do not conform in cases where the user does not carry out the inspection recommended by the manufacturer.

The inspection must be carried out, documented and maintained with the equipment by the user and is not part of the warranty of the same.

The table below gives a description of the main inspection items and recommended frequency.

Item	Inspection description	Recommended frequency
- Operating noise.	- Audibly, check the equipment for any abnormalities.	Daily
- Coupling.	Bur: - Check that the Bur bit is properly fixed according to fixing instructions. Straight handpiece: - Make sure that the instrument connection is firmly attached to the Micro Motor.	Daily
- Water leak.	- Check if the spray holes are leaking water.	Monthly
- Clogging.	- Check that the spray holes are not blocked.	Monthly

If problems are detected during the inspection, perform the procedures described in the Corrective Maintenance item.

Preventive Maintenance

The equipment must be submitted to preventive maintenance with a maximum period of 3 years. For protecting your equipment, look for a Alliage' technical assistance for periodic reviews as preventive maintenances.

Corrective Maintenance

Alliage states that the supplying of the circuits' diagram, Part lists or any other information that permits the technical assistance by the user, can be requested, since previously agreed between the buyer and Alliage.

Attention

In case that the equipment presents any abnormality; check if the problem is related to some of the listed items under the item Unpredictable (situation, cause and solution).

If it's not possible to solve the problem, shutdown the equipment and demand the presence of a Alliage technician from the nearest resale, or ask through the Attendance Service Alliage: + 55 (16) 3512-1212.

INSPECTION AND MAINTENANCE



Attention

Upon coming across any problem in operation, follow the instructions below to check and repair the problem, and/or get in touch with your representative. Handpieces may be serviced in the field only at the points described below. If they need to be disassembled, they must be taken to the manufacturer.

Problem	Probable cause	Solution
-It does not couple to the micromotor.	-Micromotor of another system.	-Ensure that the micromotor is the INTRA.
-The bur does not rotate.	-The bur is not suitably fastened. -Incorrect coupling of the micromotor.	-Fasten as per instructions. -Press until fitting it correctly.
-The bur comes loose when functioning.	-Bur out of measure. -Bur badly fastened.	-Replace as specified. -Fasten as per instructions.
-The bur does not go in.	-Bur out of measure.	-Replace as specified.

EQUIPMENT'S WARRANTY

This equipment is covered by the warranty periods, terms and conditions contained in the Warranty Certificate that comes with the product.

FINAL CONSIDERATIONS

Among the care you have to take with your equipment, the most important is regarding the spare parts replacement.

To ensure the lifetime of your device, only replace original spare parts from Alliage. They have the assurance of the standards and technical specifications required by the Alliage representative.

We call your attention to our authorized resellers' chain. Only this chain will keep your equipment constantly new, because it has trained technical assistant and specific tools for the correct maintenance of your device.

Whenever you need, demand the presence of a Alliage' technician from the nearest resale, or ask through the Attendance Service Alliage: + 55 (16) 3512-1212.

NUM. REG. ANVISA: 10069210073

