

"台灣先進"拋棄式沖吸管組

"Taiwan Surgical" Disposable Suction Irrigation Device

衛部醫器製字第004834號

⚠ 使用前，請務必詳閱原廠之使用說明書遵照使用

產品敘述

(TSI-533 / TSI-545 / TSI-533A / TSI-545A / DS501-4S / DSX01-3S 及 DSX01-4S)

拋棄式沖吸管組之組成包含2.9米雙軟管，其中輸液組件連接沖洗管端，可撓式管與吸引管端連接。另一端為插管組與含有雙按鍵之握把連接。沖洗管端對應藍色按鍵，管端有中央夾與穿刺針，吸引管端對應白色按鍵，管端有萬向可撓式連接管。

(TSI-290)

拋棄式沖吸管組之組成包含2.9米雙軟管，其中輸液組件連接沖洗管端，可撓式管與吸引管端連接。另一端為插管組與使用設備端做連接。沖洗管對端有中央夾與穿刺針，吸引管對端有萬向可撓式連接管。

適應症

本產品係僅適用於腹腔鏡手術中，搭配使用生理食鹽水進行腹腔灌洗及液體吸出之設備。

重要！

必須由經過專業訓練及經驗足夠的醫生操作拋棄式沖洗管組，進行腹腔鏡手術。執行手術之醫生必須完全了解手術風險與可能出現的併發症。並確保知會病人手術中需注意的事項。此使用說明書僅提供為協助使用本產品，並非作為外科手術技術的參考文獻。此使用說明書僅提供為本產品的使用說明，並非所有其他或類似產品的使用說明。

禁忌症

1. 本產品禁忌症與其他內視鏡手術的禁忌症和方法相同。請參閱腹腔鏡手術器的絕對和相對手冊禁忌症。
2. 禁止使用本裝置進行子宮鏡檢查或腔鏡擴張。
3. 凝血過程中不要按壓沖洗鍵。
4. 在使用過程中必須保持足夠的小心和距離，以防止與其他儀器產生的閃絡(電弧)效應。

警告及注意事項

1. 本產品經Gamma滅菌，為一次性產品，請勿重複使用及重複消毒。
2. 使用前如發現包裝破損或打開，請勿使用。
3. 使用拋棄式沖吸管組系統的所有外科手術只能由經過專業培訓的醫生進行處理，並具有足夠的內視鏡和外科手術經驗。
4. 請於室溫下儲存，應避免高溫潮濕及日光直接照射，有效期間為3年。
5. 在同一手術中，使用不同製造商之內視鏡及其附件時，要確實瞭解其同時使用之相容性。
6. 請於手術後，將沖洗管端之中央開關，移除穿刺針，蓋回針蓋，並將吸引管端與手術室之吸引器械分離，並將此器械完全丟棄。
7. 使用時須注意靜電、磁場影響。
8. 本產品需搭配「主真空系統」和「廢液收集瓶」使用，使用前須驗證其相容性。本許可證未包含上述兩項器材。
9. 本產品經安全性驗證的最小和最大耐受壓力為：

	最小	最大
沖洗壓力	400mmHg(53kPa)	740mmHg(98kPa)
吸引壓力	400mmHg(53kPa)	650mmHg(86kPa)

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示意圖

<p>TSI-533 / TSI-545</p>	<p>(A)不銹鋼管 (Stainless steel tube) (B)鋼管座 (Steel tube seat) (C)吸引鍵 (SUCTION key) (D)沖洗鍵 (IRRIGATION key) (E)聚氯乙稀軟管 (PVC soft tube) (F)握把 (Handle) (G)吸引導管接頭 (Suction tube connector) (H)中央 (Sandwiching) (I)穿刺針 (Needle for insert) (J)聚氯乙稀管 (PVC tube) (K)針蓋 (Needle cap)</p>
<p>TSI-533A / TSI-545A</p>	<p>(A)不銹鋼管 (Stainless steel tube) (B)鋼管座 (Steel tube seat) (C)鎖定鍵 (LOCK key) (D)吸引鍵 (SUCTION key) (E)沖洗鍵 (IRRIGATION key) (F)聚氯乙稀軟管 (PVC soft tube) (G)握把 (Handle) (H)吸引導管接頭 (Suction tube connector) (I)中央 (Sandwiching) (J)穿刺針 (Needle for insert) (K)聚氯乙稀管 (PVC tube) (L)針蓋 (Needle cap)</p>
<p>TSI-290</p>	<p>(A) 吸引導管接頭-連接設備 (Suction tube connector- with the Device) (B) 沖洗導管接頭-連接設備 (IRRIGATION tube connector- with the Device) (C) 聚氯乙稀軟管 (PVC soft tube) (D) 吸引導管接頭 (Suction tube connector) (E) 中央 (Sandwiching) (F) 穿刺針 (Needle for insert) (G) 聚氯乙稀管 (PVC tube) (H) 針蓋 (Needle cap)</p>
<p>DS501-4S/ DSX01-3S/ DSX01-4S</p>	<p>(A)不銹鋼管 (Stainless steel tube) (B)鋼管座 (Steel tube seat)</p>

