BD BACTEC™ Peds Plus™/F Culture Vials

Soybean-Casein Digest Broth with Resins in a Plastic Vial

CE 2797 IVD bd.com/e-labeling R_x Only

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English

REF 442020

INTENDED USE

BD BACTEC™ Peds Plus™/F Culture Vials (enriched Soybean-Casein Digest Broth with CO_2) are for aerobic blood cultures. The principal use is with the BD BACTEC™ fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (mainly bacteria and yeast) from pediatric and non-pediatric blood specimens which are generally less than 3 mL in volume.

Additional Information

The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.

SUMMARY AND EXPLANATION

The sample to be tested is inoculated into one or more vials which are inserted into the BD BACTEC™ fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO_2 produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

Resins have been described for the treatment of blood specimens both prior to and after their inoculation into culture media. Resins have been incorporated into BD BACTEC™ culture media to enhance recovery of organisms without a need for special processing.[1-3,8]

PRINCIPLES OF THE PROCEDURE

If microorganisms are present in the test sample inoculated into the BD BACTEC™ Peds Plus™/F Culture Vial, CO_2 will be produced when the organisms metabolize the substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the higher amount of CO_2 are monitored by the BD BACTEC™ fluorescent series instrument. Analysis of the rate and amount of CO_2 increase enables the BD BACTEC™ fluorescent series instrument to determine if the vial is positive, i.e., that the test sample contains viable organisms. This qualitative culture functions as an aid to diagnosis and is automated on the BD BACTEC™ fluorescent series instrument.

BD BACTEC™ Peds Plus™/F Culture Vials are a Ready-to-Use Media.

REAGENTS

The BD BACTEC™ Peds Plus™/F Culture Vials contain the following reactive ingredients prior to processing:

List of Ingredients

Processed Water	40 mL	Hemin	0.0005% w/v
Soybean-Casein Digest Broth	2.75% w/v	Menadione	0.00005% w/v
Yeast Extract	0.25% w/v	Sodium Polyanetholsulfonate (SPS)	0.02% w/v
Animal Tissue Digest	0.10% w/v	Pyridoxal HCl (Vitamin B_6)	0.001% w/v
Sodium Pyruvate	0.10% w/v	Nonionic Adsorbing Resin	10.0% w/v
Dextrose	0.06% w/v	Cationic Exchange Resin	0.6% w/v
Sucrose	0.08% w/v		

All BD BACTEC™ media are dispensed with added CO_2.

WARNINGS AND PRECAUTIONS

The prepared culture vials are for in vitro diagnostic use. For Use by Trained Laboratory Personnel.

This Product Contains Dry Natural Rubber.

EUH208: Contains (Propanoic acid, 2-oxo-, sodium salt (1:1)). May produce an allergic reaction. EUH210: Safety data sheet available on request.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[4-7] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Prior to use, each vial should be examined for evidence of contamination such as cloudiness, bulging or depressed septum, or leakage. DO NOT USE any vial showing evidence of contamination. A contaminated vial could contain positive pressure. If a contaminated vial is used for direct draw, gas or contaminated culture media could be refluxed into the patient's vein. Vial contamination may not be readily apparent. If a direct draw procedure is used, monitor the process closely to avoid refluxing materials into the patient.

Prior to use, the user should examine the vials for evidence of damage or deterioration. Vials displaying turbidity, contamination, or discoloration (darkening) should not be used. On rare occasions a vial may not be sealed sufficiently. The contents of the vials may leak or spill, especially if the vial is inverted. If the vial has been inoculated, treat the leak or spill with caution, as pathogenic organisms/agents may be present. Before discarding, sterilize all inoculated vials by autoclaving.

Positive culture vials for subculturing or staining, etc.: before sampling it is necessary to release gas which often builds up due to microbial metabolism. Sampling should be performed in a biological safety cabinet if possible, and appropriate protective clothing, including gloves and masks, should be worn. See Procedure section for more information on subculturing.

To minimize the potential of leakage during inoculation of specimen into culture vials, use syringes with permanently attached needles or BD Luer-Lok™ tips.

Molecular tests performed on positive blood cultures will detect both viable and non-viable organisms commonly found in culture media. Therefore, molecular test results should be evaluated in conjunction with Gram stain results in accordance with standard-of-care practices as well as manufacturer's instructions for use.

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

Storage Instructions

The BD BACTEC™ Peds Plus™/F Culture Vials are ready for use as received and require no reconstitution or dilution. Keep dry; store between 2 to 25 °C, keep away from light.

