

## Instructions for Use Disposable Denniston Dilator Set

**AMERICAN INSTRUMENTS EIRELI - EPP - CNPJ: 06.981.319/0001-21**

Avenue 53, 1227 – Jardim Kennedy – Zip Code: 13501-530 - Rio Claro/SP - Technical Resp.:  
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Aiming at practicality and ease of access to the information contained in the Instructions for Use of our products, American Instruments, in accordance with IN nº 4/2012 established by ANVISA, makes the documents available for download on the website: [http://www.americaninstruments.com.br/instrucao\\_uso](http://www.americaninstruments.com.br/instrucao_uso)

Important: Check the version of the Instructions for Use indicated on the product label, along with the registration number and click on "Download" on the desired document to start transferring the file.

To obtain the printed Instructions for Use free of charge, please contact our Customer Service by phone +55 (19) 3531-5100 or by email: [info@americaninstruments.com.br](mailto:info@americaninstruments.com.br)

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ANVISA Registration No. 80251140043 - Revision 00

### PRODUCT FEATURES AND TECHNICAL SPECIFICATIONS

**Technical Name:** UTERINE CERVICAL DILATOR

**Commercial Name:** DISPOSABLE UTERINE DILATOR SET

**Composition:**

The product is composed of high-density polyethylene (HDPE), injected in diameters from 05 to 14 mm, without welding, opaque white, formatted according to the application.

**Shelf life:** 2 years after the date of manufacture

**Sterile Product - Disposable Product - Sterilized by Gamma Rays**

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## Instructions for Use

### Disposable Denniston Dilator Set

#### IDENTIFICATION OF COMMERCIAL MODELS / COMPOSITION

Each kit that forms the candle set contains 5 (five) units, of different dimensions, the 1st (first) - which reaches from 5mm to 6mm, the 2nd (second) - and 7mm to 8mm, the 3rd (third) - from 9mm to 10mm, the 4th (fourth) from 11mm to 12mm, and the 5th (fifth) from 13mm to 14mm, according to the following table:

Reference	Images	Item/Part
AI3001		<p>Disposable Denniston Dilators Set with 5 units</p> <p>Ref: AI3001 - Dilator: Ø 5mm to 6mm, Dilator: Ø 7mm to 8mm, Dilator: Ø 9mm to 10mm, Dilator: Ø 11mm to 12mm and Dilator: Ø 13mm to 14mm</p>
AI3002		<p>Disposable Denniston Dilators Set with 1 unit</p> <p>Ref: AI3002 - Single dilator: Ø 9mm to 10mm</p>
AI3003		<p>Disposable Denniston Dilators Set with 2 units</p> <p>Ref: AI3003 - Dilator: Ø 7mm to 8mm and Dilator: Ø 9mm to 10mm</p>

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<p>AI3004</p>		<p>Disposable Denniston Dilators Set with 3 units</p> <p>Ref: AI3004 - Dilator: Ø 5mm to 6mm, Dilator: Ø 7mm to 8mm and the Dilator: Ø 9mm10mm</p>
<p>AI3005</p>		<p>Disposable Denniston Dilators Set with 4 units</p> <p>Ref: AI3005 - Dilator: Ø 5mm to 6mm, Dilator: Ø 7mm to 8mm, Dilator: Ø 9mm to 10mm and Dilator: Ø 11mm to 12mm</p>



Detail of the ends

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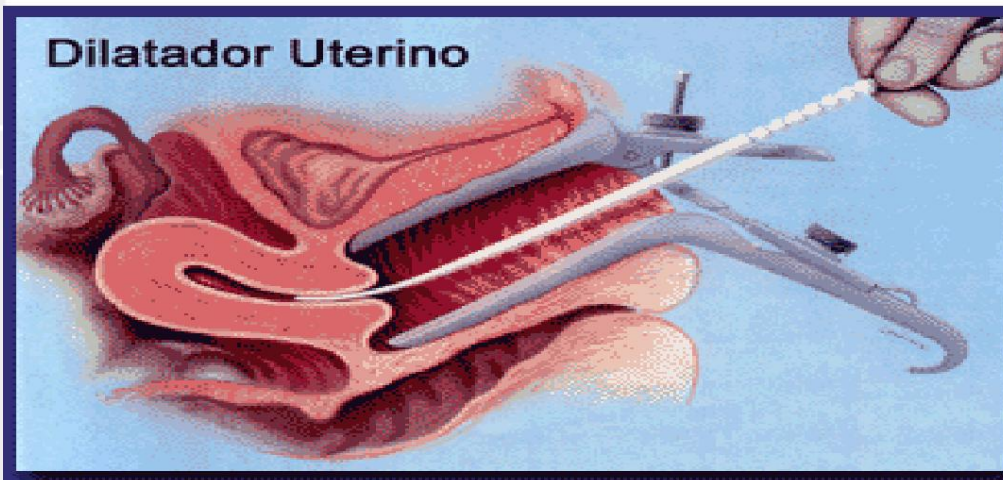
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## Instructions for Use Disposable Denniston Dilators Set



