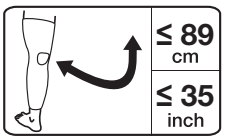
福創加壓套
Flowtron TRP40



arjo
Thigh Garment · 全腿套

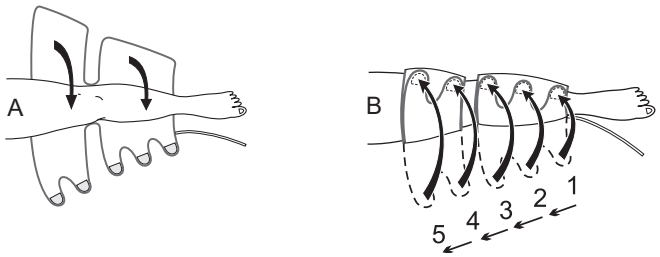
ZH-t 只可按醫師指示使用 · 未經滅菌 · 並未以天然橡膠乳膠製成 · 只可和 Flowtron® DVT 預防加壓機配合使用

小心事項：(僅適用於美國市場) 聯邦法律限制此裝置需由持有執照的醫師出售或按此醫 師之指示出售。

描述
Flowtron Active Compression System 由 Tri Pulse 加壓套及連接一個由ArjoHuntleigh製造的 Tri Pulse 支援型 Flowtron DVT 預防加壓機所構成。

使用說明
注意：請參閱相關的 Tri Pulse 支援型 Flowtron DVT 預防加壓機使用手冊，以取得完 整的系統使用資訊。
1. 從密封袋中取出加壓套，並在病患註記中記錄下批號。
2. 加壓套可用於任何一條腿。將加壓套展開，並如同加壓套上所指示，將充氣式囊袋放 在病患小腿正後方 (圖 A)。

注意：加壓套下方有個箭頭，此箭頭必須指向腳後跟。
3. 將加壓套圍在病患的腿上 (圖 A)。從腳踝開始，依次往上固定每個黏貼塊 (圖 B) 確保整個加壓套舒適地緊密貼合置於腿上。對另一條腿重複以上動作。
4. 將加壓套連接至 Tri Pulse 支援型 Flowtron DVT 預防加壓機管組，確保加壓機接頭發 出卡嗒一聲。
5. 啟動加壓機。
6. 檢查加壓機螢幕上的圖示，確認每條腿是否已接上正確的加壓套類型。
7. 按下「開始」即可開始治療；指示燈此時應顯示綠色。
8. 按下「停止」即可結束治療。




將加壓套置於腿上時，箭頭必須指向腳後跟。

適應症
Tri Pulse 加壓套用於預防深層靜脈血管栓塞形成。

一般建議
· 確認加壓機管組和加壓套管道裡並未扭結。
· 時常檢查加壓套是否仍正確接於病患身上。

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。
· 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。
· 已知或疑似存在急性深部靜脈栓塞 (DVT) 或靜脈炎。
· 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。

注意：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
· 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，可能會導致病患有生物相容性、感染或產品失效的風險。
· 加壓套的放置應避免對皮膚持續形成壓力點，請特別留意無意識、無感覺或較無法感 知及/或較無法移動腿部的病患。
· 每個輪班都應該時常檢查病患的皮膚狀況。
· 必須運用臨床判斷，判定是否需針對病患的皮膚狀況採取其他額外的保護措施，或是否應停止治療。
· 若病患感到刺痛、麻木或疼痛，應該立即取下加壓套。
· 當用於預防 DVT 時，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。
· 對於四肢較不敏感、患有糖尿病、具有循環受損，或是皮膚較脆弱或受損的病患，應 謹慎使用本系統。

注意：這些應僅視為指南，不應取代臨床判斷與臨床經驗。

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
Hans Michelsensgatan 10
211 20 Malmo
SWEDEN
www.arjo.com

CE

314903ZH-t Rev 05 2023-11

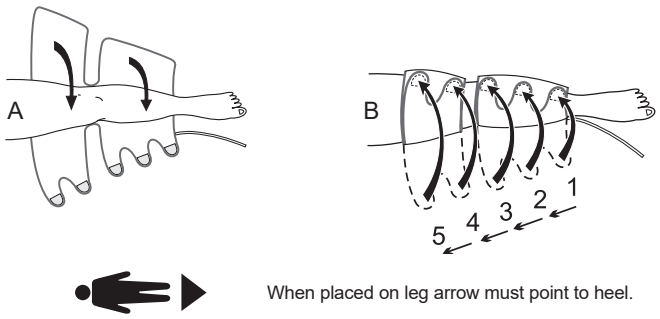
EN To be used only under the direction of a physician • Non-Sterile • For Single Patient Use Only • Not made with natural rubber latex • For use with Flowtron® DVT-prevention pumps only

Caution: (Applicable to the USA market only) Federal law restricts this device to sale by or on the order of a licensed practitioner.

Description
The Flowtron Active Compression System is comprised of a Tri Pulse garment connected to a Tri Pulse enabled Flowtron DVT prevention pump manufactured by ArjoHuntleigh.

Instructions For Use
Note: Refer to the relevant Tri Pulse enabled Flowtron DVT prevention pump Instructions For Use, for complete information on the use of the system.

1. Remove the garments from the sealed bag and record the Lot Number in the patient notes.
2. The garments may be used on either leg. Unfold a garment and position the inflatable bladder directly behind the patient's calf as indicated on the garment (Fig. A).
   Note: The arrow on the underside of the garment must point to the heel.
3. Wrap the garment around the patient's leg (Fig. A).
   Then starting at the ankle and working upwards, secure each fastener tab in turn (Fig. B), ensuring that the entire garments fits snugly. Repeat with the other leg.
4. Attach the garments to the Tri Pulse enabled Flowtron DVT prevention pump tubeset ensuring a "click" is heard from the pump connector.
5. Power up the pump.
6. Check the icons on the pump display to confirm that the correct type of garment has been connected to each leg.
7. Press "Start" to begin therapy, the indicators should be illuminated green.
8. Press "Stop" to end therapy.



When placed on leg arrow must point to heel.

Indications
The intended use of the Tri Pulse garment is to help prevent Deep Vein Thrombosis (DVT).

General Recommendations
- Check that there are no kinks in the pump tubeset and garment tubing.
- Regularly check that the garments remain correctly fitted to the patient.

Contraindications
IPC should not be used in the following conditions:
- Severe arteriosclerosis or other ischaemic vascular diseases.
- Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
- Known or suspected acute Deep Vein Thrombosis (DVT) or phlebitis.
- Any local condition in which the garments would interfere, including gangrene, recent skin graft, dermatitis or untreated, infected leg wounds.

Note: If you are unsure of any contraindications refer to the patient's physician before using the device.

Cautions
- 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.
- Garments should be positioned to prevent sustained pressure points on the skin, paying particular attention to patients who are unconscious, cannot feel or have reduced sensation and/or ability to move their leg(s).
- The patient's skin should be inspected frequently during every shift.
- Clinical judgement is required to determine if the patient's skin condition requires additional protective measures, or if the therapy should be discontinued.
- Garments should be removed immediately if patient experiences tingling, numbness or pain.
- When used for DVT prevention, continuous intermittent pneumatic compression is recommended until the patient is fully amulatory. Uninterrupted use of the system is recommended.
- The system should be used WITH CAUTION on patients with insensitive extremities, diabetes, impaired circulation, or fragile or impaired skin.

Note: These are guidelines only and should not replace clinical judgment and experience.

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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