



S504.200

ZOE[®] GYNECOLOGIC SIMULATOR

USER GUIDE



The ZOE[®] Gynecologic Simulator is an interactive educational system developed to assist a certified instructor. It is not a substitute for a comprehensive understanding of the subject matter and not intended for clinical decision making

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1. INTRODUCTION

1.1 SPECIFICATIONS

- 40 lbs.
- 36x24x18 inches

The Zoe Standard Package comes pre-installed with one normal cervix, transparent IUD uterus, a normal perineum with rectum, vagina and urethra insert.

1.2 TERMINOLOGY

Facilitator: The person conducting the simulation; an instructor or lab staff member.

Provider: A person participating in the simulation as a healthcare provider.

Perineum Insert: The structure that includes perineum with rectum, vagina, and urethra.

Pelvic Opening: The opening in the pelvic region of the trainer for installing the perineum insert.

Fill kit: Syringe and tubes used to fill urinary reservoir.

1.3 CARE AND MAINTENANCE

The lubricant and other accessories provided are for use with the accompanying patient simulator only. The lubricant and other accessories are not suitable for human use or medical treatment/ diagnosis and should never be used for such purposes.

CAUTION: Damage caused by misuse may void the manufacturer's warranty. Failure to comply with the following guidelines could result in damage to the equipment.

General

- Do not wrap this or any other Gaumard product in newsprint.
- Marks made with ballpoint pens, ink or marker cannot be removed.
- Only use simulated blood provided by Gaumard. Other simulated blood containing sugars and other additive may cause blockage of the fluid system.

Operating Conditions

- Operating the simulator outside these ranges may affect performance:
- Operating temperature: 50°- 95° F (10°- 35° C).
- Humidity: 5%-95% (non-condensing).

Cautions

- Treat the simulator with the same precautions that should be used with a real patient.
- Have providers wash their hands prior to use to prevent dirt and oils from clinging to the material.

- Do not palpate using fingernails as this may tear the skin.
- Palpate using the pads of the fingers.

CAUTION: To avoid damage to the simulator, please store and ship it in the clear poly bag provided.

Storage

- Store the simulator in a cool, dry place. Extended storage should be between 32°F to 85°F (0°C to 29°C). Other temperatures will cause the material to soften and slowly warp.
- It is acceptable to operate ZOE at an ambient temperature of 95°F (35°C). Humidity: 40%-60% (non-condensing).
- Do not stack or store heavy materials on top of the box.

Cleaning

- Remove all traces of lubricant after each procedure.
- Remove the fluid using the fill kit.
- Flush the fluid reservoirs with a 30:70 mix of isopropyl alcohol to water after each day of simulation then suction all fluid out.
- The simulator is “splash-proof” but not water proof. Do not submerge in water.
- The simulator should be cleaned with a cloth dampened with diluted liquid dishwashing soap.
- Do not clean with harsh abrasives.
- Do not use povidone iodine on the simulator.
- Dry thoroughly after every cleaning.
- After drying, application of talcum powder can return the simulator to its lifelike feel.
- Never drag or slide the simulator during transportation, or damage to the skin may occur.

2. OVERVIEW

2.1 FEATURES

- Uniform skin and accurate anatomy, including ischial spines, pubic bone, and sacrum, facilitate performing realistic examinations.
- Soft abdominal cover allows palpation of pregnant and non-pregnant uteri.
- Multiple interchangeable uteri aid facilitators in teaching specific skills to all levels of providers.
- Transparent uterus allows visualization of IUD placement and removal.
- Urethra that connects to a realistic bladder built for catheterization exercises with real instruments.
- Use interchangeable cervixes for visualization with speculum.
- Non-pregnant abdominal cover with two precut laparotomy incisions; one suprapubic and one subumbilical
- Normal anteverted and retroverted uteri whose fallopian tubes and ovaries are removable and replaceable for procedures including oophorectomy and tubal ligation
- Transparent IUD uterus with fallopian tubes and ovaries permanently affixed. The transparency of the uterus allows validation of positioning of the IUD
- Pregnant uteri for palpation and assessment:
 - 6-8 week pregnant uterus
 - 6 -8 week pregnant uterus with shortened ligaments
 - 10-12 week pregnant uterus
 - 20-week pregnant uterus
- 5 Normal patent cervixes - one installed and 4 spare
- 2 sets of Replacement fallopian tubes and ovaries
- Set of 6 abnormal cervixes for visual recognition of normal and abnormal characteristics including normal parous, polyp, cervical erosion, nabothian cyst, purulent cervicitis, and carcinoma
- 6-8 week pregnant cervixes for vaginal examination
- 10-12 week pregnant cervixes for vaginal examination