Median and numerical detail



Human anatomical model where the Dilator is used inside the uterus



Final packaging model Disposable Denniston Dilators Set **Ref: AI3004**

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## Instructions for Use Disposable Denniston Dilators Set

### PRODUCT PRESENTATION FORM

Each kit that forms the Disposable Denniston Dilators Set contains 5 units (sticks), 4 units, 3 units, 2 units or 1 unit of different diameters with a double rounded and conical curved terminal, in white, being

what:  $\varnothing$  11mm to 12mm and Dilator:  $\varnothing$  13mm to 14mm.

Ref: AI3001 - Dilator:  $\varnothing$  5mm to 6mm, Dilator:  $\varnothing$  7mm to 8mm, Dilator:  $\varnothing$  9mm to 10mm, Dilator: Disposable Denniston Dilators Set

Ref: AI3002 - Single dilator:  $\varnothing$  9mm to 10mm.

Ref: AI3003 - Dilator:  $\varnothing$  7mm to 8mm and Dilator:  $\varnothing$  9mm to 10mm.

Ref: AI3004 - Dilator:  $\varnothing$  5mm to 6mm, Dilator:  $\varnothing$  7mm to 8mm and Dilator:  $\varnothing$  9mm to 10mm.

Ref: AI3005 - Dilator:  $\varnothing$  5mm to 6mm, Dilator:  $\varnothing$  7mm to 8mm, Dilator:  $\varnothing$  9mm to 10mm and Dilator:  $\varnothing$  11mm to 12mm.

The set is sold in individual envelope-type packaging, manufactured with surgical grade paper and laminated Polyester/Polypropylene film, which allows aseptic opening without tears in the film and with less release of fibers.

The pouch packaging is packaged in an external cardboard packaging measuring 38x15x11cm containing 10 units. An identification label is glued to the external packaging, containing the information necessary to identify the product.

The label also contains the following information: Instructions for Use available at [http://www.americaninstruments.com.br/instrucao\\_uso](http://www.americaninstruments.com.br/instrucao_uso). Reg. ANVISA: 80251140043 - Revision: 00. To obtain the printed version, contact: Phone: +55 19 3531-5116 - [info@americaninstruments.com.br](mailto:info@americaninstruments.com.br). Information that are in compliance with Normative Instruction No. 4 of June 15, 2012, which establishes rules for making Instructions for Use available in non-printed format for health products.

We would like to point out that it is necessary to observe the correlation between the version of the Instructions for Use available on the website, or printed, with the version indicated on the product label.

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## Instructions for Use Disposable Denniston Dilators Set

### LABELING TEMPLATE



### INDICATION AND PURPOSE

The product is easy to handle, indicated to gradually and quickly dilate the uterine cervical part (uterine cervix muscle) with the purpose of leaving a channel for penetration of other instruments during surgical procedures.

### WORKING PRINCIPLE/ MECHANISM OF ACTION

The candles in the kit (differentiated by diameter: 5 to 14 mm) are used according to the age and condition of the uterine cervix muscle (completely closed, slightly dilated or already well dilated).

It has two dimensions at both ends of each candle. It also has an engraved diameter number and a technical scale.

It is a disposable kit to be used by healthcare professionals in surgical procedures.

### HOW TO USE

1. Carefully examine the pelvic region, determining the size of the uterus and the direction of the cervical canal, as well as performing uterine palpation to confirmation.
2. Open the packaging at the indicated location and remove the kit, taking care not to contaminate parts of the product.
3. When you are sure of the direction of the cervical canal and after the paracervical block, fix the anterior cervical lip of the cervix with the tenaculum and gently insert the smaller tip of the dilator (candle) into the cervical canal.

