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Epidural Puncture LOR Indicator Syringe™





P Clinical problems

According to Mackenzie et al [1], epidural anesthesia is one of the most difficult procedures to perform in anesthesiology. High failure rate occurs in epidural anesthesia.

- According to the study of Pan et al, a failure rate of 14% was found in epidural anesthesia for laboring women [2].
- Hermanides et al [3] also investigated a number of studies on epidural anesthesia, and the overall failure rate was about 30%. Among the failed epidurals, incorrect catheter placement related to identification of epidural space was responsible for half of the failures, Motamed said [4].

Puncture Maneuver

Correct placement obviously requires correct identification of the epidural space. While, the most common method used for epidural space identification is sudden loss-of-resistance (LOR) when the tip of the needle passes the ligamentum flavum. (Tielens et al [5])

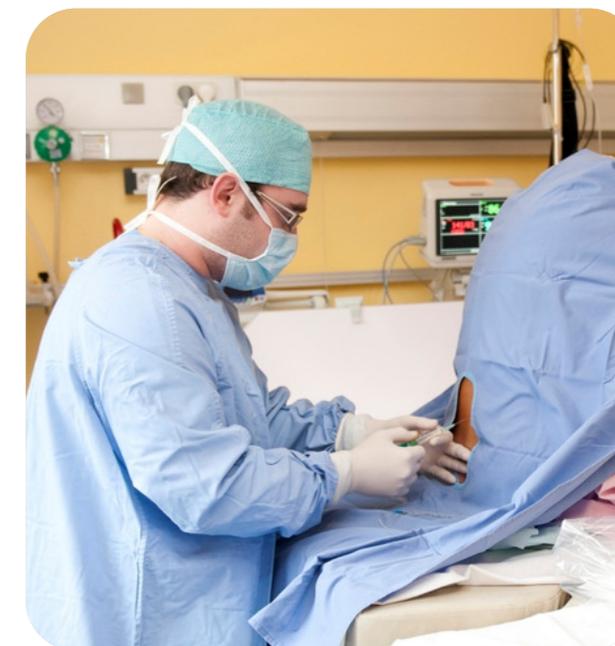
The traditional methods are overdependent on experiences and skills of anesthetists. (Levin J et al [6])

For inexperienced practitioners

- It's very difficult to learn and judge the epidural space by feeling. To the physicians, it is hard to see whether their internships puncture to the right position or not, increasing the difficulty of clinical teaching.
- The loss-of-resistance is a subjective feeling, higher failure rates occur with inexperienced practitioners. (Eappen et al [7])

For experienced anesthetists

Even with rich experience, they cannot have a visible judgment and repeatedly pushing action and feeling make the puncture process more complex.





No. 401 Hospital of PLA (Chinese People's Liberation Army) has developed a pressure bladder indicator, which can provide a visible “brake signal” to indicate correctly that the needle has reached the epidural space. Tuoren Medical transforms the technique into a product named LOR Indicator Syringe.

- Intended Use**
 LOR Indicator Syringe is used for epidural anesthesia, combined spinal-epidural anesthesia to indicate that the epidural needle reaches the epidural space.
- Principle**
 The pressure in balloon is higher than that of epidural space, so the balloon gets deflated immediately when the needle reaches the epidural space.



Notice

Sometimes, the balloon gets deflated slowly because not the whole needle tip enters the epidural space. In this case, advancing the needle 1 to 2mm is suggested.



- Confirm the LOR Indicator Syringe is intact before operation; Fill the syringe with about 5 ml normal saline; puncture the epidural needle into ligamentum flavum.
- Remove the stylet, and connect the prepared syringe with epidural needle tightly.
- Push the plunger rod to the mark of 2ml to make the balloon inflated; Next, push the needle forward slowly, and avoid moving backwards.
- When the balloon gets deflated promptly, it means the needle reaches the epidural space successfully.

Accuracy and reliability

The combination of visible indication and experience improves the accuracy and reliability to identify the epidural space.

Safety

The pressure in balloon is low and stable with a deviation of 3Kpa, which makes the puncture process more safe.

Simple operation

Reduce the actions of pushing the syringe repeatedly. Anesthesiologists can control the needle with both hands, improving the stability and effectiveness.

Clinical teaching

The visibility can make the teacher and student judge the depth of the needle tip intuitively, facilitating clinical teaching and improving the success rate of puncture for students.

