ComfortGel SE™ support surface

Operations Manual

REF 1805

1805-009-001

EN

1805-009-001 Rev AA.0 2021-11

Symbols

	Refer to instruction manual/booklet
	Consult instructions for use
	General warning
	Caution
REF	Catalogue number
SN	Serial number
US Patents	For US Patents see www.stryker.com/patents
EC REP	Authorized representative in the European Community
MD	European medical device
	Manufacturer
	Date of manufacture
	Importer
CE	CE mark
	Safe working load
	Type B applied part
	Mass of product
	Wash by hand
	Do not tumble dry
	Do not dry clean
	Do not iron
	Allow to completely air dry

	Chlorinated bleach
	Keep dry
	Stacking limit by number
	Do not use sharp objects to open the package.

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Warning/Caution/Note Definition

The words **WARNING**, **CAUTION**, and **NOTE** carry special meanings and should be carefully reviewed.

WARNING

Alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

CAUTION

Alerts the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the product or other property. This includes special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

Note - Provides special information to make maintenance easier or important instructions clearer.

Summary of safety precautions

Always read and strictly follow the warnings and cautions listed on this page. Service only by qualified personnel.

WARNING

- Always use a minimum of two people to move the support surface.
- Always check patient's skin regularly. Consult a physician if erythema or skin breakdown occurs. Serious injury could result if the patient's skin condition is left untreated.
- Always use extra caution and supervision to help reduce the risk of a patient fall. Patient stability and siderail coverage may be compromised with the use of an overlay.
- Always consider the use of siderails. The safe use of the support surface is maximized when used in conjunction with siderails and there may be an increased risk of falls when siderails are not present. Serious injury or death can result from the use (potential entrapment) or non-use (potential patient falls) of siderails or other restraints. Consider local policies regarding the use of siderails. The physician operator, or responsible parties should determine whether and how to use siderails based on each patient's individual needs.
- Always use extra caution with a patient at risk of a fall (such as agitated or confused) to help reduce the likelihood of a fall.
- Do not use the support surface on a larger or smaller frame width or length. This product is intended to match the stretcher litter deck. This is to avoid the risk of the support surface sliding and patient injury.
- Always inspect for foreign objects between support surface and support platform. Foreign objects may cause the support surface to slide on the support platform.
- Do not use the support surface when gaps are present. The risk of entrapment can develop when the support surface is placed on frames that leave gaps of even a few inches between the support surface and the headboard, footboard, and siderails.
- Do not stick needles into a support surface through the support surface cover. Holes may allow body fluids to enter the inside (inner core) of the support surface and could cause cross-contamination, product damage, or product malfunction.
- Do not use the support surface as a transfer device.
- Do not exceed the safe working load of the support surface. Excess weight could cause unpredictable safety and performance of this product.
- Always make sure that the patient support platforms and their respective transfer gaps are adequate to support the patient. If the space between the two patient support platforms is greater than 3 in. (7.6 cm), use a transfer bridge to fill the gap. A transfer bridge is meant to ease transfer of a patient from one patient support platform to another.
- Always make sure that the opposite siderail is raised when placing a patient on the support surface to reduce the risk of patient fall.
- Always monitor the patient condition at regular intervals for patient safety.
- Do not wash the internal components of this support surface. Discard the support surface if a contamination is found inside.
- Do not immerse the support surface.

- Do not allow liquid to pool on the support surface.
- Always inspect support surface covers (top and bottom) for tears, punctures, excessive wear, and misaligned zippers before each use. If compromised immediately remove the support surface from service.
- Always make sure that you wipe each product with clean water and thoroughly dry each product after any application of chemical solutions. Some chemical solutions are corrosive in nature and may cause damage to the product if you use them improperly. If you do not properly rinse and dry the product, a corrosive residue may be left on the surface of the product that may cause premature degradation of critical components. Failure to follow these instructions may void your warranty.
- Always apply the supplied Velcro to the 0747 stretcher to make sure that the mattress is secure. Non-use may result in patient harm due to mattress movement.

