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ACCEPTED

OCT 21 1968

UNDER THE FEDERAL INSECTICIDE
FUNGICIDE AND RODENTICIDE ACT
FOR ECONOMIC PEST CONTROL REGISTERED
ED UNDER NO. 94171 SUBJECT
TO ATTACHED COMMENTS.

CONTENTS: 60 AMPULES • 12 LINE

ANPROL

STERILIZING GAS A

CAUTION :

- READ INSTRUCTIONS AND CAUTIONS BEFORE USING
- FLAMMABLE
- STORE IN COOL PLACE
- FOR PROFESSIONAL USE ONLY
- AIR GAS SORBENT MATERIALS BEFORE USING
- USE ONLY IN ANPROLENE STERILIZING CONTAINERS
CATALOG NUMBER AN-74

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CONTENTS: 60 AMPULES • 12 LINER BAGS • 12 CLOSURES

ANIPROLENE®

STERILIZING GAS AMPULES

INSTRUCTIONS AND CAUTIONS BEFORE USING

COOL PLACE

PROFESSIONAL USE ONLY

ABSORBENT MATERIALS BEFORE USING

IN ANIPROLENE STERILIZING CONTAINERS

NUMBER AN-74

Net contents each ampule 0.16 av. oz.

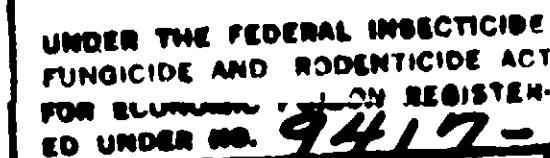
Active ingredient ethylene oxide 84%

Inert ingredients 16%

Manufactured by: H. W. ANDERSON PRODUCTS INC.

45 EAST MAIN ST., OYSTER BAY, N. Y. 11771

Patent Pending U.S.A. and Foreign Countries USDA Reg. No. 9417-1



(over)

Instructions for using Anprolene gas ampules

Each ampule of Anprolene has a plastic shield around the ampule. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability whose function is to contain the gas given off by the ampule and release it at a controlled rate during the sterilization cycle. The plastic shield around the ampule prevents broken glass from the opened ampule from puncturing the gas release bag.

- Catheters—plastic, rubber, cloth
- Tubing—plastic, rubber, metal, glass, cloth
- Anesthesia equipment—endotracheal tubes, masks, rubber tubing
- Tape (a common source of cross infection)
- Bandages, dressing sets (reuse plastic forceps) —
- Syringes—plastic, rubber, glass, bulb syringes
- Gloves—rubber, plastic, cloth
- Surgical instruments—steel, chrome plate, brass, plastic
- Optical instruments—scopes, cameras, lenses, mirrors
- Electrical equipment—whether autoclavable or not
- Painted equipment—metal, wood
- High speed steel—drills, burrs, chisels
- Airways—plastic, rubber, metal
- Fabric—cloth, rubber, plastic, leather
- Electric wire—whether autoclavable or not
- Dry cell batteries, battery cases, bulbs
- Sutures—plastic, silk, cotton, stainless steel
- Thermometers, tongue depressors, applicator sticks
- Rectal tubes, duodenal tubes—rubber, plastic
- Specula—plastic, metal

Aniprole is a highly drainable, nonionic surfactant. In the case of sprays or stylets must be formulated with a buffer so that the solution is not too acidic. Do not pack the container so tightly with foam so that it is difficult to fill. Do not use too much foam and plastic material in the container. The foam should not be from the same source as the buffer and should not be from the same source as the buffer and should not be from the same source as the buffer.

Attributed to the staff of the American Council on Education, "The American and the Communist," *Communist Party in the U.S.A.*, 1956, pp. 10-11. The leader or principal of the school is responsible for the staff administration. When he is on leave, it is the duty of the principal to assign a temporary substitute and make his effective use of the staff and building. The principal is often the principal of the school, but not always. The principal is not a person, but a position. (p. 11)

1. 2. Affixation method with A1-Z1 container.

Remove five Angiomedic samples from the cordoned-off sterilization. Do not open the plastic bags in which the samples are sealed. Return all five plastic bags to the sterilization area and place them in a container to facilitate removal from the sterilization area. Seal the container with the bag of the five samples. Hold and snap the top of the container, thus sealing the samples within the angurol. Place the five plastic bags, still wrapped in their sealed plastic bags, inside the liner bag on top of the material to be sterilized. After loading the liner bag with the samples and the materials to be sterilized, it is advisable to press any excess air out of the liner bag before closing the mouth of the liner bag. If you fail to do this, you may experience difficulty in closing the Angiomedic due to "billowing" of the liner bag.

1. Put the liner bag shut and hold the seal with one of the fast seal clips which are provided in the kit.

Put the filled liner bag into the container, place the lid on the container and lock the lid in place. Mark the liner with the date and hour that sterilization has been completed.

