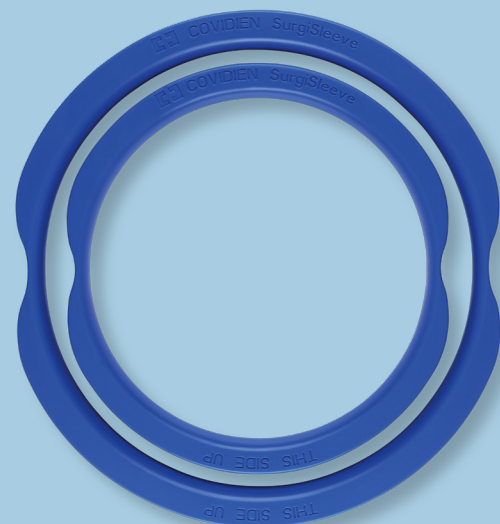


MAXIMIZED EXPOSURE. WOUND PROTECTION. **SUPERIOR STRENGTH.¹**

Product Information Guide

SurgiSleeve™ Wound Protector
with Retraction Ring



Medtronic
Further, Together

SurgiSleeve™ wound protector is ideal for colorectal, thoracic, cardiac, OB/GYN, and other open/laparoscopic abdominal procedures


Wound protectors can be used to retract an incision site, increase exposure to the body, and more importantly, help protect against wound contamination²⁻⁶. With our portfolio of SurgiSleeve™ wound protectors, you get the maximum field of vision with added protection and strength, so you can focus more on the patient without having to worry about the performance of your protector.

The portfolio of SurgiSleeve™ wound protectors:

- Are easy to use
- Are superior in film strength to Alexis™* wound protector/retractors¹
- Offer equivalent or greater exposure vs. Alexis™* O with a retraction ring in the large and extra-large sizes^{7,8}
- Are economically efficient
- Provide the choice you need for the procedure at hand



Product details

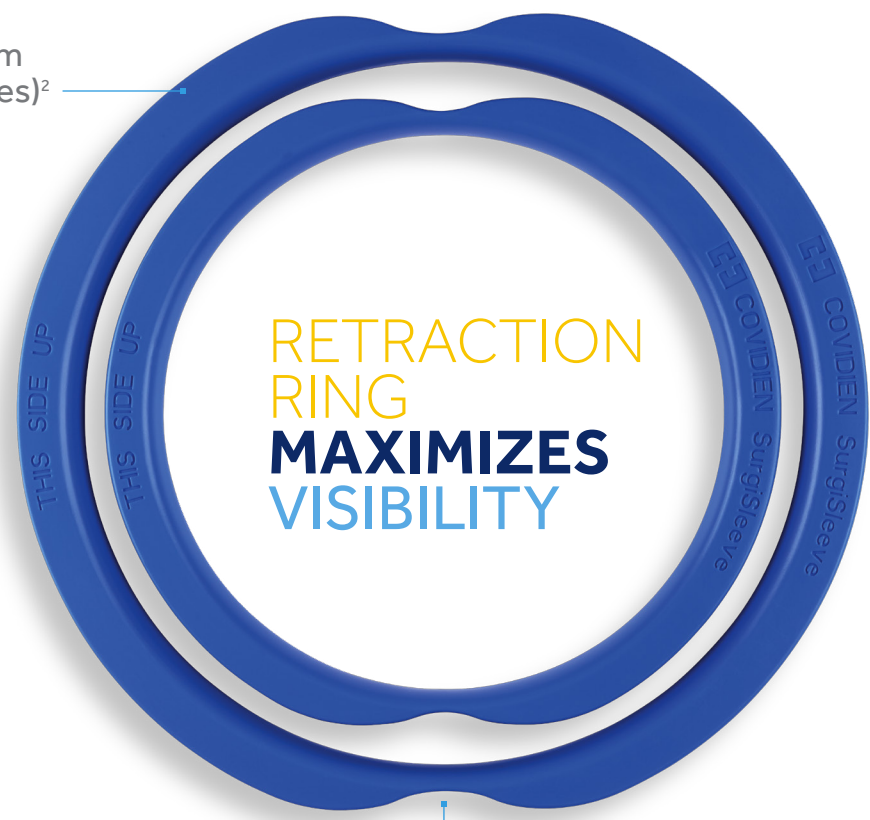


Retraction Ring
Provides greater retraction and visibility versus standard wound protectors and a stable platform for access to the body (large and extra-large sizes)²

