

**Professional Medical Supplies** 



No.380, Sec.6, Nanjing E.Rd, Neihu Dist. Taipei City, Taiwan TEL:+886-2-27122211 EXT.6227 FAX:+886-2-27126113

E-MAIL : allentsai@npc.com.tw







# 抗沾黏膜 Nanya anti-adhesion membrane

- ·南亞抗沾黏膜可作為保護層用於防止傷疤組織向內生長,從而防止不同的組織黏在一起。南亞抗沾黏膜是由乳酸共聚物製成。這種乳酸共聚物可經水解在體內降解和消溶,並最終經人體代謝成二氧化碳(CO<sub>2</sub>)和水(H<sub>2</sub>O)。
- ·內含玻尿酸可改善膜面親水性,使其容易貼附於患處, 且可在體內降解吸收。植入體內的抗沾黏膜可在傷癒 過程中保護並維持軟組織的穩定性,並最終在體內 消溶。植入抗沾黏膜可避免以後需再次動手術取出。 但如果是植入永久性隔膜,則在以後需要取出時就 必須再動手術。此種抗沾黏膜不可用於需要使用永久 性隔膜的情況。

The Nanya anti-adhesion membrane serves as a protective layer to prevent scar tissue from growing inward, thus avoiding adhesion between different tissues. This membrane is made from a polylactic acid copolymer, which can undergo hydrolysis, gradually degrading and dissolving within the body. Eventually, it metabolizes into carbon dioxide (CO<sub>2</sub>) and water (H<sub>2</sub>O). The membrane also contains hyaluronic acid, enhancing its hydrophilic properties and allowing it to adhere more easily to the affected area. It is absorbed and degraded in the body.

When implanted, the anti-adhesion membrane protects and stabilizes soft tissues throughout the healing process, ultimately dissolving in the body. Since it is absorbable, it eliminates the need for additional surgery to remove it later. However, if a permanent barrier is required, this type of anti-adhesion membrane is unsuitable, as a permanent implant would need surgical removal in the future.

### 產品特點 FEATURE

1.柔軟度佳 Good flexibility.

2.分解速度快(8週) Fast degradation rate (8 weeks).

3.親水性較佳 Superior hydrophilicity.

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4.與組織患處貼附性佳 Excellent adhesion to tissue at the affected site.

## 產品應用 APPLICATION

適用情況肝臟、大腸直腸、 腹腔鏡、婦科相關手術、 剖腹產、開腹手術。

- Liver surgeries
- · Colorectal surgeries
- Laparoscopic procedures
- Gynecological surgeries
- Cesarean sections
- Open surgeries

### 儲存和使用 STORAGE AND USAGE

・不要曝露於溫度超過攝氏50度。 Do not expose to temperatures above 50°C.

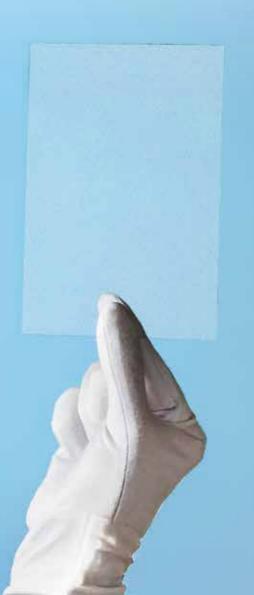
・方形消毒標記呈現紅色方可使用。

The square sterilization mark should appear red to indicate readiness for use.

· 儲藏溫度需控制在攝氏15-30度之間。

Storage temperature should be maintained between 15 - 30°C.