2.2 PROCEDURES

- Perform bimanual examinations with palpable, realistic uteri.
- Practice catheterization exercises multiple times with the aid of the urine reservoir.
- Simulate minilaparotomy, interval and postpartum tubal occlusion, and oophorectomy with the aid of the precut incisions on the abdominal cover and the additional ovaries and fallopian tubes provided.
- Simulate interval laparoscopic occlusion (Falope rings or Hulka clips) with the replacement ovarian ligaments and fallopian tubes.
- Practice introducing a female condom, or sizing a 75mm diaphragm through the vaginal introitus.
- Perform hysteroscopy and use a uterine manipulator through the realistic vaginal introitus.
- Perform bimanual examination, vaginal examination with easily interchangeable cervixes, and have visual recognition of normal and abnormal variations with a speculum.
- Perform uterine sounding with real tenaculum and sound with the interchangeable uteri.
- Evaluate multiple conditions using the interchangeable cervixes with normal and abnormal pathologies.
- Simulate bladder distention with the realistic bladder.
- Insert suppository in the patent rectum.

3. INITIAL SETUP

3.1 CARE AND CAUTIONS DURING UNBOXING

- When unboxing the simulator, hold and lift from both sides of the torso.
- Do not pull or drag from the upper legs.
- Lay on a clean, flat surface for use.

No assembly is required before using the ZOE simulator.

3.2 PACKAGE CONTENTS



- | | | |
|---|-------------------------------------|--------------------|
| 1. Non - pregnant abdomen | 8. Anteverted uterus | 16. Urine fill kit |
| 2. Normal perineum insert | 9. 20 week pregnant uterus | |
| 3. 6 to 8 week pregnant uterus with shortened ligaments | 10. 5 normal patent cervixes | |
| 4. 10 to 12 week pregnant uterus | 11. 6 to 8 week pregnant cervixes | |
| 5. 6 to 8 week pregnant uterus | 12. 10 to 12 week pregnant cervixes | |
| 6. Transparent IUD uterus | 13. 6 abnormal cervixes | |
| 7. Retroverted uterus | 14. 2 sets of ovaries | |
| | 15. 2 sets of fallopian tubes | |

3.3 REMOVING THE ABDOMINAL COVER

1. The abdominal cover attaches with magnets. To remove the abdominal cover, gently lift holding both sides.



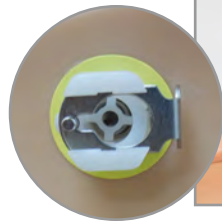
2. To secure the abdominal cover, simply orient it with the magnets and press down gently.



CAUTION: Exposure to excessive heat will warp the material inside the abdomen and alignment will be off.

3.4 FILLING THE URINARY RESERVOIR

1. Disconnect the urethral extension from the yellow urinary fill port by squeezing the release button.



2. Use the syringe in the urinary filling kit to fill the bladder through this port with up to 400mL of fluid.



3. Reconnect the urethral extension to the yellow urinary fill port.



4. To simulate bladder distention, add an additional 240mL of simulated urine by injecting fluid directly through the urethra.

