June 14, 2019

UNiPACK Medical Corporation
Joe Pomparelli
Vice President
9830 Norwalk Blvd., Suite 100
Santa Fe Springs, California 90670

Re: K183263
Trade/Device Name: UNiPACK Barrier Sleeve and Barrier Film and UNiGLIDE Barrier Envelope
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: May 14, 2019
Received: May 20, 2019

Dear Joe Pomparelli:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth F. Claverie-Williams, MS
Assistant Director,
THT4B2: Disinfection Reprocessing and Personal Protection
Acting Assistant Director,
THT4B1: Sterility Devices
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Number *(if known)* K183263

Device Name

UNiPACK Barrier Sleeve and Barrier Film and UNiGlide Barrier Envelope

Indications for Use *(Describe)*

UNiPACK Barrier Sleeve and Barrier Film and UNiGlide Barrier Envelope are intended to be used as a barrier to cover dental instruments. This device is non-sterile and intended for single patient use only.

Item #	Description	Designed For
UBC-8010E	E Tray Sleeve, 11-1/2" x 16"	Instrument trays
UBC-8011A	A Tray Sleeve, 11-5/8" x 14-1/2"	Instrument trays
UBC-8012B	B Tray Sleeve, 10-1/2" x 14"	Instrument trays
UBC-8013F	F Tray Sleeve, 7-1/2" x 10-1/2"	Instrument trays
UBC-8021	Full Chair Cover, 29" x 80"	Chairs/Stools
UBC-8022	Full Chair Cover, 48" x 56"	Chairs/Stools
UBC-8023	Half Chair Cover, 27-1/2" x 24"	Chair Headrest
UBC-8024	Headrest Cover, 11" x 9-1/2" x 2"	Chair Headrest
UBC-8025	Headrest Cover, 14" x 9-1/2" x 2"	Chair Headrest
UBC-8028	Syringe Sleeve with Opening, Clear, 2-1/2"x 10"	3-way syringes, saliva ejectors and HVE valves
UBC-8029	Syringe Sleeve with Opening, Blue, 2-1/2"x 10"	3-way syringes, saliva ejectors and HVE valves
UBC-8031	T-Handle Cover (T Shape), 4" x 5-3/4"	Most T-style dental chair light handles
UBC-8032	Universal X-Ray Cover, 23" x 31"	X-Ray head, Extra-Long
UBC-8033	Universal X-Ray Cover, 15" x 26"	X-Ray head, Regular
UBC-8034	Curing Light, Pistol (Handle Only)	Curing Lights, Pen Type
UBC-80341-F	Curing Light, Pistol (Full Cover with Vented Design)	Curing Lights, Pen Type
UBC-80342-S	Curing Light, Pen Type (Small), 2" x 12-1/2"	Curing Lights, Pen Type
UBC-80343-L	Curing Light, Pen (Large), 3-1/8" x 12-1/2"	Curing Lights, Pen Type
UBC-8035	Low Speed Pen Sleeve, 1-1/2" x 9"	Curing Lights, Pen Type
UBC-8036	High Speed Universal, 1" x 9"	Curing Lights, Pen Type
UBC-8035	Low Speed Pen Sleeve, 1-1/2" x 9"	Curing Lights, Pen Type
UBC-8036	High Speed Universal, 1" x 9"	Curing Lights, Pen Type
UBC-8037	Sensor Sleeve, Size 0 - Small	Digital X-Ray sensor, universal, small, 1 3/8"X8"