項目 ITEM	說明 DIRECTIONS
醫療器材等級 Medical Device Classification	III
材質 Material	PLA/Hyaluronic acid
厚度 Thickness	30µm
尺寸 Dimensions	13*15cm



### 使用方法 USAGE INSTRUCTIONS

### 1.取出抗沾黏膜 Removing the Anti-Adhesion Membrane .

- · 鋁箔袋提供第一個無菌屏障,並包含一個裝有植入物的雙層無菌 Tyvek® 袋。 The aluminum foil pouch provides the first sterile barrier and contains a double-layer sterile Tyvek® pouch holding the implant.
- · 非無菌操作員打開鋁箔袋,露出裡面的雙層 Tyvek® 袋。 A non-sterile operator should open the aluminum foil pouch to expose the inner double-layer Tyvek® pouch.
- · 雙層Tyvek® 袋應由無菌操作員接收並在無菌區域內打開。
  The double-layer Tyvek® pouch should be handed to a sterile operator, who will open it in a sterile environment.
- ·雙層Tyvek® 袋打開後內部含有抗沾黏膜和Tyvek保護片。
  Upon opening, the inner pouch contains the anti-adhesion membrane and a protective Tyvek sheet.
- · Tyvek保護片內有白色抗沾黏膜。
  Inside the Tyvek protective sheet is the white anti-adhesion membrane.

· 抗沾黏膜取出交給臨床醫生。

- · 建議將白色抗沾黏膜放置在Tyvek保護片內,直到使用時再將其取出。 It is recommended to keep the anti-adhesion membrane within the Tyvek protective sheet until ready for use.
- · 白色抗沾黏膜截角在右上方時,正面含有玻尿酸,將正面(含玻尿酸)貼附於患處。
  With the cut corner at the top right, the front side with hyaluronic acid should be placed against the affected area.
- ·玻尿酸面具有透明點狀物,可由外觀及截角處進行分辨。
  The hyaluronic acid side can be identified by transparent dot-like patterns and the cut corner.

The anti-adhesion membrane should be handed to the clinician when needed.

### A 2.開放手術程序 Open Surgery Procedure ——

· 植入 Implantation

在筋膜閉合開始之前,可以使用無菌剪刀根據需要將片材裁 剪為任何所需的形狀。將抗沾黏膜放置在較弱的組織或筋膜 缺損處。抗沾黏膜的邊緣應延伸到傷口的兩端。抗沾黏膜遇水 後會呈現半透明狀,可在術中重新調整位置。

Before starting the fascia closure, use sterile scissors to cut the membrane into any desired shape. Place the anti-adhesion membrane on the weaker tissue or fascia defect area, ensuring it extends beyond both ends of the wound. Once hydrated, the membrane becomes semi-transparent, allowing for repositioning during surgery.

· 縫合 Suturing

為防止抗沾黏膜移動,建議將抗沾黏膜固定於患處,縫合時將 第一針和最後一針縫線時,穿透片材進行固定。

To prevent movement, secure the anti-adhesion membrane to the affected area with sutures. Pierce the membrane with the first and last stitches to hold it in place.

### → 3.腹腔鏡/封閉手術 Laparoscopic/Closed Surgery Procedure

· 準備 Preparation

利用無菌剪刀將片材裁剪為任何所需的形狀。抗沾黏膜由腹腔鏡抓握器在一端固定。抗沾黏膜隨後可通過 10 毫米或更大的套管針放置到手術部位。

Cut the membrane to the desired shape using sterile scissors. Secure one end of the anti-adhesion membrane with a laparoscopic grasper. The membrane can then be inserted through a trocar of 10 mm or larger to reach the surgical site.

·植入 Insertion

抗沾黏膜放置到手術部位後,將其攤平貼附於軟組織上。 抗沾黏膜可以用一根或兩根細縫線或夾子固定到位。抗沾 黏膜可以在術中使用抓握器重新定位,吸收水分後會變為 半透明狀,手術中可看到底層組織,利於放置。

Once at the site, flatten and adhere the membrane to the soft tissue. It can be held in place with one or two fine sutures or clips. The membrane can be repositioned during surgery using graspers, and it will turn semi-transparent upon hydration, allowing visibility of the underlying tissue for accurate placement.

### 南亞抗沾黏膜屬一種物理阻隔物,用於:

### NAN YA ANTI-ADHESION MEMBRANE IS A TYPE OF PHYSICAL BARRIER USED FOR

1.隔離不同的組織及防止傷疤組織向內生長,並防止緊靠阻黏膜部分的組織形成或重新修復。

Separating Tissues and Preventing Scar Tissue Overgrowth

It acts as a barrier to prevent scar tissue from growing inward and forming adhesions with adjacent tissues near the membrane.

