Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

Miss I Thistlethwaite
HM Assistant Coroner
Rutland and North Leicestershire
HM Coroner's Office
County Hall
Glenfield
LE3 8RA

Reference: [redacted]

30 May 2025

Dear Miss Thistlethwaite,

Regulation 28: Inquest to investigate the death of Mrs Susan Marion LAKIN.

We acknowledge your Regulation 28 prevention of future death report, received by MHRA on 11 April 2025, relating to the conclusions of the inquest investigating the sad death of Susan Marion Lakin. We would like to offer our sincere condolences to her family.

Your report raises the following concerns:

- The sale of Support Belts that contain no warnings in relation to the risks of physical restraint, tissue viability risks and finally the risk of strangulation.

- The sale of Support Belts that contain no suggestion that the product should be used or fitted under the guidance/supervision of a therapist or medical professional.

- Support Belts, and other seemingly basic pieces of healthcare equipment, are readily available for people to purchase online without them being appraised of the risks that come with their use.

I have taken the opportunity to provide you with some supporting information below, before providing comments to your matters of concern.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care ("DHSC"). We are the regulator of medicines, medical devices and blood components for transfusion in the UK.

With respect to medical devices, one major area of the MHRA's responsibilities is the investigation of adverse incidents. An adverse incident is an event involving a medical device, which produces, or has the potential to produce, unwanted effects involving the safety of patients, users and other persons.

The MHRA operates a voluntary reporting scheme, called the Yellow Card scheme[1], where health professionals and members of the public can report adverse incidents to us directly. Additionally, manufacturers of medical devices are required to report details of all serious incidents involving medical devices to the MHRA as part of their mandatory vigilance reporting.

Where serious incidents involving medical devices have been reported to other authorities including the police and coroners, the MHRA provides input if required. The MHRA will then ensure any concerns raised from these investigations, if required, are disseminated to either healthcare professionals directly or to healthcare institutions to help to prevent further incidents and take up the concerns directly with the manufacturer of the medical device.

Manufacturers placing a medical device on the market are required to identify the potential hazards associated with the use of the medical device, evaluate the related risks and eliminate or reduce these risks as far as possible; finally users of the device must be informed of any residual risks. Manufacturers are expected to follow the principles set out in BS EN ISO 14971:2019+A11:2021 *Medical devices - Application of risk management to medical devices*. This approach aims to also ensure that any new risks are incorporated into risk management process therefore facilitating ongoing improvement throughout the product's lifecycle.

Manufacturers should also demonstrate how their devices meet the relevant Designated/Harmonized Standards. If they have not applied these standards, then they must provide a description of the solutions adopted to fulfil the requirements which apply to the devices. This information should be included within their technical documentation for the devices.

It is important to note that the MHRA does not conduct inspections of medical devices, nor do we directly authorise or certify medical devices for placement onto the market. However, all medical devices are required to be registered with the MHRA prior to selling them in the UK.

Each medical device is assigned a classification (I, IIa, IIb or III) based largely upon its considered "risk" factor to the patient according to medical device classification rules in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)[2]. To place a medical device on the market, manufacturers must obtain certification that demonstrates their conformity to the regulatory requirements[3]. This certification is represented as a CE or UKCA mark and is displayed on the medical device itself. To gain CE or UKCA

[1] Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)
[2] The Medical Devices Regulations 2002 (legislation.gov.uk)
[3] Regulating medical devices in the UK - GOV.UK (www.gov.uk)

marking, the higher risk (class IIa, IIb and III) devices need to be certified by an approved conformity assessment body. Whereas manufacturers of the lowest risk/class devices (class I) self-certify against the requirements in relevant legislation.[4]

Background

In April 2015 the MHRA released Medical Device Alert (MDA/2015/018), for all posture or safety belts fitted to supportive seating[5]. The Alert stated, "*Using the wrong type of belt or a belt that isn't fitted or adjusted properly can lead to serious injury or death of the person using the equipment*."

The Alert goes on to explain that all users and carers need to have received training on how to check, adjust, clean, and maintain each device; and individuals need to be reviewed to check that the right type of belt is used and adjusted correctly.