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4. Advance slowly, allowing the dilator to open space into the uterine cavity.
5. Push gently until you feel less resistance in the uterine cavity or reach 5 mm (whichever comes first). This will indicate that the dilator has stopped compressing. Be careful not to cause perforation.
6. Repeat the procedure using the other side of the dilator.
7. Repeat the procedure using the subsequent larger size and continue with this procedure until the dilation is adequate for the proposed intentions.
8. Move the dilators gently during the procedure, avoiding any injury to the cervical canal.
9. Use the "no touching" technique, handling the instruments properly from the central part.
10. Manufacturer Recommends Single Use.

### TECHNICAL INFORMATION

Each kit that forms the set of candles contains 5, 4, 3, 2 or 1 unit. Ref: AI3001

Diameters:

1st candle - 5 to 6mm,

2nd spark plug - 7 to 8mm, 3rd spark plug - 9 to 10mm, 4th

spark plug - 11 to 12mm, 5th spark plug - 13 to 14mm.

Ref: AI3002

Diameters:

Single candle - 9 to 10mm. Ref: AI3003

Diameters: 1st spark plug - 7 to 8mm,

2nd spark plug - 9 to 10mm.

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## Instructions for Use Disposable Denniston Dilators Set

Ref: AI3004

Diameters:

1st candle - 5 to 6mm,

2nd spark plug - 7 to 8mm,

3rd spark plug - 9 to 10mm.

Ref: AI3005

Diameters:

1st candle - 5 to 6mm,

2nd spark plug - 7 to 8mm,

3rd spark plug - 9 to 10mm,

4th spark plug - 11 to 12mm.

Size of each candle: 28cm.

**STERILIZATION:** The Disposable Denniston Dilators Set is supplied as a sterile product and must only be removed from its original packaging in a sterile surgical environment and used immediately.

The sterilization method used is Ethylene Oxide Sterilization – ETO  
Sterilization validity: 02 years from the date of manufacture.

### STORAGE AND TRANSPORTATION CARE

The product must be stored in a clean, ventilated place, protected from sunlight.

The product must be transported and stored in a clean, airy place, protected from sunlight, heat sources and humidity.

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## Instructions for Use Disposable Denniston Dilators Set

### PRODUCT HANDLING

The product must only be used when the packaging is not compromised (broken).

Handle the material only with sanitized hands protected with gloves.

After use, this product constitutes a biological risk. The product must be disposed of in accordance with current municipal, state or federal legislation.

### WARNINGS

- This product is not designed, manufactured or marketed for purposes other than those indicated;
- The product is non-toxic and non-irritating, therefore it does not pose any risks to those handling it;
- Surgical techniques must be used, that is, the choice of the size of the candle to be first introduced, depending on the analysis carried out on the patient;
- Do not force the product, when moving it internally you must be precise and not move too quickly, looking at the scale to know when you have reached the bottom of the uterus;
- The middle portion is always thicker than the ends;
- Do not bend the product;
- Do not use if the candles are damaged, tampered with and/or modified.  
from its default state;
- The product is sterile, therefore use aseptic techniques for handling;
- The Manufacturer recommends single use. Reuse of the material may present an infection control risk, cause tissue irritation or malfunction;
- The product is sterilized in its final packaging, which must be handled with care so as not to cause folds and perforations.

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## Instructions for Use Disposable Denniston Dilators Set

The sterilization validity must always be observed on the packaging. Sterilization is performed using Ethylene Oxide - ETO, under a service provision contract with American Instruments;

- After use, this product may constitute a biological risk. The disposal of the product must be carried out in accordance with current municipal, state or federal legislation, always respecting the recommendations made for the treatment of hospital waste by the local Environmental Control Agency;
- Check the sterilization expiration date before using the product.

### PRECAUTIONS

- Always follow the instructions for use. The external labeling will provide a way to obtain the correlation between the product supplied and the version of the corresponding instructions for use;
- Check which one will be used based on the diameter and thickness of each candle. The difference between the candle sizes is visible.  
Each stick has two dimensions, one at each end.

**CONTRAINDICATIONS:** Not applicable.

**ADVERSE EFFECTS:** Not applicable.

### COMPLAINTS AND CUSTOMER SERVICE

Any customer or user of American products who has questions or wants further clarification about the products offered may contact American Instruments using the contact details contained in the instructions for use and labels on the product packaging.

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## Instructions for Use Disposable Candle Set

**MANUFACTURED BY:**

**AMERICAN INSTRUMENTS EIRELI EPP**

BRAZILIAN INDUSTRY

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