Place the container in a safe, well-ventilated place away from fire or sparks. Leave the container at room temperature (15-25°C/60-80°F) for twelve hours before using for the modified stool.

any information that has been removed from the record must be posted and empty gas release valves must be disposed of in ordinary trash.

References

to be used for 10 to 15 days of plastic or rubber tubing, and to be changed every 2 to 24 hours.

1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. 16. 17. 18. 19. 20. 21. 22. 23. 24. 25. 26. 27. 28. 29. 30. 31. 32. 33. 34. 35. 36. 37. 38. 39. 40. 41. 42. 43. 44. 45. 46. 47. 48. 49. 50. 51. 52. 53. 54. 55. 56. 57. 58. 59. 60. 61. 62. 63. 64. 65. 66. 67. 68. 69. 70. 71. 72. 73. 74. 75. 76. 77. 78. 79. 80. 81. 82. 83. 84. 85. 86. 87. 88. 89. 90. 91. 92. 93. 94. 95. 96. 97. 98. 99. 100. 101. 102. 103. 104. 105. 106. 107. 108. 109. 110. 111. 112. 113. 114. 115. 116. 117. 118. 119. 120. 121. 122. 123. 124. 125. 126. 127. 128. 129. 130. 131. 132. 133. 134. 135. 136. 137. 138. 139. 140. 141. 142. 143. 144. 145. 146. 147. 148. 149. 150. 151. 152. 153. 154. 155. 156. 157. 158. 159. 160. 161. 162. 163. 164. 165. 166. 167. 168. 169. 170. 171. 172. 173. 174. 175. 176. 177. 178. 179. 180. 181. 182. 183. 184. 185. 186. 187. 188. 189. 190. 191. 192. 193. 194. 195. 196. 197. 198. 199. 200. 201. 202. 203. 204. 205. 206. 207. 208. 209. 210. 211. 212. 213. 214. 215. 216. 217. 218. 219. 220. 221. 222. 223. 224. 225. 226. 227. 228. 229. 230. 231. 232. 233. 234. 235. 236. 237. 238. 239. 240. 241. 242. 243. 244. 245. 246. 247. 248. 249. 250. 251. 252. 253. 254. 255. 256. 257. 258. 259. 260. 261. 262. 263. 264. 265. 266. 267. 268. 269. 270. 271. 272. 273. 274. 275. 276. 277. 278. 279. 280. 281. 282. 283. 284. 285. 286. 287. 288. 289. 290. 291. 292. 293. 294. 295. 296. 297. 298. 299. 300. 301. 302. 303. 304. 305. 306. 307. 308. 309. 310. 311. 312. 313. 314. 315. 316. 317. 318. 319. 320. 321. 322. 323. 324. 325. 326. 327. 328. 329. 330. 331. 332. 333. 334. 335. 336. 337. 338. 339. 340. 341. 342. 343. 344. 345. 346. 347. 348. 349. 350. 351. 352. 353. 354. 355. 356. 357. 358. 359. 360. 361. 362. 363. 364. 365. 366. 367. 368. 369. 370. 371. 372. 373. 374. 375. 376. 377. 378. 379. 380. 381. 382. 383. 384. 385. 386. 387. 388. 389. 390. 391. 392. 393. 394. 395. 396. 397. 398. 399. 400. 401. 402. 403. 404. 405. 406. 407. 408. 409. 410. 411. 412. 413. 414. 415. 416. 417. 418. 419. 420. 421. 422. 423. 424. 425. 426. 427. 428. 429. 430. 431. 432. 433. 434. 435. 436. 437. 438. 439. 440. 441. 442. 443. 444. 445. 446. 447. 448. 449. 450. 451. 452. 453. 454. 455. 456. 457. 458. 459. 460. 461. 462. 463. 464. 465. 466. 467. 468. 469. 470. 471. 472. 473. 474. 475. 476. 477. 478. 479. 480. 481. 482. 483. 484. 485. 486. 487. 488. 489. 490. 491. 492. 493. 494. 495. 496. 497. 498. 499. 500. 501. 502. 503. 504. 505. 506. 507. 508. 509. 510. 511. 512. 513. 514. 515. 516. 517. 518. 519. 520. 521. 522. 523. 524. 525. 526. 527. 528. 529. 530. 531. 532. 533. 534. 535. 536. 537. 538. 539. 540. 541. 542. 543. 544. 545. 546. 547. 548. 549. 550. 551. 552. 553. 554. 555. 556. 557. 558. 559. 560. 561. 562. 563. 564. 565. 566. 567. 568. 569. 570. 571. 572. 573. 574. 575. 576. 577. 578. 579. 580. 581. 582. 583. 584. 585. 586. 587. 588. 589. 590. 591. 592. 593. 594. 595. 596. 597. 598. 599. 600. 601. 602. 603. 604. 605. 606. 607. 608. 609. 610. 611. 612. 613. 614. 615. 616. 617. 618. 619. 620. 621. 622. 623. 624. 625. 626. 627. 628. 629. 630. 631. 632. 633. 634. 635. 636. 637. 638. 639. 640. 641. 642. 643. 644. 645. 646. 647. 648. 649. 650. 651. 652. 653. 654. 655. 656. 657. 658. 659. 660. 661. 662. 663. 664. 665. 666. 667. 668. 669. 670. 671. 672. 673. 674. 675. 676. 677. 678. 679. 680. 681. 682. 683. 684. 685. 686. 687. 688. 689. 690. 691. 692. 693. 694. 695. 696. 697. 698. 699. 700. 701. 702. 703. 704. 705. 706. 707. 708. 709. 710. 711. 712. 713. 714. 715. 716. 717. 718. 719. 720. 721. 722. 723. 724. 725. 726. 727. 728. 729. 730. 731. 732. 733. 734. 735. 736. 737. 738. 739. 740. 741. 742. 743. 744. 745. 746. 747. 748. 749. 750. 751. 752. 753. 754. 755. 756. 757. 758. 759. 760. 761. 762. 763. 764. 765. 766. 767. 768. 769. 770. 771. 772. 773. 774. 775. 776. 777. 778. 779. 780. 781. 782. 783. 784. 785. 786. 787. 788. 789. 790. 791. 792. 793. 794. 795. 796. 797. 798. 799. 800. 801. 802. 803. 804. 805. 806. 807. 808. 809. 810. 811. 812. 813. 814. 815. 816. 817. 818. 819. 820. 821. 822. 823. 824. 825. 826. 827. 828. 829. 830. 831. 832. 833. 834. 835. 836. 837. 838. 839. 840. 84

