S411 Lumbar Puncture Trainer

User Guide
Disclaimer

The Lumbar Puncture Trainer (S411) is to be used only as part of an approved educational program for health professionals. It should not be used for clinical decision making.

Warning

The replaceable Spinal Canal Assembly tubing contains latex which may cause allergic reactions. Users allergic or sensitive to latex should avoid contact. Discontinue use of this product and seek medical attention if an allergic reaction occurs.

Care should be taken against having anything resting or pressing against the Lumbar Puncture Spinal Insert when packing the model into the carrying bag. If this occurs, "dents" or indentations will form on the Insert at the pressure points. The indentation may return after the pressure is relieved.

Please read Section III: Equipment Set-Up before beginning training exercises with the Lumbar Puncture Trainer.

Caution

Treat the Lumbar Puncture Trainer with the same precautions used with a real patient. Damage caused by misuse is not covered by your warranty.

- Have trainees wash their hands prior to use.
- Palpate using the pads of the fingers. Do not palpate using fingernails as this may tear the skin.
- Do not press the Lumbar Trainer against soiled surfaces, ink or newsprint.
- Do not use iodine or betadine type solutions; these will most likely permanently stain the simulator.
- Do not write on the trainer.

The use of needles larger than 18 gauge will reduce the lifetime of the Lumbar Puncture Spinal Insert. When replacement is required, refer to “Lumbar Puncture Spinal Insert” in the “Simulator Components” Section.

Cleaning

The Lumbar Puncture Trainer should be cleaned with a cloth dampened with diluted liquid dishwashing soap. If medical adhesives remain on the skin, clean with alcohol wipes.

The Lumbar Puncture Trainer is water resistant but not water proof. Do not submerge or allow a large volume of fluid to enter the interior of the simulator.

Only use distilled water for the simulated CSF. Any other simulated CSF containing sugar or any additive may cause blockage and/or interruption of the CSF supply system.

Place talcum powder on the insert surface to reduce tackiness. This can be reapplied as needed.

Storage

Store the Lumbar Puncture Trainer in a cool, dry place. Extended storage above 85 degrees Fahrenheit (29 Celsius) will cause the simulator to soften and slowly warp. It is acceptable to operate the Lumbar Puncture Trainer at an ambient temperature of 95 degrees Fahrenheit (35 Celsius).

How to Contact Gaumard®

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By Phone: Toll-free in the USA: 800.882.6655
           Worldwide: 305. 971.3790
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           Office hours: Monday-Friday, 8:30 - 4:30 PM EST

Note: Before contacting Gaumard you must:

1. Have the Simulator Serial Number (if applicable) and/or model number available.
2. Have the Simulator available if troubleshooting is needed.
I. Introduction

Your S411 Lumbar Puncture Trainer is a training tool that was developed to assist health professionals in teaching the processes and skills required to perform both a lumbar puncture and an epidural procedure.

The Lumbar Trainer provides realistic tactile feedback combined with a fluid supply and pressure system. The fluid supply and pressure system allows the simulated cerebrospinal fluid to be pressurized to a specific set-point representing low, normal, or high CSF pressure values.

The system allows the measurement of CSF Opening Pressure, and the measured value can be compared with the system set-point, read from the LED display, to assess accuracy.

Features of the Lumbar Puncture Trainer

Your trainer is equipped with the following features:

- Replaceable Lumbar Insert with skin layer, subcutaneous layer, connective tissue, and lumbar vertebrae.
- Anatomic features include: iliac crests, lumbar vertebrae L2 – L5, ligamentum flavum, epidural space, and dura.
- Needle insertion possible between vertebrae.
- Lifelike needle resistance, including pops when needle traverses ligamentum flavum and dura.
- Self-healing skin that allows 15 uses with an 18 gauge needle and 25 uses with a 22 gauge needle before replacement is necessary.
- Simple to fill simulated CSF and set fluid pressure, thereby allowing students to collect CSF and measure CSF Opening Pressure.
- Pressure system with simple push-button operation to increase or decrease pressure.
- LED displays pressure set-point ranging from 0 to 57 cm H2O.
- A replaceable Spinal Canal Assembly.
- Trainer can be used to simulate aseptic technique and local anesthetic at puncture site.
- Easy assembly and disassembly.
- Supporting stand to allow procedures in both, the left lateral decubitus or sitting position.
- Medium skin tone is the standard color of the simulator. Light or dark skin tone is available at no extra cost.