Visibility

Compared with the blinded traditional syringe, LOR Indicator Syringe makes the puncture process visualized.

Low resistance

The use of rubber plug and its dynamic fit with the barrel make the injection smooth.



Study & Research

The balloon pressure is 10 ± 2 KPA.
Why?

- Too low pressure in the balloon might not be able to deflate the balloon when the epidural needle reaches the epidural space. (false-negative indication)
- Extremely high working pressure would make balloon shriveled before the needle reaches the epidural space. (false-positive indication)

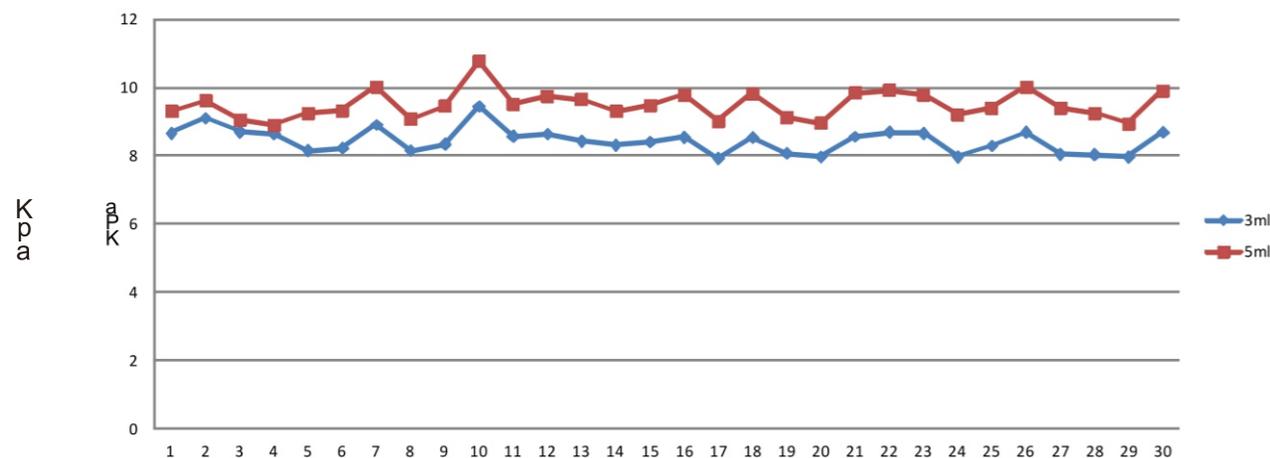


Test Data

Two groups were tested(30pcs LOR Indicator Syringes for each group). In the first group, balloons are filled with 3ml normal saline,the second 5 ml normal saline.