5. Catheterize the simulator, then inject fluid through the drain end of the catheter (size 16 Fr recommended).



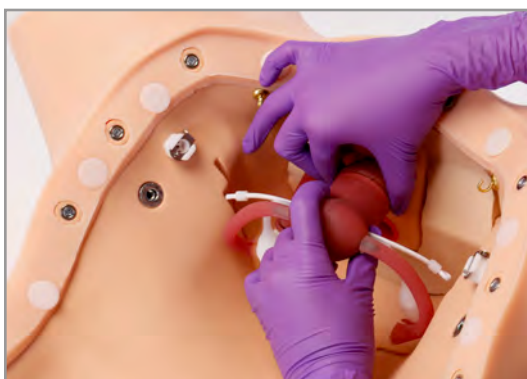
4. WORKING WITH THE SIMULATOR

4.1 CHANGING THE UTERUS

1. Unhook the round ligament from both sides.



2. Gently twist the uterus 1/4 of a turn counter-clockwise with one hand and hold the cervix with the other.



3. Select the desired uterus and align the receiving holes with the white connectors. To secure it, twist the uterus clockwise.

Note: If the cervix and uterus are sticking, you may use isopropyl alcohol to lubricate the area to prevent tearing and ease assembly.



4. Hook the round ligament on each side to the pelvic wall.



4.2 CHANGING THE CERVIX

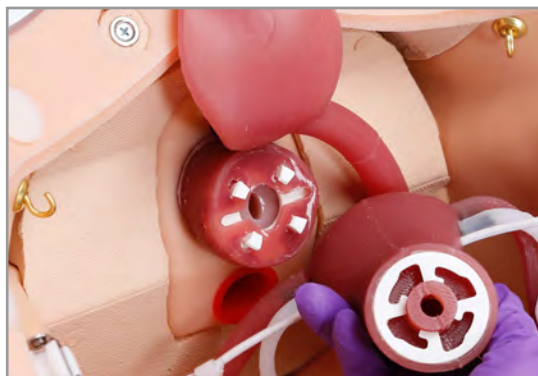
1. Gently slide the top of the vaginal wall off the 4 white connectors of the installed cervix, and pull from the end of the vagina.



2. Select the desired cervix and insert it into the end of the vagina facing the vaginal opening.



3. Secure the cervix into the vagina by aligning the 4 white connectors and inserting them into the receiving holes.



4. Once the cervix is securely in place, install the desired uterus.



Abnormal Cervix Identification



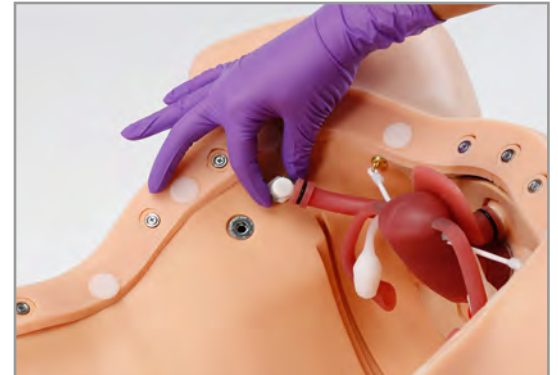
The 6 Non-patent cervixes include:

1. Cervical Erosion with some mucus
2. Normal Parous
3. Cervical Polyp
4. Inflamed Nabothian Cyst
5. Acute Purulent Cervicitis
6. Squamous Cell Cancer of the Cervix

The number on the back of the cervix correlates to the listed pathology.

4.3 CHANGING THE PERINEUM INSERT

1. Detach the yellow urinary fill port by squeezing the release button.



2. Unhook the round ligament from the pins on the pelvic wall.



3. Locate the posts embedded in the skin around the pelvic opening, and then gently pull them out one at a time.



CAUTION: Pulling the skin in other areas not near the posts may cause tearing. Pull close to the posts to avoid damage.

4. Untuck the edges of the perineum insert from the skin around the pelvic opening and push the perineum insert through the pelvic opening from the inside.



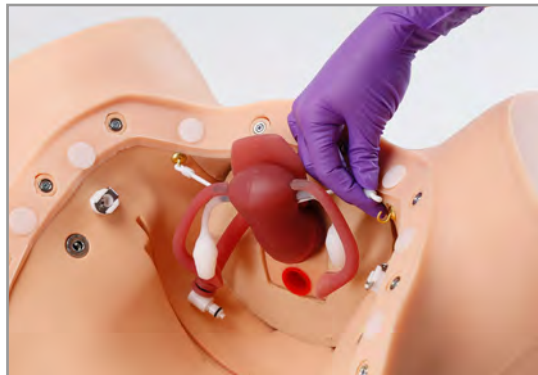
5. Place the new perineum insert against the outside and push the perineum insert through the pelvic opening.



