

"Caution: Ink from this manual can stain the Lumbar Puncture Model - do not let it touch the model."

※このマニュアルがモデルの皮膚に直接触れないように御注意ください。色移りすることがあります。

M43B Lumbar Puncture Simulator II

M43B 腰椎硬膜外穿刺シミュレータ ルンバールくんII

Instruction Manual

English 3-21

取扱説明書

日本語 23-43

KYOTOKAGAKU Co.,Ltd. KYOTOKAGAKU Co.,Ltd. KYOTOKAGAKU Co.,Ltd.

 **KYOTO KAGAKU co.,LTD**

Welcome

Today, medical professionals have ready access to advanced imaging technologies such as CT, MRI and ultrasound scans that clearly enhance the quality of medical care. However, despite its use for more than 100 years, the lumbar puncture remains indispensable for the rapid diagnosis of meningitis, encephalitis or fever of unknown origin. The lumbar puncture also remains important for the diagnosis and treatment of numerous conditions seen by emergency care, primary care, neurology, oncology and anesthesia services. Thus, even today, medical competency requires skillful performance of this procedure.

In the past, medical students could practice lumbar punctures on live patients in order to develop the requisite technical skills. However, for good reasons, this is no longer the case. Although medical schools and residency training programs recognize the need for formal procedural skills training, there are limited opportunities for such programs to teach and assess procedural competency.

This unfortunate situation has now changed. Keio University Medical School, in partnership with Kyoto Kagaku, has created a realistic lumbar puncture simulator that allows students and medical professionals to practice frequently and achieve high levels of procedural competence without placing any patients at risk of harm.

By all means, please try this innovative lumbar puncture simulator. Through practice on this special equipment, students at all levels of training can increase their procedural comport, competence and efficiency.

We wish you, and your patients, well.

Takahiro Amano, MD
Professor and Head,
Medical Education Center
Gregory A. Plotnikoff, MD, MTS
Associate Professor
Keio University Medical School

Before You Begin

This lumbar puncture simulator has been developed for the training of medical professionals only. Any other use, or any use not in accordance with the enclosed instructions, is strictly prohibited. The manufacturer cannot be held responsible for any accident or damage resulting from such use. Please use this model carefully and refrain from subjecting in to any unnecessary stress or wear. Should you have any questions on this simulator, please feel free to contact our distributor in your area or KYOTOKAGAKU at any time. (Our contact address is on the next page)

-
- The contents of the instruction manual are subject to change without prior notice.
 - No part of this instruction manual may be reproduced or transmitted in any form without permission from the manufacturer. Please contact manufacturer for extra copies of this manual which may contain important updates and revisions.
 - Please contact manufacturer with any discrepancies, typos, or mistakes in this manual or product feedback. Your cooperation is greatly appreciated.

Table of Contents

Welcome.....	P3
Before You Begin.....	P3
Table of Contents.....	P4
Consumables.....	P4
Set Includes.....	P5
Before training.....	P6-10
(CSF pads).....	P7-9
(Epidural Pad).....	P10
While Your Training Session.....	P6-10
After Training.....	P12-13
FAQs, DOs and DON'Ts.....	P14

Lumbar Puncture-Five Steps for proficiency....P15-21

Consumables

Product Code	Mark	Part Name
11348-090	N	Normal CSF Puncture Block
11348-110	O	Normal Obesity CSF Puncture Block
11348-120	S	Senior CSF Puncture Block
11348-130	SO	Senior Obesity CSF Puncture Block
11348-140	EP	Epidural Puncture Block
11348-150		Skin Cover

For inquiries and service, please contact your distributor or:



<http://www.kyotokagaku.com> rw-kyoto@kyotokagaku.co.jp

Main Office and Factory

15 Kitanekeoya-cho Fushimi-ku Kyoto 612-8388, Japan Telephone : 81-75-605-2510 Facsimile : 81-75-605-2519

LA Office (for USA , CANADA and Mexico customers)

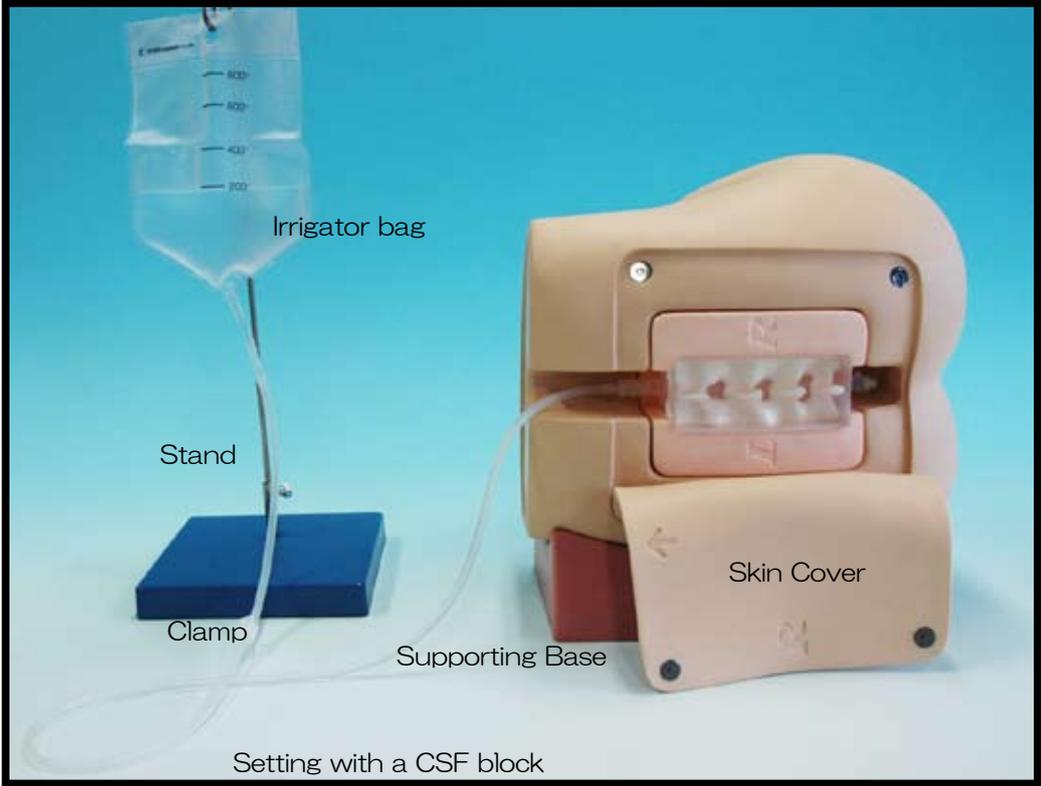
3109Lomita Boulevard, Torrance, CA 90505 ,USA Telephone : 1-310-325-8860 Facsimile : 1-310-325-8867

