ComfortGel support surface

Operations Manual

REF 2850

EN

2850-109-001 Rev AB.0 2024-08

Symbols

	Consult instructions for use
	General warning
	Patient stability and siderails coverage may be compromised with the use of an overlay
	Caution
REF	Catalogue number
SN	Serial number
LOT	Batch code
EC REP	Authorized representative in the European Community
CH REP	Authorized representative in Switzerland
MD	European medical device
US Patents	For US Patents see www.stryker.com/patents
	Manufacturer
	Date of manufacture
	CE mark
UK CA	UK Conformity Assessment mark
	Importer
UDI	Unique device identifier
	Safe working load
	Mass of equipment

	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
	This side up
	Fragile
	Do not use sharp objects to open the package
	Do not use hand hooks

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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 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 leave the bed frame in the lowest position when the patient is unattended to help reduce the number and severity of falls.
- 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.
- 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.
- Do not use the support surface on a larger or smaller bed frame width or length to avoid the risk of the support surface sliding and patient injury.
- Do not use the support surface when gaps are present. The risk of entrapment can develop when the support surface is placed on bed 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 use the support surface handles to lift or move the support surface with a patient on board.
- Do not exceed the safe working load of the hospital bed frame when supporting both the patient and 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 the transfer bridge to fill the gap. The transfer bridge is meant to ease transfer of a patient from one patient support platform to another.
- Do not use a transfer bridge to support patient load.
- 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 you find contamination inside.
- Do not immerse the support surface in cleaning or disinfectant solutions.
- Do not allow fluid to pool on the support surface.
- Always inspect support surface covers (top and bottom) for tears, punctures, excessive wear, and misaligned zippers each time the covers are cleaned. If compromised immediately remove the support surface from service and replace the covers to prevent cross-contamination.
- Always perform preventative maintenance more often based on the usage level of the product. An increase in product use may include more frequent cleaning and disinfection, which may affect the life of the support surface.
- Always make sure that you wipe each product with clean water and dry each product after you clean. Some cleaning agents are corrosive in nature and may cause damage to the product. Failure to follow these cleaning instructions may void your warranty.
- Always disinfect the support surface between patients to avoid the risk of cross-contamination and infection.
- Do not allow fluid to pool on the support surface.

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 for use with this product before you operate.
- Do not allow fluid to seep into the zipper area or watershed cover barrier when you clean 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 cause malfunction and damage the product.
- Always dry the support surface covers before you store, add linens, or place a patient on the surface. Dry the product to help prevent the performance of the product from impairment.
- Do not over expose the covers to higher concentration disinfectant 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.

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

The Stryker Model 2850 ComfortGel is a non-powered support surface that assists in improving human patient outcomes by focusing on equalizing pressure and enhancing comfort.

Intended use

The Model 2850 support surface is intended to assist in the prevention and treatment of Pressure Injury Stages (1, 2, 3, 4, Unstageable, and Deep Tissue Injury) and is recommended to be implemented in combination with clinical evaluation of risk factors and skin assessments made by a health care professional.

Intended users

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

This product is not intended to be used in a home health environment or with a patient less than two years of age. This product is not sterile, does not include a measuring function, and should not be used to support a patient in a prone position.

Clinical benefits

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

Contraindications

None known.

Expected service life

The ComfortGel support surface has a five year expected service life under normal use conditions and with appropriate periodic maintenance.

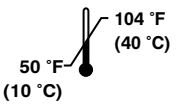
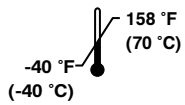
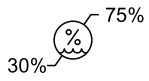
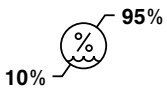
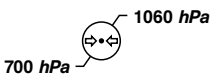
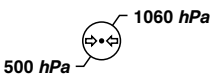
The ComfortGel cover has a three year expected service life under normal use conditions and with appropriate periodic maintenance.

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	500 lb	226.8 kg
	Note - The patient must not exceed safe working load specified by the support surface.	
Model	2850-000-013, 2850-000-015	2850-000-014
Dimensions	84 in. x 35 in. x 7 in.	213.4 cm x 88.9 cm x 17.8 cm
Product compliance	Without fire barrier	With fire barrier
Compliance reference	16 CFR 1632 EN 597-1 EN 597-2 Canada-Method 27.7-1979 of CAN 2-4.2 M77	16 CFR 1632 16 CFR 1633 CAL TB 129 Canada Method 27.7-1979 of CAN 2-4.2 M77 BOSTON-BFD IX - 11 UNI 9175 Class 1.IM EN 597-1 EN 597-2 BS 6807
This product is compatible with Stryker bed frames and other flat deck frames that can support these dimensions:	84 in. x 35 in.	213.4 cm x 88.9 cm

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.

