SAFE LOCK®

EN - AUTOMATIC IMPACTOR

EN - INSTRUCTIONS FOR USE

Anthogyr
A Straumann Group Brand

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I. DESCRIPTION OF SYMBOLS USED

DANGER

Please wear gloves

Visual examination

Please read this!

SN Serial number

REF Device reference

Sterilisable up to 135°C

Manufacturing date

Manufacturer

MD Medical Device (Impactor + Instruments)

Non-sterile device

II. AREA OF APPLICATION

This **MD** is intended for use in dental treatment in the field of dental surgery, particularly for the placement of prosthetic parts.
Any other use is prohibited and may be dangerous.

Applied directive:
For the **MD** , we applied Community Directive 93/42/CEE (Amended 2007/47) transposed by the French regulations on medical equipment (Official Bulletin - L169 - 12th of July, 1993).

In accordance with these provisions, the **MD** must only be used by someone with experience of dental medicine for the application described, and in compliance with the provisions in effect in relation to the prevention of accidents at work, protection of employment and the instructions for use. This **MD** must be prepared and maintained only by people trained in the prevention of infection, self-protection and protection of patients.

In accordance with these provisions, the user must :

- only use working instruments without defects,
- only use the the device on drive units which comply with the directives of Standard : EN 60 601
- observe correct use,
- protect themselves and the patient or third party against any danger,
- prevent all contamination by the product.

III. GENERAL SAFETY INFORMATION

Before use, check that the **MD** is not damaged and that no part of it is missing.

- Use protective gloves, glasses and a mask.
- When inserting or changing the instrument, make sure that the **MD** is stationary.
- After insertion of a instrument, check that it is correctly held by a slight rotary movement.
- Do not handle the instrument during operation.
- Only operate the locking catch when the motor is stopped.
- The attachments should be connected or disconnected and away from the patient's mouth.
- The **MD** should be connected or disconnected to the motor when the motor is stationary.

In the event of visible malfunction or damage, immediately stop using the instrument and inform your approved distributor or the manufacturer.
In the event of any questions on the equipment, contact either your approved distributor or the manufacturer.

No alteration or addition is to be made to the product without Anthogyr's express agreement.

Only use accessories designed for this device. Do not use the accessories of **MD** on another type or another brand of **MD**.

IV. TECHNICAL SPECIFICATIONS 6920

Color code	1 blue ring
Weight (g)	110
Total length (mm)	145,5
Light	No
Nb of spray outlets	0
Minimum recommended motor speed (rpm)	10 000
Connection for inserts	Anthogyr M4 only
Compatible inserts	OPIP 100 / OPIP 200 / OPIP 400
Irrigation system	No
Coupling size (NF EN ISO 3964: 2016)	Long
Type of coupling (NF EN ISO 3964: 2016)	Type 1

V. PRODUCT DESCRIPTION

1 Motor connection
2 Attachment connection (tightened)
3 Handle2

VI. USING MD

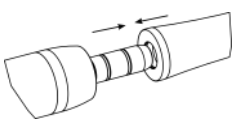
The **MD** is supplied **unlubricated and unsterilised**. Before first use, the **MD** should be **cleaned, disinfected, lubricated and sterilised**. (Cf §7: "Hygiene and maintenance")

Before use, check that The **MD** is not damaged and no part is missing.

6.1 Connecting to the motor :

WARNING: **MD** should be connected to the motor only when the motor is stationary and away from the patient's mouth.

Lock the **MD** to the motor coupling (as for EN 23964). To do so, keep the motor and The **MD** on the same axis.
For certain motors, it is necessary to operate the side button to allow connection. Pull The **MD** slightly before use in order to check that it is securely connected to the motor coupling.



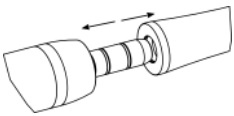
• Operating test

Activate the motor in the normal direction (the device will not function if the motor is in "reverse" mode), and exert traction on an attachment which has already been affixed (See §6.3 Connecting an attachment) to engage the system. Check to make sure that the Device is producing regular strokes.

NOTE: If you notice heating, irregularities, vibrations or abnormal sounds during the operation of **MD**, immediately contact your approved technical department.

