

(FR)

Médical device of class 1 according to MDR (EU) 2017/745.
Règlement (UE) 2017/745.
Ces dispositifs est prévu pour être manipulé par toute personne ayant la capacité à lire et à comprendre la notice d'utilisation. **Patient patient** : tout type de patient dont la pathologie nécessite l'utilisation d'un dispositif de prévention et/ou d'aide au traitement d'escarres. **Profil utilisateur pour installation, mise en œuvre, réglages et maintenance** : Patient, healthcare professionals, maintenance technicians, third party. There are no particular restrictions on the handling and use of the device.

INTENDED USE OF PRODUCT
Postural aid in sitting position. Equipment for use in chair with armrests.

INDICATION
P951D: Back support and Therapeutic Combi-Packs can be used to improve positioning in wheel chair, improve seating orientation, reduce forward sliding and relieve back pain. **P951F**: Designed for patients presenting partial or complete postural deficits in sitting position following nerve or muscle damage. The P951F is positioning device is used to position the upper limbs in a sitting position. The choice of device must be approved by the healthcare professional.

CONDITIONS OF USE
Devices with an integral POLYMAILLE® / POLYMAILLEHD cover can be used for single or multiple patients. They can be reconditioned in accordance with the product instructions and the cleaning and disinfection instructions. **CONTRA-INDICATIONS**
Do not use the device beyond the intended use and indications. Do not use if you are allergic to polyurethane. For any problem, consult your healthcare provider. The device is not appropriated for using in bed. **SIDE EFFECTS**
There are no undesirable side effects. However, the patient may experience the effects inherent to immersion: possible (limited) reduction in perception and mobility. Increased sensation of heat.

DEVEICE PERFORMANCES
Maintaining posture in sitting position. **CLINICAL BENEFIT**
P951D: Improved patient comfort. Contributes to the reduction of back pain and to the stability of the trunk. **P961F**: Reduces the risk of shoulder subluxation and contributes to the maintenance/stability of trunk balance.

INFORMATION FOR HEALTHCARE PROFESSIONAL
Make sure the device is suitable for the patient's environment. Ensure continuity of treatment. **STORAGE, HANDLING, TRANSPORT**
- Preferably flat. Do not expose close to a significant heat source. - Store in a protective bag, in a dry temperate place away from heat and light.

- Handle the device with care to avoid damaging the cover. - Transport in a transport bag or in its box.

PRECAUTIONS OF USE
- Do not use without cover. - Do not place any foreign body between the patient and the equipment besides clothing.

- Be careful not to damage the cover. Frequent degradations observed: scapulae burns, pet scratches, needle holes, cuts with scalpels or sharp objects, damage caused by the use of equipment with sharp edges. - We recommend obtaining an additional protective cover as a spare cover.

- Do not use spare covers, accessories or components other than those supplied by SYSTAM®. - Refer to «Cleaning & Disinfection» instructions.

- If you observe deterioration of the product (foam deformation or leakage) or bottoming effect, contact your provider.

- Keep away from flammable sources. - Report to your caregiver as soon as possible any abnormal event such as pain or redness or whitening of support points.

- Any serious incident that has occurred in connection with the device should be notified to the manufacturer and to the local competent authority.

TECHNICAL SPECIFICATIONS

P951D / P961F: Polyurethane (PU) viscoelastic foam with memory effect (80 kg/m³).

P952D: High resilience polyurethane (PU) foam (40 kg/m³).

Covers material:
POLYMAILLE®: Polyurethane coating on jersey fabric.

EXPECTED LIFETIME
The lifespan of these products is 5 years when used in strict accordance with the care and maintenance instructions. Product lifetime can be extended by careful maintenance and considerably shortened by extreme or inappropriate use. This does not constitute an additional guarantee on these products.

GUARANTEE
Two years against any manufacturing defaults, from the date of purchase by the customer. Small imperfections (small tears, marbling, surface defects, etc.) due to the manufacturing process in no way affect the quality and effectiveness of the product and cannot be a reason for replacing the product under warranty. The warranty does not cover misuse of the support, normal wear of the device or of its cover, in the event of default, please contact your provider, and provide the product lot number.

SAFETY & ENVIRONMENT
Do not burn or dispose of in the environment. Respect the recycling labels in place in your country. Do not ingest. 0 % C.F.C. foam. Complies with fire standards EN 597-1 & 597-2.

(DE)

Medizinprodukt der Klasse 1 nach MDR (EU) 2017/745.
Bedienungsanleitung zur Installation, Implementierung, Einstellungen und Wartung: Patient, medizinisches Fachpersonal, Wartungstechniker, Drittperson. Es gibt keine besonderen Einschränkungen bei der Handhabung und Verwendung des Produkts.

