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**BARRIÈRE ANTI-ADHÉRENCES**

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**BARRERA ANTI-ADERENCIA**  
**ΦΡΑΓΜΑ ΣΥΜΦΥΣΣΩΝ**  
**ADEZYON BARIYERİ**

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Sepra Film and design is a registered trademark of  
Genzyme Corporation, Cambridge, MA, USA.

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Genzyme Corporation, Cambridge, MA, USA.

This product is covered by U.S. Patent Number 5,017,229

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CE 0086  
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**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, and to reduce adhesive small bowel obstruction when placed in the abdomen.

**INTENDED USE**

Seprafilm should be applied to sites of potentially adhesiogenic tissue and organ structures in the abdominal/c 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 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.

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.

**Information for the Patient**

Foreign body reaction may occur as with most surgical adjuncts but has 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® 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 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, modify 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.  
• Extend placement up to 8 cm beyond margins of direct trauma to achieve adequate coverage with the membrane.  
• Apply Seprafilm to direct trauma to achieve adequate coverage with the membrane.  
• Let exposed membrane adhere to desired graden av postoperativt. Each use unique. Chaque 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 thoracic indication. Allow overlap of 2-3 cm between individual membranes to ensure coverage.  
• 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 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.

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- PMS 334
- PMS 356
- Black

Le Seprafilm ne doit pas être enroulé directement autour d'une ligne d'agrafage ou de suture anastomotique fraîche de l'intestin. Les données d'essai clinique sur le Seprafilm indiquent qu'une telle utilisation peut accroître le risque d'événements liés à une fuite anastomotique (fistule, abcès, fuite, sépticémie et péritonite). L'incidence de ces événements n'était pas affectée lorsque le Seprafilm était placé ailleurs dans l'abdomen.

**PRÉCAUTIONS**

Ne pas utiliser si la pochette en aluminium est endommagée ou semble avoir été altérée ou couverte avant l'utilisation.  
• Aucune étude préclinique n'a été réalisée quant aux effets sur la reproduction. Aucune étude clinique n'a été réalisée chez les femelles qui tombent enceintes dès le premier mois suivant l'application du Seprafilm. Par conséquent, il faut envisager d'éviter une grossesse au cours du premier cycle menstruel complet suivant l'application du Seprafilm.

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Faire attention de ne pas bouger la membrane après la mise en place.  
• Ne pas suture la membrane en place.  
• Fermer la cavité abdomino-pelvienne ou thoracique conformément à la technique chirurgicale standard.

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vorliegen, dass der Folienbeutel auf unbedufte Weise manipuliert oder vor dem Zeitpunkt des Gebrauchs geöffnet wurde.  
• Der Einsatz von Seprafilm in Verbindung mit anderen zur Vermeidung von Adhäsionen vorgesehenen Produkten wurde nicht klinisch ausgewertet.  
• Es wurden keine kontrollierten Studien an Patienten mit aktiven Infektionen durchgeführt.

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Gebruiksaanwijzing  
**Vorbereitung**  
• Maak het foliezakje open en laat de kunststofhoes op een droog, steriel veld vallen.  
• Neem de Tyvek® houder voorzichtig uit de kunststofhoes.  
• Houd het membraan droop in

- Ikke sy membranen på plass.
- Lukk lukk- og bekenhulen eller brysthulen i samsvar med vanlige kirurgiske rutiner.

Seprafilm er kun til engangsbruk og må ikke resteriseres. Seprafilm er en midlertidig bioresoorbierbar barriere som resorberes innen en uke og skilles ut fra kroppen før det har gått 30 dager. Det er derfor ikke nødvendig å bruke andre prosedyrer for å fjerne membranen og ingen fare for gjentak. Etter at fillospen er åpnet må brukeren membranen eller deler av dem kasseres.

#### AKTSMOEH

Ved rapportering av ugunstige hendelser, ta kontakt med:
Genzyme Europe B.V.
Goomeer 10
1411 DD Naarden
The Netherlands
Tel: +31 (0)35 699 1299
Fax: +31 (0)35 694 8756

For mer informasjon vennligst ta kontakt med **den lokale salgspresentant.**

**Genzyme A/S**  
**Islands Bygge 57 st tv**  
**DK-2300 Copenhagen S**

**Denmark**  
**Tel: +45 32 712 600**  
**Fax: +45 32712 601**

\*Tyvek® er et registrert varemærke som tilhør DuPont Company, Wilmington, DE, U.S.A.



