Revisions

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Notes:

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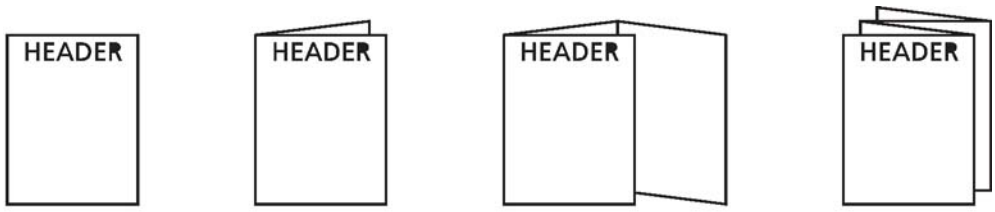

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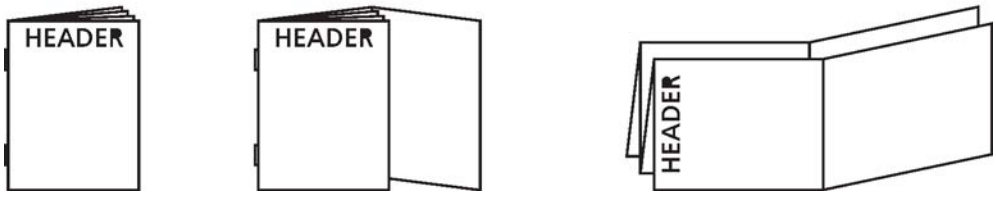

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4. See Specification Control Number VS8800781PR for Material Information
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Label Design Date Proofer Date Checked By Date Part Number: 8800781JAA		BD Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA	
	Category and Description Package Insert, BBL GasPak Anaerobic Systems	Sheet: 1 of 3 Scale: N/A	A

BD BBL™ GasPak™ Anaerobic Systems

8800781JAA
2008/05

INTENDED USE

GasPak™ systems are multiple-use, self-contained systems that produce atmospheres suitable to support the primary isolation and cultivation of anaerobic or microaerophilic bacteria by use of gas-generating envelopes or, alternatively, externally introduced gases.[1-3]

SUMMARY AND EXPLANATION

Prior to the mid-1960s, routine isolation and cultivation of anaerobes from clinical and other specimens was handicapped by the cumbersome methods necessary to achieve anaerobiosis in anaerobic jars.

The performance of anaerobic bacteriology as a routine laboratory procedure was greatly facilitated when, in 1966, Brewer and Allgeier introduced a disposable hydrogen generator envelope and a self-contained anaerobic system which eliminated the requirement for gas cylinders, vacuum pumps and other external equipment.[4]

The **GasPak** 100 jar with rack holds up to 12, 100 x 15 mm-style Petri dishes. The **GasPak** 150 jar with rack holds up to 36, 100 x 15 mm Petri dishes; the jar alone will hold 12, 150 x 15 mm-style dishes.

GasPak™ Plus and **CampyPak™** Plus are disposable hydrogen and carbon dioxide generator envelopes with integral catalyst, which eliminates the requirement for catalyst pellets in the reaction chambers of **GasPak** systems when these envelopes are used.

PRINCIPLES OF THE PROCEDURE

The **GasPak** anaerobic system, vented, combines the flexibility of an evacuation-replacement system using tank gasses with the safety of a room temperature catalyst. The system may also be used with the **GasPak** Plus and **CampyPak** Plus hydrogen and carbon dioxide generator envelopes by closing the vent.

PRODUCT DESCRIPTION

Each **GasPak™** 100 Anaerobic System (260626 and 260627) contains:

One Jar, polycarbonate, 2.5 L – Cat. No. 260463,
One Lid, non-vented with O-ring Gasket – Cat. No. 260637,
or vented with O-ring Gasket – Cat. No. 260638,
One Clamp and Clamp Screw – Cat. No. 260414,
One Wire Rack – Cat. No. 260619,
One Tube Holder – Cat. No. 260630,
One Rubber Tubing and Tubing Clamp (260627 only).

Each **GasPak™** 150 Anaerobic System (260628 and 260629) contains:

One Jar, polycarbonate, non-vented – Cat. No. 260607,
or vented – Cat. No. 260608,
One Outer Lid with Thumbscrew – Cat. No. 271031,
One Inner Lid with O-ring Gasket – Cat. No. 270124,
One Wire Rack – Cat. No. 260618,
One Tube Holder – Cat. No. 260630,
One Rubber Tubing and Tubing Clamp (260629 only).

