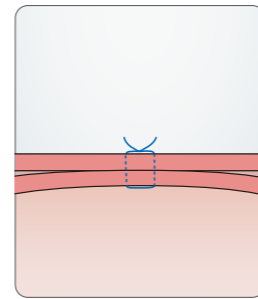
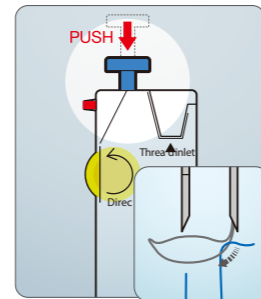
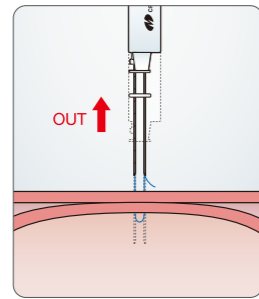
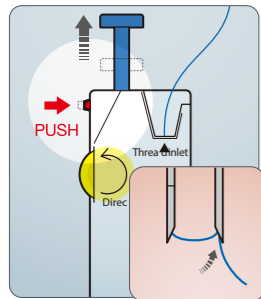
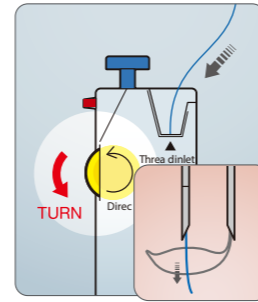
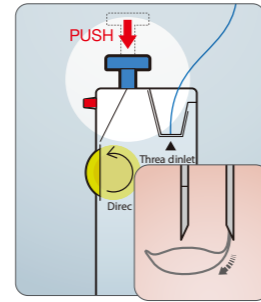
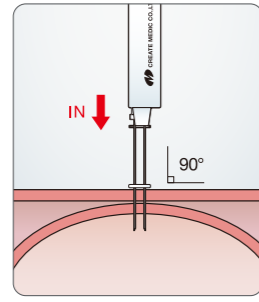
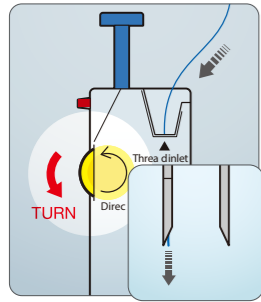


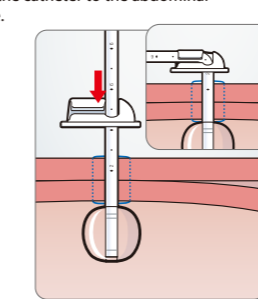
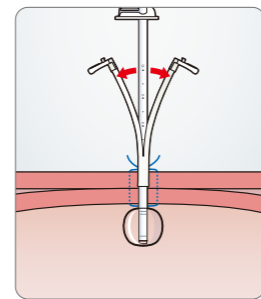
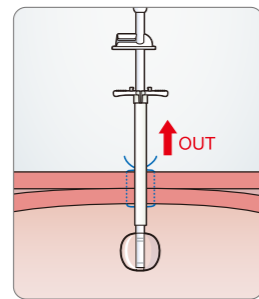
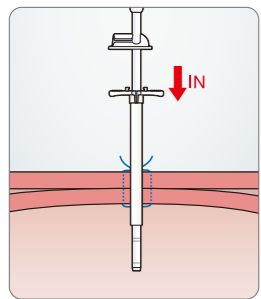
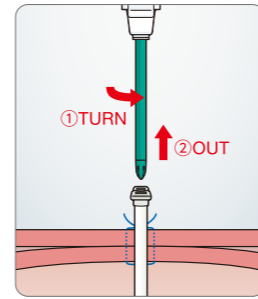
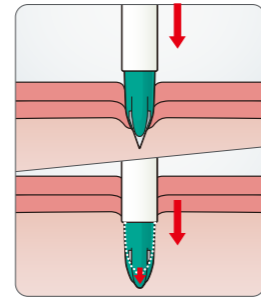
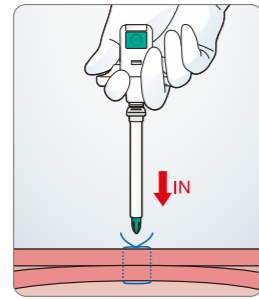
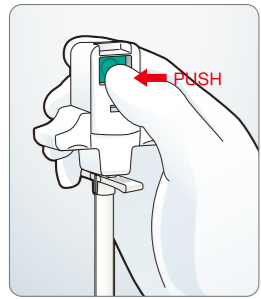
Procedure of the Gastric and Abdominal Walls Fixation

