ASPEO®

FR - RECUPERATEUR D'OS
EN - BONE COLLECTOR
DE - KNOCHENSAMMLER
ES - COLECTOR DE HUESO
IT - RECUPERATORE D'OSSO
PT - RECUPERADOR DE OSSO
NL - BOTCOLLECTOR
ZH - 骨质收集器
AR - مُجمِّع العظم

FR - NOTICE D'INSTRUCTION
EN - INSTRUCTIONS FOR USE
DE - GEBRAUCHSANWEISUNG
ES - NOTA INFORMATIVA DE INSTRUCCIÓN
IT- FOGLIO D'ISTRUZIONI
PT - MANUAL DE INSTRUÇÕES
NL- GEBRUIKSAANWIJZING
ZH - 使用说明
AR - تعليمات الاستخدام

Anthogyr
A Straumann Group Brand

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I. MEANING OF SYMBOLS USED

CE 0459 These **MDs** comply with the Community Directive 93/42/CEE as amended by the 2007/47/CEE directive.

Caution: it is necessary to refer to the precautions of use for any important information related to safety

Do not reuse

STERILE R Sterilized using irradiation

Not sterile

Wear gloves

Sterilisation by autoclave, at the specified temperature

Use by date

REF Catalog reference number

LOT Batch code

SN Serial number

Do not use if package is damage

Keep dry

Keep away from sunlight

Manufacturer

Date of manufacture

II. INDICATIONS FOR USE

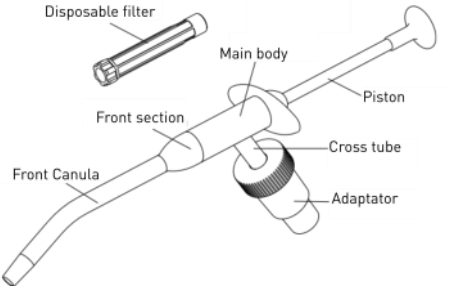
The Aspeo® system is designed to gather bone fragments which can be used to perform autogenous bone fillings may it be deemed necessary during the implant surgery. It is particularly recommended for implant and periodontal surgery. Bone fragments harvested and mixed with the patient's blood may, for example, be used as space maintainers or to fill in a bone defect in order to facilitate rehabilitation during reconstruction procedures.

III. GENERAL INFORMATION

Aspeo® is to be used by practitioners who have completed the relevant practical and theoretical trainings. Through a systematic use of the Aspeo® bone collector, surgeries can be made more secure and optimised. Endogeneous bone can be made available for every surgery to make up for the lack of bone or to better deal with the aesthetic aspect.

IV. DESCRIPTION

The system is constitued by a main body with a detachable front section, a removable front canula, a cross tube to be plugged to the chair suction system, a movable piston, all parts in stainless steel, to be completed with an inner cylindrical filter, made of polyethylene high density, restrained at one end by the piston.



Each package (Ref.12010) contains:
- a main body (Stainless steel)
- a front section (Stainless steel)
- a front canula (Stainless steel)
- a piston fitted with a removable button. (Stainless steel)
- an adaptor (Plastic)
- three single use sterile filters (Plastic)

The device is to be plugged to the suction systems by means of a connector of inner Ø6,5mm or by using an adaptor (Ref.12041) for Ø11mm and Ø16mm. The Aspeo® system comes with 3 disposable filters. It must be used EXCLUSIVELY with one of the filters of batches Ref. 12006 or 12012 supplied by Anthogyr. Each filter is individually packaged in a sealed pouch and Gamma Ray sterilised. Only unaltered packaging can guarantee that the filter's sterility is maintained.

⚠ Used filters or filters featuring defective packaging should be immediately discarded. ONLY Anthogyr's filters Ref. 12006 or 12012 should be used with the Aspeo® system.

V. IMPORTANT

⚠ • The Aspeo® system must be cleaned, disinfected and sterilized before its first use and after each utilisation.

⚠ • Proceed stringently when working with the Aspeo® at the sampling site and always use a second suction system for the saliva.