CAUTION

- Improper usage of the product can cause injury to the patient or operator. Operate the product only as described in this manual.
- Do not modify the product or any components of the product. Modifying the product can cause unpredictable operation resulting in injury to patient or operator. Modifying the product also voids its warranty.
- Always be aware of devices or equipment that are placed on the top of the support surface. Damage to the surface may occur due to the weight of the equipment, heat generated by the equipment, or sharp edges on the equipment.
- Do not put overlays or accessories inside the cover to avoid the risk of reducing pressure redistribution performance.
- Always evaluate the appropriate Cardiopulmonary Resuscitation (CPR) protocol to be used with this product before operating.
- Do not allow liquid to seep into the zipper area or watershed cover barrier when washing the underside of the support surface. Fluids allowed to come in contact with the zipper may leak into the support surface.
- Do not iron, dry-clean, or tumble dry the support surface covers.
- Do not power wash the support surface as this may damage the product.
- Always completely dry the support surface covers before storing, adding linens, or placing a patient on the surface. Drying the product helps to prevent the performance of the product from being impaired.
- Do not over expose the covers to higher concentration chemical solutions as these may degrade the covers.
- Do not use accelerated hydrogen peroxides or quaternaries that contain glycol ethers as they may damage the cover and reduce the legibility of the graphics.
- Failure to follow manufacturing instructions may also affect useful life of the support surface cover.

Introduction

This manual assists you with the operation or maintenance of your Stryker product. Read this manual before operating or maintaining this product. Set methods and procedures to educate and train your staff on the safe operation or maintenance of this product.

CAUTION

- Improper usage of the product can cause injury to the patient or operator. Operate the product only as described in this manual.
- Do not modify the product or any components of the product. Modifying the product can cause unpredictable operation resulting in injury to patient or operator. Modifying the product also voids its warranty.

Note

- This manual is a permanent part of the product and should remain with the product even if the product is sold.
- Stryker continually seeks advancements in product design and quality. This manual contains the most current product information available at the time of printing. There may be minor discrepancies between your product and this manual. If you have any questions, contact Stryker Customer Service or Technical Support at 1-800-327-0770.

Product description

ComfortGel SE™ is a non-powered support surface that assists in improving human patient outcomes, through redistribution of pressure and enhancing comfort. The three sided zipper helps to improve infection prevention.

Indications for use

ComfortGel SE assists in the prevention and treatment of all pressure injury stages (including stages 1, 2, 3, 4, Unstageable Pressure Injury, and Deep Tissue Pressure Injury) and is recommended to be implemented in combination with clinical evaluation of risk factors and skin assessments made by a healthcare professional.

This support surface is for use with human patients with existing or at risk of incurring pressure injuries. The sloped heel section of the product assists in off-loading pressure on the heels.

The dimensions of **ComfortGel** SE is intended to match the stretcher litter deck. The stretcher support surface is intended to be used for short-term stays (treatment and recovery). This product is not intended to be used for long term patient stays. Additionally, this product is not intended to be used within a home healthcare setting.

ComfortGel SE shall be used with a support surface cover at all times. The support surface cover can interact with all external skin.

Operators of this support surface include healthcare professionals (such as nurses, nurse aids, or doctors).

This support surface is for use by patients in an acute care setting. This may include emergency department, Pre-operative, Transport, Endoscopy, GI, critical care, step down, progressive care, med/surg, sub-acute care, and post anesthesia care unit (PACU), operating room, or other locations as prescribed.

Clinical benefits

Assists in the prevention and treatment of all pressure ulcers or pressure injuries

Contraindications

None known.

Expected life

The **ComfortGel** SE internal components have a three year expected life under normal use, conditions, and with appropriate periodic maintenance for the support surface.

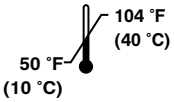
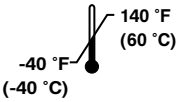
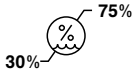
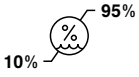
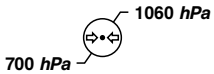
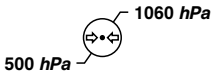
The **ComfortGel** SE cover has a one year expected service life under normal use, conditions, and with appropriate periodic maintenance for the support surface.

Disposal/recycle

Always follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.