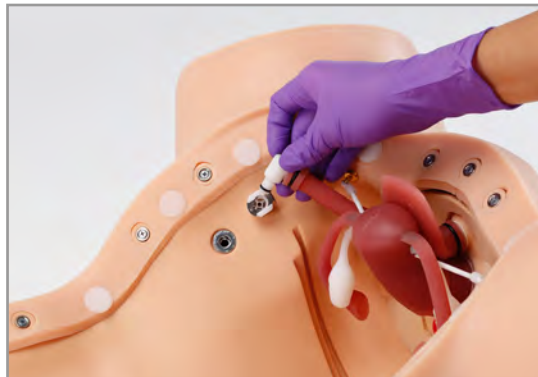
6. To secure the perineum, tuck in the edges to orient the holes of the perineum insert with the 6 holes located around the pelvic opening, then gently push the 6 snaps embedded in the skin into each hole.



7. Attach the round ligaments on the uterus to the pins on each side of the pelvic wall.

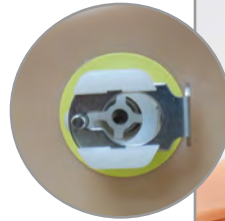


8. Connect the urethral extension to the yellow urinary fill port.



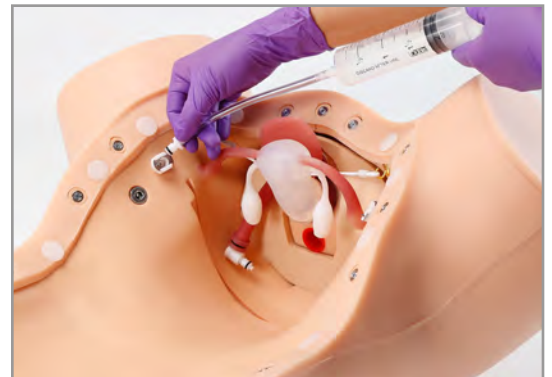
4.4 DRAINING THE URINARY RESERVOIR

1. Locate the yellow urinary fill port and disconnect the urethral extension.

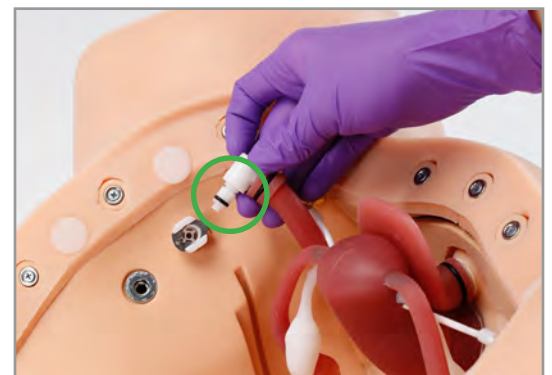


2. Using the syringe provided with the urinary fill kit, suction the reservoir until all the remaining fluid is collected.

NOTE: Reference the cleaning section for more details when draining reservoir to prepare for storage.



3. To drain the bladder, you may catheterize the simulator or press the port on the end of the urethral extension.



4.5 CHANGING THE FALLOPIAN TUBES AND OVARIES

The IUD uterus has permanently attached fallopian tubes and ovaries, however, the anteverted and retroverted uteri have replaceable ones for surgical exercises.

