

570

MF580439/2 0069

10 January 1990

COMMERCIAL IN CONFIDENCE

NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

WORKING PARTY ON BOVINE SPONGIFORM ENCEPHALOPATHY

SURGICAL CATGUT SUTURES

ACTION TAKEN IN RESPONSE TO CSM/VPC GUIDELINES FOR INDUSTRY, AND
FURTHER PROPOSALS.

1. Introduction

1.1 This paper is to outline the steps taken in relation to
Surgical Catgut Sutures in response
to the Joint CSM/VPC Guidelines for Industry.

1.2 The Company has now submitted further proposals.

2. Background

2.1 At the first meeting of the Working Party on Bovine
Spongiform Encephalopathy on 6 September 1989, detailed
consideration was given to Surgical Catgut. This
arose from the Company's response to the Letter to Licence
Holders, indicating that the bovine small intestine source
material was derived from UK cattle, unlike 8 other
licenced catgut sutures. In contrast Surgical
Catgut was stated to hold over 90% share of the market for
catgut sutures, and to constitute approximately 83% of all
sutures used in U.K.

233

90/01.10/8.1

88

The proposal is that decontamination of equipment, disassembled components, remaining fixed plant and the working environment should be by one or more of the following procedures following detergent cleaning.

- i. Porous load autoclaving at 134-138°C for 18 min.
- ii. Immersion for 1 hour in sodium hypochlorite solution containing 2% available chlorine.
- iii. Washing down with sodium hypochlorite solution containing 2% available chlorine.
- iv. Immersion in 1N sodium hydroxide for 2 hours followed by rinsing with water.
- v. Washing down with 1N sodium hydroxide (where sodium hypochlorite or autoclaving cannot be applied).

5. Secretariat Comment

- 5.1 The progress made by the Company in implementing the proposed changeover to Australasian sourced material has been rapid and in advance of predicted timescale.
- 5.2 Setting a date for changeover from UK to Australasian sourced production, with prior decontamination of manufacturing facilities, is prudent. The opinion of the Working Party is sought on the reassurance offered by the proposed strategy for decontamination.

It may be felt that the decontamination procedures should be more fully described for methods 2-5, in particular:-

- a) The minimum temperature at which the decontamination is carried out should be stated and relate to the experimental work on which the procedure is based.
- b) The sodium hypochlorite fluid should be freshly prepared and checked for available chlorine both at the beginning and end of the incubation period. A minimum free chlorine level at the end of the period should be defined.
- c) Where washing of structures or equipment is to be performed rather than immersion, the contact time and temperature should be defined. The method of ensuring that the materials will remain wet for the specified period should be defined.

220

- d) It may be safer to ask the Company to renew equipment rather than "wash down", where practicable (e.g. plastic carboys).
- e) Work clothing should be decontaminated or renewed (e.g. gloves/shoes) to avoid contamination of the decontaminated environment.

5.3 The introduction of the heat-setting step may not be considered appropriate at this stage, with the imminent change to Australasian sourced material.

6. Secretariat Recommendation

The advice of the Working Party is sought on the secretariat view that, in the light of 5.1 above, further action by the Licensing Authority is not currently necessary.

J.M.Raine

J.S.Sloggen

21