the gas is not used for any other purpose. In concentrated form, the gas is as irritating to the eyes as ammonia gas.

the system. The system is designed to be able to handle a large number of requests, and to be able to handle requests from a large number of users. The system is designed to be able to handle requests from a large number of users, and to be able to handle requests from a large number of users.

the fact that the majority of the respondents being interviewed were in the age group of 18 to 24 years, the majority of the respondents were young people, and the majority of the respondents were male.

Journal of Management Education, 20(6), 709-728
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10.1177/002203219628142
<http://jme.sagepub.com>

the results obtained are stabilized by this method. The results obtained by the method of least squares are not stable in the case of small changes in the data. The results obtained by the method of least squares are not stable in the case of small changes in the data. The results obtained by the method of least squares are not stable in the case of small changes in the data.

ACCEPTED WITH COMMENTS

As with other chemical vapors, there is a chance of an occasional allergic response to Anprolene in a sensitive individual. Such individuals should not handle Anprolene nor breathe its vapors nor allow material sterilized in it to come in contact with their skin or mucous membranes. If skin contact with liquid Anprolene occurs irrigate the area with copious amounts of cold water.

Vapors in dehydration, chemical dehydration or prolonged exposure to ambient relative humidity below 10% have been demonstrated to produce spores highly resistant to sterilization by Anprolene. Rehydration of spores so changed and hence reversion to normal sensitivity does not seem to occur until they have been actually wetted or placed in essentially 100% relative humidity. Do not attempt to sterilize materials which may be carrying dried spores without first soaking them in water or washing the articles with water, soap, or detergents for an overall pretreatment routine of approximately one hour. If the nature of the material is such that the water treatments specified above are harmful, then a pre-treatment in a chamber having a saturated humidity will be necessary.

Anprolene is a potent polymerizing agent. It should not be used for sterilizing food-stuffs or drugs.

7. WARNING--Variations from these instructions.

Any variation from these instructions are done at the user's risk. Anprolene is designed to be used in the liner bag provided with the ampules and in a genuine Anprolene Sterilizer container.

If, despite this warning, the user wishes to vary container size, he should verify his unauthorized technique with adequate biological controls.

3. Technical description of the system.

The Anprolene Sterilizer container serves as a guard against inadvertent ignition of the contents by spark or open flame during the sterilization cycle. The liner bag, when properly twist closed, has a 35 liter capacity. It serves as a second gas diffusion membrane, retaining Anprolene long enough to sterilize its contents and then diffusing it into the surrounding room air at a slow enough rate to insure that toxic levels are not reached in the room. Each ampule releases approximately 3,800 mgm of Anprolene at room temperature (68°F., 20°C.) and sea level atmospheric pressure. Five ampules produce a minimum peak concentration within the liner bag of 500 mgm/1,000 cc. Tests in our laboratory confirm that this configuration will kill the most resistant spores known (providing they have not been desiccated) within the 12 hour cycle.