Specifications

Safe working load	700 lb (317 kg)			
Model	1805-034-300		1805-034-600	
Length	76 in.	193 cm	76 in.	193 cm
Width	30 in.	76 cm	26 in.	66 cm
Thickness	5.5 in.	14 cm	5.5 in.	14 cm
Product weight	22.5 lb	10,2 kg	20.2 lb	9,2 kg
Top cover material	Polyurethane polyamide			
Bottom cover material	Polycarbonate polyurethane			
Mattress material	Polyurethane foam 55%			
	Dry polymer gel 45%			
Product compliance reference	USA 16 CFR 1632			

Environmental conditions	Operation	Storage and transportation
Ambient temperature		
Relative humidity (non-condensing)		
Atmospheric pressure		

Stryker reserves the right to change specifications without notice.

Contact information

Contact Stryker Customer Service or Technical Support at: 1-800-327-0770.

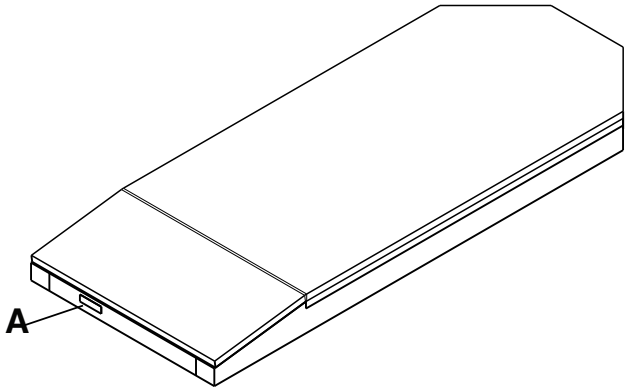
Stryker Medical
3800 E. Centre Avenue
Portage, MI 49002
USA

Note - The user and/or the patient should report any serious product-related incident to both the manufacturer and the Competent authority of the European Member State where the user and/or patient is established.

To view your operations or maintenance manual online, see https://techweb.stryker.com/.

Have the serial number (A) of your Stryker product available when calling Stryker Customer Service or Technical Support. Include the serial number in all written communication.

Serial number location



Setup

WARNING

- Always use a minimum of two people to move the support surface.
- Always check patient's skin regularly. Consult a physician if erythema or skin breakdown occurs. Serious injury could result if the patient's skin condition is left untreated.
- Always use extra caution and supervision to help reduce the risk of a patient fall. Patient stability and siderail coverage may be compromised with the use of an overlay.
- Always consider the use of siderails. The safe use of the support surface is maximized when used in conjunction with siderails and there may be an increased risk of falls when siderails are not present. Serious injury or death can result from the use (potential entrapment) or non-use (potential patient falls) of siderails or other restraints. Consider local policies regarding the use of siderails. The physician operator, or responsible parties should determine whether and how to use siderails based on each patient's individual needs.
- Always use extra caution with a patient at risk of a fall (such as agitated or confused) to help reduce the likelihood of a fall.
- Do not use the support surface on a larger or smaller frame width or length. This product is intended to match the stretcher litter deck. This is to avoid the risk of the support surface sliding and patient injury.
- Always inspect for foreign objects between support surface and support platform. Foreign objects may cause the support surface to slide on the support platform.
- Do not use the support surface when gaps are present. The risk of entrapment can develop when the support surface is placed on frames that leave gaps of even a few inches between the support surface and the headboard, footboard, and siderails.
- Do not stick needles into a support surface through the support surface cover. Holes may allow body fluids to enter the inside (inner core) of the support surface and could cause cross-contamination, product damage, or product malfunction.

CAUTION

- Always be aware of devices or equipment that are placed on the top of the support surface. Damage to the surface may occur due to the weight of the equipment, heat generated by the equipment, or sharp edges on the equipment.
- Do not put overlays or accessories inside the cover to avoid the risk of reducing pressure redistribution performance.

Note - Always use extra caution when reading radiology images taken of a patient on this support surface as internal components can cause artifacts and distort readings.

To setup the support surface:

1. Make sure that the support surface fits the frame on that the product is being placed.
2. Make sure that the dedicated sloped heel section is installed at the foot end of the frame.
3. Place linens on the support surface per hospital protocols.

