SAFE RELAX®
SAFE REMOVER®

AUTOMATIC / MANUAL CROWN REMOVER

EN - INSTRUCTIONS FOR USE

Anthogyr
PRIME MOVER IN IMPLANTOLOGY

TABLE OF CONTENTS

I.DESCRIPTION OF SYMBOLS USED

WARNING : Important information !

NON STERILE

Please wear gloves

General indications without danger to people or objects

Please read this !

Visual examination

Autoclave at 135°C

REF Reference

SN Serial number

Manufacturer

MD Medical Device

II. AREA OF APPLICATION

This **MD** is intended for use in dental treatment in the field of dental surgery, particularly for the removal of permanent prostheses (single or multiple, bridges). 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 **MD** on drive units which comply with the directives of Standard : EN 60 601 / 93/42/CEE,
• 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.
• After insertion of a instrument, check that it is correctly held by a slight rotary movement.
• When inserting or changing the instrument, make sure that the **MD** is stationary.

For Safe Relax® only :

• 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 **MD**. Do not use the accessories of **MD** on another type or another brand of **MD**.

IV. TECHNICAL SPECIFICATIONS

4.1 Automatic crown remover (Safe Relax®) :

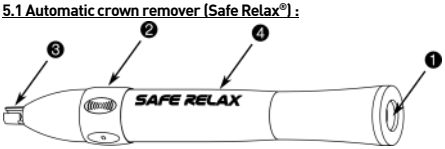
REFERENCE	6950C	6961C
Weight (g)	260	288
Length MINI / MAXI (mm) of Crown-remover (excluding tool)	132 / 140	
Maximum diameter (mm)	Ø 20	
Motor connection standard	EN 23964	
Minimum recommended motor speed (rpm)	5 000	
Maximum recommended motor speed (rpm)	25 000	
Minimum stroke frequency at 5000 rpm	200 Strokes/min	
Maximum stroke frequency at 25000 rpm	1 000 Strokes/min	
Number of intensity adjustment settings	5	
Number of hooks	4	
Number of wire tips	0	3
Attachments to use	Only Anthogyr!	
Attachment connection	Licensee Anthogyr	
Coupling size (NF EN ISO 3964: 2016)	Long	
Type of coupling (NF EN ISO 3964: 2016)	Type 1	

4.2 Manual crown remover (Safe Remover®) :

REFERENCE	1820A	ATD310B
Weight (g)	177	279
Maximum length MAXI (mm) of Crown-remover (excluding tool)	190	
Number of hooks	4	
Number of wire tips	0	
Attachments to use	Only Anthogyr!	
Attachment connection	Licensee Anthogyr	

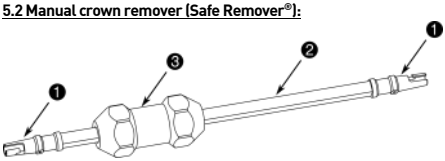
V. PRODUCT DESCRIPTION

5.1 Automatic crown remover (Safe Relax®) :



1. Motor connection
2. Intensity adjustment band
3. Attachment connection (Bayonet)
4. Handle

5.2 Manual crown remover (Safe Remover®):



1. Attachment connection (Bayonet)
2. Rod
3. Counterweight

VI. USING SAFE RELAX

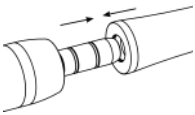
The **MD** is supplied **unlubricated* and unsterilised**. Before first use, the **MD** should be **cleaned, disinfected, lubricated* and sterilised**. (Cf §**VII**: "Hygiene and maintenance")

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

*For Safe Relax® only

6.1 Connecting to the motor (For Safe Relax® only) :

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



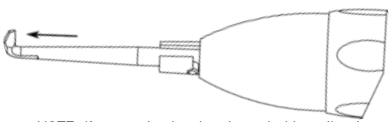
Lock the **MD** to the motor coupling (as for EN 23964). To do so, keep the motor and The **MD** on the same axis.

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 **MD** will not function if the motor is in "reverse" mode), to engage the system, exert slight traction on an attachment which has already been affixed (see § 6.3 - Connecting an attachment) until you feel micro-strokes.

Check to make sure that the **MD** is producing regular strokes.