SPECIMEN COLLECTION

The specimen must be collected using sterile techniques to reduce the chance of contamination. The range of blood volume which can be cultured is 0.5 to 5.0 mL. If the volume of blood cultured is less than 0.5 mL, recovery of some fastidious organisms, such as *Haemophilus* species, may require the use of an appropriate supplement, as described later in this Package Insert. It is recommended that the specimen be inoculated into the BD BACTEC™ Peds Plus™/F Culture Vials at bedside. Most commonly, a syringe with a BD Luer-Lok™ brand tip is used to draw the sample. If appropriate, a BD Vacutainer® brand Needle Holder and a BD Vacutainer® brand Blood Collection Set, BD Vacutainer® Safety-Lok™ Blood Collection Set or other tubing "butterfly" set may be used. If using a needle and tubing set (direct draw), carefully observe the direction of blood flow when starting sample collection. The vacuum in the vial will usually exceed 5 mL, so the user should monitor the volume collected by means of the 5 mL graduation marks on the vial label. When the recommended 1–3 mL has been drawn, the flow should be stopped by crimping the tubing and removing the tubing set from the BD BACTEC™ Peds Plus™/F Culture Vial. **The inoculated BD BACTEC™ Peds Plus™/F Culture Vial should be transported as quickly as possible to the laboratory.**

PROCEDURE

Materials Provided

BD BACTEC™ Peds Plus™/F Culture Vials

Materials Required But Not Provided

- Syringe with permanently attached needles or BD Luer-Lok™ tips or a BD Brand Needle Holder and a BD Vacutainer® Brand Blood Collection Set, BD Vacutainer® Safety-Lok™ Blood Collection set or other tubing "butterfly" set
- Alcohol
- BD BACTEC™ Fluorescent series instrument
- Microscope and materials for downstream staining of slides and subculturing of vials

Remove the flip-off cap from the BD BACTEC™ Peds Plus™/F Culture Vial top and inspect the vial for cracks, contamination, excessive cloudiness, and bulging or indented septum. DO NOT USE if any defect is noted. Before inoculating, swab the septum with alcohol (iodine is not recommended). Aseptically inject or draw directly a maximum of 5 mL of specimen per vial (see Limitations of the Procedure). Inoculated vials should be placed in the BD BACTEC™ fluorescent series instrument as soon as possible for incubation and monitoring. If placement of an inoculated vial into the instrument has been delayed and visible growth is apparent, it should not be tested in the BD BACTEC™ fluorescent series instrument, but rather it should be subcultured, Gram stained and treated as a presumptively positive vial.

Vials entered into the instrument will be automatically tested every ten minutes for the duration of the testing protocol period. Positive vials will be determined by the BD BACTEC™ fluorescent series instrument and identified as such (see the appropriate BD BACTEC™ Fluorescent Series Instrument User's Manual). The sensor inside the vial will not appear visibly different in positive and negative vials, however, the BD BACTEC™ fluorescent series instrument can determine a difference in fluorescence.

If at the end of the testing period a negative vial appears visually positive (i.e., chocolatized blood, bulging septum, and/or lysed), it should be subcultured and Gram stained and treated as a presumptively positive.

Positive vials should be subcultured and Gram stained. In a great majority of cases, organisms will be seen and a preliminary report can be made to the physician. Subcultures to solid media and a preliminary direct antimicrobial susceptibility test may be prepared from fluid in the BD BACTEC™ Peds Plus™/F Culture Vials.

Subculturing

After wiping the septum of an upright vial with an alcohol wipe, a single device such as the BD BACTEC™ Subculturing/Aerobic Venting Unit, Catalog Number 249560 or equivalent, can be used to both vent and subculture the vial.

Alternatively, prior to subculturing, put the vial in an upright position, and place an alcohol wipe over the septum. To release pressure in the vial, insert a sterile needle with an appropriate filter through the alcohol wipe and septum. The needle should be removed after the pressure is released and before sampling the vial for subculture. The insertion and withdrawal of the needle should be done in a straight-line motion, avoiding any twisting motions.

For maximum yield of isolates, negative cultures may be checked by stain and/or subcultured prior to discarding as negative.

QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

DO NOT USE culture vials past their expiration date.

DO NOT USE culture vials that exhibit any cracks or defects; discard the vial in the appropriate manner.