Large solid bodies may place a volume of air equal to the volume of the liner bag. Therefore, the effective concentration of Anprolene in the liner bag. Sterilization of such material may be achieved with fewer than the five ampules of Anprolene recommended for routine, unattended use in the AN-74 container. If the user wishes to utilize such a procedure with fewer than five ampules, he should verify his technique with an adequate biological challenge. The AN-70 Steritest™ unit provides one convenient way of doing this. In the first procedure, the user should place the material to be sterilized in the liner bag, add the five ampules of Anprolene, and seal the bag. In the second procedure, the user should place the material to be sterilized in the liner bag, add the five ampules of Anprolene, and seal the bag. In the third procedure, the user should place the material to be sterilized in the liner bag, add the five ampules of Anprolene, and seal the bag. 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In the one hundredth procedure, the user should place the material to be sterilized in the liner bag, add the five ampules of Anprolene, and seal the bag.

Increasing temperature and prolonging the cycle time have resulted in spore kill with much lower Anprolene concentrations.

2. Storage - Shelf Life.

Anprolene must be stored in a cool place out of direct sunshine. Under normal conditions shelf life will exceed one year. As long as the material in the ampule is liquid at 18°C it is ready for use.

Net weight each ampule 0.125 g.
Active ingredient ethylene oxide 0.125 g.
Inert ingredients 0.125 g.

Anprolene Modular Sterilizing System

- AN-70 Anprolene Cylinder Module Kit (includes 1 ea. AN-71)
- AN-71 Anprolene 25 ampule Refill Dispenser Module
- AN-72 Anprolene Tray Module kit (includes 1 ea. AN-73)
- AN-73 Anprolene 60 ampule Refill Dispenser Module
- AN-74 Anprolene Large Tray Module Kit (includes 1 each AN-75)
- AN-75 Anprolene Refill Dispenser Module for AN-74 (includes supplies for 12 cycles)
- AN-76 Steritest™ Biological and Chemical Sterilizer Control, (10 box)
- AN-77 Anprolene Exposure Indicator Strips (20 box)
- AN-78 Anprolene Spore Strips (20 box)
- AN-79 Seal and Peel™ Electric Impulse Sealer
- AN-80 2' x 21" Seal and Peel™ Packaging Pouches 100 box
- AN-81 3' x 21" Seal and Peel™ Packaging Pouches 100 box
- AN-82 7' x 12" Seal and Peel™ Packaging Pouches 100 box

Anprolene is a registered trademark of H. W. Andersen Products, Inc. in

| | |
|--------------------|--------------------------|
| U.S.A. 815273 | Great Britain 8933,236 |
| Spain 102,980 | Holland 109,254 |
| Australia 4201,531 | Malaya 130,761 |
| Belgium 103,024 | New Zealand 8351A |
| Canada 112,057 | Norway 70031 |
| Denmark 2222-1067 | Republic of South Africa |
| France 111,7016 | A 66/1103 |
| Germany 137,356 | Sweden 120,035 |

Patent No. 210,010

Anprolene patents are pending in the U.S.A. and many foreign countries.

Anprolene is sold in
Canada 679,298
France 1,175,759
Germany 1,175,759
Japan 1,175,759

Manufactured by
H. W. Andersen Products, Inc.
1000 N. 1st St., Des Moines, Iowa 50319

U.S. Pat. No. 2,174,174

ACCEPTED WITH COMMENTS

2273

ACCEPTED
10-31-68
UNDER THE FEDERAL INSECTICIDE
FUNGICIDE AND RODENTICIDE ACT
FOR ECONOMIC PEST CONTROL REGISTERED
UNDER NO. 9417-1

BARD® Sterilizer System

CAUTION: Flammable • For Professional Use Only
• Read Instructions and Cautions before using
• Store in Cool Place
• Use Only in Bard Sterilizing Containers

ETO UNIT AMPULES

Net contents
each ampule 0
Active ingredient
Inert ingredient

Distributed by: C. R. BARD, INC. Murray Hill, N.J. 07974
Made in U.S.A. by: H. W. Andersen Products, Inc.

ACCEPTED

10-31-68

UNDER THE FEDERAL INSECTICIDE
FUNGICIDE AND RODENTICIDE ACT
FOR ECONOMIC PEST CONTROL REGISTERED
UNDER NO. 9417-1

BARD® Sterilizer system

Professional Use Only
Read Instructions and Cautions before using
• Store in Cool Place
in Bard Sterilizing
Containers

ETO UNIT AMPULES

Net contents
each ampule 0.16 av. oz.
Active ingredients ethylene oxide 84%
Inert ingredients 16%

Distributed by: C. R. BARD, INC. Murray Hill, N.J. 07974

Made in U.S.A. by: H. W. Andersen Products, Inc.