Warnings and Precautions: For Laboratory Use

Hydrogen is a flammable gas. A mixture of hydrogen with oxygen or air in a confined area will explode if ignited by a spark, flame, or other source of ignition. All usual precautions attendant to handling hydrogen gas should be observed when employing GasPak™ Plus hydrogen plus carbon dioxide generator envelopes or CampyPak™ Plus envelopes. The historical incidence rate of reported hydrogen gas ignition is approximately two (2) incidents per million envelopes.

Do not use envelopes if there is evidence of premature activation, which may cause the package to appear bloated.

GasPak Plus hydrogen and carbon dioxide envelopes, and **CampyPak** Plus hydrogen and carbon dioxide envelopes, are intended for use in properly maintained and operated **GasPak** 100 jars and **GasPak** 150 jars. Their use in other systems may yield misleading results and may even be hazardous to laboratory personnel. For satisfactory and safe use, carefully follow the instructions provided with each system.

ANY UNSATISFACTORY ENVELOPE MUST BE CUT OPEN AND EXAMINED FOR INTACT OR PARTIALLY INTACT TABLETS. ANY REMAINING TABLETS SHOULD BE PLACED IN A CONVENIENT SINK AND DISSOLVED IN FLOWING WATER. DO NOT DISCARD INTACT ENVELOPES.

Product Deterioration: Do not use **GasPak** lids, clamps and jars that show cracks, chips, split O-ring grooves, or other irregularities.

PROCEDURE

Material Provided: GasPak Anaerobic System – Cat. Nos. 260626, 260627, 260628 or 260629.

Materials Required But Not Provided:

1. **GasPak** Plus hydrogen and carbon dioxide envelopes – Cat Nos. 271040 and 271041.
2. **CampyPak** Plus hydrogen and carbon dioxide envelope – Cat No. 271045.
3. **GasPak** Anaerobic Indicator – Cat. No. 271051.
4. Pipette, 10 mL, or syringe.
5. Materials required for operation of a vented system; manometer, gas source and vacuum source.

Test Procedure

GasPak 100 and GasPak 150 Anaerobic Systems

1. The use of catalyst pellets is not required when using **GasPak** Plus (271040) or **CampyPak** Plus (271045) envelopes.
2. Place inoculated plates or tubes in the appropriate **GasPak** 100 or **GasPak** 150 rack. When using either the **GasPak** Plus or **CampyPak** Plus envelope cut off the corner of the envelope and place behind the shielded clip of the rack with the printed side facing the *inside* of the jar (catalyst sachet toward the outside). One envelope is to be used in each **GasPak** 100 system and three envelopes are to be used in each **GasPak** 150 system. **Do not crease, fold or crush the envelope(s).**
3. When using **GasPak** Plus envelopes always use an anaerobic indicator (Cat. No. 271051). Place indicator strip in center of metal indicator holder (see Fig. 1,**A**) with indicator pad upright. Place the rack in the **GasPak** jar. (**Note:** No indicator clip is available on the 150 rack.)

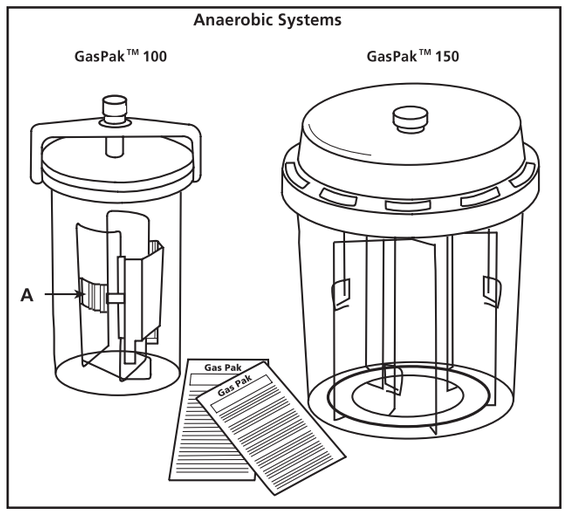

Figure 1

4. Add 10 mL of tap, distilled or deionized water through the open/cut corner of the envelope. Use a pipette or syringe inserting only the tip into the open corner. **Never push any object down into the envelope.**
5. Close the **GasPak** jar promptly after activation and *finger tighten only* the **GasPak** 100 lid clamp or **GasPak** 150 lid assembly.
6. Incubate at conditions appropriate for the organisms being cultured.
7. Periodically during incubation, observe that the indicator is decolorized.
8. After use, jar should be opened and allowed to aerate for approximately 15 s *prior* to removing rack and its contents so as to achieve atmosphere equilibration.

