





# 關於南亞

#### **About**

台塑企業南亞公司,為世界最大塑膠加工廠,橫跨化工、電子等多種產業,累積許多豐富的經驗及資源,近年來更是跨足醫療領域,朝醫療器材持續研究發展。

2021年於南亞樹林廠擴建醫療廠房,透過南亞公司的經驗 以及資源結合各醫療產業專業技術,以垂直整合的方式 開發規模化、高品質,創造完整的供應鏈,落實國產化 生產,為醫療領域產品提供解決方案。

Nanya Plastics Corporation is the world's largest plastic processing plant, spanning various industries such as chemicals and electronics, etc. We have accumulated a lot of rich experience and resources, and in recent years we have branched out into the medical field and continued to research and develop medical equipment.

In 2021, the medical factory will be expanded at Nanya Shulin Site. Through experience and resources, we combine the expertise of various medical industries to develop large-scale, high-quality products in a vertically integrated manner, create a complete supply chain, implement localized production, and provide solutions for products in the medical field.



# 無菌細胞培養袋

## **Cell Culture Bag**

南亞細胞培養袋是經過輻射滅菌的無菌透氣袋, 其材質為低密度聚乙烯(LDPE),每一細胞培養袋 套組為單獨包裝,外層包裝為PE潔淨袋,可用於 培養懸浮型細胞,如T細胞(Tcell)、NK細胞(Natural killer cell)等。細胞培養袋注入細胞及培養基後, 放置在二氧化碳培養箱中,薄膜可使二氧化碳和 氧氣進行通透交換,有利於細胞生長。操作者可 藉由免針接頭或公針基接頭添加培養基、生長因子 或是取樣檢測。

Nanya's cell culture bags are sterile, breathable bags that have been sterilized by radiation. The material is low density polyethylene (LDPE). Each cell culture bag set is individually packaged, and the outer packaging is a PE clean bag. It can be used to culture suspension cells, such as T cells, NK cells (Natural killer cells), etc. After the cells and culture medium are injected into the cell culture bag, it is placed in a carbon dioxide incubator. The film allows for transparent exchange of carbon dioxide and oxygen, which is beneficial to cell growth. Operators can add culture media, growth factors, or take samples for testing through the needle-free connector or the male needle-based connector.



- 高細胞培養能力:可在袋中進行高密度大規模細胞 培養
- 安全性高:袋中不含對細胞培養產生不良影響的物質,如塑化劑、溶出物質
- 高透明度袋體:適合顯微鏡觀察,採輻射滅菌的 無菌袋體
- 無針支援:可在不使用針的情況下進行試劑和採樣

- High cell culture ability: Enabling mass cell culture with high density in the bag.
- High safety:Substances that may induce a negative effect for cell culture, such as plasticizing agent and eluted substance are not contained in the bag.
- High transparency film: Best for microscopic observation. Sterilized by gamma irradiation
- Needleless support: Reagents and sampling can be done without a needle.

# 產品規格 Specification

南亞細胞培養袋之標準規格如下,另袋體(最大尺寸:寬45\*長55cm) 及接頭可配合使用者需求進行客製化。

The standard specifications of Nanya's cell culture bags are as follows. The bag body (Maximum Size: Width 45\*Length 55cm) and connectors can be customized to meet user needs

#### 袋體尺寸 Size

#### 接頭 Connector

圖示 Picture

500ml 17.5  $\times$  23.5cm 1000ml 35  $\times$  23.5cm

- 1.免針接頭(管長2cm) Needle-free connector (tube length 2cm)
- 2.公針基 (管長20cm) Male needle base (tube length 20cm)
- 3.免針接頭 (管長50cm) Needle-free connector (tube length 50cm)

※ 此產品只用在體外細胞培養,不能應用於人體體內。



有效期限:1年

## 使用方式 Description

#### STEP 1

拆除細胞培養袋外袋,將免針接頭蓋子用酒 精消毒後打開並與針筒連接。可藉由針筒將 培養基及細胞注入袋體內。

Remove the outer bag from the cell culture bag, disinfect the needle-free connector cap with alcohol, and open it to connect with the syringe. Use the syringe to inject the culture medium and cells into the bag.