Blue Proximal Ring
Adjusts to variable thicknesses of the abdominal wall and is easy to roll down

3X Stronger Material¹
Offers optimal wound protection

Flexible Gray Distal Ring
Easily inserted and removed through the incision

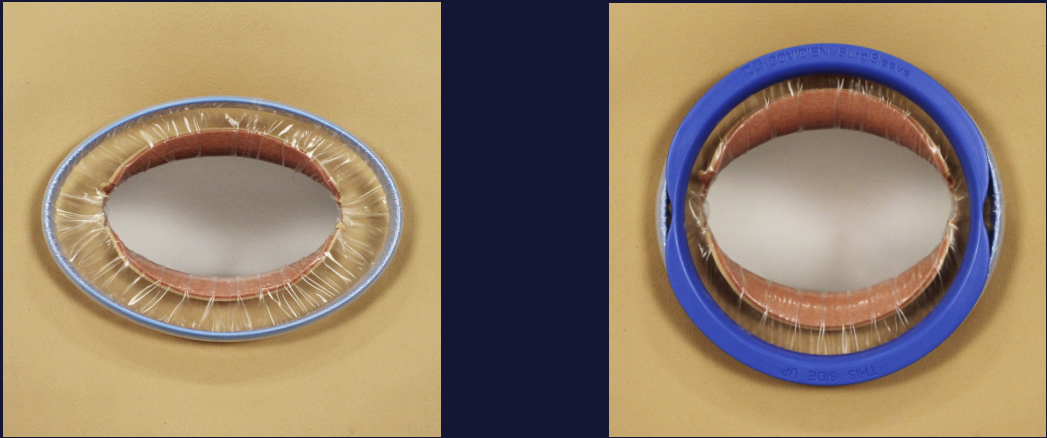


**RETRACTION RING
MAXIMIZES
VISIBILITY**

Finger Cutouts
Facilitate easy insertion and removal of the retraction ring

Maximized Wound Exposure

More incision retraction area — up to 9% on the extra-large and up to 17% on the large size.⁷



Circumferential elastic retraction ring maximizes working area for optimal exposure and visualization.

SurgiSleeve™ Wound Protector Outperforms Alexis™ O

Compared with Alexis™ O, the SurgiSleeve™ Wound Protector offers:

Retraction Ring

- Equivalent or greater wound exposure⁹

Superior strength

- Film material is 3X stronger¹

As fast/faster to use

- Including the retraction ring⁸

Easier to roll down

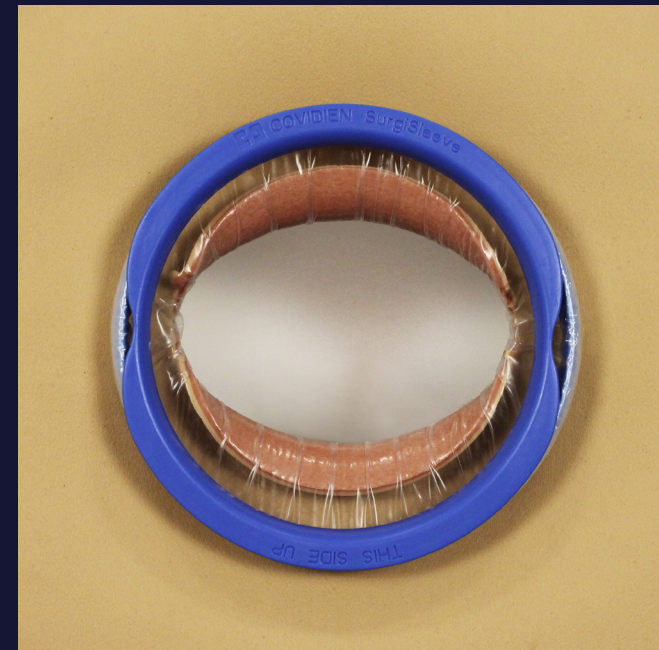
- Flexible proximal ring for easy roll down⁸

