SEGUFX®-Thigh Restraint



Item 2211 / Item 2311 / Item 2411

Consisting of:

1 SEGUFIX®-Thigh Restraint (for both thighs)

4 SEGUFIX®-Locks (key not included)

Sizes: S / M / L

Versions: basic version / b / e / r

Component part: item 2111 (for both thighs, locks and keys not included)



Item 2711 Thigh Restraint Velcro®

Consisting of:

1 SEGUFIX®- Thigh Restraint Velcro® (with Buckle lock, for both thighs)

Sizes: S / M / L

Versions: basic version / b / e







The Thigh Restraint (green label) is part of the SEGUFIX®-Bed Restraint System and is made from a cotton/rayon mix.

3 Versions → SEGUFIX®-Locks:					
IP II PA					
1206 / 1208	1306 / 1308	1406 / 1408			
Item 2211	Item 2311	Item 2411			

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	Versions - Item no. / identification							
Item no.	Product features	Span width* (with eyelets)	Span width* (Velcro®)				
Version	1 Toddet Teatures	mm	inches	mm	inches			
	Attachment strap: medium	1200 - 1450	47.2 - 57.1	950 - 1540	37.4 - 60.6			
/b	Attachment strap: short	1000 - 1200	39.4 - 47.2	920 - 1330	36.2 - 52.4			
/e	Attachment strap: long	1450 - 1700	57.1 - 66.9	950 - 1800	37.4 - 70.9			
/r	Eyelet strap reinforced for higher demands							

^{*}Span width: distance between the attachment points on the bed approx. measurements – about 8 % shrinkage possible (products are not pre-washed)

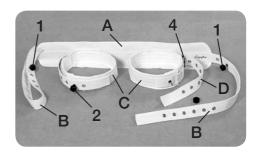
SEGUFX®-Thigh Restraint

3 Locking Systems: Item 2211 / 2311 / 2411

Intended use:

- Limits movement of the legs in bed
- Optional addition to a 5-point-restraint
- Physically restraining patients

 (e.g. pathology or disability that requires restraint in a defined position in bed to restrict patients from harming themselves or care givers, e.g. anxiety disorders)



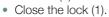
Instructions for use item 2211 / 2311 / 2411 and 2111

Locks and keys see pages 6 and 7

How to attach the SEGUFIX®-Thigh Restraint to the bed:

- Insert the pin of the lock (1) through one of the eyelets of the pin flap.
- Lay the Thigh Restraint on the bed at the height of the patient's thighs with the padded straps (C) laying on top of the bed belt (A).
- Direct the attachment strap (B) from inside out around the bed frame or the frame of the folding part of the bed. Install the attachment strap in such manner that it cannot slide along the bed frame. Be sure to pull the attachment strap firmly down and then up around the frame. Then lay the attachment strap tightly with one eyelet over the pin of the lock (1).





- Install the second attachment strap in the same manner.
- Ensure that the attachment straps are installed very tightly to the bed.

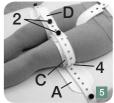




How to fasten the Thigh strap to the patient:

- Wrap the padded strap (C) around the patient's thigh.
- Insert the eyelet strap (D) of the thigh strap through the metal buckle (4) and pull it back over the buckle.
- Lay the eyelet strap (D) tightly with one eyelet over the metal pin of the lock (2).
- Close the lock (2).
- Install the second thigh strap in the same manner.
- For restless patients: After closing you may secure one eyelet strap (D) to the lock (2) of the other thigh strap.





- The thigh straps must fit snugly, but not cause pressure marks.
- Pull on each lock to test for a secure hold. Then lock bed side rails in an up position.

How to release the restraint and remove it:

See page 7 on how to open the respective locking systems.

- To release the restraint open the locks (2) and lift all belt parts off of the pins.
- Remove the eyelet straps (D) of the thigh straps from the metal loops (4), and open the Velcro® fasteners.
- Then open both locks (1) of the attachment straps and remove the restraint from the bed.





Follow SEGUFIX®-Safety Information and Warnings on pages 8 - 11

Note: To additionally restrict movement the SEGUFIX®-Brace Strap for legs (item 3110/r) may be used in connection with the thigh restraint **with lock**.