ACCEPTED

227/1

10-31-68

UNDER THE FEDERAL INSECTICIDE
FUNGICIDE AND RODENTICIDE ACT
FOR ECONOMIC PEST CONTROL
REGISTERED UNDER NO. 9477-1

Crimmer

BARD® sterilizer system

ETO UNIT AMPULES

CAUTION: Store in Cool Place
Flammable • For Professional Use Only
Read Instructions and Cautions before using
Use Only in Bard Sterilizing Containers
Net contents each ampule 0.16 av. oz.
Active ingredients ethylene oxide 84%
Inert ingredients 16%

Distributed by: C. R. BARD, INC. Murray Hill, N.J. 07974

Made in U.S.A. by: H. W. Andersen Products, Inc.

L 1479

8. Technical description of the system.

The Bard ETO Sterilizer container serves as a guard against inadvertent ignition of the contents by spark or open flame during the sterilization cycle. The liner bag, when properly twist closed, has a seven liter capacity. It serves as a second gas diffusion membrane, retaining Bard ETO long enough to sterilize its contents and then diffusing it into the surrounding room air at a slow enough rate to insure that toxic levels are not reached in the room. Each ampule releases approximately 3,800 mgm of Bard ETO at room temperature (68°F., 20°C.) at sea level atmospheric pressure giving a minimum peak concentration within the liner bag of 500 mgm/1,000 cc. Tests in our laboratory confirm that this configuration will kill the most resistant spores known (providing they have not been desiccated) within the 12 hour cycle.

Increasing temperature and prolonging the cycle time have resulted in spore kill with much lower Bard ETO concentrations.

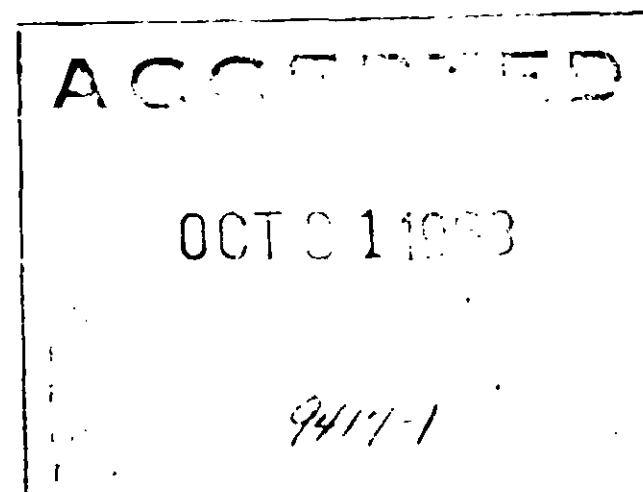
9. Storage — Shelf Life.

Bard ETO must be stored in a cool place out of direct sunshine. Under normal conditions its shelf life will exceed one year. As long as the material in the ampule is liquid at 68°F., it is sufficiently potent to use.

| | |
|----------------------------------|--------------|
| Net contents each ampule | 0.16 av. oz. |
| Active ingredient ethylene oxide | 84% |
| Inert ingredients | 16% |

Bard ETO patents are pending in the U.S.A. and many foreign countries.

Bard ETO is patented in
Belgium 679,298
France 1,475,399
South Africa 1692/66
Spain 325/170
Canada 791,915
Italy 800,099
New Zealand 144,583



Manufactured for

C. R. BARD, INC.

731 CENTRAL AVE., MURRAY HILL, N. J. 07971

By H. W. ANDERSEN PRODUCTS, INC.

OYSTER BAY, N. Y.

U.S.D.A. REG. NO. 9417-1

BARD ETO™

BRAND GASEOUS STERILANT FOR ROOM TEMPERATURE,
ATMOSPHERIC PRESSURE STERILIZATION.

Instructions for using Bard ETO gas ampules

1. Do not open the plastic bag in which each individual Bard ETO ampule is sealed.

Each ampule of Bard ETO has a plastic shield around the ampule. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability whose function is to contain the gas given off by the ampule and release it at a controlled rate during the sterilization cycle. The plastic shield around the ampule prevents broken glass from the opened ampule from puncturing the gas release bag.

2. Typical products conveniently sterilized by Bard ETO.

Catheters—plastic, rubber, cloth
Tubing—plastic, rubber, metal, glass, cloth
Anesthesia equipment—endotracheal tubes, masks, rubber tubing
Tape (a common source of cross infection)
Bandages, dressing sets (reuse plastic forceps)
Syringes—plastic, rubber, glass, bulb syringes
Gloves—rubber, plastic, cloth
Surgical instruments—steel, chrome plate, brass, plastic
Optical instruments—scopes, cameras, lenses, mirrors
Electrical equipment—whether autoclaveable or not
Painted equipment—metal, wood
High speed steel—drills, burrs, chisels
Airways—plastic, rubber, metal
Fabric—cloth, rubber, plastic, leather
Electric wire—whether autoclaveable or not
Dry cell batteries, battery cases, bulbs
Sutures—plastic, silk, cotton, stainless steel
Thermometers, tongue depressors, applicator sticks
Rectal tubes, douche tubes—rubber, plastic
Specula—plastic, metal

3. Preparation of material for sterilization.

Bard ETO is a highly diffusible gaseous sterilant. Occlusive caps, plugs or stylets must be removed from instruments so that the gas can penetrate freely. Do not pack the container so tightly with cloth or gauze that gas diffusion is slowed. Hollow bore needles and plastic or rubber tubing must be open and free from plugs. Syringes must be packaged with their plungers out of the barrel.