6.2 Disconnecting from the motor :

WARNING: The **MD**, should only be disconnected when the motor has stopped and away from the patient's mouth.Remove the **MD** whilst keeping it in the motor axis.For certain motors, it is necessary to operate the side button to disconnect the **MD**.



NOTE: In the event of prolonged non-use of **MD**, do not leave it connected to the motor so as to avoid oil leakage into the motor. The motor could be damaged.

6.3 Adjustment :

Stroke frequency adjustment:

The stroke frequency is directly linked to the rotation speed of the motor. Maximum speed: 10 000 rpm.The higher the input speed, the higher the stroke frequency will be (close strokes).Conversely, a decrease in motor speed will produce widely spaced strokes.

The table below illustrates the relationship between motor speed and stroke frequency:

rpm	2000	4000	6000	8000	10000
Strokes/min	21	42,5	62,5	85	100

6.4 Connection/disconnection of the instrument :

It is preferable to wear protective gloves for all tool handling. Cut risk.

Check the condition of the rotary instruments used and handle them cautiously and carefully.

It is essential that the motor is stopped when inserting or extracting the instrument and away from the patient's mouth (except wires).

To connect or disconnect the instrument, screw or unscrew them on to the connection.

MD lifecycle

If used in a proper manner, all **MD** parts have a lifecycle corresponding to 100 sterilisation cycles.

However, these indications are not a warranty because wear may appear prematurely, depending on how the **MD** is maintained (cleaning and sterilisation).

VII. HYGIENE AND MAINTENANCE

Re-sterilization of reused medical appliances has to be done by someone who has been trained and is protected, and the regulations in force have to be adhered to. The re-sterilization protocol must be adapted to the infectious risk.

GENERAL RULES

• Refer to the manufacturer's instructions for each product used. Take particular care to adhere to the instructions regarding concentrations, lengths of exposure, the replacement of solutions, and the lifespan of the products.

• Only use products intended for the maintenance of medical and surgical equipment.

• Do not use antiseptics which are designed to be used on the skin and mucous membranes. Use only products which are pH neutral or alkaline. Do not use products containing Aldehydes, alcohol or other products liable to set proteins.

• Use only products compatible with aluminiums (no Alkaline solution Ph>7)

• Wear suitable protective clothing. In order to avoid any risk of infection and injury, it is vital to wear protective gloves.

• Never immerse the **MD** in any kind of solution. Never clean the **MD** in an ultrasonic tank. The motor must always be disconnected or stopped before handling the equipment in any way.

• Sterilization of reused medical appliances has to be done by someone who has been trained and is protected, and the regulations in force have to be adhered to. The sterilisation protocol must be adapted to the infectious risk.

• Never combine products. Adhere to the guidelines regarding the disposal of used products.

• The following procedures are to be carried out after each operation: Pre-disinfection, cleaning, disinfection, lubrication and sterilisation.

7.1 Pre-disinfection :

Pre-disinfection has to be made immediately after the operation.

• External disinfection using a spray or microbiologically-controlled disinfectant wipes.

Never immerse the **MD** in any kind of solution. Never clean the **MD** in an ultrasonic tank.

7.2 Cleaning :

• Rinse the device in demineralised water.

• Carefully dry each part.

7.3 Disinfection :

With disinfectant wipes (recommended) or a spray. Follow the manufacturer's instructions for use.

7.4 Lubrification :

• This should be done before first use.
• It also must be done before every sterilization.
• Keep away from any heat or fire source. Do not smoke!
• Wear a protective mask.
• Remove the instrument
• Insert the spray into the **MD**.
• Make sure that the nozzle is the right one.
• Cover the head of the **MD** with a small decontaminating cloth.
• Put the head upside down.
• Spray several times until the liquid coming out of the **MD** is clear.
• Wipe the oil excess off with a rag or with a small cloth.

7.5 Operating test :

This test must be performed prior to each sterilisation.

Connect the **MD** to the motor ; point the head of the **MD** downwards. Operate the **MD** slowly (5 000 rpm motor) for 30 seconds in order to get rid of the excess oil, then at full speed (10 000 rpm motor) for 30 seconds. Wipe the **MD** with a disinfectant wipe if the oil has dripped.