#### KVALUIS

Seprafilm®-kinnkammodustoksen estääj (Seprafilm) on steriili, bioresorbottiva, läpinäkyvä kalvo, joka koostuu kahdesta kemiallisesti muunnellusta anionista polyaskaridista, natriumhyaluronatista (HA) ja karboksimetylellisestä (CMC).

**KÄYTTÖAIHE**  
Seprafilm on tarkoitettu apuvälineeksi vatsa-, rintatouho- tai lantokirurgiassa vähentämään leikkauksen jälkeisten kinnikkeiden muodostumista, kokoa ja vaikeusastetta kohdassa, johon kalvo on asennettu ja varoitteluun asennettuna vähentämään kinnikkeistä johtuvaa ohutsuolen ahtaumaa.

**KÄYTTÖTARKOITUS**  
Seprafilm asennetaan kinnikkeille alttien kudosten ja elinten päälle vatsa- rinta- ja lantion alueella. Se toimii väliaikaisena esteenä, joka estottaa vastakkaiset osat toisistaan.

#### VAROITUKSIA

Seprafilmin käytössä tulee noudattaa käyttöohjeita. Ohjeet on luettava ennen tuotteen käyttöä. Seprafilm toimittaan steriilinä, eikä sitä saa steriloida uudelleen. Kalvo on tarkoitettu yksittäiseen käyttöön. Kaikki avajat ja käyttämättömät Seprafilm-pussit on hävitettävä.

Seprafilmiä ei pidä käyttää suoran suolen tuoreen anastomosisovmelmirrin tai sinkkilävien ympärillä. Kinnikset kotelut eivät sovitteen, eikä tämä suurentaa anastomosisuovuotoa (fiistat, absessit, vuoto, sepsis ja peritonitit). Näiden ilmaantuvuuten ei vakuuttanut Seprafilmiin sijaitseminen muualle vatsataoleen alueella.

#### VAROTOIMIA

- Tuotetta ei saa käyttää, jos pakkaspussi on vaurioitunut tai avattu tai sitä on iämetesti käsitelty väärin.
- Seprafilmiin käytä muuten kinnikkeitä estävien tuotteiden yhteydessä ei ole tutkittu kliinisesti.
- Kontrolloituja kliinisiä tutkimuksia ei ole tehty potilaille, joilla on käynnissä olevia infektoita.

#### Potilain tiedot

- Vierassiennerakotilla voi limetit kukaan mutakin leikkauksissa käytettyjä tarvikkeita käytettäessä, jokin niistä on kliinisessä käytössä harvoin rajoittamatta käyttöä.
- Präkliniisiä isäntämyrkytyskokeita ei ole suoritetu. Kliinisiä kokeita ei ole tehty naisilla, jotka tulivat raskaaksi kukaavuden aikana Seprafilmin käytössä. Tiesä tyysti on suositeltavaa, että raskaaksi tulemista vältetään ensimmäisen kukaavuskierron aikana Seprafilmin käytön jälkeen.

#### SÄÄLYTYS

Seprafilm säilytetään 2–30 °C:n lämpötilassa.

#### TOIMITUS

Seprafilm on pakattu Tyvek®-kuoreen, jossa on muovisuojus; nämä ovat ylimääräissä suljetuissa foliosissa. Foliosien sisältö on steriloitu 25–40 KG:n gammasäteilyllä.

Pakkauksen etiketissä on mainittu kalvojen koko ja lukumäärä.

#### KÄYTTÖOHJE

**Vaalistelu**  
• Aava foliosissa ja laske muovisuojus kuivalle steriilille pinnalle.  
• Poista Tyvek®-kuori varovasti muovisuojuksesta.  
• Säilytä kalvo kuivana kuoren sisällä ennen asennusta.  
• Kun kalvo on vielä kuoreessa, leikkaa se sakallia halutun kokoiseksi.  
• Poista 2 cm pituus kuoren avimesta päästä kalvon päältä, jolloin kalvo tulee este.