- The suture thread is inserted via the thread inlet. The thread feeding roller is rotated to further advance the thread to a point just in front of the needle tip.
- The marked site is punctured with both needles vertically.
- The loop insertion rod is pushed forward to form the thread holding loop.
- The thread feeding roller is rotated to advance the thread, and pass it through the thread holding loop.
- The release button is pushed and the thread holding loop is returned into the needle, resulting in the thread to be held at the tip of the needle.
- The device holding the suture thread is gently withdrawn out of the body, resulting in the thread to be guided out via each punctured site.
- The loop insertion rod is pushed forward to free the thread.
- The thread guided out of the body is ligated outside the abdominal wall.
- Another suture thread is set in place, and same manipulations are made on the opposite marked site.



Procedure of the "INTRODUCER" Method

- Push the green Release button located on main body of the PS needle with sheath to unlock the protection sleeve.
- Slowly insert the PS needle with sheath vertically without rotating until it reaches the inside of the stomach.
- When the distal end of the sheath reaches the inside of the stomach, the protection sleeve slides and the cutting edge of the PS needle hides in the sleeve.
- (1) Turn the main body only counterclockwise to 90 degrees to unfix the sheath. (2) Remove only the PS needle while ensuring that the sheath is not removed from patient's body.
- Close the sheath with finger in order to prevent air leakage and insert the catheter applied lubricant into the sheath until its depth marks disappear.
- Inflate the balloon by injecting the specified volume of sterile distilled water through the valve.
- Lightly splitting the sheath handle into right and left and then remove the sheath.
- Pull the balloon to the extent that the balloon slightly comes into contact with the anterior wall of the stomach and then endoscopically check the state of the placement. Slide the stabilizer along the shaft of the catheter to the abdominal wall side.



Be sure to read through the instructions for use attached to the device before use.

CREATE MEDIC CO.,LTD.

5-25 Chigasakiminami, 2-Chome, Tsuzuki-Ku, Yokohama 224-0037 Japan
Tel: +81-45-943-2741 Fax: +81-45-943-2746
E-mail: exportsales@createmedic.co.jp URL: <http://www.createmedic.co.jp>

For further details please contact:
 MEDI NIPPON healthcare pvt ltd
No.6, Zakariah Colony III St.,
Choolaimedu, Chennai - 600 094, Tamil Nadu, INDIA
Tel: +91-44-24733255 / 42031515; Fax: +91-44-24732186
Mob: +91-9444083551 | E-mail: mail@medinippon.jp
www.medinippon.com

CREATE MEDIC CO.,LTD.

CLINY Introducer PEG Kit

With 20Fr Balloon Catheter

Needle Protection

Newly-designed
PS Needle
With
Needle protection
Decreasing the risks of...

Needle-stick
accident in
medical
personnel

Inadvertent
puncture into
the posterior
wall of the
stomach

for **P**ercutaneous **E**ndoscopic **G**astrostomy

New PS Needle

Main body shaped for the best operability

The main body is lighter and easier to hold than the former PS needle.

Release button

When the button is pushed, the protection sleeve at the end of the needle is unlocked and the cutting edge is ready to project from the sleeve. This state can be checked from the upper part.



The green mark shows that the cutting edge does not project.

Gripper on main body

The gripper is shaped to ensure easy gripping during puncture.

Needle Protection



Former product New PS Needle

Placement of 20 Fr catheter with single time operation

Although a 15 Fr catheter was used for the former kit, 20Fr catheter can be used from the initial placement by using the new kit.

