

... TECHNICAL SHEET ...

DISPOSABLE VAGINAL SPECULUM WITH CENTRAL PIN, STERILE

CODES	C.N.D. CODES	IDENTIFICATION n° ALLOTTED BY THE NOTIFIED BODY
0104 (small size, white pin)	U089006	11770/R
0104/S (medium-small, blue pin)	U089006	11770/R
0105/S (medium size, red pin)	U089006	11770/R
0106 (large size, green pin)	U089006	11770/R

TRADE MARK	EXPORT-SPEC
MANUFACTURER	G.P.S. S.R.L. – Via Del Chioso n. 8 – 24030 Mozzo (BG) - Italy Tel. 035-4376456 Fax 035-617844 E-mail: gps@gpsmedical.com website: www.gpsmedical.com
CLASS	I STERILE
RULES	Product conforming with 93/42/CEE dd 14.06.1993, Annex V
CE-MARKING	 certificate n° 099 QPS 301 09 issued on 22nd May, by the Notified Body 0373 Istituto Superiore di Sanità – Roma

1. USE

Device for temporary use as a help for the vaginal inspections for the dilatation of the vaginal canal and the exposition of the uterine neck during gynaecological visits.

2. DESCRIPTION/ADVANTAGES/PRODUCT INTRODUCTION

- The speculum has been manufactured with a fully anatomic contour.
- The central pin speculum allows to block the speculum at the required opening.
- The low temperature of stainless steel vaginal speculum, at the time of impact with the vulva may cause strong contractions. Consequently any possible cysts may break.
The vulva temperature is 1,1 °C warmer than the body's.
The plastic material, due to its own intrinsic characteristics, can keep a temperature of about 1 up to 2 °C warmer than the ambient temperature and it reduces the vaginal contractions as plastic is more flexible than stainless steel.
- It is transparent and by a light source it allows to check the internal vaginal walls.
- During diatermocoagulation it does not transmit heat and/or discharges when the electrosurgical lancet strikes against the vaginal speculum.
- The advantage of sterile and disposable products is due to the fact that surgeries usually do not have autoclaves.
- The physician's professionalism is improved when using disposable and sterile articles.
- The Export Spec opening is of 45°.
- The opening section, from where the visit takes place (observation section turned towards outside) is of approx. 1200 sq.mm.

3. FEATURES

The disposable vaginal speculum is manufactured with transparent, atoxic material.

PHTALATES : the raw material of the devices is phtalate-free

LATEX FREE : the production material as well as packaging material are latex free.

Raw material: polystyrene – Colour : transparent

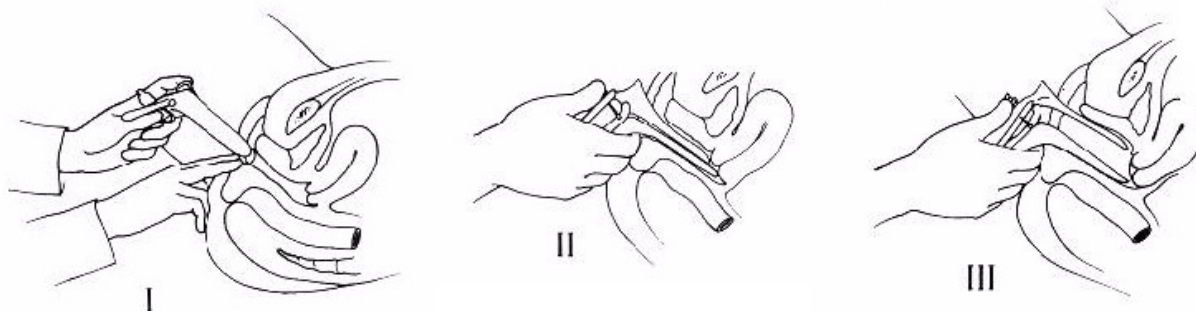


- Sizes	: Cod. 0104	Small size	Ø 20 mm.	White pin
	Cod. 0104/S	Small-medium size	Ø 24 mm.	Blue pin
	Cod. 0105/S	Medium size	Ø 26 mm.	Red pin
	Cod. 0106	Large size	Ø 30 mm.	Green pin

4. INSTRUCTIONS FOR USE

- It is preferable to lubricate the device before using it.
- Introduce slowly and gently the speculum into the vagina with the two bills closed.
- Therefore operate delicately the two handles until they get near. Screw the pin until it blocks, without any pressure of the hand.
- To take it out, unscrew. Close the two bills again. Take it out gently and dispose of it.

CAUTION: device to be used under medical control. Use it soon after opening the package.



5. MICROBIOLOGICAL CHARGE BEFORE STERILIZATION

Max 500 UFC each sample

6. RISK CONDITIONS

Description

The polystyrene (PS) is an amorphous vitreous solid with a molecular weight which may vary from 150.000 to 250.000 and it softens at a temperature of about 100°C.