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產品型號及規格

產品系列	型號	握柄連接沖洗和吸引功能	不銹鋼管直徑	不銹鋼管長度	引流管組規格
TSI 系列	TSI-533	--	5mm	330mm	2900mm
	TSI-545	--	5mm	450mm	2900mm
	TSI-533A	有	5mm	330mm	2900mm
	TSI-545A	有	5mm	450mm	2900mm
	TSI-290	--	--	--	2900mm
DS 系列	DS501-4S	--	5mm	450mm	--
	DSX01-3S	--	10mm	330mm	--
	DSX01-4S	--	10mm	450mm	--

示意圖

TSI 系列	DS 系列
<p>步驟 1. 請按照正常的方式，打開無菌包裝。</p>	<p>步驟 1. 請按照正常的方式，打開無菌包裝。</p>
<p>步驟 2. 請確認沖洗管端及握把，並確保管子沒有彎折。</p>	<p>步驟 2. 請將插管組及軟管連接，確認沖洗管端及握把，並確保管子沒有彎折。</p>
<p>步驟 3. 請將沖洗端的中央開關，針蓋移除，並將穿刺針插入欲使用之輸液，而吸引管端則與手術室之吸引器械進行連接。</p>	<p>步驟 3. 請將沖洗端的中央開關，針蓋移除，並將穿刺針插入欲使用之輸液，而吸引管端則與手術室之吸引器械進行連接。</p>
<p>步驟 4. 打開中央輸液通過，使用前，請將管內空氣排出。如需更換輸液，請將中央開關後，再進行更換。</p>	<p>步驟 4. 打開中央輸液通過，使用前，請將管內空氣排出。如需更換輸液，請將中央開關後，再進行更換。</p>

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吸引與沖洗

產品狀態	TSI-533 / TSI-545	TSI-533A / TSI-545A
1.自由狀態	自由狀態 	自由狀態
2.吸引	按下吸引鍵 	按下吸引鍵至鎖定狀態
3.沖洗	按下沖洗鍵 	按下沖洗鍵至鎖定狀態
4.恢復自由狀態	鬆開以恢復自由狀態 	按下鎖定鍵以恢復自由狀態

Taiwan Surgical Corporation

藥商/製造廠名稱：台灣先進手術醫療器材股份有限公司
藥商/製造廠地址：新竹縣竹北市新竹科學園區生醫路二段12號3樓
Tel: +886 3 6588129 Fax: +886 3 6588355

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"Taiwan Surgical" Disposable Suction Irrigation

User Manual

PLEASE READ THE FOLLOWING INFORMATION THOROUGHLY BEFORE USING THE PRODUCT.

IMPORTANT!

These instructions for use are to assist in using this product, but not a reference to surgical techniques. All surgical procedures using the single use suction and irrigation system must be handled only by doctors who have been professionally trained and have sufficient experience to use laparoscopic and surgical techniques. Any surgeon who undertakes a procedure must understand well the risks and possible complications involved with this surgical technique. Please make sure that the patient has been notified about the manner the operation will take place, as required by local recommendations. These instructions for use are not a reference document for surgical techniques. Please refer to existing works for all information regarding surgical operations and techniques utilizing suction and irrigation devices and the relevant complications and risks. These instructions for use contain only information concerning the suction and irrigation system with and how to use it. It could not be regarded as general instructions concerning the techniques for using suction and irrigation system made by other manufactures.

INTENDED USE

Suction irrigation is indicated for general purpose use as suction irrigation device to facilitate lavage during laparoscopic surgery and general surgery. The device functions to aid flushing blood and tissue debris from the surgical site.

CONTRAINDICATIONS

- Contraindications of endoscopic techniques which apply to this product and other devices and methods. See operator's manual of your laparoscope for absolute and relative contraindications.
- Contraindications of using of this device for hysteroscopy or for cavity distention.
- Do not press irrigation key during coagulation.
- Sufficient care and distance must be maintained during use to prevent arcing to other instruments.

WARNINGS AND PRECAUTIONS

- The device is sterilized and single use. Do not reuse and re-sterilize.
- Do not use if the package has been damaged or opened.
- All surgical procedures using the single-use suction and irrigation system must be handled only by doctors who have been professionally trained and have sufficient experience to use laparoscopic and surgical technique.
- This device is obtainable only on a physician's prescription.
- Store at room temperature, 25°C. Avoid prolonged exposure to elevated temperature.
- If it is necessary to use endoscopy devices from different manufacturers in the same surgical procedure, please verify its compatibility before surgery.
- By finishing the operation, close the irrigation tube clamp, disconnect the universal flexible connector on the aspiration, and discard the whole cannula handle-tubing assembly.
- Static electricity and magnetic field influence should be noted when using the device.
- The temperatures must under 130°F (54°C) when product in transportation condition.
- The device has to be assembled on the main vacuum system of operating room, please verify its compatibility before using.
- The verified minimum and maximum pressure tolerance of the main vacuum system are as follows:

	Min	Max
Irrigation Pressure	400 mmHg (53kPa)	740 mmHg (98kPa)
Suction Pressure	400 mmHg (53kPa)	650 mmHg (86kPa)

PRODUCT DESCRIPTION

(TSI-533, TSI-545, TSI-533A, TSI-545A, DS501-4S, DSX01-3S, DSX01-4S)

The disposable suction and irrigation system consists of 2.9 meters of double tubing, with fluid bag spike and a clamp fitted on the irrigation tube, and a universal flexible connector on the suction tube. On the other side, the cannula (diameter 5 mm/10mm, length 330mm / 450mm) is connected to the tubing by the double piston hand-piece. The irrigation circuit corresponds to the blue piston, and its tubing is fitted with a clamp and the pouch spike. The aspiration circuit corresponds to the white piston, and its tubing is fitted with the universal flexible connector.

(TSI-290)

The disposable suction and irrigation system consists of 2.9 meters of double tubing, with fluid bag spike and a clamp fitted on the irrigation tube, and a universal flexible connector on the suction tube. On the other side, the cannula is connected to the Device.

SCHEMATIC VIEW

TSI-533 / TSI-545		(A) Stainless steel tube (B) Steel tube seat (C) SUCTION key (D) IRRIGATION key (E) PVC soft tube (F) Handle (G) Suction tube connector (H) Sandwicheing (I) Needle for insert (J) PVC tube (K) Needle cap
TSI-533A / TSI-545A		(A) Stainless steel tube (B) Steel tube seat (C) LOCK key (D) SUCTION key (E) IRRIGATION key (F) PVC soft tube (G) Handle (H) Suction tube connector (I) Sandwicheing (J) Needle for insert (K) PVC tube (L) Needle cap
TSI-290		(A) Suction tube connector- with the Device (B) IRRIGATION tube connector- with the Device (C) PVC soft tube (D) Suction tube connector (E) Sandwicheing (F) Needle for insert (G) PVC tube (H) Needle cap
DS501-4S/ DSX01-3S/ DSX01-4S		(A) Stainless steel tube (B) Steel tube seat

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SPECIFICATIONS

Product Series	Product No.	The function of locking to continuous suction and irrigation	Stainless steel tube diameters	Stainless steel tube length	PVC tube length
TSI Series	TSI-533	--	5mm	330mm	2900mm
	TSI-545	--	5mm	450mm	2900mm
	TSI-533A	Yes	5mm	330mm	2900mm
	TSI-545A	Yes	5mm	450mm	2900mm
	TSI-290	--	--	--	2900mm
DS Series	DS501-4S	--	5mm	450mm	--
	DSX01-3S	--	10mm	330mm	--
	DSX01-4S	--	10mm	450mm	--

OPERATION NOTE

TSI Series	DS Series
Step 1. Please open the sterile packaging according to correct practice.	Step 1. Please open the sterile packaging according to correct practice.
Step 2. Please make sure the irrigation cannula, hand-piece and about one meter of tubing remain on the drape.	Step 2. Please combine stainless steel probe and make sure the irrigation cannula, hand-piece and about one meter of tubing remain on the drape.
Step 3. Please close the clamp on the irrigation tubing remove the protective cap from the spike and pierce the pouch or bottle of solution in sterile way. Aspiration of the body liquids and/or debris resulting from cleansing is effected by suction using the main vacuum system of operating room.	
Step 4. Open the irrigation tubing clamp to allow the liquid passing through. Before using the cannula, please expel all the air from the tubing. By changing a fluid bag, please close the irrigation tube clamp and replace the bag or bottle of solution in sterile method.	

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OPERATION GUIDE

Mode	TSI-533 / TSI-545	TSI-533A / TSI-545A
1. Free mode	Free mode 	Free mode
2. Suction	Depress the SUCTION key 	Depress the SUCTION key to be locked by LOCK key
3. Irrigation	Depress the IRRIGATION key 	Depress the IRRIGATION key to be locked by LOCK key
4. Free mode	Release all the keys to back to Free mode 	Depress the LOCK key to back to Free mode

Taiwan Surgical Corporation

3F., No. 12, Sec. 2, Sheng Yi Rd., Zhubei City, Hsinchu County 30261, Taiwan
Tel: +886 3 6588129 Fax: +886 3 6588355
<http://www.twsc.com.tw>

	Catalogue number		Batch code		Sterilized using irradiation
	Date of manufacture		Manufacturer		Caution
	Use-by-date		Do not re-use		Do not re-sterilize
	Temperature limit		Keep dry		Keep away from sunlight
	Do not use if package is damaged		DEHP Free		Consult instruction for use
	EC REP	MDSG GmbH Schiffgraben 41, 30175 Hannover, Germany			

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