


Flowtron FG200

			
US (M) ≥ 7.5	US (F) ≥ 9.5	Euro ≥ 41	UK ≥ 7.5

EN

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

Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

Description

For use with Flowtron® Deep Vein Thrombosis (DVT)-Prevention pumps manufactured by ArjoHuntleigh. Must not be used with the Flowtron® Hydroven 3 or Flowtron® Hydroven 12 Intermittent Pneumatic Compression (IPC) pumps, or the Flowtron® Excel DVT pump which is for calf/thigh garments only.

More comprehensive information on the garment can be found in the relevant *Flowtron* DVT pump Instructions For Use document.

Instructions For Use

- Refer to the relevant *Flowtron* DVT pump IFU for complete information on setting up and operating the system.
- Remove the garments from the sealed bags and apply to the feet as shown. The garments may be used on either foot.
- The foot garments are fitted as follows:
 - Place the foot in the centre of garment. Ensure the back of the garment is in line with the heel as indicated.
 - Bring flap (1) over the top of the foot and hold in place.
 - Bring flap (2) over the foot and secure.
 - Bring flap (3) over the foot and secure. The fit should be snug but comfortable.
 - Bring strap (4) around the back of the heel and fix in place as indicated.
 - Tension strap so garment is secure and comfortable.

- Attach the garment to the pump tubuset, ensuring that a "click" is heard with each snap-lock connection. Ensure that the tubing is attached securely to each connector.

- Turn the pump on. The pump will perform a short self-test cycle and will automatically adjust to the default settings of 130 mmHg pressure, 3 seconds inflation hold and 30 seconds cycle time. Check the garments after a few inflations and, if necessary, re-adjust for comfort and security of fit.

Indications

Clinical applications for the foot garments are as follows:

- Prevention of Deep Vein Thrombosis (DVT).
- Enhancement of venous & arterial circulation.
- Prevention of venous stasis.
- Assistance in the healing of cutaneous ulcers, including venous ulcers.
- Reduction of acute & chronic edema.
- Reduction of lower limb pain due to trauma or surgery.
- Reduction of compartment pressures.

Recommendations

General Recommendations:

- Garments should be removed regularly to inspect the skin.
- Where appropriate, patients should be instructed in the proper use of the system, the purpose of therapy and any problems that 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 postoperatively 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

- The foot garments 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 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.
- Patients should be instructed not stand or walk with the foot garments on.
- 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.

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주의 사항:
연방법은 의사의 지시에 따라 또는 의사만이 본 장치를 판매하도록 제한합니다.

설명
ArjoHuntleigh에서 제조한 Flowtron® 심부 정맥 혈전증(DVT) 예방 펌프 전용 제품입니다. 종아리/허벅지 가먼트 전용 제품인 Flowtron® Hydroven 3 또는 Flowtron® Hydroven 12 간헐적 공기 압박법 (IPC) 펌프 또는 Flowtron® Excel DVT 펌프와 사용해서는 안 됩니다.
가먼트에 대한 더 자세한 정보는 해당 *Flowtron* DVT 펌프 사용 지침 문서에서 확인할 수 있습니다.

사용 지침

- 시스템 준비 및 작동에 대한 자세한 정보는 해당 *Flowtron* DVT 펌프 IFU를 참조하십시오.
- 밀봉된 백에서 가먼트를 꺼내고 그림과 같이 발에 착용하십시오. 가먼트는 두 다리 중 어느 쪽에도 사용 가능합니다.
- 발 가먼트는 다음과 같이 착용합니다.
 - 발을 가먼트 중앙에 올려 놓으십시오. 그림과 같이 가먼트 뒷부분이 뒷꿈치와 맞춰지도록 하십시오.
 - 플랩 1로 발 윗부분을 덮고 제자리에 고정하십시오.
 - 플랩 2로 발 윗부분을 덮고 고정하십시오.
 - 플랩 3으로 발 윗부분을 덮고 고정하십시오. 착용 상태는 발을 충분히 조이는 동시에 편안해야 합니다.

