GUNZE

GUNZE MEDICAL

ABSORBABLE ADHESION BARRIER

TENALEAF

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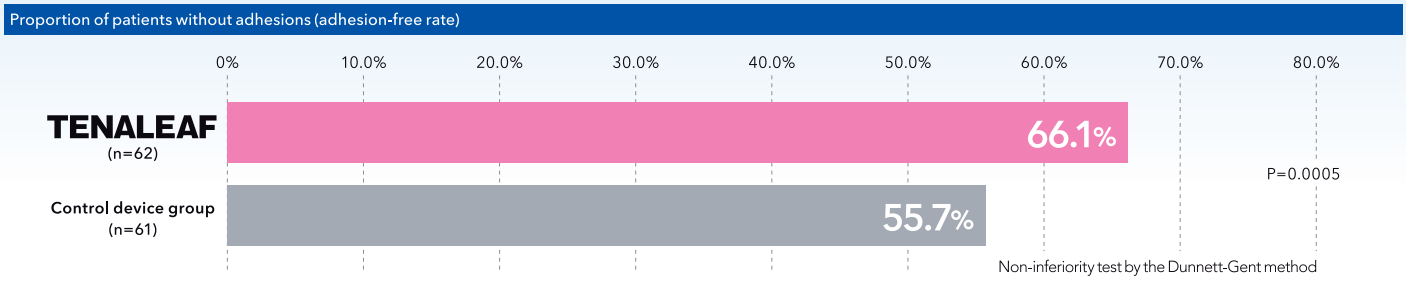
Strength and Flexibility

- 100% gelatin
- Resistant to cracking, maintains ideal durability for easy handling
- Turns into a gel upon contact with peritoneal moisture, conforming to tissue surfaces
- Point-contact surface provides controlled, optimal adherence

•Prevents adhesions by remaining as a gel at the application site for approximately 7 days
•Degraded enzymatically within about 28 days

■ Clinical study in Japan (abdominal surgery)

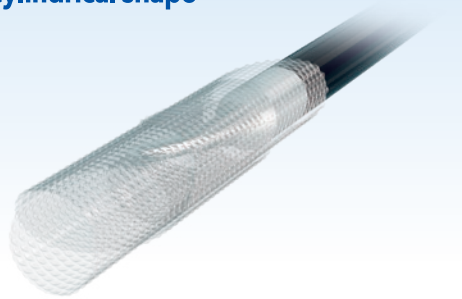


Assessment of postoperative adhesions demonstrated the non-inferiority of TENALEAF to the control device.

Subjects: 123 patients with primary colorectal cancer who underwent temporary laparoscopic loop ileostomy.
Method: TENALEAF and the control device were applied to a subcutaneous incisional wound, and postoperative adhesion of the subcutaneous incisional wound was assessed by laparoscopic observation at the time of closure of the ileostomy.
Safety: 2 events of "paralytic ileus" in 2 patients and 1 event of "abdominal abscess" in 1 patient were reported as adverse events for which a causal relationship with TENALEAF could not be denied. Both events were non-serious.

GUNZE LIMITED data on file

Flexible enough to be rolled into a thin cylindrical shape



■ Flexibility test

Test group	No. of samples broken
TENALEAF (n=10)	0

Method: TENALEAF was winded around a 2 mm tube, and the presence or absence of breakage was confirmed.
Dimensions of the test piece: 60 mm × 60 mm
Test conditions: Temperature, 20.9°C; humidity, 32.7%RH

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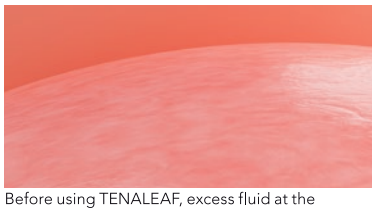
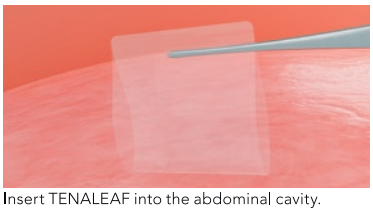
How to use



Before using TENALEAF, excess fluid at the application site should be removed.



Insert TENALEAF into the abdominal cavity. Apply and accustom it to the application site.

