UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Johnson & Johnson Medical, Inc.
2500 Arbrook Boulevard
P.O. Box 90120
Arlington, TX 76004-3130

MAY 24 1994

Attention: T. M. Wendt, Ph.D., Director
Regulatory Affairs

Paul J. Kruger, Agent
for Johnson & Johnson Medical, Inc.

Subject: CIDEX PLUS* 28 Day Solution
EPA Registration No. 7078-14
Your Amendment Dated April 8, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise the product labeling to include a package insert as per FDA 510(k) labeling requirements, has been reviewed by the Agency and found to be acceptable, provided you make the following change.

Amend the submitted product label with the following statement prior to releasing the product for shipment. Immediately under "DIRECTIONS FOR USE" include: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." Your release for shipment of the product constitutes acceptance of this condition.

The submitted package insert is appropriate, acceptable, and complies with FDA 510(k) labeling requirements for liquid chemical germicides, as per 21 CFR Section 801.5.

A stamped copy of the product label and package insert is enclosed for your records.

If you have any questions concerning this letter, please contact Doreen Aviado at (703) 305-6554.

Sincerely,

Marshall Swindell
Acting Product Manager-31
Antimicrobial Program Branch
Registration Division (7505C)

Enclosures

	CONCURRENCES							
SYMBOL	7505C							
SURNAME	DAviado							
DATE	5/23/94							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

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INDICATIONS FOR USE

STERILIZATION: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not available. Medical equipment which should always be sterilized is that which is categorized as critical (i.e., used in procedures in which contact will be made with tissues that is normally considered sterile).

HIGH LEVEL DISINFECTION: This solution should be used for the high level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be categorized for high level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (i.e., used in procedures in which contact will be made with mucous membranes or other body surfaces which are not normally considered to be sterile).

INTERMEDIATE LEVEL DISINFECTION: This solution should be used for the disinfection of medical equipment for which a risk of cross contamination exists. Medical equipment which should always be disinfected is that which is to be used in procedures categorized as non-critical (i.e., used in procedures in which contact will only be made with intact skin).

DIRECTIONS FOR USE

ACTIVATION: Activate the CIDEX PLUS Solution by adding the entire contents of the activator vial which is attached to the CIDEX PLUS Solution container. Shake well. When activated, solution changes color to green. Record the date of activation on the indicated space below, in a log book or a label affixed to any secondary container used for the activated solution. See package insert for additional instructions and information regarding activated solution.

CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of the disinfectant or sterilant. For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX PLUS Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX PLUS Solution. See package insert for additional cleaning/decontamination instructions.

STERILIZATION: Immerse medical instruments/equipment completely in CIDEX PLUS Solution for a minimum of 10 hours at 20°C - 25°C. Remove equipment from the solution using aseptic technique and rinse thoroughly with sterile water. See package insert for complete instructions/information on sterilization.

HIGH LEVEL DISINFECTION: Immerse medical instruments/equipment completely in CIDEX PLUS Solution for a minimum of 20 minutes at 20°C. Remove from the solution and rinse thoroughly with sterile water or with potable tap water. The quality of rinse water used is dependent upon the intended use of the instruments/equipment. See package insert for complete instructions/information on high level disinfection.

INTERMEDIATE LEVEL DISINFECTION: Immerse medical instruments/equipment completely in CIDEX PLUS Solution for a minimum of 10 minutes at 20°C - 25°C to destroy all vegetative bacteria except, for large numbers of *Mycobacterium tuberculosis*, but including *Pseudomonas aeruginosa*, pathogenic fungi and specified viruses, as indicated in the package insert.

A 10 minute immersion at 20°C will kill 99.9% *Mycobacterium tuberculosis* (Quantitative TB Method)

A 10 minute immersion at 20°C will kill 99.99% *Mycobacterium tuberculosis* (Quantitative TB Method)

Remove instruments/equipment from the solution and thoroughly rinse with sterile water or potable tap water. The quality of the rinse water used is dependent upon the intended use of the instruments/equipment. See package insert for complete instructions/information on intermediate level disinfection.

Reorder No.

2786

REUSABLE

Sterilizing and Disinfecting Solution

Sporicidal Fungicidal Bactericidal
Virucidal Tuberculocidal Pseudomonacidal

Cidexplus*

28 day solution

Active Ingredient	
Glutaraldehyde	3.4%
Inert Ingredients	96.6%
Total	100.0%

NOTE – Contents of attached vial must be added to solution before this product is effective.
See Directions for Use - Activation.

EPA REG. No. 7078-14
EPA EST. No. 36126-PR-1

Keep out of reach of children.

DANGER: See right side panel for additional precautionary statements.

Johnson & Johnson MEDICAL INC.

*TRADEMARK CONTENTS: 0.946 L (ONE QT.)