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Practice injection of local anesthesia at puncture site.

Exercise needle insertion between vertebrae.

Train on collecting simulated CSF.

Practice measuring of the CSF Pressure.

Familiarize with the needle resistance, including the “pops” when needle traverses the simulated ligamentum flavum and dura.

Practice procedure in the left lateral decubitus or sitting position.

### II. Contents

The S411 Lumbar Puncture Trainer includes:

- Adult Torso
- Three Spinal Canals
- Two Spinal Cord Inserts
- Stand
- Two Fasteners with washers
- Filling Kit that includes: one Syringe and filling tube with white Luer-Lock and one draining tube with black Luer-Lock
- Power Supply
- Soft Carrying Case
- User Guide

### III. Equipment Set-Up

1. Remove the pre-assembled S411 Lumbar Puncture Trainer, Stand, Power Supply and Filling Kit from the carrying case and place it on a flat, clean and dry surface.

   The Lumbar Puncture Trainer comes pre-assembled with one Spinal Canal and Spinal Cord Insert in place. In order to replace these components, please refer to the “Simulator Components” section.

#### Filling the Simulated CSF

⚠️ **Warning**

To collect Cerebral Spinal Fluid to measure the pressure of the simulated CSF you need to fill the Lumbar Trainer with distilled water.

The Lumbar Trainer is equipped with easy fill and drain ports to add and drain simulated CSF. The ports and Luer-Locks are color coded for easy assembly.
**Warning**
Only use distilled water for the simulated CSF. Any other simulated CSF containing sugar or any additive may cause blockage and/or interruption of the CSF Supply system.

**Warning**
Always place the Lumbar Trainer on a vertical position when adding the simulated CSF.

1. Fill the supplied filling syringe with distilled water.
2. With the Lumbar Trainer on a vertical position, connect the filling tube, using the Luer-Lock, to the white fill Port.
3. Connect the draining Tube, using the Luer-Lock, to the black drain port.
4. Place the end of the draining tube in a collection container.
5. Inject the fluid into the system by depressing the syringe.
6. Re-fill the syringe with the desired fluid, and inject the fluid into the system.

**Information**
Approximately 120 mL of fluid is required to fill the system.

**Information**
The system is completely filled when no entrapped air bubbles are seen venting from the drain port.

7. Once the system is completely full, continue with the next section.

**Power Supply Connection**

1. Locate the power supply connector on the Lumbar Trainer, and insert the power supply plug. Connect the power supply to a power outlet.
When the Lumbar Trainer is connected to a power supply, the LED display, located on the right torso, would light up. The starting pressure point for the Lumbar Trainer is zero.

Pressurizing the System

1. Disconnect the draining tube. Leave the filling syringe attached to the filling port.
2. Refill the syringe with water if necessary and insert more fluid into the closed system.
3. Continue filling the system until the LED display shows OL (overload).
4. When the LED display shows OL, stop filling in the simulated CSF into the Lumbar Trainer and reattach the draining tube.
5. Continue inserting fluid in the system to remove entrapped air.

The LED display would show the pressure of the system while the fluid is being inserted.

The system is completely filled when no entrapped air bubbles are seen venting from the drain port.

The air from the system has been purged and the Lumbar Trainer is ready for use.

Stand Assembly

The stand allows the Lumbar Puncture Trainer to be set up in either the Left Lateral Decubitus position or the Sitting position.

To set up the stand, gather the stand, fasteners and the Lumbar Trainer.

