

MINISTRY OF HEALTH, LABOUR AND WELFARE
JAPANESE GOVERNMENT
2-2,1-CHOME,KASUMIGASEKI,CHIYODA-KU,TOKYO
100-8916 JAPAN

CERTIFICATE

It is hereby certified that the following pharmaceutical product manufactured by SARAYA CO.,LTD., 2-2-8, Yuzato, Higashisumiyoshi-ku, OSAKA, 546-0013, JAPAN. is subject to our supervision as stipulated in the Pharmaceutical Affairs Law of Japan and is allowed to be sold in Japan.

1. Product, Date of Manufacturing License and Approval Number :
(Product) (Date of Manufacturing License) (Approval Number)
A C E C I D E October 4, 2001 21300AMZ00770000

2. Dosage and Administration :

1. Method of preparation

The practical use solution of this product is prepared by the following method: Reagents are mixed in a ratio of 50mL of Acecide Reagent One to 50mL of Acecide Reagent Two to 900mL of purified water in order to produce a 0.3w/v% practical use solution.

2. Directions for use

- (1) Completely soak precleaned medical instruments in the practical solution. For medical instruments that have fine pores or have a complicated structure, use pressurized injection or suction to assure that these instruments come into contact with the practical use solution.
- (2) Soak for at least 5 minutes. In cases where spore destruction is required, soak for at least 10 minutes.
- (3) After soaking, rinse the medical instruments completely for more than 15 seconds using sterilized water. For certain purposes, water may also be used. For medical instruments having fine pores or complicated structures, some of the solution may easily remain within the pores and thus, adequate rinsing by using pressurized water or extending the rinsing time is necessary.

3. Indications :

high level disinfection and chemical sterilization for medical instruments.

No. 5022

TOKYO, date OCT. 29. 2003

S. Kishida



Syuuichi Kishida
Director, Evaluation and Licensing
Division
Pharmaceutical and Food Safety
Bureau
Ministry of Health, Labour and Welfare