• Care should be taken to ensure that the harvested bone fragments are not

dried by the continuous airflow going through the filter; when the device is not in use, shut off the suction airflow.

• Handle the harvested bone fragments with great care, complying with well established surgical protocol.

• Aspeo® may be used several times during a same intervention to harvest a significant volume of bone from/on the same patient.

⚠ • Connect the device to a CE medical suction system compliant with the NF EN ISO 10637 standard.

⚠ • Maintain copious irrigation to avoid burning the bone.

⚠ • If the bone is not placed immediately, it is recommended to deposit it in a sterile cup containing a sterile saline solution until ready to put in place.

• It is recommended to carry out a preoperative rinsing of the mouth.

• It is recommended to use a mouthwash for several days after the procedure to avoid bacterial growth in the mouth.

⚠ • Prior to use the Aspeo®, after its complete mounting and plugging onto the chair's suction system, make sure to pull the piston back until it clicks into its rear position. Take care not to engage the piston when the front canula is in position. This could result in ejection of the canula and of the bone fragments.

• In the event of a significant drop in suction, clean all the tube sections: the front canula, the filter and tube.

⚠ • All parts should be taken apart and cleaned immediately after each intervention.

⚠ • The filter is DISPOSABLE. It is to be discarded after use and eliminated through the waste disposal network.

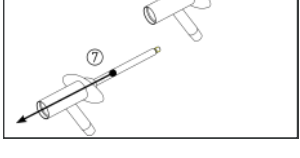
Single-use devices : do not reuse and / or re-sterilize (potential risks of contamination and modification of functional surfaces).

VI. ASSEMBLING / DISMANTLING

<u>To dismantle :</u>

❶ Disconnect Aspeo® from the suction line.
❷ Disconnect the adaptator
❸ Remove the front canula of the bone collector.

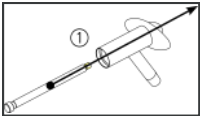
❹ Unscrew the front section.
❺ Remove the filter.
❻ Unscrew the piston button.
❼ Remove the piston by pushing it through the Aspeo® body.

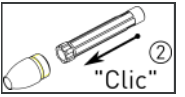


Insert:

❶ Insert the piston (without its button) from left to right into the body and pull it out entirely.

❷ Put the filter in position in its housing.



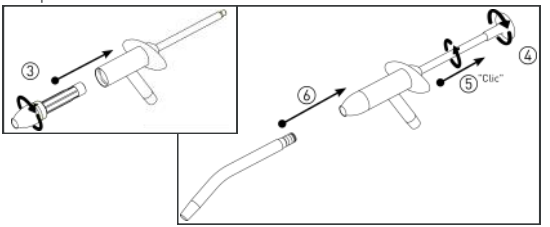


❸ Screw the front section on fully.

❹ Screw on the piston button.

❺ Pull the piston back until you hear a locking "click".

❻ Replace the front canula.

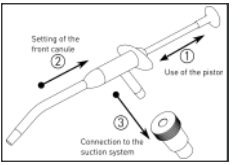


VII. SURGERY PROCEDURE

Before use, ensure that the product is assembled and the piston is working correctly. The front canula should be set into its housing. The piston should be in the rear position.

• Connect the Aspeo® to the suction system.

• Keep the front canula close to the implant site while drilling.

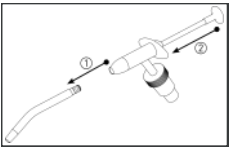


TO DISPOSE OF THE BONE FRAGMENTS:

• Remove the front canula.

• Engage the piston by pushing it forward as on a syringe.

Collected bone fragments may then be deposited in a cup or directly placed on the site to be filled.

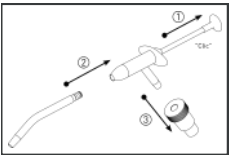


TO RESUME BONE FRAGMENT HARVESTING:

• Pull the piston back to its initial rear position. A "click" will confirm its correct positioning.

• Replace the front canula.

• Reconnect the Aspeo® to the suction system.