1. Choose the orientation preferred to complete the procedure.
2. Secure the stand to the Task Trainer by threading the fasteners through the designated holes on the Stand and into the threaded inserts in the back of the Trainer.

If you are placing the Trainer in the sitting position, thread the fasteners through the inner holes on the stand.

The base of the stand has rubber strips that prevent slippage on the table surface.

Setting the Pressure on the Lumbar Trainer

The LED display, located on the right side of the torso, can be used to display the pressure set point and either increase or decrease that pressure from 0 to 57 cm H₂O, based on the procedural needs.

The display includes 3 buttons which are to 1) turn the display on and off, 2) increase the pressure, and 3) decrease the pressure. When the system is first powered up, the pressure is automatically set to zero.

⚠️ Warning
Do not increase the pressure of the Lumbar Trainer until you have filled the system with simulated CSF.

1. To set the pressure, turn the LED display ON using the labeled button.

The pressure can be increased using the “Up” button.

If you overshoot the mark, the pressure can be decreased using the “Down” button.
To calibrate the pressure of the Lumbar Trainer refer to “Calibrating the Lumbar Trainer” on Section V: Appendix.

The pressure can be increased or decreased at any time during the procedure using the “Up” and “Down” buttons. During the Lumbar Puncture or Epidural Procedure, the display can be turned off so that the pressure set point is not visible.

Information
Even when the display is turned off, the system maintains its pressure; however, if the power supply is disconnected, the pressure will revert back to 0 cm H₂O.

IV. Simulator Components

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<thead>
<tr>
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<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Torso</td>
<td>Iliac crests for anatomical location</td>
</tr>
<tr>
<td></td>
<td>Supporting stand for upright and left lateral decubitus positioning.</td>
</tr>
<tr>
<td>Spinal Insert</td>
<td>Multi-layer including simulated skin, subcutaneous, connective tissue, and lumbar vertebrae</td>
</tr>
<tr>
<td></td>
<td>Anatomic features including iliac crest, lumbar vertebrae L2 – L5, simulated ligamentum flavum, epidural space, dura</td>
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<tr>
<td></td>
<td>Replaceable</td>
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</tbody>
</table>

CSF Supply System

- Simple to fill simulated CSF and set fluid pressure
- Electronically controlled pressure system with push button to increase or decrease pressure
- LED displays pressure set-point ranging from 0 – 57 cm H₂O
- CSF collection and opening pressure measurement
- Replaceable Spinal Canal

Other

- Aseptic technique
- Easy Assembly and Disassembly
- Portable

Disclaimer
The content of this table is subject to change without prior notice. Please contact Gaumard Scientific for the most current information.

Adult Torso

The Adult Torso consists of a lower torso segment with a recess or opening designed to receive the Lumbar Puncture Spinal Insert.

The Torso includes critical anatomic landmarks, including the location of the iliac crests, to provide the visual cues for the location of the puncture site between the L4 and L5 vertebrae (or alternately between the L3 and L4 vertebrae).

The Adult Torso is shipped with a Supporting Stand that allows the Lumbar Trainer to be secured in either the Upright (Sitting) Position or the Left Lateral Decubitus Position. The Supporting Stand includes non-slip feet to ensure the trainer remains secured during the procedure.
For an explanation on how to assemble the Adult Torso to the Supporting Stand, please refer to “Stand Assembly” in the “Equipment Set-Up” Section.

⚠️ Warning
Do not use any solvents, including alcohol, to clean any internal components of the Lumbar Trainer; doing so can permanently damage it. Please refer to the Care and Cautions section of this manual for instructions on the care and maintenance of this product.

Lumbar Puncture Spinal Cord Insert

The Lumbar Puncture Insert provides a lifelike representation of an adult spinal segment. The Insert consists of the skin layer, subcutaneous layer, simulated ligamentum flavum, and lumbar vertebrae (L2, L3, L4, and L5). The vertebrae is optimized to provide a realistic tactile feedback for the injection process. The skin and subcutaneous layer can be palpated for optimized positioning of the needle between the vertebrae.