Easy to use

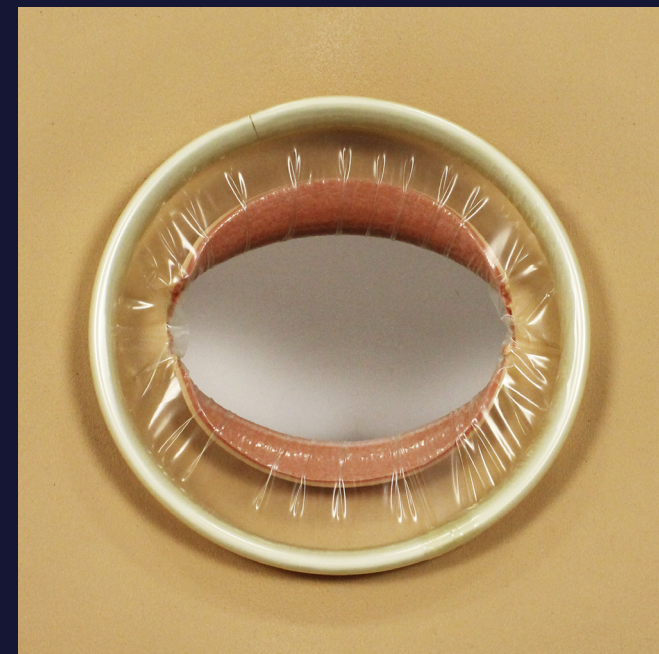
- Large and extra-large retraction rings are fast to place and remove⁸

Standardized

- 5 SKUs cover all your wound protection needs versus 15 SKUs for Alexis™ O wound protector/retractor



Equal or Greater Wound Exposure with SurgiSleeve™ Wound Protector with Retraction Ring



Alexis™ O Wound Protector

Cost Savings and Hassle-Free Conversion Process

Cost Savings

Save an average of 25% – 30% when switching from Alexis™ wound protector.¹⁰ Our partner hospitals could save even more through our flexible contracting system.

Product Standardization and SKU Reduction

Decrease SKUs from 15 to 5 to help reduce inventories and save cost.

Hassle-Free Conversion Process'

No technique changes are required when switching from the Alexis™ wound protector.

Competitive Product	Competitive Code	Quantity	Unit Price	Total	SurgiSleeve™ Code	Quantity	Unit Price	Total
Alexis™(XXS) Short	C8323				WPXSM24 (XS)			
Alexis™(XXS)	C8313				WPXSM24 (XS)			
Alexis™ (XS) Short	C8322				WPXSM24 (XS)			
Alexis™ (XS)	C8312				WPXSM24 (XS)			
Alexis™ (SM)	C8301				WPSM256 (SM)			
Alexis™ (MED)	C8302				WPMD509 (MED)			
Alexis™ (LG)	C8303				WPLGR914 (LG)			
Alexis™ (XL)	C8304				WPXLGR1117 (XL w/RR)			
Alexis™ O (SM)	C8401				No Match			
Alexis™ O (MED)	C8402				No Match			
Alexis™ O (LG)	C8403				WPLGR914 (LG w/RR)			
Alexis™ O (XL)	C8404				WPXLGR1117 (XL w/RR)			
Alexis™ O (XXL)	C8405				No Match			
Alexis™ C-Section (LG)	G6303				WPLGR914 (LG w/RR)			
Alexis™ O C-Section (LG)	G6313				WPLGR914 (LG w/RR)			
Mobius™ (MINI)	900-508				WPSM256 (SM)			
Mobius™ (SM)	900-500				WPSM256 (SM)			
Mobius™ (MED)	900-515				WPMD509 (MED)			
Mobius™ (MED-LG)	900-517				WPLGR914 (LG w/RR)			
Mobius™ (LG)	900-520				WPXLGR1117 (XL w/RR)			

