DENTAL SYRINGE FOR CARTRIDGES

EN - INSTRUCTIONS FOR USE

Anthogyr
A Straumann Group Brand

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I. DESCRIPTION OF SYMBOLS USED

DANGER SIGNALS

WARNING : important information !

Wear gloves

Wear goggles

REMARKS

General indications with no danger to people or objects

Please read this !

Visual examination

II. AREA OF APPLICATION

The syringe is used for dental requirements in the area of the field of local or regional anaesthesia, any other form of use is forbidden and can cause danger.

These MDs comply with the community Directive 93/42/ CEE as amended by the 2007/47/CEE directive.

In accordance with these provisions, the contra angle must 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 ofemployment and the instructions for use.

Preparation and maintenance of this medical appliance have to be done exclusively by someone having training on prevention against infections, on self-protection and on protection of the patients.

In accordance with these provisions, the user must:

- only use working cartidges and needles without defects,
- observe the principle of 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 syringe is notdamged and that no part of it is missing.

No modification or addition may be made to the device without the company's express prior agreement.

Significant risk of injury and contamination when handling the device and needles.
We recommend using a needle recapper (Anthogyr, ref. 2470).

Remove the needle immediately after the anaesthetic and place it in a suitable collector.
Comply with current legislation on disposal of medical waste.

Risk of complications related to the anaesthetic: The user must have been trained in first aid and have suitable resuscitation equipment available. When choosing an anaesthetic, the patient's specific counter-indications must be taken into account (carry out an appropriate medical questionnaire).

Choosing the type of needle, the type of anaesthetic, the quantity injected and the speed of the injection are the user's responsibility. The user is also responsible for the aspiration technique (particularly in the case of block or para-apical anaesthetics).

All anaesthetic cartridges which have been used, even partially, must be thrown away.

Risk of the anaesthetic cartridge bursting: use a protective tube, particularly for intraligament or intraseptal anaesthetics.

IV. TECHNICAL SPECIFICATIONS

The cartridge capacity, the type of thread on the needle and, as appropriate, the type of aspiration, are specified on the product label.

Ref.	Designation	Needle thread	Cartridge capacity	Ratio	Tip	Aspiration	Type
1640	Non aspirating syringe with handle	Metric thread	1,8 cc	1	Straight	None	1
3800	Aspirating syringe with handle	Metric thread	1,8 cc	1	Straight	With	2a
3800A	Aspirating syringe with ring handle	Metric thread	1,8 cc	1	Straight	With	2a
2310	Non aspirating Sterilife syringe	Metric thread	1,8 cc	1	Straight	None	1
2320	Auto-aspiration Sterilife syringe	Metric thread	1,8 cc	1	Straight	Auto	2b
2330	Aspirating Sterilife Syringe	Metric thread	1,8 cc	1	Straight	With	2a
2300	Miniject Syringe	Metric thread	1,8 cc	5	Angulated	None	1
2400	Ergoject Syringe	Metric thread	1,8 cc	3	Straight	None	1

V. USING THE SYRINGE

⚠ Risks owing to non-sterile products:
The syringe is not sterile when supplied.

The syringe must be sterilised before it is first used. (See paragraph on "Hygiene and maintenance").

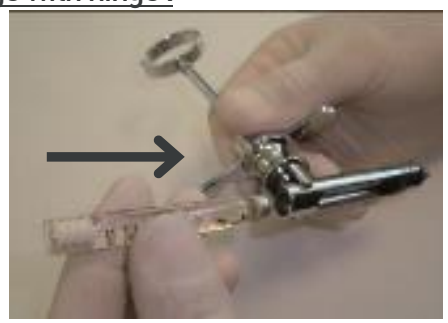
Before use, check that the syringe is not damaged and that there are no parts missing.

Only use high quality anaesthetic cartridges which conform to ISO 11499.
Use a syringe which is suitable for the anaesthetic cartridge's capacity. See label.

Only use high quality needles which conform to ISO7889.

For needles with a non-metric thread on the hub, use a syringe with a reference including the letters US.

5.1. Syringe with hinge :



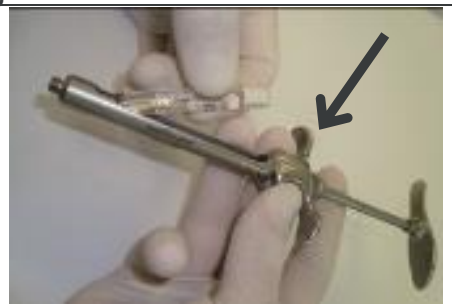
1. Pull back the rod of the piston thoroughly and hold it.

