福創加壓套
Flowtron DVT20

Calf Garment · 小腿套

ZH-t 僅可遵醫囑使用 · 僅能與 Arjo 製造的 Flowtron DVT 預防加壓機搭配使用 · 並非由橡膠乳膠製成 · 未經滅菌

只可和 ArjoHuntleigh 製造的 Flowtron DVT 預防加壓機配合使用。絕不得和 Flowtron Hydroven 3 或 Flowtron Hydroven 12 間歇式氣動壓縮 (IPC) 加壓機配合使用。可參閱相關的 Flowtron DVT 加壓機使用說明文件，取得更廣泛的加壓套資訊。

使用說明
1. 將加壓機的插頭插入適當的用電插座。此時請勿啟動加壓機。
2. 從密封袋中取出加壓套。加壓套可用於任何一條腿。將加壓套展開，並將充氣式氣囊 放在病患小腿正後方。
3. 將加壓套緊貼包覆病人的腿，並固定每個黏貼塊。對另一條腿重複以上動作。應適當放置加壓套，確保加壓套不會在病患的四肢上產生任何持續性壓力點。若使用具有束帶或固定裝置的器械（如截石位托腿架），請確保連接管不會放置在束帶內與病患的皮膚有接觸的位置，並時常檢查病患皮膚狀況是否有發紅或壓力點的跡象。在加壓套空氣氣囊置於腿後側位置時，最能夠有效預防靜脈瘀滯。如果無法將加壓套置於腿後側，可將加壓套繞著小腿旋轉到其他能協助預防靜脈瘀滯之替代位。
4. 將加壓套連接至加壓機管組，確保彈簧鎖接頭發出卡嗒一聲。
5. 若您的 Flowtron DVT加壓機具有調整式壓力調節器，除非醫生另有指示，否則請將 調節器的刻度盤轉動至建議的壓力。
6. 啟動加壓機。此時綠色的電源指示燈應會亮起。

適應症
Flowtron DVT 加壓套用於預防深層靜脈血管栓塞形成。

建議事項
- 每隔一段時間就應取下加壓套，檢查皮膚狀況有無任何發紅或壓力點的跡象。
- 建議持續使用間歇式氣動加壓直到 病患完全能走動為止。
  建議本系統在使用上不要間斷。
- 對於非外科病人，一旦確定有形成 DVT 的風險後，就應該立即使用本系統。

禁忌症
以下病況不應使用間歇式氣動壓縮 (IPC)：
- 存在嚴重的動脈硬化症或其他缺血性血管疾病。
- 已知或疑似存在急性深部靜脈栓塞 (DVT) 或靜脈炎。
- 存在嚴重的充血性心臟衰竭，或任何流至心臟的血量增加有可能會有害人體的情況。
- 肺栓塞。
- 任何會被加壓套所干擾的局部病況，包括壞疽、近期接受皮膚移植、皮膚炎，或受感染且未治療之腿部傷口。

如果您對任何禁忌症感到不確定，請在使用裝置之前先向病患的醫師求助。

注意事項
- 若病患感到刺痛、麻木或疼痛，應該立即取下加壓套。
- 用於預防深層靜脈血管栓塞形成 (DVT) 時，建議持續性地使用，如欲中斷長時間的治療，應由病患的主診醫師根據臨床判斷作決定。
- 加壓套和連接管相關的下肢放置事宜也應該納入考量，請特別留意無意識、無感覺或 較法感知及/或較無法移動腿部的病患。
- 若腿或腳已變形，或腿部明顯水腫，為該腿或該腳放上加壓套時應格外小心。
- 使用者不可對本產品進行清潔及/或滅菌以便重複使用本產品，本產品只供單一病患使用。若嘗試對這些產品進行清潔或滅菌，病患可能會有生物相容性、感染或產品失效的風險。

操作指示 - 請參考使用說明

嚴重事故
若本醫療器材造成嚴重事故，波及使用者或病患，則使用者或病患應向本醫療器材製造商或分銷商通報此 嚴重事故。
若事故地點位於歐盟，使用者應同時向會員國當地主管機關通報此重大事故。