Quality Control Certificates are provided with each carton of media. Quality Control Certificates list test organisms, including ATCC® cultures specified in the CLSI Standard M22, *Quality Control for Commercially Prepared Microbiological Culture Media*. The range of time-to-detection in hours was ≤72 hours for each of the organisms listed on the Quality Control Certificate for this medium:

Peds Plus™ Medium Organisms	
Streptococcus pyogenes ATCC® 19615	*Neisseria meningitidis* ATCC® 13090
Escherichia coli ATCC® 25922	*Alcaligenes faecalis* ATCC® 8750
*Streptococcus pneumoniae** ATCC® 6305	*Haemophilus influenzae* ATCC® 19418
Pseudomonas aeruginosa ATCC® 27853	*Staphylococcus aureus* ATCC® 25923
Candida albicans ATCC® 18804	

* CLSI-recommended strain

For information on Quality Control for the BD BACTEC™ fluorescent series instrument, refer to the appropriate BD BACTEC™ Fluorescent Series Instrument User's Manual.

RESULTS

A positive sample is determined by the BD BACTEC™ fluorescent series instrument and indicates the presumptive presence of viable microorganisms in the vial.

LIMITATIONS OF THE PROCEDURE

Contamination

Care must be taken to prevent contamination of the sample during collection and inoculation into the BD BACTEC™ Peds Plus™/F Culture Vial. A contaminated sample will give a positive reading, but will not indicate a relevant clinical sample. Such a determination must be made by the user based on such factors as type of organism recovered, occurrence of the same organism in multiple cultures, patient history, etc.

Recovery of SPS Sensitive Organisms From Blood Samples

Because blood can neutralize the toxicity of SPS toward organisms sensitive to SPS (such as some *Neisseria* species), the presence of recommended volumes of blood (1–3 mL) can help to optimize recovery of these organisms.

Some organisms may be dependent on having a minimum amount of blood in the medium for optimal growth. Fastidious organisms, such as certain *Haemophilus* species, require growth factors from the blood specimen, such as NAD, or factor V. Optimal growth of these organisms is dependent on having greater than a minimum of 0.5 mL blood in the specimen. If the blood specimen volume is very small (0.5 mL or less), an appropriate supplement may be required for recovery of these organisms. BD BACTEC™ FOS™ Fastidious Organism Supplement (Catalog Number 442153) may be used as a nutritional supplement.

Nonviable Organisms

A Gram stained smear from a culture medium may contain small numbers of nonviable organisms derived from media constituents, staining reagents, immersion oil, glass slides, and specimens used for inoculation. In addition, the patient specimen may contain organisms that will not grow in the culture medium or in media used for subculture. Such specimens should be subcultured to special media as appropriate.

Antibiotic Activity

Neutralization of the antibiotic activity by resins varies depending on dosage level and timing of specimen collection.

Studies have demonstrated that the resins present in this medium do not adequately neutralize meropenem preparations.

Studies have demonstrated that the resins present in this medium adequately neutralize the antifungal agent fluconazole with *Candida albicans*. However, other antifungal agents/yeast combinations have not been tested/evaluated.

Recovery of *Streptococcus pneumoniae*

In aerobic media, *S. pneumoniae* will typically be visually and instrument positive, but in some cases no organism will be seen on Gram stain or recovered on routine subculture. If an anaerobic vial was also inoculated, the organism can usually be recovered by performing an aerobic subculture of the anaerobic vial, since this organism has been reported to grow well under anaerobic conditions.[9]

General Considerations

Recovery of isolates will be achieved by adding the recommended volume 1–3 mL of blood. Use of lower or higher volumes may adversely affect recovery and/or detection. Blood may contain antimicrobials or other inhibitors which may slow or prevent the growth of microorganisms. False negative readings may result when certain organisms are present which do not produce enough CO_2 to be detected by the system or significant growth has occurred before placing the vial into the system. False positivity may occur when the white blood cell count is high. The default 5-day (120 hours) protocol was utilized for all analytical testing with the BD BACTEC™ Peds Plus™/F Culture Vial and protocol lengths of >5 days have not been evaluated.

EXPECTED VALUES AND SPECIFIC PERFORMANCE CHARACTERISTICS

Internal studies have demonstrated that antibiotics are effectively neutralized by the resins used in BD BACTEC™ resin media. In these tests, antibiotics were added in clinically relevant concentrations directly to resin media prior to inoculation with susceptible strains. These tests showed equivalent performance in BD BACTEC™ Peds Plus™ in plastic vial compared to BD BACTEC™ Peds Plus™ in glass vial.

