

USER MANUAL 1023727, 1023731

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> PRODUCT INTRODUCTION

Developed in collaboration with leading obstetricians in Germany, the Postpartum Hemorrhage (PPH) Simulator P97 PRO provides a solution for hands-on and realistic training sessions for early recognition, systematic evaluation and treatment of PPH. Severe bleeding after birth can be fatal for the new mother within hours if she is not diagnosed and treated. To improve PPH outcomes, the PPH trainer P97 PRO from 3B Scientific helps obstetric and healthcare professional teams train the timely management and care of postpartum bleeding.

In addition to the stand-alone product P97 PRO (1023727), a version of the PPH add-on module (1023731) for the existing Birthing Simulator P90 (1022879 or 1022878) is also available. The instructions and application possibilities are identical for both products unless expressly indicated.

> DELIVERY CONTENT



- 1. P97 PRO Trainer
- 2. Deflation bulb with tube
- 3. Vaginal rupture insert + 1 Replacement part
- 4. Placenta with 3 residual pieces + 1 Set of replacement residuals
- 5. 2 Foam uteri
- 6. 3 Color-coded tubes for specific blood delivery

- 7. Color-coded bleeding connector
- 8. Blood reservoir 3000 ml
- 9. Artificial blood concentrate (2*250 ml)
- 10. Lubricant (250 ml)
- 11. Drying stand for uterus cavity



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SAFETY INSTRUCTIONS

Please read the below safety instructions before using the P97 PRO



Follow the instructions and keep in mind the warnings while using the product.



Wear gloves at all times while using the product. Fingernails can damage the silicone parts.



Do not wear any jewellery items.



Keep away from heating sources. Do not expose the product to naked flames. Avoid the use of flammable solvents near or on this product.



Do not use any attachments other than those supplied in the package.



Follow the cleaning instructions after the training sessions.

> FUNCTIONS

Thanks to a 3000 ml blood reservoir and the compact tubing sysstem, major severe PPH scenarios can be simulated. With P97 PRO, three main postpartum bleeding causes can be evaluated and treated: Tonus, trauma and tissue. Different levels of the uterine tone are easy to adjust. On this PPH trainer, even the suturing of vaginal tears is possible and the rupture inserts are replaceable. The placenta is made of silicone for a realistic feel and softness. A retained placenta can be manually removed from the uterine cavity to train the required medical interventions.

With P97 PRO you can train on:

- Performing fundal massage and bimanual compression
- Suturing of vaginal tears
- 360-degree cervical visual inspection
- Manual removal of a retained placenta
- Intrauterine balloon tamponade
- Uterine packing with gauze
- Blood loss estimation
- Bladder catheterization
- Demonstration of uterine compression suture techniques e.g. B-Lynch, Haymann, Pereira, Cho and Ouabha is possible on the separated foam uteri















> INSTALLING THE P97 PRO

To begin your PPH training, you need to install the P97 PRO trainer; you can easily do it by following the steps given below.

 Add artificial blood by mixing 250 ml of blood concentrate with 1.5 l water. Fill the blood reservoir bag up with artificial blood and hang it on the infusion stand*.



Note: you can mix and add artificial blood up to 3000 ml.



Note: Make sure to close the valve in the upward direction before use.







3. Connect the blood delivery tubes to the corresponding color codes on the connector.



4. Unbutton the silicon piece and remove the abdominal wall foam backing.



Note: If you have purchased the P97 PRO Module, please follow the steps 1-5 under "Assembling the P97 Pro after cleaning" on page 12 instead, before you move to the next step.



*infusion stand is not part of the scope of delivery.

5. Reach the color-coded openings at the bottom of the uterus and connect the corresponding ends of the blood delivery tubes.





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Note: The tube with color code red has to be inserted few inches deep into the slot so that the vaginal rupture could be connected to it from the vaginal canal.



6. Connect the deflation bulb to the point found at the bottom end of the uterus.



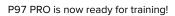
7. Re-insert the abdominal foam backing and button the abdominal wall silicone piece.



8. Finally, fix the vaginal rupture insert into the dedicated spot in the vagina. Make sure that the blood delivery tube is inserted firmly into the rupture insert.



Note: For a firm fixation and to avoid unwanted blood leakage, the edges of the rupture insert must be fully covered by the surrounding silicone layer.





> HOW TO START THE BLEEDING DELIVERY

P97 PRO allows you to demonstrate 3 types of bleeding scenarios in PPH. To initiate your choice of bleeding scenario please follow the instructions below:



Note:

Please observe the opening position for the blood delivery to start.

1. Uterus bleeding:

To start the uterus bleeding open the valve on the bleeding connector with color code ${\sf -}$ blue.

2. Cervix bleeding:

To start the cervix bleeding open the valve on the bleeding connector with color code – yellow.

3. Vaginal bleeding:

To start the vaginal bleeding, please incise the vaginal rupture using skallpell* and then open the valve on the bleeding connector with color code – red.





Note: The incision in the rupture should be deep enough i.e cutting through the silicone layer to reach into the foam layer of the rupture insert.



*skallpell is not a part of the delivery content.

> APPLICATION POSSIBILITIES

P97 PRO is a comprehensive PPH trainer, which allows you to teach your students to diagnose and perform the treatment required to control the blood loss in a patient. Here are the various application possibilities you get using this trainer:

1. Removal of retained placenta:

A placenta with three residual pieces can be placed in the uterus to train the required medical interventions like manual removal a retained placenta.