Finally, the alert clarifies that the problems associated with these devices include "*the person in the seat slipping down and suffering positional asphyxiation or strangulation...*". The targeted audience was those involved in the provision, prescription, use and maintenance of the belts and it was cascaded through the Central Alerting System (CAS). This was withdrawn in 2022 as the number of reports had reduced to zero and the actions should have been incorporated into good practice within the NHS.

Action undertaken by MHRA to date

Establishment of the appropriate Regulator
On receipt of the regulation 28 letter we sought further confirmation that the support belt purchased by Mrs Lakin's family was the ORTONES Wheelchair and Geriatric Armchair Belt Restraint, reference D2100 (henceforth referred to the ORTONES belt).

Through our investigations, the manufacturer Eurobaston S.L, confirmed that the ORTONES belt is marketed as a class I medical device in Spain, however they had not registered the ORTONES belt with the MHRA, which is a legal requirement for all medical devices sold in the UK. They informed us that they were unaware that their distributor, Comercial Nespral S.L, was selling the product in the UK. Comercial Nespral S.L, has confirmed that the ORTONES belt is no longer marketed in the UK.

The MHRA's Borderline team have reviewed the intended use and claims of the ORTONES belt and concluded that wheelchair belts are unlikely to meet the definition of a medical device in their own right, as the intended purpose is to prevent accidents and falls, which is not considered to be a medical purpose.

We also considered whether the belt would meet the definition of an accessory to a medical device. An "accessory" to a medical device, as defined by regulation 5(1) of the UK MDR, means a product which, whilst not itself a medical device, is intended specifically by its manufacturer to be used together with a medical device, to enable that device to be used in accordance with its intended use. Wheelchair belts are considered accessories if they are specifically designed by the manufacturer for use in conjunction with a specific wheelchair,

[4] Guidance on Class I medical devices - GOV.UK (www.gov.uk)
[5] Medical Device Alert

and the manufacturer of the wheelchair has evidenced in their instructions for use that their wheelchair cannot fulfil its intended purpose without the belt.

In considering the Instructions for Use for the ORTONES belt (Annex A), we do not consider it would be classified as an accessory to a medical device based on the following:

1. There are no claims that the belt is intended to be used with a specific wheelchair
2. The belt seems to be designed for general use as it is also promoted for use on non-medical products (armchairs)
3. The intended use is stated to provide "*maximum support and safety: It is designed to bring maximum comfort to the user of a wheelchair. Provides extra support to prevent accidents and falls*", which is not a medical purpose

It is worth noting that in the UK, not all products which are used in a healthcare environment, by a disabled person, or by a healthcare professional or carer, qualify as medical devices.

It should be noted that wheelchairs may come already supplied with a belt, and in these cases, the belt is a component of the wheelchair and the wheelchair as a whole, including the belt, is regulated as a medical device.

In addition to the concerns regarding the ORTONES belt, we have identified several other supportive belts that are sold online that do not appear to be registered with the MHRA. However, they also make general claims, similar to the ORTONES belt, and are therefore unlikely to qualify as medical devices or accessories to a medical device.

Given this, the MHRA has advised the relevant regulator, the Office of Product Safety and Standards (OPSS), to ensure that they are aware of your concerns.

Warnings.
We have reviewed the ISO standard for Selection, placement and fixation of flexible postural support devices in seating (part 15 of the wheelchair seating series): ISO/TS 16840-15:2024. The purpose of this standard is to specify the criteria to be applied to positioning supports when used in seating systems and chairs.

According to ISO/TS 16840-15:2024, flexible postural support devices (PSD) shall be prescribed for safety when the primary purpose is to protect the occupant from injury (e.g. to prevent falling from the seat), and occupants should be assessed as to the correct style and size of PSD to be prescribed. The standard also covers the safety information to be included in the user instructions for use; for example "*any special requirements as to who can prescribe and fit a postural support*", the "*need for any periodic checking the occupant's skin for associated pressure injuries*" and "*the risks of strangulation due to poor positioning*".

The MHRA reviewed the instructions for use for the ORTONES belt (see attached document). While they did not contain the warnings required in the standard, as the belt is not considered a medical device or accessory to a medical device, addressing this is outside the MHRA's remit. However, this information will be highlighted to OPSS as the relevant regulator.