A total of 984 paired sets inoculated with 0.5 mL and 5.0 mL of blood at 10–100 CFU per vial were evaluated across the four instruments comprising the BD BACTEC™ fluorescent-series instrument family: BD BACTEC™ 9050, BD BACTEC™ 9240, BD BACTEC™ FX and the BD BACTEC™ FX40. Of the 984 paired sets 953 sets recovered organisms within the instrument series. There were 18 sets with no detection of organisms in either the plastic or glass vial that included *Candida albicans* (4 sets) *Haemophilus influenzae* (9 sets) and *Haemophilus parainfluenzae* (5 sets). There were 4 sets with no detection in the plastic vial that included *Candida albicans* (2 sets), *Enterococcus faecalis* (1 set) and *Haemophilus influenzae* (1 set). There were 9 sets with no detection in the glass vial that included *Candida albicans* (3 sets), *Haemophilus influenzae* (1 set) *Haemophilus parainfluenzae* (4 sets) and *Pediococcus acidilactici* (1 set) with no detection in the glass vial. The detection rate of *Candida albicans*, *Enterococcus faecalis* and *Pediococcus acidilactici* was 73%, 98% and 98% respectively under these test conditions. The *Haemophilus* species detection rates were 69% with 0.5 mL blood, and 100% with 5.0 mL, due to the quality (freshness) and volume of blood used in the test. There were five organisms with false negative results (i.e., end of protocol, instrument negative vials with a positive terminal subculture) observed with the BD BACTEC™ Peds Plus™/F medium contained in a plastic vial using 0.5 mL of bagged blood: *H. influenzae* inoculated at 54, 65 CFU, *Haemophilus parainfluenzae* inoculated at 4, 58 CFU, *Candida glabrata*, inoculated at 1 CFU, *Micrococcus luteus* inoculated at 0 CFU, and *Cryptococcus neoformans* inoculated at 0 CFU. Three *Haemophilus influenzae* strains were species that were retested using 0.5 and 1 mL fresh instead of bagged blood and were detected in both glass and plastic vials.

An additional study of 492 paired sets inoculated with 3mL of blood at 10–100 CFU per vial were evaluated across the four instruments comprising the BD BACTEC™ fluorescent-series instrument family: BD BACTEC™ 9050, BD BACTEC™ 9240, BD BACTEC™ FX and the BD BACTEC™ FX40. All organisms recovered from the 492 paired sets across the four BACTEC™ instruments. The *Haemophilus* species detection rate was 100% with 3.0 mL blood due to the volume of blood used in the test. There were 4 sets that favored the glass vial, the mean time to detection was <10%; these vials included *Candida glabrata*, *Stenotrophomonas maltophilia, Candida albicans* and *Haemophilus parainfluenzae*.

The following organisms were evaluated in the analytical studies: *Abiotrophia defective, Acinetobacter lwoffii, Actinobacillus actinomycetemcomitans, Aerococcus viridans, Alcaligenes faecalis, Bacillus subtilis, Candida albicans, Candida glabrata, Candida tropicalis, Candida parapsilosis, Cardiobacterium hominis, Corynebacterium jeikeium, Cryptococcus neoformans, Eikenella corrodens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, Granulicatella adiacens, Haemophilus influenzae, Haemophilus influenzae,* type a*, Haemophilus influenzae,* type b*, Haemophilis parainfluenzae, Kingella kingae, Klebsiella pneumoniae, Leuconostoc mesenteroides, Micrococcus luteus, Neisseria gonorrhoeae, Neisseria meningitidis, Pediococcus acidilactici, Proteus mirabilis, Providencia stuartii, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcusepidermidis, Stenotrophomonas maltophilia, Rothia mucilaginosa (*formerly *Stomatococcus mucilaginosus), Streptococcus agalactiae,* four strains of *Streptococcus pneumoniae, Streptococcus pyogenes,* and *Streptococcus sanguinis* (formerly *S. sanguis*).

