

# *Elansa*



Model Shown : 11615-01



**Electric Gynecological Table**  
**11610-01 / 11614-01 / 11615-01**

# Product Identification

*Model Number :*

*Serial Number :*

*Date of Purchase :*

*Name of Owner / Facility :*

*Name of Dealer :*

*Dealer's Phone Number :*

*Promotal Authorized Service Company :*

## Legal Notice

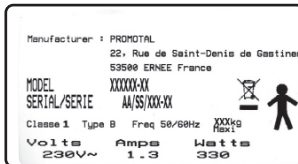
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The descriptions and specifications contained in this Operating Manual are deemed correct at the time of printing.

**Promotal**, however, reserves the right to modify its models and its procedures or render them obsolete without notice.

Before any order, we recommend that our customers consult a local sales manager.

## Type plate





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# Summary

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# Important Information

## Safety symbols



### Warning sign

Information marked with this symbol must be read and strictly complied with!

### Remark

Draws your attention to a procedure, practice or situation.



Humidity limitation



Maximum number of stacked pallets



Correct orientation for transportation



Atmospheric pressure limitation



Temperature limitation



Fragile



Keep in a dry place



Not to use sharp objects



Manufacturer



Type B applied part



Fuse rating



Protective earth



Dangerous voltage / risk of electrocution



To be disposed off separately from household waste



Equipotential terminal



Life cycle (motor cycle)  
1 minute working / 9 minutes stopped



General safety sign



Refer to the instruction manual / brochure



CE marking



Housing protection classification

### Remark

the equipotential terminal allows the connection of an equipotential conductor to bring all the different elements of an electro-medical system to the same potential.



Do not sit on the back rest



Do not sit on the leg rest



You must not use the medical device for transfers



### Warning

You must not remove the pictograms and warning signs provided by the manufacturer! The manufacturer disclaims all responsibility in case of removal of these signs.

## **Power supply**



*The equipotential bonding terminal must never be used as a protective earth connection.*



## **Electromagnetic interfere**

This Promotal examination equipment was designed and built in order to minimize electromagnetic interferences with other devices. If interferences are noted, it is necessary to withdraw the parts causing the interference and/or to connect the equipment on isolated circuits.

# Precautions when unpacking

## **Material delivered in cardboard packaging**

*Small, lightweight, easy to handle material*

In this case, the products can be easily handled without any lifting gear, taking care to position the product according to the directional arrows on the packaging.

In the absence of arrows indicating the top and bottom, use the position of the various product identity labels which are always placed at the top.

*Heavy or cumbersome material requiring the use of lifting gear*

In this case, it is possible to use a fork lift truck, provided it is used correctly. Before moving, ensure the material is properly positioned, and that the load is evenly balanced.

## **Products delivered on wooden palettes**

Products placed on a wooden palette may easily be moved using a forklift truck, provided this is used correctly. Before moving, ensure the truck is correctly positioned in relation to the palette, and that the whole is stable. Take additional caution when handling very tall or high articles (eg. cupboards).

## **Storage condition**

Ambient Temperature Range :

Relative Humidity :

Atmospheric Pressure :

The following conditions must be observed when storing any material :

- The area must be clean, well ventilated and be of a normal temperature.
- Store products away from the elements, and away from direct sunlight.
- The area must not be damp.

-15 °C to +60 °C (+5 °F to 140 °F)

10 % à 90 % (non-condensing)

0.5 bar to 1.05 bar (500 hPa to 1050 hPa)

- The products must not be subject to bumps or jolts.
- Do not store in an area where people are likely to pass.
- Articles must not be stacked on top of each other.
- Articles must remain in their original packaging until final delivery.

## **Conditions of use**

- Dry and temperate area.
- Maximum altitude : 2000 m

- Temperature 10 to 40° C
- Relative humidity 75% maxi.

## **Unpacking / Installation**

When installing, remove all staple clips and carefully remove the cardboard packaging. Fragile parts of the product (upholstery coverings, plastic casings, etc.) may be just below the packaging. Care must be taken with cutting instruments.

Once the packaging has been removed, remove any remaining protective covering.

In the case of packaging on a wooden palette, remove the packaging as above. Depending on the model, the product is fixed either by screwed flanges, or by nailed wooden stakes. Use a spanner (for metal flanges). Use a claw hammer (for wooden stakes). Lift the article off the palette, and remove the remaining protective covering. The product is now ready for use.

## **Verification**

After unpacking the device, follow the steps below :

Check the delivery documents to make sure that the consignment is complete.

Check the external components and look for possible transport damage.

Check that the package contains the device, the accessories and options, the power cord (*if electric DM*) and the Operating guide.



**Note :**

***Authorized CE representative***

Countries in the EEC should direct all questions, incidents, and complaints to Promotal's Authorized CE representative listed below :

Promotal  
22, rue de Saint-Denis de Gastines  
53500 Ernée,  
FRANCE  
Téléphone : + 33 (0)2 430 517 76  
Fax : + 33 (0)2 430 572 00

# Cleaning protocol

## Warning

You must read the installation instructions, technical instructions, and instructions for use before handling this equipment. The instrument must be used only for the specific purpose for which it is designed, and which is described in our literature. The assembly and connection to the mains must be carried out by qualified personnel.