Set Includes

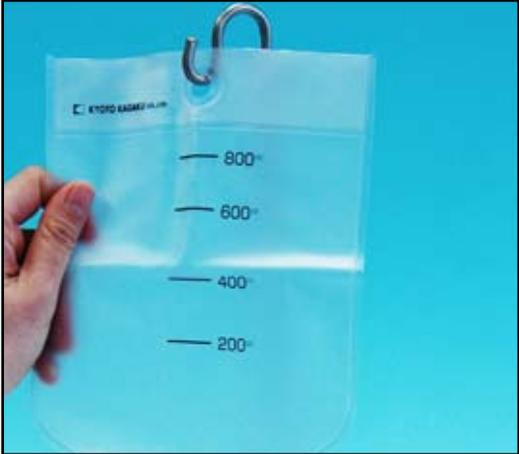


- a. Lumbar Region Model 1
- b, CSF Puncture Blocks (4variation 5 pieces)
- b-1 Normal CSF 2
- b-2 Obesity CSF 1
- b-3 Senior CSF 1
- b-4 Senior Obesity OSF . 1
- c, Epidural Puncture Block 1
- d, Lumbar Spine Model 1
- e, Skin Cover 1
- f, Syringe 1
- g, Stand 1
- h, Irrigator bag 1
- i, Support Base (Lateral Position) . . 1
- j, Support Base (Sitting Position) . . 1
- k, Support Base (Team Teaching) . . 1
- l, Carrying Case (No Picture) 1

Before Training

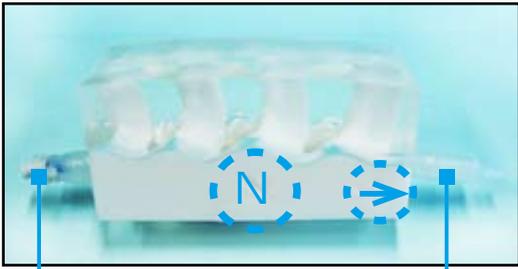


• Assembly the stand.



• Hang the irrigator bag to the stand.

Before Training : CSF Puncture Block



Connector to the Syringe

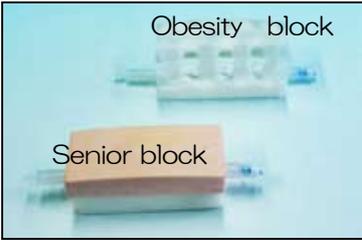
Connector to the irrigator bag

➔

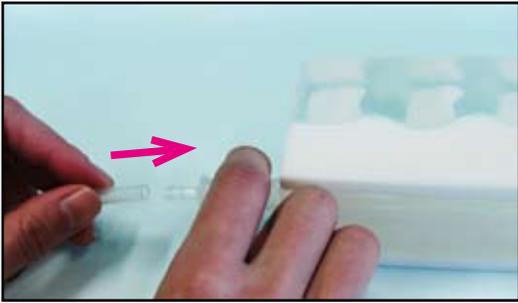
This side comes at the head-end of the Lumbar Region Model.

• Block type and the direction are indicated on the side wall of each block.

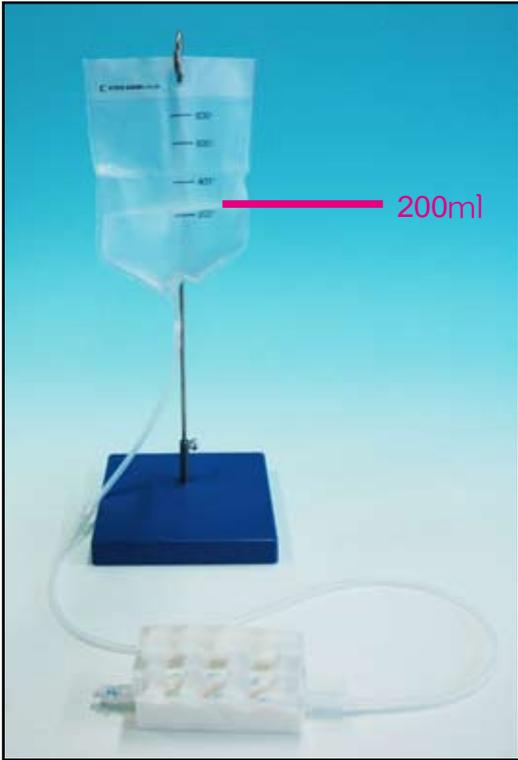
- N : Normal CSF
- O : Obesity CSF
- NS: Senior CSF
- OS: Senior Obesity CSF
- EP: Epidural



※ Obesity type has a lumbar spine in deeper position. Senior type has different tissue resistance and bone shape.