#### Kiinnitys

Aseta Seprafilm välittömästi ennen vatsa-lantio- tai rintaontelon sulkeamista:
• Varmista, että leikkauksalue on kuiva.
• Käsittele kalvoa varoen kuivilla instrumenteilla jaksä käsineillä.
• Vältä, ettei tuote tule kosketuttua muiden kudosteniögen kanssa ennen kuin varmistuneena käyttökohdassa. Ikkää kosketus tapahtuu, kohtalaita vaukoluokseilla tehtyä huhtelua voidaan käyttää irrottamaan kalvo hellävaroen näistä kudospinnoista.

• Varovassaa voit hieman koskettaa kalvoa huhteluluokseilla (1–2 ml), mikä helpottaa kalvon muotoilemistä kudoksen tai elimen lävityksellä.

• Enintään 10 (13 cm x 15 cm) kalvoa poltatta kohden on kontrolloidussa kliinisissä kokeissa asetettu vatsa-lantio-ontleoon.

Rintaontleoon on asennettu enintään 4 kalvoa. Etä kalvo pitää asettaa limittäin, 2–3 cm, jotta riittävä peitto saadaan aikaan.  
**Levityksen jälkeen**  
• Hävitä kuori (kuoret) kalvon kiinnityksen jälkeen.  
• Kiinnityksen jälkeen on varottava liikuttelemaa kalvoa.  
• Käsittele muuten onnimaalla paikkoitten.  
• Vatsa-lantio- tai rintaontleu suljetaan vakioleikkauksa noudattaden.  
• Enintään 10 (13 cm x 15 cm) kalvoa poltatta kohden on kontrolloidussa kliinisissä kokeissa asetettu vatsa-lantio-ontleoon.

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Rintaontleoon on asennettu enintään 4 kalvoa. Etä kalvo pitää asettaa limittäin, 2–3 cm, jotta riittävä peitto saadaan aikaan.

**VAROTOIMIT**  
Seprafilmiä ei pidä käyttää suoran suolen tuoreen anastomosisovmelmirrin tai sinkkilävien ympärillä. Kinnikset kotelut eivät sovitteen, eikä tämä suurentaa anastomosisuovuotoa (fiistat, absessit, vuoto, sepsis ja peritonitit). Näiden ilmaantuvuuten ei vakuuttanut Seprafilmiin sijaitseminen muualle vatsataoleen alueella.

**VAROITUKSIA**  
• Tuotetta ei saa käyttää, jos pakkaspussi on vaurioitunut tai avattu tai sitä on iämetesti käsitelty väärin.

- Seprafilmiin käytä muuten kinnikkeitä estävien tuotteiden yhteydessä ei ole tutkittu kliinisesti.
- Kontrolloituja kliinisiä tutkimuksia ei ole tehty potilaille, joilla on käynnissä olevia infektoita.

#### Potilain tiedot

- Vierassiennerakotilla voi limetit kukaan mutakin leikkauksissa käytettyjä tarvikkeita käytettäessä, jokin niistä on kliinisessä käytössä harvoin rajoittamatta käyttöä.
- Präkliniisiä isäntämyrkytyskokeita ei ole suoritetu. Kliinisiä kokeita ei ole tehty naisilla, jotka tulivat raskaaksi kukaavuden aikana Seprafilmin käytössä. Tiesä tyysti on suositeltavaa, että raskaaksi tulemista vältetään ensimmäisen kukaavuskierron aikana Seprafilmin käytön jälkeen.

#### SÄÄLYTYS

Seprafilm säilytetään 2–30 °C:n lämpötilassa.

#### TOIMITUS

Seprafilm on pakattu Tyvek®-kuoreen, jossa on muovisuojus; nämä ovat ylimääräissä suljetuissa foliosissa. Foliosien sisältö on steriloitu 25–40 KG:n gammasäteilyllä.

Pakkauksen etiketissä on mainittu kalvojen koko ja lukumäärä.

#### AVVERTENZE

Seprafilm va usata in conformia alle istruzioni per l'uso. Leggere tali istruzioni prima di usare il prodotto. Seprafilm viene fornito sterile e non deve essere risterilizzato. La membrana è esclusivamente monouso. Ogni involucro aperto e membrana non utilizzata devono essere smaltiti. Seprafilm non deve essere avvolta direttamente intorno a una linea di graffe o suture anastomotiche fresche sull'intestino. I dati degli studi clinici sulla membrana indicano che tale uso può comportare un rischio maggiore di eventi correlati a perite anastomotiche (fiiste, abscessi, perdite, sepsi e peritonite). L'applicazione di Seprafilm attorno sull'addome non ha avuto conseguenze sull'incidenza di tali eventi.