(e) 끈(4)으로 발꿈치 뒷부분을 감고 그림과 같이 제자리에 고정하십시오.
(f) 끈을 팽팽하게 하여 가먼트를 고정하고, 동시에 편안한지 확인하십시오.

- 가먼트를 펌프 튜브 세트에 연결하고, 연결 시 각 잠금 커넥터에서 “딸깍” 소리가 나는지 확인하십시오. 튜브가 각 커넥터에 단단히 고정되도록 하십시오.

- 펌프의 전원을 켜십시오. 펌프는 간단한 자가 테스트 주기를 수행하고, 자동으로 기본값 설정인 130 mmHg 압력, 3초 팽창 유지 시간, 30초 주기 시간으로 조정됩니다. 몇 차례의 팽창 후에는 가먼트를 확인하고, 필요에 따라 편안함 정도 및 고정 상태를 재조정하십시오.

조절

발 가먼트의 임상적 사용 사례는 다음과 같습니다.

- 심부 정맥 혈전증(DVT) 예방.
- 정맥 및 동맥 순환 개선.
- 정맥울혈 예방.
- 정맥 궤양을 포함한 피부 궤양 치유 보조.
- 급성 및 만성 부종 완화.
- 외상 또는 수술로 인한 하지 통증 완화.
- 구획압 완화.

권고사항

일반 권고

- 가먼트는 자주 착용 해제하여 피부를 정기적으로 검사하십시오.
- 환자는 적절한 경우에 따라 시스템의 적절한 사용 방법, 치료 목적, 그리고 간호사에게 보고해야 하는 모든 문제에 대해 교육 받아야 합니다.

DVT 예방

- 가먼트는 마취 유도에 앞서 수술 전에 환자에게 착용해야 합니다.
- 이 시스템은 수술 후 최소 72시간 이상 또는 환자가 완전히 보행하게 될 때까지 계속 사용해야 합니다.
- 가먼트를 수술 중 팔다리에 적용할 수 없는 경우 환자가 회복 병동에 도착한 다음 팔다리에 적용하게 됩니다.
- 비수술 환자의 경우 DVT 형성 위험이 식별되는 즉시 시스템을 시작해야 합니다.

비적용중

- 발 가먼트는 다음 조건에서 사용하지 않습니다.
- 심각한 동맥경화 또는 기타 허혈성 혈관 질환.
- 알려진 또는 의심되는 급성심부정맥혈전증(DVT) 또는 정맥염.
- 심각한 울혈성 심부전 또는 심장에 유해할 수 있는 유체가 증가하는 모든 증상.
- 폐색전.
- 괴저, 최근 피부 이식, 피부염 또는 치료하지 않은 부상, 감염된 다리 부상을 포함해 가먼트가 방해할 수 있는 모든 국소 증상.

어떠한 급기 사항에 대해서도 확신하지 못하는 경우 장치 사용 전에 환자의 담당 의사에게 알아보십시오.

주의

- 환자가 저림, 무감각, 또는 통증을 느끼는 경우 가먼트를 즉시 착용 해제하십시오.
- DVT 예방용으로 사용하는 경우에는 연속 사용이 권장되며, 장기간 동안 이루어지는 모든 치료 개입은 의사의 재량에 따라 결정해야 합니다.
- 환자는 발 가먼트를 착용한 상태로 서거나 걷지 않도록 지도받아야 합니다.
- 본 제품은 안전한 재사용을 위한 목적으로 적절히 청소 및/또는 멸균될 수 없는 제품이므로 단일 환자에게만 사용하십시오. 이러한 장치를 세척하거나 멸균 처리하려고 시도할 경우 환자에게 생체 적합성, 감염 또는 제품 고장 위험이 발생할 수 있습니다.