BEST AVAILABLE COPY

SCALE: 100%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 24 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

7078-14

CIDEX PLUS* 28 Day Solution is a liquid chemical sterilant and a high or intermediate level disinfectant, when used according to the **Directions for Use.**

Sterilant: CIDEX PLUS 28 Day Solution is a sterilant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days at **20°C to 25°C** with an immersion time of at least **10 hours.**

High Level Disinfectant: CIDEX PLUS 28 Day Solution is a high level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days at **25°C** with an immersion time of at least **20 minutes.**

Intermediate Level Disinfectant: CIDEX PLUS 28 Day Solution is an intermediate level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days.

A **10 minute** immersion at **20°C to 25°C** will destroy all vegetative bacteria, except for large numbers of **Mycobacterium tuberculosis**, but including **Pseudomonas aeruginosa**, pathenogenic fungi and specified viruses, as indicated in Section E - Directions for Use - Item 3(c).

A **10 minute** immersion at **20°C** will kill 99.6% **Mycobacterium tuberculosis** (Quantitative TB Method).

A **10 minute** immersion at **25°C** will kill 99.98% **Mycobacterium tuberculosis** (Quantitative TB Method).

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY 24 1994
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the Pesticide registered under EPA Reg. No. 70978-14

2) **Reuse Period**

CIDEX PLUS 28 Day Solution has demonstrated efficacy in the presence of 2% organic soil and a simulated amount of microbiological burden during reuse. CIDEX PLUS 28 Day Solution can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in **Directions for Use. DO NOT** rely solely on days in use. **Efficacy of this product during its use-life must be verified by the CIDEX PLUS* Solution Test Strip to determine that at least the minimum effective concentration (MEC) of 2.1% glutaraldehyde is present.**

*Trademark

3) **General Information on Selection and Use of Germicides for Medical Device Reprocessing**

Choose a germicide with the level of microbial activity that is appropriate for the reusable medical device or equipment surface. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical, semi-critical, or noncritical device.

- A **critical device** presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.
- A **semi-critical device** makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.
- A **noncritical device** contacts only intact skin during routine use.

Second, determine the level of germicidal activity that is needed for the reusable device.

Critical Device	Sterilization required (e.g.: products that enter sterile tissue or the vascular system, such as laparoscopes and microsurgical instruments)
Semi-critical Device	Sterilization recommended whenever practical, otherwise High Level Disinfection acceptable (e.g: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.)
Noncritical Device	Intermediate Level Disinfection recommended when there is a risk of cross-contamination, otherwise Low Level Disinfection acceptable (e.g.: bed pans, blood pressure cuffs, linens, etc.)
Medical Equipment Surface	Same as for noncritical device (e.g.: crutches, oxygen cylinders, etc.)

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

*Trademark

4) Microbial Activity

The following table indicates the spectrum of activity as demonstrated by testing of CIDEX PLUS 28 Day Solution**:

BACTERIA		FUNGI	VIRUSES	
SPORES	VEGETATIVE ORGANISMS		NON-ENVELOPED	ENVELOPED
Bacillus subtilis	Staphylococcus aureus	Trichophyton mentagrophytes	Poliovirus Type 1	Coronavirus
Clostridium sporogenes	Salmonella choleraesuis		Rhinovirus Type 14	Cytomegalovirus
	Pseudomonas aeruginosa		Adenovirus Type 2	Influenza virus Type A [WS/33]
	Mycobacterium tuberculosis		Vaccinia	HIV-1 (AIDS Virus)
			Coxsackievirus B-1	Herpes simplex Type 1, 2

** Testing was done after 28 days of simulated reuse using prescribed test methods.

*Trademark

5) **Material Compatibility**

CIDEX PLUS 28 Day Solution is recommended for use with medical devices made from the materials shown below. Care must be taken with medical and dental equipment such as anesthesia and respiratory therapy tubing, dental mirrors and burs. These devices may be damaged when cleaned with a highly alkaline detergent, poorly rinsed after disinfection, stored wet or dried at temperatures exceeding 105°F.

METALS	PLASTICS
Carbon steel**	Acrylonitrile-butadiene-styrene (ABS)**
Stainless steel**	Polyvinylchloride (PVC)**
Brass**	Polystyrene*
Nickel plate**	Polyethylene**
Chrome plate**	Polypropylene**
Aluminum**	Polysulfone*
Anodized aluminum*	Polymethylmethacrylate (Acrylic)*
Copper**	Polyethylene terephthalate (Polyester)*
Nickel silver alloy**	
Gold plate*	
Silver plate*	

ELASTOMERS

Black rubber**
Red rubber**
Polyurethane*
Silicone rubber*

NOTE:

* Represents 10 hours of continuous contact with CIDEX PLUS 28 Day Solution over 20 disinfection cycles.