Prevalence of the problem

There are many other supportive belt devices that are registered with the MHRA as medical devices. We reviewed the MHRA's adverse incident database for cases involving support belts that were reported to us between 1 April 2015 to 23 April 2025 following the release of the alert in 2015. The broad device code 'Wheelchair accessory' was used in the search, which includes types of wheelchair/chair/stander occupant restraint/support devices.

This search generated 398 reports, twenty-nine (29) of which specifically detailed the use of a support belt, one of which resulted in a fatality. See Table 1 for a breakdown of these incident reports.

Table 1: Breakdown of reported incidence reports

Incident themes	Total number of reports	Reported year of incident*
User slipping under the support belt resulting in an injury	**Three (3)**	One in 2017 One in 2016 One in 2018
Failure of postural support, or the unbuckling/detachment of the belt leading to a fall	**Nine (9)**	One in 2014 Two in 2015 Two in 2016 Two in 2017 One in 2018 One in 2023
Belt not fastened appropriately - resulting in a fall	**Three (3)**	One in 2016 One in 2017 One in 2023
Failure of postural support where the belt had either become loose, unbuckled or detached/broken (no injury reported)	**Nine (9)**	Three in 2015 One in 2016 One in 2018 Three in 2024 One in 2025
Report raising a safety concern relating to support belts namely misuse of belts and lack of guidance	**Two (2)**	Two in 2015
User misunderstanding the belt's fitting instructions	**One (1)**	One in 2017
Exposure of a sharp edge of the belt - resulting in an injury (cut on hand)	**Two (2)**	One in 2015 One in 2023
	Total: Twenty nine (29)	

** Where the date of incident has not been provided, the date of the report has been used.*

Twenty-two (22) out of twenty-nine (29) reported incidents took place between 2014 and 2018. We note that Mrs Lakin's case had not been reported to us prior to receiving the Regulation 28 report, and recognise that adverse incident reports for products not regulated as medical devices, would not be reported to the MHRA.

Further action to be undertaken by MHRA

Eurobaston S.L has committed to the re-evaluation of the ORTONES belt design, labelling and instructions for use. Eurobaston S.L have informed us that they will be working with Comercial Nespral S.L to determine what corrective actions can be implemented for ORTONES belts that have been distributed in the UK.
The MHRA will inform OPSS of this ongoing investigation into the sale of support belts without the appropriate warnings, including the ORTONES belt. In addition, we will include OPSS in our communications with the Eurobaston S.L, to assess the appropriateness of their corrective actions.

Any wheelchair belts which would fall under the definition of a medical device or accessory and are not registered with the MHRA will be referred to the MHRA's compliance team.

Conclusion

Pending the conclusion of the investigation and actions detailed above, we will continue to monitor all adverse incidence reports we receive and take any necessary action as appropriate.

Yours sincerely,

[redacted]

[redacted]
Chief Safety Officer

Annex A – Instructions For Use for the ORTONES belt

MANUAL / INSTRUCCIONES
GEBRAUCHSANWEISUNG / INSTRUCTIONS / ISTRUZIONI

REF: D2100 **REF: F5-AWH** **REF: D2101** **REF: D2104**

WHEELCHAIR BELT/CINTURON SILLA DE RUEDAS/ROLLSTUHLGURT/CEINTURE POUR FAUTEUIL ROULANT/CINTURA PER SEDIA A ROTELLE

EN

CODE			
D2100	F5-AWH2	D2101	D2104

WHEELCHAIR BELT

The Abdominal belt has maximum support and safety: It is designed to provide maximum comfort to the user of a wheelchair, geriatric chair or armchair. It provides extra support to prevent accidents and falls. It minimises the possibility of the patient falling and suffering injuries, tipping or slipping.