심각한 사고

본 의료기기와 관련하여 사용자 또는 환자에게 영향을 미치는 심각한 사고가 일어나면 사용자나 환자는 해당 심각한 사고를 의료기기 제조업체나 유통업자에게 보고해야 합니다.
유통연합에서는 사용자가 위치한 해당 주의 감독관청에도 심각한 사고를 보고해야 합니다.

수명 종료(End of Life) 제품 폐기

- 의복 재료 또는 기타 섬유, 종합체 또는 플라스틱 재료 등은 가연성 폐기물로 분류해야 합니다.

® 및 ™ 은 Arjo 그룹의 상표입니다. 제품의 지속적인 개선을 위한 노력은 당사의 방침이므로, 당사는 사전 예고 없이 설계를 변경할 수 있는 권리를 보유합니다.
아지오헌틀리의 동의 없이 본 출판물의 내용 전부 또는 일부를 복사할 수 없습니다.

TH

ใช้ภายใต้คำแนะนำของแพทย์เท่านั้น • ไม่ปลอดภัย
ใช้สำหรับผู้ป่วยรายเดียวเท่านั้น • ไม่ได้ทำมาจากรัดยางธรรมชาติ

ข้อควรระวัง: กฎหมายของรัฐบาลกลางกำหนดให้จำหน่ายอุปกรณ์นี้ตามหรือโดยใบสั่ง ของแพทย์เท่านั้น

คำอธิบาย
เพื่อการใช้ร่วมกับปั๊มป้องกันภาวะเลือดต้งในหลอดเลือดดำส่วนลึก (DVT) Flowtron® ที่ผลิตโดย ArjoHuntleigh เท่านั้น ต้องไม่ใช้ร่วมกับปั๊มเครื่องอื่นที่ไม่ใช่จุดประสงค์ (IPC) Flowtron® Hydroven 3 หรือ Flowtron® Hydroven 12 หรือปั๊ม Flowtron® Excel DVT ที่ใช้สำหรับแถบพันรัดป้องกันขาเท่านั้น
พบข้อควรที่ควรบอกคุณเกี่ยวกับแถบพันในเอกสารคำแนะนำการใช้งานปั๊ม DVT *Flowtron* ที่เกี่ยวข้อง

คำแนะนำการใช้งาน

- ดูข้อมูลเกี่ยวกับขั้นตอนเกี่ยวกับการติดตั้งและการใช้งานระบบได้ที่คู่มือการใช้งานปั๊มป้องกันภาวะ DVT *Flowtron* ที่เกี่ยวข้อง
- แกะแถบพันออกจากถุงใส่ และใช้กับเท้าตามภาพ แถบพันใช้กับเท้าด้านใดด้านหนึ่ง
- สวมใส่แถบพันเท้าตามขั้นตอนดังนี้
 - วางเท้าที่ตรงกึ่งกลางของแถบพัน ตรวจสอบว่าส่วนท้ายของแถบพันตรงกับตำแหน่งเส้นเท้าตามภาพที่ระบุ
 - ดึงแถบพัน (1) มาเหนือด้านบนเท้า และจับไว้
 - ดึงแถบพัน (2) มาวางเหนือเท้า และยึดให้แน่น
 - ดึงแถบพัน (3) มาวางเหนือเท้า และยึดให้แน่น แถบพันควรกระชับเท้าพอดี แต่ไม่แน่นเกินไป
 - ดึงสายรัด (4) มาด้านหลังเส้นเท้าและยึดให้แน่นตามภาพ
 - ปรับความตึงสายรัดเพื่อให้แถบพันยึดแน่นแต่ไม่แน่นเกินไป

- ต่อแถบพันกับชุดท่อของปั๊มโดยให้แน่ใจว่าได้ยินเสียง “คลิก” เมื่อกดล็อกแต่ละตัว ตรวจสอบว่าท่อได้เสียบต่อเข้ากับตัวล็อกแต่ละตัวอย่างแน่นหนาดีแล้ว