#### ATTENZIONE

- Non usare il prodotto se l'involucro di carta metallizzata è danneggiato, appare l'umidità o è stato aperto prima dell'uso immediato.
- L'uso di Seprafilm assieme ad altri prodotti correlati a perite anastomotiche (fiiste, abscessi, perdite, sepsi e peritonite).
- Non sono stati condotti studi clinici controllati su pazienti affetti da infezioni in atto.

#### Informazioni per il paziente

- Pub verficarsi una reazione a corpi estranei, come per la maggior parte dei coadiuvanti chirurgici, ma tale reazione è stata riportata raramente durante l'uso clinico.
- Non sono stati condotti studi preclinici di compatibilità tra Seprafilm e farmaci.
- Non sono stati condotti studi preclinici di compatibilità tra Seprafilm e altri prodotti di plastica, dentro un Tyvek® con copertina di plastica, dentro un involucro esterno sigillato di carta metallizzata. Il contenuto dell'involucro è sterilizzato a raggi gamma di 25-40 KG.

L'applicazione di Seprafilm.

#### ISTRUZIONI PER LA CONSERVAZIONE

Seprafilm va conservata a 2-30°C.

#### CONFZIONE

Seprafilm è confezionato su un supporto in Tyvek® con copertina di plastica, dentro un involucro esterno sigillato di carta metallizzata. Il contenuto dell'involucro è sterilizzato a raggi gamma di 25-40 KG.

Vedere l'etichetta sulla confezione per le dimensioni e la quantità di film.

#### ISTRUZIONI PER L'USO

**Preparazione**  
• Aprire l'involucro di carta metallizzata e lasciar cadere la copertina di plastica su una superficie sterile.  
• Rimuovere con cura il supporto in Tyvek® dalla copertina.  
• Mantenere asciutta la membrana sul supporto prima di applicarla.  
• Tagliare con le forbici la lunghezza voluta di membrana lasciando sul supporto.  
• Esporre 2 cm di membrana staccandola dal supporto nel punto in cui è stata tagliata.

**Applicazione**  
Applicare Seprafilm immediatamente prima di chiudere la cavità addomino-pelvica o toracica.

- Assicurarsi che il campo chirurgico sia asciutto.
- Mangiaregiu con cura la membrana con strumenti e/o guanti sterili.
- Evitare il contatto con superfici tessutali fucché non viene raggiunto il sito di applicazione. In caso di contatto, irrigare con una moderata quantità di soluzione standard per staccare delicatamente la membrana dalle superfici involontariamente toccate.

- Se necessario, piegare leggermente il supporto per facilitarne l'entrata nella cavità addominale, pelvica o toracica.
- Applicare Seprafilm.
- Estendere l'applicazione fino a 8 cm oltre il margine del trauma per ottenere una copertura adeguata con la membrana.
- Far aderire la membrana esposta al punto prescelto sul tessuto o sull'organo, premendo delicatamente con un quanto o uno strumento asciutto e staccandola al punto stesso dal supporto.
- Se necessario, inumidire leggermente la membrana con una soluzione irrigante (1-2 ml) per facilitarne l'adesione completa lungo il tessuto o sul contorno dell'organo. In studi clinici controllati sono state usate anche 10 membrane (13 cm x 15 cm) per paziente per applicazioni addomino-pelviche e fino a 4 membrane per paziente per appli-cazioni toraciche. Sovraporre di 2-3 cm i margini fra l'una e l'altra assicurare la copertura del sito.

**DESCRIZIONE**  
La barriera antiderivente Seprafilm® (Seprafilm) è una membrana traslucida, bioreassorbibile e sterile composta da due polissaccaridici anionici modificati chimicamente: sodio ialuronato (HA) e carbossimetilcellulosa (CMC).