INDICATIONS FOR USE

Suitable for people with reduced mobility, wheelchair and geriatric chair users, who require extra support to prevent falls and fronto-lateral slipping in a seated position.
The belts must be adjusted to the user's anatomy, so that they are tight enough to effectively hold the user in the chair, but not too tight to avoid injuries or lacerations.
For this purpose, the length of the fastening straps has to be adjusted in advance by means of the movable adjustment of the locking part of the plastic trident. The belt should be fastened at the back of the backrest of the wheelchair so that the user is secured to the backrest.
In the case of the perineal straps, pass the lower strap through the perineal area between the thighs. On the back side of the backrest, join both ends of the abdominal straps by means of a locking system, tightening both straps until the desired fastening is obtained, then fasten the perineal strap and adjust it.

FEATURES

- Dimensions:

PRODUCT	DIMENSIONS	LENGTH Including grip straps	MATERIAL	LOCK
D2100	45 x 15 cm	160 cm / 63 inches	Nylon cordura and Suede	Trident closure
F5-AWH2	45 x 15 cm	300 cm / 118 inches	Nylon cordura and Suede	Trident closure
D2101	45 x 15 cm	160 cm / 63 inches	Nylon cordura and Suede	Trident closure
D2104	45 x 15 cm	300 cm / 118 inches	Nylon cordura and Suede	Magnetic closure

CLEANING AND DISINFECTION

- Clean only with water and neutral soap. It is not recommended to use: chlorine, bleach, disinfectants with alcohol or abrasive products.
- We recommend to pre-washed a small surface area be when using hospital cleaning products.
- Never use drying presses, the waterproof layer can be broken by not letting the water molecules out.
- Do not iron.
- Machine washable, maximum 30°. Allow to dry at room temperature.

⚠ WARNINGS!

- Caustic products, paint strippers, solvents and sharp objects in direct contact with the belt are prohibited.
- Regularly inspect the belt for normal wear and tear: holes, cracks and fastening system.
- Store belts preferably in a flat position and protected from natural light and humidity.
- Do not burn or throw away in the wild, outside of the designated areas.
- The guarantee will remain in force for 3 years from the date of the consumer's original purchase. This warranty does not cover normal wear and tear of the product and does not replace legal warranties.
- Please observe the care and maintenance instructions. The manufacturer assumes no liability for damage resulting from improper care or maintenance.
- Please contact the company in the event of a problem to resolve it.
- This does not affect your legal rights.
- Please keep these instructions for future reference.
- According to the manufacturer's recommendations this product is suitable for recycling.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and patient are established.

This product is NOT intended for reuse by several persons and any modification to this product not expressly authorised by the manufacturer shall exempt the manufacturer from any liability arising from its use. As well as the use of this garment for a purpose other than that for which it was manufactured.

ES

REFERENCIA			
D2100	F5-AWH2	D2101	D2104

CINTURON SILLA DE RUEDAS

El cinturón Abdominal tiene máxima sujeción y seguridad: Está diseñado para conseguir aportar la comodidad máxima al usuario de una Silla de Ruedas, Silla Geriátrica o Sillón. Aporta una sujeción extra para prevenir accidentes y caídas. Reduce al mínimo la posibilidad de que el paciente se caiga y pueda sufrir lesiones, se ladee o se resbale.

INDICACIONES DE USO

Indicado para personas con movilidad reducida, usuarios de silla de ruedas y sillón geriátrico, que requieran un extra de sujeción para evitar caídas y deslizamientos fronto-laterales en posición de sedestación.
Los cinturones se han de ajustar a la anatomía del usuario, de forma que queden lo suficientemente ajustados para que lo sujeten efectivamente a la silla, pero no demasiado apretados para evitar lesiones o laceraciones.
Para ello, se ha de regular previamente la longitud de las cinchas de sujeción mediante el ajuste móvil de la parte del cierre del tridente de plástico. El cierre del cinturón se ha de realizar por la parte posterior del respaldo de la silla de forma que el usuario quede sujeto al mismo.
En el caso de los perineales, pase la cincha inferior por la zona perineal entre los muslos. Por la cara posterior del respaldo una ambos extremos de las cinchas abdominales mediante sistema de cierre tensando ambas cinchas hasta obtener la sujeción deseada, seguidamente fije la cincha perineal procediendo a su ajuste.