Under no circumstances must electrical parts (motor, unit housing the electrical control systems, control unit, adaptor etc.) be opened. PROMOTAL cannot be held responsible for any damage resulting from the instructions not being followed.



**Any modification of the DM without the manufacturer's written authorisation is prohibited.**



**Caution**  
**Only those accessories allowed and provided by Promotal for this DM may be used.**

## General maintenance

Apart from regular cleaning, our products do not require regular maintenance.

The mechanical parts used as blocking mechanisms (smooth arch, notched arch, ratchet mechanisms, etc.) do not require any specific attention. The gas springs on tables do not require any maintenance. Their shaft must be kept clean, must not be subject to jolts or hard knocks, and must not be cleaned with any corrosive products. The electric and hydraulic jacks do not require any particular attention.

The variable height tables, chairs and trolleys are equipped either :

- With arms fitted with self lubricating articulation rings.
- With telescopic bearing runners. In this case they should be lubricated once a year (particularly if the runners are noisy) with ordinary grease. (See the exploded drawings for access to the runners).

## Disinfection

This Medical Device must be regularly disinfected by products which qualify as Bactericides, Virucides and Fungicides.

## Maintenance Instructions

The use of ordinary cleaning products, eg. window cleaning products, is perfectly suitable for cleaning surfaces finished in epoxy polyester. **The following products are not recommended as they will damage these surface :**

### – Solvents :

Petrol  
High-grade alcohols :  
– Aliphatics  
– Aromatics  
Ketones - esters  
Tri -perchlorethylene

### – Bases :

10 % sodium  
10 % ammonium

### – Acids :

30 % nitric  
30 % chlorhydric  
10 % citric

### – Others :

Bleach  
Abrasive powders  
Any abrasive  
Cleaning product

### *Imitation leather coverings*

Use a damp cloth and soapy water (eg. household soap). For stubborn stains, dab, but do not rub, using a cloth soaked in white spirits or in a solution of water and alcohol (less than 30 % strength).

**It is not recommended to use the following :** Pure alcohol, acetone, perchlorethylene, trichlorethylene, all solvents and detergents, any abrasive cleaning agents, any kind of wax.

### *Stainless steel products*

**Cleaning and Maintenance :** For maintenance of stainless steel products, periodic cleaning of the surface is sufficient. This operation is necessary to keep the products clean, but is facilitated by the quality of stainless steel surfaces. A large range of products and cleaning methods may be used. The choice products method will depend on the nature of the marks or on the product content, and on the conditions of use of the stainless steel elements.

#### **Cleaning agents**

**a) Detergent - washing liquids :** All types of detergents, washing liquids and commercial soaps may be used, provided they do not contain any chlorine products.

**b) Abrasive powders :** These products may scratch the stainless steel surface, thereby changing the way its appearance. They should therefore not be used.

**c) Solvent :** May be useful in getting rid of grease marks. The usual solvents (benzene, methylene chloride, white spirits etc.) as well as domestic or

**Flame retardant classification :** All our coverings class are M2 or M1. We can provide you with a manufacturers certificate on request.

specially prepared industrial products may be used. Naturally their use requires certain precautions to be taken because of their flammable and toxic properties. Precautions must also be taken to avoid damaging adjacent materials which may be sensitive to their chemical action (paints, mastics, joints etc.).

**d) Acid products :** Vinegar (acetic acid) may be used to get rid of stains made by calcium deposits. Its contact with the surfaces must be of a very limited duration, and the surface must then be thoroughly and carefully rinsed with clean water. The use of chlorine based products could damage this equipment.

**e) Bases :** Not recommended.

**Others :** The use of steel wool or metal sponges could damage the surfaces of the products.

These products have been covered with a chrome coating to protect them from oxydization.

**Cleaning and Maintenance :** It is through important, in order not to damage this protective coating, abrasive and / or corrosive products the use of. The use of commercial cleaning products, such as window cleaning products, are safe for chrome coated surfaces. If necessary, an appropriate disinfectant may be used on chrome (make sure the instructions are followed).

**Cleaning and Maintenance :** The use of commercial cleaning products, such as window cleaning products, are safe for PVC and ABS surfaces. To restore up an old or dull surface, plastic restorer products may be used. Please note that the use of any solvents or any abrasive products is could damage these surfaces.

**Cleaning and Maintenance :** As for PVC. Use window cleaning products.



## **Intended use**

This appliance is designed for use in professional premises only :

Medical practices  
Care establishments

This appliance must not be installed in domestic premises.

This table is designed to be used only by healthcare staff. This examining table is used to perform gynaecological interventions under the best possible safety conditions.



This table must never be used as an obstetrical table.



## **Authorisation to use**

Only health professionals (doctors, caregivers) and/or qualified members of the technical staff can handle or use the couch.

Patients and companions must not intervene directly on the couch. They must not have access to the couch controls.

**This medical device must not be used in the presence of anaesthetics that are flammable in air or comburant gases such as oxygen or nitrous oxide in order to prevent all risks of explosion.**

## **Patient weight capacity**

 =170Kg       =170Kg

## **Features**

Electric height adjustment from 46 cm to 106 cm.

Combined height and backrest movements  
(1 actuator).

Gas-spring assisted backrest adjustments.

1 equipotential bonding terminal

Pedal control.

Adjustable feet under base.

Sliding plastic pan (6 litre capacity).