** Represents 672 hours of continuous exposure with CIDEX PLUS 28 Day Solution over the 28-day use cycle of the disinfectant.

CIDEX PLUS 28 Day solution is **not** recommended for disinfection of one piece molded, solvent bonded or sonic welded polycarbonate equipment. Stress cracking has been observed after repeated treatments.

*Trademark

6) **Precleaning Agent Compatibility**

CIDEX PLUS 28 Day Solution is compatible with enzymatic detergents (e.g.: ENZOL* Enzymatic Detergent) which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acid or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the CIDEX PLUS 28 Day Solution by altering its pH.

B) **Contraindications**

1) **Sterilant Usage**

Routine biological monitoring is not feasible with CIDEX PLUS 28 Day Solution, and therefore, CIDEX PLUS 28 Day Solution should **NOT** be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide or peroxide gas plasma.

CIDEX PLUS 28 Day Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters).

2) **High Level Disinfectant Usage**

CIDEX PLUS 28 Day Solution should **NOT** be used to high level disinfect a semi-critical device when sterilization is practical.

3) **Endoscope Usage**

CIDEX PLUS 28 Day Solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization. In general, glutaraldehyde solutions that do not contain surfactants (e.g.: CIDEX* Activated Dialdehyde Solution) are more appropriate for flexible endoscopes, since glutaraldehyde solutions containing surfactants (e.g.: CIDEX FORMULA 7* Solution or CIDEX PLUS 28 Day Solution) are more difficult to rinse from the devices. However, these surfactant containing disinfectants may be used for reprocessing of flexible endoscopes **if a validated protocol for rinsing and leak testing is employed.**

4) **Polycarbonate Equipment Usage**

CIDEX PLUS 28 Day Solution is <u>not</u> recommended for disinfection of one piece molded, solvent bonded or sonic welded polycarbonate equipment. Stress cracking has been observed after repeated treatments.

*Trademark

C) Warnings

CIDEX PLUS 28 DAY SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Keep Out of Reach of Children
Contains Glutaraldehyde

1) **Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing.**
2) **Avoid contamination of food.**
3) **Use in well ventilated area in closed containers.**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately.

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Emergency, safety, or technical information about CIDEX PLUS 28 Day Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

*Trademark

D) **Precautions**

1) Disposable latex gloves, eye protection, face masks, and liquid- proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.

2) Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the germicide.

3) The user **MUST** adhere to the **Directions for Use** since any modification will affect the safety and effectiveness of the germicide.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDEX PLUS 28 Day Solution.

5) The use of CIDEX PLUS 28 Day Solution in automated endoscope washers **must be part of a validated reprocessing procedure provided by the washer manufacturer.** Contact the manufacturer of the endoscope washer for instructions on the maximum number of reprocessing cycles which may be used before refilling with fresh CIDEX PLUS 28 Day Solution. Use CIDEX PLUS Solution Test Strips to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

*Trademark

E) Directions for Use

1) Activation

Activate the CIDEX PLUS 28 Day Solution by adding the entire contents of the Activator Vial which is attached to the CIDEX PLUS 28 Day Solution Container. Shake well. Activated solution immediately changes color to green, thereby indicating solution is ready to use. CIDEX PLUS 28 Day Solution is intended for use in manual (bucket and tray) systems made from polypropylene, ABS, polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics. Record the date of activation (mixing date) and expiration date on the CIDEX PLUS 28 Day Solution container label in the space provided, in a log book or on a label affixed to any secondary container used for the activated solution.

2) Cleaning/Decontamination

Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and objects before application of the disinfectant or sterilant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local regulations for infectious waste disposal.

For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX PLUS 28 Day Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX PLUS 28 Day Solution. **Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.**

*Trademark

3) **Usage**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

a) **Sterilization (Bucket/Tray Manual System)**

Immerse medical equipment/device completely in CIDEX PLUS 28 Day Solution for a minimum of **10 hours at 20°C to 25°C** to eliminate all microorganisms including **Clostridium sporogenes** and **Bacillus subtilis** spores. Remove equipment from the solution using sterile technique and **rinse thoroughly** with **sterile water** following the rinsing instructions below.

b) **High Level Disinfection (Bucket/Tray Manual System)**

Immerse medical equipment/device completely in CIDEX PLUS 28 Day Solution for a minimum of **20 minutes at 25°C** to destroy all pathenogenic microorganisms, except for large numbers of bacterial endospores, but including **Mycobacterium tuberculosis** (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

c) **Intermediate Level Disinfection (Bucket/Tray Manual System)**

Immerse medical equipment/device completely in CIDEX PLUS 28 Day Solution for a minimum of **10 minutes** at **20°C to 25°C** to destroy all vegetative bacteria, except for large numbers of **Mycobacterium tuberculosis**, but including **Pseudomonas aeruginosa**, pathogenic fungi, and viruses **(Poliovirus Type 1; Adenovirus Type 2; Herpes simplex Type 1,2; HIV-1 (AIDS virus); Influenza Type A [WS/33]; Vaccinia; Coronavirus; Cytomegalovirus; Rhinovirus Type 14)** on inanimate surfaces.