CARACTERÍSTICAS

- Dimensiones:

PRODUCTO	DIMENSIONES	LONGITUD Incluyendo cintas agarre	MATERIAL	CIERRE
D2100	45 x 15 cm	160 cm	Nylon cordura y Antelina	Cierre de tridente
F5-AWH2	45 x 15 cm	300 cm	Nylon cordura y Antelina	Cierre de tridente
D2101	45 x 15 cm	160 cm	Nylon cordura y Antelina	Cierre de tridente
D2104	45 x 15 cm	300 cm	Nylon cordura y Antelina	Cierre magnético

LIMPIEZA Y DESINFECCIÓN

- Limpiar solo con agua y jabón neutro. Está desaconsejado utilizar: cloro, lejía, desinfectantes con alcohol o productos abrasivos.
- Se recomienda realizar un test previo de lavado en una pequeña superficie cuando se utilicen productos limpiadores de hospitales.
- Nunca utilizar prensas de secado, se puede romper la capa impermeable al no dejar salir las moléculas de agua.
- No planchar.
- Lavable a máquina, máximo 30°. Dejar secar a temperatura ambiente.

⚠ ¡ADVERTENCIAS!

- Están prohibidos los productos cáusticos, decapantes, disolventes y objetos punzantes o cortantes en contacto directo con el cinturón.
- Examinar regularmente el desgaste normal del cinturón: orificios, grietas y sistema de cierre.
- Almacenar los cinturones preferentemente en posición plana y protegidos de la luz natural y de la humedad.
- No quemar ni tirar en la naturaleza, fuera de los lugares destinados para ello.
- La garantía permanecerá vigente durante 3 años desde la fecha de compra original del consumidor. Esta garantía no cubre el desgaste normal del producto y no sustituye a las garantías legales.
- Tenga en cuenta las instrucciones de cuidado y mantenimiento. El fabricante no asume ninguna responsabilidad por los daños derivados de un cuidado o mantenimiento incorrectos.
- Se ruega contactar con la empresa en caso de incidencia para resolverla.
- Conserve estas instrucciones para referencias futuras.
- Según las recomendaciones del fabricante este producto es adecuado para su reciclaje.
- Cualquier incidente grave relacionado con el producto debe notificarse al fabricante y a la autoridad competente del Estado miembro en el que estén establecidos el usuario y el paciente.

Este producto NO ha sido diseñado para ser reutilizado por varias personas y cualquier modificación que se realice sobre el mismo que no haya sido expresamente autorizada por el fabricante eximirá a éste de cualquier responsabilidad que pueda derivarse de su utilización. Así como del uso de esta prenda con un fin distinto para el cual fue fabricado.

FABRICADO POR:
EUROBASTÓN S.L.
Polígono de Promosa Cl. w5, nave 7
33211 Gijón, Asturias

DISTRIBUIDO POR:
COMERCIAL NESPRAL S.L.
Linares Rivas, 6, ent. dcha.
33206 Gijón, Asturias
www.comercialnespral.com

DE

REFERENZEN			
D2100	F5-AWH2	D2101	D2104

ROLLSTUHLGURT

Der Bauchgurt bietet maximalen Halt und Sicherheit: Er ist so konzipiert, dass er dem Benutzer eines Rollstuhls, eines geriatrischen Stuhls oder eines Sessels maximalen Komfort bietet. Er bietet zusätzlichen Halt, um Unfälle und Stürze zu vermeiden. Er minimiert die Möglichkeit, dass der Patient stürzt und sich Verletzungen zuzieht, kippt oder ausrutscht.

ANWENDUNGSGEBIETE

Geeignet für Personen mit eingeschränkter Mobilität, Rollstuhlfahrer und geriatrische Patienten, die zusätzliche Unterstützung benötigen, um Stürze und ein Ausrutschen im Sitzen zu verhindern.
Die Gurte müssen an die Anatomie des Benutzers angepasst werden, so dass sie eng genug sind, um den Benutzer effektiv im Stuhl zu halten, aber nicht zu eng, um Verletzungen oder Schnittwunden zu vermeiden.
Zu diesem Zweck muss die Länge der Befestigungsgurte im Voraus mit Hilfe der beweglichen Einstellung des Verschlussteils des Kunststoffdreizacks angepasst werden. Der Gurt sollte an der Rückseite der Rückenlehne des Rollstuhls befestigt werden, damit der Benutzer an der Rückenlehne gesichert ist.
Bei den Dammgurten ist der untere Gurt durch den Dammbereich zwischen den Oberschenkeln zu führen. Verbinden Sie auf der Rückseite der Rückenlehne die beiden Enden der Bauchgurte mit Hilfe eines Verschlusssystems und ziehen Sie beide Gurte fest, bis die gewünschte Befestigung erreicht ist; befestigen Sie dann den Dammgurt und stellen Sie ihn ein.