**INDICAZIONI**  
Seprafilm coadiuva la riduzione dell'incidenza, estensione e gravità delle aderenze postoperatorie sul sito di applicazione a seguito degli interventi di chirurgia addominale, pelvica o toracica, nonché la riduzione dell'ostruzione dell'intestino tenue quando viene situata nell'addome.

**USO PREVISTO**  
Seprafilm viene applicata sul sito di struttura tessuta e organica che presenta aderenze causate dalla cavità addomino-pelvica o toracica con tecnica chirurgica standard.

Seprafilm è esclusivamente monouso e non deve essere risterilizzato. Seprafilm è a

barriera bioreassorbibile temporanea che viene riassorbita entro una settimana ed eliminata dal corpo in meno di 30 giorni. Non è necessario pertanto alcuna procedura per rimuoverla, e non vi è rischio di riutilizzo. Una volta aperto l'involucro di carta metallizzata, qualsiasi membrana o porzione di membrana non utilizzata devono essere smaltiti.

**VIGILANZA**  
Per la novità di eventi avversi, rivolgersi a:
Genzyme Europe B.V.
Goomeer 10
1411 DD Naarden
The Netherlands
Tel: +31 (0)35 699 1299
Fax: +31 (0)35 694 8756

#### Per ulteriori informazioni, si prega di contattare

**Genzyme s.r.l.**  
**Via Scaglia Est 144**  
**41100 Modena**  
**Italy**  
**Tel. 059 34 98 11**  
**Fax. 059 34 80 42**

\*Tyvek® è un marchio depositato della DuPont Company, Wilmington, DE, U.S.A.



#### DESCRIZIONE

La barriera para la prevención de adherencias Seprafilm® es una membrana estéril, reabsorbible y traslúcida compuesta de hialuronato de sodio (HA) y carboximetilcelulosa (CMC), dos polisacáridos aniónicos modificados químicamente.

Seprafilm debe ser colocado en locales de estructuras de cavidades e de tejidos potencialmente adheogenicos na cavidade addomino-pelvica o torácica para servir como una barreira temporária separando superficies de tecido opostas.

#### ADVERTÊNCIAS

O Seprafilm deve ser usado de acordo com as instruções de uso. Ler as instruções antes de usar. O Seprafilm é fornecido estéril e não deve ser reesterilizado. A membrana destina-se apenas a uma única utilização. Todas as bolsas abertas e não usadas devem ser descartadas imediatamente.

O Seprafilm não deve ser colocado diretamente em volta de uma linha de agulhas ou de suturas anastomóticas recentes do intestino. Os dados de ensaios clínicos realizados com Seprafilm indicam que tal uso pode resultar num risco acrescido de episódios relacionados com fugas anastomóticas (fiístula, abscesso, fuga, sépsis e peritonite). A incidência destes episódios não foi afectada quando o Seprafilm foi aplicado em qualquer outra parte do abdómen.

#### AVISOS

Não usar se a bolsa de folha de alumínio estiver danificada, se parecer aducida ou se tiver sido aberta antes do momento da sua utilização.

O uso de Seprafilm em conjunto com outros produtos de prevenção de aderência não foi avaliado clinicamente.

Não foram efectuados estudos clínicos controlados em pacientes com infeções activas.

Informações para o paciente

- Deve usar-se de cuidado para não perturbar a membrana após a sua colocação.
- Não suturar a membrana em posição.
- Fechar a cavidade addomino-pelvica ou torácica conforme as técnicas cirúrgicas padrão.

O Seprafilm destina-se a ser utilizado como uma solução estándar de irrigação para despoliar a membrana ao longo do tecido ou em volta dos contornos do órgão.

Foram usadas até 10 membranas (13 cm x 15 cm) por paciente em estudos clínicos controlados para remoção da membrana, não havendo risco de reutilização. Depois de aberta a bolsa de folha de alumínio, quaisquer membranas ou porções de membranas não utilizadas têm de ser eliminadas.

#### AVISOS

Não usar se a bolsa de folha de alumínio estiver danificada, se parecer aducida ou se tiver sido aberta antes do momento da sua utilização.

O uso de Seprafilm em conjunto com outros produtos de prevenção de aderência não foi avaliado clinicamente.

Não foram efectuados estudos clínicos controlados em pacientes com infeções activas.