- เปิดปั๊ม ปั๊มจะทดสอบการทำงานในโหมดสั่น และจะปรับตั้งค่าเริ่มต้นโดยอัตโนมัติเป็นแรงดัน 130 mmHg เวลาเติมลม 3 วินาที และเวลาสูบ 30 วินาที ตรวจสอบแถบพันหลังการเติมลม และปรับเปลี่ยนตำแหน่งยึดเพื่อให้รู้สึกสวมใส่สบายและยังคงรู้สึกกระชับ หากจำเป็น

ข้อบ่งชี้

การใช้งานทางคลินิกสำหรับแถบพันเท้า มีดังนี้

- การป้องกันภาวะเลือดต้งในหลอดเลือดดำส่วนลึก (DVT)
- การปรับเพิ่มการไหลเวียนของหลอดเลือดแดงและหลอดเลือดดำ
- การป้องกันภาวะเลือดดำไหลช้า
- การช่วยเย็บรอยแผลที่ผิวหนัง รวมถึงแผลที่เกิดจากหลอดเลือดดำด้วย
- การลดภาวะบวมผ้าเย็บแผลและเนื้อร้าย
- การลดความเจ็บปวดแบบชาส่วนล่างเนื่องจากการบาดเจ็บหรือการผ่าตัด
- การลดขนาดของเส้นเลือดขอด

คำแนะนำ

คำแนะนำทั่วไป:

- ควรถอดแถบพันออกเป็นระยะๆ เพื่อตรวจสอบผิวหนัง
- เมื่อเหมาะสม ผู้ป่วยควรได้รับคำแนะนำเกี่ยวกับการใช้ระบบที่ถูกต้อง จุดประสงค์ของการรักษา และแนะนำให้งดออกกำลังกายหนักจนเกินกว่าที่พยายาม

การป้องกันภาวะ DVT:

- ควรใช้แถบพันกับผู้ป่วยก่อนการผ่าตัด ที่มทั้งจะดมยาสลบ
- ควรใช้ระบบอย่างต่อเนื่องไม่น้อยกว่า 72 ชั่วโมงหลังการผ่าตัดหรือจนกระทั่งผู้ป่วยเริ่มเดินได้เต็มที่
- หากไม่สามารถใส่แถบพันกับแขนขาที่ใช้งานได้ระหว่างการผ่าตัด ควรใส่กับแขนขาอื่นที่อยู่หรือสงสัยว่าเป็น
- ในกรณีของผู้ป่วยที่ใส่ห่วงพักพื้น
- ในกรณีของผู้ป่วยที่ไม่ได้ผ่าตัด ควรเริ่มใช้ระบบนี้ทันทีเมื่อพบอาการก่อตัวของเส้นเลือดขอด DVT

ข้อห้ามใช้

- ไม่ควรใช้แถบพันเท้าในสภาวะต่อไปนี้
- ภาวะหลอดเลือดแดงแข็งหรือโรคเส้นเลือดขาดเลือดแบบอื่นขั้นรุนแรง
- ภาวะเลือดต้งในหลอดเลือดดำส่วนลึก (DVT) หรือหลอดเลือดดำอักเสบที่ทราบอยู่หรือสงสัยว่าเป็น
- ภาวะหัวใจล้มเหลว หรือภาวะใดๆ ที่การไหลของเลือดไปยังหัวใจที่เพิ่มขึ้นอาจก่อให้เกิดอันตราย
- โรคเส้นเลือดอุดตันในปอด
- สภาพภายในที่แถบพันอาจเป็นอุปสรรครบกวน รวมถึงเนื้ออุ้งเท้า บาดแผลที่ปรากฏถ่ายด้วยผิวหนัง ผิวหนังอักเสบ หรือบาดแผลติดเชื้อที่ขาที่ไม่เคยรักษามาก่อน
- หากคุณไม่แน่ใจในข้อห้ามใช้ใดๆ โปรดสอบถามแพทย์ของคุณผู้ป่วยก่อนใช้อุปกรณ์นี้