Bilateral receptacle for optional colposcope holder.

Steel frame with light grey ABS casing.

Seamless upholstery with class M1 flame retardant covering, removable seat.

Paper roll holder (max. width 50 cm – ø 12,5 cm).





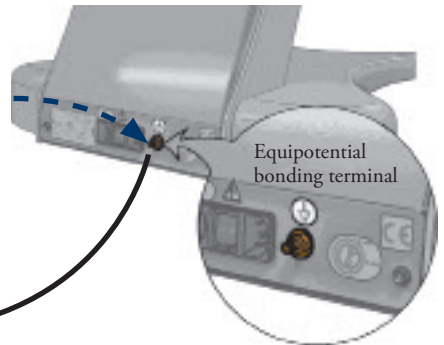
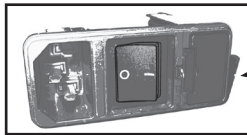


The switch situated at the base of the table allows the table to be switched on or off. If the table is not to be used for a prolonged period of time, it should be switched off.



### Caution

The power cable of this medical device may act as an obstacle and cause you to trip over it. Watch out for it when moving around the device once it is connected to the mains.



Equipotential bonding terminal

### Using the pedal control

To achieve the desired position, simply apply and maintain pressure on the pedal. As soon as this pressure is released, the movement will stop. The table is fitted with an internal device to limit the high and low positions. The position of the table may be adjusted while the patient is on the table.



### Caution

Disconnect the power cable before moving the DM.



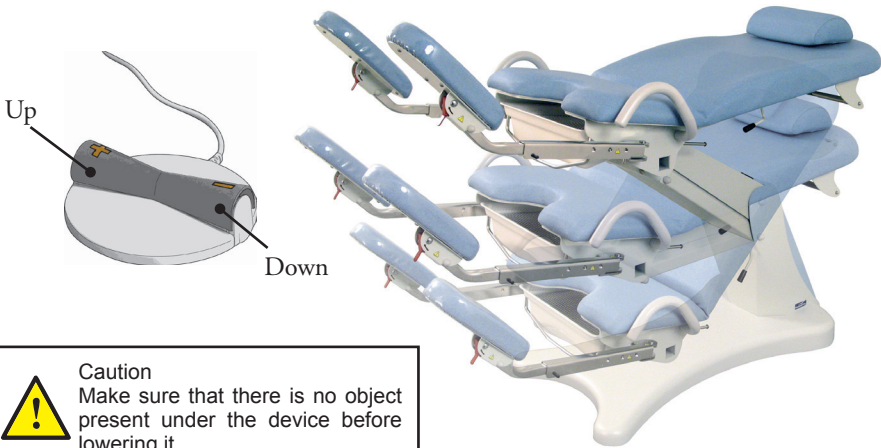
### Safety :

For safety reasons, and in order to avoid malfunctioning, no objects should be placed under the seat cushion or between the moving parts of the table.

# Using the Table

## Adjusting the height

Press on the pedal control for the desired position.



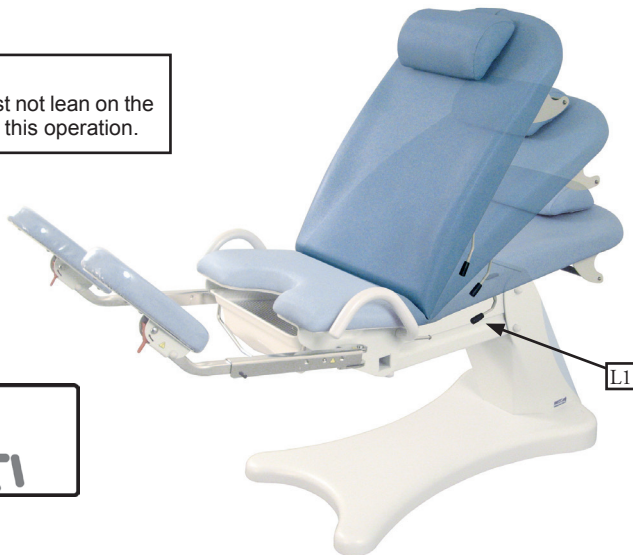
**Caution**  
Make sure that there is no object present under the device before lowering it.

## Positioning the incline of the backrest

Use one hand to guide the backrest (to the desired position) and the other to activate the gas-spring (L1).



**Caution**  
The patient must not lean on the backrest during this operation.



# Using the Table

## Plastic pan

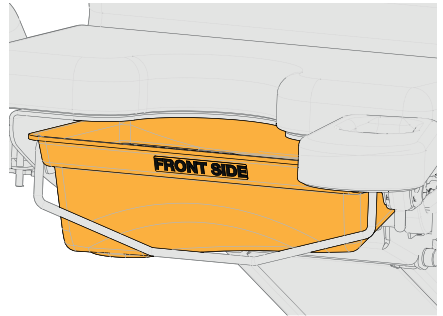
The plastic pan is removable to ensure easy cleaning, it can be moved towards the front and also be placed under the seat.

Pull the handle underneath the seat, to move the pan forward.

Remove the pan.



Ensure the plastic pan is correctly positionde.



