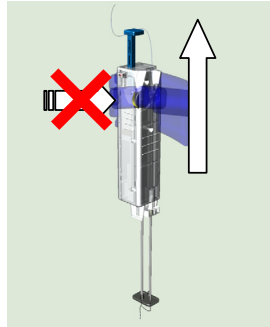



Instructional manual for Loop Fixture II

- When the device is removed, do not press down the thread feeding roller. If the thread feeding roller is pressed down, the suture thread may be fixed by the roller and may fall off the loop.



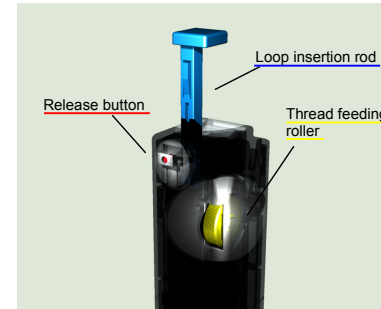
Manufacturer:  CREATE MEDIC CO.,LTD.
Chigasakiminami 2-5-25, Tsuzuki-ku, Yokohama 224-0037 JAPAN
Tel : +81-45-943-3929

Internal Control No. DC61485

2013.01.23

- This manual explains only the operation of Loop Fixture II. Please see the attached instructions for use for executing the entire operation.

[Parts names and structure]



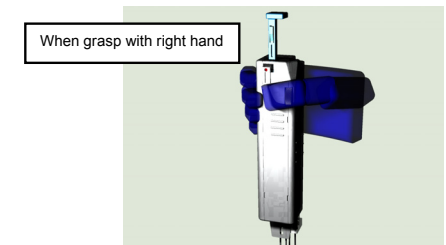
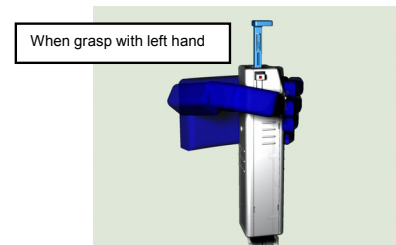
- Thread feeding roller [yellow]
It is used for feeding suture thread
(It is possible to rotate the roller downwards and upwards.)
- Loop insertion rod [blue]
It is used for pushing out the thread grasping loop.
When push it into the body, it is locked at its designated position.
※It is not used when the loop is stored in the needle.
- Release button [red]
It is used for grasping the suture thread
(and for storing the thread)

[Check before use]

- Check the following before use.
 - The thread grasping loop is formed by pressing the loop insertion rod downwards and the loop is stored by pressing the release button.
 - The thread feeding roller rotates smoothly.

[Grasping method]

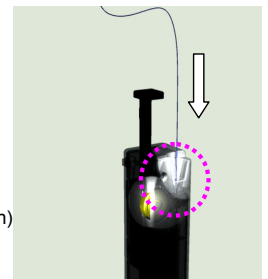
- The device is designed for better and easier handling when grasp the device with the right hand as the below picture, namely, direct the printed side of the direction of rotation toward yourself, and grasp the device by directing the thread feeding roller and the release button to a thumb (the inside). When grasp the device with the left hand, we recommend to grasp the device by directing to the opposite side (no printing side) as the below picture.



<Before puncturing the needles>

[Operating procedure 1] Setting the suture thread

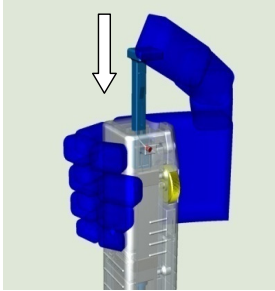
1. Insert the suture thread in the thread insertion slot until you feel some resistance (until the suture thread comes to the roller).
2. When the suture thread comes to the thread feeding roller, rotate the thread feeding roller (yellow) downwards (towards the arrow printed on the device). You can check the feeding on the side of the device.
3. After checking that the suture thread comes out from the tip of the needle, rotate the thread feeding roller (yellow) upwards (toward the opposite direction) so that the suture thread is stored in the needle.