CURRENT SPEND: \$

Total Savings: \$

PROPOSED SPEND: \$

Percent Savings: %

Note: The data above is an example of how the cost analysis tool works

SurgiSleeve™ wound protectors are packaged 5 units per box with five different sizes



SurgiSleeve™ Wound Protector Sizes and Reorder Codes

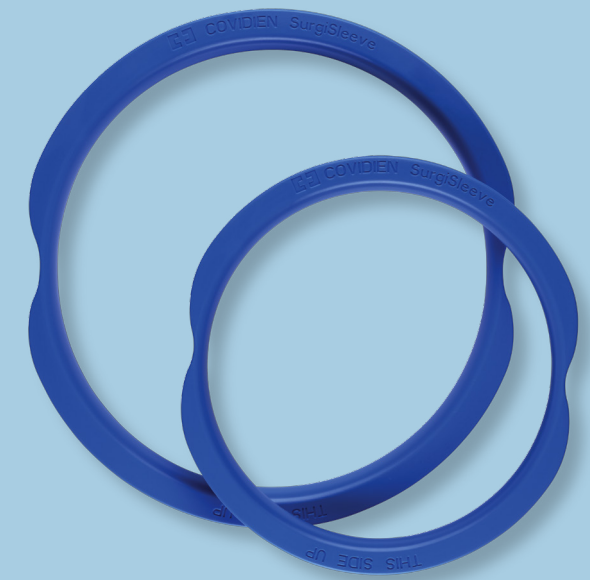
Reorder Codes	Size	Incision Size	Quantity per Box
WPXSM24	Extra Small	2 – 4 cm	5
WPSM256	Small	2.5 – 6 cm	5
WPMD509	Medium	5 – 9 cm	5
WPLG914	Large	9 – 14 cm	5
WPLGR914	Large with Retraction Ring	9 – 14 cm	5
WPXLGR1117	Extra Large with Retraction Ring	11 – 17 cm	5

Procedure Applications

Specialty	Application	XS	S	M	L	XL
OB/GYN	C-Section				•	•
Colorectal	Open/Laparoscopic		•	•	•	•
General/Bariatric	Open/Laparoscopic		•	•	•	•
Thoracic	VATS/MIS	•	•			



Cross-Reference Guide



Competitor	Competitive Product Code	Size	Incision Size
Applied			
Alexis™	C8323	Extra Extra Small, Short	1 – 3 cm
Alexis™	C8313	Extra Extra Small	1 – 3 cm
Alexis™	C8322	Extra Small, Short	2 – 4 cm
Alexis™	C8312	Extra Small	2 – 4 cm
Alexis™	C8301	Small	2.5 – 6 cm
Alexis™	C8302	Medium	5 – 9 cm
Alexis™	C8303	Large	9 – 14 cm
Alexis™	C8304	Extra Large	11 – 17 cm
Alexis™ O	C8401	Small	2.5 – 6 cm
Alexis™ O	C8402	Medium	5 – 9 cm
Alexis™ O	C8403	Large	9 – 14 cm
Alexis™ O	C8404	Extra Large	11 – 17 cm
Alexis™ O	C8405	Extra Extra Large	17 – 25 cm
Alexis™ O C-Section	G6313	Large	9 – 14 cm
Alexis™ O C-Section	G6314	Extra Large	11 – 17 cm

Cooper Surgical

OR Mobius™	900–508	Mini	2 – 6 cm
OR Mobius™	900–500	Small	4 – 9 cm
OR Mobius™	900–515	Medium	8 – 14 cm
OB Mobius™ C-Section	900–517	Retractor Medium – Large	9 – 15 cm
OB Mobius™ C-Section	900–520	Retractor Large	12 – 17 cm