The insert was designed to replicate the changes in needle resistance that are sensed during a Lumbar Puncture or Epidural procedure so, that students may gain familiarity with the tactile cues.

During insertion of the Spinal Needle or Tuohy Needle, the characteristic “pops” and loss of resistance can be felt when traversing the simulated Ligamentum Flavum and Dura.

⚠️ Information
If the needle hits bone, it will not be possible to insert it any further, and the needle will have to be removed and the process repeated.

⚠️ Information
For simulation of an Epidural Procedure, representative drugs may be administered into the epidural space. If any resistance is felt or fluid return occurs, the needle may not be within the Epidural Space, and the correct location of the needle should be verified before attempting to force the injection.

During a Lumbar Puncture Procedure, simulated CSF can be collected and pressure measured once the needle passes into the subarachnoid space.

⚠️ Information
The Lumbar Puncture Spinal Cord Insert comes equipped with a self-healing skin that allows 15 uses with an 18 gauge needle and 25 uses with a 22 gauge needle before replacement is necessary.

⚠️ Warning
While this is a replaceable insert, it is not recommended that the insert is constantly removed and replaced as this will result in progressive deterioration of the product and will shorten the usable life span.

How to remove and insert the Spinal Insert from the Lumbar Trainer

1. To remove the Spinal Cord Insert, grasp the Release Tab and pull until the Insert slides out of the recess in the Torso.
When replacing the Lumbar Puncture Spinal Cord Insert, orient it with the skin layer facing outwards and the Release Tab facing upwards when the simulator is in the sitting position or facing to the left when the simulator is in the left lateral decubitus position.

2. To insert the Spinal Cord Insert, hold the Release Tab, and gently slide the Insert into position on the trainer so that the four outer walls line up.

3. Continue to push the insert into position so that the outer edge of the skin layer fits snugly in the depression around the recess opening.

⚠️ Warning
Do not grasp the skin layer directly as applying force in this area will damage the skin and possibly the underlying layers. Using the Release Tab to remove the Insert will extend the life of the Insert.

CSF Supply System

The CSF Supply System on the Lumbar Trainer consists of a Replaceable Spinal Canal, an automated pressure system, and the supplementary tubing and connectors for filling and purging.

Spinal Canal

The Replaceable Spinal Canal Assembly simulates the Dura and Subarachnoid Space containing the CSF. This assembly can be visualized in the recess of the Adult Torso once the Spinal Cord Insert has been removed.

How to replace Spinal Canal Assembly

⚠️ Warning
When replacing the Assembly, make sure the system is disconnected and has been drained of all of its fluid. Before re-filling the system with simulated CSF, ensure that the grey connectors are securely attached to prevent any fluid leakage.

1. Drain out any fluid from the Lumbar trainer. Refer to the section “Purging fluid from the system”.
2. Remove the Spinal Insert from the Lumbar Trainer. Refer to the section “How to remove the Spinal Insert for the Lumbar Trainer”.
3. Slide the grey connectors out of place on either ends of the tubing.
4. Slide new Spinal Canal back to the Lumbar Trainer.

Information
Spinal Canal assemblies are consumable parts that can be purchased.

Pressure System

The lumbar trainer is equipped with an automated pressure system that regulates and maintains CSF pressure. Facilitators can adjust the CSF pressure using the digital dial to simulate low medium and high readings during exercises.

The LED display, located on the right side of the torso, can be used to display and adjust the pressure set point. For information on how to set and display the pressure, please refer to “Pressurizing the System” in the “Equipment Set-Up” Section.

The Opening Pressure can be measured when the simulator is in the left lateral decubitus position, and this measured value can be compared with the set-point of the system to assess accuracy in the measurement and technique.

Information
The pressure and display system will only work when the simulator power supply is connected.

Purging fluid from the system

Information
It is recommended to drain fluids from the Lumbar Trainer after each simulation to avoid mildew growth.

To purge the system adequately, the following procedure requires the inversion of ports and tubes in comparison to the filling procedure.