Item #	Description	Designed For
UBC-8038	Sensor Sleeve, Size 2 - Large	Digital X-Ray sensor, universal, large, 1 5/8"X8"
UBC-80392	Tube Sleeve, 2" x 1200', cut to length	Dental unit tubing (2”)
UBC-80394	Tube Sleeve, 4" x 1200', cut to length	Dental unit tubing (4”)
UBC-820824	X-Ray Sensor Sheath (Schick, Size 1)	Digital X-Ray sensor (Schick/Dr. Suni Plus)
UBC-820825	X-Ray Sensor Sheath (Schick, Size 2)	Digital X-Ray sensor (Schick/Dr. Suni Plus)
UBC-820861	X-Ray Sensor Sheath (Regam, Size 2)	Digital X-Ray sensor (Regam)
UBC-820978	X-Ray Sensor Sheath (Carestream/Kodak 6100, Size 1)	Digital X Ray sensor (Kodak 6100)
UBC-820979	X-Ray Sensor Sheath (Carestream/Kodak 6100, Size 2)	Digital X Ray sensor (Kodak 6100)
UBC-820999	X-Ray Sensor Sheath (Dexis/Universal)	Digital X Ray sensor (Dexis)
UBC-820831	Intraoral Camera Covers	Pro-Den Systems/Dent-X, Pro-scope 1000 & Oral Scan, Easy Doc
UBC-820855	Intraoral Camera Covers	Siemens, Ceracam/Minicam Ultra
UBC-820963	Intraoral Camera Covers	Video Dental concepts, Quickcam Smile
UBC-821013	Intraoral Camera Covers	Digital Doc, Iris
UBE-8160	UNiGLIDE PSP Barrier Envelope Size 0	Phosphor Plate Covers
UBE-8161	UNiGLIDE PSP Barrier Envelope Size 1	Phosphor Plates Covers
UBE-8162	UNiGLIDE PSP Barrier Envelope Size 2	Phosphor Plates Covers
UBE-8050	Standard PSP Barrier Envelope Size 0	Phosphor Plates Covers
UBE-8051	Standard PSP Barrier Envelope Size 1	Phosphor Plates Covers
UBE-8052	Standard PSP Barrier Envelope Size 2	Phosphor Plates Covers
UBE-8053	Standard PSP Barrier Envelope Size 3	Phosphor Plates Covers
UBE-8054	Standard PSP Barrier Envelope Size 4	Phosphor Plates Covers
UBC-8040-U	Keyboard sleeves	Computer keyboard, universal, 22"X14"
UBC-8040-L	Keyboard sleeves	Computer keyboard, large, 19"X26"
UBC-8041	LCD & Keyboard sleeves	Computer screen and keyboard, universal
UBC-8042	Laptop sleeves	Laptop, universal
UBC-8043-S	Low-speed contra-angle handpiece sleeves w/paper backing	Dental low-speed contra-angle handpiece, universal
UBC-8043-L	Low-speed long handpiece sleeves w/paper backing	Dental low-speed long handpiece, universal
UBC-8044	Optical PC mouse barriers	Computer mouse, universal
UBC-8055	Syringe sleeve w/paper backing	Air/water syringe, universal
UBC-8048	Barrier film – Blue	Covers trays, accessories
UBC-8049	Barrier Film - Clear	Covers trays, accessories

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for (K183263)

This is submitted in accordance with the requirements CFR 807.92.

Applicant Information:

Owner Name:	UNiPACK Medical Corporation
Address:	9830 Norwalk Blvd., Ste. 100
	Santa Fe Springs, CA 90670
Contact Person:	Joe Pomparelli
Phone Number:	(562) 777-8000
Email:	Joe.Pomparelli@unipackmendical.com
Date Prepared:	June 13, 2019

Device Information:

Trade Name:	UNiPACK Barrier Sleeve and Barrier Film and UNiGLIDE Barrier Envelope
Common name:	Dental Barriers and Sleeves
Classification name:	Surgical Drape and Drape Accessories
Regulation:	21 CFR 878.4370
Classification:	Class II
Product Code	PEM, Dental Barriers and Sleeves

Legally Marketed Predicate Device:

Company:	Pac-Dent International Inc.
Device:	Pac-Dent Barrier Sleeve, Cover-It™ Barrier Film
510(k):	K151123
Date Cleared:	March 3, 2016

1.1 Device Description:

The UNiPACK Barrier Sleeve and Barrier Film consist of various sizes and shapes of polyethylene covers which are positioned on various small hand-held dental instruments such as handpieces, curing lights, air/water syringes, and similar hand instruments. In other forms, they are used to cover various devices such as dental chairs, dental instrument trays, x-ray heads, etc. The devices are sold non-sterile, prepackaged, and are for single use only.

1.2 Indication for Use:

The UNiPACK Barrier Sleeve and Barrier Film are intended to be used as a barrier to cover dental instruments. This device is non-sterile and intended for single patient use only.