SurgiSleeve™ Product Code	Size	Incision Size
WPXSM24*	Extra Small	2 – 4 cm
WPXSM24*	Extra Small	2 – 4 cm
WPXSM24*	Extra Small	2 – 4 cm
WPXSM24	Extra Small	2 – 4 cm
WPSM256	Small	2.5 – 6 cm
WPMD509	Medium	5 – 9 cm
WPLG914	Large	9 – 14 cm
WPXLGR1117	Extra Large w/ Retraction Ring	11 – 17 cm
No Match		
No Match		
WPLGR914	Large w/ Retraction Ring	9 – 14 cm
WPXLGR1117	Extra Large w/ Retraction Ring	11 – 17 cm
No Match		
WPLGR914	Large w/ Retraction Ring	11 – 17 cm
WPXLGR1117	Extra Large w/ Retraction Ring	11 – 17 cm
WPSM256	Small	2.5 – 6 cm
WPMD509	Medium	5 – 9 cm
WPLG914	Large	9 – 14 cm
WPLGR914	Large w/ Retraction Ring	9 – 14 cm
WPXLGR1117	Extra Large w/ Retraction Ring	11 – 17 cm

Instructions for Use



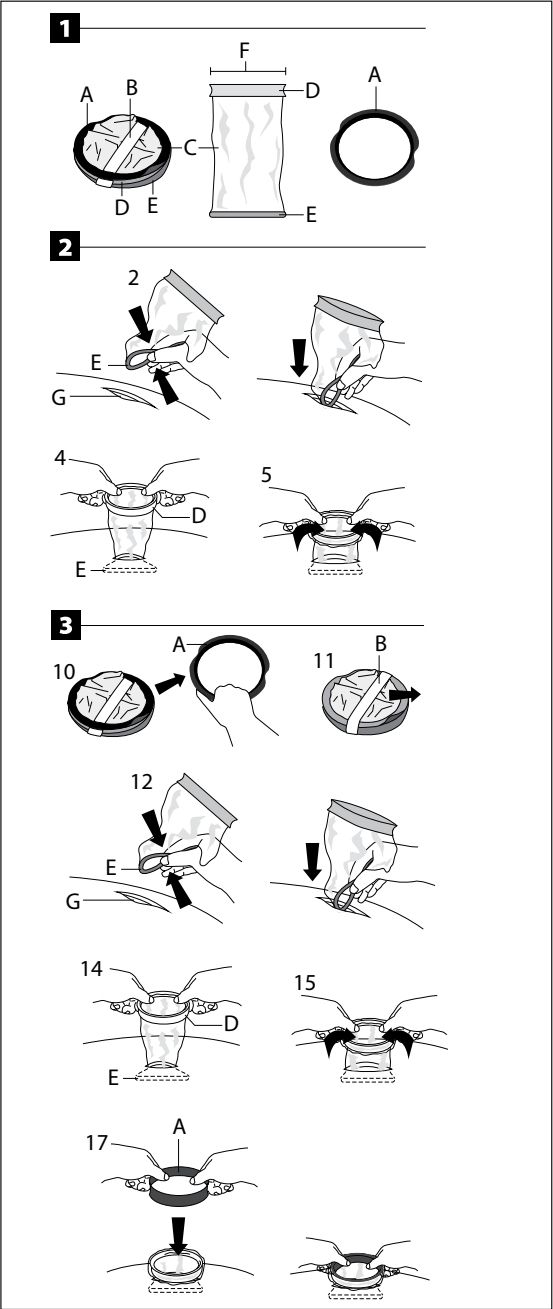
SurgiSleeve™

Wound Protector

SurgiSleeve™

Wound Protector with Retraction Ring

1080851



EN

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination, patient infection and/or device malfunction. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The SurgiSleeve™ wound protector is a one piece design consisting of a sheath film with a ring on both ends. The retraction ring is a separate piece, which is available on the large and extra large sizes only.

INDICATIONS

The SurgiSleeve™ wound protector is indicated for use to access the abdominal cavity during surgery through an atraumatically retracted incision, deliver maximum exposure of the abdominal cavity with minimum incision size, and protect against wound contamination during laparoscopic and open surgery. Additionally, the small size wound protector is indicated for use to access the thoracic cavity during cardiac and general surgical procedures through an atraumatically retracted incision. The extra small wound protector is also indicated for use to access the thoracic cavity and other soft tissue retraction during cardiac and general surgical procedures through an atraumatically retracted incision.

