# SAFE


IMPACTEUR AUTOMATIQUE
AUTOMATIC IMPACTOR
AUTOMATISCHER IMPAKTOR
IMPACTADOR AUTOMÁTICO
IMPATTATORE AUTOMATICO
IMPACTADOR AUTOMÁTICO
AUTOMATISCHE IMPACTOR
自动敲击器
آلة سحق بالصدم أوتوماتيكية

**FR - NOTICE D'INSTRUCTION**
**EN - INSTRUCTIONS FOR USE**
**US - INSTRUCTIONS FOR USE**
**DE - GEBRAUCHSANWEISUNG**
**ES - INSTRUCCIONES DE USO**
**IT - ISTRUZIONI PER L'USO**
**PT - INSTRUÇÕES DE USO**
**NL - GEBRUIKSAANWIJZING**
**ZH -** 使用说明
**AR -** تعليمات الاستخدام

Anthogyr
PRIME MOVER IN IMPLANTOLOGY

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## I. DESCRIPTION OF SYMBOLS USED

DANGER

Please wear gloves

Visual examination

Please read this!

LOT Batch number of the device

REF Device reference

Sterilisable up to 135°C

Heat disinfectable

Manufacturing date

Manufacturer

**MD** Medical Device (Impactor + Instruments)

Non-sterile device

## II. INDICATIONS FOR USE

The **MD** (Impactor + Instruments) is intended for dental surgery. The **MD** Impactor is designed to generate shocks with a controlled intensity and duration. The number of micro-impacts is regulated by the motor speed.

It is intended for use in the following areas:

➔ Osteotomy:
Combined with the "osteotome" instruments, this **MD** impactor will facilitate the performance of the "tapping" type osteotome technique without the need for a mallet. It will enable sinus lift procedures to be performed using the crestal approach and osseous condensations in the jaw where bone mineral density is low.

➔ Tooth extraction:
Combined with the "periotome" instruments, this **MD** impactor will initiate tooth mobility by enlarging the desmodontal space in the interproximal, lingual and distal areas with the ultimate aim of atraumatic extraction. The use of periotomes helps preserve the alveolar bone.

➔ The prosthesis:
Combined with the "end-piece impaction" instruments, this **MD** impactor will facilitate the placement of prosthetic components by means of impaction for the Axiom 2.8 range.

## III. AREA OF APPLICATION

This **MD** (impactor + instruments) is intended exclusively for professional use in the field of dental surgery.
Inappropriate or incorrect use could damage this device and result in hazardous risks to the user and to third parties.

In accordance with these provisions, the **MD** (impactor + instruments) may only be used by a user with experience in dental medicine, for the described application, and in line with applicable provisions concerning the prevention of accidents at work, and protection at work, as well as the indications in these operating instructions. Preparation and maintenance of this **MD** (impactor) may only be carried out by persons who have been trained in the field of infection control, in self-protection and in the protection of patients.

In accordance with these provisions, the user must:
- Use working instruments solely without defects,
- Observe the correct intended use
- Protect themselves, as well as the patient or third parties, against any dangers
- Prevent any contamination by the product

The following situations:
- Inappropriate use,
- Lack of maintenance,
- Use of accessories, instruments and spare parts that have not been authorised by Anthogyr.
- Use of accessories and instruments from this **MD** with other devices.
- Modifications or additions not validated by Anthogyr to **MD** relieve Anthogyr of any obligation with regard to the guarantee or other claims.

This **MD** comply with Community Directive 93/42/EEC, amended by Directive 2007/47/EEC.

## IV. GENERAL SAFETY INFORMATION

Before use, ensure that the **MD** (Impactor + Instruments) is not damaged and that there are no parts missing. Check the condition of the instruments used and handle them with due care and attention.
The practitioner should test the **MD** Impactor without the patient to ensure that it is working properly.

Protective gloves should preferably be used whenever the tools are handled. Wear suitable protective clothing, particularly gloves, a mask and goggles.

After insertion of an instrument, check its correct retention with a slight axial movement.

Resterilisation of reusable **MD** must be performed by properly trained and protected personnel, in accordance with the applicable regulations.

In the case of visible malfunctions or damage, stop using the instrument immediately and inform your authorised distributor or the manufacturer.

In the case of any questions regarding the device, contact either your authorised distributor or the manufacturer.

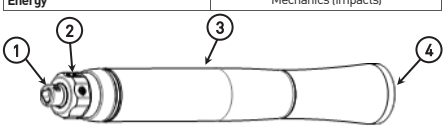
All repairs must be carried out using parts and subassemblies certified by the manufacturer.