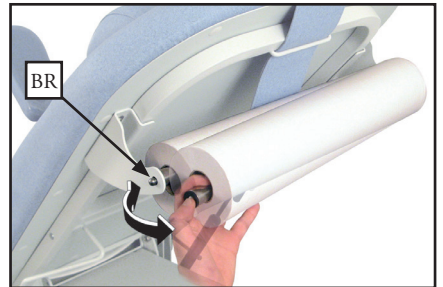
## Paper roll

### *Installing the paper roll*

The paper roll is positioned on an axis with spring clips (br) at each end. Press these springs to remove the paper roll.

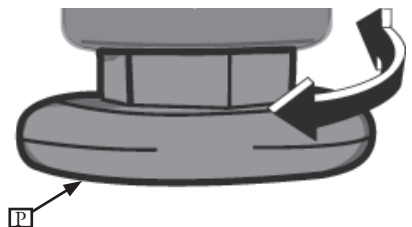


Caution  
Hold the paper roll during this procedure.



## The levellers

Screw or unscrew the leveller (P) to the desired height.



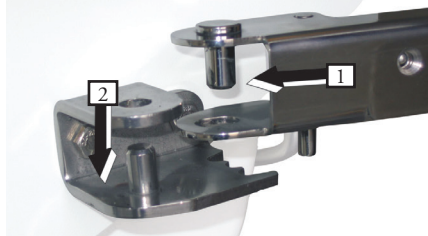


## The footrests

(only for the model 11615-01)

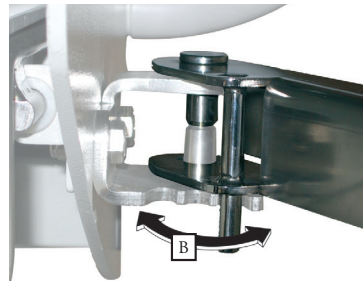
### Installing the footrests

see image opposite.



A : Take the footrest by the end and lift slightly.

B : The footrest can be opened out or closed in.

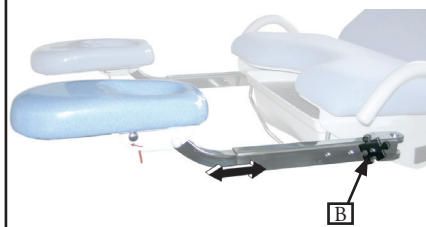


Caution  
Hold the footrest correctly when  
adjusting.

### Length adjustment of the footrests (3 positions)

Press on the spring clip to free the mechanism and  
move the footrest forward or backwards.

#### Length adjustment of the footrests



# Using the Table

## *Tilt adjustment of the footrests*

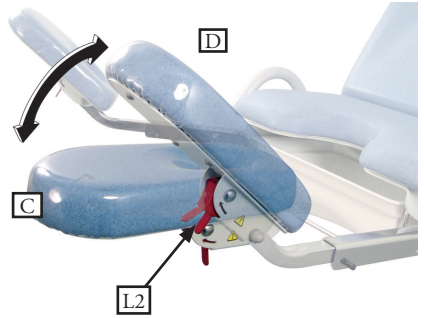
### *From position C to D :*

Take the footrest by the end and lift slightly. It will move into position D.

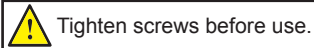
### *From position D to C :*

Holding the footrest, unlock the mechanism, the footrest returns to a straight position.

L2 : Control to unlock tilting position.



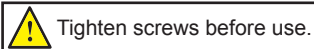
## **The pair of stirrups**



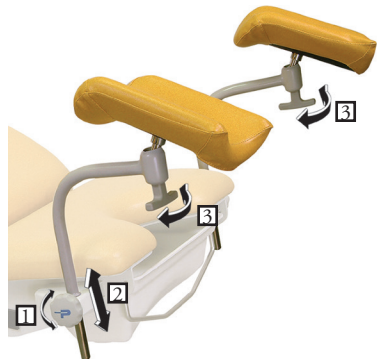
Tighten screws before use.



## **The pair of Goepfels**



Tighten screws before use.



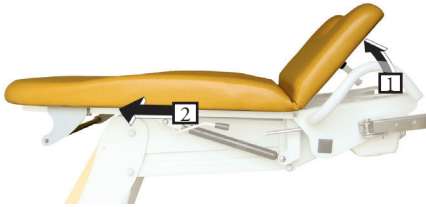
## The upholstery

### *Removing the upholstery*

**Place the backrest in a horizontal position.**

1 : Lift the seat by removing it from the studs (P).

2 : Slide the whole upholstery towards the top.



## Fill-in cushion

*(only for the model 11615-01)* Align the footrests with the seat.

Insert the fill-in cushion.

Press slightly to ensure it is correctly in place.



