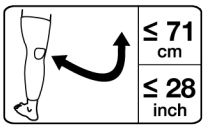
Flowtron TRP30



Thigh Garment

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.

Description

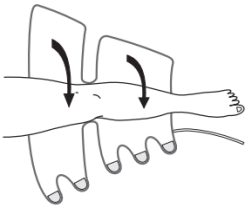
The Flowtron Active Compression System is comprised of a Tri Pulse garment connected to a Tri Pulse enabled Flowtron DVT prevention pump manufactured by Arjo.

Instructions For Use

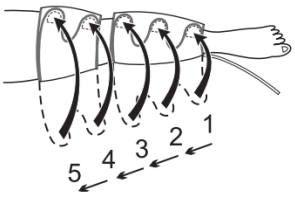
Note: Refer to the relevant Tri Pulse enabled Flowtron DVT prevention pump Instructions For Use, for complete information on the use of the system.

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.

A



B



When placed on leg arrow must point to heel

Intended use

Inflate the thigh garment by Intermittent Pneumatic Compression system. The garment will squeeze the thigh muscles to facilitate the blood and Lymph circumfluence.

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.

Disposal

Dispose of the garments using local guidelines.

Manufacturing date: see label **Expired date:3 years**

Symbols

Single Patient Use

CE marking indicating conformity with European Community harmonized legislation

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

Operating instructions - Consult Instructions for use

UDI Unique device identifier

Design Policy and copyright

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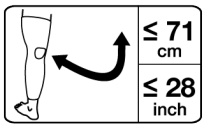


arjo
全腿套

肢体压力套

只能在医师指导下使用 • 未经灭菌• 仅供单个患者使用• 100%不含乳胶•仅可和 Flowtron 预防深静脉血栓形成的间歇式充气压力泵配合使用。

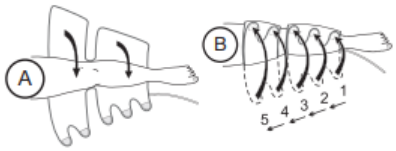
描述

Flowtron Active Compression System 间歇脉冲加压抗栓系统由 Tri Pulse 肢体压力套及连接一个由 Arjo 制造的支持 Tri Pulse 的间歇式充气压力泵构成。

使用说明

注意：请参阅相关的支持 Tri Pulse 的间歇式充气压力泵说明书，以取得完整的系统使用信息。

1. 从密封袋中取出肢体压力套，并在患者病历中记录批号。
2. 肢体压力套可用于任何一条腿。将其展开，并如同肢体压力套上所指示，将充气囊袋放在患者小腿的正后方 (图 A)。
   注意：肢体压力套下方有个箭头，此箭头必须指向脚后跟。
3. 将肢体压力套围在患者腿上 (图 A)。从脚踝开始，依次往上固定每个黏贴块 (图 B) 确保整个肢体压力套舒适地紧密贴合置于腿上。对另一条腿重复以上动作。
4. 将肢体压力套连接至 Tri Pulse 支持的 Flowtron 间歇式充气压力泵管组，确保泵接头发出咔哒一声。
5. 启动泵。
6. 检查泵荧幕上的图示，确认每条腿是否已接上正确的肢体压力套类型。
7. 按下【开始】即可开始治疗；指示灯此时应显示绿色。
8. 按下【停止】即可结束治疗。



将肢体压力套置于腿上时，箭头必须指向脚后跟。

预期用途

通过设备给肢体压力套充气加压，压力套挤压肌肉群，促进血液和淋巴液回流。

适应症

用于预防深静脉血栓形成。

一般建议：

- 确认加压泵管组和肢体压力套管道里并未扭结。
- 时常检查肢体压力套是否正确接于病患身上。

禁忌症

以下病症不应使用间歇式脉冲加压 (IPC)：

- 严重的动脉硬化或其它局部缺血性血管疾病。
- 严重的充血性心力衰竭或任何其它当进入心脏的流体增加时会造成损害的疾病。
- 已查明或怀疑患有急性深静脉血栓 (DVT) 或静脉炎。
- 肢体压力套会造成干扰的任何局部问题，包括坏疽、近期接受皮肤移植术、皮肤炎或未经处理的、感染的腿部伤

口等。

注意：如果您不能确定任何这些禁忌症，可以在使用该产品前向患者的医师咨询。

注意事项

- 使用者不可对本产品进行清洗及/或灭菌以便重复使用本产品，本产品只供单一病患使用。
- 若试图对这些产品进行清洗或灭菌，可能会导致患者有生物相容性、感染或产品失效的风险。
- 肢体压力套的放置应避免对皮肤持续形成压力点，请特别留意无意识、无感觉或较无法感知及/或无法移动腿部的患者。
- 每个轮班都应该时常检查患者的皮肤状况。
- 必须运用临床判断，判定是否需针对病患的皮肤状况采取其他额外的保护措施，或是否应停止治疗。
- 如果患者感到刺疼、麻木或疼痛，应立即取下肢体压力套。
- 当用于预防深静脉血栓形成时，建议连续使用间歇脉动充气加压直到患者完全能走动为止。建议本系统在使用上不要间断。
- 对于四肢较不敏感、患有糖尿病、具有循环受损，或是皮肤较脆弱或受损的患者，应谨慎使用本系统。

注意：这些应仅视为指南，不应取代临床判断与临床经验。

处置：

请依据当地的准则来处理肢体压力套。

生产日期：见标签　　有效期限：3 年

符号

单个患者使用　　CE 标志标明符合欧洲共同体统一立法

MD 标明按照欧盟医疗器械条例 2017/745 规定该产品是医疗器械　　操作说明 - 请参阅使用说明

UDI 设备唯一标识符

产品名称：肢体压力套

型号：TRP30

备案凭证编号/产品技术要求编号：国械备 20200544 号

备案人/生产企业名称：ArjoHuntleigh AB 而久亨特利瑞典

备案人/生产企业住所：Hans Michelsensgatan 10,211 20 Malmö,Sweden

备案人/生产企业联系方式：+46(0)10 335 45 00

生产地址：ul.Ks.Wawrzyniaka 2, 62-052 Komorniki, Poland

售后服务单位：佼捷祐（苏州）医疗设备贸易有限公司

代理人名称：佼捷祐（苏州）医疗设备贸易有限公司

代理人住所：苏州工业园区方洲路 158 号

代理人联系方式：400-087-2882

修订日期：2023 年 05 月 05 日

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