The use of a rubber dam in order to prevent tools falling into the mouth is strongly recommended.

Only use **MD**s (Instruments) that are compatible with the **MD** (Impactor).
Do not use instruments from this device on any other type or brand of **MD** or with any other device.

## V. TECHNICAL SPECIFICATIONS

| REFERENCE | 69200ST/6920 |
|---|---|
| **Total length (mm)** | 142 |
| **Sleeve length (mm)** | 124 |
| **Maximum sleeve diameter (mm)** | 20 |
| **Rod diameter (mm)** | 7 |
| **Weight (g)** | 195 |
| **Connection tool** | Standardised mandrel (ISO 1797-1) Mandrel with tri-lobe (proprietary Anthogyr connection) |
| | Locking through rotation of the ring |
| **Connection motor** | ISO 3964 |
| **Maximum torque transfer with the MD** | Using the "tri-lobe" tools: 200 N.cm Using the ISO-standard tools: 80 N.cm |
| **Energy** | Mechanics (impacts) |




1 — Tool connection
2 — Ferrule
3 — Sleeve
4 — Motor connection

**Relationship between the input rotational speed (motor) and the output impact frequency**

| | Ratio 1:1 | Safe Impactor |
|---|---|---|
| | *rpm* | *Impacts per minute* |
| | 2 000 | **20** |
| | 5 000 | **50** |
| | 10 000 | **100** |
| MAX | 15 000 | **150** |

## VI. MD START UP PROCEDURE

The **MD** (Impactor + Instruments) are supplied **non-sterile** and **non-lubricated***.

Before using for the first time, the **MD** (Impactor + Instruments) must be **cleaned, decontaminated, lubricated* and sterilised** (see the section on "Hygiene and maintenance").
*: for the "Impactor SAFE3" **MD** only

Resterilisation of reusable **MD** (Impactor + Instruments) must be performed by properly trained and protected personnel, in accordance with the applicable regulations. The resterilisation protocol must be adapted for a risk of infection.

Before use, check that the **MD** (Impactor + Instruments) and/or the osteotomes are not damaged and that no parts are missing. Check the condition of the instruments used and handle them with caution and care. *(The list of accessories is included in paragraph IX)*

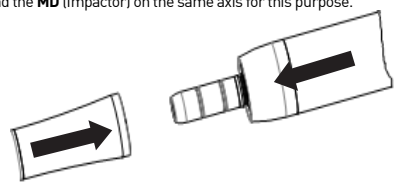
### 6.1. Motor connection:

Protective gloves should preferably be used whenever the tools are handled.

Check the condition of the **MD** Impactor used and handle it with due care and attention.

The **MD** (Impactor) may only be connected to the motor outside of the patient's mouth and when the motor has been stopped.

Position the **MD** (Impactor) on the motor coupling (in accordance with EN 23964 - ISO 3964) until it clicks into place. Keep the motor and the **MD** (Impactor) on the same axis for this purpose.



For certain motors, it is necessary to activate the side button to facilitate the connection.
Pull gently on the **MD** (Impactor) every time before use in order to verify that it is correctly engaged on the motor coupling.

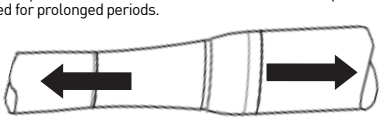
**Functional test**

Run the motor in the normal direction (the device will not operate if the motor is in "reverse" mode). Check that the **MD** (Impactor) properly generates regular micro-impacts.
NOTE: If you notice overheating, irregularities, vibrations or abnormal sounds during operation of the **MD** (Impactor), immediately contact your authorised technical service centre.

### 6.2. Disconnecting the motor:

CAUTION: The **MD** (Impactor) may only be disconnected when the motor has been stopped, and outside of the patient's mouth. Withdraw the **MD** (Impactor) while maintaining the axis of the motor. For certain motors, it is necessary to activate the side button to enable the **MD** (Impactor) to be disconnected.

NOTE: To prevent oil from leaking into the motor, do not leave the **MD** (Impactor) connected to the motor if the **MD** (Impactor) is not used for prolonged periods.



### 6.3. Connecting / disconnecting the instrument:

The instruments may only be connected to the **MD** Impactor when the motor is switched off and outside the patient's mouth.

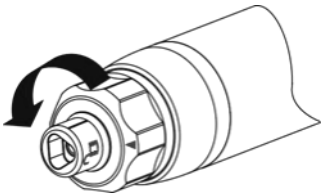
Protective gloves should preferably be used whenever the tools are handled.

Check the condition of the instruments used and handle them with caution and care.