SEGL	SEGUFIX®-Thigh Restraint						Span width*			
Size	Item	kg	Item	kg	Item	kg	Component part	kg	mm	inches
S	2211	0,83	2311	0,91	2411	0,91	2111	0,75	1200 - 1450	47.2 - 57.1
М	2211	1,00	2311	1,08	2411	1,08	2111	0,92	1200 - 1450	47.2 - 57.1
L	2211	1,06	2311	1,14	2411	1,14	2111	0,98	1200 - 1450	47.2 - 57.1
S	2211/b	0,78	2311/b	0,86	2411/b	0,86	2111/b	0,70	1000 - 1200	39.4 - 47.2
М	2211/b	0,95	2311/b	1,03	2411/b	1,03	2111/b	0,87	1000 - 1200	39.4 - 47.2
L	2211/b	1,01	2311/b	1,09	2411/b	1,09	2111/b	0,93	1000 - 1200	39.4 - 47.2
S	2211/e	0,87	2311/e	0,95	2411/e	0,95	2111/e	0,79	1450 - 1700	57.1 - 66.9
М	2211/e	1,04	2311/e	1,12	2411/e	1,12	2111/e	0,96	1450 - 1700	57.1 - 66.9
L	2211/e	1,10	2311/e	1,18	2411/e	1,18	2111/e	1,02	1450 - 1700	57.1 - 66.9
S	2211/r	0,88	2311/r	0,96	2411/r	0,96	2111/r	0,80	1200 - 1450	47.2 - 57.1
М	2211/r	1,04	2311/r	1,12	2411/r	1,12	2111/r	0,96	1200 - 1450	47.2 - 57.1
L	2211/r	1,14	2311/r	1,22	2411/r	1,22	2111/r	1,08	1200 - 1450	47.2 - 57.1
S	2211/rb	0,79	2311/rb	0,87	2411/rb	0,87	2111/rb	0,71	1000 - 1200	39.4 - 47.2
М	2211/rb	0,96	2311/rb	1,04	2411/rb	1,04	2111/rb	0,88	1000 - 1200	39.4 - 47.2
L	2211/rb	1,02	2311/rb	1,10	2411/rb	1,10	2111/rb	0,94	1000 - 1200	39.4 - 47.2
S	2211/re	0,91	2311/re	0,99	2411/re	0,99	2111/re	0,83	1450 - 1700	57.1 - 66.9
М	2211/re	1,08	2311/re	1,16	2411/re	1,16	2111/re	1,00	1450 - 1700	57.1 - 66.9
L	2211/re	1,18	2311/re	1,26	2411/re	1,26	2111/re	1,10	1450 - 1700	57.1 - 66.9

	Width o	of strap	Thig	h girth
Size	mm inches		mm	inches
S	140	5.5	200 - 360	7.9 - 14.2
М	140	5.5	340 - 580	13.4 - 22.8
L	140	5.5	580 - 750	22.8 - 29.5

*Span width: Distance between the attachment points on the bed

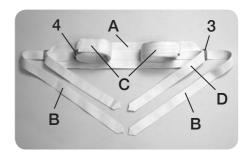
Tables: approximate measurements – about 8 % shrinkage possible (products are not pre-washed)

SEGUFX®-Thigh Restraint Velcro®

With Velcro® fastener /buckle lock: Item 2711

Intended use:

- Limits movement of the legs in bed
- Optional addition to a 5-point-restraint
- Not a restraint (note: some jurisdictions consider Velcro® products as a restraint, should the patient not be able to remove them without help)



Instructions for use item 2711

How to attach the SEGUFIX®-Thigh Restraint Velcro® to the bed:

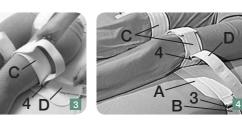
- Lay the Thigh Restraint on the bed at the height of the patient's thighs with the padded straps (C) laying on top of the bed belt (A).
- Direct the attachment strap (B) from inside out around the bed frame or the frame of the folding part of the bed. Install the attachment strap in such manner that it cannot slide along the bed frame. Be sure to pull the attachment strap firmly down and then up around the frame.
- Close the buckle lock (3).
- Install the second attachment strap in the same manner.
- Ensure that the attachment straps are installed very <u>tightly</u> to the bed.





How to fasten the Thigh strap to the patient:

- Wrap the padded strap (C) around the patient's thigh. The Velcro® on the strap prevents slipping after closing.
- Feed the narrow strap (D) of the thigh strap through the buckle lock (4) of the thigh strap.
- Close the buckle lock (4) by pulling the strap tight.
- Install the second thigh strap in the same manner.
- The thigh straps should be snug, but should not restrict blood circulation.
- Test the buckle locks for a secure hold.
 Then lock bed side rails in an up position.