**Caution**  
Make sure that the cushion of feet is well to insert.  
This is designed for a charge of 25 kg maxi.

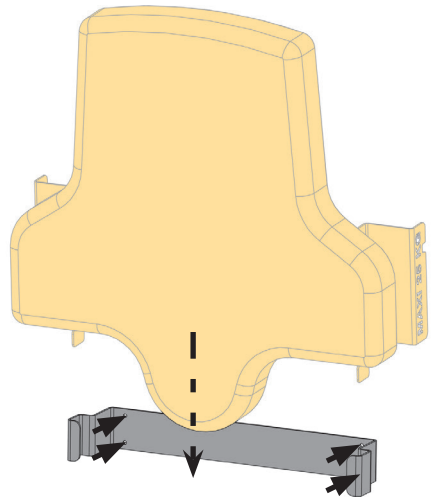


## *Installing the wall-mounted support for the foot cushion*

- The support is fixed to the wall by 3 holes Ø 6 (indicated by the arrows)

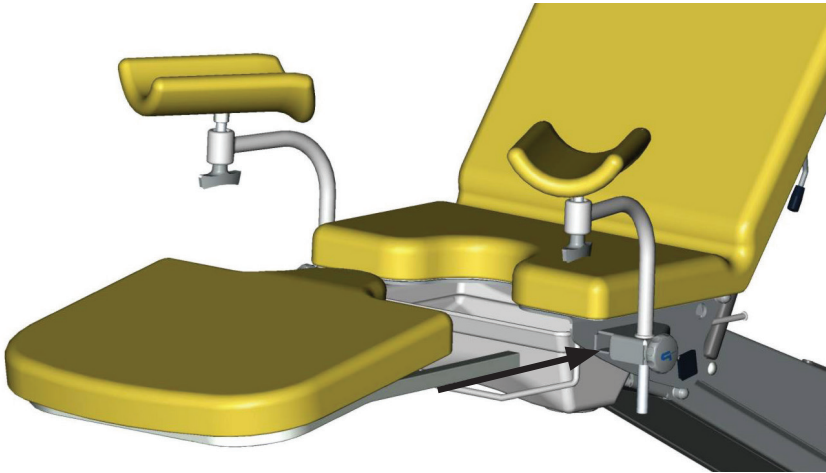


**Caution**  
Ensure correct fixation to the wall.  
(adapted screws + rawlplugs).



## Leg cushion

(only for models 11610-01 and 11614-01)



Caution  
Make sure that the cushion of feet  
is well to insert.  
This is designed for a charge of  
25 kg maxi.



### *Installing the wall-mounted support for the foot cushion*

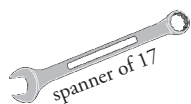
- The support is fixed to the wall by 3 holes Ø 6  
(indicated by the arrows)



Caution  
Ensure correct fixation to the wall.  
(adapted screws + rawlplugs).

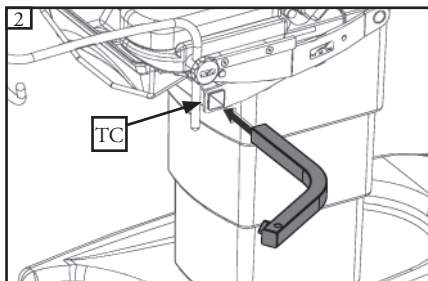
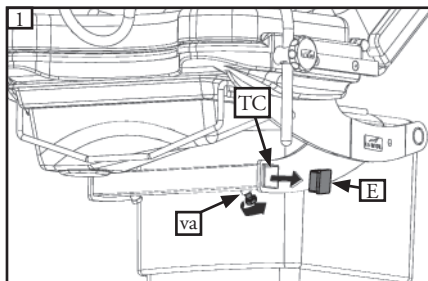


## Lamp holder



- Remove the tip (E) 40x40 on the tube (tc), and unscrew the screw (VA).

- Insert the lamp support in the tube (TC) and tighten the screw (VA).



## Lamp

(reference LEDXX)

(Insert right or left)

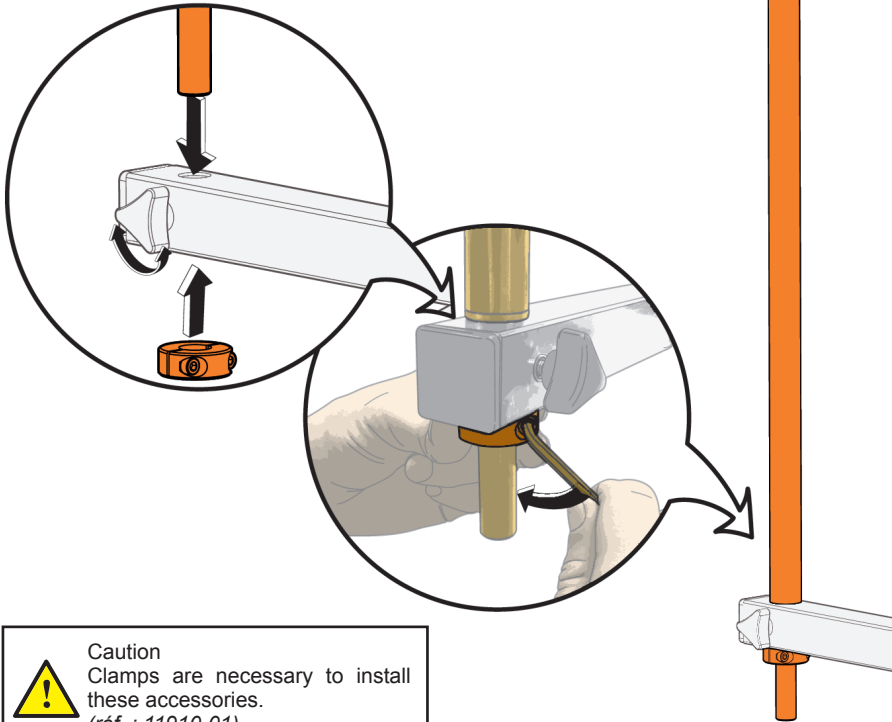


Caution  
Clamps are necessary to install  
these accessories.  
(réf. : 11910-01).