Operation

Transferring a patient from one patient support platform to another

WARNING

- Do not use the support surface as a transfer device.
- Do not stick needles into a support surface through the support surface cover. Holes may allow body fluids to enter the inside (inner core) of the support surface and could cause cross-contamination, product damage, or product malfunction.
- Do not exceed the safe working load of the support surface. Excess weight could cause unpredictable safety and performance of this product.
- Always make sure that the patient support platforms and their respective transfer gaps are adequate to support the patient. If the space between the two patient support platforms is greater than 3 in. (7.6 cm), use a transfer bridge to fill the gap. A transfer bridge is meant to ease transfer of a patient from one patient support platform to another.
- Always make sure that the opposite siderail is raised when placing a patient on the support surface to reduce the risk of patient fall.

To transfer the patient from one patient support surface to another:

Prerequisite: Follow hospital protocols required to transfer a patient from one support surface to another.

1. Position one patient support platform alongside the other patient support platform while minimizing the gap between the two platforms.
2. Set the brakes to on for both patient support platforms.
3. Adjust the patient support platform heights so that they are level with one another.
4. Transfer the patient following all applicable safety rules and institution protocols for patient and operator safety.

Managing incontinence and drainage

WARNING - Always monitor the patient condition at regular intervals for patient safety.

You can use disposable diapers or incontinence pads to manage incontinence. Always provide appropriate skin care after each incontinence episode.

Selecting the appropriate Cardiopulmonary Resuscitation (CPR) protocol

CAUTION - Always evaluate the appropriate Cardiopulmonary Resuscitation (CPR) protocol to be used with this product before operating.

Applying Velcro® to the 0747 stretcher

WARNING - Always apply the supplied Velcro to the 0747 stretcher to make sure that the mattress is secure. Non-use may result in patient harm due to mattress movement.

- (1) Fowler (A) **Velcro** pile (0785-034-007)
- (2) **Velcro** pile (adhesive back) (B) (0785-034-005)

Note - This kit is to attach the mattress to the Model 0747 Transport Stretcher frame. If the **Velcro** pattern on the mattress does not match the pattern on the frame, please follow these instructions.

Tools required

- Tape measure

Procedure

Note - Remove the product from service before you perform this upgrade.

1. Raise the product to the highest height position.
2. Remove and save the mattress.
3. Push down on the brake pedal to apply the brake.
4. Wipe the surface with isopropyl alcohol (70% alcohol).
5. Allow the surface to dry for at least two minutes.
6. Remove the backing on the Fowler **Velcro** (A) and apply the **Velcro** to the surface of the Fowler (Figure 1).

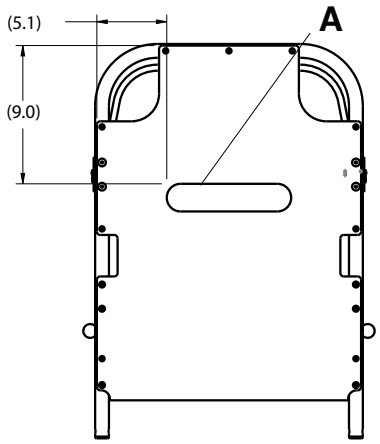


Figure 1 – Apply Velcro to the Fowler

7. Press on the center of the **Velcro** and all edges to secure to the surface.
8. Allow the adhesive to cure for at least one hour before you return the product to service.

   Note - For best results, allow the adhesive to cure for 24 hours before you return the product to service.
9. Repeat steps 1-8 to replace the **Velcro** (B) at the foot end (Figure 2).

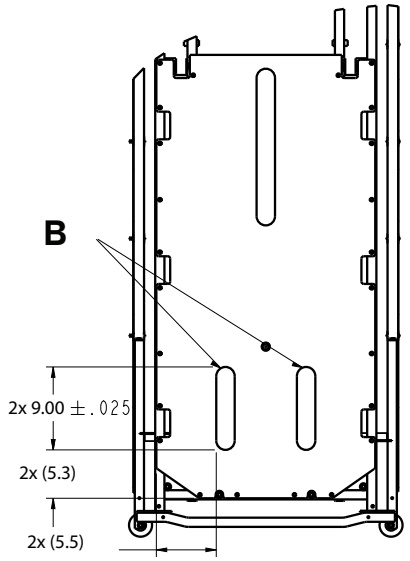


Figure 2 – Apply Velcro to the foot end

10. Verify proper operation before you return the product to service.

Accessories and parts

These parts are currently available for purchase. Call Stryker Customer Service: 1-800-327-0770 for availability and pricing.