How to release the restraint and remove it:

- Undo the buckle locks (4), open Velcro[®] fasteners, and remove the restraint.
- Undo the buckle locks (3) and remove the attachment straps from the bed.





Follow SEGUFIX®-Safety Information and Warnings on pages 8 - 11

WARNING: Read the Safety Information prior to using the SEGUFIX®-Thigh Restraint and SEGUFIX®-Thigh Restraint Velcro®.

- The SEGUFIX®-Thigh Restraint may only be used in connection with additional restraint measures.
- The SEGUFIX®-Thigh Restraint with Velcro® fastener is not a restraint. It is possible for the patient to open the Velcro® fastener and buckle lock. Note: some jurisdictions consider Velcro® products as a restraint, should the patient not be able to remove them without help.
- The attachment straps (B) of the wide bed belt (A) must be installed in such manner to the folding part of the bed that the wide bed belt lies tightly on the mattress.
- Note that attachment straps and moving mechanics of the bed or mattress may interfere with each other, causing damage, loss of function and injury.
- For more product info visit us online at www.segufix.com or www.segufix-shop.com

SEGUFIX®-Thigh Restraint Velcro®			Span width* Velcro® (without eyelets)		
Size	Item	kg	mm	inches	
S	2711	0,64	950 -1540	37.4 - 60.6	
М	2711	0,76	950 -1540	37.4 - 60.6	
L	2711	0,84	950 -1540	37.4 - 60.6	
S	2711/b	0,62	920 -1330	36.2 - 52.4	
М	2711/b	0,74	920 -1330	36.2 - 52.4	
L	2711/b	0,82	920 -1330	36.2 - 52.4	
S	2711/e	0,71	950 -1800	37.4 - 70.9	
М	2711/e	0,80	950 -1800	37.4 - 70.9	
L	2711/e	0,89	950 -1800	37.4 - 70.9	

*Span width of the attachment straps for Velcro® products (without eyelets): Distance between the attachment points on the bed

Tables: approximate measurements – about 8 % shrinkage possible (products are not pre-washed)

	Width o	of strap	Thig	h girth
Size	mm	inches	mm	inches
S	140	5.5	200 - 360	7.9 - 14.2
М	140	5.5	340 - 580	13.4 - 22.8
L	140	5.5	580 - 750	22.8 - 29.5

SEGUFX*-Locks and Keys

10	SEGUFIX®-Magnetic locking system black		
Item	Consisting of:		
1206	1 Magnetic Button black / segufix.com1 Metal Pin		
1208	1 Magnetic Key red		
1204	Magnetic Button black / segufix.com		
1205	1 Metal Pin		
1209	Magnetic Key red with key ring		

	SEGUFIX®-Patent Twist locking system green
Item	Consisting of:
1306	Patent Twist Button green Square Pin
1308	1 Patent Twist Key yellow
1304	1 Patent Twist Button green
1305	1 Square Pin

Intended use of the Lock: Closing of the SEGUFIX® systems.

Intended use of the Key: Quick release of the locks.

Caution: Each locking system only works with its own component parts and is not interchangeable with other locking systems.



WARNING: Read the Safety Information prior to using the SEGUFIX®-Locks and Keys.

- Do not submerge locks in any type of liquid. This can cause malfunction.
- Locks and keys must not be laundered.
- Test locks for proper function before each use.
- Examine the head of the pin for damage (wear and tear, rounding off or deformation).
- When closing the lock make sure that the button locks securely onto the pin. You should not be able to pull the button off of the pin.
- When opening locks, ensure movement between the upper and lower points of contact (item 1206). Therefore each lock can hold up to a maximum of 4 belt layers (exception: products with "r" or "f" in the item number have thicker belts. These allow for a maximum of 3 belt layers!). When using the Patent Twist Lock (item no. 1306) use no more then 4 belt layers. When using the Push Lock (item no. 1406) use no more then 3 belt layers.
- If damaged locks fail to open, straps can be cut with scissors or belt cutters.
- For more product info visit us online at www.segufix.com or www.segufix-shop.com

Instructions for use: SEGUFIX®-Locks and Keys

Item 1206 / 1208 (SEGUFIX®-Magnetic locking system black)

Item 1306 / 1308 (SEGUFIX®-Patent Twist locking system green)

Item 1406 / 1408 (Push locking system)

How to open the Locks:

Item 1206 / 1208

- Set the red Magnetic Key with a light push on top of the black Magnetic Lock.
- Lift both the Magnetic Key and the Magnetic Button



off of the Metal Pin (fig. 1).