2. Fundal massage & Bi-manual compression:

The student can perform fundal massage and bi-manual compression. The instructor can control the uterine tone by deflating the uterus using the deflation bulb.



Note:

To contract the uterus please turn the blue valve to the middle position as shown in the image.



3. Intrauterine balloon tamponade:

The students can learn to insert the balloon tamponade into the uterine cavity.



Note

The size of the uterine cavity is big enough to accommodate the placement of a Bakri Balloon.



4. Uterine packing with gauze



5. 360-degree cervical visual inspection



6. Vaginal tear suturing:

You can incise any common pattern of the vaginal tear on the vaginal rupture inserts. Suturing of incisions can be trained using real tools and instruments.



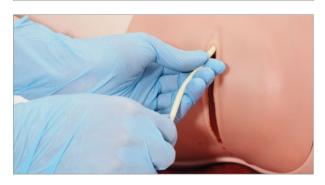
7. Uterus compression suturing:

You can use the 2 separate foam uterus (included in the delivery content) to train all kinds of common compression sutures.



8. Bladder catheterization (no fluids):

Both silicone and PVC catheters can be used. When using Foley catheters, we recommend the size CH12 or otherwise the size CH14. Catheters with straight and rounded tips should be used. Please place lubricating gel on the tip of the catheter to ensure that the catheter can be inserted smoothly.



CLEANING AND CARE

Cleaning P97 PRO is a simple process and we highly recommend you to follow these cleaning instructions after use:

1. Washing the placenta:

Remove any traces of blood or lubricant on the placenta and the residuals by washing them with a neutral soap and wipe them with a tissue or a cloth

2. Draining the blood reservoir:

To drain the blood reservoir, firstly make sure the blue valve is locked in an upward direction. Then disconnect the luer lock system.

3. Washing the reservoir:

Remove the blood reservoir and drain it completely opening the white opening on top. Wash it thoroughly with water and refill again with fresh water for further cleaning of the simulator.

4. Internal wash of P97 PRO:

Connect the color coded tubes to the blood reservoir and release water from it into the simulator in order to give it a wash internally. Do it until you see clear water coming out of the vagina.

5. Washing the blood delivery tubes:

Open the silicon body and the abdominal foam backing. Gently pull out the deflation bulb tube and the color coded blood delivery tubes.

6. Washing the vaginal rupture:

Next, remove the vaginal rupture insert and squeeze out the blood concentrate and give it a wash.



Note:

This insert is a consumable, therefore it can be thrown away and replaced with a new insert.

7. Washing the uterus & the vaginal canal:

Remove the silicon body completely by pulling the uterus in an upward direction. Fill water in the uterus via the vaginal canal and wash the uterus with a regular bottle cleaning brush. Squeeze out any remaining water from the uterus. Hang the uterus into the drying stand allowing it to air dry.

Finally, wipe out any blood stains from the abdominal cavity on the simulator.



ASSEMBLING THE P97 PRO AFTER CLEANING

After cleaning, you can easily assemble the P97 PRO trainer back to its original form by following these steps:

- 1. Place the simulator on a non-slip surface e.g. a table.
- 2. Fix the pelvic insert around the vaginal canal on the silicone piece (observe correct orientation).
- 3. Then pushing from above, insert the silicone piece along with the pelvic insert into the pelvis until the uterus is firmly positioned.
- 4. Place the abdominal wall foam backing covering the abdominal cavity
- 5. Bring the abdominal wall silicon piece on top of the foam and secure the silicon piece to the base.
- 6. Start to button the bottom of the torso; place the circular hollow space of the fastener firmly on the white fasteners and pull down until locked.
- 7. Follow the similar steps to button the top of the torso, except the circular hollow space of the fastener needs to be pulled in upward direction until locked.



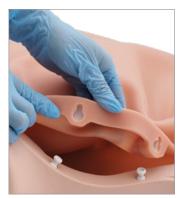


2.





4.





> REPAIR OF SILICONE PARTS:

Only persons with technical experience should perform the repair. We recommend using the ELASTOSIL® E41 TRANSPARENT adhesive from the manufacturer Wacker Chemie AG, Munich, Germany, for the repair. The manufacturer's processing and safety instructions must be observed.

Procedure:

- 1. Clean the bonding areas meticulously with readily available benzine
- 2. Apply the adhesive on both sides of the bonded areas
- 3. Join the parts quickly
- 4. Excess adhesive can be spread perpendicularly to the gluing surface and ensures a better but also stiffer bond
- 5. Ensure that the bonded area is not moved and remains fixed until complete vulcanization (curing) has taken place

The curing time at 50% relative humidity and 23°C is 12 hours per 1 mm adhesive layer thickness.

CONTACT INFORMATION



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> TECHNICAL DATA

Weight: 7.5 Kg (1023727); 3.7 Kg (1023731)

44×52×25 cm Dimension trainer:

Operating temperature: 0°C à +30°C (32°F à 86°F) Storage temperature: -10°C à +40°C (14°F à 104°F)

> ORDER LIST

Trainer Item	No.
PPH Trainer P97 PRO (stand-alone) 1023	727
PPH P97 PRO Module (add-on) 1023	731
Birthing Simulator P90 PRO 1022	879
Birthing Simulator P90 BASIC 1022	878

Consumables	Item No.
Vaginal rupture inserts 5 pieces	1023761
Foam uteri 2 pieces	1023762
Placenta with 2 sets of residual pieces	1023763
Placenta residual pieces 1 set	1023764
Artificial blood concentrat (10*250 ml)	1021572
Lubricant (2*250 ml)	1020608