FEATURES

- Abmessungen:

PRODUKT	ABMESSUNGEN	LÄNGE Einschliesslich griffschlaufen	MATERIAL	SCHLIESSSYSTEM
D2100	45 x 15 cm	160 cms	Nyloncord und Wildleder	Druckschloss
F5-AWH2	45 x 15 cm	300 cms	Nyloncord und Wildleder	Druckschloss
D2101	45 x 15 cm	160 cm	Nyloncord und Wildleder	Druckschloss
D2104	45 x 15 cm	300 cm	Nyloncord und Wildleder	Magnetischer Verschluss

REINIGUNG UND DESINFEKTION

- Wir empfehlen eine kleine Fläche zum Testen der Putzmittel zu verwenden, wenn Sie mit Krankenhausprodukte-narbeiten.
- Pressen Sie das Produkt nicht zum Trocknen, da dadurch die wasserdichte Schicht gebrochen werden kann.
- Nicht bügeln.

⚠ WARNHINWEISE!

- Ätzende Produkte, Abbeizmittel, Lösungsmittel und scharfe oder schneidende Gegenstände in direktem Kontakt mit dem Band sind verboten.
- Kontrollieren Sie den Gurt regelmäßig auf normale Abnutzung: Löcher, Risse und Befestigungssystem.
- Lagern Sie die Riemen vorzugsweise flach und vor natürlichem Licht und Feuchtigkeit geschützt.
- Nicht verbrennen oder in der freien Natur entsorgen, außerhalb der dafür vorgesehenen Bereiche.
- Die Garantie gilt für 3 Jahre ab dem Datum des ursprünglichen Kaufs durch den Verbraucher. Diese Garantie deckt nicht den normalen Verschleiß des Produkts ab und ersetzt nicht die gesetzlichen Gewährleistungen.
- Bitte beachten Sie die Pflege- und Wartungshinweise. Der Hersteller übernimmt keine Haftung für Schäden, die durch unsachgemäße Pflege oder Wartung entstehen.
- Bei Problemen wenden Sie sich bitte an das Unternehmen, um diese zu beheben.
- Bewahren Sie diese Anleitung zum späteren Nachschlagen auf.
- Gemäß den Empfehlungen des Herstellers ist dieses Produkt für das Recycling geeignet.
- Jeder schwerwiegende Zwischenfall mit dem Produkt muss dem Hersteller und der zuständigen Behörde des Mitgliedstaates, in dem der Benutzer und der Patient ansässig sind, gemeldet werden.

Dieses Produkt ist NICHT zur Wiederverwendung durch mehrere Personen bestimmt, und jede nicht ausdrücklich vom Hersteller genehmigte Änderung an diesem Produkt entbindet den Hersteller von jeglicher Haftung, die sich aus seiner Verwendung ergibt. Gleiches gilt für die Verwendung dieses Kleidungsstücks für einen anderen Zweck als den, für den es hergestellt wurde.

FR

RÉFÉRÉNCE			
D2100	F5-AWH2	D2101	D2104

CEINTURE POUR FAUTEUIL ROULANT

La ceinture abdominale offre un maximum de soutien et de sécurité : elle est conçue pour offrir un maximum de confort à l'utilisateur d'un fauteuil roulant, d'une chaise gériatrique ou d'un fauteuil. Elle offre un soutien supplémentaire pour prévenir les accidents et les chutes. Elle minimise les risques de chute et de blessure, de basculement ou de glissement du patient.