Item 1406 / 1408

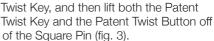
- Push the two pins of the Push Lock Key into the holes on top of the Push Button to unlock.
- Lift both the Push Lock Key and the Push Button off of the Push Pin (fig. 2).





Item 1306 / 1308

- Set the yellow Magnetic Twist Key on top of the green Magnetic Twist Lock.
- Unlock the Patent Twist Lock by turning the Patent





How to close the Locks:

- Set the respective button with the opening onto the pin so that it locks in place.
- Now test the lock for a secure hold: You should not be able to pull the button off of the pin.

Caution: Each locking system only works with its own component parts and is not interchangeable with other locking systems.

Follow SEGUFIX®-Safety Information and Warnings on pages 8 - 11

SEGUFX®-Safety Information

The following instructions for use are only applicable to original SEGUFIX® products. Do not use the SEGUFIX®-Restraint and Positioning System until you have read and understood the instructions for use.

Only use up-to-date instructions and keep them in a safe and readily available location. Product and instruction must match. Failure to use this product properly can cause serious injury or death. Your patient's safety depends on your using the SEGUFIX® system correctly.

1. Requirements for use

It is the user's responsibility to comply with all national laws. Always consider restraining protocols of your work place and current legislation. The instructions for use must be adhered to.

SEGUFIX® products may only be used by individuals with proper training and knowledge of the product. Legal provisions and doctor's orders must be strictly observed! The attending physician must ensure, that the patient's medical condition allows the application of the SEGUFIX® system.

2. Intended use

SEGUFIX® products may only be used for the medical purposes, which they were designed for.

3. Remove dangerous objects

Remove all objects from the reach of the patient, which could lead to injury or may damage the belts (e.g. glasses, jewelry and sharp objects).

4. Inspect products before use



Inspect before each use for broken stitches, torn, worn out or frayed parts and damaged eyelets. Damaged products could malfunction and cause injury. Do not use damaged or worn out products.

5. When opening, locks may not be under tension

When opening locks, ensure movement between the upper and lower points of contact (item 1206). Therefore each lock can hold up to a maximum of 4 belt layers (exception: products with "r" or "f" in the item number have thicker belts. These allow for a maximum of 3 belt layers!). When using the Patent Twist Lock (item 1306) use no more then 4 belt layers. When using the Push Lock (item 1406) use no more then 3 belt layers.



6. Always attach Side Positioning Straps

The SEGUFIX®-Standard must always be used with the Side Positioning Straps attached. Side Positioning Straps prevent the patient from helicoptering in bed or from getting over the edge of the bed causing compression of the chest, possibly resulting in death. In some cases it is possible that patients get over the edge of the bed even with the Side Positioning Straps attached and the side rails in the up position. In these cases additional restraint measures must be taken.

<u>Important</u>: Insert the Side Positioning Straps through the respective loops (according to instructions) before securing them to the bed belt.

7. Beds, chairs and stretchers

- Only use SEGUFIX® products on beds, stable chairs and stretchers that allow the product to be attached to, in accordance with the instructions.
- Products must be attached in such manner, that they cannot get out of place.
- Note that straps and moving mechanics of beds, stretchers or chairs (or alternating pressure pads and the like), may interfere with each other causing damage, loss of function and injury.
- The attachment points must be free of sharp edges.
- SEGUFIX® products do not prevent beds, chairs or stretchers from tipping over or from unintended movement.

Helpful hints:

European standards for beds: DIN EN 60601-2-52

European standards for wheelchairs: DIN EN 12182 and DIN EN 12183

8. All side rails must be in the up position



To prevent accidents always lock side rails in the up position (exception: 5-point-restraint).

<u>Caution</u>: Do not use with parted side rails except with a gap protector that effectively prevents the patient from slipping through the gap. An open gap could allow the patient to slip through even with the restraint fastened possibly causing compression of the chest.

9. Monitor patients in restraints



Patients in restraints require frequent monitoring. Aggressive, agitated or restless patients and patients in danger of aspiration require constant monitoring.

SEGUFX®-Safety Information

10. Test closure-systems prior to each use



Check SEGUFIX®-Magnetic Locks black/segufix.com, SEGUFIX®-Patent Twist Locks green, Push Locks, Snap Locks, Velcro® Fasteners and Buckle Locks for a secure hold.