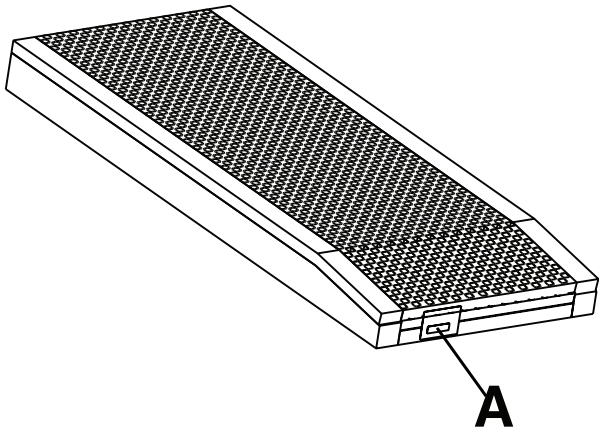
Stryker Medical
3800 E. Centre Avenue
Portage, MI 49002
USA

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



Date of manufacture

The date of manufacture is the first six digits of the serial number.

YYYYMM (YYYY = year and MM = month)

Setup

WARNING

- 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 leave the bed frame in the lowest position when the patient is unattended to help reduce the number and severity of falls.
- 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.
- 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.
- Do not use the support surface on a larger or smaller bed frame width or length to avoid the risk of the support surface sliding and patient injury.
- Do not use the support surface when gaps are present. The risk of entrapment can develop when the support surface is placed on bed 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.

To install the support surface:

1. Make sure that the support surface fits the bed frame that the product is being placed on.
2. Make sure that the dedicated sloped heel section is installed at the foot end of the bed 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 use the support surface handles to lift or move the support surface with a patient on board.
- 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 hospital bed frame when supporting both the patient and 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 the transfer bridge to fill the gap. The transfer bridge is meant to ease transfer of a patient from one patient support platform to another.
- Do not use a transfer bridge to support patient load.
- 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 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 for use with this product before you operate.

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, 84 x 35 x 7 (213.4 cm x 88.9 cm x 17.8 cm)	2850-030-100
Cover assembly, 84 x 35 x 7 (213.4 cm x 88.9 cm x 17.8 cm) (International)	2850-130-100
Fire barrier sleeve	2850-035-001

Preventive maintenance

Remove the product from service before you perform the preventive maintenance inspection. Check all items listed during annual preventive maintenance for all Stryker Medical products. You may need to perform preventive maintenance checks more often based on your level of product usage. Service only by qualified personnel.

Note - Clean and disinfect the exterior of the support surface before inspection, if applicable.

Inspect the following items:

_____ Zipper and covers (top and bottom) for tears, 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

_____ Handles for rips, cracks, stitching, or other visible signs of damage

_____ Cover straps for rips, cracks, or tears

_____ Straps secure the support surface to the crib assembly

_____ Foam and other components have not degraded or come apart

_____ Compression set of the foam is less than 1.25” (3.2 cm) (see *Checking the compression set of the foam* (page 10))

_____ Fire barrier option for rips, cracks, or other visible signs of damage (If excessive wear of the fire barrier is observed, replacement is recommended)

Product serial number:
Completed by:
Date:

Checking the compression set of the foam

Tools required:

- ≥ 35” straight edge
- Tape measure

Procedure:

1. Raise the product to the highest height position.
2. Lower the Fowler and Gatch sections to the lowest height positions.

   Note - Before you take the compression set measurement, make sure that there has not been a patient on the support surface for a minimum of one hour.
3. Unzip the cover. Start at the foot end patient right corner of the support surface and stop at the head end patient right corner.
4. Fold the top of the cover to the patient right side.
5. If the support surface has the fire barrier option, start at the foot end and roll up the fire barrier on the foam crib assembly.

   Note - Work from side to side a little at a time to get the fire barrier past the seat section of the foam crib.
6. Place a straight edge (at least 35 in. (88.9 cm) long) across the foam crib from left to right at the sacral region (patient seat section) of the support surface (Figure 1).
7. Using a tape measure, measure the maximum depth (lowest point) from the bottom of the straight edge to the top of the foam (Figure 2).