[Laparoscopic surgery (with a trocar)]

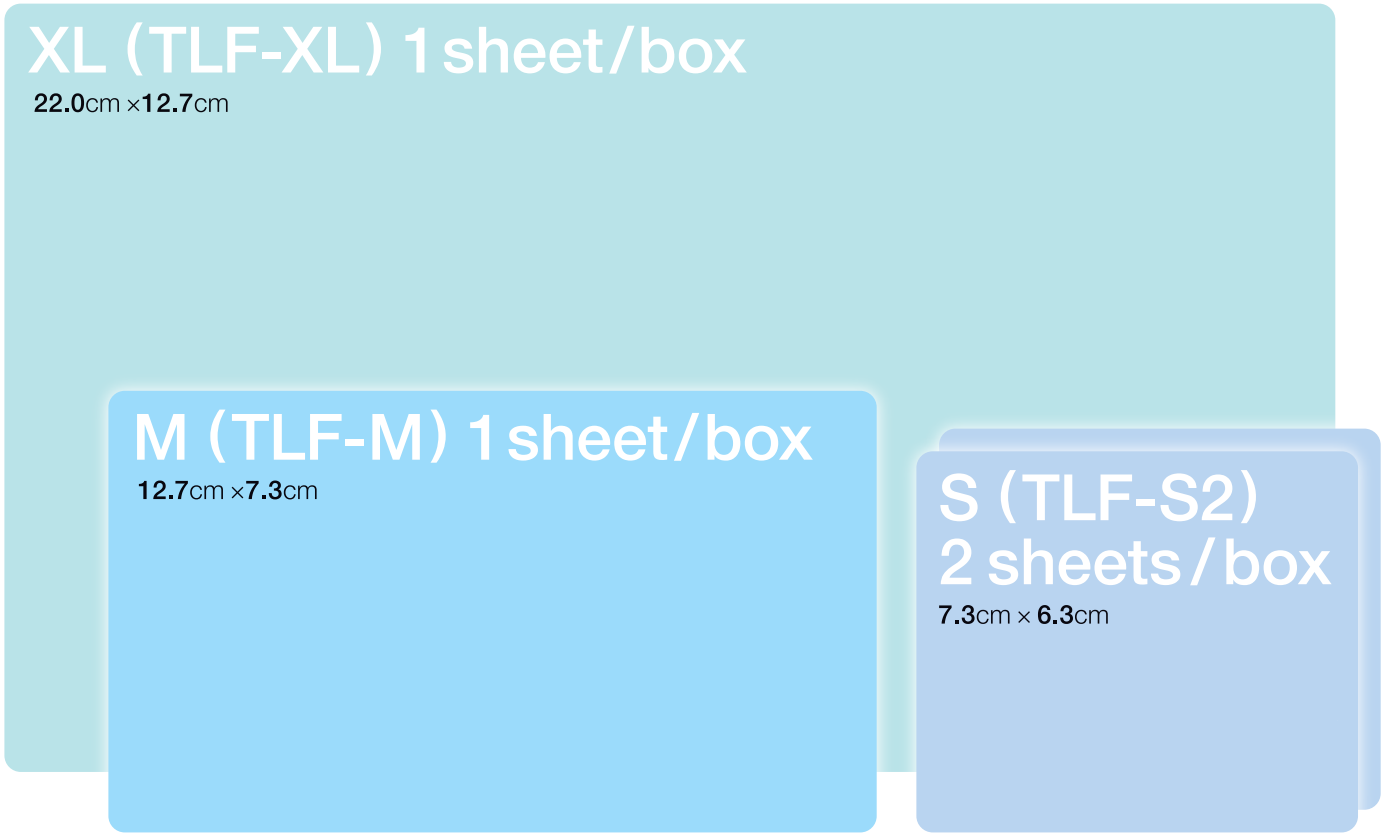
Hold the side edge of TENALEAF with a dry forceps and wind it around the shaft. Wind TENALEAF as closely to the shaft as possible.

Indications

Reduction of postoperative adhesions

TENALEAF Adhesion Barrier is indicated for use in patients undergoing abdominal or pelvic surgery to reduce the incidence, extent, and severity of postoperative adhesions beneath the abdominal incision or at sites of injury (to the peritoneum or to the uterus and its adnexa).

Size (product code)



CONTRAINDICATIONS / PRECAUTIONS

[Contraindications/prohibitions]
Indicated population (patients) (1) Do not use TENALEAF in patients with a history of hypersensitivity to gelatin.
(2) Do not use TENALEAF in patients with infection at the application site. [The infection may worsen.]

- Apply TENALEAF in a dry state to the tissue at the application site using a dry forceps. When applying it, ensure that the incision and damaged site is fully covered.
- If TENALEAF comes in contact with a site where it is not intended to be applied, it can be gently peeled off using forceps, etc.
- When using more than one sheet of TENALEAF, apply the sheets by allowing overlap between them so that the damaged site is completely and continuously covered.
- When inserting TENALEAF into the abdominal cavity using a trocar of 5 mm or less, wind the sheet to the shaft of the forceps so that the width of the combination does not exceed the diameter of the trocar.
  [It will not be possible to insert the forceps into the trocar, or the TENALEAF may be damaged.]
- Do not suture TENALEAF.
- It is not recommend to cover intestinal anastomosis with TENALEAF.
- Safety and efficacy are not confirmed for covering the dissected surface of parenchyma organs such as Liver.

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