Item #	Description	Designed For
UBC-8010E	E Tray Sleeve, 11-1/2" x 16"	Instrument trays
UBC-8011A	A Tray Sleeve, 11-5/8" x 14-1/2"	Instrument trays
UBC-8012B	B Tray Sleeve, 10-1/2" x 14"	Instrument trays
UBC-8013F	F Tray Sleeve, 7-1/2" x 10-1/2"	Instrument trays
UBC-8021	Full Chair Cover, 29" x 80"	Chairs/Stools
UBC-8022	Full Chair Cover, 48" x 56"	Chairs/Stools
UBC-8023	Half Chair Cover, 27-1/2" x 24"	Chair Headrest
UBC-8024	Headrest Cover, 11" x 9-1/2" x 2"	Chair Headrest
UBC-8025	Headrest Cover, 14" x 9-1/2" x 2"	Chair Headrest
UBC-8028	Syringe Sleeve with Opening, Clear, 2-1/2"x 10"	3-way syringes, saliva ejectors and HVE valves
UBC-8029	Syringe Sleeve with Opening, Blue, 2-1/2"x 10"	3-way syringes, saliva ejectors and HVE valves
UBC-8031	T-Handle Cover (T Shape), 4" x 5-3/4"	Most T-style dental chair light handles
UBC-8032	Universal X-Ray Cover, 23" x 31"	X-Ray head, Extra-Long
UBC-8033	Universal X-Ray Cover, 15" x 26"	X-Ray head, Regular
UBC-8034	Curing Light, Pistol (Handle Only)	Curing Lights, Pen Type
UBC-80341-F	Curing Light, Pistol (Full Cover with Vented Design)	Curing Lights, Pen Type
UBC-80342-S	Curing Light, Pen Type (Small), 2" x 12-1/2"	Curing Lights, Pen Type
UBC-80343-L	Curing Light, Pen (Large), 3-1/8" x 12-1/2"	Curing Lights, Pen Type
UBC-8035	Low Speed Pen Sleeve, 1-1/2" x 9"	Curing Lights, Pen Type
UBC-8036	High Speed Universal, 1" x 9"	Curing Lights, Pen Type
UBC-8035	Low Speed Pen Sleeve, 1-1/2" x 9"	Curing Lights, Pen Type
UBC-8036	High Speed Universal, 1" x 9"	Curing Lights, Pen Type
UBC-8037	Sensor Sleeve, Size 0 - Small	Digital X-Ray sensor, universal, small, 1 3/8"X8"
UBC-8038	Sensor Sleeve, Size 2 - Large	Digital X-Ray sensor, universal, large, 1 5/8"X8"
UBC-80392	Tube Sleeve, 2" x 1200', cut to length	Dental unit tubing (2”)
UBC-80394	Tube Sleeve, 4" x 1200', cut to length	Dental unit tubing (4”)
UBC-820824	X-Ray Sensor Sheath (Schick, Size 1)	Digital X-Ray sensor (Schick/Dr. Suni Plus)
UBC-820825	X-Ray Sensor Sheath (Schick, Size 2)	Digital X-Ray sensor (Schick/Dr. Suni Plus)
UBC-820861	X-Ray Sensor Sheath (Regam, Size 2)	Digital X-Ray sensor (Regam)
UBC-820978	X-Ray Sensor Sheath (Carestream/Kodak 6100, Size 1)	Digital X Ray sensor (Kodak 6100)