There are different types of PS, the one used for the medical devices is the shock-proof PS and it is obtained by mixing PS with BASF rubber.

Features

Shock-proof PS is not appreciable when it is modified by the water and cannot be attacked by the action of the strong and weak acids; it is attacked by the oxidative acids and it melts (if bathed) into aromatic hydrocarbons, ketones.

The shock-proof PS does not help any chemical activity, it is atoxic and heat resistant (it is often used as a container for food to be pasteurised).

PRECAUTION IN STORAGE .

The only precaution is to prevent the presence of flames, as the shock-proof PS, once lit, it keeps on burning even without the source of heat.

It is advisable not to expose it to the sunlight (because it turns yellow) or in places where electrical shocks may take place.

UTILIZATION

The shock-proof PS is used very much, because of its transparency and atoxicity, in the medical products like: disposable syringe, brushes, specula, etc.

RISK FOR ITS UTILIZATION

It is not known any contra-indication for its utilization as a medical product of class 1.

NO CONTRA-INDICATION

BIBLIOGRAPHY

Enciclopedia della Chimica; USES Edizioni Scientifiche; Issue 1976

7. PACKAGING

The product is individually packaged in transparent heatwelded cellophane to medical paper Kraft one-sided glossy

This interior packaging guarantees an adequate waterproof protection and it allows the product to reach the enduser in safe hygienic conditions. The article is supplied :

in single packaging and sterilized by ethylene oxide.

Carton box with 120 pieces.(items : 0104-0104/S-0105/S-0106)

8. STERILIZATION/VALIDITY

In autoclave by ethylene oxide according to the validated cycle.

Contents sterile in unopened, undamaged package. Validity : 5 years.

9. PRESERVATION/STORAGE

Store in a dry place. Do not expose to the direct sunlight or to sources of heat.

10. CAUTIONS

Device to be used for gynaecological inspection.

Do not insist on inserting the device or even to try to open the uterus, as the speculum may break.

The device is disposable, therefore do not re-use it again.

The device must be used by physicians or by trained staff only.



11. DISCHARGE

The product is disposable, therefore do not re-use it . It can be burnt along with the other garbage, complying anyway with the regulations of the local authorities . The burning does not cause any toxic residues.

12. PACKAGE PRINTING

Details about the paper printing:

Details about paper	Weight	Colours of print
Kraft paper (Export - Spec)F. 405 White one-side glossy medical	GR. 60 / sqmt.	One-colour print, blue

The following details are printed on the below-indicated labels :

Product description
 Manufacturer's name
 Item number
 Sterilization date
 Lot number
 Validity
 Directions for use.



EXPORT- SPEC

Speculum vaginale monouso sterile. Gettare dopo l'uso. Non riutilizzare dopo l'uso. Conservare in luogo asciutto. Non esporre alla luce diretta del sole o a fonti di calore. Sterilità garantita a confezione integra e non lacerata. Sterilizzato con ossido di etilene. Il dispositivo deve essere utilizzato solo da medici o personale specializzato.

Spéculum vaginal stéril à usage unique. Jeter après l'usage. Ne pas réutiliser après l'usage. Tenir en lieu sec, n'exposer pas à la lumière directe du soleil ou à sources de chaleur. Stérilité garantie si le conditionnement est intact et pas déchiré. Stérilisé par oxyde d'éthylène. Le dispositif doit être utilisé seulement par les médecins ou par le personnel spécialisé.

Disposable sterile vaginal speculum. After use, speculum must be destroyed. Do not use it a second time again. Store in a dry place, do not expose to direct sunlight or to sources of heat. Contents sterile in unopened or undamaged wrapper. Sterilized by ethylene oxide. The device must be used by doctors or by trained staff only.

Espéculo vaginal estéril desechable. No lo re-utilizen más tras la primera vez. Conservarlo en un sitio seco, no lo expongan a la luz directa del sol o fuentes de calor. Esterilidad garantizada con envase intacto y no roto. Esterilizado por oxido de etileno. El dispositivo debe ser utilizado solamente por personal medico o especializado.

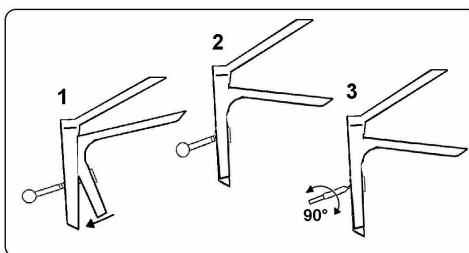
Steriler Einweggebaermutterspiegel. Nach Gebrauch nicht wiederverwenden! Trocken lagern, und keinem direkten Sonnenlicht oder waermequelle. Garantierte Sterilitaet nur bei geschlossener und unbeschadigter Verpackung. Sterilsierung mit Aethylenoxid. Das Geraet soll nur von dem Arzten oder von dem Fachpersonal gebraucht werden.

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da by **GPS**

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