2.促成緊靠阻黏膜的組織形成手術的解剖面,有助於再次手術的進行。

Facilitating Surgical Dissection Layers

By promoting tissue formation along the membrane, it creates an anatomical layer that makes future surgeries easier to perform in the same area.

3.防止緊靠阻黏膜部分的組織形成或重新形成黏連,並促成緊靠阻黏膜的組織形成便於進行 手術的解剖面,包刮下列解剖部位:

Preventing Adhesions in Specific Anatomical Areas

It helps prevent adhesions from forming or reforming around the membrane, facilitating surgical planes in areas such as:

a、心包、心外膜、胸骨後

Cardiac Area: Pericardium, epicardium, and retrosternal space

b、腹膜、腹腔膜、大腸、盲腸、器官

Abdominal Area: Peritoneum, abdominal cavity, colon, cecum, and other organs.

c、硬膜、脊椎硬膜、硬脊膜外、硬脊膜上

Spinal Area: Dura mater, spinal dura mater, extradural, and supradural spaces.

d、婦產科(如:女性骨盆、生殖器官、卵巢、子宮、輸卵管等。)

Gynecological Area: Female pelvis, reproductive organs, ovaries, uterus, fallopian tubes, etc.

4.增強軟組織的薄弱部位,或用於需要附加使用其他增強或搭橋材料才能達到期望的手術效果 的疝氣或筋膜修補手術,用於需要臨時傷口支托的場合。這些應用包括但不限於下列手術:

陰道脫垂、結腸和直腸脫垂、骨盆底部重建和陰道底部固定

Strengthening Weak Soft Tissues

outcome. It can also be used as temporary support in wound care.

# Used in hernia or fascial repair surgeries that require additional reinforcement or bridging materials to achieve the desired surgical

### 使用方法 USAGE INSTRUCTIONS

本公司提供使用指南,內含更詳細的臨床應用說明。

Our company provides a detailed user guide, which includes clinical application information.

### 禁忌症 CONTRAINDICATIONS

### 下列情況禁止使用南亞抗沾黏膜:

Do not use the South Asia anti-adhesion membrane in the following cases:

· 需要使用永久性的入口設備

When a permanent implant or entry device is required.

·目前有感染

If there is an active infection present.

·血液循環不良或潛伏感染等情況的患者

In patients with conditions such as poor blood circulation or latent infections.

### 禁忌症 STERILIZATION

### 南亞抗沾黏膜經輻射滅菌

NAN YA anti-adhesion membrane is sterilized by radiation.

### 警告 WARNINGS

·切勿用於需要使用永久性的植入物的外科手術。此類生物可降解物品僅可用做臨時固定, 不適宜替代正常的健康組織

Do not use this product for surgeries requiring permanent implants. This biodegradable product is intended for temporary fixation only and is not suitable as a replacement for normal, healthy tissue.

- ·丟棄並禁止使用已開封或損壞的物品,僅可使用未經開封和未損壞的包裝盒內的物品。 Discard any opened or damaged items. Use only items that are sealed and undamaged in their packaging.
- · 本品只可使用一次。如果本品已經失去消毒效果,切勿使用。
- This product is for single use only. Do not use if sterilization has been compromised
- · 切勿把本品之護層植入體內。分區重新消毒。

Do not implant the product's protective layer into the body. Perform localized re-sterilization as necessary.

### 注意 PRECAUTIONS

· 對本品之不正確的選擇、放置、定位和固定可能導致不良的效果。 外科醫生應在作手 術之前熟悉了解本品以及其操作程序。

Improper selection, placement, positioning, or fixation of this product may lead to adverse effects. Surgeons should be familiar with the product and its procedures before surgery.

·本品可因劇烈活動或創傷面遭撕裂或損壞,導致使用本品失敗, 並可能需要另作手術把它去除。

This product may fail if exposed to excessive activity or if the trauma site is torn or damaged, which may necessitate additional surgery for removal.