Informações para o paciente

- Deve usar-se de cuidado para não perturbar a membrana após a sua colocação.
- Não suturar a membrana em posição.
- Fechar a cavidade addomino-pelvica ou torácica conforme as técnicas cirúrgicas habituais.

La membrana Seprafilm est concebida como complément de la cirugia abdominal, pelvica o torácica, para disminuir la incidencia, extensión y gravedad de las adherencias postoperatorias en la zona de colocación y reducir la obstrucción adherencial de intestino delgado cuando se coloca en el abdomen.

#### PRECAUCIONES

- No utilizar este producto si la bolsa metalizada está dañada, muestra indicios de alteraciones o ha sido abierta con anterioridad a su uso.
- No se ha evaluado clínicamente el uso de la membrana Seprafilm junto con otros productos para la prevención de adherencias.
- No se han llevado a cabo estudios clínicos controlados en pacientes con infecciones activas.

Información para el paciente

Como es el caso de la mayoría de las membranas auxiliares de cirugía, puede producirse una reacción de cuerpo extraño. Sin embargo, esto se ha comunicado muy raramente durante el uso clínico de este producto.

No se ha llevado a cabo ningún estudio preclínico sobre la reproducción. Tampoco se han realizado estudios clínicos en mujeres que quedan embarazadas durante el mes subsiguiente a la aplicación de Seprafilm.

Por tanto, debe contemplarse la posibilidad de evitar el embarazo durante todo el ciclo menstrual que sigue al uso de Seprafilm.

#### INSTRUCCIONES DE CONSERVACION

La membrana Seprafilm debe conservarse entre 2 y 30 °C.

#### PRESENTACION

La membrana Seprafilm viene envasada en un sobre de Tyvek®, dentro de una funda plástica

contenida en una bolsa metalizada exterior pre-encartonada. El contenido de la bolsa metalizada se ha esterilizado con 25–40 kGy de radiación gamma.

En la etiqueta del envase se indica el tamaño de la membrana y la cantidad de unidades que contiene.

#### INSTRUCCIONES DE USO

**Preparación**

- Abrir la bolsa metalizada y dejar caer la funda plástica sobre un campo estéril seco.
- Retirar cuidadosamente el sobre de Tyvek® de la funda plástica.
- Mantener seca la membrana en su sobre antes de la aplicación.
- Dejando la membrana en el sobre, recortarla al tamaño deseado con tijeras.
- Retirar el extremo recortado del sobre a fin de exponer 2 cm de membrana.

#### Colocación

Aplicar la membrana Seprafilm inmediatamente antes de cerrar la cavidad addomino-pelvica o torácica.

- Cerciorarse de que el campo quirúrgico esté seco.

Usar la membrana cuidadosamente con la membrana con instrumentos y/o guantes secos.

Evitar que la membrana entre en contacto con las superficies tisulares hasta que se encuentre definitivamente en la zona de aplicación. Si se produce un contacto indeseado, aplicar con moderación una solución estándar de irrigación para despoliar la membrana.

Cuando sea necesario, facilitar la entrada de la membrana en la cavidad abdominal, pelvica o torácica curvando ligeramente el sobre.

Colocar la membrana de modo que se extienda hasta 8 cm más allá de los bordes del traumatismo directo, a fin de lograr una cobertura adecuada de la zona.

Dejar que la membrana expuesta se adhiera a la posición deseada sobre el tejido u órgano, presionando suavemente con un guante o instrumento seco al tiempo que se retira el sobre.

En caso necesario, humedecer la membrana ligeramente con un 2 o 2 ml de solución de irrigación para facilitar su moleado a lo largo del tejido o alrededor de las curvas del órgano.

En estudios clínicos controlados se emplearon hasta 10 membranas (13 cm x 15 cm) por paciente en la indicación de adherencias.

No se ha evaluado clínicamente el uso de la membrana Seprafilm junto con otros productos para la prevención de adherencias.

No se han llevado a cabo estudios clínicos controlados en pacientes con infecciones activas.

Después de la colocación

- Deshechar los sobres utilizados una vez concluido el proceso de colocación.
- Cuidar de no alterar la membrana después de su colocación.
- No suturar la membrana para fijarla a su posición.
- Cerrar la cavidad addomino-pelvica o torácica mediante técnicas quirúrgicas habituales.