Material to be sterilized by Bard ETO must be surgically clean and dry. Coatings of dry protein (like dry blood or pus) protect microorganisms and slow the sterilization process. Although water on instruments at the time of exposure to Bard ETO may react with it and reduce its effectiveness, washing contaminated instruments with water prior to exposure rehydrates desiccated spores and is strongly recommended.

(See also paragraph 6 — Cautions.)

Wrap all items individually in cloth or paper in the manner conventional for steam sterilization.

4. Sterilization method with 2270 container.

Have the material to be sterilized prepared as described above and ready to place in the liner bag.

Take a liner bag from the dispenser carton and place it fully opened within the Bard ETO sterilizer container.

Remove one Bard ETO ampule from its cardboard shipping sleeve. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag. The ampule is prescored around its neck to facilitate releasing the gas. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This releases the gas within the ampule bag. Place the ampule, still wrapped in its sealed plastic bag, inside the bottom of the liner bag.

Place the material to be sterilized on top of the gas release ampule bag, twist the liner bag shut and hold the seal with one of the twist seal closures which are provided.

Place the lid on the container and lock the lid in place. Invert the container and mark the bottom of the container with the date and hour that sterilization was begun.

Put the container in a safe, well ventilated place away from flame or spark. Leave the container at room temperature (at least 68°F.) for twelve hours before removing the sterilized material.

After the sterile material has been removed from the liner bag, the exhausted and empty gas release ampule and its bag may be disposed of in ordinary rubbish.

Sterilization method with 2272 container.

Have the material to be sterilized prepared as described above and ready to place in the liner bag.

Take a liner bag from the dispenser carton and place the wrapped material to be sterilized within it.

Remove one Bard ETO ampule from its cardboard shipping sleeve. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag. The ampule is prescored around its neck to facilitate releasing the gas. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This releases the gas within the ampule bag. Place the ampule, still wrapped in its sealed plastic bag, inside the liner bag on top of the material to be sterilized. After loading the liner bag with the gas release bag and the materials to be sterilized it is advisable to press any excess air out of the liner bag before closing the mouth of the liner bag. If you fail to do this you may experience difficulty in closing the 2272 container due to "pillowing" of the liner bag.

Twist the liner bag shut and hold the seal with one of the twist seal closures which are provided in the kit.

Put the filled liner bag into the container, place the lid on the container and lock the lid in place. Mark the container with the date and hour that sterilization has begun.

Put the container in a safe, well ventilated place away from flame or spark. Leave the container at room temperature (at least 68°F.) for twelve hours before removing the sterilized material.

After the sterile material has been removed from

the liner bag, the exhausted and empty gas release ampule and its bag may be disposed of in ordinary rubbish.

5. Special Problems.

When sterilizing long lengths of plastic or rubber tubing, use two ampules of Bard ETO and increase the cycle time to 24 hours.

6. CAUTIONS.

Do not breathe Bard ETO vapors. In concentrated amounts Bard ETO sterilizing gas is as irritating to the lungs and mucous membranes as is ammonia gas.

Bard ETO gas is flammable. Do not bring ampule or sterilizer near open flame. Do not smoke near the container while loading or unloading it.

Remove batteries from electrical instruments being sterilized in Bard ETO and wrap them separately to avoid the possibility of an electrical spark igniting the gas during the sterilization cycle.

Failure to adequately air gas absorbing materials may lead to contact chemical burns. Foam rubber, plastic foams and sealed air cushioned devices like some anesthesia masks must be aired 24 hours before use.

Rubber, plastic or cloth sterilized by this method which is to come in direct contact with skin or mucous membranes must be aired for six hours after removal from the sterilizer container. Gas absorbing materials, like rubber or plastic, which are to be implanted in the body should be aired for 24 hours. It is not necessary to remove such material from cloth or paper wrappings to obtain adequate diffusion of the residual Bard ETO vapors.

As with other chemical vapors, there is a chance of an occasional allergic response to Bard ETO in a sensitive individual. Such individuals should not handle Bard ETO nor breathe its vapors nor allow material sterilized in it to come in contact with their skin or mucous membranes. If skin contact with liquid Bard ETO occurs, irrigate the area with copious amounts of cold water.

Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 30% have been demonstrated to produce spores highly resistant to sterilization by Bard ETO. Rehydration of spores so changed and hence reversion to normal sensitivity does not seem to occur until they have been actually wetted or placed in essentially 100% relative humidity. Do not attempt to sterilize materials which may be carrying dried spores without first soaking them in water or washing the articles with water, soap, or detergents for an overall pretreatment routine of approximately one hour. If the nature of the material is such that the water treatments specified above are harmful, then a pre-treatment in a chamber having a saturated humidity will be necessary.

Bard ETO is a potent polymerizing agent. It should not be used for sterilizing food-stuffs or drugs.

7. WARNING — Variations from these instructions.

Any variation from these instructions are done at the user's risk. Bard ETO is designed to be used in the liner bag provided with the ampules and in a genuine Bard ETO Sterilizer container.

If, despite this warning, the user wishes to vary container size, he should verify this unauthorized technique with adequate biological controls.

275 74

BARD® sterilizer system ETO UNIT NO.1 CANISTER

Distributed by: C. R. BARD, INC. Murray Hill, N.J. 07974

Made in U.S.A. by: H. W. Andersen Products, Inc.

L 1474

U.S.D.A. Reg. No. 9417-1

Pat. Pend.
U.S.A. and Foreign

STERILIZER LABEL

ACCT

CCFC 1474

44474
TO AG... SUBJECT
HIS.

ACCEPTED

Cameraman's Note

Poor Copy

4444

2270

BARD®
sterilizer system
ETO UNIT NO. 1
CANISTER

Distributed by: C. R. BARD, INC. Murray Hill, N.J. 07974

Made in U.S.A. by: H. W. Andersen Products, Inc.

U.S.D.A. Reg. No. 9417-1

L 1475

Pat. Pend.
U.S.A. and Foreign

STERILIZER CANISTER LABEL

AC

Cameraman's Note

Poor Copy

2270

BARD® sterilizer system

ETO UNIT NO. 1 CANISTER

Distributed by: C. R. BARD, INC. Murray Hill, N.J. 07974

Made in U.S.A. by: H. W. Andersen Products, Inc.

U.S.D.A. Reg. No. 9417-1

L 1475

Pat. Pend.
U.S.A. and Foreign

BR

STERILIZER CARTON LABEL

Abridged Instructions for using ETO Unit Ampules Refer to complete instructions packed with Ampules.

1. Remove the plastic bag in which each individual ampule is sealed.

Each ETO Unit Ampule has a plastic shield around the ampule. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas release bag whose permeability allows the gas given off by the ampule to be released at a controlled rate during the sterilization cycle. The plastic shield around the ampule prevents broken glass from the opened ampule from puncturing the gas release bag.

2. Preparation of material for sterilization.

Occlusive caps, plugs or stylets must be removed from instruments so that the gas can penetrate freely. Do not pack the containers so tightly with cloth or gauze that gas diffusion is slowed. Hollow bore needles and plastic or rubber tubing must be open and free from plugs. Syringes must be packaged with their plungers out of the barrel.

Material to be sterilized by BARD ETO Unit must be surgically clean and dry. Items contaminated with dried bacterial spores must be soaked or washed and immediately on drying wrapped and placed in the sterilizer.

3. Sterilization method.

Have the material to be sterilized prepared and ready to place in the liner bag.

Take out liner bag from the dispenser carton and place it fully opened within the BARD ETO Sterilizer Container.

Remove one ETO Unit ampule from its cardboard shipping sleeve. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag. The ampule is prescored around its neck to facilitate releasing the gas. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This releases the gas

within the ampule bag. Place the ampule, still wrapped in its sealed plastic bag, inside the bottom of the liner bag.

Place the material to be sterilized on top of the gas release ampule bag, twist the liner bag shut and hold the seal with one of the twist seal closures which are provided.

Place the lid on the container and lock the lid in place. Invert the container and mark the bottom of the container with the date and hour that sterilization was begun.

Put the container in a safe, well ventilated place away from flame or spark. Leave the container at room temperature (at least 68°F.) for twelve hours before removing the sterilized material.

When sterilizing long lengths of plastic or rubber tubing, use two ETO Unit Ampules and increase the cycle time to 24 hours.

4. Cautions.

Prolonged contact of improperly aired material with skin or mucous membranes may cause severe local irritation. Rubber, plastic, leather, fibrous material and other similar gas absorbent materials must be aired for at least six hours outside of the liner bag before use.

The aeration period for products such as foam rubber, plastic foams, rubber or plastic intended for implantation in the body, and sealed air cushioned devices like some anesthesia masks must be extended to a minimum of 24 hours.

Do not breathe ETO vapors. In concentrated amounts ETO sterilizing gas is as irritating to the lungs and mucous membranes as is ammonia gas.

ETO gas is flammable. Do not bring ampule or sterilizer near open flame. Do not smoke near the container while loading or unloading it.

If skin contact with liquid ETO occurs irrigate with cold water.