(EN)

Medical device of class 1 according to MDR (EU) 2017/745.
Regulation (EU) 2017/745.
These devices are intended to be handled by anyone able to read and understand the instructions for use.

Patient profile: Any patient whose pathology requires the use of a pressure sore prevention and/or treatment aid. **Operator's profile for installation, implementation, adjustments and maintenance**: Patient, healthcare professionals, maintenance technicians, third party. There are no particular restrictions on the handling and use of the device.

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VERBODINGSWEECK DES PRODUKTS

Positionierungshilfsmittel in Sitzposition. Hilfsmittel zur Armauflage im Rollstuhl und für Stühle mit Armlehne.

INDIKATION
P951D: Für Patienten mit Haltungsedefizit in Sitzposition: Schädigungen des Zentralkervensystems (Apoplexie, Schädeltrauma), Teillauflass des Nervensystems, orthopädische Einschränkungen, Vasomotorenähmung... Verbesserte Positionierung im Stuhl. Vermittelt der Sitzposition im Stuhl. Verringert das Nach-Vorne-Rutschen. Unterstützt die Linderung von Rückenschmerzen... Schärft Druckentlastung an den Komfortzonen der Wirbelsäule. **P961F**: Für Patienten mit teilweisen oder vollständigen Nervensystemen in sitzender Position nach einem Handlungsdefiziten in sitzender Position. Dispositivo destinado ad un utilizzo in sedia a rotelle.

INDICAZIONI
P951D: Supporto per la schiena e pacchetti combinati terapeutici possono essere utilizzati per: migliorare il posizionamento in sedia a rotelle, migliorare l'orientamento della seduta, contribuire a ridurre lo slittamento in avanti, contribuire ad alleviare i dolori alla schiena.

NUTZUNGSBEDINGUNGEN
Hilfsmittel mit POLYMAILLE® / POLYMAILLE® HD Integralbezug können für einzelne Patienten und im Wieder Einsatz verwendet werden sind: mögliche (begrenzte) reduzierte Wahrnehmung Reinigungs- und Desinfektionsanleitung wiederanbereitet und der Mobilität. Erhöhtes Wärmeempfinden.

CONTRA-INDIKATIONEN
Verwenden Sie das Produkt nicht für andere als die vorgesehenen Verwendungszwecke und Indikationen. Nicht verwenden, wenn Sie allergisch auf Polyurethan reagieren. Bei Problemen wenden Sie sich an Ihren Arzt. Nicht im Bett anwenden.

EFFETI COLLATERALI
Non utilizzare il dispositivo oltre l'uso previsto e le indicazioni. Non vi sono effetti collaterali indesiderati. Tuttavia, il paziente può sperimentare gli effetti inerenti all'immersione: possibile (limitata) riduzione della percezione e della mobilità. Maggiore sensazione di calore.

PRESTAZIONI DEL DISPOSITIVO
Mantenimento della postura in posizione seduta.

BENEFICIO CLINICO
P951D: Migliora il comfort del paziente. Contribuisce alla riduzione dei dolori alla schiena e alla stabilità del tronco.

P961F: Riduce il rischio di sublussazione della spalla e contribuisce al mantenimento/stabilità dell'equilibrio del tronco.

INFORMAZIONI PER GLI OPERATORI SANITARI
Assicurarsi che il dispositivo sia adatto all'ambiente del paziente. Garantire la continuità del trattamento.

STOCKAGGIO, MANIPOLAZIONE, TRASPORTO
- Preferibilmente a piatto. Non esporre a una fonte di calore significativa.

- Tassativamente in un luogo asciutto e temperato, protetto dal calore e dalla luce, in una borsa di protezione.

- Manipolare il cuscinio con cura per evitare di danneggiarne la copertura.

- Trasportare in una borsa da trasporto o nella sua scatola. Per qualsiasi manipolazione/trasporto si prega di seguire queste istruzioni.

PRECAUZIONI DI USO
Non utilizzare senza copertura. Non collocare alcun corpo estraneo tra il paziente e il dispositivo, a parte gli indumenti.

- Fare attenzione a non danneggiare la copertura. Frequenti deterioramenti osservati: bruciature di sigaretta, graffi di animali da compagnia, fori di aghi, tagli con bisturi o oggetti appuntiti, danni causati dall'utilizzo di dotazioni con spigoli vivi.

- Si consiglia di provvedere a una copertura protettiva aggiuntiva.

- Non utilizzare coperture, accessori o componenti di ricambio diversi da quelli forniti da SYSTAM®.

- Fare riferimento alle istruzioni di «Pulitura e disinfezione». - Se si osserva un deterioramento del prodotto (deformazione della schiuma o perdite) o effetto di sprofondamento, contattare il proprio