MD lifecycle
If used in a proper manner, all **MD** parts have a lifecycle corresponding to 250 sterilization cycles.
However, these indications are not a warranty because wear may appear prematurely, depending on how the **MD** is maintained (cleaning and sterilization).

VIII. HYGIENE AND MAINTENANCE

The re-sterilization of the reusable medical devices must be done by a properly trained and protected staff, while respecting regulations in place. The re-sterilization protocol must be appropriate to match with the risks of infection.

For each device used please refer to the manufacturer's instructions. More particularly, please respect the concentration levels, the duration of the exposures, the liquid solutions replacement and the products' life-time. Never mix the products. Please dispose of the products as per instructed in the notices.

⚠ Use only products intended for the maintenance of the medico-surgical material.

Proscribe the antiseptics which are intended to be used for the skin and the mucous membranes

⚠ Only use products compatible with the stainless steel.

Appropriate protective clothes and gloves must be used in order to prevent any risk of infection and injury.

⚠ Do not use substances likely to set proteins (alcohol, aldehydes, etc.).

CLEANING
Use only pH neutral or slightly alkaline detergent solutions. Do not use products containing alcohol or aldehydes.

The use of sodium hypochlorite should be avoided: Significant risk of corrosion.

• Disassemble the Aspeo® (see paragraph VI : ASSEMBLING / DISMANTLING).
• 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 reach.
• Prepare a detergent solution (Cidezyme Solution (Johnson & Johnson) 8 mL/L incubated at 38-40 °C) following the manufacturer's instructions. 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.
• Ensure the cleaning has removed all visible dirt, otherwise repeat the cleaning procedure.

FUNCTIONAL TEST
Inspect the device for signs of corrosion or cracks and check its proper operation.

Ensure the product is dry; dry any water residues with medical grade compressed air, if needed.

Check that the piston shaft slides freely.

This test should be carried out before each sterilisation.

STERILISATION

The Aspéo® bone retriever **should be sterilised 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.

The sterilisation device must be approved and in compliance with the applicable standards. The manufacturer's recommendations and instructions for use must be followed.

• Reassemble all the Aspeo® pieces except the front catheter, do not assemble the filter.
• Use the sterilisation sachets suitable for the device and the autoclave, compliant with standard NF EN 868. Always one device per bag only. Observe the space between the bags and avoid overloading the autoclave.
• To avoid water retention, turn the bag toward the autoclave so that the hollow parts are turned downward.
• Run a sterilisation cycle according to the following parameters:

Country	Sterilisation parameters	Duration
UE	135°C (-1°C / +2°C)	3 mins
France	134°C (-1°C / +2°C)	18 mins

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

Store the devices in a sterilising bag away from light, humidity, and any kind of contamination. Follow the recommendations of the manufacturer of packaging.

Important: 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.

The device must not be stored for more than 1 month after sterilisation. Label the devices specifying the expiry date. Restart the cleaning and sterilisation cycle once the expiry date has passed.

IX. REPAIR

In case of breakage, contact your authorised dealer or the ANTHOGYR After-Sales Service directly (+33 (0)4 50 58 50 53).

All the repairs must be carried out by manufacturer made parts and subparts. Repairs must only be done by one authorised dealer or by the After Sales Service of the manufacturer.
For any revision or repair, the medical device must be returned back, complete and **sterile**, with a certificate of sterility.
It must be joined with a document describing the technical problem while mentioning the name and address of the dental surgeon.
So that the requests for guarantees may be taken into consideration, please have the device returned with a copy of the invoice or of the delivery slip.
Replacement parts are available for 7 years beyond sales discontinuation.

X. ACCESSORIES

To be ordered from your authorised dealer.

Description	Reference
1 single use plastic filter	12001
6 single use plastic filters	12006
12 single use plastic filters	12012
Adaptator Aspeo®/Aspiration saliva	12041

XI. WARRANTIES

This device 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 device.

XII.DISPOSAL OF THE PRODUCT

The **MD** must be sterilised before disposal in order to prevent the risk of third-party contamination.
Used filter must be placed in a suitable waste collector.
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.

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