

Information 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, pelvic, and thoracic 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 or thoracic cavity to serve as a temporary barrier separating opposing tissue surfaces.

WARNINGS

Seprafilm must be used according to the instructions for use. Read instructions prior to use. Seprafilm is supplied sterile and should not be resterilised. 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.

CAUTIONS

- 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 has not been clinically evaluated.
- No controlled clinical studies have been conducted in patients with active infections or malignancy in the abdominopelvic or thoracic cavity.

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 women who become pregnant in the first month after application of Seprafilm. Therefore, avoiding 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

sterilised 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 or thoracic 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, pelvic, or thoracic 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, while up to 4 membranes per patient have been used in controlled clinical studies for the thoracic 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 or thoracic cavity 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.

VIGILANCE

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