GasPak Vented Set-up

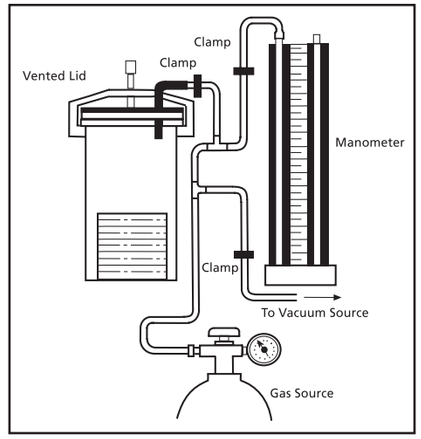

Figure 2

Evacuation-Replacement Procedure for GasPak 100 and GasPak 150 Systems, Vented

1. Place inoculated plates or tubes (in tube holders) in the appropriate **GasPak** 100 or **GasPak** 150 rack.
2. Place an anaerobic indicator in rack as described in Fig. 1 for **GasPak** 100 and **GasPak** 150 Anaerobic Systems, step 3. If using Dry Anaerobic Indicator Strips, dip indicator pad in water before placing in rack. Place the rack in the **GasPak** jar.
3. Close the **GasPak** jar and *finger tighten only* the **GasPak** 100 lid clamp or the **GasPak** 150 lid assembly.
4. Attach a short rubber tube on the vent of the **GasPak** 100 lid or the **GasPak** 150 jar to multiple stopcock or plug (Fig. 2). Outlets are needed for a manometer, gas source (hydrogen, nitrogen, methane, carbon dioxide, or a mixture of hydrogen plus carbon dioxide), and a vacuum source.
5. Close the valve on the gas source. Open clamps to the vacuum source, the manometer, and the lid vent. Evacuate the jar with a vacuum pump to approximately 700 mm of mercury.
6. Close the clamp to the vacuum source and open the valve on the gas source. Fill the jar to atmospheric pressure with desired gas. Always exercise caution when using combustible gases.
7. Evacuate and fill the jar three times or more.
8. Incubate at conditions appropriate for the organisms being cultured.
9. Periodically during incubation, observe that the indicator is decolorized.
10. After use, jar should be opened and allowed to aerate for approximately 15 s *prior* to removing rack and its contents so as to achieve atmosphere equilibration.

NOTE: The **GasPak** 100 and **GasPak** 150 Anaerobic Systems, Vented, may also be used with the **GasPak** Plus or **CampyPak** Plus hydrogen and carbon dioxide generator envelope. This eliminates the need for external connections. Prior to use, close the vent clamp and follow directions for use for the **GasPak** Anaerobic System.

Maintenance Recommendations:

Jar and Lid

Both the jar and lid assembly of the **GasPak** 100 and **GasPak** 150 system are designed to provide long, trouble-free life with a minimum of care. Proper care consists of the following:

1. Avoid contact with abrasives.
2. Avoid contact with solvents and detergents.
3. Rinse and dry thoroughly after cleaning with a mild detergent.
4. **Never** autoclave jar or lid.

Rack and Tube Holder

The **GasPak** 100 and **GasPak** 150 racks are constructed of stainless steel and may be autoclaved.

The tube holder is autoclavable. It may be washed with mild *soap* and rinsed thoroughly after washing. Drainage holes are located at the bottom of the unit. **Note:** contact with solvents, disinfectants and detergents will craze the polycarbonate.

The Polycarbonate Lid Assembly (GasPak 150 System)

The large capacity jar includes a two piece lid for positive locking and sealing. The lid serves as a carrier for the catalyst reaction chambers and has a recessed crown to permit stacking of jars if desired. The polycarbonate lid consists of an outer lid and thumbscrew, and an inner lid with an O-ring gasket and three double-screened reaction chambers (See Figs. 3a and 3b).