Name	Number
Cover assembly 30”	1805-034-335
Cover assembly 26”	1805-034-635

Preventive maintenance

Remove product from service before performing preventive maintenance. At a minimum, check all items listed during annual preventive maintenance for all Stryker Medical products. You may need to perform preventive maintenance checks more frequently based on your level of product usage.

Note - Wash the exterior of the support surface before inspection, if applicable.

Inspect the following items:

_____ Zipper and covers (top and bottom) are free of tears, cracks, cuts, holes, or other openings

_____ Internal components for signs of staining from fluid ingress or contamination by fully unzipping the covers

_____ Labels for legibility, proper adherence, and integrity

_____ Foam and gel components have not degraded or come apart

Product serial number:	
Completed by:	Date:

Cleaning and disinfecting with wipes

For United States only. Confirm availability for your configuration or region. Call Stryker Customer Service: 1-800-327-0770.

Stryker’s preferred wipes (2060-000-001 6" x 10" or 2060-000-002 9" x 12") include the following active ingredients:

- n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride - 0.154%
- n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride - 0.154%
- Isopropanol - 21.000%

Non-active ingredient: Ethylene Glycol Monobutyl Ether – < 3%

Note - For safety information, read the product label.

To clean or disinfect the external product surface:

1. To clean, wipe external surfaces with a fresh, clean wipe to remove all visible soils. Repeat as necessary until the product is clean.

   Note
   - Use as many wipes as necessary.
   - Complete step 1 before you disinfect.
2. To disinfect, wipe external surfaces with a fresh, clean wipe until wet. Allow the external surface to remain wet for two minutes at room temperature.
3. Allow the product to dry before you return it to service.

Support surface care

WARNING

- Do not wash the internal components of this support surface. Discard the support surface if a contamination is found inside.
- Do not immerse the support surface.
- Do not allow liquid to pool on the support surface.
- Always inspect support surface covers (top and bottom) for tears, punctures, excessive wear, and misaligned zippers before each use. If compromised immediately remove the support surface from service.
- Always make sure that you wipe each product with clean water and thoroughly dry each product after any application of chemical solutions. Some chemical solutions are corrosive in nature and may cause damage to the product if you use them improperly. If you do not properly rinse and dry the product, a corrosive residue may be left on the surface of the product that may cause premature degradation of critical components. Failure to follow these instructions may void your warranty.

CAUTION

- Do not allow liquid to seep into the zipper area or watershed cover barrier when washing the underside of the support surface. Fluids allowed to come in contact with the zipper may leak into the support surface.
- Do not iron, dry-clean, or tumble dry the support surface covers.
- Do not power wash the support surface as this may damage the product.
- Always completely dry the support surface covers before storing, adding linens, or placing a patient on the surface. Drying the product helps to prevent the performance of the product from being impaired.
- Do not over expose the covers to higher concentration chemical solutions as these may degrade the covers.
- Do not use accelerated hydrogen peroxides or quaternaries that contain glycol ethers as they may damage the cover and reduce the legibility of the graphics.
- Failure to follow manufacturing instructions may also affect useful life of the support surface cover.

The support surface cover is resistant to the following chemical solutions:

- Quaternaries (active ingredient - ammonium chloride) that contain less than 3% glycol ether
- Phenols (active ingredient - o-phenylphenol)
- Chlorinated bleach solution (use 1 part bleach (5.25% sodium hypochlorite) to 10 parts of water which equals 4773 ppm of available chlorine (400 mL of a 5.25% bleach solution per 4000 mL water))
- 70% isopropyl alcohol

Follow hospital protocol for support surface care in between patients to avoid the risk of cross-contamination and infection.

Cover replacement

WARNING - Do not wash the internal components of this support surface. Discard the support surface if a contamination is found inside.

Tools required:

- None

Procedure:

1. Unzip the cover.
2. Fold the top of the cover to the patient's right side and then remove the foam crib assembly from the stretcher and set aside.
3. Discard the old cover.
4. Place the new cover, unzipped and open, on the frame with the grey bottom cover on the litter and the top cover folded over the patient's right side of the stretcher.
5. Carefully place the foam crib assembly on top of the bottom part of the cover to make sure that the foam crib is Align with the cover.
6. Fold the top cover over the top of the foam crib assembly. Make sure that the top cover is aligned with the foam crib assembly.
7. Zip the cover to close.

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