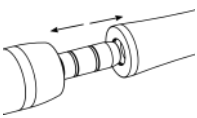


NOTE: If you notice heating, irregularities, vibrations or abnormal sounds during the operation of **MD**, immediately contact your approved technical department.

6.2 Disconnecting from the motor (For Safe Relax® only) :

WARNING: **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 (For Safe Relax® only) :

Stroke frequency adjustment:

The stroke frequency is directly linked to the rotation speed of the motor. Maximum speed: 25000 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.

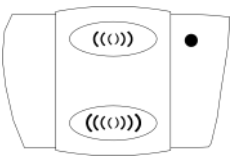
The table below illustrates the relationship between motor speed and stroke frequency:

Stroke intensity adjustment:

rpm	10000	12000	15000	20000	25000
Strokes/min	400	500	600	800	1000

The Automatic Crown-remover is fitted with a notched adjustment band which has 5 intensity settings, making it adaptable to the requirements of the specific clinical case.

The settings are identified as follows, from the lowest to the highest:



NB: The notch for the desired setting (5 shown here) should be aligned with the "Safe Relax" logo.

After the clinical case has been analysed, it is recommended that a low frequency and intensity be used to initiate treatment, and gradually increase both settings if necessary. Before any operation is carried out, it is strongly recommended to verify that the **MD** is working properly, away from the patient's mouth.

6.4 Connection/disconnection of the instrument :

(For both Safe Relax® and Safe Remover®)

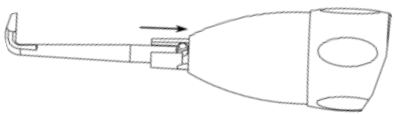
It is preferable to wear protective gloves for all tool handling. Cut risk.

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

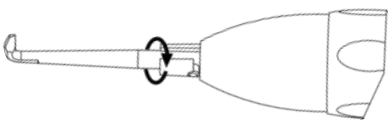
It is essential that the motor is stopped* when inserting or extracting the instrument and away from the patient's mouth (except wires).

* For Safe Relax® only

Inserting and locking the instrument:



• Insert the attachment (Hook or ATD Wire-Tip) into the bayonet by pushing it fully into the recess.

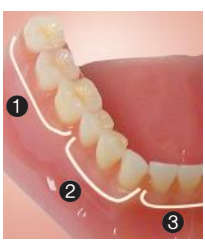


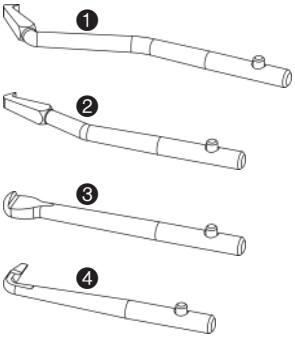
• Give a quarter-turn to the left to lock the spigot into its ratchet position.

• Check that the instrument is properly attached, through a slight axial movement with each tool change.

6.5 Use of the hooks:

(For both Safe Relax® and Safe Remover®)





1. Bended hook for posterior teeth : Réf 5928

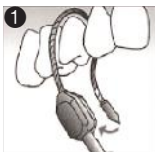
2. Simple hook for anterior teeth : Réf 5927

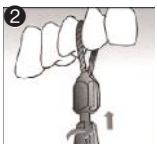
3. Flat hook with non skidding : Réf 5929

4. Hook for bridges : Réf 5925

6.6 Use of ATD Wire-Tips:
(For both Safe Relax® and Safe Remover®)

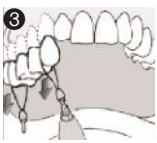
Bridges :
1. Insert the metal wire in the interdental space, as near as possible to the crown, either from palatal or labial side.
Close the loop by inseting the sharp end in its groove.
50 mm wire for the anterior.
60 mm wire for the posterior.

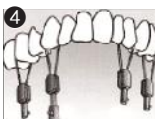




2. Attach the Wire-Tip to the Crown-Remover. (See §6.4 Connecting the attachment)

3. Activate the Crown-remover.

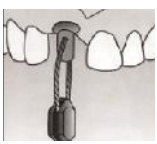




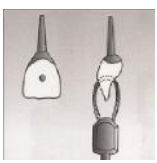
4. To remove a long span bridge :
• Fasten several wire-tips to avoid moving them.
• Move the crown-remover from one wire to the next in the given order to divide the traction power.