ข้อควรระวัง

- ควรถอดแถบพันในทันทีหากผู้ป่วยมีอาการเป็นเหน็บ ชา หรือเจ็บปวด
- เมื่อใช้สำหรับการป้องกันภาวะ DVT แนะนำให้ใช้อย่างต่อเนื่องและการขัดจังหวะการรักษาเป็นช่วงเวลานานอาจมีนัยสำคัญควรอยู่ภายใต้การพิจารณาของแพทย์
- ผู้ป่วยควรได้รับคำแนะนำไม่ให้ยืนหรือเดินขณะใช้แถบพันเท้านี้
- ผลิตภัณฑ์นี้ควรได้รับการทำความสะอาดและ / หรือฆ่าเชื้ออย่างเหมาะสมโดยผู้ใช้เพื่อที่จะให้มีการใช้ซ้ำอย่างปลอดภัย ดังนั้น ใช้กับผู้ป่วยรายเดียวกันบน ความพยายามทำความสะอาดหรือฆ่าเชื้ออุปกรณ์เหล่านี้อาจมีผลให้เกิดความเสี่ยงในความปลอดภัยหากไม่ปฏิบัติตามข้อควรระวัง การติดเชื้อ หรือผลิตภัณฑ์ล้มเหลวกับผู้ป่วย.

อุปกรณ์การนั้ร้ายแรง

หากเกิดเหตุการณ์ร้ายแรงที่เกี่ยวข้องกับอุปกรณ์ทางการแพทย์ ซึ่งส่งผลกระทบต่อผู้ใช้งานหรือผู้ขาย ผู้ใช้งานหรือผู้ขายควรรายงานเหตุการณ์ร้ายแรงดังกล่าวต่อผู้ผลิตหรือผู้จัดจำหน่ายเครื่องมือนำทางการแพทย์นี้
ในสหภาพยุโรป ผู้ใช้ควรรายงานเหตุการณ์ร้ายแรงดังกล่าวต่อเจ้าหน้าที่ผู้มีอำนาจในรัฐสมาชิกที่พวกเขาอยู่

การกำจัดเนื้อสิ่งสุดท้ายจากการใช้งาน

- วัสดุเส้นผ้า หรือ ฝักรัดอื่น ๆ วัสดุโพลีเมอร์หรือพลาสติกอื่น ๆ เป็นต้น ควรจะจัดเป็นขยะที่ติดไฟได้ต่ำ

® และ ™ เป็นเครื่องหมายการค้าของกลุ่มบริษัท Arjo เนื่องจากนโยบายของเราคือการปรับปรุงพัฒนาอย่างต่อเนื่อง เราขอสงวนสิทธิ์ในการดัดแปลงแก้ไขการออกแบบของเราโดยไม่จำเป็นต้องแจ้งให้ทราบล่วงหน้า ต่อมาผลิตภัณฑ์ใหม่ในอนาคตนี้ ไม่ว่าทั้งหมดยหรือบางส่วน หากไม่ได้รับอนุญาตจาก Arjo

VI

Chỉ để sử dụng theo sự chỉ dẫn của bác sĩ • Không Vô trùng
Chỉ Sử dụng cho Một Bệnh nhân • Không được làm từ mù cao su tự nhiên

Cảnh báo: Luật pháp liên bang hạn chế thiết bị này chỉ được bán bởi hoặc theo lệnh của người hành nghề được cấp phép.

Mô tả

Chỉ để dùng với bơm phòng chống bệnh DVT Flowtron® được sản xuất bởi ArjoHuntleigh. Không được dùng với các máy bơm Ép Khí nén Giãn đoạn (IPC) Flowtron® Hydroven 3 hoặc Flowtron® Hydroven 12 (bơm IPC), hoặc bơm DVT Flowtron® Excel chỉ dùng cho vải bọc bắp chân/dù.
Tham khảo tài liệu Hướng dẫn Sử dụng bơm *Flowtron* DVT liên quan để biết thông tin đầy đủ hơn về vải bọc.