1. Unscrew the fallopian tubes twisting them counter-clockwise.



2. Unscrew the white ovaries twisting them counter-clockwise.



3. Choose the new fallopian tube and ovaries for each side and screw them on twisting them in a clockwise motion.



5. OPTIONAL PACKAGES

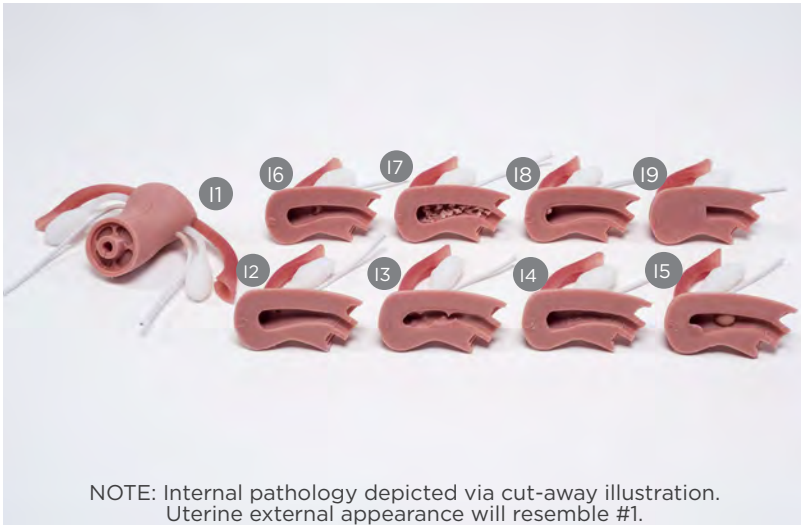
5.1 OPTIONAL PACKAGE 1: NORMAL AND ABNORMAL UTERI WITH EXTERNALLY PALPABLE PATHOLOGIES



- E1. Uterus with moderate retroversion
- E2. Myomatous uterus
- E3. Uterus with left side salpingitis
- E4. Uterus with right side salpingitis
- E5. Severely anteverted - anteflexed uterus
- E6. Uterus with large ovarian cyst
- E7. Uterus with medium ovarian cyst
- E8. Enlarged uterus
- E9. Small uterus
- E10. Bicornuate uterus

To change the uteri, follow the steps outlined in Section 4.1 Changing the Uterus.

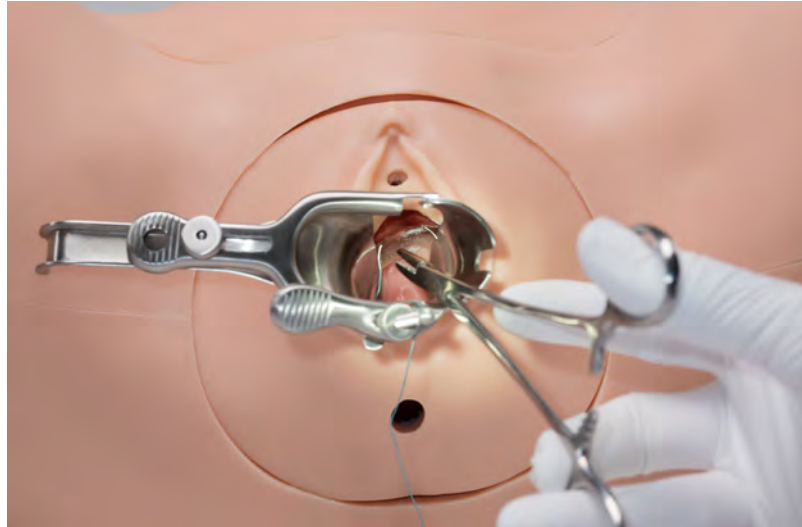
5.2 OPTIONAL PACKAGE 2: NORMAL AND ABNORMAL UTERI WITH INTERNAL PATHOLOGIES FOR HYSTEROSCOPIC VIEWING



11. Normal uterus
12. Uterus with polyposis
13. Uterus with varied polyps
14. Uterus with hyperplasia
15. Myomatous uterus
16. Uterus with early carcinoma
17. Uterus with advanced carcinoma
18. Uterus with fundus carcinoma
19. Subseptate uterus

To change the uteri, follow the steps outlined in Section 4.1 Changing the Uterus.

5.3 OPTIONAL PACKAGE 3: FISTULA MODEL PERINEUM WITH THREE FISTULA TYPES FOR SUTURE & REPAIR



1 perineum insert includes the following fistulas:

1. vesicovaginal
2. rectovaginal
3. urethrovaginal

To change the insert, follow the steps in [Section 4.3 Changing the Perineum Insert](#).