   Note - Do not push down on the tape measure when you take the measurement. The tape measure should just lightly touch the top of the foam.

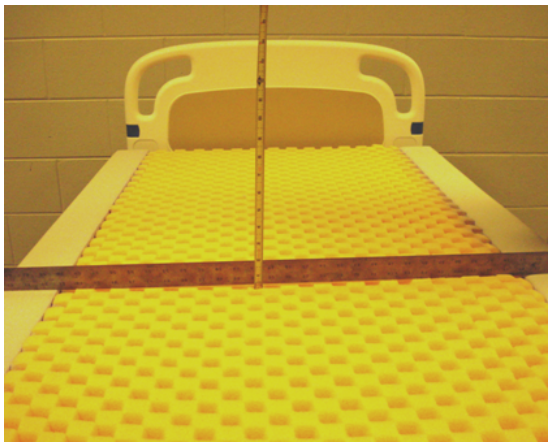


Figure 1 – Straight edge

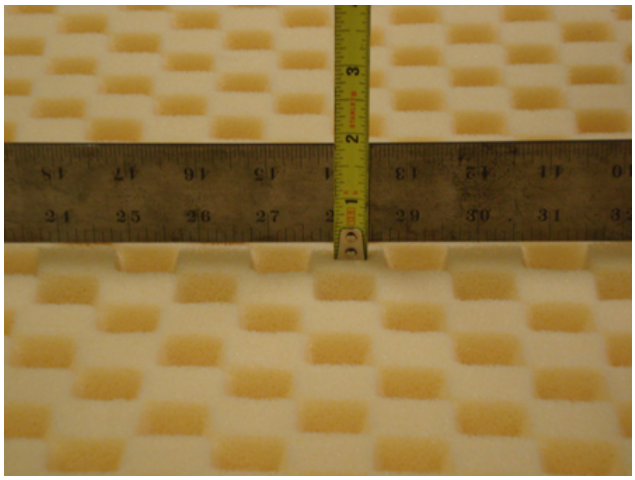


Figure 2 – Measure maximum depth

8. Document the date of the measurement, serial number, and measurement. This information will be required for warranty information, if applicable.

   Note

   - If the measurement is greater than 1.25 in. (3.2 cm), the compression set is out of tolerance. Replace the support surface. Call Customer Service at 1-800-327-0770 with the information recorded above for a replacement support surface.
   - The foam assembly of the support surface will naturally compress over time. If a compression set measurement is greater than 1.25 in. (3.2 cm) at the life of the product, Stryker will provide a replacement support surface. The support surface will not be replaced for normal body indentations or a compression set of less than 1.25 in. (3.2 cm). A Stryker representative must take the measurement.

9. Reverse steps to reinstall.
10. Verify proper operation before you return the product to service.

Cover replacement

Tools required:

- None

Procedure:

1. Raise the product to the highest height position.
2. Lower the Fowler and Gatch sections to the lowest height positions.
3. Unzip the cover. Start at the foot end patient right corner of the support surface and stop at the head end patient right corner.
4. Fold the top of the cover to the patient right side and then remove the foam crib assembly from the bed and set aside.
5. Remove and discard the cover.
6. Place the replacement cover, unzipped and open, on the bed with the black bottom cover on the litter and the top cover folded over the patient right side of the bed.
7. Place the foam crib assembly on top of the bottom part of the cover. Make sure that the foam crib aligns with the cover.
8. Fold the top cover over the top of the foam crib assembly. Make sure that the top cover aligns with the foam crib assembly.
9. Zip the cover to close. Start at the head end patient right corner and stop at the foot end patient right corner.
10. Verify proper operation before you return the product to service.

Fire barrier replacement

Tools required:

- None

Procedure:

1. Raise the product to the highest height position.
2. Lower the Fowler and Gatch sections to the lowest height positions.
3. Unzip the cover. Start at the foot end patient right corner of the support surface and stop at the head end patient right corner.
4. Fold the top of the cover to the patient right side.
5. Starting at the foot end, roll up the fire barrier on the foam crib assembly.

   Note - Work from side to side, a little at a time, to move the fire barrier to the top of the support surface.
6. Remove and discard the old fire barrier.
7. Starting at the head end, roll the new fire barrier down and slide over the foam crib assembly.