CONTRAINDICATIONS

Use of the SurgiSleeve™ wound protector is contraindicated when, in the judgment of the physician, use of this device would be contrary to the best interest of the patient.

WARNINGS AND PRECAUTIONS

Use care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the SurgiSleeve™ wound protector.

This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

1 SCHEMATIC VIEW

A) RETRACTION RING (available for large and extra large sizes only)

B) SHIPPING WEDGE

C) SLEEVE

D) BLUE PROXIMAL RING

E) GRAY DISTAL RING

F) SurgiSleeve™ WOUND PROTECTOR

INSTRUCTIONS FOR USE

2 SurgiSleeve™ wound protector without retraction ring

1. Prepare the abdominal or thoracic cavity for the SurgiSleeve™ wound protector by making an incision adequate to accommodate the wound protector.

2. Insert the gray distal ring of the SurgiSleeve™ wound protector into the incision.

G) INCISION

3. Examine and sweep the incision area to ensure that tissue is not caught between the ring and the abdominal wall.

4. Grasp the blue proximal ring in a manner that your hands are opposite to each other. Pull up on the blue proximal ring ensuring that the gray distal ring is fully seated against the peritoneal layer.

D) BLUE PROXIMAL RING

E) GRAY DISTAL RING

5. Roll the blue proximal ring inward by curling the edge over until the ring fully inverts.

6. Repeat step 5 until the incision is retracted and the SurgiSleeve™ wound protector is tight against the walls of the incision.

Removing the SurgiSleeve™ wound protector

7. If necessary, unroll the blue proximal ring of the SurgiSleeve™ wound protector.

8. Insert hand or finger through the opening, grasp gray distal ring and pull gray distal ring out of the incision.

3 SurgiSleeve™ wound protector with retraction ring

9. Prepare the abdominal cavity for the SurgiSleeve™ wound protector by making an incision adequate to accommodate the wound protector.

10. Remove the retraction ring from the SurgiSleeve™ wound protector.

A) RETRACTION RING

11. Remove the shipping wedge from the SurgiSleeve™ wound protector.

B) SHIPPING WEDGE

12. Insert the gray distal ring of the SurgiSleeve™ wound protector into the incision.

E) GRAY DISTAL RING

G) INCISION

13. Examine and sweep the incision area to ensure that tissue is not caught between the ring and the abdominal wall.

14. Grasp the blue proximal ring in a manner that your hands are opposite to each other. Pull up on the blue proximal ring ensuring that the gray distal ring is fully seated against the peritoneal layer.

D) BLUE PROXIMAL RING

E) GRAY DISTAL RING

15. Roll the blue proximal ring inward by curling the edge over until the ring fully inverts.

16. Repeat step 15 until the incision is retracted and the SurgiSleeve™ wound protector is tight against the walls of the incision.

17. Insert the retraction ring into the blue proximal ring for additional stiffness and to provide increased retraction of the incision. Ensure that the logo on the retraction ring is facing up.

A) RETRACTION RING

18. Ensure that the retraction ring is fully inserted 360 degrees around the proximal ring before proceeding.

Removing the SurgiSleeve™ wound protector with retraction ring

19. Remove the retraction ring from the blue proximal ring. Use the finger cutouts on the retraction ring to facilitate removal.

20. Unroll the blue proximal ring of the SurgiSleeve™ wound protector.

21. Insert hand or finger through the opening, grasp gray distal ring and pull gray distal ring out of the incision.

Incision Size Chart

Wound Protector Size	Incision Size
Extra Small	2 - 4 cm
Small	2.5 - 6 cm
Medium	5 - 9 cm
Large	9 - 14 cm
Extra Large	11 - 17 cm

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.



Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage. / Bei geöffnetem oder beschädigter Verpackung nicht verwenden. / Non utilizzare se la confezione è aperta o danneggiata. / No usar el dispositivo si la envoltura está abierta o dañada. / Não utilizar se a embalagem estiver aberta ou danificada. / Niet gebruiken als de verpakking beschadigd of geopend is. / Får ej användas om förpackningen är öppnad eller skadad. / Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. / Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. / Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά. / Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone. / Ambalaj açılmış ya da zarar görmüşse kullanmayın. / Не использовать изделие, если упаковка вскрыта или повреждена. / Pokud je balení otevřené nebo poškozené, produkt nepoužívejte. / Tilos felhasználni, ha a csomagolás kinyitlt vagy megsérült. / Neпоуживайте, ак је обал отворенј а лебо пошкоденј. / Skal ikke brukes hvis emballasjen er åpnet eller skadet. / Ne uporabljajte, če je embalaža odprta ali poškodovana. / Не използвайте, ако опаковката е отворена или повредена. / A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat. / Árge kasutage, kui pakend on avatud või kahjustatud. / Nelietot, ja iepakoјums ir atvērts vai bojāts. / Ne koristite ako je pakiranje otvoreno ili oštećeno. / Ne koristiti ako je pakovanje otvoreno ili oštećeno. / Nenaudokite, jei pakuotė atidaryta arba pažeista. / 如果包裝已打开或破損, 請勿使用. / 如果包裝已開啟或損毀, 則請勿使用. / 포장 이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오.



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Covidien IIc, 15 Hampshire Street, Mansfield, MA 02048 USA.

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2014 / 09 - 3

510(k) Clearance



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2014

Covidien LLC
Mr. Michael Koczocik
Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K143091
Trade/Device Name: Surgisleeve™ Wound Protector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, KKK
Dated: October 27, 2014
Received: October 28, 2014

Dear Mr. Koczocik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – Mr. Michael Koczocik

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

To learn more or to try the SurgiSleeve™ wound protector, contact your local Medtronic representative or customer service at 800-722-8772.

1. Based on internal report #2151-002, Comparison of mean film material strengths between SurgiSleeve™ wound protector and Alexis™ wound protector, as part of a puncture resistance material evaluation conducted on February 9, 2012. Statistically significant results p=0.004.
2. Edwards JP, Ho AL, Tee MC, Dixon E, Ball CG. Wound protectors reduce surgical site infection: a meta-analysis of randomized controlled trials. *Ann Surg.* 2012; 256(1): 53-9.
3. Horiuchi T, Tanishima H, Tamagawa K, et al. A wound protector shields incision sites from bacterial invasion. *Surg Infect (Larchmt).* 2010; 11(6):501-3.
4. Horiuchi T, Tanishima H, Tamagawa K, et al. Randomized, controlled investigation of the anti-infective properties of the Alexis retractor/protector of incision sites. *J Trauma.* 2007; 62(1):212-5.
5. Reid K, Pockney P, Draganic B, Smith SR. Barrier wound protection decreases surgical site infection in open elective colorectal surgery: a randomized clinical trial. *Dis Colon Rectum.* 2010; 53(10): 1374-80.
6. Lee P, Waxman K, Taylor B, Yim S. Use of wound-protection system and postoperative wound-infection rates in open appendectomy. *Arch Surg.* 2009;144(9): 872-5.
7. For the large and extra-large sizes, based on internal report #2151-021, SurgiSleeve™ large wound protector with retraction ring equivalence testing, October 30, 2014, and internal report #2151-023, SurgiSleeve™ extra large wound protector with retraction ring equivalence testing, November 4, 2014.
8. Voice-of-the-customer survey of 29 general and OB/GYN surgeons of SurgiSleeve™ wound protector and Alexis™ O large and extra large conducted during a product demonstration event, October 28-29, 2014, in San Francisco, CA.
9. For the large and extra-large sizes, based on internal report #2151-023, SurgiSleeve™ extra large wound protector with retraction ring equivalence testing, November 4, 2014, and voice-of-the-customer survey of 29 general and OB/GYN surgeons of SurgiSleeve™ wound protector and Alexis™ O large and extra large conducted during a product demonstration event, October 28-28, 2014, in San Francisco, CA.
10. IMS Health data, 2014.

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