1. Place the Lumbar Trainer in the vertical position and remove power supply cord.
2. To drain fluids, attach the draining tube on the filling port.
3. Place the end of the draining tube in a collection container.
4. Attach the filling tube on the draining port with the syringe full of air.
5. Inject air into the system by depressing the syringe.
6. Re-fill the syringe with air, and inject the fluid into the system.
Information
The system is completely empty when no fluid is seen venting from the fill port.

Aseptic Technique

The Lumbar Puncture trainer can be used to teach the principals of aseptic technique; however, we caution that the use of iodine or betadine type solutions could permanently stain the simulator. We suggest substituting isopropyl alcohol in place of these solutions.

V. Appendix

Calibrating the Lumbar Trainer

Calibration is not necessary to begin a simulation with the Lumbar Trainer. Only complete the calibration procedure when the CSF pressure reading is not equivalent to the pressure selected on the Lumbar Trainer.

The following components are needed to complete a calibration procedure:
- Lumbar trainer without Spinal Insert
- Manometer and three way stopcock
- Spinal needle

1. Power ON the Lumbar Trainer.
2. Insert the spinal needle in Spinal Canal.
3. Change the pressure of the Lumbar Trainer from the LED display to adjust the pressure reading in the manometer.
4. Adjust the pressure on the Lumbar Trainer until the manometer reads 3 cm H₂O.
5. After the manometer has a value of 3 cm H₂O, go to the display controller of the Lumbar Trainer and hold the POWER button down until the LED displays shows CA for calibration.

The system would calibrate and set the pressure of the system to 3 cm H₂O. After pressing the power button down until CA is displaying, the system would show the new set value of 3 cm H₂O automatically.

Information
The use of needles larger than 18 gauge will reduce the lifetime of the Lumbar Puncture Spinal Insert.
## Troubleshooting

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<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can't increase the pressure on the Lumbar Trainer.</td>
<td>The volume of fluid is low.</td>
<td>Fill the trainer with simulated CSF.</td>
</tr>
<tr>
<td>The readings on the manometer do not match to the pressure in the Lumbar Trainer.</td>
<td>The system might be losing fluid volume or is not calibrated.</td>
<td>Calibrate the Lumbar Trainer. Replace the Spinal Canal.</td>
</tr>
<tr>
<td>The LED display is not ON.</td>
<td>The power button was pressed.</td>
<td>Turn ON the display from the Power button.</td>
</tr>
<tr>
<td>The Lumbar Trainer is OFF.</td>
<td>To power OFF the trainer you need to disconnect the power plug.</td>
<td>Reconnect the power plug to the Lumbar Trainer.</td>
</tr>
<tr>
<td>Fluid cannot be collected.</td>
<td>Is the needle in the subarachnoid space. Has the system been filled with the simulated CSF. Has the system been pressurized to the desired level.</td>
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</tr>
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</table>

## Spare Parts

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<th>Reference</th>
<th>Part</th>
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</thead>
<tbody>
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<td>Spinal Canal</td>
</tr>
<tr>
<td>S411.002.D</td>
<td>Adult Torso – Dark Tone</td>
</tr>
<tr>
<td>S411.002.L</td>
<td>Adult Torso – Light Tone</td>
</tr>
<tr>
<td>S411.002.M</td>
<td>Adult Torso – Medium Tone</td>
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<td>S411.003.D</td>
<td>Spinal Cord Insert – Dark Color</td>
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<td>S411.003.L</td>
<td>Spinal Cord Insert – Light Tone</td>
</tr>
<tr>
<td>S411.003.M</td>
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<tr>
<td>S411.004</td>
<td>Filling Kit</td>
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<td>S411.005</td>
<td>Power Supply</td>
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<td>S411.006</td>
<td>Soft Carrying Case</td>
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<td>S411.007</td>
<td>Stand</td>
</tr>
<tr>
<td>S411.008</td>
<td>Fasteners with washers</td>
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Patent Pending