In microbial detection limit testing, a total of 360 paired sets inoculated with 0.5 mL, 5.0 mL blood at target inoculum levels of 0 to 1 and 1 to 10 CFU per vial were evaluated. This study was designed to assess the capability of the BD BACTEC™ blood culture media tested to detect one CFU, when present. Of the 360 paired sets tested, 196 grew and detected in both devices, 42 detected in glass vials only, 57 detected in plastic vials only, and 65 did not detect in either. There were a total of 107 pair sets that were not detected in plastic vials, in which 36 showed organism growth on the inoculum plate: *Neisseria meningitidis* (5 CFU), *Haemophilus parainfluenzae* (4 CFU), *Staphylococcus epidermidis* (2 CFU), 1 CFU each for *Candida albicans, Candida glabrata, Escherichia coli, Staphylococcus aureus,* and *Streptococcus sanguinis*. The remaining 71 pair sets showed no organism growth (0 CFU) on the inoculum plate: *Cryptococcus neoformans, Enterococcus faecalis, Haemophilus influenzae, Haemophilus parainfluenzae, Micrococcus luteus, Neisseria gonorrhoeae, Neisseria meningitidis, Staphylococcus epidermidis,* and *Streptococcus pneumoniae*.

In additional microbial detection limit testing, a total of 180 paired sets inoculated with 3 mL blood at target inoculum levels of 0 to 1 and 1 to 10 CFU per vial were evaluated. This study was designed to assess the capability of the BD BACTEC™ blood culture media tested to detect one CFU, when present. Of the 180 paired sets tested, 104 grew and detected in both devices, 23 detected in glass vials only, 19 detected in plastic vials only, and 34 did not detect in either. There were a total of 57 paired sets that were not detected in plastic vials, in which 23 showed organism growth on the inoculum plate: 1 CFU each for *Candida albicans, Cryptococcus neoformans, Haemophilus influenzae, Neisseria gonorrhoeae, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae,* and *Streptococcus sanguinis*. The remaining 34 paired sets showed no organism growth (0 CFU) on the inoculum plate: *Candida glabrata, Enterococcus faecalis, Escherichia coli, Haemophilus parainfluenzae, Micrococcus luteus, Neisseria meningitidis, Staphylococcus epidermidis,* and *Streptococcus pneumoniae*.

AVAILABILITY

Catalog Number	Description
442020	BD BACTEC™ Peds Plus™/F Culture Vials, Case of 50 Vials

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9. Howden, R.J. 1976. Use of anaerobic culture for the improved isolation of *Streptococcus pneumoniae*. J. Clin. Pathol. *29*:50–53.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.
For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.
Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Refer to the Eudamed website: https://ec.europa.eu/tools/eudamed for Summary of Safety and Performance.

Change History

Revision	Date	Change Summary
05	2019-09	Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling. In Warnings and Precautions section, added recommendation to perform molecular testings on positive blood cultures according to standard-of-care practices and manufacturer's instructions for use.
06	2023-03	Added CE notified body number (2797) for IVDR 2017/746. Added "Do not reuse", "Keep Dry", "Keep away from light" and "Do not Use if Package is Damaged" symbols. Updated Intented Use statement and Warning and Precautions - Intended User statement, Safe Disposal statement, and added supplemental information per SDS Updated PRINCIPLES OF THE PROCEDURE section. Added Materials Provided and Materials Required But Not Provided sections. Updated Subculturing section. Added Serious Incident statement and Eudamed link statement. Updated Symbols Glossary Removed eIFU Key code and phone number. Updated EC REP address, CH REP symbol with address, added Australian and New Zealand sponsor addresses. Updated Trademark and Copyright. Removed hyphen between Gram and stain and other minor typos for consistency. Updated Reagents section. Added EU and Swiss Importer addresses with symbol. Added U.S. Patent statement. Updated "culture media" to "Culture Vial" in General Considerations section.

SYMBOLS GLOSSARY

Please refer to product labeling for applicable symbols.

Symbol	Meaning
	Manufacturer
	Authorized representative in the European Community
	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Serial number
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
	Sterile fluid path
	Sterile fluid path (ethylene oxide)
	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
	Contains or presence of natural rubber latex
	In vitro diagnostic medical device
	Negative control
	Positive control
	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic
	Patient number
	This way
	Do not stack

Symbol	Meaning
	Single sterile barrier system
	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
	<Box #> / <Total Boxes>
	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
	UL product certification for US and Canada
	Unique device identifier
	Importer
	Place patient label in framed area only
	Magnetic resonance (MR) safe
	Magnetic resonance (MR) conditional
	Magnetic resonance (MR) unsafe
For use with	For use with
This Product Contains Dry Natural Rubber	This Product Contains Dry Natural Rubber
For Export Only	For Export Only
Instruments	Instruments

Note: Text layout in symbols is determined by label design.

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