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**LABORATORY STUDY REPORT:
HTV BUBBLE SPECIFICATION ANALYSIS**

The signatures below indicate that the best technical expertise has been presented herein to certify this laboratory study investigates the effect that bubbles have on HTV gel shell properties.

Report Originated By:

Signature	Date
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Report Approved By:

Area Manager Signature	Date
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Quality Assurance Signature	Date
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Research and Development Signature

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Appendix 1: HS222.040609.02, “Laboratory Study Protocol: HTV Bubble Specification Analysis”

Appendix 2: Protocol Deviation Form

Appendix 3: Training Record

Appendix 4: Special Projects

Appendix 5: Shop Orders



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1.0 PURPOSE

This report will summarize the results from protocol HS222.040609.02. This report documents the effect that bubbles have on sterilized HTV gel shell properties. The HTV gel shell dipping and sterilization processes identified in this study take place at the Mentor facility in Irving, TX. This Report has been prepared under the guidelines established by the Mentor Quality Manual.

2.0 SCOPE

This study provides documented evidence on the effect of bubbles on the physical properties of sterilized HTV gel shells.

3.0 RESPONSIBILITIES

3.1 Originator

3.1.1 Prepare and write this final report.

3.1.2 Review the data and attachments for accuracy and acceptable completion.

3.2 Management

3.2.1 Review and approve this final report.

4.0 BACKGROUND

All HTV gel shells are inspected for structural and cosmetic defects per QCIC 000114. HTV gel shells with bubbles embedded inside the shell material are accepted or rejected based on the criteria found in section 6.3.2 of QCIC 000114. HTV gel shells that contain bubbles that are ----- in diameter are rejected. This study documents the effect of bubbles with a diameter of 0.016" to 0.025" on HTV gel shell physical properties.

5.0 STUDY DESCRIPTION



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HTV shell inspectors collected HTV gel shells with bubbles greater than 0.015” in diameter. The inspectors marked the location of the bubble on the shell. The shells were then transferred to the General Services Laboratory (GSL) for testing and analysis as described in study protocol HS222.040609.02.

The shells were cured to duplicate the HTV gel shell assembly process. The shells were cured at the worst case time and temperature exposure documented in PROC 000339 which is ----- °----- Then, GSL operators measured and recorded the size of the bubbles in the shells with an optical comparator. The minimum sample size for this study was thirty shells with bubbles ranging in size from 0.016” to 0.025”. Tensile test coupons were cut with the bubble in the middle of the coupon. Samples were cut using the ASTM die C. Samples were placed on a flat surface and covered with a layer of gel. The gel covered coupons were cured for ----- °- as stated in DOP-MP-1105. Next, the coupons were 2X ----- sterilized ----- °- per PROC 000218 to represent the worst case sterilization cycle. All coupons were cleaned per PROC 000310 and tested for tensile strength and elongation per TM 000019.

6.0 RESULTS

Table #1 summarizes tensile test results from samples with a bubble in the test area. All samples exceeded the specification ----- for tensile break force. All samples exceeded the specification of ----- tensile elongation.

Table 1: Tensile Break Force/Elongation Results

	Specification	Average	Standard Deviation	Minimum	Maximum
Tensile Break Force (lb)	----- -----	7.630	1.823	5.326	11.5
Elongation (%)	----- -----	604.3	46.5	536.9	715.7

7.0 PROTOCOL DEVIATION



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Section 5.0 of protocol HS222.040609.02 states: HTV inspectors will collect HTV shells with bubbles greater than 0.015" in diameter. Currently, the HTV dipping yields are exceptional ----- which resulted in very low bubble rejects for this study. Therefore, an experimental shop order was generated (Ref. Appendix 5, lot # 5545268) that requested HTV dipping operators to adjust their dipping technique and manufacture shells with bubbles. After dipping and curing, the shells were submitted to GSL for bubble size determination and sample preparation.

8.0 CONCLUSION

HTV gel shell samples with bubbles were tested in this study. The bubbles exceeded the bubble diameter specification ----- . The bubble diameter range tested for this study was 0.016" to 0.025". The HTV gel shells used in this study were subjected to worst case time and temperature conditions for HTV gel shells. Results from this study show that bubbles with varying diameters between 0.016" and 0.025" in HTV gel shells do not adversely affect shell physical properties.

9.0 REFERENCE DOCUMENTATION

- 9.1 PROC000218, "----- Sterilization Procedure ----- "
- 9.2 PROC000310, "Laboratory Method for Cleaning Gel Devices Prior to Testing"
- 9.3 TM000019, "Determination of Tensile/Elongation Properties of Elastomeric Materials"
- 9.4 SOP-HS-049, "Mentor Texas Employee Training"
- 9.5 QCIC000114, "Low Bleed Moderate Profile, High Profile, Contour Profile and Testicular Gel-Filled Shell Inspection"
- 9.6 DOP-MP-1105, "Operation of -----"
- 9.7 PROC 000339, "Cure Shells"