Newly designed PS needle with shorter protrusion

The protruding part of the needle is made shorter than in the former kit for the introducer method.

Sheath

The sheath is to insert the catheter into patient's body through its lumen. The sheath is tearable by pulling it horizontally, allowing itself to be removed completely.

Protection sleeve

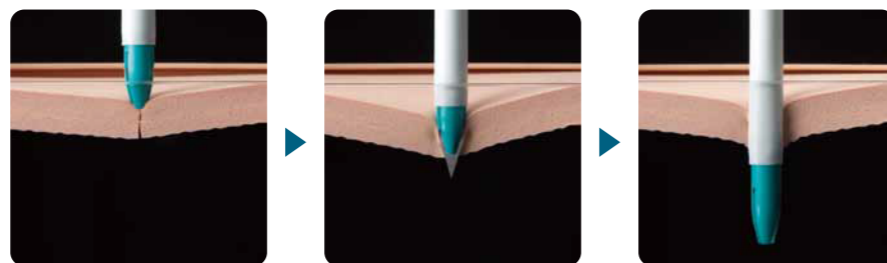
The protection sleeve is normally locked; it is unlocked when the Release button is pushed.

Cutting edge

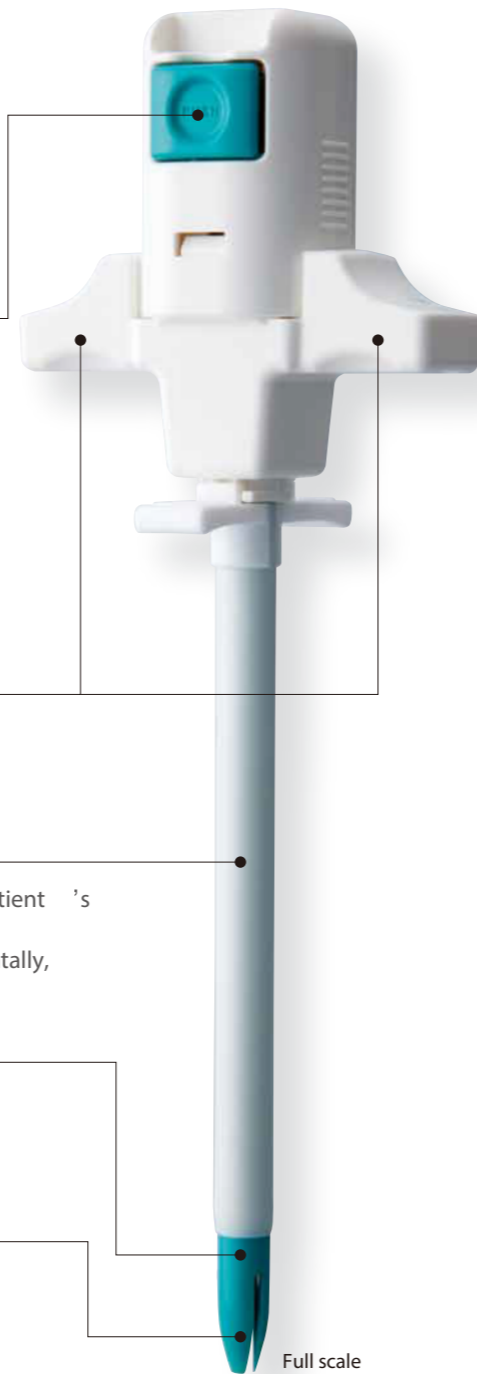
When the Release button is pushed to make a puncture, the cutting edge projects from the sleeve.

※When the Release button is not pushed, i.e. the protection sleeve is locked, the cutting edge is hidden.

Action of the Needle Protection during puncture



The cutting edge of the needle hides in the protection sleeve by the action that the sleeve returns to the original position when the sheath enters the stomach and the resistance by gastric and muscular tissues against the sleeve disappears, then the protection sleeve is locked up (The Release button returns to the original position).