## Auto-blocking I.V. pole (reference 2985-01)

Installing the IV pole



Caution  
Clamps are necessary to install  
these accessories.  
(réf. : 11910-01).



Tighten screws before use.

The IV pole has 1 sliding stem.

Use the screw to adjust the height of the lower stem  
and the bolt to adjust the upper stem.

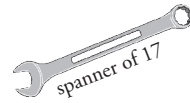


## Leisegang Colposcope holder

(reference 11810-01)

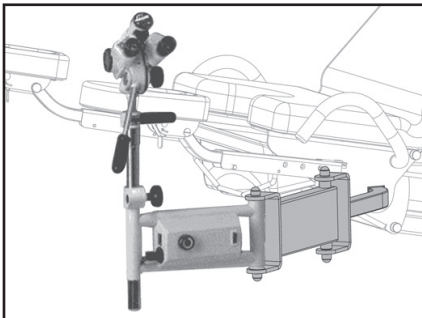
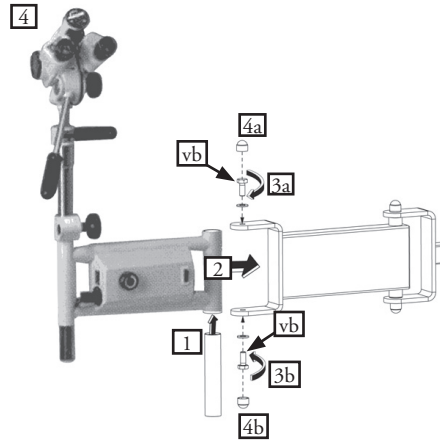
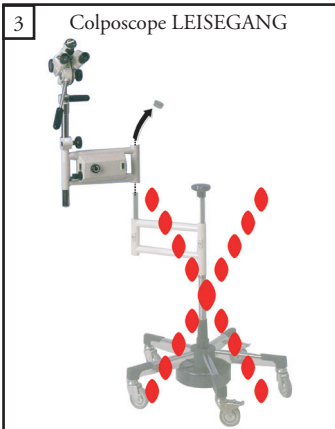
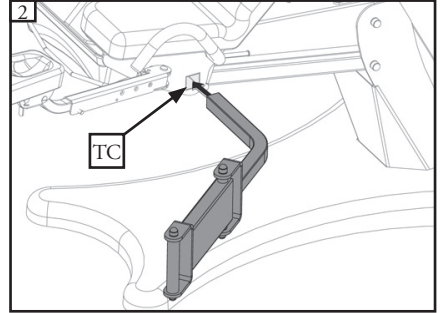
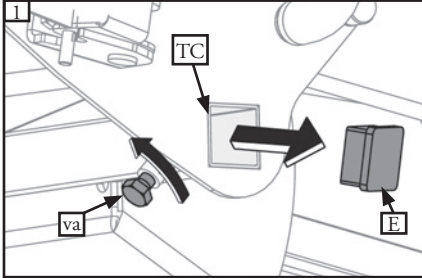
Installing the colposcope holder

(Insert right or left)



- Remove the tip (E) 40x40 on the tube (tc), and unscrew the screw (VA).

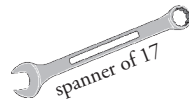
- Insert the colp support in the tube (TC) and tighten the screw (VA).



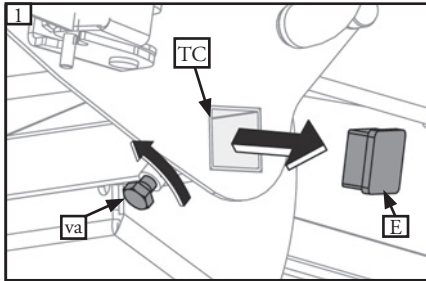
Tighten the 2 screws to the maximum (VB)



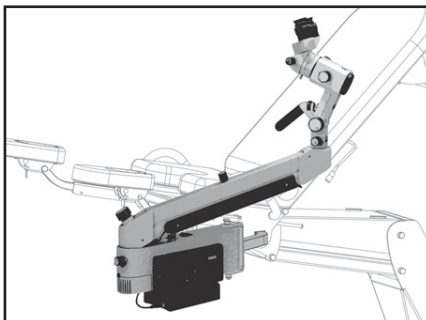
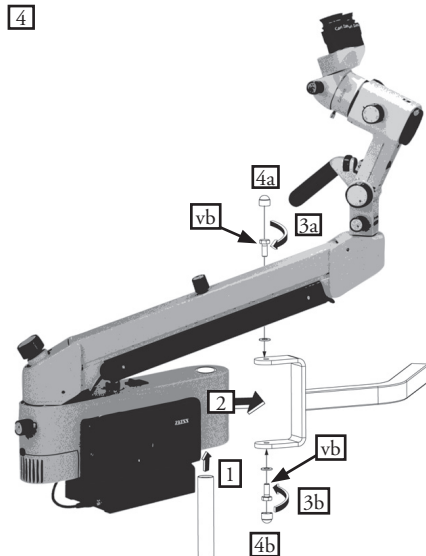
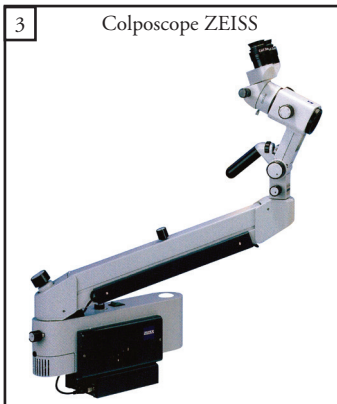
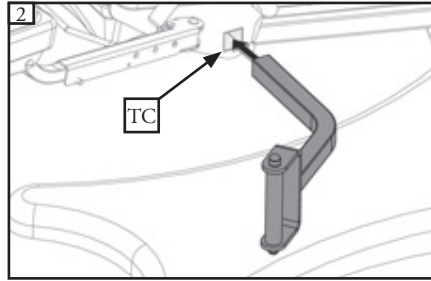
## Support Colposcope Zeiss / Colposcope KAPS