Outer Lid and Thumbscrew

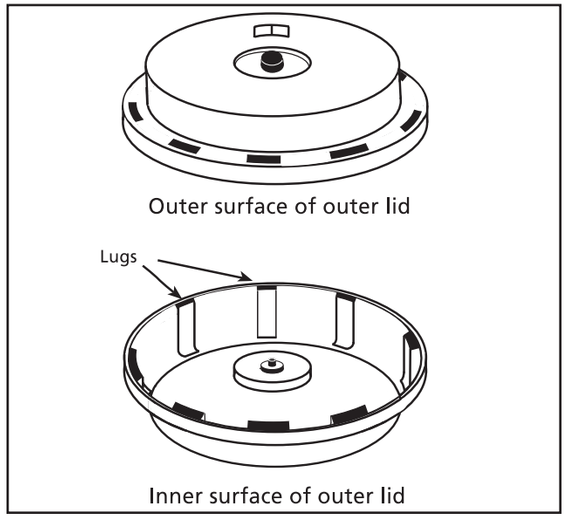

Figure 3a

Inner Lid and O-ring Gasket

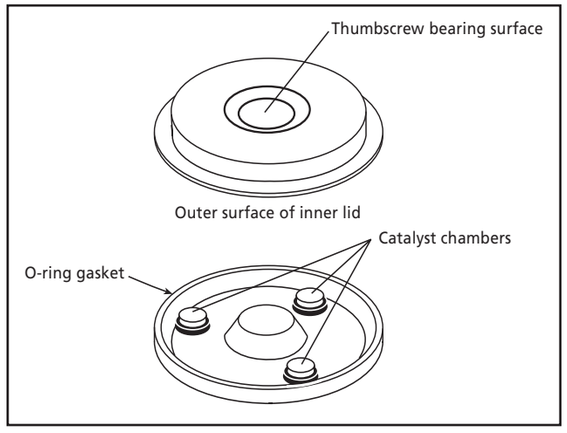

Figure 3b

User Quality Control:

1. Each **GasPak** system should be tested periodically for its ability to provide adequate conditions for the growth of appropriate bacteria.
2. If visible condensation does not occur within 60 min after a **GasPak** Plus, or **CampyPak** Plus envelope is activated, the reaction should be terminated by opening the system. Check the condition of the **GasPak** 100 or **GasPak** 150 lid and O-ring gasket as described below.
3. The following quality control checklist, if followed regularly, will help assure proper performance:
   a. The **GasPak** system should be maintained upright at all times while in operation.
   b. Gas generating envelopes must be kept upright and cut along the dotted line at the upper right hand corner, as indicated on each envelope. The gas-generating tablets must be present and not displaced or crushed, and the foil channels and reaction chambers must not be crushed or distorted and must be able to accept 10 mL of water. Improper positioning of the envelope or use of a damaged envelope may lead to imbalances in reactivity. Damage

may result in spattering and "boiling over" of the contents of the envelope and hence inadequate gas output.

c. Plastic lid and clamp – Inspect for cracks, chips, split O-ring grooves, and other irregularities. Most cracks (craze or stress lines) develop on prolonged use and forced or excessive tightening of clamps on lids. Early cracks may appear as fine black lines near the center of the lid, or along the upper edges of the **GasPak** 100 clamp near the screw. Cracked lids and clamps which exhibit these fine black lines should not be used.

d. O-ring gasket – Examine for cracks, bumps, dirt, and improper seating in the O-ring groove. Examine O-ring groove wall for splitting or cracking. The O-ring must be resilient, clean and snugly retained within the O-ring groove for satisfactory operation of the system. Replace as necessary.

RESULTS

Anaerobic conditions are achieved rapidly, generally reaching a redox potential of –100mV within 1 h and –200 mV within 2 h in media of pH 7.0 at room temperature. Within 1 h of incubation at 35°C, the carbon dioxide concentration is approximately 4 to 10%. At 35°C anaerobic indicator Cat. No. 271051 becomes decolorized within 9 h.

AVAILABILITY

Cat. No.	Description
260626	**BBL™ GasPak™** 100 Anaerobic System
260627	**BBL™ GasPak™** 100 Anaerobic System, Vented
260628	**BBL™ GasPak™** 150 Anaerobic System
260629	**BBL™ GasPak™** 150 Anaerobic System, Vented

REFERENCES

1. Murray, P.R., and D.M. Citron. 1991. General processing of specimens for anaerobic bacteria, p. 488-504. *In* A. Balows, W.J. Hausler, Jr., K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
2. Penner, J.L. 1991. *Campylobacter*, *Helicobacter*, and related spiral bacteria, p. 402-409. *In* A. Balows, W.J. Hausler, Jr., K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
3. Morello, J.A., W.M. Janda, and G.V. Doern. 1991. *Neisseria* and *Branhamella*, p. 258-276. *In* A. Balows, W.J. Hausler, Jr., K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
4. Brewer, J.H., and D.L. Allgeier. 1965. Disposable hydrogen generator. Science *147*:1033-1034.

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