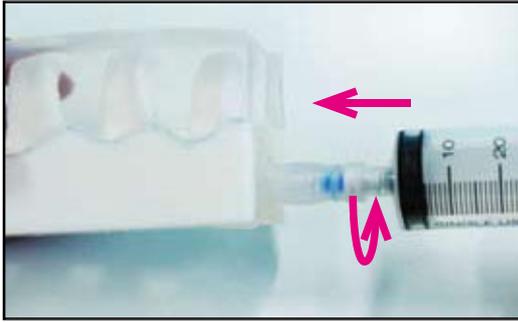


• Connect the tip of the tube from the irrigator bag to the tube at the head-end of the puncture block. Insert the tube deeply so that it won't come off during the session.

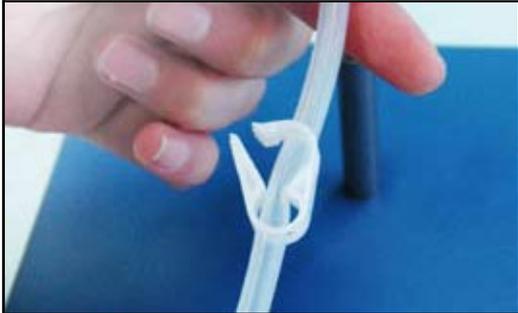
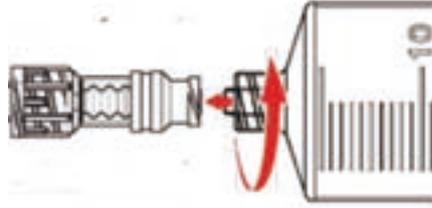


• Fill the irrigator bag with water until the surface reaches to the 200ml line.

Before Training : CSF Puncture Block



- Connect the syringe to the plug at the end opposite to that of the tube from the irrigator bag. Insert, turn clockwise and lock the syringe in place.



- With the clamp opened, aspirate a small amount of water into the syringe. Should any air bubbles remain in the system, tilt the system and aspirate fluid with the syringe until only water remains in the tubing.



- When the block has filled with water, detach the syringe from the connector by turning the syringe counter-clockwise. Then press close the tube clamp.
※ Keep the clamp closed while the session is not in action.

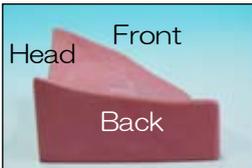


- Insert the block into the Lumbar Region Model.

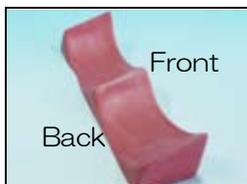
Before Training



- Noting the marks at the back of the skin cover(L,R, ↑) , attach it to the Lumbar Region Model.



- Put the Lumbar Region Model on a supporter base.
 - ※ The simulator is designed to show an appropriate CSF pressure when it used in lateral position and 200cc water in the irrigator bag.
 - Adjust the pressure to fit your training purpose when you use the system in sitting position.

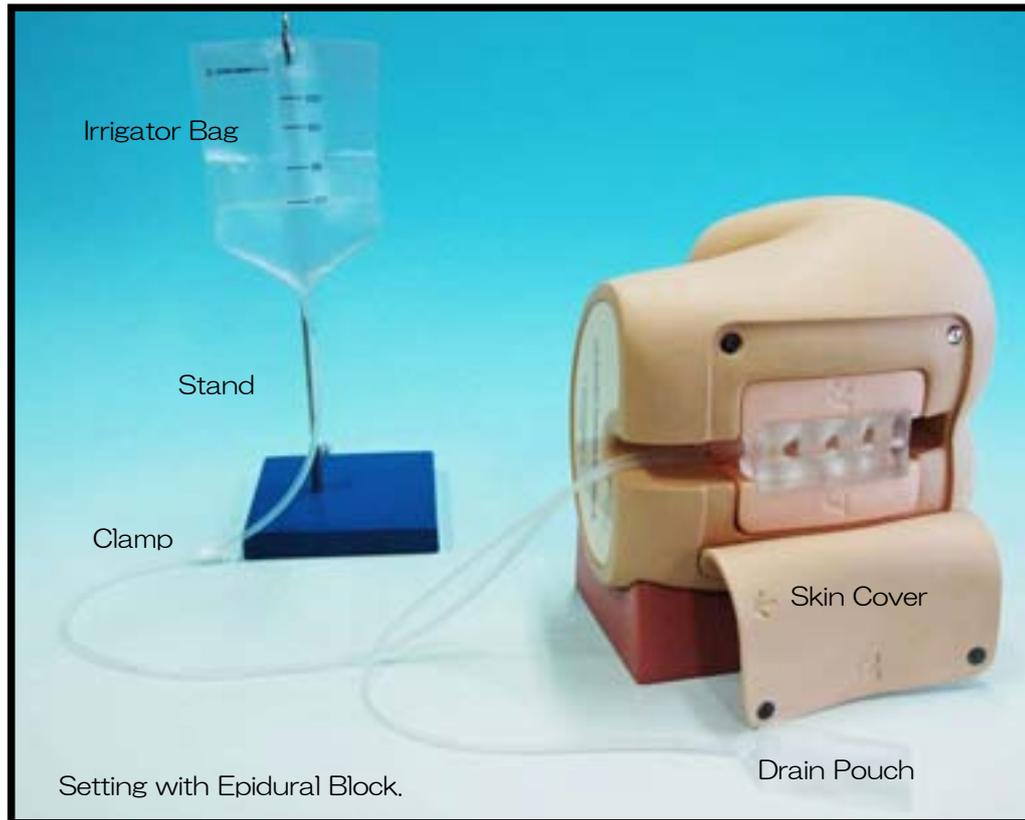


- The sitting position supporter base is designed to come to the front end of the Lumbar Region Model.