廢棄產品處理方式
加壓套布料、其他紡織品、聚合物、塑膠材料等，應分類為可燃性垃圾。

符號

CE 圖示表示符合 歐盟統一法律

單一病患使用

操作指示 - 請參考使用說明

MD 表示該產品為醫療器材，符合歐盟醫療器材法規 2017/745 之規範。

製造商的名稱和地址

UDI 唯一設備標識符

ArjoHuntleigh AB
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www.arjo.com

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EN To be used only under the direction of a physician • Only for use with Flowtron DVT prevention pumps manufactured by Arjo • Not made with natural rubber latex • Non-Sterile

For use only with Flowtron® DVT-prevention pumps manufactured by ArjoHuntleigh. Must not be used with Flowtron® Hydroven 3 or Flowtron® Hydroven 12. Intermittent Pneumatic Compression (IPC) pumps.
More comprehensive information on the garment can be found in the relevant Flowtron DVT pump Instructions For Use document.

Instructions For Use

1. Plug the pump into a suitable electrical outlet. Do not turn the pump on at this time.
2. Remove the garments from the sealed bag. The garments may be used on either leg. Unfold the garment and position the inflatable bladder directly behind the patient's calf.
3. Snugly wrap the garment around the patient's leg and secure the fastener tabs. Repeat for the other leg. Garments should be positioned in such a way that they do not create any potential for constant pressure points on the patient's limb. If using apparatus with straps or securing devices – for example lithotomy stirrups, ensure tubing is not placed inside the strap next to patient skin, and regularly check the patient's skin for signs of redness or pressure points. The garment is most effective in preventing venous stasis when the garment air bladder is located in the posterior position. If the garment cannot be placed at the posterior, the garment can be rotated around the calf to alternative positions all of which will still help to prevent venous stasis.
4. Attach the garments to the pump tubing set ensuring a 'click' is heard from each snap-lock connector.
5. If your Flowtron DVT pump has an adjustable pressure regulator, turn the regulator dial to the recommended pressure unless otherwise directed by the physician.
   For further details, refer to the relevant Flowtron DVT pump Instructions For Use document.
6. Turn the pump on. The green power indicator lights should illuminate.

Indications

The Flowtron DVT Garment is to help prevent Deep Vein Thrombosis (DVT).

Recommendations

- Garments should be removed regularly to inspect the skin for signs of redness or pressure points.
- Continuous intermittent pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of the system is recommended.
- In the non-surgical patient, the system should be initiated immediately once the risk of DVT formation is identified.

Contraindications

Intermittent Pneumatic Compression (IPC) should not be used in the following conditions:

- Severe arteriosclerosis or other ischaemic vascular diseases.
- Known or suspected acute Deep Vein Thrombosis (DVT) or phlebitis.
- Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
- Pulmonary embolism.
- Any local condition in which the garments would interfere, including gangrene, recent skin graft, dermatitis or untreated, infected leg wounds.
  If you are unsure of any contraindications refer to the patient's physician before using the device.

Cautions

- Garments should be removed immediately if patient experiences tingling, numbness or pain.
- When used for DVT prophylaxis, continuous use is recommended and any interruption of therapy for a substantial length of time should be at the discretion of physician.
- Lower limb positioning in relation to the garment and tubing should also be considered particularly when a patient is unconscious, or has reduced sensation / ability to move their legs.
- Additional care should be taken when placing the garments on any deformed leg or foot, or on legs with significant oedema.
- This product cannot be adequately cleaned and / or sterilized by the user in order to facilitate safe reuse and is therefore intended for single patient use. Attempts to clean or sterilize these devices may result in a biocompatibility, infection or product failure risk to the patient.

Serious Incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

End of Life Disposal

Garment material or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste.

Symbols

CE marking indicating conformity with European Community harmonised legislation

Single patient use

Operating instructions - Consult Instructions for use

MD Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745

Manufacturer name and address

UDI Unique device identifier

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