Hướng dẫn Sử dụng

- Tham khảo Hướng dẫn Sử dụng bơm DVT *Flowtron* để biết thông tin hoàn chỉnh về lắp đặt và vận hành hệ thống.
- Lấy vải bọc từ túi được bịt kín và đắp vào chân như được chỉ. Có thể bọc vài lần một trong hai bản chân.
- Vải bọc chân được thắt như sau:
 - Đặt bản chân vào giữa tấm vải. Đảm bảo mặt sau vải thẳng hàng với gót chân như được chỉ.
 - Đưa vạt (1) qua đỉnh đầu chân và giữ cố định.
 - Đưa vạt (2) ngang qua chân và cố định.
 - Đưa vạt (3) qua ngang qua chân và cố định. Nút thắt phải kín nhưng thoải mái.
 - Đưa dây buộc (4) ra sau gót chân và cố định tại chỗ như được chỉ.
 - Buộc căng sao cho vải được cố định và thoải mái.

- Gắn vải vào bộ ống bơm đảm bảo có nghe tiếng ‘click’ ở mỗi đầu nối khớp tự động. Đảm bảo ống được gắn cố định vào từng đầu nối.

- Bật máy bơm lên. Máy bơm sẽ thực hiện một chu kỳ tự kiểm tra ngắn và sẽ tự điều chỉnh về các cấu hình mặc định áp suất 130 mmHg, giữ phòng 3 giây và thời gian chu kỳ 30 giây. Kiểm tra vải sau một vài lần thổi phồng và, nếu cần thiết, điều chỉnh lại để nút thắt thoải mái và chắc chắn.

Chỉ định

Các ứng dụng lâm sàng cho vải bọc chân như sau:

- Phòng ngừa Huyết khối Tĩnh mạch Sâu (DVT).
- Cải thiện lưu thông tĩnh mạch và động mạch.
- Phòng ngừa ứ tĩnh mạch.
- Hỗ trợ hồi phục viêm loét da, bao gồm viêm loét tĩnh mạch.
- Giảm thiểu phù thũng cấp tính và mãn tính.
- Giảm thiểu đau chi dưới do chấn thương hay phẫu thuật.
- Giảm thiểu áp lực bộ phận.

Khuyến cáo

Các khuyến cáo chung:

- Nên cởi bỏ vải bọc thường xuyên để kiểm tra da.
- Khi phù hợp, phải hướng dẫn bệnh nhân sử dụng hệ thống đúng cách, mục đích của trị liệu và bất kì vấn đề nào mà phải được báo cáo với nhân viên điều dưỡng.

Phòng ngừa DVT:

- Bệnh nhân nên được bọc vải trước khi phẫu thuật, trước khi bắt đầu gây mê.
- Hệ thống nên được dùng liên tục không dưới 72 giờ sau phẫu thuật, hoặc cho đến khi bệnh nhân đi lại được hoàn toàn.
- Nếu không thể bọc vải vào chi phẫu thuật trong quá trình phẫu thuật, có thể bọc vài vào chi khi bệnh nhân đã tới đơn vị phục hồi.
- Ở bệnh nhân không phẫu thuật, hệ thống nên được khởi động ngay khi xác định được nguy cơ hình thành DVT.

Chống chỉ định

- Vải bọc chân không nên được dùng trong các điều kiện sau:
- Chứng xơ cứng động mạch nặng hoặc các bệnh mạch thiếu máu cục bộ khác.
- Bệnh Huyết khối Tĩnh mạch Sâu (DVT) cấp tính hoặc viêm tĩnh mạch đã được biết hoặc nghi ngờ.
- Suy tim xung huyết nặng hoặc bất kì bệnh trạng nào mà sự gia tăng chất lỏng đi vào tim có thể gây hại.
- Nghẽn mạch phổi.
- Bất kì bệnh trạng cục bộ nào mà vải vóc có thể cản trở, bao gồm hoại tử, gộp da gần đây, viêm da hoặc các vết thương ở chân chưa điều trị, bị nhiễm trùng.

