



Recherche Contrôle Qualité

Aubagne, October 18th, 2001

**MICROBIOLOGICAL ANALYSIS OF A TUBING SET
USED IN ARTHROSCOPY**

TEST REPORT N°C 99 – 0441 M

Identification of the applicant for the test :
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1. Sample Identification :

The tested products consist of two series of components :

- MONO ZONE Kit tubing / STERILE ZONE Kit / Patient set / Intermediary tubing
Ref. 4519, 4509, 4509 CV, 4509 USA 4549 called here 45X9XX and ref. 1102CV, 1142
called here 11x2xx
Sterilization date : 05/1996
Sterilization lot : 96051E
DLU : 05/2001
- Irrigation tubing / Day set
Ref. 4503, 4503 USA called here 4503XXX
Lot : 1998-10-04
Sterilization date : 12/1998
Sterilization lot : 1998-12-3
DLU : 12/2003

Laboratory code : 4/217/4/0001/99

Receipt date : 07/05/99

Tests dates : from 10/06/99 to 25/06/99

2. Principle

This study is aimed at proving the absence of contamination under normal working conditions in a system consisting of two arthroscopy tubings ref. 4503XXX and 45X9XX (or 11x2xx) connected one to the other. To this purpose the movable part of the 45X9XX (or 11x2xx) tubing, named "sterility chamber", has been contaminated by a nutritive inseminated medium. After a certain predetermined contact time, the part contaminated has been removed. The tubing 4503XXX, located in the upstream part of the system, has then been analysed in order to show that the tested micro-organisms have not passed from the downstream portion (sterility chamber of the tubing 45X9XX [or 11x2xx]) to the upstream portion (irrigation tubing 4503XXX) of the tubing set.

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SARL au capital de 365.000 F - RC : B384 238 523

3. Materials, Microbial strains, Media, Reagents

- Microbial strains
Pseudomonas aeruginosa CIP 82 118
Staphylococcus aureus CIP 4.83
- Media and Reagents
Trypcase Soy medium
Trypcase Soy solid medium
- Materials
 - Incubator 36°C ± 1°C (HERAEUS)
 - Spectrophotometer (SECOMAN)
 - Filtration device (MILLIPORE)
 - Membranes with 0,45 µm porosity (MILLIPORE)
 - Sterile petri dishes (CML)

4. Operating procedure

After assembly of the complete irrigation system (tubing 4503XXX and tubing 45X9XX [or 11x2xx]), the movable part (sterility chamber) of the 45X9XX (or 11x2xx) tubing has been contaminated by trypticase soy medium inoculated with each one of the tested strains (titre : 1 to 3.10⁵ cfu/ml).

The two strains have been treated separately.

The assembled irrigation system has been maintained at 20°C for 24 hours.

At the end of the contact time, the sterility chamber has been removed and a sterile nutritive medium of 50 ml volume has been introduced into the upstream 4503XXX tubing.

The 4503XXX tubing has been left at rest for 45 minutes at room temperature.

At the end of the contact time, all the diluent has been taken up in an aseptic way and filtered through membranes (0,45 µm porosity).

The membrane is settled on the surface of a solid medium (trypticase soy).

The box is put under incubator for 5 days at 36°C ± 1°C.

The tests have been repeated 5 times for each strain.

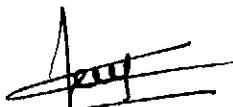
5. Results

The results obtained (number of colonies per Petri dish after filtration) are shown in the following table :

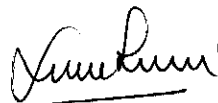
Tested strains	Number of micro-organisms in CFU per Petri dish				
	Test 1	Test 2	Test 3	Test 4	Test 5
Staphylococcus aureus	< 1	< 1	< 1	< 1	< 1
Pseudomonas aeruginosa	< 1	< 1	< 1	< 1	< 1

Conclusion

Under the test conditions and for the two bacterial tested strains, no micro-organisms have been detected in the upstream portion of the irrigation tubing ref.4503XXX after 24 hours contamination of the downstream portion of the system (sterility chamber of the tubing ref. 45X9XX [or 11x2xx]).



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