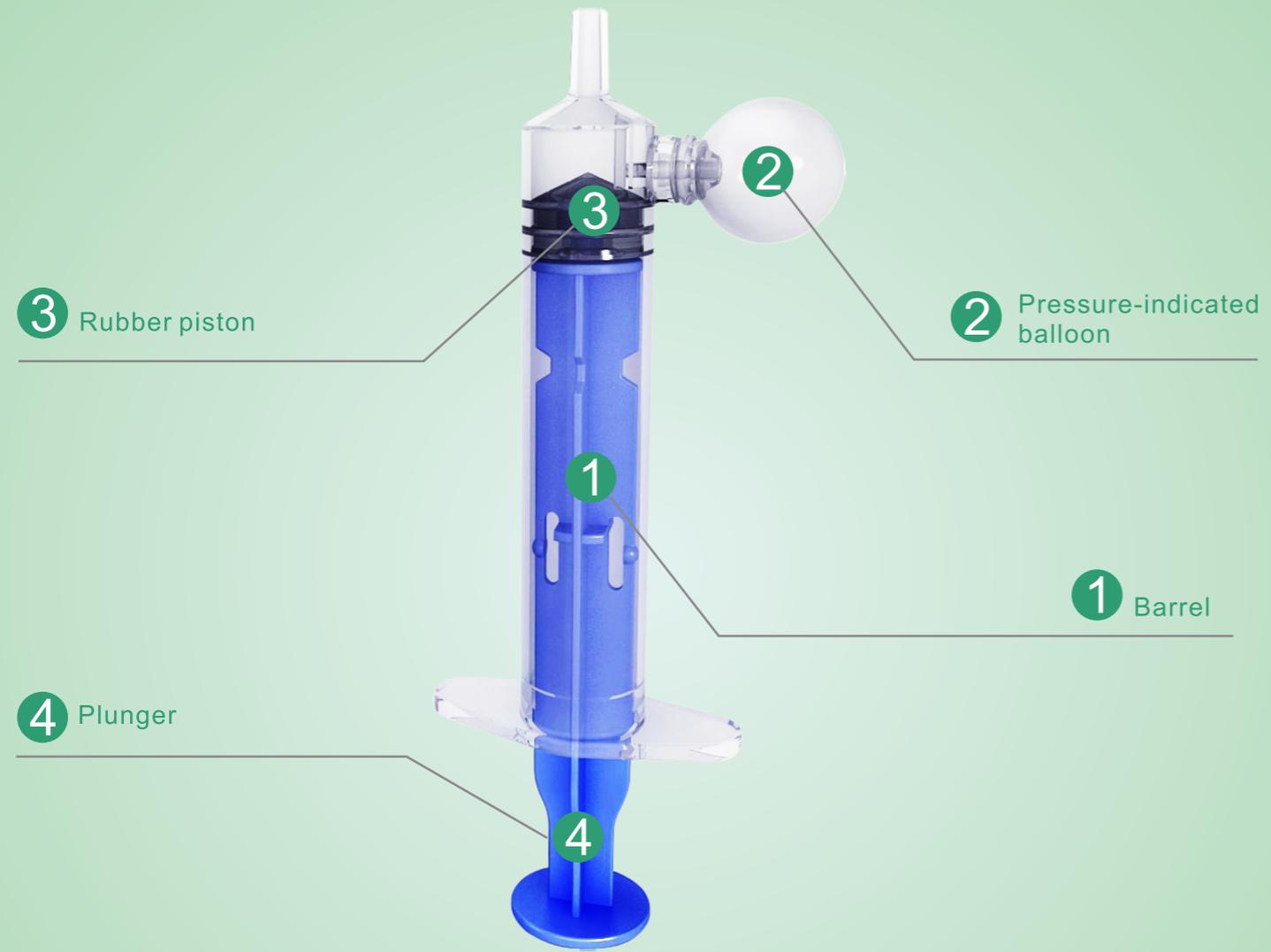
Hydrapress Measurement of Pressure-indicated Balloon



The novel developed pressure bladder indicator was a reliable and useful technique to conduct successful lumbar epidural puncture [8].

High Success Rate

- Yan et al [8] reported that 70 patients who were undergoing lumbar epidural anesthesia or combined spinal-epidural anesthesia were enrolled to use LOR Indicator Syringe. The success ratio was 100%, indicating that the sensitivity of the bladder indicator in confirming the correct location of the epidural needle is high.
- According to the study of Jize et al, 368 patients accepted epidural anesthesia with LOR Indicator Syringe. The success rate of epidural catheter placement was 100% [9].
- In the essay of Hou et al [10], the success rate and effectiveness of puncture and epidural catheter placement to use LOR Indicator Syringe is higher than using traditional syringe.



Name	Type	Quantity per box	Quantity per carton
LOR Indicator Syringe	5ml	20pcs	400pcs

LOR INDICATOR SYRINGE

KITS WITH LOR INDICATOR SYRINGE



	Combined Spinal & Epidural Kit					Continuous Epidural Kit				
Pro. Code	SE11625C	SE11625S	SE11625R	SE11625T	SE11827C	CE11690C	CE11690S	CE11690R	CE11690T	CE11890C
LOR Indicator Syringe	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Epidural Needle 16G, 90mm	✓	✓	✓	✓		✓	✓	✓	✓	
Epidural Needle 18G, 90mm					✓					✓
Spinal Needle 25G, 123mm	✓	✓	✓	✓						
Spinal Needle 27G, 123mm					✓					
Epi. Catheter 19G	✓					✓				
Epi. Catheter-&stylet 19G		✓					✓			
Epi. Catheter- Reinforced 19G			✓					✓		
Epi. Catheter- Soft tip 19G				✓					✓	
Epi. Catheter 21G					✓					✓
Medicine Filter 0.2µ	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5ml/10ml syringe	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Notice:
80mm Epidural needle is optional. Subcutaneous needle (22G, 16G) is optional.