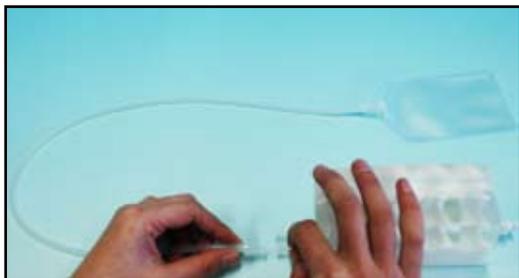


- Open the clamp and start the training session.

Before Training: Epidural Block



- Empty the drain pouch completely.



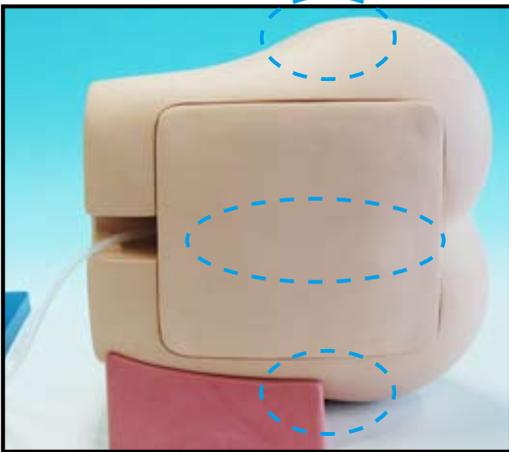
- Connect the tube tip from the drain pouch, to the side connector tube



- Following the steps of CSF block preparation, fill the block with water, set it to the Lumbar Region Model and cover with the skin cover.

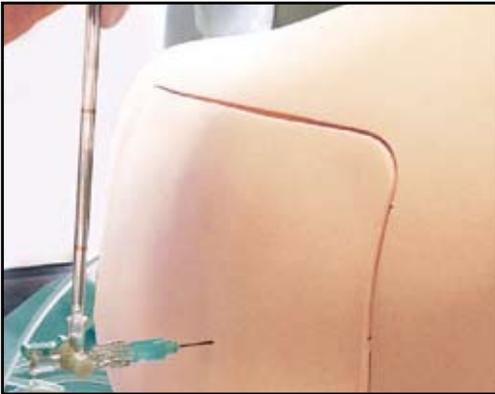
While your training session

For details, please refer "Lumbar Puncture: Five Steps for Proficiency", P15-21 on this manual.



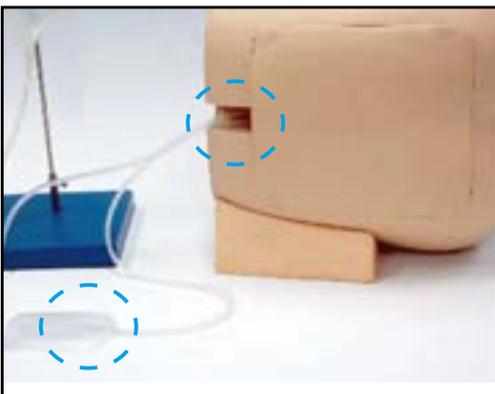
- Landmarks can be palpated.

<CSF collection>



- When the needle tip reaches in the subarachnoid space, water (simulated CSF) can be collected.
- ※ The simulator is designed to show an appropriate CSF pressure when it used in lateral position and 200ml water in the irrigator bag.
Adjust the pressure to fit your training purpose when you use the system in sitting position.

<Epidural Puncture>



- Make sure that the needle is not in the subarachnoid space (no water flows out), and then inject water (simulated saline) or air into the epidural space.
- Successful performance can be confirmed by observing the injected air/water fills the drain pouch.

- ※ Empty the drain pouch after each trial.
- ※ When the puncture pad gets worn, water/air may be able to be injected even if the needle tip has not reached the epidural space. When this occurs, change the puncture site or replace the pad by a new one.

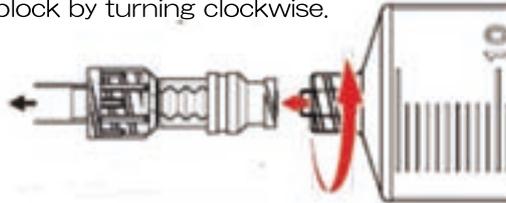
After Training



- Remove the model skin cove and remove the puncture block from the Lumber region model, holding it with its hard part.



- Pull back the syringe's piston to at least the 50 ml mark. Lock the syringe onto the connector on the block by turning clockwise.



- Release the clamp.



- Slowly depress the piston and push air into the water-filled block until all the air has been injected.

After Training



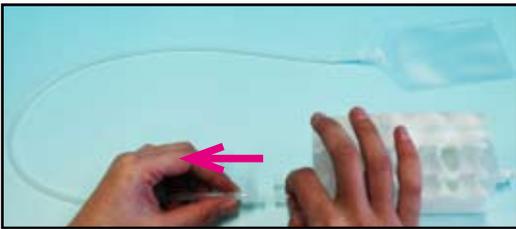
- Close the clamp



- Turn the syringe counter-clockwise to remove it from the block.



Disconnect the reservoir tube from the block.



- Disconnect the drain pouch from the epidural block and empty the pouch.

- If you continue the session, return to P6 and set a new block.
- When you finish the session for the day, empty the irrigator bag and dry all used components naturally and store them in room temperature, avoiding direct sunlight or exposure to elements.

FAQ s

Q, Water does not come out even if the needle tip is surely in the subarachnoid space.

A, Is the clamp released? Isn't the tube folded?

A, Is the water surface in the irrigator bag at 200ml or above?

A, 21G is the recommended needle size for CSF collection training with the simulator. If you still experience the difficultis, try with a larger needle.

A, Isn't your needle clogged? Use a needle as new as possible.

A, The fluid comes slowly, drop by drop. Wait and see for 2-3 seconds.

Q, The soft tissue part of the puncture block is coming off when I grab the block.

A, The soft tissue and bone part of the puncture blocks are not adhered.

The soft part may look like coming off when you grab it strongly, this is not faulty.