6. APPENDIX

6.1 PARTS LIST

Product	Item Number	Content
ZOE Standard Package	S504.200	Non-pregnant abdomen Normal perineum insert Anteverted uterus Retroverted uterus Transparent IUD uterus 6 to 8 week pregnant uterus 6 to 8 week pregnant uterus with shortened ligaments 10 to 12 week pregnant uterus 20 week pregnant uterus 5 normal patent cervixes 6 abnormal cervixes 6 to 8 week pregnant cervixes 10 to 12 week pregnant cervixes Urine fill kit
Optional Package 1: External uterus pathologies	S504.200.235	Moderate retroversion Myomatous Salpingitis (Left) Salpingitis (Right) Anteversion - anteflexed Ovarian cyst large Ovarian cyst medium Large Uterus Small Uterus Bicornate
Optional Package 2: Internal uterus pathologies	S504.200.236	Healthy characteristics Polyposis Varied polyps Hyperplasia Fibroid Early carcinoma Advanced carcinoma Fundus carcinoma Sub Septate
Optional Package 3: Fistula Package	S504.200.700.1	Fistula model including vesicovaginal Rectovaginal Urethrovaginal fistulas

6.2 EXCLUSIVE ONE-YEAR LIMITED WARRANTY

Gaumard warrants that if the accompanying Gaumard product proves to be defective in material or workmanship within one year from the date on which the product is shipped from Gaumard to the customer, Gaumard will, at Gaumard's option, repair or replace the Gaumard product.

This limited warranty covers all defects in material and workmanship in the Gaumard product, except:

- Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product;
- Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to properly clean the Gaumard product; and
- Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative.

This one-year limited warranty is the sole and exclusive warranty provided by Gaumard for the accompanying Gaumard product, and Gaumard hereby explicitly disclaims the implied warranties of merchantability, satisfactory quality, and fitness for a particular purpose. Except for the limited obligations specifically set forth in this one-year limited warranty, Gaumard will not be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory regardless of whether Gaumard has been advised of the possibilities of such damages. Some jurisdictions do not allow disclaimers of implied warranties or the exclusion or limitation of consequential damages, so the above disclaimers and exclusions may not apply and the first purchaser may have other legal rights.

This limited warranty applies only to the first purchaser of the product and is not transferable. Any subsequent purchasers or users of the product acquire the product "as is" and this limited warranty does not apply.

[This limited warranty applies only to the products manufactured and produced by Gaumard. This limited warranty does not apply to any products provided along with the Gaumard product that are manufactured by third parties.](#)

For example, third-party products such as computers (desktop, laptop, tablet, or handheld) and monitors (standard or touch-screen) are not covered by this limited warranty. However, third-party products are covered by the warranties provided by the respective third-party manufacturers and such warranties are transferred from Gaumard to purchaser upon purchase of the Gaumard product. Defects in third-party products are covered exclusively by the warranties provided by the third-parties. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Please contact the third-party manufacturer for information regarding the availability of extended warranties for third-party products. Any waiver or amendment of this warranty must be in writing and signed by an officer of Gaumard.

In the event of a perceived defect in material or workmanship of the Gaumard product, the first purchaser must:

1. Contact Gaumard and request authorization to return the Gaumard product. Do NOT return the
2. Gaumard product to Gaumard without prior authorization.
3. Upon receiving authorization from Gaumard, send the Gaumard product along with copies of (1) the original bill of sale or receipt and (2) this limited warranty document to Gaumard at 14700 SW 136 Street, Miami, FL, 33196-5691 USA.

If the necessary repairs to the Gaumard product are covered by this limited warranty, then the first purchaser will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then the first purchaser will be liable for all repair costs in addition to costs of shipping and handling.

6.3 CONTACT GAUMARD

Before contacting technical support, please make sure to have your simulator and user guide readily available.

Email: support@gaumard.com

USA: 800-882-6655

INT: 01-305-971-3790

6.4 GENERAL INFORMATION

E-mail: sales@gaumard.com

USA: 800-882-6655

INT: 01-305-971-3790

Fax: 305-252-0755

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