- Remove the tip (E) 40x40 on the tube (tc), and unscrew the screw (VA).



- Insert the colp support in the tube (TC) and tighten the screw (VA).



Tighten the 2 screws to the maximum (VB)

# Accessories

## **Headrest**

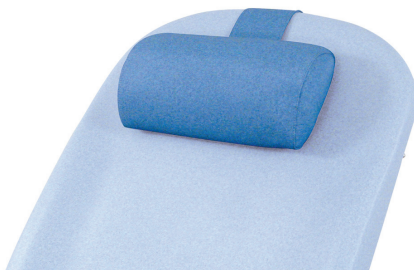
(reference 11679-01)

### *Installing*

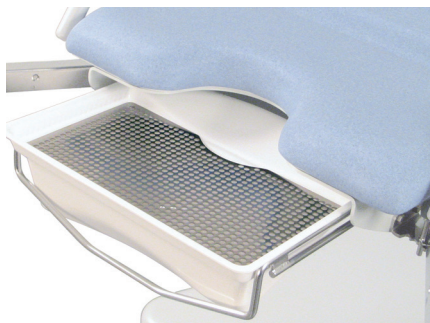
Insert the grip of the headrest in the frame of the backrest.

### *Adjustments*

Adjustments are made by pushing on the headrest to lower it and pulling on the grip to heighten it.

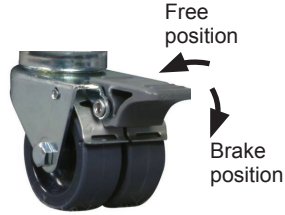


## **Splash guard cover**



## Castors with brakes (reference 81036)

*Using the castors*



### Caution

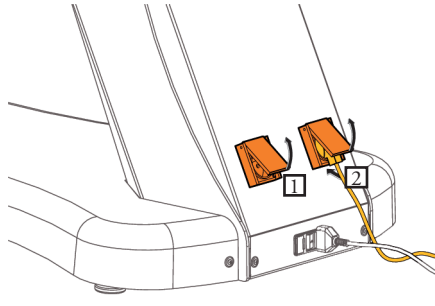
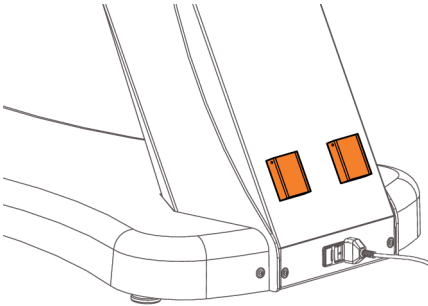
Disconnect the power cable before moving the DM.



### Caution

Ensure brakes are fully engaged before installing a patient.

## Electrical receptacles



# Lifespan of the Medical Device

This medical device was designed for a service life of 10 years, excluding wear parts in normal working conditions. This duration may change depending on the frequency of use.

## CHECK AT LEAST ONCE A YEAR THE GENERAL CONDITION OF THE DEVICE.

*The wear parts are :*

- The upholstery
- The knobs and screws

Midmetal Equipment can replace applicable parts after a maximum of 10 years of users of use.

For any intervention, please contact your local authorized dealer, indicating the serial number of the device.

## Fuse replacement

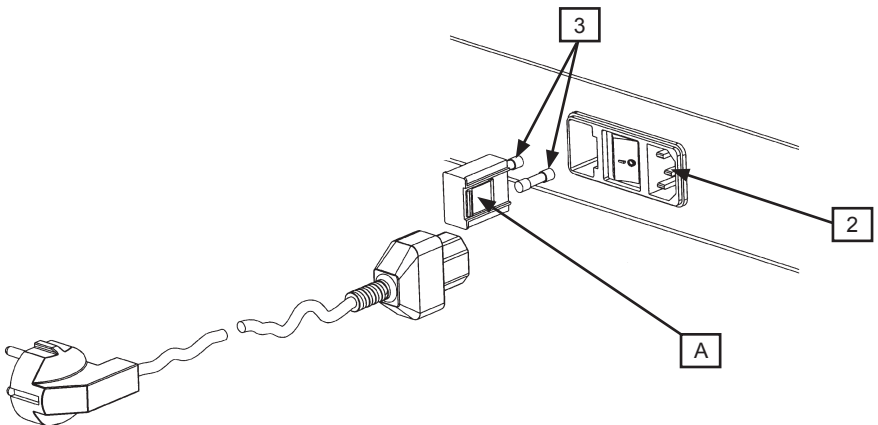
1. Remove all power to unit by unplugging unit's power cord.
2. Using a flat tipped screwdriver, gently release the plastic spring clip (A) on both sides of fuse drawer (1) then pull fuse drawer from fuse housing (2).
3. Pull both fuses (3) out of fuse drawer (1) and inspect. Check the fuses for any indication that they have blown ; i.e. burnt look, fuse cord melted through, etc. Discard fuses (3) if blown and replace them.