However, to keep the blocks longer, we recommend holding the hard part when you handle them.

Q, (Epidural puncture pad) Water/air can be able to be injected even if the needle tip has not reached the epidural space.

A, the puncture block is worn. When this occurs, change the puncture site or replace the pad by a new one.

DOs and DON'Ts

DOs

Handle the manikin and components with care. Talcum powder may be used on the manikin after use to preserve suppleness of the skin and prevent oils from staining the surface.

Store the manikin in its storage case when not in use.

Storage in a dark, cool area will keep the manikin skin from fading.

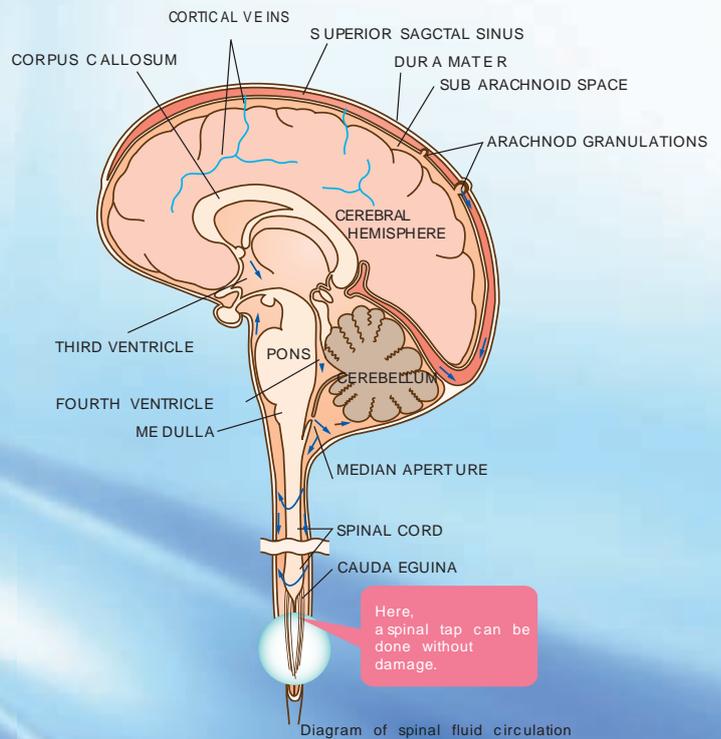
The manikin skin may be cleaned with a wet cloth and mildly soapy water or diluted detergent.

DON'Ts

Please do not let ink from pens, newspapers, these instructions or other sources come in contact with the manikin, as they cannot be cleaned off the manikin skin.

Never use ethanol or organic solvent like paint thinner to clean the skin, as this will cause deterioration of the skin.

Lumbar Puncture: Five Steps for Proficiency



Background:

Cerebrospinal fluid (CSF) is a clear saline solution produced primarily in the choroid plexus in both lateral ventricles. The rate of production is approximately 20ml per hour or 500 ml per day. The CSF is found in the subarachnoid space (between the arachnoid and pia mater layers of the meninges) with a total volume of less than one-third that of the daily production. Thus unimpaired fluid circulation is very important in health and disease.

The CSF fluid circulates from the lateral ventricles through the interventricular foramina (foramina of Monro) into the third ventricle. From there it passes through the small cerebral aqueduct in the brainstem into the fourth ventricle. The CSF then passes through three small foramina (central foramen of Magendie, which is also known as the median aperture, and the two lateral foramina of Luschka) into either the central canal of the spinal cord or into the cisterns of the subarachnoid space.

The CSF both bathes and cushions the brain and spinal cord. Its circulation includes flow distally to the lumbar cistern which encloses the cauda equina (where the lumbar puncture is performed) and then superiorly to the cerebral sagittal sinus where it is reabsorbed via the arachnoid granulations (the smaller villi and the larger Pacchioni's bodies) into the venous system.

Impaired CSF flow through the small foramina is associated with increased pressure in the lateral ventricles (hydrocephalus) or with disrupted intracranial blood flow.

Step 1:

Understand the lumbar puncture's indications, contraindications, and spinal fluid examination

The spinal fluid needs to be examined in cases of suspected meningitis, fever of unknown origin, central nervous system leukemia or lymphoma and for the evaluation of many neurologic diseases including multiple sclerosis and recurrent seizures.

Oncologists frequently use a lumbar puncture to administer chemotherapy to the central nervous system. Anesthesiologists use a lumbar puncture to administer spinal anesthesia for some types of surgery. By lumbar puncture, amphotericin B can be infused for treatment of fungal meningitis.

Lumbar punctures are contraindicated in the presence of an infection at the lumbar puncture site, papilledema, severe thrombocytopenia or uncorrected bleeding disorders. Additionally, lumbar punctures are contraindicated in the presence of cerebral mass lesions such as large abscesses, tumors and intra cranial hemorrhage. Subdural hematomas may also increase the risk of herniation. For this reason, cerebral CT scans may be performed prior to lumbar puncture.

Increased intracranial pressure can be seen in trauma or infection.

Decreased intracranial pressure can be seen with obstructed flow such as due to a spinal cord tumor.

Cloudy fluid is associated with the presence of white blood cells, increased protein or the presence of microorganisms

Bloody or reddish fluid is associated with subarachnoid hemorrhage or traumatic puncture.

Brown, orange or yellow fluid is associated with elevated protein or old blood in the CSF.

Increased protein is seen with blood in the CSF, polyneuritis, tumors, trauma, diabetes, infection and inflammation.

Decreased protein is seen with rapid CSF production.

Increased glucose is seen with hyperglycemia.

Decreased glucose is seen with hypoglycemia, bacterial or fungal infection, tuberculosis or carcinomatous meningitis.

Sometimes gamma globulin levels are measured. These are increased with demyelinating diseases such as multiple sclerosis or Guillain Barre syndrome.