L 1476

ABRIDGED INSTRUCTIONS ON
ETO UNIT No 1 CONTAINER

of BARD® STERILIZER ETO UNIT NO. 2 TRAY

ACCEPTED

10-31-68

ENTER THE SEAL IN THE TOP OF
THE LINER BAG. (SEE INSTRUCTIONS)

U.S.D.A. BUREAU OF PLANT INDUSTRY

Abridged Instructions for using ETO Unit Ampules—Refer to complete instructions packed with Ampules. 94/19-1 (Continued)
Use only with BARD Ampule and Liner bag refill kits.

1. Do not open the plastic bag in which each individual ETO ampule is sealed.

Each ampule of ETO has a plastic shield around the ampule. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability whose function is to contain the gas given off by the ampule and release it at a controlled rate during the sterilization cycle. The plastic shield around the ampule prevents broken glass from the opened ampule from puncturing the gas release bag.

2. Preparation of material for sterilization.

Occlusive cups, plugs or styrets must be removed from instruments so that the gas can penetrate freely. Do not pack the containers so tightly with cloth or gauze that gas diffusion is slowed. Cotton core needles and plastic or rubber tubing must be open and free from plugs. Syringes must be packaged with their plungers out of the barrel.

Material to be sterilized by ETO Unit No. 2 TRAY must be surgically clean and dry. It should be wrapped in cloth or paper as in conventional steam sterilization. Items contaminated with dried bacterial spores must be soaked or washed and immediately on drying wrapped and placed in the sterilizer.

3. Sterilization method.

Place the material to be sterilized wrapped and ready to place in the tray.

Take out the tray from the container and place the wrapped material in it.

Remove one ETO Unit ampule from its cardboard shipping container. Do not touch the ampule. Wrap the ampule in a paper, cloth or plastic bag. The ampule is protected around its neck to facilitate releasing the gas. Grasp the ampule through the cardboard protective shield and slip the top of the ampule. Thereafter the

gas within the ampule bag. Place the ampule in a wrapping and its sealed plastic bag. Do not touch the material to be sterilized. Twist the liner bag shut and hold the seal with one of the twist seal closures which are provided. Put the entire liner bag in the container.

Place the lid on the container and lock the lid in place. Mark the container with the date and hour that sterilization was begun.

Put the container in a safe well-ventilated place away from flame or smoke. Leave the container at room temperature (at least 68° F.) for twelve hours before removing the sterilized material.

When sterilizing long lengths of plastic or rubber tubing, use two ETO Unit ampules and increase the cycle time to 24 hours.

4. Cautions.

Prolonged contact of material with ethylene oxide gas may cause degradation of certain plastics. Rotten plastic and other materials which are other similar gas at sterilization must be removed at first to avoid contamination of the material to be sterilized.

It is recommended that material be exposed to at least 24 hours for steam sterilization. If material is wrapped in plastic or paper for sterilization, the material should be removed from the container and the material should be removed from the container.

Do not use the ETO Unit No. 2 TRAY for sterilizing ETO Unit No. 2 TRAY. Do not use the ETO Unit No. 2 TRAY for sterilizing ETO Unit No. 2 TRAY.

ETO gas is highly flammable and explosive. Do not use the ETO Unit No. 2 TRAY for sterilizing ETO Unit No. 2 TRAY.

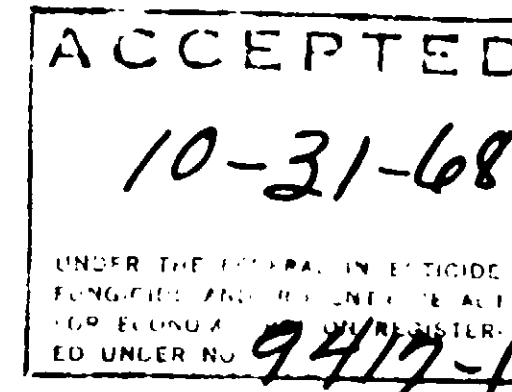
It is recommended that the material be exposed to at least 24 hours for steam sterilization. If material is wrapped in plastic or paper for sterilization, the material should be removed from the container and the material should be removed from the container.

Manufactured by BARD, Inc., Murray, N.J. 07645

Model No. 1000, 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, 1009, 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1018, 1019, 1020, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1049, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1077, 1078, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1134, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1164, 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CAUTION:

The gas within this membrane may be flammable. Keep away from spark and open flame.

Prolonged contact of improperly aired material with skin or mucous membranes may cause severe local irritation. Rubber, plastic, leather and other similar gas absorbent materials must be aired for at least six hours outside of this membrane before use. This minimum aeration period must be extended to at least 24 hours for foam rubber, plastic foams, rubber or plastic intended for implantation in the body, and sealed air cushioned devices like some anesthesia masks.

CAUTION

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