Item #	Description	Designed For
UBC-820979	X-Ray Sensor Sheath (Carestream/Kodak 6100, Size 2)	Digital X Ray sensor (Kodak 6100)
UBC-820999	X-Ray Sensor Sheath (Dexis/Universal)	Digital X Ray sensor (Dexis)
UBC-820831	Intraoral Camera Covers	Pro-Den Systems/Dent-X, Pro-scope 1000 & Oral Scan, Easy Doc
UBC-820855	Intraoral Camera Covers	Siemens, Ceracam/Minicam Ultra
UBC-820963	Intraoral Camera Covers	Video Dental concepts, Quickcam Smile
UBC-821013	Intraoral Camera Covers	Digital Doc, Iris
UBE-8160	UNiGLIDE PSP Barrier Envelope Size 0	Phosphor Plate Cover
UBE-8161	UNiGLIDE PSP Barrier Envelope Size 1	Phosphor Plate Cover
UBE-8162	UNiGLIDE PSP Barrier Envelope Size 2	Phosphor Plate Cover
UBE-8050	Standard PSP Barrier Envelope Size 0	Phosphor Plate Cover
UBE-8051	Standard PSP Barrier Envelope Size 1	Phosphor Plate Cover
UBE-8052	Standard PSP Barrier Envelope Size 2	Phosphor Plate Cover
UBE-8053	Standard PSP Barrier Envelope Size 3	Phosphor Plate Cover
UBE-8054	Standard PSP Barrier Envelope Size 4	Phosphor Plate Cover
UBC-8040-U	Keyboard sleeves	Computer keyboard, universal, 22"X14"
UBC-8040-L	Keyboard sleeves	Computer keyboard, large, 19"X26"
UBC-8041	LCD & Keyboard sleeves	Computer screen and keyboard, universal
UBC-8042	Laptop sleeves	Laptop, universal
UBC-8043-S	Low-speed contra-angle handpiece sleeves w/paper backing	Dental low-speed contra-angle handpiece, universal
UBC-8043-L	Low-speed long handpiece sleeves w/paper backing	Dental low-speed long handpiece, universal
UBC-8044	Optical PC mouse barriers	Computer mouse, universal
UBC-8055	Syringe sleeve w/paper backing	Air/water syringe, universal
UBC-8048	Barrier Film - Blue	Cover trays, accessories
UBC-8049	Barrier film - clear	Cover trays, accessories

1.3 Technical Characteristics:

Descriptive Information	UNiPACK Barrier Sleeve, Barrier Film and UniGlide Barrier Envelope (Subject Device)	Pac-Dent Barrier Sleeve Cover-It™ Barrier Film 510(k) #K151123
Indication for Use	The UNiPACK Barrier Sleeve, Barrier Film and UNiGLIDE Barrier Envelopes are intended to be used as a barrier to cover dental instruments. This device is non-sterile and intended for single patient use only.	Pac-Dent Barrier Sleeve and Cover-It Barrier Film are intended to be used as a barrier to cover dental instruments. This device is non-sterile and intended for single patient use only.
Regulation Number	21 CFR 878.4370	21 CFR 878.4370
Classification Product Code	PEM	PEM
Product Classification	Class II	Class II
Composition of Materials	LLDPE (80%) LDPE (20%)	LLDPE (80%) LDPE (20%)
Sterility	Non-Sterile	Non-Sterile
Labeling	Single Use Only, OTC	Single Use Only, OTC
Specifications	Film Thickness: 0.02-0.06mm Tolerance: 0.01mm Paper Backing – some models	Film Thickness: 0.02-0.06mm Tolerance: 0.01mm Paper Backing – some models
Performance Testing	Film Thickness Resistance to Penetration - ASTM F1670: Pass - ASTM F1671: Pass	Film Thickness Resistance to Penetration - ASTM F1670: Pass - ASTM F1671: Pass
	Tear Strength - ASTM D1424: Pass	Tear Strength - ASTM D1424: Pass
	Tensile Properties - ASTM D882: Pass	Tensile Properties - ASTM D882: Pass
	Resistance to Puncture - ASTM F1342: Pass	Resistance to Puncture - ASTM F1342: Pass
	Effectiveness of X-Ray Devices Covered with Barrier Sleeves determined to be same as without Barrier Sleeves using side-by-side visual comparison of pictures of common dental office objects.	Effectiveness of X-Ray Devices Covered with Barrier Sleeves: Pass
Biocompatibility	ISO 10933-5 (cytotoxicity): Pass ISO 10933-10 (irritation): Pass ISO 10933-10 (sensitization): Pass	ISO 10933-5 (cytotoxicity): Pass ISO 10933-10 (irritation): Pass ISO 10933-10 (sensitization): Pass

Descriptive Information	UNiPACK Barrier Sleeve, Barrier Film and UniGlide Barrier Envelope (Subject Device)	Pac-Dent Barrier Sleeve Cover-It™ Barrier Film 510(k) #K151123
FDA Recognized Standards	ASTM F1670 ASTM D1004 ASTM D882 ASTM F1342 ASTM F1671 ISO 10993-5 ISO 10993-10	ASTM F1670 ASTM D1004 ASTM D882 ASTM F1342 ASTM F1671 ISO 10993-5 ISO 10993-10

1.4 Summary of Non-Clinical Tests

The following table summarizes the non-clinical performance testing.

