INSTRUCTIONS FOR USE

Seprafilm®
Adhesion Barrier

DESCRIPTION
Seprafilm® Adhesion Barrier (Seprafilm) is a sterile, bioresorbable, translucent membrane composed of two chemically modified anionic polysaccharides, sodium hyaluronate (HA) and carboxymethylcellulose (CMC).

INDICATION
Seprafilm is intended as an adjunct in abdominal and pelvic surgery for reducing the incidence, extent and severity of postoperative adhesions at the site of placement.

INTENDED USE
Seprafilm should be applied to sites of potentially adhesiogenic tissue and organ structures in the abdominopelvic cavity to serve as a temporary barrier separating opposing tissue surfaces.

CONTRAINDICATIONS
Seprafilm is contraindicated in patients with a history of hypersensitivity to Seprafilm and/or to any component of Seprafilm.

WARNINGS
Seprafilm must be used according to the instructions for use. Read instructions prior to use. Seprafilm is supplied sterile and should not be resterilized. The membrane is for single use only. Every opened and unused Seprafilm pouch must be discarded.

Seprafilm should not be wrapped directly around a fresh anastomotic suture or staple line of the intestine. Clinical trial data on Seprafilm indicate that such use may result in an increased risk of anastomotic leak-related events (fistula, abscess, leak, sepsis and peritonitis). The incidence of these events was not affected when Seprafilm was placed elsewhere in the abdomen. An increased potential for abdominal events related to anastomotic leak was identified in a post-approval study when Seprafilm was wrapped directly around a fresh anastomotic suture or staple line.

In patients undergoing surgery for ovarian, primary peritoneal or fallopian tube malignancies, Seprafilm use has been reported as having an increased risk of intra-abdominal fluid collection and/or abscess, particularly when extensive debulking surgery was required.

PRECAUTIONS

- Foreign body reactions may occur with Seprafilm, as with any implanted material.
- Do not use if foil pouch is damaged or appears to have been tampered with or opened prior to time of use.
- The use of Seprafilm in combination with other adhesion prevention products and/or in other surgical procedures not within the abdominopelvic cavity have not been clinically evaluated.

- No controlled clinical studies have been conducted in patients with active infections.
- Seprafilm has limited controlled clinical trial information in patients with abdominopelvic malignancy.

ADVERSE REACTIONS

Gastrointestinal Disorders: intra-abdominal fluid collection

General disorders and administration site conditions: foreign body (fibrotic) reaction, inflammation

Immune System Disorders: hypersensitivity

Infections and infestations: sepsis, peritonitis, abscess, post-procedural wound infection/wound dehiscence

Injury, poisoning and procedural complications: anastomotic leak

Muscoloskeletal and connective tissue disorders: fistula

Information for the Patient

- Foreign body reaction may occur as with most surgical adjuncts but have been rarely reported during clinical use.
- No pre-clinical reproductive studies have been conducted. No clinical studies have been conducted in pregnant women or women who become pregnant in the first month after application of Seprafilm. Therefore, this product is not recommended for use during pregnancy and avoiding of pregnancy during the first complete menstrual cycle after the use of Seprafilm should be considered.

STORAGE INSTRUCTIONS

Seprafilm should be stored at 2-30°C.

HOW SUPPLIED

Seprafilm is packed in a Tyvek®[1] holder within a plastic sleeve and packed in an outer, sealed, foil pouch. The contents of the foil pouch are sterilized by gamma radiation of 25-40 kGy.

Refer to package label for film size and quantity.

DIRECTIONS FOR USE

Preparation

- Open the foil pouch and drop the plastic sleeve on a dry, sterile field.
- Carefully remove the Tyvek® holder from the plastic sleeve.
- Keep membrane dry in the holder prior to application.

- While membrane remains in the holder, cut to desired size with scissors.
- Expose 2 cm of membrane through open end of the holder.

Placement

Apply Seprafilm immediately prior to closure of the abdominopelvic cavity:

- Ensure surgical field is dry.
- Handle membrane carefully with dry instruments and/or gloves.
- Avoid contact with tissue surfaces until directly at site of application. If contact occurs, moderate application of a standard irrigating solution may be used to gently dislodge membrane from unintended tissue surfaces.
- When necessary, facilitate entry in abdominal or pelvic cavity by slightly curving the holder.
- Apply Seprafilm.
- Extend placement up to 8 cm beyond margins of direct trauma to achieve adequate coverage with the membrane.
- Let exposed membrane adhere to desired position on the tissue or organ by gently pressing down with a dry glove or instrument, while withdrawing the holder.
- When necessary, moisten membrane lightly with irrigating solution (1-2 ml) to facilitate moulding of membrane along the tissue or around the organ contours.
- Up to 10 (13 cm x 15 cm) membranes per patient have been used in controlled clinical studies for the abdominopelvic indication. Allow overlap of 2-3 cm between individual membranes to ensure coverage.

After placement

- Discard holder(s) following placement.
- Care should be taken not to disturb membrane after placement.
- Do not suture membrane in place.
- Close abdominopelvic according to standard surgical technique.

Seprafilm is a temporary bioresorbable barrier that is resorbed within one week and excreted from the body in less than 30 days. Therefore, no procedure is required to remove the membrane.

For adverse event reporting, for general inquiries, or for medical and product complaints, please contact:

sanofi-aventis Canada Inc.
2905 Place Louis-R.-Renaud, Laval (Québec) Canada, H7V 0A3
Tél: 1-800-265-7927

For further information, please contact your local sales representative.

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[1] Tyvek® is a registered trademark of the DuPont Company, Wilmington, DE, USA