#### STEP 2

培養基及細胞注入袋體後先用管夾將PVC管封閉,接著移除針筒,並用酒精消毒後蓋上免針接頭蓋子。

After injecting the culture medium and cells into the bag, use a tube clamp to seal the PVC tube. Then, remove the syringe, disinfect the needle-free connector cap with alcohol, and cover it.



## STEP 3

培養過程中,如需要添加生長因子或補充 培養基時,可使用免針接頭進行添加。

During the cultivation process, if there is a need to add growth factors or supplement the culture medium, the needle-free connector can be used for addition.

## 注意事項 Notice

- 1. 不建議任意裁切或熱封袋體,避免影響產品密閉性。 It is not recommended to arbitrarily cut or heat-seal the bag body to avoid affecting the product's sealing.
- 2. 使用過程中需避免尖銳突起物劃傷培養袋表面。
  During use, avoid sharp protrusions that may scratch the surface of the culture bag.
- 3. 使用前需檢查產品外觀,如PE袋或細胞培養袋已破損,請勿使用。 Before use, check the appearance of the product. Do not use if the PE bag or cell culture bag is damaged.
- 4. 為一次性使用耗材,請勿重複使用。 Culture Bags are designed for single use only, do not reuse the device.
- 5. 細胞培養袋不可離心。 Do not centrifuge the cell culture bag.
- 6. 細胞培養袋不可冷凍保存。 Do not freeze and store the cell culture bag.
- 7. 有機溶劑如(Dimethyl sulfoxide)可能會損害培養袋。
  Organic solvents such as Dimethyl sulfoxide may damage the culture bag.
- 8. 培養袋管蓋擰開時需倒置擺放,避免管口接觸物品或檯面造成汙染。 When unscrewing the cap of the culture bag, invert and place it to avoid the mouth of the tube coming into contact with items or surfaces, causing contamination.
- 9. 進行轉袋或補液過程中,如管口有液體殘留,須用70%酒精棉片擦乾消毒,然後鎖上管蓋。 During the process of transferring or replenishing fluids, if there is liquid residue at the mouth of the tube, wipe it dry with a 70% alcohol swab and then lock the cap.
- 10. 此產品是經過輻射滅菌消毒的無菌細胞培養袋,請勿重複消毒。
  This product is a sterile cell culture bag that has been sterilized by radiation.
  Do not sterilize again.

#### STEP 4

細胞培養袋放置於二氧化碳培養箱內時, 袋體需平整且不可重疊。

When placing the cell culture bag in the carbon dioxide incubator, ensure that the bag is flat and not overlapped.

#### STEP 5

備有公針基接頭,可與其他裝置進行串接, 但使用前需先用管夾將管件關閉,將公針基 接頭蓋子用酒精消毒後打開並連接。

Equipped with a male luer lock base connector, it can be connected to other devices. However, before use, close the connector with a tube clamp, disinfect the male needle base connector cap with alcohol, and open it to connect.

# COA

項目 Inspection Item	標準 Standard Value	檢測結果 Test results
外觀 Appearance	完整無破損 intact and undamaged	Pass
功能性-洩漏性 Leakage	無洩漏 without leakage	Pass
功能性-黏著密合性 Fitting strength with tube	無脫落 without falling off	Pass
穿透率 Transmittance	>90	Pass
滅菌劑量 Sterilization dose	25-40 kGy	Pass
內毒素 (Endotoxin)	≤0.25 Eu/mL	Pass
粒子數 Number of particles	<3000 for 10 $\mu$ m <300 for 25 $\mu$ m	Pass





NANYA medical

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