La membrana Seprafilm es de un solo uso y no se debe reesterilizar. Seprafilm es una barrera provisional de separación entre superficies tisulares opuestas.

#### ADVERTENCIAS

La membrana Seprafilm debe emplearse según las instrucciones de uso. Leer las instrucciones antes de utilizar este producto. Seprafilm se suministra estéril y no se debe reesterilizar. La membrana está destinada a un solo uso. Deben desecharse todas las bolsas de Seprafilm que estén abiertas y sin usar.

No debe utilizar la membrana Seprafilm para envolver líneas de sutura o grapas anatómicas recientes del intestino. Los datos de ensayos clínicos realizados con Seprafilm indican que el uso de Seprafilm puede resultar en un riesgo aumentado de episodios relacionados con fugas anastomóticas (fiístula, absceso, fuga, sépsis e peritonitis). La incidencia de estos sucesos no se vio afectada cuando la membrana Seprafilm se colocó en otras partes del abdomen.

**PRECAUCIONES**  
• No utilizar este producto si la bolsa metalizada está dañada, muestra indicios de alteraciones o ha sido abierta con anterioridad a su uso.

No se ha evaluado clínicamente el uso de la membrana Seprafilm junto con otros productos para la prevención de adherencias.

No se han llevado a cabo estudios clínicos controlados en pacientes con infecciones activas.

#### Información para el paciente

Como es el caso de la mayoría de las membranas auxiliares de cirugía, puede producirse una reacción de cuerpo extraño. Sin embargo, esto se ha comunicado muy raramente durante el uso clínico de este producto.

No se ha llevado a cabo ningún estudio preclínico sobre la reproducción. Tampoco se han realizado estudios clínicos en mujeres que quedan embarazadas durante el mes subsiguiente a la aplicación de Seprafilm.

Por tanto, debe contemplarse la posibilidad de evitar el embarazo durante todo el ciclo menstrual que sigue al uso de Seprafilm.

#### INSTRUCCIONES DE USO

Abrir la bolsa de folha de alumínio e colocar a manga plástica sobre um campo estéril e seco.

- Retirar cuidadosamente o suporte de Tyvek® da funda plástica.
- Mantêr a membrana seca na suporte antes da sua aplicação.
- Manter a membrana permanente no suporte, cortando segundo as dimensões pretendidas usando uma tesoura.
- Expor 2 cm da membrana destacando-a da extremidade aberta do suporte.

#### Colocação

Aplicar a membrana imediatamente antes do encerramento da cavidade addomino-pelvica ou torácica.

Chamar a atenção para o campo cirúrgico estar seco.

Manusear a membrana cuidadosamente usando instrumentos secos e/ou luvas.



**DESCRIZÃO**  
A barreira anti-aderência Seprafilm® (Seprafilm) é uma membrana translúcida, bioreabsorvível e estéril, composta por dois polissaccarídicos aniónicos químicamente modificados, hialuronato de sódio (HA) e carboximetilcelulose (CMC).

#### INDICAÇÕES

O Seprafilm destina-se a ser utilizado como um auxílio de cirurgia abdominal, pélvica ou torácica para reduzir a incidência, grau e gravidade de aderências pós-operatórias na área de colocação, e para reduzir a obstrução do intestino delgado por aderência quando colocado no abdômen.

Quando necessário, deve-se humedecer a membrana ligeiramente com a solução de irrigação (1 a 2 ml) para facilitar a aplicação da membrana ao longo do tecido ou em volta dos contornos do órgão.

Foram usadas até 10 membranas (13 cm x 15 cm) por paciente em estudos clínicos controlados para a indicação adomino-pelvica, enquanto que foram usadas até 4 membranas por paciente em estudos clínicos controlados para a indicação torácica. Permittir uma sobreposição de 2 a 3 cm entre membranas individuais, de modo a garantir a cobertura.

Seprafilm destina-se a ser utilizado como uma solução estándar de irrigação para despoliar a membrana ao longo do tecido ou em volta dos contornos do órgão.

Foram usadas até 10 membranas (13 cm x 15 cm) por paciente em estudos clínicos controlados para remoção da membrana, não havendo risco de reutilização. Depois de aberta a bolsa de folha de alumínio, quaisquer membranas ou porções de membranas não