A 10 minute immersion at **20°C** will kill 99.6% **Mycobacterium tuberculosis** (Quantitative TB Method).

A 10 minute immersion at **25°C** will kill 99.98% **Mycobacterium tuberculosis** (Quantitative TB Method).

Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

*Trademark

d) Rinsing Instructions

Following immersion in CIDEX PLUS 28 Day Solution, thoroughly rinse the equipment or medical device by immersing it completely in three separate copius volumes of water. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device or equipment manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Refer to the reusable device/equipment manufacturer's labeling for additional rinsing instructions.

STERILE WATER RINSE

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

1. Devices intended for use in normally sterile areas of the body;

2. Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served) and;

3. When practicable, bronchoscopes, due to a risk of **atypical Mycobacteria** contamination from potable water supply.

POTABLE WATER RINSE

For all other devices a sterile water rinse is recommended when practicable, otherwise a high quality potable tap water rinse is acceptable. A high quality potable water is one that meets Federal Clean Water Standards at the point of use.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with **Pseudomonads** and **atypical** (fast growing) **Mycobacteria** often present in potable water supplies. A device (e.g.: colonoscope) that is not completely dried provides an ideal situation for rapid colonization of bacteria. Additionally, **Mycobacteria** are highly resistant to drying, therefore, rapid drying will avoid possible colonization but may not result in a device free from **atypical Mycobacteria**. Although these bacteria are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

*Trademark

e) **Reusage**

CIDEX PLUS 28 Day Solution has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. This solution **may be used and reused** within the limitations indicated above for up to **28 days** after activation. **Do not use activated solution beyond 28 days. Efficacy of this product during its use-life can be verified by the CIDEX PLUS Solution Test Strip to determine that the minimum effective concentration (MEC) of 2.1% is present.**

4) **Monitoring of Germicide to Ensure Specifications are Met**

During the usage of CIDEX PLUS 28 Day Solution, as a high or intermediate level disinfectant and/or sterilant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. In addition, it is recommended that the CIDEX PLUS 28 Day Solution be tested with the CIDEX PLUS Solution Test Strip prior to each usage. This is to insure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 7.5 and 8.1.

5) **Post-Processing Handling and Storage of Reusable Devices**

Disinfected and/or sterilized reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

*Trademark

F) **Storage Conditions and Expiration Date**

1) Prior to activation, CIDEX PLUS 28 Day Solution should be stored in its original sealed container at controlled room temperature 15°-30°C (59°-86°F).

Once the CIDEX PLUS 28 Day Solution has been activated, it should be stored in the original container until transferred to the closed containers in which the immersion for disinfection or sterilization is to take place. Containers should be stored in a well ventilated, low traffic area at controlled room temperature.

2) The expiration date of the inactivated CIDEX PLUS 28 Day Solution will be found on the bottom of the immediate container.

3) The use period for activated CIDEX PLUS 28 Day Solution is for no longer than 28 days following activation or as indicated by the CIDEX PLUS Solution Test Strip. Once activated, the solution requires no further dilution prior to its usage.

G) **Emergency and Technical Product Information**

Emergency, safety, and technical information about CIDEX PLUS 28 Day Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

H) **User Proficiency**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information on CIDEX PLUS 28 Day Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

*Trademark

I) **Disposal Information**

Germicide Disposal

Discard residual solution in drain. Flush thoroughly with water.

Container Disposal

- **0.946 L (One Quart) and 3.785 L (One Gallon) Size Containers**
  Do not reuse empty container. Wrap container and put in trash.

- **9.462 L (2 1/2 Gallon) Size Container**
  Triple rinse empty container with water and dispose of in an incinerator or landfill approved for pesticide containers.

J) **How Supplied**

Reorder	Description	Case Contains
2786	0.946 L (One Quart) Container	4 x 0.946 L (4qts)/box; 4 boxes/case; 16 x 0.946 L (16 qts)/case
2785	3.785 L (One Gallon) Container	4 x 3.785 L (4 gals)/case
2787	9.462 L (2 1/2 Gallon) Container	2 x 9.462 L (2 x 2 1/2 gals) /case
2924	CIDEX PLUS Solution Test Strips	60 strips/btl, 2 btls/case
2926	CIDEX PLUS Solution Test Strips	15 strips/btl, 2 btls/case

References supplied upon request.

*Trademark