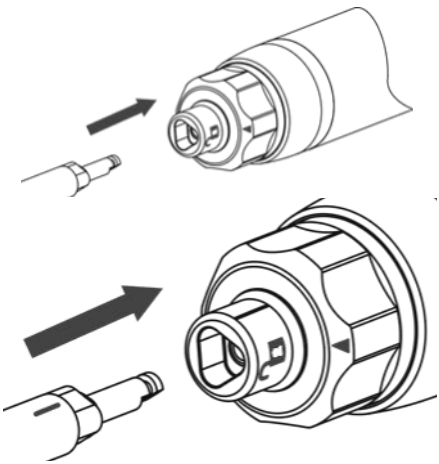
### 6.4. Locking/unlocking the MD (Instruments) in the MD (Impactor) :

**Positioning a tool:**

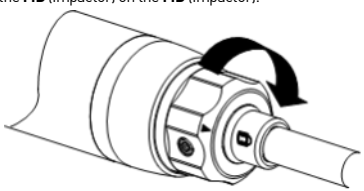
• Align the arrow on the ferrule with the open padlock



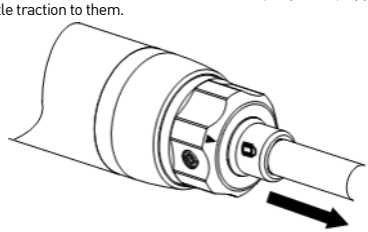
• If the **MD** (Instruments) has a trefoil symbol, align the symbol on the **MD** (Instruments) with the symbol at the end of the **MD** Impactor connection and insert the **MD** (Instruments).



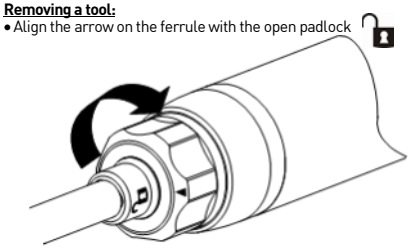
• If the **MD** (Impactor) is standard, insert the tool by locating the drive bar.
• Turn the collet to align the arrow with the closed padlock and lock the **MD** (Impactor) on the **MD** (Impactor).



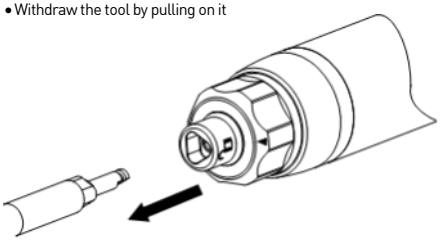
• Check that the **MD**s (Instruments) are firmly in place by applying gentle traction to them.



**Removing a tool:**
• Align the arrow on the ferrule with the open padlock



• Withdraw the tool by pulling on it



After insertion of an instrument, check its correct retention with a slight axial movement.
It is essential that the motor is stopped and outside of the patient's mouth whenever the instrument is inserted or extracted.

The **MD** (Impactor + Instruments) does not require maintenance work. Nevertheless, should you notice a functional defect in the locking or gripping mechanism, this could mean that it is damaged. In this case, immediately return the device to the Anthogyr after-sales service department.
Make sure that the device does not have any areas of corrosion or cracks, and check that it is working properly.

**MD lifecycle**
If used in a proper manner, all **MD** parts have a lifecycle corresponding to 250 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

Sterilisation of **MD** (Impactor + Instruments) must be performed by properly trained and protected personnel, in accordance with the applicable regulations. The sterilisation protocol must be adapted for the risk of infection.

In order to avoid any risk of infection and injury, it is essential to wear protective gloves.

Refer to the manufacturer's instructions for each product used. Observe the concentrations, lengths of exposure and the lifespan of the products. Do not combine products and observe the provisions regarding their disposal.

Only use products that are intended for the maintenance of medical and surgical equipment, compatible with stainless steel (no chlorine compounds), and compatible with aluminium (no soda).

Avoid the use of antiseptics that are intended for use on the skin and on mucous membranes.
Avoid the use of products containing aldehydes, alcohol or other products that are likely to bind proteins.
Preference should be given to detergents / disinfectants that are pH neutral or slightly alkaline.

The device must be cleaned and sterilised after every procedure.

The motor must be disconnected or stopped before handling.

Instruments must not be connected to the **MD** Impactor.

The **MD** Impactor is not removable and is not submersible.

The instruments are submersible.

**7.1. Manual preparation for sterilisation:**
Reprocessing of the **MD** (Impactor + Instruments) must be carried out as soon as possible after treatment (within max. 2 hours).

**By brushing:**
• Brush under running water using a soft brush.
• Clean the entire **MD** (Impactor + Instruments) using a disinfectant wipe.