   Note - Align the fire barrier on the foam crib before sliding over the foam crib assembly.
8. Slide the fire barrier down the foam crib assembly, work from side to side. Make sure that the fire barrier is tight on the foam crib assembly.
9. Align the foam crib assembly on top of the bottom part of the cover.

   Note - Spread the excess fire barrier material below the foam crib assembly at the foot end.
10. Fold and align the top cover over the top of the foam crib assembly.
11. Zip the cover to close. Start at the head end patient right corner and stop at the foot end patient right corner.
12. Verify proper operation before you return the product to service.

Cleaning and disinfecting with SideKick

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

Stryker’s preferred 6" x 10" wipes (2060-000-001) 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 with SideKick wipe:

To clean:

1. Wipe down the external product surface with a fresh, clean wipe to remove all visible soils.
2. Repeat as necessary until the external product surface is visibly clean.
3. Wipe dry with a cloth or allow the external product surface to air dry before you return the product to service.

Note - Use as many wipes as necessary.

To disinfect:

1. Clean first.
2. Wipe down the external product surface with a fresh, clean wipe until wet.
3. Allow the external product surface to remain wet for two minutes at room temperature.
4. Wipe dry with a cloth or allow the external product surface to air dry before you return the product to service.

Cleaning

WARNING

- Do not wash the internal components of this support surface. Discard the support surface if you find contamination inside.
- Do not immerse the support surface in cleaning or disinfectant solutions.
- Do not allow fluid to pool on the support surface.
- Always inspect support surface covers (top and bottom) for tears, punctures, excessive wear, and misaligned zippers each time the covers are cleaned. If compromised immediately remove the support surface from service and replace the covers to prevent cross-contamination.
- Always perform preventative maintenance more often based on the usage level of the product. An increase in product use may include more frequent cleaning and disinfection, which may affect the life of the support surface.
- Always make sure that you wipe each product with clean water and dry each product after you clean. Some cleaning agents are corrosive in nature and may cause damage to the product. Failure to follow these cleaning instructions may void your warranty.

CAUTION

- Do not allow fluid to seep into the zipper area or watershed cover barrier when you clean 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 cause malfunction and damage the product.
- Always dry the support surface covers before you store, add linens, or place a patient on the surface. Dry the product to help prevent the performance of the product from impairment.

Always follow hospital protocol for cleaning and disinfecting.

To clean the support surface covers between patient uses:

1. Use a clean and soft cloth with a mild soap and water solution to remove foreign material from the support surface covers.
2. Wipe the support surface covers with a clean, dry cloth to remove excess fluid or cleaning agent.
3. Check that the product is dry.

Disinfecting

WARNING

- Always disinfect the support surface between patients to avoid the risk of cross-contamination and infection.
- Always make sure that you wipe each product with clean water and dry each product after you clean. Some cleaning agents are corrosive in nature and may cause damage to the product. Failure to follow these cleaning instructions may void your warranty.
- Do not immerse the support surface in cleaning or disinfectant solutions.
- Do not allow fluid to pool on the support surface.

CAUTION

- Always dry the support surface covers before you store, add linens, or place a patient on the surface. Dry the product to help prevent the performance of the product from impairment.
- Do not over expose the covers to higher concentration disinfectant solutions as these may degrade the covers.
- Do not allow fluid to seep into the zipper area or watershed cover barrier when you clean the underside of the support surface. Fluids allowed to come in contact with the zipper may leak into the support surface.
- Do not use accelerated hydrogen peroxides or quaternaries that contain glycol ethers as they may damage the cover.

Recommended disinfectants:

- Quaternaries (active ingredient - ammonium chloride) that contain less than 3% glycol ether
- Phenolic disinfectants
- Chlorinated bleach solution (5.25% bleach 1:100 dilution with water)
- 70% Isopropyl alcohol

To disinfect the support surface covers after each patient use, follow these steps in order:

1. Clean and dry the support surface covers before you apply disinfectants.
2. Apply recommended disinfectant solution by spray or pre-soaked wipes (do not soak the support surface).

   Note - Make sure that you follow the disinfectant's instructions for appropriate contact time and rinsing requirements.
3. Wipe the support surface covers with a clean, dry cloth to remove any excess fluid or disinfectant.
4. Allow the support surface covers to dry before you return to service.

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

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WCR: AF.6