Step 2:

Locate the puncture site and position the patient

The spinal cord as a single trunk ends at the distal end of L1. For this reason, the lumbar puncture is performed preferentially in the interspaces between the posterior elements of L4 and L5. Alternately, the space between L3 and L4 can be used when the L4 L5 interspace is not available. In adults, no puncture is ever done between L1 L2. In small children, the medulla oblongata ends more proximally and thus, if necessary, the L1 L2 space can be used.

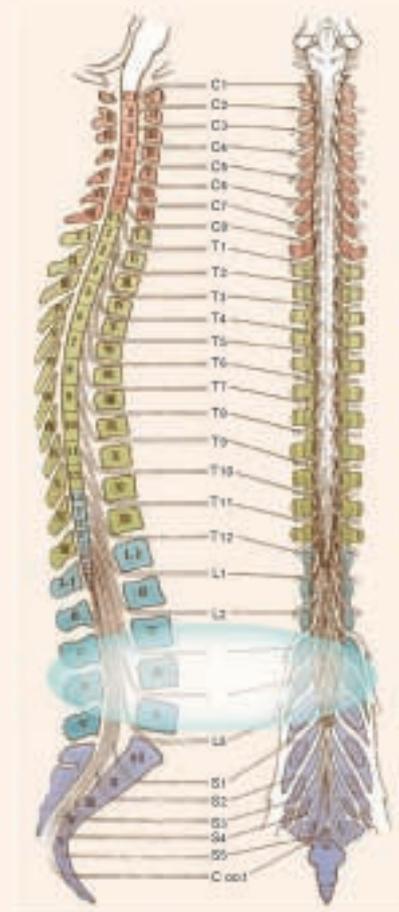
The superior, posterior iliac crest is located at the level of L4 L5. The imaginary transverse line that connects the crests is termed Jacoby's line. To identify the L4 L5 vertebrae, place the palms of your hands over the posterior iliac crest so that the superior edge is under your second (pointer) finger. Your thumbs will connect at, or point to, the location of the L4 L5 vertebrae.

The lumbar puncture can be performed in two positions.

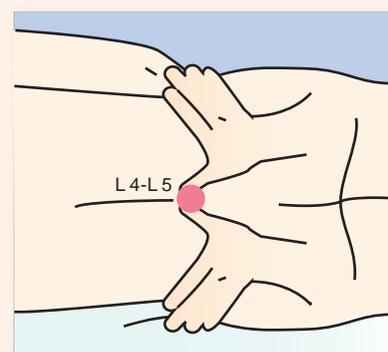
The most common, the lateral recumbent position, is performed with the patient on his or her side with their head propped up on a pillow. The knees and torso are flexed to optimize the inter lamina foramen of the vertebrae. Ask or assist the patient to draw their legs up to their chest. Make certain that the craniospinal and transverse planes remain stable. Please note that excessive flexion can compromise the upper airway.

In patients with pulmonary disorders or with potential airway compromise in the lateral recumbent position, the sitting position can be used. Seat the patient on the edge of the examination table. Flex the trunk by having the patient lean forward and rest their elbows on their knees. The disadvantage of this position is that CSF pressure cannot be measured.

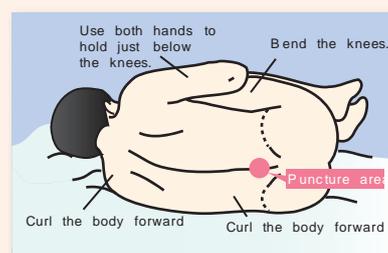
In either position, the craniospinal and transverse planes must remain stable. For this reason, assistance with restraining/stabilizing the patient is crucial.



Locations of spinal and medullar structures



How to find L4&L5



Lateral recumbent position

Step 3:

Practice the lumbar puncture technique on the simulator

This lumbar puncture simulator provides additional equipment to emphasize the importance of spinal flexion as well as lumbar region stabilization.

The importance of spinal flexion is readily seen with the model of the lumbar spine that is provided for teaching (c). As the spine flexes forward, note that the inferior articular processes of the upper vertebrae move upwards. Also note the corresponding remarkable increase in the inter lamina space between the inferior notch of the superior lamina and the superior notch of the inferior lamina. This inter lamina space is the route of the needle insertion into the subarachnoid or intradural space.

This importance of lumbar region stabilization is taught using different bases for the lumbar region model. The larger base (j) puts the model in the correct recumbent position. When the model (a) is attached to this base (j), students can practice technique by themselves as illustrated below. This does not approximate clinical reality, however.

The smaller base (k) requires students to practice as a team for correct positioning and stabilizing of the model. The smaller base simulates the instability of a living patient. Use of this base allows the assistant to practice keeping the craniospinal and transverse planes stable and the spine flexed. This teamwork which does approximate clinical reality is illustrated below.

To conduct actual lumbar practice, assemble the model as noted above. To approximate normal CSF pressure of 150-180 mm Hg, fill the reservoir pouch to 14-18 cm in height.

After locating L4 L5, place the needle perpendicular to the vertical plane. With the bevel pointed toward the ceiling (parallel to the direction of the ligamentum flavum) and the stylet in place, support the needle between your index fingers and stabilize the hub of the needle with your thumbs. Advance slowly through the skin in the direction of the umbilicus.

As the needle enters deeper structures, there will be a change of resistance consistent with the presence of the spinous ligaments. This continues until the needle reaches the dura at which time a change in resistance will be felt. Should the needle hit bone or other resistance, the needle with stylet in place should be withdrawn and redirected.

The change in resistance, sometimes felt as a pop indicates that the needle is in the subarachnoid space. Remove the stylet and check for flow of the CSF.