Test Item	Methodology	Purpose	Acceptance Criteria	Results
ASTM F1670: Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Study conducted per ASTM F1670 Study Endpoint: Observed for synthetic blood penetration at conclusion of study	Evaluate resistance of protective materials to penetration by synthetic blood under conditions of continuous liquid contact.	Acceptance criteria per ASTM F1670 Pass/Fail based on synthetic blood penetration observations. Pass=no penetration	Material used for Unipack Dental Barrier Film and Sleeves could not be penetrated by synthetic blood under study conditions. The material meets the requirements of ASTM F1670 in preventing synthetic blood penetration.
ASTM F1671: Resistance of Materials used in Protective Clothing to Penetration by Blood-Borne Pathogens using Phi-X174 Bacteriophage Penetration as a Test System Penetration	Study conducted per ASTM F1671	Evaluate barrier performance of protective materials which are intended to protect against blood borne pathogen hazards.	Acceptance criteria per ASTM F1671	Material used for Unipack Dental Barrier Film and Sleeves met criteria of test standard under study conditions. The material meets the requirements of ASTM F1671 in preventing blood borne pathogen penetration.
ASTM D882: Standards Test Methods for Tensile Properties of Thin Plastic Sheeting	Study conducted per ASTM D882 Study Endpoint: To failure of test article	Determine tensile strength.	Per ASTM D882, there is currently no acceptance criteria for this test method.	The results are for information only as there is no P/F criteria.

Test Item	Methodology	Purpose	Acceptance Criteria	Results
ASTM F1342: Standard Test method for protective Clothing Material Resistance to Puncture	Study conducted per ASTM F1342 Study Endpoint: At the point of material puncture.	Determine puncture resistance of a protective clothing material.	Per ASTM F1342, there is currently no acceptance criteria for this test method.	The results are for information only as there is no P/F criteria.
ASTM D1004: Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting	Study conducted per ASTM D1004 Study Endpoint: At the point of material tearing.	Determine tear strength of plastic film and sheeting.	per ASTM D1004, there is currently no acceptance criteria for this test method.	The results are for information only as there is no P/F criteria.
ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Study conducted in compliance to ISO 10993-5: 2009 and BS EN ISO 10993-5: 2009 (Tests for in vitro Cytotoxicity). Test and/or control article prepared in compliance to ISO 10993-12: 2012 and BS EN ISO 10993-12: 2012 (Sample Preparation and Reference Materials).	Purpose of MEM Elution Cytotoxicity test was to determine cytotoxic response from test article which was extracted in cell culture media which was then plated onto L-929 mouse fibroblast cell monolayer.	Acceptance criteria per ISO 10993-5.	Test article passed test and determined non-cytotoxic.

Test Item	Methodology	Purpose	Acceptance Criteria	Results
ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Studies (2) conducted in compliance to ISO)10993-10: 2010 and BS EN ISO 10993-10: 2013 (Tests for Irritation and Skin Sensitization). Test or control article prepared in compliance to ISO 10993-12: 2012 and BS EN ISO 10993-12: 2012 (Sample Preparation and Reference Materials).	Study 1 purpose: To evaluate sensitization or allergenic potential of a test article. Test is used as method for screening contact allergens in guinea pigs. Results are used as predictive measures for detecting potential sensitizers in humans.	Acceptance criteria for both studies per ISO 10993-10.	Study completed and test article considered non-sensitizer.
		Study 2 purpose: To evaluate irritation potential of a test article. Test is used as method for screening irritants in rabbits. Results are used as predictive measures for detecting potential irritants in humans.		Study completed and test article considered non-irritant.
X-Ray Effectiveness: Currently no standard is available.	Side-by-side visual comparison of X-Ray pictures of common dental office objects.	Determine effectiveness of X-Ray devices covered with Barrier Sleeves.	Expert X-Ray reader should not be able to observe differences between images of same objects captured with and w/o Barrier Sleeves covering X-Ray source.	Images were deemed to be the same by a trained X-Ray reader.

1.5 Clinical Performance Test

No clinical testing was performed.

1.6 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Pac-Dent Barrier Sleeve and Cover-It Barrier Film (K151123).