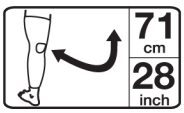
Flowtron DVT30



Thigh Garment

To be used only under the direction of a physician ● Non-Sterile ● Not made with natural rubber latex ● For Single Patient Use Only

☞ For use only with Flowtron® DVT-prevention pumps manufactured by Arjo. 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.
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.

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

To help prevent Deep Vein Thrombosis (DVT).

Recommendations

— **General recommendations**

- Garments should be removed regularly to inspect the skin for signs of redness or pressure points.
- Where appropriate, patients should be instructed in the proper use of the system, the purpose of the therapy and that any problems should be reported to the nursing staff.

DVT prophylaxis:

- The garments should be applied to the patient pre-operatively, prior to the induction of anaesthesia.
- The system should be used continuously for no less than 72 hours post-operatively or until the patient becomes fully ambulatory.
- If the garment cannot be applied to the operative limb during surgery, it may be applied to the limb once the patient reaches the recovery unit.
- In the non-surgical patient, the system should be initiated immediately once the risk of DVT formation is identified.

Contraindications

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 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 the 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 the physician.

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

Symbols

 Single Patient Use  CE marking indicating conformity with European Community harmonized legislation

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

 Operating instructions - Consult Instructions for use

 Unique device identifier

Design Policy and copyright

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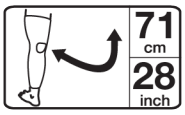

arjo
全腿套

肢体压力套

只能在医师指导下使用• 未经灭菌 ·100% 不含乳胶• 仅供单个患者使用

☞ 仅与 Arjo 制造的 Flowtron 预防深静脉血栓泵结合使用。不能与 Flowtron Hydroven 3 或者 Flowtron Hydroven 12 间歇式充气压力气泵 (Intermittent Pneumatic Compression) 一起使用。

☞ 有关护套更为全面的信息，可在 Flowtron 预防深静脉血栓形成气泵相关使用说明文件中找到。

使用说明

1. 将泵的电源插头插入合适的电源插座。此时不要开启泵。
2. 从密封袋中取出肢体压力套，可被用于任何一条腿。展开肢体压力套并将充气式囊袋直接置于患者小腿的后面。
3. 用肢体压力套将患者的腿紧贴舒适地包裹起来并将拉链卡舌固定好，用同样的方式包裹另外一条腿。
4. 将肢体压力套与泵管组连接起来，确保听到每个卡口式连接器发出咔哒声。
5. 如果您的 Flowtron 预防深静脉血栓形成气泵具备可调节压力调整器，请将调整器表盘旋转到所建议的压力值，医生另有指示的情况除外。如需更多信息，请参阅 Flowtron 预防深静脉血栓形成气泵相关使用说明文件。
6. 启动泵。绿色电源指示灯应发亮。

预期用途

通过仪器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。

建议

一般建议：

• 肢体压力套应被定期取下以检查皮肤
• 在适当情况下，患者应得到关于正确使用该系统、治疗的目的以及患者遇到问题向护理人员报告的指导

深静脉血栓的预防：

- 应在术前麻醉诱导之前给患者戴上肢体压力套
- 手术后系统应在患者身上被连续使用至少 72 小时，或直到患者完全能自己走动为止
- 如果在手术中肢体压力套不能在患者被施术的肢体上使用，则一旦患者到达恢复病房，肢体压力套即可被用于该肢体。
- 在非手术患者身上，一旦确定深静脉血栓形成风险的存在，应立即启动该系统。

禁忌症

间歇式充气压力系统不得被用于下面的病症：

- 严重的动脉硬化或其它局部缺血性血管疾病。
- 已查明或怀疑患有急性深静脉血栓 (DVT) 或静脉炎。
- 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。
- 肺栓塞。
- 护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。

如果您不能确定任何这些禁忌症，可以在使用该系统前向患者的医师咨询。

注意

- 如果患者感到刺疼、麻木或疼痛，肢体压力套应被立即取下。
- 当用于深静脉血栓形成的预防时，建议连续使用该系统，任何一个相当长时间的治疗中断应该由医师酌情决定。

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：DVT30
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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