INDICATIONS D'UTILISATION

Convient aux personnes à mobilité réduite, aux utilisateurs de fauteuils roulants et de chaises gériatriques, qui ont besoin d'un soutien supplémentaire pour prévenir les chutes et les glissements fronto-latéraux en position assise.
Les ceintures doivent être ajustées à l'anatomie de l'utilisateur, de sorte qu'elles soient suffisamment serrées pour maintenir efficacement l'utilisateur dans le fauteuil, mais pas trop pour éviter les blessures ou les lacérations.
À cette fin, la longueur des sangles de fixation doit être réglée à l'avance au moyen de l'ajustement mobile de la partie de verrouillage du trident en plastique. La ceinture doit être fixée à l'arrière du dossier du fauteuil roulant de manière à ce que l'utilisateur soit attaché au dossier.
Dans le cas des sangles périnéales, passez la sangle inférieure dans la zone périnéale entre les cuisses. Sur la face arrière du dossier, joindre les deux extrémités des sangles abdominales au moyen d'un système de verrouillage, en serrant les deux sangles jusqu'à obtenir la fixation souhaitée, puis fixer la sangle périnéale et l'ajuster.

FONCTIONNALITÉS

- Dimensions:

PRODUIT	DIMENSIONS	LONGUEUR Compris les sangles de préhension	MATÉRIEL	FERMETURE
D2100	45 x 15 cm	160 cms	Nylon sain d'esprit et Suède	Fermoir trident
F5-AWH2	45 x 15 cm	300 cms	Nylon sain d'esprit et Suède	Fermoir trident
D2101	45 x 15 cm	160 cm	Nylon sain d'esprit et Suède	Fermoir trident
D2104	45 x 15 cm	300 cm	Nylon sain d'esprit et Suède	Fermeture magnétique

NETTOYAGE ET DÉSINFECTION

- Nettoyez uniquement avec de l'eau et du savon neutre. Il n'est pas recommandé d'utiliser : du chlore, de l'eau dejavel, des désinfectants à base d'alcool ou des produits abrasifs.
- Nous recommandons un test de prélavage sur une petite surface lors de l'utilisation de produits de nettoyage hospitaliers.
- N'utilisez jamais de presse à sécher, la couche imperméable peut être brisée en ne laissant pas sortir les molécules d'eau.
- Ne pas repasser.

⚠ AVERTISSEMENTS!

- Les produits caustiques, les décapants, les solvants et les objets tranchants ou coupants en contact direct avec la ceinture sont interdits.
- Contrôler régulièrement l'usure normale de la ceinture : trous, fissures et système de fixation.
- Stocker les courroies de préférence à plat et à l'abri de la lumière naturelle et de l'humidité.
- Ne pas brûler ou jeter dans la nature, en dehors des zones prévues à cet effet.
- La garantie est valable 3 ans à compter de la date d'achat initial par le consommateur. Cette garantie ne couvre pas l'usure normale du produit et ne remplace pas les garanties légales.
- Veuillez respecter les instructions d'entretien et de maintenance. Le fabricant n'assume aucune responsabilité pour les dommages résultant d'un entretien ou d'une maintenance inappropriés.
- Veuillez contacter l'entreprise en cas de problème pour le résoudre.
- Conservez ces instructions pour toute référence ultérieure.
- Selon les recommandations du fabricant, ce produit peut être recyclé.
- Tout incident grave impliquant le produit doit être signalé au fabricant et à l'autorité compétente de l'État membre où l'utilisateur et le patient sont établis.

Ce produit n'est PAS destiné à être réutilisé par plusieurs personnes et toute modification de ce produit non expressément autorisée par le fabricant exonère ce dernier de toute responsabilité liée à son utilisation. De même que l'utilisation de ce vêtement dans un but autre que celui pour lequel il a été fabriqué.

IT

REFERENZA			
D2100	F5-AWH2	D2101	D2104

CINTURA PER SEDIA A ROTELLE

La cintura addominale offre il massimo sostegno e sicurezza: è progettata per offrire il massimo comfort all'utente di una sedia a rotelle, di una sedia geriatrica o di una poltrona. Fornisce un sostegno supplementare per prevenire incidenti e cadute. Riduce al minimo la possibilità che il paziente cada e subisca lesioni, si ribalti o scivoli.