**Or by spraying:**
• Spray the disinfectant on to the **MD** (Impactor + Instruments) and wipe using a clean cloth.

**Rinsing and drying**
• Rinse properly[1]
• Dry the entire **MD** (Impactor + Instruments).

**7.2. Automatic preparation for sterilisation:**
Only use a washer-disinfector appropriate for the reprocessing of this type of **MD** (Impactor + Instruments). Follow the instructions provided by the manufacturer of the unit.

• If the unit is equipped with nozzles for contra-angles: Fit the **MD** Impactor onto the nozzle of the device.

• If the unit is not equipped with nozzles for contra-angles: without disassembling the **MD** impacor, position it with the tool connection component pointing upwards. Position the parts so that any retention of fluid is avoided. Immobilise each part.

• The thermal disinfection cycle must be at least 10 minutes at 93° C (203°F).

• Follow the instructions for use provided by the thermal disinfector manufacturer, and in particular the recommendations regarding the products that should or should not be used with the unit.

• Observe the drying cycle (Caution: Do not exceed 140°C (284°F) during the drying cycle)

• Check that there is no residue and that all parts of the **MD** (Impactor + Instruments) are perfectly dry at the end of the cycle.

**The MD impactor is not submersible.**

**7.3. Lubrication:**

• Wear a protective face mask.

• Disconnect the **MD** (Impactor) from the motor before handling.
• Remove the connected instrument in the **MD** (Impactor)
• Check that the nozzle of the spray is the correct one for use with the **MD** (Impactor).
• Insert the aerosol spray at the back of the **MD** (Impactor).
• Cover the head (connecting part) of the **MD** (Impactor) with a wipe.
• Position the head (connecting part) of the **MD** (Impactor) downward.
• Spray several times, keeping the **MD** (Impactor) closed.
• Wipe off surplus oil with a soft cloth or a wipe.

Lubricate after each decontamination and before each sterilisation, and repeat in the event of prolonged use.

Keep away from heat and ignition sources. Smoking is strictly prohibited!

**7.4. Functional test:**
This test must be performed every time prior to sterilisation. Connect the **MD** (Impactor) to the motor and point the head downwards. Run at low speed (5000 motor rpm) for 30 seconds in order to clear the excess oil, then at full speed (10,000 motor rpm) for 30 seconds. Wipe the **MD** (Impactor) with a disinfectant wipe if the oil has dripped.

**Note:** If you notice overheating, irregularities, vibrations or abnormal sounds during operation of the **MD** (Impactor) , immediately contact your authorised technical service centre.

**7.5. Sterilisation:**
Resterilisation of reusable **MD**s must be performed by properly trained and protected personnel, in accordance with the applicable regulations. The resterilisation protocol must be adapted for a risk of infection.

The **MD** (Impactor + Instruments) and the accessories must be sterilised before they are used for the first time, and every time after they are used (after cleaning and disinfection).
Do not sterilise instruments unless they have been pre-disinfected, cleaned, decontaminated, lubricated (only the **MD** Impactor) and tested.

No disassembly of the **MD** is envisaged prior to performing sterilisation.

*[1]: Temperature <38°C, demineralised water is recommended instead of running water, for example if the latter contains too much chlorine (see the FD98-135 standard)*

We strongly advise the use of a class B autoclave.
All other methods of sterilisation must be avoided.
Read the instructions for use provided by the autoclave manufacturer.
Maintain the space between the bags and do not overload the autoclave.
Only sterilise instruments that have been predisinfected, cleaned, lubricated and tested.
Remove the instruments from the **MD** Impactor before sterilisation (See Section 5.5).
Make sure that the **MD** (Impactor + Instruments) do not have any areas of corrosion or cracks, and check that it is working properly.
Ensure that the **MD** (Impactor + Instruments) are dry; if necessary, dry any residual water using medical quality pressurised air.
Use the sterilisation bags that are designed for the **MD** (Impactor + Instruments) and for the autoclave, or use a sterilisation cassette.
**Each bag should always only contain one MD or sterilisation tray.**

⚠ In order to avoid any retention of water, place the bag in the autoclave in such a way that any hollow parts are face down.

If the pre-vacuum autoclave offers a number of different cycles, choose a cycle for **MD** (**at least 135°C at 2.13 bar (275°F at 30.88 psi) for 3 minutes with a drying time of 16 minutes)**.

After every sterilisation cycle, check that there is no water remaining on the inside and outside of the packaging.
Check that the change in colour of the flow indicator is correct.

**7.6. Storage:**

Keep the **MD** (Impactor + Instruments) in the sterilisation bags away from light, moisture and contamination of any kind. Follow the recommendations of the packaging manufacturer.