Inlays-cores :
To remove an artificial tooth stump (inlaycore), bore an horizontal labiolingual hole of a least 1 mm diameter.

Insert the metal wire and proceed as with a bridge.



Richmond :
To remove a Richmond proceed in the same way.

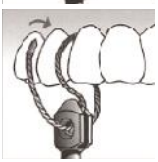


CERAM wire tip :
To remove a small ceramic bridge (without metal frame) or a ceramo metallic bridge or a temporarily fixed bridge on parallel abutments :
Take the ceramic-tip with a 95 mm screwed wire for a 3 el. bridge, or with a 150 mm screwed wire for a 4 el. bridge.

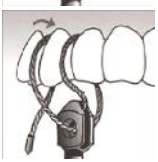
• Insert the metal wire in vestibulo-palatin or lingual way in the first interdentalspace, starting with the most anterior tooth of the bridge.

• Place the wire in anterior/molar direction through the hole of the tip.

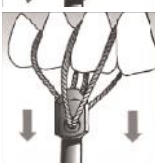
• Insert the wire in the following interdental space in the same vestibulo-palatin or lingual direction.



• Close the metal loop by passing the sharp end in its groove.



• Do it a third time if necessary. Fasten the adaptor on the wire-tip and activate the crown-remover.



To change the wire :
• Unscrew the screw preferably (above a plate to avoid losing it).
• Place the new wire short and unsharp side in the threading spot (marqued 0). Screw thoroughly.

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

⚠ Re-sterilisation 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-sterilisation 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 (between 2.5 and 9.0 inclusive). Do not use products containing Aldehydes, alcohol or other products liable to set proteins.
• Use only products compatible with stainless steel (chlorine-free ingredients).
• Wear suitable protective clothing. In order to avoid any risk of infection and injury, it is vital to wear protective gloves. Furthermore, the motor must always be stopped before handling the equipment.
• Sterilisation 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.

* For Safe Relax® only

7.1 Pre-disinfection :
Pre-disinfection has to be made immediately after the operation. The motor must always be disconnected or stopped before handling the equipment in any way.
• For Safe Relax®, external disinfection using a spray or microbiologically-controlled disinfectant wipes.
Never immerse the Safe Relax® in any kind of solution. Never clean the Safe Relax® in an ultrasonic tank.

• For Safe Remover®, by immersion in a disinfection bath or in an ultrasound tub

7.2 Cleaning :
• Rinse the **MD** 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 Lubrication (For Safe Relax® only) :
• This should be done before first use. It also must be done before every sterilisation.

⚠ • 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 (For Safe Relax® only) :
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 (25 000 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.

• The **MD** 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 NF EN 868. Always use one single **MD** per pouch.

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

• Make sure that the **MD** 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 **MD** 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 **MD** is kept after sterilisation should not exceed 1 month. Label the **MD**, specifying the expiration date. After the expiration date, repeat the cleaning and sterilisation procedure.

* For Safe Relax® only

VIII. REPAIR

In the event of breakdown, please contact your approved distributor or the Anthogyr after sales service 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 ans 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
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Direct line : +33 (0)4 50 58 50 53
Mail : s.serra.sav@anthogyr.com

IX.ACCESSORIES

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

Description	Reference
Plain ATD wire-tip	ATD012
CERAM ATD tip	ATD022
ATD cables, 50 and 60 mm (par 4)	ATD014
ATD cables, 95 and 150 mm (par 4)	ATD024
M2x3 screw for wire-tip	ATD080
Screwdriver for wire-tip	ATD082
Set of 4 cables 50 mm long	ATD014-50
Set of 4 cables 60 mm long	ATD014-60
Set of 4 cables 95 mm long	ATD014-95
Set of 4 cables 150 mm long	ATD014-150

Bridge hook	5925
Plain hook for anterior teeth	5927
Elbow hook for posterior teeth	5928
Flat hook with non-slip grooves	5929
Disassembly key for device head	87M

X. 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 and tear parts.
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**.

XI. CONDITIONS OF STORAGE AND TRANSPORT

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.

Anthogyr
PRIME MOVER IN IMPLANTOLOGY

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