Erect spine



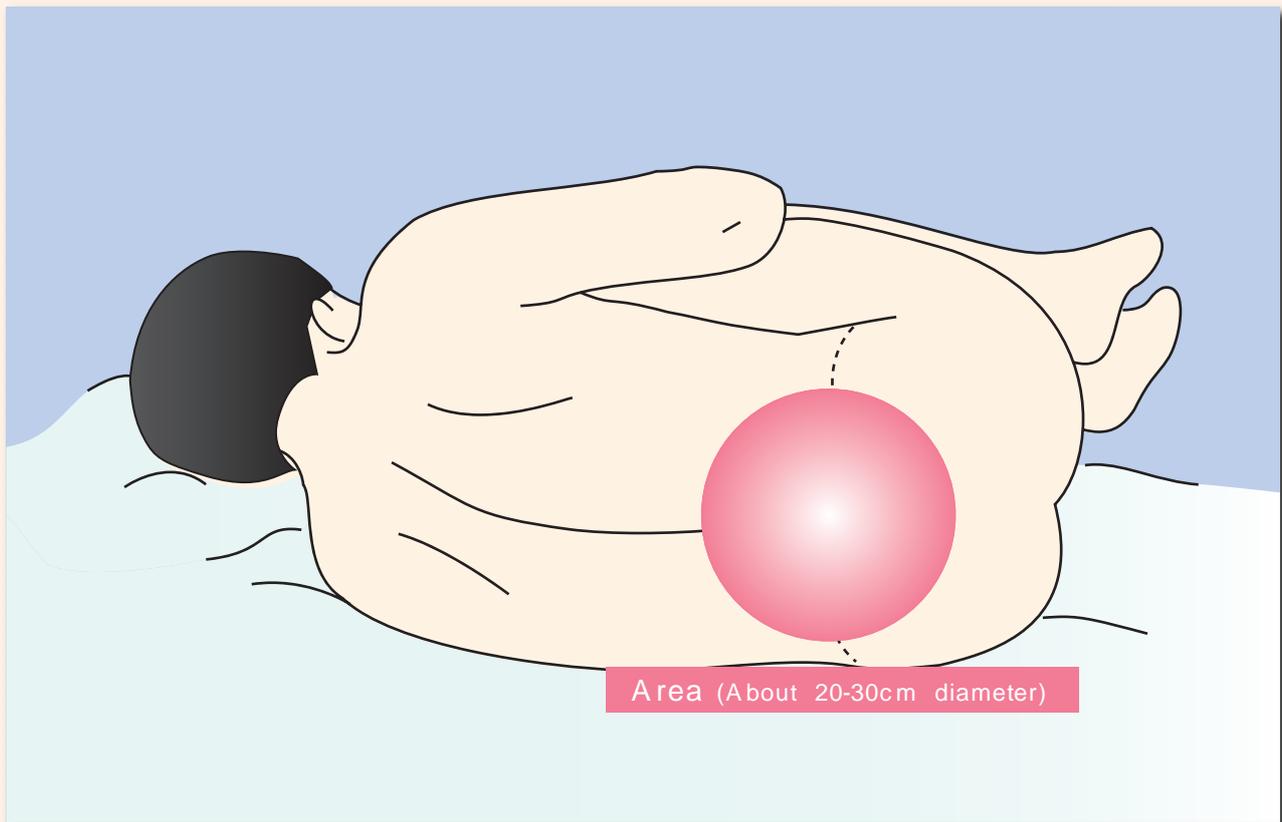
Spine bending forward



Team support practice



Individual practice



Sterilizing

Step 4:

Practice sterile technique

Proficient performance of the lumbar puncture requires more than knowledge of the indications, location and technique of subarachnoid space needle insertion. Clearly, the lumbar puncture must be performed under entirely sterile conditions. Failure to do so places the patient at great risk. Thus, proficiency in sterile technique is a mandatory component of lumbar puncture skills training.

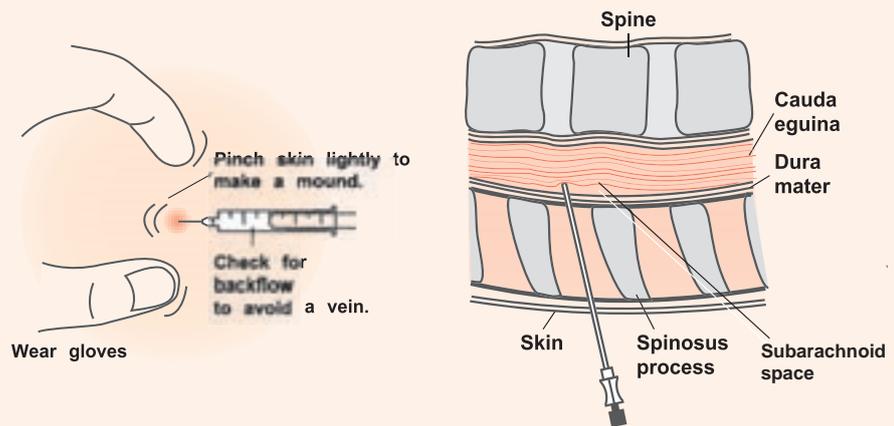
Key elements include the following:

1. Remove or reposition any personal items which could contaminate the sterile field during the performance of the procedure. Examples include long hair, necklaces, sleeves, stethoscopes, ID badges, etc.
2. Use unencumbered space for opening and placing the sterile lumbar puncture tray.
3. Apply the gloves by sterile technique.
4. Open the betadine package into the provided well.
5. Dip one sponge stick at a time into the betadine.
6. Wipe the skin with a circular motion starting at the needle insertion site and working out. Repeat twice for a total of three times.
7. Discard away from the sterile field the used sponge sticks after each is used.
8. Open and place the sterile drapes over the sterilized field.
9. Arrange the needle, stopcock and sterile tubes for ready access.
10. Keep all sterile materials in the sterile field until the needle is removed and the bandage placed.