Nếu quý vị chưa chắc chắn về bất kì chống chỉ định nào, xin tham khảo bác sĩ của bệnh nhân trước khi sử dụng thiết bị.

Cảnh báo

- Phải cởi bỏ vải bọc ngay nếu bệnh nhân trải nghiệm ngứa ran, tê liệt hoặc đau.
- Khi sử dụng cho dự phòng DVT, khuyến cáo nên dùng liên tục và bất kì sự gián đoạn trị liệu nào trong khoảng thời gian đáng kể phải theo quyết định của bác sĩ.

Arjo

Foot Garment • 발 가먼트 • แแถบพันเท้า • Vải bọc Chân

- Bệnh nhân nên được chỉ dẫn không đứng hoặc đi bộ khi còn bọc vải ở chân.
- Sản phẩm này không thể được vệ sinh và / hoặc khử trùng đầy đủ bởi người dùng để tạo điều kiện tái sử dụng an toàn và do đó chỉ để sử dụng cho một bệnh nhân. Những nỗ lực để vệ sinh hay khử trùng những thiết bị này có thể dẫn đến nguy cơ tương thích về sinh học, nhiễm trùng hay hỏng sản phẩm với bệnh nhân.

Sự cố Nghiêm trọng

Nếu xảy ra sự cố nghiêm trọng liên quan tới thiết bị y tế này, gây ảnh hưởng tới người sử dụng hoặc bệnh nhân, người sử dụng hoặc bệnh nhân phải báo cáo sự cố nghiêm trọng ấy tới nhà sản xuất thiết bị y tế hoặc nhà phân phối.
Trong Liên minh châu Âu, người sử dụng cũng phải báo cáo sự cố nghiêm trọng ấy tới Cơ quan có thẩm quyền tại quốc gia thành viên nơi họ đang sinh sống.

Tiêu hủy khi hết vòng đời sử dụng

- Các vật liệu vải bọc hay các vật liệu vải, polymer hay nhựa khác... phải được phân thành rác có thể đốt được.

® và ™ là các nhãn hiệu thuộc tập đoàn Arjo.
Vị chính sách của chúng tôi là chính sách cải tiến liên tục, chúng tôi bảo lưu quyền chỉnh sửa thiết kế mà không thông báo trước. Không được phép sao chép toàn bộ hay một phần nội dung của bản này trừ khi có sự đồng ý của Arjo.

CE marking indicating conformity with European Community harmonised legislation / 유럽 공동체의 조율 규정을 준수하였음을 나타내는 CE 마킹 / เครื่องหมาย CE แสดงถึงความปลอดภัยกับประชาชนยุโรปที่ปฏิบัติตามที่สอดคล้องกับ / Dấu CE chứng tỏ đã tuân thủ luật định hài hòa của Cộng đồng Châu Âu.

Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745 / 본 제품은 EU 의료 기기 규정 2017/745에 따른 의료 장치임을 나타냄. / บ่งบอกว่าผลิตภัณฑ์ที่เป็นอุปกรณ์ทางการแพทย์ตามกฎระเบียบอุปกรณ์ทางการแพทย์สหภาพยุโรป 2017/745 / Cho biết rằng sản phẩm này là Thiết bị Y tế theo Quy định của EU về Thiết bị Y tế 2017/745

- Single Patient Use / 단일 환자용 / ใช้สำหรับผู้ป่วยรายเดียว / Sử dụng cho Một Bệnh nhân
- Do not stand or walk / 서 있거나 걷지 마십시오 / อย่ายืนหรือเดิน / Không đứng hoặc đi