Do not submerge locks in any type of liquid. This may cause malfunction. If damaged locks fail to open, straps can be cut with scissors or belt cutters. Check the head of the pin for signs of wear and tear (rounding off

or deformation).

11. Pacemaker Warning



A distance of 10 cm (4 inches) must be maintained between a patient's pacemaker and magnetic locks and keys to prevent the pacemaker from possible malfunction (alternatively use Push Locks).

For possible interference of strong magnets with other patient implants please refer to manufacturer's instructions of these products.

12. Test products for correct attachment

Frequently check products for correct attachment. The straps must be secured to the frame of the bed (or the folding part of the frame of the bed) in such a way, that they cannot slide out of place.

13. Only use original SEGUFIX® products

For safety reasons SEGUFIX® products must not be altered or be combined with third party products.

14. Use of SEGUFIX® products in vehicles



The SEGUFIX®-Transport Belt System does not replace the vehicle's legally required seat belt system. SEGUFIX®-Transport Belts may only be used as additional support or for restraint of a patient. Make sure that the patient can be rescued quickly in case of emergency (e.g. clearly visible and handy belt cutters).

15. Secure but not too tight

The restraints must be fastened tightly, but not interfere with breathing or blood circulation. Loosely fastened products may jeopardize the patient's safety. Frequently check products for correct position.

16. Storage

To prolong product life store belts and locking systems in dry and dark conditions at about 20 °C.



17. Flammability of SEGUFIX®-Bed Restraints



According to DIN EN 71-2 section 4.3 non-flammable.

According to DIN 75200 the burning rate is zero.

However, products may not come in contact with cigarettes or be exposed to open flame, as this could permanently damage the products, and this could lead to injury.

18. Correct sizing

Choosing the right size is of essential importance. Make sure that the size matches body and waist sizes (refer to sizing tables). Products that are too small or too large compromise the patient's comfort and safety.

19. Disposal

Carton and plastic wrapping can be disposed of in recyclable disposal, defective products in household garbage.

20. Declaration of conformity

For the declaration of conformity please visit: https://www.segufix.com/conformity_en.php

21. Expert recommandation to prevent accidents

(Prof. Dr.-Ing. U. Boenick, TU-Berlin)

- 1. Always use Side Positioning Straps
- 2. Lock non-parted side rails in the up position (exception: five-point-restraint)
- 3. The use of additional restraint elements may be necessary to eliminate bed egress.

22. Ensure prior to each use

- Test locks for a secure hold
- Visual inspection of belts, straps and eyelets
- Ensure sufficient medical indication
- Check legal requirements

Care Instructions

SEGUFIX®-Restraints (white) are made of a cotton/rayon mix and are washable in hot
wash cycles up to 95 °C. Lower temperature and laundry nets will prolong product life.
Avoid methods that might bend metal parts of the system (e.g. laundry line, dry pressing,
rotary irons), eyelets may be damaged.

Not pre-washed, up to 8 % shrinkage. Store in a dry place.

<u>Detergents</u>: non-aggressive, no fabric softener, no bleach.

Dryer: delicate cycle at low temperature and preferably in the laundry net.

Disinfection: may be disinfected using chemothermal disinfection washing procedure.

Overdosing can damage the product.

• SEGUFIX®-Transport Belts (coloured/black) are made of polyester and are washable in warm wash cycles up to 30 °C.

Avoid methods that might bend metal parts of the system (e.g. laundry line, dry pressing, rotary irons), evelets may be damaged. Store in a dry place.

Detergents: non-aggressive, no fabric softener, no bleach.

<u>Dryer</u>: delicate cycle at low temperature and preferably in the laundry net.

- SEGUFIX®-Locks and metal pins: remove all locks and metal pins before washing or drying. Laundering will damage locks and possibly cause them to fail. Locks may be cleaned with a damp cloth. Never submerge locks in any type of liquid.
- Velcro® Fastener: fasten before washing and drying to prevent lint buildup.
 Occasionally use a stiff brush to remove lint from Velcro® Fastener. Even with normal use, Velcro® material has the tendency to collect lint. This can reduce the grip strength.
 Before each use, test grip strength of the Velcro® Fastener.
- **Durability:** depends on the intensity of use and is prolonged by gentle laundry procedures (detergent/laundry net).

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https://www.segufix.com/PDFs/AGBs/ Terms and Conditions.pdf

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