### EQUIPMENT ALERT

Use fuses of the same voltage rating, amperage rating, and type. Failure to do so could result in damage to the equipment.

4. If necessary, obtain new fuse(s) (3). The replacement fuse(s) must be a 250 VAC, 6.3 amp, IEC 127 rated, 5 x 20 mm, Type T "Slo-Blo".
5. Insert fuse(s) (3) into fuse drawer (1).
6. Insert fuse drawer (1) into fuse housing (2) until fuse drawer snaps into place (both side of use drawer are locked into fuse housing).
7. Plug in power cord to equipment. If fuse blows again, call your Promotal distributor.



# Lifespan of the Medical Device

## Obligatory/specific maintenance

- Check the good tightening of the screws and the rods.
- *Once per year :*
  - Check the state of fixings of the articulated parts.
  - Check the good tightening of the screws and the rods.
  - Check the which structure did not undergo any deformation.
  - Check the state of fixings of the articulated parts.
  - Check the good state of the fuses.
  - Check the which structure did not undergo any deformation.
  - Check that the cord of food does not present a cut or another material damage.
  - Check the good state of the fuses.
  - Control the various connections (excessive play, noise...)
  - Check that the cord of food does not present a cut or another material damage.
  - Note this information and the date of checking on the notebook of maintains.
  - Control the various connections (excessive play, noise...)
- Note this information and the date of checking on the notebook of maintains.

## End of the device's useful life

Your dealer is responsible for reclaiming and processing this device at the end of its service life.

Do not hesitate to contact Promotal, if necessary. We will suggest to you a solution to process this equipment in the best conditions.

Your dealer is responsible for reclaiming and processing this device at the end of its service life. Do not hesitate to contact Midmark Europe, if necessary. We will suggest to you a solution to process this equipment in the best conditions.



### Equipment warning

All mattresses with torn covers must be promptly replaced in order to guarantee optimum functionality of this DM.



### Material warning

#### Do not dismantle the equipment

If a defect is detected, immediately contact your retailer or the after-sales department of your retailer (cf Warranty Information) for a complete diagnosis. If a doubt remains, do not use the equipment.





# Note







# Warranty Information

## Warranty

Promotal warrants, to the original purchaser, products manufactured by Promotal and components to be free from defects in materials and workmanship for a period of two (2) years\* from the date of purchase.

Promotal will, at its discretion and expense, replace defective parts reported to Promotal within the applicable warranty period, and which, upon examination by Promotal, prove to be defective.

In accordance with CE regulation, Promotal's distributor is responsible for after sales service during and after the warranty period.

- This warranty does not extend to :

- (1) Spare parts and consumables.
- (2) Travel and labour expenses.
- (3) Breakdowns due to improper use, manifest neglect, or to moving the device.
- (4) Equipment whose original characteristics have been changed by the user.
- (5) Control units, hydraulic and electric jacks if opened by the user (seals broken).
- (6) Damage, breakdowns, failures, or defects attributable to outside causes (lightning, electric surges, floods, natural catastrophes, impacts, etc.) or to the presence of foreign objects.
- (7) Damage caused by improper hook-up or by the power supply, damage caused by corrosion or by gradual deterioration of the product.
- (8) Indirect damage related to loss of use and penalties generated by poor performance.
- (9) Aesthetic damage incurred by the outside parts of the equipment, which does not hinder proper operation, such as scratches, chips, and scrapes.
- (10) Devices whose serial number has been rendered illegible or has been changed or removed

Promotal's only obligation under this warranty is the replacement of defective parts. Promotal shall not be liable for any direct, indirect, special, incidental, exemplary, or consequential damages or delay, including, but not limited to, damages for loss of profits or loss of use.

No person or firm is authorized to create for Promotal any other obligation or liability in connection with the products.

**THIS WARRANTY IS PROMOTAL'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED.**

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\* Upholstery sets are warranted 1 year from manufacturing defaults.

# EU Declaration of Conformity

We,

**Promotal**

22 rue de Saint Denis de Gastines

53500 Ernée – France

SRN: FR-MF-000001666

declare, under our sole responsibility, that the following electrical medical device:

Commercial name: Elansa 11610-01 / 11614-01 / 11615-01

Description: Electric Gynecological Table

Basic UDI-DI: 37014094ELANSABC

is a Class I medical device,

complies with the requirements of **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017,

complies with the following European directives:

- **Directive 2011/65/EU (RoHS 2)** of the European Parliament and of the Council of 8 June 2011

- **Delegated Directive (EU) 2015/863** of the Commission of 31 March 2015

- **Directive (EU) 2017/2102** of the European Parliament and of the Council of 15 November 2017

meets the applicable European standards,

bears, as such, the CE marking.

Year that the CE (Medical Devices) marking was initially affixed: 2005

Signed in Ernée,

On 26 May 2021



Rudolf MOURADIAN

Chairman

Promotal

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