**The duration for which the MD (Impactor + Instruments) may be kept after sterilisation may not exceed 1 month.**
Label the **MD** (Impactor + Instruments), specifying the expiration date. After the expiration date, repeat the cleaning and sterilisation cycle.

## VIII. REPAIRS

In the case of device failure, please contact your authorised distributor, or contact our after-sales service department directly.
Repairs may only be carried out by an authorised repair service or by the Anthogyr after-sales service department, and only using original Anthogyr replacement parts.
For any servicing or repair work, the **MD** must be returned complete and **sterile** with proof of sterility. It must be accompanied by a document that describes the problem in question and also includes the complete contact details of the practitioner who used the device.
Exchange of replacement parts is possible for 7 years after sales discontinuation.

**CONTACT DETAILS: AFTER-SALES SERVICE**
AFTER-SALES SERVICE DEPARTMENT
Anthogyr
2237 Avenue André Lasquin - 74700 Sallanches - FRANCE
Direct line: +33 (0)4 50 58 50 53
Mail: sav@anthogyr.com

## IX. GUARANTEE

These **MD** (Impactor + Instruments) are guaranteed for parts and labour against any defect in manufacture for a period of **12** months from the date of invoicing. This guarantee does not apply to wear parts and does not cover transport costs. For claims to be considered under the guarantee, please enclose a copy of the invoice or the delivery note with the **MD** (Impactor + Instruments) .
Any modification of or addition to the product without the express consent of Anthogyr will nullify this guarantee.
The guarantee shall become null and void if the technical instructions supplied with all of our equipment are not observed.
Anthogyr cannot be held responsible for damage and ensuing damage resulting or possibly resulting from normal wear and tear, incorrect use, cleaning or maintenance, non-compliance with the provisions regarding use or connection, scaling or corrosion, impurities in the water supply system or abnormal chemical or electrical effects, or non-compliance with the instructions for use, maintenance or installation provided by Anthogyr, and other manufacturer instructions.

## X. ACCESSORIES - INSTRUMENTS

### Instruments

| References | Designation | |
|---|---|---|
| **OSTSCC34** | OsteotomeØ3.4 concave straight | OSTEOSAFE Solution |
| **OSTSCC40** | OsteotomeØ4.0 concave straight | |
| **OSTSCC46** | OsteotomeØ4.6 concave straight | |
| **OSTSCC52** | OsteotomeØ5.2 concave straight | |
| **OSTSCX34** | OsteotomeØ5.2 convex straight | |
| **OSTSCX40** | OsteotomeØ4.6 convex straight | |
| **OSTSCX46** | OsteotomeØ4.0 convex straight | |
| **OSTSCX52** | OsteotomeØ3.4 convex straight | |
| **OSTECC34** | Osteotome Ø3.4 concave bayonet | |
| **OSTECC40** | Osteotome Ø4.0 concave bayonet | |
| **OSTECC46** | Osteotome Ø4.6 concave bayonet | |
| **OSTECC52** | Osteotome Ø5.2 concave bayonet | |
| **OSTECX34** | Osteotome Ø3.4 convex bayonet | |
| **OSTECX40** | Osteotome Ø4.0 convex bayonet | |
| **OSTECX46** | Osteotome Ø4.6 convex bayonet | |
| **OSTECX52** | Osteotome Ø5.2 convex bayonet | |
| **OPIP100** | Tip for abutment 0°/7° | SAFE LOCK® Solution |
| **OPIP200** | Tip for abutment 15°/23° | |
| **OPIP400** | Tip for extra-orally cemented prosthesis | |
| **PERI001** | Cx right Fine Periotome | EXO SAFE Solution |
| **PERI002** | Cx right Wide Periotome | |
| **PERI003** | Cx Ang. Vertical Periotome | |
| **PERI004** | Cx Ang. Horizontal Periotome | |
| **PERI005** | Cc right Fine Periotome | |
| **PERI006** | Cc right Medium Periotome | |

### Accessories

| References | Designation | |
|---|---|---|
| **1930X** | Lubricating spray | All solutions |
| **1932X** | ISO type E connection tip | |

## XI. CONDITIONS OF STORAGE & TRANSPORT


## XII. DISPOSAL OF THE PRODUCT

The **MD** (Impactor + Instruments) must be sterilised before disposal in order to prevent the risk of third-party contamination.
On the basis of current knowledge, the product does not contain any substances that are harmful to the environment. Observe national legislation, standards and provisions with regard to disposal.

Anthogyr
PRIME MOVER IN IMPLANTOLOGY

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