INDICAZIONI PER L'USO

Indicato per persone con mobilità ridotta, utenti di sedie a rotelle e poltrone geriatriche, che necessitano di un supporto extra per prevenire cadute e scivolamenti fronto-laterali in posizione seduta.
Le cinture devono essere regolate in base all'anatomia dell'utente, in modo che siano sufficientemente strette per tenere efficacemente l'utente sulla sedia, ma non troppo per evitare lesioni o lacerazioni.
A tal fine, la lunghezza delle cinghie di fissaggio deve essere regolata in anticipo mediante la regolazione mobile della parte di bloccaggio del tridente di plastica. La cintura deve essere fissata sul retro dello schienale della carrozzina in modo che l'utente sia assicurato allo schienale.
Nel caso delle cinghie perineali, far passare la cinghia inferiore attraverso l'area perineale tra le cosce. Sul lato posteriore dello schienale, unire le due estremità delle cinghie addominali mediante un sistema di bloccaggio, stringendo entrambe le cinghie fino a ottenere il fissaggio desiderato, quindi allacciare la cinghia perineale e regolarla.

CARATTERISTICHE

- Dimensioni:

PRODOTTO	DIMENSIONI	LUNGHEZZA Comprese le cinghie di presa	MATERIALE	CHIUSURA
D2100	45 x 15 cm	160 cm	Nylon cordura e Camoscio	Chiusura a tridente
F5-AWH2	45 x 15 cm	300 cm	Nylon cordura e Camoscio	Chiusura a tridente
D2101	45 x 15 cm	160 cm	Nylon cordura e Camoscio	Chiusura a tridente
D2104	45 x 15 cm	300 cm	Nylon cordura e Camoscio	Chiusura magnetica

PULIZIA E DISINFEZIONE

- Pulire solo con acqua e sapone neutro. Si sconsiglia l'uso di: cloro, candeggina, disinfettanti con alcool o prodotti abrasivi.
- Si consiglia di prelavare una piccola superficie quando si utilizzano prodotti per la pulizia ospedaliera.
- Non utilizzare mai presse essiccanti, lo strato impermeabile può essere rotto non lasciando uscire le molecoled'acqua.
- Non stirare.
- Lavabile in lavatrice, massimo 30°. Lasciare asciugare a temperatura ambiente.

⚠ AVVERTENZE!

- Sono vietati prodotti caustici, sverniciatori, solventi e oggetti taglienti o affilati a diretto contatto con il nastro.
- Ispezionare regolarmente il cintura per verificarne la normale usura: fori, crepe e sistema di fissaggio.
- Conservare i cinture preferibilmente in posizione piana e al riparo dalla luce naturale e dall'umidità.
- Non bruciare o gettare in natura, al di fuori delle aree designate.
- La garanzia rimarrà in vigore per 3 anni dalla data di acquisto originale del consumatore. Questa garanzia non copre la normale usura del prodotto e non sostituisce le garanzie legali.
- Osservare le istruzioni per la cura e la manutenzione. Il produttore non si assume alcuna responsabilità per danni derivanti da una cura o manutenzione impropria.
- Si prega di contattare il reparto qualità dell'azienda in caso di problemi per risolverli.
- Ciò non pregiudica i vostri diritti legali.
- Si prega di conservare queste istruzioni per riferimento futuro.
- Secondo le raccomandazioni del produttore questo prodotto è adatto al riciclaggio.
- Qualsiasi incidente grave relativo al prodotto deve essere se gnalato al produttore e all'autorità competente dello Stato membro in cui sono stabiliti l'utente e il paziente.

Questo prodotto NON è stato progettato per essere riutilizzato da più persone e qualsiasi modifica apportata allo stesso che non sia stata espressamente autorizzata dal produttore esonera quest'ultimo da qualsiasi responsabilità che possa derivare dal suo utilizzo. Così come l'uso di questo indumento per uno scopo diverso da quello per cui è stato fabbricato.

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FABRICADO POR:
EUROBASTÓN S.L.
Polígono de Promosa Cl. w5, nave 7
33211 Gijón, Asturias

DISTRIBUIDO POR:
COMERCIAL NESPRAL S.L.
Linares Rivas, 6, ent. dcha.
33206 Gijón, Asturias
www.comercialnespral.com