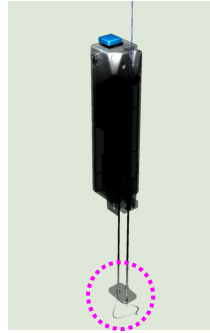
<After puncturing the needles>

【Operating procedure 2】 Projecting the loop

1. Push the loop insertion rod [blue] into the body of the device until it locks. (about 2cm deep)

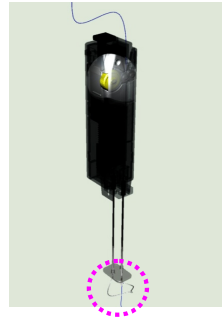
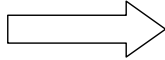
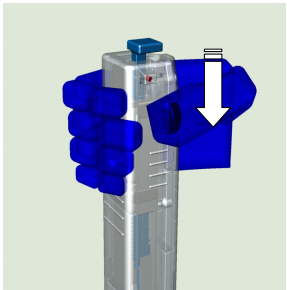


2. Check if the loop is formed properly.



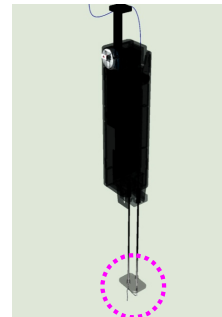
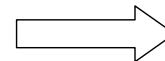
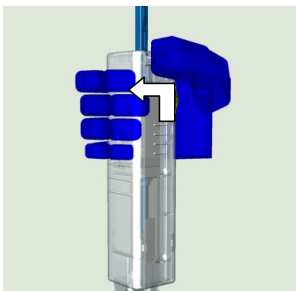
【Operating procedure 3】 Inserting the suture thread

○ Rotate the thread feeding roller [yellow] downwards (towards the printed rotation direction on the device body) and pass the preset suture thread through the loop. (Pass the thread over about 2cm from the loop.)



【Operating procedure 4】 Grasping the suture thread

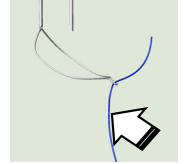
○ After checking that the suture thread passed through the loop, release the lock of the loop insertion rod [blue] by pressing the release button [red] slightly so that the loop can be stored in the needle and the suture thread can be grasped simultaneously.



<After taking out the needles>

【Operating procedure 5】 Releasing the suture thread

○ Push the loop insertion rod [blue] in the same way as 【Operating procedure 2】 to form the loop and to release the suture thread from the loop tip fully. (Push the suture thread towards the center of the loop so that it can come off easily.)

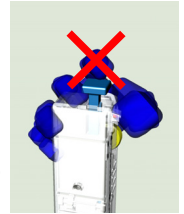


【Operating procedure 6】 Preparation for puncture and checking before puncture

○ When the release button [red] is pressed (when the loop insertion rod is put back to the original position), do not place a load on the loop insertion rod [blue].

[If the release button is operated while the fingers or the like touch the loop insertion rod, the loop insertion rod [blue] may not return to the original position completely.]

○ If the loop protrudes a little from the needle tip after pressing the release button [red], pull up the loop insertion rod [blue] and keep the loop inside the needle completely.



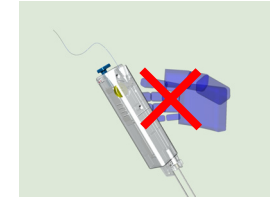
【Contraindication, prohibition and caution】

<Contraindication and prohibition>

○ Do not use any irregular suture threads except Nylon monofilament size2-0. Wrong sized thread can cause the thread to break or difficulty in operation. Blade type thread might not be able to be inserted into the needle.

<Caution>

○ Do not release the device from your hand when the needles are punctured. It may cause the device to fall, which might cause damage inside the stomach.



○ Do not puncture the needles when the thread grasping loop protrudes from the needle. It may cause breakage and distortion of the loop.

○ If the puncture is done while putting the finger(s) on the loop insertion rod, pressure may be added unexpectedly and the loop may protrude from the needle and it may be deformed. Particularly when the puncture at the second site is done, make sure that the loop is completely kept inside the needle. [If the puncture is done while the loop protrudes a little from the needle tip, the loop may be deformed or broken.]