Checklist for Risk Management

Prior to lumbar puncture, assess for..

- Risk of increased intra-cranial pressure.
- Presence in the patient chart of valid informed consent.
- Absence of lumbar puncture site infection.
- Allergies to latex, betadine, lidocaine or similar medication.



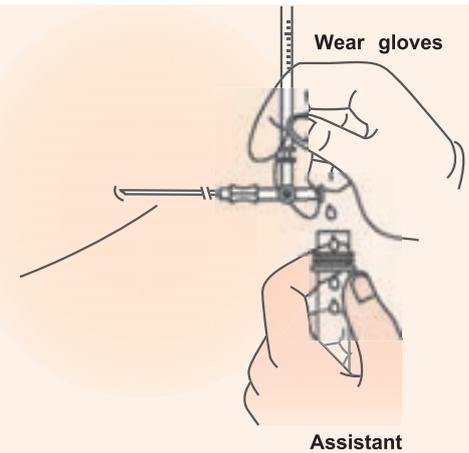
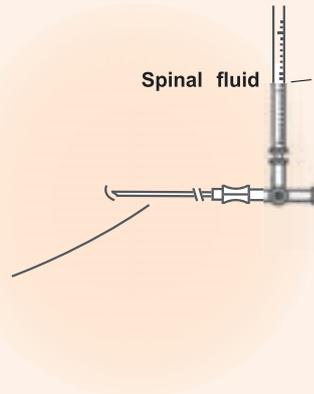
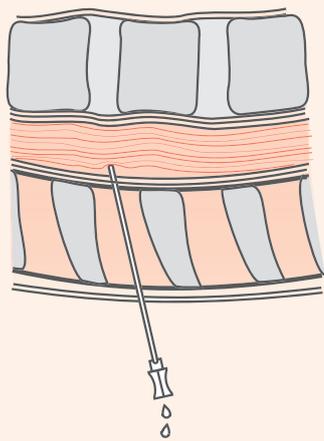
■ Key Points for Proper Technique

- 1** When sterilizing the lumbar puncture site, start at the site of puncture and spiral outwards in a continuous stroke with the cleansing solution (betadine or other). Repeat twice for a total of three times. Maintain strict sterile technique throughout the procedure.
- 2** When injecting lidocaine or similar local anesthetic, check first to make certain that the needle tip is not in a vessel or in the subdural space by gently pulling back on the syringe's plunger.
- 3** When performing the lumbar puncture, make certain that the patient is positioned so that the back is flexed, the airways are not compromised, and that the vertical and horizontal axes of the patient remain stable.

Step 5:

Perform a supervised lumbar puncture on a patient

- 1.** Obtain the informed consent of the patient for the procedure. The most common complication is post-lumbar puncture headache which is described as a dull, non-throbbing, fronto-occipital headache that worsens in the upright position. Treatment includes lying flat, fluid replenishment and OTC analgesics. In severe or persistent cases, an epidural hematoma can be created to block CSF fluid leakage. Uncommon complications include lidocaine or latex hypersensitivity, bleeding into the spinal canal, infection or spinal cord injury (especially if the patient moves during the procedure).
- 2.** Do not perform the procedure on any patient with significant risk of increased intra-cranial pressure. Always check for papilledema or other evidence of a cerebral mass lesion.
- 3.** After identification and sterilization of the needle insertion site, inject enough 1% lidocaine intradermally by 25 gauge needle to raise a wheal. Change to a 22 gauge needle and advance this needle slowly into the subcutaneous tissues. Check for entrance into a blood vessel prior to injection of lidocaine. Do not inject into a blood vessel or into the spinal canal.
- 4.** Select a spinal needle length appropriate for the size of the patient. The following formula can be helpful: LP depth (cm) = 1 + 17 x weight (kg) / height (cm).
Source: Abe KK, Yamamoto LG, Itoman EM, Nakasone TAF, Kanayama SK. American Journal of Emergency Medicine 2005; 23: 742-6.
- 5.** Make certain that the stylet is in place before advancing the needle.
- 6.** Advance the needle slowly in the direction of the umbilicus with the bevel facing up toward the ceiling.



4 When inserting the needle, make certain that the inner stylet is in place. When withdrawing the spinal needle after collecting the fluid, make certain that the inner stylet is not in place.

5 When using the three-way stopcock, remember that the handle always points to the port that is closed.

6 When collecting the spinal fluid, maintain the precise order of the pre-numbered tubes.

Lumbar puncture step-by-step

- 7.** Advance slowly through the spinous ligament resistance until you feel or even hear a “pop” with a change in resistance as the needle enters the subarachnoid space.
- 8.** Remove the stylet and check for flow of spinal fluid. If there is no flow, replace the stylet, rotate the spinal needle a few millimeters and then recheck. Repeat this step as necessary.
- 9.** If obstructed, or if the needle meets resistance, withdraw the needle with the stylet in place, recheck the position and re-attempt the procedure.
- 10.** With the flow of CSF, attach the manometer and stopcock to the needle, turn the stopcock upwards to allow CSF fluid to fill the manometer. Check for respiratory variation in the fluid level to ensure that the needle is in the proper position.
- 11.** Place the first of the three or four sterile tubes under the stopcock, turn the stopcock down, and collect 1-2 cc's of fluid in each of the tubes. Make certain that the collection order of the three tubes is maintained. Screw on the cap of each tube and place in order in the tray. The general recommendation for the tube order is as follows: 1) gram stain, culture and sensitivity, 2) CSF glucose, CSF protein, 3) CSF cell count with differential, and 4) CSF latex agglutination. Some centers recommend sending two separate labeled tubes for CSF cell count to assess for the possibility of a traumatic tap.
- 12.** Withdraw the needle without replacing the stylet and place a bandage over the needle insertion site.
- 13.** Instruct the patient to remain lying on their back for several hours.