NOTE : if you notice a rise in temperature, irregularities, vibrations, or abnormal noises during operation of the **MD**, contact your approved technical service immediately.

7.6 Sterilisation :

The **MD** is supplied unlubricated and unsterilised. The **MD** should be sterilised before they are first used and following each use.

• Only sterilise instruments which have previously been disinfected, cleaned, lubricated and tested.

135°C The Device should be sterilised at 135°C at 2.13 bars (275°F at 30.88 psi), in a steam steriliser only, for a minimum duration of 20 minutes (time for which sterilisation must be continued).

• We strongly recommend the use class B autoclave .

• Any other method of sterilisation should be avoided.

Read the instruction leaflet provided by the steriliser manufacturer.

• Remove the instrument from the **MD** prior to sterilisation.

• Use sterilisation pouches suitable for **MD** and the steriliser, in accordance with the standard in force. Always use one single **MD** per pouch.

• Adhere to the space specified between pouches and do not overload the steriliser.

• Make sure that the device does not have any areas of corrosion or cracks, and check that it is operating properly. Ensure that the product is dry ; if necessary, dry any residual water with medical quality pressurised air.
• After each sterilisation cycle, check that there is no water remaining on the inside and outside of the packaging. Make sure that the flow indicator has changed to the correct color.
• In order to avoid any retention of water, place the pouch in the steriliser in such a way that any concave parts are face down.
• Keep the devices in the sterilisation pouches away from light, moisture and any contamination. Follow the manufacturer's recommendations as seen on the packaging.
• The duration for which the device is kept after sterilisation should not exceed 1 month. Label the devices, specifying the expiration date.
After the expiration date, repeat the cleaning and sterilisation procedure.

VIII. REPAIR

In the event of breakdown, please contact your approved distributor or the Anthogyr after sales sevice department directly.

All repairs must be carried out with parts and subassemblies approved by the manufacturer.Repairs must only be carried out by an approved distributor or by the after sales service department at the factory.
For any revision or repair the instrument must be returned complete and sterile with proof of sterility.
It must be sent together with a document stating the problem as well as the complete name and address of the dentist.

For any claims to be considered under the warranty, please enclose a copy of the invoice or the delivery note with the equipment.
Replacement of parts is guaranteed for 7 years after the product ceases to be marketed.

AFTER-SALES DEPARTEMENT CONTACT DETAILS

Service S.A.V.
ANTHOGYR
2237, Avenue André Lasquin – 74700 Sallanches - FRANCE
Direct line : +33 (0)4 50 58 50 53
Mail : contact@anthogyr.com

IX. MEDICAL DEVICE REFERENCES

Description	References
AUTOMATIC MICRO IMPACTOR	6920
AUTOMATIC MICRO IMPACTOR	6920-P

X.ACCESSORIES

To be ordered from your approved distributor.
Use Anthogyr attachments ONLY.

Description	References
Tip for abutment 0°/7°	OPIP 100
Tip for abutment 15°/23°	OPIP 200
Tip for extra-orally cemented prosthesis	OPIP 400

XI. WARRANTY

This **MD** is guaranteed parts and labour against all manufacturing defects for 12 months from the date of invoice.
This guarantee does not apply to wear.
All changes or additions to the product without the express agreement of Anthogyr render this guarantee null and void.
The guarantee becomes null and void if the technical instructions are not followed.
Anthogyr cannot be held responsible for damage resulting from or which could result from normal wear, use, cleaning or incorrect maintenance, the non-observance of instructions for use or connection, scaling or corrosion, impurities in the water supply system or unusual chemical or electrical influences or non observance of the instructions, maintenance instructions and assembly of Anthogyr and other manufacturer's instructions.
Delivery charges incurred when sending an instrument back to anthogyr for repair will be paid by the client, even if the repair itself is covered by the guarantee.
Postage and packing fees when returning the instrument to the client are covered by the guarantee.
So that guarantee requests are taken into consideration, please attach a copy of the invoice or a copy of the delivery slip to the **MD**.

XII. DISPOSAL OF THE PRODUCT

As far as is currently known, the product does not contain any substances which are harmful to the environment.
The product must be sterilised before being disposed of.
Observe national rules with regard to disposal.

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