Full scale

Loop Fixture

The new kit contains the Loop Fixture II which is essential for Percutaneous Endoscopic Gastrostomy (PEG) with Introducer method.

Thread feeding roller

The thread feeding roller is used to insert the suture thread into the stomach (both anterograde and retrograde manipulation are possible). The suture thread can be fed into the stomach just by turning the roller in the arrow direction.

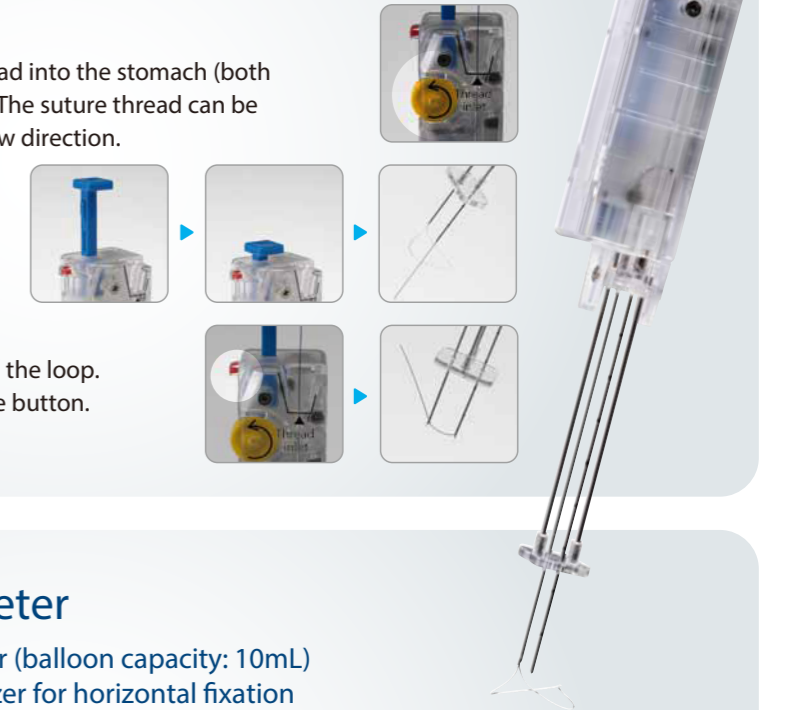
Loop insertion rod

The loop insertion rod is used to form a thread holding loop within the stomach.

Release button

The release button is used to hold the suture thread with the loop. The suture thread can be held just by pushing the release button.

Dr. Funada-Type Gastric wall fixation device enabling single-hand manipulation



20Fr Balloon Catheter

Enlarged catheter size to 20Fr (balloon capacity: 10mL) with special designed stabilizer for horizontal fixation

Balloon is designed to have a non-protruding tip in order to decrease the risk of causing contact ulcers in the posterior wall of the stomach.

20 Fr catheter that has a larger lumen than the catheter in the former kit to minimize the possibility of getting clogged with nutritional supplement. It allows semisolid nutritional supplement to be fed with ease.

Stabilizer that allows the catheter to be fixed horizontally along the patient's body is available to hold the catheter in a convenient position when feeding nutritional supplement is not done.



Specifications

Gastrostomy Kit 20Fr with Loop Fixture



| Product No. | Nominal Size | Contents of Kit | |
|--------------|--------------|-------------------------------------|--|
| 800 001 2171 | PEG 20 | Balloon Catheter × 1Pc. | 20Fr (6.7mm) 10mL, L-225mm Open tip, Radiopaque Line Depth marks at 10mm intervals between 20 and 110mm from the proximal end of the balloon |
| | | PS Needle with TPA Sheath × 1Pc. | Sheath: I.D.-7.4mm, L-100mm |
| | | Loop Fixture II × 1Pc. | Total length 230mm Puncture Needle: 20G(0.9mm) Effective length 81mm |

1 Kit per box, Sterilized with EtO gas

Please note that a partial amendment in specification is made occasionally, as studies and developments have been performed.