2. Rock the tube of the syringe to open the back hole of the tube.

3. Insert the injection cartidge, the sealed part first.

4. Put the tube of the syringe in its initial position holding the rod pulled.

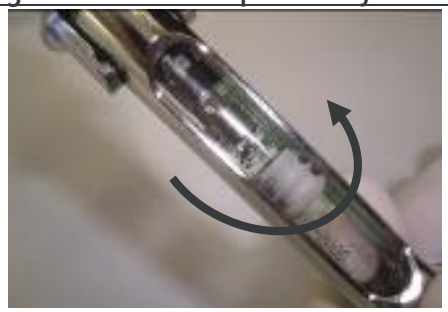
5.2. Syringe with lateral insertion of the cartridge :



1. Pull back the rod of the piston thoroughly.

2. Insert laterally the injection cartidge, the sealed part first, in the tube of the syringe.

5.3. Syringe with manual aspiration system (type 2a) :



1. Turn the handle clockwise sticking the corkscrew into the piston plug of the cartridge or push the handle to insert the harpoon into the piston plug of the injection cartidge.

2. Aspiration will be applied with a back movment of the piston.

5.4. Self aspirating syringe (type 2b) :

Release the injection pressure to create aspiration within the cartridge.

⚠ It may happen that the self-aspirating principle does not satisfactory work with some cartridges or some needles. You must then test the right work of the self-aspiration before the first use.

5.5. Bayonet syringe (intraligament):

1. Unscrew the bayonet and remove the syringe barrel.

2. Insert the cartridge, capsule part first, into the back part of the syringe barrel.

3. Screw on the syringe barrel by engaging the bayonet.

Screw the needle following the instructions given by needles manufacturer. Place the protective tube on the syringe tube prior to using the syringe in the mouth.

Medical device lifecycle

If used in a proper manner, all medical device 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 device is maintained (cleaning and sterilisation).

VI. 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-sterilization protocol must be adapted to the infectious risk.

For each used product : please refer to the manufacturer's instructions. Respect in particular the concentrations, the exposure durations, the solutions' replacement and the products' lifetime.

Never mix the products. Please dispose of products as per their instructions.

Wear adapted protective clothes.

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

Plastic protective tubes for intraligament syringes are not suitable for autoclave sterilisation: they must be replaced after every use.

The syringes 2300 (Miniject) and 2400 (Ergoject) with a black plastic part are not submersible. Do not immerse in water.

The DM should be processed as soon as possible after treatment (up to 2 hours).

6.1. Cleaning

Use only detergent or disinfectant solutions with a neutral or slightly alkaline pH. It is extremely unadvisable to use products which may fix X proteins to the unit (eg. alcohol, aldehydes...).

⚠ Do not use sodium hypochlorite : There is a high risk of corrosion.

• Brush thoroughly with a soft brush (e.g. nylon) under tap water at room temperature for at least 3 minutes. Use a finer brush to clean the areas most difficult to access.

• Prepare a detergent solution (Cidezyme Solution (Johnson & Johnson) 8 mL/L incubated at 38-40 °C) following the manufacturer's instructions.

For submersible devices or parts: immerse in the detergent solution for at least 3 minutes.

• Rinse with demineralised water for at least 2 minutes.

• Rinse for an additional 2 minutes with demineralised water brushing with a soft brush (e.g. nylon).

• Dry with a lint free cloth.

6.2. Operating test

This test has to be done prior to each sterilization.

Check that the piston rod slides freely.

6.3. Sterilization

The syringe **must be sterilized before the first use and after each use.**

Anthogyr recommends class B autoclave sterilisation according to standard EN 13060 for all devices bearing the logo (135 °C).
Devices should not be sterilised without first being cleaned/disinfected.
The sterilisation device must be approved and in compliance with the applicable standards. The manufacturer's recommendations and instructions for use must be followed.
• Remove the anaesthetic and the needle before sterilisation.
• Sterilization pouches must be adapted to the syringe and to the autoclave and in accordance with the standard NF EN868.
Observe the space between the bags and avoid overloading the autoclave.
Do not sterilise the protective tubes.
• Run a sterilisation cycle according to the following parameters:

Country:	Sterilisation parameters	Duration
UE	135°C (-1°C / +2°C)	3 mins
France	135°C (-1°C / +2°C)	18 mins

Allow to cool to room temperature for at least 10 minutes.

Keep the syringe and its accessories within the sterilization bag in a clean and dry place.

Warning : Following each sterilisation cycle, check to make sure there is no residual water inside and outside the package.

Check that the colour change in the passage is correct.

VII. 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 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 DEPARTMENT CONTACT DETAILS

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

VIII. ACCESSORIES

To be ordered from your approved distributor.

Description	Ref
Aspiration corkscrew	3804F
Batch of 12 protective plastic tubes for	2429
Needle recapper	2470

IX. 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.

X. DISPOSAL

Respect current legislation.

In particular: used needles must be placed in a suitable collector.

Conform to current legislation regarding the disposal of medical waste.

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