



Microtest

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Testing Certificate Summary

Client: Innovative Medical Products
87 Spring Lane
Plainville, CT 06062

Sample #s: 11-04377/04399 & 11-04402/04403
Date Started: 20Jun11
Date Completed: 30Aug11

Procedures: GLP-11-182/SPN #11-029 rev 000, Pre-Vacuum Steam Sterilization Dry Time Validation
GLP-11-187/SPN #11-030 rev 000, Pre-Vacuum Steam Sterilization Validation
GLP-11-188/SPN #11-032 rev 000, Pre-Vacuum Steam Sterilization Dry Time Validation
GLP-11-189/SPN #11-033 rev 000, Pre-Vacuum Steam Sterilization Validation

Sample Description: 706-S case with 803-BP, DeMayo Knee Positioner Base and 706-L case with 803-ABD aluminum boot, 903 Single Level Clamp, and 907 Distractor

Dry Time Results Summary:

Table I: 706-S CSR Wrap Weights and Visual Assessment

Run Number	Dry Time	Cycle Parameters	CSR Wrap Weight Before	CSR Wrap Weight After	Percent Weight Gain	Visual Moisture (yes/no)	Pass/Fail
1	20 Minutes	Pre-Vacuum, 132°C, 4.0 minute exposure, double wrapped in CSR	158.0g	156.0g	-1.3%	No	Pass

Table II: 706-L Case CSR Wrap weights and Visual Assessment

Run Number	Dry Time	Cycle Parameters	CSR Wrap Weight Before	CSR Wrap Weight After	Percent Weight Gain	Visual Moisture (yes/no)	Pass/Fail
1	20 Minutes	Pre-Vacuum, 132°C, 4.0 minute exposure, double wrapped in CSR	206.5g	203.0g	-1.7%	No	Pass

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NOTE: All service Undertaken Subject to the following General Policy: MICROTEST LABORATORIES, INC. Reports are Submitted For Exclusive Use of The Clients to Whom they are addressed. Their Significance is Subject to the Adequacy and Representative Character of the samples and to the Comprehensiveness of the Tests, Examination or Surveys Made. No Quotations from MICROTEST LABORATORIES, INC., Reports or use of MICROTEST LABORATORIES, INC., Name is Permitted Except as Expressly Authorized in writing. The liability of MICROTEST LABORATORIES, INC., with respect to services rendered shall in no event exceed the amount of the invoice.

Sterilization Results Summary:

Table I: 706-S Case Sterilization Results

Run #	Biological Indicator Strip Sterility Failures	Cycle Parameters	Minimum 6 log reduction for 3 consecutive runs (Pass/Fail)
1-3	0 of 18	Pre-Vacuum cycle, 132°C, 2 minute exposure (half cycle), 4 pulses, 0.0 minute dry, double layer CSR wrap	Pass

Table II: 706-L Case Sterilization Results

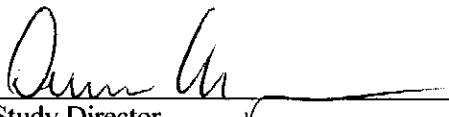
Run #	Biological Indicator Strip Sterility Failures	Device Sterility Failures	Cycle Parameters	Minimum 6 log reduction for 3 consecutive runs (Pass/Fail)
1-3	0 of 15	0 of 6	Pre-vacuum, 4 pulses, 132°C, 2 minute exposure (half cycle), 0.0 minute dry, double layer CSR wrap	Pass

Conclusion:

A dry time of twenty (20) minutes was successfully validated for the four (4.0) minute Pre-vacuum cycle (4 pulses), at 132°C for the Innovative Medical Products (IMP) 706-L case with 803-ABD aluminum boot, 903 Single Level Clamp, and 907 Distractor and the Innovative Medical Products (IMP) 706-S case with 803-BP, De Mayo Knee Positioner Base.

The results of the Biological Indicators indicated no spore survivors for three consecutive half cycles. The Innovative Medical Products (IMP) 706-L case with 803-ABD aluminum boot, 903 Single Level Clamp, and 907 Distractor and the Innovative Medical Products (IMP) 706-S case with 803-BP, De Mayo Knee Positioner Base was judged to be effectively sterilized at 132°C for 2 minutes Pre-Vacuum half cycle and a zero (0.0) minute dry time.

The cycle conditions are considered adequate to achieve an SAL minimum of 10^{-6} at twice the stated exposure time. The thermocouples passed the verification calibration. All positive and negative controls were satisfactory.



 Study Director



 Date